For MiniMed™ 770G System Users Ages 2-13:

The low sensor glucose alert functionality is distinct from the automated insulin dosing function of the MiniMed™ 770G System. When used in SmartGuard Auto Mode, the MiniMed™ 770G System has been shown to be safe and effective for its intended use in this population. However, do not rely solely on the use of a low sensor glucose (SG) value for "Alert on Low" or "Alert before Low" for alerts set at 50 mg/dL and 60 mg/dL. A low sensor glucose alert may not reflect the user's true blood glucose at these levels, or may not alert. Do not ignore symptoms of low glucose. Always confirm your sensor glucose readings with your blood glucose meter, and treat according to the recommendations of your healthcare professional. Solely relying on these sensor glucose alerts and readings for treatment decisions could result in missing severe hypoglycemia (low blood glucose) events.

(01)00763000372484

REF MMT-702BUS   M986009A012_1

Medtronic

Guardian™ Sensor (3)

User Guide

Medtronic

Introduction

The Guardian™ Sensor (3) glucose sensor is part of the Continuous Glucose Monitoring (CGM) system. The sensor continuously converts tiny amounts of glucose from the interstitial fluid under the skin into an electronic signal. The system then uses these signals to provide sensor glucose values.
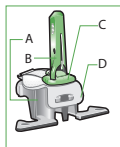
A. pedestal
B. needle housing
C. sensor
D. clear liner

Potential risks related to sensor use

General risks with sensor use include:

- Skin irritation or other reactions
- Bruising
- Discomfort
- Redness
- Bleeding
- Pain
- Rash
- Infection
- Raised bump
- Appearance of a small freckle-like dot where needle was inserted
- Allergic reaction
- Fainting secondary to anxiety or fear of needle insertion
- Soreness or tenderness
- Swelling at insertion site
- Sensor fracture, breakage, or damage
- Minimal blood splatter associated with sensor needle removal
- Residual redness associated with adhesive or tapes or both
- Scarring

Indications for use

The Guardian™ Sensor (3) is intended for use with compatible Medtronic systems to continuously monitor glucose levels in persons with diabetes.

The sensor is intended for single use and requires a prescription.

The Guardian™ Sensor (3) is indicated for 7 days of continuous use. For approved age ranges for use, refer to the compatible Medtronic system user guide.

Contraindications

None known.

Assistance

Department	Telephone Number
Local Medtronic support representative (calls within the United States)	800 646 4633
Local Medtronic support representative (calls outside the United States)	+1 818 576 5555
Website	www.medtronicdiabetes.com

General warnings

Read this entire user guide before attempting to insert the sensor. The one-press serter (MMT-7512) does not work the same as other Medtronic insertion devices. Failure to follow directions or using a different serter may result in improper insertion, pain, or injury.

The Guardian™ Sensor (3) was developed, and its performance evaluated, for use with the approved system only. The sensor should not be used as part of unapproved systems, as it may provide inaccurate sensor glucose readings.

The sensor is designed to work with approved transmitters only. The sensor is not interchangeable with transmitters or recorders that are not compatible with the sensor. Connecting the sensor to a transmitter or recorder that is not approved for use with the sensor may cause damage to the components or inaccurate sensor glucose values.

Refer to the compatible Medtronic system user guide for guidance on therapy decisions.

Taking medications with acetaminophen, such as Tylenol™*, fever reducers, or cold medicine, while wearing the sensor may falsely raise the sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in the body and may be different for each person. Always check the label of any medications to confirm whether acetaminophen is an active ingredient.

Do not expose the sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields as the performance of the sensor has not been evaluated under those conditions and may be unsafe. If the sensor is inadvertently exposed to a strong magnetic field, discontinue use and contact a local Medtronic support representative for further assistance.

A retractable needle is attached to the sensor, and minimal blood splatter may occur. Healthcare professionals or caregivers, wrap sterile gauze around the sensor to minimize contact with blood. Keep as much distance as possible from the patient when removing the needle.

Keep the needle housing within sight at all times to avoid an accidental needlestick or puncture.

Always inspect the packaging for damage prior to use. Sensors are sterile and non-pyrogenic, unless the package has been opened or damaged. Do not use the sensor if the sterile package has been opened or damaged. Use of an unsterile sensor can cause site infection.

This product contains small parts and may pose a choking hazard for children.

Watch for bleeding at the insertion site (under, around, or on top of the sensor).

If bleeding occurs, do the following:

1. Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes. The use of unsterile gauze can cause site infection.

2. If bleeding stops, connect the transmitter to the sensor.

   If bleeding does not stop, do not connect the transmitter to the sensor. This can allow blood to get into the transmitter connector, and could damage the device.

If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the plastic base of the sensor, do the following:

plastic base

1. Remove the sensor and continue to apply steady pressure until the bleeding stops. Discard the sensor in a sharps container.

2. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. Treat based on instructions from a healthcare professional.

3. Insert a new sensor in a different location.

For warnings on use, refer to the compatible Medtronic system user guide.

General precautions

Wash the hands with soap and water before inserting the sensor to help prevent site infection.

Wear gloves when inserting the sensor into someone else to avoid contact with patient blood.

Do not insert the sensor through tape. Inserting the sensor through tape may cause improper sensor insertion and function.

Only use alcohol to prepare the insertion site, to ensure that residue is not left on the skin.

Rotate the sensor insertion site so that sites do not become overused.

Discard used sensors and needle housings in a sharps container after each use to avoid accidental needlestick or puncture.

Do not clean, resterilize, or try to extract the needle from the needle housing. An accidental needlestick or puncture may occur.

Do not reuse sensors. Reuse of a sensor may cause damage to the sensor surface and lead to inaccurate glucose values, site irritation, or infection.

Where to insert the sensor

CAUTION: Avoid the 2 inch (5.0 cm) area around the navel to help ensure a comfortable insertion site and to help with sensor adhesion.

Choose an insertion site that has an adequate amount of subcutaneous fat. The Guardian™ Sensor (3) has been studied and is approved for use in the abdomen and other insertion sites. For approved age ranges for use and alternate insertion sites, refer to the compatible Medtronic system user guide.
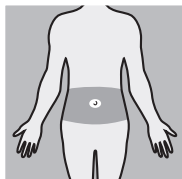
Do not insert the sensor in muscle or areas constrained by clothing or accessories, areas with tough skin or scar tissue, sites subjected to rigorous movement during exercise, or in sites under a belt or on the waistline for best sensor performance and to avoid accidental sensor removal.

Removing the sensor

To change the sensor, disconnect the transmitter from the sensor as described in the transmitter user guide. Gently pull the sensor from the body to remove it. Place the sensor in a sharps container.

Reagents

The sensor contains two biological reagents: glucose oxidase, and human serum albumin (HSA). Glucose oxidase is derived from *Aspergillus niger* and manufactured to meet industry requirements for extraction and purification of enzymes for use in diagnostic, immunodiagnostic, and biotechnical applications. The HSA used on the sensor consists of purified and dried albumin fraction V, derived from pasteurized human serum which is cross-linked via glutaraldehyde. Approximately 3 µg of glucose oxidase and approximately 10 µg of HSA are used to manufacture each sensor. HSA is approved for IV infusion in humans at quantities much larger than in the sensor.

Storage and handling

CAUTION: Do not freeze the sensor, or store it in direct sunlight, extreme temperatures, or humidity. These conditions may damage the sensor.
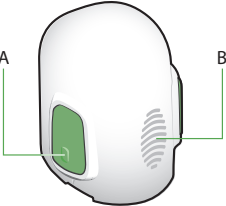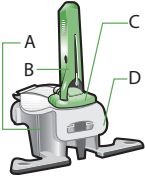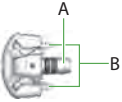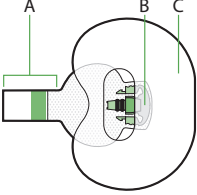
Only store sensors at room temperature between 36°F to 80°F (2°C to 27°C).

Discard the sensor after the "Use by date" indicated on the label, if the package is damaged, or the seal is broken.

Sensor life

The sensor can be used one time, and it has a maximum life of 170 hours (seven days). The 170-hour life span of the sensor begins when the sensor is connected to the transmitter.

Components

|	
	One-press serter A. bump on both buttons B. thumbprint marking
	Glucose sensor assembly A. pedestal B. needle housing C. sensor D. clear liner
	Sensor base A. sensor connector B. sensor snaps
	Transmitter
	Tape and sensor components A. adhesive tab B. sensor base C. oval tape

Inserting the sensor

This section gives instructions to insert the sensor into the abdomen. For approved age ranges for use and alternate insertion sites, refer to the compatible Medtronic system user guide.
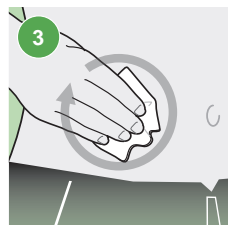
WARNING: Wear gloves when inserting the sensor into someone else to avoid contact with patient blood. Minimal bleeding may occur. Contact with patient blood can cause infection.
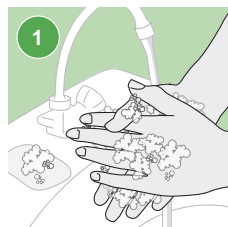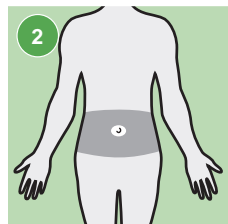
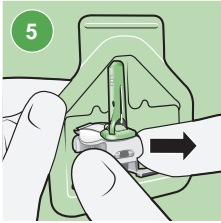|	
	1. Wash the hands with soap and water.
	2. Choose an insertion site that has an adequate amount of subcutaneous fat. For approved age ranges for use and alternate insertion sites, refer to the compatible Medtronic system user guide.
	3. Clean the insertion site with alcohol. Let the area air dry.
	4. Open the sensor package.

5. Hold the pedestal and remove the glucose sensor assembly from the package. Place the pedestal on a flat surface.

Note: The pedestal and glucose sensor assembly are the established definitions in the component table.
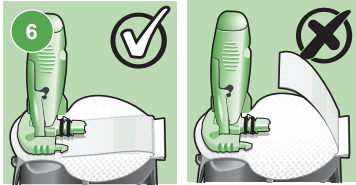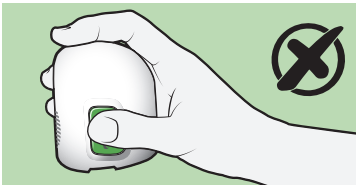

6. Make sure that the adhesive tab of the sensor is tucked under the sensor connector and sensor snaps.
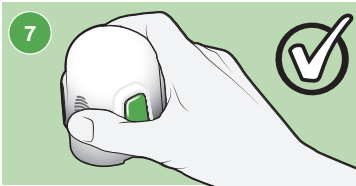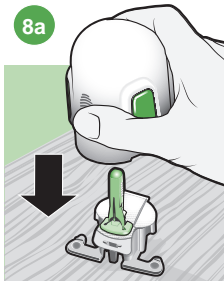

7. Holding serter correctly

Place a thumb on the thumbprint marking to hold the serter without touching the buttons.
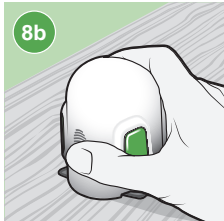
Holding serter incorrectly

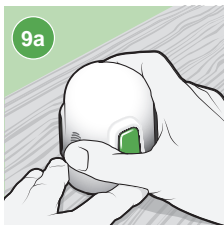Fingers should not be touching the buttons.

8a–8b. Grip the serter, placing a thumb on the thumbprint marking, **without holding the buttons**. Carefully push the serter down onto the pedestal until the base of the serter sits flat on the table and a click is heard.

9a. To detach the serter from the pedestal, place the thumb of one hand on the thumbprint marking and grip the serter **without touching any buttons**. With the other hand, place two fingers on the pedestal arms.
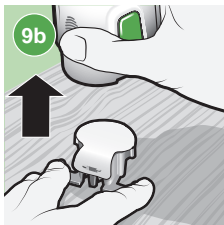
**9b.** Slowly pull the serter straight up without holding the buttons. Do not detach the pedestal from the serter in midair, as this might damage the sensor.
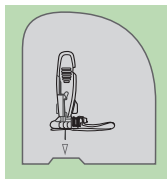
Note: The arrow on the side of the serter aligns with the needle inside the serter.

WARNING: Never point a loaded serter toward any body part where insertion is not desired. An accidental button-push may cause the needle to inject the sensor in an undesired location, causing minor injury.
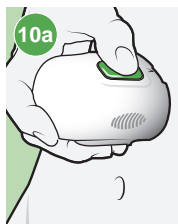
10a. Hold the serter steady against the cleaned insertion site, without pushing the serter too deeply into the skin.

Note: Failing to hold the serter securely flat against the body during insertion may let the serter spring back after pressing the buttons, and result in improper insertion of the sensor.
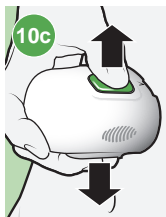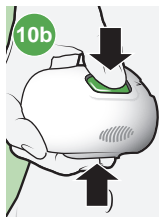
10b-10c. Press and release the bump on both buttons at the same time, while holding the serter flat against the body.
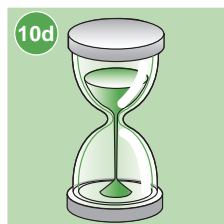
10d. Continue holding the serter flat against the body for at least five seconds to let the adhesive stick to the skin.
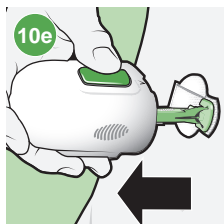
10e. Slowly lift the serter away from the body, making sure that the buttons are not pressed.

For patients who inserted the sensor, complete step 11a.

For healthcare professionals or caregivers who inserted the sensor into the patient, complete step 11b.
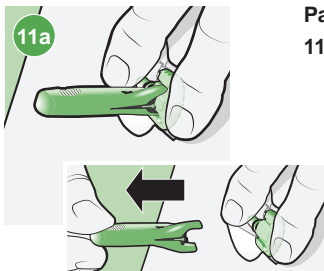
Patient:

11a. Gently hold the sensor base against the skin at the sensor connector and the opposite end of the sensor base. Hold the needle housing **at the top** and slowly pull straight out, away from the sensor.

OR
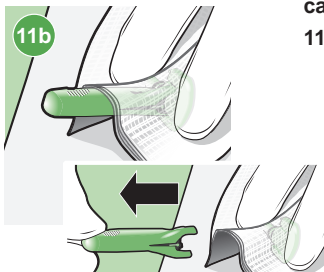
Healthcare professional or caregiver:

11b. Wrap sterile gauze around the sensor (as shown in image 11b). Gently hold the sensor base against the skin at the sensor connector and the opposite end of the sensor base. Hold the needle housing **at the top** and slowly pull straight out, away from the sensor.

WARNING: Watch for bleeding at the insertion site. If bleeding occurs under, around, or on top of the sensor, apply steady pressure using sterile gauze or a clean cloth placed on top of the sensor for up to three minutes. The use of unsterile gauze can cause an infection. If bleeding does not stop, remove the sensor and apply steady pressure until the bleeding stops.

Note: Medtronic adhesives are pressure-sensitive. Pressing the adhesive against the skin ensures that the sensor remains adhered to the skin throughout the wear period.
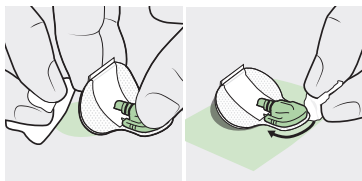
	Note: After insertion, use of adhesive products such as Skin Tac™* in addition to the tape is optional. If optional adhesive products are used, apply to the skin under the adhesive pad prior to removing the liner. It can also be applied to the adhesive pad or the skin around the sensor base. Allow the product to dry.
	12a. Hold the sensor in place and gently remove the adhesive liner from under the adhesive pad. Do not remove the adhesive liner from the rectangular adhesive tab. This tab will be used to secure the transmitter in a later step.
	12b. Firmly press the adhesive pad against the skin to make sure that the sensor remains adhered to the skin.
	13a. Untuck the adhesive tab from under the connector.
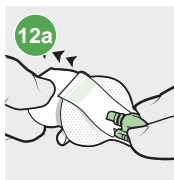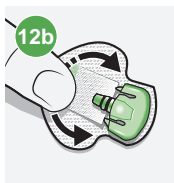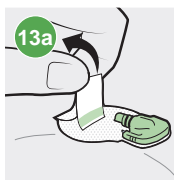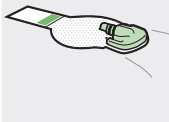
13b. Straighten the sensor adhesive tab so that it lies flat against the skin.

Applying Oval Tape

1. Remove liner 1.
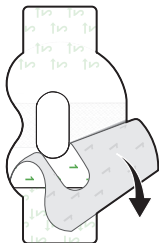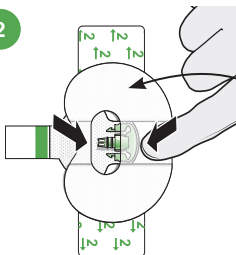
2. Apply the tape as shown and press it down firmly.

The wide part of tape covers half of the sensor base.
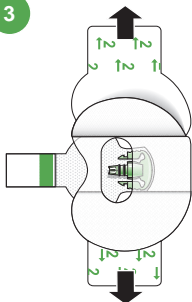
3. Remove the liner marked 2 from each side.
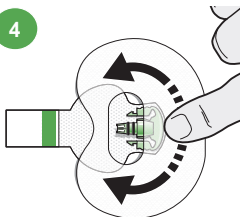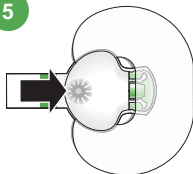
4	**4.** Smooth the tape.
5	**5.** Connect the transmitter to the sensor. **Note:** Wait for the green light on the transmitter to flash. If the green light does not flash, refer to the troubleshooting section of the transmitter user guide.
6	**6.** Cover the transmitter with the adhesive tab. **Note:** Do not pull the tab too tightly.
7	**7.** To apply a 2nd tape, remove liner 1.
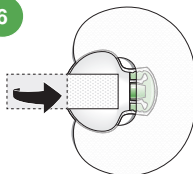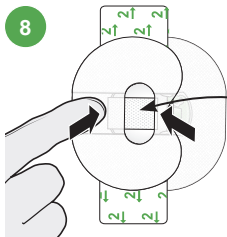
8	**8.** Apply the 2nd tape in the opposite direction to the first tape and place it on the transmitter. Press it down firmly. The wide part of the tape covers the end of transmitter and the skin.
9	**9.** Remove the liner marked 2 from each side.
10	**10.** Smooth the tape. **Note:** Be sure to regularly check the sensor site. If the device is not secure, apply an additional off-the-shelf adhesive.
11	**11.** For details on how to set up CGM, refer to the compatible Medtronic system user guide.
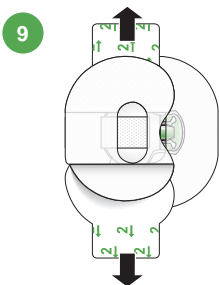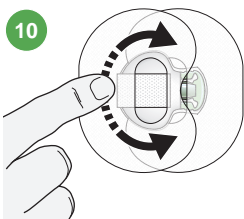
Icon glossary

For a definition of the symbols on the device and package labels, see www.medtronicdiabetes.com/symbols-definitions.

Medtronic

R_X *Only*

REF MMT-7020

M978506A011_A

GETTING STARTED
WITH MINIMED™ 770G
CONTINUOUS GLUCOSE MONITORING

Medtronic

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Continuous Glucose Monitoring

Contents

■ **Training handouts**

Getting started with continuous glucose monitoring (CGM)

Section 1: Welcome to CGM

Continuous glucose monitoring (CGM) gives you a more complete picture of your glucose control than blood glucose (BG) monitoring alone. Using a sensor allows you to receive up to 288 sensor glucose (SG) readings every 24 hours, filling the gaps between your BG checks. CGM alerts notify you of high and low glucose values. Graphs and trend arrows show the speed and direction your glucose levels are moving.

The MiniMed 770G system with smart device connectivity includes SmartGuard features which automatically adjust insulin delivery based on SG values. The SmartGuard technology can be used in two modes: Manual Mode or Auto Mode. In this section, you will learn about using CGM and the following SmartGuard suspend features in Manual Mode: SmartGuard Suspend before low and SmartGuard Suspend on low. You will learn about SmartGuard Auto Mode later.

The first step in using CGM is understanding the items included in your CGM system.

Your CGM system includes 3 key items:

❶ Transmitter*

The Guardian Link (3) transmitter connects to the glucose sensor and sends glucose readings to your insulin pump. "GL3" is marked on the transmitter. Only the transmitter marked with "GL3" can communicate with the MiniMed 770G insulin pump.

❷ Glucose sensor

The Guardian Sensor (3) measures glucose levels in the body.

❸ Insulin pump

The MiniMed 770G insulin pump displays glucose readings.

Other items include: one-press serter, oval tape, charger, and tester.

Always use the components that were sent with the MiniMed 770G system.

Drawings throughout this document are only generic representations of the system components.

* The transmitter must be within 1.8 meters (6 feet) of the insulin pump with no obstacles in order to communicate sensor readings.

Section 2: SG and BG

Your **BG meter** measures glucose levels in your blood. The glucose sensor measures glucose in the fluid surrounding the cells of your tissue called **interstitial fluid**.

Glucose travels between blood and interstitial fluid. Most of the time, glucose travels to your blood first, and then to your interstitial fluid. Because of how glucose moves, **your BG meter readings and SG readings will be close, but will rarely match exactly**. This difference is normal and should be expected.
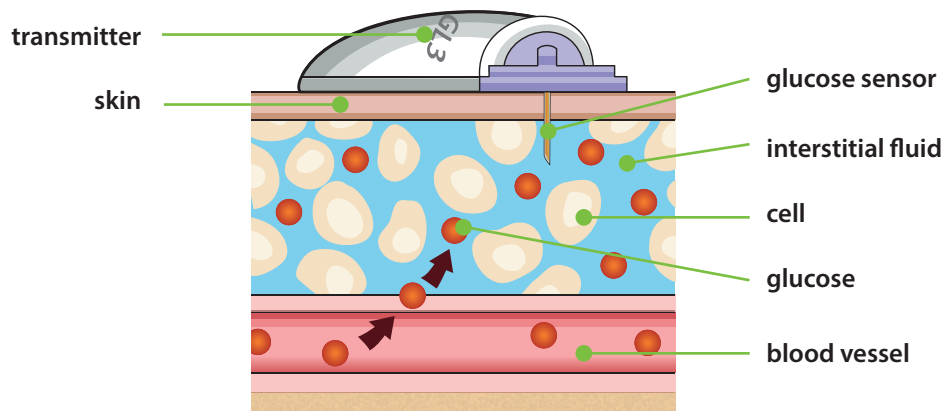
When glucose levels are rising or falling quickly, you should expect to see an even larger difference between your BG meter readings and the SG readings.

Examples of times when this larger difference may occur include:

- after meals or taking a bolus of insulin
- during exercise
- when arrows appear on your pump screen, as explained in *Trends, on page 3*

> **WARNING:** SG is not the same as BG. Your SG and BG readings will be close to one another, but will rarely match exactly.
>
> Always use the values from your BG meter for treatment decisions. The MiniMed 770G system CGM does not replace a BG meter to make treatment decisions. BG values may differ from SG values. Using the SG readings for treatment decisions could lead to high or low BG.

Section 3: Trends

When using CGM, you will want to focus on SG trends. These trends give insight into the direction and the speed that your glucose is changing. The sensor graph and trend arrows are used to show your SG trend information.

NOTE: When using CGM, focus less on each individual glucose number and more on the direction and speed that your glucose is changing.

Example of sensor information on the Home screen
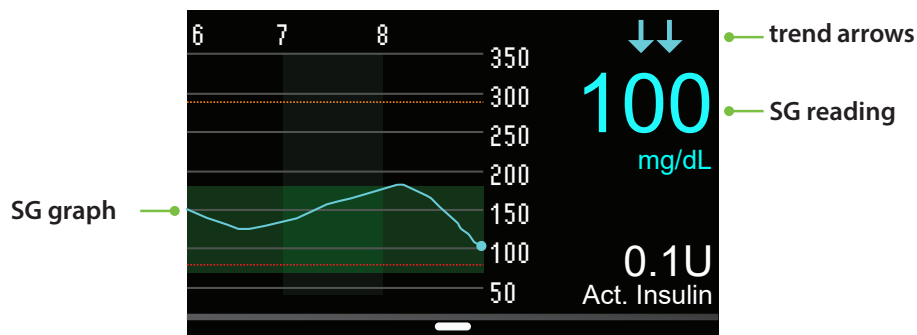
By looking at the sensor information above, you can see that the current glucose reading is 100 mg/dL. When you look at the graph, you can see that your SG is falling.

In this example, you see arrows above the number. The arrows indicate the rate that the glucose values are moving up or down:

↑ or ↓ - SG has been rising or falling by at least 1 but less than 2 mg/dL per minute.

↑↑ or ↓↓ - SG has been rising or falling by at least 2 but less than 3 mg/dL per minute.

↑↑↑ or ↓↓↓ - SG has been rising or falling by at least 3 or more mg/dL per minute.

NOTE: You may be likely to notice your glucose trending up or down after eating, giving a bolus, or when exercising.

Section 4: Personalized alerts

The alert and SmartGuard suspend features are most beneficial if they are personalized for your needs. These features will be set during your CGM training. They can then be adjusted as you learn more about the information provided by your sensor while you wear it. Your healthcare professional will work with you to determine your initial settings and help with adjustments that need to be made.

Your alert settings apply to both Manual Mode and SmartGuard Auto Mode. However, the SmartGuard suspend settings apply only to Manual Mode. When the pump switches from Manual Mode into Auto Mode, the SmartGuard suspend settings turn off. See *GETTING STARTED WITH MINIMED™ 770G SMARTGUARD™ AUTO MODE* for information on how Auto Mode works.

The graph below shows the different settings that can be personalized for both high and low SG readings.

250 mg/dL

Alert on high

Alert before high

Rise Alert

Suspend before low
Alert before low

Suspend on low
Alert on low

SG readings

70 mg/dL

🔔 **SG alert and suspend settings**
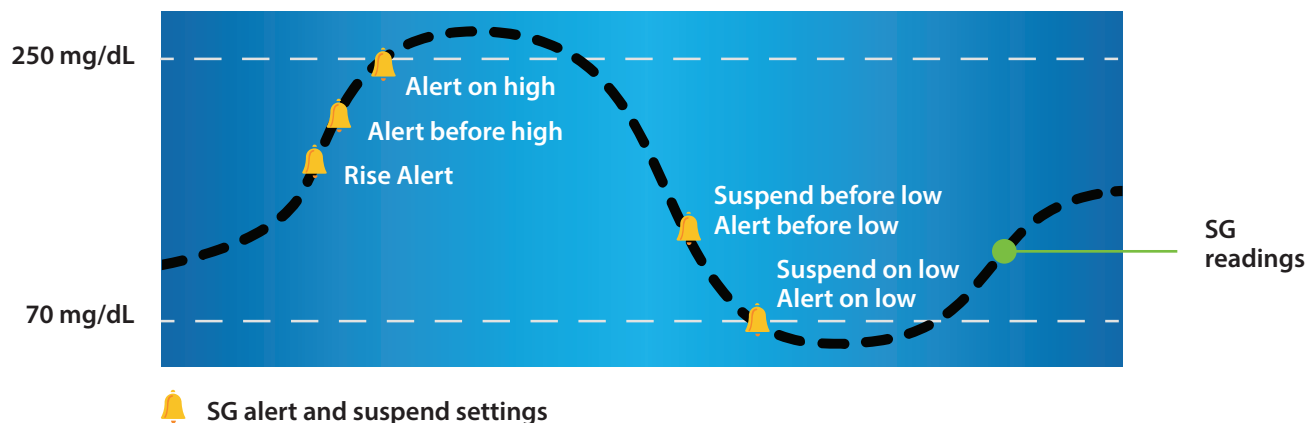
NOTE: Please make sure the settings prescribed for you by your healthcare professional are available at the time of your in-person training.

Turning the Sensor feature on

Before you set up any of the SmartGuard features, you must first turn the Sensor feature on.

✅ **To turn the Sensor feature on:**

1) Press ⵔ.

2) Select **Options**.

3) Select **Utilities**.

4) Select **Sensor Settings**.

5) Select **Sensor** to turn feature **On**.

   You can now access the SmartGuard features menu and enter the settings.

Utilities
Sensor Settings
Display Options
Time & Date
Block
Self Test

Sensor Settings	
Sensor	On
Sensor Connections	
Calibrate Sensor	
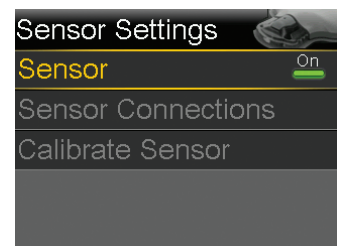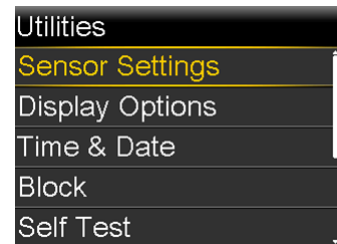
High Setup

These settings alert you:

- **Rise Alert**–when your SG is rising rapidly
- **Alert before high**–when your SG is approaching your high limit
- **Alert on high**–when your SG has reached your high limit

High Limit

SG readings

Alert on high
Alert before high
Rise Alert

🔔 **High SG alert settings**

High Limit

The first step is to set the high (**Hi**) limit. The high limit can be set from 100 to 400 mg/dL. This is the value on which other high SG settings are based. You can set up to eight high limits for different time segments throughout the day or night. The high (**Hi**) limit or limits that you enter also apply to SmartGuard Auto Mode.

> **NOTE:** Your high limit is not the same as your glucose target. Your healthcare professional will help you determine the best setting, so that you are alerted only when needed.

Alert before high

When **Alert before high** is on, you will receive an alert any time the SG is predicted to reach your high limit, making you aware of a potential high glucose level before it occurs. This can help you to evaluate what has occurred and take any necessary action as directed by your healthcare professional.

Time before high

Time before high determines how many minutes before reaching the high limit that you will receive an **Alert before high**. This can be set from 5 to 30 minutes.

Alert on high

When the **Alert on high** is on, you will receive an alert any time your SG reading reaches or exceeds your high limit. This allows you to evaluate and treat if necessary as instructed by your healthcare professional.

> **ALERT ON HIGH...**
>
> Sara has been working hard to keep her glucose levels under control. Her healthcare professional has set her high limit at 225 mg/dL and instructed her to use the **Alert on high**. If her glucose reaches this limit, she checks her BG and takes insulin if necessary to help make sure her glucose levels return to her normal range.

Rise Alert

The **Rise Alert** will notify you when your glucose is rising rapidly. This alert can help you understand how much your glucose levels are affected by meals or, for example, when forgetting to give a bolus.

The **Rise Alert** can be set to alert if glucose is rising as follows:

⬆ - SG is rising at a rate of 1 mg/dL per minute or more.

⬆⬆ - SG is rising at a rate of 2 mg/dL per minute or more.

⬆⬆⬆ - SG is rising at a rate of 3 mg/dL per minute or more.

Custom - SG is rising at the rate that you set. This can be set from 1.0 to 5.0 mg/dL per minute.

7

Setting up your High Setup

1) Press ⊙.

2) Select **Options**.

Enter BG	🔴
Basal	
Audio Options	🎵
Status	📋
Suspend Delivery	⏸
Options	⚙

3) Select **SmartGuard**.

| Options |
| SmartGuard |
| History |
| Reservoir & Tubing |
| Delivery Settings |
| Event Markers |

4) Select **High Setup**.

| SmartGuard |
| Auto Mode |
| High Setup |
| Low Setup |
| Snooze |

5) Press ⊙ on the time segment.

If you are setting only one time segment, press ⊙. If you are setting multiple time segments, press ⌃ to the end of the first segment, and press ⊙.

In this example, only one time segment is set.

High Setup

| Start | End | Hi (mg/dL) |
| 12:00 A | 12:00 A | --- | ▶ |

6) Press ⌃ or ⌄ to set **Hi** limit and press ⊙.

In this example, the limit is set to 250 mg/dL.

7) Press ⊙ to continue onto the next screen.
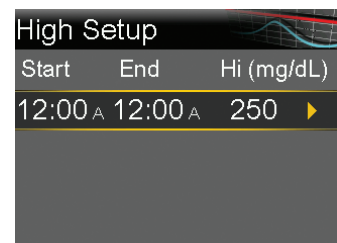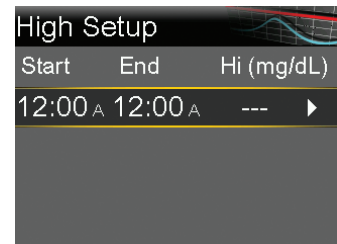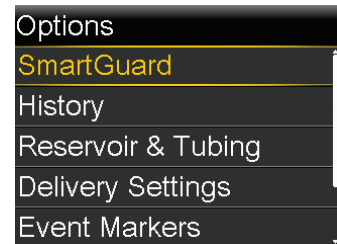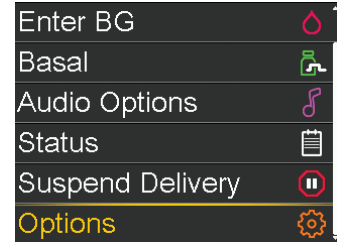
High Setup

| Start | End | Hi (mg/dL) |
| 12:00 A | 12:00 A | 250 | ▶ |

8) Select each feature you wish to turn on. If a feature is on, select it again to turn it back off.

> 12:00 A-12:00 A 250 mg/dL
> **Alert before high**   Off
> Time before high   15 min
> Alert on high   Off
> Rise Alert   Off
> **Next**
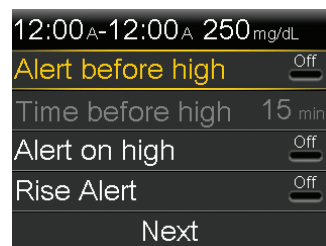
9) Once settings are selected, select **Next**.

In this example, the Alert on high has been turned on.

> 12:00 A-12:00 A 250 mg/dL
> Alert before high   Off
> Time before high   15 min
> Alert on high   On
> Rise Alert   Off
> **Next**

10) Select **Done**.
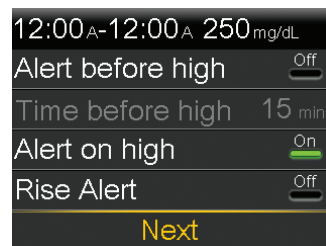
> High Setup
> Start   End   Hi (mg/dL)
> 12:00 A 12:00 A   250 ▶
> **Done**

11) Verify that settings are correct and select **Save**.
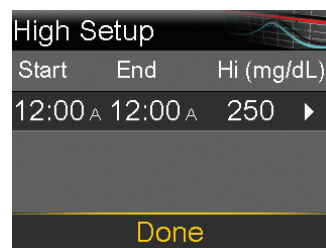
> High Setup
> 12:00A-12:00A   250 mg/dL
> Alert on high   On
> **Save**
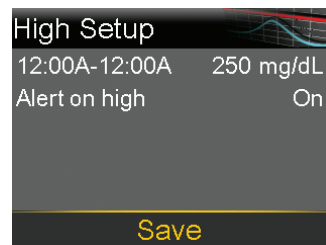
Your High Setup is now complete.

⚠️ **WARNING:** Always use the values from your BG meter for treatment decisions. The MiniMed 770G system CGM does not replace a BG meter to make treatment decisions. BG values may differ from SG values. Using the SG readings for treatment decisions could lead to high or low BG.

📝 **NOTE:** You can set up to 8 different time segments throughout the day and night. Each time segment can have different high SG limits and high SG alerts that work best for you during that time of day or night.

Low Setup

Let's now look at the **Low Setup**. You can choose to be alerted before or when you have reached your low limit. You can also use the SmartGuard suspend features to have your insulin delivery automatically suspended if your SG values are approaching or have reached your low limit. The low SG settings that can be chosen are shown here:
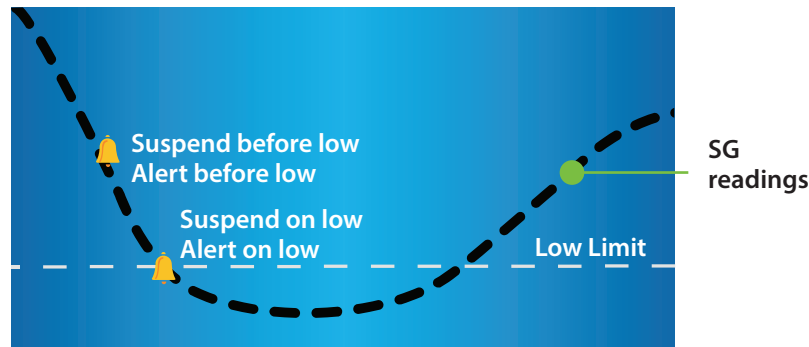
🔔 **Low SG alert and suspend settings**

Low Limit

The first step is to set the low (**Lo**) limit. This can be set from 50 to 90 mg/dL. This is the value on which the other low settings are based. You can think of this limit as the lowest SG value that you would like to avoid reaching. Furthermore, if you do reach it, you would like to spend as little time at or below it as possible. You can set up to eight low limits for different periods of the day or night.

SmartGuard Suspend before low

Suspend before low is a SmartGuard suspend feature. When **Suspend before low** is on, your pump will temporarily stop delivering insulin if the SG value is approaching your low limit. This will keep you from getting additional insulin that would continue to lower your SG level.

> **NOTE:** Insulin delivery will not be suspended if you are more than 70 mg/dL above your low limit.

Alert before low

When **Alert before low** is set to on, you will receive an alert when you are approaching your low limit, making you aware of potential low glucose levels before they occur. **Alert before low** behaves differently depending on your SmartGuard suspend settings:

- If **Suspend before low** is on, an **Alert before low** occurs when insulin is suspended.
- If **Suspend before low** is off, an **Alert before low** occurs when the sensor predicts you will reach your low limit in 30 minutes.

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SUSPEND BEFORE LOW...

Sam uses the **Suspend before low** feature during the night. He knows that if his SG values are approaching his low limit, his insulin delivery will stop. He has the **Alert before low** set to off – he does not want to be alerted when this occurs. He is comfortable knowing the pump will stop insulin delivery and he will receive an **Alert on low** if he reaches his low limit.

Suspend on low

Suspend on low is a SmartGuard suspend feature. When **Suspend on low** is set to on, your pump temporarily stops insulin delivery if your SG has reached or fallen below your low limit. This keeps additional insulin from being delivered.

NOTE: Only one suspend feature can be used during each time segment; you cannot turn both **Suspend before low** and **Suspend on low** on.

Alert on Low

When **Alert on low** is on, you receive an alert any time your SG reading reaches or falls below your low limit. This allows you to check your BG and treat if necessary as instructed by your healthcare professional.

NOTE: Alert on low is automatically turned on if either **Suspend on low** or **Suspend before low** is turned on so you know that your glucose is at or below your low limit.

Low SG XX mg/dL (50 mg/dL or below):

Your system also has a fixed **Low SG XX mg/dL** (50 mg/dL or below) alarm. This fixed alarm is factory set and cannot be changed or turned off. You receive this alarm if your SG reaches or falls below 50 mg/dL. This alarm occurs in both Manual Mode and SmartGuard Auto Mode.

WARNING: Do not use the Suspend on low feature to prevent or treat low glucose. Always confirm your sensor glucose reading using your BG meter, and follow the instructions of your healthcare professional to treat low glucose. Using Suspend on low alone to prevent or treat low glucose may result in prolonged hypoglycemia.

SMARTGUARD SUSPEND ON LOW...

Alexa's healthcare professional advised her to use the **Alert before low** and the **Suspend on low** feature during the daytime. If she receives an alert before she reaches her low limit, she checks her BG and treats with carbohydrates if necessary. In case her SG still reaches her low limit, she knows she will be alerted and her pump will suspend insulin.

Resume basal alert

In addition to suspending insulin delivery, the pump can also automatically resume delivery of basal insulin. If insulin has been suspended by either the **Suspend before low** or the **Suspend on low** feature, basal insulin delivery automatically resumes if either of these conditions apply:

- if SG values are above the low limit and are rising
- after a maximum suspend time of 2 hours

When the **Resume basal alert** is on, the alert occurs when basal insulin is automatically resumed because SG values are above the low limit and rising. If the **Resume basal alert** is off, basal insulin is still resumed, you just will not receive an alert.

If basal insulin resumes after the maximum 2 hour suspend time, you receive an alert even if the **Resume basal alert** is off. It is important that you check your BG and ensure your glucose is at a safe level.

IMPORTANT: The maximum time insulin will be suspended is 2 hours. Additional information regarding SmartGuard suspend features can be found in *Sensor alerts and suspend, on page 41.*

Setting up your Low Setup

1) Press ◎.

2) Select **Options**.
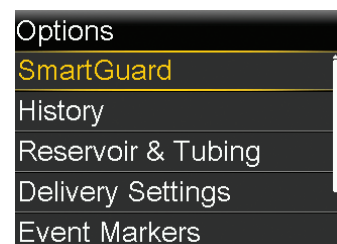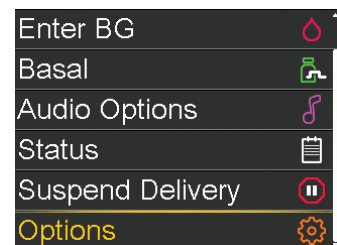
Enter BG	⬤
Basal	
Audio Options	♪
Status	
Suspend Delivery	⬤
Options	⚙

3) Select **SmartGuard**.

Options	
SmartGuard	
History	
Reservoir & Tubing	
Delivery Settings	
Event Markers	

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4) Select **Low Setup**.

| SmartGuard |
| Auto Mode |
| High Setup |
| Low Setup |
| Snooze |

5) Press ⊙ on the time segment.

If you are setting only one time segment, press ⊙. If you are setting multiple time segments, press ⌃ to the end of the first segment, and press ⊙.

In this example, multiple time segments are set.

Low Setup		
Start	End	Lo (mg/dL)
12:00 A	8:00 A	--- ▶
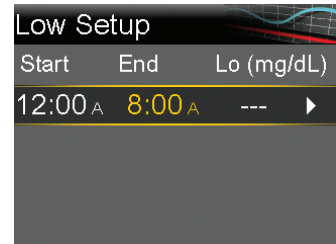
6) Press ⌃ or ⌄ to set **Lo** limit and press ⊙.

In this example, the limit is set to 70 mg/dL.
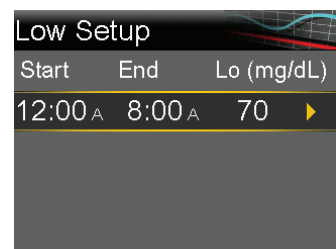
7) Press ⊙ to continue onto the next screen.

Low Setup		
Start	End	Lo (mg/dL)
12:00 A	8:00 A	70 ▶

8) Select each feature you wish to turn on. If a feature is on, select it again to turn it back off.

*In this example, **Suspend before low** has been turned on.*

| 12:00A-8:00A 70 mg/dL |
| Alert before low   Off |
| Alert on low   On |
| Low Management |
| Suspend before low   On |
| Next |

9) Once settings are selected, select **Next**.

NOTE: Only one Suspend feature can be used during each time segment. If either Suspend feature is turned on, **Alert on low** will automatically be turned on.

| 12:00A-8:00A   70 mg/dL |
| Alert before low   Off |
| Alert on low   On |
| Low Management |
| Suspend before low   On |
| Suspend on low   Off |
| Resume basal alert   Off |
| Next |

10) Press ⊙ on the time segment.

11) Press ⌃ to set the **End** time of the second segment and press ⊙.

Low Setup		
Start	End	Lo (mg/dL)
12:00 A	8:00 A	70 ▶
8:00 A	12:00 A	--- ▶
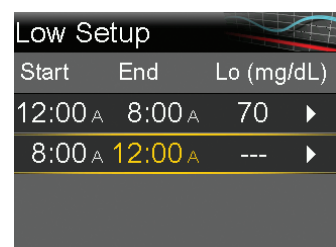
12) Press ⌃ or ⌄ to set the **Lo** limit and press ⊙.

13) Press ⊙ to continue onto the next screen.
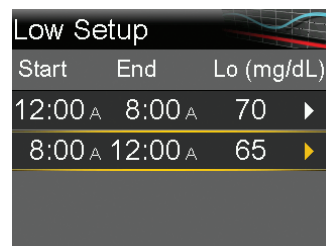
14) Select each feature you wish to turn on. If a feature is on, you can select it again to turn it back off.

   In this example, **Alert before low**, **Suspend on low***, and* **Resume basal alert** *have been turned on.*
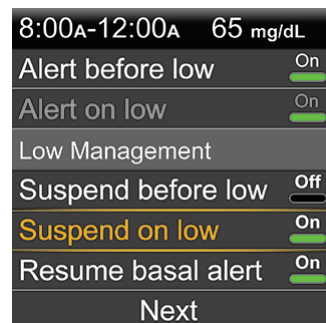
15) Select **Next**.
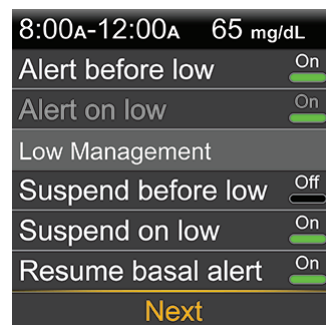
16) Select **Done**.
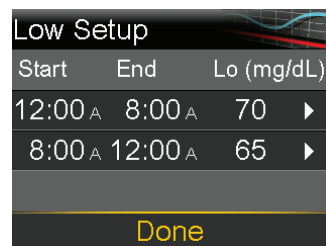
17) Verify that settings are correct and select **Save**.
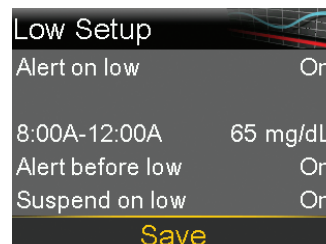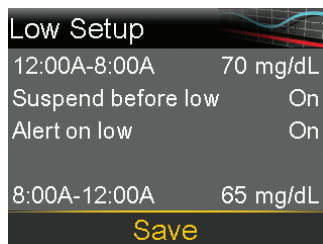
Your Low Setup is now complete.

NOTE: You can set up to 8 different time segments throughout the day and night. Each time segment can have different low limits and low SG alerts that work best for you during that time of day or night.

Snooze

The **High Snooze** and **Low Snooze** features can be set for the amount of time that you want to wait to be reminded that an alert condition still exists. Once a high or low alert is received and cleared, you will be alerted again only if the alert condition still exists after the snooze time you have set. The snooze time for your high SG alerts can be set from 5 minutes to 3 hours. The snooze time for your low SG alerts can be set from 5 minutes to 1 hour.

1) Press ⊙.

2) Select **Options**.

3) Select **SmartGuard**.

4) Select **Snooze**.

SmartGuard
Auto Mode
High Setup
Low Setup
Snooze

5) Select **High Snooze**.

6) Press ⌃ or ⌄ to set the desired time and press ⊙.

Snooze	
High Snooze	1:00 hr
Low Snooze	0:20 hr
Save	

7) Select **Low Snooze**.

8) Press ⌃ or ⌄ to set the desired time and press ⊙.

9) Verify that the settings are correct and select **Save**.

Snooze	
High Snooze	1:00 hr
Low Snooze	0:20 hr
Save	
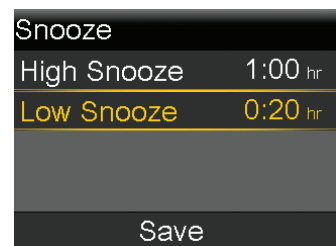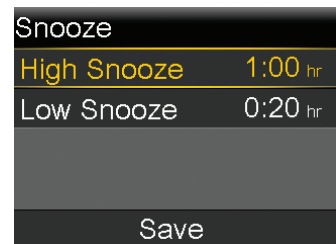
NOTE: Additional details about the SmartGuard suspend features can be found in the *Training handouts, on page 49*. See the *MiniMed™ 770G SYSTEM USER GUIDE* for a complete explanation of the technical and operational aspects of your pump.

NOTE: The SmartGuard **Suspend on low** and SmartGuard **Suspend before low** features are automatically turned off when SmartGuard Auto Mode becomes active.

SNOOZE...

Robert's healthcare professional instructed him to turn **Alert on high** on and to set his **High Snooze** at 2 hours. If his SG reaches his high limit, he checks his BG and gives a bolus if he needs it. His pump will alert him again in 2 hours if his glucose level is still at or above his high limit.

Changing High or Low Setup

As you use CGM, you and your healthcare professional may find that changes need to be made to the existing settings. To make these changes:

1) Press ⓞ.

2) Select **Options**.

3) Select **SmartGuard**.

4) Select **High Setup** or **Low Setup**.

5) Select **Edit**.

6) Select time segment you wish to change.

   a. Change **End** time if necessary and press ⓞ.

   b. Change **Hi** or **Lo** limit if necessary and press ⓞ.

   c. Press ⓞ when the arrow is highlighted to continue onto the next screen.

7) Select any feature that is off if you wish to turn it on. Select any feature that is on if you wish to turn it off.

8) Select **Next**.

9) When finished, select **Done**.

10) Verify settings are correct and select **Save**.

Alert Silence feature

The **Alert Silence** feature allows you to silence sensor alerts for a set period of time. If a sensor alert occurs when the **Alert Silence** feature is on, a message is displayed to notify you that a sensor alert occurred and the notification light flashes, but there is no beep or vibration. You can go to Alarm History in the History menu to see which sensor alert or alerts occurred. If you have not cleared the message when the **Alert Silence** period ends, the pump will beep, vibrate, or beep and vibrate until cleared.

To set Alert Silence

1) Press ⬭.

2) Select **Audio Options**.

3) Select **Alert Silence Options**.

Audio Options
Alert Silence Options
Audio   ◁   On
Vibrate   ⟨□⟩   Off
Volume   -   3   +
Save

4) Select the alerts that you want to be silenced.

5) Select **Duration**.

6) Press ⌃ to set the time that you want alerts to be silenced and press ⬭.

Alert Silence
High Alerts Only   ▬
High & Low Alerts   Silenced
All Sensor Alerts   ▬
Duration   0:30 hr
Begin

7) Select **Begin**.

Alert Silence
High Alerts Only   ▬
High & Low Alerts   Silenced
All Sensor Alerts   ▬
Duration   0:30 hr
Begin
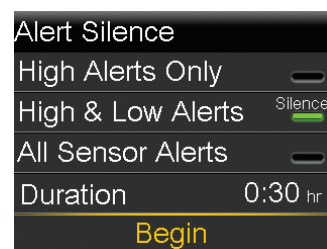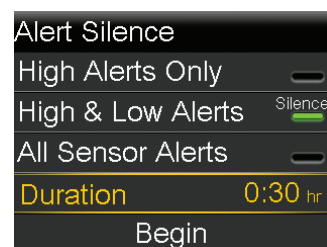
Alerts will automatically return to audio or vibrate at the end of the duration that you set. The **Low SG XX mg/dL** (50 mg/dL or below) alarm and **Alert on low** alert cannot be silenced.

SILENCING ALERTS...

Sandra uses the **Alert Silence** feature when she is in class so that she does not disrupt her classmates if an alert occurs. She routinely looks at her pump to check for alerts, and can take action if necessary.

Section 5: Pairing your pump and transmitter

Before using the sensor for the first time, you will need to pair the pump with the transmitter so that they can communicate with each other. This allows the sensor information to be displayed on the pump screen.

To pair your pump with the transmitter:

1) Attach your transmitter to the charger and make sure it is fully charged.
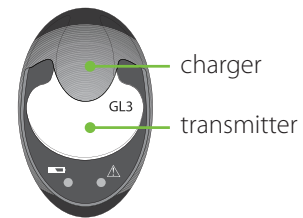
> **NOTE:** No lights are flashing on the charger when the transmitter is fully charged. For more information on charging the transmitter, see *Charging and storing the Guardian Link (3) transmitter, on page 45*.

2) Press ⊙.

3) Select **Options**.

4) Select **Utilities**.

5) Select **Device Options**.
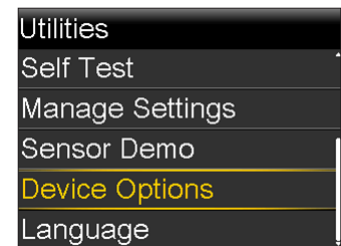
   Only one transmitter can be paired with the pump at one time. When you need to pair a new transmitter, you must first select **Manage Devices**, select the old transmitter number, and then select **Delete.**

6) Select **Pair Device**.
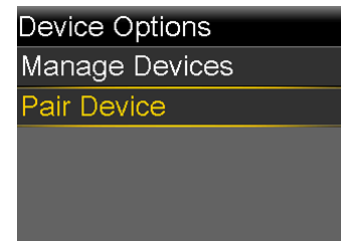
   The New Device screen appears.

7) Place the transmitter, still attached to the charger, next to the pump.

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8) Select **Search** on your pump and immediately remove the transmitter from the charger.

New Device
See device instructions and make the device ready to pair.

Select Search below when ready.
Search
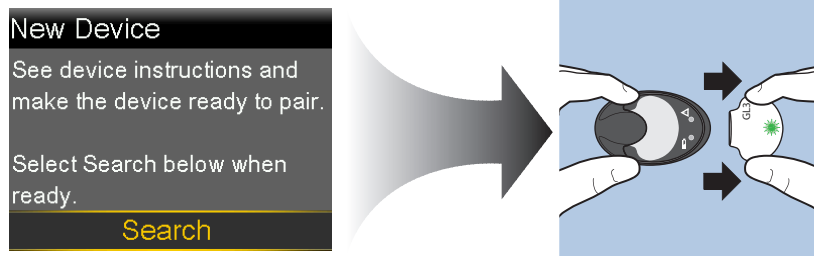
The following happens when you start the search process:

- On your pump, a message appears to let you know your pump is searching for compatible devices.

- On your transmitter, a green light starts to flash.

NOTE: The search process can take up to two minutes. You cannot access your pump screens or suspend your pump during the search process.

The Select Device screen appears with a list of available devices.

9) Select the CGM device that matches the serial number on the back of the transmitter.

Select Device
Meter XXXXXXXX
CGM XXXXXXXX
Meter XXXXXXXX
Meter XXXXXXXX
[Phone name]

10) Ensure the transmitter serial number on your pump screen matches the serial number on the back of your transmitter, and then select **Confirm**.

Confirm Device
Type: CGM Transmitter
SN: XXXXXXXX

Cancel   Confirm

Medtronic MiniMed, Inc.
Northridge, California 91325
IP48 Guardian™ Link (3)
REF MMT-7911WW
SN GT _ _ _ _ _ _ _ _
FCC ID: OH27821
IC: 3408B-7821   CE 0459
XXXX
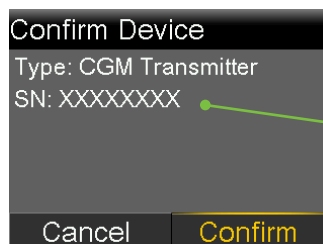
Your pump displays a message if the pump and transmitter are paired successfully. If the Sensor feature is turned on, the Connection icon appears on the Home screen.

If your pump does not find your transmitter, the Device not found alert appears. See the *MiniMed™ 770G SYSTEM USER GUIDE* if your pump does not find your transmitter.

NOTE: These steps only need to be done as a first time set-up of the transmitter. You will not have to repeat them every time you start a new sensor.

Section 6: Inserting and starting the sensor

Before you insert your sensor, gather all of your supplies:

Guardian Sensor (3) system components*
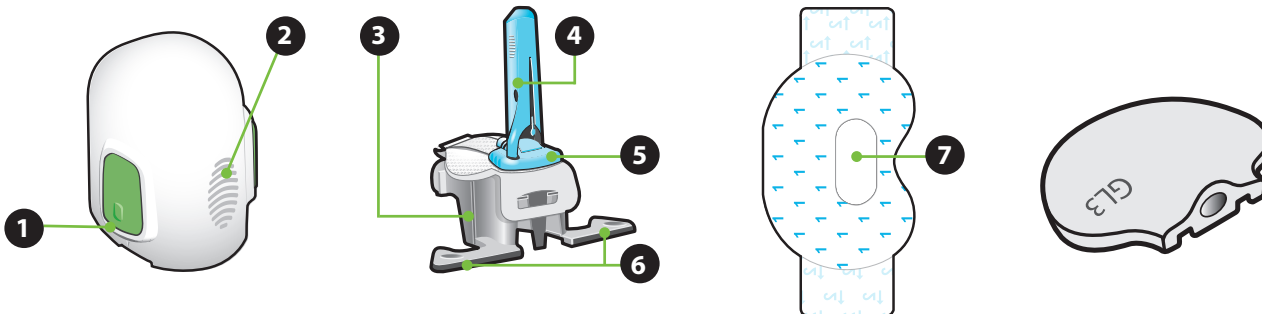
One-press serter	Guardian Sensor (3) & plastic pedestal	Oval tape	Guardian Link (3) transmitter
1 Bump on button	**3** Pedestal	**7** Precut hole	
2 Thumb print	**4** Needle housing		
	5 Sensor		
	6 Pedestal feet		

- **One-press serter** is required in order to insert the sensor properly.

- **Guardian Sensor (3)** is individually packaged and comes attached to a plastic pedestal which is necessary for proper loading into the serter.

- **Oval tape** is required to keep the sensor securely in place.

- The **Guardian Link (3) transmitter** is connected after the sensor is inserted and covered with the oval tape.

*For more details on the Guardian Sensor (3) components, consult the user guides for Guardian Link (3) transmitter, Guardian Sensor (3), and one-press serter.

Selecting your site

Your sensor can be inserted in any of the shaded areas according to your age.

> **NOTE:** Assistance will likely be needed for sensor insertion into the back of the upper arm and into the buttocks. Some users found it difficult to insert the sensor into their arm and buttocks by themselves.

Ages 2 to 13		Ages 14 and older	
Front of body	Back of body	Front of body	Back of body
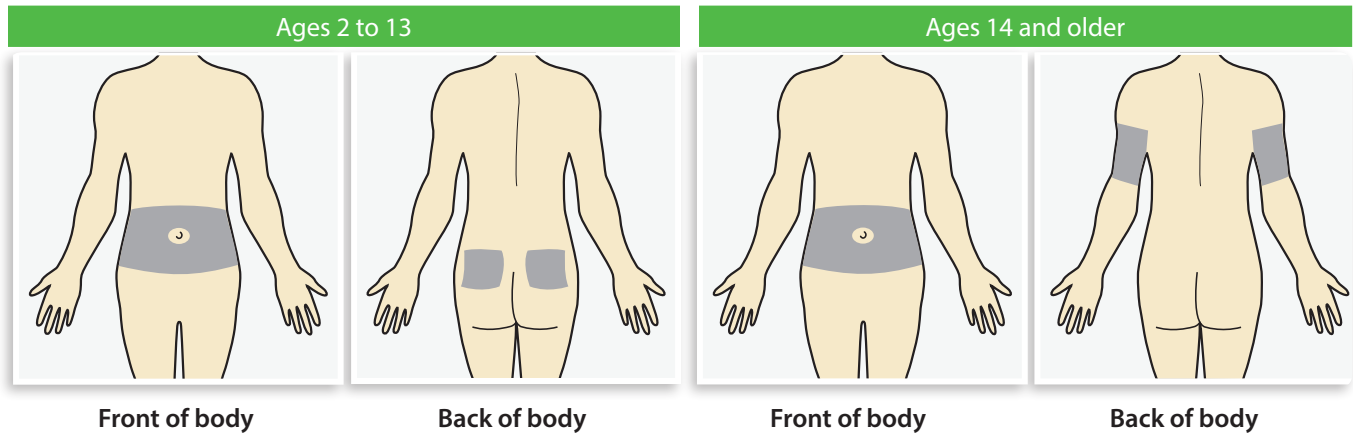
The Guardian Sensor (3) has been studied and is approved for use in the following sensor insertion sites by persons of the following ages:

Approved Age	Sensor Insertion Site
2-13	Abdomen and Buttocks
14 and older	Abdomen and Arm

The sensor insertion site should be at least:

- 2 inches (5 centimeters) from your navel.
- 1 inch (2.5 centimeters) from your insulin pump infusion site.
- 1 inch (2.5 centimeters) from any manual insulin injection site.

For best sensor glucose performance, avoid these sites:

- Where clothing may rub or constrict (for example, your belt line)
- Where your body naturally bends a great deal and may cause the sensor to pull out
- Where there are scars, hardened tissue, or stretch marks
- Where there is a great deal of motion or friction

Prepare your site:

- Wash your hands with soap and water.
- Clean the site you chose with an alcohol swab and allow the alcohol to dry. Do not use IV prep.

Inserting your sensor
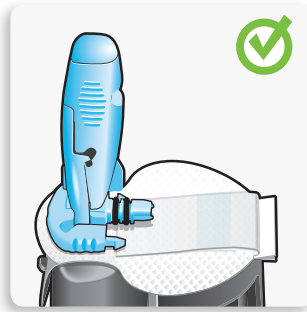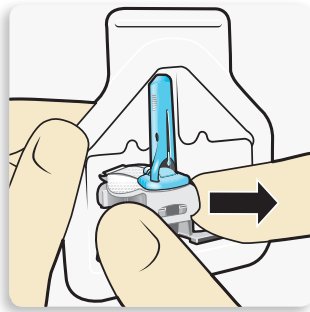
Correct   **Incorrect**

1 **Open the sensor package.** Pull the corner of the paper covering to open the sensor package.

2a **Hold the sensor by the plastic pedestal.** Remove the sensor with attached pedestal by holding the pedestal only. Place the sensor and pedestal on a clean, flat surface (such as a table).

2b **Tuck the adhesive tab.** Make sure that the sensor's adhesive tab is tucked under the sensor connector and snaps.

NOTE: Refer to the illustrations for correct and incorrect ways to hold serter for loading.

Correct   **Incorrect**
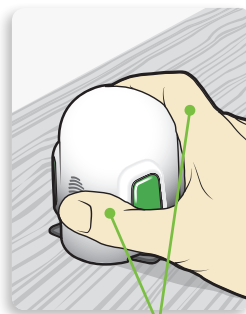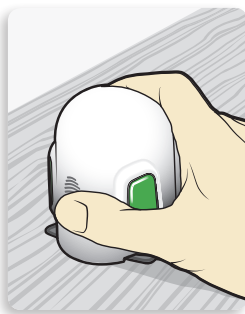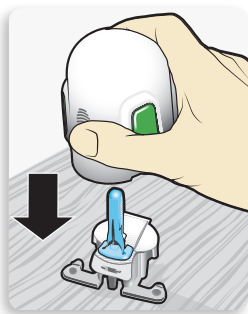
Fingers are NOT holding the side buttons.
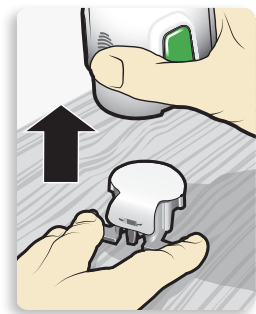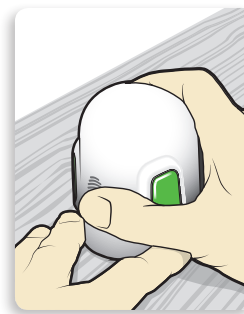
3 **Load the sensor into the serter.** Grip the serter exactly as shown **with your thumb placed on the thumb print on the serter. Do not hold the side buttons.** Push the serter down onto the pedestal until the base of the serter sits flat on the table.

4 **Detach the serter from the pedestal.** To detach the serter from the pedestal, grip the serter as shown with thumb placed on thumb print on the serter. With the other hand, place two fingers on the pedestal arms, and slowly pull the serter straight up.

NOTE: Make sure that the pedestal is firmly on the table before pulling the serter away.

CAUTION: Do not detach the pedestal from the serter in mid-air as this may damage the sensor.

NOTE: The thumb print on the serter can be used for either left-handed or right-handed insertion.

NOTE: The sensor remains inside the serter after removing the pedestal. The arrow on both sides of serter indicate location of the sensor needle.
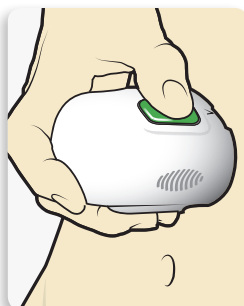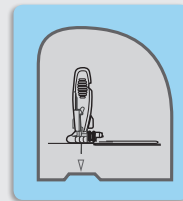
5a **Place the serter on your body**. Hold the serter steadily against your cleaned insertion site, without pushing the serter too deeply into the skin.
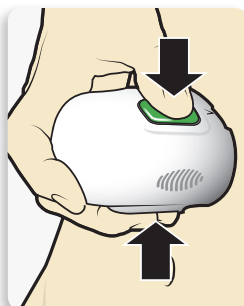
5b **Insert the sensor**. Press and release the **bump** on both buttons at the same time. Do not pull the serter away from your body just yet.
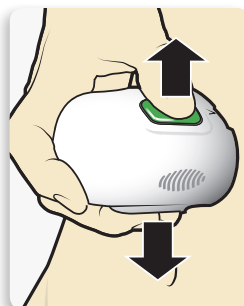
5c **Hold the serter against your body**. Continue to hold the serter against your body for at least five seconds to allow the adhesive to stick to your skin.
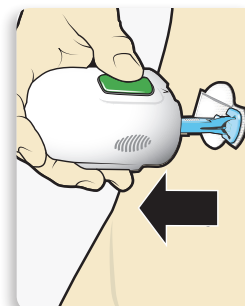
5d **Remove the serter from your body**. Slowly pull the serter away from the skin, making sure the buttons are not pressed.

NOTE: Failing to hold the serter securely flat against the body may allow the serter to spring back after pressing the buttons and result in improper insertion of the sensor.
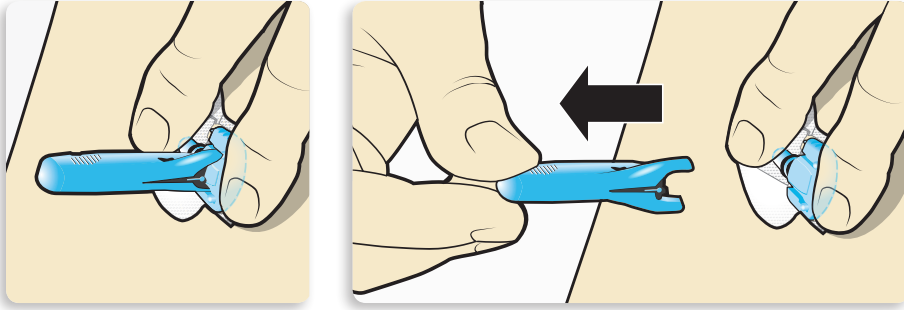
6 **Remove the needle housing.** Gently hold the base of the sensor against the skin with one hand. With other hand, hold the needle housing at the top and slowly pull it straight away from the sensor. Dispose of the needle housing in a sharps container.

NOTE: Apply additional liquid adhesive. You may use an optional adhesive such as Skin Tac under the adhesive pad prior to removing the liner. Allow it to dry.
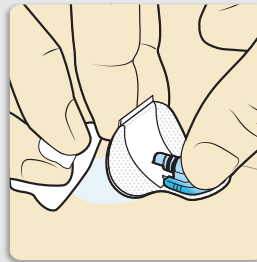
IMPORTANT: All sensor tapes and adhesives stick best when you apply pressure after putting them on your skin. Doing so helps the sensor stay securely placed and fully inserted.
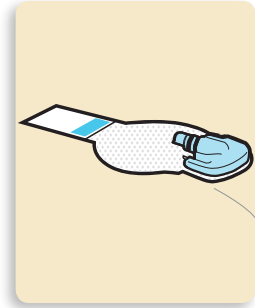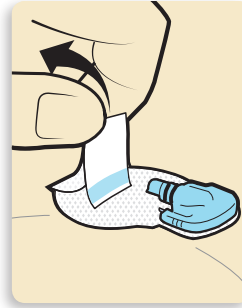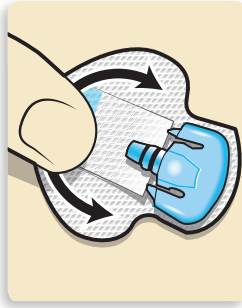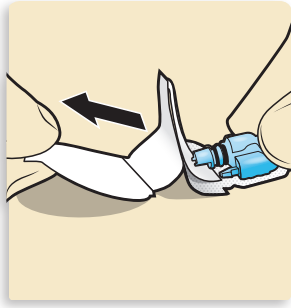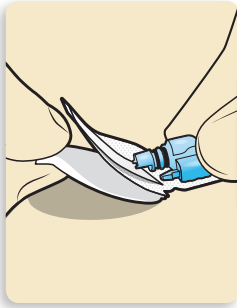
7a **Remove the adhesive pad liner**. Hold the sensor in place and gently remove the adhesive liner from under the adhesive pad. Do not remove the liner on the rectangular adhesive tab yet.

7b **Press the entire adhesive pad to your skin.** Firmly press the adhesive against the skin and smooth the entire adhesive pad so that it sticks to your skin.

8a **Untuck the adhesive tab**. Untuck the adhesive tab from under the sensor connector.

8b **Straighten the adhesive tab**. Straighten the adhesive tab so that it lies flat against your skin, but do not remove the adhesive liner yet.

NOTE: The Guardian Sensor (3) adhesive is sensitive to pressure. Continue applying pressure on the adhesive to ensure that the sensor remains inserted in the skin for up to 7 days of wear.

Taping your sensor

Before you connect the transmitter to your sensor, it is very important that you properly secure the sensor against your skin using the provided tape.
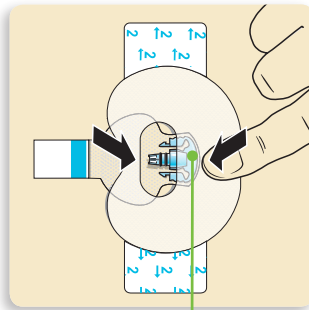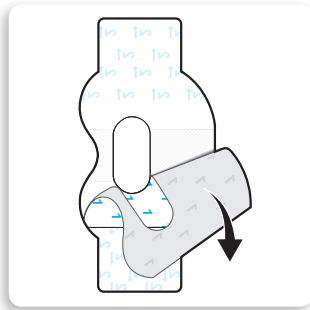
Wide part of tape covers half of sensor base.
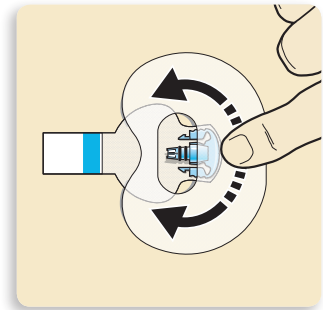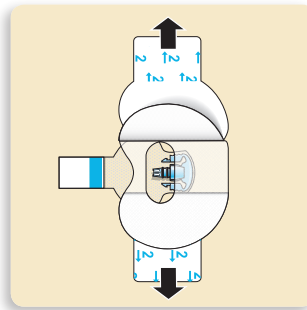
1 **Remove liner 1.**

2 **Apply the tape as shown and press it down firmly**.

3 **Remove liner 2 from each side.**

4 **Smooth the tape.**

! **IMPORTANT:** All Guardian Sensor (3) tapes and adhesives stick best when you continue to apply pressure after putting them on your skin. Doing so helps the sensor stay securely placed and fully inserted.

Connecting your transmitter
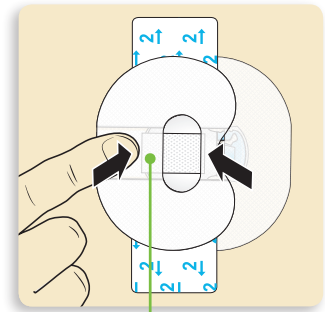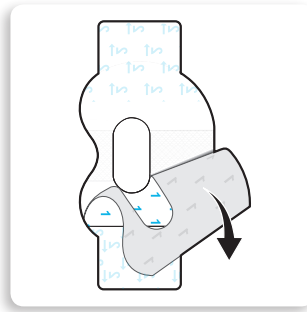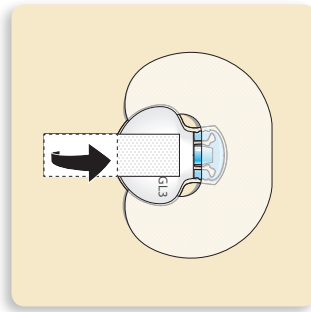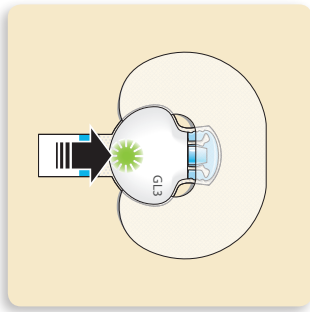
Wide part of tape covers end of transmitter and skin.

1 **Connect the transmitter to the sensor. A green light flashes 6 times when the sensor is properly connected to the transmitter.**

2 **Remove the liner from the adhesive tab. Cover the transmitter with the adhesive tab. Do not pull the tab too tightly.**

3 **To apply the 2nd tape, remove liner 1.**

4 **Rotate the 2nd tape and place the tape over the transmitter. Press it down firmly.**

NOTE: Wait for the green light on the transmitter to flash. If the green light does not flash, refer to the Troubleshooting section of your transmitter user guide.

IMPORTANT: If you do not see a green light flashing on the transmitter after it is connected to the sensor, disconnect the transmitter and place it back on the charger to ensure that it is fully charged. Then reconnect the transmitter to the sensor.
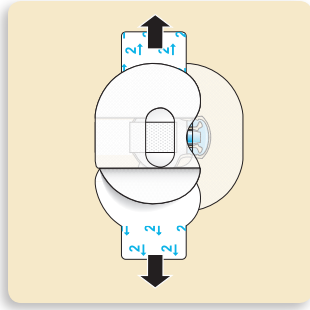
5 **Remove liner 2 from each side**.
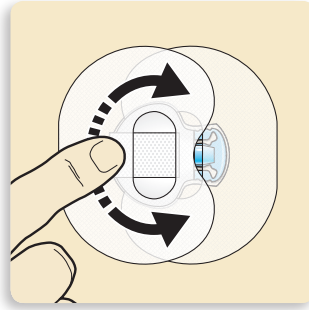
6 **Smooth the tape**.

NOTE: Check your sensor site regularly. Apply additional tape if the sensor and transmitter are not secure.

It is very helpful to remember the order of these four steps when changing your sensor:

1. **Insert** the sensor.
2. **Tape** the sensor in place.
3. **Connect** the transmitter.
4. **Apply** a second oval tape.

NOTE: When your transmitter is connected to your sensor they form a water-tight seal to a depth of 2.4 meters (8 feet) for up to 30 minutes. You can shower and swim without removing them.

NOTE: Properly applying the oval tape is key to ensuring your success with the sensor. Due to the sensor's small size and flexible nature, the oval tape helps to secure it from body motion or physical activity that can cause it to be pulled out.

Checking for proper tape application

It is important to check your sensor site periodically to make sure the sensor is still secure and has not been pulled out. If the sensor has been pulled out, do not try to push it back into place. A new sensor may need to be inserted.

Correct
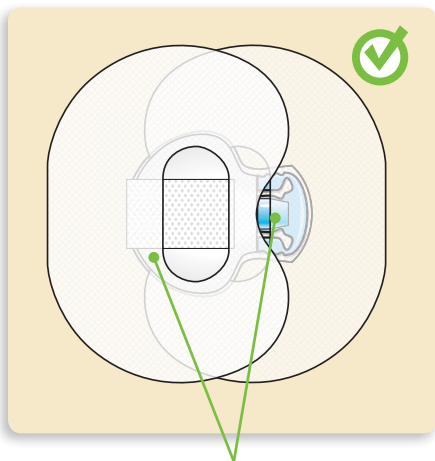
Oval tape is covering the sensor, skin around sensor, and back of transmitter.

Starting the sensor

Once you have inserted the sensor and connected the transmitter, the pump and transmitter begin to communicate.

Make sure your pump is on the Home screen so that the **Sensor connected** message will be displayed when the sensor is ready to be started. *This typically takes less than a minute, but may take up to 10 minutes.*

1) Select **Start New Sensor**.

Sensor
connected

Start new sensor.

Start New Sensor
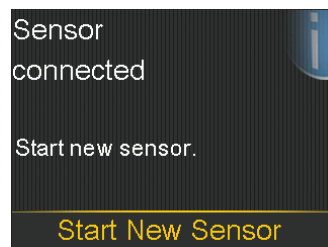
2) The **Sensor warm-up started** message appears.

3) Press ⌄ and then ◯ to clear.

Sensor warm-up
started
12:00 AM
Warm-up takes up to 2 hours. You will be notified when calibration is needed.

Sensor warm-up
started
when calibration is needed.

OK
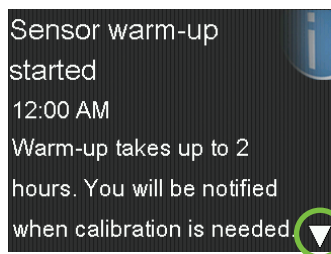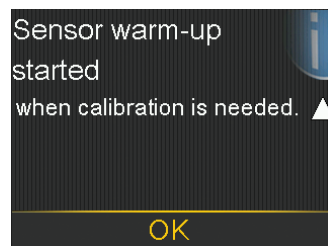
4) **Warm up...** appears on the Home screen until sensor is ready for the first calibration.

*If 15 minutes have passed and the Warm up bar does not appear or it looks like it is not progressing, look into the **Quick Status** screen. If you see the time of **Next cal** listed, the sensor is in Warm up.*
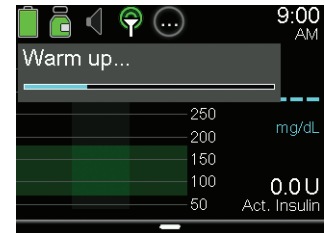
NOTE: The next time you connect a transmitter, you will see these screens. Select **Start New Sensor** if you have just inserted a new sensor. Select **Reconnect Sensor** if you have only disconnected and reconnected the transmitter.
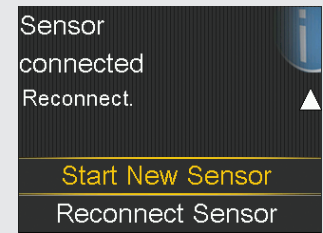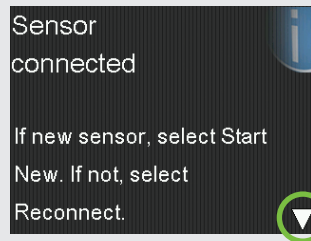
NOTE: The *Quick Reference Guide for Using the One-press Serter with Guardian™ Sensor (3), on page 53* is available in the *Training handouts on page 49* to help you during your sensor setup and sensor insertion.

Section 7: Calibration

Your CGM system requires BG meter readings in order to provide you with SG readings. These BG meter readings are entered into the pump and are for sensor calibrations. Calibration is essential for optimal CGM performance. CGM does not eliminate the need for BG meter checks.

To calibrate, you must use a *fingerstick* blood sample to check your BG on your meter, and then enter that value into your pump. The pump accepts BG meter readings between 20 and 600 mg/dL. The BG meter reading must be between 40 and 400 mg/dL to calibrate.

> **WARNING:** Always use the fingertip for blood samples used for calibrating the sensor while in Auto Mode. The fingertip was the only site studied for use with Auto Mode. Do not use blood samples from the palm to calibrate the sensor as this site was not studied for use with Auto Mode and the performance of the system is not known.

After inserting a new sensor, a calibration is needed:

- Within 2 hours after you connect the transmitter to your sensor and start the warm-up period

> **NOTE:** Your pump notifies you with a **Calibrate now** alert when it is ready for its first calibration.

- Again within 6 hours (first day of inserting sensor only)
- Again every 12 hours
- When the system detects that a calibration is needed for optimal performance

After the first day, the minimum number of calibrations required is one every 12 hours, but you may receive a **Calibrate now** alert if one is needed sooner. Calibrating three or four times per day is optimal. It is best to calibrate when your glucose is not changing rapidly. For example, before meals is often a good time to calibrate. Calibrating when there are ↑↑, ↓↓, ↑↑↑, ↓↓↓ may decrease sensor accuracy.

> **IMPORTANT:** BG readings should be entered immediately. Avoid the use of an old BG reading or a BG reading used for previous calibrations.
> Wait at least 15 minutes in between calibration attempts.

> **NOTE:** Calibrations are necessary in order to continue to receive SG readings, alerts, and alarms.

Within two hours after starting a new sensor, or any other time a calibration is necessary, you will receive a **Calibrate now** alert. If you cannot calibrate right away (for example, if you are driving or in a meeting), you can set the **Snooze** to remind you to calibrate in the time that you set. You can change the time if you desire.
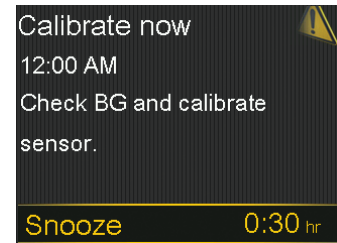
If you plan to check your BG and calibrate right away, simply select **Snooze**.

Once you select Snooze, **Calibration required** will appear on the Home screen until you enter a BG to calibrate.
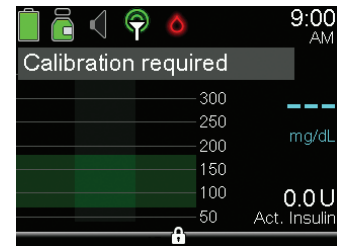
You will not receive SG readings or sensor alerts and alarms until a calibration BG is entered.

Calibrating the sensor

There are several different ways that you can enter a BG reading to calibrate the sensor.

Calibrate by using the Accu-Chek® Guide Link meter

When you use the Accu-Chek Guide Link meter, the meter value automatically appears on the BG Meter screen.

1) Check your BG. Press 🔙 on the meter to send the BG reading to the pump.

2) Select **Yes** to confirm the BG meter reading.

If you do not believe the meter result is accurate, do not confirm now. Select **No**, wash your hands, and recheck your BG.

3) Select **Calibrate Sensor** to calibrate using the BG value.

If you plan to give a bolus using the Bolus Wizard feature, select **Bolus**.
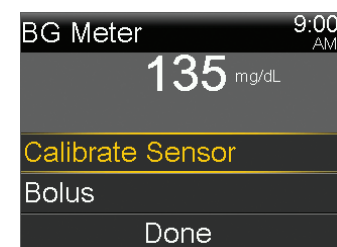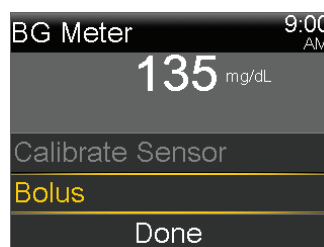
Select **Done** if you wish to do neither.

33

Calibrate through Enter BG

You are able to calibrate through Enter BG.

1) Press ⬡.

2) Select **Enter BG**.

Bolus	
Enter BG	
Basal	
Audio Options	
Status	
Suspend Delivery	

3) Select **Enter BG**.

BG   9:00 AM

Enter BG   --- mg/dL

Save

4) Press ⌃ or ⌄ to enter your BG reading and press ⬡.

5) Select **Save**.

BG   9:00 AM

Enter BG   135 mg/dL

Save

A message appears asking if you want to calibrate using the entered BG.

6) Select **Yes** if you want to calibrate.

   Select **No** if you do not want to calibrate.

Calibrate sensor?

Calibrate sensor with BG 135 mg/dL?

No   Yes

7) The Home screen appears, indicating that your pump is calibrating.

> **NOTE:** You can perform other tasks while your pump is calibrating.

9:00 AM

Calibrating...

250
200
150
100
50

mg/dL

0.4 U
Act. Insulin

34
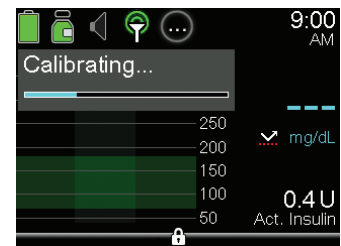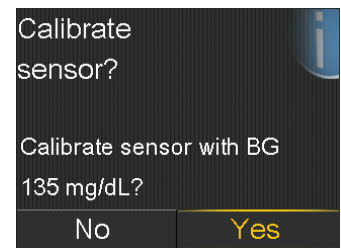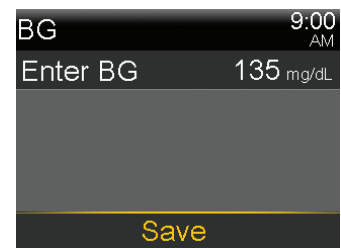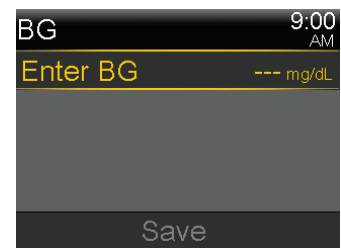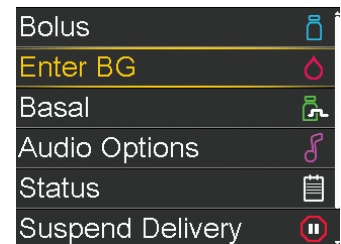
✔ **Calibrating through the Bolus Wizard feature**

You are able to calibrate when using the Bolus Wizard feature.

1) Press ⊙.

2) Select **Bolus**.

3) Select **Bolus Wizard**.

4) Press ⊙.

5) Press ⌃ or ⌄ to enter BG value and press ⊙.

6) Press ⊙.

7) Press ⌃ to enter your carbs and press ⊙.

8) Select **Next**.

9) Select **Deliver Bolus**.

10) Press ❯ and select **Yes** to calibrate sensor.
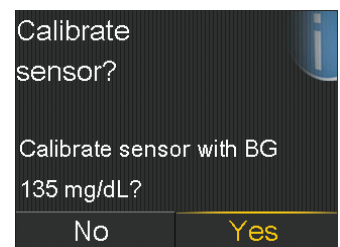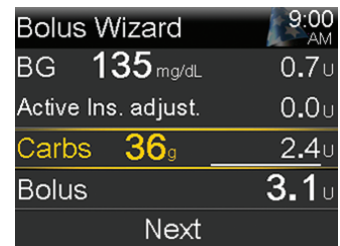
You can also calibrate through the Sensor Settings and Event Markers menu. For complete instructions, see the *MiniMed™ 770G SYSTEM USER GUIDE*.

After you have entered a BG for calibration, the Home screen shows you that the system is calibrating.

You will start seeing SG readings again within 5 minutes.
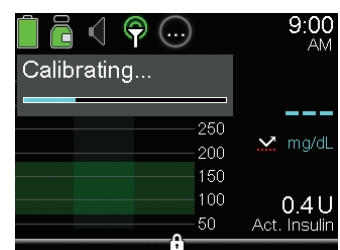
⚠ **WARNING:** If you notice a large difference between your BG meter reading and sensor glucose readings, wash your hands and do another BG fingerstick test to help ensure a more accurate reading. Check the sensor site to ensure the sensor overtape is still holding the sensor in place. If it is not, you will need to remove and insert a new sensor.

Calibration reminder

You can use the **Calibration reminder** to give you notice before the next calibration is necessary. For example, let's say you calibrated at 07:00 and your reminder is set for 4 hours. Since your next calibration would be due at 19:00 (12 hours), you would receive a **Calibration reminder** at 15:00, which is 4 hours before the calibration is due. This can help ensure that you calibrate 3 or 4 times a day. The **Calibration reminder** default setting is On with a reminder time of 1:00 hour.

To change the Calibration reminder

1) Press ⊙.

2) Select **Options**.

3) Select **Reminders**.

4) Select **Calibration**.

5) Press ⌄ to **Time** and press ⊙.

6) Press ⌃ or ⌄ to desired time and press ⊙.

   In this example, the reminder is set for 1 hour.

7) Select **Save**.

Calibration	
Reminder	On
Time	1:00 hr
	Save
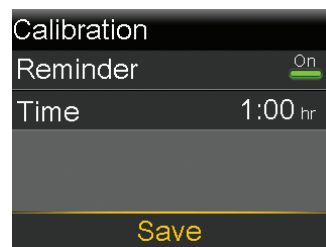
CALIBRATE BEFORE BED...

Pam does not want to be awakened during the night by a **Calibrate now** alert, so she checks her BG and calibrates her sensor before she goes to bed.

Section 8: Reading the sensor display

Once the sensor starts to send SG readings to the pump, the Home screen shows your readings in a way that is similar to the example shown below.

high limit

three-hour SG graph

low limit

status icons

trend arrows

most recent
SG reading

SmartGuard
suspend icon
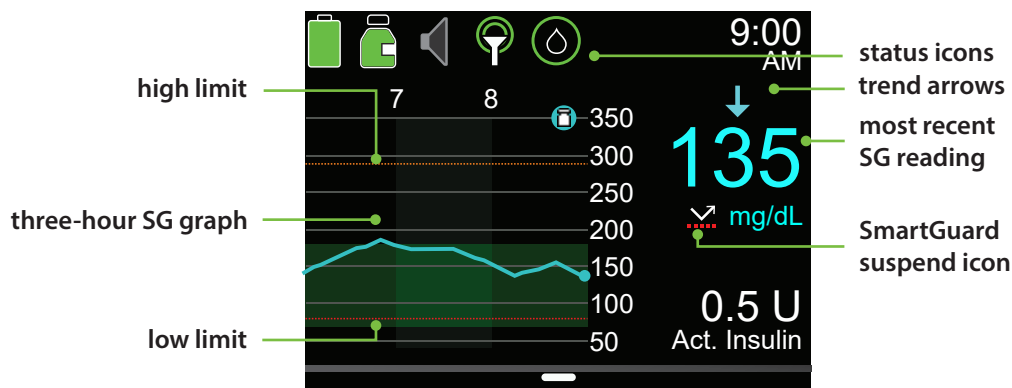
NOTE: This is the sensor display when your pump is in Manual Mode. The display is different when your pump is in SmartGuard Auto Mode. See *GETTING STARTED WITH MINIMED™ 770G SMARTGUARD™ AUTO MODE* for information about Auto Mode display.

Status icons

In addition to the pump icons, you will see additional sensor icons when using CGM.

Connection: The connection icon appears green when the Sensor feature is on and your transmitter is successfully communicating with your pump. The connection icon appears with a red cross when the Sensor feature is turned on, but the transmitter is not connected, or communication with your pump has been lost.

Calibration: The calibration icon shows the approximate time left until your next sensor calibration is due. The calibration icon appears only when the Sensor feature is turned on. The color and the circle around the icon indicate the status of calibration. When your sensor is fully calibrated, the icon has a solid green circle around it. As the time for your next sensor calibration approaches, the green circle around the icon becomes smaller, and the color of the icon changes. When the icon turns red, a sensor calibration is required. If the time until your next sensor calibration is unavailable, the icon has a solid blue circle around a question mark. The circle shows three dots when a new sensor is connected or when the sensor is calibrating. This also occurs within 15 minutes of a Calibration not accepted alert.

Audio icon: If Alert Silence is on: audio, vibrate, or audio and vibrate.

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SmartGuard suspend icon

During any time segment when either **SmartGuard Suspend before low** or **SmartGuard Suspend on low** is set to On, you will see the SmartGuard suspend icon on the Home screen.

Suspend before low or **Suspend on low** is on and ready. If either suspend feature becomes active, the icon will flash while insulin delivery is stopped.

Suspend before low or **Suspend on low** is on but unavailable. This can be due to a recent suspend event or when no SG values are available.

Sensor status

You can go to the Sensor status menu to see, for example, when your next calibration is due, time left on your sensor, and battery life remaining on your transmitter.

1) From the Home screen, press 🔘.

2) Select **Status**.

3) Select **Sensor**.

You will also see additional sensor status information in the **Notifications**, **Quick Status**, and **Settings** screens.
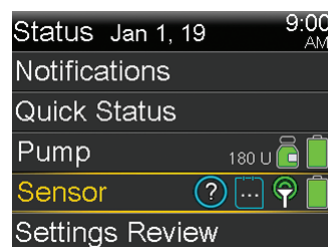
Current sensor value

The most current sensor reading is displayed on the Home screen. This is updated every 5 minutes. The sensor reads glucose values from 40 to 400 mg/dL.

NOTE: One, two, or three trend arrows may sometimes appear above the SG reading. These give you insight on the speed and direction that your SG is moving. See *Trends, on page 3* to review these arrows.

Sensor graph

A graph that shows the last 3 hours of SG readings is displayed on the Home screen. Your high glucose limit entered in your sensor settings is shown in orange, and your low glucose limit is shown in red.
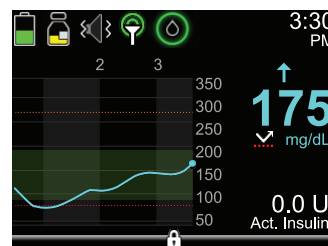
Additional sensor graphs

In addition to the 3-hour graph, you can also view 6-hour, 12-hour, and 24-hour glucose trend graphs.
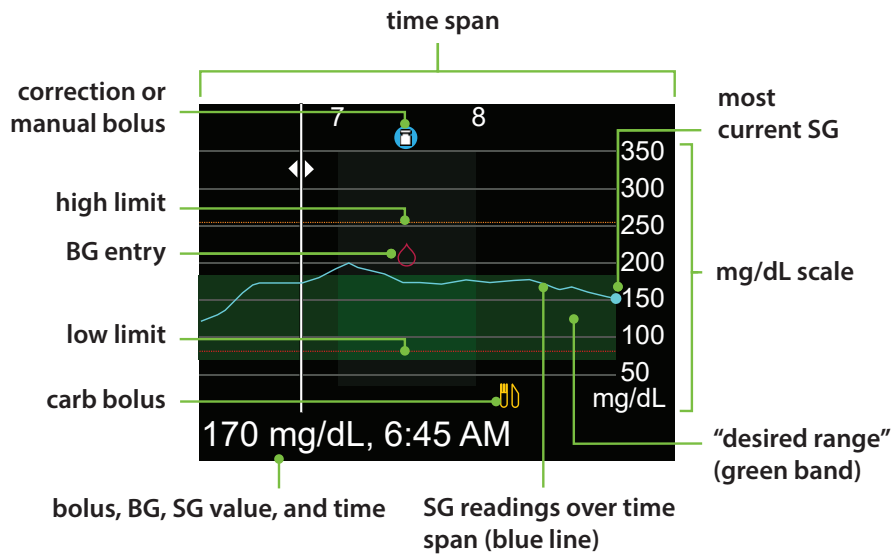
The graph shows a range of SG values from 40 to 400 mg/dL. The green band across the screen represents an SG range from 70 to 180 mg/dL. The blue line shows your actual SG values over the time span. At the right end of the blue line is a blue dot representing the most current SG value.

Details about correction bolus, BG entry, and carb or food bolus are shown on the graph. To view details for an icon, look for the icon on the graph, and press ⟨ or ⟩ to scroll to that icon. The details for that icon are located along the bottom of the screen. Icons shown on the graph are:

- – indicates either a correction bolus or manual bolus

- – indicates a BG entered either manually or using a meter

- – indicates a bolus that includes a carb entry; it displays for a carb only or a carb plus correction bolus

Press ⟨ or ⟩ to cycle through the time span. The SG values and times, BG readings and times, and Bolus amounts display along the bottom of the screen.

A bolus amount followed by an (N) indicates a Normal bolus delivered through the bolus feature. A BG entry is labeled BG, for example: BG, 121 mg/dL, 12:30. An SG is displayed with the value and time only, for example: 121 mg/dL, 12:35.

Press ⌃ or ⌄ to change the time span shown on the graph. The choices are 3 hours, 6 hours, 12 hours, and 24 hours.

To access these graphs:

1) From the Home screen, press ✤.

2) Press ❮ to scroll back over the graph. Sensor values will be shown at the bottom of the graph.

3) Press ⌃ to see the 6-hour, 12-hour, and 24-hour graphs.

4) Press ↩ to return to the Home screen.

NOTE: Remember to download the MiniMed Mobile app onto your iOS or Android device. More information about the MiniMed Mobile app can be found in the *MINIMED™ MOBILE APP USER GUIDE* sent with your pump.

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Section 9: Sensor alerts and suspend

Alerts are an important part of using CGM. We discussed some of these alerts earlier in *Personalized alerts, on page 4.* A table of the most common alerts that occur can be found in the *Quick Reference Guide for Sensor Alerts, on page 51.*

You are notified of an alert or a SmartGuard suspend event in the following ways:

- The notification light flashes.
- The pump beeps, vibrates, or beeps and vibrates depending on your Audio Options setting.
- A message that describes the alert or suspend event appears on the pump.

Follow these steps when you receive an alert:

1. Read the text on the screen. Take any action necessary.
2. Press ⌄.
3. Press ◎ on the desired option.

Sensor alerts

This is an example of the **Alert before low** screen.

Alert before low ⚠	Alert before low ⚠
12:00 AM	12:00 AM
Sensor glucose	Sensor glucose
approaching Low Limit.	approaching Low Limit.
Check BG.	Check BG.
▼	OK
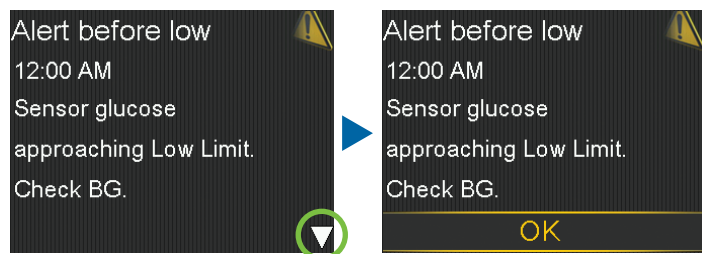
This is an example of the **Sensor expired** screen.

Sensor expired ⚠	Sensor expired ⚠
12:00 AM	12:00 AM
Insert new sensor.	Insert new sensor.
▼	OK

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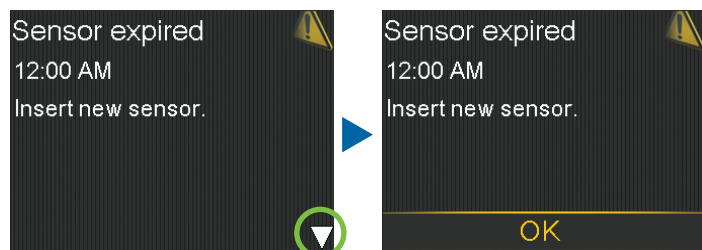
SmartGuard suspend features

Suspend before low

When a **Suspend before low** event occurs, an alert appears. Insulin delivery stops. Press ⌄ and ⊙ to clear the alert. Insulin remains suspended. If **Alert before low** is on, the pump beeps or vibrates every minute until the alert is cleared. If the alert is not cleared in 10 minutes, the pump begins to siren.
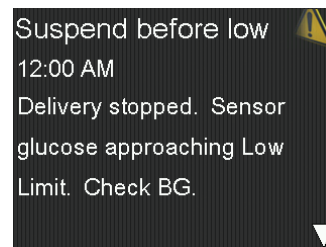
> **NOTE:** If SG still reaches the low limit, an **Alert on low** alert occurs.

Suspend on low

When a **Suspend on low** event occurs, an alarm appears. Insulin delivery stops. The pump continues to beep or vibrate every minute for 10 minutes until you press ⌄ and ⊙ to clear the alarm.
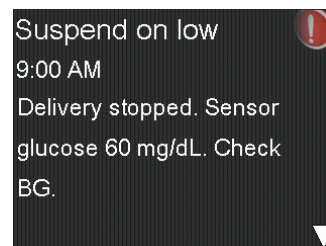
If the **Suspend on low** alarm is not cleared after 10 minutes:

- The pump begins to siren.
- The Medical device alarm appears.

Insulin remains suspended for a maximum of 2 hours.
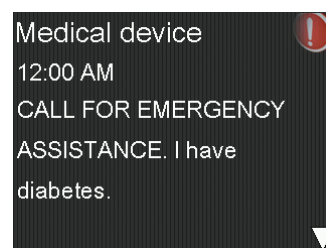
SmartGuard Suspend Home screen

After the **Suspend before low** or **Suspend on low** message is cleared and insulin delivery stops, the Home screen displays:

- **Suspended before low** or **Suspended on low** appears in a red banner at the bottom of the Home screen.
- The graph on the Home screen is shaded to represent the duration the insulin was suspended.
- The SmartGuard suspend icon flashes.
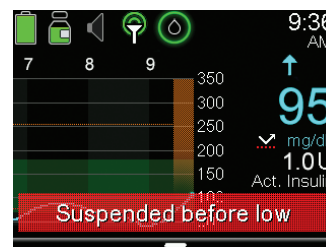
Resuming basal insulin

There are two ways insulin can be restarted when a SmartGuard suspend feature is active: automatic and manual resume.

Automatic basal resume

Basal rates automatically resume in the following situations:

- SG values are above the low limit and are trending upward. If you have the **Resume basal alert** on, an alert occurs when basal delivery automatically resumes.

- Insulin has been suspended for the maximum of 2 hours. You always receive a message and are alerted when this occurs.

> **NOTE:** Any bolus that was delivering at the time the suspend occurred will not restart when insulin delivery resumes. The basal pattern active at the time the suspend occurred restarts when insulin delivery is resumed. If a temp basal was running and there is still time remaining, the temp basal resumes.

Manual basal resume

There may be times when you choose to resume basal insulin delivery yourself. Perhaps your healthcare professional has advised you to eat carbohydrates to bring your glucose level up, and does not want insulin to continue to be suspended. You can take these steps to resume basal delivery:

1) From the Home screen, press ⊙.
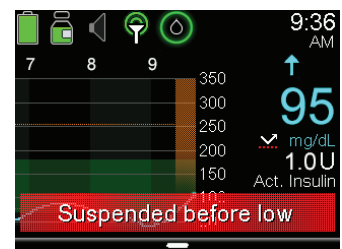
2) Select **Resume Basal**.
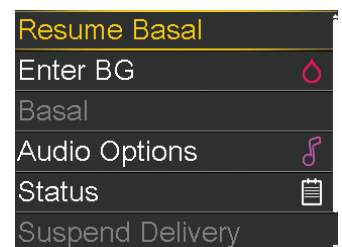
3) Select **Resume Basal**.
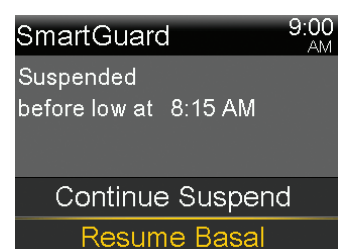
4) Select **Yes** to resume basal delivery.
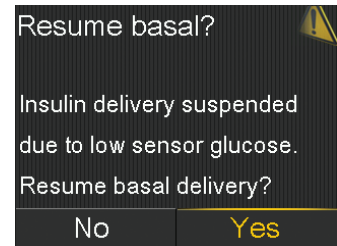
SmartGuard suspend features unavailable

SmartGuard suspend features are unavailable for a period of time after basal delivery has been resumed following a **Suspend on low** or **Suspend before low** event.

The amount of time the SmartGuard suspend features are unavailable is determined by the following:

Unavailable for 30 minutes if any of the following occurs:

- You have manually resumed the basal insulin.
- Basal insulin is automatically resumed based on the SG.
- You have responded to the alert, and the suspend reaches the 2 hour maximum suspend time.

Unavailable for 4 hours if all of the following occur:

- SG has reached the low limit.
- You did not respond to the alert.
- Basal insulin was suspended for the 2 hour maximum suspend time.

NOTE: If the alert is cleared during the 4 hour unavailable period, the SmartGuard suspend feature becomes available after 30 minutes has passed.

Section 10: Charging and storing the Guardian Link (3) transmitter

Charge the transmitter before each use. When the transmitter is charging, a green light flashes on the charger. When charging is complete, the green light on the charger stays on, without flashing, for 15 to 20 seconds and then turns off. You need to charge the transmitter after each sensor use. A fully charged transmitter can be used for a maximum of seven days without recharging. It can take up to two hours to fully recharge.
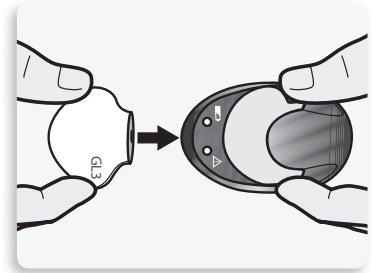
When you remove the transmitter from the charger, a green light should flash on the transmitter. This indicates that the transmitter has enough battery power to be connected to the sensor. If you do not see the green light flash on the transmitter, place the transmitter back on the charger until it is fully charged.

Store the transmitter, charger, and tester in a clean, dry location at room temperature. Although not required, you may store the transmitter on the charger.

 CAUTION: The transmitter must be charged every 60 days. Do not store the transmitter on the charger for more than 60 days. Otherwise, the transmitter battery will be permanently damaged. Disconnect and reconnect to the charger to re-charge again before use.

If you connect your transmitter to the charger and you see no lights on the charger: Replace the battery in the charger. If there are still no lights on the charger after replacing batteries, the transmitter pins may be damaged. Contact 24-Hour Technical Support.

While charging your transmitter, if you see a flashing red light on the charger: Replace the battery in the charger.

While charging your transmitter, if you see a mix of short and long flashing red lights on the charger: Charge the transmitter for one hour. If the red lights continue to flash, charge the transmitter for eight hours. If the red lights continue to flash after eight hours of charging, please contact 24-Hour Technical Support.

Refer to your Guardian Link (3) transmitter and charger user guides for more information.

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Section 11: Traveling by air

If you wear a CGM device, it is safe for use on commercial airlines. If questioned by airline personnel about the use of your device, please show them your Medical emergency card.

> **IMPORTANT:** Be extra attentive to monitoring your glucose levels while traveling. Always be prepared to respond to changes in glucose if needed.

Section 12: X-rays, MRI, or CT scan

WARNING: Do not expose your pump to MRI equipment, diathermy devices or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). The strong magnetic fields can cause the devices to malfunction, and result in serious injury. If your pump is exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance. Magnetic fields, and direct contact with magnets, may affect the accurate functioning of your system, which may lead to health risks such as hypoglycemia or hyperglycemia.

Cannula infusion sets such as the Quick-set, Silhouette and Mio can be left in place during the procedure. However, infusion sets that use a needle instead of a cannula to infuse insulin, such as the Sure-T, must be removed prior to the procedure.

Do not expose your sensor or transmitter to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields. Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury, or be unsafe. If your sensor or transmitter are inadvertently exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.

Training handouts

This section contains handouts that you can use during or after your training.

- The **Quick Reference Guide for Sensor Alerts** provides information about alerts that you might receive.
- The **Quick Reference Guide for Using the One-press Serter with Guardian™ Sensor (3)** reminds you of the steps to take when inserting a new sensor.
- The **Quick Reference Guide for SmartGuard™ Suspend Features** provides further details about the SmartGuard™ suspend features.

Feel free to remove these handouts and keep them in a place where they are easily accessible.

Sensor Alerts

This table shows some of the most common alerts that you may receive when using CGM.

NOTE: To silence an alert, press ⌄, and then press ◎ on the desired option.

Alert	Reason	Steps to take
Alert on high	The SG value is equal to or higher than the high limit that you set.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat it if necessary based on instructions from your healthcare professional and continue to monitor.
Alert on low	The SG value is equal to or lower than the low limit that you set.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat it if necessary based on instructions from your healthcare professional and continue to monitor.
Alert before high	The SG reading is expected to reach the high glucose limit in the length of time you set for the Time before high.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat it if necessary based on instructions from your healthcare professional and continue to monitor.
Alert before low	The SG reading is expected to reach the low glucose limit within 30 minutes.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat it if necessary based on instructions from your healthcare professional and continue to monitor.
Rise Alert	The SG reading is increasing at a rate that is equal to or faster than the rate limit that you set.	Do not treat your glucose based on SG. Confirm it using your BG meter. Treat it if necessary based on instructions from your healthcare professional and continue to monitor.

Quick Reference Guide for Sensor Alerts

Alert	Reason	Steps to take
Calibrate now	A calibration is needed in order to receive SG readings.	Enter BG value into your pump to calibrate.
Lost sensor signal	Communication between pump and transmitter has been lost for 30 minutes during or after warm-up.	Check that the sensor is still inserted in the skin and the transmitter and sensor are still connected. Move your pump closer to your transmitter.
Calibration not accepted	Your system was unable to use the BG meter reading you entered to calibrate your sensor.	In 15 minutes, your pump will prompt you to enter a new BG meter reading for calibration. Wash your hands and dry thoroughly before checking BG.
BG not received	The transmitter was unable to receive the calibration BG reading from the pump.	Move your pump closer to your transmitter and select OK. The pump will try sending the BG again.
Sensor expired	The sensor has reached its maximum usage of 7 full days.	Remove the sensor and follow the instructions for inserting and starting a new sensor.
Sensor updating	The sensor is updating.	Do not calibrate unless notified. This could take up to 3 hours.
Change sensor	You have received two Calibration not accepted alerts in a row.	Remove the sensor and follow the instructions for inserting and starting a new sensor.

Inserting a new sensor

Wash your hands and clean the insertion site with alcohol.

1. **Open the sensor package**. Pull the corner of the paper covering to open the sensor package.

2a. **Hold the sensor by the plastic pedestal**. Remove the sensor with the attached plastic pedestal from the packaging by holding the pedestal only. Place the sensor and the pedestal on a clean, flat surface (such as a table).
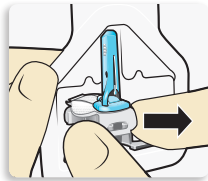
2b. **Tuck the adhesive tab.** Make sure that the sensor's adhesive tab is tucked under the sensor connector and snaps.
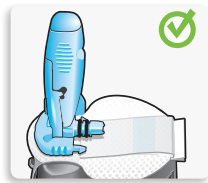
Correct   **Incorrect**

3. **Load the sensor into the serter**. Grip the serter exactly as shown **with your thumb on the thumb print on the serter. Do not hold the side buttons.** Push the serter down onto the pedestal until the base of the serter sits flat on the table.
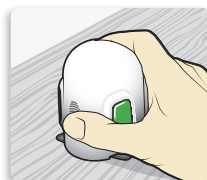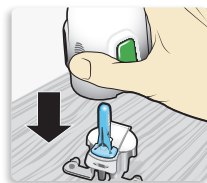
Correct   **Incorrect**

4. **Detach the serter from the pedestal.** To detach the serter from the pedestal, grip the serter as shown with your thumb on the thumb print on the serter. With the other hand, place two fingers on the pedestal arms, and slowly pull the serter straight up.
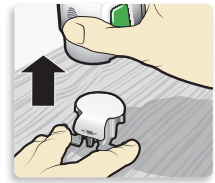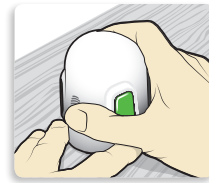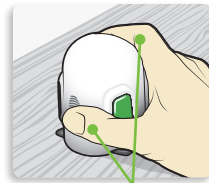
Fingers are NOT holding the side buttons.

NOTE: Make sure that the plastic pedestal is firmly on the table before pulling the serter away.

CAUTION: Do not detach the pedestal from the serter in mid-air as this may damage the sensor.

5a. **Place the serter on the body**. Hold the serter steadily against the cleaned insertion site, without pushing the serter too deeply into the skin.

NOTE: Failing to hold the serter securely flat against the body may allow the serter to spring back after pressing the buttons and result in an improper insertion of the sensor.

5b. **Insert the sensor**. Press and release the **bump** on both of the buttons at the same time.
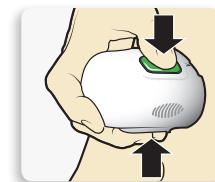
5c. **Hold the serter against the body**. Continue holding the serter against the body for at least five seconds to allow the adhesive to stick to the skin.
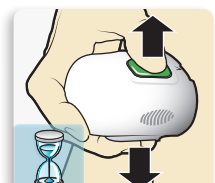
5d. **Remove the serter from the body**. Slowly pull the serter away from the skin, making sure the buttons are not pressed.
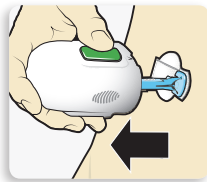
6. **Remove the needle housing**. Gently hold the base of the sensor against the skin with one hand. With the other hand, hold the needle housing **at the top** and slowly pull it straight away from the sensor. Dispose of the needle housing in a sharps container.
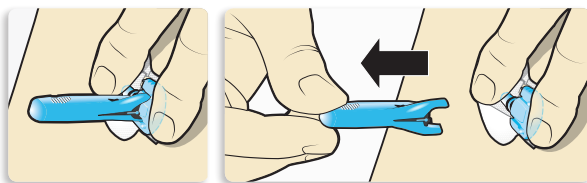
NOTE: Apply additional liquid adhesive. You may use an optional adhesive such as Skin Tac™* under the adhesive pad prior to removing the liner. Allow the optional adhesive to dry.

7a. **Remove the adhesive pad liner**. Hold the sensor in place and gently remove the adhesive liner from under the adhesive pad.
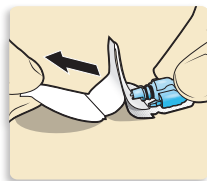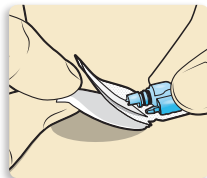
7b. **Press the entire adhesive pad to the skin**. Firmly press the adhesive against the skin and smooth the entire adhesive pad so it sticks to the skin.
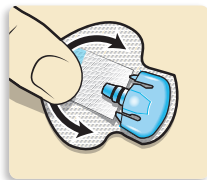
NOTE: The Guardian™ Sensor (3) adhesive is sensitive to pressure. Continue applying pressure on the adhesive to ensure that the sensor remains inserted in the skin for up to 7 days of wear.

8a. **Untuck the adhesive tab**. Untuck the adhesive tab from under the sensor connector.

8b. **Straighten the adhesive tab**. Straighten the adhesive tab so it lies flat against the skin, but do not remove the adhesive liner yet.
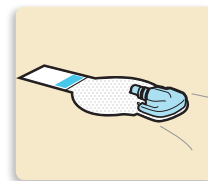
Taping the sensor

1. Remove liner 1.
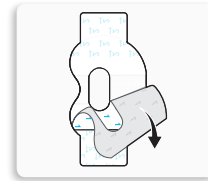
2. Apply the tape as shown and press it down firmly.

Both the sensor and the skin are taped.
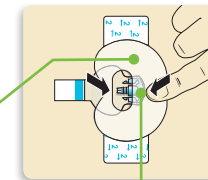
The wide part of the tape covers half of the sensor base.

3. Remove liner 2 from each side.

The connector and snaps in the hole of the tape.
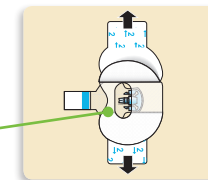
4. Smooth the tape.
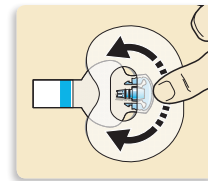
Connecting your transmitter

1. Connect the transmitter to the sensor.
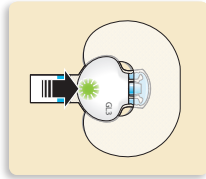
NOTE: Wait for the green light on the transmitter to flash. If the green light does not flash, refer to the Troubleshooting section of the transmitter user guide.

2. Remove the liner from the adhesive tab. Cover the transmitter with the adhesive tab.
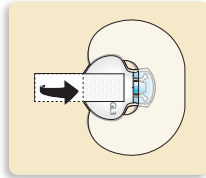
NOTE: Do not pull the adhesive tab too tightly.

3. To apply the 2nd tape, remove liner 1.
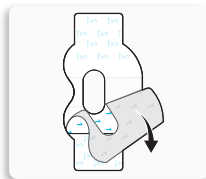
4. Rotate the 2nd tape and place the tape over the transmitter. Press it down firmly.

The wide part of the tape covers the end of the transmitter and the skin.
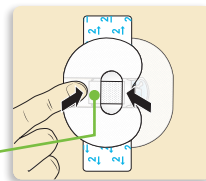
5. Remove liner 2 from each side.
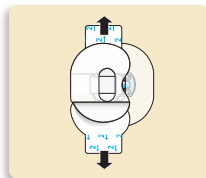
6. Smooth the tape.
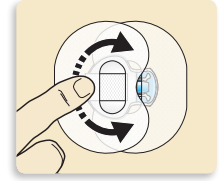
NOTE: Check the site regularly. Apply additional tape if the sensor and the transmitter are not secure.

7. This image is an example of oval tape applied correctly.
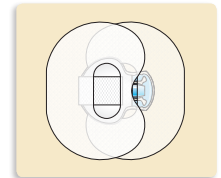
Starting the sensor

1. Once the **Sensor connected** message appears, press ⌄. *This typically takes less than a minute, but may take up to 10 minutes.*

> Sensor connected
> If new sensor, select Start New. If not, select Reconnect.

2. Select **Start New Sensor**.
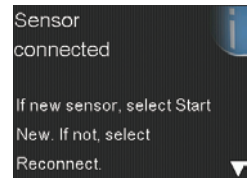
> Sensor connected
> Reconnect.
> **Start New Sensor**
> Reconnect Sensor
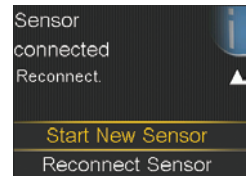
3. The **Sensor warm-up started** message will appear. Press ⌄ and then ◎ to clear.

> Sensor warm-up started
> 12:00 AM
> Warm-up takes up to 2 hours. You will be notified when calibration is needed.
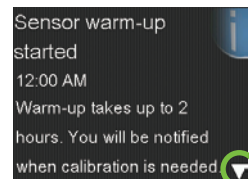
4. **Warm up...** will appear on the Home screen until the sensor is ready for the first calibration.

> 9:00 AM
> Warm up...
> 250
> 200
> 150
> 100 mg/dL
> 50
> 0.0 U
> Act. Insulin
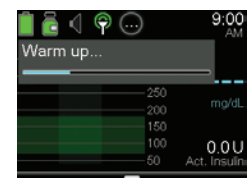
Quick Reference Guide for Using the One-press Serter with Guardian™ Sensor (3)

Calibrating

1. Select **Snooze**.
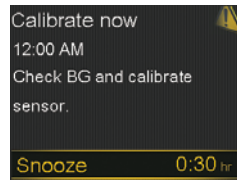
2. The pump will display this screen. Check the BG, and use that BG value to calibrate the sensor. See *Calibration, on page 32* if you need help calibrating.
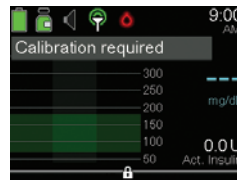
3. After a BG for calibration is entered, this screen will display. You will begin receiving SG readings within 5 minutes.
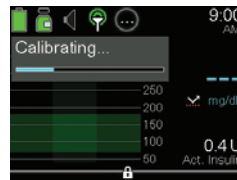
The images below show additional details about using the SmartGuard™ suspend features of the MiniMed™ 770G system.

────────	SG trend
─ ─ ─ ─	Estimated SG trend
▪▪▪▪▪▪▪	SG trend during suspend
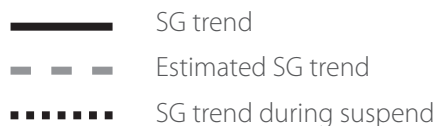
Suspend on low event:
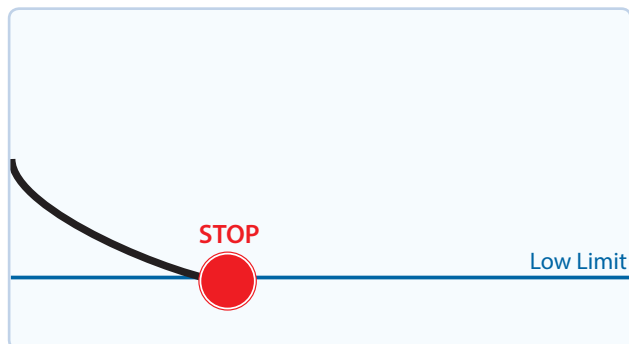
STOP

Low Limit

If SG reaches your low limit, insulin delivery will be stopped.

You will always receive a message and alarm when this occurs.

You will have 10 minutes to respond before the pump begins to siren and the Medical device alarm appears.

Suspend before low event:

70 mg/dL above Low Limit

STOP

20 mg/dL above Low Limit
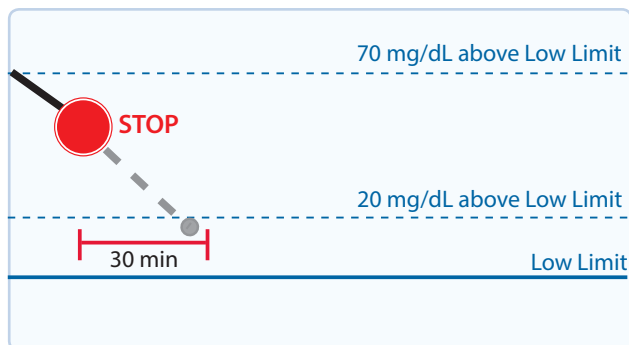
30 min   Low Limit

To help keep SG from reaching your low limit, insulin delivery will be stopped in the following situations:

- SG is at or within 70 mg/dL above the low limit.

- It is predicted that your SG will approach the low limit in 30 minutes.

If **Alert before low** is on, you will receive an alert when insulin is suspended.

Alert on low during a Suspend before low event:
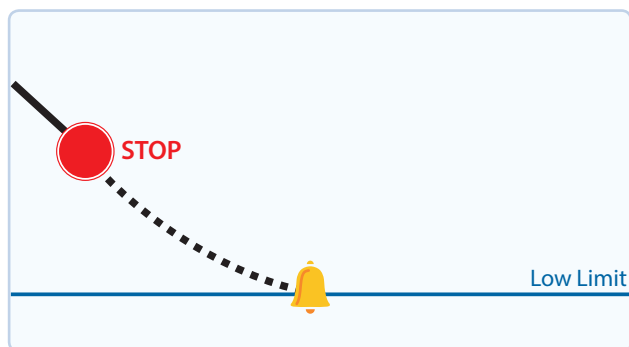
STOP

Low Limit

If insulin delivery has stopped due to **Suspend before low**, SG may still reach your low limit.

You will always be alerted when this occurs.

You will have 10 minutes to respond before the pump begins to siren and the Medical device alarm appears.

Quick Reference Guide for SmartGuard™ Suspend Features

Automatic basal resume based on SG value:

40 mg/dL above Low Limit
START
20 mg/dL above Low Limit
Low Limit
30 min
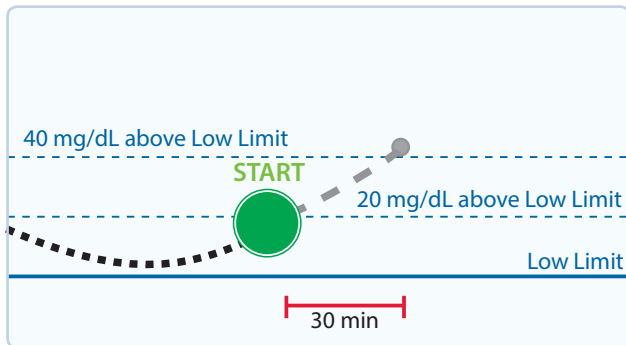
During a **Suspend before low** or **Suspend on low** event, basal insulin automatically resumes in the following situations:

- SG is above the low limit and trending upward.
- Insulin has been suspended by low management for at least 30 minutes.

If **Resume basal alert** is on, you will receive an alert when this occurs. Remember, you can manually resume basal insulin at any time.

Automatic basal resume due to 2 hour maximum suspend:

STOP 20 mg/dL above Low Limit **START**
Low Limit
2 hours
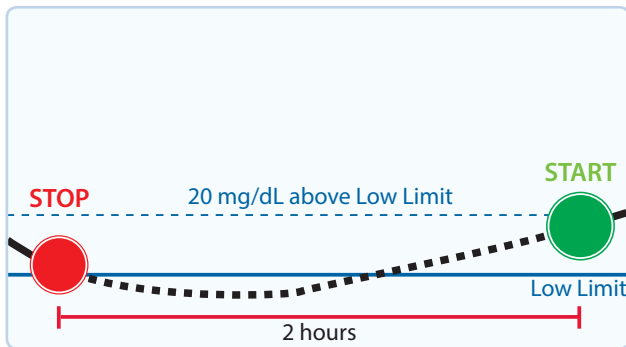
During either a **Suspend before low** or **Suspend on low** event, if basal insulin is not resumed due to SG values, it automatically resumes after 2 hours.

You will always receive an alert when you reach the 2 hour maximum suspend time, even if the **Resume basal alert** is set to Off. Remember, you can manually resume basal insulin at any time.

SmartGuard™ suspend unavailable:

START
30 min
Low Limit
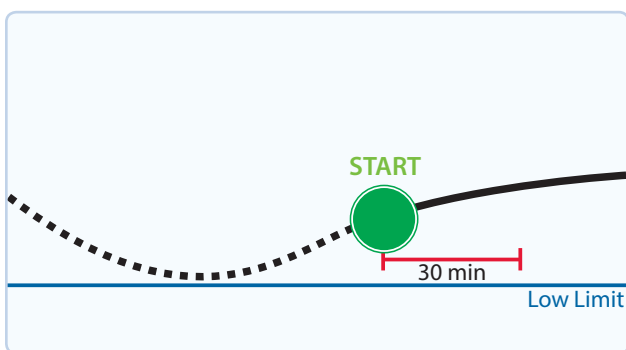
Once basal insulin resumes following either a **Suspend before low** or **Suspend on low** event, there will be a period of time when the SmartGuard™ suspend features are unavailable.

SmartGuard™ suspend features are most often not available for 30 minutes if you respond to the suspend alarm. However, it can be up to 4 hours. See the *MiniMed™ 770G SYSTEM USER GUIDE* for more specific information about the unavailability period of the SmartGuard™ suspend features.

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GETTING STARTED
WITH MINIMED™ 770G
SMARTGUARD™ AUTO MODE

Medtronic

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Contents

■ **Welcome to SmartGuard Auto Mode**

■ **Training handouts**

■ **Appendix**

Welcome to SmartGuard Auto Mode

In this *GETTING STARTED WITH MINIMED™ 770G SMARTGUARD™ AUTO MODE* guide, you will learn about SmartGuard technology that automatically adjusts your basal insulin delivery based on your sensor glucose (SG) values. To use this technology, your pump needs to be in SmartGuard Auto Mode. In this section, you will learn about Auto Mode and how it works.

For complete information about Auto Mode and the MiniMed 770G system with smart device connectivity, see the *MiniMed™ 770G SYSTEM USER GUIDE*.

NOTE: Any time your pump is not in Auto Mode, it is referred to as Manual Mode. Manual Mode is not a mode that you turn on or off in a menu, but is simply the mode the pump is in when it is not in Auto Mode.

In Auto Mode:

- Basal insulin is delivered based on your SG values and recent insulin delivery needs. This basal insulin delivery is referred to as Auto Basal.
- Auto Mode uses a target of 120 mg/dL.
- You can temporarily change the target to 150 mg/dL for exercise, or other times you would like the target raised.
- You are still required to enter carbs when you eat, and blood glucose (BG) values to calibrate the sensor.
- When you enter a BG over 150 mg/dL, Auto Mode may recommend a correction bolus, depending on its calculations for your insulin needs.
- You will receive a BG required alert if your pump needs a BG to enter or stay in Auto Mode.

NOTE: There are times in Auto Mode when basal insulin is being delivered according to your recent insulin needs, but is not being adjusted based on an SG reading. This is called Safe Basal. You will learn about Safe Basal after you learn about Auto Mode basics.

Section 1: Reviews and reminders before starting SmartGuard Auto Mode

It is important that you read and follow these general reminders before you begin.

BG testing

The BG readings you enter into your pump may be used to do the following:

- Calibrate your sensor.
- Enter Auto Mode.
- Remain in Auto Mode when notified by your pump.
- Recommend a correction bolus when a BG of 150 mg/dL or higher is entered.

If you believe any BG result is inaccurate, wash your hands and recheck your BG. When the pump prompts you to enter a new BG, it is important to do a fingerstick and enter the new BG value.

Calibrating

After the first day of sensor use, the minimum number of calibrations required is one every 12 hours. You may receive an additional **Calibrate now** alert if the system detects that a calibration is required for accuracy of SG readings. Calibrating 4 times a day is optimal. It is best to calibrate when your glucose is not changing very rapidly. Calibrating when there are ⬆⬆, ⬇⬇ or ⬆⬆⬆, ⬇⬇⬇ arrows may decrease sensor accuracy. Many find that a good time to calibrate is before meals. Review the calibration guidelines in the *Calibration* section of *GETTING STARTED WITH MINIMED™ 770G CONTINUOUS GLUCOSE MONITORING* for more information.

Carb entry

While you are in Auto Mode, it is important that you enter your carbs and confirm insulin delivery for you to receive your food boluses.

Section 2: Using SmartGuard Auto Mode for the first time

There are several steps that you need to complete before using SmartGuard Auto Mode for the first time. Some steps take longer than others to process, and some need to be completed before others. Below are the instructions for how to put your pump into Auto Mode for the first time.

IMPORTANT: Work with your healthcare professional to determine when you should turn the Auto Mode feature on, and to determine your individual settings.

To get your pump ready for SmartGuard Auto Mode

NOTE: When the Auto Mode setting is turned **On**, other steps must be completed for it to activate or start working. If you are using the **SmartGuard Suspend before low** or **SmartGuard Suspend on low** features they are automatically turned off when Auto Mode becomes active.

1) Use your pump to deliver your insulin for at least 48 hours. This is called the Auto Mode warm-up. During the warm-up period, the pump tracks your personalized insulin delivery needs for Auto Mode. Auto Mode warm-up begins the first midnight after your pump starts delivering insulin, and takes 48 hours to complete. Your pump does not require the Auto Mode setting to be turned on for the Auto Mode warm-up to occur. We will turn Auto Mode on later.

For example, if your pump starts delivering insulin at 3:00 p.m. on Day 1, the warm-up starts at 12:00 a.m. (midnight) on Day 2, and completes at 12:00 a.m. (midnight) on Day 4.

3
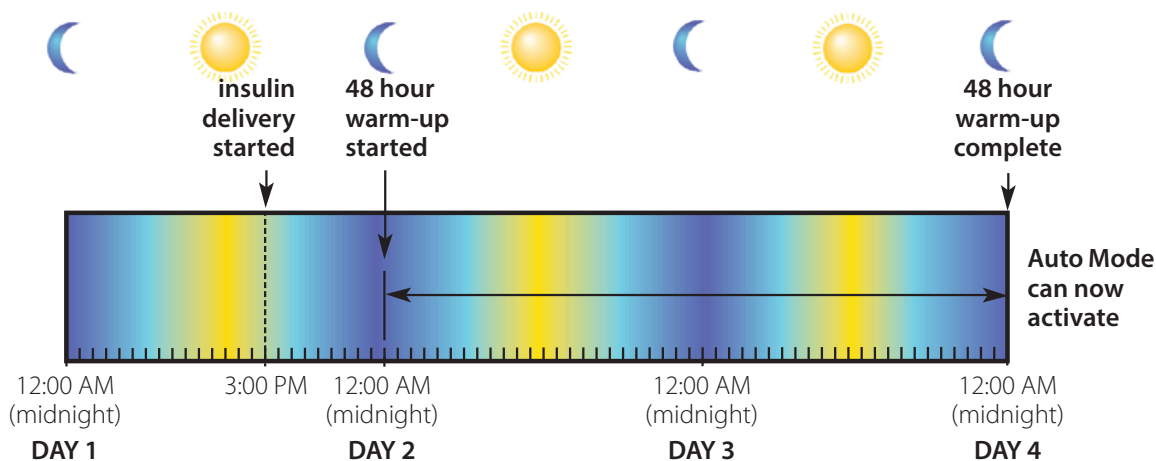
2) Turn on the Sensor option and start a sensor, if you are not currently using one. For Auto Mode to work, you must have a working glucose sensor.

To review instructions on sensor use and continuous glucose monitoring (CGM), see *GETTING STARTED WITH MINIMED™ 770G CONTINUOUS GLUCOSE MONITORING*. Check with your healthcare professional if you have not received training on using your sensor.

If your Bolus Wizard feature is already set up with settings from your healthcare professional, skip to step 4.

Next, enter your Carb Ratio and Active Insulin Time in the Bolus Estimate Setup screen. These settings can be entered as individual Bolus Estimate settings, or as part of the Bolus Wizard setup. If you choose to enter the settings within the Bolus Wizard feature, all of the Bolus Wizard settings must be completed: Carb Ratio, Insulin Sensitivity Factor, BG Target, and Active Insulin Time.

NOTE: If you have entered practice settings into your Bolus Wizard feature, be sure to check with your healthcare professional and enter your personalized settings. If you have practice settings in your Bolus Wizard feature and will not use the Bolus Wizard feature in Manual Mode, make sure your personalized Carb Ratio and Active Insulin Time are entered, and turn the Bolus Wizard feature off.

3) Enter your Carb Ratio and Active Insulin Time using one of the following methods:

Individual Bolus Estimate Settings

To enter your Carb Ratio and Active Insulin Time as individual settings:

a) Press Ⓞ.

b) Select **Options**.

c) Select **Delivery Settings**.

d) Select **Bolus Estimate Setup**.

e) Select **Carb Ratio** or **Active Insulin Time**.

f) Enter your settings.

Bolus Wizard Settings

To use the Bolus Wizard feature to enter your Carb Ratio, Active Insulin, and other Bolus Wizard settings, see *GETTING STARTED WITH MINIMED™ 770G INSULIN PUMP.*

4)   Check the Home screen for the following:

- An active temp basal

- A current bolus delivery, including a Square Wave bolus or Dual Wave bolus

- Delivery suspended

SmartGuard Auto Mode cannot activate, or start working, until each condition is either completed or canceled.

5)   Read the following warning. Then follow the steps to turn the Auto Mode setting on.

⚠️   **WARNING:** Do not put your pump into Auto Mode if you have used the pump in the last 3 days to practice button pressing, or if basal insulin that was programmed into your pump was not your actual basal delivery. Doing so may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. Auto Mode uses the recent delivery history on your pump to determine the Auto Basal delivery amount you receive.

a)   Press ⓞ.

b)   Select **Options**.
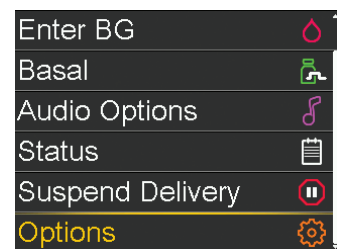
Enter BG	🩸
Basal	🔧
Audio Options	♪
Status	🗒
Suspend Delivery	⏸
Options	⚙️

c)   Select **SmartGuard**.

Options
SmartGuard
History
Reservoir & Tubing
Delivery Settings
Event Markers

d)   Select **Auto Mode**.

SmartGuard
Auto Mode
High Setup
Low Setup
Snooze

5

e)   Select **Auto Mode** again to turn Auto Mode on.
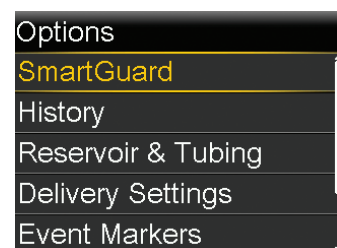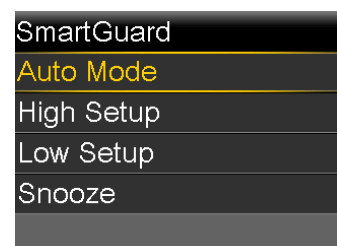
Auto Mode
Auto Mode   On
Auto Mode BG alert   On
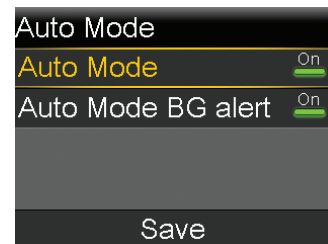
Save

f)   Check the screen to make sure that Auto Mode is set to On. Select **Save**.

Notice that the Auto Mode BG alert is set to **On**. You will learn about this alert in *Information about Safe Basal, on page 20*.

Auto Mode
Auto Mode   On
Auto Mode BG alert   On

Save

NOTE: If SmartGuard Auto Mode is not yet ready, after selecting **Save**, an alert occurs and instructs you to check the Auto Mode Readiness screen.

6)   The last step is to enter a BG value. You can enter the BG either manually in the Enter BG menu, or using the Accu-Chek® Guide Link meter.

If you have entered a BG within the past 12 minutes, your pump might already be in Auto Mode. Your pump will tell you when it is time to enter a BG. Look at your pump screen and follow the instructions.

NOTE: If you are using a new sensor and it is still warming up, or if the first calibration for a new sensor was just entered, the pump will not be ready for you to enter a BG.

NOTE: If you enter a BG over 150 mg/dL, your pump may recommend a correction bolus as it enters Auto Mode, see *Using your pump in SmartGuard Auto Mode, on page 12.*

Screen	Steps
SmartGuard Auto Mode Shield 9:00 AM 135 mg/dL 0.7 U Act. Insulin	This shield on the Home screen means that your pump is in Auto Mode. a) Go to *Viewing the sensor graph in SmartGuard Auto Mode, on page 10* to continue learning about Auto Mode features. b) You may need to review *What to do if your pump is not in SmartGuard Auto Mode, on page 8* at a later time.
Auto Mode not ready message with or without a flashing notification light on your pump Auto Mode not ready Check Auto Mode Readiness screen for details. Auto Mode not ready details. OK	This means that your pump is not in SmartGuard Auto Mode. a) Read the message on the first screen. b) Press ⌄ to finish reading the message. c) Select **OK**. d) To learn about the Auto Mode Readiness screen, go to *pages 8-11, What to do if your pump is not in SmartGuard Auto Mode,* and complete any actions required. Check the Home screen if the notification light is flashing: a) Press ⬅ to return to the Home screen. b) Follow the instructions on the screen and complete the required action.

NOTE: Entering a BG before your pump is ready to receive it does not help you enter Auto Mode more rapidly.

Section 3: Checking SmartGuard Auto Mode Readiness

How to tell when your pump is in SmartGuard Auto Mode

After SmartGuard Auto Mode is turned on and each of the Auto Mode Readiness steps has been completed, Auto Mode becomes *active*. When Auto Mode is *active*, a large shield outlined in blue, with an SG value, appears on the center of your Home screen.

If you see this Home screen, your pump is in Auto Mode, and is delivering Auto Basal.
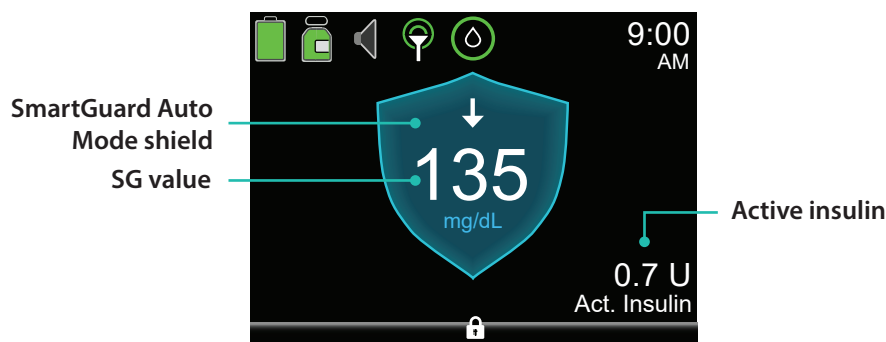
What to do if your pump is not in SmartGuard Auto Mode

If Auto Mode is turned on but not active, or working, check the Auto Mode Readiness screen. This screen helps you determine why Auto Mode is not active. There may be actions that you can take to make Auto Mode active.

To check Auto Mode Readiness

1) From the Home screen, press ⊙.

2) Select **Status**.

3) Select **Auto Mode Readiness**.

   The Auto Mode Readiness screen appears showing you what is ready for Auto Mode, and what is not ready for Auto Mode.
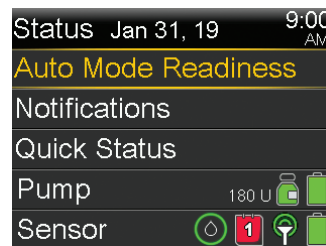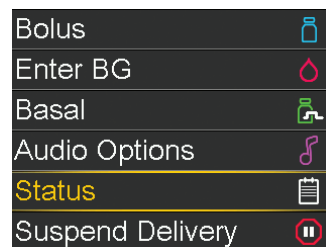
The following Auto Mode Readiness screen shows items that are ready, items that require you to take an action, and items that require you to wait:

- A checkmark icon ✔ means the item is ready. The item appears grayed out.
- A question icon ❓ by the item means that there is an action that you need to take to get your pump into Auto Mode.
- A wait icon ⋯ by the item means that the pump is updating and there is no action for you to take at this time.

Auto Mode Readiness

BG OK for Auto Mode	✓	checkmark icon
Auto Mode turned on	✓	
Sensor not ready	⋯	wait icon
No bolus in progress	✓	
Delivery OK	✓	
Carb ratio not set	?	question icon
Basal rate OK	✓	
Active insulin updated	✓	
Auto Mode updated	✓	
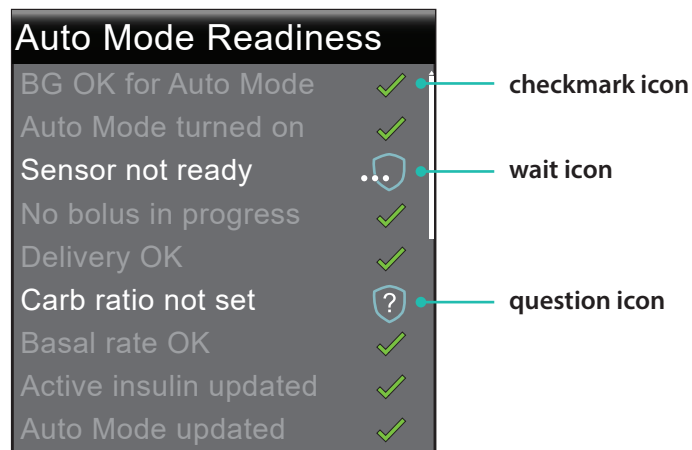
NOTE: For help with question items ❓ and wait items ⋯, see *Quick Reference Guide for SmartGuard™ Auto Mode Readiness Screen, on page 31.*

When your pump is in SmartGuard Auto Mode, the Auto Mode Readiness screen shows all items grayed out and checked. This means that all the steps required for Auto Mode are complete, and Auto Mode is working or active.

Auto Mode Readiness

BG OK for Auto Mode	✓
Auto Mode turned on	✓
Sensor OK	✓
No bolus in progress	✓
Delivery OK	✓
Carb ratio OK	✓
Basal rate OK	✓
Active insulin updated	✓
Auto Mode updated	✓
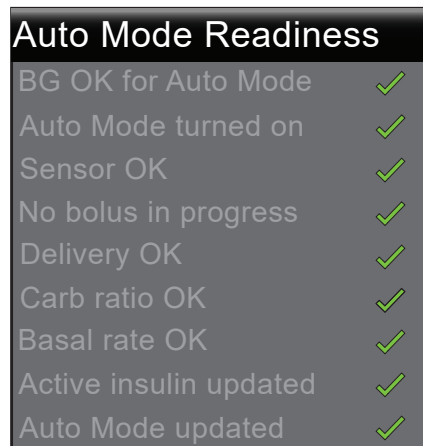
If all items **are not** grayed out and checked, see *Quick Reference Guide for SmartGuard™ Auto Mode Readiness Screen, on page 31.*

Viewing the sensor graph in SmartGuard Auto Mode

The sensor graph in Auto Mode displays information about your SG values and trends, BG entries, Auto Basal deliveries, and bolus entries.

To use the sensor graph

From the Home screen, press � to view the sensor graph.
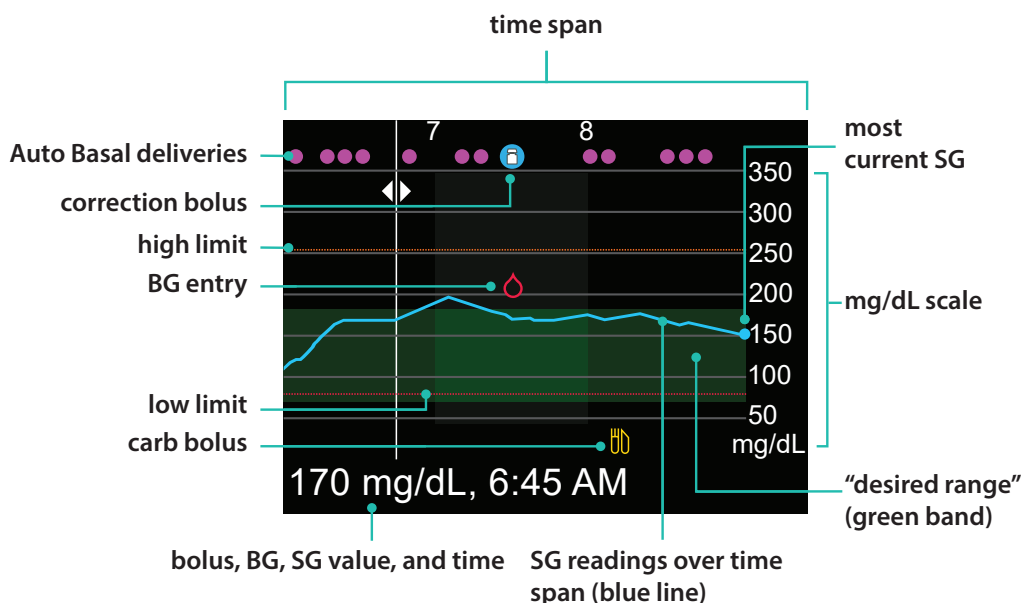
time span

- Auto Basal deliveries
- correction bolus
- high limit
- BG entry
- low limit
- carb bolus

7   8

350
300
250
200
150
100
50
mg/dL

170 mg/dL, 6:45 AM

- most current SG
- mg/dL scale
- "desired range" (green band)

bolus, BG, SG value, and time   **SG readings over time span (blue line)**

The graph shows a range of SG values from 40 to 400 mg/dL. The green band across the screen represents an SG range from 70 to 180 mg/dL. The blue line shows your actual SG values over the time span. At the right end of the blue line is a blue dot representing the most current SG value.

Details about correction bolus, BG entry, and meal (carb) bolus are shown on the graph. To locate details for an icon, look for the icon on the graph, and press ⟨ or ⟩ to scroll to that icon. The details for that icon are located along the bottom of the screen. Icons shown on the graph are:

● – indicates Auto Basal or Safe Basal delivery

🔒 – indicates a bolus for correction only

🔴 – indicates a BG entered either manually or using a meter

🟡 – indicates a bolus that includes a carb entry; it displays for a carb only or a carb plus correction bolus

Press ⟨ or ⟩ to cycle through the time span. The SG values and times, BG readings and times, and Bolus amounts display along the bottom of the screen.

A bolus amount followed by an (N) indicates a normal bolus delivered through the bolus feature. Basal indicates the amount of Auto Basal or Safe Basal that was delivered at that time. A BG entry is labeled BG, for example BG, 121 mg/dL, and an SG is displayed with the value only for example, 121 mg/dL.

Press ⌃ or ⌄ to change the time span shown on the graph. The choices are 3 hours, 6 hours, 12 hours, and 24 hours.

To access these graphs:

1) From the Home screen, press ✦.

2) Press ⟨ to scroll back over the graph. Sensor values are shown at the bottom of the graph.

3) Press ⌃ to see the 6-hour, 12-hour, and 24-hour graphs.

4) Press ⬅ to return to the Home screen.

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Section 4: Using your pump in SmartGuard Auto Mode

Now you will learn how to use your pump when it is in SmartGuard Auto Mode. Auto Mode screens are similar to, but not exactly the same as, Manual Mode screens. To use Auto Mode, you will follow the instructions on the screens, and apply what you already know about using your pump. First, we will start with some of the basic functions, such as entering a BG and carbs, delivering a bolus, calibrating your sensor, and entering and canceling your temp target.

Entering a BG in SmartGuard Auto Mode

You will enter a BG into the pump:

- To calibrate the sensor

- To continue in Auto Mode when the pump alerts you

There are two ways to enter a BG when you are in Auto Mode. You can enter a BG value manually or use the Accu-Chek Guide Link meter.

Using the Accu-Chek Guide Link meter to enter a BG with or without carbs for food, deliver a bolus, and calibrate your sensor

1) Check your BG. Press ⤵ on the meter to send the BG reading to the pump.

2) Select **Yes** to confirm the BG meter reading.

   If you do not believe the meter result is accurate, do not confirm now. Select **No**, wash your hands, and recheck your BG.

3) Bolus will be highlighted. If you want to calibrate with this BG, select **Calibrate Sensor**.
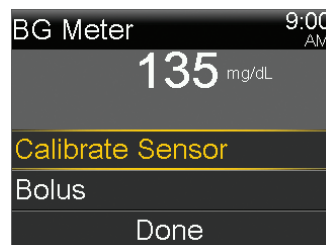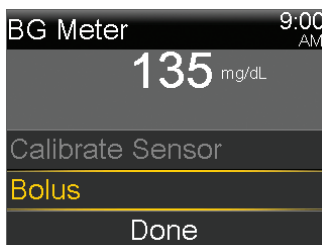
4) If you want to give a bolus, select **Bolus**.

   If you do not want to give a bolus, press ⌄, and select **Done**.

BG Meter	9:00 AM
135 mg/dL	
Calibrate Sensor	
Bolus	
Done	
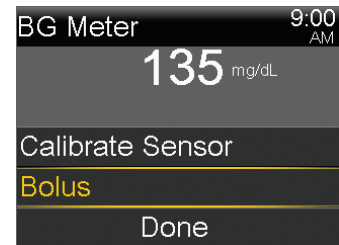
5) Select **Carbs** to enter carbs for food.

   If you are not eating carbs, go to the next step.

Bolus	9:00 AM
BG	135 mg/dL
Carbs	0 g
Active Insulin	0.0 U
Next	
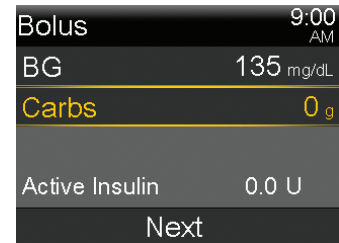
6) Select **Next** to review the calculated bolus amount.

Bolus	9:00 AM
BG	135 mg/dL
Carbs	20 g
Active Insulin	0.0 U
Next	

7) Select **Deliver Bolus** to deliver the bolus.
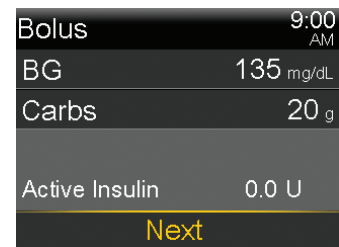
Bolus	9:00 AM
Bolus	2.3 U
Deliver Bolus	
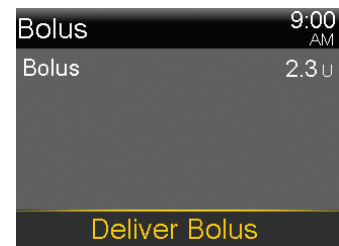
The Bolus Started message briefly appears, then the Home screen appears, with a banner showing the bolus being delivered.
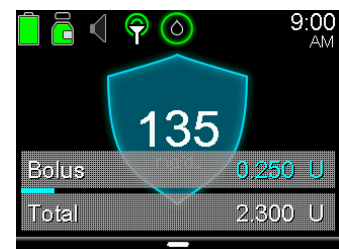
	9:00 AM
135	
Bolus	0.250 U
Total	2.300 U

NOTE: If you entered a BG over 150 mg/dL, Auto Mode may recommend a correction bolus. Proceed through the bolus menu and enter carbs if necessary, and select **Deliver Bolus**.

NOTE: Just like in Manual Mode, you can easily stop a bolus at any time. Press ◯ and select **Stop Bolus**. Then, select **Yes** to stop the bolus. View the amount of bolus delivered, and then select **Done**.

To manually enter a BG and carbs for food, deliver a bolus, and calibrate your sensor

1) Press ⦿.

2) Select **Bolus**.

Bolus	🔋
Enter BG	🔴
Temp Target	🏃
Audio Options	🎵
Status	📋
Suspend Delivery	⏸

3) Select **BG**.

Bolus	9:00 AM
BG	--- mg/dL
Carbs	0 g
Active Insulin	0.0 U
Next	

4) Press ⌃ or ⌄ to enter your BG reading, and press ⦿.

Bolus	9:00 AM
BG	135 mg/dL
Carbs	0 g
Active Insulin	0.0 U
Next	

5) Select **Carbs**.

Bolus	9:00 AM
BG	135 mg/dL
Carbs	0 g
Active Insulin	0.0 U
Next	

6) Press ⌃ or ⌄ to enter carbs for your food, and press ⦿.

Bolus	9:00 AM
BG	135 mg/dL
Carbs	20 g
Active Insulin	0.0 U
Next	

7) Select **Next**.

Bolus	9:00 AM
BG	135 mg/dL
Carbs	20 g
Active Insulin	0.0 U
Next	
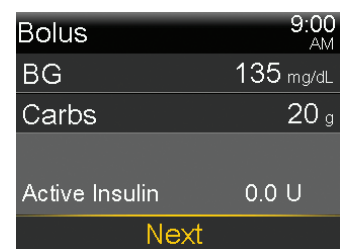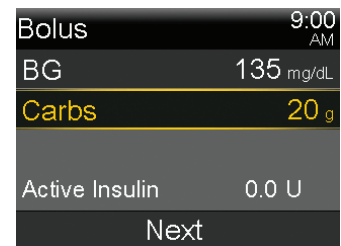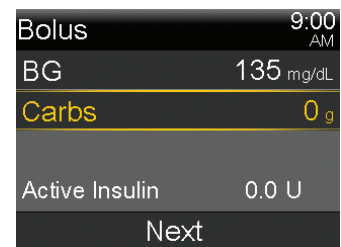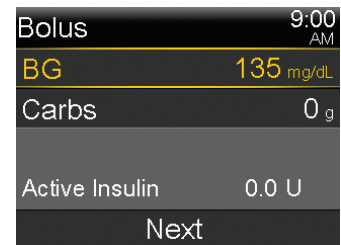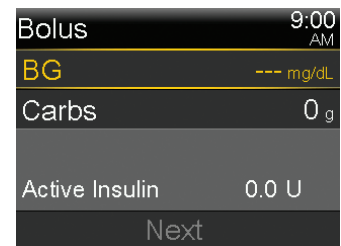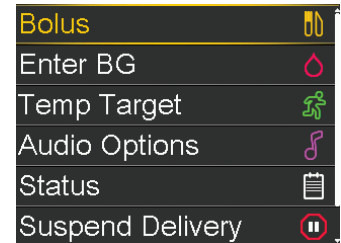
8) Review the calculated bolus amount.

9) Select **Deliver Bolus** to deliver the bolus.

   Press ⬅ if you do not wish to deliver the bolus.
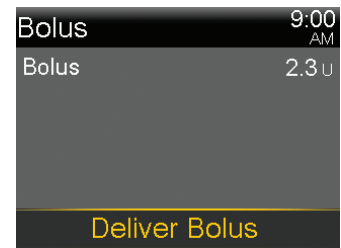
The message Bolus Started briefly appears.

A message appears asking if you want to calibrate using the entered BG.

10) Select **Yes** if you want to calibrate.

   Select **No** if you do not want to calibrate.
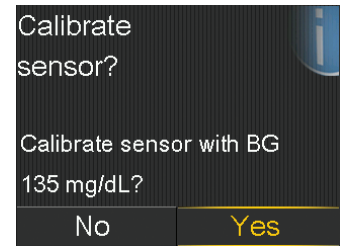
The Home screen appears showing the bolus being delivered.

NOTE: If you entered a BG over 150 mg/dL, Auto Mode may recommend a correction bolus. Proceed through the bolus menu and enter carbs if necessary, and select **Deliver Bolus**.

NOTE: Just like in Manual Mode, you can easily stop a bolus at any time. Press ⊙ and select **Stop Bolus**. Then, select **Yes** to stop the bolus. View the amount of bolus delivered, and then select **Done**.

To manually enter your BG only

1) Press ⊙.
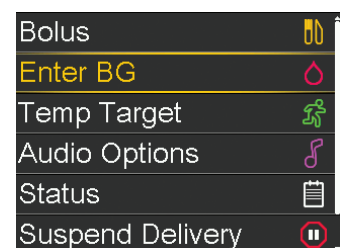
2) Select **Enter BG**.

3)   Select **Enter BG** to adjust the BG value.
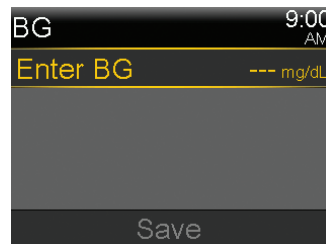
4)   Press 🔼 or 🔽 to enter your BG reading and press ⊙.
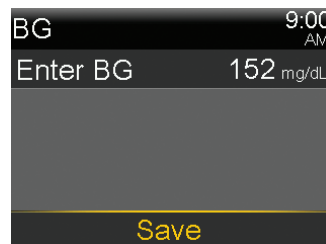
5)   Select **Save**.

A message appears asking if you want to calibrate using the entered BG.

6)   Select **Yes** if you want to calibrate.

Select **No** if you do not want to calibrate.
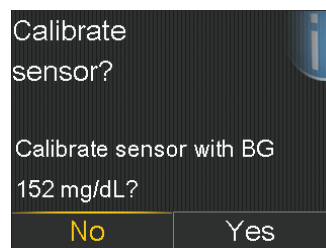
If your BG reading is over 150 mg/dL, your pump may recommend a correction bolus.

a)   Read the message on the first screen.

b)   Press 🔽 to finish reading the message.

c)   Select **Bolus**.

d)   Start with step 5 in the previous instructions, *To manually enter a BG and carbs for food, deliver a bolus, and calibrate your sensor, on page 14*.
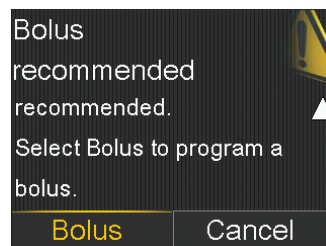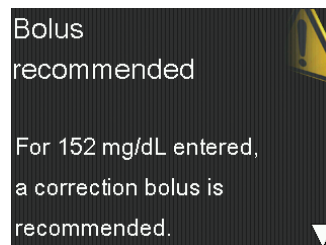
Entering and Canceling Temp Target

▶ **To enter your Temp Target**

The standard Auto Mode target is 120 mg/dL. You can temporarily change your Auto Mode target to 150 mg/dL for exercise, or other times you would like the Auto Mode target raised. Check with your healthcare professional for recommendations regarding your temp target use.

1) Press ⊙.

2) Select Temp Target.

Bolus	
Enter BG	
Temp Target	
Audio Options	
Status	
Suspend Delivery	

3) Press ⌃ or ⌄ to set the temp target duration, and then press ⊙. The duration can be set in 30-minute increments. The default is 2 hours.

4) Select **Start**.

Temp Target 9:00 AM

Duration 2:00 hr

Set target to 150 mg/dL

Start

The message Temp Target Started briefly appears, then the Home screen appears, where a banner shows the remaining Temp Target time.

9:00 AM

135 mg/dL

1.0 U
Act. Insulin
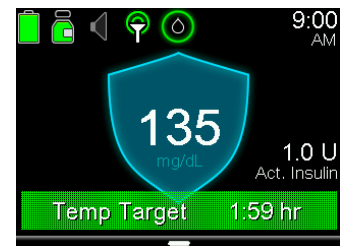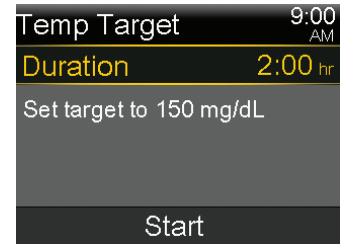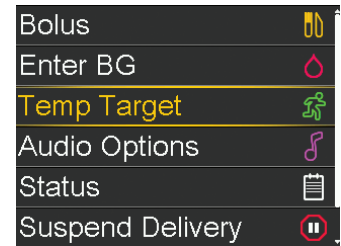
Temp Target 1:59 hr

To cancel your Temp Target

If you need to return to your standard Auto Mode target of 120 mg/dL before your Temp Target duration expires, you can cancel the Temp Target.

1) Press ⊙.

2) Select **Cancel Temp Target**.

The Temp Target screen appears and shows the details of the temp target.

Bolus	
Enter BG	
Cancel Temp Target	
Audio Options	
Status	
Suspend Delivery	

3) Select **Cancel Temp Target** to cancel the temp target.

If you do not want to cancel the Temp Target after reviewing the details, press ↩.

Temp Target 9:00 AM

Temp Target 150 mg/dL

Duration 2:00 hr

1:59 hr remaining

Cancel Temp Target
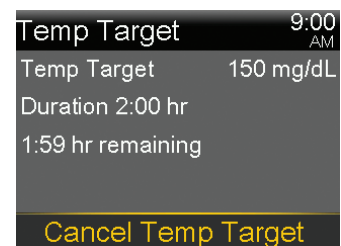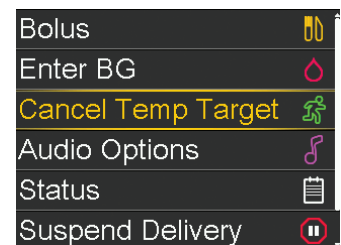
The Temp Target Ended message and duration of the Temp Target briefly appear. Then the Home screen appears.

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Section 5: Suspending and Resuming Delivery in SmartGuard Auto Mode

When your pump is in SmartGuard Auto Mode, you can suspend insulin delivery any time you need to.

To suspend delivery

When you bathe, shower, or temporarily disconnect your pump for any reason, suspend insulin delivery so that Auto Mode tracks the correct amount of insulin that you received.

1) Press ⦾.

2) Select **Suspend Delivery**.

Bolus	
Enter BG	
Temp Target	
Audio Options	
Status	
Suspend Delivery	

3) Select **Yes** to confirm.

Suspend Delivery?

No   Yes
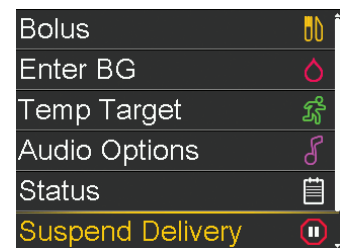
The message Delivery Suspended briefly appears. Then the Home screen appears with a red shield and a red Delivery Suspended banner.

10:00 AM

↓↓
120
mg/dL

0.5 U
Act. Insulin

Delivery Suspended
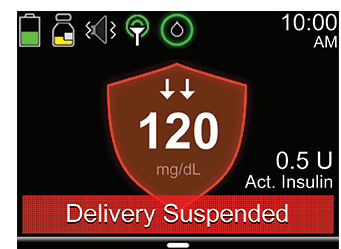
NOTE: To avoid a Lost sensor signal alert, keep your pump nearby if you disconnect for 30 minutes or longer.

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To resume delivery

1) Press ⭕.

2) Select **Resume Delivery**.

3) Select **Yes** to resume delivery.
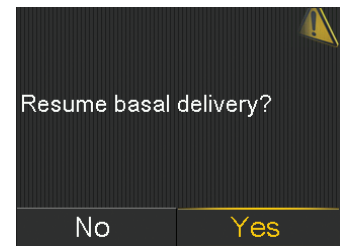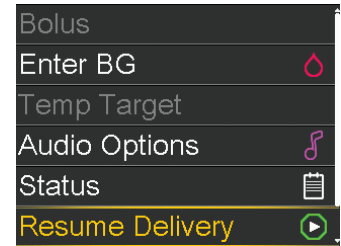
The message Delivery Resumed Successfully briefly appears, then the Home screen appears.

Section 6: Information about Safe Basal

When your pump is in SmartGuard Auto Mode, but is not adjusting the basal based on SG readings, it is in Safe Basal. Similar to Auto Basal, Safe Basal automatically delivers insulin to cover your basal needs based on your recent insulin needs. However, Safe Basal does not adjust delivery amounts based on your SG values.

When your pump is in Safe Basal, the outline of the SmartGuard Auto Mode shield is white, as shown in the following example. Depending on the situation, there may or may not be an SG reading displayed.
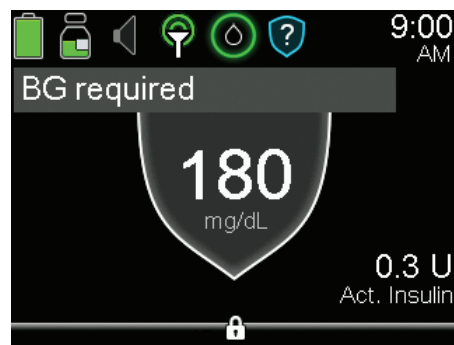
Safe Basal activates in the following situations:

- An SG reading is not available because your transmitter and pump are not communicating, or the sensor calibration has expired.
- Your sensor might be reading lower than your actual glucose values.
- Your BG value is different from your SG value by 35% or more.
- You have changed your sensor, and it is in the sensor warm-up period.
- Auto Mode has been at your personal minimum Auto Mode basal delivery rate for 2 1/2 hours.
- Auto Mode has been at your personal maximum Auto Mode basal delivery rate for 4 hours.

The maximum time your pump stays in Safe Basal is 90 minutes. However, it may be shorter than that, and resolve itself before you are aware of it. For example, the pump goes into Safe Basal temporarily if it misses an SG value from the transmitter, but then receives the next one.

At other times, when the pump is in Safe Basal and there is an action you can take to help resolve the issue, an alert occurs that shows you the action to take. Examples of these actions are entering a calibration, entering a new BG, or responding to a Lost sensor signal alert.

There is an optional setting called Auto Mode BG alert that is designed to help limit the time spent in Safe Basal. When this alert is turned on, the Auto Mode BG alert occurs when a BG entry is recommended. Your pump arrives with this setting turned on. The following alerts are triggered when the Auto Mode BG alert setting is on:

- Auto Mode max delivery
- Auto Mode min delivery
- BG required
- Cal required for Auto Mode

NOTE: Make sure that the Auto Mode BG alert is turned on, and follow the instructions on the pump alert screens to help limit the time that your pump is in Safe Basal delivery.

NOTE: The MiniMed 770G insulin pump modes and insulin delivery table in the *Appendix*, *on page 33,* shows information on Manual Mode, Auto Mode with Auto Basal delivery, and Auto Mode with Safe Basal delivery.

To edit the SmartGuard Auto Mode BG alert setting

1) Press ⊙.

2) Select **Options**.

Enter BG	⬤
Temp Target	
Audio Options	
Status	
Suspend Delivery	
Options	

3) Select **SmartGuard**.

Options	
SmartGuard	
History	
Reservoir & Tubing	
Delivery Settings	
Event Markers	

4) Select **Auto Mode**.
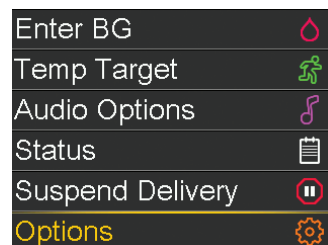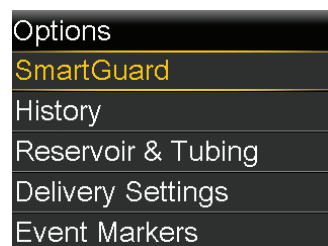
SmartGuard
Auto Mode
High Setup
Low Setup
Snooze

The Auto Mode screen appears with the Auto Mode BG alert set to **On** by default.

If you want to turn the Auto Mode BG alert off, select **Auto Mode BG alert** to change the setting to **Off**.

Auto Mode	
Auto Mode	On
Auto Mode BG alert	On
Save	

5) Select **Save**.

Auto Mode	
Auto Mode	On
Auto Mode BG alert	On
Save	
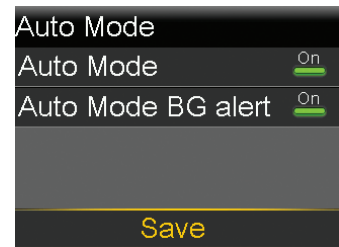
NOTE: The maximum time the pump can stay in Safe Basal is 90 minutes. After 90 minutes in Safe Basal, if the condition that caused the transition into Safe Basal is not resolved, the pump exits Auto Mode and enters Manual Mode. When your pump is in Manual Mode, it uses the Basal settings that you have set up. For more information, see *Information about Safe Basal, on page 20*.

Section 7: Information about SmartGuard Auto Mode automatic exits

Under certain conditions, your pump will exit SmartGuard Auto Mode automatically:

- After it has been in Safe basal for 90 minutes, and the condition that caused Safe Basal has not resolved.

- When an Auto Mode exit occurs, the Auto Mode exit screen appears. Select **Yes** to view the Auto Mode Readiness screen.
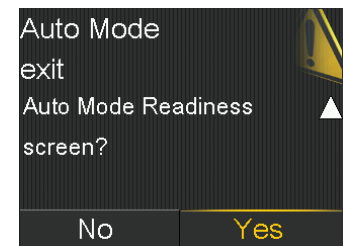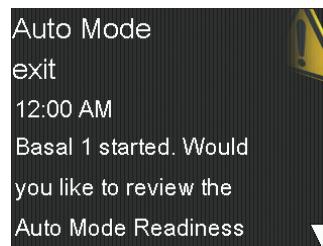
- A High SG alert causes the pump to exit SmartGuard Auto Mode. Select **OK** and follow the instructions on the Auto Mode exit screen to re-enter Auto Mode.
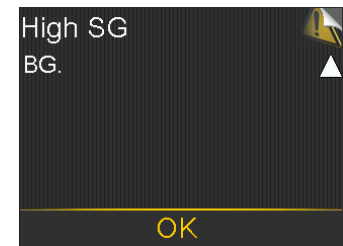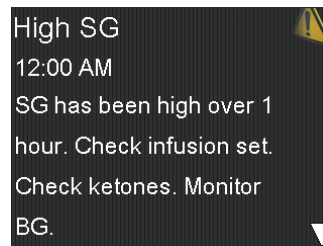
Remember that any time you no longer see the SmartGuard Auto Mode shield on your Home screen, you can check the Auto Mode Readiness screen to determine what is needed to re-enter Auto Mode.

NOTE: If your pump exits SmartGuard Auto Mode and you want to use the SmartGuard Suspend before low or the Suspend on low feature, you need to go to the Low Setup screen and turn the feature on. For instructions, see *Setting up your Low Setup in GETTING STARTED WITH MINIMED™ 770G CONTINUOUS GLUCOSE MONITORING*. If you want to go back into Auto Mode, see *Returning to SmartGuard Auto Mode, on page 25*.

Section 8: Exiting SmartGuard Auto Mode manually

You can manually exit SmartGuard Auto Mode and return to Manual Mode any time.

To exit SmartGuard Auto Mode

1) Press ⊙.

2) Select **Options**.

Enter BG	⬥
Temp Target	🏃
Audio Options	🎵
Status	📋
Suspend Delivery	⬤
Options	⚙

3) Select **SmartGuard**.

Options
SmartGuard
History
Reservoir & Tubing
Delivery Settings
Event Markers

4) Select **Auto Mode** to access the Auto Mode screen.

SmartGuard
Auto Mode
High Setup
Low Setup
Snooze

5) Select **Auto Mode** again to turn Auto Mode off.

Auto Mode	
Auto Mode	Off
Auto Mode BG alert	Off
Save	

6) Select **Save**.

Auto Mode	
Auto Mode	Off
Auto Mode BG alert	Off
Save	
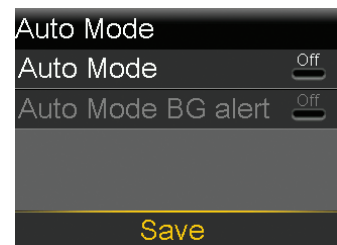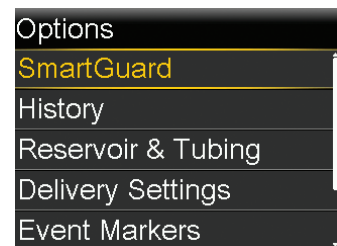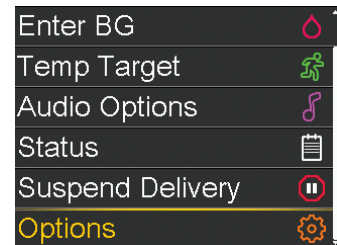
Section 9: Returning to SmartGuard Auto Mode

WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode. Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.

Your pump may re-enter Auto Mode if the condition that caused it to exit has been resolved and you have entered a BG into your pump. If you have manually turned the Auto Mode setting off, you will need to turn it back on to use Auto Mode again.

To turn on SmartGuard Auto Mode

1) Press ⚪.

2) Select **Options**.

Enter BG	⬡
Temp Target	🏃
Audio Options	♪
Status	📋
Suspend Delivery	⏸
Options	⚙

3) Select **SmartGuard**.

| Options |
| SmartGuard |
| History |
| Reservoir & Tubing |
| Delivery Settings |
| Event Markers |

4) Select **Auto Mode** to access the Auto Mode screen.

| SmartGuard |
| Auto Mode |
| High Setup |
| Low Setup |
| Snooze |

5) Select **Auto Mode** again to turn Auto Mode on.

| Auto Mode |
| Auto Mode | On |
| Auto Mode BG alert | On |
| Save |

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6) Select **Save**.
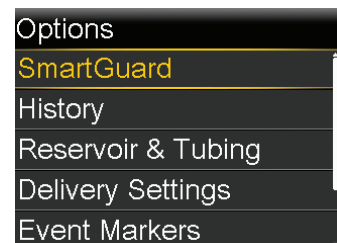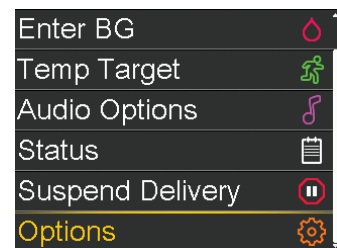
Auto Mode	
Auto Mode	On
Auto Mode BG alert	On
Save	

7) If your pump does not go into Auto Mode, see *Checking SmartGuard Auto Mode Readiness, on page 8.*

Section 10: Alarms and alerts in SmartGuard Auto Mode

In addition to the pump and sensor alarms that were introduced in *GETTING STARTED WITH MINIMED™ 770G INSULIN PUMP,* you may receive the following alerts and alarms only when the pump is in SmartGuard Auto Mode.

Title and text	Cause	Next Steps
Auto Mode started The following SmartGuard settings are now turned off: • Suspend before low • Suspend on low	Your pump has started Auto Mode. The SmartGuard Suspend before low and Suspend on low settings are now turned off.	• Select **OK** to clear the alert. • Alert is information only. No action is required at this time.
Auto Mode Exit *Basal Name* started. Would you like to review the Auto Mode Readiness screen?	Your pump has exited Auto Mode.	Follow instructions on the pump screen. Check the Auto Mode Readiness screen for information to re-enter Auto Mode.
Auto Mode max delivery Auto Mode has been at maximum delivery for 4 hours. Enter BG to continue in Auto Mode.	Alerts you when your pump has been delivering insulin at your maximum Auto Mode basal delivery rate for 4 hours. Your personal maximum Auto Mode basal delivery rate is automatically determined.	• Select **OK** to clear the alert. • Enter a BG to continue in Auto Mode.

Title and text	Cause	Next Steps
Auto Mode max delivery Auto Mode has been unable to bring your SG down. Enter BG and resume delivery to continue in Auto Mode.	Auto Mode has been unable to lower your SG value. Your pump is suspended, and your predicted SG is above target. **NOTE:** • The title of this alert appears the same as the previous Auto Mode max delivery alert in the table. • If you suspend your pump, the pump does not deliver insulin. However, the alert can still occur.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump. • Follow instructions from your healthcare professional and continue to monitor your BG.
Auto Mode min delivery Auto Mode has been at minimum delivery for 2:30 hr. Enter BG to continue in Auto Mode.	Alerts you when your pump has been delivering insulin at your minimum Auto Mode basal delivery rate for 2 1/2 hours. Your personal minimum Auto Mode basal delivery rate is automatically determined.	• Select **OK** to clear the alert. • Enter a BG to continue in Auto Mode.
Auto Mode min delivery Your SG has been below target for 2:30 hr. Enter BG and resume delivery when ready to continue in Auto Mode.	Your pump is suspended, and your predicted SG has been below target for 2 1/2 hours. **NOTE:** • The title of this alert appears the same as the previous Auto Mode min delivery alert in the table. • If you suspend your pump, the pump does not deliver insulin. However, the alert can still occur.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump. • Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Cause	Next Steps
BG required Enter a new BG for Auto Mode.	A new BG entry is required for Auto Mode.	Perform fingerstick and enter a new BG.
Bolus recommended For XXX mg/dL entered, a correction bolus is recommended. Select Bolus to program a bolus.	Auto Mode recommends a correction bolus based on a BG that you have entered.	Consider delivering the recommended correction bolus.
Cal required for Auto Mode Enter a BG and calibrate sensor for Auto Mode.	A calibration is required to keep your pump in Auto Mode.	Perform a fingerstick. Enter BG and calibrate your sensor.
High BG XXX mg/dL Check infusion set. Check ketones. Monitor BG. Confirm BG?	A BG that you entered is above 250 mg/dL. **NOTE:** The instructions for a High BG alert are different when the Auto Mode feature is off.	Check infusion set. Check ketones. Monitor BG. Confirm BG.

High SG
 	
SG has been high over 1 hour. Check infusion set. Check ketones. Monitor BG.
 	
Followed by
 	
Auto Mode exit
 	
Monitor BG and treat as necessary. *Basal Name* started. Enter BG to continue in Auto Mode.
	SG has been high for over one hour. This value is based on a set glucose threshold and length of time: 300 mg/dL or higher for one hour; 250 mg/dL or higher for three hours.	• **High SG**
		
		  Check infusion set. Check ketones. Monitor BG.
		
		• **Auto Mode Exit**
		
		  Monitor BG and treat as necessary. Enter BG to continue in Auto Mode.

Low SG XX mg/dL SG is under 50 mg/dL. Check BG and treat.	SG is under 50 mg/dL.	Perform fingerstick and treat as needed. Monitor BG.

NOTE: You can use the Alert Silence feature in Auto Mode to silence the majority of the alerts, but the following alarms and alerts will still sound.

- Auto Mode exit alert
- High SG alert
- Low SG XX mg/dL (50 mg/dL or below) alarm

What to do if SmartGuard™ Auto Mode is not ready
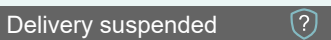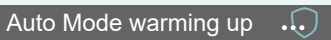
The **Auto Mode Readiness Table** shows what to do when the wait icon or the question icon appears by items on the Auto Mode Readiness screen. To open the Auto Mode Readiness screen, from the main menu, select **Status**, and then select **Auto Mode Readiness**.

```
        Auto Mode Readiness
1 ——●   BG required               ?
2 ——●   Auto Mode turned off      ?
3 ——●   Sensor not ready
4 ——●   Bolus in progress         ?
5 ——●   Delivery suspended        ?
6 ——●   Carb ratio not set        ?
7 ——●   Temp Basal rate           ?
8 ——●   Active insulin updating
9 ——●   Auto Mode warming up
```
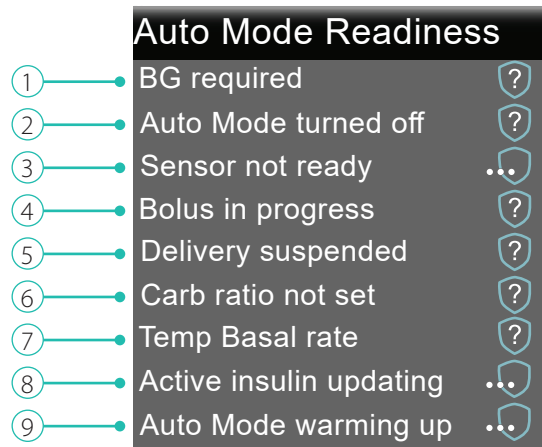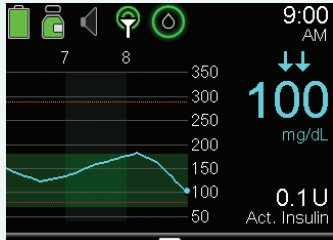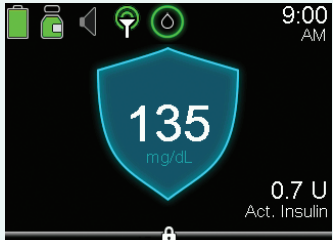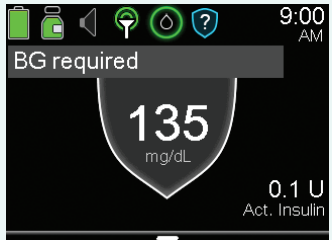
Auto Mode Readiness Table

Line	Item	Instructions
1	Calibration required ?	Perform a fingerstick and calibrate your sensor.
	BG required ?	Perform a fingerstick and enter a new BG. Your BG must be within the 40–400 mg/dL range for your pump to enter Auto Mode.
	Wait to enter BG...	Wait until the pump prompts you to enter a BG.
	Processing BG...	Wait until the BG has processed.
2	Auto Mode turned off ?	Turn on Auto Mode in the SmartGuard, Auto Mode screen.
3	Sensor not ready	a) Go to **Utilities** > **Device Options** to check if a transmitter ID has already been entered in your pump. For example, GT6133333F. If your pump does not have a transmitter ID entered, see *Pairing your pump and transmitter* in *GETTING STARTED WITH MINIMED™ 770G CONTINUOUS GLUCOSE MONITORING*.

Line	Item	Instructions
		b) Check your Home screen. If you see ![icon], move your pump and transmitter closer together. The pump will try to find the transmitter signal.
		If after 30 minutes the pump and transmitter are still not communicating, you will receive a Lost sensor signal alert. Check that the sensor is still inserted in the skin and the transmitter and sensor are still connected. Move your pump closer to your transmitter.
	Sensor off	Turn on the sensor in the Utilities, Sensor Settings screen.
4	Bolus in progress	Wait until the bolus is complete or stop the bolus yourself before Auto Mode can activate.
5	Delivery suspended	If insulin delivery is suspended, Auto Mode cannot activate. Treat low BG if necessary as instructed by your healthcare professional.
6	Carb ratio not set	When you turn on the Bolus Wizard feature for the first time, enter your Carb Ratio in the Edit Carb Ratio screen. You can also enter your Carb Ratio in the Bolus Estimate Setup screen, even if the Bolus Wizard feature is not turned on.
7	Temp Basal rate	If a temp basal is currently active, you must wait until it has completed or cancel the temp basal yourself before Auto Mode can activate.
8	Active insulin updating	If active insulin is currently updating, it may take up to 5 hours to complete. You must wait until this amount is updated.
9	Auto Mode warming up	Auto Mode is gathering information on your insulin delivery history in order to personalize its automatic delivery of insulin.

MiniMed 770G insulin pump modes and insulin delivery

	Manual Mode	SmartGuard Auto Mode Auto Basal delivery	SmartGuard Auto Mode Safe Basal delivery
Home screen display			
Availability	When Auto Mode is not active. May be used with or without CGM.	When Auto Mode is turned on, after a minimum of 48 hour initial Auto Mode warm-up, and a working, calibrated sensor. Requires a BG entry as last step to enter Auto Mode*, and ongoing BG entries and calibrations.	Pump automatically transitions to Safe Basal delivery from Auto Basal delivery when valid SG values are not available, or minimum or maximum Auto Basal delivery limits have been reached.
Basal insulin delivery	Uses the basal settings programmed in Basal menu to deliver the basal rates.	Uses the SG values *and* the recent insulin delivery needs to automatically adjust and deliver the basal rates.	Uses the recent insulin delivery to automatically deliver a fixed rate. SG values are *not* used to determine the automatic basal rates. You receive an alert if you need to take an action to return to Auto Basal.** Maximum time in Safe Basal is 90 minutes. If the cause is not resolved, the pump exits to Manual Mode.

	Manual Mode	**SmartGuard Auto Mode Auto Basal delivery**	**SmartGuard Auto Mode Safe Basal delivery**
Bolus Wizard settings	Uses all of the Bolus Wizard settings to determine the Bolus Wizard recommended dose.	Bolus feature uses Carb Ratio and Active Insulin Time only for bolus recommendations.	Bolus feature uses Carb Ratio and Active Insulin Time only for bolus recommendations.

*For a complete list of SmartGuard Auto Mode entry requirements, see *SmartGuard Auto Mode Readiness* in the SmartGuard Auto Mode chapter of the *MiniMed™ 770G SYSTEM USER GUIDE*.

**The Auto Mode BG alert in the SmartGuard menu must be turned On to receive an audible BG required alert. The Auto Mode BG alert default setting is On. If the Auto Mode BG alert is Off, only a visible banner appears on the pump.

R_X *Only*

M998593A012_1

WALLET CARD

MiniMed™ 770G System

Press ◎	Press ◎	
Bolus	→	Bolus Deliver Bolus
Enter BG	→	Enter BG
Basal	→	Temp Basal Basal Patterns Delivery Settings
Audio Options	→	Alert Silence Options* Audio Vibrate Volume
Status	→	Auto Mode Readiness Notifications Quick Status Pump Sensor* Settings Review
Suspend Delivery	→	No Yes
Options	→	SmartGuard* History Reservoir & Tubing Delivery Settings Event Markers Reminders Utilities

*Menu choice appears only if certain settings are turned on or off.

Home screen without CGM in Manual Mode

- status icons
- 9:00 AM — current time
- BG
- 110 mg/dL — BG reading
- Active Insulin 1.0 U — active insulin

Home screen with CGM in Manual Mode

- status icons
- 7 8
- 9:00 AM — current time
- ↓ — trend arrows
- 350
- 300
- 250
- 200
- 150
- 100
- 50
- 165 mg/dL — SG reading
- SmartGuard™ suspend icon
- 0.5 U Act. Insulin — active insulin
- sensor graph
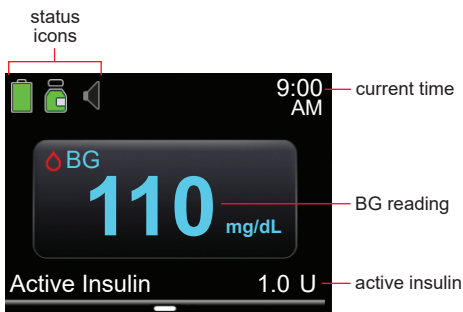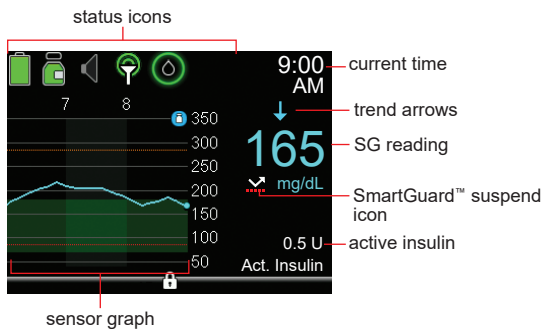
Home screen in SmartGuard™ Auto Mode

status icons

| 9:00 AM — current time |
| SmartGuard™ Auto Mode shield |
| **135** mg/dL — SG value |
| active insulin |
| 0.7 U Act. Insulin |
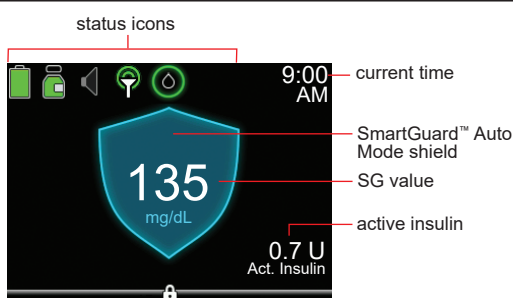
Stopping and resuming insulin delivery

Stopping all insulin delivery The Suspend Delivery option stops all insulin delivery (basal and bolus).	**To stop all insulin delivery:** 1. Press ◎ from the Home screen and select **Suspend Delivery**. 2. Select **Yes** when prompted.
Resuming basal insulin delivery The Resume Delivery option restarts your basal delivery after your pump has been suspended. The Resume Delivery option does not restart a bolus delivery.	**To resume your basal insulin delivery:** 1. Press ◎ from the Home screen and select **Resume Delivery**. 2. Select **Yes** when prompted. **NOTE:** If a temp basal is active when you suspend your pump, it will resume if there is still time remaining.
Stopping a bolus delivery The Stop Bolus option stops a bolus delivery only. The Stop Bolus option does not stop your basal delivery.	**To stop a SmartGuard™ Auto Mode bolus, a Manual Mode Normal bolus, or the Now portion of a Dual Wave™ bolus:** 1. Press ◎ from the Home screen and select **Stop Bolus**. 2. Select **Yes** when prompted. 3. Select **Done**. **To stop a Square Wave™ bolus or the Square portion of a Dual Wave™ bolus:** 1. Press ◎ from the Home screen and select **Bolus**. 2. Select **Stop Bolus**. 3. Select **Yes** when prompted. 4. Select **Done**.
Manually resuming basal delivery during a SmartGuard™ suspend event If you do not want to wait for your pump to automatically resume your basal insulin during a SmartGuard™ suspend event, you can manually resume your basal delivery.	**To manually resume basal delivery:** 1. Press ◎ from the Home screen and select **Suspended before low** or **Suspended on low**. The SmartGuard™ suspend status screen appears. 2. Select **Resume Basal**. 3. Select **Yes** when prompted.

I wear a required medical device prescribed by my physician.

Medtronic

In an emergency, please contact

Physician name:

Phone number:

Emergency contact:

Phone number:

I have diabetes

If my behavior is peculiar, if I appear intoxicated, or if I am unconscious, it may be a result of severe low blood sugar.

I am not intoxicated
Call for medical assistance

If I am awake and able to swallow, give me a source of sugar (for example: juice, candy, or non-diet soft drink). Do not try to give me food or drink if I am unconscious.

Healthcare professionals

I wear an insulin pump.

- The pump delivers rapid-acting insulin at a constant rate.
- To stop insulin delivery on the pump:
  - Press any button to wake the pump.
  - Press ◎.
  - Press the highlighted button shown on the screen to unlock the pump.
  - Press ⌄ to highlight **Suspend Delivery**.
  - Press ◎.
  - Press ⟩ to highlight **Yes**.
  - Press ◎ to suspend insulin delivery.
- **Do not** remove the pump battery.
- **Do not** remove the pump without medical consent.
- If the pump sounds an alarm, follow the instructions on the pump screen or call the 24-Hour Technical Support at 1-800-646-4633.

Airport information

I wear a required medical device prescribed by my physician.

Medtronic

Airport security

- Because travel rules are subject to change, it is advisable to check with the Transportation Safety Administration (TSA) before traveling. TSA information is found at http://www.tsa.gov/travel/specialprocedures or by calling 1-866-289-9673.
- The pump **must not** go through the x-ray machine that is used for carry-on or checked luggage.
- The full body scanner is also a form of x-ray. If you choose to go through the full body scanner, you must remove your insulin pump and disconnect the infusion set at the insertion site. If you use continuous glucose monitoring (CGM), you must also remove your sensor and transmitter before the scan.
- To avoid removing your devices, you must request an alternative screening process that does not use x-ray.
- The insulin pump, infusion set, reservoir, and CGM system can withstand exposure to airport metal detectors used at airport security checkpoints.

In flight

The MiniMed™ 770G insulin pump and system devices are suitable for use in aircraft. When flying in an aircraft, it is important that you keep your pump connected to your body and check your blood glucose levels frequently.

Patient information

My name:

My address:

Phone number:

Medical device information

Medical device type:

Device serial number:

Medtronic

M998594A011_A

GUARDIAN™ LINK (3)

TRANSMITTER

Bluetooth®

Medtronic

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  Geschäftsbereich Diabetes
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  Telefax: +49 2159 8149-110
  24-Stdn-Hotline: 0800 6464633

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  24-hour helpline: +852 2919-6441

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  Mobile: (+91)-9611633007
  Patient Care Helpline:
  1800 209 6777

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  or +65 6436 5000

Israel: Medtronic
Tel. (orders):
  +9729972440, option 3 + option 1
  Tel. (product support):
  +9729972440, option 2
  Helpline (17:00 – 08:00
  daily/weekends – Israel time):
  1-800-611-888

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  Fax: +39 02 24138 210
  Servizio assistenza tecnica:
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  24 Hr. Support Line: 0120-56-32-56

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  24 – Stunden – Hotline: 0820 820 190

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  Zákaznický servis (8:00 - 17:00):
  +420 233 059 950

The Guardian™ Link (3) transmitter with Bluetooth™* wireless technology is a component of the continuous glucose monitoring (CGM) system for a MiniMed™ insulin pump with smart device connectivity. The transmitter is compatible only with the Guardian™ Sensor (3) glucose sensor. The transmitter collects data from the sensor. The transmitter then wirelessly sends the data to the insulin pump.

tester

transmitter
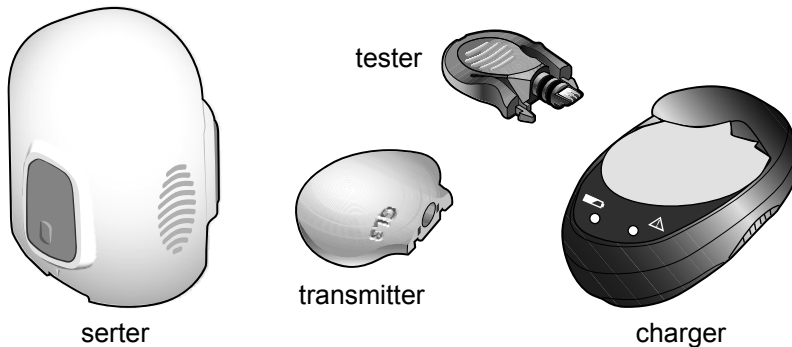
serter

charger

Guardian™ Link (3) transmitter kit components

A complete transmitter kit includes the following components:

- Guardian™ Link (3) transmitter (MMT-7911)
- Two testers (MMT-7736L)
- Charger (MMT-7715)
- One-press serter (MMT-7512)

Indications for use

The Guardian™ Link (3) transmitter (MMT-7911) is intended for use with MiniMed™ 770G System. The transmitter powers the glucose sensor, collects and calculates sensor data, and sends the data to a compatible MiniMed™ insulin pump system with smart device connectivity for the management of diabetes mellitus. The transmitter is intended for single-patient, multi-use.

Contraindications

None known.

Warnings

- Do not use the transmitter adjacent to other electrical equipment that may cause interference with the normal system operation. Other electrical equipment that may compromise normal system operation has been contraindicated. For more information on electrical equipment that may compromise normal system operation, see *Exposure to magnetic fields and radiation, on page 2*.
- Always refer to the sensor user guide for all precautions, warnings, and instructions relating to the sensor. Not referring to the sensor user guide can result in serious injury or damage to the sensor.
- Do not allow children to put small parts in their mouth. This product poses a choking hazard for young children.
- Do not change or modify the device unless expressly approved by Medtronic Diabetes. Modifying the device can cause serious injury, interfere with your ability to operate the device, and void your warranty.
- Do not use the tester if it comes in contact with blood. Touching blood can cause infection. Dispose of the tester according to the local regulations for medical waste disposal, or contact your healthcare professional for disposal information.
- Bleeding may occur after inserting the sensor. Always make sure that the site is not bleeding before connecting the transmitter to the sensor. Blood can get into the transmitter connector and damage the device. Discard the device if damaged. If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, connect the transmitter to the sensor.
- Contact 24-Hour Technical Support if you experience any adverse reactions associated with the transmitter or sensor. Adverse reactions can cause serious injury.
- Do not discard the transmitter in a medical waste container or expose it to extreme heat. The transmitter contains a battery that may ignite and result in serious injury.

Exposure to magnetic fields and radiation

- Do not expose your transmitter to Magnetic Resonance Imaging (MRI) equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury, or be unsafe. If your transmitter is exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.

- Always remove your sensor and transmitter before entering a room that has x-ray, MRI, diathermy, or CT scan equipment. Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury, or be unsafe. If your sensor or transmitter is exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.
- Always carry the Medical emergency card provided with your device when you are traveling. The Medical emergency card provides critical information about airport security systems and using your transmitter safely on an airplane that can help you and others. Not following the guidance on the Medical emergency card could result in serious injury.

Precautions

- Do not attempt to use the Guardian™ Link (3) transmitter (MMT-7911) with a MiniMed™ insulin pump without smart device connectivity. Only a MiniMed™ insulin pump with smart device connectivity can communicate with the Guardian™ Link (3) transmitter (MMT-7911).
- Only use the Guardian™ Sensor (3) glucose sensor (MMT-7020) with the transmitter. Do not use any other sensor. Other sensors are not intended for use with the transmitter and will damage the transmitter and the sensor.
- Only use the green colored tester (MMT-7736L) with the transmitter. Pockets on the transmitter are visible when connected to the tester. Do not use any other test plug. Other test plugs are not intended for use with the transmitter and will damage the transmitter and the tester.

pockets
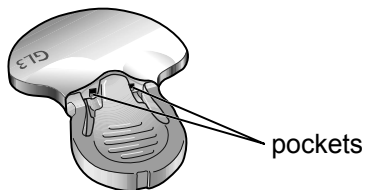
- Always use the tester when cleaning the transmitter. Do not use any other test plug with the transmitter. Use of another test plug can allow water to get into the transmitter or can prevent proper cleaning. Water can damage the transmitter.
- Do not twist the tester or sensor while attached to the transmitter. Twisting the tester or sensor will damage the transmitter.
- Do not allow the tester to come in contact with any liquid when not connected to the transmitter. A wet tester can damage the transmitter.

- Do not allow the transmitter to come in contact with any liquid when not connected to a sensor or to the tester. Moisture will damage the transmitter and a wet transmitter can damage the sensor.
- Do not clean the O-rings on the tester with any substances. Cleaning the O-rings can damage the tester.

O-rings
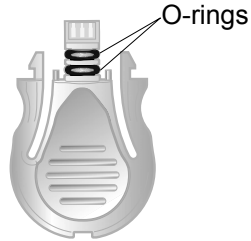
Radio Frequency (RF) communication

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. This device complies with Part 15 of the FCC Rules. Operation is subject to two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, even when installed and used in accordance with the instructions, no particular installation can guarantee that harmful interference will not occur. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the device and the receiver.
- Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.
- Increase the separation between the transmitter and the equipment that is receiving or emitting interference.

Note: Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

Changes or modifications made to this equipment not expressly approved by Medtronic Diabetes could void the user's authority to operate the equipment.

IEC 60601-1-2:2014, 4th Edition; Special EMC Precautions for Medical Electrical Equipment

1 Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment where common levels of radiated "E" (V/m) or "H" fields (A/m) exist, such as cellular phones, Wi-Fi™*, Bluetooth™* wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.

2 Portable and mobile RF communications equipment can affect medical electrical equipment. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.

3 Be careful when you use your transmitter closer than 12 in (30 cm) to portable radio frequency (RF) equipment or electrical equipment. If you must use your transmitter next to portable RF equipment or electrical equipment, observe the transmitter to verify correct system operation. Degradation of the performance of the transmitter could result.

Assistance

Medtronic MiniMed provides 24-Hour Technical Support for assistance. When calling the HelpLine, please have the serial number of your device available. The serial number and 24-Hour Technical Support phone number are listed on the back of your device.

Please contact 24-Hour Technical Support if you need a copy of a MiniMed™ system user guide.

Department	Telephone number
24-Hour Technical Support (calls within the United States)	800 646 4633

Department	Telephone number
24-Hour Technical Support (calls outside the United States)	+1 818 576 5555
Website	www.medtronicdiabetes.com

Preparing your transmitter

The transmitter contains a non-replaceable, rechargeable battery that you can recharge as needed with the charger. The transmitter needs to be charged before you use it. The charger has a green light that shows the charging status and a red light that communicates any problems during charging. If you see a red light, see *Troubleshooting, on page 15*. The charger needs one AAA alkaline battery.

Note: If the battery is installed incorrectly or is low, the charger will not work. Repeat the battery installation steps using a new battery.

Installing a battery in the charger

To install a battery in the charger:

1   Push the battery cover in and slide it off (as shown in the image in step 3).
2   Insert a new AAA alkaline battery. Make sure the + and - symbols on the battery align with these same symbols shown on the charger.
3   Slide the cover back on the charger until it clicks into place.
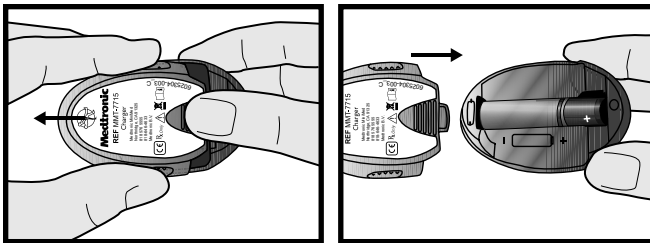
Charging the transmitter

CAUTION: Always charge the transmitter before inserting your sensor. A depleted transmitter does not function. A fully charged transmitter works at least seven days without recharging. A depleted transmitter can take up to two hours to recharge.

CAUTION: Do not store the transmitter on the charger for more than 60 days. Disconnect and reconnect to the charger to re-charge before use. If the transmitter is left on the charger for more than 60 days, the transmitter battery will be permanently damaged.

To charge the transmitter:

1   Push the transmitter and the charger together to connect the transmitter to the charger.

2   Within 10 seconds after the transmitter is connected, a green light on the charger will flash for one to two seconds as the charger powers on. For the rest of the charging time, the green light on the charger will continue to flash in a pattern of four flashes with a pause between the four flashes.

3   When charging is complete, the green light on the charger will stay on, without flashing, for 15 to 20 seconds and then turn off.

4   After the green charger light turns off, disconnect the transmitter from the charger. The green light on the transmitter starts to flash.
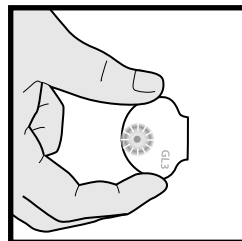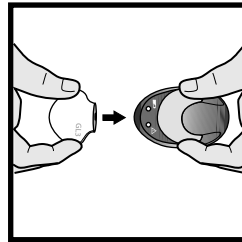
Pairing your transmitter

Always refer to the system user guide for instructions on how to pair your transmitter with your pump. The pump and the transmitter must be paired before data from the sensor can be sent to the pump. The pump and the transmitter are only required to be paired once. There is no need to pair the pump with the transmitter again when you insert a new sensor.

Inserting the sensor

Always refer to your sensor user guide for instructions on how to insert the sensor.

Connecting the transmitter to the sensor

Before proceeding, have your MiniMed™ insulin pump system user guide available.

To connect the transmitter to the sensor:

1   After the sensor is inserted, consult your sensor user guide for details on how to apply the required tape before connecting the transmitter.
2   Hold the rounded end of the inserted sensor to prevent it from moving during connection.
3   Hold the transmitter as shown. Line up the two notches on the transmitter with the side arms of the sensor. The flat side of the transmitter should face the skin.
4   Slide the transmitter onto the sensor connector until the sensor arms snap into the notches on the transmitter. If the transmitter is properly connected, and if the sensor has had enough time to become hydrated with the interstitial fluid, the green light on the transmitter will flash 6 times.
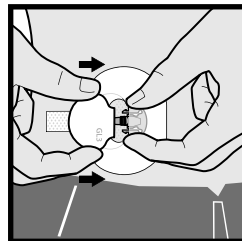
   Note: If the transmitter does not flash, see Troubleshooting, on page 15.

5   When the transmitter light flashes green after connecting to the sensor, use your pump to start the sensor. For more instructions, see your system user guide.
6   Attach the adhesive tab of the sensor to the transmitter.
7   After the transmitter is connected, consult your sensor user guide for details on how to apply the required tape.
8   Follow the instructions that appear on the pump screen or in your system user guide.

Disconnecting the transmitter from the sensor

Before proceeding, have your MiniMed™ insulin pump system user guide available.

To disconnect the transmitter from the sensor:

1   Carefully remove any tape from the transmitter and sensor.
2   Remove the adhesive tab from the top of the transmitter.
3   Hold the transmitter as shown, and pinch the flexible side arms of the sensor between your thumb and forefinger.
4   Gently pull the transmitter away from the sensor.
5   Follow the instructions that appear on the pump or in your system user guide.
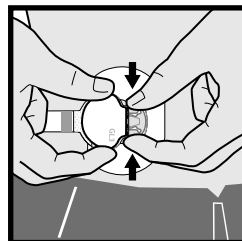
Removing the sensor

Always refer to the sensor user guide for instructions on how to remove the sensor.

Reconnecting the transmitter to a sensor that is already inserted

You can reconnect your transmitter to the sensor you are currently using. Simply connect your transmitter to the sensor that is already inserted. When the pump detects the transmitter, confirm that you want to Reconnect Sensor. It may take a few seconds to establish a connection when reconnecting a sensor. Reattach the adhesive tab of the sensor to the transmitter and reapply any required tape. When you reconnect a sensor, the sensor will go through another warm-up period before you can calibrate it.

Tester

The tester is used to test the transmitter to make sure it is working. The tester is also used as a required component to create a waterproof seal when cleaning the transmitter. Properly connecting the tester to the transmitter ensures that fluids do not come in contact with the connector pins inside the transmitter. Fluids can cause connector pins to corrode and affect the performance of the transmitter.

Do not twist the tester while it is attached to the transmitter. This will damage the transmitter.

The tester can be used for one year. If you continue to use the tester for more than one year, the connector pins inside the transmitter could be damaged, because the tester cannot continue to provide a waterproof seal. For instructions on how to check the connector pins, see *Inspecting the transmitter connector pins, on page 10*.

CAUTION: Only use the green colored tester (MMT-7736L) with the transmitter. Pockets on the transmitter are visible when connected to the tester. Do not use any other test plug. Other test plugs are not intended for use with the transmitter and will damage the transmitter and the tester.

green tester

pockets
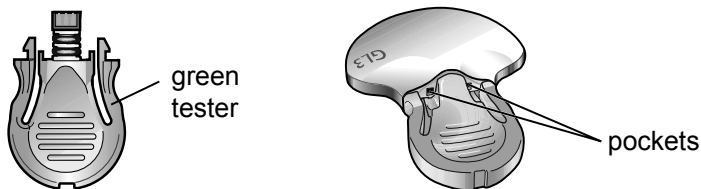
Inspecting the transmitter connector pins

This image is an example of how the connector pins should look.

connector opening

connector pins

housing
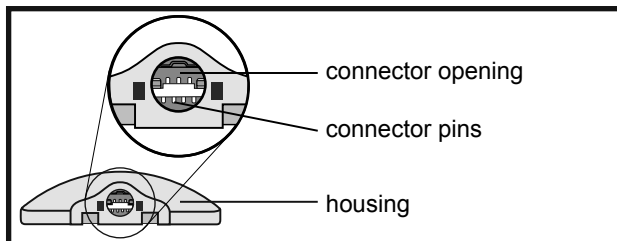
Look inside the connector opening of the transmitter to make sure that the connector pins are not damaged or corroded. If the connector pins are damaged or corroded, the transmitter cannot communicate with the charger or the pump. Contact 24-Hour Technical Support. It may be time to replace your transmitter.

Also look for moisture inside the connector opening. If you see any moisture, allow the transmitter to dry for at least one hour. Moisture inside the connector opening could cause the transmitter to not work properly and could cause corrosion and damage over time.

Connecting the tester for testing or cleaning

Before proceeding, have your MiniMed™ insulin pump system user guide available.

To connect the tester:

1   Hold the transmitter and the tester as shown. Line up the flat side of the tester with the flat side of the transmitter.

2   Push the tester into the transmitter until the flexible side arms of the tester click into the notches on both sides of the transmitter. When properly connected, the green light on the transmitter flashes 6 times.

3   To test the transmitter, check the sensor icon on the pump to ensure that the transmitter is sending a signal (see your system user guide).

4   To clean the transmitter, see *Cleaning the transmitter, on page 11*.

5   After testing or cleaning, disconnect the tester from the transmitter.
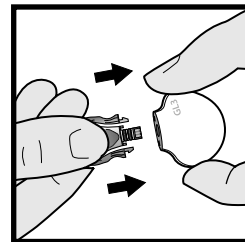
Disconnecting the tester

To disconnect the tester:

1 Hold the transmitter body as shown and pinch the side arms of the tester.
2 With the tester arms pinched, gently pull the transmitter away from the tester.

> *Note: To save transmitter battery life, do NOT leave the tester connected after cleaning or testing.*
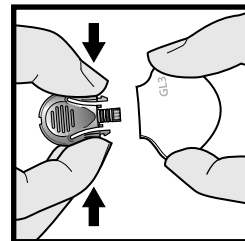
Cleaning the transmitter

The transmitter is a single-patient use device and not intended for multi-patient use.

WARNING: Do not discard the transmitter in a medical waste container or expose it to extreme heat. The transmitter contains a battery that may ignite and result in serious injury.

Note: The tester is a required component for cleaning the transmitter. For details, see Tester, on page 9.

CAUTION: Do not use automated washer-disinfector to clean or disinfect the device. Using automated washer-disinfector to clean or disinfect the device will cause damage to the transmitter.

Always clean the transmitter after each use.

To clean the transmitter, you need the following materials:

• mild liquid soap
• soft-bristled toddler toothbrush
• container
• clean, lint-free dry cloths

Use life

The transmitter can be cleaned up to 122 times or for one year, whichever comes first. Discard the transmitter at this point. If you continue to use the transmitter beyond 122 times or one year, the cleaning process may damage the device. Contact Medtronic to order a new transmitter.

WARNING: Do not use the device if you see any cracking, flaking, or damage to the housing. Cracking, flaking, or damage to the housing are signs of deterioration. Deterioration of the housing can affect the ability to properly clean the transmitter and result in serious injury. Call 24-Hour Technical Support and discard the device according to local regulations for battery disposal (non-incineration), or contact your healthcare professional for disposal information.

To clean the transmitter:

1 Wash your hands thoroughly.
2 Attach the tester to the transmitter to create a waterproof seal.
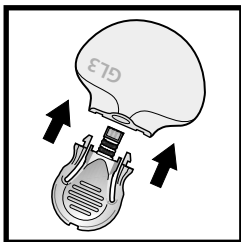
3 If there is adhesive residue on the transmitter, see *Removing adhesive residue, on page 14*.
4 Rinse the transmitter under room temperature tap water for at least one minute, and until visibly clean. Make sure all hard-to-reach areas are rinsed completely.
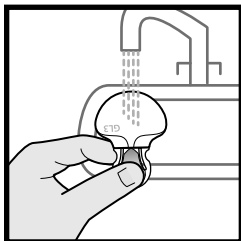
5 Prepare a mild liquid soap solution using 1 teaspoon (5 milliliters) of mild liquid soap per 1 gallon (3.8 liters) of room temperature tap water.

6 With the tester still attached, submerge the transmitter in the mild liquid soap solution and soak for one minute.
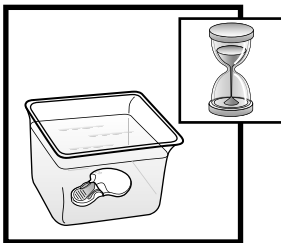
7 Holding the tester, brush the entire surface of the transmitter using a soft-bristled toddler toothbrush. Make sure to brush all hard-to-reach areas until visibly clean.

8 Rinse the transmitter under running room temperature tap water for at least one minute, and until all visible liquid soap is gone.
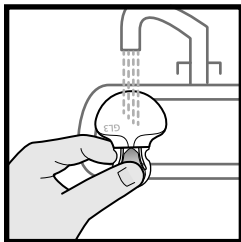
9 Dry the transmitter and tester with a clean, dry cloth.
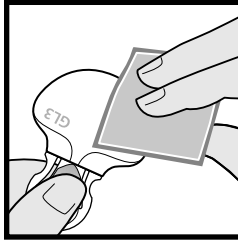
10 Place the transmitter and tester on a clean, dry cloth and air dry them completely.
11 Disconnect the tester from the transmitter by gently squeezing the arms of the tester.
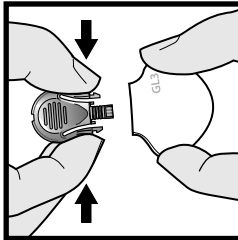
Removing adhesive residue
You may need to perform this procedure if there is adhesive residue present on the transmitter. If you visually inspect the transmitter and see adhesive residue on it, follow these instructions.

To remove adhesive residue, you need cotton swabs and a medical adhesive remover such as Detachol™*, which is a mineral spirit.

Note: During testing, Medtronic MiniMed used Detachol™ to remove the adhesive residue from the transmitter.*

To remove adhesive residue:

1 Make sure the tester is attached to the transmitter.
2 Soak a cotton swab in the medical adhesive remover.

3   Hold the tester and gently rub the adhesive remover on the transmitter until the residue is removed.
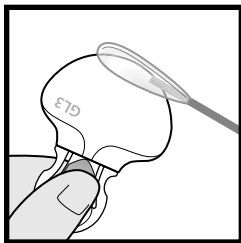
4   Continue with the cleaning procedure. See *Cleaning the transmitter, on page 11* for details.

Bathing and swimming

After the transmitter and sensor are connected, they form a waterproof seal to a depth of 8 feet (2.4 meters) for up to 30 minutes. You can shower and swim without removing them.

Cleaning the charger

This procedure is for general cleaning as required, based on physical appearance.

CAUTION: Do not immerse the charger in water or any other cleaning agent. The charger is not waterproof. Water can damage the charger and cause the device to malfunction.

WARNING: Dispose the charger according to the local regulations for battery disposal, or contact your healthcare professional for disposal information. The charger may ignite upon incineration.

To clean the charger:

1   Wash your hands thoroughly.
2   Use a damp cloth with mild cleaning solution, such as a dishwashing detergent, to clean any dirt or foreign material from the outside of the charger. Never use organic solvents, such as paint thinner or acetone, to clean the charger.
3   Place the charger on a clean, dry cloth and air dry for two to three minutes.

Troubleshooting

The following table contains troubleshooting information for the transmitter, charger, and tester. For more information about troubleshooting, see your system user guide.

Problem	Likely Cause(s)	Resolution
You connected the transmitter to the charger and no lights came on.	The transmitter connector pins are damaged or corroded. Your charger battery has no power or no battery is inserted.	1 Check the transmitter connector pins for damage or corrosion. For more information about your connector pins, see *Inspecting the transmitter connector pins, on page 10*. If the pins are damaged or corroded, contact 24-Hour Technical Support. It may be time to replace your transmitter. 2 If there is no damage to the connector pins, replace the battery in the charger. For instructions on replacing your charger battery, see *Installing a battery in the charger, on page 6*.
During charging, the flashing green light on the charger turns off and you see a longer flashing red light on the charger.	Your charger battery is low on power.	Replace the battery in the charger. For instructions on replacing your charger battery, see *Installing a battery in the charger, on page 6*.
During charging, the flashing green light on the charger turns off and you see a series of quick flashing red lights on the charger for two seconds at a time.	Your transmitter is low on power.	1 Charge the transmitter continuously for one hour. If flashing does not stop, proceed to step 2. 2 Charge the transmitter continuously for eight hours. If flashing does not stop, call 24-Hour Technical Support. It may be time to replace your transmitter.
During charging, a mix of quick and long flashing red lights appear on the charger.	Your charger *and* your transmitter are low on power.	1 Replace the battery in the charger. For instructions on replacing your charger battery, see *Installing a battery in the charger, on page 6*. 2 Charge the transmitter continuously for one hour. If the quick flashing red lights do not stop, proceed to step 3. 3 Charge the transmitter continuously for eight hours. If flashing does not stop, call 24-Hour Technical Support. It may be time to replace your transmitter.

Problem	Likely Cause(s)	Resolution
The green light on the transmitter does not flash when you connect it to the sensor.	Your transmitter is not fully connected. Your transmitter is low on power. Your sensor is not properly inserted into your body.	1 Disconnect the transmitter from the sensor. 2 Wait for five seconds and reconnect them. If the green light still does not flash, proceed to step 3. 3 Fully charge the transmitter and connect it to the tester. If the green light still does not flash, see troubleshooting on "The green light on the transmitter does not flash when you connect it to the tester". If the green light flashes, proceed to step 4. 4 Disconnect the transmitter from the tester, wait at least five seconds, and connect the transmitter to the sensor. If the green light still does not flash, proceed to step 5. 5 The sensor may not be properly inserted into your body. Remove the sensor from your body and insert a new sensor.
The green light on the transmitter does not flash when you connect it to the tester.	Your transmitter is not fully connected. Your transmitter is low on power.	1 Check the connection between the transmitter and the tester. If the green light still does not flash, proceed to step 2. 2 Fully charge the transmitter. 3 Test the transmitter with the tester again. If you still do not see the green light flash, call 24-Hour Technical Support. It may be time to replace your transmitter.
Your transmitter battery does not last for seven days.	Your transmitter is not fully charged when you connect it to the sensor. The transmitter and pump frequently lose wireless connection.	1 Fully charge the transmitter before connecting it to the sensor. If the transmitter battery still does not last for the duration of one sensor use, proceed to step 2. 2 Move away from any equipment that can cause RF interference. For more information on RF interference, see *Radio Frequency (RF) communication, on page 4*. 3 Make sure your pump and your transmitter are located on the same side of your body to minimize any RF interference. If your fully charged transmitter battery continues to lose power before a full seven days, call 24-Hour Technical Support. It may be time to replace your transmitter.

Problem	Likely Cause(s)	Resolution
Your transmitter has lost connection with your pump.	Your pump is out of range. There is RF interference from other devices.	1 Move away from any equipment that can cause RF interference. For more information on RF interference, see *Radio Frequency (RF) communication, on page 4*. If your transmitter is still not communicating with your pump, proceed to step 2. 2 Make sure your pump and your transmitter are located on the same side of your body to minimize any RF interference. If your transmitter is still not communicating with your pump, call 24-Hour Technical Support for assistance.

Note: *An alarm or alert occurs and a message appears when your transmitter has lost connection with your pump for 30 minutes.*

Storage

Store the transmitter, charger, and tester in a clean, dry location at room temperature. If the transmitter is not in use, you must charge the transmitter at least once every 60 days.

CAUTION: Do not store the transmitter on the charger. If the transmitter is left on the charger for more than 60 days, the battery will be permanently damaged.

Disposal

Do not dispose the transmitter in unsorted municipal waste stream. Discard the transmitter according to local regulations for battery disposal, or contact your healthcare professional for disposal information.

Specifications

Biocompatibility	Transmitter: Complies with EN ISO 10993-1
Applied parts	Transmitter
	Sensor

Operating conditions	Transmitter temperature: 32°F to 113°F (0°C to 45°C)
	Caution: When operating the transmitter on a tester in air temperatures greater than 106°F (41°C), the temperature of the transmitter may exceed 109°F (43°C).
	Transmitter relative humidity: 10% to 95% with no condensation
	Transmitter pressure: 8.4 psi to 15.4 psi (57.60 kPa to 106.17 kPa)
	Charger temperature: 50°F to 104°F (10°C to 40°C)
	Charger relative humidity: 30% to 75% with no condensation
Storage conditions	Transmitter temperature: -4°F to 131°F (-20°C to 55°C)
	Transmitter relative humidity: up to 95% with no condensation
	Transmitter pressure: 8.4 psi to 15.4 psi (57.6 kPa to 106 kPa)
	Charger temperature: 14°F to 122°F (-10°C to 50°C)
	Charger relative humidity: 10% to 95% with no condensation
Battery life	Transmitter: Seven days of continuous glucose monitoring immediately following a full charge.
	Charger: The charger uses one new AAA battery to charge the transmitter.
Transmitter frequency	2.4 GHz band, Bluetooth™* wireless technology (version 4.0)
Effective radiated power (ERP)	0.06 mW (-12.05 dBm)
Effective isotropic radiated power (EIRP)	0.1 mW (-9.9 dBm)
Operating range	Up to 6 feet (1.8 meters) in free-air
Transmitter expected service life	The transmitter expected service life is one year depending on patient usage.

Transmitter wireless communication

Quality of service

The transmitter and insulin pump connect via smart device connectivity. The transmitter sends glucose data and system-related alerts to the pump. The pump verifies the integrity of received data after wireless transmission.

Data security

The transmitter is designed to only accept radio frequency (RF) communications from recognized and linked devices. You must pair your pump with the transmitter before the pump will accept information from the transmitter.

The MiniMed™ insulin pumps and system components (meters and transmitters) ensure data security via proprietary means and data integrity using error checking processes, such as cyclic redundancy checks.

Traveling by air
Your transmitter is safe for use on commercial airlines. If questioned by airline personnel about the use of your device, please show them your Medical emergency card.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	CISPR 11 Group 1, Class B	The transmitter uses RF energy only for system communications. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Not applicable	***Note:*** *The preceding statement is required by IEC 60601-1-2 for Group 1, Class B devices. Since the transmitter is battery powered, its emissions will not be affected by the establishment power supply and there is no evidence of any issues associated with the use of the system in domestic establishments.*
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2:2014 Test Level**	**Max foreseeable use condition per IEC 60601-1-2:2014**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	For use in a typical domestic, commercial, or hospital environment.
Conducted disturbances induced by RF fields	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands between 150 kHz to 80 MHz	Not applicable	Requirement does not apply to this battery powered device.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	Not applicable	Requirement does not apply to this battery powered device.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2:2014 Test Level**	**Max foreseeable use condition per IEC 60601-1-2:2014**	**Electromagnetic Environment Guidance**
Surge IEC 61000-4-5	Line to Line: ±0.5 kV, ±1 kV Line to Ground: ±0.5 kV, ±1 kV, ±2 kV	Not applicable	Requirement does not apply to this battery powered device.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-4-11	0% U_T; 0.5 cycles (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 0% U_T; 1 cycle (at 0°) 70% for 25/30 cycles (at 0°) 0% for 250/300 cycles	Not applicable	Requirement does not apply to this battery powered device.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	For use in a typical domestic, commercial, or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	IEC 60601-1-2:2014, Table 9	IEC 60601-1-2:2014, Table 9	For use in a typical domestic, commercial, or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2:2014 Test Level**	**Max foreseeable use condition per IEC 60601-1-2:2014**	**Electromagnetic Environment Guidance**
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 6 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the transmitter than the recommended separation distance of 12 in (30 cm). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Note: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.*

Warranty

Medtronic MiniMed, Inc. (or such other legal entity as may be referred to as manufacturer on the labeling of this device "Medtronic MiniMed") warrants the Medtronic transmitter to the purchaser of the product against defects in material and workmanship for a period of one (1) year and the charger for up to one (1) year from the date of purchase.

During the warranty period, Medtronic MiniMed will replace or repair, at its discretion, any defective transmitter or charger, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a transmitter or charger is replaced, the warranty period will not be extended past its original expiration date.

This warranty is valid only if the Medtronic transmitter or charger is used in accordance with the manufacturer's instructions. Without limitation, this warranty will not apply:

- If damage results from changes or modifications made to the transmitter or charger by the user, or third persons, after the date of purchase.

- If damage results from service or repairs performed by any person or entity other than the manufacturer.
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer.
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water, physical abuse, (such as dropping).
- If damage results from use of the device in a manner other than according to the manufacturer's product labeling, instructions for use, or regulatory notifications.

This warranty shall be personal to the original purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original purchaser shall cause this warranty to immediately terminate. This warranty does not apply to Glucose Sensors and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic MiniMed nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

All other conditions and warranties, other than mandatory statutory warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

This warranty gives the purchaser specific legal rights, and the purchaser may also have other rights that vary under local law. This warranty does not affect the purchaser's statutory rights.

Open Source Software (OSS) disclosure

This document identifies the Open Source Software that may be separately called, executed, linked, affiliated, or otherwise utilized by this product.

Such Open Source Software is licensed to users subject to the terms and conditions of the separate software license agreement for such Open Source Software.

Use of the Open Source Software by you shall be governed entirely by the terms and conditions of such license.

The source/object code and applicable license for the Open Source Software can be obtained at the following site: http://www.ouah.org/ogay/hmac/.

Icon glossary

For definition of the symbols displayed on the device and package labels, please see www.medtronicdiabetes.com/symbol-definitions.

Medtronic

REF MMT-7911, MMT-7736L, MMT-7715, MMT-7512

℞ Only

M998596A011_B

GETTING STARTED
WITH MINIMED™ 770G
INSULIN PUMP

Medtronic

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The MiniMed 770G Insulin Pump

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Getting started with the MiniMed 770G Insulin Pump

Section 1: Welcome

Welcome! We are glad that you have chosen insulin pump therapy and are excited for you to begin using your insulin pump.

Whether you have chosen pump therapy because of its convenience, the flexibility it provides, or to help improve your glucose control, your pump will be a valuable tool in helping to manage your diabetes.

This guide provides step-by-step instructions on the basic operation and programming of your pump. Using your pump to complete each practice exercise helps you become comfortable with the basics and prepare you for your in-person training.

> **NOTE:** Did you know that a complete explanation of the technical and operational aspects of your pump can be found in the *MiniMed 770G SYSTEM USER GUIDE?*

During your in-person training, your trainer helps ensure that you are confident to begin pump therapy.

Here are some quick tips to keep in mind as you work through this information:

- Be sure you are not attached to your new insulin pump while you practice.
- If you press the wrong button, press the ⬅ button to go back to the previous screen and try again.
- If you do not touch a button for 15 seconds, the pump screen turns dark. Press any button and the pump screen will return.
- Avoid the Reservoir & Tubing screen until you have completed all practice necessary to feel comfortable using this insulin pump.

We hope you enjoy learning about your new insulin pump.

> ⚠ **WARNING:** Do not insert the reservoir until you have been instructed to do so by your healthcare professional and have received formal training with a certified product trainer. Attempting to use insulin in your pump before you have received training may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.

Section 2: Pump mechanics and the delivery of insulin

Before we begin, let's make sure you know how insulin is delivered when using an insulin pump. The parts that make up the delivery system of the pump are the infusion set, the reservoir, and the pump.

1 Tubing
2 Tubing connector
3 Insertion site section
4 Cannula
5 Adhesive
6 Reservoir compartment

Infusion set*
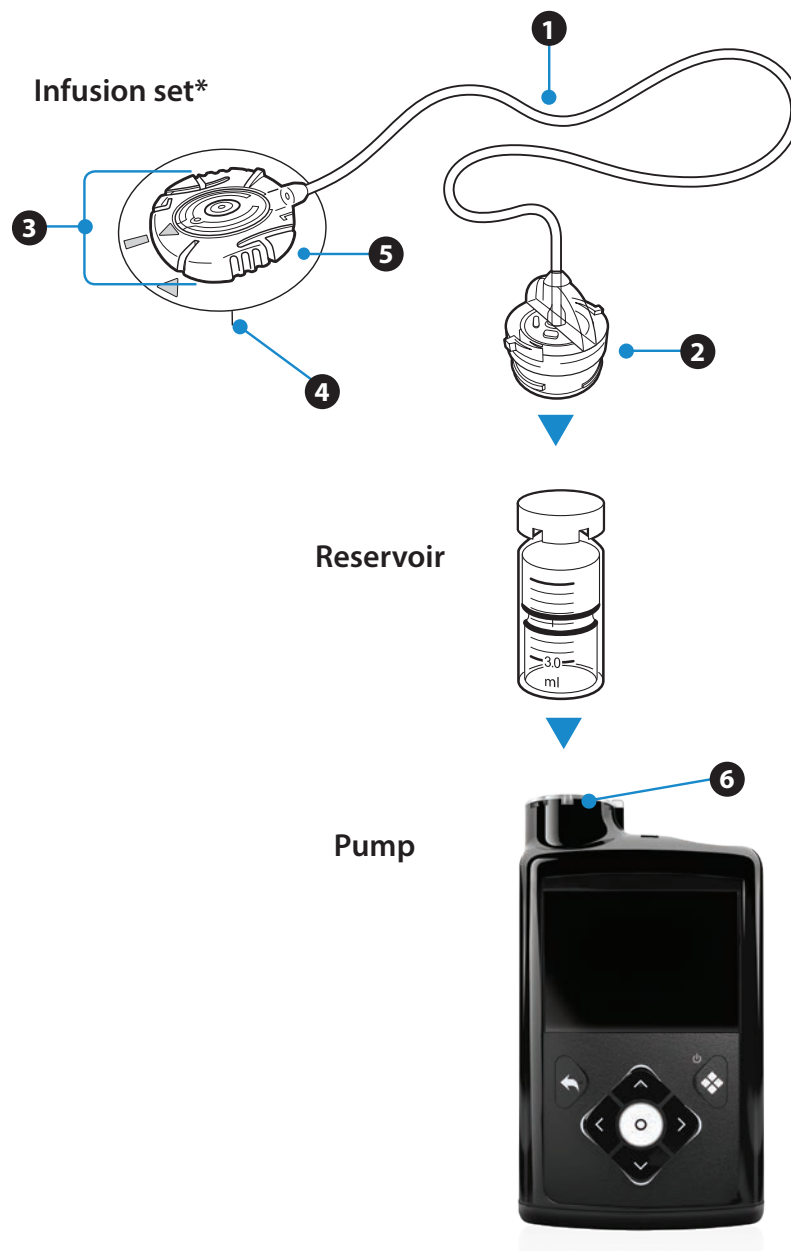
Reservoir

Pump

*Quick-set infusion set shown in illustration.

Infusion set

The infusion set consists of tubing (1) that carries insulin from the pump to you. On one end of the tubing is the reservoir connector (2) that attaches to the reservoir which holds the insulin. On the other end is the insertion site section (3) that attaches to you.

The insertion site section has a small insertion needle that places a tiny flexible tube called a cannula (4) into your body*. Once the infusion set is inserted, you remove the needle, leaving just the cannula behind. A small piece of adhesive (5) holds the infusion set in place. Replace the infusion set every 2 to 3 days. Insulin is not labeled for more than three days when it is used in an infusion set.

Reservoir

The reservoir fits into the reservoir compartment of the pump (6). Replace your reservoir and infusion set at the same time.

Pump

Inside the pump, at the bottom of the reservoir compartment, is a piston. The piston acts like the plunger rod on a syringe, pushing up on the bottom of the reservoir, moving insulin into the tubing, through the cannula, and into your body.

The piston is controlled by a mini computer inside the pump that is able to deliver insulin in very small doses, as small as 0.025 units. **It must be rewound each time a newly filled reservoir is placed into the reservoir compartment.**

*Some infusion sets do not use a cannula but have a small needle that remains inserted in the body.

Section 3: Pump basics

Before inserting the battery or pressing any buttons, let's take a closer look at your pump.

The front of your pump

⌃ **Up**, ⌄ **Down**, ⌃ **Left**, and ⌃ **Right**

- Press to scroll up or down through a menu or list.
- Press to move to the desired area on the screen.
- Press to change the value in an area.
- Press to unlock your pump when it has been in sleep mode.

↩ **Back**

- Press to return to a previous screen.
- Press and hold to return to the starting screen, called the Home screen.

◎ **Select**

- Press to select or confirm a value or menu option that is highlighted.
- Press when directions say select.
- Press to access the menu when you are on the Home screen.

❖ **Graph**

- Press to show the sensor glucose (SG) graph when you are on the Home screen.
- Press to return to the Home screen when you are on the SG graph.
- Press and hold to put the pump into sleep mode.

> 📝 **NOTE:** ⏻ reminds you that you can press and hold ❖ to put the pump into sleep mode.

● **Notification light**

- Flashes when an alert or an alarm occurs.

up

back

left

notification light

down

graph; sleep mode

right

select

5

Important numbers

Pump serial number
You may need to provide the pump serial number if you call for assistance.

24-Hour Technical Support
For product assistance, call this number to be routed to your local support team.

Inserting the battery

Your insulin pump is powered by a AA battery. A lithium, alkaline, or rechargeable AA battery can be used. The battery you place into your pump should always be new or fully charged.

> **NOTE:** Lithium batteries have been shown to have the longest battery life. Batteries should be stored at room temperature, not in the refrigerator or other cold locations.

You will need the following items to insert the battery. These can be found in the pump box with the accessories:

- Battery cap
- Pump clip
- AA battery
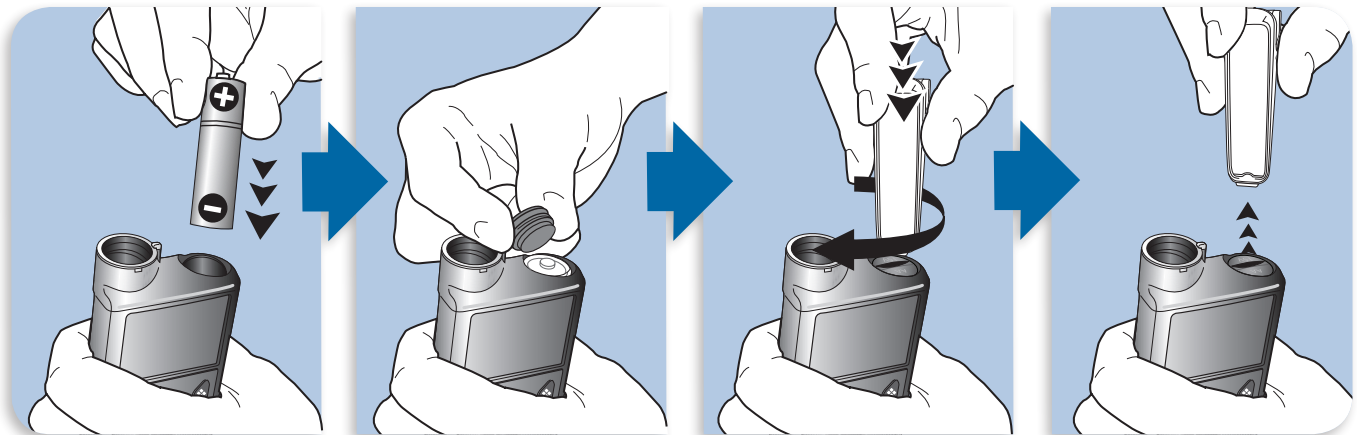
1 Place the battery into the battery compartment with the flat end going in first.

2 Place the battery cap onto the pump. Use the bottom edge of the pump clip to turn the cap to the right and tighten.

CAUTION: Do not overtighten or undertighten the battery cap. A battery cap that is too tight can cause damage to your pump case. A battery cap that is too loose prevents detection of the new battery. Turn the battery cap clockwise until the slot in the cap is aligned horizontally with the pump case, as shown in the example to the right.
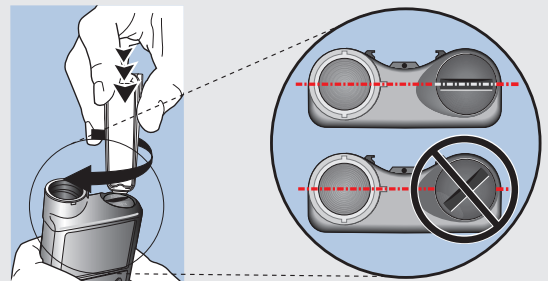
Section 4: Startup Wizard

NOTE: Always look for the item on the screen that is highlighted in yellow. This is the item that can be selected. Press the ⌃ and ⌄ buttons to highlight the item you want to choose and press the ◉ button to select it.

Language
Select Language
English ✓
中文
Español

Startup 1/3
Select Time Format
12 Hour
24 Hour

The pump powers on and the Startup Wizard begins.

Select your language.

Select **12 Hour** (AM/PM) or press ⌄ to select **24 Hour** and press ◉. *This example uses 12 Hour.*

Startup 2/3
Enter Time
Time   12:00 AM
Next

Startup 3/3
Enter Date
Year   2019
Month   Jan
Day   1, Tue
Next

Rewinding
Please wait...

The hour flashes. Press ⌃ or ⌄ to the correct hour and press ◉.

The minutes flash. Press ⌃ or ⌄ to the correct minutes and press ◉.

If the 12-hour mode is selected, the AM/PM flashes. Press ⌃ or ⌄ if needed and press ◉.

Select **Next**.

Select **Year**. Press ⌃ to the correct year and press ◉. Select **Month**. Press ⌃ or ⌄ to the correct month and press ◉.

Select **Day**. Press ⌃ or ⌄ to the correct day and press ◉.

Select **Next**.

Wait a moment.

Startup
Congratulations! Startup Wizard complete
✓
OK
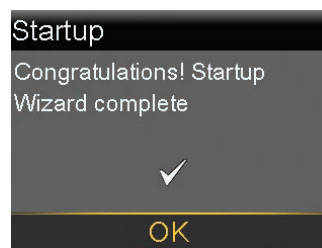
Select **OK**.

NOTE: To scroll faster, press and hold the ⌃ or ⌄ button. Once you reach the correct value or item, press ◉ to select.

Section 5: Home screen

You are now on the Home screen. The Home screen is your starting point. The following information is shown on the Home screen.

status icons: provides a quick look at the status of the pump

current time: shows the current time of day

9:00
AM

○ BG

- - -

mg/dL

Active Insulin   1.0 U

BG reading: shows a BG taken in the last 12 minutes

active insulin: shows any insulin still active from a previous bolus

Status icons

The status icons show a quick status of your pump system. When using your pump, you will see the following icons:

Battery icon:

- The color and fill of the battery icon indicate the charge level of your pump battery.

- When your battery is full, the icon is solid green.

- As your battery life is used, the icon changes from solid green in the following order.

- When your battery is low, the icon has a single red bar. When your battery needs to be replaced immediately, the icon is solid black with a red outline.

Reservoir icon:

The reservoir is representative of the MiniMed reservoir MMT-332A, 3.0 mL (300-unit).

- Approximately 85%–100% of the reservoir remains.
- Approximately 71%–84% of the reservoir remains.
- Approximately 57%–70% of the reservoir remains.
- Approximately 43%–56% of the reservoir remains.
- Approximately 29%–42% of the reservoir remains.
- Approximately 15%–28% of the reservoir remains.
- Approximately 1%–14% of the reservoir remains.
- The reservoir remaining amount is unknown.

Audio icon:

- The icons show the audio option that you are currently using.
- Audio
- Vibrate
- Audio and vibrate

NOTE: There will be times when you need more information than what is indicated by the status icons. For instance, the Reservoir icon may indicate your reservoir is getting low on insulin, and you need to know how many units are left. This additional information can be found in the status screens, see *Status, on page 39*.

Unlocking the pump

After the backlight has been off for a few minutes, the pump goes into sleep mode and the pump is locked. When you wake up your pump from sleep mode, you must unlock your pump before navigating to the menu. Press the button that is highlighted to unlock the pump. This confirms you are reading the screen and the button presses are not accidental.
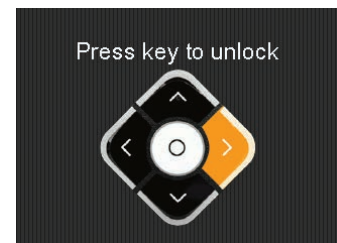
If you press an incorrect button, the screen prompts you to try again.

If you press , you are taken to the current Home screen.

You can press and hold if you wish to put the pump into sleep mode and keep it locked when you are not using it. Doing this can also help save battery life.

Backlight

When you are not pressing buttons on your pump, the backlight soon turns off. The pump is still on, it is just saving battery life. You can simply press any button to make the screen reappear.

KEEPING THE SCREEN ON LONGER...

Margaret noticed when she was not pressing buttons on her pump, the screen would turn dark. This happens to save battery life. She soon learned she could simply press any button to turn the screen back on.

HELPFUL HINT: If the pump screen is going dark too quickly, the Backlight setting can be changed. To learn how to do this, see *Display Options, on page 17*.

Section 6: Menu

There are seven items on the main menu. Each menu item contains the features and functions that pertain to that menu item.

From the Home screen, press ⊙ to go to the menu.

Bolus	🍶
Enter BG	🔴
Basal	🔧
Audio Options	🎵
Status	📋
Suspend Delivery	⏸
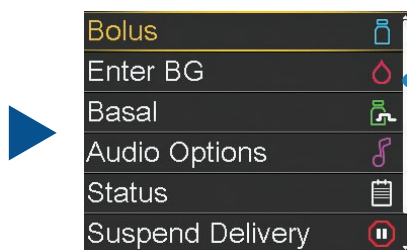
scroll bar
When a screen or a menu has more than six lines the scroll bar appears on the right side of the screen. Press ⌄ to view the additional items.

Menu options

Here you see a brief summary of the information found within each menu item.

Bolus	Lets you choose between Bolus Wizard, Manual Bolus, or Preset Bolus. You can also access your Delivery Settings from here.
Enter BG	You can manually enter a BG reading from this screen.
Basal	Lets you switch to a Temp Basal or a Preset Temp basal rate, or change to a different Basal Pattern. You can also access your Delivery Settings from here.
Audio Options	Lets you choose Audio, Vibrate, or both to inform you of alerts and notifications. You can also change the volume here and go to the Alert Silence screen.

Status	Status screens let you view information about Auto Mode Readiness; Notifications you have received in the last 24 hours; Quick Status including your last bolus, last BG entry, current basal rate, estimated reservoir volume, and battery status; Pump status including estimated reservoir volume, when it was started, and the pump serial number, name, and model; Sensor status including last calibration and next calibration due; and Settings Review, which includes your current pump settings.
Suspend Delivery	Lets you stop all insulin delivery. This is commonly used when disconnecting to swim or bathe.
Options	Lets you select SmartGuard, History, Reservoir & Tubing, Delivery Settings, Event Markers, Reminders, and access the Utilities menu.
Utilities	Lets you select Sensor Settings, Display Options, Time & Date, Block, Self Test, Manage Settings, Sensor Demo, Device Options, and Language.

NOTE: You will not use all of these options right away. We will focus on the ones that you need to get started.

THE MENU...

When Lisa first started on her pump, she did not know if she could ever learn how to use all the features the pump had available. But, she just focused on the basics first, and then she started learning the additional features that she found helped her the most.

HELPFUL HINT: Take some time to get comfortable with the basics first. Then learning the additional features will be much easier to do.

MAIN MENU

Manual Mode

Bolus
Enter BG
Basal
Audio Options
Status
Suspend Delivery
Options

Bolus 🍶

Bolus Wizard
Manual Bolus
Preset Bolus
Delivery Settings

Basal

Temp Basal
Preset Temp
Basal Patterns
Delivery Settings

Options ⚙

SmartGuard*
▶ Auto Mode
  ▶ Auto Mode
  ▶ Auto Mode BG Alert
▶ High Setup
  ▶ Alert before high
  ▶ Time before high
  ▶ Alert on high
  ▶ Rise Alert
  ▶ Rise Limit
▶ Low Setup
  ▶ Alert before low
  ▶ Alert on low
  ▶ Suspend before low
  ▶ Suspend on low
  ▶ Resume basal alert
▶ Snooze
  ▶ High Snooze
  ▶ Low Snooze

History
▶ Summary
▶ Daily History
▶ Alarm History
▶ Sensor Glucose Review*
▶ ISIG History*

Reservoir & Tubing
▶ New Reservoir
▶ Fill Cannula

Delivery Settings
▶ Bolus Estimate Setup
  ▶ Carb Ratio
  ▶ Bolus Wizard
  ▶ Insulin Sensitivity Factor
  ▶ BG Target
  ▶ Active Insulin Time
▶ Basal Pattern Setup
▶ Preset Temp Setup
▶ Preset Bolus Setup
▶ Dual/Square Wave
▶ Bolus Increment
▶ Max Basal/Bolus
▶ Easy Bolus
▶ Auto Suspend
▶ Bolus Speed

Event Markers
▶ BG
▶ Injection
▶ Food
▶ Exercise
▶ Other

Reminders
▶ Personal
▶ Bolus BG Check
▶ Missed Meal Bolus
▶ Low Reservoir
▶ Set Change

▶ Calibration*

Utilities
▶ Sensor Settings
  ▶ Sensor
  ▶ Sensor Connections*
  ▶ Calibrate Sensor*
▶ Display Options
  ▶ Brightness
  ▶ Backlight
▶ Time & Date
▶ Block
▶ Self Test
▶ Manage Settings
  ▶ Save Settings
  ▶ Restore Settings
  ▶ Clear All Settings
  ▶ Clear Active Insulin
  ▶ Settings History
▶ Sensor Demo
▶ Device Options
  ▶ Manage Devices
  ▶ Pair Device
▶ CareLink
▶ Language

MAIN MENU

Auto Mode
Bolus
Enter BG
Temp Target
Audio Options
Status
Suspend Delivery
Options

Bolus

BG
Carbs

Enter BG

BG Entry

Temp Target

Duration
Cancel Temp Target

Audio Options

Alert Silence Options
▶ High Alerts Only*
▶ High & Low Alerts*
▶ All Sensor Alerts*
▶ Duration*
Audio
Vibrate
Volume

Status

Auto Mode Readiness
Notifications
Quick Status
Pump
Sensor*
Settings Review

Suspend Delivery

*Menu option only appears if the sensor feature is on.

Section 7: Main menu items—a closer look

Now you are ready to set some basic features found within the Menu.

Audio Options

You use Audio Options to set the pump to beep (Audio), vibrate (Vibrate), or beep and vibrate (Audio and Vibrate). If you choose Audio or Audio and Vibrate, you can also increase or decrease the Volume.

✔ Let's practice:

1) Press ◎ to open the Menu.

2) Press ⌄ to **Audio Options** and press ◎.

3) Press ⌄ to the option that you prefer and press ◎.

   If you choose Audio, you are able to adjust the volume.

4) Press ⌄ to **Volume** and press ◎.

5) Press ◁ or ▷ to the desired volume and press ◎.

6) Select **Save**.

> **NOTE:** You can have both Audio and Vibrate on at the same time.

The icon shown here appears on the Home screen.

Audio Options
Alert Silence Options
Audio   On
Vibrate   Off
Volume   - 3 +
        Save

On appears when option is selected.

16

Display Options

Display Options allows you to choose the brightness of your pump screen. This is also where you go to change the amount of time your pump stays on before it goes into Power Save mode.

✔ Let's practice:

1) Press ⊙ to open the Menu.

2) Press ⌄ to **Options** and press ⊙.

3) Press ⌄ to **Utilities** and press ⊙.

4) Press ⌄ to **Display Options** and press ⊙.

   If you want to adjust the screen brightness:

5) Select **Brightness**.

6) Press ⌃ or ⌄ to the setting you prefer and press ⊙.

> **NOTE:** The Auto setting automatically adjusts the screen brightness to match your current environment. Your pump arrives set to Auto.

To adjust the backlight:

7) Select **Backlight**.

8) Press ⌃ or ⌄ to the setting you prefer and press ⊙.

9) Select **Save**.

> **NOTE:** How you adjust these settings can affect battery life. Increasing the Backlight time decreases the life of your battery.

Section 8: Basal Patterns

Remember, your body needs insulin so glucose can be moved into your cells and provide energy for your body. Insulin is needed 24 hours a day, even between meals and during the night. This is called basal insulin. The pump supplies basal insulin by delivering small amounts throughout each hour, every hour of the day and night. This allows for insulin to be increased and decreased to adjust for the needs of your body.

U/hr

12:00 A   **24 Hours**   12:00 A

Basal insulin amounts must be programmed into your pump. This is done by setting a basal pattern. A basal pattern consists of one or more basal rates being delivered over the course of 24 hours.

BEFORE HER PUMP...

Lynn always had to remember to take her shot of long-acting insulin at bedtime. Taking it at the same time every night like her doctor asked her to was difficult. She is in college and some nights she would go to bed early, others she would be at the library until late studying. Now that her doctor has prescribed a pump, she does not have to worry about taking a shot. She is getting her basal insulin automatically 24 hours a day.

Basal Pattern Setup—one basal rate

Your healthcare professional will calculate the hourly basal rate or rates that are best for you when you start to use your pump. You may start with a basal pattern that has only one basal rate. The pump delivers that exact basal amount evenly throughout each hour, 24 hours a day.

For example, if your starting basal rate is 1.0 unit, your pump would deliver one unit of insulin throughout each hour. This means you would receive a total of 24 units of basal insulin every 24 hours. To set Basal Patterns, go to **Delivery Settings**.

1) Press ⊚ to open the Menu.

2) Press ⌄ to highlight **Basal**. Press ⊚.

3) Press ⌄ to highlight **Delivery Settings**. Press ⊚.

NOTE: You can also access Delivery Settings from the Options menu.

⚠ **WARNING:** The following are some examples of basal rates for you to practice entering while learning how to use your pump. You will need to work with your healthcare professional to get your personal basal rates. Do not use these practice basal rates for your therapy. Attempting to use these settings in your pump could result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.

✔ **Let's practice: setting a Basal Pattern that has *only one* basal rate**

Let's set a basal pattern with a basal rate of 0.750 U/hr from 12:00A–12:00A.

1) Press ⊙ to open the Menu.

2) Press ⌄ to **Basal** and press ⊙.

3) Press ⌄ to **Delivery Settings** and press ⊙.

4) Press ⌄ to **Basal Pattern Setup** and press ⊙.

5) Select **Basal 1**.

6) Select **Options**.

7) Select **Edit**.
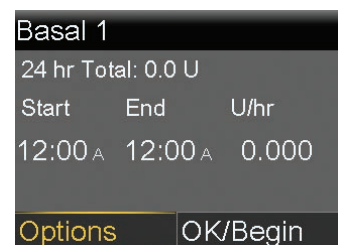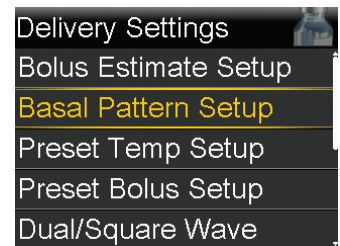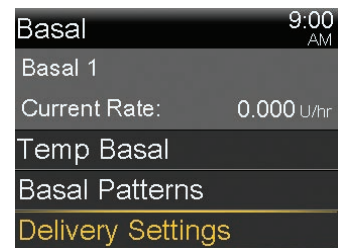
8) Press ⊙ on the time segment. The **End** time flashes.

9) Since you have only one basal rate, you do not need to change the **End** time. Press ⊙ on the 12:00A.

> **Edit Basal 1**
> Start   End   U/hr
> 12:00 A 12:00 A   0.000
>
>   Done
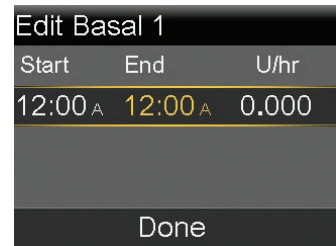
10) Press ⌃ to enter 0.750 and press ⊙.

> **Edit Basal 1**
> Start   End   U/hr
> 12:00 A 12:00 A   0.750
>
>   Done

11) Select **Done**.
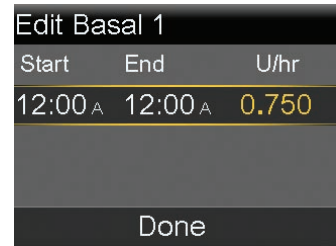
> **Edit Basal 1**
> Start   End   U/hr
> 12:00 A 12:00 A   0.750
>
>   Done

12) Verify that the basal pattern is entered correctly. Make sure the **24 hr Total** is accurate.
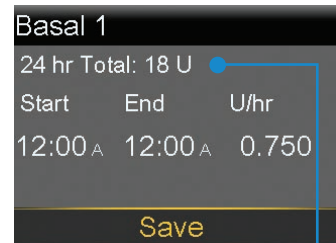
13) If no changes need to be made, select **Save**.

   If changes need to be made, press ⬅ to return to the Edit Basal 1 screen.

14) Press ⌃ and ⊙ to edit the time segment.

15) Select **Done**.

16) When finished, select **Save**.

This basal rate amount entered, 0.750 units per hour in this example, is automatically delivered throughout each hour continuously from one day to the next.

> **Basal 1**
> 24 hr Total: 18 U
> Start   End   U/hr
> 12:00 A 12:00 A   0.750
>
>   Save

NOTE:
This basal pattern delivers 18 U over 24 hours.
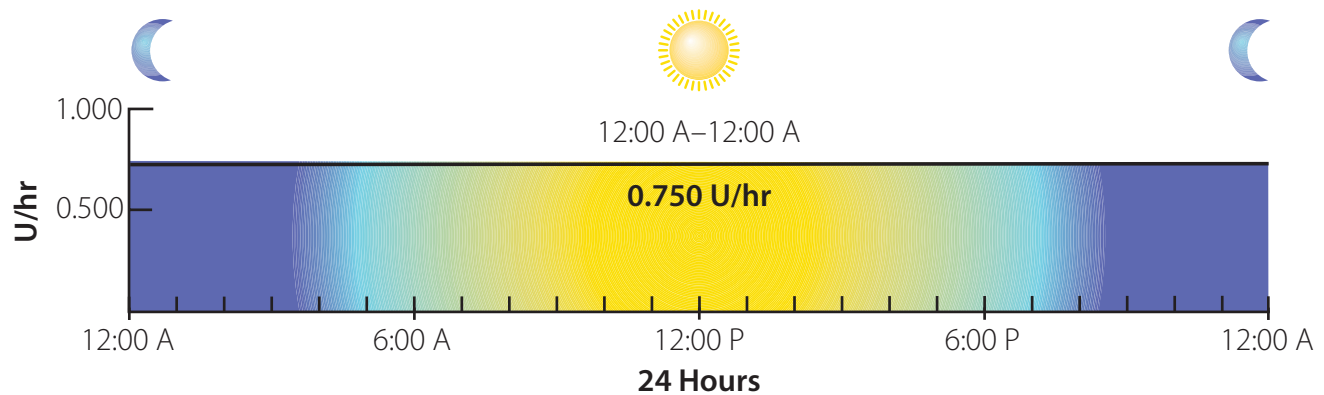
Basal Pattern Setup—changing a basal rate

When you check your blood glucose (BG) as instructed, the BG readings help you and your healthcare professional determine if your basal pattern needs to be changed. If your glucose levels are running too high or too low, this basal amount may need to be changed.

Let's practice: changing a basal rate

Change the **Basal 1** basal rate from 0.750 to 0.900 U/hr.

1) Press ⦿ to go to the Menu.

2) Press ⌄ to **Basal** and press ⦿.

3) Press ⌄ to **Delivery Settings** and press ⦿.

4) Press ⌄ to **Basal Pattern Setup** and press ⦿.

5) Select **Basal 1**.

6) Select **Options**.

7) Select **Edit**.

8) Press ⦿ on the time segment.

9) Press ❯ to **Rate** and do not select it.

10) Press ⌃ to change 0.750 to 0.900 and press ⦿.

11) Select **Done**.

21

12) Verify that **Basal 1** is entered correctly.

13) Select **Save**.

Basal 1
24 hr Total: 21.6 U
Start   End   U/hr
12:00 A 12:00 A 0.900
Save

Basal Pattern Setup—multiple basal rates

Not only might you need to increase or decrease a single basal rate, you may also need to add basal rates to give you different amounts of basal insulin during certain parts of the day or night.

HAVING MORE THAN ONE BASAL RATE...

When Jessica was taking shots, her BG readings were always high in the morning. If she increased her nighttime insulin, then she would have low BGs later in the day. Now that she has her pump, it is set to deliver more insulin in the early morning so her BG values are not high when she wakes up, and less insulin later in the day when she needs a lower dosage.

HELPFUL HINT: Most people need more than one basal rate to get the best control with their pump. Work with your healthcare professional to get your basal rates adjusted correctly when you start on pump therapy.

In this example, a healthcare professional reviewed the BG readings and determined that one basal rate works well for part of the day, but the basal rate needs to be lowered to 0.650 units per hour between the hours of 8:00A and 6:00P.

The new basal pattern looks like this:
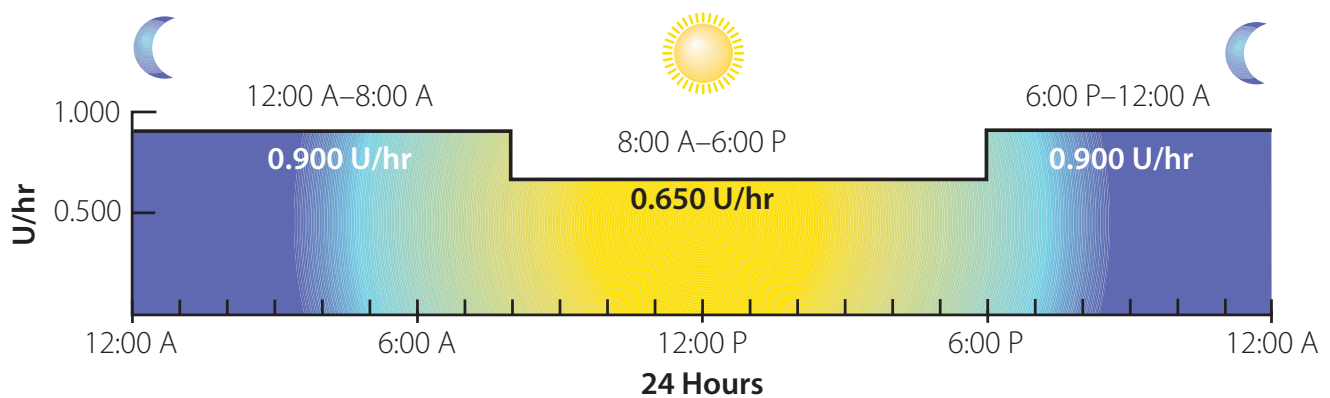
Now, let's make the changes to the basal pattern.

Let's practice: setting multiple basal rates

1) Press ⊙ to go to the Menu.

2) Press ⌄ to select **Basal** and press ⊙.

3) Press ⌄ to **Delivery Settings** and press ⊙.

4) Press ⌄ to **Basal Pattern Setup** and press ⊙.

5) Select **Basal 1**.

6) Select **Options**.

7) Select **Edit**.

8) Press ⊙ on the time segment.

The 0.900 basal rate now needs to end at 08:00A since this is the time that your basal rate needs to decrease.

9) Press ⌃ to 08:00A and press ⊙.

10) Press ⊙ again for this basal to stay the same.

You can see you are automatically asked to enter the end time of the second basal rate. This basal rate needs to end at 6:00P and needs to be changed to 0.650.

11) Press ⊙ to change the **End** time.

12) Press ⌃ to 6:00P and press ⊙.

13) Press ⌃ to 0.650 and press ⊙.

You can now enter the next end time. You need to enter 12:00A to complete the full 24-hour period.

14) Press ⊙ to change the **End** time.

15) Press ⌃ to 12:00A and press ⊙.

16) Press ⌃ to 0.900 and press ⊙.

17) Select **Done**.

Edit Basal 1		
Start	End	U/hr
12:00 A	12:00 A	0.900
	Done	

Edit Basal 1		
Start	End	U/hr
12:00 A	8:00 A	0.900
8:00 A	8:30 A	---
	Done	

Edit Basal 1		
Start	End	U/hr
12:00 A	8:00 A	0.900
8:00 A	6:00 P	0.650
6:00 P	6:30 P	---
	Done	

Edit Basal 1		
Start	End	U/hr
12:00 A	8:00 A	0.900
8:00 A	6:00 P	0.650
6:00 P	12:00 A	0.900
	Done	

18) Verify that **Basal 1** is entered correctly. Press ⌄ to view all the basal rates.

19) Select **Save**.

Basal 1
24 hr Total: 19.1 U

Start	End	U/hr
12:00 A	8:00 A	0.900
8:00 A	6:00 P	0.650

Save

✔ **Let's practice: changing multiple basal rates**

Now change the 8:00A to 6:00P basal rate to 8:00A to 5:30P and change to 0.700 U/hr.

1) Press ◎ to go to the Menu.

2) Press ⌄ to select **Basal** and press ◎.

3) Press ⌄ to **Delivery Settings** and press ◎.

4) Press ⌄ to **Basal Pattern Setup** and press ◎.

5) Select **Basal 1**.

6) Select **Options**.

7) Select **Edit**.

8) Press ⌄ to the 8:00A to 6:00P time segment and press ◎.

9) Press ⌄ to 5:30P and press ◎.

10) Press ⌃ to 0.700 and press ◎. Notice the start time of the 3rd time segment changed to 5:30P.

11) Press ◎ to change the **End** time.

12) Press ⌃ to 12:00A and press ◎.

13) Press ⌃ to 0.900 and press ◎.

14) Select **Done**.

15) Verify that the **Basal 1** is entered correctly. Press ⌄ to view all the basal rates.

16) Select **Save**.

Edit Basal 1

Start	End	U/hr
12:00 A	8:00 A	0.900
8:00 A	6:00 P	0.650
6:00 P	12:00 A	0.900

Done

▼

Edit Basal 1

Start	End	U/hr
12:00 A	8:00 A	0.900
8:00 A	5:30 P	0.700
5:30 P	12:00 A	0.900

Done

Basal 1
24 hr Total: 19.7 U

Start	End	U/hr
12:00 A	8:00 A	0.900
8:00 A	5:30 P	0.700

Save

Basal Pattern Setup—removing basal rates

There may be times when you have basal rates entered that need to be removed. This is done by simply changing the end time of the last basal rate that you need to 12:00A.

Let's practice: removing basal rates

1) Press ⊙ to go to the Menu.

2) Press ⌄ to **Basal** and press ⊙.

3) Press ⌄ to **Delivery Settings** and press ⊙.

4) Press ⌄ to **Basal Pattern Setup** and press ⊙.

5) Select **Basal 1**.

6) Select **Options**.

7) Select **Edit**.

8) Press ⊙ on the 12:00A to 8:00A time segment.

9) Press ⌄ to 12:00A and press ⊙.

10) Press ⊙ again for this basal rate to stay the same. Notice that all other basal rates have been removed.

11) Select **Done**.

12) Verify that **Basal 1** is entered correctly.

13) Select **Save**.

Edit Basal 1		
Start	End	U/hr
12:00 A	8:00 A	0.900
8:00 A	5:30 P	0.700
5:30 P	12:00 A	0.900
	Done	

▼

Edit Basal 1		
Start	End	U/hr
12:00 A	12:00 A	0.900
	Done	

Basal 1		
24 hr Total: 21.6 U		
Start	End	U/hr
12:00 A	12:00 A	0.900
	Save	

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Suspend Delivery

Remember that your pump is delivering basal insulin throughout every hour of the day. Although you should never stop this insulin delivery for more than an hour or so, there will be times when you want to manually suspend, or stop insulin delivery, and disconnect from your pump. This is done using the manual Suspend Delivery feature. Using Suspend Delivery stops all insulin delivery. The most common reasons to manually suspend delivery might include bathing and water activities. Infusion sets are designed so you can easily disconnect from your pump and leave it in a safe place. Talk with your healthcare professional about a plan including BG checks and possible correction boluses when disconnecting and reconnecting your pump.

SUSPENDING THE PUMP...

Danielle prefers not to wear her pump when she is swimming, so she disconnects it. She always manually suspends her pump so that insulin is not delivered while the pump is not attached to her.

Helpful hint: While the pump is suspended, it beeps, vibrates, or beeps and vibrates every 15 minutes to remind you insulin delivery is suspended unless a button is pressed.

Let's practice: placing the pump in manual suspend

1) Press ⊙ to open the Menu.

2) Press ⌄ to highlight Suspend Delivery.

3) Select **Suspend Delivery**.

Bolus	🍼
Enter BG	🔴
Basal	📊
Audio Options	🎵
Status	📋
Suspend Delivery	⏸

4) Press ⟩ and select **Yes** to suspend delivery.

Suspend Delivery?

| No | Yes |

A confirmation screen appears.

Delivery Suspended
Successfully
✓

26
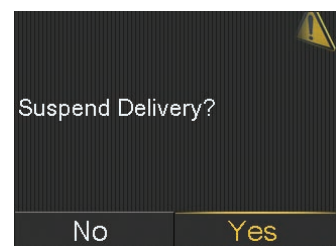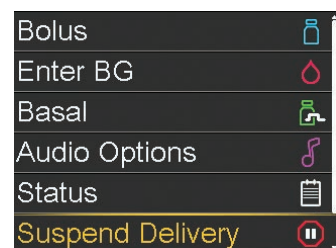
Notice that the Home screen has changed. The pump beeps, vibrates, or beeps and vibrates every 15 minutes while the pump is manually suspended unless a button is pressed.
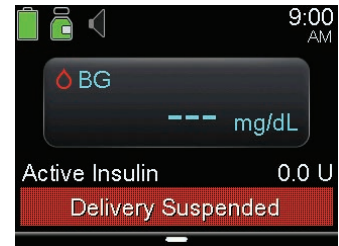
WARNING: When delivery is resumed, basal insulin will begin to deliver again. The pump will not deliver any of the basal insulin you missed while the pump was suspended.

If you manually suspend delivery while a bolus is delivering, the bolus delivery will stop. When you resume delivery, the remainder of the bolus will not be delivered.

Let's practice: resuming basal insulin delivery

1)   Press ◎ to open the Menu.

2)   Select **Resume Delivery**.

3)   Press ❯ and select **Yes** to resume insulin delivery.
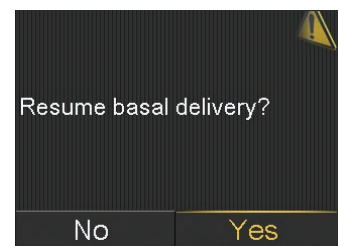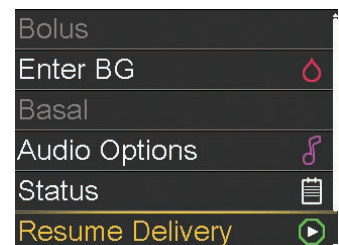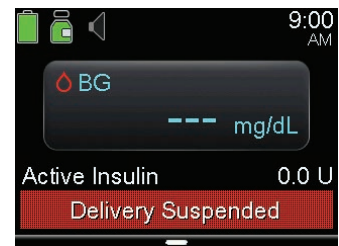
A confirmation screen appears.
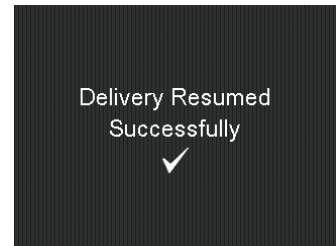
The Home screen appears.
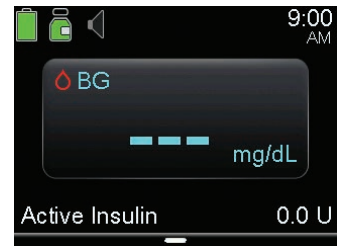
Section 9: Giving boluses

A bolus is given for two reasons: to cover food that contains carbohydrate or to correct glucose levels that are above your target range. Giving a bolus is one of the most common things you will do with your pump. Instead of having to take shots at meals, or between meals if your glucose is too high, you can program your pump to give the insulin. When using the pump, you are able to give precise bolus amounts.

GIVING A BOLUS...

Susie finds it easier to give herself a bolus on her pump than it was to give an injection at her meals. When she went out to eat, she would sometimes forget to take her insulin along. Now it is always with her.

Giving a manual bolus

When giving a manual bolus, you simply enter the amount of bolus insulin that you think you need for the carbohydrates you are eating, or to lower your BG if it is high.

⚠ **WARNING:** Make sure you are NOT connected to the pump while you are giving practice boluses.

1) Press ⊚ to open the Menu.

2) Select **Bolus**.

3) Press ⌃ to 1.0 u and press ⊚.

4) Select **Deliver Bolus**.
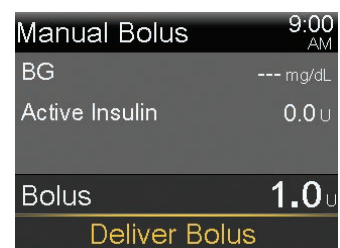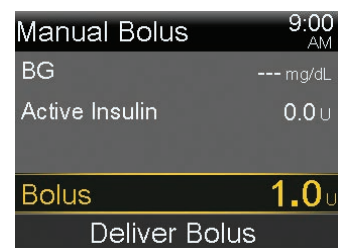
5)   Confirmation that the Bolus has started appears.

> Bolus 1.0 U
> started
> ✓
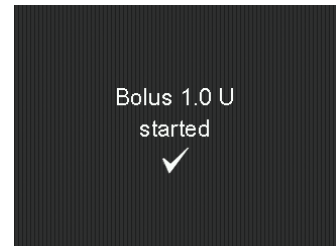
The Home screen shows the bolus amount as it is being delivered. Once the bolus has finished delivering, the pump returns to the normal Home screen.

> 9:00 AM
> ◇ BG
> --- mg/dL
> Bolus   0.450 U
> Total   1.000 U
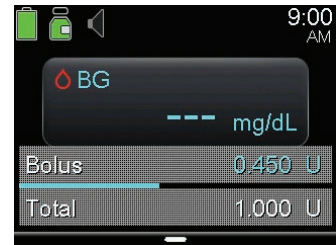
Notice there is **Active Insulin** now displayed. Active insulin is insulin from previous boluses that is still working to lower blood glucose levels. Each time you give a bolus, it is added to the active insulin amount. As time passes, the amount decreases. You will learn more about active insulin during your training.

> 9:00 AM
> ◇ BG
> --- mg/dL
> Active Insulin   1.0 U
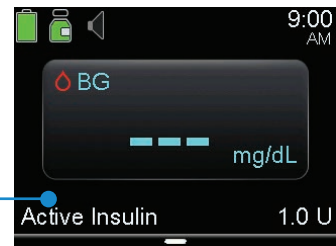
Stopping a bolus that you have started

There may be times when you need to stop your bolus. Perhaps you realized you entered the wrong amount, or you get a phone call and cannot eat right now as planned. Go to the Main Menu to find the **Stop Bolus** option.

1)   Press ◎ to open the Menu.

2)   Select **Stop Bolus**.

> Stop Bolus
> Enter BG
> Basal
> Audio Options
> Status
> Suspend Delivery

3)   Press ◈ and select **Yes**.

> Stop bolus delivery?
>
> No   Yes
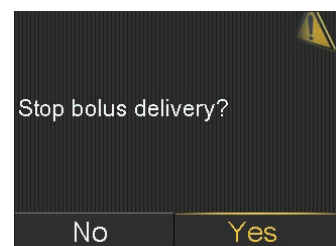
4) Review the **Bolus Stopped** screen to see how much of the bolus was delivered.

5) Select **Done**.

> **NOTE:** The **Bolus Stopped** screen shows you how much of the bolus insulin was delivered before the bolus was stopped.

Bolus Stopped   9:00 AM
Delivered
     0.250 of 1.000 U
Done

STOPPING A BOLUS...

Karen gives a bolus for lunch, but before she can begin eating, the phone rings. It is her cousin calling long distance, so Karen knows this phone call will take a while. She decides to wait to eat until after the call so she stops the bolus.

HELPFUL HINT: Always check the Bolus Stopped screen to see how much insulin you received before the bolus was stopped. Depending on the amount, you may decide you need to eat something so you do not experience a low blood glucose.

✔ Let's practice: stopping a bolus

Give a manual bolus of 1.5 units and stop the bolus once it has started to deliver.

1) Press ⊙ to open the Menu.

2) Select **Bolus**.

3) Press ⌄ to 1.5 u and press ⊙.

4) Select **Deliver Bolus**.

5) Press ⊙ to open the menu, then select **Stop Bolus**.

6) Press ⟩ and select **Yes** to stop delivery.

7) Review the **Bolus Stopped** screen. How much of the bolus was delivered?

8) Select **Done**.

Bolus Wizard feature

Calculating how much bolus insulin to give can be challenging. When using the Bolus Wizard feature, you will enter your current BG reading along with the amount of carbs you are about to eat. Once you do this, the Bolus Wizard feature uses the individual settings provided by your healthcare professional to calculate your bolus amount.

By counting carbs and using the Bolus Wizard feature, you are able to give the right amount of insulin for your food and correction bolus. This can help to keep your glucose levels better controlled.

> ⚠️ **WARNING:** The following are some examples of Bolus Wizard settings for you to practice entering while learning how to use your pump. You will need to work with your healthcare provider to get your personal Bolus Wizard settings. Do not use these practice Bolus Wizard settings for your therapy. Attempting to use these settings in your pump could result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.

Bolus Wizard Setup

To use the Bolus Wizard feature, you must first enter your personal settings provided by your healthcare professional. You need your Carb Ratio, Insulin Sensitivity Factor, BG Targets, and your Active Insulin Time to complete the setup. If you do not have your personal settings yet, you may practice with the practice settings in the examples below. Be sure your personal settings are entered before actually using the Bolus Wizard feature for your therapy.

✅ **Let's practice: entering Bolus Wizard settings**

1) Press ⊙.

2) Select **Options**.

3) Select **Delivery Settings**.

4) Select **Bolus Estimate Setup**.

5) Select **Bolus Wizard** to turn it on.
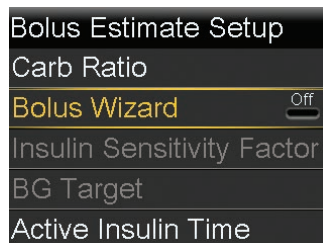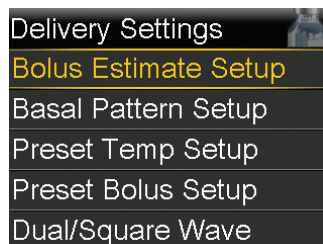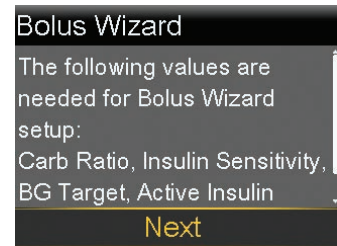
Delivery Settings
Bolus Estimate Setup
Basal Pattern Setup
Preset Temp Setup
Preset Bolus Setup
Dual/Square Wave

Bolus Estimate Setup
Carb Ratio
Bolus Wizard   Off
Insulin Sensitivity Factor
BG Target
Active Insulin Time

6) Press ⌄ to continue reading text.

7) Select **Next**.

Bolus Wizard

The following values are needed for Bolus Wizard setup:
Carb Ratio, Insulin Sensitivity, BG Target, Active Insulin

Next

8) Review the description of Carb Ratio and select **Next**.

Carb Ratio 1/4

Carb Ratio is the amount of carbs covered by 1 unit of insulin.

Next

9) Press ⊙ on the time segment.

10) If you have only one Carb Ratio, press ⊙.

If you have more than one Carb Ratio, press ⌃ or ⌄ to enter the time that your Carb Ratio ends and the second begins and press ⊙.

Edit Carb Ratio 1/4

Start	End	g/U
12:00 A	12:00 A	---
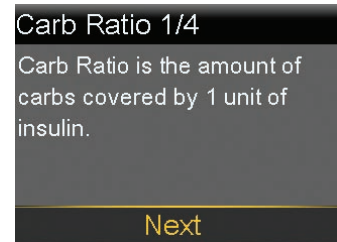
11) Press ⌃ or ⌄ to enter the **g/U** of your Carb Ratio and press ⊙.

If you have more than one Carb Ratio, continue by entering your time segments and Carb Ratios until all are entered.

This example shows only one Carb Ratio of 15. Enter this practice Carb Ratio, or if you know your personal Carb Ratio, enter it now.
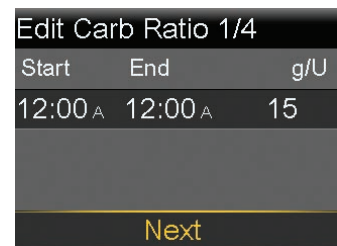
Edit Carb Ratio 1/4

Start	End	g/U
12:00 A	12:00 A	15

Next

12) Select **Next**.

13) Review the description of Insulin Sensitivity Factor and select **Next**.

Sensitivity 2/4

Insulin Sensitivity Factor (Sensitivity) is the BG amount reduced by 1 unit of insulin.

Next

14) Press ⊙ on the time segment.

15) If you have only one sensitivity factor, press ⊙.

If you have more than one sensitivity factor, press ⌃ or ⌄ to enter the time that your first sensitivity factor ends and the second begins and press ⊙.

16) Press ⌃ or ⌄ to enter the **mg/dL per U** of your sensitivity factor and press ⊙.

If you have more than one sensitivity factor, continue by entering your time segments and sensitivity factors until all are entered.

This example shows only one sensitivity factor of 50. Enter this practice sensitivity factor, or if you know your personal sensitivity factor, enter it now.
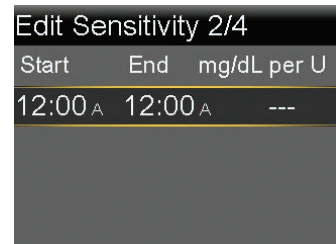
17) Select **Next**.

18) Review the description of BG Target and select **Next**.
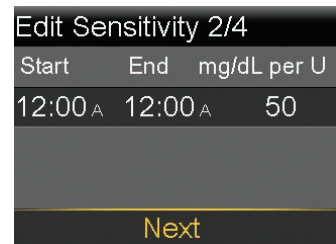
19) Press ⊙ on the time segment.

20) If you have only one BG Target range, press ⊙.

If you have more than one BG Target range, press ⌃ or ⌄ to enter the time that your BG Target range ends and the second begins and press ⊙.

Edit Sensitivity 2/4
Start   End   mg/dL per U
12:00 A 12:00 A   ---
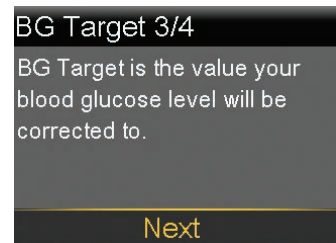
Edit Sensitivity 2/4
Start   End   mg/dL per U
12:00 A 12:00 A   50
Next

BG Target 3/4
BG Target is the value your blood glucose level will be corrected to.
Next

Edit BG Target 3/4
Start   End   Lo-Hi (mg/dL)
12:00 A 12:00 A   --- - ---

21) Press ⌃ or ⌄ to enter the low (**Lo**) BG target and press ⊙.

22) Press ⌃ or ⌄ to enter the high (**Hi**) BG target and press ⊙.

> If you have more than one BG Target range, continue by entering your time segments and low (**Lo**) and high (**Hi**) BG targets until all are entered.

> *This example shows only one BG Target range of 100-100. Enter this practice BG Target range, or if you know your personal BG Target range, enter it now.*

23) Select **Next**.

24) Review the description of Active Insulin Time and select **Next**.

25) Select **Duration**.

26) Press ⌃ or ⌄ to enter the **Duration** of your Active Insulin Time and press ⊙.

> *This example shows an Active Insulin Time of 4:00 hours. Enter this practice Active Insulin Time, or if you know your personal Active Insulin Time, enter it now.*
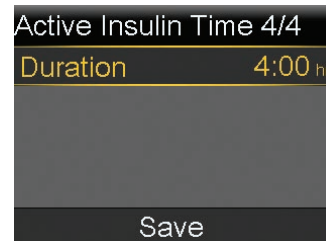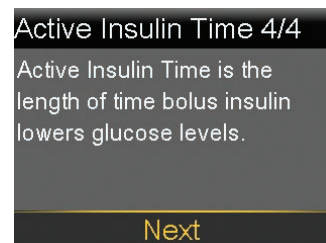
27) Select **Save**.

The Bolus Wizard setup is now complete.
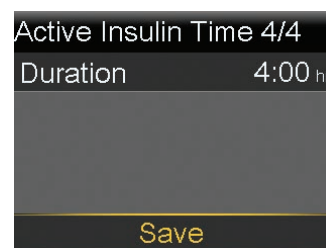
Now that you have completed the initial setup, you can see that the individual settings are now accessible menu items. If you need to make a change to any of these settings, you can press down to the setting, select it, and make the necessary changes.

Edit BG Target 3/4

Start	End	Lo-Hi (mg/dL)
12:00 A	12:00 A	100 - 100

Next

Active Insulin Time 4/4

Active Insulin Time is the length of time bolus insulin lowers glucose levels.

Next

Active Insulin Time 4/4

Duration   4:00 hr

Save

Active Insulin Time 4/4

Duration   4:00 hr

Save

Bolus Estimate Setup
Carb Ratio
Bolus Wizard   On
Insulin Sensitivity Factor
BG Target
Active Insulin Time
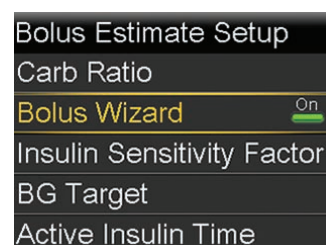
Using the Bolus Wizard feature

Before we start, let's take a look at the Bolus Wizard entry screen.

current BG from BG meter ⎯⎯

active insulin being subtracted from correction insulin because it is still lowering glucose levels

number of grams of carbs you are eating

Bolus Wizard   09:00 AM
BG   --- mg/dL   0.0 U
Active Ins. adjust.   0.0 U
Carbs   0 g   0.0 U
Bolus   0.0 U
Next

⎯⎯ correction insulin needed for BG above target, or insulin subtracted for BG below target

⎯⎯ amount of active insulin being deducted

⎯⎯ insulin needed for carbs

⎯⎯ total estimated bolus amount

> **WARNING:** Do not use Alternative Site Testing to make insulin dosing calculations.

✔ Let's practice: food and correction bolus

Now you are ready to practice giving a bolus. This example shows giving a bolus for a BG and carbs. This example uses a BG value of 124 mg/dL and 35 grams of carbs.

1) Press ⊙.

2) Select **Bolus**.

3) Select **Bolus Wizard**.

Bolus   9:00 AM
BG   --- mg/dL
Active Insulin   0.3 U
Bolus Wizard
Manual Bolus
Delivery Settings

4) Select **BG**.

5) Press ⌃ or ⌄ to enter the current BG, and press ⊙.

Active Ins. adjust. is the active insulin from previous boluses that is being adjusted (subtracted) from the correction dose.

Bolus Wizard   9:00 AM
BG   124 mg/dL   0.4 U
Active Ins. adjust.   -0.3 U
Carbs   0 g   0.0 U
Bolus   0.1 U
Next

6) Select **Carbs**.

7) Press ⌃ to enter the amount of carbs you are eating and press ⊙.

8) Select **Next**.

Bolus Wizard   9:00 AM
BG   124 mg/dL   0.4 U
Active Ins. adjust.   -0.3 U
Carbs   35 g   2.3 U
Bolus   2.4 U
Next

9) Select **Deliver Bolus**.

NOTE: The BG value entered appears on the Home screen and remains there for 12 minutes.

There may be times you enter either a BG value or Carbs. For example, you would enter:

- Only grams of carbs if you finished your meal, but are eating additional carbs
- Only a BG value if you checked two hours after your meal to see if you needed a correction bolus

Let's practice: food bolus with no BG

1) Press ⊙.

2) Select **Bolus**.

3) Select **Bolus Wizard**.

4) Press ⌄ to **Carbs** and press ⊙.

5) Press ⌃ to enter the amount of carbs you are eating and press ⊙.

6) Select **Next**.

7) Select **Deliver Bolus**.
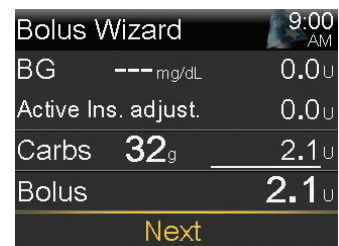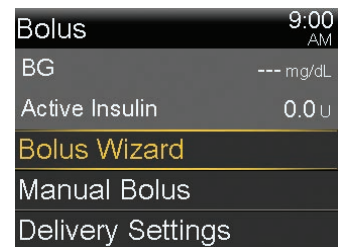
NOTE: You will receive a message when you enter a BG below 70 mg/dL or above 250 mg/dL. Each message prompts you to take appropriate steps to treat as instructed by your healthcare professional. You will see an example in the next practice exercise.

Let's practice: correction bolus with no food

1) Press ⊙.

2) Select **Bolus**.

3) Select **Bolus Wizard**.

4) If using the compatible meter, BG will be on the screen. If not, select **BG**.

5) Press ⌃ or ⌄ to enter the current BG, and press ⊙.

6) Press ⌄ to **Next** and press ⊙.

7) The High BG message appears. Read the text and press ⌄.

8) Continue reading the text and take appropriate action to prevent diabetic ketoacidosis (DKA).

9) Select **OK**.

Bolus	9:00 AM
BG	--- mg/dL
Active Insulin	0.0 U
Bolus Wizard	
Manual Bolus	
Delivery Settings	

Bolus Wizard	9:00 AM
BG 264 mg/dL	3.2 U
Active Ins. adjust.	0.0 U
Carbs 0 g	0.0 U
Bolus	3.2 U
Next	

High BG
264 mg/dL

Check infusion set. Check ketones. Consider insulin injection. Monitor BG. ▼

High BG
264 mg/dL
injection. Monitor BG. ▲

OK
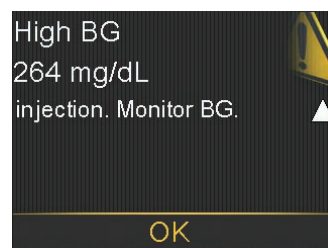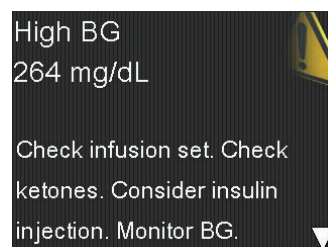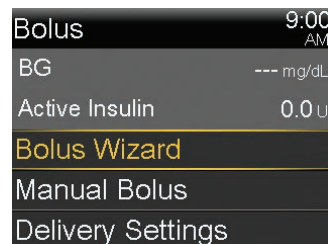
10) Select **Deliver Bolus**.

> ⚠️ **WARNING:** Do not use the Bolus Wizard feature to calculate a bolus for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in the active insulin amount. Therefore, the Bolus Wizard feature could prompt you to deliver more insulin than needed. Too much insulin can cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you can rely on the active insulin calculation made by the Bolus Wizard feature.

Status

There are times when you need information about your pump status. For example, the status icon on your Home screen shows you if the insulin in your reservoir is getting low, but you may need to know exactly how many units are left. This information can be found in the Status screens.

1) From the Home screen, press ⊙.

2) Press ⌄ to highlight **Status**.

3) Press ⊙ to select **Status**.

4) Press ⌄ to highlight the status item you wish to view and press ⊙.
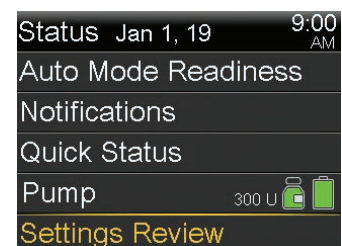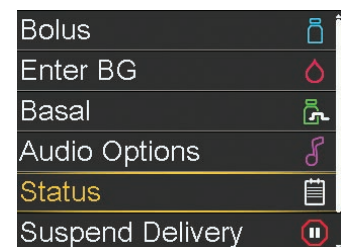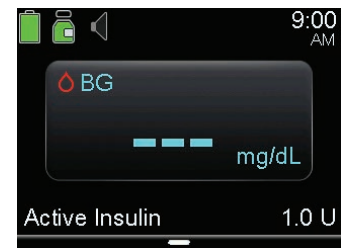
Here you can see the status information that can be found when you select each menu item:

Auto Mode Readiness	Displays messages and information letting you know whether or not you are ready to enter into Auto Mode.
Notifications	Shows the names and times of alarms, alerts, messages, and reminders that you have received over the past 24 hours. To see more alerts and alarms, go to History in Utilities.
Quick Status	Provides a current summary of pump information including the last bolus you delivered, the last BG entered, and your current basal rate.
Pump	Provides detailed information about your pump, including the date you last changed the reservoir, and the number of units left in it.
Sensor	Provides detailed information about your sensor, including when the next calibration is due, the sensor life, and the transmitter battery status. **NOTE:** This information is only available after the sensor feature has been turned on.
Settings Review	Displays the current settings you have programmed into your pump.

NOTE: You can go back to the previous screen by pressing ⬅.

Checking last bolus

There may be times when you need to see the time or amount of the last bolus that was given. For example, you may not remember if you took a bolus at lunch and want to check to make sure. You can see the last bolus delivered in the **Quick Status** screen.

✓ **Let's practice: checking last bolus**

1) Press ⊙.

2) Press ⌄ to **Status** and press ⊙.

3) Press ⌄ to **Quick Status** and press ⊙.

The (N) behind the Last bolus amount means the bolus was delivered as a Normal bolus. There are additional ways to give a bolus which you will learn about later in your training.

Quick Status	9:00 AM
Last bolus	2.800 U (N)
	9:02 AM
	Jan 1
Last BG	265 mg/dL
	9:03 AM
	Jan 1

Checking bolus history

You may also want to review the last several boluses that were delivered. For example, a parent might want to view the boluses their child gave throughout the day. You can see the last several boluses delivered in Daily History.

✓ **Let's practice: checking bolus history**

You can see the last several boluses you delivered in **Daily History**.

1) Press ⊙.

2) Press ⌄ to **Options** and press ⊙.

3) Press ⌄ to **History** and press ⊙.

4) Press ⌄ to **Daily History** and press ⊙.

5) Press ⊙ on the day you would like to review.

Daily History	9:00 AM
Bolus (N) 0.050 U	3:32 PM
Bolus (N) 0.100 U	2:07 PM
Bolus (N) 0.050 U	11:55 AM
◀ Fri, Mar 30	▶

NOTE: You can press the ‹ and › arrows to move from day to day. You can also see further details by pressing ⊙ on any item listed.

Section 10: Using the Accu-Chek Guide Link meter

The MiniMed 770G insulin pump can only pair with an Accu-Chek® Guide Link meter to receive remote BG readings. You can set up your insulin pump to automatically receive BG readings, which can be used with the Bolus Wizard feature.

NOTE: The Accu-Chek Guide Link meter may not be available in all countries.

Review the parts of your meter here:

display

back button

power/ set/ OK button

up arrow and
down arrow buttons

test strip slot with light

Accu-Chek Guide Link Meter

You can pair your pump with your meter at your in-person training. Steps on how to pair your pump with your meter are in *Pairing the Pump and Meter Quick Reference Guide, on page 82*. For more information on using your meter, see the User's Manual found in the meter box.

Section 11: Using the MiniMed Mobile app

Search the app store on your mobile device for the MiniMed Mobile app. Download the app and tap [icon] on your mobile device to open it.

MiniMed Mobile app setup

If you need help with the app setup, see the *MiniMed MOBILE APP USER GUIDE* that was sent with your pump.

CareLink Personal software

If you do not already have a CareLink Personal account, you will be asked to set one up during the MiniMed Mobile app setup. CareLink Personal software is a secure, web-based program that organizes your data into easy-to-read reports. The reports help you and your healthcare professional identify glucose patterns and adjust pump settings as needed.

To let a care partner access your data, go to the app Menu, Sync to CareLink, and Manage Care Partners to give them access.

If you are not able to use the MiniMed Mobile app, you can upload your pump data to CareLink software by using the Blue Adapter. Contact 24-Hour Technical Support to order the Blue Adapter. If you do not already have a CareLink account, follow these steps to set one up:

1) Go to **https://carelink.minimed.com.**

2) Click **Change country/language** to select your country and language.

3) Select the **Sign Up Now** button.

4) Choose your country and language.

5) Read and **Accept** the Terms of Use and Privacy Statement.

6) Create a Username and Password and enter all required information.

7) Select **Submit**.

USING CARELINK SOFTWARE...

Julia uploads her pump information to CareLink Personal software before each visit with her doctor. She has given him access to her reports so he can review them, saving a great deal of time during her office visit. Her doctor has the information he needs to make adjustments to her pump settings.

You will learn more about using CareLink software at your in-person training.

Section 12: Frequently asked questions

As with learning anything new, you typically have questions. Here is a list of commonly asked questions. You may wish to make a note of any additional questions you may have to ask your Certified Product Trainer.

Where should I wear my pump?

Where and how to wear the pump are commonly asked questions among new pump users. Most individuals find that wearing an insulin pump presents no problem and that it can be worn in a variety of ways. It typically takes only a day or two to find the ways that work best for you. Below are just a few ideas to help get you started:

- Use the clip that comes with your pump and clip it to a waist band or belt.
- Place the pump (with or without the clip) into the pocket of your pants.
- Keep it in your shirt pocket.
- Slip it into your bra with the screen facing away from your skin.
- Use the longer tubing lengths and place the pump in your sock.

Where can I put the pump when I sleep?

- Clip it to the waist of your pajama pants.
- Clip it onto your pajama top or in a pocket.
- Place it next to you in the bed, under your pillow, or on the bedside table.

Medtronic Diabetes offers accessories that can add to the convenience of wearing, protecting, and concealing your pump. Refer to the accessories catalog or to the accessories information found on our website at www.medtronicdiabetes.com.

What about intimacy?

What to do with the pump during intimate moments is another question that is frequently asked. An open discussion with your partner usually resolves any concerns you may have. Some individuals simply choose to leave the pump in place. Others choose to use the longer tubing which allows them to place the pump well out of reach. Another idea is to temporarily disconnect from the pump and tubing. Just remember that disconnecting from the pump for long periods of time can result in high glucose levels that could lead to DKA. So, always be sure you reconnect the pump afterwards.

Talk to your healthcare professional about a plan including BG checks and possible correction boluses when disconnecting and reconnecting to your pump.

Should the pump be removed for X-rays, CT scans, and MRIs?

WARNING: Do not expose your pump to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). The strong magnetic fields can cause the devices to malfunction and result in serious injury. If your pump is exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance. Magnetic fields, and direct contact with magnets, may affect the accurate functioning of your system, which may lead to health risks such as hypoglycemia or hyperglycemia.

Cannula infusion sets such as the Quick-set, Silhouette, and Mio can be left in place during the procedure. However, infusion sets that use a needle instead of a cannula to infuse insulin such as the Sure-T, must be removed prior to the procedure.

Do not expose your sensor or transmitter to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields. Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury, or be unsafe. If your sensor or transmitter are inadvertently exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.

What do I need to know about traveling with my insulin pump?

Going through Airport Security

You can wear your insulin pump while going through an airport metal detector. If you are asked to go through a full body scanner, you must remove your insulin pump and CGM (sensor and transmitter). **The full body scanner is a form of x-ray. To avoid removing your devices, you must request an alternative screening process**.

⚠ **WARNING:** Do not send your devices through the x-ray machine as the radiation can make your pump nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over delivery and hypoglycemia.

Print and complete the information on your Medical emergency card to carry with you.

Notify security screeners that you have diabetes, that you are wearing an insulin pump and are carrying supplies with you. If there is any question, ask that they visually inspect the pump rather than removing it from your body. Remember, you may ask for a private screening if removal or lifting of clothing is required to display your pump.

If you encounter difficulty, ask to speak with the TSA ground security commissioner or their international equivalent. The American Diabetes Association (ADA) asks that you also contact them at 1.703.549.1500 ext. 1768 should you encounter any problems.

General Travel Tips

- Pack extra supplies including reservoirs, infusion sets, batteries and ketone strips. Keep your supplies, insulin, and a prescription with you in case your luggage is lost. This will also prevent your insulin from being exposed to hot or cold temperatures. The TSA requires that lithium batteries be kept in their original packaging and with you in your carry-on baggage.

⚠ **WARNING:** Never store insulin in checked luggage as it may be exposed to extreme temperatures. Extreme heat or cold can cause insulin to lose its effectiveness which could result in hyperglycemia.

- Pack glucose tablets or carbohydrate for treatment of low glucose. In case flights are delayed or canceled, pack extra food that is easy to carry, such as nutrition bars.

- If you travel outside the continental United States, you may want to take advantage of Medtronic's travel loaner plan. This program allows you to take a "back-up" insulin pump with you when you travel.

Always Be Prepared

The MiniMed 770G insulin pump and system devices are suitable for use in aircraft. When flying in an airplane, it is important that you stay connected to your pump and check your blood glucose more frequently. The routine hassle of travel, including stress, changes in time zones, schedules and activity levels, meal times and types of food, can all affect your diabetes control. Be extra attentive to your BG readings, and be prepared to respond if needed.

When traveling, make sure that you have backup syringes, vials of insulin or insulin pens (rapid-acting and long-acting insulin), and instructions from your healthcare provider should you need to return to insulin injections if your pump stops working.

Because travel rules are subject to change, it is advisable to check with the Transportation Safety Administration (TSA) before traveling. They can also provide current information about traveling with your other diabetes supplies (lancets, syringes etc.) You can find TSA information at https://www.tsa.gov/blog/2014/04/01/tsa-travel-tips-travelers-diabetes-or-other-medical-conditions or by calling 1-866-289-9673. International passengers should consult their individual air carriers for international regulations. For more information on traveling with a pump, go to: https://www.medtronicdiabetes.com/customer-support/traveling-with-an-insulin-pump-or-device.

When should I call the 24-Hour Technical Support?

Medtronic Diabetes provides 24-Hour Technical Support that is staffed with highly trained and skilled service technicians. These technicians are available to assist you with any technical issues or questions that you may have regarding the operation of your pump.

- You are concerned that the pump is not functioning properly.

- You are reading about a pump function in the User Guide that you do not understand and need assistance.

- Your pump has alarmed and you have followed the instructions to clear the alarm and it alarms again.

The number for 24-Hour Technical Support is located on the bottom of your pump.

When should I call my healthcare professional?

Consult your healthcare professional about when, how often, and under what circumstances you should contact them. Typically, they will review your glucose information more frequently when you first start on pump therapy. This allows them to adjust and fine-tune your pump settings. Once adjusted, most healthcare professionals ask that you maintain a routine follow-up schedule. Examples of other situations that you should notify your healthcare professional about are:

Hypoglycemia (BG less than 70 mg/dL)

- Any severe hypoglycemic event that requires another person's assistance to treat the low BG; or any event that results in loss of consciousness

- Frequent hypoglycemia

- Hypoglycemia that occurs around the same time each day or that routinely occurs after certain activities (such as vacuuming or washing the car)

- Hypoglycemia that occurs after or during exercise

Hyperglycemia (BG above your maximum target range or above 250 mg/dL)

- Hyperglycemia that is frequent or persistent

- Hyperglycemia that is accompanied by nausea or vomiting

- Hyperglycemia and positive ketones

- Hyperglycemia that occurs around the same time each day or routinely after a certain event (such as eating)

As always, when low or high blood sugars occur, follow the guidelines provided in the Safety Rules Quick Reference Guide in the Training Handouts section of this guide.

Section 13: Additional features for experienced users

You have learned the features that are necessary to use your pump. There are additional features that you might find helpful. This section discusses some additional menu options and features that are available on your insulin pump. Refer to the *MiniMed 770G SYSTEM USER GUIDE* for information about additional features and complete instructions for use.

Dual Wave and Square Wave bolus

The practice boluses that were given earlier were delivered as **Normal** boluses; that is, as a single immediate dose of insulin. This is the type of bolus you would typically use to cover normal food intake and to correct a high BG.

This pump also lets you deliver bolus insulin as a Dual Wave or Square Wave bolus. These can help better match the effects food has on your glucose levels.

Normal bolus

7.5 units

8.0u

6.0u

4.0u

2.0u

8 AM   9 AM   10 AM
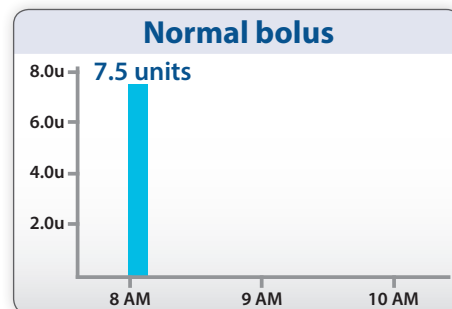
Turning Dual and Square Wave bolus on

1) Press ⊙.

2) Select **Options**.

3) Select **Delivery Settings**.

4) Select **Dual/Square Wave**.

5) Select **Dual Wave** to turn **On** if desired.

6) Select **Square Wave** to turn **On** if desired.

7) Select **Save**.

Dual/Square
Dual Wave   On
Square Wave   On

Save

Square Wave bolus

A Square Wave bolus delivers a bolus for an extended period of time. This can be helpful:

- For delayed food digestion due to gastroparesis
- For meals very low in carbohydrates but high in fat
- When snacking on small amounts of carbs over a period of time, for example, at a reception

Square Wave bolus

8.0u

6.0u

4.0u

2.0u

7.5 units in the next 2 hours

8 AM   9 AM   10 AM
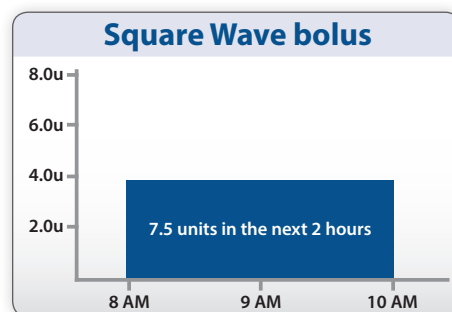
When setting a Square Wave bolus, you will need to determine the duration of the bolus delivery. The duration can be set from 30 minutes to 8 hours in 15-minute increments. This will vary depending on you individually, as well as the situation for which the Square Wave bolus is being used. Frequent glucose testing should be done until you and your healthcare professional have determined the best use for you.

Correction boluses calculated by the Bolus Wizard feature cannot be delivered as a Square Wave bolus since that insulin is needed right away.

USING SQUARE WAVE BOLUS...

Karen eats at her desk at work and it takes her a while to finish because she often gets distracted. She delivers her lunch bolus as a Square Wave over 45 minutes to help make sure her insulin does not start to work before her carbs are digested.

Giving a Square Wave bolus

This example shows a Square Wave bolus using the Bolus Wizard feature with a BG value of 103 mg/dL and 41 grams of carbs.

1) Press ◎.

2) Select **Bolus**.

3) Select **Bolus Wizard**.

4) Enter BG and Carbs.

5) Select **Next**.

6) Press ⌃ and ⌄ to **Square** and press ◎.

7) Select **Duration**.

8) Press ⌃ to desired time and press ◎.

9) Select **Deliver Bolus**.

Bolus Wizard	9:00 AM
BG **103** mg/dL	0.0 u
Active Ins. adjust.	0.0 u
Carbs **41** g	2.7 u
Bolus	2.7 u
Next	

Bolus Wizard	9:00 AM
Bolus	2.7 u
Dual	Square
Deliver Bolus	

Bolus Wizard	9:00 AM
Bolus	2.7 u
Duration	2:00 hr
Deliver Bolus	
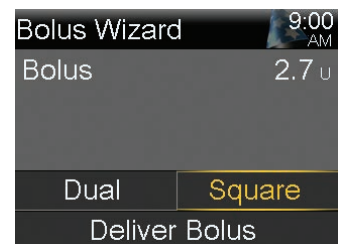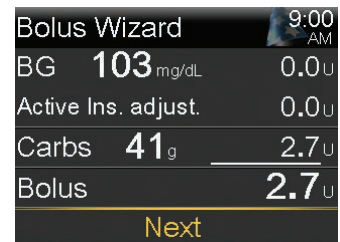
NOTE: A **Square Bolus** banner appears on the Home screen until bolus delivery is complete.
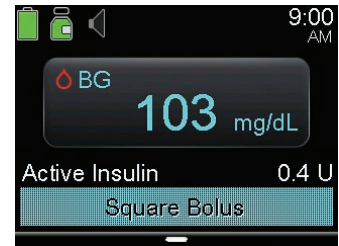
From the menu, select **Bolus** and choose from the following options:

- Review bolus status, then press ⟲ to return to the menu.
- Select **Stop Bolus** to stop delivery.
- Select **Bolus Menu** to deliver a Normal bolus while the Square Bolus is delivering.
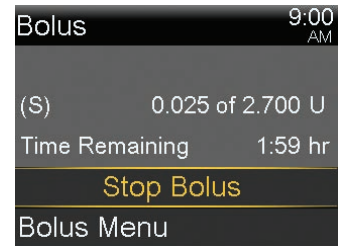
Dual Wave bolus

A Dual Wave bolus combines the Normal and the Square Wave bolus. It delivers part of the bolus as a Normal Bolus (now) and part as a Square Wave bolus (over time).

A Dual Wave bolus can be helpful for meals high in both carbs and fat. Fat delays the digestion of carbs, meaning glucose does not enter the bloodstream right away. Giving some insulin as a Normal bolus covers any immediate glucose rise. Giving the rest over time as a Square helps to match the delayed glucose rise.

When setting a Dual Wave bolus, you will need to determine:

- The percentage or amount of insulin you want delivered immediately and how much over time
- The duration of time over which you want the Square portion delivered
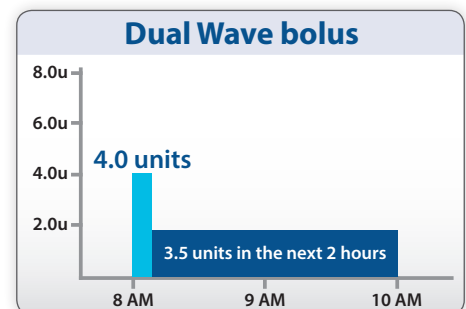
This will vary depending on you individually, as well as the types of food that are in the meal for which the Dual Wave bolus is being used. Frequent glucose testing should be done until you and your healthcare professional have determined the best use for you.

Giving a Dual Wave bolus

This example shows a Dual Wave bolus using the Bolus Wizard feature with a BG value of 131 mg/dL and 63 grams of carbs.

53

1) Press ◎.

2) Select **Bolus**.

3) Select **Bolus Wizard**.

4) Enter BG and Carbs.
   Notice in this example the total bolus for BG is 0.6 U and 4.2 U for carbs.

5) Select **Next**.

6) Press ⌄ to **Dual** and press ◎.
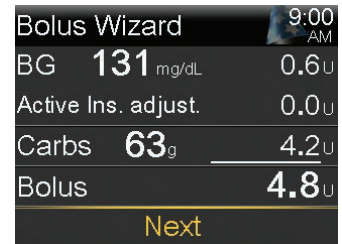
> 📝 **NOTE: Square** is not an option since a correction bolus was estimated so some insulin is needed now.
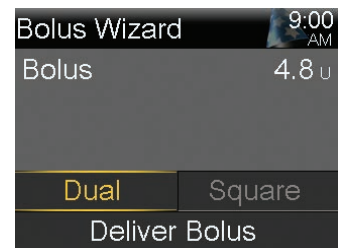
7) Select the Now/Square field and press ⌃ or ⌄ to change the amount of the bolus that is delivered **Now** and the amount delivered as **Square** if needed.

8) Select **Duration**.

9) Press ⌃ to desired time and press ◎.

10) Select **Deliver Bolus**.
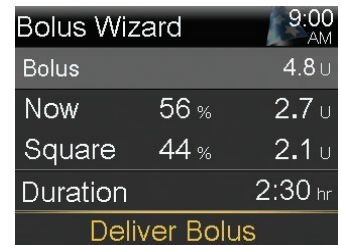
> 📝 **NOTE:** Bolus for carbs is divided 50% Now and 50% Square. Correction bolus amount is added to the Now portion.

> 📝 **NOTE:** A **Bolus (D)** banner that displays the bolus delivery progress appears on the Home screen while the Now portion is delivering.

NOTE: A **Dual Bolus** banner appears on the Home screen until the Square delivery is complete.

9:00 AM

◇ BG

131 mg/dL

Active Insulin   0.4 U

Dual Bolus

From the menu select **Bolus** and choose from the following options:

Bolus   9:00 AM

(DS)   0.050 of 2.100 U
Time Remaining   2:27 hr
Stop Bolus
Bolus Menu

- Review bolus status, then press ⬅ to return to the menu.
- Select **Stop Bolus** to stop delivery.
- Select **Bolus Menu** to deliver a Normal bolus while the Square Wave bolus is delivering.
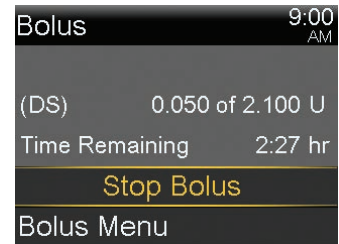
USING DUAL WAVE BOLUS...

When William ate pizza, his glucose level would be good for a while, but then 3 or 4 hours later it would be high. Now he uses a Dual Wave bolus to help reduce these post-meal highs.

Temp Basal

This feature lets you immediately increase or decrease your basal insulin for the period of time (duration) that you set. It is often used for exercise and sick days.

A Temp Basal can be set in either:

- **Percent:** delivers a percent of the current basal rate.
- **Rate:** delivers the amount that you enter.

A Temp Basal can be set to deliver more or less than your current basal rate. It can be set from 30 minutes to 24 hours, in 15-minute increments.

Let's practice: setting a Temp Basal

This example shows setting a Temp Basal to deliver 60% of the current basal rate for the next two hours.

1) Press ⊙.

2) Select **Basal**.

3) Select **Temp Basal**.

4) Press ⌃ to set duration and press ⊙.

5) Select **Next**.

6) Select **Percent**.

7) Press ⌃ or ⌄ to enter the percent of the current basal rate desired and then press ⊙.
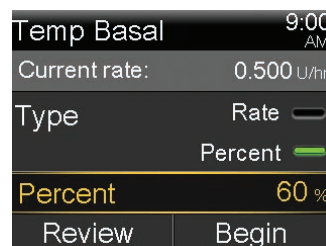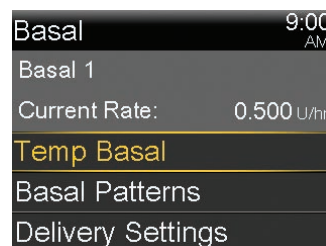
NOTE: If you choose to use Rate, press ⌃ to Type and press ⊙. You can then enter the U/hr you want delivered.

8) Select **Begin**.

The Home screen displays a **Temp Basal** banner to indicate that you have a Temp Basal active.

From the menu select **Cancel Temp Basal** to review the details of the active Temp Basal.

When the Temp Basal delivery is complete, the basal delivery automatically returns to your regularly programmed basal rate.

USING A TEMP BASAL...

Patricia loves to work in her garden. She often finds, however, that her glucose levels run lower when she does. Now she uses a temp basal rate to decrease the amount of insulin she gets while she is working. This helps keep her glucose levels from dropping too low.

✔ Let's practice: cancelling a Temp Basal

If you need to return to your regularly programmed basal rate before your Temp Basal is completed, you can cancel it.

1)   Press ⊚.

2)   Select **Cancel Temp Basal**.
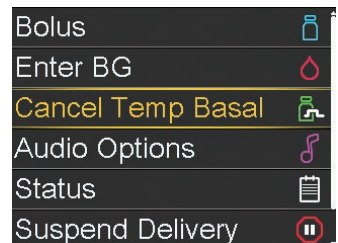
57

3) You can see the details about the Temp Basal. Select **Cancel Temp Basal**.

   If you decide not to cancel, just press ⬅.

   You can see that the Home screen no longer displays the Temp Basal banner.

Temp Basal	9:05 AM
60%	0.500 U/hr
Duration 2:00 hr	
1:55 hr remaining	
Cancel Temp Basal	
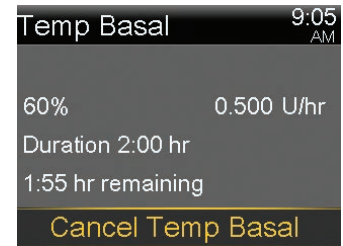
Adding new or copying Basal Patterns

You may be using additional Basal Patterns. These are Basal Patterns set to account for days that require different basal amounts. For example, a pattern might be used for weekends because a person is less active than they are during the week. When setting an additional pattern, you can simply enter the basal rates into a new pattern, or you can copy and then make edits to a Basal Pattern that is already set. To enter another Basal Pattern, follow these steps:

1) Press ⓞ.

2) Select **Basal**.

3) Press ⌄ and select **Delivery Settings**.

4) Press ⌄ and select **Basal Pattern Setup**.

Choose one of these two options:

> **How to add a new Basal Pattern**

5) Press ⌄ and select **Add New**.

6) Select a name.

7) Enter times and basal rates for the additional pattern.

8) Select **Done**.

9) Press ⓞ to save.

> **How to Copy and Edit an existing Basal Pattern**

5) Select **Basal 1** or another currently programmed Basal Pattern.

6) Select **Options**.

7) Press ⌄ to **Copy**. This copies the Basal Pattern that you have programmed and allows you to make the necessary changes.

8) Select name for this Basal Pattern.

9) Press ⌃ to **Edit**.

10) Continue by making the necessary changes to the programmed basal rates. To change active Basal Pattern, see *Let's practice: changing which Basal Pattern is active, on page 60*.

11) Select **Done**.

12) Press ⓞ to save.

Basal Patterns review

You will use the Basal Patterns option to do two things:

- Review the Basal Patterns that are currently set up.
- Choose the Basal Pattern that you wish to be active.

Let's practice: reviewing Basal Patterns

1) Press ⊙.

2) Select **Basal**.

Bolus	🗴
Enter BG	⬡
Basal	⬚
Audio Options	♪
Status	目
Suspend Delivery	⏸

3) Select **Basal Patterns**.

Basal	9:00 AM
Basal 1	
Current Rate:	0.900 U/hr
Temp Basal	
Preset Temp	
Basal Patterns	

4) Select the Basal Pattern you wish to review.

| Basal Patterns | 9:00 AM |
| Basal 1 | 19.25 U ✓ |

5) Review basal rates.

> **NOTE:** If you see a scroll bar on the right, press ⌄ to see all basal rates in the Basal Pattern.

Basal 1		9:00 AM
24 hr Total: 19.25 U (Active)		
Start	End	Rate (U/hr)
12:00 A	4:00 A	0.650
4:00 A	6:00 A	0.900
	OK	
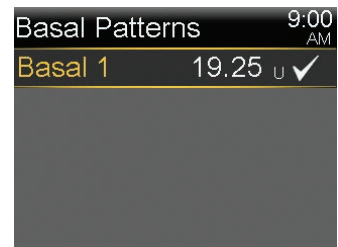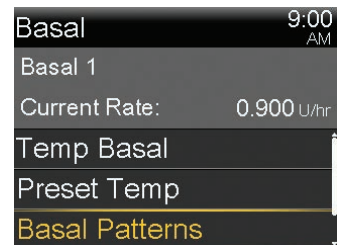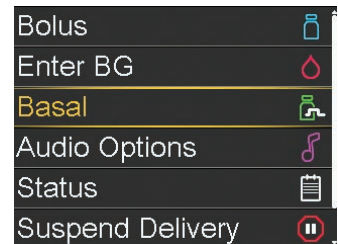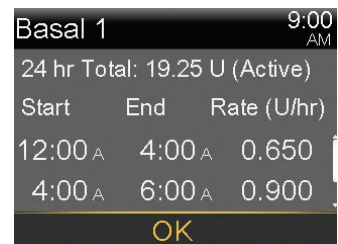
6) Select **OK**.

✓ Let's practice: changing which Basal Pattern is active

1) Press ⃝.

2) Select **Basal**.

3) Press ⌄ to **Basal Patterns** and press ⃝.

4) Select the Basal Pattern you want to make active.

> **NOTE:** The checkmark indicates which Basal Pattern is active.

5) Select **Begin**.

6) Repeat step 1 through step 3 to see that the active Basal Pattern has changed.

Basal Patterns	9:00 AM
Basal 1	19.25 U ✓
Day Off	17.4 U

Day Off	9:00 AM
24 hr Total: 17.4 U	

Start	End	Rate (U/hr)
12:00 A	12:00 A	0.725

Begin

Basal Patterns	9:00 AM
Basal 1	19.25 U
Day Off	17.4 U ✓

Max Basal/Max Bolus

Max Basal

Max Basal is the maximum amount of basal insulin that can be delivered in one hour. Before you practice setting your Basal Patterns, you may need to change your Max Basal limit. Check your Max Basal setting on the pump you are currently using for your therapy. If your Max Basal is an amount other than 2.0 U/hr, follow these steps to change:

1) Press ⊙.

2) Select **Options** or **Basal**.

3) Select **Delivery Settings**.

4) Select **Max Basal/Bolus**.

5) Select **Max Basal**.

6) A screen appears to ensure you are entering a value that has been determined by you and your healthcare professional. If this change has been recommended by your healthcare professional, press ⟩ and select **Continue**.

7) Select **Max Basal**.

8) Press ⌃ or ⌄ to enter number of U/hr and press ⊙.

9) Select **Save**.
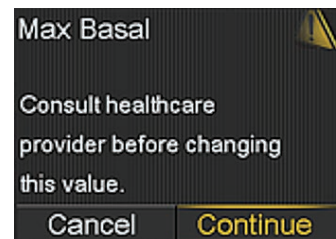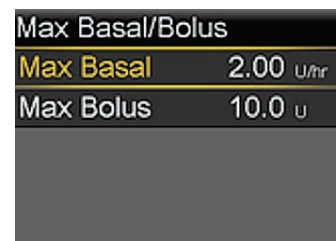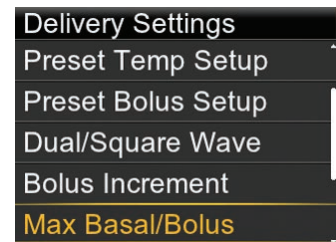
Max Bolus

Before you continue, you may need to change your **Max Bolus** amount. Max Bolus is the maximum amount that can be given by any one bolus. Check your current pump settings. If your Max Bolus is an amount other than 10.0 U, follow these steps to change:

1) Press ⊙.

2) Select **Options** or **Bolus**.

3) Select **Delivery Settings**.

4) Select **Max Basal/Bolus**.

5) Select **Max Bolus**.

6) A screen appears to ensure you are entering a value that has been determined by you and your healthcare professional. If this change has been recommended by your healthcare professional, press ⟩ and select **Continue**.

7) Select **Max Bolus**.

8) Press ⌃ or ⌄ to enter number of units and press ⊙.

9) Select **Save**.
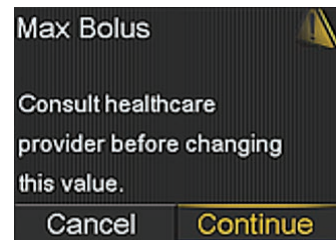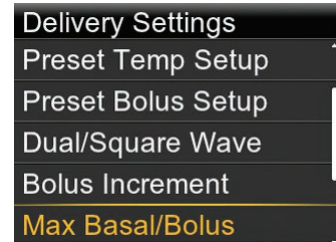
Auto Suspend

Auto Suspend is a safety feature that sounds an alarm and stops all insulin delivery if you do not press any buttons for the number of hours that you set. It is meant for situations where you are not responding to hypoglycemia.

Auto Suspend is most useful if you live or travel alone. It is important to use if you have difficulty responding appropriately to lows, have hypoglycemia unawareness, if you are susceptible to lows due to alcohol intake, or have a history or fear of lows at night.

Auto Suspend should be set based on your schedule. Let's say you typically go to bed about 11:00P. At about 10:00P each evening you do a BG check and check your pump (buttons would be pressed). You usually get up at 7:00A and eat breakfast around 8:00A. What happens if:

- Auto Suspend is set for 8 hours: Alarm would go off at 6:00A if no buttons had been pressed. Since you do not get up until 7:00A, this could be a nuisance.

- Auto Suspend is set for 12 hours: Alarm would go off at 10:00A if no buttons had been pressed. You should have been up by now and given a bolus. If in a dangerous situation, receiving this alarm and stopping insulin could be very helpful.

- Auto Suspend is set for 18 hours: Alarm would go off at 4:00P if no buttons have been pressed. You should have been up and given bolus several hours ago. If in a dangerous situation, you may want to be alarmed and have delivery stopped sooner.

Choose the number of hours that seems right for you.

Setting Auto Suspend

1) Press ⊙.

2) Select **Options**.

3) Select **Delivery Settings**.

4) Select **Auto Suspend**.

5) Select **Alarm** to turn **On**.

6) Press ⌄ to **Time** and press ⊙.

7) Press ⌃ or ⌄ to change number of hours.
   This example shows Auto Suspend set at 12 hours.

8) Press ⊙.

9) Select **Save**.

Auto Suspend

Suspends insulin delivery if no button press within specified time.

Alarm	On
Time	12:00 hr

Save

USING AUTO SUSPEND...

Thomas is a runner and finds the days he runs, he is more prone to hypoglycemia at night. He often sets a Temp Basal, but using Auto Suspend, he sleeps even more confidently because he knows his pump will stop delivering insulin and an alarm will occur if he is not waking up when he should.

Training handouts

This section contains handouts that you can use during or after your training.

- **Safety Rules Quick Reference Guide**
- **Alerts**
- **Alarms**
- **Basal Quick Reference Guide**
- **Bolus Wizard™ Quick Reference Guide**
- **Changing the Quick-set™ Infusion Set Quick Reference Guide**
- **Pairing the Pump and Meter Quick Reference Guide**

Feel free to remove these handouts and keep them in a place where they are easily accessible.

Glucose monitoring

Schedule for adjusting pump settings

When first starting pump therapy or any time pump settings need adjusting:

- Check your blood glucose (BG):
  - When you wake up
  - Before each meal
  - 2 hours after each meal
  - Bedtime
  - Mid-sleep or every 3–4 hours during sleep

- Do not eat between meals.

Checking BGs at these times provides the information needed to adjust and fine-tune pump settings as directed by your healthcare professional.

Schedule for routine monitoring

Once your pump settings are adjusted correctly and your glucose levels are stable, establish a routine that includes always checking your BG:

- When you wake up
- Before each meal
- Bedtime
- Occasionally mid-sleep
- More frequently during travel, times of stress, and illness

Treating low BG levels

How to treat mild and moderate lows

15–15 Rule
If BG drops below 70 mg/dL:

1. Eat 15 grams of fast-acting carbohydrate.

2. Recheck BG in 15 minutes.

3. If BG is still below 70 mg/dL, repeat Steps 1 & 2 every 15 minutes until BG is within range.

Items that contain 15 grams:

- 3 to 4 glucose tablets
- 5 jelly beans
- 4 oz juice or soda (not diet)
- 8 oz milk (low or non-fat)
- 1 Tbsp sugar or honey

If BG is lower than 50 mg/dL, start treatment by eating 20 to 30 grams of carbohydrate or as otherwise directed by your healthcare professional.

How to treat a severe low

Keep a glucagon emergency kit on hand in case you experience a severe low BG. Glucagon can be given by injection to raise glucose levels if you are unable to eat or drink to treat a low, or if you are unconscious.

A family member, co-worker, or friend should be instructed on how to give glucagon.

NOTE: If you are using continuous glucose monitoring (CGM), do not rely on sensor glucose values for making treatment decisions or the Suspend on low feature to prevent or treat a low blood glucose.

Treating high glucose levels

General guidelines: if BG is high but is lower than 250 mg/dL

1. Enter the BG reading into your pump.

2. Allow the Bolus Wizard™ feature to calculate the correction bolus amount.

3. Confirm the bolus amount and select **Deliver Bolus**.

4. Recheck your BG in one hour and again each hour until your BG is back within target range.

Never ignore high BG readings. Always consult the Bolus Wizard™ feature to see if a correction bolus should be taken.

General guidelines: if BG is higher than 250 mg/dL, check for ketones

If ketone test is negative:

1. Enter the BG reading into pump or consult the Bolus Wizard™ feature to see if correction dose is needed. Use the pump to give any recommended correction dose.

2. Recheck BG in 1 hour:
   - If BG is starting to decrease, continue to monitor until normal.
   - If BG is same or higher:
     - Give correction dose using a syringe.
     - Change infusion site, infusion set, reservoir, and insulin.
     - Continue to check BG every hour until BG returns to normal.

If ketone test is positive:

1. Take correction dose using a syringe.

2. Change infusion site, infusion set, reservoir, and insulin.

3. Troubleshoot pump.

4. Check BG every 1 to 2 hours. Give correction boluses as needed.

5. Drink non-carbohydrate fluids.

6. If BG continues to rise or if you have moderate to high ketones, nausea, vomiting, or difficulty breathing, notify physician or go to the nearest emergency room.

Diabetic ketoacidosis (DKA) prevention

Sick day guidelines

Illness or infection usually causes BGs to run higher than normal. Therefore, the risk of developing DKA is increased when you are ill.
Because DKA symptoms are similar to flu and stomach virus symptoms, check your BG and monitor for ketones often during illness.

- Check BG every 2 hours or as directed by your healthcare professional.
- Check urine or blood for ketones as directed by your healthcare professional.
- Immediately check ketones if you have nausea, vomiting, or abdominal pain.

- Notify doctor if ketones are positive, if you are unable to keep food down, or if no improvement within a few hours. Give a correction dose of insulin with a syringe according to your healthcare professional's recommendations and change infusion set and reservoir.

Check for ketones
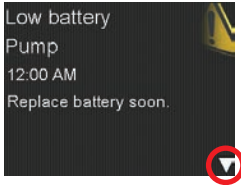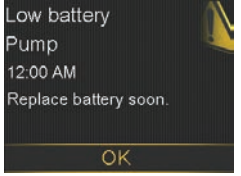
Follow the instructions in your ketone testing kit.

Unexplained highs that do not decrease with a correction bolus may be caused by a dislodged or kinked infusion set or a weak vial of insulin.

Alerts

An alert makes you aware of a situation that may need your attention. When an alert occurs, you should check to see what your pump is telling you.

Alert	When alert occurs	Steps to take
Examples of alerts include **Low reservoir**, **Low battery**	**Notification Light:** The red light on the pump blinks once followed by a pause, blinks again followed by a pause. This sequence continues until the alert is cleared. The flashing pattern is shown here: ● ● ● ● ● **Audio:** Depending on your Audio Options settings, the pump emits a repeated alert tone, a continuous two-pulse vibration, or both. **Display:** The pump shows a notification with a yellow icon and instructions on what to do.	To address and clear the alert: 1) Read the text on the screen to understand the alert and the steps that should be taken. 2) Press ∨. 3) Press ⊙ on the desired option.

The audio or vibration pattern repeats every 5 minutes or every 15 minutes, depending on the alert, until the alert is cleared.

Alarms

When an alarm occurs, something has been detected that is preventing insulin from being delivered. You are not getting insulin. **It is important that you address an alarm right away.**

Alarm	When alarm occurs	Steps to take
Examples of alarms include **Insulin flow blocked** and **Replace battery now**.	**Notification Light:** The red light on the pump blinks twice, followed by a pause, blinks twice again followed by a pause. This sequence continues until the alarm is cleared. The flashing pattern is shown here: ●● ●● ●● ●● ●● **Audio:** Depending on your Audio Options settings, the pump emits a repeated alert tone, a continuous three-pulse vibration, or both. **Display:** The pump shows a notification with a red icon and instructions on what to do.	To address and clear the alarm: 1) Read the text on the screen to understand the alarm and the steps that should be taken. 2) Press ⌄. 3) Press ◎ on the desired option.
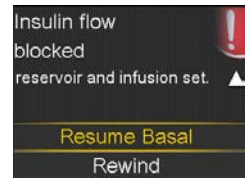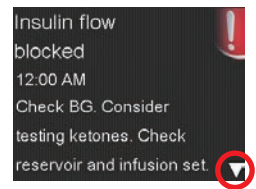
The audio or vibration pattern repeats every minute for 10 minutes if the alarm is not cleared. **After 10 minutes, the alarm begins to siren.**

> **NOTE:** An Insulin flow blocked alarm occurs when insulin cannot be pushed through the tubing or cannula. If this alarm occurs, make sure your reservoir is not empty and check the tubing for kinks, knots or other obvious blockages.
> - If you detect an issue and are able to resolve it, check BG and select **Resume Basal**. If an Insulin flow blocked alarm occurs again, follow the steps on the screen and select **Rewind** to change your reservoir and infusion set.
> - If you are unable to detect an issue, follow the steps on the screen and select **Rewind** to change your reservoir and infusion set.

Change a basal rate

1. From the Home screen, press ⊙.
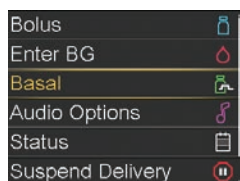
2. Select **Basal**.

   > Bolus
   > Enter BG
   > Basal
   > Audio Options
   > Status
   > Suspend Delivery

3. Select **Delivery Settings**.

   > Basal   9:00 AM
   > Basal 1
   > Current Rate: 0.500 U/hr
   > Temp Basal
   > Basal Patterns
   > Delivery Settings

4. Select **Basal Pattern Setup**.

   > Delivery Settings
   > Bolus Estimate Setup
   > Basal Pattern Setup
   > Preset Temp Setup
   > Preset Bolus Setup
   > Dual/Square Wave
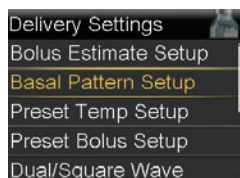
5. Select the Basal Pattern you wish to edit.

6. Select **Options**.

7. Select **Edit**.
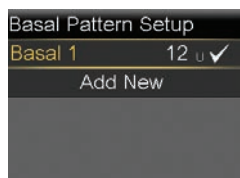
   > Basal Pattern Setup
   > Basal 1   12 U ✔
   > Add New

8. Press ⊙ on the time segment.

9. Press ⊙ on **End** time.

10. Press ⌃ or ⌄ to change **U/hr** and press ⊙.

    > Edit Basal 1
    > Start   End   U/hr
    > 12:00 A   12:00 A   0.500
    > Done

11. Select **Done**.
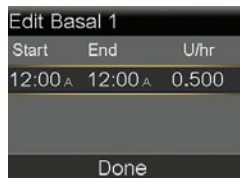
    > Edit Basal 1
    > Start   End   U/hr
    > 12:00 A   12:00 A   0.550
    > Done

12. Review rates and select **Save**.

    > Basal 1
    > 24 hr Total: 13.2 U
    > Start   End   U/hr
    > 12:00 A   12:00 A   0.550
    > Save
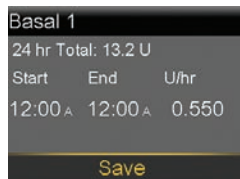
Reviewing Basal Patterns

1. From the Home screen, press ⊙.
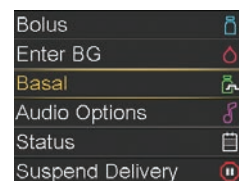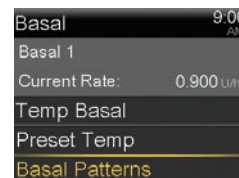
2. Select **Basal**.

   > Bolus
   > Enter BG
   > Basal
   > Audio Options
   > Status
   > Suspend Delivery

3. Select **Basal Patterns**.

   > Basal   9:00 AM
   > Basal 1
   > Current Rate: 0.900 U/hr
   > Temp Basal
   > Preset Temp
   > Basal Patterns

4. Select the Basal Pattern you wish to review.

   > Basal Patterns   9:00 AM
   > Basal 1   19.25 U ✔

5. Review basal rates.

   NOTE: If you see a scroll bar on the right, press ⌄ to see all basal rates in the Basal Pattern.

   > Basal 1   9:00 AM
   > 24 hr Total: 19.25 U (Active)
   > Start   End   Rate (U/hr)
   > 12:00 A   4:00 A   0.650
   > 4:00 A   6:00 A   0.900
   > OK
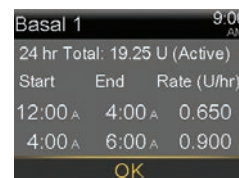
6. Select **OK**.

Add a basal rate to a Basal Pattern

1. From the Home screen, press ⊙.
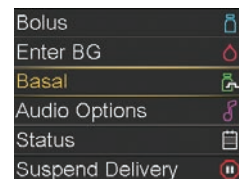
2. Select **Basal**.

   > Bolus
   > Enter BG
   > Basal
   > Audio Options
   > Status
   > Suspend Delivery

3. Select **Delivery Settings**.

   > Basal   9:00 AM
   > Basal 1
   > Current Rate: 0.500 U/hr
   > Temp Basal
   > Basal Patterns
   > Delivery Settings

4. Select **Basal Pattern Setup**.

   > Delivery Settings
   > Bolus Estimate Setup
   > Basal Pattern Setup
   > Preset Temp Setup
   > Preset Bolus Setup
   > Dual/Square Wave
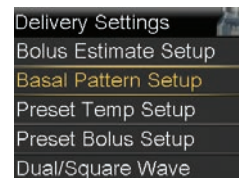
NOTE: The basal rates shown are for illustration purposes only—your basal settings will be different.

5. Select the Basal Pattern you are adding a rate to.

6. Select **Options**.

7. Select **Edit**.

Basal Pattern Setup
Basal 1   12 U ✓
Add New
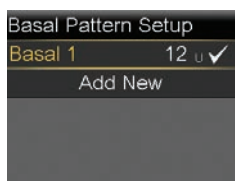
8. Press ◎ on the time segment.
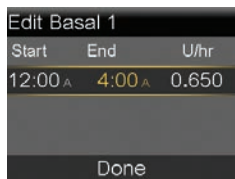
9. Enter the new **End** time (this is the same as the start time of the basal rate you are adding) and press ◎.

Edit Basal 1
Start   End   U/hr
12:00 A 4:00 A   0.650
Done

10. Press ◎ if **U/hr** is not changing (Press ⌃ or ⌄ to change value and press ◎).

Edit Basal 1
Start   End   U/hr
12:00 A 4:00 A   0.650
4:00 A   4:30 A   ---
Done
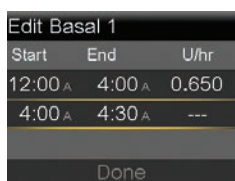
11. Press ◎ on the new time segment.
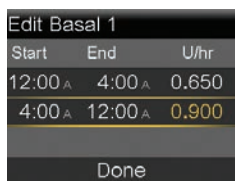
12. Press ⌃ to enter the new **End** time and press ◎.

13. Press ⌃ to enter the new rate and press ◎.

Edit Basal 1
Start   End   U/hr
12:00 A 4:00 A   0.650
4:00 A   12:00 A 0.900
Done

14. Continue adding end times and basal rates if necessary.

15. Select **Done**.

Edit Basal 1
Start   End   U/hr
12:00 A 4:00 A   0.650
4:00 A   12:00 A 0.900
Done

16. Review basal rates.

17. Select **Save**.
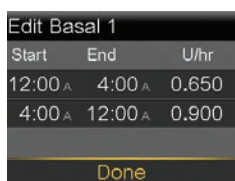
Basal 1
24 hr Total: 20.6 U
Start   End   U/hr
12:00 A 4:00 A   0.650
4:00 A   12:00 A 0.900
Save
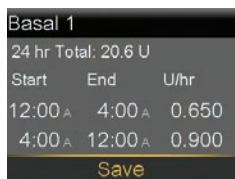
Temporary (Temp) basal rate

This feature lets you immediately increase or decrease your basal insulin for the period of time (duration) that you set. It is often used for exercise and sick days. A Temp Basal can be set in either Percent (delivers a percent of the current basal rate) or by Rate (delivers the amount that you enter).

Setting a Temp Basal
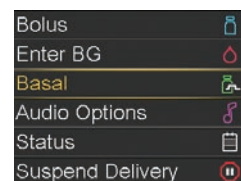
1. From the Home screen, press ◎.

2. Select **Basal**.

Bolus
Enter BG
Basal
Audio Options
Status
Suspend Delivery

3. Select **Temp Basal**.

Basal   9:00 AM
Basal 1
Current Rate: 0.500 U/hr
Temp Basal
Basal Patterns
Delivery Settings

4. Press ⌃ to set duration and press ◎.

5. Select **Next**.

Temp Basal   9:00 AM
Current rate: 0.500 U/hr

Duration   2:00 hr
Next
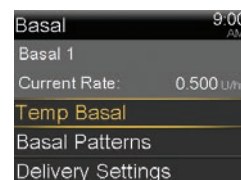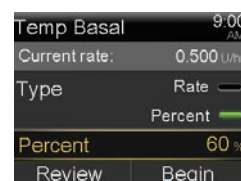
6. Select **Percent**.

7. Press ⌃ or ⌄ to enter the percent of current basal rate desired and press ◎.
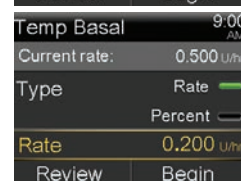
Temp Basal   9:00 AM
Current rate: 0.500 U/hr
Type   Rate ▬
                   Percent ▬
Percent   60 %
Review   Begin

> **NOTE:** If you choose to use Rate, press ⌃ to Type and press ◎.

Temp Basal   9:00 AM
Current rate: 0.500 U/hr
Type   Rate ▬
                   Percent ▬
Rate   0.200 U/hr
Review   Begin

8. Select **Begin**.

The Home screen displays a **Temp Basal** banner to indicate that you have a Temp Basal active.

From the menu select **Cancel Temp Basal** to review the details of the active Temp Basal.

9:00 AM
BG
--- mg/dL
Active Insulin   0.0 U
Temp Basal   1:59 hr

Bolus
Enter BG
Cancel Temp Basal
Audio Options
Status
Suspend Delivery
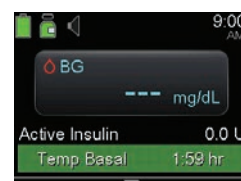
When the Temp Basal is complete, the basal delivery automatically returns to your regularly programmed basal rate.

> **NOTE:** The basal rates shown are for illustration purposes only—your basal settings will be different.

Cancel Temp Basal rate

If you need to return to your regularly programmed basal rate before your Temp Basal is completed, you can cancel it.

1. From the Home screen, press ◎.

2. Select **Cancel Temp Basal**.
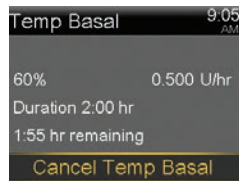
   Bolus
   Enter BG
   Cancel Temp Basal
   Audio Options
   Status
   Suspend Delivery

3. You can see the details about the Temp Basal.

   Select **Cancel Temp Basal**.

   If you decide not to cancel, just press ↩.

   You can see that the Home screen no longer displays the Temp Basal Banner.

   Temp Basal   9:05 AM
   60%   0.500 U/hr
   Duration 2:00 hr
   1:55 hr remaining
   Cancel Temp Basal

Multiple Basal Patterns

Setting multiple Basal Patterns helps you more easily accommodate routine schedule changes that cause different basal needs (for example, weekday vs. weekend; day vs. night shift).

Set an additional Basal Pattern

1. From the Home screen, press ◎.

2. Select **Basal**.

   Bolus
   Enter BG
   Basal
   Audio Options
   Status
   Suspend Delivery

3. Select **Delivery Settings**.

4. Select **Basal Pattern Setup**.

   Basal   9:00 AM
   Basal 1
   Current Rate: 0.500 U/hr
   Temp Basal
   Basal Patterns
   Delivery Settings
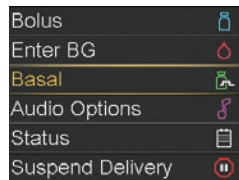
5. Select **Add New**.

   Basal Pattern Setup
   Basal 1   12 U ✔
   Add New

6. Select the name you would like to use.

7. Enter the basal rates needed for this pattern.

   Select Name
   Basal 2
   Workday
   Day Off
   Sick Day

8. Select **Save**.
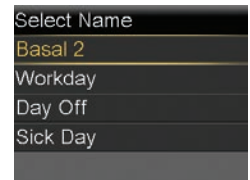
   NOTE: The Basal pattern that your pump is currently using has a checkmark next to it.

   Day Off
   24 hr Total: 17.7 U
   Start   End   U/hr
   12:00 A   6:00 A   0.650
    6:00 A   6:00 P   0.750
   Save

   Basal Pattern Setup
   Basal 1   12 U ✔
   Day Off   17.7 U
   Add New
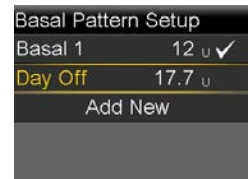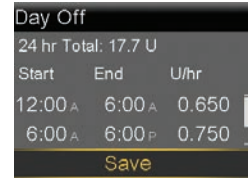
How to change which Basal Pattern is Active

1. From Home screen, press ◎.

2. Select **Basal**.

   Bolus
   Enter BG
   Basal
   Audio Options
   Status
   Suspend Delivery

3. Select **Basal Patterns**.

   Basal   9:00 AM
   Basal 1
   Current Rate: 0.900 U/hr
   Temp Basal
   Preset Temp
   Basal Patterns
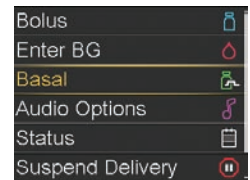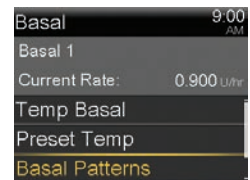
4. Select the Basal Pattern you wish to be active.

   NOTE: The checkmark indicates which Basal Pattern is active.
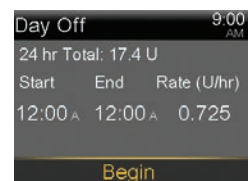
   Basal Patterns   9:00 AM
   Basal 1   20.4 U ✔
   Day Off   17.4 U

5. Select **Begin**.

   Day Off   9:00 AM
   24 hr Total: 17.4 U
   Start   End   Rate (U/hr)
   12:00 A   12:00 A   0.725
   Begin

NOTE: The basal rates shown are for illustration purposes only—your basal settings will be different.

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Bolus Wizard™ Quick Reference Guide

Entering your Bolus Wizard™ settings

Using either your most recent CareLink™ Personal settings report or your completed Setting Guide with your settings, follow these steps to enter your Bolus Wizard™ settings into your new pump.

1. From the Home screen, press Ⓞ.

2. Select **Options**.

3. Select **Delivery Settings**.

4. Select **Bolus Estimate Setup**.

5. Select **Bolus Wizard** to turn on.
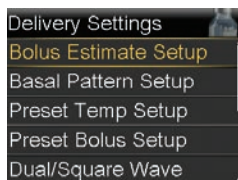
6. Press ⌄ to continue reading text.
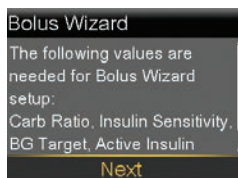
7. Select **Next**.

8. Review the description of Carb Ratio and select **Next**.
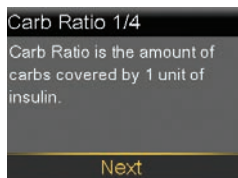
9. Press Ⓞ on the time segment.

10. If you have only one Carb Ratio, press Ⓞ.

    If you have more than one Carb Ratio, press ⌃ or ⌄ to enter the time that your Carb Ratio ends and the second begins and press Ⓞ.

11. Press ⌃ or ⌄ to enter the **g/U** of your Carb Ratio and press Ⓞ.

    If you have more than one Carb Ratio, continue by entering your time segments and Carb Ratios until all are entered.

12. Select **Next**.

13. Review the description of Insulin Sensitivity Factor and select **Next**.
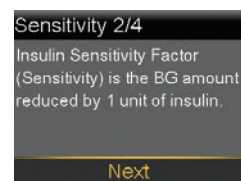
14. Press Ⓞ on the time segment.
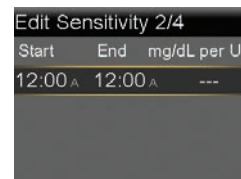
15. If you have only one sensitivity factor, press Ⓞ.

    If you have more than one sensitivity factor, press ⌃ or ⌄ to enter the time that your first sensitivity factor ends and the second begins and press Ⓞ.

16. Press ⌃ or ⌄ to enter the **mg/dL per U** of your sensitivity factor and press Ⓞ.
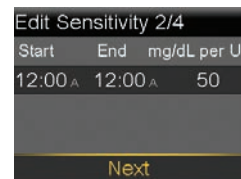
    If you have more than one sensitivity factor, continue by entering your time segments and sensitivity factors until all are entered.

17. Select **Next**.

18. Review the description of BG Target and select **Next**.
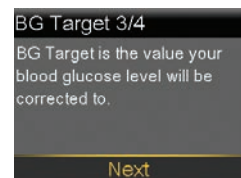
19. Press Ⓞ on the time segment.
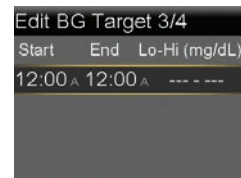
20. If you have only one BG Target range, press Ⓞ.

    If you have more than one BG Target range, press ⌃ or ⌄ to enter the time that your first BG Target range ends and the second begins and press Ⓞ.

NOTE: The boluses shown are for illustration purposes only—your settings and bolus results will be different.

21. Press ∧ or ∨ to enter the low (**Lo**) target and press ◎.

22. Press ∧ or ∨ to enter the high (**Hi**) target and press ◎.

    If you have more than one BG Target range, continue by entering your time segments and low (**Lo**) and high (**Hi**) BG targets until all are entered.

23. Select **Next**.

24. Review the description of Active Insulin Time and select **Next**.
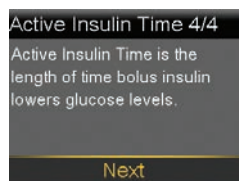
25. Select **Duration**.

26. Press ∧ or ∨ to enter the **Duration** of your Active Insulin Time and press ◎.
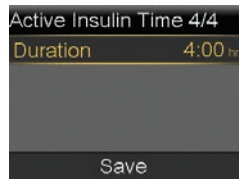
27. Select **Save**.

    The Bolus Wizard™ setup is now complete.
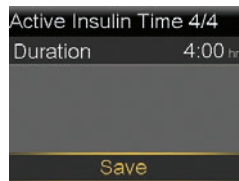
Deliver food and correction bolus
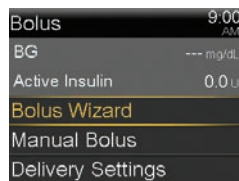
1. Check BG.

2. Press ◎.

   Select **Bolus > Bolus Wizard**.

3. If using linked meter, **BG** is on screen. If not, select **BG**.

   Press ∧ or ∨ to enter BG and press ◎.

4. Select **Carbs**.

5. Press ∧ to enter grams of carbs and press ◎.

6. Select **Next**.

7. Select **Deliver Bolus**.

NOTE: Active Ins. adjust. is the active insulin from previous boluses that is adjusted (subtracted) from the correction dose. In this example, there was no active insulin to subtract.

Deliver correction bolus—no food
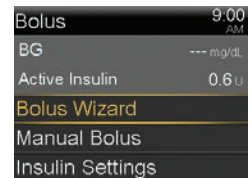
1. Check BG.

2. Press ◎.

   Select **Bolus > Bolus Wizard**.

3. If using linked meter, **BG** is on screen. If not, select **BG**.

   Press ∧ or ∨ to enter BG and press ◎.
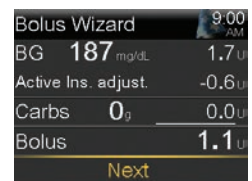
4. Press ∨ to **Next**.

5. Select **Deliver Bolus**.
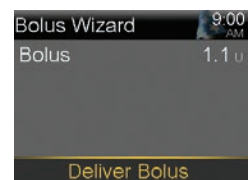
NOTE: In this example, there was active insulin to adjust—it was subtracted from the correction dose.

Deliver food bolus—no correction
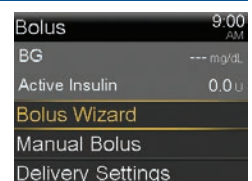
1. Press ◎.

   Select **Bolus > Bolus Wizard**.

NOTE: The boluses shown are for illustration purposes only—your settings and bolus results will be different.

2. Press ⌄ to **Carbs** and press ◎.

3. Press ⌃ to enter the amount of carbs you are eating and press ◎.

4. Select **Next**.

Bolus Wizard	9:00 AM
BG --- mg/dL	0.0 U
Active Ins. adjust.	0.0 U
Carbs 32 g	2.1 U
Bolus	2.1 U
Next	

5. Select **Deliver Bolus**.

Bolus Wizard	9:00 AM
Bolus	2.1 U
Deliver Bolus	
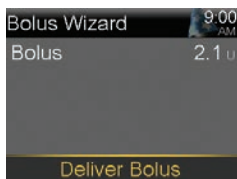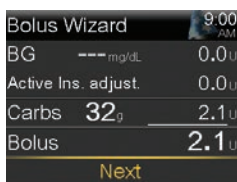
NOTE: Active insulin is never adjusted (subtracted) from a food bolus.

Checking bolus history

1. Press ◎.

   Select **Options > History**.

2. Select **Daily History**.
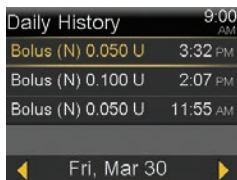
History	9:00 AM
Summary	
Daily History	
Alarm History	

3. Press ◎ on the day you would like to review.

Daily History	9:00 AM
Bolus (N) 0.050 U	3:32 PM
Bolus (N) 0.100 U	2:07 PM
Bolus (N) 0.050 U	11:55 AM
◀ Fri, Mar 30 ▶	

NOTE: You can press the ⟨ and ⟩ arrows to move from day to day. You can also see further details by pressing ◎ on any item listed.

Edit Bolus Wizard™ settings

1. Press ◎.

   Select **Options > Delivery Settings > Bolus Estimate Setup**.

Delivery Settings	
Bolus Estimate Setup	
Basal Pattern Setup	
Preset Temp Setup	
Preset Bolus Setup	
Dual/Square Wave	

2. Select the setting to be changed.

3. Select **Edit**.

4. Press ◎ on the time segment. Press ⌃ or ⌄ to change the times or values.

Bolus Estimate Setup	
Carb Ratio	
Bolus Wizard	On
Insulin Sensitivity Factor	
BG Target	
Active Insulin Time	

5. Select **Save**.
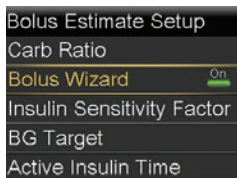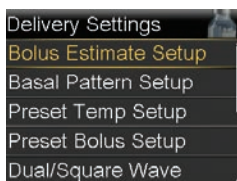
Review Bolus Wizard™ settings

1. Press ◎.

   Select **Status > Settings Review**.

2. Press ⌄ to scroll through the list of settings.

Status Jan 1, 19	9:00 AM
Auto Mode Readiness	
Notifications	
Quick Status	
Pump	300 U
Settings Review	

Settings	9:00 AM
- Insulin Settings -	
Bolus Wizard	On
Current	
Carb Ratio	15 g/U
Current	
Sensitivity	50 mg/dL per U

NOTE: The boluses shown are for illustration purposes only—your settings and bolus results will be different.

START HERE

1

Wash your hands. Press ○ Select **Options**.

2

Options
History
Reservoir & Tubing
Delivery Settings
Event Markers
Reminders

Select **Reservoir & Tubing**.

3

Reservoir & Tubing
New Reservoir
Fill Cannula

Select **New Reservoir**.

4

New Reservoir
1. Remove infusion set from body.
2. Remove reservoir from pump.

Rewind

Remove the infusion set you have been using by loosening the adhesive and pulling away from body.

5

New Reservoir
1. Remove infusion set from body.
2. Remove reservoir from pump.

Rewind

Remove the used reservoir from the pump.
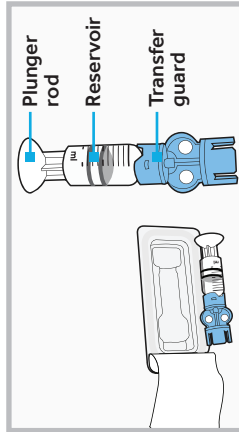
6

New Reservoir
1. Remove infusion set from body.
2. Remove reservoir from pump.

Rewind

Select **Rewind**.

Rewinding

Please wait...
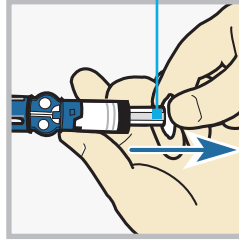
New Reservoir
1. Fill reservoir.
2. Connect tubing to reservoir.
DO NOT CONNECT TO BODY.

Next

FILL RESERVOIR & CONNECT TO THE INFUSION SET TUBING
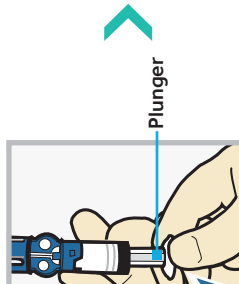
Follow the next steps to fill reservoir with insulin and connect to the infusion set tubing.

1

Plunger rod
Reservoir
Transfer guard
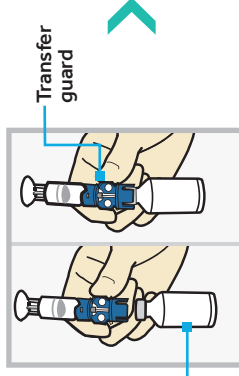
Remove from package. Make sure insulin vial is at room temperature to reduce the risk of air bubbles.

2

Plunger

Pull plunger down to the amount that you plan to fill with insulin.

3

Transfer guard
Insulin vial
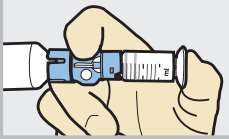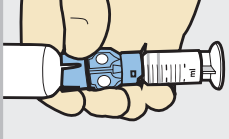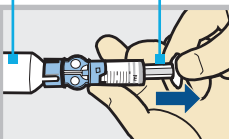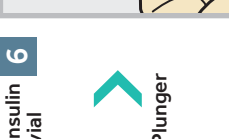
Wipe vial with alcohol. Place vial on table. Firmly press the blue transfer guard onto vial.

4

Push and hold plunger down.

WARNING: If insulin or any liquid gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly fill the infusion set. This may result in the delivery of too little or too much insulin, which could cause hyperglycemia or hypoglycemia.

5

Insulin vial — Plunger

With your thumb still on the plunger, flip over so vial is on top. Release thumb and pull plunger down to fill with insulin.

6

7
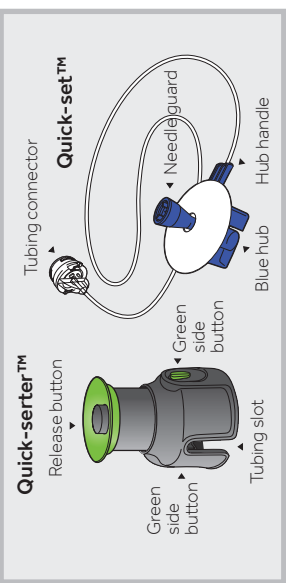
Tap the reservoir to move air bubbles to top of reservoir. Push plunger up to move air into vial.

8
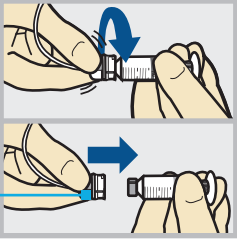
If needed, pull plunger back down to amount of insulin needed for 2–3 days.
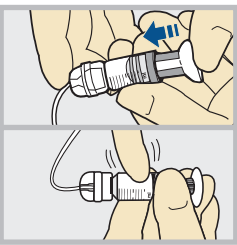
To avoid getting insulin on the top of the reservoir, turn vial over so it is upright. Hold transfer guard and turn reservoir counterclockwise and remove from transfer guard.
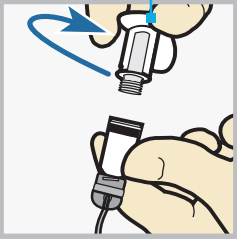
CONNECT RESERVOIR TO INFUSION SET

Place the tubing connector on the end of the infusion set onto the filled reservoir.

1

Quick-serter™
Release button
Green side button
Green side button
Tubing slot

Tubing connector
Quick-set™
Needle guard
Blue hub — Hub handle

Remove infusion set from package. Remove the paper that holds the tubing together.

2

Connector

Gently push the tubing connector onto reservoir. Turn clockwise until locked and you hear a click.

3

If you see air bubbles, tap reservoir to move them to top. Push plunger just a bit to move them into tubing.

4

Plunger

Twist plunger counter-clockwise to loosen and remove.

THE BACKLIGHT MAY HAVE TURNED OFF
Press any button to turn the screen back on.

9:00 AM
◊ BG
--- mg/dL
Active Insulin 0.0 U
Load Reservoir
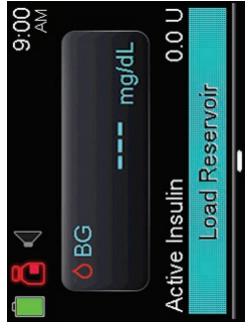
Press ⊙ to open the menu. If the pump is locked, you need to unlock the pump after pressing ⊙.

Load Reservoir
Enter BG
Basal
Audio Options
Status
Suspend Delivery
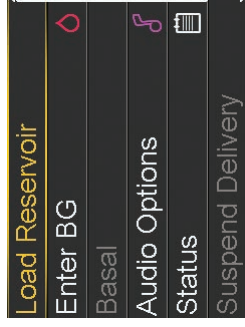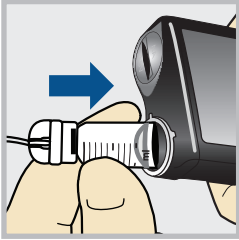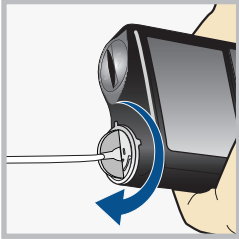
Select **Load Reservoir** from the menu.

New Reservoir
1. Fill reservoir.
2. Connect tubing to reservoir. DO NOT CONNECT TO BODY.
Next
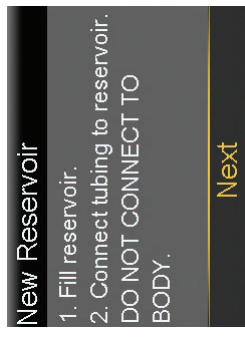
Select **Next**.

PLACE RESERVOIR INTO PUMP

Now place the filled reservoir into the reservoir compartment of the pump.

1

New Reservoir
3. Place reservoir into pump and lock.
DO NOT CONNECT TO BODY.

Next

Place reservoir into pump.

2
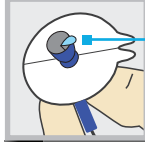
Turn clockwise until you feel reservoir lock into place.

3

New Reservoir
3. Place reservoir into pump and lock.
DO NOT CONNECT TO BODY.

Next

Select **Next**.

LOAD RESERVOIR AND FILL TUBING

Follow these steps to load the reservoir and fill the tubing.

1

Load Reservoir
Select Load and hold until complete.
DO NOT CONNECT TO BODY.

Load   Next

Select **Load** and keep holding ○.

2

Load Reservoir
Complete

DO NOT CONNECT TO BODY.

Load   Next
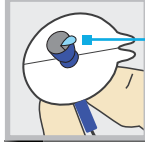
When you see this screen, select **Next**.

3

Fill Tubing
DO NOT CONNECT TO BODY.
Hold Fill until drops appear.
Then select Next.
0.0 u

Fill   Next

Select **Fill** and keep holding ○ until you see drops at the end of tubing, then let go.

Drops at end of tubing

4

Fill Tubing
DO NOT CONNECT TO BODY.
Hold Fill until drops appear.
Then select Next.
11.3 u

Fill   Next

After you see drops, press ⌄ and select **Next**.

INSERT INFUSION SET

Next, follow the steps to insert the infusion set into your body.

1

Fill Cannula?
1. Insert infusion set into body.
2. Select Fill to fill cannula or Done if not needed.

Fill   Done

Blue hub

Tubing slot

Place the MiniMed™ Quick-serter™ insertion device onto a sturdy flat surface with handle facing down. Place **blue** hub into serter, placing the handle in the tubing slot.

2

Use two fingers to seat the infusion set inside the serter securely and gently push down.

3

Needle guard
Adhesive

4
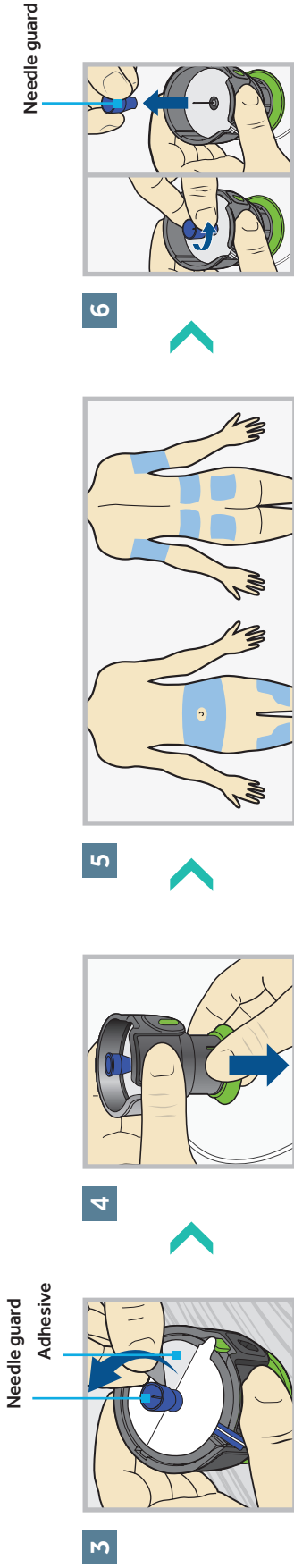
Peel the paper from the adhesive on both sides of the needle guard.

5

Choose an insertion site from the shaded areas shown here. Wipe with alcohol or other antiseptic.

6
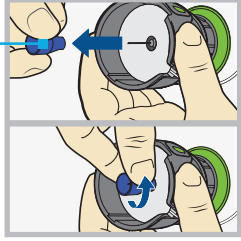
Needle guard

Turn to loosen needle guard and pull.

7
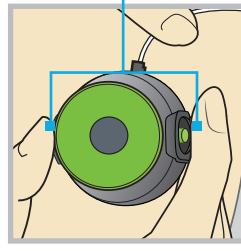
Green side buttons

Hold serter against cleaned site.
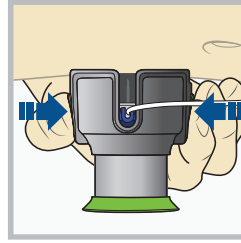
8

Press the two **green** side buttons at the same time.

9

Pull **green** handle down until you hear it click.

10
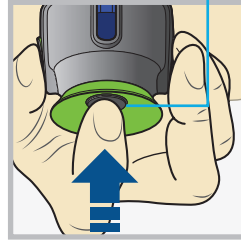
Release button

Press down the release button to unlock.
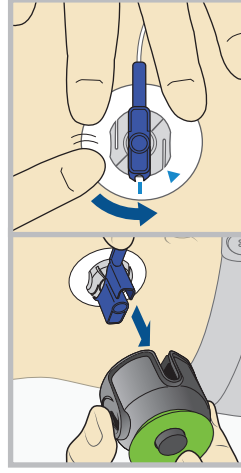
Pull serter away from body. Press adhesive against skin.
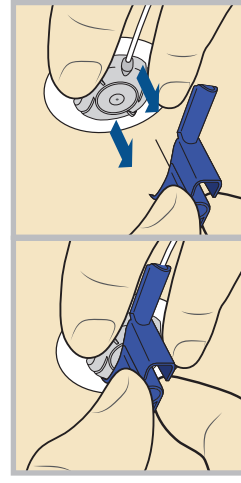
11

Hold infusion set. Pull **blue** handle straight out to remove needle.

12
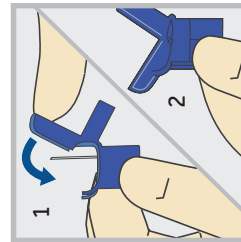
1 2

Fold **blue** handle until locked. Dispose **blue** handle into a sharps container.

Continued on next page

FILL CANNULA

You now fill the cannula, the little tube under your skin, with insulin.

1

Fill Cannula?

1. Insert infusion set into body.
2. Select Fill to fill cannula or
Done if not needed.

Fill   Done

Select **Fill**.

2

Fill Cannula

1. Verify Fill amount.
2. Select Fill Now when
ready. Select Back to cancel.

Fill amount   --- u

Fill Now

✎ **NOTE:** Your pump remembers the **Fill amount** that you used last. Always verify that the Fill amount is correct.
- If it is correct, press ⌄ to **Fill Now** and press ○.
- If it is incorrect, press ○. Change to correct amount and press ○. Select **Fill now.**

Select **Fill amount** and enter:
- 0.300 if using 6mm cannula
- 0.500 if using 9mm cannula

Then press ○.

3

Fill Cannula

1. Verify Fill amount.
2. Select Fill Now when
ready. Select Back to cancel.

Fill amount   0.300 u

Fill Now

Select **Fill Now**.

4

9:00
AM

▽

Fill Cannula   0.025 u
Total: 0.300 u
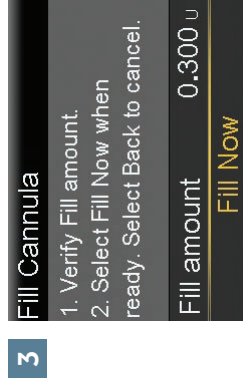
Stop Filling

The Home screen displays the insulin as it fills the cannula.

✎ **NOTE:** Select **Stop Filling** if you need to stop, for example, if you notice the **Total** amount is incorrect. This should rarely happen if you have verified the **Fill amount** on the previous screen.

Your infusion set change is now complete!

Follow these steps to pair your Accu-Chek® Guide Link meter with your MiniMed™ 770G insulin pump:

1. Press the **OK** button on the meter to turn on the meter.

2. Select **Settings**.
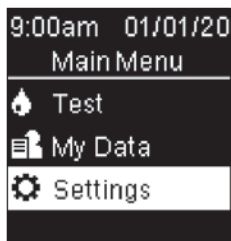
3. Select **Wireless**.

4. Select **Yes** if the confirmation screen appears on the meter screen. Or, select **Pairing** if the confirmation screen does not appear.
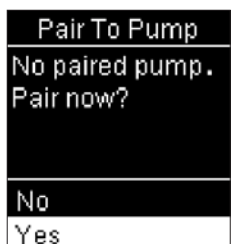
    The serial number of the meter appears on the meter screen. The meter is now ready to pair with the pump.

    Put the meter down and pick up your pump.

5. Press ⬡.

6. Select **Options**.

7. Select **Utilities**.

8. Select **Device Options**.

9. Select **Pair Device**.

10. Select **Search**.

11. Select the meter that matches the serial number on the meter screen.

12. Ensure the serial numbers shown on the pump and meter screens match, and then select **Confirm**.

13. If the connection is successful, a "Pairing successful!" message appears on the pump. A "Paired with pump" message with the serial number of the pump appears on the meter screen.

When you do a BG check using the Accu-Chek® Guide Link meter, you have the option to add a comment.

NOTE: Press ↰ on the meter to automatically send the BG result to a paired pump if you choose not to add a comment. If ↰ is not pressed or a comment is not added, there will be a delay seeing the BG result on the pump.

Medtronic

R_x *Only*

M998591A012_2

SYSTEM USER GUIDE

MiniMed™ 770G

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SYSTEM USER GUIDE

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WARNING:

Do not use SmartGuard Auto Mode for people who require less than eight units or more than 250 units of total daily insulin per day. A total daily dose of at least eight units, but no more than 250 units, is required to operate in Auto Mode.

Warranty

The expected life of the MiniMed insulin pump is a maximum of 4 years. Medtronic Diabetes warrants the MiniMed insulin pump against defects in materials and workmanship for a period of 4 years from the date of purchase.

During the warranty period, Medtronic Diabetes will, at its discretion, replace (with a new or recertified pump, at Medtronic Diabetes' discretion) any defective pump or motor, subject to the conditions and exclusions stated herein. In the event that a pump is replaced, the warranty period will not be extended.

This warranty is valid only if the MiniMed insulin pump is used in accordance with the manufacturer's instructions. This warranty will not apply:

- If damage results from changes or modifications made to the pump by the user or third persons after the date of manufacture.

- If damage results from use of non-Medtronic reservoirs and/or infusion sets.

- If damage results from service or repairs performed by any person or entity other than the manufacturer.

- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer.

- If damage results from negligence or improper use, including but not limited to improper storage; water submersion that does not meet the instructions of the manufacture; or physical abuse, such as dropping or otherwise.

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate. This warranty does not apply to batteries, infusion sets, reservoirs, and other accessories.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic Diabetes nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

All other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

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■ **Before you begin**

■ First steps

■ Basal

■ Bolus

■ Reservoir and infusion set

■ Meter

■ History and events

■ Reminders

■ General settings

■ Setting up CGM

■ **Using CGM**

■ **SmartGuard Auto Mode**

■ Alarms, alerts, and messages

■ Troubleshooting

■ Maintenance

■ Product specifications and safety information

■ MiniMed 770G System Performance Data and Technical Information

■   **Appendix A: Open Source Software disclosure**

■   **Glossary**

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1

1

Before you begin

This user guide is designed to help you understand the operation of the MiniMed 770G System with smart device connectivity and SmartGuard technology, our latest advancement in diabetes management. In the MiniMed 770G System, SmartGuard technology can automatically adjust basal insulin delivery based on your sensor glucose (SG) values. The system can be used in two modes: Manual mode and SmartGuard Auto Mode. Work closely with your healthcare professional when you start insulin pump therapy.

In this user guide, the term Auto Mode refers to the automatic control of basal insulin delivery. For more information, see *About SmartGuard Auto Mode, on page 221*. When your pump is not operating in Auto Mode, the term Manual Mode is used to describe its functions.

Using this user guide

This user guide contains valuable information about using your new insulin pump. To help you find the information you need, you can use the table of contents at the beginning of the user guide and the index at the end of the user guide. There is also a glossary of terms, which starts on *page 409*.

The following table describes certain terms, conventions, and concepts used in this user guide.

Convention	What it means
Select	To activate a screen item, accept a value, or initiate an action.
Select and hold	To perform an action using your pump screen, press the Select button and hold until the action is complete.

Convention	What it means
Press	To push and then release a button.
Press and hold	To push and keep pressure on a button.
Bold text	To indicate screen items and buttons. For example, "Select **Next** to continue."
X	To indicate a numeric value or name that appears differently on your pump screen.
Note	**Note:** A note provides helpful information.
Caution	**CAUTION:** A caution tells you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage to the equipment.
WARNING	**WARNING: A warning tells you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.**

The MiniMed 770G System User Guide includes instructions on how to set up devices on the MiniMed 770G insulin pump. For additional instructions not included in the MiniMed 770G System User Guide, refer to the instructions for the device.

Device	For instructions see
Reservoir	Reservoir user guide
Infusion Sets	Infusion set user guide
Transmitter	Guardian Link (3) transmitter user guide
Sensor	Guardian Sensor (3) user guide

Device	For instructions see
Meter	Accu-Chek® Guide Link User's Manual

Acronyms and abbreviations

The following table defines acronyms and abbreviations used in this guide.

Acronyms and abbreviations	Definition
BG	blood glucose
CDC	Centers for Disease Control and Prevention
CGM	continuous glucose monitoring
CT scan	computerized tomography scan
DKA	diabetic ketoacidosis
EMC	electromagnetic compatibility
ESD	electrostatic discharge
FCC	Federal Communications Commission
FDA	U.S. Food and Drug Administration
GPS	global positioning system
ISIG	input signals, which are read from the sensor and measured in nanoamperes (nA)
IV	intravenous
MRI	magnetic resonance imaging
NiMH	nickel-metal hydride
RF	radio frequency
SG	sensor glucose
SN	serial number
TDD	total daily dose

Emergency kit

Keep an emergency kit with you at all times to make sure that you always have necessary supplies. Tell a family member, co-worker, or friend where you keep your emergency kit.

It is important that you test your blood glucose (BG) more frequently while you travel. The routine hassle of travel, including stress, changes in time zones, schedules and activity levels, meal times and types of food, can all affect your diabetes control. Be extra attentive to monitoring your BG frequently, and be prepared to respond if needed.

Your emergency kit should include these items:

- Fast-acting glucose tablets
- BG monitoring supplies
- Urine or blood ketone monitoring supplies
- Extra MiniMed infusion set and MiniMed reservoir
- Extra new AA lithium or alkaline batteries, or fully charged NiMH batteries
- Insulin syringe and rapid-acting insulin (with dosage instructions from your healthcare professional)
- Wallet card (packaged with your pump accessories)
- Adhesive dressing
- Glucagon emergency kit

WARNING: Do not use the Bolus Wizard feature to calculate a bolus for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in the active insulin amount. Therefore, the Bolus Wizard feature could prompt you to deliver more insulin than needed. Too much insulin can cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you can rely on the active insulin calculation of the Bolus Wizard feature.

> ⚠️ **WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode. Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.**

For details on pump safety, see *User safety, on page 7*.

User safety

> ⚠️ **WARNING: Do not use the MiniMed 770G system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed 770G system.**

Indications

MiniMed 770G System

The MiniMed 770G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in persons two years of age and older requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 770G System includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the SG value falls below or is predicted to fall below predefined threshold values.

The Medtronic MiniMed 770G System consists of the following devices: MiniMed 770G Insulin Pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), one-press serter, the Accu-Chek Guide Link blood glucose meter, and the Accu-Chek Guide Test Strips. The system requires a prescription.

The Guardian Sensor (3) has not been evaluated and is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. All therapy adjustments should be based on measurements obtained using a blood glucose meter and not on values provided by the Guardian Sensor (3).

> ⚠️ **WARNING: Do not use the Suspend on low feature to prevent or treat low glucose. Always confirm your sensor glucose reading using your blood glucose meter, and follow the instructions of your healthcare professional to treat low glucose. Using Suspend on low alone to prevent or treat low glucose may result in prolonged hypoglycemia.**

Guardian Sensor (3)

The Guardian Sensor (3) is intended for use with the MiniMed 770G system, MiniMed 670G system, MiniMed 630G system, and Guardian Connect system to continuously monitor glucose levels in persons with diabetes.

The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for seven days of continuous use.

The Guardian Sensor (3) has been studied and is approved for use in the systems, insertion sites, and ages listed in the following table:

System	Approved Age	Sensor Insertion Site
MiniMed 770G system	2-13	Abdomen and Buttocks
	14 and older	Abdomen and Arm
MiniMed 670G system	7-13	Abdomen and Buttocks
	14 and older	Abdomen and Arm
MiniMed 630G system	14 and older	Abdomen and Arm
Guardian Connect system	14 and older	Abdomen and Arm

One-press Serter

The serter is used as an aid for inserting the sensor. It is indicated for single-patient use and is not intended for multiple patient use.

Guardian Link (3) Transmitter

The Guardian Link (3) Transmitter is intended for use with MiniMed 770G System. The Guardian Link (3) Transmitter powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the MiniMed 770G insulin pump. The Transmitter is intended for single-patient multi-use.

Accu-Chek Guide Link Blood Glucose Monitoring System

The Accu-Chek Guide Link Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Link meter and the Accu-Chek Guide test strips.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended for in vitro diagnostic single-patient use by people with diabetes

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosing or screening for diabetes mellitus and not for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used to wirelessly transmit glucose values to the MiniMed 770G system with Bluetooth wireless technology through the use of Bluetooth low energy communication.

> ⚠️ **WARNING:**
> - Do not use Alternative Site Testing to calibrate a continuous glucose monitoring system.
> - Do not use Alternative Site Testing to make insulin dosing calculations.

Contraindications

Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms.

Do not use the serter on products other than the Guardian Sensor (3). Medtronic cannot guarantee the safety or efficacy of this product if used with other products.

The reservoir is contraindicated for the infusion of blood or blood products.

Infusion sets are indicated for subcutaneous use only and not for intravenous (IV) infusion or the infusion of blood or blood products.

Insulin pump therapy is not recommended for those who are unwilling to perform at least four BG tests per day. As insulin pumps use rapid-acting insulin only, BG testing is required to help identify rapid glycemic deterioration due to insulin infusion occlusion, infusion site problems, insulin stability issues, user error, or a combination of these.

> ⚠️ **WARNING: Do not use SmartGuard Auto Mode for people who require less than eight units or more than 250 units of total daily insulin per day. A total daily dose of at least eight units, but no more than 250 units, is required to operate in Auto Mode.**

Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional.

Potential risks

Risks related to insulin pump infusion set

General risks related to insulin pump infusion set may include:

- Localized infection
- Skin irritation or redness
- Bruising
- Discomfort or pain
- Bleeding
- Irritation
- Rash

- Occlusions that can interrupt insulin delivery and lead to hyperglycemia or diabetic ketoacidosis

Patients should be instructed to follow the provided user guides for insertions and care of infusion sets. If an infusion site becomes irritated or inflamed, the infusion set should be removed and another placed in a new location.

Risks related to insulin administration and pump use

Due to the use of insulin, there is risk related to the infusion of insulin and the potential interruptions of insulin delivery. These general risks may include:

- Hypoglycemia
- Hyperglycemia
- Diabetic ketoacidosis
- Seizure
- Coma
- Death

Risks related to sensor use

General risks related to sensor use may include:

- Skin irritation or other reactions
- Bruising
- Discomfort
- Redness
- Bleeding
- Pain
- Rash
- Infection
- Raised bump
- Appearance of a small "freckle-like" dot where needle was inserted
- Allergic reaction
- Fainting secondary to anxiety or fear of needle insertion
- Soreness or tenderness

- Swelling at insertion site

- Sensor fracture, breakage or damage

- Minimal blood splatter associated with sensor needle removal

- Residual redness associated with adhesive, tape, or both

- Scarring

Specific risks related to sensor use

Taking medications with acetaminophen, including, but not limited to Tylenol, fever reducers, or cold medicine, while wearing the sensor may falsely raise your SG readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person. Always use BG meter readings to verify your glucose level before making therapy decisions, including when you could have acetaminophen active in your body. Avoid taking medications with acetaminophen while in Auto Mode. If acetaminophen is taken, use additional BG meter readings to verify your glucose levels, and consider exiting Auto Mode. Do not use these additional BG meter readings to calibrate the sensor. Always check the label of any medications to confirm whether acetaminophen is an active ingredient.

For persons two to thirteen years of age, sensor placement and insertion has been studied in the belly (abdomen) and buttocks only and is not approved for other sites.

For persons that are fourteen years of age and older, sensor placement and insertion has been studied in the belly (abdomen) and back of upper arm only and is not approved for other sites.

Specific risks related to meter use

- For the most current warnings, see the User's Manual that came with your device.

- A list of warnings for the meter are provided in the meter section on *page 23*.

> **⚠ WARNING:**
> - Do not use Alternative Site Testing to calibrate a continuous glucose monitoring system.
> - Do not use Alternative Site Testing to make insulin dosing calculations.

Risks related to serter use

General risks with serter use may include skin infection around the area where the serter is used.

Risks related to the MiniMed 770G insulin pump system

General risks related to the MiniMed 770G insulin pump system may include:

- Hypoglycemia
- Hyperglycemia
- Diabetic ketoacidosis
- Seizure
- Coma
- Death

General warnings

Pump

- Do not use the pump when a flammable anesthetic mixture with air, oxygen, or nitrous oxide is present. These environmental conditions can damage your pump and result in serious injury.

- Always use the fingertip for blood samples used for calibrating the sensor while in Auto Mode. The fingertip was the only site studied for use with Auto Mode. Do not use blood samples from the palm to calibrate the sensor as this site was not studied for use with Auto Mode and the performance of the system is not known.

- Always use the values from your BG meter for treatment decisions. The MiniMed 770G system CGM does not replace a BG meter to make treatment decisions. BG values may differ from SG values. Using the SG readings for treatment decisions could lead to high or low BG.

- For MiniMed 770G System Users Ages 2-13:

  The low SG alert functionality is distinct from the automated insulin dosing function of the MiniMed 770G System. When used in Auto Mode, the MiniMed 770G System has been shown to be safe and effective for its intended use in this population. However, do not rely solely on the use of a low SG value for "Alert on Low" or "Alert before Low" for alerts set at 50 mg/dL and 60 mg/dL. A low SG alert may not reflect the user's true BG at these levels, or may not alert. Do not ignore symptoms of low glucose. Always confirm your SG readings with your BG meter, and treat according to the recommendations of your healthcare professional. Solely relying on these SG alerts and readings for treatment decisions could result in missing severe hypoglycemia (low BG) events.

- Never rely on the pump beeps or vibrations alone to navigate through the pump screens or menus. Always check your pump screen as you navigate. The pump beeps and vibrations are intended to notify you of a condition that may require attention. Relying on the pump beeps or vibrations alone to navigate can result in incorrect menu selection or settings.

- Do not use your pump if the screen appears broken or unreadable. In some instances, impact to the pump can damage the screen while the buttons continue to function. If the screen is broken or unreadable, do not press any buttons. Remove the pump and begin using your backup insulin plan per the direction of your healthcare professional. If the pump is accidentally programmed while the screen is broken or unreadable, this could result in high or low BG levels. If your screen is damaged, contact 24-Hour Technical Support to arrange for shipment of a replacement pump.

- Only use rapid-acting U-100 insulin (Humalog and NovoLog) that has been prescribed by your healthcare professional for use with an infusion pump. Do not put any other drugs or medications inside your reservoir for use with this pump. Other drugs or medications are not intended for use with this pump. Use of other drugs or medications can cause serious injury.

- Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin.

- Do not insert the reservoir in the pump if you did not rewind your pump. Doing so could result in an accidental infusion of insulin.

- Do not use the MiniMed 770G insulin pump or additional system devices adjacent to other electrical equipment which may cause interference with the normal system operation. This includes mobile communication devices such as cell phones that are not paired with the MiniMed 770G System, GPS navigation systems, anti-theft systems, and any electrical equipment that has an output transmitter power greater than 1W. For more information about recommended separation distance guidelines between the insulin pump and common RF emitters, see *Guidance and manufacturer's declaration, on page 319*. The recommended separation distance between the insulin pump and common RF emitters is 12 inches. Other electrical equipment that may compromise normal system operation has been contraindicated. For more information, see *Exposure to magnetic fields and radiation, on page 24*.

- Do not unscrew or retighten the tubing connector on the reservoir while the infusion set is connected to your body. Doing so could result in an accidental infusion of insulin.

- Do not use standard Luer sets with the MiniMed 770G insulin pump. Standard Luer sets are not compatible with the pump. The MiniMed reservoirs and the MiniMed infusion sets are specifically designed for use with the MiniMed 770G insulin pump.

- Do not change or modify the MiniMed reservoir or the MiniMed infusion set unless expressly approved by Medtronic Diabetes. Modifying the devices can cause serious injury, interfere with your ability to operate the device, and void your warranty.

- Do not rely on preset pump alarms or reminders alone to prompt you to check your BG. This can cause you to forget to check your BG. Set additional reminders on other devices, such as your cell phone.

- Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.

- Do not attempt to use any transmitter other than the Guardian Link (3) transmitter with Bluetooth wireless technology (MMT-7911). "GL3" is marked on the transmitter. Only the "GL3" transmitter can communicate with the MiniMed 770G insulin pump with smart device connectivity.

- If other devices, outside those being used as part of the MiniMed 770G System, employ radio frequencies such as cell phones, cordless phones, walkie-talkies, and wireless networks, they may prevent communication between the transmitter and the insulin pump. This interference does not cause any incorrect data to be sent and does not cause any harm to your devices. Moving away from, or turning off, these other devices may enable communication. If you continue to experience RF interference, contact 24-Hour Technical Support.

- Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist; such as cellular phones that are not paired with the MiniMed 770G System, Wi-Fi networks, Bluetooth wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.

- Portable and mobile RF communications equipment can affect Medical Electrical Equipment as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.

- This device can generate, use, and radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. If the device does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:

- Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.

- Decrease the distance between the meter and the insulin pump to 6 feet (1.8 meters) or less.

- Increase the separation between the transmitter and the device that is receiving/emitting interference.

> **Note:** Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

- The safety of the MiniMed 770G System has not been studied in people with impaired kidney function. Let your healthcare professional know if you have kidney disease so you and your healthcare professional can determine if the potential benefits of using the system outweigh the risks.

- The safety of the MiniMed 770G System has not been studied in pregnant women, people with type 2 diabetes, or in people using other anti-hyperglycemic therapies that do not include insulin. Let your healthcare professional know if any of these conditions apply to you so you and your healthcare professional can determine if the potential benefits of using the system outweigh the risks.

- The safety of using Auto Mode, Suspend before low, and Suspend on low in people who have no pump experience is not known. Auto Mode, Suspend before low, and Suspend on low should not be used if insulin pump settings have not been previously established. Insulin pump settings include basal rates, insulin to carb ratio, or insulin sensitivity factors. Always discuss with your healthcare professional before using Auto Mode, Suspend before low, or Suspend on low.

Reservoir and infusion sets

For the most current warnings, see the user guide that came with your device.

- Only use rapid-acting U-100 insulin (Humalog and NovoLog) that has been prescribed by your healthcare professional for use with an infusion pump. Do not put any other drugs or medications inside your reservoir for use with this pump. Other drugs or medications are not intended for use with this pump, and can result in serious injury.

- If insulin, or any liquid, gets inside the tubing connector, it can temporarily block the vents that allow the pump to properly prime the infusion set. This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. If this occurs, start over with a new reservoir and infusion set.

- Do not reinsert the introducer needle into the infusion set. Reinsertion may cause tearing of the soft cannula, which may result in unpredictable medication flow.

- If infusing insulin, and your BG level becomes unexplainably high, or an occlusion alarm occurs, check for clogs and leaks.

- If in doubt, change the infusion set because the soft cannula may be dislodged, crimped, or partially clogged. Should any of these problems arise, make a plan with your healthcare professional for rapidly replacing insulin. Check your BG level to make sure the problem is corrected.

- Reuse of the infusion set may cause damage to the cannula or needle and lead to infection, site irritation, and inaccurate medication delivery.

- Dispose of transfer guard safely in sharps container.

- Never prime the set or attempt to free a clogged line while the set is inserted. You may accidentally inject too much medication.

- Do not put disinfectants, perfumes, or deodorants on the infusion set as these may affect the integrity of the set.

- Dispose of the infusion set and introducer needle safely, in a sharps container, after a single use. Do not clean or re-sterilize.

- Store infusion sets in a cool, dry place. Do not leave infusion sets in direct sunlight or inside a vehicle.

- Only use reservoir and infusion sets manufactured or distributed by Medtronic Diabetes. The pump has undergone extensive testing to confirm appropriate operation when used with compatible reservoirs and infusion sets

manufactured or distributed by Medtronic Diabetes. We cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third parties. We are not responsible for any injury or malfunctioning of the pump that may occur in association with such use.

- Use aseptic techniques when temporarily disconnecting the set and consult your healthcare provider on how to compensate for missed medication when disconnected.

- If infusing insulin, carefully monitor your BG levels when disconnected and after reconnecting.

- Reservoir and transfer guard are sterile, non-pyrogenic, and for single use only.

- Do not clean or re-sterilize. Reuse of the reservoir may lead to insulin degradation, infection, inaccurate medication delivery, and leaks which may cause damage to the pump.

- Inaccurate medication delivery, infection, or site irritation may result from improper insertion and maintenance of the infusion site.

- If using this infusion set for the first time, do the first set-up in the presence of your healthcare professional.

- Do not leave air in the infusion set. Prime completely.

- Replace the infusion set every 48 to 72 hours according to Centers for Disease Control guidelines, or per your healthcare professional's instructions.

- If infusing insulin, do not change the infusion set just before bedtime unless you can check your BG 1 to 3 hours after insertion.

- Do not use if package has been opened or damaged.

- Ensure sterility by checking that the sterile paper and tamper-proof seal are not damaged.

- This device is sterile and non-pyrogenic unless the package has been opened or damaged. Do not use if the package has been opened or damaged. Do not use the infusion set if the tubing connector needle has been damaged.

- Do not use the infusion set for more than three days. Insulin is not labeled for more than three days of use when it is used in an infusion set. If insulin is used in the infusion set for more than three days, it may increase the risk of set occlusions and cause problems with insulin absorption, which may lead to severe hyperglycemia and DKA.

- Before insertion, clean the insertion site with isopropyl alcohol.

- Check frequently to make sure the soft cannula remains firmly in place as you may not feel pain if it pulls out. The soft cannula must always be completely inserted to receive the full amount of medication.

- Release the tubing with caution as a hard pull of the tubing can result in damage to the infusion set and introducer needle. Ensure that the infusion set is properly in place when the tubing is fully released.

- If the infusion site becomes inflamed, replace the set, and use a new site until the first site has healed. Replace the infusion set if the tape becomes loose, or if the soft cannula becomes fully or partially dislodged from the skin.

- Failure to remove trapped air from reservoir may result in inaccurate delivery of medication.

- Never point a loaded insertion device towards the body part where insertion is not desired.

- Remove the needle guard before inserting the infusion set.

Sensor and serter

For the most current warnings, see the user guide that came with your device.

- Keep the sensor away from children. This product contains small parts and may pose a choking hazard.

- Keep the serter away from children. This product contains small parts and may pose a choking hazard.

- A retractable needle is attached to the sensor and minimal blood splatter may occur. If you are a healthcare professional or caregiver, wrap sterile gauze around the sensor to minimize contact with blood. Keep as much distance as possible between you and the patient when removing the needle.

- Do not attempt to remove the sensor yourself if you suspect that the sensor is broken. While there is no evidence of a sensor breaking in a patient's body, sensor breakage can result in serious injury. Contact your healthcare professional for assistance in removing the sensor.

- Always inspect the packaging for damage prior to use. Sensors are sterile and non-pyrogenic, unless the package has been opened or damaged. Do not use the sensor if the sterile package has been opened or damaged. Use of an unsterile sensor can cause site infection.

- If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the plastic base of the sensor, do the following:

  a. Remove the sensor and continue to apply steady pressure until the bleeding stops. Discard the sensor in a sharps container.

  b. Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. Treat based on instructions from your healthcare professional.

  c. Insert a new sensor in a different location.

- The one-press serter (MMT-7512) does not work the same as other Medtronic insertion devices. Failure to follow directions or using a different serter may result in improper insertion, pain, or injury.

- Keep the needle housing within sight at all times to avoid an accidental needlestick or puncture.

- Taking medications with acetaminophen while wearing the sensor may falsely raise your SG readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person.

- Make sure the sensor is securely placed in the serter to avoid improper insertion, pain, or minor injury.

- Watch for bleeding at the insertion site (under, around, or on top of the sensor). If bleeding occurs, do the following:

  a. Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes. The use of unsterile gauze can cause site infection.

b.   If bleeding stops, connect the transmitter (or recorder) to the sensor. If bleeding does not stop, do not connect the transmitter to the sensor because blood can get into the transmitter connector, and could damage the device.

- The sensor is designed to work with Guardian Link (3) transmitter only. It is not interchangeable with transmitters and recorders that are not compatible with the sensor. Connecting your sensor to a transmitter or recorder that is not approved for use with the sensor may cause damage to the components or inaccurate sensor glucose values.

- It is not known how different conditions or medications common to the critically ill population may affect the performance of the system. Therefore, the use of this sensor in the critically ill population is not recommended.

Transmitter

For the most current warnings, see the user guide that came with your device.

- Do not allow children to put small parts in their mouth. This product poses a choking hazard for young children.

- Do not use the tester if it comes in contact with blood. Touching blood can cause infection. Dispose of the tester according to the local regulations for medical waste disposal, or contact your healthcare professional for disposal information.

- Bleeding may occur after inserting the sensor. Always make sure that the site is not bleeding before connecting the transmitter to the sensor. Blood can get into the transmitter connector and damage the device. Discard the device if damaged. If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, connect the transmitter to the sensor.

- Do not use the transmitter adjacent to other electrical equipment which may cause interference with the normal system operation. This includes mobile communication devices such as cell phones, GPS navigation systems, and other devices that have an output transmitter power greater than 1W. Other electrical equipment that may compromise normal system operation has been contraindicated.

- Do not change or modify the device unless expressly approved by Medtronic Diabetes. Modifying the device can cause serious injury, interfere with your ability to operate the device, and void your warranty.

Meter

For the most current warnings, see the User's Manual that came with your device.

Always use the fingertip for blood samples used for calibrating the sensor while in Auto Mode. The fingertip was the only site studied for use with Auto Mode. Do not use blood samples from the palm to calibrate the sensor as this site was not studied for use with Auto Mode and the performance of the system is not known.

Limitations

- Do not use the meter at high hematocrit levels above 65% or low hematocrit levels below 10%.

- Not for use in diagnosis or screening of diabetes mellitus.

- Not for neonatal use.

- Abnormally high concentrations of ascorbic acid (vitamin C) resulting in blood concentrations in excess of 5 mg/dL may cause inaccurate test results. If you are not sure please check with your doctor.

- Do not use the meter system to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.

- Do not use this system during xylose absorption test.

- Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients.

- This system has not been tested at altitudes higher than 10,150 feet.

⚠️ **WARNING:**
- Do not use Alternative Site Testing to calibrate a continuous glucose monitoring system.

- Do not use Alternative Site Testing to make insulin dosing calculations.

Potential Biohazard

- During normal testing, any blood glucose meter or lancing device may come in contact with blood. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from bloodborne pathogens, even after you have performed cleaning and disinfecting.[1, 2]

- The meter and lancing device should never be used by more than one person. Do not share the meter and lancing device with anyone, including family members, due to the risk of infection from bloodborne pathogens.[1, 2] Do not use on multiple patients!

- Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, bloodborne pathogens.[3]

- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.

- Disinfect the meter and lancing device before allowing anyone else to handle them. Do not allow anyone else to test with the meter or lancing device.

- It is important to keep the meter and lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see the chapter Meter and Lancing Device Cleaning and Disinfecting.

- Wash hands and dry thoroughly before and after handling the meter, lancing device, or test strips.

Exposure to magnetic fields and radiation

- Do not expose your pump to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). The strong magnetic fields can cause the system to

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1   FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). Update 11/29/2010." http://wayback.archive-it.org/7993/20161022010458/ http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. Accessed January 17, 2018.

2   CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010)." http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html. Accessed January 17, 2018.

3   Centers for Disease Control and Prevention (CDC): "Guideline for Disinfection and Sterilization in healthcare Facilities, 2008." Update: May 2019. William A. Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC). https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf. Accessed September 23, 2019.

malfunction, and result in serious injury. If your pump is exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.

Magnetic fields, and direct contact with magnets, may affect the accurate functioning of your system, which may lead to health risks such as hypoglycemia or hyperglycemia.

- Do not expose your transmitter to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields. Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury, or be unsafe. If your transmitter is inadvertently exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.

- Do not expose your sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields as the performance of the sensor has not been evaluated under those conditions and may be unsafe. If your sensor is inadvertently exposed to a strong magnetic field, discontinue use and contact 24-Hour Technical Support for further assistance.

- Always remove your pump, sensor, transmitter, and meter before entering a room that has x-ray, MRI, diathermy, or CT scan equipment. The magnetic fields and radiation in the immediate vicinity of this equipment can make your devices nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over delivery and severe hypoglycemia.

- Do not expose your pump to a magnet, such as pump cases that have a magnetic clasp. Exposure to a magnet may interfere with the motor inside the pump. Damage to the motor can cause the device to malfunction, and result in serious injury.

- Always carry the Medical emergency card provided with your device when you are traveling. The Medical emergency card provides critical information about airport security systems and pump use on an airplane, which can help you and others. Not following the guidance on the Medical emergency card could result in serious injury.

■ **Before you begin**

General precautions

Always check your BG levels at least four times per day. Although the pump has multiple safety alarms, it cannot notify you if the infusion set is leaking, or the insulin has lost its effectiveness. If your BG is out of range, check the pump and the infusion set to ensure that the necessary amount of insulin is being delivered.

Waterproof capabilities

• At the time of manufacture and when the reservoir and tubing are properly inserted, your pump is waterproof. It is protected against the effects of being underwater to a depth of up to 12 feet (3.6 meters) for up to 24 hours.

• If the pump is dropped, hit against a hard object, or otherwise damaged, the waterproof characteristics of the outer casing of the pump may be compromised. If your pump has been dropped or you suspect your pump is damaged, carefully inspect your pump to ensure there are no cracks before exposing your pump to water.

• This waterproof capability rating applies only to your pump.

• If you believe that water has entered your pump or you observe any other possible pump malfunction, check your BG, and treat high BG as necessary, using an alternative source of insulin. Contact 24-Hour Technical Support for further assistance. Always contact your healthcare professional if you experience excessively high or low BG levels or if you have any questions about your care.

Electrostatic discharge

• Although the MiniMed 770G insulin pump is designed to be unaffected by typical levels of electrostatic discharge (ESD), very high levels of ESD can result in a reset of the pump's software and a pump error alarm. After clearing the alarm, verify that your pump is set to the correct date and time, and that all other settings are programmed to the desired values. The software reset could erase your previously programmed settings. Following a pump reset, Auto Mode will be unavailable for five hours to allow active insulin to be updated.

- For more information on pump alarms, see *Pump alarms, alerts, and messages, on page 246*. For more information on re-entering your pump settings, see *My pump is asking me to enter my settings, on page 288*. If you are unable to re-enter your pump settings, or otherwise believe there is a problem with your pump, contact 24-Hour Technical Support.

Extreme temperatures

Exposure to extreme temperatures can damage your device, which can adversely affect safety and effectiveness of your device. Avoid the following conditions:

- Avoid exposing your pump to temperatures above 104°F (40°C) or below 41°F (5°C). This may damage your device.

- Insulin solutions freeze near 32°F (0°C) and degrade at temperatures higher than 98.6°F (37°C). If you are outside in cold weather, wear your pump close to your body and cover it with warm clothing. If you are in a warm environment, take measures to keep your pump and insulin cool.

- Do not steam, heat, sterilize, or autoclave your pump. Exposure to high temperatures may damage your device.

Lotion, sunscreen, and insect repellent

Some skin care products, such as lotion, sunscreen, and insect repellents, can cause damage to plastics, which is a material used in your pump case. After using such products, be sure to wash your hands prior to handling your pump. If you get any skin care products or insect repellents on your pump, wipe them off as soon as possible with a damp cloth and mild soap. For instructions on cleaning your pump, see *Cleaning your pump, on page 295*.

Infusion sets and sites

Always refer to the infusion set user guide for all precautions, warnings, and instructions relating to the infusion set and your insertion sites. Not referring to the infusion set user guide can result in minor injury or damage to the infusion set.

Sensor

Always refer to the sensor user guide for all precautions, warnings, and instructions relating to the sensor. Not referring to the sensor user guide can result in minor injury or damage to the sensor.

Transmitter

Always refer to the transmitter user guide for all precautions, warnings, and instructions relating to the transmitter. Not referring to the transmitter user guide can result in minor injury or damage to the transmitter.

Meter

Always refer to the Accu-Chek Guide Link User's Manual for all precautions, warnings, and instructions relating to compatible meters. Not referring to the User's Manual can result in minor injury or damage to the meter.

Security precautions

The MiniMed 770G insulin pump system is designed with security features to help keep the system and the data secure. These security features in the insulin pump system are set in the factory and ready to use when the insulin pump is received. For example, when the pump communicates with other devices in the system, such as the BG meter, transmitter, or compatible mobile device, the data that it is sending and receiving is encrypted and protected by cyclic redundancy checks. This helps prevent other people from being able to see system data, or to interfere with insulin pump therapy.

To help keep the system secure, follow these instructions:

- Do not leave the insulin pump or the paired devices unattended.
- Do not share the pump, transmitter, or BG meter serial number.
- Do not connect the pump to any third-party devices not authorized by Medtronic.
- Do not use any software not authorized by Medtronic to control the system.
- Be attentive to pump notifications, alarms, and alerts because they may indicate that someone else is trying to connect to or interfere with the device.
- Disconnect the Blue Adapter from the computer whenever it is not being used.
- Use good cyber security practices; use anti-virus software and keep computer software up to date.
- Refer to the MiniMed Mobile App User Guide for information on how to keep the compatible mobile device safe to use with the Medtronic devices.

The pump only communicates with paired devices. The short time that it takes to pair the pump with other devices is a sensitive time for security. During this time, it is possible for an unintended device to pair with the pump. While Medtronic has designed security features into the system to prevent this, to keep the system safe during pairing always follow these instructions:

- Pair the transmitter, BG meter, or the compatible mobile device with the pump away from other people and devices.

- When the transmitter successfully pairs with the pump, the green LED on the transmitter stops blinking. If the green LED on the transmitter continues to blink for several minutes or more after it is successfully paired, it may have been paired with an unintended device. See *Deleting the transmitter from your pump, on page 204* to delete the transmitter from the pump and then follow the steps to pair it again.

- After pairing the BG meter or the compatible mobile device with the pump, make sure that the BG meter or compatible mobile device indicates that pairing was successful.

Consult a healthcare professional if there are symptoms of severe hypoglycemia or diabetic ketoacidosis, or suspect that the insulin pump settings, or insulin delivery changed unexpectedly.

If there is a concern that someone else is trying to connect to or interfere with the device, stop using it and contact 24-Hour Technical Support immediately.

Adverse reactions

Always refer to the sensor user guide for adverse reactions related to the sensor. Not referring to the sensor user guide can result in minor injury or damage to the sensor.

Keeping track of your system information

The serial number (SN) is located on the back of your pump. If you are using the pump clip, you need to remove the pump clip to view the serial number. It also displays in your Pump status screen. For more details on the status screens, see *Status screens, on page 52*. You will need your pump serial number if you call 24-Hour Technical Support. For future reference, enter the serial number of your pump and the purchase date in the following table:

Pump serial number and purchase date
Serial Number:
Purchase Date:

Insulin guidelines

> **WARNING: Never start on insulin until directed by your healthcare professional. Do not use insulin in your pump while you are practicing by either inserting an insulin filled reservoir into your pump, or connecting an insulin filled infusion set to your body. Doing so could result in an infusion of insulin, not prescribed by your healthcare professional, which may result in low or high blood glucose.**

The MiniMed 770G insulin pump has been studied with, and is intended for use with, the following rapid-acting U-100 insulins:

- U-100 NovoLog
- U-100 Humalog

The use of any other insulin in the MiniMed 770G insulin pump has not been tested and may not be appropriate for use with this device.

> **WARNING: Only use rapid-acting U-100 insulin (Humalog and NovoLog) in the MiniMed 770G insulin pump. Use of the incorrect insulin, or insulin with a greater or lesser concentration, may result in over delivery or under delivery of insulin. Over delivery or under delivery of insulin may result in high or low blood glucose levels. High blood glucose levels may lead to diabetic ketoacidosis. Low blood glucose levels may lead to coma or death. If you are unsure about whether you can use a specific insulin with this pump, contact your healthcare professional.**

Consumables

The pump uses disposable, single-use, MiniMed reservoirs and infusion sets for insulin delivery.

⚠ **WARNING: Only use reservoir and infusion sets manufactured or distributed by Medtronic Diabetes. The pump has undergone extensive testing to confirm appropriate operation when used with compatible reservoirs and infusion sets manufactured or distributed by Medtronic Diabetes. We cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third parties and therefore we are not responsible for any injury or malfunctioning of the pump that may occur in association with such use.**

- **Reservoirs**–Use the MiniMed reservoir MMT-332A, 3.0 mL (300-unit).

- **Infusion sets**–Medtronic Diabetes provides a variety of infusion sets to fit your needs. Contact your healthcare professional for help in choosing an infusion set. Change your infusion set every two to three days per your infusion set manufacturer's instructions.

    The following table lists the compatible infusion sets. The MMT numbers may change if other compatible infusion sets become available.

Type	MMT number
MiniMed Quick-set infusion set	MMT-386, MMT-387, MMT-394, MMT-396, MMT-397, MMT-398, MMT-399
MiniMed Silhouette infusion set	MMT-368, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384
MiniMed Sure-T infusion set	MMT-862, MMT-864, MMT-866, MMT-874, MMT-876, MMT-884, MMT-886
MiniMed Mio infusion set	MMT-921, MMT-923, MMT-925, MMT-941, MMT-943, MMT-945, MMT-961, MMT-963, MMT-965, MMT-975
MiniMed Mio Advance infusion set	MMT-211, MMT-212, MMT-213, MMT-231, MMT-232, MMT-233, MMT-242, MMT-243, MMT-244

Additional MiniMed 770G System devices

- **Accu-Chek Guide Link meter**–the MiniMed 770G System is compatible with an Accu-Chek Guide Link meter. The meter pairs with your pump, allowing you to send BG meter readings to your pump.

- **Guardian Link (3) transmitter (MMT-7911)**–pairs with your pump for CGM. A device that connects to a glucose sensor. The transmitter collects data measured by the sensor and wirelessly sends this data to monitoring devices.

- **Guardian Sensor (3) (MMT-7020)**–used with your pump for CGM. The sensor is a small part of the CGM system that you insert just below your skin to measure glucose levels in your interstitial fluid. The sensor is a disposable, single-use, device. Only use the Guardian Sensor (3) (MMT-7020) glucose sensor with the transmitter. Do not use any other sensor. Other sensors are not intended for use with the transmitter, and will damage the transmitter and the sensor.

- **MiniMed Mobile app (MMT-6101 for Android or MMT-6102 for iOS)**–can be downloaded onto multiple compatible mobile devices from the app store, but the pump can be paired with only one compatible mobile device at any time. Refer to the app user guide for setup and operation. This product should only be used with supported mobile devices. Refer to your local Medtronic Diabetes website for information about supported devices and operating systems.

- **CareLink Connect app (MMT-6111 for Android or MMT-6112 for iOS)**–can be downloaded onto compatible mobile devices from the app store. Refer to the app user guide for setup and operation within the app. This optional app is available to care partners to view patient therapy data and to be notified of selected patient alerts. This app does not replace the real-time display of insulin pump or CGM data on the primary display device. All therapy decisions should be based on the primary display device. Refer to your local Medtronic Diabetes website for information about supported devices and operating systems.

- **Blue Adapter**–uploads system data to CareLink software through a USB port on your computer. Refer to the CareLink software user guide for setup and operation of the Blue Adapter.

Accessories

The following accessories may be used with the MiniMed 770G System.

- **Pump clip**–used to wear the pump on your belt. Also, you can use the tip of the pump clip to open the battery compartment on your pump. Refer to your pump clip user guide for instructions on using your pump clip.

- **Activity guard**–used if you are active in sports, or if a child is wearing the pump. Using the activity guard prevents the reservoir from being rotated or removed from the pump.

- **Skins**–personalize the look of the pump as decorative overlays and provide additional protection against surface scratches.

Ordering supplies and accessories

To order supplies or accessories, call 800 646 4633, +1 818 362 5958 (outside U.S.), refer to the contacts list at the beginning of this user guide, or visit our website at www.medtronicdiabetes.com.

2

First steps

First steps

This chapter gives you an overview of your pump so you can become familiar with the buttons and screens. Read this entire chapter to understand the basic features before using your pump to deliver insulin.

Your pump

The following illustration shows the different parts of your pump. The reservoir, with the tubing connector attached, is inserted into the reservoir compartment.

tubing connector

reservoir compartment

battery compartment

screen

buttons

Using the buttons

> ⚠️ **CAUTION:** Do not use sharp objects to press the buttons on your pump. The use of sharp objects can damage your pump.

The following picture shows the buttons and the notification light on your pump. The notification light flashes when your pump has an alarm or alert. The notification light is not visible unless it flashes.

The following table describes how to use the buttons.

To do this:	Follow these steps:
Display the menu.	From the Home screen, press the ◎ button.

To do this:	Follow these steps:
Scroll up or down a menu or list, or increase or decrease the value of a setting.	Press the ∧ or ∨ buttons.
Select an item on a screen or menu.	Press the ∧, ∨, ‹, or › buttons to select the desired item, and then press the ◎ button.
Enter a value into a field.	Press the ∧, ∨, ‹, or › buttons to select the desired field, and then press the ◎ button. The field you select flashes. Press the ∧ or ∨ buttons to enter the desired value, and then press the ◎ button.
Return to the previous screen.	Press the ◀ button.
Display the Home screen.	Press and hold the ◀ button to return to the Home screen.
Put the pump in sleep mode.	Press and hold the ❖ button for about two seconds. **Note:** ⏻ reminds you that you can press and hold ❖ to put the pump into sleep mode.
Wake up the pump.	Press any button.

About batteries

The pump requires one new AA (1.5 V) battery. For best results, use a new AA lithium (FR6) battery. The pump also accepts an AA alkaline (LR6) or a fully charged AA NiMH (HR6) nickel-metal hydride rechargeable battery.

CAUTION: Do not use a carbon zinc battery in your pump. Carbon zinc batteries are not compatible with the pump. Use of carbon zinc batteries can cause the pump to report inaccurate battery levels.

Carbon zinc batteries have a short shelf life, they deteriorate rapidly in cold weather, and oxidation of the zinc wall eventually causes the contents to leak out. They will not perform as well as other battery types to power the pump and may potentially damage your pump.

Note: Do not use cold batteries because the battery life may incorrectly appear as low. Allow cold batteries to reach room temperature before you insert them in your pump.

Inserting the battery

Your pump does not ship with the battery cap on. The battery cap is located in the pump box with the accessories.
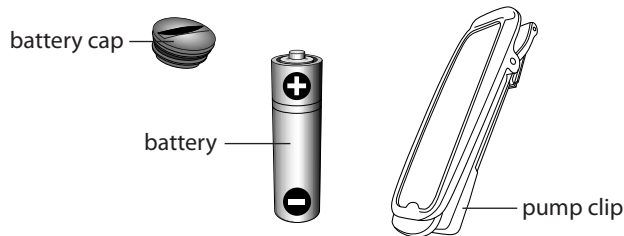
To insert the battery:

1. Insert the new or fully charged AA battery. Be sure to insert the flat end first.
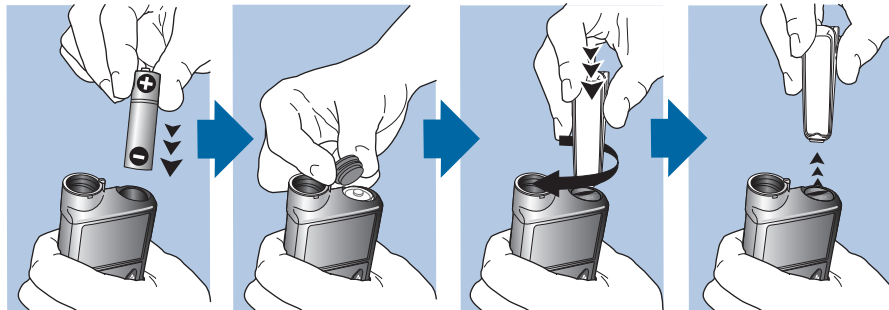
2. Place the battery cap onto the pump. Use the bottom edge of the pump clip to turn the cap to the right and tighten.

> ⚠️ **CAUTION:** Do not overtighten or undertighten the battery cap. A battery cap that is too tight can cause damage to your pump case. A battery cap that is too loose prevents detection of the new battery. Turn the battery cap clockwise until the slot in the cap is aligned horizontally with the pump case, as shown in the following example.
>
>
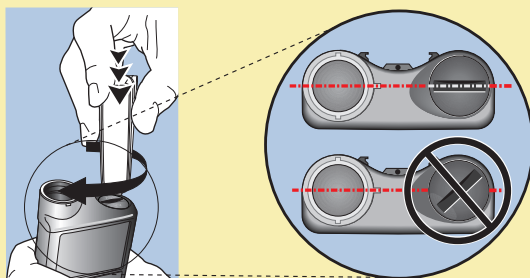
> 📝 **Note:** If this is the first time you have inserted a battery in your pump, the Startup Wizard begins. For more information about the Startup Wizard, see *Entering your startup settings, on page 43*. If this is not the first time you have inserted a battery into your pump, the Home screen appears and the pump resumes your basal insulin delivery.

Removing the battery

> ⚠️ **CAUTION:** Do not remove the battery unless you insert a new battery or store the pump. Your pump cannot deliver insulin while the battery is removed. After you remove an old battery, be sure to replace it with a new battery within 10 minutes to clear the Insert battery alarm and avoid a Power loss alarm. If power loss occurs, you must re-enter your time and date settings.

To remove the battery:

1. Before you remove a battery from your pump, clear any active alarms or alerts.

2. Use the pump clip to loosen and remove the battery cap.

> **Note:** Use your pump clip to remove and retighten the battery cap. If the pump clip is unavailable, you may use a coin.

3. Remove the battery.
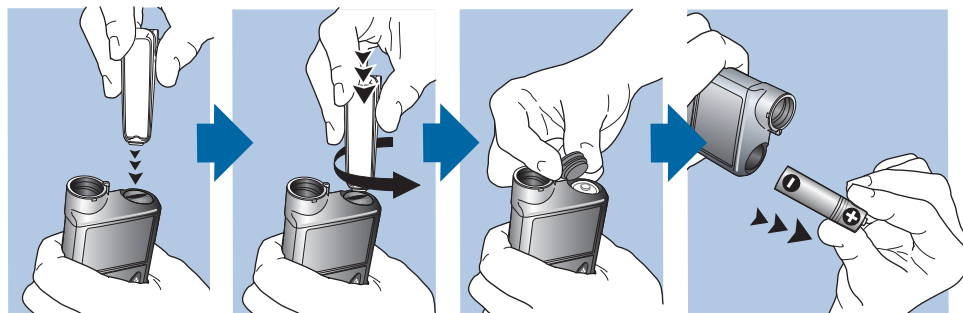
4. Dispose of old batteries according to local regulations for battery disposal (nonincineration), or contact your healthcare professional for disposal information.

5. After you remove your battery, wait until the Insert Battery screen appears before you insert a new battery.

If you remove the battery to place your pump in storage, see *Storing your pump, on page 296* for more information.

Getting to know your pump

The following section shows you how to navigate through the screens and menus on your pump. It also helps you learn how to enter information and view the status of your pump.

Entering your startup settings

Your pump has a Startup Wizard that begins when you insert your battery for the first time. You set the language, time format, current time, and the current date in the Startup Wizard.

> **Note:** Use this procedure when you enter your settings for the first time. If this is not the first time you enter your pump settings, and your pump is asking you to re-enter your settings, see *My pump is asking me to enter my settings, on page 288*.

To use the Startup Wizard:

1. The Startup Wizard begins after the Welcome screen appears. When the Select Language screen appears, select your language.

Language	
Select Language	
English	✓
中文	
Español	

2. When the Select Time Format screen appears, select a **12 Hour** or a **24 Hour** time format.

Startup 1/3
Select Time Format
12 Hour
24 Hour
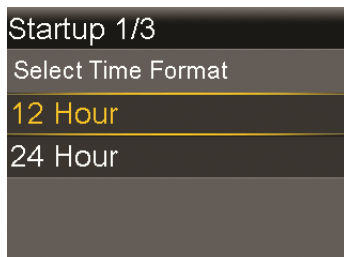
3. When the Enter Time screen appears, adjust the setting to the current time. If you use a 12-hour clock, be sure to specify AM or PM. Select **Next**.

Startup 2/3
Enter Time
Time   9:00 AM

Next

4. When the Enter Date screen appears, adjust the **Year**, **Month**, and **Day** to the current date. Select **Next**.

Startup 3/3
Enter Date
Year   2020
Month   Oct
Day   10, Sat

Next

5. A "Rewinding" message appears. The piston returns to its start position in the reservoir compartment. This may take several seconds.

Rewinding

Please wait...

6. When rewinding is complete, a message appears to confirm the startup is complete. Select **OK** to go to the Home screen.

Startup
Congratulations! Startup
Wizard complete

✓

OK
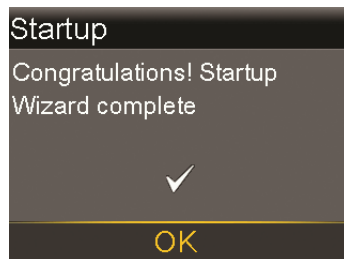
To become familiar with the buttons and screens on your pump, see the following sections in this chapter.

Unlocking your pump

Your pump automatically locks when entering sleep mode. When you wake up your pump from sleep mode, you must unlock your pump before navigating to the menu. When you press ◎, a screen appears and tells you to unlock your pump. Press the highlighted button to unlock your pump.

The selected screen appears after you press the correct button. If you press an incorrect button, the screen tells you to try again. If you press the ← button, the Home screen appears.

After your pump is unlocked, it remains unlocked until you re-enter sleep mode. For information about the different power modes, or to put your pump to sleep, see *Power modes, on page 60*.

Home screen

The Home screen appears by default after you change the battery, when you wake the pump from sleep mode, and when you are not actively using another screen.

To see what your Home screen looks like if you use a sensor, see *Home screen with CGM in Manual Mode, on page 175*.

To see what your Home screen looks like when you are in Auto Mode, see *Home screen with SmartGuard Auto Mode, on page 227*.

status icons — 9:00 AM — current time

◇BG — BG reading

mg/dL

Active Insulin 1.0 U — active insulin
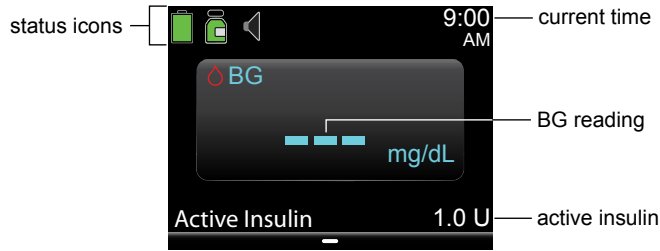
The following items appear on your Home screen:

Item	Description
Status icons	The status icons show a quick status of your pump system. For more information, see *Status icons, on page 46*.
Current time	The current time of day is shown. For details on setting the time, see *Time and date, on page 170*.
BG meter readings	The pump shows the blood glucose (BG) meter readings from your Accu-Chek Guide Link meter or the BG meter readings you have entered manually. The pump only shows BG meter readings taken within the last 12 minutes.

You can enter your BG meter reading manually using the Enter BG feature, Event Markers feature, or when you use the Bolus Wizard feature to deliver a bolus. For details on using the Bolus Wizard feature, see *Bolus Wizard feature, on page 92*. |
| Active insulin | The screen shows the amount of bolus insulin the pump estimates is still working to lower your BG levels. For more details on active insulin, see *About active insulin, on page 98*. |

Status icons

The status icons appear at the top of the Home screen to provide a way for you to quickly check the status of your system. The status icons are described in the following table. For information on viewing detailed status screens, see *Status screens, on page 52*.

Icon	Icon name	What it means
	Battery	The color and fill level of the battery icon indicate the charge level of your pump battery.

When a new battery is inserted and your battery is full, the icon is solid green . This indicates that approximately 100% of your battery capacity remains. In most cases, you can expect at least seven days of use remaining.

As the battery life is used, the icon changes from solid green in the following order . This indicates that the charge level of your battery is decreasing from 100% to 0%. The yellow icon indicates that the battery needs to be replaced soon. It is recommended that you have a new or fully charged battery available. The remaining charge level of your battery varies based on the battery type and how you use the pump.

When your battery is low, the icon has a single red bar . This indicates that under typical use you have up to 10 hours of use remaining.

When your battery needs to be replaced immediately, the icon is solid black with a red outline . This indicates you have less than 30 minutes of use remaining.

Icon	Icon name	What it means
	Reservoir	The reservoir icon shows the approximate amount of insulin left in your reservoir. The color and the fill level of the icon indicate the status. The reservoir icon is representative of the MiniMed reservoir MMT-332A, 3.0 mL (300-unit). When your reservoir is full, the icon is solid green. As your insulin is used, the icon becomes emptier, and the color of the icon changes as shown in the following example. For more information about your reservoir, see *Reservoir and infusion set* on *Setting up the reservoir and infusion set, on page 119.*

- Approximately 85%–100% of the reservoir remains.

- Approximately 71%–84% of the reservoir remains.

- Approximately 57%–70% of the reservoir remains.

- Approximately 43%–56% of the reservoir remains.

- Approximately 29%–42% of the reservoir remains.

- Approximately 15%–28% of the reservoir remains.

- Approximately 1%–14% of the reservoir remains.

- The reservoir remaining amount is unknown.

Icon	Icon name	What it means
	Audio	The audio mode you are using: vibrate only , audio only , or vibrate and audio .
		When the Alert Silence option is turned on, the audio icons appear as follows: vibrate only , audio only , or vibrate and audio .

Icon	Icon name	What it means
	Connection	The connection icon appears green when the Sensor feature is on and your transmitter is successfully communicating with your pump. The connection icon appears with a red X when the Sensor feature is turned on, but the transmitter is not connected or communication with your pump has been lost. For more information about the Sensor feature, see *Understanding CGM, on page 173*.
	Temporary network connection	The temporary network connection icon replaces the connection icon while you are temporarily connected to a remote upload device.

Icon	Icon name	What it means
	Calibration	The calibration icon indicates the approximate time left until your next sensor calibration is due. The calibration icon appears only when the Sensor feature is turned on. The color and the circle around the icon indicate the status of calibration. When your sensor is fully calibrated, the icon has a solid green circle around it. As the time for your next sensor calibration approaches, the green circle around the icon becomes smaller, and the color of the icon changes as shown in the following example. For more information about calibrating your sensor, see *Calibrating your sensor, on page 206*.

-   Time to your next sensor calibration is more than 10 hours.

-   Time to your next sensor calibration is 8 to 10 hours.

-   Time to your next sensor calibration is 6 to 8 hours.

-   Time to your next sensor calibration is 4 to 6 hours.

-   Time to your next sensor calibration is 2 to 4 hours.

-   Time to your next sensor calibration is less than 2 hours.

-   Sensor calibration is required now.

-   Time to your next sensor calibration is unavailable.

-   Sensor calibration has not completed. This occurs when a new sensor is connected or when the sensor is calibrating. This also occurs within 15 minutes of a Calibration not accepted alert.

Icon	Icon name	What it means
	Sensor life	The number in the center of the sensor life icon indicates the number of days that remain until the sensor expires. The icon appears only when the Sensor feature is turned on. When you insert a new sensor, the icon color is solid green. When one day remains until the sensor expires, the icon color turns red.
		If the number of days that remain until the sensor expires is unavailable, the sensor life icon appears with three dots .
		When the system is waiting for the sensor to be started, the sensor life icon appears with a question mark .
	Auto Mode Readiness	The Auto Mode Readiness icon indicates whether your pump is ready to enter Auto Mode. The icon appears with a loading symbol when the pump is updating a condition that requires you to wait. The icon appears with a question mark when the pump requires an action from you to enter Auto Mode. For more information about Auto Mode Readiness, see *SmartGuard Auto Mode Readiness, on page 225*.
	Block Mode	The Block Mode icon indicates that the pump is in Block Mode, and that certain functions are restricted. Caregivers, such as parents of a young child, can use Block Mode to restrict access to critical pump settings. For more information about Block Mode, see *Block Mode, on page 162*.

Using the menu

The menu is where you access the various features and functions of your system. To display the menu, press ◎ from the Home screen.

The following options are available from the menu:

Select this	Menu Indicators	To do this
Bolus	📱	Set up and deliver your bolus insulin delivery.
Enter BG	🔴	Enter your BG value.
Basal	🟢	Set up your basal insulin delivery.
Audio Options	🎵	Set your audio, vibrate, and volume options for the notifications you receive.
Status	📋	View information about your pump, any notifications you have received, your current settings, and optional sensor.
Suspend Delivery	⏸	Stop your current basal and bolus insulin delivery.
Options	⚙	Set your SmartGuard settings, reminders, delivery settings, enter event markers, view your history, and access the Utilities menu.

Status screens

The Status screens provide information about your pump, any notifications you have received, your current settings, and optional sensor. The Status screens are described in the following table:

Status screen	Displays this information
Auto Mode Readiness	A list of conditions your pump has to meet before it can enter Auto Mode. For more information on Auto Mode, see the *SmartGuard Auto Mode* chapter.

Status screen	Displays this information
Notifications	A list of alarms, alerts, and reminders that have occurred over the past 24 hours. You can display further details about a particular alarm, alert, or reminder by selecting it from the list. For more information on alarms and alerts, see the *Alarms, alerts, and messages* chapter.
Quick Status	A summary of status information, including your last bolus, last BG meter reading, current basal rate, reservoir level, and pump battery charge level. If you are using a sensor, this screen also displays the time that your next calibration is due and the status of the SmartGuard features.
Pump	The pump screen provides a detailed view of your pump status, including whether your pump is in a specific mode, the reservoir status, battery status, pump serial number, pump name, model number, and other details about your pump.
Sensor	The Sensor screen is available only if your sensor feature is turned on. The Sensor screen indicates if any alert silence options are turned on. It also shows the status of your calibrations, your sensor life, ISIG, transmitter battery, serial number and version number of your transmitter, and the status of the SmartGuard features.
Settings Review	The Settings Review screen provides a list of all your pump settings. The settings are organized by where they appear in the menu for your pump. For example, your bolus settings appear under the Insulin Settings section, and your brightness level setting appears under the Utilities section.

Viewing the Status screens

1. From the Home screen, press ◎ and select **Status** from the menu.

 The Status screen appears.

2. Press ⋀ or ⋁ to move up or down the screen. Select the status screen that you want to view. Refer to the table at the beginning of this section for a description of the different status screens.

Modes

The MiniMed 770G insulin pump includes SmartGuard technology that automatically adjusts basal insulin delivery based on sensor glucose (SG) values. These glucose sensor-enabled features include SmartGuard Suspend on low, SmartGuard Suspend before low, and SmartGuard Auto Mode. The following tables show the differences between each mode and the delivery and suspend options available.

Manual Mode

Mode CGM options	Bolus delivery options	Basal insulin delivery	Suspend options
Pump without CGM 	• Bolus Wizard feature, which uses programmed carb ratio, insulin sensitivity, BG target, and active insulin time settings. • Normal bolus • Square Wave bolus • Dual Wave bolus • Preset bolus • Easy Bolus feature For more information, see the *Bolus* chapter.	• Programmed basal insulin delivery settings—For more information, see *Basal insulin settings, on page 66.* • Temporary basal rates—For more information, see *Temp basal rates, on page 73.* • Preset temporary basal rates—For more information, see *Preset temp basal rates, on page 76.*	Manual suspend—For more information, see *Stopping and resuming your insulin delivery, on page 80.*

Mode CGM options	Bolus delivery options	Basal insulin delivery	Suspend options
Pump with CGM 	• Bolus Wizard feature, which uses programmed carb ratio, insulin sensitivity, BG target, and active insulin time settings. • Normal bolus • Square Wave bolus • Dual Wave bolus • Preset bolus • Easy Bolus feature For more information, see the *Bolus* chapter.	• Programmed basal insulin delivery settings—For more information, see *Basal insulin settings, on page 66.* • Temporary basal rates— For more information, see *Temp basal rates, on page 73.* • Preset temporary basal rates— For more information, see *Preset temp basal rates, on page 76.*	Manual suspend—For more information, see *Stopping and resuming your insulin delivery, on page 80.*

Mode CGM options	Bolus delivery options	Basal insulin delivery	Suspend options
Pump with CGM and with SmartGuard features enabled: Suspend before low or Suspend on low	• Bolus Wizard feature, which uses programmed carb ratio, insulin sensitivity, BG target, and active insulin time settings. • Normal bolus • Square Wave bolus • Dual Wave bolus • Preset bolus • Easy Bolus feature For more information, see the *Bolus* chapter.	• Programmed basal insulin delivery settings—For more information, see *Basal insulin settings, on page 66*. • Temporary basal rates— For more information, see *Temp basal rates, on page 73*. • Preset temporary basal rates— For more information, see *Preset temp basal rates, on page 76*.	• Manual suspend— For more information, see *Stopping and resuming your insulin delivery, on page 80*. • SmartGuard Suspend before low —For more information, see *SmartGuard Suspend before low, on page 181*. • SmartGuard Suspend on low—For more information, see *SmartGuard Suspend on low, on page 185*.

SmartGuard Auto Mode

	Bolus delivery options	Basal insulin delivery	Suspend options
SmartGuard Auto Mode (Auto Basal delivery)	• Auto Mode Bolus impacted by Carb Ratio and Active Insulin Time settings • Patient enters carb grams and BGs • Pump may recommend bolus when BG ≥150 mg/dL entered • Patient accepts or cancels bolus For more information, see the *SmartGuard Auto Mode* chapter.	• Automatic delivery of basal insulin based on recent insulin delivery needs and SG values to target of 120 mg/dL • May set a temporary target of 150 mg/dL for up to 12 hours For more information, see the *SmartGuard Auto Mode* chapter.	Manual suspend— For more information, see *Stopping and resuming your insulin delivery, on page 80.*

	Bolus delivery options	Basal insulin delivery	Suspend options
SmartGuard Auto Mode (Safe Basal delivery) 	• Auto Mode Bolus impacted by Carb Ratio and Active Insulin Time settings • Patient enters carb grams and BGs • Pump may recommend bolus when BG ≥150 mg/dL entered • Patient accepts or cancels bolus For more information, see the *SmartGuard Auto Mode* chapter.	• Automatic delivery of basal insulin at a fixed rate • Does not use SG values to adjust rate For more information, see the *SmartGuard Auto Mode* chapter.	Manual suspend—For more information, see *Stopping and resuming your insulin delivery, on page 80.*

Scroll bar

The scroll bar is located on the right side of the screen, as shown in the following example. It appears only when there is more information available to view on the screen. Press ∧ or ∨ to move up or down the screen.

scroll bar
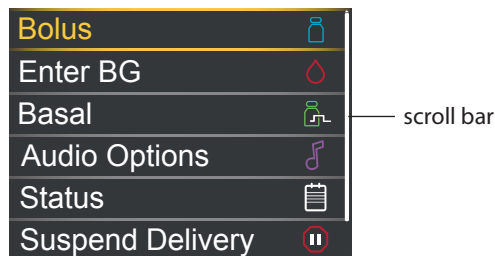
Power modes

Your pump is designed to conserve battery power when you are not actively using the pump screens.

In this mode	Your pump behaves like this
Awake	Your pump screen is on. Unless you are actively using another screen, your Home screen appears. To wake up your pump from being in power save or sleep mode, press any button. If your pump has been in sleep mode, the pump is locked. To unlock your pump, see *Unlocking your pump, on page 45*.
Power save	Your pump is fully functional, but the screen goes dark to save power. You can set how long it takes for your screen to enter power save mode with the Backlight setting. For more information, see *Display Options, on page 163*. If any button is pressed while the pump is in power save mode, the pump returns to the screen that was last displayed.
Sleep	Your pump automatically enters sleep mode when you have not pressed any buttons for about two minutes after your screen goes dark (power save mode). Your pump is still fully functional. When you press ◎, a screen appears and tells you to unlock your pump. Press the highlighted button to unlock your pump. For details, see *Unlocking your pump, on page 45*. To put your pump into sleep mode, press and hold the ❖ button for about two seconds.

If you remove your pump

You may have an occasion when you need or want to remove your pump. If you have to remove and store your pump, it is recommended that you do the following:

- Write down a record of your current basal rates and use the Save Settings feature. See *Saving your settings, on page 164* for more information.

- Remove the battery. See *Storing your pump, on page 296* for more information.

Remember, your body still needs insulin while your pump is removed.

Consult your healthcare professional to determine an alternate method of receiving insulin. Disconnecting from your pump for less than one hour may not require an insulin adjustment. If you remove your pump for more than one hour, you should take your insulin another way, as prescribed by your healthcare professional.

3

Basal

3

Basal

Basal insulin is the "background" insulin that you need throughout the day and night to maintain your target blood glucose (BG) values when you are not eating. Your basal insulin accounts for approximately one half of your daily insulin requirements. Your pump mimics a pancreas by delivering insulin continuously over 24 hours.

> **Note:** In Manual Mode, your basal insulin is delivered according to your programmed basal pattern. In SmartGuard Auto Mode, insulin is delivered based on sensor values and your recent insulin delivery needs. For more information on Manual Mode, see *Manual Mode, on page 222*. For more information on Auto Mode, see *SmartGuard Auto Mode, on page 221*.

Your basal insulin is delivered according to a basal pattern. Basal patterns and other basal settings are described in the following sections.

Basal rate

Your basal rate is the specific amount of basal insulin that your pump continuously delivers each hour. While some people use one basal rate all day, others require different rates at different times of the day.

Your basal rates are set in one or more basal patterns. Each basal pattern covers 24 hours. For specific information about basal patterns, see *Basal patterns, on page 68*.

Basal insulin settings

Your basal insulin delivery settings are described in the following table.

Setting	Description	Purpose
Basal Pattern	A basal pattern is a set of one or more basal rates that cover a 24-hour period.	A basal pattern lets you vary your basal rate according to your needs. You can set up to eight basal patterns. To set up basal patterns, see *Adding a new basal pattern, on page 69*. To start a basal pattern, see *Changing from one basal pattern to another, on page 72*.
Temp Basal	A temp basal rate is a basal rate that you use in place of your scheduled basal rate for short-term situations.	A temp basal rate lets you temporarily change your current basal rate for a duration of time that you specify. To start a temp basal rate, see *Starting a temp basal rate, on page 75*.
Preset Temp	A preset temp is a temporary basal rate that you can define ahead of time.	A preset temp lets you set and save temporary basal rates for known short-term situations, such as when you are sick or have times of increased or decreased activity. To set up a preset temp basal rate, see *Preset temp basal rates, on page 76*. To start a preset temp basal rate, see *Starting a preset temp basal rate, on page 77*.
Max Basal	The max basal rate is the maximum amount of basal insulin that your pump can deliver per hour.	The max basal rate is a safety feature that limits the total amount of basal insulin your pump can deliver per hour. To set your Max Basal rate, see *Max Basal rate, on page 67*.

Max Basal rate

Max Basal rate limits the amount of basal insulin that can be delivered per hour based on the maximum rate you set. You are unable to set any basal rates, temp basal rates, or preset temp basal rates that exceed the max basal rate amount. You can set your max basal rate from 0 to 35 units per hour. Set your max basal rate as prescribed by your healthcare professional.

> **Note:** If you set your max basal rate after you have set up your basal patterns or preset temp basal rates, you cannot set your max basal rate lower than any of your existing basal rates. You cannot access this feature during a normal bolus delivery.

To set your Max Basal rate:

1. Press ◎ and go to the Max Basal/Bolus screen.

   Options > Delivery Settings > Max Basal/Bolus

2. Select **Max Basal** to set the maximum number of basal insulin units that can be delivered each hour.

   Because the max basal rate setting determines your basal insulin limits, a Max Basal alert appears any time you enter the screen to change the value.

3. Select **Continue**.

4. In the Max Basal Rate screen, select **Max Basal** to set the maximum units per hour.

5. Select **Save**.

Example 1: Max basal rate

Helen has a very low insulin requirement. Her highest basal rate is only 0.400 units per hour. As a safety measure, Helen's healthcare professional set her pump with a max basal rate of 1.00 units per hour.

Example 2: Max basal rate

Rusty needs large amounts of insulin to control his BG levels. His new pump was delivered from the factory with a max basal rate of 2.00 units per hour, but he needs 2.80 units per hour in the early morning. Rusty plans to consult his healthcare professional about increasing his max basal rate to 3.00 units per hour to accommodate his needs.

Basal patterns

Your basal pattern determines the amount of basal insulin you receive throughout the day and night. Because your basal insulin needs can vary, you can set up to eight basal patterns. For example, you might use one basal pattern during the week and a different basal pattern during the weekend.

A basal pattern is made up of one to 48 basal rates that you set up to cover a full 24-hour period. If you only need one basal rate throughout the day, you set only one rate for the 24-hour period. If you need the basal rates to change during the day or night to better match your insulin needs, you can set more than one rate, each with a separate start and end time.

The following example represents one basal pattern with three basal rates set for three different time periods.
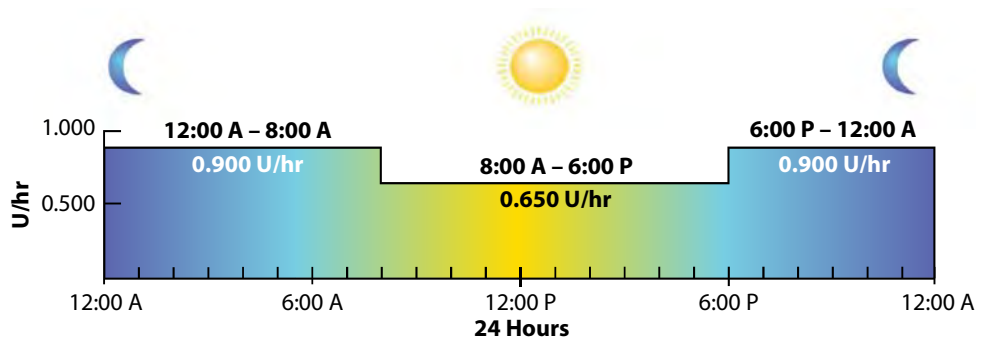
Your healthcare professional will determine what rates are right for you.

Note: If you have already set up basal patterns and want to switch from using one basal pattern to another, see *Changing from one basal pattern to another, on page 72*.

Adding a new basal pattern

This procedure shows you how to add a new basal pattern.

To add a new basal pattern:

1. Press ◎ and go to the Basal Pattern Setup screen.

   Options > Delivery Settings > Basal Pattern Setup

   The Basal Pattern Setup screen appears. Your active basal pattern appears with a check mark and the 24-hour delivery amount, as shown in the following example.

   Basal Pattern Setup
   Basal 1   0.0 U ✓
            Add New

2. If this is your first time setting up a basal pattern, the unit amount is 0.0. Select **Basal 1** and go to step 5.

   If this is not your first time setting up a basal pattern, go to step 3 to add a new pattern.
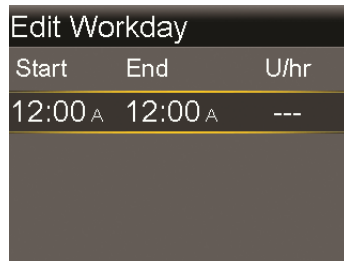
3. To add a new basal pattern, select **Add New**.

   The Select Name screen appears.

   Select Name
   Basal 2
   Workday
   Day Off
   Sick Day
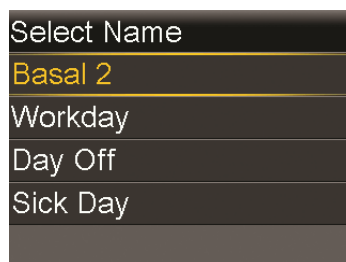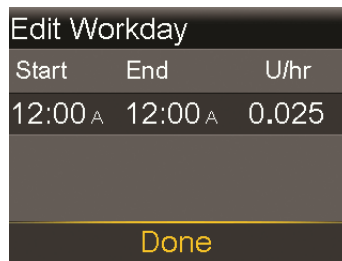
   Note: The Workday, Day Off, and Sick Day patterns are available so that you can match a basal pattern name to your insulin needs on those particular days.

4. Select a basal pattern. An edit screen appears for the pattern you selected. The following example shows the Edit Workday screen.

Edit Workday		
Start	End	U/hr
12:00 A	12:00 A	---

5. To create one continuous 24-hour basal rate for your basal pattern, continue with this step. To create more than one basal rate for your new basal pattern, go to step 6.

   a. Leave End time at 12:00 AM to set a 24-hour rate. The Start time of the first time segment is always 12:00 AM.

   b. Set your rate in units per hour.

Edit Workday		
Start	End	U/hr
12:00 A	12:00 A	0.025
	Done	

   c. Go to Step 7.

6. To create more than one basal rate for your new basal pattern, enter one basal rate at a time, as described in the following steps:

   a. Set the End time and the Rate for your first basal rate. You set your rates in 30-minute increments.

   If you set the End time to anything other than 12:00 AM, a second basal rate setting appears.

```
Edit Workday
Start       End         U/hr
12:00 A     7:30 A      0.075
 7:30 A     6:00 P       ---
```

The Start time for the next rate is always the same as the End time of the previous rate.

> **Note:** If you need to make a change, press ∧ to scroll up to the rate and adjust the End time or Rate values.
>
> Press ∧ or ∨ when a field is selected to adjust the value of that field. When there is no field selected, press ∧ or ∨ to scroll up or down the list of basal rates.

b. Continue to set rates for different time periods as needed. The End time for your last rate must be 12:00 AM, as shown in the example that follows.

```
Edit Workday
Start       End         U/hr
12:00 A     7:30 A      0.075
 7:30 A     6:00 P      0.025
 6:00 P    12:00 A      0.050
```

7. Select **Done**. The Done option appears only when the last End time in your basal pattern is set to 12:00 AM.

A screen appears that lets you review your basal pattern. If you need to make any changes, press ⬅ to return to the previous screen.

> **Note:** If you do not select **Done** and press ⬅ to return to the previous screen, your changes are not saved or implemented.

8. Select **Save**.

To activate your basal pattern, see *Changing from one basal pattern to another, on page 72*.

Editing, copying, or deleting a basal pattern

To edit, copy, or delete a basal pattern:

1. Press ◎ and go to the Basal Pattern Setup screen.

    Options > Delivery Settings > Basal Pattern Setup

    The Basal Pattern Setup screen shows all of your existing basal patterns.

2. Select the desired basal pattern.

3. Select **Options**.

4. Do any of the following:

    -   Select **Edit** to adjust the End time or rate values for one or more of the basal rates in this basal pattern.

    -   Select **Copy** to copy the basal rate information from the selected basal pattern to a new basal pattern. When the Select Name screen appears, you can select any available name from the list. Use the Edit option to adjust the new basal pattern as desired.

    -   Select **Delete** to delete the selected basal pattern. You cannot delete the active basal pattern.

Changing from one basal pattern to another

When you change to a new basal pattern, your pump delivers your basal insulin according to the basal pattern you selected.

To change to a different basal pattern:

1. Press ◎ and go to the Basal Patterns screen.

    Basal > Basal Patterns

    The Basal Patterns screen shows the basal patterns you have set up. The active basal pattern is indicated with a check mark.

2. Select the desired basal pattern.

    The Basal screen shows the details for the selected basal pattern.

3. Select **Begin**.

Example 1: Basal patterns

Ken has had his insulin pump for about a month. He tests his BG four to six times a day and records his results in his logbook. He is happy with his glucose control during the week but on the weekends, he noticed that he has to eat more food to prevent his BG from running too low.

Ken has realized that during the week while he is at work, he is very inactive and sits at a desk most of the time. On the weekends, though, he is busy with yard work, running errands, and playing with his kids. Ken plans to speak with his healthcare professional to see if he should add a different Basal Pattern to lower his basal settings to receive less insulin during active times, such as his weekends.

He can use the Basal Patterns feature to support his weekend change in activity. During the week, he can set his pump to deliver his Basal 1 pattern, and on Saturday morning, he can switch over to his Weekend pattern, which he can set with lower basal rates for the weekend. On Monday morning, he can return his pump to the Basal 1 pattern for his weekday insulin needs.

Example 2: Basal patterns

Cynthia has had diabetes for about 12 years and has been on her pump for several weeks. Every Monday, Wednesday, and Friday, Cynthia goes on a two mile walk in the morning. To prevent hypoglycemia on these days, she uses a different basal pattern. For those days, she simply switches over to Basal 2, which she has programmed with a lower set of basal rates. Before she learned to use the patterns feature, she would have to eat more food throughout the day to keep her BG at a safe level. Cynthia has also noticed that a few days prior to menstruation, her BG levels seem to rise, requiring more insulin. She has programmed a Basal 3 pattern on her pump with higher basal rates for this time.

Temp basal rates

The Temp Basal feature and Preset Temp feature allow you to set temporary basal rates to manage BG levels during short-term activities or conditions that require a basal rate different than your current one, such as an illness or a change in physical activity. You can make an immediate change to your basal insulin to a value up to your max basal rate. The period of time of your temporary basal rate can range from 30 minutes to 24 hours.

> **Note:** SmartGuard Auto Mode is not available if a temp basal rate is active. To switch your pump to Auto Mode, you must first cancel the temp basal rate. For more information on canceling a temp basal rate, see *Canceling a temp basal or preset temp basal rate, on page 79*.

About temp basal rates

A temp basal rate temporarily overrides all other basal programming. Your programmed basal pattern resumes after the temp basal rate delivery is completed or canceled.

The Temp Basal feature lets you set and start a temporary basal rate immediately. The Preset Temp feature lets you set up a temp basal rate ahead of time for known situations. You define temp basal rates and preset temp basal rates using either a percentage of your current basal pattern, or by setting a specific rate, as described in the following table.

This temp basal type:	Works like this:
Percent	Percent delivers a percentage of the basal rates programmed in your active basal pattern for the duration of the temp basal rate. The temp basal amount is rounded down to the next 0.025 units if your basal rate is set at less than 1 unit per hour, or to the next 0.05 units if your basal rate is set at more than 1 unit per hour.
	Temp basal rates can be set to deliver from 0% to 200%, twice the amount, of your scheduled basal rate. The percent amount you can use is based on the largest basal rate scheduled during the temp basal duration and is limited by your max basal rate.
Rate	Rate delivers a fixed basal insulin rate in units per hour for the duration of your temporary basal. The amount you can set is limited by your max basal rate.

To use the Temp Basal feature, see *Starting a temp basal rate, on page 75*. To use the Preset Temp Basal feature, see *Preset temp basal rates, on page 76*.

Example 1: Temp basal rates

Jessica enjoys her exercise classes, but finds that her glucose levels drop after she attends them. Jessica works with her healthcare professional to learn how to use the Temp Basal feature so that she receives a reduced percentage of her usual basal insulin while she exercises.

Starting a temp basal rate

When you start a temp basal rate, your basal insulin delivery changes to the temporary basal rate for the duration you set. When the duration is complete, your basal insulin delivery automatically returns to the active basal pattern.

To start a temp basal rate:

1. Press ◎ and go to the Temp Basal screen.

   Basal > Temp Basal

2. Set the **Duration**. The duration can be set in 15-minute increments from 30 minutes to 24 hours.

3. Select **Next**.

4. Select **Type** to select Percent or Rate.
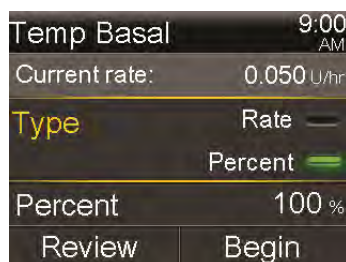
5. Depending on the Type you selected, do one of the following:

   • Enter a percentage:
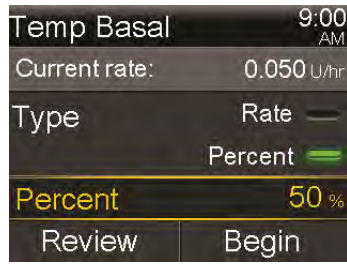
- Enter a basal rate. You cannot exceed your max basal rate.

6. If desired, select **Review** to review your temp basal setting.

7. Select **Begin** to start the temp basal rate.

   Your temp basal rate continues for the duration you set. A Temp Basal banner appears on the Home screen during your temp basal delivery. Your scheduled basal rate automatically starts again when your temp basal rate finishes.

Preset temp basal rates

The Preset Temp feature lets you set up basal rates for recurring short-term situations where you need to temporarily change your basal rate.

There are four names you can use to match your preset temp basal rate to a situation: High Activity, Moderate Activity, Low Activity, and Sick. There are also four additional preset temp rates available to use for other circumstances (Temp 1 through Temp 4).

Setting up and managing preset temp basal rates

This section describes how to set up, edit, rename, or delete a preset temp basal rate. For information on how to start using a preset temp basal rate, see *Starting a preset temp basal rate, on page 77*.

To set up a preset temp basal rate:

1. Press ◎ and go to the Preset Temp Setup screen.

2. Select **Add New**.

3. Select a name for the preset temp basal rate. For example, Temp 1, High Activity, Moderate Activity, Low Activity, or Sick.

4. Select **Type** to select Percent or Rate.

5. If you use Percent, enter a percentage. If you use Rate, enter the rate in units per hour. You cannot exceed your max basal rate.

6. Set the **Duration** for the preset temp basal rate to be active. The duration can be set in 15-minute increments from 30 minutes to 24 hours.

7. Select **Save**.

To edit, rename, or delete a preset temp basal rate:

1. Press ◎ and go to the Preset Temp Setup screen.

    Options > Delivery Settings > Preset Temp Setup

    The Preset Temp Setup screen appears. This screen shows the settings for any existing preset temp.

2. Select the desired preset temp basal rate.

    > **Note:** You cannot select a preset temp basal rate that is currently in use.

3. The next screen displays the temp basal info. Do any of the following:

    •   Select **Edit** to adjust the Type (Percent or Rate), the Percentage or Rate amount, and the Duration for the preset temp basal rate.

    •   Select **Rename** to assign a different name to the preset temp basal rate. When the Select Name screen appears, select any available name from the list.

    •   Select **Delete** to delete the preset temp basal rate.

Starting a preset temp basal rate

You must set up preset temp basal rates before you can use the Preset Temp feature. For more information, see *Preset temp basal rates, on page 76*.

To start a preset temp basal rate:

1. Press ◎ and go to the Preset Temp screen. The Preset Temp feature only appears if you have set up preset temp basal rates.

    Basal > Preset Temp

    The Preset Temp screen shows the preset temp basal rates you have set up, along with their percentage or rate amounts.

Preset Temp	5:08 PM
Current rate:	0.025 U/hr
Temp 1	**0.100 U/hr**
High Activity	25 %
Moderate...	50 %

    > **Note:** Depending on your active basal pattern, it is possible for a percentage preset temp basal rate to exceed your max basal limit. You cannot use a preset temp basal rate that exceeds your max basal limit. These rates appear grayed out in the list.

2. Select the preset temp basal rate you want to start.

3. Select **Begin**.

Temp 1		5:10 PM
0.100 U/hr for 5:00 hr		
Start	End	Temp (U/hr)
5:10 P	10:10 P	0.100
	Begin	

    Your preset temp basal rate continues for the duration you set. A Temp Basal banner appears on the Home screen during your preset temp basal delivery. Your scheduled basal rate automatically starts again when your preset temp basal rate finishes.

Canceling a temp basal or preset temp basal rate

You can cancel a temp basal or preset temp basal rate at any time. When you do so, your scheduled basal pattern automatically starts again.

To cancel a temp basal rate:

1. From the Home screen, press ◎ and go to the Temp Basal screen.
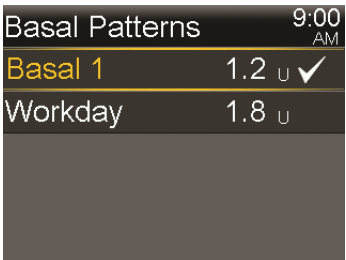
    Cancel Temp Basal > Temp Basal

    The Temp Basal screen shows the name (Preset Temp only), current basal rate, the set duration, and the remaining time.

2. Select **Cancel Temp Basal**.

Viewing your basal information

The following table describes how you can view your basal rates and patterns.

To do this:	Do this:
View your current basal rate	From the Quick Status, you can view your current basal rate. Press ◎ and go to the Quick Status screen.
	Status > Quick Status
View your basal patterns	Press ◎ and go to the Basal Patterns screen:
	Basal > Basal Patterns
	The Basal Patterns screen shows the basal patterns you have set up, and the 24-hour insulin total for each basal pattern. A check mark appears next to the active basal pattern.
	  Basal Patterns 9:00 AM Basal 1 1.2 U ✓ Workday 1.8 U
	To see the individual basal rates, select the desired basal pattern.

Stopping and resuming your insulin delivery

Use Suspend Delivery if you need to stop all active basal and bolus insulin deliveries. While your insulin delivery is suspended, your pump beeps, vibrates, or both depending on your audio settings. This reminder occurs every 15 minutes to remind you that insulin is not being delivered.

> **Note:** The first reminder occurs 15 minutes after your pump display times out. If you press a button and wake up your pump, the reminder does not occur until 15 minutes after your pump display times out again. To adjust your timeout setting, see *Display Options, on page 163*.

To continue your basal insulin delivery, use the Resume Delivery feature. Your pump starts your programmed basal pattern but does not start any previously programmed bolus deliveries.

> **Note:** If you want to stop a bolus delivery only, without stopping your basal insulin delivery, see *Stopping a bolus delivery, on page 114*.

> **WARNING:** Always check the pump Daily History after you resume insulin delivery to determine the amount that was delivered. If needed, program a new bolus or fill the cannula. A bolus delivery or fill cannula that was suspended does not restart when you resume. Failure to resume insulin delivery can result in hyperglycemia and ketoacidosis.

> **WARNING:** Do not rely solely on the audio or vibration notifications when using the Audio or Vibrate options. These notifications may not occur as expected if the speaker or vibrator in your pump malfunctions. A missed notification could result in the delivery of too much or too little insulin. This is most common when using the Easy Bolus feature, or when your pump is in Manual Suspend.
>
> **Contact 24-Hour Technical Support with any concerns.**

To suspend all insulin delivery:

1. Press ◎ and go to the **Suspend Delivery** screen.

   A confirmation message appears.

2. Select **Yes** to suspend your pump and stop all insulin delivery.

   The Home screen indicates that your insulin delivery is suspended. Your pump functions are limited until you resume your basal insulin delivery.

To resume basal insulin delivery:

1. While insulin delivery is suspended, press ◎ and go to the **Resume Delivery** screen.

   A confirmation message appears.

2. To resume your basal insulin delivery, select **Yes**. If a temp basal rate was active when you suspended your pump, it resumes if the time is still within the duration that you set.

   > **Note:** If you still need a bolus delivery that was in progress before you suspended your insulin delivery, check the Daily History screen for the actual bolus units delivered and the intended bolus amount. Then you can set up a new bolus amount as needed. See *Daily History, on page 145* for details about using the Daily History screen.

4

4 Bolus

A bolus is the amount of insulin taken to cover an expected rise in blood glucose (BG), typically when you eat a meal or snack. You can also use a bolus to correct a high BG reading.

About bolus deliveries

There are different types of bolus deliveries you can use, depending on your insulin needs at the time. There are also different ways you can deliver a bolus. Discuss these options with your healthcare professional to determine what is best for you.

Bolus types

> **Note:** While in SmartGuard Auto Mode, you can only deliver a Normal bolus.

The following table provides general information about the available bolus types.

Bolus type	Description	Purpose
Normal	Normal bolus provides a single immediate dose of insulin.	This is the typical bolus type you use to cover your food intake or to correct a high BG meter reading. For details about using the Normal bolus feature, see *Normal bolus, on page 100*.

Bolus type	Description	Purpose
Square Wave bolus	Square Wave bolus delivers a single bolus evenly over an extended period of time from 30 minutes up to 8 hours.	You might use a Square Wave bolus for the following reasons: • You have delayed food digestion due to gastroparesis or meals high in fat. • When you snack over an extended period of time. • A Normal bolus drops your BG too rapidly. For details about using the Square Wave bolus feature, see *Square Wave bolus, on page 103*.
Dual Wave bolus	Dual Wave bolus delivers a combination of an immediate Normal bolus followed by a Square Wave bolus.	You might use a Dual Wave bolus for the following reasons: • When you eat meals that are both high in carbs and fat which may delay digestion. • When your meal bolus is combined with a correction bolus for an elevated BG. For details about using a Dual Wave bolus, see *Dual Wave bolus, on page 106*.

Bolus type example

The following example shows how the different bolus types work.

86   Chapter 4
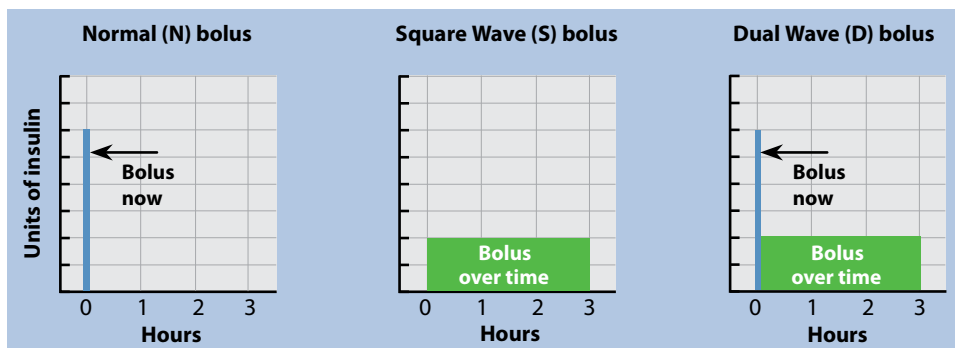
Bolus delivery options

The following table describes the different ways you can deliver a bolus.

> **Note:** Different bolus delivery options are available depending on whether the pump is in Manual Mode or Auto Mode. For a list of delivery options available for each mode, see *Modes, on page 54*.

Delivery method	Bolus types	How it works
Bolus Wizard feature	Normal bolus, Square Wave bolus, Dual Wave bolus	You enter your BG meter reading or the carbs you plan to eat, or both. Then the Bolus Wizard feature calculates an estimated bolus amount based on your individual settings.
		The Bolus Wizard feature is only available in Manual Mode.
		For details about using the Bolus Wizard feature, see *Bolus Wizard feature, on page 92*.
		Refer to the corresponding section to deliver one of the following bolus types:
		• Normal bolus using the Bolus Wizard feature, see *Delivering a Normal bolus with the Bolus Wizard feature, on page 100*.
		• Square Wave bolus using the Bolus Wizard feature, see *Delivering a Square Wave bolus with the Bolus Wizard feature, on page 104*.
		• Dual Wave bolus using the Bolus Wizard feature, see *Delivering a Dual Wave bolus with the Bolus Wizard feature, on page 107*.

Delivery method	Bolus types	How it works
Auto Mode Bolus	Normal bolus	You enter your BG meter reading or the carbs you plan to eat, or both. Then the Auto Mode Bolus feature calculates a bolus amount to cover the meal or correction.
		The Auto Mode Bolus feature is only available in Auto Mode.
		For details about using the Auto Mode Bolus feature, see *SmartGuard Auto Mode Bolus, on page 234*.
Manual	Normal bolus, Square Wave bolus, Dual Wave bolus	You do your own calculation and manually enter your bolus amount.
		Refer to the corresponding section to deliver one of the following bolus types:
		• Normal bolus, see *Delivering a Normal bolus using Manual Bolus, on page 103*
		• Square Wave bolus, see *Delivering a Square Wave bolus using Manual Bolus, on page 106*
		• Dual Wave bolus, see *Delivering a Dual Wave Bolus using Manual Bolus, on page 108*
Preset Bolus	Normal bolus, Square Wave bolus, Dual Wave bolus	You select from specific bolus settings that you define ahead of time for recurring situations.
		For details about using the Preset Bolus feature, see *Preset bolus, on page 112*.

Delivery method	Bolus types	How it works
Easy Bolus feature	Normal bolus	After the Easy Bolus feature is set up, you can deliver a Normal bolus by using the ∧ button when the pump is in sleep mode.
		For details about using the Easy Bolus feature, see *Easy Bolus feature, on page 109*.

Bolus settings

The following table describes some bolus settings that you may need to change before you use your bolus options. Consult with your healthcare professional for the settings that are right for you.

> **Note:** Additional settings are required to use the Bolus Wizard feature. These are described in the section, *Bolus Wizard feature, on page 92*.

Setting	What it is	What it does for you
Max bolus	Max bolus is the maximum amount of bolus insulin in units your pump can deliver in a single bolus.	Max bolus provides a safety feature that limits the total amount of bolus insulin you can program for a single bolus delivery.
		To set the max bolus amount, see *Max bolus, on page 90*.

Setting	What it is	What it does for you
Bolus Increment	The amount of insulin in units that is increased or decreased with each button press when adjusting your bolus amount. The Bolus Wizard feature and Auto Mode Bolus also uses the increment to display the total amount and the adjustment amount of the bolus. This setting does not apply to the Easy Bolus feature.	You can set your increment value according to your typical bolus amounts. To set the bolus increment, see *Bolus increment, on page 91*.
Bolus Speed	The speed that your pump delivers your bolus insulin.	You can set your bolus insulin delivery speed to Standard or Quick. To set your bolus speed, see *Bolus speed, on page 92*.

Max bolus

The Max Bolus setting limits the amount of insulin that can be delivered in a single bolus. Your pump prevents single bolus insulin deliveries that exceed the max bolus you set. You can set your max bolus from 0 to 25 units. Set your max bolus as prescribed by your healthcare professional.

If you set your max bolus after you have set up your Preset Bolus deliveries, you cannot set your max bolus lower than any of your Preset Bolus amounts.

The max bolus setting applies to both Manual Mode and Auto Mode.

To set your max bolus:

1. Press ◎ and go to the Max Basal/Bolus screen.

    Options > Delivery Settings > Max Basal/Bolus

2. Select **Max Bolus**.

3. Because the max bolus setting determines your bolus insulin limit, a Max Bolus alert appears any time you go to the screen to change the value. To continue to the Max Bolus screen, select **Continue**.

4. Select **Max Bolus**, and then set the maximum number of insulin units your pump can deliver in one bolus.

5. Select **Save**.

Example 1: Max bolus

Shelby takes very small doses of insulin for her meal boluses. As a safety limit, her healthcare professional had her reset her pump with a max bolus of 5.0 units.

Example 2: Max bolus

David is a growing teenager. He loves to eat big meals and requires very large doses of insulin for his food. David's healthcare professional had him reset his pump with a max bolus of 20.0 units so he can take more insulin when needed.

Bolus increment

The Bolus Increment setting determines the number of units that are increased or decreased with each button press when you adjust your bolus delivery amount in the Bolus Wizard, Manual Bolus, and Preset Bolus screens. Depending on your typical bolus amount, you can set your increment to 0.1 units, 0.05 units, or 0.025 units.

> **Note:** The Easy Bolus feature uses a setting called Step Size to determine the number of insulin units for each button press. See *Setting up the Easy Bolus feature, on page 110* for more information.

To set your bolus increment:

1. Press ◎ and go to the Bolus Increment screen.

   Options > Delivery Settings > Bolus Increment

2. Select **Increment** to set your desired increment value.

3. Select **Save**.

Bolus speed

The Bolus Speed setting sets the rate at which your pump delivers bolus insulin. You can set a Standard rate (1.5 units per minute), or a Quick rate (15 units per minute).

To set your bolus speed:

1. Press ◎ and go to the Bolus Speed screen.

   Options > Delivery Settings > Bolus Speed

2. Select **Standard** or **Quick**.

3. Select **Save**.

Bolus Wizard feature

The Bolus Wizard feature uses your individual Bolus Wizard settings to calculate an estimated bolus amount based on the BG values and carbs that you enter. Work with your healthcare professional to define your personal settings, which include your carb ratio, insulin sensitivity, BG target range, and active insulin time.

> **WARNING: Do not use Alternative Site Testing to make insulin dosing calculations.**

> **Note:** If you do not know how to count carbs, consult with your healthcare professional before using the Bolus Wizard feature.

After you set up the Bolus Wizard feature, you can use it to calculate and deliver a food bolus, a correction bolus, or a food plus correction bolus using a Normal bolus (see *Delivering a Normal bolus with the Bolus Wizard feature, on page 100*), Square Wave bolus (see *Delivering a Square Wave bolus with the Bolus Wizard feature, on page 104*), or Dual Wave bolus (see *Delivering a Dual Wave bolus with the Bolus Wizard feature, on page 107*).

The following sections describe how to set up the Bolus Wizard feature. Bolus delivery instructions are provided in the individual sections for each bolus type.

Understanding your Bolus Wizard settings

Your pump tells you to enter the following settings when you first turn on the Bolus Wizard feature. Get your prescribed settings from your healthcare professional, and always consult your healthcare professional before you change your settings. The setup procedure begins on *page 94*.

Setting	Description
Carb Ratio	The carb ratio setting is used for food bolus calculations.
	The number of carb grams that are covered by 1 unit of insulin.
Insulin Sensitivity Factor	The insulin sensitivity factor setting is used to calculate correction bolus amounts.
	Your insulin sensitivity factor is the amount that BG is reduced by one unit of insulin.
BG Target	The Bolus Wizard feature calculates your estimated bolus based on your BG target range. The high and low values you set are the values to which your BG is corrected. To use a single target value rather than a range, set the same value for the high and low value of your BG target.
	If your BG value is above the high target value, a correction dose is calculated. If your BG value is below the low target value, a negative correction is calculated and subtracted from your food bolus.
Active Insulin Time	Active insulin is the bolus insulin that has been delivered by the pump and is still working to lower your BG levels. Active insulin time is the length of time that bolus insulin is tracked as active insulin.
	Work with your healthcare professional to get the active insulin time that best represents the insulin type you use and your physiological insulin absorption rate.
	For more information about how the Bolus Wizard feature uses your active insulin amount, see *About active insulin, on page 98*.

Setting up the Bolus Wizard feature

Before you can use the Bolus Wizard feature to calculate a bolus, you must turn on the Bolus Wizard feature and enter your Bolus Wizard settings.

To set up the Bolus Wizard feature:

1. Press ◎ and go to the Bolus Estimate Setup screen.

    Options > Delivery Settings > Bolus Estimate Setup

    The Bolus Estimate Setup screen appears with the Bolus Wizard feature turned off.
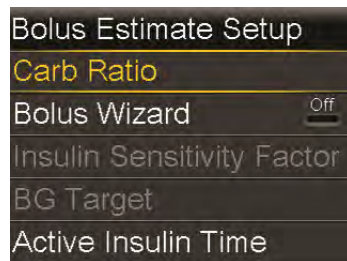
2. Select **Bolus Wizard** to turn on the feature.

    If this is the first time you have turned on the Bolus Wizard feature, your pump displays information about the settings you need to enter.
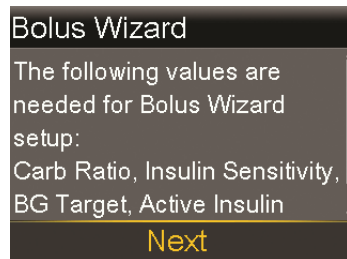
    Make sure you have the values you need, and then select **Next** to continue.

    > **Note:** As you enter your personal settings, your pump displays information about each setting. Select **Next** to continue when you have read each explanation.

3. When the Edit Carb Ratio screen appears, enter your carb ratio. You can set up to eight carb ratios using different time segments. The time segments must cover a 24-hour period.

Edit Carb Ratio 1/4

Start	End	g/U
12:00 A	12:00 A	---
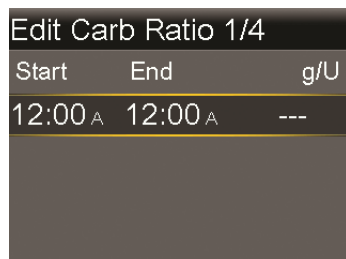
If your ratio value is outside the range of 5 to 50 grams per unit, a message appears asking you to confirm your setting.

4. When the Edit Sensitivity screen appears, enter your insulin sensitivity factor. You can set up to eight different sensitivity factors using different time segments. The time segments must cover a 24-hour period.

Edit Sensitivity 2/4

Start	End	mg/dL per U
12:00 A	12:00 A	---
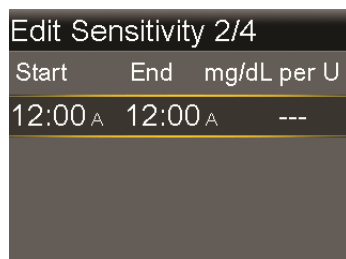
If the value you enter is outside the range of 20 to 100 mg/dL per U, a message appears asking you to confirm your setting.

5. When the Edit BG Target screen appears, enter your Bolus Wizard BG target range. You can set up to eight different BG target ranges using different time segments. The time segments must cover a 24-hour period.

Edit BG Target 3/4

Start	End	Lo-Hi (mg/dL)
12:00 A	12:00 A	--- - ---

If your Bolus Wizard BG target is outside the range of 90 to 140 mg/dL, a message appears asking you to confirm your setting.

6. When the Active Insulin Time screen appears, enter your active insulin time value. The default is four hours.
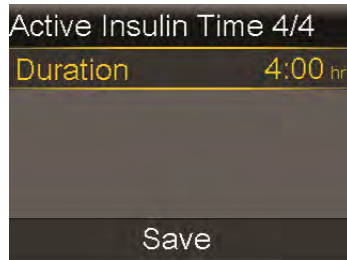
7. Select **Save**.

A message appears letting you know the Bolus Wizard setup is complete.

You can now use the Bolus Wizard feature to calculate a bolus.

Changing your Bolus Wizard settings

This section shows you how to make changes to your personal settings after you initially set up the Bolus Wizard feature. Except for the carb ratio setting, these settings are available only if the Bolus Wizard feature is turned on. Always consult with your healthcare professional before you make changes to your personal settings.

Changing your carb ratio

The carb ratio setting is always available whether or not you have the Bolus Wizard feature turned on.

To change your carb ratio:

1. Press ◎ and go to the Carb Ratio screen.

   Options > Delivery Settings > Bolus Estimate Setup > Carb Ratio

2. Select **Edit**.

3. Select the carb ratio to adjust the Start time, the End time, and the ratio. You can set up to eight different carb ratios using different time segments. The time segments must cover a 24-hour period.

If you set a value outside the typical range of 5 to 50 grams per unit, a screen appears and tells you to confirm your setting.

4. Select **Save** after you make your changes.

Changing your insulin sensitivity factor

The insulin sensitivity factor option is only available if the Bolus Wizard feature is turned on.

To change your insulin sensitivity factor:

1. Press ◎ and go to the Sensitivity screen.

   Options > Delivery Settings > Bolus Estimate Setup > Insulin Sensitivity Factor

2. Select **Edit**.

3. Select the insulin sensitivity factor to adjust the Start time, the End time, and the Sensitivity amount. You can set up to eight different sensitivity amounts using different time segments. The time segments must cover a 24-hour period.

   If you set a value that is outside the typical range of 20 to 100 mg/dL per unit, a screen appears and tells you to confirm your setting.

4. Select **Save** after you make your changes.

Changing your Bolus Wizard BG target

Your target range can be from 60 to 250 mg/dL. The Bolus Wizard BG target option is only available if the Bolus Wizard feature is turned on.

To change your Bolus Wizard BG target range:

1. Press ◎ and go to the BG Target screen.

   Options > Delivery Settings > Bolus Estimate Setup > BG Target

2. Select **Edit**.

3. Select the BG target to adjust the Start time, the End time, and the Lo (low) and Hi (high) BG Target values. Your high value cannot be less than your low value. You can set up to eight different values using different time segments. The time segments must cover a 24-hour period.

If your BG target is outside the typical range of 90 to 140 mg/dL, a screen appears and tells you to confirm your setting.

4. Select **Save** after you make your changes.

Changing your active insulin time

The active insulin time setting lets the pump know which active insulin time to use in calculating the amount of active insulin to subtract before estimating a bolus. Your healthcare professional prescribes the active insulin time that is best for you.

To change your active insulin time:

1. Press ◎ and go to the Active Insulin Time screen.

   Options > Delivery Settings > Bolus Estimate Setup > Active Insulin Time

2. Select **Duration**, and then adjust your active insulin time in hours, using 15-minute increments.

3. Select **Save**.

Turning off the Bolus Wizard feature

You can turn off the Bolus Wizard feature at any time. Your Bolus Wizard settings remain in your pump. When the Bolus Wizard feature is turned off, the Bolus Wizard option does not appear in the Bolus menu, and you cannot edit your Insulin Sensitivity Factor or BG Target settings from the Bolus Estimate Setup screen.

To turn off the Bolus Wizard feature:

1. Press ◎ and go to the Bolus Estimate Setup screen.

   Options > Delivery Settings > Bolus Estimate Setup

2. Select **Bolus Wizard** to turn the feature off.

About active insulin

Active insulin is the bolus insulin that has already been delivered to your body and is still working to lower your BG levels. The pump uses your active insulin time setting to determine if any active insulin is still in your body from prior boluses. This may help prevent hypoglycemia caused by overcorrection of high BG.

Your current active insulin amount displays on the Home screen and includes only the bolus insulin you already received.

When you use the Bolus Wizard feature, the Bolus Wizard calculator uses your current active insulin value to determine if there is an active insulin adjustment needed. The active insulin adjustment calculation considers both the bolus insulin that has previously been delivered (the amount shown on the Home screen), as well as any insulin that will be delivered by an active Square Wave bolus.

> ⚠️ **WARNING: Do not use the Bolus Wizard feature to calculate a bolus for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in the active insulin amount. Therefore, the Bolus Wizard feature could prompt you to deliver more insulin than needed. Too much insulin can cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you can rely on the active insulin calculation of the Bolus Wizard feature.**

Bolus Wizard feature alerts

When you use the Bolus Wizard feature, there may be times when you see one of the following:

Alert:	What it means:	What to do:
High BG	Your BG meter reading is above 250 mg/dL.	• Check infusion set. • Check ketones. • Consider an insulin injection. • Monitor your BG.
Low BG	Your BG meter reading is below 70 mg/dL.	Treat your low BG. Do not give yourself a bolus until your BG returns to normal.

Alert:	What it means:	What to do:
Max Bolus exceeded	The bolus amount exceeds your Max Bolus setting.	Check the bolus amount. Select **No** to cancel, or **Yes** to continue. If you select Yes, the bolus amount is reduced to your max bolus limit.
		Let your healthcare professional know if you routinely receive the Max Bolus exceeded alert so they can adjust your pump settings.

Normal bolus

A Normal bolus provides a single immediate dose of insulin. Use a Normal bolus to cover your food intake or to correct a high BG meter reading.

You cannot access the Reservoir & Tubing, Delivery Settings, or Sensor Settings menu options during a Normal bolus delivery.

> **Note:** Your pump lets you deliver a Normal bolus while a Square Wave bolus or the Square portion of a Dual Wave bolus is being delivered.

Delivering a Normal bolus with the Bolus Wizard feature

To deliver a Normal bolus using the Bolus Wizard feature:

1. For a correction bolus or a food bolus with a correction, use your BG meter to check your BG. For a food bolus only, go to step 2.

2. Press ◎ and go to the Bolus Wizard screen.

   Bolus > Bolus Wizard

The Bolus Wizard screen shows your current BG meter reading, if applicable, and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 98.* For more information about the meter, see *About your Accu-Chek Guide Link meter, on page 135.*

Bolus Wizard		9:00 AM
BG	**130** mg/dL	0.2 u
Active Ins. adjust.		-0.2 u
Carbs	**0** g	0.0 u
Bolus		0.0 u
	Next	

3. If you are not using a paired meter, you can select **BG** to manually enter your BG meter reading.

> **Note:** If you choose not to enter a BG value, three dashes appear on the screen in place of the BG value.

4. For a food bolus, select **Carbs** to enter the carb count of your meal. For a correction bolus where no food was eaten, leave the Carbs value at 0.

5. Your calculated bolus appears in the Bolus field.

Bolus Wizard		9:00 AM
BG	**130** mg/dL	0.2 u
Active Ins. adjust.		-0.2 u
Carbs	**35** g	1.4 u
Bolus		**1.4** u
	Next	
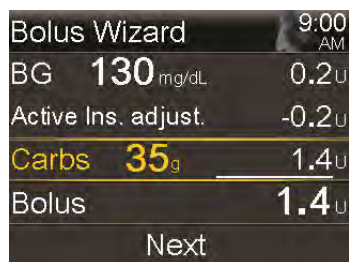
If a change to the bolus amount is needed, select **Bolus**. If you change your bolus amount, the word "Modified" appears next to the new bolus amount.
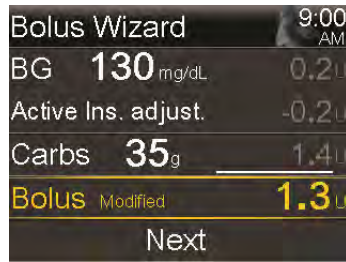
6. Select **Next** to review your bolus information.

   Your bolus amount appears.

> 📝 **Note:** If you modified your bolus amount in the previous step, **Bolus Calculated** shows your original bolus amount, **Modification** shows the amount you added or subtracted from your bolus, and **Bolus** shows the actual bolus amount.
>
>
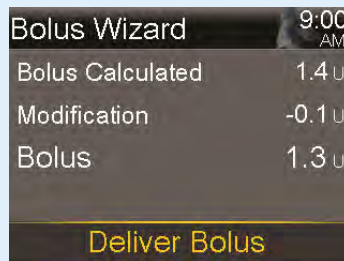
7. Select **Deliver Bolus** to start your bolus.

   Your pump beeps or vibrates and a message appears when your bolus starts. The Home screen shows your bolus amount as it is being delivered. Your pump beeps or vibrates when your bolus is complete.

Delivering a Normal bolus using Manual Bolus

The following procedure describes how to deliver a Normal bolus using the Manual Bolus feature.

To deliver a Normal bolus using Manual Bolus:

1. Press ◎ and go to the Manual Bolus screen.

   Bolus > Manual Bolus

   > **Note:** If the Bolus Wizard feature is turned off, the Manual Bolus screen appears when you select Bolus.
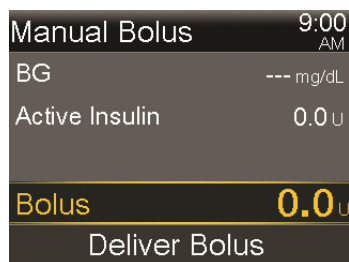
   The Manual Bolus screen shows your current BG value, if applicable, and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 98*.

2. Select **Bolus** to set your bolus delivery amount in units.

3. Select **Deliver Bolus** to start your bolus.

   Your pump beeps or vibrates and a message appears when your bolus starts. The Home screen shows your bolus amount as it is being delivered. Your pump beeps or vibrates when your bolus is complete.

Square Wave bolus

A Square Wave bolus delivers a bolus evenly over a period of time from 30 minutes up to 8 hours.

When using the Bolus Wizard feature, a Square Wave bolus is available only when giving a food bolus without a correction for an elevated BG. A Square Wave bolus is not available for a correction bolus alone or a correction bolus with food bolus.

A Square Wave bolus can be useful in the following situations:

- You have delayed food digestion due to gastroparesis or meals high in fat.

- When you snack over an extended period of time.

- A Normal bolus drops your BG too rapidly.

Since the Square Wave bolus extends delivery over a period of time, the insulin is more likely to be available as you need it.

> **Note:** You cannot perform the following functions during a Square Wave bolus delivery:
>
> - Enable Auto Mode.
>
> - Change the Max Bolus or the Active Insulin Time settings.
>
> - Set a second Square Wave or a Dual Wave bolus.
>
> - Turn off the Dual Wave or Square Wave options.
>
> - Fill the cannula.
>
> - Rewind your pump.
>
> - Run a self test.
>
> - Access the Manage Settings menu.
>
> All other functions are available during the Square Wave bolus.

Turning on or off the Square Wave bolus feature

You can deliver a Square Wave bolus only after you turn on the Square Wave bolus feature.

To turn on or turn off the Square Wave bolus feature:

1. Press ◎ and go to the Dual/Square screen.

   Options > Delivery Settings > Dual/Square Wave

2. Select **Square Wave** to turn the feature on or off.

3. Select **Save**.

Delivering a Square Wave bolus with the Bolus Wizard feature

You can deliver a Square Wave bolus with the Bolus Wizard feature only after you turn the Square Wave option on. Also, you must have entered a value for your carbs.

To deliver a Square Wave bolus with the Bolus Wizard feature:

1. Press ◎ and go to the Bolus Wizard screen.

    Bolus > Bolus Wizard

    The Bolus Wizard screen shows your current BG meter reading, if applicable, and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 98.* For more information about the meter, see *About your Accu-Chek Guide Link meter, on page 135.*

2. If you are not using a paired meter, you can select **BG** to manually enter your BG meter reading.

    > **Note:** If you choose not to enter a BG meter reading, three dashes appear on the screen instead.

3. Select **Carbs** to enter the amount of carbs in your food.

4. Review your calculated bolus amount in the Bolus field. If you want to change the bolus amount, select **Bolus** and make your desired change. Remember, if there is a correction bolus amount calculated, you are not able to give a Square Wave bolus.

    > **Note:** If you change your bolus amount, the word "Modified" appears next to the new bolus amount.

5. Select **Next** to review your bolus information.

6. Select **Square**.

    The Bolus Wizard screen appears with your bolus amount.

7. Select **Duration** to adjust the time period over which you want your Square Wave bolus to be delivered. The duration can be set in 15-minute increments from 30 minutes to 8 hours.

8. Select **Deliver Bolus** to start your bolus.

During a Square Wave bolus delivery, the Square Bolus banner displays on your Home screen until bolus delivery is complete. You can press ◎ and select **Bolus** to stop the bolus, to see details on the insulin that has been delivered, or to access the Bolus menu.

Delivering a Square Wave bolus using Manual Bolus

The Square Wave bolus option is available in the Manual Bolus screen only after you turn on the Square Wave feature.

To deliver a Square Wave bolus manually:

1. Press ◎ and go to the Manual Bolus screen.

    Bolus > Manual Bolus

2. Set your bolus delivery amount in units, and then select **Next**.

3. Select **Square**.

4. Select **Duration** to adjust the time period over which you want your Square Wave bolus to be delivered. The duration can be set in 15-minute increments from 30 minutes to 8 hours.

5. Select **Deliver Bolus** to start your bolus.

    During a Square Wave bolus delivery, the Square Bolus banner displays on your Home screen until bolus delivery is complete. You can press ◎ and select **Bolus** to stop the bolus, to see details on the insulin that has been delivered, or to access the Bolus menu.

Dual Wave bolus

The Dual Wave bolus feature meets both immediate and extended insulin needs by delivering a combination of an immediate Normal bolus followed by a Square Wave bolus.

A Dual Wave bolus can be useful in these situations:

*   When you need to correct an elevated BG before a meal, and you also need a delayed bolus for food that is absorbed slowly.

*   When you eat meals with mixed nutrients, such as carbs, fats and proteins, that are absorbed at different rates.

Turning on or off the Dual Wave bolus feature

You can deliver a Dual Wave bolus only after you turn on the Dual Wave bolus feature.

To turn on or turn off the Dual Wave bolus feature:

1. Press ◎ and go to the Dual/Square screen.

   Options > Delivery Settings > Dual/Square Wave

2. Select **Dual Wave** to turn the feature on or off.

3. Select **Save**.

Delivering a Dual Wave bolus with the Bolus Wizard feature

You can deliver a Dual Wave bolus with the Bolus Wizard feature only after you turn on the Dual Wave bolus feature.

To deliver a Dual Wave bolus with the Bolus Wizard feature:

1. For a correction bolus or a food bolus with a correction, use your BG meter to check your BG. For a food bolus only, go to step 2.

2. Press ◎ and go to the Bolus Wizard screen.

   Bolus > Bolus Wizard

   The Bolus Wizard screen shows your current BG meter reading, if applicable, and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 98*. For more information about the meter, see *About your Accu-Chek Guide Link meter, on page 135*.

3. If you are not using a paired meter, you can select **BG** to manually enter your BG meter reading.

   > **Note:** If you choose not to enter a BG value, three dashes appear on the screen in place of the BG value.

4. For a food bolus, select **Carbs** to enter the carb count of your meal. For a correction bolus where no food was eaten, leave the Carbs value as 0.

5. Review your calculated Bolus amount. If you want to change the amount, select **Bolus** and make your desired change.

6. Select **Next** to review your bolus information.

7. Select **Dual**.

   The Bolus Wizard screen appears, with the food bolus amount split evenly between the Now and Square portions.

8. If you need to change the amounts, select the area of the screen with the Now value and adjust the **Now** amount.

   When you adjust the Now amount, the Square amount adjusts automatically.

Bolus Wizard		9:00 AM
Bolus		1.8 u
Now	28 %	0.5 u
Square	72 %	1.3 u
Duration		3:00 hr
Deliver Bolus		

9. Adjust the **Duration** over which you want the Square Wave bolus portion to be delivered. The duration can be from 30 minutes to 8 hours.

10. Select **Deliver Bolus** to start your bolus.

    During a Dual Wave bolus delivery, the Home screen shows the progress of the Now portion of your delivery. When the Now portion is complete, the Dual Bolus banner displays until bolus delivery is complete. You can press ◎ and select **Bolus** to stop the bolus, to see details on the amount of bolus insulin delivered, or to access the Bolus menu.

Delivering a Dual Wave Bolus using Manual Bolus

You can deliver a Dual Wave bolus from the Manual Bolus screen only after you turn on the Dual Wave bolus feature.

To deliver a Dual Wave bolus using Manual Bolus:

1. Press ◎ and go to the Manual Bolus screen.

   Bolus > Manual Bolus

The Manual Bolus screen appears.

2. Set your bolus delivery amount in units, and then select **Next**.

3. Select **Dual**.

The Manual Bolus screen appears, with the Now and Square portions split evenly.

Manual Bolus		9:00 AM
Bolus		0.8 U
Now	50 %	0.4 U
Square	50 %	0.4 U
Duration		0:30 hr
Deliver Bolus		

4. If you need to change the amounts, select the area of the screen with the Now value and adjust the **Now** amount. When you adjust the Now amount, the Square amount adjusts automatically.

5. Adjust the **Duration** over which you want the Square Wave bolus portion to be delivered. The duration can be from 30 minutes to 8 hours.

6. Select **Deliver Bolus** to start your bolus.

During a Dual Wave bolus delivery, the Home screen shows the progress of the Now portion of your delivery. When the Now portion is complete, the Dual Bolus banner displays until bolus delivery is complete. You can press ◎ and select **Bolus** to stop the bolus, to see details on the amount of bolus insulin delivered, or to access the Bolus menu.

Easy Bolus feature

The Easy Bolus feature lets you quickly deliver a Normal bolus using only the ∧ button. Your pump must be in sleep mode to use the Easy Bolus feature.

Before you use the Easy Bolus feature, you must turn on the feature and set the step size. The step size determines the number of units the bolus amount increases each time you press the ∧ button. Your Easy Bolus delivery is limited to 20 steps or your max bolus limit, whichever comes first.

To help you count your Easy Bolus steps, each time you press the ⌃ button, your pump makes a different tone. There are five different tones that repeat in a pattern for every five steps you use. If your audio options are set to Vibrate only, the pump does not beep at all, and instead it vibrates once with each key press.

Understanding the Easy Bolus step sizes

When you set up the Easy Bolus feature, you can set the step size from 0.1 to 2.0 units. Your step size cannot be higher than your max bolus. Set the step size to a number that makes it easy for you to calculate your bolus amount.

The following example shows how your bolus amount is increased with each step or each press of the ⌃ button when using the Easy Bolus feature to deliver a bolus. In this example, the step size is 0.5 units. For a delivery of 2.0 units, you need four steps. Press the ⌃ button four times when using the Easy Bolus feature.

Total number steps = 4
Total number button presses = 4
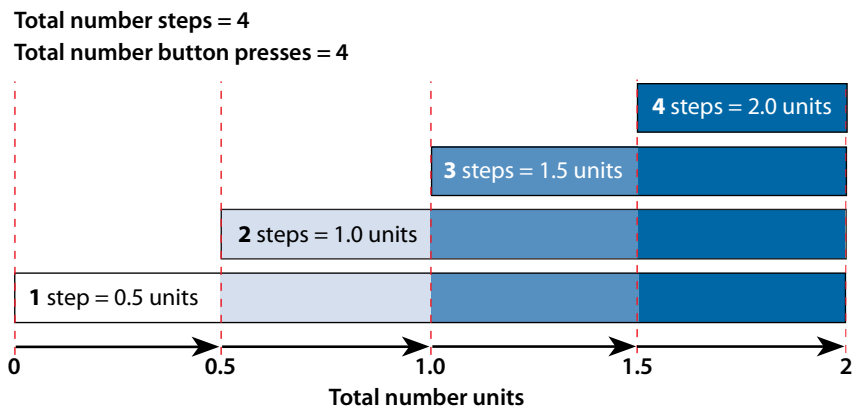
Setting up the Easy Bolus feature

The Easy Bolus option is available only after you turn on the Easy Bolus feature.

To set up the Easy Bolus feature:

1. Press ◎ and go to the Easy Bolus screen.

   Options > Delivery Settings > Easy Bolus

2. Select **Easy Bolus** to turn on the feature.

3. Set the **Step Size** amount in units. You can set the step size from 0.1 to 2.0 units. Your step size cannot be higher than your max bolus.

4. Select **Save**.

Delivering a bolus using the Easy Bolus feature

Initially, use the Easy Bolus feature while you look at the pump screen as you count the tones or vibrations.

> ⚠️ **WARNING: Never rely on beeps or vibrations alone while using the Easy Bolus feature. Always confirm your insulin delivery by looking at your pump screen. When using the Audio or Vibrate options, it is possible that an audio or vibration notification may not occur as expected if the speaker or vibrator in your pump malfunctions. Relying on beeps or vibrations while using the Easy Bolus feature could result in over delivery of insulin.**

To use the Easy Bolus feature, your pump must be in sleep mode. Your pump automatically goes into sleep mode two minutes after the screen turns off. Press and hold the ❖ button for about two seconds to manually put your pump into sleep mode.

To deliver a bolus using the Easy Bolus feature:

1. While your pump is in sleep mode, press and hold ∧ for about one second. After your pump beeps or vibrates, release ∧. You can now start to program your bolus with the Easy Bolus feature.

   > **Note:** If your pump does not respond when you press ∧, it may not be in sleep mode, even if the screen is dark.

2. Press ∧ the number of times needed to set your bolus amount.

   Each time you press ∧, your pump makes a tone or vibrates, and your bolus amount increases by the number of units set for the step size.

   > **Note:** You cannot use ∨ to select the Easy Bolus values. Pressing ∨ cancels the Easy Bolus delivery.

3. When you reach the desired bolus amount, press and hold ⋀ to confirm the amount. Your pump beeps or vibrates for each button press. Count to ensure the amount is correct. If the amount is incorrect, press and hold ⋁ until you hear a tone, and then start again from step 1.

4. When the bolus amount is confirmed, press and hold ⋀ for about one second to deliver your bolus. Your pump beeps or vibrates. Your bolus starts immediately after the confirmation.

> **Note:** If you do not start your bolus within 10 seconds, the bolus is canceled and a message appears to notify you that your bolus was not delivered.

Preset bolus

The Preset Bolus feature lets you set up in advance bolus deliveries you expect to use frequently. There are four preset bolus names that let you match a bolus to a meal with a known carb content: Breakfast, Lunch, Dinner, and Snack. There are four additional preset bolus names you can set for other circumstances. These are numbered from Bolus 1 to Bolus 4.

> **Note:** To set up a Dual Wave bolus or Square Wave bolus, the Dual Wave bolus or Square Wave bolus feature must be turned on.

Setting up and managing preset bolus deliveries

To set up preset bolus amounts:

1. Press ◎ and go to the Preset Bolus Setup screen.

    Options > Delivery Settings > Preset Bolus Setup

    The Preset Bolus Setup screen appears and shows any existing Preset Bolus settings.

2. Select **Add New**.

    The Select Name screen appears with the available Preset Bolus names.

3. Select a preset bolus.

The Edit screen for that particular preset bolus appears.

4. Select **Bolus** to set the bolus amount.

5. Select **Type** to set this as a Normal bolus, Square Wave bolus, or Dual Wave bolus.

> **Note:** The **Type** field appears only when you have the Dual Wave bolus or Square Wave bolus features turned on.

If you set the type to Square Wave or Dual Wave, do the following:

- For a Square Wave bolus, set the **Duration** of time for the bolus delivery.

- For a Dual Wave bolus, adjust the **Now/Square** percentages as needed, and then set the **Duration** of time for the Square Wave portion of the bolus.

> **Note:** If you later turn off the Dual Wave bolus or Square Wave bolus feature, your existing Preset Bolus settings are still available for use.

6. Select **Save**.

Editing, renaming, or deleting a preset bolus

You cannot delete, rename, or edit a preset bolus during preset bolus delivery.

> **Note:** You can only edit a Dual Wave Preset Bolus or Square Wave Preset Bolus when the Dual Wave bolus or Square Wave bolus features are turned on.

To edit, rename, or delete a preset bolus:

1. Press ◎ and go to the Preset Bolus Setup screen.

   Options > Delivery Settings > Preset Bolus Setup

   The Preset Bolus Setup screen appears and shows any existing Preset Bolus settings.

2. Select the preset bolus you want to change.

3. Select **Options**.

4. Do any of the following:

   - Select **Edit** to adjust the Bolus value and Type, if applicable. If you change to a Square Wave bolus, enter the Duration. If you change to a Dual Wave bolus, enter the Now and Square amounts, and the Duration.

   - Select **Rename** to assign a different name to this preset bolus. When the Select Name screen appears, select any available name from the list.

   - Select **Delete** to delete this preset bolus.

Delivering a preset bolus

You must set up preset bolus deliveries before you can use the Preset Bolus feature. For more information, see *Setting up and managing preset bolus deliveries, on page 112*.

To deliver a preset bolus:

1. Press ◎ and go to the Preset Bolus screen.

   Bolus > Preset Bolus

   The Preset Bolus screen shows your current BG value, if applicable, and any insulin that is still active from previous boluses. For more information about active insulin, see *About active insulin, on page 98*.

2. Select the preset bolus you want to deliver.

3. Review your bolus amounts, and then select **Deliver Bolus**.

   Your pump displays a progress bar on the Home screen when your bolus starts. The pump beeps or vibrates when delivery starts and when delivery finishes.

Stopping a bolus delivery

The following procedures describe how to stop a Normal bolus or a Dual Wave bolus during the Now portion delivery. The procedures also describe how to stop a Square Wave bolus or a Dual Wave bolus during the Square portion delivery.

> **Note:** If you need to stop all insulin delivery, use the Suspend Delivery feature (press ◎ and select **Suspend Delivery**). For more information on using the Suspend Delivery feature, see *Stopping and resuming your insulin delivery, on page 80.*

To stop a Normal bolus delivery or the Now portion of a Dual Wave bolus delivery:

1. While your pump is delivering your Normal bolus or the Now portion of a Dual Wave bolus, press ◎ from the Home screen.
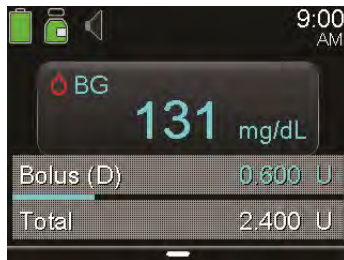
2. Select **Stop Bolus**, then select **Yes** to confirm.

The Bolus Stopped screen appears and shows the amount of bolus delivered, and the original bolus amount you set up.

To stop a Square Wave bolus delivery or the Square portion of a Dual Wave bolus delivery:

1. Press ◎ from the Home screen.

2. Select **Bolus**.

3. Select **Stop Bolus**.

4. To stop your bolus, select **Yes** to confirm.

The Bolus Stopped screen appears and shows the amount of bolus delivered, and the original bolus amount you set up.

5

Reservoir and infusion set

5
Reservoir and infusion set

Setting up the reservoir and infusion set

When you are ready to use your pump with insulin, make sure the time and date are correct on your pump. For details on changing the time and date on your pump, see *Time and date, on page 170*. You must also program your settings as instructed by your healthcare professional.

You need the following items:

* MiniMed 770G insulin pump

* Vial of insulin (U-100)

* MiniMed reservoir

* MiniMed-compatible infusion set and its user guide

> ⚠️ **WARNING: Clear the active insulin value before using your pump to deliver insulin for the first time. If you have practiced giving boluses on your pump before using insulin, the active insulin value could be inaccurate. This could result in inaccurate insulin delivery, and serious injury. For details, see *Clearing your active insulin, on page 166.***

Removing the reservoir

If this is the first time you are inserting a reservoir into your pump and you do not currently have a reservoir loaded, go to *Rewinding your pump, on page 120*.

> ⚠️ **WARNING:** Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which may cause low blood glucose.

To remove your reservoir:

1. Wash your hands.

2. Disconnect the infusion set from the body.

3. If you have the optional activity guard attached to the reservoir compartment on your pump, remove it now.

4. Turn the tubing connector counter-clockwise until the reservoir and tubing connector can be pulled free of the pump.
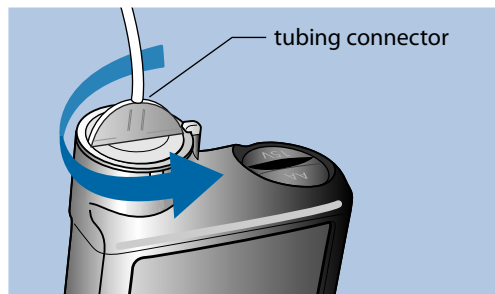
5. Dispose of the used reservoir and infusion set according to local regulations, or contact your healthcare professional for disposal information.

Rewinding your pump

> ⚠️ **WARNING:** Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause low blood glucose.

When you rewind your pump, the piston in the reservoir compartment returns to its starting position and lets a new reservoir be placed into the pump.

> **Note:** The piston is located in the reservoir compartment of your pump. It engages the reservoir and pushes insulin through the tubing.
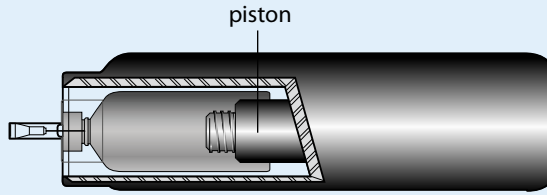
piston

To rewind your pump:

1. Press ◎ and go to the New Reservoir screen.

    Options > Reservoir & Tubing > New Reservoir

    The New Reservoir screen appears.

    If you have not yet removed the infusion set and reservoir, do so now.
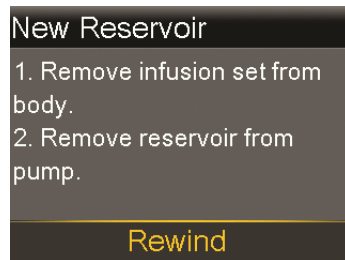
2. Select **Rewind**.

    The piston in the reservoir compartment of your pump returns to its starting position. This may take several seconds. During this process, a "Rewinding" message appears.

    Another message appears to notify you that your pump has finished rewinding, and then the New Reservoir screen appears.

New Reservoir

1. Fill reservoir.
2. Connect tubing to reservoir. DO NOT CONNECT TO BODY.

Next

3. Follow the instructions in the next section to fill your reservoir.

Filling the reservoir

⚠️ **WARNING:** Do not use the reservoir or infusion set if any liquid gets on the top of the reservoir or inside the tubing connector (as shown in the image). Liquid can temporarily block the vents. This may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. If any liquid gets on the top of the reservoir or inside the tubing connector, start over with a new reservoir and infusion set.

Top of reservoir

Tubing connector
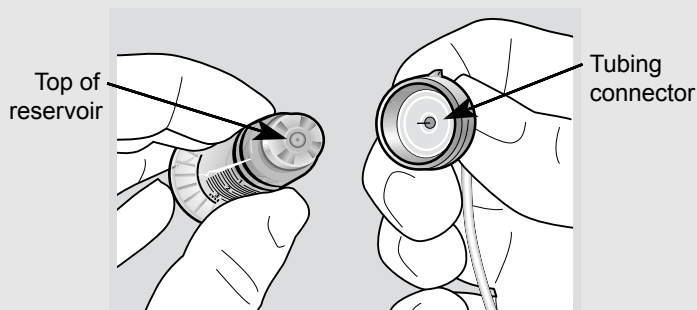
⚠️ **WARNING:** Always allow your insulin to reach room temperature before use. Cold insulin can cause air bubbles in the reservoir and tubing, which may result in inaccurate insulin delivery.

To fill the reservoir, do these steps:

1. Remove the reservoir from the package and fully extend the plunger.
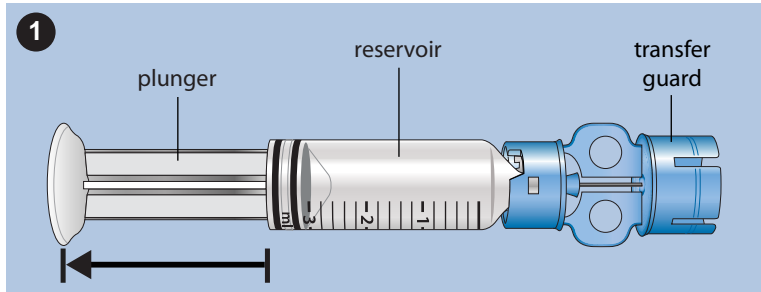
2. Swab the vial with alcohol (not shown).

3. Press the transfer guard onto the vial without pushing down on the plunger.
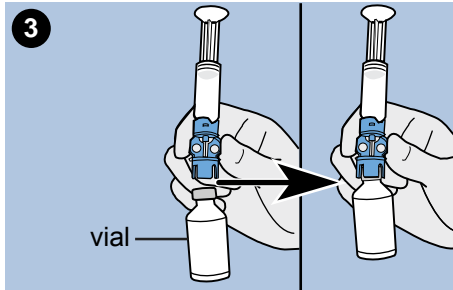
4. Push down on the plunger to pressurize the vial. Hold down the plunger rod.

5. While still holding down the plunger rod, flip the vial over so the vial is on top. Slowly pull down on the plunger to fill the reservoir.

6. Gently tap the side of the reservoir to make any air bubbles rise to the top of the reservoir.
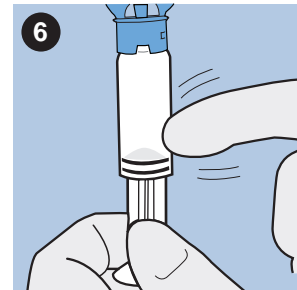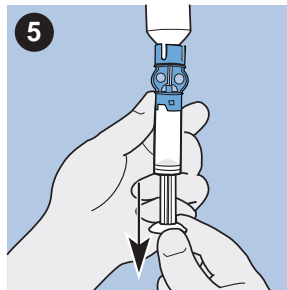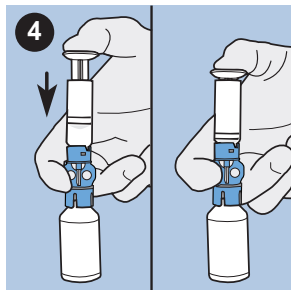
7. Slowly push up on the plunger just enough to remove any air bubbles from the reservoir.

8. Slowly pull down on the plunger to fill the reservoir to the number of units desired.

9. To avoid getting liquid on the top of the reservoir, flip the vial over so that it is upright. Turn the reservoir counter-clockwise, then pull straight up to remove the reservoir from the transfer guard.

10. Place the tubing connector onto the reservoir. Turn the connector clockwise, pressing gently against the reservoir until you feel it slide in. Push in and continue turning until the reservoir and the connector lock with a click.
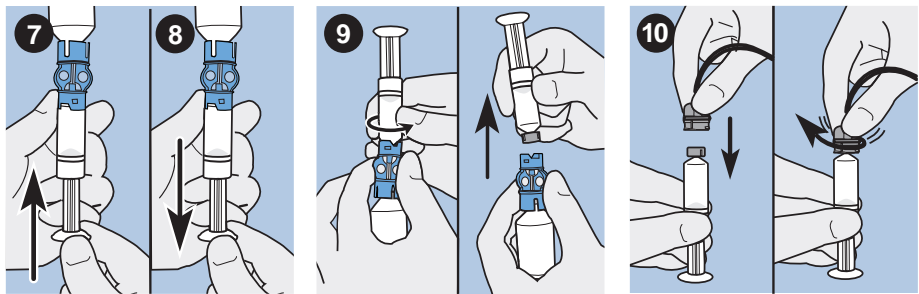
11. Tap the side of the reservoir to remove any air bubbles.

12. To purge air bubbles that have risen to the top of the reservoir, push up on the plunger until you see insulin in the tubing.

13. Without pulling, turn the plunger counter-clockwise to remove it from the reservoir.
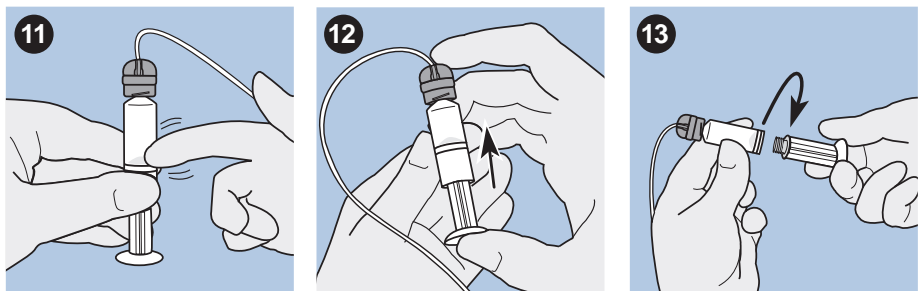
14. Select **Next** from the New Reservoir screen.

New Reservoir

1. Fill reservoir.
2. Connect tubing to reservoir.
DO NOT CONNECT TO
BODY.

Next

The New Reservoir screen now instructs you to place the reservoir in your pump.

New Reservoir

3. Place reservoir into pump and lock.
DO NOT CONNECT TO
BODY.
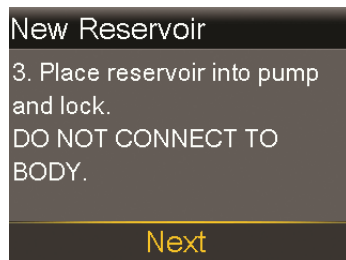
Next

15. Follow the instructions in the next section to insert the reservoir into the reservoir compartment of your pump immediately after filling it.

Inserting the reservoir into your pump

Be sure to perform the following steps in the order they are presented.

Note: Do not insert the reservoir into your pump until you receive training.

WARNING: **Always rewind your pump before inserting a new reservoir. Failing to rewind your pump could result in an accidental infusion of insulin, which can cause hypoglycemia.**

Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause hypoglycemia.

To insert the reservoir into your pump:

1. If you are using the pump for the first time, remove the shipping cap from the reservoir compartment.

2. Rewind your pump if you have not yet done so. See *Rewinding your pump, on page 120* for more information.

3. Insert the reservoir into the top of the reservoir compartment.

4. Turn the tubing connector clockwise until the connector is locked into the pump. The tubing connector should be aligned horizontally with the pump case as shown in the following example.
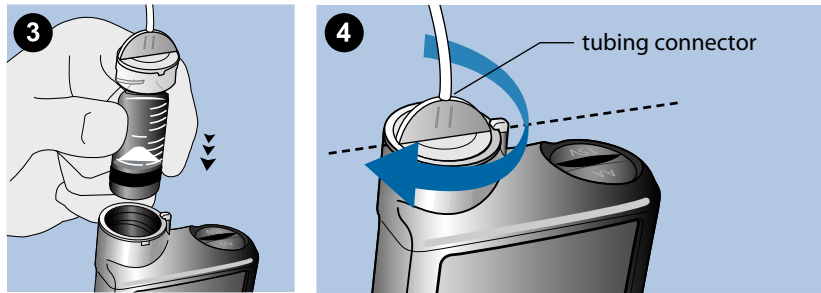
5. Your pump should be displaying the New Reservoir screen shown in the following example. Select **Next** to continue.

6. Select and hold **Load** until you see a checkmark on the screen and your pump beeps or vibrates. Holding **Load** moves the piston up in the reservoir compartment until it engages with the bottom of the reservoir.

> **Note:** If you press the **Back** button after the loading process begins, a Loading incomplete alarm will occur.

When the loading process is completed, the following screen appears.

7. Select **Next** to continue.

8. Follow the instructions in the next section to fill the tubing with insulin.

Filling the tubing

You need to fill the infusion set tubing with insulin before you insert the set into the body.

> ⚠️ **WARNING: Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause low blood glucose.**

> ⚠️ **WARNING:** Always check your tubing for air bubbles. Continue to press **Fill** until the bubbles have been removed from the tubing. Air bubbles may result in inaccurate insulin delivery.

To fill the tubing:

1. After you load your reservoir and select **Next** from the Load Reservoir screen, the Fill Tubing screen appears.

Fill Tubing
DO NOT CONNECT TO BODY.
Hold Fill until drops appear.
Then select Next.
0.0 u
Fill   Next
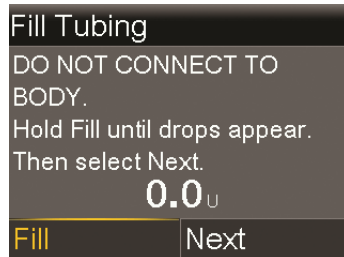
2. Select and hold **Fill**. Your pump beeps six times as it dispenses insulin into the tubing toward the infusion set needle. Continue to hold **Fill** until insulin droplets form on the tip of the infusion set needle, and then release. Your pump beeps as it fills the tubing, and the amount of insulin used appears on the screen.

   If the Max Fill reached alarm occurs, it means you have used more than 30 units of insulin to fill your tubing. For details, go to *Pump alarms, alerts, and messages, on page 246*, and see the description for Max Fill reached.

3. Select **Next** to continue.

4. Follow the instructions in the next section to insert the infusion set into your body before filling the cannula.

Inserting the infusion set

> ⚠️ **WARNING:** Do not remove the reservoir from the pump while the infusion set is connected to your body. Doing so could result in the delivery of too little or too much insulin, which can cause high blood glucose or low blood glucose.

You must complete the following procedures, as described previously, before you insert the infusion set into your body:

- Rewind your pump.
- Fill your reservoir.
- Insert the reservoir into pump.
- Fill the tubing with insulin.

The best body areas for infusion set insertion are shaded in the following example. Avoid the 2-inch (5.0 cm) area around the navel to help ensure a comfortable infusion site and to help with adhesion.

> ⚠️ **CAUTION:** Do not use the same infusion set insertion site for an extended period of time. This can cause the site to become overused. Rotate the infusion set insertion sites regularly.
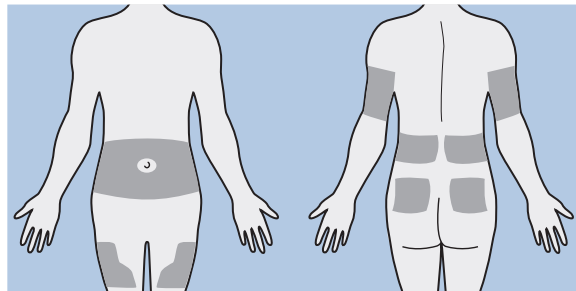
> ⚠️ **CAUTION:** Always change your infusion set according to the product labeling. Using the same infusion set for an extended period of time can cause infusion set occlusion or site infection.

To keep sites healthy, use a visual scheme to help you rotate your insertion sites in an organized way. The following methods are commonly used. For maximum effectiveness, alternate the use of both methods.

- Visualize an imaginary clock drawn on your abdomen around your belly button. Rotate infusion set insertion sites by starting at 12 o'clock and then rotate the infusion site clockwise to 3 o'clock, 6 o'clock, and so on.
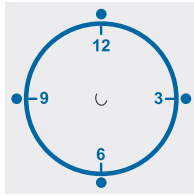
- Imagine a letter M or a letter W on either side of your belly button. Start at the end of one letter and proceed through the letter, rotating to each intersection in turn.
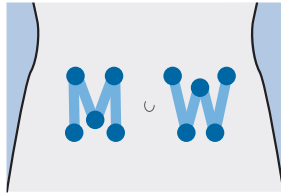
Medtronic Diabetes offers a variety of infusion sets for your pump.

> **Note:** Always refer to your infusion set user guide for instructions to insert an infusion set.

After your infusion set is inserted, see *Filling the cannula, on page 130* to fill the infusion set cannula.

Filling the cannula

Filling the soft cannula with insulin is required after the infusion set is inserted into your body and the introducer needle is pulled out. The insulin amounts required to fill the cannula depend on the type of infusion set you use. Refer to your infusion set instructions for this information.

> **Note:** If you use a steel needle infusion set, there is no cannula to fill. Select **Done** on the **Fill Cannula?** screen.

⚠ **WARNING: Never leave your pump on the Fill Cannula? screen. Insulin delivery is suspended while on the Fill Cannula? screen. Always finish filling your cannula or return to the Home screen to avoid continued insulin delivery suspension. Failing to do this can result in hyperglycemia.**

To fill the cannula:

1.   After you fill your tubing and insert your infusion set, the Fill Cannula? screen appears.

> **Fill Cannula?**
> 1. Insert infusion set into body.
> 2. Select Fill to fill cannula or Done if not needed.
>
> Fill   Done
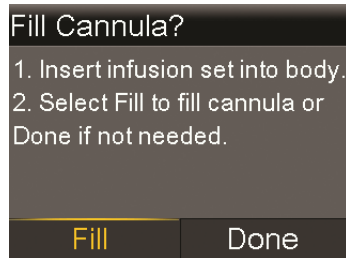
> **Note:** If your screen turns off before you are ready to fill your cannula, press any button on your pump to turn it on again.

2.   To fill your cannula now, select **Fill**. If you use a steel needle infusion set, there is no cannula to fill. Select **Done**.

The Fill Cannula screen appears.

> **Fill Cannula**
> 1. Verify Fill amount.
> 2. Select Fill Now when ready. Select Back to cancel.
>
> Fill amount   --- U
>   Fill Now

3.   Adjust the Fill amount for your particular infusion set, and then select **Fill Now**. If you are unsure about the fill amount, see the instructions that came with your infusion set.

4. As the cannula fills, your screen displays the amount of units being delivered. The pump beeps or vibrates when the delivery is complete.

   After the cannula is filled, the Home screen appears. Your pump is now ready to deliver insulin.

To stop filling the cannula:

1. Select **Stop Filling** to stop filling the cannula.

2. Select **Yes**.

   The Fill Stopped screen appears and shows amount delivered.

3. Select **Done**.

Disconnecting your infusion set

Always refer to your infusion set user guide for instructions on how to disconnect your infusion set.

Reconnecting your infusion set

Always refer to your infusion set user guide for instructions on how to reconnect your infusion set.

6

Meter

6 Meter

The MiniMed 770G insulin pump with smart device connectivity can only pair with an Accu-Chek Guide Link meter to receive remote blood glucose (BG) readings. If you do not pair an Accu-Chek Guide Link meter with your pump, you must enter your BG readings manually. To pair your pump and meter, you need the following items:

- MiniMed 770G insulin pump with smart device connectivity
- Accu-Chek Guide Link meter

About your Accu-Chek Guide Link meter

You can set up your pump to automatically receive BG readings from your Accu-Chek Guide Link meter. When the pump is on the Home screen, it beeps or vibrates when it receives a BG reading from the meter. After you confirm the BG value, the BG Meter screen appears. You can view your current BG reading and, if necessary, deliver a bolus. Once you have received the BG value from the meter, you must confirm the value on your pump. Your BG values appear on your pump screen for 12 minutes, as well as any insulin that is still active from any previous boluses. If your BG reading is outside the range of 70 to 250 mg/dL, an alert appears. Treat your low BG or high BG as directed by your healthcare professional.

> **Note:** You can pair up to four Accu-Chek Guide Link meters to your pump. In order for your pump to use the BG reading, you must confirm the reading on your pump.

Pairing your pump and meter

The MiniMed 770G insulin pump can be paired with the Accu-Chek Guide Link meter. The pump automatically receives BG readings from a paired Accu-Chek Guide Link meter.

To prepare the meter to pair with the pump:

1. Press the **OK** button on the meter to turn on the meter.
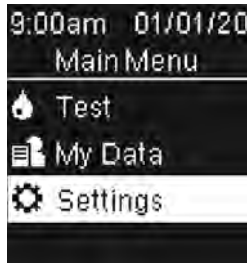
2. Select **Settings**.

    9:00am 01/01/20
        Main Menu
    🔴 Test
    📊 My Data
    ⚙ Settings

3. Select **Wireless**.

    Settings
    Time/Date
    Beeper
    Wireless
    More Options

4. Select **Yes** if the confirmation screen appears on the meter screen. Or, select **Pairing** if the confirmation screen does not appear.

    Pair To Pump
    No paired pump.
    Pair now?

    No
    Yes
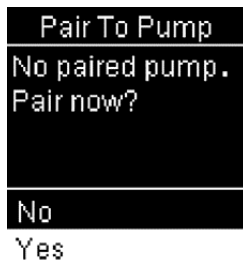
    The serial number of the meter appears on the meter screen. The meter is now ready to pair with the pump.

To prepare the pump to pair with the meter:

1. Press ◎ and go to the Device Options screen.

   Options > Utilities > Device Options

2. Select **Pair Device**.

Device Options
Manage Devices
Pair Device
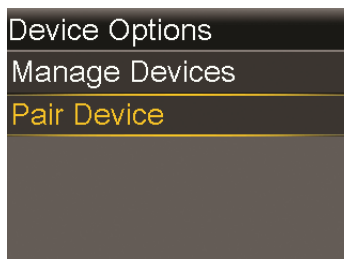
   The New Device screen appears.

3. Select **Search**.

New Device
See device instructions and make the device ready to pair.
Select Search below when ready.
Search
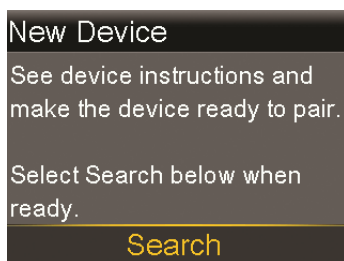
   The Select Device screen appears with a list of available devices.

4. Select the meter that matches the serial number on the meter screen.

Select Device
Meter XXXXXXXX
CGM XXXXXXXX
Meter XXXXXXXX
[Phone name]

5. Ensure the serial numbers shown on the pump and meter screens match, and then select **Confirm**.

```
┌─────────────────────────────────────┐
│ Confirm Device                      │
│ Type: BG Meter                      │
│ SN: XXXXXXXX                        │
│                                     │
│                                     │
│                                     │
│     Cancel      │   Confirm         │
└─────────────────────────────────────┘
```

If the connection is successful, a "Pairing successful!" message appears on the pump. A "Paired with pump" message with the serial number of the pump appears on the meter screen.

Deleting a meter from your pump

Follow this procedure to delete your Accu-Chek Guide Link meter from the pump.

To delete the meter from the pump:

1. Press ◎ and go to the Manage Devices screen.

    Options > Utilities > Device Options > Manage Devices

    The Manage Devices screen appears.

2. Select the serial number of the meter you want to delete. The Accu-Chek Guide Link meter serial number is located on the back of the meter.

3. Select **Delete**. A screen appears and tells you to confirm.

4. Select **Yes** to confirm or **No** to cancel.

Deleting your pump from a meter

For steps to delete the pump from a meter, see the Accu-Chek Guide Link User's Manual.

7

7 History and events

History and events

This chapter describes the History and Event Markers features. The History screens provide details about your personal therapy with your pump, including information about your insulin deliveries, blood glucose (BG) meter readings, sensor glucose (SG) readings, and any alarms and alerts you received. You can enter and save information, such as manual BG readings, carbohydrates eaten, and exercise with the Event Markers feature.

You can view updates on the Daily History screen to learn the following information about your therapy with your pump over a period of time:

- Automatic and manual transitions into and out of SmartGuard Auto Mode

- Start time and the end time for all your Temp Target events

- Correction boluses that your pump automatically calculates for you

For more information about the Auto Mode feature on your pump, refer to *SmartGuard Auto Mode, on page 221*.

History

The History feature includes the Summary, Daily History, and Alarm History screens. The SG Review and ISIG History screens are available if you use the Sensor feature.

Summary screen

The Summary screen shows details about past insulin deliveries and meter readings. If you use a sensor, the Summary screen also shows information about your sensor alerts and SG readings.

You can view historical details for a single day. You can select multiple days to view an average of all the results for the number of days that you selected.

History and events   141

To view your Summary screen:

1. Press ◎ and go to the Summary screen.

   Options > History > Summary

2. Select the time period for the Summary screen.

   The Summary screen appears and shows the information for the number of days that you selected.

3. You can scroll down to view the entire screen. If you use the 1 Day view, you can use the 〈 and 〉 buttons on your pump to view the results for each day in history.

Understanding the Summary screen

The Summary screen separates information into the following categories:

- Auto Mode
- Overview
- Bolus
- BG meter
- Sensor
- Low management mode

Summary screen: Auto Mode

The following table describes the Auto Mode portion of the Summary screen.

Name	Description
Time in Auto Mode	number of hours / percent of time in SmartGuard Auto Mode
Time in target range	number of hours / percent of time in target range (70 to 180 mg/dL)
Time below range	number of hours / percent of time below target range (below 70 mg/dL)
Time above range	number of hours / percent of time above target range (above 180 mg/dL)

Summary screen: overview

The following table describes the overview portion of the Summary screen.

> **Note:** If you view a single day of Summary results, then the values shown are the actual results for the selected day. If you view more than one day of Summary results, then the value is an average of the days that you selected.

Name	Description
TDD	Total daily dose of insulin units.
Basal	• Insulin units devoted to basal insulin delivery. • Percentage of insulin devoted to basal insulin delivery.
Bolus	• Insulin units devoted to bolus delivery. • Percentage of insulin devoted to bolus delivery.
Total Carbs	Daily carbohydrate amount, in grams.

Summary screen: bolus

The following table describes the bolus portion of the Summary screen:

> **Note:** If you view a single day of Summary results, then the values shown are the actual results for the selected day. If you view more than one day of Summary results, then the value is an average of the days that you selected.

Name	Description
Carb bolus	• Total insulin units delivered using the Bolus Wizard feature or Auto Mode Bolus with food or with food and correction amount. • Number of times the Bolus Wizard feature or Auto Mode Bolus delivered a food bolus or a food with correction bolus.
BG Correction Only	• Total insulin units delivered using the Bolus Wizard feature or Auto Mode Bolus with BG correction amount only. • Number of times the Bolus Wizard feature or Auto Mode Bolus delivered a BG correction bolus only.

Summary screen: BG meter

The following table describes the BG meter portion of the Summary screen:

Name	Description
BG	Total number of BG meter readings, including readings from an Accu-Chek Guide Link meter and BG meter readings entered manually.
Average BG	Average BG meter readings.
BG Std. Dev.	Standard deviation of BG meter readings.
Low BG	Lowest BG meter reading.
High BG	Highest BG meter reading.

Summary screen: sensor

The following table describes the sensor portion of the Summary screen. If the sensor feature has never been turned on, this portion of the screen does not appear. If the sensor feature was turned on at least once, but is currently turned off, this portion of the screen appears gray.

Name	Description
SG Average	Average SG value.
SG Std. Dev.	Standard deviation of the SG readings.

Summary screen: low management mode

The following table describes the low management mode portion of the Summary screen. This portion shows information about the SmartGuard suspend features. For details on the SmartGuard suspend features, see *SmartGuard Technology, on page 174*.

Name	Description
Suspend before low	The average number of Suspend before low events per day.
Suspend on low	The average number of Suspend on low events per day.
Time suspended by sensor	The average duration (amount of time) suspended as a result of Suspend on low or Suspend before low events per day.

Daily History

The Daily History screen displays a list of actions you performed on your pump or event entries that you made for the selected day, such as your BG meter readings, sensor calibrations, bolus deliveries, any temp basal rates you have used, and so on. The list displays the most recent action or event first. From this list, you can display further details about any action or event.

To view your Daily History:

1. Press ◎ and go to the Daily History screen.

   Options > History > Daily History

   A list of dates appears.

2. Select a specific date of history to view. A list appears with any pump actions or events entered on the specified day.

3. You can select any item in the list to open the Detail screen, which displays more information about the selected action or event. For example, if you view the details of a bolus delivered using the Bolus Wizard feature, the Detail screen shows you all of the data associated with that bolus, such as the BG correction amount, active insulin adjustment, carbs entered, and calculated bolus.

Alarm History

The Alarm History screen displays a list of alarms and alerts that occurred on the selected day. The list displays the most recent alarm or alert first. From this list, you can display further details about any alarm or alert.

To view your Alarm History:

1. Press ◎ and go to the Alarm History screen.

   Options > History > Alarm History

   A list of dates appears.

2. Select a specific date of alarm history to view. A list appears showing any alarms or alerts that occurred on the specified day.

3. You can select any alarm or alert in the list to open the Alarm Detail screen, which displays more information about the selected alarm or alert.

Sensor Glucose Review

The Sensor Glucose Review feature is available if you use the Sensor feature.

The Sensor Glucose Review feature lets you view a graph of your SG history, based on high and low limits you enter. You can view information for one day, or view an average of your SG data over a number of days.

> **Note:** The high and low limits that you set in the SG Review screen are only used to view your SG data. These limits are not the same as the high and low glucose limits used for your sensor alerts. Changing your limits in the SG Review screen does not affect the high and low glucose limits used for your sensor alerts.

To review your SG history:

1. Press ◎ and go to the SG Review screen.

    Options > History > Sensor Glucose Review

    The SG Review screen appears. The high and low limits that appear are either the values you entered for the last SG Review, or the default values of 180 mg/dL for the High Limit and 70 mg/dL for the Low Limit.
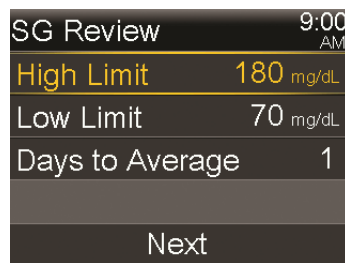
2. Enter the High Limit and Low Limit that you want to use to view your SG data.

    There must be a minimum of 20 mg/dL difference between the High Limit and the Low Limit.

3. Enter the number of days of SG history to average, and select **Next**.

A graph of your SG data appears. If you specified one day of history to view, the graph shows details about when your SG was above, below, or within your specified limits. You can scroll down to view the number of hours and percentage of time you were above, within, and below your SG limits.

If you have no data saved, a message appears to notify you that there is no data available.
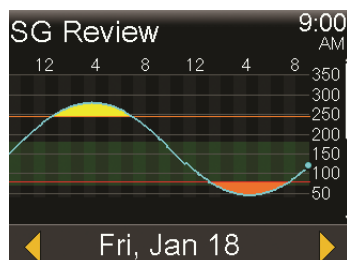
If you view information for multiple days, the graph shows the average percentage of time that your SG was above, below, or within your specific limits.
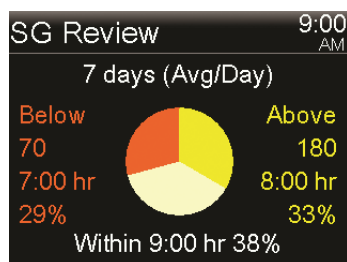
ISIG History

ISIG is an electronic reading from your sensor that is used in conjunction with your calibration numbers to calculate the current glucose reading on your pump.

To review your ISIG History:

1. Press ◎ and go to the ISIG History screen.

    Options > History > ISIG History

    The ISIG History screen displays an hourly sequence for one 24-hour day.

2. Scroll through the list to highlight an hour, then press ◎ to select it.

    Use the ∧ or ∨ buttons to scroll through the listing of ISIG readings, which occur every five minutes.

Event Markers

The Event Markers feature lets you electronically save certain types of information.

When using this feature, enter events when they happen because the system records the time of the entry. You cannot edit entries after you enter the information into your pump. You can view your saved events in the Daily History screen.

The information you entered can be sent to CareLink Personal software, where it can be used to generate reports you can share with your healthcare professional.

To enter Event Markers:

1. Press ◎ and go to the Event Markers screen.

    Options > Event Markers

2. Select and enter event information for any of the following categories:

BG	🔴	If you are not recording your BG meter readings in your pump by entering them manually or by using the Bolus Wizard feature, Auto Mode Bolus, or an Accu-Chek Guide Link meter, you can enter them in this screen. If you use a sensor, you may use a BG meter reading you enter in this screen for calibration. You can also enter non-calibration BG meter readings, such as those readings taken when eating or when your BG is rising or falling rapidly.
Injection		Enter the number of units of any insulin you have given by injection.

> **Note:** Insulin units entered using the injection event marker are not added to your Active Insulin amount tracked on the pump.

Food		Enter the amount of carbohydrates that you have eaten or drunk that have not been entered in the Bolus Wizard feature or Auto Mode Bolus. For example, you might enter carbs that you ate to correct a low BG.
		Do not use this screen to enter carbs that you have already entered in the Bolus Wizard feature or Auto Mode Bolus screen.
Exercise		Enter the length of time you exercised. It is helpful to be consistent and enter the information either before or after each time you exercise.
Other		Examples of Other event markers can include when you take medications, when you feel ill, or when you are under stress.

8

8 Reminders

Reminders help you remember to do important routine activities. There are specific reminders that prompt you to check your blood glucose (BG) after a bolus, give a food bolus, check your reservoir level, and change your infusion set. There are also personal reminders you can use for any purpose. If you have the sensor feature turned on, the calibration reminder prompts you to calibrate your sensor.

Personal reminders

The Personal reminders include six numbered reminders, along with the specific reminders for BG Check and Medication.

To create a new Personal reminder:

1. Press ◎ and go to the Personal screen.

    Options > Reminders > Personal

2. Select **Add New**.

    The Select Name screen shows the available reminders.

3. Select the reminder that you want to set.

    The Edit screen appears for the selected reminder.

4. Enter the time that you want the reminder to occur.

5. Select **Save**. The Personal reminder occurs at the specified time each day unless you change or delete it.

To edit, rename, or delete an existing Personal reminder:

1. Press ◎ and go to the Personal screen.

Options > Reminders > Personal

2. Select the reminder you want to change.

3. Do any of the following:

   • Select **Reminder** to turn the reminder on or off.

   • Select **Edit** to change the time of the reminder.

   • Select **Rename** to assign a different name to the reminder. When the Select Name screen appears, select any available name from the list.

   • Select **Delete** to delete the reminder.

Bolus BG Check reminder

The Bolus BG Check reminder tells you to check your BG after a bolus. After you start a bolus, the BG Check screen appears and lets you set a reminder to check your BG. The timer counts down from the time the bolus started.

To turn on or turn off Bolus BG Check reminders:

1. Press ◎ and go to the BG Check screen.

   Options > Reminders > Bolus BG Check

2. To turn the reminder on or off, select **Reminder**.

3. Select **Save**.

To use a Bolus BG Check reminder when delivering a bolus:

1. After you turn on the Bolus BG Check reminder, each time you start a bolus, the following screen appears:
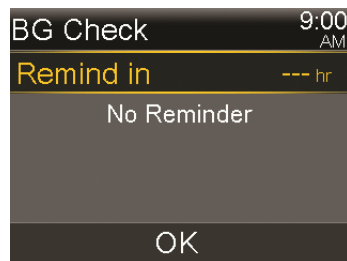
2. Enter a time from 30 minutes to 5 hours, in 30-minute increments. Select **OK**. If you do not want a reminder after the bolus delivery, select the dashes without adding a time, and then select **OK**. If needed, press ∨ to return to the dashes.

Missed Meal Bolus reminder

The Missed Meal Bolus reminder tells you if a bolus is not delivered within a time period that you set. Set time periods around your typical meal times to help ensure a meal bolus is not missed. You can set up to eight Missed Meal Bolus reminders.

To create a new Missed Meal Bolus reminder:

1. Press ◎ and go to the Missed Meal Bolus screen.

   Options > Reminders > Missed Meal Bolus

2. Select **Add New**.

3. Select **Start Time** and enter a time.

4. Select **End Time** and enter a time. The time range is from one minute to 24 hours.

5. Select **Save**.

To turn on or off, edit, or delete existing Missed Meal Bolus reminders:

1. Press ◎ and go to the Missed Meal Bolus screen.

   Options > Reminders > Missed Meal Bolus

2. Select the reminder you want to change.

3. Change any of the following:

   • Select **Reminder** to turn this reminder on or off.

   • Select **Edit** to change the time of this reminder.

   • Select **Delete** to delete this reminder.

Low Reservoir reminder

The Low Reservoir reminder tells you when the insulin level in your reservoir is low. It tells you when your reservoir has a specified number of units remaining and again when half of the remaining units are used.

> **Note:** The number of units that remain in your reservoir can be found on the Quick Status screen. For more information on accessing the Status screens, see *Status screens, on page 52*.

> **WARNING: When the pump detects a low reservoir condition during a bolus or fill cannula delivery, the Low reservoir alert displays. When delivery has finished, check the amount left in the reservoir to make sure your pump does not run out of insulin, as this could lead to an under delivery of insulin, which may cause hyperglycemia.**

Low Reservoir reminder setup:

1. Press ◎ and go to the Low Reservoir screen.

   Options > Reminders > Low Reservoir

2. Select **Units** to enter the number of units. Set a value from 5 to 50 units.

3. Select **Save**.

Set Change reminder

The Set Change reminder tells you when your infusion set is due to be changed. After you turn on this reminder, it automatically tracks the time between infusion set changes and reminds you to change your infusion set.

To turn on or off, or change the Set Change reminder:

1. Press ◎ and go to the Set Change screen.

   Options > Reminders > Set Change

2. Select **Reminder** to turn the reminder on or off. If you turn on the reminder, select **Time** and choose two or three days for the reminder.

3. Select **Save**.

Calibration reminder

The Calibration reminder is available if you use the Sensor feature. This feature helps you remember to calibrate your sensor. For example, if you set your reminder to four hours, you receive a Calibrate by message four hours before the next BG meter reading is due.

To turn on or off, or change the Calibration reminder:

1. Press ◎ and go to the Calibration screen.

    Options > Reminders > Calibration

2. Select **Reminder** to turn the reminder on or off.

3. If you turn on the reminder, select **Time** and enter a time between five minutes and six hours. The time can be set in five-minute increments.

4. Select **Save**.

9

9 General settings

This chapter provides information about common tasks for various settings.

Audio Options

The audio and vibrate options are set in the Audio Options screen. You can also change the volume of most alerts and notifications if audio is enabled.

An audio icon appears on the Home screen. An audio icon indicates if your current settings are audio only ◀, vibrate only ⁊■⁊, or audio and vibrate both ⁊◀⁊. For more information, see *Status icons, on page 46*.

To adjust the audio and vibrate settings:

1. Press ◎ and select **Audio Options** to go to the Audio Options screen.

2. Select **Audio** or **Vibrate** to turn on the setting you want to use. You can use one option or both.

3. If the Audio option is enabled, the volume can be changed. Select **Volume** and press ⟨ or ⟩ to adjust to the desired level.

4. Select **Save**.

Auto Suspend

Auto Suspend is a safety feature that stops all insulin delivery and sounds an alarm if you do not press any buttons for a specified period of time. For example, your healthcare professional may have you set the time based on the number of hours that you typically sleep at night. Discuss with your healthcare professional how to best use this feature.

> **Note:** The Auto Suspend feature continues working when your pump switches to SmartGuard Auto Mode.

To set up Auto Suspend:

1. Press ◎ and go to the Auto Suspend screen.

   Options > Delivery Settings > Auto Suspend

2. Select **Alarm**.

3. Select **Time** and enter the number of hours you want to set.

4. Select **Save**.

Block Mode

The Block Mode feature lets caregivers, such as parents of a young child, restrict access to critical pump settings.

> ⚠️ **WARNING: Always monitor the pump when it is used in Block Mode. You can manually suspend while in Block Mode. This could result in hyperglycemia and ketoacidosis.**

When Block Mode is on, you cannot start a new bolus delivery, start a new basal pattern, or start a new temp basal delivery. Any previous bolus and basal deliveries continue normally, and the pump user can stop a bolus delivery at any time.

When your pump is in Block Mode, you can suspend insulin delivery, receive sensor glucose (SG) values, receive blood glucose (BG) values from your Accu-Chek Guide Link meter, review history, test the pump, and clear alarms and alerts. However, you cannot change any settings.

> **Note:** The Block Mode feature has some differences when your pump is in Auto Mode. See *Block Mode when in SmartGuard Auto Mode, on page 230.*

To turn Block Mode on or off:

1. Press ◎ and go to the Block Mode screen.

Options > Utilities > Block

2. Select **Block Mode** to turn the feature on or off.

3. Select **Save**. While Block Mode is turned on, a lock icon ![lock] appears on the Home screen.

Display Options

In the Display Options screen, you can increase or decrease the brightness of your screen. You can also adjust the amount of time the backlight stays on after you press a button.

To adjust the display options:

1. Press ◎ and go to the Display Options screen.

   Options > Utilities > Display Options

2. Select **Brightness** to adjust the brightness of your screen. You can set a level from 1 to 5, or select **Auto** to have the screen automatically adjust to your current environment.

   > **Note:** The brightness setting you select can affect the life of your battery. Use a lower level setting to preserve battery life.

3. Select **Backlight** to adjust the timeout for the backlight on your pump screen. You can select 15 seconds, 30 seconds, 1 minute, or 3 minutes.

   > **Note:** The backlight can affect the life of your battery. Set the screen timeout to 15 or 30 seconds to preserve battery life.

4. Select **Save**.

Language

You can change the language that your pump uses to display information.

To change the Language setting:

1. Press ◎ and go to the Language screen.

   Options > Utilities > Language

A checkmark indicates which language is active.

2. Select your desired language.

3. Select **Yes** when the confirmation message appears.

Managing your pump settings

The Manage Settings feature lets you save, restore, or clear your settings.

The following table describes the Manage Settings options:

Option	Description
Save Settings	The Save Settings option records your current settings that you can use if a future event requires you to re-enter your settings.
Restore Settings	The Restore Settings option lets you restore your settings with the backup settings that you saved using the Save Settings feature.
Clear All Settings	The Clear All Settings option erases your settings and returns them to the factory defaults. To use your pump again after you clear all settings, you may use Restore Settings or manually re-enter your settings. This option enables you to restore a previous version of your settings or enter your settings again.
Clear Active Insulin	This option appears only if you have never cleared your active insulin. It clears both active insulin and sets your total daily dose to 0 for Auto Mode. Use this option when you are ready to use your pump with insulin for the first time or when directed by your healthcare professional. You can only clear your active insulin once.
Settings History	The Settings History option shows a history of recent activities that relate to managing your settings, such as when you saved, cleared, or restored your settings.

Saving your settings

Save a record of your settings so they can be restored at a later date, if necessary.

To save your current settings:

1. Press ◎ and go to the Manage Settings screen.

   Options > Utilities > Manage Settings

2. Simultaneously press and hold 〉 and ◀ until the Manage Settings screen appears.

3. Select **Save Settings**.

   If these are the first settings you have saved, a message appears to confirm that your settings are saved.

   If you have previously saved settings, a message appears to ask if you would like to replace your previous settings with your current settings. Select **Yes** to accept. Select **No** to cancel.

Restoring your settings

The Restore Settings option replaces your current pump settings with the last settings that you have saved. The Restore Settings menu option is available only if you have previously saved your settings.

To restore your previous settings:

1. Press ◎ and go to the Manage Settings screen.

   Options > Utilities > Manage Settings

2. Simultaneously press and hold 〉 and ◀ until the Manage Settings screen appears.

3. Select **Restore Settings**.

4. To replace your current settings with your previous settings, select **Yes**. To cancel, select **No**.

Clearing your settings

The Clear All Settings option erases your current settings and returns them to the factory defaults. After you clear your settings, your pump displays the Startup Wizard, where you re-enter your pump settings. You must re-enter your settings to continue using your pump.

The Clear All Settings option does not delete paired devices, such as your transmitter or meter.

> ⚠️ **CAUTION:** Do not clear your pump settings unless directed by your healthcare professional. If you clear your pump settings, it will be necessary to reprogram all your personal pump settings as directed by your healthcare professional.

To clear all your settings:

1. Make sure the pump is not connected to your body.

2. Press ◎ and go to the Manage Settings screen.

    Options > Utilities > Manage Settings

3. Simultaneously press and hold ⟩ and ← until the Manage Settings screen appears.

4. Select **Clear All Settings**.

    A screen appears and tells you to confirm.

5. To continue clearing your settings, select **Yes**. If you do not want to clear your settings, select **No**.

    If you clear your settings, your pump displays the Welcome screen and continues to the Startup Wizard. For more details on entering your startup settings, see *Entering your startup settings, on page 43*.

Clearing your active insulin

Use the Clear Active Insulin option when you are ready to use your pump with insulin for the first time. This feature clears the total daily dose and any active insulin values that your pump has tracked and then sets the active insulin value to zero. If you have practiced delivering a bolus with your pump prior to using your pump with insulin, you must clear the active insulin. This ensures that the Bolus Wizard feature has an accurate active insulin amount for bolus calculations.

You can clear your active insulin only once. After you clear your active insulin, the feature is no longer available.

To clear your active insulin:

1. Press ◎ and go to the Manage Settings screen.

    Options > Utilities > Manage Settings

2. Simultaneously press and hold $\rangle$ and ← until the Manage Settings screen appears.

    The Manage Settings screen appears. If you have never cleared your active insulin, the Clear Active Insulin option appears.

Manage Settings
Save Settings
Restore Settings
Clear All Settings
Clear Active Insulin
Settings History
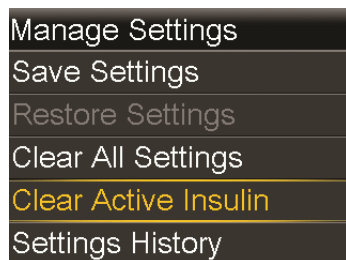
> **Note:** If the Clear Active Insulin selection does not appear on the Manage Settings screen, it means that you have already cleared your active insulin on the pump.

3. Select **Clear Active Insulin**.

    A screen appears and tells you to confirm.

4. Select **Clear** to clear your active insulin value from your pump. If you do not want to clear your active insulin at this time, select **Cancel**.

    A message appears to confirm that your active insulin value is cleared.

Viewing your pump setting history

The Settings History shows you a history of activities you have performed in the Manage Settings area, such as when you saved, restored, or cleared your settings.

1. Press ◎ and go to the Manage Settings screen.

    Options > **Utilities** > **Manage Settings**

2. Simultaneously press and hold $\rangle$ and ← until the Manage Settings screen appears.

3. Select **Settings History**.

    The Settings History screen appears.

Upload to CareLink software

Upload system data to CareLink software with the MiniMed Mobile app or the Blue Adapter.

The following steps are instructions to upload system data to CareLink software with the Blue Adapter. Refer to the MiniMed Mobile app user guide for instructions to upload system data to CareLink software with the app.

To upload to CareLink software with the Blue Adapter:

1. Press and hold ∨, or press ◎ and go to the CareLink screen.

   Options > Utilities > CareLink

2. Follow the instructions on the CareLink uploader.

3. The CareLink uploader tells you to enter a pump code if the pump is new to the CareLink account. Enter the **Pump Code** from the CareLink screen on the pump.

4. Select **Next** on the CareLink uploader.

5. Select **Upload Now** on the pump screen.

Self Test

Self Test is a safety utility that lets you check if your pump is operating properly. This self-diagnostic feature can be used for maintenance or to check that your pump is operating properly. Self Test is additional to the routine tests that run independently while the pump operates.

> **Note:** Your insulin delivery suspends for up to two minutes while your pump runs a self test.

Self Test includes the following tests:

Test	Description
Display	The display turns on for up to 45 seconds.
Notification light	The notification light turns on for three seconds, and then turns it off.
Vibration	Two vibration tones are generated.

Test	Description
Tone	An alert tone, an Easy Bolus step tone, and an alarm tone are generated.

The pump performs a series of tests as listed in the previous table. Self Test requires you to observe the pump during the test.

To run the Self Test:

1.   Press ◎ and go to the Self Test screen.

     Options > Utilities > Self Test

     A message indicates that the Self Test is in progress.

     Self Test takes up to two minutes to complete. During that time, the display briefly turns white, the notification light blinks, the pump vibrates, and the pump beeps.

2.   If Self Test does not detect a problem, the display returns to the Utilities screen.

     If Self Test detects a problem, a message appears with more information about the problem. If Self Test displays an error message or you observe the pump not behaving as indicated during the test, contact 24-Hour Technical Support.

Sensor Demo

Sensor Demo lets you see what the Home screen would look like if you were using the optional CGM feature. For more information about sensor graphs, see *The sensor graph, on page 213*.

⚠️ **WARNING: Do not use Sensor Demo to make any decisions related to your therapy. Information seen in the Sensor Demo is not real data. It is an example of the type of information you can access when using the sensor feature. Making treatment decisions based on data that is not real can cause hypoglycemia or hyperglycemia.**

To view the sensor graph example screens:

1.   Press ◎ and go to the Sensor Demo screen.

Options > Utilities > Sensor Demo

The Sensor Demo screen appears as an example of what your Home screen looks like when you are using the optional CGM feature.
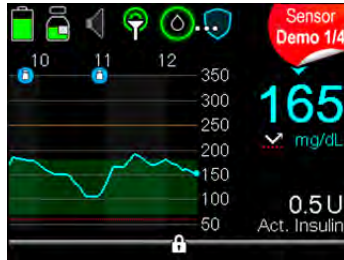
2. Press $\rangle$ to view the sensor graph examples.

3. Press the $\langle$ or $\rangle$ buttons to view the different sensor screen examples.

Sensor Demo simulates an SG graph, showing an example of the general trend of glucose as it rises and falls over time. The top of the graph indicates the time of day, while the side bar shows the mg/dL scale. For details, see *The sensor graph, on page 213*.

4. To exit Sensor Demo, press ⬅.

Time and date

Make sure the time and date are always set correctly on your pump. This is necessary to ensure the correct basal insulin delivery and to keep an accurate record of pump functions. You may need to change the time or the date if you travel to a different time zone or practice daylight saving time. After the time and date are changed, the pump adjusts all settings automatically.

To change the time and the date:

1. Press ◎ and go to the Time & Date screen.

Options > Utilities > Time & Date

2. Select and change the **Time**, **Time Format**, or **Date** as necessary. If you are using a 12-hour clock, be sure to specify AM or PM.

3. Select **Save**.

10

10 Setting up CGM

This chapter explains how to pair your pump and transmitter, enter your sensor settings, and set up CGM on your pump. You need the following:

- MiniMed 770G insulin pump

- Sensor glucose (SG) settings provided by your healthcare professional

- Guardian Sensor (3)

- Guardian Link (3) transmitter with Bluetooth wireless technology kit

> ⚠ **WARNING: Do not make therapy treatment decisions based on sensor glucose values. Sensor glucose (SG) and blood glucose (BG) values may differ. If your sensor glucose reading is low or high, or if you feel symptoms of low or high glucose, confirm your sensor glucose reading with your blood glucose meter prior to making therapy decisions to avoid hypoglycemia or hyperglycemia.**

Understanding CGM

The Sensor feature on the pump lets you integrate and use CGM. CGM is an SG monitoring tool that uses a glucose sensor that is placed below your skin to continuously measure the amount of glucose in your interstitial fluid. CGM helps you better manage your diabetes in the following ways:

- It records your glucose values throughout the day and night.

- It shows the effects that your diet, exercise, and medication can have on your glucose levels.

- It gives you additional tools to help you prevent high and low glucose levels.

> **Note:** If you lose sensor functionality, you will no longer have access to CGM features. For details on restoring sensor functionality, see *Troubleshooting sensor issues, on page 290*.

SG readings and BG meter readings are not the same.

SmartGuard Technology

SmartGuard technology automatically adjusts basal insulin delivery based on your SG values. SmartGuard technology can be used in two modes: Manual Mode and Auto Mode. This chapter describes SmartGuard technology used in Manual Mode with the SmartGuard suspend (Suspend before low and Suspend on low) features. SmartGuard suspend features can automatically stop and resume insulin delivery based on your SG values and low limit. When your pump suspends insulin delivery based on your SG values and your low limit, it is called a SmartGuard suspend event. Your low limit should be set based on recommendations from your healthcare professional. When a SmartGuard suspend event occurs, basal insulin delivery automatically resumes if your SG values are rising and have met the specified criteria, or if the maximum suspend time of two hours is reached.

Auto Mode is also part of SmartGuard technology. When your pump is in Auto Mode, your basal insulin delivery is automatically controlled. For details, see *About SmartGuard Auto Mode, on page 221*.

The following table lists SmartGuard features and where to find them.

To learn more about:	Go to this section:
How to use SmartGuard technology to automatically suspend your insulin delivery before you reach your low limit.	*SmartGuard Suspend before low, on page 181*.
How to use SmartGuard technology to automatically suspend your insulin delivery when you reach your low limit.	*SmartGuard Suspend on low, on page 185*.
How SmartGuard technology automatically resumes your basal insulin delivery after a SmartGuard suspend event.	*Automatically resuming basal insulin delivery after a SmartGuard suspend event, on page 188*.

To learn more about:	Go to this section:
How SmartGuard Auto Mode works.	*About SmartGuard Auto Mode, on page 221*.

To set up the SmartGuard suspend features, see *Setting up the low SG settings, on page 197*.

Home screen with CGM in Manual Mode

When you turn on the Sensor feature, the Home screen on your pump changes to display a real-time graph that shows your SG information. For more information, see *Turning on the Sensor feature, on page 194*.

Note: To see the Home screen in Auto Mode, see *Home screen with SmartGuard Auto Mode, on page 227*.
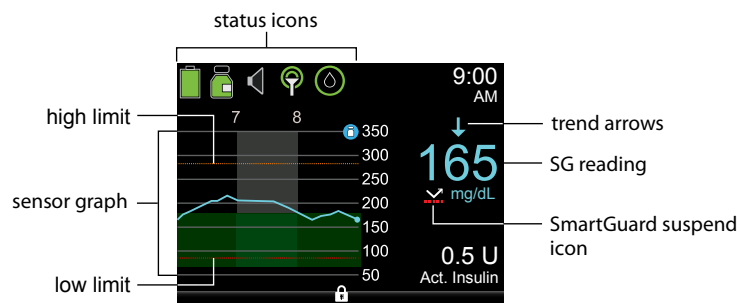
The following items appear on your Home screen with CGM in Manual Mode:

Item	Description
Calibration icon	The calibration icon indicates the approximate time left until your next sensor calibration is due. The calibration icon appears only when the Sensor feature is turned on. The color and the circle around the icon indicate the status of calibration. When your sensor is fully calibrated, the icon has a solid green circle around it. As the time for your next sensor calibration approaches, the green circle around the icon becomes smaller, and the color of the icon changes as shown in the following example. For more information about calibrating your sensor, see *Calibrating your sensor, on page 206*. • Time to your next sensor calibration is more than 10 hours. • Time to your next sensor calibration is 8 to 10 hours. • Time to your next sensor calibration is 6 to 8 hours. • Time to your next sensor calibration is 4 to 6 hours. • Time to your next sensor calibration is 2 to 4 hours. • Time to your next sensor calibration is less than 2 hours. • Sensor calibration is required now. • Time to your next sensor calibration is unavailable. • Sensor calibration has not completed. This occurs when a new sensor is connected or when the sensor is calibrating. This also occurs within 15 minutes of a Calibration not accepted alert.
Connection icon	The connection icon appears green when the Sensor feature is on and your transmitter is successfully communicating with your pump. The connection icon appears with a red X when the Sensor feature is turned on, but the transmitter is not connected or communication with your pump has been lost. For more information about the Sensor feature, see *Understanding CGM, on page 173*.

Item	Description
Auto Mode Readiness icon	The Auto Mode Readiness icon indicates whether your pump is ready to enter Auto Mode. The icon appears with a loading symbol when the pump is updating a condition that requires you to wait. The icon appears with a question mark when the pump requires an action from you to enter Auto Mode. For more information about Auto Mode Readiness, see *SmartGuard Auto Mode Readiness, on page 225*.
	When your pump is in Auto Mode, the SmartGuard Auto Mode shield appears in the center of your Home screen. For more information, see *Home screen with SmartGuard Auto Mode, on page 227*.
Sensor graph	The sensor graph shows your SG readings over a period of three hours. The orange line represents your high SG limit, and the red line represents your low SG limit. The blue line represents your SG trends during the specified period. For more information, see *The sensor graph, on page 213*.
Sensor life icon	The number in the center of the sensor life icon indicates the number of days that remain until the sensor expires. The icon appears only when the Sensor feature is turned on. When you insert a new sensor, the icon is solid green. When one day remains until the sensor expires, the icon color turns red.
	If the number of days that remain until the sensor expires is unavailable, the sensor life icon appears with three dots .
	When the system is waiting for the sensor to be started, the sensor life icon appears with a question mark .
SG reading	The pump shows your current SG reading, which is sent wirelessly to your pump by the transmitter.

Item	Description
SmartGuard suspend icon	The SmartGuard suspend icon appears only when either the Suspend before low or Suspend on low feature is set to on. For details on SmartGuard technology, see *SmartGuard Technology, on page 174*.
	The SmartGuard suspend icon indicates the current status of the suspend features, as follows:
	• The icon is a white arrow with a dotted red line when either the Suspend on low or Suspend before low is turned on and ready.
	• The arrow icon flashes if your insulin delivery is currently suspended due to a Suspend on low or Suspend before low event.
	• The icon appears as a gray cross with a dotted line under it when neither suspend feature is available. The suspend features might be unavailable due to a recent suspend or because there are no SG values available. It might also be unavailable because the pump is not currently delivering insulin.
Trend arrows	The trend arrows indicate the rate at which the most recent SG level is rising or falling.
	• ↑ or ↑↑ or ↑↑↑ - Rising trend arrows
	• ↓ or ↓↓ or ↓↓↓ - Falling trend arrows
	For more information about trend arrows, see *Identifying rapid changes in SG, on page 214*.

Understanding glucose settings

There are several types of glucose alerts you can set to tell you when your glucose values change at a particular rate, or when they approach or reach a specified low or high limit. You can also set your pump to automatically suspend insulin delivery before or when you reach your low limit.

The following graph shows the different high and low glucose alerts you can use.
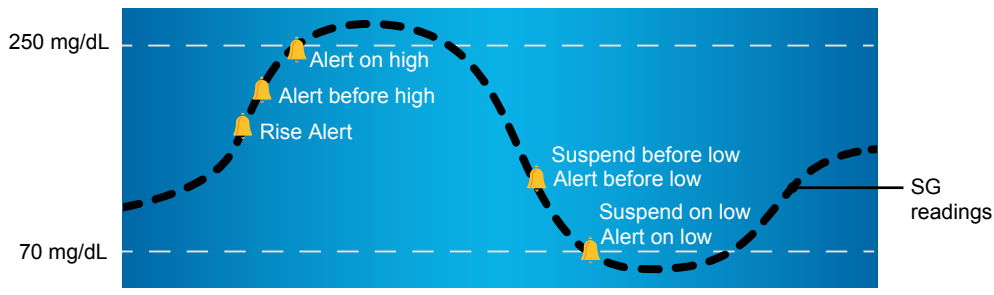
🔔 SG alert and suspend settings

The high alerts are described in the *High SG settings* section on *page 179*. For details on low alerts and suspend options, see *Low SG settings, on page 180*.

High SG settings

These settings alert you:

- When your SG is rising rapidly (Rise Alert)

- When your SG is approaching your high limit (Alert before high)

- When your SG has reached your high limit (Alert on high)

The following graph shows the different high SG settings you can use:

🔔 High SG alert settings

The following table describes the high SG settings.

High glucose setting	Description
High limit	Your high limit is the value your other high SG settings are based on. Your high limit can be set from 100 to 400 mg/dL. You can set a different high limit for up to eight time segments throughout the day or night.

High glucose setting	Description
Alert before high	When Alert before high is on, the pump alert tells you any time the SG is predicted to reach the high limit. This makes you aware of potential highs before they occur.
Time before high	Time before high is only available when using Alert before high. Time before high determines when you will receive an Alert before high. You can set a time between 5 and 30 minutes.
Alert on high	When Alert on high is on, your system tells you when your SG reading reaches or exceeds your High Limit.
Rise Alert	The Rise Alert tells you when your glucose is rising rapidly. This alert helps you understand how much your glucose levels are affected by meals or, for example, when forgetting to give a bolus. You can set the rise rate to match the arrows that display on the Home screen during a glucose rise, or to a custom rise rate. • ⬆ - SG is rising at a rate of 1 mg/dL per minute or more. • ⬆⬆ - SG is rising at a rate of 2 mg/dL per minute or more. • ⬆⬆⬆ - SG is rising at a rate of 3 mg/dL per minute or more. • **Custom** - SG is rising at the rate that you set which can be set from 1.0 to 5.0 mg/dL per minute.
Rise Limit	The Rise Limit determines when you will receive a Rise Alert. Rise Limit is only available when using Rise Alert.

To set up your high SG settings, see *Setting up the high SG settings, on page 194*.

Low SG settings

The low SG settings alert or suspend insulin delivery when you either approach or reach your low limit. For more information, see *SmartGuard Technology, on page 174*.

The following graph shows the different low SG settings you can use:
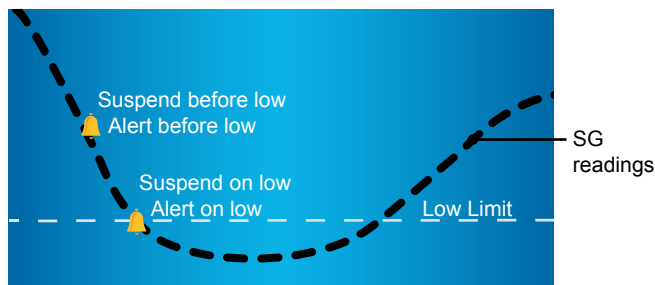
🔔 Low SG alert and suspend settings

> ⚠️ **WARNING: Suspend before low and Suspend on low are not intended to be a treatment for low blood glucose. Having insulin suspended when glucose is low may not bring your blood glucose back to your target range for several hours. In that case, you run the risk of hypoglycemia. Always confirm your blood glucose readings with your blood glucose meter and treat according to the recommendations of your healthcare professional.**

The following sections describe how to set up your low SG settings in Manual Mode. For details on setting up your low SG settings in Manual Mode, see *Setting up the low SG settings, on page 197*.

Low limit

The low limit is the value on which the other low SG settings are based. The low limit can be set from 50 to 90 mg/dL. You can set a different low limit for up to eight time segments throughout the day or night.

SmartGuard Suspend before low

The SmartGuard Suspend before low feature stops insulin delivery when your SG values are approaching your low limit. This feature is intended to suspend insulin delivery to minimize the amount of time spent with low BG values.

The default setting for the Suspend before low feature is off. Consult your healthcare professional for the Suspend before low setting that is best for you.

If you turn on Suspend before low, then Alert on low is automatically turned on. You also have the option to turn on Alert before low.

- If Alert before low is on, your pump tells you when insulin delivery is suspended. For details, see *Alert before low, on page 184.*

- If Alert before low is off, then Suspend before low appears on the screen, but the pump will not beep or vibrate when insulin delivery is suspended.

- The user can enable Alert before low, Alert on low, Suspend before low, and Suspend on low. There is an additional fixed low alert at 50 mg/dL that cannot be turned off.

- Suspend before low and Suspend on low cannot be enabled at the same time. When either is enabled, the user can enable the Resume basal alert.

- The Low SG alarm appears when your SG values reach or fall below 50 mg/dL. This alarm cannot be turned off. When the alarm appears on your screen, it shows your SG value next to your Low SG alarm. In this user guide, the SG value will be represented as "Low SG XX" for this alarm.
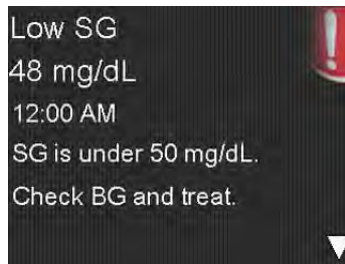
> ⚠️ **WARNING: Always confirm your sensor glucose readings with your blood glucose meter and treat according to the recommendations of your healthcare professional. The Suspend before low feature uses the sensor glucose value, not your blood glucose value, to automatically suspend insulin delivery. Your pump automatically suspends insulin delivery when your sensor glucose is approaching the low limit. However your blood glucose reading may be higher or lower than the sensor glucose value. Assuming that your sensor glucose value is accurate may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.**

Suspend before low conditions

When a Suspend before low event occurs, all insulin delivery is suspended. A Suspend before low event occurs in the following situations:

• Your SG value is at or within 70 mg/dL above your low limit.

• Your SG is predicted to reach or fall below a level that is 20 mg/dL above your low limit within approximately 30 minutes.

Responding to a Suspend before low event

When you clear the Suspend before low alert, the SmartGuard suspend icon flashes and "Suspended before low" appears on your Home screen. If your SG reaches your low limit, an Alert on low occurs.

When a Suspend before low event occurs, insulin delivery will remain suspended for at least 30 minutes. Insulin delivery will be suspended for a maximum of two hours. You can manually resume basal insulin delivery at any time. For details, see *Manually resuming basal insulin delivery during a SmartGuard suspend event, on page 200.* After the minimum 30-minute suspend time, basal insulin delivery will automatically resume if the following conditions are met:

• Your SG is at least 20 mg/dL above your low limit.

• Your SG is estimated to be more than 40 mg/dL above your low limit within 30 minutes.

If you do not respond to the Suspend before low alert, your pump resumes basal insulin delivery after two hours and displays a Basal delivery resumed alert.

When Suspend before low is unavailable

After a Suspend before low event occurs, there is a period of time when the Suspend before low functionality is unavailable. This is to prevent prolonged suspended basal delivery. The length of time it is unavailable will vary. You can manually suspend insulin delivery at any time. For details, see *Stopping and resuming your insulin delivery, on page 80.*

> **Note:** The maximum amount of time the Suspend before low feature will be unavailable is four hours.

When the SmartGuard suspend features are unavailable, the SmartGuard suspend icon on the Home screen appears as a gray cross ![X].

When a Suspend before low event occurs and you respond within two hours and:

- Stay suspended for the two-hour maximum suspend time, the SmartGuard suspend features will be unavailable for 30 minutes after your basal insulin delivery resumes.

- Your basal insulin delivery automatically resumes due to your rising SG levels, the SmartGuard suspend features will be unavailable for 30 minutes after your basal insulin delivery resumes.

- Manually resume your basal insulin delivery, the SmartGuard suspend features will be unavailable for 30 minutes after your basal insulin delivery resumes.

If your pump has been suspended for two hours and you have not responded, basal insulin delivery automatically resumes.

If you respond within 30 minutes of basal insulin delivery being resumed, the SmartGuard suspend features will be unavailable for a total of 30 minutes. For example:

- If you respond 10 minutes after your basal insulin delivery resumes, the SmartGuard suspend features will be unavailable for an additional 20 minutes.

- If you respond 20 minutes after your basal insulin delivery resumes, the SmartGuard suspend features will be unavailable for an additional 10 minutes.

If you respond 30 minutes to four hours after your basal insulin delivery resumes, the SmartGuard suspend features will be available immediately.

If you do not respond, the SmartGuard suspend features will be unavailable for four hours after basal insulin delivery resumes.

Alert before low

When Alert before low is on, you will receive an alert when you are approaching your low limit. This makes you aware of potential lows before they occur.

The Alert before low feature can be used with the Suspend before low and Suspend on low features. The Alert before low feature works as follows:

- If Alert before low is on, and both SmartGuard suspend features are off, you receive the Alert before low 30 minutes before you reach your low limit.

- If Suspend on low is on, and Alert before low is on, you receive an Alert before low 30 minutes before you reach your low limit.

- If Suspend before low is on, and Alert before low is on, you receive a Suspend before low alert when insulin delivery is suspended. For details, see *SmartGuard Suspend before low, on page 181*.

You can also choose to have the Alert before low off.

SmartGuard Suspend on low

The SmartGuard Suspend on low feature stops insulin delivery when your SG value reaches or falls below the low limit that you set. When a Suspend on low event occurs, all insulin delivery is suspended. This feature is used for situations when you cannot respond to a low glucose condition. It is intended to suspend insulin delivery and minimize the amount of time spent with low BG values.

> ⚠️ **WARNING: Do not use the Suspend on low feature until you have read the information in this user guide and received training from your healthcare professional. The Suspend on low feature causes the pump to temporarily suspend insulin delivery for a maximum of two hours. Under some conditions of use, the pump can suspend again, resulting in limited insulin delivery. Prolonged suspension can increase the risk of serious hyperglycemia, ketosis, and ketoacidosis.**

The default setting for the Suspend on low feature is off. Consult your healthcare professional for the Suspend on low setting that is best for you.

If you turn on Suspend on low, then Alert on low is turned on automatically. For more information, see *Alert on low, on page 187*.

> ⚠️ **WARNING: Always confirm your sensor glucose readings with your blood glucose meter and treat according to the recommendations of your healthcare professional. The Suspend on low feature uses the sensor glucose value, not your blood glucose value, to automatically suspend your pump. Your pump may automatically suspend when your sensor glucose is at or below the low limit, while your blood glucose is above that limit. Assuming that your sensor glucose value is accurate may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia.**

Responding to a Suspend on low event

When you clear the Suspend on low alarm, the SmartGuard suspend icon ▼ flashes and "Suspended on low" appears on your Home screen.

When a Suspend on low event occurs, the pump tells you.

When a Suspend on low event occurs, insulin delivery will remain suspended for at least 30 minutes. Insulin delivery will be suspended for a maximum of two hours. You can manually resume basal insulin delivery at any time. For details, see *Manually resuming basal insulin delivery during a SmartGuard suspend event, on page 200*. After the minimum 30-minute suspend time, basal insulin delivery will automatically resume if the following conditions are met:

- Your SG is at least 20 mg/dL above your low limit.
- Your SG is estimated to be more than 40 mg/dL above your low limit within 30 minutes.

If you do not respond to the Suspend on low alarm, your pump resumes basal insulin delivery after two hours and continues to display an emergency message.

When Suspend on low is unavailable

After a Suspend on low event occurs, there is a period of time when the suspend functionality is unavailable. This time will vary depending on whether or not you respond to the Suspend on low event. You can manually suspend insulin delivery at any time. For details, see *Stopping and resuming your insulin delivery, on page 80*.

Note: The maximum amount of time the Suspend on low feature will be unavailable is four hours. After this time period, the Suspend on low feature automatically enables.

When the SmartGuard suspend features are unavailable, the SmartGuard suspend icon on the Home screen appears gray ![icon].

When a Suspend on low event occurs and you respond within two hours and:

- Stay suspended for the two-hour maximum suspend time, the SmartGuard suspend features will be unavailable for 30 minutes after your basal insulin delivery resumes.

- Your basal insulin delivery automatically resumes due to your rising SG levels, the SmartGuard suspend features will be unavailable for 30 minutes after your basal insulin delivery resumes.

- Manually resume your basal insulin delivery, the SmartGuard suspend features will be unavailable for 30 minutes after your basal insulin delivery resumes.

If your pump has been suspended for two hours and you have not responded, basal insulin delivery automatically resumes.

If you respond within 30 minutes of basal insulin delivery being resumed, the SmartGuard suspend features will be unavailable for a total of 30 minutes. For example:

- If you respond 10 minutes after your basal insulin delivery resumes, the SmartGuard suspend features will be unavailable for an additional 20 minutes.

- If you respond 20 minutes after your basal insulin delivery resumes, the SmartGuard suspend features will be unavailable for an additional 10 minutes.

If you respond 30 minutes to four hours after your basal insulin delivery resumes, the SmartGuard suspend features will be available immediately.

If you do not respond, the SmartGuard suspend features will be unavailable for four hours after basal insulin delivery resumes.

Alert on low

The Alert on low feature is automatically turned on when either the Suspend before low or the Suspend on low feature is turned on.

When Alert on low is set to on, you receive an alert when your SG reading reaches or falls below your low limit. If your pump is suspended and you have not responded, an emergency message appears.

Automatically resuming basal insulin delivery after a SmartGuard suspend event

In addition to suspending insulin delivery, the pump can also automatically resume delivery of basal insulin. If insulin delivery has been suspended by either the Suspend before low or the Suspend on low feature, basal insulin delivery will automatically be resumed if either of the following conditions are met:

*   If insulin delivery has been suspended for a minimum of 30 minutes and SG values are at least 20 mg/dL above the low limit and expected to be more than 40 mg/dL above the low limit in 30 minutes

*   After a maximum of two hours

Resume basal alert

When the Resume basal alert is on, you will be alerted when basal insulin delivery is automatically resumed. If the Resume basal alert is off, basal insulin delivery resumes, but you do not receive an alert. However, you will get a message indicating that the basal insulin delivery has automatically resumed.

If basal insulin delivery resumes after the maximum suspend time of two hours, you will be alerted even if the Resume basal alert is set to off. It is important that you check your BG and ensure your glucose is at a safe level.

For details on setting up the Resume basal alert, see *Setting up the low SG settings, on page 197*.

SmartGuard suspend examples

The following table shows the different scenarios that occur during and after a Suspend before low or Suspend on low event. Examples of scenarios are shown after the table.

	Suspend features	
What happens	**Suspend on low**	**Suspend before low**
The pump suspends insulin delivery.	Your SG value reaches or falls below the low limit that you set. The pump suspends insulin delivery for at least 30 minutes and up to a maximum of 2 hours. The pump automatically resumes basal insulin delivery between 30 minutes and 2 hours if your SG value is predicted to go above the low limit that you set.	Your SG value is approaching your low limit and is predicted to be reached within 30 minutes. The pump suspends insulin delivery for at least 30 minutes and up to a maximum of 2 hours. The pump automatically resumes basal insulin delivery between 30 minutes and 2 hours if your SG value is predicted to go above the low limit that you set.
You manually resume basal insulin delivery.	Your pump resumes basal insulin delivery at the programmed basal rate. The SmartGuard suspend features are unavailable for 30 minutes after basal insulin delivery resumes. The pump will not automatically suspend insulin delivery again until after the suspend features are available and your SG value is below the low limit that you set.	Your pump resumes basal insulin delivery at the programmed basal rate. The SmartGuard suspend features are unavailable for 30 minutes after basal insulin delivery resumes. The pump will not automatically suspend insulin delivery again until after the suspend features are available and your SG value is approaching the low limit that you set.

	Suspend features	
What happens	Suspend on low	Suspend before low
Your SG value is predicted to go above your low limit while insulin delivery is automatically suspended.	The pump automatically resumes basal insulin delivery after 30 minutes and if your SG values are at least 20 mg/dL above your low limit and predicted to be more than 40 mg/dL above your low limit in 30 minutes.	The pump automatically resumes basal insulin delivery after 30 minutes and if your SG values are at least 20 mg/dL above your low limit and predicted to be more than 40 mg/dL above your low limit in 30 minutes.
You respond to the alert that occurs while insulin delivery is suspended. Insulin delivery is suspended for the maximum two hour suspend time.	Your pump resumes basal insulin delivery at the programmed basal rate. The SmartGuard suspend features are unavailable for 30 minutes after basal insulin delivery resumes. The pump will not automatically suspend insulin delivery again until after the suspend features are available and your SG value is below the low limit that you set.	Your pump resumes basal insulin delivery at the programmed basal rate. The SmartGuard suspend features are unavailable for 30 minutes after basal insulin delivery resumes. The pump will not automatically suspend insulin delivery again until after the suspend features are available and your SG value is approaching the low limit that you set.
The pump resumes basal insulin delivery after the maximum two hour suspend time. You respond to the alert that occurs after basal insulin delivery resumes.	Your pump resumes basal insulin delivery at the programmed basal rate. The SmartGuard suspend features are unavailable for 30 minutes. The pump will not automatically suspend insulin delivery again until after the suspend features are available and your SG value is below the low limit that you set.	Your pump resumes basal insulin delivery at the programmed basal rate. The SmartGuard suspend features are unavailable for 30 minutes. The pump will not automatically suspend insulin delivery again until after the suspend features are available and your SG value is approaching the low limit that you set.

	Suspend features	
What happens	**Suspend on low**	**Suspend before low**
You do not respond to the alerts that occur while insulin delivery is suspended. Insulin delivery is suspended for the maximum two hour suspend time.	Your pump resumes basal insulin delivery at the programmed basal rate. The SmartGuard suspend features are unavailable for 4 hours after basal insulin delivery resumes. The pump will not automatically suspend insulin delivery again until after the suspend features are available and your SG value is below the low limit that you set.	Your pump resumes basal insulin delivery at the programmed basal rate. The SmartGuard suspend features are unavailable for 4 hours after basal insulin delivery resumes. The pump will not automatically suspend insulin delivery again until after the suspend features are available and your SG value is approaching the low limit that you set.

The following examples describe several scenarios that illustrate different types of suspend events, user actions in response to these events, and what happens to insulin delivery in each case.

The examples cover the following:

- Example 1: Suspend before low, non-responsive, auto resume basal insulin delivery (trending upwards)

- Example 2: Suspend before low, responsive, manually resume basal insulin delivery

- Example 3: Suspend before low, responsive, stays suspended

- Example 4: Suspend on low, response after basal insulin delivery resumes

> **Note:** During the Suspend on low siren, you can press any button to silence your pump for two minutes. The temporary silencing of the alarm does not affect the suspension or delivery of insulin.

Example 1: Suspend before low, non-responsive, auto resume basal insulin delivery (trending upwards)

Sarah has been experiencing low SG values. Her healthcare professional has recommended she use the Suspend before low feature. While at a concert, Sarah's SG values are approaching her low limit. Her pump recognizes that her glucose will be at or within 20 mg/dL above her low limit within 30 minutes and suspends her insulin delivery. Sarah has her Alert before low set to off so that she is not alerted when this occurs.
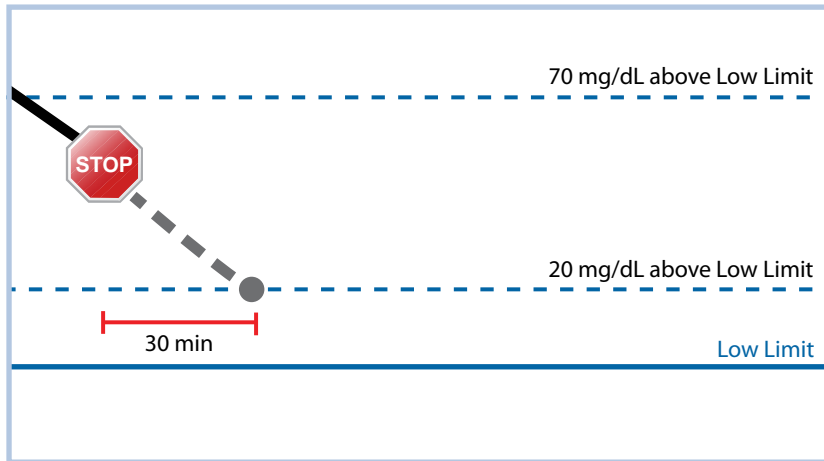
An hour later, her SG values are 21 mg/dL above her low limit. Her pump estimates her SG values will be 45 mg/dL above her low limit within 30 minutes. Her pump automatically resumes her basal insulin delivery.

When the concert ends, Sarah sees that her pump automatically suspended and resumed her insulin delivery and a potential low was avoided. She clears the messages by selecting OK.

Example 2: Suspend before low, responsive, manually resume basal insulin delivery

Kate decides to meet her friends at the mall. While shopping, she gets a Suspend before low alert. This indicates that her SG values are approaching the low limit she has set. She clears the alert and sees that her insulin delivery has been suspended. Kate checks her BG to confirm. Based on her healthcare professional's recommendation, Kate stops for a snack to help avoid hypoglycemia. Knowing the

carbohydrate will make her glucose rise, Kate manually resumes her basal insulin delivery by selecting Suspended before low from the Home screen and choosing Resume basal.

Kate knows that after she has manually resumed her basal insulin delivery, the suspend functions will be unavailable for 30 minutes. However, she will be alerted if she reaches her low limit.

Example 3: Suspend before low, responsive, stays suspended

Doug has just finished his evening jog on the beach. As he is walking home, he receives a Suspend before low alert. He sees that his pump has automatically suspended his insulin delivery. Doug clears the alert by selecting OK on his pump. He knows that his pump is now suspended and insulin delivery has been stopped. He checks his BG to confirm and keeps his insulin delivery suspended.

A while later, Doug receives another alert. He looks at his pump and sees that he has received an Alert on low. His SG has reached his low limit. He clears the alert and checks his BG to confirm. He eats carbohydrates to treat the low glucose as instructed by his healthcare professional.

Doug keeps his insulin delivery suspended as directed by his healthcare professional. He knows that once his SG is above his low limit and trending upward, or reaches the maximum suspend time of two hours, basal insulin delivery will automatically resume.

Example 4: Suspend on low, response after basal insulin delivery resumes

Michael is on his college hockey team. He played in a hockey tournament all day and is so exhausted that he falls asleep watching television. His SG value begins to drop. When his SG value reaches his low limit, the pump begins to alarm. His pump automatically suspends all insulin delivery. Michael does not respond to the alarm. After ten minutes, his pump begins to siren and shows the emergency message.

About three hours later, Michael's roommate comes home. He hears the pump sirening and wakes up Michael. Michael clears any messages by selecting OK. He sees that his basal insulin was suspended for the two hour maximum and had automatically resumed delivery. He checks his blood sugar and sees that it is within the target range.

20 mg/dL above Low Limit

STOP

START

Low Limit

2 hours
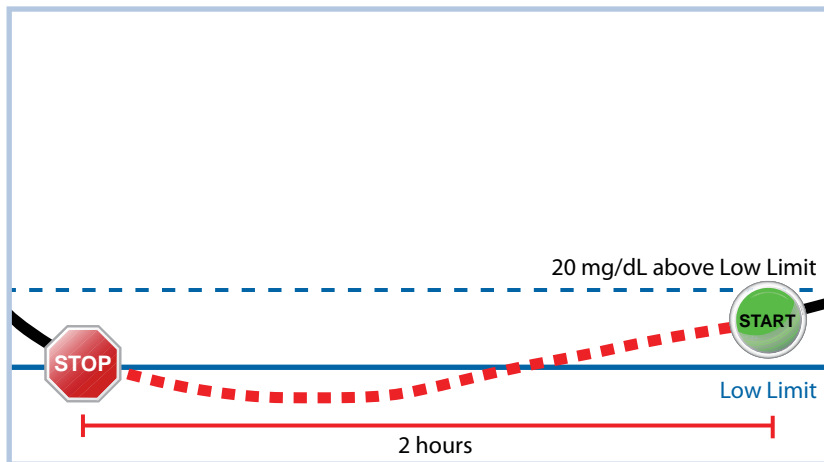
Michael has responded to his alert. The pump will suspend insulin delivery and alarm again if his sensor value reaches or falls below his low limit again.

Turning on the Sensor feature

You must turn on the Sensor feature before you can set up your glucose alerts and start monitoring your SG levels.

To turn on the Sensor feature:

1. Press ◎ and go to the Sensor Settings screen.

    Options > Utilities > Sensor Settings

2. Select **Sensor** to turn on the sensor feature. The sensor settings become accessible.

Setting up the high SG settings

The steps below show you how to set up the high SG settings. For details on your high SG settings, see *High SG settings, on page 179*.

> **Note:** When you enter your settings, you first define the time segment, and then select the high SG settings you want during that time segment.

To set up the high SG settings:

1. Press ◎ and go to the High Setup screen.

    Options > SmartGuard > High Setup

The High Setup screen appears.
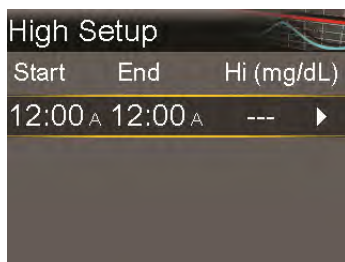
2. Select the time segment. The End time starts flashing.

   The Start time of the first time segment is always 12:00 A. You can set up to eight time segments, each with a different high limit. If you set more than one time segment, the time segments must cover a 24-hour period.

3. Set the End time.

4. Set your High limit. You can enter a value from 100 to 400 mg/dL, in increments of 5 mg/dL.

5. Select the arrow to the right of the End time to select the high alerts for this time segment.

   A screen appears and shows the high alerts for the selected time segment.
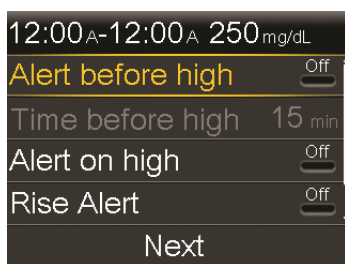
6. Set the following alerts as desired:

   a. Select **Alert before high** to receive an alert before you reach your high limit.

   b. Set the **Time before high** option between 5 to 30 minutes to receive an alert before you reach your high limit.

   c. Select **Alert on high** to receive an alert when you reach your high limit.

   d. Select **Rise Alert** to receive an alert when your SG is rising quickly.

      Go to step 11 if you do not select Rise Alert.

7. If you turned on the Rise Alert, you must set the Rise Limit. Scroll down and select **Rise Limit** to access this option.

The Rise Limit screen appears.
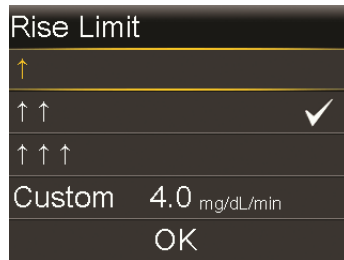
8. Select one, two, or three arrows for the rise rate. To use a custom rate, go to step 9.

   • Select ⬆ for an alert when your SG has been rising at a rate of 1 mg/dL per minute or more.

   • Select ⬆⬆ for an alert when your SG has been rising at a rate of 2 mg/dL per minute or more.

   • Select ⬆⬆⬆ for an alert when your SG has been rising at a rate of 3 mg/dL per minute or more.

   Select **OK**, and go to step 11.

   > **Note:** These arrows appear on your Home screen to indicate the rate at which your SG has been rising.

9. To enter a custom rise limit, do the following:

   a. Select **Custom**. The Custom Limit screen appears.

   b. Select **Rise Limit** and set a rise rate in 0.1 mg/dL/min increments from 1 to 5 mg/dL/min.

   c. Select **OK** to return to the Rise Limit screen, and then select **OK** again to confirm your settings.

10. After you set all the high SG settings for the selected time segment, select **Next** to continue.

11. If you entered an End time of anything other than 12:00 A, another time segment appears. After you enter the high SG settings, select **Done**.

12. Review your settings and select **Save**.

To change your high SG settings:

1. Press ◎ and go to the High Setup screen.

   Options > SmartGuard > High Setup

   The High Setup screen appears.

2. Select **Edit**.

3. Select and adjust the time segment you want to change.

4. Select any alert setting to turn it on or off or to adjust the setting.

5. Select **Next**.

6. Select **Done**.

7. Review your settings and select **Save**.

High Snooze

The High Snooze option is available once you set your high SG settings. The High Snooze option lets you set the amount of time that you want to wait before you are reminded that an alert condition still exists. You are alerted again only if the high alert condition still exists after the specified snooze time.

To set the High Snooze:

1. Press ◎ and go to the Snooze screen.

   Options > SmartGuard > Snooze

   The Snooze screen appears.

2. Select **High Snooze** and enter a value in 5-minute increments from 5 minutes to 3 hours.

3. Select **Save** to save your Snooze settings.

Setting up the low SG settings

The steps below show you how to set up the low SG settings. For details on the low SG settings, see *Low SG settings, on page 180.*

> **Note:** When you enter your settings, you first define the time segment, and then select the low SG settings you want during that time segment.

To set up the low SG settings:

1. Press ◎ and go to the Low Setup screen.

   Options > SmartGuard > Low Setup

   The Low Setup screen appears.
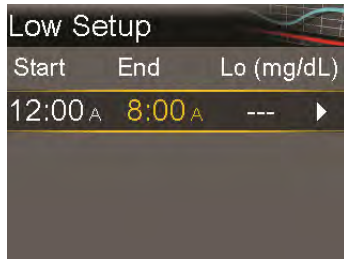
2. Select the time segment. The End time flashes.

   The Start time of the first time segment is always 12:00 A. You can set up to eight time segments, each with a different low limit. If you set more than one time segment, the time segments must cover a 24-hour period.

3. Set the End time.

4. Set your low limit. Enter a value in increments of 5 mg/dL from 50 to 90 mg/dL.

5. Select the arrow to the right of the End time to select the low SG settings for this time segment.

   A screen appears and shows the available settings for the selected time period.
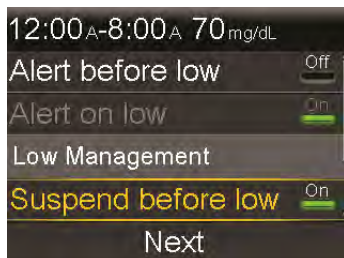
6. Set the following features as desired:

a. Select **Suspend before low** to have insulin delivery suspended before you reach your low limit. The Alert on low alert is automatically turned on and cannot be turned off.

b. Select **Alert before low** to receive an alert before you reach your low limit. If Suspend before low is also on, you are alerted when insulin delivery is suspended.

c. Select **Suspend on low** to have insulin delivery suspended when you reach or fall below your low limit. The Alert on low alert is automatically turned on and cannot be turned off.

d. Select **Alert on low** if you want to receive an alert when your SG reaches or falls below your low limit. If either suspend feature is on, this will already be on.

e. Select **Resume basal alert** if you want an alert when basal insulin delivery resumes based on SG values during a SmartGuard suspend event. If you do not turn on the alert, the Basal delivery resumed message still appears, but you will not receive an alert.

> **Note:** When you set your low alerts:
>
> - If you turn on Suspend before low or Suspend on low, Alert on low is turned on automatically.
>
> - Only one SmartGuard suspend feature can be used during each time segment. You cannot turn on both Suspend before low and Suspend on low in the same time segment.

7. When you have set all the low SG settings for the selected time segment, select **Next** to continue.

8. If you entered an End time of anything other than 12:00 A, another time segment appears.

    When you are finished entering your low SG settings, select **Done**.

9. Review your settings, and select **Save**.

To change your low SG settings:

1. Press ◎ and go to the Low Setup screen.

   Options > SmartGuard > Low Setup

   The Low Setup screen appears.

2. Select **Edit**.

3. Select, and if needed, adjust the time segment you would like to change.

4. Select any alert setting to turn it on or off or to adjust the setting.

5. Select **Next**.

6. Select **Done**.

7. Review your settings, and select **Save**.

Low Snooze

The Low Snooze option is available once you set your low SG settings. The Low Snooze option lets you set the amount of time that you want to wait before you are reminded that an alert condition still exists. You are alerted again only if the low alert condition still exists after the specified snooze time.

To set the Low Snooze:

1. Press ◎ and go to the Snooze screen.

   Options > SmartGuard > Snooze

   The Snooze screen appears.

2. Select **Low Snooze** and enter a time between 5 minutes and 1 hour.

Manually resuming basal insulin delivery during a SmartGuard suspend event

When your pump suspends insulin delivery due to a Suspend before low or Suspend on low event, the bottom of your Home screen shows either Suspended before low or Suspended on low depending on which is active.
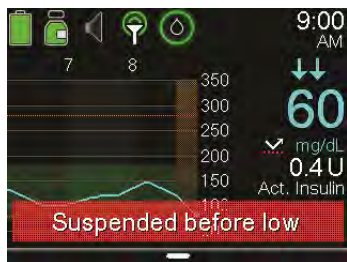
If you do not want to wait for your pump to automatically resume your basal insulin delivery, you can follow the procedure below to manually resume your basal insulin delivery.

To manually resume basal insulin delivery:

1. Press ◎ and select **Resume Basal**.

2. Select **Resume Basal**.

3. Select **Yes** to resume basal insulin delivery.

Pairing your pump and transmitter

Before you can start using your sensor, you must first pair your pump with your transmitter so they can begin communicating with each other when they are wirelessly connected.

Note that you can pair only one transmitter with your pump. If you already have a transmitter paired with your pump, you must delete it before continuing. For instructions on deleting a transmitter from your pump, see *Deleting the transmitter from your pump, on page 204.*

To pair the pump and transmitter:

1. Attach your transmitter to the charger and make sure the transmitter is fully charged. Keep your transmitter attached to the charger.
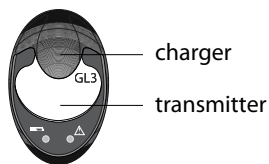
charger

transmitter

2. Press ◎ and go to the Device Options screen.

    Options > Utilities > Device Options

3. Select **Pair Device**.
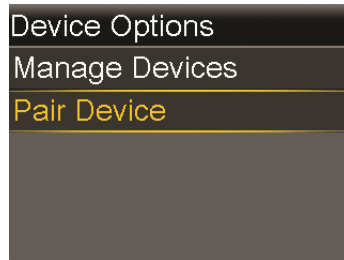
    The New Device screen appears.

4. Place the transmitter (still attached to the charger) next to the pump.
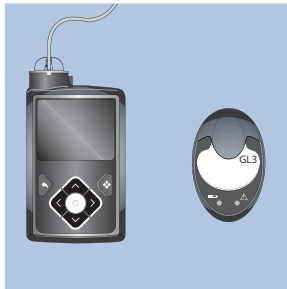
5. Select **Search** on your pump and immediately remove the transmitter from the charger.
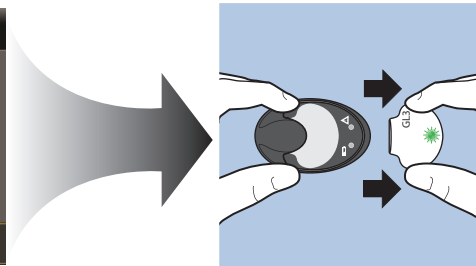
The following happens when you start the search process:

- On your pump, a message appears to let you know your pump is searching.

- On your transmitter, a green light starts to flash.

> **Note:** The search process can take up to two minutes. You cannot access your pump screens or suspend your pump during the search process.

The Select Device screen appears with a list of available devices.

6. Select the CGM device that matches the serial number on the back of the transmitter.

```
Select Device
Meter XXXXXXXX
CGM  XXXXXXXX
Meter XXXXXXXX
[Phone name]
```

7. Ensure the transmitter serial number on your pump screen matches the serial number on the back of your transmitter, and then select **Confirm**.

```
Confirm Device
Type: CGM Transmitter
SN: XXXXXXXX



   Cancel        Confirm
```
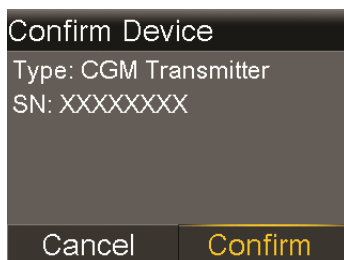
A message appears if the pump and transmitter are paired successfully. If the Sensor feature is turned on, the Connection icon 🔗 appears on the Home screen.

If your pump does not find your transmitter, the Device not found alert appears. See the following procedure, *If your pump does not find your transmitter*.

If your pump does not find your transmitter:

1. Select **OK** on the Device not found alert. The Select Device screen appears.

2. Select CGM from the list and reconfirm to retry pairing.

3. If the pairing is unsuccessful and the Device not found alert appears a second time, select **OK**. When the Select Device screen appears, select the **Back** button to return to the New Device screen to restart the pairing process from the beginning.

Deleting the transmitter from your pump

Follow this procedure to delete the transmitter from your pump. Use this process when you are replacing your transmitter.

To delete your transmitter from your pump:

1. Press ◎ and go to the Manage Devices screen.

    Options > Utilities > Device Options > Manage Devices

2. Select CGM.

3. Select **Delete**. A confirmation screen appears asking if you want to delete the device.

4. Select **Yes** to confirm or **No** to cancel.

Inserting the sensor

Choose an insertion site that has an adequate amount of subcutaneous fat. The Guardian Sensor (3) has been studied and is approved for use in the following sensor insertion sites by persons of the following ages:

Approved Age	Sensor Insertion Site
2-13	Abdomen and Buttocks
14 and older	Abdomen and Arm

The following image shows the best body areas (shaded) for sensor insertion.
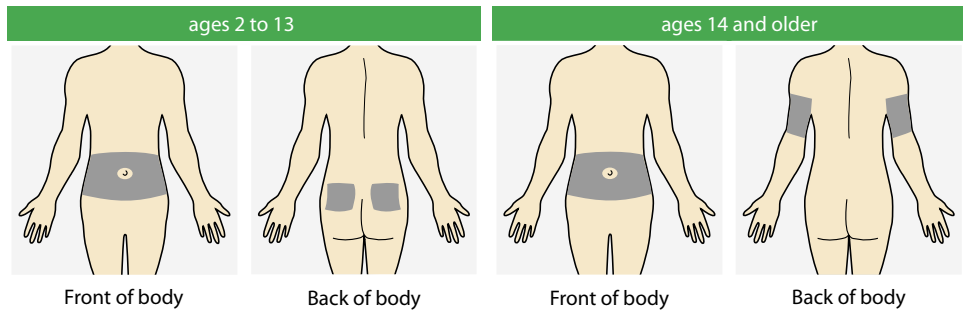
ages 2 to 13		ages 14 and older	
Front of body	Back of body	Front of body	Back of body

> **Note:** Assistance will likely be needed for sensor insertion into the back of the upper arm and into the buttocks. Some users found it difficult to insert the sensor into their arm and buttocks by themselves.

Always refer to your sensor user guide for specific instructions on how to insert the sensor. The sensor user guide uses the abdomen insertion site as an example in the instructions.

Connecting the transmitter to the sensor

Always refer to your transmitter user guide for instructions on how to connect the transmitter to the sensor.

Starting the sensor

After you insert your sensor and connect your sensor and transmitter, your pump starts to communicate with the transmitter. The pump tells you when the sensor is ready to use.

To start a new sensor:

1. Select **Start New Sensor** when it appears on the pump screen.

    The "Sensor warm-up started" message appears.

    > **Note:** It may take up to five minutes for the "Sensor warm-up started" message to appear.

2. Select **OK**.

"Warm up…" appears on the Home screen until the sensor is ready for first calibration.

Reconnecting the sensor

There are times when you remove the transmitter from an inserted sensor. After you reconnect the transmitter to the sensor, the pump detects the connected transmitter. A "Sensor connected" message appears.

To reconnect a sensor:

1. Select **Reconnect Sensor**.

    The "Sensor warm-up started" message appears.

    > **Note:** It may take up to five minutes for the "Sensor warm-up started" message to appear.

2. Select **OK**.

    "Warm up…" appears on the Home screen until the sensor is ready for its first calibration.

Calibrating your sensor

Calibration is the process of entering a BG meter reading to calculate SG values. You must calibrate your sensor regularly to ensure you continue to receive SG data. For details, see *Guidelines for calibrating, on page 209*.

> ⚠ **WARNING: Do not use Alternative Site Testing to calibrate a continuous glucose monitoring system.**

Within two hours after you use your pump to start the sensor, your pump displays a Calibrate now alert to let you know that a calibration is due. This BG meter reading is the first calibration for your sensor. It takes up to five minutes after calibration to see the first SG reading on your Home screen. You enter your second calibration within six hours after your first calibration.

After you have entered your first two calibrations, you must calibrate your sensor again within 12 hours. If you do not enter a BG meter reading within 12 hours, your pump displays the Calibrate now alert and stops calculating SG values until a calibration BG is successfully entered. The sensor must be calibrated at a minimum of every 12 hours throughout the life of the sensor. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day at regular times throughout the day, such as before meals.

You may also receive additional Calibrate now alerts to let you know that another calibration is required to improve performance.

When the Calibrate now alert appears, the system stops calculating SG values until a calibration BG is successfully entered.

> **Note:** Sensor calibration is successful only if your BG entry is in the range of 40 to 400 mg/dL. Remember to calibrate three or four times throughout the day for optimal results.

To calibrate your sensor:

1. Take a BG meter reading.

2. Press ◎ and go to the Calibrate Sensor screen.

   Options > Utilities > Sensor Settings > Calibrate Sensor

3. Select **BG** and enter the value.

4. Select **Calibrate**.

Where to enter your calibration BG meter reading

There are several screens on the pump where you can enter a BG meter reading for calibration. These screens are described in the following table. These options are available only if you are using a sensor.

> **Note:** After your Accu-Chek Guide Link meter wirelessly transmits your BG reading to your pump, you will be required to confirm your BG on your pump before you can use it for calibration.

Pump screen	How to enter your calibration BG
BG screen When you manually enter a BG, the pump will prompt if you want to calibrate your sensor with the BG reading. Press ◎ then select **Enter BG**.	Enter a BG meter reading specifically for calibration.
Calibrate Sensor screen Press ◎, then select: **Options > Utilities > Sensor Settings > Calibrate Sensor**	Enter a BG meter reading specifically for calibration.
BG Meter screen The BG Meter screen appears after your Accu-Chek Guide Link meter sends a BG meter reading to your pump, and after you confirm the BG.	Select the Calibrate Sensor option to calibrate your sensor with the current BG meter reading.
BG screen in Event Markers Press ◎, then select: **Options > Event Markers > BG**	When you enter a BG meter reading in Event Markers, the Event Markers screen has an option to use the BG value for calibration.
BG field in the Bolus Wizard screen Press ◎, then select: **Bolus > Bolus Wizard** The Bolus Wizard feature is only available in Manual Mode.	When you enter a BG meter reading to deliver a bolus using the Bolus Wizard feature, the Bolus Wizard feature gives you the option to use the BG value for calibration after the bolus is delivered.
BG field in the Auto Mode Bolus screen Press ◎, then select **Bolus**. Auto Mode Bolus is only available in Auto Mode.	When you enter a BG meter reading to deliver a bolus using the Auto Mode Bolus feature, Auto Mode gives you the option to use the BG value for calibration after the bolus is delivered.

When to calibrate

The following table describes when to calibrate your sensor.

Calibrate	Description
After warm-up is complete.	Do your first sensor calibration.
	Your pump displays a Calibrate now alert within two hours after starting a new sensor. Your first SG reading appears up to five minutes after you calibrate.
Within six hours after your first calibration.	Do your second sensor calibration.
	Six hours after you calibrate for the first time, a Calibrate now alert appears, and your pump stops calculating your SG values. It takes up to five minutes after you calibrate to receive SG values again.
Within 12 hours after your second calibration and at least every 12 hours thereafter.	After you do your second calibration, you need to calibrate at least every 12 hours. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day.
	If you do not calibrate for more than 12 hours, a Calibrate now alert appears. It takes up to five minutes after you calibrate to receive SG values again.
When the Calibrate now alert appears.	You may also receive additional Calibrate now alerts to let you know that another calibration is required to improve performance. It takes up to five minutes after you calibrate to receive SG values again.

Note: When a BG is entered for calibration, dashes appear in place of the SG reading, and "Calibrating…" appears on the sensor graph.

Guidelines for calibrating

Follow these guidelines for best sensor calibration results:

- Calibrate three or four times spread out throughout the day to improve accuracy. For details, see *When to calibrate, on page 208*.

- You can calibrate any time. However, calibrating with two or three trend arrows may temporarily decrease accuracy until the next calibration. For an example of trend arrows on the Home screen, see *Home screen with CGM in Manual Mode, on page 175*.

- Always calibrate immediately after you check your BG. Never calibrate with a BG meter reading taken more than 12 minutes earlier as that BG value would no longer be considered valid.

- Always use clean, dry fingers when you check your BG levels.

- Use only your fingertips when obtaining blood samples for calibration.

> **Note:** If your BG meter readings are significantly different than your SG readings, wash your hands and calibrate again.

Disconnecting the transmitter from the sensor

Always refer to your transmitter user guide for instructions on disconnecting the transmitter from the sensor.

Removing the sensor

Always refer to the sensor user guide for instructions on how to remove the sensor.

Turning off Sensor Settings

You can turn off Sensor Settings at any time. If you disconnect the transmitter from the sensor, turn off the Sensor Settings to avoid getting a sensor alert. Your sensor settings remain in your pump. You cannot make changes to the settings until you turn on the Sensor Settings again.

To turn off Sensor Settings:

1. Press ◎ and go to the Sensor Settings screen.

   Options > Utilities > Sensor Settings

2. Select **Sensor**.

3. Select **Yes** to turn off the sensor feature.

11

Using CGM

11

Using CGM

This chapter provides information on how to use CGM on your pump and view your sensor glucose (SG) data. This information helps you identify SG trends, including being notified if your SG is falling or rising rapidly. You can also view historical SG readings in a graph format. Information is also included on how to silence your glucose alerts.

The sensor graph

The sensor graph displays your current SG reading that is wirelessly sent to your pump by the transmitter.
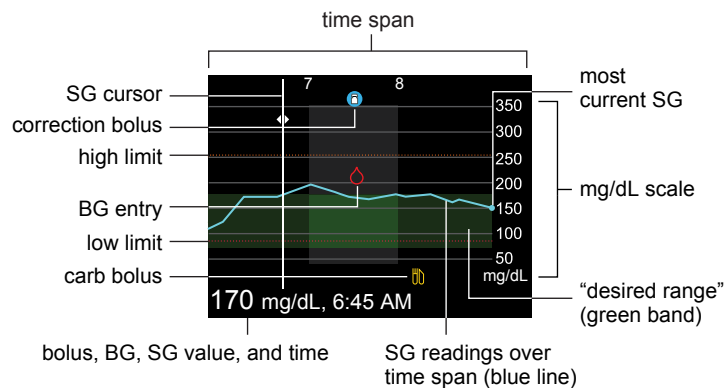
The sensor graph includes the following information:

- The most recent SG reading.

- Your historical SG readings for the last 3-hour, 6-hour, 12-hour, or 24-hour periods.

- Your high and low SG limits.

- The bolus deliveries you have given during the time period shown on the graph.

- Any suspend events that have occurred.

If an SG reading does not appear on the graph, some possible reasons for this include:

- An error condition or a sensor-related alert is occurring.

- A new sensor that you just inserted is still initializing.

- A new sensor that just initialized is still calibrating.

- An existing sensor that you have recently reconnected is not ready.

- More than six hours have passed since the initial sensor calibration.

- More than 12 hours have passed since the last sensor calibration.

To view the sensor graph:

1. From the Home screen, press the ❖ button.

   A full-screen view of the 3-hour graph appears.

2. Press ∧ to navigate to the 6-hour, 12-hour, and 24-hour graphs.

3. Press ⟨ to view SG readings and event details.

4. To exit the full-screen view, press ↩, or press the ❖ button again.

Identifying rapid changes in SG

When you use a sensor, trend arrows appear on the Home screen if your SG has been rising or falling faster than a certain per-minute rate. The number of arrows that appear tell you how quickly your SG is changing.

The following table shows the trend arrows and their corresponding rates.

↑	SG has been rising at a rate of 1 mg/dL per minute or more, but less than 2 mg/dL per minute.
↓	SG has been falling at a rate of 1 mg/dL per minute or more, but less than 2 mg/dL per minute.
↑↑	SG has been rising at a rate of 2 mg/dL per minute or more, but less than 3 mg/dL per minute.

↓↓	SG has been falling at a rate of 2 mg/dL per minute or more, but less than 3 mg/dL per minute.
↑↑↑	SG has been rising at a rate of 3 mg/dL per minute or more.
↓↓↓	SG has been falling at a rate of 3 mg/dL per minute or more.

Silencing glucose alerts

The Alert Silence option lets you make SG alerts silent for a set period of time. This is useful in situations where you do not want to disturb others, such as when you are in a business meeting or in a movie theater. When using this option, one of the following status icons appears on the Home screen, depending on your Audio Options settings: vibrate only 《⬛》, audio only 🔊, or vibrate and audio 《🔊》. Your system still records the time and glucose value for any alerts that occur. You can view this information in the Alarm History screen.

> **Note:** Alert Silence does not silence the Auto Mode exit alert, the High SG alert, or the Low SG XX mg/dL (XX represents 50 mg/dL or below) alarm. These are based on set glucose thresholds and cannot be silenced.

If a glucose alert occurs when you are using the Alert Silence option, the notification light begins to flash and the Sensor alert occurred alert appears to let you know an alert was silenced, but there is no vibration or beep. If you have not cleared the alert by the end of the preset alert silence duration, your pump begins to beep or vibrate periodically until the alert is cleared.

The following table describes the glucose alerts that are silenced with each option.

Option	Silences these alerts
High Alerts Only	Alert on high, Alert before high, and Rise Alert

Option	Silences these alerts
High & Low Alerts	Alert on high, Alert before high, Rise Alert, Alert on low, Alert before low, Suspend before low, and Resume Basal Alert

> **Note:** Alert on low cannot be silenced if the SmartGuard Suspend on low or SmartGuard Suspend before low options are turned on.

Option	Silences these alerts
All Sensor Alerts	All of the alerts listed previously for High & Low Alerts, plus the following:

- All calibration alerts, reminders, or error messages
- All alerts relating to sensor insertion, including alerts about sensor warm-up, changing your sensor, sensor expiration, sensor errors, connection issues, and so on
- All alerts related to your transmitter, including all alerts about your transmitter battery and all connection issues

To silence glucose alerts:

1. Press ◎ and go to the Alert Silence screen.

   Audio Options > Alert Silence Options

   Alert Silence
   High Alerts Only
   High & Low Alerts
   All Sensor Alerts
   Duration --- hr
   Begin
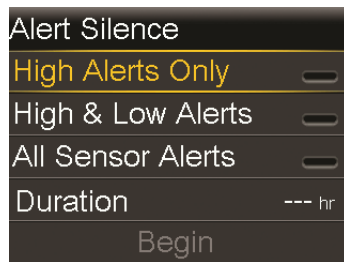
2. Select **High Alerts Only**, **High & Low Alerts**, or **All Sensor Alerts** to set the alerts you want silenced. Refer to the previous table for details about the alerts silenced with each selection.

> **Note:** If you select **All Sensor Alerts**, you will not receive most alerts related to your SG readings, your sensor, calibration requirements, or your transmitter. The Low SG XX mg/dL (XX represents 50 mg/dL or

below) alarm, the Auto Mode exit alert, and the High SG alert cannot be silenced. You still receive and hear these alerts when Alert Silence is on. If a silenced glucose alert occurs, the notification light flashes and a message appears to notify you that a silenced alert occurred, but there is no vibration or beep. You can view the specific alert in Alarm History. For more information, see *Alarm History, on page 145*.

3. Set the **Duration**. The duration can be set in 30-minute increments from 30 minutes to 24 hours.

4. Select **Begin**. The Alert Silence settings immediately take effect and you are returned to the Sensor Settings screen.

To cancel Alert Silence:

1. Press ◎ and go to the Alert Silence screen.

   Audio Options > Alert Silence

   ```
   Alert Silence
   All Sensor Alerts silenced
   Time Remaining:     0:28 hr


     Cancel Alert Silence
   ```

2. Select **Cancel Alert Silence**.

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SmartGuard Auto Mode

The Auto Mode feature is part of SmartGuard technology. It automatically controls basal insulin delivery. However, the Auto Mode feature still requires your input for meals, calibrations, and times when you need the target value raised.

Note: A total daily dose of at least 8 units, but no more than 250 units, is required to operate in Auto Mode.

About SmartGuard Auto Mode

SmartGuard Auto Mode is an insulin delivery feature designed to help people on intensive insulin therapy to achieve better control 24 hours a day. This is achieved by automatically controlling basal insulin delivery to regulate glucose levels to a target sensor glucose (SG) amount. The standard target SG setting is 120 mg/dL and the target can be set temporarily to 150 mg/dL for exercise and other events.

When Auto Mode is active, the SG values it receives from the transmitter are used to automatically calculate the basal insulin dose. This process of automatic delivery of insulin is called Auto Basal.

Auto Mode depends on reliable, accurate sensor measurements and your accurate entry of carbs to deliver insulin for meals. Therefore, the basic management of the therapy requires the following activities:

- Periodic blood glucose (BG) readings using a BG meter to calibrate the sensor. The minimum calibration is every 12 hours. For better sensor performance, it is recommended that you calibrate your sensor three or four times each day. You may also receive periodic requests from your pump for BG readings without the need for calibration.

- Use of the Auto Mode Bolus feature to deliver boluses to cover meals, and when your pump recommends a bolus.

> **Note:** Delivering a bolus in SmartGuard Auto Mode is similar to delivering a bolus with the Bolus Wizard feature in Manual Mode.

A BG reading above 150 mg/dL causes Auto Mode to automatically calculate if a correction bolus is needed to bring BG down to the 150 mg/dL BG correction target. If needed, a correction bolus will be recommended.

Manual Mode

In this user guide, the term Manual Mode refers to system functions other than Auto Mode. In other words, if Auto Mode is not active, the system is in Manual Mode.

Before using SmartGuard Auto Mode

SmartGuard Auto Mode can be enabled at any time, but it does not activate until the system completes a 48-hour warm-up period while you use the pump to deliver insulin. This warm-up period begins the midnight after the pump starts delivering insulin and it does not require sensor use. During the warm-up period, your Auto Mode system collects and processes data that help enable its automatic function.

> ⚠️ **WARNING: Do not put your pump into Auto Mode if you have used the pump in the last 3 days to practice button pressing, or if basal insulin that was programmed into your pump was not your actual basal delivery. Doing so may result in the delivery of too little or too much insulin, which can cause hyperglycemia or hypoglycemia. Auto Mode uses the recent delivery history on your pump to determine the Auto Basal delivery amount you receive. If you have been practicing with your pump, you must clear the active insulin and the total daily doses in the pump before using Auto Mode. Use the Clear Active Insulin option in the Manage settings menu to clear both active insulin and the total daily dose.**

To prepare your pump for SmartGuard Auto Mode:

1. Cancel any active Temp Basal rates. See *Canceling a temp basal or preset temp basal rate, on page 79*.

2. Ensure your delivery is not suspended. See *Stopping and resuming your insulin delivery, on page 80*.

3. Set your carb ratio. See *Changing your carb ratio, on page 96*.

4. Review your high and low limit settings. Your high and low limit settings apply to Auto Mode. See *Understanding glucose settings, on page 178* for details.

5. Enter a BG reading if you have not entered one in the past 12 minutes. If necessary, calibrate your sensor. If you have just started a new sensor, calibrate your sensor, and then wait 30 minutes before you enter a BG for Auto Mode. For more information about calibrating your sensor, see *Calibrating your sensor, on page 206*.

Setting up SmartGuard Auto Mode

Auto Mode can be enabled at any time but does not activate until the 48-hour warm-up period has been completed. For details about the warm-up period, see *Before using SmartGuard Auto Mode, on page 222*. Once enabled, Auto Mode begins automatically when all conditions are met and a BG is entered. For more information, see *SmartGuard Auto Mode Readiness, on page 225*.

To set up Auto Mode:

1. Press ◎ and go to the Auto Mode screen.

    Options > SmartGuard > Auto Mode

2. Select **Auto Mode** to turn the feature on or off.

3. Select **Auto Mode BG alert** to turn it on or off.

> **Note:** The Auto Mode BG alert is set to On by default. When this setting is on, your pump tells you when Auto Mode requires a BG to remain active. For information about the conditions that cause Auto Mode to require a BG, see *Safe Basal, on page 228*.

4. Select **Save**.

Conditions to activate SmartGuard Auto Mode

If you have been using Auto Mode and you turn off your pump for less than two weeks, there will only be a five-hour warm-up period once the pump is restarted. The other conditions must still be met before Auto Mode will activate.

If you have turned off your pump for more than two weeks, a new 48-hour warm-up period will be required.

If Auto Mode is enabled but not active, the Auto Mode Readiness screen indicates the reason why Auto Mode has not yet activated. See *SmartGuard Auto Mode Readiness, on page 225*.

It takes five hours for the Auto Mode Active Insulin to be updated. This update time happens under the following conditions:

*   When your pump is turned on the first time
*   May occur following a complete pump reset caused by a loss of power or a software error
*   Following a Suspend lasting four hours or longer

Once the Active Insulin is updated, it will be valid unless one of the conditions above happens, which will restart the update period. Auto Mode will then be locked out for another five hours.

SmartGuard suspend features and SmartGuard Auto Mode

When SmartGuard Auto Mode is active, the SmartGuard suspend features are unavailable and automatically turned off. If Suspend before low or Suspend on low are on, they are automatically turned off when Auto Mode becomes active. If your pump exits Auto Mode, the SmartGuard suspend features are not active until you turn them on after you exit Auto Mode. If you want to use the SmartGuard suspend features, you must manually turn them on after you exit Auto Mode. See *Low SG settings, on page 180*.

SmartGuard Auto Mode Readiness

The Auto Mode Readiness screen indicates whether your pump is ready to enter Auto Mode, or return to Auto Basal from Safe Basal.

The following table shows what to do when the wait icon 🔵 or the question icon ❓ appear by items on the Auto Mode Readiness status screen.
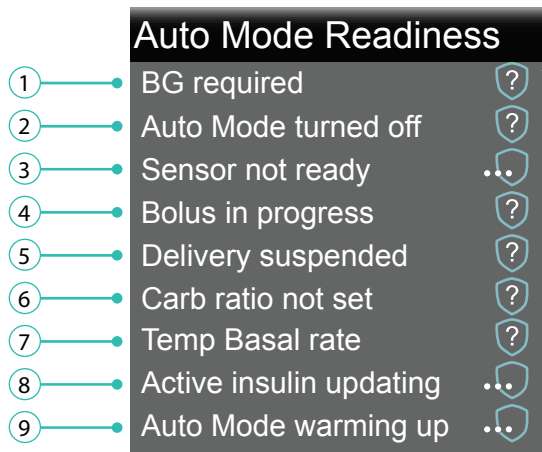
Line	Item		Instructions
1	Calibration required	?	Perform a fingerstick and calibrate your sensor.
	BG required	?	Perform a fingerstick and enter a new BG.
	Wait to enter BG...	🔵	Wait until the pump prompts you to enter a BG.
	Processing BG...	🔵	Wait until the BG has processed.

Line	Item	Instructions
(2)	Auto Mode turned off	Turn on Auto Mode in the SmartGuard, Auto Mode screen.
(3)	Sensor not ready	Do the following: • Check to see if your pump has a transmitter ID entered in Utilities, Device Options. For example, GT6133333M. Make sure your pump is paired with a transmitter. For more information, see *Pairing your pump and transmitter, on page 201*. • Check your Home screen. If you see ✖, move your pump and transmitter closer together. The pump will try to find the transmitter signal. If after 30 minutes the pump and transmitter are still not communicating, you will receive a Lost sensor signal alert. Check that the sensor is still inserted in the skin, and the transmitter and sensor are still connected. Move your pump closer to your transmitter. • If your SG is outside of the 40 to 400 mg/dL range, your pump will not enter Auto Mode.
	Sensor off	Turn on the sensor in the Utilities, Sensor Settings screen.
(4)	Bolus in progress	Wait until the bolus is complete or stop the bolus yourself before Auto Mode can activate.
(5)	Delivery suspended	If insulin delivery is suspended, Auto Mode cannot activate. Treat low BG if necessary as instructed by your healthcare professional.

Line	Item	Instructions
6	Carb ratio not set (?)	When you turn on the Bolus Wizard feature for the first time, enter your Carb Ratio in the Edit Carb Ratio screen. You can also enter your Carb Ratio in the Bolus Estimate Setup screen, even if the Bolus Wizard feature is not turned on.
7	Temp Basal rate (?)	If a temp basal rate is currently active, you must wait until it has completed or cancel the temp basal rate yourself before Auto Mode can activate.
8	Active insulin updating	If active insulin is currently updating, it may take up to five hours to complete. You must wait until this amount is updated before Auto Mode can activate.
9	Auto Mode warming up	Auto Mode gathers information on your insulin delivery history in order to personalize its automatic delivery of insulin. This may require up to 48 hours to complete.

To check Auto Mode Readiness:

1. Press ◎ and select **Status** to go to the Status screen.
2. Select **Auto Mode Readiness**.

Home screen with SmartGuard Auto Mode

When your pump transitions into Auto Mode, the Home screen on your pump changes to display a shield that contains a real-time display of your current SG level. The Home screen also displays your current Active Insulin value.

SmartGuard Auto Mode 227
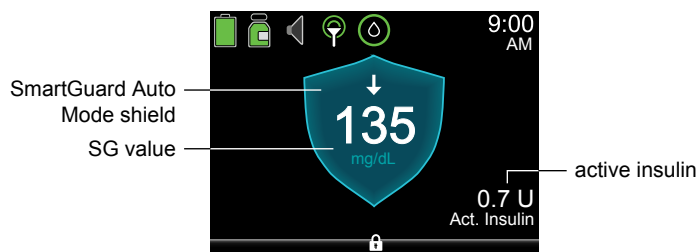
Using SmartGuard Auto Mode

The following sections provide information on how to use SmartGuard Auto Mode and how to view your SG data. This information helps you identify SG trends, including indications that your SG is falling or rising rapidly. You can also view historical SG readings in a graph format.

Safe Basal

Safe Basal is an automatic function within SmartGuard Auto Mode and cannot be modified. The Safe Basal rate is determined by the Auto Mode feature based on your insulin delivery history. It lets you have time to perform additional actions required to ensure Auto Mode remains active. Safe Basal delivers insulin at a constant rate to cover your basal needs. Safe Basal does not adjust insulin delivery based on your current SG values.

When the pump is in Safe Basal, the Auto Mode shield appears with a white outline.
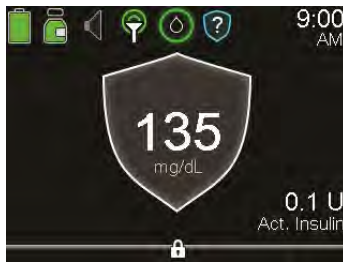
Several conditions can cause a transition into Safe Basal. The following table describes these conditions and the actions you must take to resume Auto Basal delivery. An optional setting called the Auto Mode BG alert can be set to have the pump alert you when a BG entry is required. This setting is turned on by default. For more information about the Auto Mode BG alert, see *Setting up SmartGuard Auto Mode, on page 223*.

Condition	Instructions
Auto Mode has been at the minimum delivery limit for 2 1/2 hours.	Enter a BG. An Auto Mode min delivery alert occurs if the Auto Mode BG alert is enabled.

Condition	Instructions
Auto Mode has been at the maximum delivery limit for four hours.	Enter a BG. An Auto Mode max delivery alert occurs if the Auto Mode BG alert is enabled.
Your sensor might be reading lower values than your actual glucose values.	Enter a BG. A BG required alert occurs if the Auto Mode BG alert is enabled.
An entered BG is 35% or more different than your current SG value.	Enter a BG. A BG required or Cal required for Auto Mode alert occurs if the Auto Mode BG alert is enabled.
No SG data has been received for more than five minutes.	• If SG data is not available due to a signal interference, three dashes appear on the screen in place of the SG data. If the interference is intermittent, the Auto Mode shield appears with a white outline, and no action is required. • If your pump has not received SG data for 30 minutes or more, a Lost sensor signal alert occurs. For more information, see *CGM (sensor) alarms, alerts, and messages, on page 264*. • If the SG data is not available because you need to calibrate the sensor again, calibration has expired, or when the system detects another calibration is required to improve sensor performance, you receive a Calibrate now alert. Calibrate your sensor. See *CGM (sensor) alarms, alerts, and messages, on page 264*. The Auto Mode BG alert does not apply to this condition.

After 90 minutes in Safe Basal, if the condition that caused the pump to transition into Safe Basal is not resolved, the pump enters Manual Mode.

> **Note:** When you change your sensor, your pump switches to Safe Basal for up to 90 minutes. The pump tells you to calibrate and enter a BG for Auto Mode.

Example: Safe Basal

Alex's pump is in Auto Mode. Before lunch, he checks his BG, and enters the value into his pump. Alex notices the BG he entered was much higher than his current SG reading. Alex receives a BG required alert for Auto Mode. His pump displays a gray shield, indicating that Auto Mode is now in Safe Basal delivery. He washes his hands, repeats his fingerstick, and enters the new BG into the pump.

Alex checks his user guide and realizes that his pump entered Safe Basal because the difference between his SG and BG entry was greater than 35%.

Block Mode when in SmartGuard Auto Mode

Block Mode lets a caregiver block the patient from changing settings or delivering a bolus directly on the pump. In Block Mode, the following actions can be done while the pump is in Auto Mode:

• Auto Basal delivery

• BG correction bolus if BG was sent from your Accu-Chek Guide Link meter

• Calibration if BG was sent from your Accu-Chek Guide Link meter

The following actions cannot be done in Block Mode:

• Bolus delivery or entry unless prompted by the Bolus Recommended screen

• Changes to Auto Mode settings

• Manual BG entry

Setting Temp Target

You can set a temporary SG target (Temp Target) of 150 mg/dL for situations in which you would like your target to be temporarily higher, such as exercise. Check with your healthcare professional regarding use of a Temp Target.

To set a Temp Target:

1. Press ◎ and select **Temp Target** to go to the Temp Target screen.
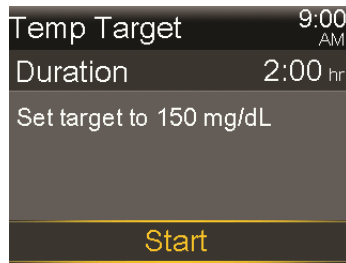
2. Set the duration. The default is two hours and the maximum duration is 12 hours. Use ∧ and ∨ to set the duration in 30-minute increments.

3. Select **Start**.

    The screen shows Temp Target Started, and then changes to the Home screen, where a banner shows the remaining Temp Target time.
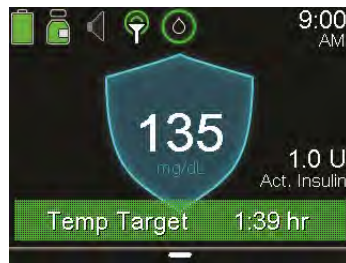
    When the Temp Target time runs out, the banner disappears from the Home screen.

To cancel Temp Target:

1. Press ◎ and select **Cancel Temp Target** to go to the Temp Target screen.
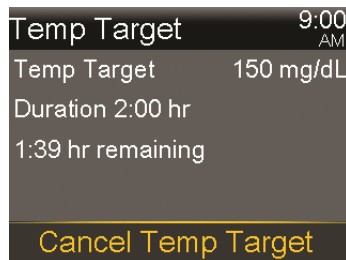
2. Select **Cancel Temp Target**.

    The Temp Target will be canceled and the Home screen will appear, with no Temp Target banner.

SmartGuard Auto Mode sensor graph

Your Auto Mode sensor graph displays your current SG reading that is wirelessly sent to your pump by your transmitter.
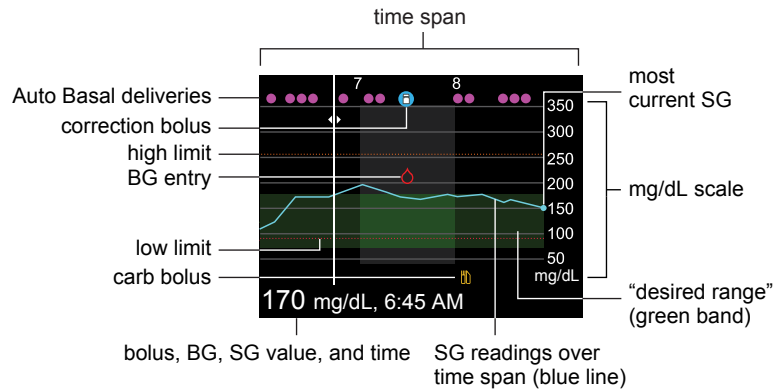
The Auto Mode sensor graph includes the following information:

- The bolus, BG, SG value, and time are displayed at the bottom of the screen. When you select a location on the graph, the specific details of the SG or event appear. Each Auto Basal delivery is displayed as a separate event rather than a delivery in units per hour. In addition, it is labeled as "Basal." For example, "Basal, 0.225 U" means 0.225 U was fully delivered at that time.

- Historical SG readings are displayed for the last 3-hour, 6-hour, 12-hour, or 24-hour periods. They appear as a blue line across the screen.

- Correction boluses are shown as white vials inside blue circles.

- Meal (carb) boluses are shown as yellow knife and fork symbols. These represent any bolus amounts that include a carb entry.

- BG entries appear as red drop symbols.

- The numerous small magenta dots along the top represent the automatically delivered basal insulin (Auto Basal or Safe Basal) delivered by SmartGuard Auto Mode.

- A time change event appears as a white clock symbol.

If an SG reading does not appear on the graph, some possible reasons for this include:

- An error condition or a sensor-related alert is occurring.

- A new sensor that you just inserted is still initializing.

- A new sensor that just initialized is still calibrating.

- An existing sensor that you have recently reconnected is not ready.

- More than six hours have passed since the initial sensor calibration.

- More than 12 hours have passed since the last sensor calibration.

To view the sensor graph:

1. From the Home screen, press the ❖ button to display the SG graph.

   A full-screen view of the 3-hour graph appears.

2. Press ∧ to navigate to the 6-hour, 12-hour, and 24-hour graphs.

3. Press ⟨ to view SG readings and event details.

4. To exit the full-screen view, press ↩ or press the ❖ button again.

Enter BG

The BG screen lets you manually enter a BG value. When you access the BG screen, it does not show any previously entered manual or linked meter BG values. If a BG value is received from a linked meter, that value will immediately display in a separate BG Meter screen and you will be prompted to confirm the BG value.

When you enter a BG while in Auto Mode, a correction bolus may be suggested.

To manually enter BG readings:

1. Press ◎ and select **Enter BG** to go to the BG screen.

2. Select **Enter BG**.

3. Enter a BG value.

4. Select **Save**.

5. A screen appears prompting you to calibrate your sensor with the BG value if you want. Select **Yes** or **No**.

SmartGuard Auto Mode Bolus

Delivering a bolus in SmartGuard Auto Mode is similar to delivering a bolus using the Bolus Wizard feature in Manual Mode. The Bolus feature in Auto Mode requires you to enter either carbs or a BG value. You may also choose to enter both. Auto Mode then calculates the bolus amount needed to cover the meal or correction. Once you confirm this amount, Auto Mode will deliver the bolus.

The Auto Mode Bolus screen shows your current Active Insulin value.

> ⚠️ **WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode. Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.**

> **Note:** Auto Mode Bolus only supports Normal boluses. Square Wave, Dual Wave, Easy, Manual, and Preset bolus types cannot be delivered while in Auto Mode.

When a BG reading is over 150 mg/dL in Auto Mode, the pump may recommend a correction bolus. SmartGuard Auto Mode calculates the recommended correction bolus. SmartGuard Auto Mode takes several factors into account that include your BG reading and active insulin.

After you confirm your BG reading from an Accu-Chek Guide Link meter on the pump, Bolus recommended appears below the BG value if the pump calculates that a correction bolus is needed. Select **Bolus** to deliver the recommended bolus. If you manually enter your BG, a Bolus recommended screen appears. Select **Bolus** to deliver the recommended bolus.

If the BG is under 150 mg/dL or if the bolus is zero after the pump accounts for active insulin, no correction is recommended.

```
Bolus                    9:00
                          AM
BG              --- mg/dL
Carbs              0 g

Active Insulin     0.0 U
              Next
```
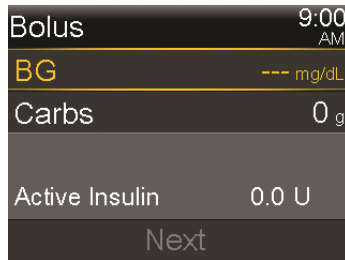
If you use an Accu-Chek Guide Link meter, you can send your BG meter readings directly to your pump. A confirmation screen appears for you to confirm the BG value on the pump. Confirmed BG values are automatically used in the BG field of the Auto Mode Bolus screen. The confirmed BG values are valid for up to 12 minutes after sending them to the pump. Confirm the BG meter reading from an Accu-Chek Guide Link meter before you use the Auto Mode Bolus feature. If you do not use an Accu-Chek Guide Link meter, you must manually enter your BG value.

Note: Do not use a BG meter reading in the Auto Mode Bolus screen if more than 12 minutes have passed since you have taken the BG meter reading. That BG meter reading and the corresponding bolus amount may no longer be accurate.

To use the Auto Mode Bolus feature:

1. Press ◎ and select Bolus to go to the Bolus screen in Auto Mode.

2. If you use an Accu-Chek Guide Link meter, go to step 3. Otherwise, enter your BG value. You can enter a value within the range of 20 to 600 mg/dL.

3. Enter your Carb amount in grams. If you choose not to enter a Carb amount, go to step 4.

4. Select **Next**.

   The screen indicates the amount of the calculated bolus.

5. Select **Deliver Bolus**.

   A screen appears briefly to indicate the bolus delivery has started. Then, the Home screen appears and shows the progress of the bolus delivery.
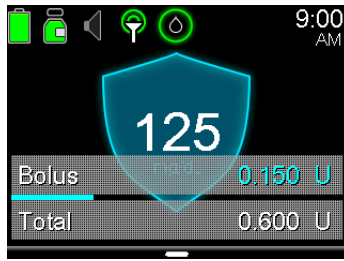
> **Note:** You can stop a bolus at any point by pressing ◎ and selecting **Stop Bolus**.

6. If a new BG value is used in the Auto Mode Bolus feature, the following screen also appears to ask you to calibrate your sensor. Select **Yes** or **No**.
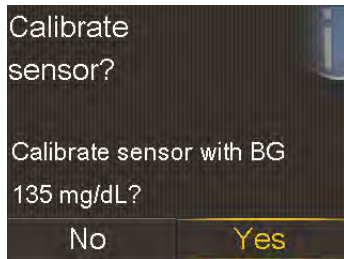
Alert Silence

The Alert Silence option ![icon] lets you temporarily silence SG alerts. This is useful in situations where you do not want to disturb others, such as when you are in a business meeting or in a movie theater. When using this option, your system still records the time and glucose value for any alerts that occur. You can view this information in the Alarm History screen. See *Alarm History, on page 145* for details.

If a glucose alert occurs when you are using the Alert Silence option, the notification light begins to flash and the Sensor alert occurred alert appears to let you know an alert was silenced, but there is no vibration or sound. If you have not cleared the alert by the end of the preset alert silence duration, your pump begins to beep or vibrate periodically until the alert is cleared.

> **Note:** The following alarms and alerts are never silenced:
> • Low SG XX mg/dL (XX represents 50 mg/dL or below) alarm

- Auto Mode exit alert

- High SG alert

For more information about the Auto Mode exit alert or the High SG alert, see *SmartGuard Auto Mode alerts and messages, on page 275*. For more information about the Low SG XX mg/dL (XX represents 50 mg/dL or below) alarm, see *CGM (sensor) alarms, alerts, and messages, on page 264*.

You can check the status of the Alert Silence option in the Sensor screen. For more information, see *Status screens, on page 52*.

The following table describes the glucose alerts that are silenced with each option.

Option	Silences these alerts
High Alerts Only	Alert on high, Alert before high, and Rise Alert
High and Low Alerts	Alert on high, Alert before high, Rise Alert, Alert on low, and Alert before low

> **Note:** Alert on low cannot be silenced if the SmartGuard Suspend on low or SmartGuard Suspend before low options are turned on.

All Sensor Alerts	All of the alerts listed previously for High and Low Alerts, plus the following:

- All calibration alerts, reminders, or error messages

- All alerts relating to sensor insertion, including alerts about sensor warm-up, changing your sensor, sensor expiration, sensor errors, connection issues, and so on

- All alerts related to your transmitter, including all alerts about your transmitter battery and all connection issues

To set Alert Silence in Auto Mode:

1. Press ◎ and go to the Alert Silence screen.

   Audio Options > Alert Silence Options

Alert Silence
High Alerts Only
High & Low Alerts
All Sensor Alerts
Duration   --- hr
Begin
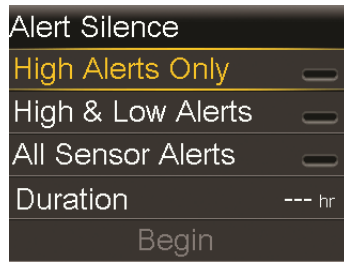
2.   Select High Alerts Only, High and Low Alerts, or All Sensor Alerts to set the
     alerts you want silenced. Refer to the previous table for details about the
     alerts silenced with each selection.

> **Note:** If you select **All Sensor Alerts**, you will not receive most alerts
> related to your SG readings, your sensor, calibration requirements, or
> your transmitter. The Low SG XX mg/dL (XX represents 50 mg/dL or
> below) alarm, the Auto Mode exit alert, and the High SG alert cannot
> be silenced. You still receive and hear these alerts when Alert Silence
> is on. If a silenced glucose alert occurs, the notification light flashes
> and a message appears to notify you that a silenced alert occurred,
> but there is no vibration or beep. You can view the specific alert in
> Alarm History. For more information, see *Alarm History, on page 145*.

3.   Set the **Duration**. The duration can be set in 30-minute increments from 30
     minutes to 24 hours.

4.   Select **Begin**. The Alert Silence settings immediately take effect and you are
     returned to the Sensor Settings screen.

To cancel Alert Silence:

1.   Press ◎ and go to the Alert Silence screen.

     Audio Options > Alert Silence

2. Select **Cancel Alert Silence**.

Exiting SmartGuard Auto Mode

The pump will exit SmartGuard Auto Mode:

- Auto Mode has been in Safe Basal for 90 minutes. See *Safe Basal, on page 228*.

- A High SG alert has occurred.

- You have not cleared any suspend event messages within four hours.

- You manually turned off the Sensor feature or disconnected the transmitter.

Some alarms cause the pump to exit SmartGuard Auto Mode and also turn the Auto Mode feature off. Auto Mode is turned off if an alarm initiates a pump reset. If this occurs, you will no longer see the SmartGuard Auto Mode shield on your Home screen. You must turn the Auto Mode feature on again and go through a five-hour warm-up period.

You can turn off Auto Mode at any time. For more information, see *Setting up SmartGuard Auto Mode, on page 223*.

Returning to SmartGuard Auto Mode

If you have automatically transitioned to Manual Mode, you can return to Auto Mode if all readiness conditions are satisfied and you enter a BG. For more information, see *SmartGuard Auto Mode Readiness, on page 225*.

> **Note:** If you have turned Auto Mode off, you cannot return to Auto Mode until you turn Auto Mode on again.

You can return to Auto Mode if the following conditions are satisfied:

- Auto Mode is enabled on your pump.

- Your sensor is providing good SG values.

- A bolus is not in progress.

- A temp basal rate is not in progress.

- 48-hour warm-up is complete.

- Auto Mode is not in a five-hour warm-up period.

- You have entered a new BG reading.

If any of these conditions are not met, Auto Mode cannot restart.

13

13 Alarms, alerts, and messages

This chapter describes the general behavior of the most common and the most serious notifications and how to resolve them. For information about how to set your notification preferences in the app, see the MiniMed Mobile app user guide.

About alarms, alerts, and messages

Your pump has a sophisticated safety network. If this safety network detects anything unusual, it conveys this information in the form of notifications. Notifications include alarms, alerts, and messages.

When you receive more than one notification and there are multiple messages to view, a small white flap appears on the notification icon in the upper-right corner of the screen . When you clear the first notification, the next notification becomes visible.

> **Note:** It is important that you promptly respond to all notifications and confirmations that appear on your pump. In the event that you do not respond, your pump may remain on that screen until addressed.
>
> When you respond to a message, there may be times when another message appears. Always be sure to address all notifications you have received.

A white triangle in the lower-right corner means you must press ∨ to continue.

> ⚠️ **WARNING: If you receive a Critical pump error alarm on your pump, the following screen displays and the pump sirens.**
>
>
>
> **Immediately disconnect from your insulin pump and discontinue use. Contact 24-Hour Technical Support for assistance.**
>
> **Remember, your body still needs insulin while your pump is removed.** It is important that you consult your healthcare professional to determine an alternate method of receiving insulin while your pump is removed. For more information on the Critical pump error alarm, see *Pump alarms, alerts, and messages, on page 246.*

Alarms

An alarm warns you of a condition that needs your immediate attention. Stopped insulin delivery and low glucose levels are the most common reasons for alarms.

> ⚠️ **WARNING: Always address alarms immediately when they occur. Ignoring an alarm can result in hyperglycemia or hypoglycemia.**
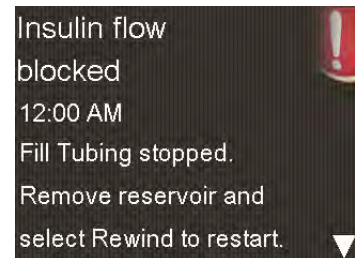
When an alarm occurs:

Display: The pump displays a notification with a red icon and instructions.

Notification light: The red notification light blinks twice, followed by a pause, in a continuous repeating pattern.

Audio: Depending on your Audio Options settings, the pump emits an alarm tone, a continuous three-pulse-and-pause vibration pattern, or both the alarm tone and vibration.

You must resolve the underlying problem that triggered the alarm. In most cases, you clear an alarm by pressing ⌄ and then you make a selection. In some cases, however, clearing the alarm does not fix the underlying problem. The alarm repeats until the underlying problem is fixed.

If you do not respond to an alarm, after ten minutes the alarm tone escalates to a loud emergency siren.

Alerts

An alert makes you aware of a situation that may require your attention. When an alert occurs, always check your pump screen to see if any action is required.

When an alert occurs:

Display: The pump displays a notification with a yellow icon and instructions.

Low battery
Pump
12:00 AM
Replace battery soon.
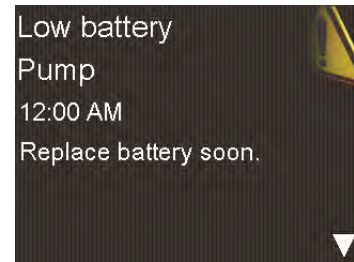
Notification light: The red notification light on your pump blinks once, followed by a pause, then blinks once again in a continuous repeating pattern.

Audio: Depending on your Audio Options settings, the pump either beeps or vibrates in a continuous three-pulse-and-pause pattern, or does both.

To clear an alert, press ⌄ and then make a selection. If you do not respond to an alert, the pump beeps every five minutes or every fifteen minutes, depending on the alert. Some alerts will also escalate to a loud emergency siren after ten minutes.

> **Note:** If an alert occurs when you are in a screen other than the Home screen, the alert message may appear after you return to the Home screen.

Messages

A message informs you about the status of your pump or if you need to make a decision.

When a message occurs:

Display: The pump displays a notification with a blue icon and instructions.

Notification light: Does not illuminate or blink.

Audio: Depending on the message, the pump emits a message tone, an alert tone, or no tone. Depending on your Audio Options settings, you may hear a tone, feel a one-pulse-only vibration, or hear a tone and feel a vibration.

You clear the message by pressing ∨ and making a selection.
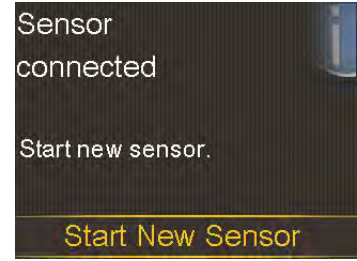
Pump alarms, alerts, and messages

The following table lists the most common or serious alarms, alerts, and messages related to your pump. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution.

Title and text	Type	Explanation	Next steps
Active Insulin cleared Any Active Insulin amount has been cleared.	Alert	Your active insulin amount is now at 0 units. This may occur because certain alarms automatically clear active insulin.	• Select **OK** to clear the alarm. • The active insulin tracked prior to pump restart is not included in new Bolus Wizard calculations. Consult your healthcare professional for how long you need to wait after active insulin is cleared before you can rely on the active insulin calculation of the Bolus Wizard feature. • You can check Daily History for the time and amount of your last bolus.
Auto Suspend Insulin delivery suspended. No buttons pressed within time set in Auto Suspend.	Alarm	Insulin delivery is currently suspended by Auto Suspend. Auto Suspend is a feature you enabled to automatically suspend insulin delivery and trigger an alarm after no buttons are pressed for a specified period of time. Insulin delivery is suspended until you clear the alarm and resume basal insulin delivery.	• To clear the alarm and resume basal insulin delivery, select **Resume Basal**. • Check your blood glucose (BG) and treat as necessary.

Title and text	Type	Explanation	Next steps
Battery failed Insert a new AA battery.	Alarm	The pump battery does not have enough power.	• Select **OK** to clear the alarm. • Remove the old battery and insert a new AA battery.
Battery not compatible. See User Guide.	Alarm	The battery that you inserted into the pump is not compatible.	• To clear the alarm, remove the incompatible battery. • Insert a new AA battery.
Bolus not delivered Bolus entry timed out before delivery. If bolus intended, enter values again.	Alert	Bolus values entered, but bolus was not delivered within 30 seconds.	• Select **OK** to clear the alert. • If bolus delivery was intended, check your BG, re-enter bolus values and deliver bolus.
Bolus stopped Cannot resume bolus or cannula fill. XX.XXX of YY.YYY U delivered. ZZ.ZZZ U not delivered. If needed, enter values again.	Alarm	The battery power was exhausted while a bolus or Fill Cannula was in progress, or you did not respond to the Resume bolus? message after replacing the battery.	• Note the amount of insulin not delivered. • Replace the AA battery. • Select **OK** to clear the alarm. • Deliver the remaining bolus amount if needed.

Title and text	Type	Explanation	Next steps
Check settings Startup Wizard settings complete. Check and set up your other settings.	Alert	Some settings have been cleared or reverted to factory default values.	• Select **OK** to clear the alert. • Review any settings that you have not already set in Startup Wizard and re-enter the values, if necessary.
Critical pump error Delivery stopped. Pump not working properly. Stop using pump. Remove infusion set from body. Consider other insulin treatment. See User Guide.	Alarm	Your pump has encountered an error that cannot be resolved. For example, your pump may have a mechanical problem.	The pump is not able to deliver insulin. Remove your infusion set and stop using your pump. • Consider another form of insulin delivery. • Check your BG, and treat as necessary. • Write down the error code that appears on the alarm screen. • Call 24-Hour Technical Support for assistance with your pump.
Delivery limit exceeded Delivery stopped. Check BG. See User Guide for more information.	Alarm	Your pump has suspended because the hourly delivery limit was met. This limit is based on the maximum bolus and maximum basal setting. If this alarm occurs during a bolus, the bolus is canceled before it can complete.	• Check your BG. • Select **Resume Basal**. • Check Bolus History and re-evaluate your need for insulin. • Continue to monitor your BG.

Title and text	Type	Explanation	Next steps
Device Limit You must delete an existing device (device type) before you can pair a new one (device type).	Message	The pump is already paired with the maximum number of devices for this type. The following list describes the maximum number of each device type to pair with the pump: • Meter–four Accu-Chek Guide Link meters • CGM–one Guardian Link (3) transmitter • Mobile Device–one compatible mobile device	• Select **OK** to clear the message. • Go to the Manage Devices screen and select the device you want to delete from the list of devices. Select **Delete**, and then select **Yes** to confirm or **No** to cancel. Pair the pump and the desired device.
Device not compatible Device cannot be used with this pump.	Alert	The pump cannot pair with the selected device.	• Select **OK** to clear the alert. • Call 24-Hour Technical Support for assistance.

Title and text	Type	Explanation	Next steps
Device not found Make sure device is in range and in pairing mode.	Alert	The pump did not pair with the device.	• Select **OK** to clear the alert. • Make sure the device is not already paired with a pump. • Make sure the device is ready to pair with the pump. • Make sure you are away from any electronic devices that might cause interference, such as cellular phones that are not paired with the MiniMed 770G System and other wireless devices. • Move the device closer to the pump. • Try to pair the pump with the device again.
Fill Cannula? Select Fill to fill cannula or select Done if not needed.	Alarm	You had the Fill Cannula screen displayed for 15 minutes.	• To proceed and fill the cannula, select **Fill**. • If you do not need to fill the cannula, select **Done** to skip this process.

Title and text	Type	Explanation	Next steps
High BG XXX mg/dL Check infusion set. Check ketones. Consider insulin injection. Monitor BG. Confirm BG?	Alert	Your BG meter reading is above 250 mg/dL. This alert applies when the Auto Mode feature is off. For High BG XXX mg/dL when the Auto Mode feature is on, see *SmartGuard Auto Mode alerts and messages, on page 275*.	• Select **No** to prevent the remote BG from being used by your pump. Select **Yes** to confirm the BG reading. • Check your BG and treat as necessary.
Insert battery Delivery stopped. Insert a new battery now.	Alarm	The battery was removed from the pump. If a bolus was in progress when the battery was removed, a Resume bolus? message appears and a tone sounds when a new battery is inserted. The message indicates how much bolus was delivered.	• Insert a new AA battery. • The alarm clears when you insert a new battery. • The pump powers off after 10 minutes unless you insert a new battery.

Title and text	Type	Explanation	Next steps
Insulin flow blocked Check BG. Consider testing ketones. Check reservoir and infusion set.	Alarm	Your pump has detected that the basal or bolus insulin flow was blocked.	• Check your BG. Consider checking ketones and take an injection if needed. • Remove your infusion set and reservoir. • Select **Rewind** to start the new reservoir process using a new infusion set and reservoir. If a bolus delivery was in progress when the alarm occurred: • Check the Daily History screen for the amount of bolus already delivered before the pump alarmed. • Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.

⚠ **WARNING: Do not use Auto Mode for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in Auto Mode. Therefore, Auto Mode could deliver too much insulin. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you resume Auto Mode.**

Title and text	Type	Explanation	Next steps
Insulin flow blocked Check BG. Consider testing ketones. Estimated 0 U insulin in reservoir. Change reservoir and infusion set.	Alarm	Your pump has detected that the insulin flow was blocked and there is no insulin in the reservoir.	• Check your BG. Consider checking ketones and take an injection if needed. • Remove your infusion set and reservoir. • Select **Rewind** to start the new reservoir process using a new infusion set and reservoir. If a bolus delivery was in progress when the alarm occurred: • Check the Daily History screen for the amount of bolus already delivered before the pump alarmed. • Consider delivering remaining bolus, if the bolus insulin was not included in an insulin injection.

Title and text	Type	Explanation	Next steps
Insulin flow blocked Fill Cannula stopped. Remove infusion set from body. Change reservoir and infusion set.	Alarm	Your pump has detected the insulin flow was blocked while filling the cannula.	• Check your BG. Consider checking ketones and take an injection if needed. • Remove your infusion set and reservoir. • Select **Rewind** to start the new reservoir process using a new infusion set and reservoir.
Insulin flow blocked Fill Tubing stopped. Remove reservoir and select Rewind to restart.	Alarm	Your pump has detected the insulin flow was blocked while filling the tubing. Possible connection issue between the tubing and reservoir.	• Remove the reservoir and select **Rewind** to restart the fill tubing process. • Disconnect tubing from reservoir. • Be sure tubing is not crimped or bent. • Continue following the steps displayed on the pump using the same infusion set and reservoir. • If this alarm occurs again, use a new infusion set.
Loading incomplete Remove reservoir and select Rewind to restart loading.	Alarm	You pressed ◄ after loading began.	• Remove the reservoir to start again. • Select **Rewind** and follow the on-screen instructions.

Alarms, alerts, and messages

Title and text	Type	Explanation	Next steps
Low battery Pump Replace battery soon.	Alert	The battery in the pump is low on power. Remaining battery life is 10 hours or less.	• Select **OK** to clear the alert. • Replace the AA battery as soon as possible. Otherwise, insulin delivery stops, and the Replace Battery Now alarm occurs. • If the pump is delivering a bolus or filling the cannula, wait until delivery is complete to replace battery.
Low BG XX mg/dL Treat Low BG. Do not bolus until BG is normal. Monitor BG. Confirm BG?	Alert	Your BG meter reading is below 70 mg/dL.	• Select **No** to prevent the remote BG from being used by your pump. Select **Yes** to confirm the BG reading. • Check your BG and treat as necessary.
Low reservoir XX units remaining. Change reservoir.	Alert	Your reservoir is low on insulin, according to the number of units set in the Low Reservoir Reminder.	• Select **OK** to clear the alert. • Change the reservoir soon. • If you do not change the reservoir after you receive this alert, you will receive a second Low reservoir alert when the insulin level reaches half of your original alert amount.

Title and text	Type	Explanation	Next steps
Manage settings error Delivery stopped. Backup settings cleared from Manage Settings. Current settings are working properly. Select OK to restart. See User Guide.	Alarm	A pump error has occurred, and you need to restart your pump. Your backup settings have been lost, but your current settings are unchanged.	• Select **OK** to restart your pump. Your current settings are unchanged. Only your backup settings are lost. • When the pump restarts, follow instructions on the pump display. • If the pump was delivering a bolus or filling the cannula, check Daily History and evaluate your need for insulin.
Max Fill reached 3X.X U. Did you see drops at the end of tubing?	Alarm	You have exceeded the number of units expected to fill the tubing. By now, insulin should be at the end of the tubing.	• If you see drops at the end of the tubing, select **Yes**. • If you do not see drops, select **No**. • Follow instructions displayed on the pump.
Max Fill reached 4X.X U. Remove reservoir and select Rewind to restart New Reservoir procedure.	Alarm	You have exceeded the number of units expected to fill the tubing. By now, insulin should be at the end of the tubing.	• Remove the reservoir. • Check if you still have insulin in the reservoir. If you do, you can continue using the same reservoir. • Select **Rewind** to restart the new reservoir procedure.

Title and text	Type	Explanation	Next steps
No reservoir detected Rewind before loading reservoir.	Alarm	There is no reservoir in the pump or the reservoir is not properly locked into place.	• Select **Rewind**. • Ensure that your reservoir is filled with insulin. • When prompted, ensure that your reservoir is inserted and properly locked into place.
Power error detected Delivery stopped. Record your settings by uploading to CareLink or write your settings on paper. See User Guide.	Alarm	The internal power source in your pump is unable to charge. Your pump is operating on the AA battery only.	• Select **OK** to clear the alarm. • Check your BG and treat as necessary. • Record your settings as soon as possible because your AA battery may not last long. • Call 24-Hour Technical Support for assistance with your pump.
Power loss AA battery was removed for more than 10 min or power was lost. Select OK to re-enter time and date.	Alarm	Your pump battery has been out for more than ten minutes, and your pump has lost power. You must reset your time and date.	• Select **OK** to go to the Time & Date screen. • Enter the current time, time format, and date.

Title and text	Type	Explanation	Next steps
Pump error Delivery stopped. Current settings cleared. Pump restart needed. Select OK to restart and then re-enter your settings. See User Guide.	Alarm	Your pump encountered an error and will restart. Your pump settings will return to factory default values.	• Select **OK** to restart your pump. • When the pump restarts, follow instructions on the pump display. • After restart, check settings and re-enter values as needed. • If you recently saved backup settings in Manage Settings, use Restore Settings. • If the pump was delivering a bolus or filling the cannula, check Daily History and re-evaluate your need for insulin. • If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and call 24-Hour Technical Support.

Title and text	Type	Explanation	Next steps
Pump error Delivery stopped. Settings unchanged. Pump restart needed. Select OK to restart. See User Guide.	Alarm	A pump error has occurred, you need to restart your pump.	• Select **OK** to restart your pump. • If the pump was delivering a bolus or filling the cannula, check Daily History and re-evaluate your need for insulin. • If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and call 24-Hour Technical Support.
Pump error Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Alarm	Your pump encountered an error but a restart is not necessary. The issue is resolved. Your settings are not changed.	• Select **OK** to resume basal insulin delivery. • If the pump was delivering a bolus or filling the cannula, check Daily History and re-evaluate your need for insulin. • If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and call 24-Hour Technical Support.

Title and text	Type	Explanation	Next steps
Pump restarted Delivery stopped. Settings unchanged. Select OK to continue. See User Guide.	Alarm	Your pump has encountered a problem and has restarted. Your settings have not been changed.	• Select **OK** to continue. • If the pump was delivering a bolus or filling the cannula, check Daily History and re-evaluate your need for insulin. • If this alarm recurs frequently, write down the error code displayed on the alarm screen (you can also find it in your Alarm History) and call 24-Hour Technical Support.
Replace battery Battery life less than 30 minutes. To ensure insulin delivery, replace battery now.	Alert	Battery life is low and will be exhausted within 30 minutes.	• Select **OK** to clear the alert. • Replace the AA battery.
Replace battery now Delivery stopped. Battery must be replaced to resume delivery.	Alarm	Insulin delivery has stopped due to low power. Battery was not replaced after the Low battery Pump alert.	Replace the battery immediately to resume basal insulin delivery.

Title and text	Type	Explanation	Next steps
Reservoir estimate at 0 U To ensure insulin delivery, change reservoir.	Alert	Your reservoir level is estimated at 0 units.	• Select **OK** to clear the alert. • Change the reservoir now.
Resume bolus? XXX of YYY U delivered. Resume delivery of ZZZ U?	Message	A normal bolus delivery has been interrupted because the pump battery was removed. If it is within 10 minutes since this interruption, you can resume this bolus.	• Check the message to see how much of the bolus was actually delivered. • To cancel remaining amount of bolus, select **Cancel**. • To resume remaining amount of bolus, select **Resume**.
Resume Dual bolus? XX of YY U delivered. Resume delivery of ZZ U for XX:XX hr?	Message	The Square portion of Dual Bolus delivery has been interrupted. If it is within 10 minutes since this interruption, you can resume this bolus.	• Check the message to see how much of the Dual Wave bolus was actually delivered. • To cancel remaining amount of bolus, select **Cancel**. • To resume remaining amount of bolus, select **Resume**.

Title and text	Type	Explanation	Next steps
Resume Dual bolus? XX of YY U delivered. Resume delivery of ZZ U now, and AA U Square for XX:XX hr?	Message	The Now portion of a Dual Wave bolus delivery has been interrupted because the pump battery was removed. If it is within 10 minutes since this interruption, you can resume this bolus.	• Check the message to see how much of the Dual Wave bolus was actually delivered. • To cancel remaining amount of bolus, select **Cancel**. • To resume remaining amount of bolus, select **Resume**.
Resume Square bolus? XX of YY U delivered for XX:XX hr. Resume delivery of ZZ U for XX:XX hr?	Message	The Square Wave bolus delivery was interrupted. If it is within 10 minutes since this interruption, you can resume this bolus.	• Check the message to see how much of the Square Wave bolus was actually delivered. • To cancel remaining amount of bolus, select **Cancel**. • To resume remaining amount of bolus, select **Resume**.
Rewind required Delivery stopped. Rewind was required due to pump error. Select OK to continue. See User Guide.	Alarm	Your pump encountered an error.	• Select **OK** to clear the alarm after the pump has completed rewinding. • Select **Reservoir & Tubing** from the Home screen to start the new reservoir process using a new infusion set and reservoir. For details, see *Setting up the reservoir and infusion set, on page 119.*

Title and text	Type	Explanation	Next steps
Stuck button Button pressed for more than 3 minutes.	Alarm	The pump has detected that a button has been pressed for an unusually long time.	• Select **OK** to clear the alarm. • If this alarm occurs again, call 24-Hour Technical Support for assistance with your pump. If you are unable to clear the alarm: • See *Troubleshooting pump issues, on page 285*. • Consider another form of insulin, because your pump is not delivering insulin. • Check your BG and treat as necessary. • Call 24-Hour Technical Support for assistance with your pump.

CGM (sensor) alarms, alerts, and messages

The following table lists the most common or serious alarms, alerts, and messages related to your sensor glucose (SG) readings, as well as the status of your transmitter and sensor. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution.

Title and text	Type	Explanation	Next steps
Alert before high Sensor glucose approaching High Limit. Check BG.	Alert	Your SG value is approaching your specified high limit.	• Select **OK** to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Alert before low Sensor glucose approaching Low Limit. Check BG.	Alert	Your SG value is approaching your specified low limit.	• Select **OK** to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Alert on high XXX mg/dL High sensor glucose. Check BG.	Alert	Your SG value is at or above your specified high limit.	• Select **OK** to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Alert on low XXX mg/dL Low sensor glucose. Check BG.	Alert	Your SG value is at or below your specified low limit.	• Select **OK** to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Alert on low XXX mg/dL Low sensor glucose. Insulin delivery suspended since XX:XX AM/PM. Check BG.	Alarm	Your SG value is at or below your specified low limit, and the pump has suspended insulin delivery due to a Suspend on low or Suspend before low event.	• Select **OK** to clear the alarm. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Type	Explanation	Next steps
Basal delivery resumed Basal delivery resumed at XX:XX AM/PM after suspend by sensor. Check BG.	Message	Your pump is resuming basal insulin delivery after a Suspend on low or Suspend before low event occurred.	• Select **OK** to clear the message. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Basal delivery resumed Low settings change caused basal to be resumed at XX:XX AM/PM. Check BG.	Alert	Your pump is resuming basal insulin delivery after a Suspend before low or a Suspend on low event occurred, because you have turned off the Suspend before low or the Suspend on low feature.	• Select **OK** to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
Basal delivery resumed Maximum 2 hour suspend time reached. Check BG.	Alert	Your pump is resuming basal insulin delivery two hours after a Suspend before low or Suspend on low event occurred.	• Select **OK** to clear the alert. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Type	Explanation	Next steps
Basal delivery resumed Maximum 2 hour suspend time reached. SG is still under Low limit. Check BG.	Alarm	Your pump is resuming basal insulin delivery two hours after a Suspend before low or Suspend on low event occurred.	• Your pump has resumed basal insulin delivery; however, your SG value is still at or below your low limit. • Select **OK** to clear the alarm. • Check your BG. • Follow instructions from your healthcare professional and continue to monitor your BG.
BG not received Place pump close to transmitter. Select OK to resend BG to transmitter.	Alert	The transmitter was unable to receive the calibration BG meter readings from the pump.	• Move your pump and transmitter closer together. • Select **OK**. Your pump tries again to send your BG to your transmitter for sensor calibration.
Calibrate now Check BG and calibrate sensor.	Alert	A BG meter reading is needed immediately to calibrate your sensor so that you can continue receiving SG readings.	If you are unable to calibrate now, you can use the Snooze feature. Set the desired time, and select **Snooze**. If you do not calibrate before the Snooze time is up, the Calibrate now alert occurs again.

Title and text	Type	Explanation	Next steps
Calibration not accepted Wait at least 15 minutes. Wash hands, test BG again and calibrate.	Alert	Your system was unable to use the BG meter readings you entered to calibrate your sensor.	• Wash and dry hands thoroughly. See *Guidelines for calibrating, on page 209*. • Select **OK** to clear the alert. • After 15 minutes, enter a new BG meter reading for calibration as instructed in *Calibrating your sensor, on page 206*. If you receive a Calibration not accepted alert on your second calibration after 15 minutes, a Change sensor alert occurs. • Call 24-Hour Technical Support if you have questions.
Change sensor Insert new sensor and Start New Sensor.	Alert	You selected **No** in the Check sensor insertion message, indicating that your sensor is not fully inserted.	• Select **OK** to clear the alert. • Change your sensor. For details, see your sensor user guide. • After you change your sensor, refer to *Starting the sensor, on page 205*.
Change sensor Second calibration not accepted. Insert new sensor.	Alert	This alert occurs when you receive two Calibration not accepted errors in a row.	• Select **OK** to clear the alert. • Change your sensor. For details, see your sensor user guide.

Title and text	Type	Explanation	Next steps
Change sensor Sensor not working properly. Insert new sensor.	Alert	This alert occurs when the transmitter diagnoses a problem with the sensor that cannot be resolved.	• Select **OK** to clear the alert. • Change your sensor. For details, see your sensor user guide.
Check connection Ensure transmitter and sensor connection is secure, then select OK.	Alert	The pump fails to detect the transmitter and is unable to receive sensor signal.	• Select **OK** to clear the alert. • If your sensor is fully inserted, select **Yes**. If your sensor is not fully inserted, select **No**. • If your sensor was not fully inserted, insert a new sensor. • If you still cannot connect your sensor, see *My pump cannot find the sensor signal, on page 290*.
Lost sensor signal Move Pump closer to transmitter. May take 15 minutes to find signal.	Alert	Transmitter signal has not been received for 30 minutes during or after initialization.	• Move your pump closer to your transmitter. It can take up to 15 minutes for your pump to start communicating with your transmitter. • Select **OK** to clear the alert.
Low battery transmitter Recharge transmitter within 24 hours.	Alert	The battery in the transmitter needs to be recharged within 24 hours.	• Select **OK** to clear the alert. • Recharge your transmitter as soon as possible.

Title and text	Type	Explanation	Next steps
Low SG XX mg/dL SG is under 50 mg/dL. Check BG and treat.	Alarm	Your SG value has reached or fallen below 50 mg/dL. This alarm is factory set and cannot be changed or turned off. This alarm cannot be silenced and is always enabled, whether the pump is in Auto Mode or Manual Mode.	• Select **OK** to clear the alarm. • Check your BG and treat as necessary.

Note: XX represents the SG value that appears on your pump.

WARNING: For MiniMed 770G Users Ages 2-13: Do not rely solely on the use of a low sensor glucose (SG) value for "Alert on Low" or "Alert before Low" for alerts set at 50 mg/dL and 60 mg/dL. A low sensor glucose alert may not reflect the user's true blood glucose at these levels, or may not alert. Do not ignore symptoms of low glucose. Always confirm your sensor glucose readings with your blood glucose meter, and treat according to the recommendations of your healthcare professional. Solely relying on these sensor glucose alerts and readings for treatment decisions could result in missing severe hypoglycemia (low blood glucose) events.

Title and text	Type	Explanation	Next steps
Medical device CALL FOR EMERGENCY ASSISTANCE. I have diabetes.	Alarm	Your pump is suspended due to low SG, and you have not responded to the alarm within 10 minutes.	• Select **Dismiss**. • Immediately call for emergency assistance.
No calibration occurred Confirm sensor signal. Calibrate by XX:XX AM/PM.	Alert	The transmitter was unable to receive the calibration BG meter readings from the pump.	• Select **OK** to clear the alert. • Check the status icons on your Home screen to ensure that your pump has a signal from your sensor. If there is no sensor signal, see *My pump cannot find the sensor signal, on page 290*. • Calibrate again by the time shown on the pump screen to ensure you continue SG monitoring.
No calibration occurred Confirm sensor signal. Check BG again to calibrate sensor.	Alert	The transmitter was unable to receive the required calibration BG from the pump. Calibration is required by the system for SG values to resume. "Calibration required" appears on your sensor graph.	• Select **OK** to clear the alert. • Take another BG meter reading and calibrate again.

Title and text	Type	Explanation	Next steps
Possible signal interference Move away from electronic devices. May take 15 minutes to find signal.	Alert	There may be interference from another electronic device that is affecting the communication between your pump and transmitter.	• Move away from other electronic devices. It can take up to 15 minutes for your pump to start communicating with your transmitter. • Select **OK** to clear the alert.
Rise Alert Sensor glucose rising rapidly.	Alert	Your SG value has been rising as fast or faster than your preset Rise Alert Limit.	• Select **OK** to clear the alert. • Monitor trend and glucose level. • Follow instructions from your healthcare professional.
Sensor alert occurred Check Alarm History for silenced alerts.	Alert	Sensor alert occurred when Alert Silence is on.	• Select **OK** to clear the alert. • Check the Alarm History screen to see which alerts were silenced. • Select the alert to open the Alarm Detail screen. • Take action based on the selected alert.

Title and text	Type	Explanation	Next steps
Sensor connected If new sensor, select Start New. If not, select Reconnect.	Message	The transmitter has detected that you have connected a sensor. The pump needs to know if this is a new sensor or if you have reconnected your old sensor.	• If you have connected a new sensor, select **Start New Sensor**. • If you have reconnected a sensor you have been using, select **Reconnect Sensor**. • In either case, a "Warm-up" message appears on your Home screen, and you will be prompted to enter a BG value when your sensor is ready for calibration. Your pump starts receiving your SG values again after the two-hour initialization is complete.
Sensor connected Start new sensor.	Message	The pump has detected that this is a new sensor, which needs to be started and warmed-up.	Select **Start New Sensor**. The alert will close and a "Warm-up" message appears on the sensor graph with a progress bar.
Sensor expired Insert new sensor.	Alert	The sensor has reached the end of its useful life.	• Change your sensor. For details, see your sensor user guide. • Select **OK** to clear the alert.
Sensor signal not found See User Guide.	Alert	After multiple attempts, the pump failed to detect the transmitter and is unable to receive sensor signal.	• Select **OK** to clear the alert. • If your pump still cannot find the sensor signal, call 24-Hour Technical Support for assistance.

Title and text	Type	Explanation	Next steps
Sensor warm-up started Warm-up takes up to 2 hours. You will be notified when calibration is needed.	Message	The sensor warm-up has begun.	Select **OK** to clear the message. A "Warm-up" message with a progress bar appears on the sensor graph during warm-up, which takes up to two hours. You will be notified when calibration is needed.
Sensor updating Do not calibrate unless notified. This could take up to 3 hours.	Alert	The SG value is unavailable due to a temporary situation.	• Select **OK** to clear the alert. • Follow the instructions on the pump screen. You do not need to change the sensor.
Suspend before low Delivery stopped. Sensor glucose approaching Low Limit. Check BG.	Alert	Your SG value is falling. Insulin delivery is suspended according to your Suspend before low setting and your SG is approaching your specified low limit. Suspend before low is not available in Auto Mode.	• Select **OK** to clear the alert. • Check your BG. If necessary, treat your BG as directed by your healthcare professional.

Title and text	Type	Explanation	Next steps
Suspend on low Delivery stopped. Sensor glucose XXX mg/dL. Check BG.	Alarm	Your SG value is at or below the low limit you specified. Suspend on low is not available in Auto Mode.	• Select **OK** to clear the alarm. • Check your BG. If necessary, treat your BG as directed by your healthcare professional.
Transmitter battery depleted Recharge transmitter now.	Alert	The battery in the transmitter needs to be recharged. SG values are not recorded or transmitted until you recharge transmitter.	• Select **OK** to clear the alert. • Recharge your transmitter.

SmartGuard Auto Mode alerts and messages

The following table lists the most common or serious alerts and messages related to Auto Mode. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides any necessary steps for problem resolution.

Title and text	Type	Explanation	Next steps
Auto Mode started Current action canceled.	Alert	This alert happens when the user starts an operation that is not allowed in Auto Mode while the pump is transitioning to Auto Mode.	• Select **OK** to clear the alert. • Allow your pump to complete its transition to Auto Mode.

Title and text	Type	Explanation	Next steps
Auto Mode started The following SmartGuard settings are now turned off: - Suspend before low - Suspend on low	Alert	Your pump has started Auto Mode. The Suspend before low and Suspend on low settings are now turned off.	• Select **OK** to clear the alert. • Allow your pump to complete the transition into Auto Mode.
Auto Mode exit X started. Would you like to review the Auto Mode Readiness screen?	Alert	Your pump has exited Auto Mode because you have turned off your sensor, a suspend event message has not been cleared within 4 hours, or you have been in Safe Basal the maximum of 90 minutes. This alert cannot be silenced, and is always enabled whenever the system is in Auto Mode.	• Select **No** to clear the alert. Select **Yes** to view the Auto Mode Readiness screen. • Check your BG. • Calibrate your sensor. • Follow instructions from your healthcare professional and continue to monitor your BG. For details, see *Exiting SmartGuard Auto Mode, on page 239* and *Returning to SmartGuard Auto Mode, on page 239*.

Title and text	Type	Explanation	Next steps
High SG SG has been high over 1 hour. Check infusion set. Check ketones. Monitor BG. Followed by **Auto Mode exit** Monitor BG and treat as necessary. X started. Enter BG to continue in Auto Mode.	Alert	Your pump has exited Auto Mode based on a set glucose threshold and length of time: • 300 mg/dL or higher for one hour • 250 mg/dL or higher for three hours. This alert cannot be silenced and is always enabled whenever the pump is in Auto Mode.	• Select **OK** to clear the alert. • Check your BG and treat as necessary.
Auto Mode max delivery Auto Mode has been at maximum delivery for 4 hours. Enter BG to continue in Auto Mode.	Alert	Auto Mode has been delivering at your maximum Auto Mode basal insulin delivery rate for four hours. This rate is determined automatically by your system.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump to exit Safe Basal and return to Auto Basal. • Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Type	Explanation	Next steps
Auto Mode max delivery Auto Mode has been unable to bring your SG down. Enter BG and resume delivery to continue in Auto Mode.	Alert	Auto Mode has been unable to lower your SG value. Your pump is suspended, and your predicted SG is above target.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump. • Follow instructions from your healthcare professional and continue to monitor your BG.

> **Note:**
> • The title of the alert appears the same as the previous Auto Mode max delivery alert in the table.
> • If you have suspended your pump, you will have no delivery. However, the alert may still occur.

Title and text	Type	Explanation	Next steps
Auto Mode min delivery Auto Mode has been at minimum delivery for 2:30 hr. Enter BG to continue in Auto Mode.	Alert	Your pump has been delivering at your minimum Auto Mode basal insulin delivery rate for two and a half hours. This rate is determined automatically by your system.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump to exit Safe Basal and return to Auto Basal. • Follow instructions from your healthcare professional and continue to monitor your BG.

Title and text	Type	Explanation	Next steps
Auto Mode min delivery Your SG has been below target for 2:30 hr. Enter BG and resume delivery when ready to continue in Auto Mode.	Alert	Your pump is suspended, and your predicted SG has been below target for two and a half hours.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump. • Follow instructions from your healthcare professional and continue to monitor your BG.

> **Note:**
> - The title of the alert appears the same as the previous Auto Mode min delivery alert in the table.
> - If you have suspended your pump, you will have no delivery. However, the alert may still occur.

Title and text	Type	Explanation	Next steps
BG required Enter a new BG for Auto Mode.	Alert	Auto Mode requires a BG to check the reliability of the sensor.	• Select **OK** to clear the alert. • Enter a BG to return to Auto Basal from Safe Basal, or to enter Auto Mode from Manual Mode.
Bolus recommended For XXX mg/dL entered, a correction bolus is recommended. Select Bolus to program a bolus.	Alert	Auto Mode calculated that a bolus is recommended based on the BG value that you entered.	• Select **Bolus** to program a correction bolus. • Select **Cancel** if you do not want to deliver a correction bolus.

Title and text	Type	Explanation	Next steps
Cal required for Auto Mode Enter a BG and calibrate sensor for Auto Mode.	Alert	Calibration may be required by Auto Mode, even when SG values are available.	• Select **OK** to clear the alert. • Check your BG and enter it into your pump. • Calibrate your sensor using the BG that you entered.
High BG XXX mg/dL Check infusion set. Check ketones. Monitor BG. Confirm BG?	Alert	Your BG meter reading is above 250 mg/dL. This alert applies only to Auto Mode. There is an equivalent alert for Manual Mode. See *Pump alarms, alerts, and messages, on page 246*.	Select **No** to prevent the remote BG from being used by your pump. Select **Yes** to confirm the BG reading.

CareLink software alert and message

The following table lists the most common or serious alerts and messages related to CareLink software. The table also explains the meaning, consequences, and the reasons why these notifications appear, and provides steps for problem resolution. If you get an alarm, alert, or message that is not listed, select **OK** to clear the notification and call 24-Hour Technical Support.

Title and text	Type	Explanation	Next steps
CareLink uploader not found. Follow instructions on the CareLink uploader.	Message	The pump cannot find the CareLink uploader because the wrong pump code was entered, or the search timed out before the pump found the uploader.	• Select **OK** to clear the message. • Follow the instructions on the CareLink uploader. For details, see *Upload to CareLink software, on page 168*.

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Troubleshooting

This chapter contains procedures and information to help you understand and address conditions that might occur with your pump.

For a list of alarms, alerts, and messages that may appear on your pump, see *Pump alarms, alerts, and messages, on page 246*.

Troubleshooting pump issues

> ⚠️ **WARNING:** If you receive a critical error on your pump, the following screen displays and the pump sirens.
>
>
>
> **Immediately disconnect from your insulin pump and discontinue use. Contact 24-Hour Technical Support for assistance.**
>
> **Remember, your body still needs insulin while your pump is removed.** It is important that you consult your healthcare professional to determine an alternate method of receiving insulin while your pump is removed. For more information on pump alarms, see *Pump alarms, alerts, and messages, on page 246*.

My pump buttons are stuck

During atmospheric pressure changes, your pump buttons may not work for up to 45 minutes. For example, during airplane travel your pump buttons may get stuck. This is rare. If this occurs, either wait for the problem to correct itself, or if you have a new AA battery with you:

1. Remove the battery cap.

2. Place the battery cap back onto the pump.

   Your pump will check the AA battery power, and may require a new AA battery.

3. If prompted, insert a new AA battery.

   If these steps do not correct the problem, contact 24-Hour Technical Support for assistance.

What is a Check Settings alarm?

This alarm occurs when a condition causes your pump to reset to factory settings. The Check Settings alarm occurs after you re-enter the Startup Wizard settings.

The Check Settings alarm tells you that other settings may have been cleared or reverted to factory default values. Review any settings that you have not already set in Startup Wizard and re-enter the values, if necessary.

My pump is asking me to rewind

> ⚠ **WARNING: Always make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin, which can cause hypoglycemia.**

You must rewind your pump when you change the reservoir. Rewinding returns the piston in the reservoir compartment to its starting position. It is normal for your pump to ask you to rewind any time you remove and replace the reservoir, such as when you resolve an Insulin Flow Blocked alarm or address a problem when you load the reservoir.

I dropped my pump

> ⚠️ **CAUTION:** Always inspect your pump to ensure there are no cracks before exposing your pump to water, especially if your pump has been dropped, or you suspect your pump is damaged. Water leakage can cause the pump to malfunction, and result in injury.

Do the following:

1. Check that all connections are still tightly in place.

2. Check the display, button area, and pump case for cracks or damage.

3. Check the infusion set, including the tubing connector and tubing for cracks or damage.

4. Review the status screen, basal rates, and other pump settings.

5. Perform a self test. Press ◎ and select:

   Options > Utilities > Self Test

6. If the self test does not complete successfully, or if you are concerned about your pump, call 24-Hour Technical Support for assistance and check your blood glucose (BG).

I cannot get to the Manage Settings screen

These personalized settings, under the Manage Settings screen, should be provided by your healthcare professional in your training session. If you go to **Options > Utilities > Manage Settings**, a message appears telling you that the feature is not normally accessible and to consult your user guide. To access the Manage Settings screen press ◎ and select:

1. **Options > Utilities > Manage Settings**

2. Simultaneously press and hold ❯ and ↩ for about two seconds until the Manage Settings screen appears.

My pump display times out too quickly

Your pump display times out after 15 seconds by default in order to conserve battery power. You can increase this setting up to three minutes. Press ◎ and select **Options > Utilities > Display Options**, and then adjust the Backlight setting as desired.

Where is my pump status screen?

1. Press ◎ and select Status to go to the Status screen.

   The Status screen appears.

2. From the Status screen, you can select the type of status information you want to view. For example, to see a quick status of your pump and recent insulin deliveries, go to Quick Status. For details, see *Status screens, on page 52*.

My pump is asking me to enter my settings

Certain pump errors can clear your settings and return them to their factory default values. This also happens if you intentionally clear your settings. Do not clear your settings unless directed to do so by your healthcare professional.

If you have saved your settings using the Save Settings option, you can restore them using the Restore Settings option. If you restore your settings, ensure the restored settings match the settings prescribed most recently by your healthcare professional.

The Startup Wizard appears automatically when your pump restarts. The wizard tells you to enter the following information. Have the following values ready when you begin:

- Time format, time, and date

- Active insulin time

- Basal patterns

After you enter your pump settings, you have the option of entering the following Bolus Wizard settings:

- Carb ratio
- Insulin sensitivity factor
- BG target

To enter your pump settings:

1. Select your language, and then select **Next** to go to each new screen.

2. When the Select Time Format screen appears, select a **12 Hour** or a **24 Hour** time format.

3. When the Enter Time screen appears, adjust the setting to the current time. If you are using a 12-hour clock, be sure to specify AM or PM.

4. When the Enter Date screen appears, adjust the **Year**, **Month**, and **Day** to the current date.

5. When the Active Insulin Time screen appears, enter the **Duration**.

   For details, see *About active insulin, on page 98*.

6. Enter the End time and the rate for your first basal rate. You can enter more basal patterns after you complete the startup wizard.

   For details, see *Adding a new basal pattern, on page 69*.

   After you complete your basal pattern, a screen appears for you to review your basal information.

7. A screen appears and tells you to set up the Bolus Wizard settings. Do one of the following:

   - Select **Yes** to continue to enter your settings, and then continue to the next section.

   - Select **No** if you do not want to enter your Bolus Wizard settings. A message appears to confirm the startup is complete. Select **OK** to continue to use your pump.

To enter your Bolus Wizard settings:

1. When your pump shows a list of settings for the Bolus Wizard feature, make sure you have the values you need before you continue.

2. When the Carb Ratio screen appears, enter your carb ratio by entering the End time and the ratio. You can adjust your carb ratio at any time.

   For details, see *Changing your carb ratio, on page 96*.

3. When the Sensitivity screen appears, enter your insulin sensitivity factor by entering the End time and the mg/dL per unit. You can adjust your insulin sensitivity factor at any time.

   For details about entering insulin sensitivity factors, including how to set multiple time periods, see *Changing your insulin sensitivity factor, on page 97*.

4. When the BG Target screen appears, enter your BG Target range by entering the End time and your Lo (low) and Hi (high) values. You can adjust your BG Target ranges at any time.

   For details, see *Changing your Bolus Wizard BG target, on page 97*.

5. A message appears to confirm the startup is complete. Select **OK** to continue to use your pump.

Troubleshooting sensor issues

My pump cannot find the sensor signal

If your pump cannot find the sensor signal after 30 minutes of normal use, the Lost sensor signal alert appears. Follow the instructions on the pump screen to troubleshoot the issue, as described in the following steps:

> **Note:** If the Alert Silence option is on and a glucose alert occurs, the notification light begins to flash and the Sensor alert occurred alert appears, but no explanatory text is shown. All silenced alerts are shown with explanatory text in the Alarm History screen.

1. Move your pump closer to your transmitter and select **OK**. It can take up to 15 minutes for your pump to find the sensor signal.

   If your pump still cannot find the sensor signal, the Possible signal interference alert appears.

2. Make sure you are away from any electronic devices that might cause interference, such as cellular phones that are not paired with the MiniMed 770G System and other wireless devices, and select **OK**.

If your pump does not find the sensor signal within 15 minutes after you selected OK, the Check connection alert appears.

3. Ensure the transmitter and sensor connection is secure, and then select **OK**.

    The "Check sensor insertion" message appears.

4. If your sensor is fully inserted, select **Yes** and skip to step 7.

5. If your sensor is not fully inserted, select **No**. A Change sensor alert appears.

6. Select **OK** and change your sensor.

7. If you selected **Yes** and your pump still cannot find the sensor signal after 15 minutes, or if your sensor graph displays "Sensor signal not found. See User Guide," call 24-Hour Technical Support for assistance.

Calibration not accepted

Calibration not accepted alert occurs when one of the following happens:

*   System was unable to use the BG meter readings you entered to calibrate your sensor.

*   System rejects two calibrations in a row from the same sensor.

*   The transmitter was unable to receive the calibration BG meter readings from the pump due to failed sensor signal.

For details on when and how to calibrate your sensor, see *Calibrating your sensor, on page 206*.

Why does the SmartGuard suspend icon on my Home screen appear gray?

The SmartGuard suspend icon appears gray ▨ on the Home screen when either the Suspend on low or Suspend before low feature is unavailable. The SmartGuard suspend features may be unavailable due to the following conditions:

*   A suspend event has occurred recently.

    After a Suspend before low or Suspend on low event occurs, there is a period of time when the suspend functionality is unavailable. This time will vary depending on whether or not you respond to the suspend event. Typically, the suspend features will be unavailable for 30 minutes after your basal insulin delivery is resumed. For details, see *When Suspend before low is unavailable, on page 183* or *When Suspend on low is unavailable, on page 186*.

- No sensor glucose (SG) values are available.

  SG values may be unavailable because:

  - Sensor calibration is required.

    For details on when and how to calibrate your sensor, see *Calibrating your sensor, on page 206*.

  - Your pump has lost connection to the sensor.

    Move your pump closer to the sensor. For more details, see *My pump cannot find the sensor signal, on page 290*.

  - The SG value received was outside the expected range and was not displayed.

    Select **OK** to clear the alert. If the issue continues, you may need to replace the sensor.

If the issue persists, call 24-Hour Technical Support for assistance.

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Cleaning your pump

> ⚠️ **CAUTION:** Never use organic solvents, such as lighter fluid, nail polish remover, or paint thinner to clean your pump. Never use lubricants with your pump. When you clean your pump, be sure to keep the reservoir compartment dry and away from moisture. When you clean your pump with organic solvents, it can cause the pump to malfunction and result in minor injury.

Make sure you have the following supplies ready for cleaning your pump: three or four small, clean, soft cloths, a mixture of water with a mild detergent, clean water, 70% alcohol, and a few clean cotton tips and cotton balls.

To clean your pump:

1. Dampen a cloth with water mixed with a mild detergent.
2. Using the cloth, wipe the outside of the pump.
3. Dampen a clean cloth with water and wipe to remove any detergent residue.
4. Dry with a clean cloth.
5. Wipe your pump with a 70% alcohol wipe.
6. Using a dry clean cotton tip, remove any battery residue from the battery cap.
7. Using a dry clean cloth, remove any battery residue from the battery compartment opening.

Cleaning your transmitter

Always refer to your transmitter user guide for instructions on cleaning the transmitter.

Storing your pump

Storage mode lets you safely place your pump in storage while not in use.

> **Note:** If you place your pump in storage mode, it is important to insert a new AA battery for 8 to 12 hours every six months to ensure that the internal battery does not discharge to a deep discharge. A battery that is deeply discharged may experience decreased performance.

> **WARNING: After placing your pump in storage mode, do not rely on active insulin tracked in the pump when making new Bolus Wizard calculations. Storage mode clears active insulin. Inaccurate Bolus Wizard calculations could result in inaccurate insulin delivery, and serious injury.**

To place your pump in storage mode:

1. Remove the AA battery from the pump. For details, see *Removing the battery, on page 41*.

   > **Note:** When you remove the battery, your pump issues an Insert Battery alarm for 10 minutes or until you place your pump into storage mode.

2. Press and hold ← for eight seconds or more to turn the pump power off completely.

> ⚠️ **CAUTION:** Never expose the pump to temperatures below -4°F (-20°C) or above 122°F (50°C) while it is in storage without a battery. Storing your pump in temperatures outside of this range can damage your pump.

To wake your pump from storage mode:

1. Insert a new AA battery into your pump. For details, see *Inserting the battery, on page 40*.

   A Pump Error message appears.

2. Select **OK**.

   Your pump displays a Power Loss alarm.

3. Select **OK**.

   The Time & Date screen appears.

4. Enter the current **Time**, **Time Format**, and **Date**.

5. Select **Save**.

   Your pump displays an Active Insulin Cleared alert.

6. Select **OK**.

   Make sure that all of your settings, such as basal rate, are set as desired. If you need to, reapply your last saved settings by using the Restore Settings option as instructed in *Restoring your settings, on page 165*.

7. You must repeat the pairing process for your transmitter and meter. For transmitter details, see *Pairing your pump and transmitter, on page 201*. For meter details, see *Pairing your pump and meter, on page 136*.

Storing your transmitter

Always refer to your transmitter user guide for instructions on storing your transmitter.

Pump disposal

Contact 24-Hour Technical Support for information on the proper disposal of the MiniMed 770G insulin pump. Always follow local laws and regulations for the disposal of medical devices.

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Product specifications and safety information

This chapter provides detailed product specifications and safety information.

Product specifications

This section provides detailed information on product specifications.

Alarm and alert escalation

The following alerts may escalate to a siren if not cleared:

• Alert before high	• Lost sensor signal
• Alert before low	• No calibration occurred
• Alert on high	• Possible signal interference
• Alert on low	• High SG
• Basal delivery resumed	• Rise Alert
• BG not received	• Sensor expired
• Calibration not accepted	• Sensor signal not found
• Calibrate now	• Low SG XX mg/dL (XX represents 50 mg/dL or below)
• Change sensor	• Sensor updating
• Check connection	• Transmitter battery depleted

For alerts that escalate to a siren, the pump will begin to siren if the alert is not cleared in 10 minutes. Before the siren occurs, your pump will beep, vibrate, or both, depending on your audio settings.

Minutes	Audio	Audio and vibration	Vibration
0	Audio	Audio and vibrate	Vibrate
1	Audio	Audio and vibrate	Vibrate
2	Audio	Audio and vibrate	Vibrate
3	Audio	Audio and vibrate	Vibrate
4	Audio	Audio and vibrate	Vibrate
5	Audio	Audio and vibrate	Vibrate
6	Audio and vibrate	Audio and vibrate	Audio and vibrate
7	Audio and vibrate	Audio and vibrate	Audio and vibrate
8	Audio and vibrate	Audio and vibrate	Audio and vibrate
9	Audio and vibrate	Audio and vibrate	Audio and vibrate
10	Siren and vibrate	Siren and vibrate	Siren and vibrate

Note: The Medical device alarm sirens immediately when this screen appears.
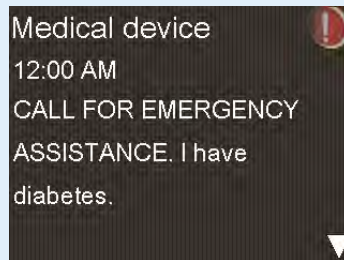
Altitude range

- Pump operating range is from 10.2 psiA (70.33 kPa) to 15.4 psiA (106.18 kPa)
- Storage range is from 7.2 psiA (49.64 kPa) to 15.4 psiA (106.18 kPa)

Audio frequency

The following table lists the various audible tones and their corresponding frequencies:

Tone name	Frequency
Alarm	1655 Hz followed by 3310 Hz
Alternate Alarm	1850 Hz
Siren (escalated alarm)	1655 Hz, followed by 3310 Hz
Alert	934 Hz
High Sensor Glucose	1312 Hz, followed by 1410 Hz, 1500 Hz, 1619 Hz, 1722 Hz
Low SG	1722 Hz, 1619 Hz, 1500 Hz, 1410 Hz, 1312 Hz
Lost SG	1485 Hz, followed by 1395 Hz, 1320 Hz, 1395 Hz
Message tone	1655 Hz
Reminder tone	934 Hz
Fill tubing tone	1850 Hz
Bolus delivery cancellation tone	1485 Hz, followed by 1655 Hz and 1485 Hz
Loading complete tone	934 Hz
Reservoir loading in progress tone	1850 Hz
Easy Bolus activation	1045 Hz
Easy Bolus step 1 increment	1175 Hz
Easy Bolus step 2 increment	1320 Hz
Easy Bolus step 3 increment	1395 Hz
Easy Bolus step 4 increment	1570 Hz
Easy Bolus step 5 increment	1760 Hz

Backlight

Type	LED (Light-emitting Diode)
Time out	15 seconds (default), 30 seconds, one minute, three minutes
Time out when battery is low	15 seconds (default), 30 seconds

Basal insulin delivery

Delivery rate range	0 to 35 units per hour or the Max Basal Rate amount, whichever is lower.
Max Basal Rate default	2 units per hour
Basal patterns	Maximum of 8 patterns. Each pattern covers a 24-hour period and can have up to 48 rates. Rates are set in 30-minute increments.
Basal pattern names	Fixed names: Basal 1, Basal 2, Basal 3, Basal 4, Basal 5, Workday, Day Off, Sick Day
Increments	• 0.025 units per hour for basal amounts in the range 0 to 0.975 units • 0.05 units per hour for basal amounts in the range 1 to 9.95 units • 0.1 units per hour for basal amounts of 10 to 35 units

BG Target

Maximum targets	8
Range	60 to 250 mg/dL
Default value for High blood glucose (BG) targets and Low BG targets	None

Note: Auto Mode uses a fixed BG Target of 150 mg/dL.

BG meter value

The most recent BG value received from the meter. If you are using an Accu-Chek Guide Link meter, this value appears on the Home screen when the Sensor feature is off. This value also appears in the Bolus Wizard screen when setting up a bolus.

Expiration	12 minutes
Range	20 to 600 mg/dL

Bolus delivery

Bolus Speed options	• Standard: 1.5 units/minute
	• Quick: 15 units/minute
Bolus programming increments	• 0.025 units
	• 0.05 units
	• 0.1 units
Fluid delivered/stroke	• 0.25 µL (microliter) for 0.025 unit pump stroke
	• 0.5 µL for 0.05 unit pump stroke
	• 2.0 µL for 0.2 unit pump stroke

Bolus Wizard feature default settings

Item	Default	Limits	Increments
Carb units	grams	-	-
Insulin to carb ratio	None	1–200 g/u	0.1 g/u for 1–9.9 g/u; 1 g/u for ratios of 10 g/u to 200 g/u
Insulin Sensitivity Factor	None	5–400 mg/dL	1 mg/dL
BG Target	None	60–250 mg/dL	1 mg/dL
Active Insulin Time	4 hours	2 to 8 hours	15 minutes

Bolus Wizard feature specifications

There are four different formulas the Bolus Wizard feature uses to estimate a bolus, depending on your current BG. The following formulas apply only when the carb units are in grams.

1. If your current BG is greater than your High BG Target, the Bolus Wizard feature subtracts active insulin from the BG correction estimate, then adds this to the food estimate to get the total bolus estimate. However, if the result of subtracting active insulin from BG correction estimate is a negative number (less than zero), the total bolus estimate is based only on the food estimate.

$$\underset{\text{estimate}}{\text{total bolus}} = \underset{\text{(food estimate)}}{\frac{A}{B}} + \underset{\text{(correction estimate)}}{\frac{C - D}{E}} - \text{active insulin}$$

where: A = food (grams)
B = carb ratio
C = current BG
D = High BG Target
E = insulin sensitivity

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - High BG Target) ÷ Insulin sensitivity - Active insulin = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

2. If your current BG is less than your Low BG Target, the Bolus Wizard feature adds the BG correction estimate to the food estimate to get the total bolus estimate.

$$\underset{\text{estimate}}{\text{total bolus}} = \underset{\text{(food estimate)}}{\frac{A}{B}} + \underset{\text{(correction estimate)}}{\frac{C - D}{E}}$$

where: A = food (grams)
B = carb ratio
C = current BG
D = Low BG Target
E = insulin sensitivity

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

Correction estimate:

(Current BG - Low BG Target) ÷ Insulin sensitivity = Units of insulin

Total bolus estimate:

Food estimate + Correction estimate = Units of insulin

3. If your current BG is within your High or Low BG Target, the total bolus estimate is based only on the food estimate.

(food estimate)

$$\text{total bolus estimate} = \frac{\text{food (grams)}}{\text{carb ratio}}$$

Food estimate:

Carb grams ÷ Carb ratio = Units of insulin

> **Note:** When the current BG is below the Low BG Target, an active insulin amount is not considered in the Bolus Wizard feature calculations.

Total bolus estimate = Food estimate

4. If you do not enter a BG, the total bolus estimate is based only on the food estimate.

Following are some notes about using the Bolus Wizard feature:

*   If a Dual Wave bolus is less than the estimate due to the Max Bolus limit or a change that you make, the Square portion is reduced first.

*   Based on the Active Insulin Time setting you choose, your pump keeps track of how much insulin is still active in your body. This is shown as Active Insulin or Act. Insulin on the Home screen, Bolus screen, Manual Bolus screen, Preset Bolus, and Daily History screens. This prevents stacking of insulin, and lowers the chances of hypoglycemia.

*   The Bolus Wizard feature may utilize your current BG measurement, carbohydrate consumption, and active insulin to calculate your estimated bolus.

*   The following Active Insulin Curve represents how long a bolus of insulin lowers your glucose after the bolus is given. The percentage of insulin remaining lowers at varying rates depending on how long the insulin is active in your body.

Active Insulin Curve

% Insulin Remaining (y-axis) vs **Time (hours)** (x-axis)

Legend:
- 8 Hour
- 7 Hour
- 6 Hour
- 5 Hour
- 4 Hour
- 3 Hour
- 2 Hour
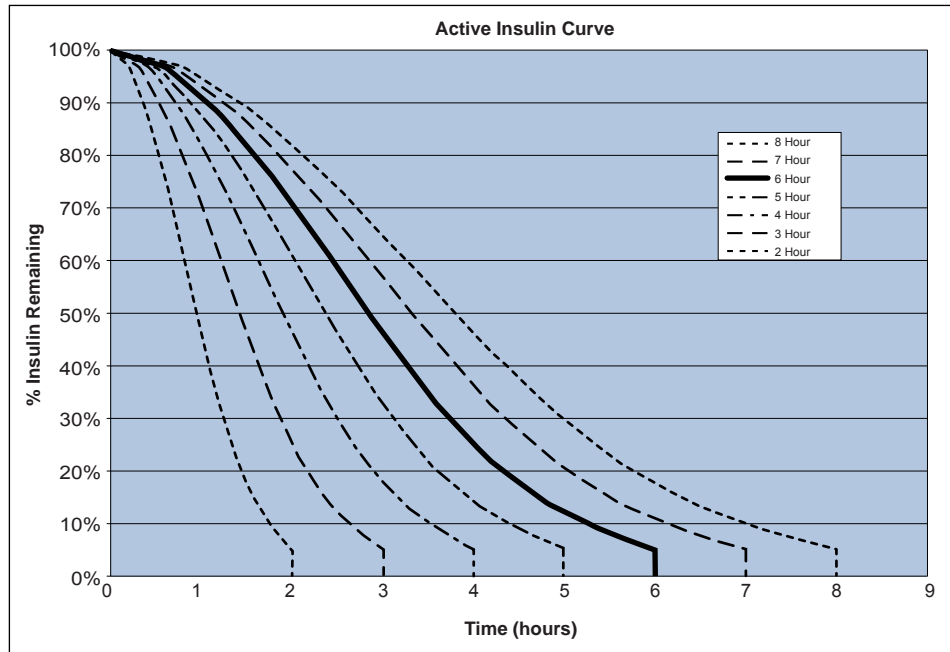
Graph adapted from Mudaliar and colleagues, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501.

Carb ratios

Maximum ratio settings	Range
8	1 to 200 grams/unit

Delivery accuracy

- For a basal rate of 1.0 U/h, the delivery accuracy is ±5%.

  For a basal rate of 0.025 U/h, the delivery accuracy is ±10%.

  Delivery accuracy for bolus volumes < 0.1 unit is ±20% and delivery accuracy for bolus volumes ≥ 0.1 unit is ±5%.

- All Normal boluses are delivered within 16 minutes, 41 seconds ±3 seconds at Standard rate (25 units, at 1.5 units per minute), and within 1 minute, 41 seconds ±3 seconds at Quick rate (25 units, at 15 units per minute).

- During delivery, the maximum infusion pressure generated and the occlusion threshold pressure using a 3.0-mL reservoir is 13.15 psi (90.67 kPa). The average resulting bolus volume generated upon clearing the occlusion is 0.0112 mL (equivalent to 1.12 units of U-100 insulin).

- The following image is a representative delivery accuracy curve. The Trumpet Curve represents the maximum percentage change from the expected insulin dosage for a given time interval, known as the observation window, during the infusion of insulin. The upper curve corresponds to positive changes, and the lower curve corresponds to negative changes.

Trumpet Curve at intermediate rate of 1 U/h
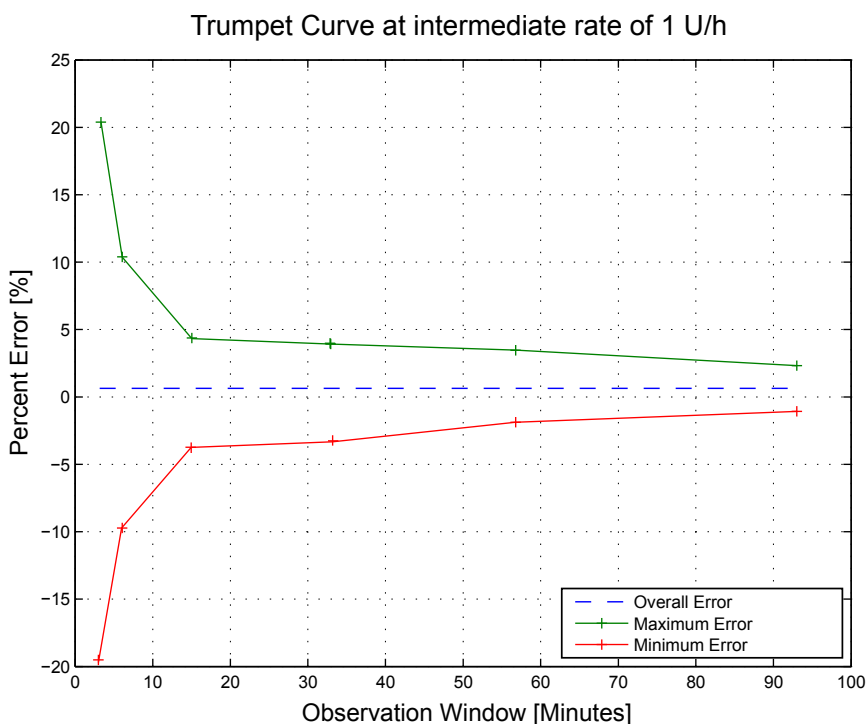
Easy Bolus feature

The Easy Bolus feature lets the user set up and deliver a Normal Bolus when the pump is in Sleep Mode. This is done using ∧ and with the help of audio and vibration cues.

Audio mode range	0 to 20 increments or Max Bolus limit, whichever comes first

Vibrate mode range	0 to 20 increments or Max Bolus limit, whichever comes first
Default step size	0.1 unit
Adjustable step size	0.1 to 2 units per increment up to Max Bolus limit

Environmental conditions

The MiniMed 770G insulin pump system is designed to withstand most conditions encountered in your daily life. For more details about environmental conditions, such as exposure to magnetic fields and radiation, waterproof capabilities, and extreme temperatures, see *User safety, on page 7*.

- Pump storage temperature range without a AA battery is from -4°F (-20°C) to 122°F (50°C).

- Pump operating temperature range is from 41°F (5°C) to 104°F (40°C).

- Operating air pressure range is from 10.2 psi (700 hPa) to 15.4 psi (1060 hPa).

- Storage air pressure range is from 7.2 psi (496.4 hPa) to 15.4 psi (1060 hPa).

- Relative humidity (RH) range during operation is from 20% to 90%.

- RH range during storage is from 5% to 95%.

Essential performance

The pump will maintain the following functionalities to avoid under-infusion and over-infusion:

- Delivery accuracy

- Occlusion detection

- Empty reservoir detection

- Detection of power loss

- Pump therapy status–UI component: LCD

- Notification annunciation and display–UI components: piezo-electric speaker, LCD–applies to all features above

Filling the infusion set and cannula

- The cannula can be filled from 0.025 units to 5.1 units, in increments of 0.025 units.

- The standard fill rate is 1.5 units per minute.

  The quick fill rate is 15 units per minute.

- When filling the tubing, a warning occurs at 30 units. A second warning occurs at 40 units indicating that the pump must be rewound.

- Insulin used to fill the infusion set is recorded in the Daily History.

Infusion pressure

The maximum infusion pressure and occlusion pressure during the fill tubing process are 25 psi (172.4 kPa).

Insulin delivery default settings

Bolus settings

Item	Default setting	Limits	Increments
Bolus Wizard feature:	Off	-	-
Easy Bolus feature:	Off	-	-
Easy Bolus step size:	0.1 U	0.1 U to 2 U	-
Bolus increment:	0.10 U	0.025 U 0.05 U 0.10 U	-
Dual/Square bolus:	Off	-	-
Max bolus:	10 U	0 to 25 U (per single bolus)	-
Bolus BG Check Reminder:	Off	0:00 to 5:00	0:30

Basal settings

Item	Default setting	Limits	Increments
Max Basal Rate	2 U/h	0–35 U/h	0.025 U for 0.025–0.975 U/h 0.05 U for 1.00–9.95 U/h 0.1 U for rates of 10.0 U/h or more
Basal Rate	0.000 U/h	0.000 U/h to Max Basal Rate setting	0.025 U for 0.025–0.975 U/h 0.05 U for 1.00–9.95 U/h 0.1 U for rates of 10.0 U/h or more
Temp Basal Type	Percent	Percent, Rate	N/A
Temp Basal Percent	100%	0–200%	5%
Temp Basal Rate	Current basal rate	0.0 U/hr to Max Basal Rate	0.025 U for 0.025–0.975 U/h 0.05 U for 1.00–9.95 U/h 0.1 U for rates of 10.0 U/h or more

Insulin sensitivity factor

Maximum settings	8
Default	None. Insulin sensitivity is set during Startup of the Bolus Wizard feature.
Range	5 to 400 mg/dL/unit

Note: The insulin sensitivity factor only applies while the pump is in Manual Mode.

Low Reservoir reminder

The values are based on amount shown, not actual amount.

Alert range	Increment	Default value
First reminder occurs at 5 to 50 units. Second reminder occurs at 50 percent of the remaining specified amount. The second reminder is automatic and cannot be changed by the user.	1 unit	20 units

Max bolus

Range	0 to 25 units
Default	10 units

Normal bolus

Range is 0.025 to 25 units of insulin, and limited by the Max Bolus setting.

Occlusion detection

When occlusion is detected, the Insulin flow blocked alarm occurs. The occlusion alarm is triggered by an average of 2.23 units of missed insulin (standard bolus) or 1.97 units of missed insulin (quick bolus). The MiniMed 770G insulin pump is intended for use with U-100 insulin. This table shows occlusion detection for four different situations when using U-100 insulin.

Rate	Minimum time before alarm	Average time before alarm	Maximum time before alarm
bolus delivery (10 units at standard speed)	71 seconds	95 seconds	136 seconds
bolus delivery (10 units at quick speed)	9 seconds	10 seconds	14 seconds
basal delivery (1.0 u/h)	2.00 hours	2.50 hours	3.80 hours
basal delivery (0.025 u/h)	123.38 hours	142.03 hours	178.33 hours

Note: Certain factors, such as ambient temperature changes or the presence of air in the infusion set or the reservoir, can delay an occlusion alarm.

Percent temp basal rate

The default value is 100 percent of basal programming. For example, if you program six units of basal per day, the default temp basal rate will be six units per day.

Range	0 to 200%
Default	100% of basal programming
Increment	5%

Program safety checks

A single fault condition will cause the pump to suspend insulin delivery. Maximum infusion with a single fault condition is 0.2 units.

Pump dimensions

The pump dimensions in inches are no greater than 3.78 length x 2.11 width x 0.96 depth.

The pump dimensions in centimeters are no greater than 9.60 length x 5.36 width x 2.44 depth.

Pump memory

User settings and pump history are stored in non-volatile memory which will retain data. The memory size will hold 90 days of pump history before it becomes full and has to be written over. The viewable history on the pump is 30 days. This information can be accessed on the History screen.

Pump weight

The mass of the insulin pump without battery and consumables is less than 106 grams.

Sensor default settings

High sensor settings			
Item	**Default setting**	**Limits**	**Increments**
High SG alert limit	250 mg/dL	100 to 400 mg/dL	5 mg/dL

High sensor settings

Item	Default setting	Limits	Increments
Alert before high	Off	-	-
Alert on high	Off	-	-
Time before high	15 minutes	5 to 30 minutes	5 minutes
Rise Alert	Off	-	-
Rise Limit	Two up arrows	• 1 up arrow (1 mg/dL/min) • 2 up arrows (2 mg/dL/min) • 3 up arrows (3 mg/dL/min) • Custom limit (1.0 to 5.0 mg/dL/min)	
High Snooze	1 hour	5 minutes to 3 hours	5 minutes

Low sensor settings

Item	Default setting	Limits	Increments
Low SG alert limit	60 mg/dL	50 to 90 mg/dL	5 mg/dL
Suspend before low	Off	-	-
Suspend on low	Off	-	-
Alert before low	Off	-	-
Alert on low	Off	-	-
Low Snooze	20 minutes	5 minutes to 1 hour	5 minutes
Resume basal alert	Off	-	-

Auto Mode settings			
Item	Default setting	Limits	Increments
Auto Mode	Off	-	-
Auto Mode BG alert	On	-	-

Wireless communication

The MiniMed 770G insulin pump communicates using smart device connectivity.

Operating frequency/ Modulation type(s)	2.4 GHz band, GFSK
Effective radiated power (ERP)	1.48 mW (1.69 dBm)
Effective isotropic radiated power (EIRP)	2.42 mW (3.83 dBm)

FCC notice

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. These standards are designed to provide reasonable protection against excessive radio frequency interference, and prevent undesirable operation of the devices from unwanted electromagnetic interference.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.

- Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.

- Decrease the distance between the meter and the insulin pump to 6 feet (1.8 meters) or less.

- Increase the separation between the transmitter and the device that is receiving/emitting interference.

IMPORTANT: Do not change or modify the internal RF transmitter or antenna unless expressly approved by Medtronic Diabetes. Doing so could interfere with your ability to operate the equipment.

Note: Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

IEC60601-1-2:4th Edition notice

IEC60601-1-2:4th Edition; Special EMC Precautions for Medical Electrical Equipment

1. Special Precautions regarding Electromagnetic Compatibility (EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated "E" (V/m) or "H" fields (A/m) exist; such as cellular phones that are not paired with the MiniMed 770G System, Wi-Fi networks, Bluetooth wireless technology, electric can openers, microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.

2. Portable and mobile RF communications equipment can affect Medical Electrical Equipment as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.

IEC60601-1-2:4th Edition; 5.2.1.1

The MiniMed 770G insulin pump should not be used adjacent to other electrical equipment. If adjacent use becomes necessary, the MiniMed 770G insulin pump should be observed to verify normal system operation.

Guidance and manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The MiniMed 770G insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniMed 770G insulin pump should make sure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions Test: 47 CFR Part 15, Subpart C Section 15.247/FCC Part 15 Subpart B Section 15.109	• 6 dB and 99% Bandwidths: Complies • Maximum Output Power: Complies • TX Spurious Emissions: Complies • Power Spectral Density: Complies • Radiated Emission at Band Edge: Complies	The MiniMed 770G insulin pump must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	
RF emissions CISPR 11 (2009)+A1	Complies Group 1 Class B	The MiniMed 770G insulin pump is suitable for use in aircraft and in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RTCA DO 160G (2010) 20.5 and 21.5	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MiniMed 770G insulin pump is intended for use in the electromagnetic environment specified below. The customer or the user of the MiniMed 770G insulin pump should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2, 60601-1-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	For use in a typical domestic, commercial, or hospital environment.
Conducted disturbances induced by RF fields	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands between 150 kHz to 80 MHz	Not applicable	Requirement does not apply to this battery powered device.
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	Line to Line: ±0.5 kV, ±1 kV Line to Ground: ±0.5 kV, ±1 kV, ±2 kV	Not applicable	Requirement does not apply to this battery powered device.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-4-11	0% U_T; 0.5 cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 0% U_T; 1 cycle (at 0°) 70% for 25/30 cycles (at 0°) 0% for 250/300 cycles	Not applicable	Requirement does not apply to this battery powered device.
Power frequency (50/60 Hz) electromagnetic field IEC 61000-4-8, IEC 60601-1-2	30 A/m (continuous field at 60 seconds)	30 A/m 400 A/m per IEC 60601-2-24: 1998	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	IEC 60601-1-2;2014, Table 9	IEC 60601-1-2:2014, Table 9	For use in a typical domestic, commercial, or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The MiniMed 770G insulin pump is intended for use in the electromagnetic environment specified below. The customer or user of the MiniMed 770G insulin pump should assure that it is used in such an electromagnetic environment.			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated RF IEC 61000-4-3 IEC 60601-1-2	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the MiniMed 770G insulin pump, including cables, than the recommended separation distance of 12 inches (30 cm). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: $((\cdot))$

Icon glossary

For a definition of the symbols displayed on the device and package labels, please see http://www.medtronicdiabetes.com/symbol-definitions.

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MiniMed 770G System Performance Data and Technical Information

I. Performance data for users 14 years old and older

A. Device performance for users 14 years and older

The clinical data presented in this section was obtained from studies (users ages 14 years and older) using the MiniMed 670G system. The MiniMed 770G system uses the same SmartGuard Auto Mode technology as the MiniMed 670G system. Therefore, this clinical data also applies to the MiniMed 770G system.

⚠️ **CAUTION:** Since the study presented below did not include a control group, no claims regarding effectiveness can be made. However, it does support that the device is relatively safe for use.

The MiniMed 670G System can automatically increase or decrease insulin delivery when informed by continuous glucose monitoring (CGM) values; however, the user must still calculate and administer meal boluses. Previous clinical studies that did not involve the MiniMed 670G System have shown that other integrated insulin pump and CGM systems may provide better diabetes management, compared with multiple daily injections or with the pump alone. Some studies also suggest

that when you pair pump therapy with the information provided by the sensor, it may significantly improve HbA1C levels without increasing the risk of hypoglycemia.[1, 2, 3]

The MiniMed 670G System also features SmartGuard technology with different types of diabetes management. There are two levels of SmartGuard technology:

- The first level of SmartGuard technology automatically suspends insulin delivery when the sensor reaches a preset low limit or before the low limit is reached, referred to as Suspend on low and Suspend before low, respectively. When a Suspend on low event occurs, you can choose to continue to keep insulin delivery suspended, or you can choose to resume basal insulin delivery. When a Suspend before low occurs, basal insulin delivery will automatically resume when the sensor glucose (SG) levels recover. The Suspend on low and Suspend before low features are optional features available when the system is in Manual Mode.

- The second level of SmartGuard technology automatically calculates insulin dose using CGM data, referred to as Auto Mode. The Auto Mode feature can automatically increase or decrease the amount of insulin delivered based on sensor values. Elevated SG readings result in increased delivery rates and decreased SG values result in decreased insulin delivery rates.

During Auto Mode operation, the user must deliver meal boluses by entering the estimated amount of carbohydrates for meals at the time they are eaten. Failure to deliver meal boluses in association with meals during Auto Mode operation can result in significant post meal hyperglycemia.

Since adjustments to insulin delivery rates when the system is in Auto Mode are based on SG readings, it is critical to monitor blood glucose (BG) values using a home glucose meter regardless of whether the system is operating in the Manual Mode or the Auto Mode. If these home glucose meter measurements indicate

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1   Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes [STAR3 Study]. N Engl J Med.2010;363:311–320.

2   Battelino T, Conget I, Olsen B, et al. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy [SWITCH study]. Diabetologia. 2012 Dec;55(12):3155-62. doi: 10.1007/s00125-012-2708-9. Epub 2012 Sept 11.

3   Bergenstal RM, Klonoff DC, Bode BW, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia [ASPIRE in-home study]. N Engl J Med. 2013;369(3):224-232.

hypoglycemia or hyperglycemia, you must follow your physician's instruction for treating these conditions and you should not rely on the MiniMed 670G System to automatically restore your glucose levels to normal.

The SmartGuard technology contains two insulin delivery suspend options: Suspend on low and Suspend before low. The Suspend on low was previously evaluated and is currently available on commercially available pumps (MiniMed 530G Pump and MiniMed 630G Pump).

The Suspend before low feature was evaluated for safety in a multi-center, single-arm, in-clinic study.[4] Study subjects included persons aged 14 to 75 years diagnosed with type 1 diabetes mellitus who were on pump therapy at the time of screening. A total of 71 subjects were subjected to hypoglycemic induction, followed by an observation period. For hypoglycemic induction, the target was set to 65 mg/dL, using the rate of change basal increase algorithm. Suspend before low was activated with the Low Limit setting for Suspend before low ON set to 65 mg/dL, and the subject was observed with frequent sample testing (FST) for a maximum of 19 hours. The observation period included the suspension period, the insulin resumption period, and if applicable, an insulin resuspension after basal insulin delivery resumed.

Five adverse events were reported during the study. Four adverse events were neither device nor procedure related. One adverse event was procedure related.

Data from this in-clinic study demonstrated that the Suspend before low feature is safe to use. Study success criteria, as defined in the protocol, were met (i.e. there were no device related serious adverse events, no diabetic ketoacidosis events related to the Suspend before low feature, and no unanticipated adverse device effects).

The second level of SmartGuard technology was evaluated under a pivotal, single-arm, multi-center, home and hotel study in subjects with type 1 diabetes on insulin pump therapy.[5] Study subjects included persons aged 14 to 75 years

4 Buckingham B.A., Bailey T.S., Christiansen M., Garg S., Weinzimer S., Bode B., Anderson S.M., Brazg R., Ly T.T., Kaufman F.R. Evaluation of a Predictive Low-Glucose Management System In-Clinic. Diabetes Technology and Therapeutics (2017) 19:5 (288-292).

5 Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a hybrid closed-loop insulin delivery system in patients with type 1 diabetes. JAMA - Journal of the American Medical Association. 2016;316(13): 1407-1408.

diagnosed with type 1 diabetes mellitus for two years or more that had used pump therapy for more than 6 months prior to screening. Study subjects had an HbA1C value of less than 10.0% at the time of screening.

This study consisted of a 2-week run-in phase and a 3-month study phase. A total of 124 subjects used the MiniMed 670G System in Manual Mode only first, before transitioning to Auto Mode during the study phase. In addition to system use at home, the study phase included a 6-day and 5-night hotel stay during which subjects underwent daytime and nighttime FST for a total of approximately 24 hours. Subjects were allowed to eat as they normally would, and participated in a daily exercise or activity regimen for a minimum of 4 hours per day, spread throughout the day, during the hotel stay. Two of the 124 subjects did not participate in a hotel stay. One of these two subjects withdrew from the study.

The MiniMed 670G System was used for 12,389 patient days. No serious adverse events, diabetic ketoacidosis (DKA), or severe hypoglycemia were reported during the study. Compared to Manual Mode use during the run-in phase, use of the system was associated with a higher percentage of SG values within the range of 71–180 mg/dL and lower percentage of SG values in the low and high glucose ranges. A change in mean A1C from 7.4 ± 0.91 (median 7.3) at the start of the study to 6.9 ± 0.61 (6.8) at the end of the study was observed. This observation was associated with a modest increase in the mean total daily dose of insulin (47.5 baseline to 50.9) and mild increase in mean weight (76.9 baseline to 77.6).

Device related adverse events reported during the different phases of the pivotal trial are listed in the following table.

Table A-1: Device Related Adverse Events		
Event	Run-In Period	Study Period
Severe hyperglycemia	5	12
Hyperglycemia	0	6
Skin irritation	3	0
Irritation on sensor site	0	1
Rash	0	1

The following table shows the time spent per day in specific glucose ranges during the run-in and study phases by all subjects.

Table A-2: Time Spent in Specific Glucose Ranges During the Run-In and Study Phases by All Subjects		
Glucose Range (mg/dL)	Run-In Phase Time in Glucose Range Mean ±SD	Study Phase Time in Glucose Range Mean ±SD
≤50	12.8 mins ± 14.5 mins	7.7 mins ± 7.6 mins
≤60	35.2 mins ± 31.2 mins	19.9 mins ± 14.8 mins
≤70	1 hr 18.6 mins ± 55.3 mins	42.9 mins ± 25.4 mins
70–180	14 hrs 54.4 mins ± 3 hrs 1.4 min	16 hrs 2.2 mins ± 2 hrs 35.6 mins
>180	6 hrs 2.1 mins ± 2 hrs 52.7 mins	5 hrs 20.7 mins ± 1 hr 46.9 mins
>250	1 hr 30.4 mins ± 1 hr 32.3 mins	1 hr 12.1 mins ± 52.6 mins
>300	29.6 mins ± 51.7 mins	21.1 mins ± 22.2 mins
>350	8.9 mins ± 20.7 mins	6.1 mins ± 8.35 mins

The following table shows the range of changes in HbA1C observed in the study and indicates the number of subjects that demonstrated each type of change in HbA1C observed.

Table A-3: Number of Subjects with Change in HbA1C at Different Baselines					
HbA1C Change Range	Number of Subjects (% of Subjects) with Change in A1C				
Baseline A1C (%)	Decrease >1%	Decrease 0 to 1%	No Change	Increase 0 to 1%	Increase >1%
5% ≤ A1C < 6%	0 (0.0%)	1 (0.8%)	0 (0.0%)	3 (2.4%)	0 (0.0%)
6% ≤ A1C < 7%	1 (0.8%)	20 (16.1%)	5 (4.0%)	11 (8.9%)	0 (0.0%)
7% ≤ A1C < 8%	8 (6.5%)	34 (27.4%)	1 (0.8%)	9 (7.3%)	0 (0.0%)
8% ≤ A1C < 9%	11 (8.9%)	12 (9.7%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
9% ≤ A1C < 10%	6 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	26 (21.0%)	67 (54.0%)	7 (5.6%)	23 (18.5%)	0 (0.0%)

The following table shows the number of subjects that spent a specific range of time per day in specific glucose ranges during the study phase.

Table A-4: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase								
Time Range	Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated							
	≤50	≤60	≤70	70 to 180	>180	>250	>300	>350
0 to 15 mins	105 (84.7%)	58 (46.8%)	12 (9.7%)	0 (0.0%)	0 (0.0%)	8 (6.5%)	66 (53.2%)	112 (90.3%)
15 to 30 mins	16 (12.9%)	43 (34.7%)	33 (26.6%)	0 (0.0%)	0 (0.0%)	16 (12.9%)	31 (25.0%)	6 (4.8%)
30 to 45 mins	3 (2.4%)	12 (9.7%)	29 (23.4%)	0 (0.0%)	0 (0.0%)	24 (19.4%)	12 (9.7%)	6 (4.8%)
45 mins to 1 hr	0 (0.0%)	10 (8.1%)	25 (20.2%)	0 (0.0%)	0 (0.0%)	17 (13.7%)	6 (4.8%)	0 (0.0%)
1 to 4 hr	0 (0.0%)	1 (0.8%)	25 (20.2%)	0 (0.0%)	34 (27.4%)	58 (46.8%)	9 (7.3%)	0 (0.0%)
4 to 8 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	83 (66.9%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
8 to 12 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	12 (9.7%)	7 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12 to 16 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	38 (30.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
16 to 20 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	70 (56.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
20 to 24 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

The following table shows the average amount of time spent in Auto Mode per day.

Table A-5: Time Spent in Auto Mode at Different Glucose Ranges during the Study Phase	
Glucose Range (mg/dL)	**Study Phase Time in Glucose Range Mean±SD (95% CI)**
≤50	4.8 mins ± 4.6 mins (4.0 mins, 5.6 mins)
≤60	13.2 mins ± 10.1 mins (11.4 mins, 15.0 mins)
≤70	29.9 mins ± 18.8 mins (26.6 mins, 33.2 mins)
70 to 180	13 hrs 50.3 mins ± 3 hrs 1.4 mins (13 hrs 18.1 min, 14 hrs 22.5 mins)
>180	4 hrs 5.2 mins ± 1 hr 5.0 mins (3 hrs 53.7 mins, 4 hrs, 16.8 mins)
>250	44.8 mins ± 24.9 mins (40.4 mins, 49.2 mins)
>300	9.3 mins ± 7.6 mins (8.0 mins, 10.7 mins)
>350	1.7 mins ± 2.0 mins (1.3 mins, 2.0 mins)
All	18 hrs 25.4 mins ± 2 hrs 44.4 mins (17 hrs 56.2 mins, 18 hrs 54.7 mins)

The pivotal clinical trial of the MiniMed 670G System suggested that the system was safe; however, this trial had a number of limitations which included the following:

- The study involved a relatively small number of patients.

- There was no control group for comparison purposes.

- The amount of time the system was used in the Manual Mode was much shorter than the time it was programmed to the Auto Mode. Additionally, for each subject, the study period lasted only three months.

Due to these limitations, the results of the clinical trial must be interpreted with caution and you should understand that your individual results when using the MiniMed 670G System may be significantly different from those of the subjects who participated in the trial.

B. Guardian Sensor (3) Performance for 14 years old and older

CGM performance

The use of the Guardian Sensor (3) with the Guardian Link (3) transmitter enables CGM technology. The transmitter transmits SG values calculated by the real-time algorithm to a primary display device, allowing you to monitor your SG values.

Clinical study description

The performance of the Guardian Sensor (3) was evaluated in a clinical study.[6] This inpatient (in-clinic) and outpatient (at home) study included subjects 14 to 75 years in age. The study design was a multi-center, prospective single-sample correlational design without controls.

All subjects were assigned to treatment. Three sensors were worn at the same time by each subject.

Each subject was instructed to wear two real-time CGM systems in the abdomen area:

- One Guardian Sensor (3) connected to the Guardian Link (3) transmitter, which transmitted to the insulin pump (for display purposes only).

- One Guardian Sensor (3) connected to the Guardian Connect transmitter which transmitted to the Guardian Connect app, a standalone CGM display device.

Each subject was also instructed to wear another Guardian Sensor (3) in the arm area that was connected to a blinded glucose sensor recorder (GSR).

The SG data collected by the blinded GSRs were retrospectively processed through the real-time CGM algorithm. This is the same algorithm used in the Guardian Connect and pump CGM systems. Thus all data is representative of real-time sensor usage.

The CONTOUR NEXT LINK 2.4 Wireless Meter was the study meter used for all calibrations in this study, and was the only meter evaluated with the Guardian Sensor (3) CGM systems. The sensor has not been tested with other meters. Therefore, the performance with other BG meters may differ from the performance with the CONTOUR NEXT LINK 2.4 Wireless Meter described below.

FST was performed on days 1, 3, and 7 over the life of the sensor. Reference blood (plasma) glucose values were obtained with a Yellow Springs Instrument (YSI) Glucose Analyzer every 5 to 15 minutes. During the FSTs, the subjects were instructed to calibrate the sensors once every 12 hours, or as requested by the display device. During home use (outside the clinic), subjects were instructed to calibrate both sensors 3 or 4 times spread throughout the day.

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6   Medtronic Inc., A Performance Evaluation of the Enlite™ 3 Glucose Sensor to Support a Full 168 hours (7 Days) of Use, CER292DOC/F. Oct 2016.

A total of 93 subjects previously diagnosed with type 1 or 2 diabetes were enrolled in the study, and 88 subjects participated in at least one day of FST. The overall number of subjects that participated in FST procedures on days 1, 3, and 7 were 88, 87, and 79, respectively. During each FST period, subjects with an established insulin sensitivity ratio and insulin carbohydrate ratio underwent a hypoglycemic challenge and a hyperglycemic challenge to evaluate performance at high and low glycemic ranges.

During the study, subjects were instructed to continue with their current diabetes regimen (including glucose monitoring with their own meter when appropriate) independent of their use of the study devices. The insulin pumps were not used to infuse insulin, and neither of the two real-time CGM systems nor the blinded GSR system was used to manage diabetes during this study. The study meter was used for confirmation of alerts, treatment decisions, and sensor calibrations.

Results

Sensor accuracy

The following information highlights the Guardian Sensor (3) performance from 88 subjects only during FST.

Mean absolute relative difference, by number of daily calibrations

Table B-1 shows the sensor accuracy measured by the mean absolute relative difference (MARD). MARD represents the average relative difference (regardless if positive or negative) between the SG values and the paired BG values measured by YSI.

YSI glucose ranges (mg/dL)	Abdomen Insertion Site				Arm Insertion Site			
	Calibration every 12 hours		Calibration 3 or 4 times a day		Calibration every 12 hours		Calibration 3 or 4 times a day	
	Number of paired SG-YSI	MARD (%)	Number of paired SG-YSI	MARD (%)	Number of paired SG-YSI	MARD (%)	Number of paired SG-YSI	MARD (%)
Overall	12090	10.55	11664	9.64	10526	9.09	10771	8.68
<40*	12	17.03	11	16.41	7	17.24	7	17.24
40–60*	353	7.96	324	7.53	335	6.44	349	6.42
61–80*	1445	9.44	1403	8.81	1345	7.76	1372	7.44
81–180	6505	9.94	6342	9.33	5644	8.64	5795	8.35
181–300	3277	10.00	3114	8.57	2766	8.58	2785	7.95
301–350	366	9.63	341	8.13	308	9.09	338	8.27

Table B-1: SG MARD Versus YSI (within YSI glucose ranges).

Table B-1: SG MARD Versus YSI (within YSI glucose ranges).								
YSI glucose ranges (mg/dL)	Abdomen Insertion Site				Arm Insertion Site			
	Calibration every 12 hours		Calibration 3 or 4 times a day		Calibration every 12 hours		Calibration 3 or 4 times a day	
	Number of paired SG-YSI	MARD (%)	Number of paired SG-YSI	MARD (%)	Number of paired SG-YSI	MARD (%)	Number of paired SG-YSI	MARD (%)
351–400	117	9.58	114	8.56	111	8.47	115	8.23
>400	15	10.85	15	10.92	10	10.71	10	11.44

* For YSI reference range ≤80 mg/dL, the differences in mg/dL are included instead of percent difference (%).

Note: SG Readings are within 40-400 mg/dL.

Percent agreement, by number of daily calibrations

In Tables B-2 through B-9, the agreement of the SG values to paired YSI values was assessed by calculating the percentage of YSI values that were within 15%, 20%, 30%, 40% and greater than 40% of the paired SG values. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Results are shown for defined SG ranges when calibrating every 12 hours and calibrating three or four times a day for sensors.

Table B-2: Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen.						
SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	12090	76.6	85.7	94.3	97.3	2.7
≥40–60*	781	57.7	73.2	90.7	96.9	3.1
>60–80*	1350	76.1	83.4	93.4	96.8	3.2
>80–180	6769	76.5	85.3	93.5	96.5	3.5
>180–300	2833	80.8	90	97.1	98.9	1.1
>300–350	286	86.4	95.1	99.7	100	0
>350–400	71	93	100	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG Readings are within 40–400 mg/dL.

Table B-3: Agreement (%) of SG paired points within SG ranges on FST Day 1; Calibration every 12 hours, Abdomen.						
SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	4294	65.3	76.6	89.5	94.7	5.3
≥40–60*	278	46.8	61.9	83.5	94.2	5.8
>60–80*	474	61	71.7	88	93.5	6.5
>80–180	2443	64.9	75.4	87.6	93.2	6.8

Table B-3: Agreement (%) of SG paired points within SG ranges on FST Day 1; Calibration every 12 hours, Abdomen.						
SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
>180–300	985	71.6	83.8	95.5	98.5	1.5
>300–350	90	82.2	95.6	100	100	0
>350–400	24	91.7	100	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects. SG Readings are within 40–400 mg/dL.

Table B-4: Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen.						
SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	11664	80.6	88.9	95.9	98.2	1.8
≥40–60*	686	60.2	75.1	92	98.1	1.9
>60–80*	1303	78.7	85.7	93.5	96.7	3.3
>80–180	6549	79.9	88.5	95.7	98	2
>180–300	2782	86.4	93.5	98	99.4	0.6
>300–350	279	92.5	97.8	99.6	100	0
>350–400	65	95.4	100	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG Readings are within 40–400 mg/dL.

Table B-5: Agreement (%) of SG paired points within SG ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen.						
SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	4136	71.4	81.9	92.3	96.3	3.7
≥40–60*	247	50.2	64.4	84.6	95.5	4.5
>60–80*	429	66.2	73.9	86.5	92.8	7.2
>80–180	2353	70.6	81.4	91.8	95.5	4.5
>180–300	988	78.6	89.1	97.2	99.5	0.5
>300–350	97	88.7	96.9	100	100	0
>350–400	22	100	100	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects. SG Readings are within 40–400 mg/dL.

Table B-6: Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.						
SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	10526	82.5	90.3	96.3	98.7	1.3
≥40–60*	520	77.1	86.9	96	99.6	0.4

Table B-6: Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
>60–80*	1238	88.2	92.5	96.4	99	1
>80–180	5957	80.3	88.5	95.5	98.2	1.8
>180–300	2495	85	93.2	98	99.4	0.6
>300–350	256	90.6	96.9	100	100	0
>350–400	60	90	93.3	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG Readings are within 40–400 mg/dL.

Table B-7: Agreement (%) of SG-YSI paired points within SG ranges on FST Day 1; Calibration every 12 hours, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	3390	74.7	84.2	93.2	97.8	2.2
≥40–60*	168	60.1	73.2	90.5	98.8	1.2
>60–80*	339	75.5	79.4	88.8	97.3	2.7
>80–180	2017	73.2	83.1	92	97	3
>180–300	760	80.5	90.8	98.2	99.6	0.4
>300–350	91	84.6	93.4	100	100	0
>350–400	15	60	73.3	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 82 subjects. SG Readings are within 40–400 mg/dL.

Table B-8: Overall agreement (%) of SG-YSI paired points within SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	10771	84.3	91.6	97.3	99.1	0.9
≥40–60*	503	77.1	87.5	96.6	99.6	0.4
>60–80*	1291	89.3	93.4	97.7	99.1	0.9
>80–180	6076	82	90	96.7	98.7	1.3
>180–300	2569	87	94.4	98.3	99.7	0.3
>300–350	271	94.8	98.5	100	100	0
>350–400	61	95.1	96.7	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG Readings are within 40–400 mg/dL.

Table B-9: Agreement (%) of SG-YSI paired points within SG ranges on FST Day 1; Calibration 3 or 4 times a day, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
Overall	3591	76.8	86	95	98.5	1.5

Table B-9: Agreement (%) of SG-YSI paired points within SG ranges on FST Day 1; Calibration 3 or 4 times a day, Arm.						
SG ranges (mg/dL)	Number of paired SG-YSI	Percent of YSI within 15/15% of SG (%)	Percent of YSI within 20/20% of SG (%)	Percent of YSI within 30/30% of SG (%)	Percent of YSI within 40/40% of SG (%)	Percent of YSI greater than 40/40% of SG (%)
≥40–60*	162	62.3	75.3	91.4	98.8	1.2
>60–80*	346	76.3	81.5	92.8	97.4	2.6
>80–180	2108	75.1	85	94.2	98	2
>180–300	869	81.8	91	97.7	99.9	0.1
>300–350	93	92.5	96.8	100	100	0
>350–400	13	84.6	84.6	100	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 83 subjects. SG Readings are within 40–400 mg/dL.

Agreement when the CGM system reads "Below 40 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 40 mg/dL and 400 mg/dL. It displays "Below 40 mg/dL" when the SG value detected is below 40 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. Tables B-10, B-11, B-12, and B-13 illustrate the number and percentage of the paired YSI values in different BG levels when the CGM system displays "Below 40 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table B-10: The number and percentage of YSI values collected when CGM displays "Below 40 mg/dL" (LOW); Calibration every 12 hours.								
CGM Display	Insertion Site	CGM-YSI pairs	YSI (mg/dL)					
			<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	42	77	139	150	4	154
		Cumulative %	27%	50%	90%	97%	3%	100%
	Arm	Cumulative, n	17	35	67	74	1	75
		Cumulative %	23%	47%	89%	99%	1%	100%

Table B-11: The number and percentage of YSI values collected when CGM displays "Below 40 mg/dL" (LOW); Calibration 3 or 4 times a day.								
CGM Display	Insertion Site	CGM-YSI pairs	YSI (mg/dL)					
			<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	33	64	108	119	4	123
		Cumulative %	27%	52%	88%	97%	3%	100%
	Arm	Cumulative, n	18	35	66	72	1	73
		Cumulative %	25%	48%	90%	99%	1%	100%

Table B-12: The number and percentage of YSI values collected when CGM displays "Above 400 mg/dL" (HIGH); Calibration every 12 hours.

CGM Display	Insertion Site	CGM-YSI pairs	YSI (mg/dL)					
			<340	<320	<280	<240	>240	Total
HIGH	Abdomen	Cumulative, n	8	9	9	9	0	9
		Cumulative %	89%	100%	100%	100%	0%	100%
	Arm	Cumulative, n	8	8	9	9	0	9
		Cumulative %	89%	89%	100%	100%	0%	100%

Table B-13: The number and percentage of YSI values collected when CGM displays "Above 400 mg/dL" (HIGH); Calibration 3 or 4 times a day.

CGM Display	Insertion Site	CGM-YSI pairs	YSI (mg/dL)					
			<340	<320	<280	<240	>240	Total
HIGH	Abdomen	Cumulative, n	8	9	9	9	0	9
		Cumulative %	89%	100%	100%	100%	0%	100%
	Arm	Cumulative, n	8	8	8	8	0	8
		Cumulative %	100%	100%	100%	100%	0%	100%

Concurrence of SG and YSI values

Tables B-14 through B-21 show, for each SG range, the percentage of concurring data points where the paired YSI values were in different BG ranges.

Table B-14: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)

SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	154	0.0% (0/154)	50.0% (77/154)	47.4% (73/154)	2.6% (4/154)	0.0% (0/154)	0.0% (0/154)	0.0% (0/154)	0.0% (0/154)	0.0% (0/154)	0.0% (0/154)	0.0% (0/154)
B) ≥40–60	781	1.2% (9/781)	30.7% (240/781)	57.2% (447/781)	10.6% (83/781)	0.3% (2/781)	0.0% (0/781)	0.0% (0/781)	0.0% (0/781)	0.0% (0/781)	0.0% (0/781)	0.0% (0/781)
C) >60–80	1350	0.2% (3/1350)	8.3% (112/1350)	60.1% (811/1350)	29.2% (394/1350)	2.1% (28/1350)	0.1% (2/1350)	0.0% (0/1350)	0.0% (0/1350)	0.0% (0/1350)	0.0% (0/1350)	0.0% (0/1350)
D) >80–120	2953	0.0% (0/2953)	0.0% (1/2953)	6.3% (185/2953)	73.0% (2157/2953)	18.2% (537/2953)	2.0% (60/2953)	0.4% (13/2953)	0.0% (0/2953)	0.0% (0/2953)	0.0% (0/2953)	0.0% (0/2953)
E) >120–160	2784	0.0% (0/2784)	0.0% (0/2784)	0.1% (2/2784)	8.8% (245/2784)	67.7% (1885/2784)	20.3% (565/2784)	2.8% (79/2784)	0.3% (8/2784)	0.0% (0/2784)	0.0% (0/2784)	0.0% (0/2784)
F) >160–200	1875	0.0% (0/1875)	0.0% (0/1875)	0.0% (0/1875)	0.1% (2/1875)	10.0% (188/1875)	60.2% (1128/1875)	28.2% (529/1875)	1.5% (28/1875)	0.0% (0/1875)	0.0% (0/1875)	0.0% (0/1875)
G) >200–250	1382	0.0% (0/1382)	0.0% (0/1382)	0.0% (0/1382)	0.0% (0/1382)	0.3% (4/1382)	8.0% (111/1382)	61.1% (844/1382)	28.1% (389/1382)	2.3% (32/1382)	0.1% (2/1382)	0.0% (0/1382)

Table B-14: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen												
Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
H) >250–300	608	0.0% (0/608)	0.0% (0/608)	0.0% (0/608)	0.0% (0/608)	0.0% (0/608)	0.3% (2/608)	10.9% (66/608)	61.2% (372/608)	25.5% (155/608)	2.1% (13/608)	0.0% (0/608)
I) >300–350	286	0.0% (0/286)	0.0% (0/286)	0.0% (0/286)	0.0% (0/286)	0.0% (0/286)	0.0% (0/286)	1.0% (3/286)	19.9% (57/286)	55.2% (158/286)	22.4% (64/286)	1.4% (4/286)
J) >350–400	71	0.0% (0/71)	0.0% (0/71)	0.0% (0/71)	0.0% (0/71)	0.0% (0/71)	0.0% (0/71)	0.0% (0/71)	1.4% (1/71)	29.6% (21/71)	53.5% (38/71)	15.5% (11/71)
K) >400	9	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	11.1% (1/9)	77.8% (7/9)	11.1% (1/9)

Table B-15: Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration every 12 hours, Abdomen												
Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	71	0.0% (0/71)	38.0% (27/71)	57.7% (41/71)	4.2% (3/71)	0.0% (0/71)	0.0% (0/71)	0.0% (0/71)	0.0% (0/71)	0.0% (0/71)	0.0% (0/71)	0.0% (0/71)
B) ≥40–60	278	2.2% (6/278)	23.0% (64/278)	55.8% (155/278)	18.7% (52/278)	0.4% (1/278)	0.0% (0/278)	0.0% (0/278)	0.0% (0/278)	0.0% (0/278)	0.0% (0/278)	0.0% (0/278)
C) >60–80	474	0.4% (2/474)	12.0% (57/474)	47.7% (226/474)	34.8% (165/474)	4.6% (22/474)	0.4% (2/474)	0.0% (0/474)	0.0% (0/474)	0.0% (0/474)	0.0% (0/474)	0.0% (0/474)
D) >80–120	1071	0.0% (0/1071)	0.1% (1/1071)	4.6% (49/1071)	66.6% (713/1071)	23.4% (251/1071)	4.5% (48/1071)	0.8% (9/1071)	0.0% (0/1071)	0.0% (0/1071)	0.0% (0/1071)	0.0% (0/1071)
E) >120–160	978	0.0% (0/978)	0.0% (0/978)	0.1% (1/978)	8.3% (81/978)	58.4% (571/978)	26.8% (262/978)	5.9% (58/978)	0.5% (5/978)	0.0% (0/978)	0.0% (0/978)	0.0% (0/978)
F) >160–200	662	0.0% (0/662)	0.0% (0/662)	0.0% (0/662)	0.3% (2/662)	9.1% (60/662)	52.6% (348/662)	35.3% (234/662)	2.7% (18/662)	0.0% (0/662)	0.0% (0/662)	0.0% (0/662)
G) >200–250	515	0.0% (0/515)	0.0% (0/515)	0.0% (0/515)	0.0% (0/515)	0.0% (0/515)	6.2% (32/515)	56.3% (290/515)	33.8% (174/515)	3.3% (17/515)	0.4% (2/515)	0.0% (0/515)
H) >250–300	202	0.0% (0/202)	0.0% (0/202)	0.0% (0/202)	0.0% (0/202)	0.0% (0/202)	0.0% (0/202)	9.4% (19/202)	55.0% (111/202)	32.2% (65/202)	3.5% (7/202)	0.0% (0/202)
I) >300–350	90	0.0% (0/90)	0.0% (0/90)	0.0% (0/90)	0.0% (0/90)	0.0% (0/90)	0.0% (0/90)	0.0% (0/90)	20.0% (18/90)	54.4% (49/90)	23.3% (21/90)	2.2% (2/90)
J) >350–400	24	0.0% (0/24)	0.0% (0/24)	0.0% (0/24)	0.0% (0/24)	0.0% (0/24)	0.0% (0/24)	0.0% (0/24)	4.2% (1/24)	37.5% (9/24)	50.0% (12/24)	8.3% (2/24)
K) >400	1	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 88 subjects.

Table B-16: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)

SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	123	0.0% (0/123)	52.0% (64/123)	44.7% (55/123)	3.3% (4/123)	0.0% (0/123)	0.0% (0/123)	0.0% (0/123)	0.0% (0/123)	0.0% (0/123)	0.0% (0/123)	0.0% (0/123)
B) ≥40–60	686	1.3% (9/686)	31.6% (217/686)	57.0% (391/686)	9.9% (68/686)	0.1% (1/686)	0.0% (0/686)	0.0% (0/686)	0.0% (0/686)	0.0% (0/686)	0.0% (0/686)	0.0% (0/686)
C) >60–80	1303	0.2% (2/1303)	8.1% (106/1303)	63.4% (826/1303)	26.2% (342/1303)	1.9% (25/1303)	0.2% (2/1303)	0.0% (0/1303)	0.0% (0/1303)	0.0% (0/1303)	0.0% (0/1303)	0.0% (0/1303)
D) >80–120	2864	0.0% (0/2864)	0.0% (1/2864)	6.5% (186/2864)	74.5% (2133/2864)	17.5% (502/2864)	1.3% (36/2864)	0.2% (6/2864)	0.0% (0/2864)	0.0% (0/2864)	0.0% (0/2864)	0.0% (0/2864)
E) >120–160	2681	0.0% (0/2681)	0.0% (0/2681)	0.0% (0/2681)	9.0% (241/2681)	69.9% (1874/2681)	19.1% (512/2681)	1.8% (49/2681)	0.2% (5/2681)	0.0% (0/2681)	0.0% (0/2681)	0.0% (0/2681)
F) >160–200	1820	0.0% (0/1820)	0.0% (0/1820)	0.0% (0/1820)	0.1% (2/1820)	10.3% (188/1820)	63.6% (1157/1820)	24.9% (454/1820)	1.0% (19/1820)	0.0% (0/1820)	0.0% (0/1820)	0.0% (0/1820)
G) >200–250	1314	0.0% (0/1314)	0.0% (0/1314)	0.0% (0/1314)	0.0% (0/1314)	0.5% (7/1314)	8.5% (112/1314)	65.3% (858/1314)	24.6% (323/1314)	1.1% (14/1314)	0.0% (0/1314)	0.0% (0/1314)
H) >250–300	652	0.0% (0/652)	0.0% (0/652)	0.0% (0/652)	0.0% (0/652)	0.0% (0/652)	0.3% (2/652)	11.3% (74/652)	63.5% (414/652)	22.9% (149/652)	2.0% (13/652)	0.0% (0/652)
I) >300–350	279	0.0% (0/279)	0.0% (0/279)	0.0% (0/279)	0.0% (0/279)	0.0% (0/279)	0.0% (0/279)	0.0% (0/279)	17.9% (50/279)	59.5% (166/279)	21.1% (59/279)	1.4% (4/279)
J) >350–400	65	0.0% (0/65)	0.0% (0/65)	0.0% (0/65)	0.0% (0/65)	0.0% (0/65)	0.0% (0/65)	0.0% (0/65)	0.0% (0/65)	18.5% (12/65)	64.6% (42/65)	16.9% (11/65)
K) >400	9	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	11.1% (1/9)	77.8% (7/9)	11.1% (1/9)

Table B-17: Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)

SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	62	0.0% (0/62)	37.1% (23/62)	58.1% (36/62)	4.8% (3/62)	0.0% (0/62)	0.0% (0/62)	0.0% (0/62)	0.0% (0/62)	0.0% (0/62)	0.0% (0/62)	0.0% (0/62)
B) ≥40–60	247	2.4% (6/247)	21.5% (53/247)	58.7% (145/247)	17.0% (42/247)	0.4% (1/247)	0.0% (0/247)	0.0% (0/247)	0.0% (0/247)	0.0% (0/247)	0.0% (0/247)	0.0% (0/247)
C) >60–80	429	0.2% (1/429)	12.6% (54/429)	52.0% (223/429)	30.3% (130/429)	4.4% (19/429)	0.5% (2/429)	0.0% (0/429)	0.0% (0/429)	0.0% (0/429)	0.0% (0/429)	0.0% (0/429)
D) >80–120	1014	0.0% (0/1014)	0.1% (1/1014)	5.3% (54/1014)	70.7% (717/1014)	20.4% (207/1014)	3.1% (31/1014)	0.4% (4/1014)	0.0% (0/1014)	0.0% (0/1014)	0.0% (0/1014)	0.0% (0/1014)

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Table B-17: Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)

SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
E) >120–160	973	0.0% (0/973)	0.0% (0/973)	0.0% (0/973)	9.1% (89/973)	61.6% (599/973)	24.8% (241/973)	4.0% (39/973)	0.5% (5/973)	0.0% (0/973)	0.0% (0/973)	0.0% (0/973)
F) >160–200	633	0.0% (0/633)	0.0% (0/633)	0.0% (0/633)	0.3% (2/633)	10.7% (68/633)	56.7% (359/633)	30.3% (192/633)	1.9% (12/633)	0.0% (0/633)	0.0% (0/633)	0.0% (0/633)
G) >200–250	497	0.0% (0/497)	0.0% (0/497)	0.0% (0/497)	0.0% (0/497)	0.2% (1/497)	7.8% (39/497)	64.6% (321/497)	26.4% (131/497)	1.0% (5/497)	0.0% (0/497)	0.0% (0/497)
H) >250–300	224	0.0% (0/224)	0.0% (0/224)	0.0% (0/224)	0.0% (0/224)	0.0% (0/224)	0.0% (0/224)	12.9% (29/224)	58.0% (130/224)	23.7% (53/224)	5.4% (12/224)	0.0% (0/224)
I) >300–350	97	0.0% (0/97)	0.0% (0/97)	0.0% (0/97)	0.0% (0/97)	0.0% (0/97)	0.0% (0/97)	0.0% (0/97)	19.6% (19/97)	59.8% (58/97)	18.6% (18/97)	2.1% (2/97)
J) >350–400	22	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	27.3% (6/22)	63.6% (14/22)	9.1% (2/22)
K) >400	1	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)

Note: The overall number of available SG-YSI points on FST Day 1 was from 88 subjects.

Table B-18: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)

SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	75	2.7% (2/75)	44.0% (33/75)	52.0% (39/75)	1.3% (1/75)	0.0% (0/75)	0.0% (0/75)	0.0% (0/75)	0.0% (0/75)	0.0% (0/75)	0.0% (0/75)	0.0% (0/75)
B) ≥40–60	520	1.0% (5/520)	41.9% (218/520)	51.7% (269/520)	5.4% (28/520)	0.0% (0/520)	0.0% (0/520)	0.0% (0/520)	0.0% (0/520)	0.0% (0/520)	0.0% (0/520)	0.0% (0/520)
C) >60–80	1238	0.2% (2/1238)	9.2% (114/1238)	70.3% (870/1238)	20.0% (247/1238)	0.4% (5/1238)	0.0% (0/1238)	0.0% (0/1238)	0.0% (0/1238)	0.0% (0/1238)	0.0% (0/1238)	0.0% (0/1238)
D) >80–120	2722	0.0% (0/2722)	0.1% (3/2722)	7.5% (203/2722)	74.0% (2014/2722)	17.7% (481/2722)	0.8% (21/2722)	0.0% (0/2722)	0.0% (0/2722)	0.0% (0/2722)	0.0% (0/2722)	0.0% (0/2722)
E) >120–160	2348	0.0% (0/2348)	0.0% (0/2348)	0.1% (3/2348)	9.2% (215/2348)	70.4% (1652/2348)	18.0% (423/2348)	2.3% (54/2348)	0.0% (1/2348)	0.0% (0/2348)	0.0% (0/2348)	0.0% (0/2348)
F) >160–200	1614	0.0% (0/1614)	0.0% (0/1614)	0.0% (0/1614)	0.1% (2/1614)	9.4% (151/1614)	64.7% (1044/1614)	24.8% (400/1614)	0.9% (14/1614)	0.2% (3/1614)	0.0% (0/1614)	0.0% (0/1614)
G) >200–250	1212	0.0% (0/1212)	0.0% (0/1212)	0.0% (0/1212)	0.0% (0/1212)	0.6% (7/1212)	6.8% (83/1212)	63.9% (774/1212)	27.3% (331/1212)	1.4% (17/1212)	0.0% (0/1212)	0.0% (0/1212)
H) >250–300	556	0.0% (0/556)	0.0% (0/556)	0.0% (0/556)	0.0% (0/556)	0.0% (0/556)	0.2% (1/556)	9.4% (52/556)	65.1% (362/556)	23.9% (133/556)	1.4% (8/556)	0.0% (0/556)
I) >300–350	256	0.0% (0/256)	0.0% (0/256)	0.0% (0/256)	0.0% (0/256)	0.0% (0/256)	0.0% (0/256)	0.0% (0/256)	18.0% (46/256)	56.6% (145/256)	24.6% (63/256)	0.8% (2/256)

Table B-18: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Arm.

SG ranges (mg/dL)	Number of paired SG-YSI	\<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
		Percent of matched pairs in each YSI glucose range for each SG range (mg/dL) — YSI Glucose Range (mg/dL)										
J) >350–400	60	0.0% (0/60)	0.0% (0/60)	0.0% (0/60)	0.0% (0/60)	0.0% (0/60)	0.0% (0/60)	0.0% (0/60)	3.3% (2/60)	16.7% (10/60)	66.7% (40/60)	13.3% (8/60)
K) >400	9	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	11.1% (1/9)	55.6% (5/9)	33.3% (3/9)

Table B-19: Concurrence of YSI values and SG readings using SG ranges on FST Day 1; Calibration every 12 hours, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)

SG ranges (mg/dL)	Number of paired SG-YSI	\<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
		YSI Glucose Range (mg/dL)										
A) <40	54	3.7% (2/54)	29.6% (16/54)	64.8% (35/54)	1.9% (1/54)	0.0% (0/54)	0.0% (0/54)	0.0% (0/54)	0.0% (0/54)	0.0% (0/54)	0.0% (0/54)	0.0% (0/54)
B) ≥40–60	168	1.8% (3/168)	22.0% (37/168)	64.3% (108/168)	11.9% (20/168)	0.0% (0/168)	0.0% (0/168)	0.0% (0/168)	0.0% (0/168)	0.0% (0/168)	0.0% (0/168)	0.0% (0/168)
C) >60–80	339	0.6% (2/339)	11.2% (38/339)	58.1% (197/339)	29.2% (99/339)	0.9% (3/339)	0.0% (0/339)	0.0% (0/339)	0.0% (0/339)	0.0% (0/339)	0.0% (0/339)	0.0% (0/339)
D) >80–120	895	0.0% (0/895)	0.3% (3/895)	6.6% (59/895)	69.8% (625/895)	21.6% (193/895)	1.7% (15/895)	0.0% (0/895)	0.0% (0/895)	0.0% (0/895)	0.0% (0/895)	0.0% (0/895)
E) >120–160	803	0.0% (0/803)	0.0% (0/803)	0.0% (0/803)	10.0% (80/803)	64.6% (519/803)	21.4% (172/803)	4.0% (32/803)	0.0% (0/803)	0.0% (0/803)	0.0% (0/803)	0.0% (0/803)
F) >160–200	549	0.0% (0/549)	0.0% (0/549)	0.0% (0/549)	0.2% (1/549)	8.9% (49/549)	61.4% (337/549)	28.1% (154/549)	1.5% (8/549)	0.0% (0/549)	0.0% (0/549)	0.0% (0/549)
G) >200–250	355	0.0% (0/355)	0.0% (0/355)	0.0% (0/355)	0.0% (0/355)	0.3% (1/355)	7.9% (28/355)	63.9% (227/355)	27.0% (96/355)	0.8% (3/355)	0.0% (0/355)	0.0% (0/355)
H) >250–300	175	0.0% (0/175)	0.0% (0/175)	0.0% (0/175)	0.0% (0/175)	0.0% (0/175)	0.0% (0/175)	10.9% (19/175)	65.7% (115/175)	21.1% (37/175)	2.3% (4/175)	0.0% (0/175)
I) >300–350	91	0.0% (0/91)	0.0% (0/91)	0.0% (0/91)	0.0% (0/91)	0.0% (0/91)	0.0% (0/91)	0.0% (0/91)	20.9% (19/91)	52.7% (48/91)	24.2% (22/91)	2.2% (2/91)
J) >350–400	15	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	13.3% (2/15)	33.3% (5/15)	53.3% (8/15)	0.0% (0/15)
K) >400	1	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 82 subjects.

Table B-20: Overall concurrence of YSI values and SG readings using SG ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)

SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	73	2.7% (2/73)	45.2% (33/73)	50.7% (37/73)	1.4% (1/73)	0.0% (0/73)	0.0% (0/73)	0.0% (0/73)	0.0% (0/73)	0.0% (0/73)	0.0% (0/73)	0.0% (0/73)
B) ≥40–60	503	1.0% (5/503)	45.9% (231/503)	48.3% (243/503)	4.8% (24/503)	0.0% (0/503)	0.0% (0/503)	0.0% (0/503)	0.0% (0/503)	0.0% (0/503)	0.0% (0/503)	0.0% (0/503)
C) >60–80	1291	0.2% (2/1291)	8.9% (115/1291)	72.3% (933/1291)	18.4% (237/1291)	0.3% (4/1291)	0.0% (0/1291)	0.0% (0/1291)	0.0% (0/1291)	0.0% (0/1291)	0.0% (0/1291)	0.0% (0/1291)
D) >80–120	2756	0.0% (0/2756)	0.1% (3/2756)	7.0% (194/2756)	75.9% (2092/2756)	16.5% (456/2756)	0.4% (11/2756)	0.0% (0/2756)	0.0% (0/2756)	0.0% (0/2756)	0.0% (0/2756)	0.0% (0/2756)
E) >120–160	2442	0.0% (0/2442)	0.0% (0/2442)	0.1% (2/2442)	9.3% (228/2442)	71.4% (1743/2442)	18.0% (439/2442)	1.2% (30/2442)	0.0% (0/2442)	0.0% (0/2442)	0.0% (0/2442)	0.0% (0/2442)
F) >160–200	1588	0.0% (0/1588)	0.0% (0/1588)	0.0% (0/1588)	0.1% (2/1588)	9.4% (150/1588)	66.3% (1053/1588)	23.5% (373/1588)	0.6% (9/1588)	0.1% (1/1588)	0.0% (0/1588)	0.0% (0/1588)
G) >200–250	1246	0.0% (0/1246)	0.0% (0/1246)	0.0% (0/1246)	0.0% (0/1246)	0.5% (6/1246)	7.4% (92/1246)	65.7% (818/1246)	25.1% (313/1246)	1.4% (17/1246)	0.0% (0/1246)	0.0% (0/1246)
H) >250–300	613	0.0% (0/613)	0.0% (0/613)	0.0% (0/613)	0.0% (0/613)	0.0% (0/613)	0.2% (1/613)	8.6% (53/613)	65.1% (399/613)	24.6% (151/613)	1.5% (9/613)	0.0% (0/613)
I) >300–350	271	0.0% (0/271)	0.0% (0/271)	0.0% (0/271)	0.0% (0/271)	0.0% (0/271)	0.0% (0/271)	0.0% (0/271)	16.2% (44/271)	59.8% (162/271)	23.2% (63/271)	0.7% (2/271)
J) >350–400	61	0.0% (0/61)	0.0% (0/61)	0.0% (0/61)	0.0% (0/61)	0.0% (0/61)	0.0% (0/61)	0.0% (0/61)	4.9% (3/61)	11.5% (7/61)	70.5% (43/61)	13.1% (8/61)
K) >400	8	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	62.5% (5/8)	37.5% (3/8)

Table B-21: Concurrence of YSI values and SG readings using SG ranges on FST) Day 1; Calibration 3 or 4 times a day, Arm.

Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)

SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
A) <40	54	3.7% (2/54)	29.6% (16/54)	64.8% (35/54)	1.9% (1/54)	0.0% (0/54)	0.0% (0/54)	0.0% (0/54)	0.0% (0/54)	0.0% (0/54)	0.0% (0/54)	0.0% (0/54)
B) ≥40–60	162	1.9% (3/162)	25.3% (41/162)	61.7% (100/162)	11.1% (18/162)	0.0% (0/162)	0.0% (0/162)	0.0% (0/162)	0.0% (0/162)	0.0% (0/162)	0.0% (0/162)	0.0% (0/162)
C) >60–80	346	0.6% (2/346)	11.6% (40/346)	61.3% (212/346)	25.7% (89/346)	0.9% (3/346)	0.0% (0/346)	0.0% (0/346)	0.0% (0/346)	0.0% (0/346)	0.0% (0/346)	0.0% (0/346)
D) >80–120	899	0.0% (0/899)	0.3% (3/899)	6.3% (57/899)	74.0% (665/899)	18.2% (164/899)	1.1% (10/899)	0.0% (0/899)	0.0% (0/899)	0.0% (0/899)	0.0% (0/899)	0.0% (0/899)
E) >120–160	878	0.0% (0/878)	0.0% (0/878)	0.0% (0/878)	10.0% (88/878)	67.0% (588/878)	21.0% (184/878)	2.1% (18/878)	0.0% (0/878)	0.0% (0/878)	0.0% (0/878)	0.0% (0/878)

Table B-21: Concurrence of YSI values and SG readings using SG ranges on FST) Day 1; Calibration 3 or 4 times a day, Arm.												
Percent of matched pairs in each YSI glucose range for each SG range (mg/dL)												
SG ranges (mg/dL)	Number of paired SG-YSI	YSI Glucose Range (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
F) >160–200	571	0.0% (0/571)	0.0% (0/571)	0.0% (0/571)	0.2% (1/571)	9.3% (53/571)	62.3% (356/571)	27.3% (156/571)	0.9% (5/571)	0.0% (0/571)	0.0% (0/571)	0.0% (0/571)
G) >200–250	427	0.0% (0/427)	0.0% (0/427)	0.0% (0/427)	0.0% (0/427)	0.2% (1/427)	8.2% (35/427)	62.5% (267/427)	27.6% (118/427)	1.4% (6/427)	0.0% (0/427)	0.0% (0/427)
H) >250–300	202	0.0% (0/202)	0.0% (0/202)	0.0% (0/202)	0.0% (0/202)	0.0% (0/202)	0.0% (0/202)	9.9% (20/202)	59.9% (121/202)	26.7% (54/202)	3.5% (7/202)	0.0% (0/202)
I) >300–350	93	0.0% (0/93)	0.0% (0/93)	0.0% (0/93)	0.0% (0/93)	0.0% (0/93)	0.0% (0/93)	0.0% (0/93)	16.1% (15/93)	59.1% (55/93)	22.6% (21/93)	2.2% (2/93)
J) >350–400	13	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	15.4% (2/13)	7.7% (1/13)	76.9% (10/13)	0.0% (0/13)
K) >400	-	-	-	-	-	-	-	-	-	-	-	-

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 83 subjects.

Note: For the blank cells (-), there are no paired points in this reference range.

Percent agreement post calibration

The agreement of the SG values to paired YSI values was assessed for every 2-hour period post sensor calibration. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Tables B-22 and B-23 show the percent agreement rates post calibration for sensors inserted into the abdomen. Performance when sensors are inserted in the arm is at least comparable to results when sensors are inserted in the abdomen.

Table B-22: Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Abdomen.						
Time after calibration	Number of paired SG-YSI	Percent Agreement (%)				
		Percent of SG within 15/15% of YSI	Percent of SG within 20/20% of YSI	Percent of SG within 30/30% of YSI	Percent of SG within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
0–2 hours	2999	85	92.6	97.8	99.6	0.4
2–4 hours	2667	75.1	85.9	95.3	98.8	1.2
4–6 hours	2138	71.4	82	92.7	97.6	2.4
6–8 hours	1521	77.6	88.4	97	99.3	0.7
8–10 hours	1523	84.2	91.1	97.6	99.3	0.7
10–12 hours	1242	79.8	89.5	96.3	98.6	1.4

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG Readings are within 40–400 mg/dL.

Table B-23: Agreement rates for every 2-hour period post calibration; Calibration 3 or 4 times a day, Abdomen.						
Time after calibration	Number of paired SG-YSI	Percent Agreement (%)				
		Percent of SG within 15/15% of YSI	Percent of SG within 20/20% of YSI	Percent of SG within 30/30% of YSI	Percent of SG within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
0–2 hours	4585	87	93.5	98.1	99.7	0.3
2–4 hours	3949	80.7	89.9	96.7	99	1
4–6 hours	2856	78.7	87.6	95.5	98.5	1.5
6–8 hours	227	74.9	86.3	96.9	99.6	0.4
8–10 hours	35	82.9	85.7	91.4	94.3	5.7
10–12 hours	12	91.7	91.7	91.7	100	0

* For reference range ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG Readings are within 40–400 mg/dL.

Trend accuracy

Tables B-24 through B-25 show, for each SG rate-of-change range (indicated on display by number of arrows), percentage of SG-YSI paired values that fell into different YSI rate-of-change ranges. The tables show the trend accuracy for sensors inserted into the abdomen. Performance when sensors are inserted in the arm is at least comparable to results when sensors are inserted into the abdomen.

Table B-24: Trend accuracy; Calibration every 12 hours, Abdomen.							
Percent of Matched Pairs-in Each YSI Rate-of-Change Range for Each SG Rate-of-Change Range							
SG Rate-of-Change Range (mg/dL/min)	Number of Paired SG-YSI	YSI Rate-of-Change Ranges (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
A) <-2	162	38.3% (62/162)	40.1% (65/162)	20.4% (33/162)	0.6% (1/162)	0.6% (1/162)	0.0% (0/162)
B) [-2, -1]	1001	4.8% (48/1001)	39.9% (399/1001)	51.3% (514/1001)	3.7% (37/1001)	0.3% (3/1001)	0.0% (0/1001)
C) [-1, 0]	5960	0.5% (30/5960)	3.8% (228/5960)	77.6% (4627/5960)	17.1% (1020/5960)	0.8% (49/5960)	0.1% (6/5960)
D) [0, 1]	3517	0.2% (7/3517)	0.5% (18/3517)	25.7% (903/3517)	63.4% (2231/3517)	9.3% (326/3517)	0.9% (32/3517)
E) [1, 2]	1059	0.1% (1/1059)	0.4% (4/1059)	4.5% (48/1059)	37.9% (401/1059)	48.6% (515/1059)	8.5% (90/1059)
F) >2	391	0.0% (0/391)	0.0% (0/391)	2.8% (11/391)	7.4% (29/391)	40.9% (160/391)	48.8% (191/391)

Table B-25: Trend accuracy; Calibration 3 or 4 times a day, Abdomen.							
Percent of Matched Pairs-in Each YSI Rate-of-Change Range for Each SG Rate-of-Change Range							
SG Rate-of-Change Range (mg/dL/min)	Number of Paired SG-YSI	YSI Rate-of-Change Ranges (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
A) <-2	159	39.0% (62/159)	39.6% (63/159)	19.5% (31/159)	0.6% (1/159)	1.3% (2/159)	0.0% (0/159)
B) [-2, -1]	967	5.1% (49/967)	38.7% (374/967)	51.9% (502/967)	4.0% (39/967)	0.3% (3/967)	0.0% (0/967)

Table B-25: Trend accuracy; Calibration 3 or 4 times a day, Abdomen.							
Percent of Matched Pairs-in Each YSI Rate-of-Change Range for Each SG Rate-of-Change Range							
SG Rate-of-Change Range (mg/dL/min)	Number of Paired SG-YSI	YSI Rate-of-Change Ranges (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
C) [-1, 0]	5753	0.5% (28/5753)	4.0% (228/5753)	77.5% (4456/5753)	17.2% (990/5753)	0.8% (46/5753)	0.1% (5/5753)
D) [0, 1]	3387	0.2% (8/3387)	0.5% (18/3387)	26.5% (898/3387)	62.5% (2118/3387)	9.3% (316/3387)	0.9% (29/3387)
E) [1, 2]	1024	0.0% (0/1024)	0.2% (2/1024)	5.0% (51/1024)	38.8% (397/1024)	47.5% (486/1024)	8.6% (88/1024)
F) >2	374	0.0% (0/374)	0.0% (0/374)	2.4% (9/374)	8.0% (30/374)	42.8% (160/374)	46.8% (175/374)

Precision

Precision of the system was evaluated by comparing the results from two separate sensors worn in the abdomen on the same subject at the same time. A total of 83 subjects provided 30,350 paired SG-YSI measurements, with a mean Percent Absolute Relative Difference (PARD) of 9.07% with a coefficient of variation (%CV) of 6.5%.

Though precision in the arm has not been specifically assessed, arm vs. arm and arm vs. abdomen is likely comparable to the abdomen precision based on internal evaluation by Medtronic.

Sensor life

After the first successful calibration, 72.3% of sensors worn operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the abdomen insertion site over the course of the study was 144.2 hours, with a median functional life of 167.6 hours.

The mean functional sensor life for sensors worn in the arm insertion site over the course of the study was 146.1 hours, with a median functional life of 167.9 hours.

Safety

There were no moderate or severe device-related or procedure-related adverse events, device-related or procedure-related serious adverse events, or unanticipated adverse device effects through seven days of use.

C. Alert performance for users 14 years and older

The CGM system enables your device to display SG readings, glucose trend arrows, glucose trend graphs, and SG alerts (for example, High and Low Limit Threshold alerts, High and Low Predictive alerts, and Rise and Fall rate-of-change alerts).

The high and low limit alerts (Threshold alerts) let the user know when the SG is at or above the high limit or at or below the low limit. Using only a high or low limit alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit.

Predictive alerts notify users that their SG level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their SG level reaches a high limit setting. The earliest warning is 30 minutes before reaching a high limit setting, but users can reduce the amount of warning down to 5 minutes. Users will receive a warning approximately 30 minutes prior to when their SG level is predicted to reach their low limit setting. In general, the earlier the warning, the more time a user will have to react to a potential high or low limit setting, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future SG level compared to the high or low limit setting. If the predicted SG value is above the high limit or below the low limit, then a predictive alert is sounded even though the current SG level has not crossed the high or low limit. The predicted SG level is calculated using the current SG level, the derivative of previous SG readings (the trend or slope of the SG readings) and the amount of early warning duration the user selects.

The device will always alert the user when the CGM system reads that the user is below 50 mg/dL, regardless of the high threshold, low threshold, or predictive alerts that the user sets.

Glucose TRUE Alert Rate

The glucose true alert rate is the rate at which the BG confirmed that the CGM alert was triggered correctly. For example:

True Threshold Hypoglycemic alert rate alerted when the CGM system read that the user was below the low threshold and the user's BG was actually below that low threshold.

True Threshold Hyperglycemic alert rate alerted when the CGM system read that the user was above the high threshold and the user's BG was actually above that high threshold.

True Predictive Hypoglycemic alert rate alerted when the CGM system predicted that the user would reach below the low threshold and the user's BG was actually below that low threshold within 15 or 30 minutes.

True Predictive Hyperglycemic alert rate alerted when the CGM system predicted that the user would reach above the high threshold and the user's BG was actually above that high threshold within 15 or 30 minutes.

The true alert rate is important because it is necessary that users be notified when their BG is low (or high) so that they can correct the low (or high) BG. A high true alert rate indicates that when the CGM system says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold.

For example, per the following table, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only) or both (predictive and threshold) 66.9%, 52.7%, or 58.3% of the time within 30 minutes (or 66.9%, 47.7%, or 55.2% of the time within 15 minutes) when the user had BG values lower than 70 mg/dL for a sensor inserted in the abdomen.

mg/dL	Insertion Site	Glucose TRUE Alert Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	25.0%	25.0%	15.2%	12.3%	18.2%	16.2%
	Arm	36.8%	36.8%	21.9%	16.7%	26.1%	22.4%
60	Abdomen	53.5%	51.9%	40.7%	37.1%	46.2%	43.4%
	Arm	69.0%	67.8%	47.5%	45.6%	55.1%	53.5%
70	Abdomen	66.9%	66.9%	52.7%	47.7%	58.3%	55.2%
	Arm	77.4%	75.3%	57.4%	54.5%	65.6%	63.0%
80	Abdomen	69.3%	69.3%	57.8%	51.1%	62.2%	58.2%
	Arm	77.5%	76.4%	59.9%	53.0%	66.5%	61.9%
90	Abdomen	75.1%	74.4%	64.0%	58.5%	67.9%	64.3%
	Arm	74.9%	74.9%	69.0%	63.2%	71.3%	68.0%
180	Abdomen	93.7%	92.8%	70.5%	66.9%	78.0%	75.4%
	Arm	92.9%	92.9%	68.0%	63.2%	76.5%	73.7%

Table C-1: Glucose TRUE Alert Performance using Calibration every 12 hours

Table C-1: Glucose TRUE Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose TRUE Alert Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
220	Abdomen	91.9%	91.9%	68.9%	66.3%	76.6%	74.8%
	Arm	92.2%	92.2%	65.7%	62.2%	74.5%	72.2%
250	Abdomen	90.2%	90.2%	64.0%	60.1%	72.5%	69.8%
	Arm	91.4%	91.4%	62.0%	59.8%	71.1%	69.6%
300	Abdomen	81.3%	81.3%	57.8%	54.0%	65.4%	62.7%
	Arm	81.9%	80.6%	51.7%	49.7%	61.2%	59.3%

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the BG did not confirm that the CGM alert was triggered correctly. For example:

False Threshold Hypoglycemic alert rate alerted when the CGM system read that the user was below the low threshold but the user's BG was actually above that low threshold.

False Threshold Hyperglycemic alert rate alerted when the CGM system read that the user was above the high threshold but the user's BG was actually below that high threshold.

False Predictive Hypoglycemic alert rate alerted when the CGM system predicted that the user would be below the low threshold but the user's BG was actually above that low threshold within 15 or 30 minutes.

False Predictive Hyperglycemic alert rate alerted when the CGM system predicted that the user would be above the high threshold but the user's BG was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their BG is low (or high) so that they can correct the low (or high) BG. A low false alert rate indicates that when the CGM system says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold.

For example, per the following table, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e. predictive only), or both (threshold and predictive)

6.30%, 29.5%, or 22% of the time within 30 minutes (or 7.2%, 33.1%, or 24.6% of the time within 15 minutes) when the user had BG less than 180 mg/dL for a sensor inserted in the abdomen.

Table C-2: Glucose FALSE Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose FALSE Alert Rate					
		Threshold Only		Predictive Only		Threshold and Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	75.0%	75.0%	84.8%	87.7%	81.8%	83.8%
	Arm	63.2%	63.2%	78.1%	83.3%	73.9%	77.6%
60	Abdomen	46.5%	48.1%	59.3%	62.9%	53.8%	56.6%
	Arm	31.0%	32.2%	52.5%	54.4%	44.9%	46.5%
70	Abdomen	33.1%	33.1%	47.3%	52.3%	41.7%	44.8%
	Arm	22.6%	24.7%	42.6%	45.5%	34.4%	37.0%
80	Abdomen	30.7%	30.7%	42.2%	48.9%	37.8%	41.8%
	Arm	22.5%	23.6%	40.1%	47.0%	33.5%	38.1%
90	Abdomen	24.9%	25.6%	36.0%	41.5%	32.1%	35.7%
	Arm	25.1%	25.1%	31.0%	36.8%	28.7%	32.0%
180	Abdomen	6.30%	7.20%	29.5%	33.1%	22.0%	24.6%
	Arm	7.10%	7.10%	32.0%	36.8%	23.5%	26.3%
220	Abdomen	8.10%	8.10%	31.1%	33.7%	23.4%	25.2%
	Arm	7.80%	7.80%	34.3%	37.8%	25.5%	27.8%
250	Abdomen	9.80%	9.80%	36.0%	39.9%	27.5%	30.2%
	Arm	8.60%	8.60%	38.0%	40.2%	28.9%	30.4%
300	Abdomen	18.8%	18.8%	42.2%	46.0%	34.6%	37.3%
	Arm	18.1%	19.4%	48.3%	50.3%	38.8%	40.7%

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the BG was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert.

Glucose detection rates are important because it is necessary that users be notified when their BG is low (or high) so that they can correct the low (or high) BG. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their BG is low or high.

For example, per the following table, the threshold alert, the predictive alert, or both (threshold and predictive) notified the user 64%, 76%, or 76% of the time within 30 minutes (or 64%, 68%, or 68% within 15 minutes) when the user had BG less than 50 mg/dL for a sensor inserted in the abdomen.

Table C-3: Glucose Correct Detection Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose Correct Detection Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	64.0%	64.0%	76.0%	68.0%	76.0%	68.0%
	Arm	66.7%	66.7%	95.2%	71.4%	95.2%	76.2%
60	Abdomen	83.3%	82.1%	94.0%	88.1%	94.0%	89.3%
	Arm	86.3%	83.6%	98.6%	94.5%	98.6%	97.3%
70	Abdomen	90.5%	90.5%	94.2%	89.8%	94.2%	92.0%
	Arm	90.2%	88.6%	92.7%	90.2%	93.5%	91.9%
80	Abdomen	87.2%	87.2%	93.6%	87.2%	93.6%	89.9%
	Arm	89.0%	88.4%	94.8%	86.6%	95.9%	92.4%
90	Abdomen	91.1%	88.7%	94.6%	89.5%	95.7%	92.2%
	Arm	91.7%	90.4%	96.9%	91.7%	97.8%	95.6%
180	Abdomen	93.1%	91.4%	96.6%	93.4%	96.9%	95.4%
	Arm	93.2%	92.2%	98.1%	94.2%	98.7%	96.4%
220	Abdomen	90.1%	89.2%	94.8%	93.5%	95.3%	94.4%
	Arm	90.1%	89.2%	96.1%	93.6%	96.1%	95.6%
250	Abdomen	81.5%	80.9%	96.5%	91.3%	96.5%	93.6%
	Arm	80.9%	79.6%	96.7%	90.8%	96.7%	91.4%
300	Abdomen	75.3%	75.3%	95.3%	92.9%	95.3%	94.1%
	Arm	74.4%	71.8%	93.6%	89.7%	93.6%	89.7%

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the BG was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their BG is low (or high), so that they can correct the low (or high) BG. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their BG is low or high.

For example, per the following table, the threshold alert, predictive alert, or both alerts (threshold and predictive) did not sound 36%, 24%, or 24% of the time within 30 minutes (or 36%, 32%, or 32% within 15 minutes) when the user had BG less than 50 mg/dL for a sensor inserted in the abdomen.

mg/dL	Insertion Site	Glucose Missed Detection Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	36.0%	36.0%	24.0%	32.0%	24.0%	32.0%
	Arm	33.3%	33.3%	4.8%	28.6%	4.8%	23.8%
60	Abdomen	16.7%	17.9%	6.0%	11.9%	6.0%	10.7%
	Arm	13.7%	16.4%	1.4%	5.5%	1.4%	2.7%
70	Abdomen	9.5%	9.5%	5.8%	10.2%	5.8%	8.0%
	Arm	9.8%	11.4%	7.3%	9.8%	6.5%	8.1%
80	Abdomen	12.8%	12.8%	6.4%	12.8%	6.4%	10.1%
	Arm	11.0%	11.6%	5.2%	13.4%	4.1%	7.6%
90	Abdomen	8.9%	11.3%	5.4%	10.5%	4.3%	7.8%
	Arm	8.3%	9.6%	3.1%	8.3%	2.2%	4.4%
180	Abdomen	6.9%	8.6%	3.4%	6.6%	3.1%	4.6%
	Arm	6.8%	7.8%	1.9%	5.8%	1.3%	3.6%
220	Abdomen	9.9%	10.8%	5.2%	6.5%	4.7%	5.6%
	Arm	9.9%	10.8%	3.9%	6.4%	3.9%	4.4%
250	Abdomen	18.5%	19.1%	3.5%	8.7%	3.5%	6.4%
	Arm	19.1%	20.4%	3.3%	9.2%	3.3%	8.6%
300	Abdomen	24.7%	24.7%	4.7%	7.1%	4.7%	5.9%
	Arm	25.6%	28.2%	6.4%	10.3%	6.4%	10.3%

Table C-4: Glucose Missed Detection Alert Performance using Calibration every 12 hours

II. Performance data for users ages 7 through 13

D. Device Performance data for users ages 7 through 13

The clinical data presented in this section was obtained from studies (users ages 7 through 13) using the MiniMed 670G system. The MiniMed 770G system uses the same SmartGuard Auto Mode technology as the MiniMed 670G system. Therefore, this clinical data also applies to the MiniMed 770G system.

⚠️ **CAUTION:** Since the study presented below did not include a control group, no claims regarding effectiveness can be made. However, it does support that the device is relatively safe for use.

The SmartGuard technology has two levels that include 1) the Suspend on low and Suspend before low features that automatically suspends insulin delivery based on the CGM system and 2) Auto Mode that automatically calculates insulin dosing using the CGM system. A study was performed to evaluate for safety in a

multi-center, single-arm, home and hotel clinical investigation.[7, 8] Study subjects included persons aged 7 to 13 years of age diagnosed with type 1 diabetes mellitus and who were on pump therapy for more than 6 months prior to screening. All study subjects had an HbA1C less than 10.0% at the time of screening.

The first level of SmartGuard technology included evaluation of the "Suspend before low" feature. A total of 105 subjects were asked to exercise in an in-clinic setting, in order to lower blood sugars sufficiently to trigger Suspend before low. Activation was followed by an observation period to ensure subject safety. The target for Suspend before low was set to 65 mg/dL. Subjects underwent FST for a maximum of 12 hours, which included the exercise period, insulin suspension, and approximately 4 hours after resumption of insulin delivery (which may also have included insulin resuspension).

Data from this in-clinic study demonstrated that the Suspend before low feature is safe to use. Study success criteria, as defined in the protocol, were met (i.e. there were no device related serious adverse events, no diabetic ketoacidosis events related to the Suspend before low feature, and no unanticipated adverse device effects).

The second level of SmartGuard technology was the evaluation of Auto Mode, which was accomplished during the 3-month study phase. A total of 105 subjects first used the MiniMed 670G System in Manual Mode (approximately 2 weeks during the run-in phase and 1 additional week at the start of the study phase), before transitioning to Auto Mode at specific points in time during the study phase. The timing of the transition to Auto Mode was based on the scheduling of a 6-day and 5-night hotel or house stay during the study phase. At the hotel or house, subjects underwent daytime and nighttime FST for a total of approximately 24 hours. Subjects were allowed to eat as they normally would, and participated in a daily exercise or activity regimen for a minimum of 4 hours per day, spread throughout the day. All subjects participated in a hotel or house stay and finished the study. During this study, the MiniMed 770G System was used for over 15,353 patient days (including the 2-week run-in phase and the 3-month study phase)

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7   Forlenza G, Shulman D, Wood M, et al. Evaluation of the MiniMed 670G system predictive low glucose management feature in children. Diabetes Technology and Therapeutics. 2018;20:A19-A20.

8   Forlenza GP, Pinhas-Hamiel O, Liljenquist DR, et al. Safety Evaluation of the MiniMed 670G System in Children 7-13 Years of Age with Type 1 Diabetes. Diabetes Technol Ther. 2019;21(1):11-19.

without any reported device-related serious adverse events, such as severe hypoglycemia or diabetic ketoacidosis. Compared to Manual Mode used during the run-in phase, use of Auto Mode was associated with reduction in mean SG values, an increase within the range of 71 to 180 mg/dL, and a lower percentage of glucose values in the hyperglycemic and hypoglycemic ranges. There was a significant reduction in mean HbA1c from 7.9±0.8 (median 7.9) at the start of study to 7.5±0.6 (median 7.5) at the end of study. There was a small change in mean total daily dose of insulin/kg (0.8±0.2 baseline to 0.9±0.2 end of study) and modest increase in weight. Weight gain would also be expected for pediatric patients 7 to 13 years of age as part of the normal growth process.

Of the 203 adverse events reported through the end of the study period, 39% (N=80) were classified as device related. Of the 80 device-related adverse events, 65 were glycemic events (hyperglycemia, severe hyperglycemia, and severe hyperglycemia with ketosis) and 14 were related to skin issues (cellulitis, skin infection at the infusion set site, infection at the sensor insertion site, pump site infection on lower abdomen, eczema, and skin irritation). Five adverse events were classified as procedure related (these included neurocardiogenic syncope, headache, and angioedema) and two of the adverse events (hyperglycemia and skin irritation) were classified as both device and procedure related.

There were 104 reports of severe hyperglycemia and there was no diabetic ketoacidosis while on the MiniMed 670G System during the study. The majority of these severe hyperglycemic events (77/104) were mild in intensity. Ketone levels were available for 102 of the 104 severe hyperglycemia episodes and the majority of ketone levels (83/104) were low (10.8–27 mg/dL).

One severe hyperglycemic event was associated with an emergency room visit, however, the ER visit was primarily due to concurrent acute gastroenteritis.

Of the 62 device related episodes of severe hyperglycemia, 51 were believed to be due to infusion set issues such as occlusion, bent cannula or cannula pull out. These issues are typically seen in relatively high rates in the pediatric population (causes provided in Table D-1 and Table D-2). Unlike insulin pump therapy which may or may not have alerts associated with infusion set failure, the MiniMed 670G System has fixed alarms (high alerts) that serve as an additional mitigation for subjects.

Table D-1: Run-In Period Severe Hyperglycemia:	
Cause	**Total**
Infusion set change	9
Occlusion Alarm	3
Infusion set fell out	2
Bent or Kinked Cannula	1
Total	15

Table D-2: Study Period Severe Hyperglycemia:	
Cause	**Total**
Infusion set change	28
Occlusion Alarm	12
Infusion set fell out	7
Bent or Kinked Cannula	5
Infusion set change or safe basal	3
Safe basal	2
Suspend before low suspension	1
Automatic & manual suspensions	1
Unclipped infusion set	1
Internal Battery Connector Resistance	1
Manual suspension and safe basal	1
Total	62

The following table shows the time spent per day in specific glucose ranges during the run-in and study phases by all subjects.

Table D-3: Time Spent in Specific Glucose Ranges During the Run-In and Study Phases by All Subjects		
Glucose Range (mg/dL)	**Run-In Phase**	**Study Phase**
	Time in Glucose Range (min) Mean±SD	**Time in Glucose Range (min) Mean±SD**
≤50	12.2±16.9	7.8±7.3
≤60	32.3±32.7	20.3±14.2
≤70	68.3±55.4	43.1±23.6
70–180	808.6±163.5	936.2±110.4
>180	563.1±184.3	460.7±110.5
>250	191.0±111.5	148.4±74.1
>300	68.1±54.8	53.7±39.4
>350	23.0±24.9	17.4±17.1

The following table shows the ranges of changes in HbA1C observed in the study and indicates the number of subjects that demonstrated each type of change in HbA1C observed.

Table D-4: Number of Subjects with Change in HbA1C at Different Baselines					
HbA1C Change Range	Number of Subjects (% of Subjects) with Change in A1C				
Baseline A1C (%)	Decrease >1%	Decrease 0 to 1%	No Change	Increase 0 to 1%	Increase >1%
5% ≤ A1C < 6%	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)
6% ≤ A1C < 7%	0 (0.0%)	1 (1.0%)	0 (0.0%)	9 (8.6%)	0 (0.0%)
7% ≤ A1C < 8%	3 (2.9%)	22 (21.0%)	6 (5.7%)	16 (15.2%)	0 (0.0%)
8% ≤ A1C < 9%	9 (8.6%)	21 (20.0%)	3 (2.9%)	4 (3.8%)	0 (0.0%)
9% ≤ A1C < 10%	4 (3.8%)	6 (5.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	16 (15.2%)	50 (47.6%)	9 (8.6%)	30 (28.6%)	0 (0.0%)

The following table shows the number of subjects that spent a specific range of time in specific glucose ranges during the study phase.

Table D-5: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase						
Time Range	Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated					
	≤50 mg/dL	≤60 mg/dL	≤70 mg/dL	70 to 180 mg/dL	>180 mg/dL	>250 mg/dL
0 to 15 mins	93 (88.6%)	41 (39.0%)	13 (12.4%)	0 (0.0%)	0 (0.0%)	1 (1.0%)
15 to 30 mins	10 (9.5%)	46 (43.8%)	23 (21.9%)	0 (0.0%)	0 (0.0%)	1 (1.0%)
30 to 45 mins	2 (1.9%)	12 (11.4%)	24 (22.9%)	0 (0.0%)	0 (0.0%)	4 (3.8%)
45 mins to 1 hr	0 (0.0%)	3 (2.9%)	23 (21.9%)	0 (0.0%)	0 (0.0%)	2 (1.9%)
1-4 hr	0 (0.0%)	3 (2.9%)	22 (21.0%)	0 (0.0%)	2 (1.9%)	83 (79.0%)
4-8 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	54 (51.4%)	14 (13.3%)
8-12 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (4.8%)	49 (46.7%)	0 (0.0%)
12-16 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	54 (51.4%)	0 (0.0%)	0 (0.0%)
16-20 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	45 (42.9%)	0 (0.0%)	0 (0.0%)
20-24 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)

The following table shows the average amount of time spent in Auto Mode per day.

Table D-6: Time Spent in Auto Mode at Different Glucose Ranges during the Study Phase	
Glucose Range (mg/dL)	Study Phase Time in Glucose Range (min) Mean±SD
≤50	5.0±4.0
≤60	14.0±9.0
≤70	31.2±16.8
70–180	797.0±142.2
>180	321.9±59.2
>250	84.2±32.4
All	1150.1±132.9

The pediatric pivotal clinical trial of the MiniMed 670G System suggested that the system was safe; however, this trial had a number of limitations which included the following:

- The study involved a relatively small number of patients.

- There was no control group for comparison purposes.

- The amount of time the system was used in the Manual mode was much shorter than the time it was programmed to the Auto Mode.

- Additionally, for each subject, the study period lasted only three months.

Due to these limitations, the results of the clinical trial must be interpreted with caution and you should understand that your individual results when using the MiniMed 670G System may be significantly different from those of the subjects who participated in the trial.

E. Guardian Sensor (3) Performance in users ages 7 to 13

CGM performance

The use of the Guardian Sensor (3) with the Guardian Link (3) transmitter enables CGM technology. The transmitter transmits SG values calculated by the real-time algorithm to a primary display device, allowing you to monitor your SG values.

Clinical study description

The performance of the Guardian Sensor (3) was evaluated in a clinical study.[9] This in-patient (in-clinic) and outpatient (at home) study included subjects 7 to 13 years in age. The study design was a multi-center, prospective single sample correlational design without controls.

All subjects were assigned to treatment. Each subject was instructed to wear two Guardian Sensor (3) sensors in the abdomen or buttock.

- One Guardian Sensor (3) connected to the Guardian Connect Transmitter, which transmitted to the Guardian Connect app, a standalone CGM display device.

- One Guardian Sensor (3) connected to the Guardian Link (3) transmitter, which served as a glucose sensor recorder (GSR, transmitter and recorder for sensor-integrated pump systems).

9   Medtronic Inc., A Performance Evaluation of the Enlite™ and Enlite™ 3 Glucose Sensor to Support Use in Children; CEP249 Data From Subjects 7-13 Years of Age 10703807DOC. November 2017.

The SG data collected by the blinded GSRs were retrospectively processed through the real-time CGM algorithm. This is the same algorithm used in the Guardian Connect and pump CGM systems. Thus all data is representative of real-time sensor usage.

The CONTOUR NEXT LINK 2.4 Wireless Meter was the study meter used for all calibrations in this study, and was the only meter evaluated with the Guardian Sensor (3) CGM systems. The sensor has not been tested with other meters. Therefore, the performance with other BG meters may differ from the performance with the CONTOUR NEXT LINK 2.4 Wireless Meter described below.

FST was performed on day 1, 3, or 7 for 6 hours each, over the life of the sensor. Reference blood (plasma) glucose values were obtained with a YSI Glucose Analyzer every 5 to 15 minutes. During the FSTs, the subjects were instructed to calibrate the sensors once every 12 hours, or as requested by the display device. During home use (outside the clinic), subjects were instructed to calibrate both sensors three to four times spread throughout the day. During the FST procedures, glucose challenges were limited to 30 minutes of exercise. Therefore, there were a limited number of glucose values in the high and low glucose ranges.

The overall number of subjects that participated in FST procedures on day 1, 3, or 7 were 21, 13, and 10 respectively.

During the study, the meter was used for confirmation of alarms, treatment decisions, and sensor calibrations.

Results

Sensor accuracy

The following information highlights the Guardian Sensor (3) performance from 50 subjects (7 to 13 years old) wearing the Guardian Link (3) Transmitter that served as a glucose sensor recorder (GSR, transmitter and recorder for sensor-integrated pump systems) and the Guardian Connect Transmitter, which transmitted to the Guardian Connect app (a standalone CGM display device) during FST.

Mean absolute relative difference, by number of daily calibrations

Table E-1 shows the sensor accuracy measured by the MARD. MARD represents the average relative difference (regardless if positive or negative) between the SG values and the paired BG values measured by YSI.

Table E-1: SG MARD Versus YSI (within YSI glucose ranges)								
YSI Glucose Ranges (mg/dL)	Abdomen Insertion Site				Buttock Insertion Site			
	Calibration every 12 hours		Calibration 3 or 4 times a day		Calibration every 12 hours		Calibration 3 or 4 times a day	
	Number of Paired SG-YSI	MARD (%)	Number of Paired SG-YSI	MARD (%)	Number of Paired SG-YSI	MARD (%)	Number of Paired SG-YSI	MARD (%)
Overall	733	10.46	710	9.84	710	9.14	686	8.79
40-60*	4	19.16	2	31.9	7	5.43	7	3.61
61-80*	20	10.59	18	8.54	34	10.85	28	7.86
81-180	378	11.59	367	11.04	393	9.63	374	8.99
181-300	290	8.76	282	8.4	255	7.92	253	8.56
301-350	32	7.11	32	5.63	15	4.64	18	7.67
351-400	9	8.59	9	5.57	6	5.05	6	3.01

* For YSI reference range ≤80 mg/dL, the differences in mg/dL are included instead of percent difference (%).

Note: SG Readings are within 40-400 mg/dL.

Percent agreement, by number of daily calibrations

In Tables E-2 through E-9, the agreement of the SG values to paired YSI values was assessed by calculating the percentage of YSI values that were within 15%, 20%, 30%, 40%, and greater than 40% of the paired SG values. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Results are shown for defined SG ranges when calibrating every 12 hours and calibrating three or four times a day for sensors.

Table E-2: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen						
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	733	78.9	87.7	95.9	98.9	1.1
≥40-60*	4	50	50	75	100	0
>60-80*	20	70	80	90	95	5
>80-180	378	74.1	83.1	92.9	98.1	1.9
>180-300	290	83.1	93.1	100	100	0
>300-350	32	100	100	100	100	0
>350-400	9	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG readings are within 40-400 mg/dL.

Table E-3: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Day 1; Calibration every 12 hours, Abdomen

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	403	81.9	90.6	96.5	99	1
≥40-60*	2	100	100	100	100	0
>60-80*	11	63.6	72.7	90.9	100	0
>80-180	196	75.5	84.2	93.4	98	2
>180-300	160	86.9	97.5	100	100	0
>300-350	27	100	100	100	100	0
>350-400	7	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 16 subjects. SG readings are within 40-400 mg/dL.

Table E-4: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	710	81.7	90	97.2	99.4	0.6
≥40-60*	2	0	0	50	100	0
>60-80*	18	83.3	88.9	94.4	94.4	5.6
>80-180	367	74.9	84.5	95.1	99.2	0.8
>180-300	282	88.3	96.5	100	100	0
>300-350	32	100	100	100	100	0
>350-400	9	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG readings are within 40-400 mg/dL.

Table E-5: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	372	83.9	92.2	97.3	99.5	0.5
>60-80*	9	77.8	88.9	100	100	0
>80-180	182	76.9	86.3	94.5	98.9	1.1
>180-300	147	89.1	98	100	100	0
>300-350	27	100	100	100	100	0
>350-400	7	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 15 subjects. SG readings are within 40-400 mg/dL.

Table E-6: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Buttock						
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	710	84.8	92.3	96.8	98.6	1.4
≥40-60*	7	100	100	100	100	0
>60-80*	34	70.6	79.4	94.1	100	0
>80-180	393	80.9	89.8	94.9	97.5	2.5
>180-300	255	91	96.9	99.6	100	0
>300-350	15	100	100	100	100	0
>350-400	6	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG readings are within 40-400 mg/dL.

Table E-7: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Day 1; Calibration every 12 hours, Buttock						
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	335	78.8	87.2	93.7	97	3
>60-80*	19	52.6	63.2	89.5	100	0
>80-180	178	71.9	82.6	89.9	94.4	5.6
>180-300	133	91	96.2	99.2	100	0
>300-350	3	100	100	100	100	0
>350-400	2	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 14 subjects. SG readings are within 40-400 mg/dL.

Table E-8: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock						
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	686	84.7	92.7	97.1	99.1	0.9
≥40-60*	7	100	100	100	100	0
>60-80*	28	85.7	89.3	100	100	0
>80-180	374	82.4	90.4	95.7	98.4	1.6
>180-300	253	87.4	96	98.4	100	0
>300-350	18	83.3	94.4	100	100	0
>350-400	6	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: SG readings are within 40-400 mg/dL.

Table E-9: Agreement (%) of SG-YSI paired points within YSI glucose ranges on FST Day 1; Calibration 3 or 4 times a day, Buttock						
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	Percent of SG Within 15/15% of YSI	Percent of SG Within 20/20% of YSI	Percent of SG Within 30/30% of YSI	Percent of SG Within 40/40% of YSI	Percent of SG greater than 40/40% of YSI
Overall	311	80.7	90.4	95.5	98.7	1.3
>60-80*	13	69.2	76.9	100	100	0
>80-180	159	77.4	86.8	92.5	97.5	2.5
>180-300	131	87	96.2	98.5	100	0
>300-350	6	50	83.3	100	100	0
>350-400	2	100	100	100	100	0

* For glucose ranges ≤80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 13 subjects. SG readings are within 40-400 mg/dL.

Agreement when CGM reads "Below 40 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 40 mg/dL and 400 mg/dL. It displays "Below 40 mg/dL" when the SG value detected is below 40 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. Tables E-10 through E-13 illustrate the number and percentage of the paired YSI values in different BG levels when the CGM system displays "Below 40 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table E-10: The number and percentage of YSI values collected when CGM displays "Below 40 mg/dL" (LOW); Calibration every 12 hours								
CGM Display	Insertion Site	CGM-YSI pairs	YSI (mg/dL)					
			<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	2	2	2	2	0	2
		Cumulative %	100%	100%	100%	100%	0%	
	Buttocks	Cumulative, n	3	4	7	7	1	8
		Cumulative %	38%	50%	88%	88%	13%	

Table E-11: The number and percentage of YSI values collected when CGM displays "Below 40 mg/dL" (LOW); Calibration 3 or 4 times a day								
CGM Display	Insertion Site	CGM-YSI pairs	YSI (mg/dL)					
			<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	
	Buttocks	Cumulative, n	3	4	6	6	1	7
		Cumulative %	43%	57%	86%	86%	14%	

Table E-12: The number and percentage of YSI values collected when CGM displays "Above 400 mg/dL" (HIGH); Calibration every 12 hours								
CGM Display	Insertion Site	CGM-YSI pairs	YSI (mg/dL)					
			>340	>320	>280	>240	<240	Total
HIGH	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	

Table E-13: The number and percentage of YSI values collected when CGM displays "Above 400 mg/dL" (HIGH); Calibration 3 or 4 times a day.								
CGM Display	Insertion Site	CGM-YSI pairs	YSI (mg/dL)					
			>340	>320	>280	>240	<240	Total
HIGH	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	

Concurrence of SG and YSI values

The following tables show the percentage of concurring SG readings with FST reference values.

Table E-14: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen											
Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)									
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	6	33.3% (2/6)	33.3% (2/6)	0.0% (0/6)	33.3% (2/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)
C) >60-80	20	0.0% (0/20)	10.0% (2/20)	55.0% (11/20)	35.0% (7/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)	0.0% (0/20)
D) >80-120	124	0.0% (0/124)	4.8% (6/124)	13.7% (17/124)	66.1% (82/124)	15.3% (19/124)	0.0% (0/124)	0.0% (0/124)	0.0% (0/124)	0.0% (0/124)	0.0% (0/124)	0.0% (0/124)
E) >120-160	169	0.0% (0/169)	0.0% (0/169)	0.6% (1/169)	21.3% (36/169)	62.1% (105/169)	15.4% (26/169)	0.6% (1/169)	0.0% (0/169)	0.0% (0/169)	0.0% (0/169)	0.0% (0/169)
F) >160-200	160	0.0% (0/160)	0.0% (0/160)	0.0% (0/160)	1.9% (3/160)	25.0% (40/160)	64.4% (103/160)	8.8% (14/160)	0.0% (0/160)	0.0% (0/160)	0.0% (0/160)	0.0% (0/160)
G) >200-250	151	0.0% (0/151)	0.0% (0/151)	0.0% (0/151)	0.0% (0/151)	1.3% (2/151)	40.4% (61/151)	56.3% (85/151)	2.0% (3/151)	0.0% (0/151)	0.0% (0/151)	0.0% (0/151)
H) >250-300	64	0.0% (0/64)	0.0% (0/64)	0.0% (0/64)	0.0% (0/64)	0.0% (0/64)	0.0% (0/64)	32.8% (21/64)	64.1% (41/64)	3.1% (2/64)	0.0% (0/64)	0.0% (0/64)
I) >300-350	32	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	40.6% (13/32)	59.4% (19/32)	0.0% (0/32)	0.0% (0/32)
J) >350-400	9	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	88.9% (8/9)	11.1% (1/9)	0.0% (0/9)

Table E-15: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration every 12 hours, Abdomen

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	4	50.0% (2/4)	50.0% (2/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)
C) >60-80	11	0.0% (0/11)	18.2% (2/11)	45.5% (5/11)	36.4% (4/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)
D) >80-120	50	0.0% (0/50)	6.0% (3/50)	8.0% (4/50)	62.0% (31/50)	24.0% (12/50)	0.0% (0/50)	0.0% (0/50)	0.0% (0/50)	0.0% (0/50)	0.0% (0/50)	0.0% (0/50)
E) >120-160	94	0.0% (0/94)	0.0% (0/94)	1.1% (1/94)	19.1% (18/94)	58.5% (55/94)	20.2% (19/94)	1.1% (1/94)	0.0% (0/94)	0.0% (0/94)	0.0% (0/94)	0.0% (0/94)
F) >160-200	95	0.0% (0/95)	0.0% (0/95)	0.0% (0/95)	2.1% (2/95)	17.9% (17/95)	69.5% (66/95)	10.5% (10/95)	0.0% (0/95)	0.0% (0/95)	0.0% (0/95)	0.0% (0/95)
G) >200-250	83	0.0% (0/83)	0.0% (0/83)	0.0% (0/83)	0.0% (0/83)	1.2% (1/83)	27.7% (23/83)	68.7% (57/83)	2.4% (2/83)	0.0% (0/83)	0.0% (0/83)	0.0% (0/83)
H) >250-300	34	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	0.0% (0/34)	44.1% (15/34)	52.9% (18/34)	2.9% (1/34)	0.0% (0/34)	0.0% (0/34)
I) >300-350	27	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	37.0% (10/27)	63.0% (17/27)	0.0% (0/27)	0.0% (0/27)
J) >350-400	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	100.0% (7/7)	0.0% (0/7)	0.0% (0/7)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 16 subjects.

Table E-16: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	2	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	100.0% (2/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)
C) >60-80	18	0.0% (0/18)	0.0% (0/18)	61.1% (11/18)	38.9% (7/18)	0.0% (0/18)	0.0% (0/18)	0.0% (0/18)	0.0% (0/18)	0.0% (0/18)	0.0% (0/18)	0.0% (0/18)
D) >80-120	120	0.0% (0/120)	3.3% (4/120)	15.8% (19/120)	67.5% (81/120)	13.3% (16/120)	0.0% (0/120)	0.0% (0/120)	0.0% (0/120)	0.0% (0/120)	0.0% (0/120)	0.0% (0/120)
E) >120-160	162	0.0% (0/162)	0.0% (0/162)	0.0% (0/162)	17.9% (29/162)	64.8% (105/162)	16.7% (27/162)	0.6% (1/162)	0.0% (0/162)	0.0% (0/162)	0.0% (0/162)	0.0% (0/162)
F) >160-200	161	0.0% (0/161)	0.0% (0/161)	0.0% (0/161)	1.2% (2/161)	25.5% (41/161)	65.2% (105/161)	8.1% (13/161)	0.0% (0/161)	0.0% (0/161)	0.0% (0/161)	0.0% (0/161)
G) >200-250	145	0.0% (0/145)	0.0% (0/145)	0.0% (0/145)	0.0% (0/145)	1.4% (2/145)	42.8% (62/145)	53.8% (78/145)	2.1% (3/145)	0.0% (0/145)	0.0% (0/145)	0.0% (0/145)
H) >250-300	61	0.0% (0/61)	0.0% (0/61)	0.0% (0/61)	0.0% (0/61)	0.0% (0/61)	0.0% (0/61)	32.8% (20/61)	65.6% (40/61)	1.6% (1/61)	0.0% (0/61)	0.0% (0/61)
I) >300-350	32	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	0.0% (0/32)	37.5% (12/32)	62.5% (20/32)	0.0% (0/32)	0.0% (0/32)

Table E-16: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
J) >350-400	9	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	55.6% (5/9)	44.4% (4/9)	0.0% (0/9)

Table E-17: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
C) >60-80	9	0.0% (0/9)	0.0% (0/9)	55.6% (5/9)	44.4% (4/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)
D) >80-120	46	0.0% (0/46)	2.2% (1/46)	10.9% (5/46)	67.4% (31/46)	19.6% (9/46)	0.0% (0/46)	0.0% (0/46)	0.0% (0/46)	0.0% (0/46)	0.0% (0/46)	0.0% (0/46)
E) >120-160	85	0.0% (0/85)	0.0% (0/85)	0.0% (0/85)	16.5% (14/85)	60.0% (51/85)	22.4% (19/85)	1.2% (1/85)	0.0% (0/85)	0.0% (0/85)	0.0% (0/85)	0.0% (0/85)
F) >160-200	91	0.0% (0/91)	0.0% (0/91)	0.0% (0/91)	2.2% (2/91)	16.5% (15/91)	70.3% (64/91)	11.0% (10/91)	0.0% (0/91)	0.0% (0/91)	0.0% (0/91)	0.0% (0/91)
G) >200-250	76	0.0% (0/76)	0.0% (0/76)	0.0% (0/76)	0.0% (0/76)	1.3% (1/76)	27.6% (21/76)	68.4% (52/76)	2.6% (2/76)	0.0% (0/76)	0.0% (0/76)	0.0% (0/76)
H) >250-300	31	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	38.7% (12/31)	58.1% (18/31)	3.2% (1/31)	0.0% (0/31)	0.0% (0/31)
I) >300-350	27	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	29.6% (8/27)	70.4% (19/27)	0.0% (0/27)	0.0% (0/27)
J) >350-400	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	57.1% (4/7)	42.9% (3/7)	0.0% (0/7)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 15 subjects.

Table E-18: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Buttock

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	11	36.4% (4/11)	63.6% (7/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)
C) >60-80	37	8.1% (3/37)	24.3% (9/37)	43.2% (16/37)	24.3% (9/37)	0.0% (0/37)	0.0% (0/37)	0.0% (0/37)	0.0% (0/37)	0.0% (0/37)	0.0% (0/37)	0.0% (0/37)
D) >80-120	156	0.6% (1/156)	5.1% (8/156)	9.0% (14/156)	75.6% (118/156)	9.6% (15/156)	0.0% (0/156)	0.0% (0/156)	0.0% (0/156)	0.0% (0/156)	0.0% (0/156)	0.0% (0/156)
E) >120-160	170	0.0% (0/170)	0.0% (0/170)	2.9% (5/170)	16.5% (28/170)	67.6% (115/170)	12.9% (22/170)	0.0% (0/170)	0.0% (0/170)	0.0% (0/170)	0.0% (0/170)	0.0% (0/170)

Table E-18: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Buttock											
Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
F) >160-200	144	0.0% (0/144)	0.0% (0/144)	0.0% (0/144)	0.0% (0/144)	16.0% (23/144)	75.7% (109/144)	8.3% (12/144)	0.0% (0/144)	0.0% (0/144)	0.0% (0/144)	0.0% (0/144)
G) >200-250	130	0.0% (0/130)	0.0% (0/130)	0.0% (0/130)	0.0% (0/130)	2.3% (3/130)	38.5% (50/130)	56.2% (73/130)	3.1% (4/130)	0.0% (0/130)	0.0% (0/130)	0.0% (0/130)
H) >250-300	49	0.0% (0/49)	0.0% (0/49)	0.0% (0/49)	0.0% (0/49)	0.0% (0/49)	0.0% (0/49)	40.8% (20/49)	53.1% (26/49)	6.1% (3/49)	0.0% (0/49)	0.0% (0/49)
I) >300-350	15	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	33.3% (5/15)	60.0% (9/15)	6.7% (1/15)	0.0% (0/15)
J) >350-400	6	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	50.0% (3/6)	50.0% (3/6)	0.0% (0/6)

Table E-19: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration every 12 hours, Buttock											
Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range											
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	4	100.0% (4/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)
C) >60-80	22	13.6% (3/22)	27.3% (6/22)	31.8% (7/22)	27.3% (6/22)	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)
D) >80-120	68	1.5% (1/68)	11.8% (8/68)	13.2% (9/68)	58.8% (40/68)	14.7% (10/68)	0.0% (0/68)	0.0% (0/68)	0.0% (0/68)	0.0% (0/68)	0.0% (0/68)	0.0% (0/68)
E) >120-160	74	0.0% (0/74)	0.0% (0/74)	6.8% (5/74)	23.0% (17/74)	56.8% (42/74)	13.5% (10/74)	0.0% (0/74)	0.0% (0/74)	0.0% (0/74)	0.0% (0/74)	0.0% (0/74)
F) >160-200	76	0.0% (0/76)	0.0% (0/76)	0.0% (0/76)	0.0% (0/76)	18.4% (14/76)	72.4% (55/76)	9.2% (7/76)	0.0% (0/76)	0.0% (0/76)	0.0% (0/76)	0.0% (0/76)
G) >200-250	67	0.0% (0/67)	0.0% (0/67)	0.0% (0/67)	0.0% (0/67)	3.0% (2/67)	19.4% (13/67)	73.1% (49/67)	4.5% (3/67)	0.0% (0/67)	0.0% (0/67)	0.0% (0/67)
H) >250-300	27	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	44.4% (12/27)	48.1% (13/27)	7.4% (2/27)	0.0% (0/27)	0.0% (0/27)
I) >300-350	3	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	100.0% (3/3)	0.0% (0/3)	0.0% (0/3)
J) >350-400	2	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	50.0% (1/2)	50.0% (1/2)	0.0% (0/2)

Note: The overall number of available paired SG-YSI points on FST Day 1 was from 14 subjects.

Table E-20: Overall concurrence of YSI values and SG readings using YSI ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	11	36.4% (4/11)	63.6% (7/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)
C) >60-80	30	6.7% (2/30)	10.0% (3/30)	50.0% (15/30)	33.3% (10/30)	0.0% (0/30)	0.0% (0/30)	0.0% (0/30)	0.0% (0/30)	0.0% (0/30)	0.0% (0/30)	0.0% (0/30)
D) >80-120	144	0.7% (1/144)	1.4% (2/144)	7.6% (11/144)	80.6% (116/144)	9.7% (14/144)	0.0% (0/144)	0.0% (0/144)	0.0% (0/144)	0.0% (0/144)	0.0% (0/144)	0.0% (0/144)
E) >120-160	164	0.0% (0/164)	0.0% (0/164)	1.8% (3/164)	16.5% (27/164)	67.1% (110/164)	14.0% (23/164)	0.6% (1/164)	0.0% (0/164)	0.0% (0/164)	0.0% (0/164)	0.0% (0/164)
F) >160-200	140	0.0% (0/140)	0.0% (0/140)	0.0% (0/140)	0.0% (0/140)	14.3% (20/140)	75.0% (105/140)	10.7% (15/140)	0.0% (0/140)	0.0% (0/140)	0.0% (0/140)	0.0% (0/140)
G) >200-250	127	0.0% (0/127)	0.0% (0/127)	0.0% (0/127)	0.0% (0/127)	1.6% (2/127)	42.5% (54/127)	51.2% (65/127)	4.7% (6/127)	0.0% (0/127)	0.0% (0/127)	0.0% (0/127)
H) >250-300	53	0.0% (0/53)	0.0% (0/53)	0.0% (0/53)	0.0% (0/53)	0.0% (0/53)	0.0% (0/53)	41.5% (22/53)	39.6% (21/53)	17.0% (9/53)	1.9% (1/53)	0.0% (0/53)
I) >300-350	18	0.0% (0/18)	0.0% (0/18)	0.0% (0/18)	0.0% (0/18)	0.0% (0/18)	0.0% (0/18)	0.0% (0/18)	38.9% (7/18)	38.9% (7/18)	22.2% (4/18)	0.0% (0/18)
J) >350-400	6	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	16.7% (1/6)	83.3% (5/6)	0.0% (0/6)

Table E-21: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration 3 or 4 times a day, Buttock

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range

YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
B) ≥40-60	4	100.0% (4/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)
C) >60-80	15	13.3% (2/15)	0.0% (0/15)	40.0% (6/15)	46.7% (7/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)	0.0% (0/15)
D) >80-120	56	1.8% (1/56)	3.6% (2/56)	12.5% (7/56)	66.1% (37/56)	16.1% (9/56)	0.0% (0/56)	0.0% (0/56)	0.0% (0/56)	0.0% (0/56)	0.0% (0/56)	0.0% (0/56)
E) >120-160	68	0.0% (0/68)	0.0% (0/68)	4.4% (3/68)	25.0% (17/68)	57.4% (39/68)	13.2% (9/68)	0.0% (0/68)	0.0% (0/68)	0.0% (0/68)	0.0% (0/68)	0.0% (0/68)
F) >160-200	72	0.0% (0/72)	0.0% (0/72)	0.0% (0/72)	0.0% (0/72)	15.3% (11/72)	75.0% (54/72)	9.7% (7/72)	0.0% (0/72)	0.0% (0/72)	0.0% (0/72)	0.0% (0/72)
G) >200-250	64	0.0% (0/64)	0.0% (0/64)	0.0% (0/64)	0.0% (0/64)	1.6% (1/64)	29.7% (19/64)	62.5% (40/64)	6.3% (4/64)	0.0% (0/64)	0.0% (0/64)	0.0% (0/64)
H) >250-300	31	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	45.2% (14/31)	29.0% (9/31)	22.6% (7/31)	3.2% (1/31)	0.0% (0/31)
I) >300-350	6	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	50.0% (3/6)	50.0% (3/6)	0.0% (0/6)	0.0% (0/6)
J) >350-400	2	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	50.0% (1/2)	50.0% (1/2)	0.0% (0/2)

Table E-21: Overall concurrence of YSI values and SG readings using YSI ranges on FST Day 1; Calibration 3 or 4 times a day, Buttock												
Percent of Matched Pairs-in Each SG Glucose Range for Each YSI Glucose Range												
YSI Glucose Ranges (mg/dL)	Number of Paired SG-YSI	SG (mg/dL)										
		<40	≥40–60	>60–80	>80–120	>120–160	>160–200	>200–250	>250–300	>300–350	>350–400	>400
Note: The overall number of available paired SG-YSI points on FST Day 1 was from 13 subjects.												

Percent Agreement Post Calibration

The agreement of the SG values to paired YSI values was assessed for every 2-hour period post sensor calibration. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI values was calculated.

Tables E-22 through E-25 show the percent agreement rates post calibration for sensors inserted into the abdomen and buttock.

Table E-22: Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Abdomen						
Time after calibration	Number of paired YSI-sensor points	Percentage (%) Agreement				
		±15% (±15 mg/dL)	±20% (±20 mg/dL)	±30% (±30 mg/dL)	±40% (±40 mg/dL)	>±40% (±40 mg/dL)
0–2 hours	224	84.4	93.3	98.7	99.6	0.4
2–4 hours	181	77.9	85.1	94.5	98.3	1.7
4–6 hours	145	72.4	84.1	94.5	98.6	1.4
6–8 hours	77	74	83.1	97.4	100	0
8–10 hours	52	80.8	82.7	86.5	96.2	3.8
10–12 hours	54	81.5	94.4	100	100	0

Table E-23: Agreement rates for every 2-hour period post calibration; Calibration 3 or 4 times a day, Abdomen						
Time after calibration	Number of paired YSI-sensor points	Percentage (%) Agreement				
		±15% (±15 mg/dL)	±20% (±20 mg/dL)	±30% (±30 mg/dL)	±40% (±40 mg/dL)	>±40% (±40 mg/dL)
0-2 hours	360	83.3	90.8	97.8	99.4	0.6
2-4 hours	174	83.9	92.5	98.3	100	0
4-6 hours	53	75.5	90.6	98.1	100	0
6-8 hours	64	73.4	82.8	96.9	100	0
8-10 hours	36	75	77.8	83.3	94.4	5.6
10-12 hours	23	87	95.7	100	100	0

Table E-24: Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Buttock						
Time after calibration	Number of paired YSI-sensor points	Percentage (%) Agreement				
		±15% (±15 mg/dL)	±20% (±20 mg/dL)	±30% (±30 mg/dL)	±40% (±40 mg/dL)	>±40% (±40 mg/dL)
0–2 hours	196	81.6	94.9	96.4	98.5	1.5

Table E-24: Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Buttock						
Time after calibration	Number of paired YSI-sensor points	Percentage (%) Agreement				
		±15% (±15 mg/dL)	±20% (±20 mg/dL)	±30% (±30 mg/dL)	±40% (±40 mg/dL)	>±40% (±40 mg/dL)
2–4 hours	195	78.5	85.1	92.8	96.9	3.1
4–6 hours	157	87.9	91.1	99.4	99.4	0.6
6–8 hours	76	96.1	100	100	100	0
8–10 hours	45	97.8	100	100	100	0
10–12 hours	41	82.9	95.1	97.6	100	0

Table E-25: Agreement rates for every 2-hour period post calibration period; Calibration 3 or 4 times a day, Buttock						
Time after calibration	Number of paired YSI-sensor points	Percentage (%) Agreement				
		±15% (±15 mg/dL)	±20% (±20 mg/dL)	±30% (±30 mg/dL)	±40% (±40 mg/dL)	>±40% (±40 mg/dL)
0–2 hours	314	81.8	92.4	95.9	98.1	1.9
2–4 hours	195	79.5	88.2	96.4	100	0
4–6 hours	70	94.3	95.7	100	100	0
6–8 hours	52	94.2	100	100	100	0
8–10 hours	37	100	100	100	100	0
10–12 hours	18	94.4	100	100	100	0

Trend accuracy

Tables E-26 through E-29 show, for each SG rate-of-change range (indicated on display by number of arrows), percentage of SG-YSI paired values that fell into different YSI rate-of-change ranges. The tables show the trend accuracy for sensors inserted into the abdomen or buttock.

Table E-26: Trend Accuracy; Calibration every 12 hours, Abdomen							
Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range							
SG Rate Ranges (mg/dL/min)	Numbered of Paired SG-YSI	YSI (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	19	47.4% (9/19)	47.4% (9/19)	0.0% (0/19)	5.3% (1/19)	0.0% (0/19)	0.0% (0/19)
[-2, -1]	107	2.8% (3/107)	31.8% (34/107)	60.7% (65/107)	3.7% (4/107)	0.9% (1/107)	0.0% (0/107)
[-1, 0]	276	0.7% (2/276)	5.8% (16/276)	71.7% (198/276)	21.0% (58/276)	0.7% (2/276)	0.0% (0/276)
[0, 1]	209	0.0% (0/209)	1.0% (2/209)	22.5% (47/209)	62.2% (130/209)	13.9% (29/209)	0.5% (1/209)
[1, 2]	98	0.0% (0/98)	0.0% (0/98)	1.0% (1/98)	37.8% (37/98)	59.2% (58/98)	2.0% (2/98)
>2	23	0.0% (0/23)	0.0% (0/23)	4.3% (1/23)	8.7% (2/23)	30.4% (7/23)	56.5% (13/23)

Table E-27: Trend Accuracy; Calibration 3 or 4 times a day, Abdomen							
Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range							
SG Rate Ranges (mg/dL/min)	Numbered of Paired SG-YSI	YSI (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	17	41.2% (7/17)	47.1% (8/17)	5.9% (1/17)	5.9% (1/17)	0.0% (0/17)	0.0% (0/17)
[-2, -1]	105	2.9% (3/105)	32.4% (34/105)	60.0% (63/105)	3.8% (4/105)	1.0% (1/105)	0.0% (0/105)
[-1, 0]	273	0.4% (1/273)	6.2% (17/273)	72.5% (198/273)	20.1% (55/273)	0.7% (2/273)	0.0% (0/273)
[0, 1]	199	0.5% (1/199)	0.5% (1/199)	22.6% (45/199)	63.3% (126/199)	12.6% (25/199)	0.5% (1/199)
[1, 2]	98	0.0% (0/98)	0.0% (0/98)	2.0% (2/98)	36.7% (36/98)	59.2% (58/98)	2.0% (2/98)
>2	17	0.0% (0/17)	0.0% (0/17)	5.9% (1/17)	11.8% (2/17)	41.2% (7/17)	41.2% (7/17)

Table E-28: Trend Accuracy; Calibration every 12 hours, Buttock							
Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range							
SG Rate Ranges (mg/dL/min)	Numbered of Paired SG-YSI	YSI (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	35	37.1% (13/35)	45.7% (16/35)	17.1% (6/35)	0.0% (0/35)	0.0% (0/35)	0.0% (0/35)
[-2, -1]	83	7.2% (6/83)	31.3% (26/83)	59.0% (49/83)	2.4% (2/83)	0.0% (0/83)	0.0% (0/83)
[-1, 0]	272	0.0% (0/272)	4.8% (13/272)	69.9% (190/272)	21.7% (59/272)	2.9% (8/272)	0.7% (2/272)
[0, 1]	199	0.0% (0/199)	0.5% (1/199)	22.1% (44/199)	60.8% (121/199)	15.6% (31/199)	1.0% (2/199)
[1, 2]	97	0.0% (0/97)	0.0% (0/97)	4.1% (4/97)	36.1% (35/97)	54.6% (53/97)	5.2% (5/97)
>2	23	0.0% (0/23)	0.0% (0/23)	0.0% (0/23)	26.1% (6/23)	34.8% (8/23)	39.1% (9/23)

Table E-29: Trend Accuracy; Calibration 3 or 4 times a day, Buttock							
Percent of Matched Pairs-in Each YSI Rate Range for Each SG Rate Range							
SG Rate Ranges (mg/dL/min)	Numbered of Paired SG-YSI	YSI (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	31	41.9% (13/31)	38.7% (12/31)	19.4% (6/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)
[-2, -1]	83	7.2% (6/83)	32.5% (27/83)	56.6% (47/83)	3.6% (3/83)	0.0% (0/83)	0.0% (0/83)
[-1, 0]	261	0.0% (0/261)	5.0% (13/261)	71.6% (187/261)	21.1% (55/261)	2.3% (6/261)	0.0% (0/261)
[0, 1]	194	0.0% (0/194)	0.5% (1/194)	22.2% (43/194)	62.9% (122/194)	13.4% (26/194)	1.0% (2/194)
[1, 2]	94	0.0% (0/94)	0.0% (0/94)	4.3% (4/94)	36.2% (34/94)	56.4% (53/94)	3.2% (3/94)
>2	22	0.0% (0/22)	0.0% (0/22)	0.0% (0/22)	22.7% (5/22)	36.4% (8/22)	40.9% (9/22)

Precision

Precision of the system was evaluated by comparing the results from two separate sensors worn on the same subject at the same time.

Data from two sensors worn at the same time for 11 subjects, both inserted in the abdomen, provided 772 pairs of CGM measurements, with a mean PARD during the study of 7.83% and a coefficient of variation (%CV) of 5.7%.

Data from two sensors worn at the same time for 18 subjects, one inserted in the abdomen and one in the buttock, provided 1302 pairs of CGM measurements, with a mean PARD during the study of 11.33% and a coefficient of variation (%CV) of 7.8%.

Data from two sensors worn at the same time for 10 subjects, both inserted in the buttock, provided 695 pairs of CGM measurements, with a mean PARD during the study of 10.93% and a coefficient of variation (%CV) of 8.1%.

Sensor life

After the first successful calibration, 64.3% of sensors worn in the abdomen operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the abdomen insertion site over the course of the study was 122.1 hours, with a median functional life of 128.4 hours.

After the first successful calibration, 81.3% of sensors worn in the buttock operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the buttock insertion site over the course of the study was 142.7 hours, with a median functional life of 158.1 hours.

Safety

There were no moderate or severe device-related or procedure-related adverse events, device-related or procedure-related serious adverse events, or unanticipated adverse device effects through seven days of use.

F. Alert performance for user ages 7 through 13

The CGM system enables your device to display SG readings, glucose trend arrows, glucose trend graphs, and SG alerts (for example, High and Low Limit Threshold alerts, High and Low Predictive alerts, and Rise and Fall rate-of-change alerts).

The high and low limit alerts (Threshold alerts) let the user know when the SG is at or above the high limit or at or below the low limit. Using only a high or low limit alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit.

Predictive alerts notify users that their SG level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their SG level reaches a high limit setting. The earliest warning is 30 minutes before

reaching a high, but users can reduce the amount of warning down to 5 minutes. Users will receive a warning approximately 30 minutes prior to when their SG level is predicted to reach their low limit setting. In general, the earlier the warning, the more time a user will have to react to a potential high or low, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future SG level compared to the high or low limit setting. If the predicted SG value is above the high limit or below the low limit, then a predictive alert is sounded even though the current SG level has not crossed the high or low limit. The predicted SG level is calculated using the current SG level, the derivative of previous SG readings (the trend or slope of the SG readings) and the amount of early warning duration the user selects.

The device will always alert the user when the CGM system reads that the user is below 50 mg/dL, regardless of the high threshold, low threshold, or predictive alerts that the user sets.

Glucose TRUE Alert Rate

The glucose true alert rate is the rate at which the BG confirmed that the CGM alert was triggered correctly. For example

True Threshold Hypoglycemic alert rate alerted when the CGM system read that the user was below the low threshold and the user's BG was actually below that low threshold.

True Threshold Hyperglycemic alert rate alerted when the CGM system read that the user was above the high threshold and the user's BG was actually above that high threshold.

True Predictive Hypoglycemic alert rate alerted when the CGM system predicted that the user would reach below the low threshold and the user's BG was actually below that low threshold within 15 or 30 minutes.

True Predictive Hyperglycemic alert rate alerted when the CGM system predicted that the user would reach above the high threshold and the user's BG was actually above that high threshold within 15 or 30 minutes.

The true alert rate is important because it is necessary that users be notified when their BG is low (or high) so that they can correct the low (or high) BG. A high true alert rate indicates that when the CGM system says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold.

For example, per the following table, when wearing the sensor in the abdomen, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only), or both (predictive and threshold) 44.4%, 28.6%, or 36.4% of the time within 30 minutes (or 44.4%, 14.3%, or 27.3% of the time within 15 minutes) when the user had BG values lower than 70 mg/dL.

mg/dL	Insertion Site	Glucose TRUE Alert Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	33.3% (1/3)	33.3% (1/3)	12.5% (1/8)	12.5% (1/8)	18.2% (2/11)	18.2% (2/11)
	Buttock	25.0% (1/4)	25.0% (1/4)	11.1% (1/9)	11.1% (1/9)	16.7% (2/12)	16.7% (2/12)
60	Abdomen	25.0% (1/4)	25.0% (1/4)	8.3% (1/12)	8.3% (1/12)	12.5% (2/16)	12.5% (2/16)
	Buttock	60.0% (3/5)	60.0% (3/5)	25.0% (3/12)	16.7% (2/12)	35.3% (6/17)	29.4% (5/17)
70	Abdomen	44.4% (4/9)	44.4% (4/9)	28.6% (4/14)	14.3% (2/14)	36.4% (8/22)	27.3% (6/22)
	Buttock	60.0% (6/10)	60.0% (6/10)	36.8% (7/19)	26.3% (5/19)	40.7% (11/27)	33.3% (9/27)
80	Abdomen	33.3% (4/12)	33.3% (4/12)	31.6% (6/19)	15.8% (3/19)	32.3% (10/31)	22.6% (7/31)
	Buttock	61.1% (11/18)	61.1% (11/18)	46.2% (12/26)	38.5% (10/26)	51.2% (22/43)	46.5% (20/43)
90	Abdomen	55.0% (11/20)	55.0% (11/20)	46.2% (12/26)	30.8% (8/26)	47.7% (21/44)	38.6% (17/44)
	Buttock	70.8% (17/24)	70.8% (17/24)	58.3% (21/36)	44.4% (16/36)	62.5% (35/56)	53.6% (30/56)
180	Abdomen	78.4% (40/51)	78.4% (40/51)	66.2% (47/71)	66.2% (47/71)	70.5% (79/112)	70.5% (79/112)
	Buttock	83.3% (40/48)	81.3% (39/48)	64.3% (45/70)	62.9% (44/70)	70.6% (77/109)	68.8% (75/109)
220	Abdomen	87.5% (21/24)	87.5% (21/24)	60.0% (27/45)	57.8% (26/45)	68.2% (45/66)	66.7% (44/66)
	Buttock	75.0% (21/28)	75.0% (21/28)	51.0% (25/49)	49.0% (24/49)	58.3% (42/72)	56.9% (41/72)
250	Abdomen	81.3% (13/16)	81.3% (13/16)	53.1% (17/32)	46.9% (15/32)	63.0% (29/46)	58.7% (27/46)
	Buttock	73.3% (11/15)	73.3% (11/15)	41.2% (14/34)	35.3% (12/34)	50.0% (23/46)	45.7% (21/46)
300	Abdomen	77.8% (7/9)	77.8% (7/9)	44.4% (8/18)	44.4% (8/18)	55.6% (15/27)	55.6% (15/27)
	Buttock	57.1% (4/7)	57.1% (4/7)	31.3% (5/16)	31.3% (5/16)	38.1% (8/21)	38.1% (8/21)

Table F-1: Glucose TRUE Alert Performance using Calibration every 12 hours

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the BG did not confirm that the CGM alert was triggered correctly. For example:

False Threshold Hypoglycemic alert rate alerted when the CGM system read that the user was below the low threshold but the user's BG was actually above that low threshold.

False Threshold Hyperglycemic alert rate alerted when the CGM system read that the user was above the high threshold but the user's BG was actually below that high threshold.

False Predictive Hypoglycemic alert rate alerted when the CGM system predicted that the user would be below the low threshold but the user's BG was actually above that low threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their BG is low (or high) so that they can correct the low (or high) BG. A low false alert rate indicates that when the CGM system says that their glucose values are, or will reach a specified threshold, the user's BG is likely to be at or approaching that threshold.

For example, per the following table, when wearing the sensor in the abdomen, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e. predictive only), or both (threshold and predictive) 21.6%, 33.8%, or 29.5% of the time within 30 minutes (or 21.6%, 33.8%, or 29.5% of the time within 15 minutes) when the user had BG less than 180 mg/dL.

Table F-2: Glucose FALSE Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose FALSE Alert Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	66.7% (2/3)	66.7% (2/3)	87.5% (7/8)	87.5% (7/8)	81.8% (9/11)	81.8% (9/11)
	Buttock	75.0% (3/4)	75.0% (3/4)	88.9% (8/9)	88.9% (8/9)	83.3% (10/12)	83.3% (10/12)
60	Abdomen	75.0% (3/4)	75.0% (3/4)	91.7% (11/12)	91.7% (11/12)	87.5% (14/16)	87.5% (14/16)
	Buttock	40.0% (2/5)	40.0% (2/5)	75.0% (9/12)	83.3% (10/12)	64.7% (11/17)	70.6% (12/17)
70	Abdomen	55.6% (5/9)	55.6% (5/9)	71.4% (10/14)	85.7% (12/14)	63.6% (14/22)	72.7% (16/22)
	Buttock	40.0% (4/10)	40.0% (4/10)	63.2% (12/19)	73.7% (14/19)	59.3% (16/27)	66.7% (18/27)
80	Abdomen	66.7% (8/12)	66.7% (8/12)	68.4% (13/19)	84.2% (16/19)	67.7% (21/31)	77.4% (24/31)
	Buttock	38.9% (7/18)	38.9% (7/18)	53.8% (14/26)	61.5% (16/26)	48.8% (21/43)	53.5% (23/43)
90	Abdomen	45.0% (9/20)	45.0% (9/20)	53.8% (14/26)	69.2% (18/26)	52.3% (23/44)	61.4% (27/44)
	Buttock	29.2% (7/24)	29.2% (7/24)	41.7% (15/36)	55.6% (20/36)	37.5% (21/56)	46.4% (26/56)
180	Abdomen	21.6% (11/51)	21.6% (11/51)	33.8% (24/71)	33.8% (24/71)	29.5% (33/112)	29.5% (33/112)
	Buttock	16.7% (8/48)	18.8% (9/48)	35.7% (25/70)	37.1% (26/70)	29.4% (32/109)	31.2% (34/109)

Table F-2: Glucose FALSE Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose FALSE Alert Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
220	Abdomen	12.5% (3/24)	12.5% (3/24)	40.0% (18/45)	42.2% (19/45)	31.8% (21/66)	33.3% (22/66)
	Buttock	25.0% (7/28)	25.0% (7/28)	49.0% (24/49)	51.0% (25/49)	41.7% (30/72)	43.1% (31/72)
250	Abdomen	18.8% (3/16)	18.8% (3/16)	46.9% (15/32)	53.1% (17/32)	37.0% (17/46)	41.3% (19/46)
	Buttock	26.7% (4/15)	26.7% (4/15)	58.8% (20/34)	64.7% (22/34)	50.0% (23/46)	54.3% (25/46)
300	Abdomen	22.2% (2/9)	22.2% (2/9)	55.6% (10/18)	55.6% (10/18)	44.4% (12/27)	44.4% (12/27)
	Buttock	42.9% (3/7)	42.9% (3/7)	68.8% (11/16)	68.8% (11/16)	61.9% (13/21)	61.9% (13/21)

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the BG was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert.

Glucose detection rates are important because it is necessary that users be notified when their BG is low (or high) so that they can correct the low (or high) BG. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their BG is low or high.

For example, per the following table, when wearing the sensor in the abdomen, the threshold alert, the predictive alert, or both (threshold and predictive) notified the user 100%, 100%, or 100% of the time within 30 minutes (or 100%, 100%, or 100% within 15 minutes) when the user had BG less than 50 mg/dL.

Table F-3: Glucose Correct Detection Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose Correct Detection Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
	Buttock	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
60	Abdomen	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)
	Buttock	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	66.7% (2/3)	100.0% (3/3)	100.0% (3/3)
70	Abdomen	80.0% (4/5)	80.0% (4/5)	80.0% (4/5)	40.0% (2/5)	80.0% (4/5)	80.0% (4/5)
	Buttock	85.7% (6/7)	85.7% (6/7)	85.7% (6/7)	71.4% (5/7)	85.7% (6/7)	85.7% (6/7)
80	Abdomen	66.7% (4/6)	66.7% (4/6)	83.3% (5/6)	50.0% (3/6)	83.3% (5/6)	66.7% (4/6)
	Buttock	85.7% (12/14)	85.7% (12/14)	85.7% (12/14)	78.6% (11/14)	85.7% (12/14)	85.7% (12/14)

		Table F-3: Glucose Correct Detection Alert Performance using Calibration every 12 hours					
mg/dL	Insertion Site	Glucose Correct Detection Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
90	Abdomen	91.7% (11/12)	91.7% (11/12)	91.7% (11/12)	66.7% (8/12)	91.7% (11/12)	91.7% (11/12)
	Buttock	86.4% (19/22)	86.4% (19/22)	90.9% (20/22)	72.7% (16/22)	95.5% (21/22)	86.4% (19/22)
180	Abdomen	95.1% (39/41)	95.1% (39/41)	100.0% (41/41)	100.0% (41/41)	100.0% (41/41)	100.0% (41/41)
	Buttock	97.5% (39/40)	95.0% (38/40)	100.0% (40/40)	100.0% (40/40)	100.0% (40/40)	100.0% (40/40)
220	Abdomen	92.6% (25/27)	85.2% (23/27)	96.3% (26/27)	88.9% (24/27)	96.3% (26/27)	88.9% (24/27)
	Buttock	95.7% (22/23)	95.7% (22/23)	100.0% (23/23)	95.7% (22/23)	100.0% (23/23)	100.0% (23/23)
250	Abdomen	77.8% (14/18)	77.8% (14/18)	88.9% (16/18)	83.3% (15/18)	88.9% (16/18)	83.3% (15/18)
	Buttock	68.8% (11/16)	62.5% (10/16)	100.0% (16/16)	93.8% (15/16)	100.0% (16/16)	100.0% (16/16)
300	Abdomen	80.0% (8/10)	80.0% (8/10)	100.0% (10/10)	90.0% (9/10)	100.0% (10/10)	90.0% (9/10)
	Buttock	60.0% (3/5)	60.0% (3/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)	100.0% (5/5)

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the BG was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their BG is low (or high), so that they can correct the low (or high) BG. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their BG is low or high.

For example, per the following table, when wearing the sensor in the abdomen, the threshold alert, predictive alert, or both alerts (threshold and predictive) did not sound 0%, 0%, or 0% of the time within 30 minutes (or 0%, 0%, or 0% within 15 minutes) when the user had BG less than 50 mg/dL.

		Table F-4: Glucose Missed Detection Alert Performance using Calibration every 12 hours					
mg/dL	Insertion Site	Glucose Missed Detection Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
	Buttock	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
60	Abdomen	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)
	Buttock	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	33.3% (1/3)	0.0% (0/3)	0.0% (0/3)

Table F-4: Glucose Missed Detection Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose Missed Detection Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
70	Abdomen	20.0% (1/5)	20.0% (1/5)	20.0% (1/5)	60.0% (3/5)	20.0% (1/5)	20.0% (1/5)
	Buttock	14.3% (1/7)	14.3% (1/7)	14.3% (1/7)	28.6% (2/7)	14.3% (1/7)	14.3% (1/7)
80	Abdomen	33.3% (2/6)	33.3% (2/6)	16.7% (1/6)	50.0% (3/6)	16.7% (1/6)	33.3% (2/6)
	Buttock	14.3% (2/14)	14.3% (2/14)	14.3% (2/14)	21.4% (3/14)	14.3% (2/14)	14.3% (2/14)
90	Abdomen	8.3% (1/12)	8.3% (1/12)	8.3% (1/12)	33.3% (4/12)	8.3% (1/12)	8.3% (1/12)
	Buttock	13.6% (3/22)	13.6% (3/22)	9.1% (2/22)	27.3% (6/22)	4.5% (1/22)	13.6% (3/22)
180	Abdomen	4.9% (2/41)	4.9% (2/41)	0.0% (0/41)	0.0% (0/41)	0.0% (0/41)	0.0% (0/41)
	Buttock	2.5% (1/40)	5.0% (2/40)	0.0% (0/40)	0.0% (0/40)	0.0% (0/40)	0.0% (0/40)
220	Abdomen	7.4% (2/27)	14.8% (4/27)	3.7% (1/27)	11.1% (3/27)	3.7% (1/27)	11.1% (3/27)
	Buttock	4.3% (1/23)	4.3% (1/23)	0.0% (0/23)	4.3% (1/23)	0.0% (0/23)	0.0% (0/23)
250	Abdomen	22.2% (4/18)	22.2% (4/18)	11.1% (2/18)	16.7% (3/18)	11.1% (2/18)	16.7% (3/18)
	Buttock	31.3% (5/16)	37.5% (6/16)	0.0% (0/16)	6.3% (1/16)	0.0% (0/16)	0.0% (0/16)
300	Abdomen	20.0% (2/10)	20.0% (2/10)	0.0% (0/10)	10.0% (1/10)	0.0% (0/10)	10.0% (1/10)
	Buttock	40.0% (2/5)	40.0% (2/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

III. Performance data for users 2 through 6 years old

G. Device Performance data for users ages 2 through 6

The clinical data presented in this section was obtained from studies (users ages 2 through 6) using the MiniMed 670G system. The MiniMed 770G system uses the same SmartGuard Auto Mode technology as the MiniMed 670G system. Therefore, this clinical data also applies to the MiniMed 770G system.

> ⚠️ **CAUTION:** Since the study presented below did not include a control group, no claims regarding effectiveness can be made. However, it does support that the device is relatively safe for use.

The SmartGuard technology has two levels that include the 1) Suspend on low and Suspend before low that automatically suspends insulin based on CGM and 2) Auto mode that automatically calculates insulin dosing using CGM. A study was

performed to evaluate for safety in a multi-center, single arm, clinical investigation.[10] Study subjects included persons aged 2 to 6 years of age diagnosed with type 1 diabetes mellitus and who were on pump therapy for more than 90 days prior to screening. All study subjects had an HbA1C less than 10.0% at the time of screening visit.

For the first level of SmartGuard technology, the "Suspend before low" feature, subjects 2-6 years of age were set up but did not participate in frequent sample testing.

For this study, there were 47 subjects in the 2-6 year old cohort that entered the run-in phase. During the run-in phase, 1 subject withdrew. Therefore, 46 subjects in the 2-6 year old cohort entered the study-phase. The second level of SmartGuard technology, the "Auto Mode" feature, was evaluated during the 3-month study phase. Subjects 2-6 years of age are not required to participate in a hotel study. Instead, they will participate in an out-of-home study for 5 consecutive days, 4-6 hours per day. During that 5 day period, subjects should engage in significant activity/exercise. Such activities could include utilizing gym play areas appropriate for toddlers and young children, swimming, and playground games. Evidence of geographic location and exercise/activity will be documented by daily photograph. In addition, investigational center staff will be present daily for the 4-6 hours of exercise during the 5 day period.

During this study, data was collected for subjects 2-6 years old for over 6697 patient days (prior to Run-In + Run-In + Study periods). Subjects used the 670G system during the run-in and study periods without any reported device-related serious adverse events, such as severe hypoglycemia or diabetic ketoacidosis. Compared to Manual Mode used during the Run-In phase, use of Auto Mode was associated with reduction in mean sensor glucose values, an increase within the range of 71 to 180 mg/dL and a lower percentage of glucose values in the hyperglycemic and hypoglycemic ranges. There was a reduction in mean HbA1c from 8.0±0.9% (median 8.1) at the baseline to 7.5±0.6% (median 7.5) at the end of study. There was a small change in mean total daily dose of insulin/kg (0.8±0.1 baseline to 0.8±0.2 end of study) and modest increase in weight. Weight gain would also be expected for pediatric patients 2-6 years of age as part of the normal growth process.

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10 Medtronic Inc., Clinical Study Report, CEP302 Data Analysis From Subjects 2-6 Years of Age. 10927511DOC. July 2019.

Of the 138 adverse events reported through the end of the study period, 39% (N=54) were classified as device related, including glycemic events (severe hyperglycemia) and skin issues (abscess, dermatitis, skin infection at the infusion set site and skin irritation). Of the 54 device-related adverse events, 49 were severe hyperglycemia events that were thought to be device related. There were no procedure related events.

There were 86 reports of severe hyperglycemia and there was no diabetic ketoacidosis while on the MiniMed 670G System during the study. The majority of these severe hyperglycemic events (81/86) were mild in intensity. Ketone levels were available for 83 of the 86 severe hyperglycemia episodes and the majority of ketone levels (57/86) were low (0.6–1.5 mmol/L).

Of the 49 device related episodes of severe hyperglycemia, 46 were believed to be due to infusion set issues such as occlusion, bent cannula or cannula pull out. These issues are typically seen in relatively high rates in the pediatric population (causes provided in Table G-1 and Table G-2). Unlike insulin pump therapy which may or may not have alerts associated with infusion set failure, the MiniMed 670G System has fixed alarms (high alerts) that serve as an additional mitigation for subjects.

Table G-1. Run in Period Severe Hyperglycemia:	
Cause	Total
Infusion set change	9
Occlusion alarm	0
Infusion set fell out	0
Bent or Kinked Cannula	0
Total	9

Table G-2. Study Period Severe Hyperglycemia	
Cause	Total
Infusion set change	29
Occlusion alarm	3
Infusion set fell out	2
Bent or Kinked Cannula	1
Infusion set change or safe basal	1
Safe basal	1
Suspend before low suspension	1
Automatic & manual suspensions	1
Total	39

The following table shows the time spent per day in specific glucose ranges during the run-in and study phases by all subjects.

Table G-3: Time Spent in Specific Glucose Ranges During the Run-In and Study Phases by All Subjects		
Glucose Range (mg/dL)	Run-In Phase	Study Phase
	Time in Glucose Range (min) Mean±SD	Time in Glucose Range (min) Mean±SD
≤50	7.5±8.8	7.4±6.5
≤60	22.4±20.2	21.4±13.6
≤70	51.9±37.7	49.7±23.7
>70–180	797.6±191.6	915.5±134.8
>180	590.5±211.1	474.8±142.6
>250	210.6±136.0	153.5±85.4
>300	75.0±70.8	53.5±41.2
>350	23.9±30.8	16.6±16.4

The following table shows the ranges of changes in HbA1C observed in the study and indicates the number of subjects that demonstrated each type of change in HbA1C observed.

Table G-4: Number of Subjects with Change in HbA1C at Different Baselines					
HbA1C Change Range	Number of Subjects (% of Subjects) with Change in A1C				
Baseline A1C (%)	Decrease >1%	Decrease 0 to 1%	No Change	Increase 0 to 1%	Increase > 1%
5% ≤ A1C<6%	-	-	-	-	-
6% ≤ A1C<7%	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (13.0%)	0 (0.0%)
7% ≤ A1C<8%	2 (4.3%)	7 (15.2%)	0 (0.0%)	4 (8.7%)	0 (0.0%)
8% ≤ A1C<9%	4 (8.7%)	11 (23.9%)	1 (2.2%)	2 (4.3%)	0 (0.0%)
9% ≤ A1C<10%	5 (10.9%)	2 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Overall	11 (23.9%)	20 (43.5%)	1 (2.2%)	12 (26.1%)	0 (0.0%)
Note: For the blank cells (-), there are no subjects age 2-6 with a baseline A1C in this category.					

The following table shows the number of subjects that spent a specific range of time in specific glucose ranges during the study phase.

Table G-5: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase								
Time Range	Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated							
	≤ 50 mg/dL	≤ 60 mg/dL	≤ 70 mg/dL	70 to 180 mg/dL	> 180 mg/dL	> 250 mg/dL	>300 mg/dL	>350 mg/dL
0 to 15 mins	41 (89.1%)	17 (37.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	11 (23.9%)	28 (60.9%)
15 to 30 mins	4 (8.7%)	21 (45.7%)	8 (17.4%)	0 (0.0%)	0 (0.0%)	2 (4.3%)	5 (10.9%)	9 (19.6%)
30 to 45 mins	1 (2.2%)	5 (10.9%)	16 (34.8%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	7 (15.2%)	6 (13.0%)
45 mins to 1 hr	0 (0.0%)	2 (4.3%)	12 (26.1%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	6 (13.0%)	2 (4.3%)
1-4 hr	0 (0.0%)	1 (2.2%)	10 (21.7%)	0 (0.0%)	3 (6.5%)	34 (73.9%)	17 (37.0%)	1 (2.2%)

Table G-5: Number of Subjects that Spent a Certain Time Range in Each Glucose Range During the Study Phase								
Time Range	Number of Subjects (% of Subjects) in the Glucose Range (mg/dL) Indicated							
	≤ 50 mg/dL	≤ 60 mg/dL	≤ 70 mg/dL	70 to 180 mg/dL	> 180 mg/dL	> 250 mg/dL	>300 mg/dL	>350 mg/dL
4-8 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	18 (39.1%)	7 (15.2%)	0 (0.0%)	0 (0.0%)
8-12 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (6.5%)	22 (47.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
12-16 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	25 (54.3%)	3 (6.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
16-20 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	17 (37.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
20-24 hr	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Table G-6: Time Spent in Auto Mode at Different Glucose Ranges during the Study Phase	
Glucose Range (mg/dL)	Study Phase Time in Glucose Range (min) Mean±SD
≤ 50	6.2±5.4
≤ 60	18.1±11.4
≤ 70	42.4±19.8
70–180	805.1±139.8
>180	371.9±106.1
>250	107.7±56.5
>300 mg/dL	32.3±23.9
>350 mg/dL	7.7±7.5
All	1219.4±93.0

The pediatric pivotal clinical trial of the 670G suggested that the system was safe; however, this trial had a number of limitations which included the following:

- The study involved a relatively small number of patients.

- There was no control group for comparison purposes.

- The amount of time the system was used in the Manual mode was much shorter than the time it was programmed to the Auto mode.

- Additionally, for each subject, the study period lasted only three months.

Due to these limitations, the results of the clinical trial must be interpreted with caution and you should understand that your individual results when using the 670G system may be significantly different from those of the subjects who participated in the trial.

H. Guardian Sensor (3) Performance in users ages 2 through 6
CGM performance

The use of the Guardian Sensor (3) with the Guardian Link (3) transmitter enables CGM technology. The transmitter transmits sensor glucose values calculated by the real-time algorithm to a primary display device, allowing you to monitor your sensor glucose values.

Clinical study description

The performance of the Guardian Sensor (3) was evaluated in a clinical study.[11, 12] This in-patient (in-clinic) and outpatient (at home) study included subjects 2 to 6 years in age. The study design was a multi-center, prospective single sample correlational design without controls.

All subjects were assigned to treatment. Each subject was instructed to wear two Guardian™ Sensor (3) sensors in the abdomen and/or buttock.

1. One Guardian Sensor (3) connected to the Guardian Connect Transmitter, which transmitted to the Guardian Connect app, a standalone CGM display device.

2. One Guardian Sensor (3) connected to the Guardian Link (3) transmitter, which served as a glucose sensor recorder (GSR, transmitter/recorder for sensor integrated pump systems).

The sensor glucose data collected by the blinded GSRs were retrospectively processed through the real-time CGM algorithm. This is the same algorithm used in the Guardian™ Connect and pump CGM systems. Thus, all data is representative of real-time sensor usage.

The CONTOUR®NEXT LINK 2.4 Wireless Meter was the study meter used for all calibrations in this study, and was the only meter evaluated with the Guardian Sensor (3) CGM systems. The sensor has not been tested with other meters. Therefore, the performance with other blood glucose meters may differ from the performance with the CONTOUR NEXT LINK 2.4 Wireless Meter described below.

Subjects aged 2-6 years old were randomly assigned to which day to come in for the FST and their parents chose the area for sensor placement.

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11 Medtronic Inc., A Performance Evaluation of the Enlite® and Enlite 3 Glucose Sensor to Support Use in Children; Phase 2 (Enlite 3). 10542175DOC March 2016.

12 Medtronic Inc., Engineering Report: CEP249 (Analysis of Data From Subjects 2-6 Years of Age). 10901316DOC May 2019.

Frequent Sample Testing (FST) was performed on day 1, 3, or 7, for 6 hours each, over the life of the sensor. Reference blood glucose values were obtained every 5 to 30 minutes with a Blood Glucose Meter (BGM) for subjects for whom YSI testing was not believed to be appropriate due to the subject's size and age (all but two of the subjects in the 2-6 year old age group). Reference BG values were obtained every 5 to 15 minutes using a Yellow Springs Instrument (YSI®) Glucose Analyzer for the remaining two subjects in the 2-6 year old age group. During the FSTs, the subjects were instructed to calibrate the sensors once every 12 hours, or as requested by the display device. During home use (outside the clinic), subjects were instructed to calibrate both sensors three to four times spread throughout the day.

The overall number of subjects that participated in FST procedures on day 1, 3, or 7 were 6, 7, and 8, respectively. During the FST procedures, glucose challenges were limited to 30 minutes of exercise. Therefore, there were a limited number of glucose values in the high and low glucose ranges.

During the study, the meter was used for confirmation of alarms, treatment decisions and sensor calibrations.

Results

Sensor accuracy

The following information highlights the Guardian Sensor (3) performance from 21 subjects (2 to 6 years old) wearing the Guardian Link (3) Transmitter that served as a glucose sensor recorder (GSR, transmitter/recorder for sensor-integrated pump systems) and the Guardian Connect Transmitter, which transmitted to the Guardian Connect app (a standalone CGM display device) during FST.

Mean absolute relative difference, by number of daily calibrations

Table H-1 shows the sensor accuracy measured by the mean absolute relative difference (MARD). MARD represents the average relative difference (regardless if positive or negative) between the sensor glucose (SG) values and the paired blood glucose values measured by YSI (or BGM).

Table H-1: SG MARD Versus YSI or BGM (within YSI or BGM glucose ranges)								
YSI or BGM Glucose Ranges (mg/dL)	Abdomen Insertion Site				Buttock Insertion Site			
	Calibration every 12 hours		Calibration 3 or 4 times a day		Calibration every 12 hours		Calibration 3 or 4 times a day	
	Number of Paired SG-YSI or BGM	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI or BGM	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI or BGM	Mean Absolute Relative Difference (%)	Number of Paired SG-YSI or BGM	Mean Absolute Relative Difference (%)
Overall	62	10.7	62	10.96	195	10.1	159	10.05
40-60*	-	-	-	-	2	21.5	2	23
61-80*	1	7	1	7	12	14.76	12	11.51
81-180	26	10.12	26	10.12	99	10.72	78	11.54
181-300	30	11.9	30	11.98	73	7.09	60	6.03
301-350	5	6.73	5	9.46	8	6.63	7	7.5
351-400	-	-	-	-	1	7.71	-	-

*For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).

Note: SG Readings are within 40-400 mg/dL.

Note: For the blank cells (-), there are no paired points in this reference range.

Percent agreement, by number of daily calibrations

In Tables H-2 through H-9, the agreement of the SG values to paired YSI (or BGM) values were assessed by calculating the percentage of SG values that were within 15%, 20%, 30%, 40% and greater than 40% of the paired YSI (or BGM) values. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI (or BGM) values were calculated.

Results are shown for defined YSI (or BGM) ranges when calibrating every 12 hours and calibrating three or four times a day for sensors.

Table H-2: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration every 12 hours, Abdomen						
YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of SG Within 15/15% of YSI or BGM	Percent of SG Within 20/20% of YSI or BGM	Percent of SG Within 30/30% of YSI or BGM	Percent of SG Within 40/40% of YSI or BGM	Percent of SG >40/40% of YSI or BGM
Overall	62	72.6	85.5	96.8	100	0
≥40-60*	-	-	-	-	-	-
>60-80*	1	100	100	100	100	0
>80-180	26	80.8	88.5	96.2	100	0
>180-300	30	60	80	96.7	100	0
>300-350	5	100	100	100	100	0
>350-400	-	-	-	-	-	-

Table H-2: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration every 12 hours, Abdomen						
YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of SG Within 15/15% of YSI or BGM	Percent of SG Within 20/20% of YSI or BGM	Percent of SG Within 30/30% of YSI or BGM	Percent of SG Within 40/40% of YSI or BGM	Percent of SG >40/40% of YSI or BGM

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Note: For the blank cells (-), there are no paired points in this reference range.

Table H-3: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Day 1; Calibration every 12 hours, Abdomen						
YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of SG Within 15/15% of YSI or BGM	Percent of SG Within 20/20% of YSI or BGM	Percent of SG Within 30/30% of YSI or BGM	Percent of SG Within 40/40% of YSI or BGM	Percent of SG >40/40% of YSI or BGM
Overall	11	72.7	100	100	100	0
≥40-60*	-	-	-	-	-	-
>60-80*	-	-	-	-	-	-
>80-180	1	100	100	100	100	0
>180-300	10	70	100	100	100	0
>300-350	-	-	-	-	-	-
>350-400	-	-	-	-	-	-

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Note: For the blank cells (-), there are no paired points in this reference range.

Table H-4: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen						
YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of SG Within 15/15% of YSI or BGM	Percent of SG Within 20/20% of YSI or BGM	Percent of SG Within 30/30% of YSI or BGM	Percent of SG Within 40/40% of YSI or BGM	Percent of SG >40/40% of YSI or BGM
Overall	62	71	83.9	98.4	100	0
≥40-60*	-	-	-	-	-	-
>60-80*	1	100	100	100	100	0
>80-180	26	80.8	88.5	96.2	100	0
>180-300	30	60	80	100	100	0
>300-350	5	80	80	100	100	0
>350-400	-	-	-	-	-	-

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Note: For the blank cells (-), there are no paired points in this reference range.

Table H-5: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing Day 1; Calibration 3 or 4 times a day, Abdomen

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of SG Within 15/15% of YSI or BGM	Percent of SG Within 20/20% of YSI or BGM	Percent of SG Within 30/30% of YSI or BGM	Percent of SG Within 40/40% of YSI or BGM	Percent of SG >40/40% of YSI or BGM
Overall	11	72.7	100	100	100	0
>60-80*	-	-	-	-	-	-
>80-180	1	100	100	100	100	0
>180-300	10	70	100	100	100	0
>300-350	-	-	-	-	-	-
>350-400	-	-	-	-	-	-

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Note: For the blank cells (-), there are no paired points in this reference range.

Table H-6: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Days 1, 3, and 7; Calibration every 12 hours, Buttock

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of SG Within 15/15% of YSI or BGM	Percent of SG Within 20/20% of YSI or BGM	Percent of SG Within 30/30% of YSI or BGM	Percent of SG Within 40/40% of YSI or BGM	Percent of SG >40/40% of YSI or BGM
Overall	195	81.5	88.7	97.4	98.5	1.5
≥40-60*	2	50	50	50	100	0
>60-80*	12	75	83.3	91.7	91.7	8.3
>80-180	99	78.8	85.9	97	98	2
>180-300	73	84.9	93.2	100	100	0
>300-350	8	100	100	100	100	0
>350-400	1	100	100	100	100	0

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Table H-7: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing (FST) Day 1; Calibration every 12 hours, Buttock

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of SG Within 15/15% of YSI or BGM	Percent of SG Within 20/20% of YSI or BGM	Percent of SG Within 30/30% of YSI or BGM	Percent of SG Within 40/40% of YSI or BGM	Percent of SG >40/40% of YSI or BGM
Overall	93	71	83.9	96.8	97.8	2.2
≥40-60*	1	100	100	100	100	0
>60-80*	10	70	80	90	90	10
>80-180	46	63	78.3	95.7	97.8	2.2
>180-300	31	77.4	90.3	100	100	0
>300-350	4	100	100	100	100	0
>350-400	1	100	100	100	100	0

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of SG Within 15/15% of YSI or BGM	Percent of SG Within 20/20% of YSI or BGM	Percent of SG Within 30/30% of YSI or BGM	Percent of SG Within 40/40% of YSI or BGM	Percent of SG >40/40% of YSI or BGM
Overall	159	84.3	88.7	96.2	97.5	2.5
≥40-60*	2	50	50	50	50	50
>60-80*	12	75	91.7	100	100	0
>80-180	78	78.2	83.3	93.6	96.2	3.8
>180-300	60	93.3	95	100	100	0
>300-350	7	100	100	100	100	0
>350-400	-	-	-	-	-	-

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Note: For the blank cells (-), there are no paired points in this reference range.

Table H-9: Agreement (%) of SG-YSI (or BGM) paired points within YSI (or BGM) glucose ranges on Frequent Sample Testing Day 1; Calibration 3 or 4 times a day, Buttock

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of SG Within 15/15% of YSI or BGM	Percent of SG Within 20/20% of YSI or BGM	Percent of SG Within 30/30% of YSI or BGM	Percent of SG Within 40/40% of YSI or BGM	Percent of SG >40/40% of YSI or BGM
Overall	70	74.3	81.4	94.3	97.1	2.9
≥40-60*	1	100	100	100	100	0
>60-80*	10	80	90	100	100	0
>80-180	37	59.5	70.3	89.2	94.6	5.4
>180-300	19	94.7	94.7	100	100	0
>300-350	3	100	100	100	100	0
>350-400	-	-	-	-	-	-

*For glucose ranges ≤ 80 mg/dL, agreement was based on 15/20/30/40 mg/dL.

Note: Sensor glucose readings are within 40-400 mg/dL.

Note: For the blank cells (-), there are no paired points in this reference range.

Agreement when CGM reads "Below 40 mg/dL" or "Above 400 mg/dL"

The real-time CGM systems display glucose values between 40 mg/dL and 400 mg/dL. It displays "Below 40 mg/dL" when the SG value detected is below 40 mg/dL. It displays "Above 400 mg/dL" when the SG value detected is above 400 mg/dL. Tables H-10 through H-13 illustrate the number and percentage of the paired YSI (or BGM) values in different blood glucose levels when the CGM system displays "Below 40 mg/dL" (LOW) or "Above 400 mg/dL" (HIGH).

Table H-10: The number and percentage of YSI (or BGM) values collected when CGM displays 'Below 40 mg/dL' (LOW); Calibration every 12 hours.

CGM Display	Insertion Site	CGM-YSI or BGM pairs	YSI (or BGM) (mg/dL)					
			<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%

Table H-11: The number and percentage of YSI (or BGM) values collected when CGM displays 'Below 40 mg/dL' (LOW); Calibration 3 or 4 times a day.

CGM Display	Insertion Site	CGM-YSI or BGM pairs	YSI (or BGM) (mg/dL)					
			<55	<60	<70	<80	>80	Total
LOW	Abdomen	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%

Table H-12: The number and percentage of YSI (or BGM) values collected when CGM displays 'Above 400 mg/dL' (HIGH); Calibration every 12 hours.

CGM Display	Insertion Site	CGM-YSI or BGM pairs	YSI (or BGM) (mg/dL)					
			>340	>320	>280	>240	<240	Total
HIGH	Abdomen	Cumulative, n	0	0	1	1	0	1
		Cumulative %	0%	0%	100%	100%	0%	100%
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%

Table H-13. The number and percentage of YSI (or BGM) values collected when CGM displays 'Above 400 mg/dL' (HIGH); Calibration 3 or 4 times a day.

CGM Display	Insertion Site	CGM-YSI or BGM pairs	YSI (or BGM) (mg/dL)					
			>340	>320	>280	>240	<240	Total
HIGH	Abdomen	Cumulative, n	0	0	1	1	0	1
		Cumulative %	0%	0%	100%	100%	0%	100%
	Buttocks	Cumulative, n	0	0	0	0	0	0
		Cumulative %	0%	0%	0%	0%	0%	0%

Concurrence of SG and YSI or BGM values

The following tables show the percentage of concurring SG readings with FST reference values.

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
Table H-14: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Abdomen												
Percent of Matched Pairs-in Each SG Glucose Range for Each YSI (or BGM) Glucose Range												
						SG (mg/dL)						
B) ≥40-60	-	-	-	-	-	-	-	-	-	-	-	-
C) >60-80	1	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
D) >80-120	11	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	63.6% (7/11)	36.4% (4/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)
E) >120-160	10	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	20.0% (2/10)	60.0% (6/10)	20.0% (2/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)
F) >160-200	11	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	18.2% (2/11)	63.6% (7/11)	18.2% (2/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)
G) >200-250	6	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	16.7% (1/6)	0.0% (0/6)	33.3% (2/6)	50.0% (3/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)
H) >250-300	19	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	21.1% (4/19)	47.4% (9/19)	21.1% (4/19)	5.3% (1/19)	5.3% (1/19)
I) >300-350	5	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	20.0% (1/5)	80.0% (4/5)	0.0% (0/5)	0.0% (0/5)
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Note: For the blank cells (-), there are no paired points in this reference range.

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
Table H-15: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration every 12 hours, Abdomen												
Percent of Matched Pairs-in Each SG Glucose Range for Each YSI (or BGM) Glucose Range												
						SG (mg/dL)						
B) ≥40-60	-	-	-	-	-	-	-	-	-	-	-	-
C) >60-80	-	-	-	-	-	-	-	-	-	-	-	-
D) >80-120	-	-	-	-	-	-	-	-	-	-	-	-
E) >120-160	1	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
F) >160-200	4	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	50.0% (2/4)	50.0% (2/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)
G) >200-250	2	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	50.0% (1/2)	50.0% (1/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)
H) >250-300	4	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	75.0% (3/4)	25.0% (1/4)	0.0% (0/4)	0.0% (0/4)
I) >300-350	-	-	-	-	-	-	-	-	-	-	-	-

Table H-15: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration every 12 hours, Abdomen

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI (or BGM) Glucose Range										
		SG (mg/dL)										
		<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Note: For the blank cells (-), there are no paired points in this reference range.

Table H-16: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Abdomen

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI (or BGM) Glucose Range										
		SG (mg/dL)										
		<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	-	-	-	-	-	-	-	-	-	-	-	-
C) >60-80	1	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
D) >80-120	11	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	63.6% (7/11)	36.4% (4/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)
E) >120-160	10	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	20.0% (2/10)	60.0% (6/10)	20.0% (2/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)
F) >160-200	11	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	18.2% (2/11)	63.6% (7/11)	18.2% (2/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)
G) >200-250	6	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)	16.7% (1/6)	0.0% (0/6)	33.3% (2/6)	50.0% (3/6)	0.0% (0/6)	0.0% (0/6)	0.0% (0/6)
H) >250-300	19	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	26.3% (5/19)	42.1% (8/19)	21.1% (4/19)	5.3% (1/19)	5.3% (1/19)
I) >300-350	5	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	0.0% (0/5)	20.0% (1/5)	20.0% (1/5)	60.0% (3/5)	0.0% (0/5)	0.0% (0/5)
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Note: For the blank cells (-), there are no paired points in this reference range.

Table H-17: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	Percent of Matched Pairs-in Each SG Glucose Range for Each YSI (or BGM) Glucose Range										
		SG (mg/dL)										
		<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
C) >60-80	-	-	-	-	-	-	-	-	-	-	-	-
D) >80-120	-	-	-	-	-	-	-	-	-	-	-	-

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	SG (mg/dL) <40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
E) >120-160	1	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
F) >160-200	4	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	50.0% (2/4)	50.0% (2/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)
G) >200-250	2	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	50.0% (1/2)	50.0% (1/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)
H) >250-300	4	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	75.0% (3/4)	25.0% (1/4)	0.0% (0/4)	0.0% (0/4)
I) >300-350	-	-	-	-	-	-	-	-	-	-	-	-
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Table H-17: Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration 3 or 4 times a day, Abdomen

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI (or BGM) Glucose Range

Note: For the blank cells (-), there are no paired points in this reference range.

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	SG (mg/dL) <40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	2	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)
C) >60-80	12	0.0% (0/12)	25.0% (3/12)	33.3% (4/12)	41.7% (5/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)
D) >80-120	31	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	87.1% (27/31)	12.9% (4/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)
E) >120-160	45	0.0% (0/45)	0.0% (0/45)	0.0% (0/45)	17.8% (8/45)	60.0% (27/45)	22.2% (10/45)	0.0% (0/45)	0.0% (0/45)	0.0% (0/45)	0.0% (0/45)	0.0% (0/45)
F) >160-200	41	0.0% (0/41)	0.0% (0/41)	0.0% (0/41)	0.0% (0/41)	17.1% (7/41)	65.9% (27/41)	17.1% (7/41)	0.0% (0/41)	0.0% (0/41)	0.0% (0/41)	0.0% (0/41)
G) >200-250	31	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)	16.1% (5/31)	77.4% (24/31)	6.5% (2/31)	0.0% (0/31)	0.0% (0/31)	0.0% (0/31)
H) >250-300	24	0.0% (0/24)	0.0% (0/24)	0.0% (0/24)	0.0% (0/24)	0.0% (0/24)	4.2% (1/24)	16.7% (4/24)	70.8% (17/24)	8.3% (2/24)	0.0% (0/24)	0.0% (0/24)
I) >300-350	8	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	62.5% (5/8)	25.0% (2/8)	12.5% (1/8)	0.0% (0/8)
J) >350-400	1	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)

Table H-18. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Days 1, 3, and 7; Calibration every 12 hours, Buttock

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI (or BGM) Glucose Range

Table H-19. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration every 12 hours, Buttock

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI (or BGM) Glucose Range

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	SG (mg/dL)										
		<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	1	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
C) >60-80	10	0.0% (0/10)	30.0% (3/10)	40.0% (4/10)	30.0% (3/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)
D) >80-120	14	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	78.6% (11/14)	21.4% (3/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)	0.0% (0/14)
E) >120-160	21	0.0% (0/21)	0.0% (0/21)	0.0% (0/21)	14.3% (3/21)	47.6% (10/21)	38.1% (8/21)	0.0% (0/21)	0.0% (0/21)	0.0% (0/21)	0.0% (0/21)	0.0% (0/21)
F) >160-200	19	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	31.6% (6/19)	47.4% (9/19)	21.1% (4/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)
G) >200-250	11	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)	18.2% (2/11)	72.7% (8/11)	9.1% (1/11)	0.0% (0/11)	0.0% (0/11)	0.0% (0/11)
H) >250-300	12	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	8.3% (1/12)	16.7% (2/12)	58.3% (7/12)	16.7% (2/12)	0.0% (0/12)	0.0% (0/12)
I) >300-350	4	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	50.0% (2/4)	25.0% (1/4)	25.0% (1/4)	0.0% (0/4)
J) >350-400	1	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)

Table H-20. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI or BGM Glucose Range

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	SG (mg/dL)										
		<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	2	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)	0.0% (0/2)
C) >60-80	12	0.0% (0/12)	25.0% (3/12)	33.3% (4/12)	41.7% (5/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)	0.0% (0/12)
D) >80-120	23	0.0% (0/23)	0.0% (0/23)	8.7% (2/23)	73.9% (17/23)	13.0% (3/23)	4.3% (1/23)	0.0% (0/23)	0.0% (0/23)	0.0% (0/23)	0.0% (0/23)	0.0% (0/23)
E) >120-160	36	0.0% (0/36)	0.0% (0/36)	0.0% (0/36)	11.1% (4/36)	61.1% (22/36)	27.8% (10/36)	0.0% (0/36)	0.0% (0/36)	0.0% (0/36)	0.0% (0/36)	0.0% (0/36)
F) >160-200	33	0.0% (0/33)	0.0% (0/33)	0.0% (0/33)	0.0% (0/33)	6.1% (2/33)	72.7% (24/33)	18.2% (6/33)	3.0% (1/33)	0.0% (0/33)	0.0% (0/33)	0.0% (0/33)
G) >200-250	27	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)	18.5% (5/27)	70.4% (19/27)	11.1% (3/27)	0.0% (0/27)	0.0% (0/27)	0.0% (0/27)
H) >250-300	19	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	0.0% (0/19)	10.5% (2/19)	78.9% (15/19)	10.5% (2/19)	0.0% (0/19)	0.0% (0/19)

Table H-20. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Days 1, 3, and 7; Calibration 3 or 4 times a day, Buttock

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI or BGM Glucose Range

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	SG (mg/dL)										
		<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
I) >300-350	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	71.4% (5/7)	14.3% (1/7)	14.3% (1/7)	0.0% (0/7)
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Note: For the blank cells (-), there are no paired points in this reference range.

Table H-21. Overall concurrence of YSI (or BGM) values and SG readings using YSI (or BGM) ranges on FST Day 1; Calibration 3 or 4 times a day, Buttock

Percent of Matched Pairs-in Each SG Glucose Range for Each YSI (or BGM) Glucose Range

YSI or BGM Glucose Ranges (mg/dL)	Number of Paired SG-YSI or BGM	SG (mg/dL)										
		<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	1	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
C) >60-80	10	0.0% (0/10)	30.0% (3/10)	40.0% (4/10)	30.0% (3/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)	0.0% (0/10)
D) >80-120	13	0.0% (0/13)	0.0% (0/13)	7.7% (1/13)	69.2% (9/13)	15.4% (2/13)	7.7% (1/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)
E) >120-160	16	0.0% (0/16)	0.0% (0/16)	0.0% (0/16)	6.3% (1/16)	50.0% (8/16)	43.8% (7/16)	0.0% (0/16)	0.0% (0/16)	0.0% (0/16)	0.0% (0/16)	0.0% (0/16)
F) >160-200	13	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	69.2% (9/13)	23.1% (3/13)	7.7% (1/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)
G) >200-250	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	14.3% (1/7)	71.4% (5/7)	14.3% (1/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)
H) >250-300	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	71.4% (5/7)	28.6% (2/7)	0.0% (0/7)	0.0% (0/7)
I) >300-350	3	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	66.7% (2/3)	0.0% (0/3)	33.3% (1/3)	0.0% (0/3)
J) >350-400	-	-	-	-	-	-	-	-	-	-	-	-

Note: For the blank cells (-), there are no paired points in this reference range.

Percent Agreement Post Calibration

The agreement of the SG values to paired YSI (or BGM) values was assessed for every 2-hour period post sensor calibration. For readings less than or equal to 80 mg/dL, the absolute difference in mg/dL between the SG and paired YSI (or BGM) values was calculated.

Tables H-22 through H-25 show the percent agreement rates post calibration for sensors inserted into the abdomen and buttock.

Table H-22. Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Abdomen						
Time after calibration	No. paired YSI or BGM-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0-2 hours	20	65	85	100	100	0
2-4 hours	16	68.8	93.8	100	100	0
4-6 hours	11	90.9	90.9	100	100	0
6-8 hours	8	62.5	62.5	87.5	100	0
8–10 hours	6	100	100	100	100	0
10-12 hours	1	0	0	0	100	0

Table H-23. Agreement rates for every 2-hour period post calibration period; Calibration 3 or 4 times a day, Abdomen						
Time after calibration	No. paired YSI or BGM-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0-2 hours	24	62.5	79.2	100	100	0
2-4 hours	13	61.5	92.3	100	100	0
4-6 hours	11	90.9	90.9	100	100	0
6-8 hours	8	62.5	62.5	87.5	100	0
8–10 hours	6	100	100	100	100	0
10-12 hours	-	-	-	-	-	-

Note: For the blank cells (-), there are no paired points in this reference range.

Table H-24. Agreement rates for every 2-hour period post calibration period; Calibration every 12 hours, Buttock						
Time after calibration	No. paired YSI or BGM-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0-2 hours	64	85.9	92.2	98.4	100	0
2-4 hours	60	78.3	86.7	95	96.7	3.3
4-6 hours	52	75	84.6	98.1	98.1	1.9
6-8 hours	11	90.9	90.9	100	100	0
8–10 hours	4	100	100	100	100	0
10-12 hours	4	100	100	100	100	0

Table H-25. Agreement rates for every 2-hour period post calibration period; Calibration 3 or 4 times a day, Buttock						
Time after calibration	No. paired YSI or BGM-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
0-2 hours	84	86.9	90.5	97.6	98.8	1.2
2-4 hours	46	87	91.3	93.5	93.5	6.5
4-6 hours	22	63.6	72.7	95.5	100	0

Table H-25. Agreement rates for every 2-hour period post calibration period; Calibration 3 or 4 times a day, Buttock						
Time after calibration	No. paired YSI or BGM-sensor points	Percentage (%) Agreement				
		± 15% (± 15 mg/dL)	± 20% (± 20 mg/dL)	± 30% (± 30 mg/dL)	± 40% (± 40 mg/dL)	> ±40% (± 40 mg/dL)
6-8 hours	5	100	100	100	100	0
8–10 hours	2	100	100	100	100	0
10-12 hours	-	-	-	-	-	-
Note: For the blank cells (-), there are no paired points in this reference range.						

Trend Accuracy

Tables H-26 through H-29 show, for each SG rate-of-change range, percentage of SG-YSI (or BGM) paired values that fell into different YSI (or BGM) rate-of-change ranges. The tables show the trend accuracy for sensors inserted into the abdomen or buttock.

Table H-26. Trend Accuracy; Calibration every 12 hours, Abdomen							
Percent of Matched Pairs-in Each YSI (or BGM) Rate Range for Each SG Rate Range							
SG Rate Ranges (mg/dL/min)	Number of Paired SG-YSI or BGM	YSI (or BGM) (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	2	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	0.0% (0/2)
[-2, -1]	7	14.3% (1/7)	57.1% (4/7)	0.0% (0/7)	28.6% (2/7)	0.0% (0/7)	0.0% (0/7)
[-1, 0]	6	0.0% (0/6)	33.3% (2/6)	50.0% (3/6)	16.7% (1/6)	0.0% (0/6)	0.0% (0/6)
[0, 1]	7	0.0% (0/7)	14.3% (1/7)	14.3% (1/7)	57.1% (4/7)	0.0% (0/7)	14.3% (1/7)
[1, 2]	5	0.0% (0/5)	0.0% (0/5)	60.0% (3/5)	20.0% (1/5)	20.0% (1/5)	0.0% (0/5)
>2	3	0.0% (0/3)	0.0% (0/3)	33.3% (1/3)	33.3% (1/3)	0.0% (0/3)	33.3% (1/3)

Table H-27. Trend Accuracy; Calibration 3 or 4 times a day, Abdomen							
Percent of Matched Pairs-in Each YSI (or BGM) Rate Range for Each SG Rate Range							
SG Rate Ranges (mg/dL/min)	Number of Paired SG-YSI or BGM	YSI (or BGM) (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	2	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	50.0% (1/2)	0.0% (0/2)	0.0% (0/2)
[-2, -1]	7	14.3% (1/7)	57.1% (4/7)	0.0% (0/7)	28.6% (2/7)	0.0% (0/7)	0.0% (0/7)
[-1, 0]	6	0.0% (0/6)	33.3% (2/6)	50.0% (3/6)	16.7% (1/6)	0.0% (0/6)	0.0% (0/6)
[0, 1]	8	0.0% (0/8)	12.5% (1/8)	25.0% (2/8)	50.0% (4/8)	0.0% (0/8)	12.5% (1/8)
[1, 2]	4	0.0% (0/4)	0.0% (0/4)	50.0% (2/4)	25.0% (1/4)	25.0% (1/4)	0.0% (0/4)
>2	3	0.0% (0/3)	0.0% (0/3)	33.3% (1/3)	33.3% (1/3)	0.0% (0/3)	33.3% (1/3)

Table H-28. Trend Accuracy; Calibration every 12 hours, Buttock							
Percent of Matched Pairs-in Each YSI (or BGM) Rate Range for Each SG Rate Range							
SG Rate Ranges (mg/dL/min)	Number of Paired SG-YSI or BGM	YSI (or BGM) (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	3	66.7% (2/3)	33.3% (1/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
[-2, -1]	8	0.0% (0/8)	62.5% (5/8)	12.5% (1/8)	12.5% (1/8)	12.5% (1/8)	0.0% (0/8)
[-1, 0]	13	0.0% (0/13)	7.7% (1/13)	30.8% (4/13)	30.8% (4/13)	23.1% (3/13)	7.7% (1/13)
[0, 1]	6	0.0% (0/6)	16.7% (1/6)	16.7% (1/6)	16.7% (1/6)	50.0% (3/6)	0.0% (0/6)
[1, 2]	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	42.9% (3/7)	57.1% (4/7)	0.0% (0/7)
>2	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	42.9% (3/7)	57.1% (4/7)

Table H-29. Trend Accuracy; Calibration 3 or 4 times a day, Buttock							
Percent of Matched Pairs-in Each YSI (or BGM) Rate Range for Each SG Rate Range							
SG Rate Ranges (mg/dL/min)	Number of Paired SG-YSI or BGM	YSI (or BGM) (mg/dL/min)					
		<-2	[-2, -1]	[-1, 0]	[0, 1]	[1, 2]	>2
<-2	3	66.7% (2/3)	33.3% (1/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
[-2, -1)	8	0.0% (0/8)	62.5% (5/8)	12.5% (1/8)	12.5% (1/8)	12.5% (1/8)	0.0% (0/8)
[-1, 0)	13	0.0% (0/13)	7.7% (1/13)	38.5% (5/13)	30.8% (4/13)	15.4% (2/13)	7.7% (1/13)
[0, 1]	6	0.0% (0/6)	16.7% (1/6)	0.0% (0/6)	16.7% (1/6)	66.7% (4/6)	0.0% (0/6)
(1, 2]	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	42.9% (3/7)	57.1% (4/7)	0.0% (0/7)
>2	7	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	0.0% (0/7)	42.9% (3/7)	57.1% (4/7)

Precision

Precision of the System was evaluated by comparing the results from two separate sensors worn on the same subject at the same time.

Data from two sensors worn at the same time for 2 subjects, both inserted in the abdomen, provided 124 pairs of CGM Measurements, with a mean Percent Absolute Relative Difference (PARD) during the study of 10.29% and a coefficient of variation (%CV) of 7.6%.

Data from two sensors worn at the same time for 2 subjects, one inserted in the abdomen and one in the buttock, provided 108 pairs of CGM Measurements, with a mean Percent Absolute Relative Difference (PARD) during the study of 6.98% and a coefficient of variation (%CV) of 4.7%.

Data from two sensors worn at the same time for 11 subjects, both inserted in the buttock, provided 754 pairs of CGM Measurements, with a mean PARD during the study of 5.98% and a coefficient of variation (%CV) 4.2%.

Sensor life

After the first successful calibration, 50% of sensors worn in the abdomen operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the abdomen insertion site over the course of the study was 142.1 hours, with a median functional life of 163.2 hours.

After the first successful calibration, 72.2% of sensors worn in the buttock operated more than six days and up to the full seven days of wear (144 to 168 hours). The mean functional sensor life for sensors worn in the buttock insertion site over the course of the study was 146.4 hours, with a median functional life of 166.8 hours.

Safety

There were no moderate or severe device-related or procedure-related adverse events, device- related or procedure-related serious adverse events, or unanticipated adverse device effects through seven days of use.

I. Alert performance for users ages 2 through 6

CGM enables your device to display sensor glucose readings, glucose trend arrows, glucose trend graphs, and sensor glucose alerts (for example, High and Low Limit Threshold alerts, High and Low Predictive alerts, and Rise and Fall rate-of-change alerts).

The high and low limit alerts (**Threshold alerts**) let the user know when the sensor glucose is at or above the high limit or at or below the low limit. Using only a high or low limit alert may reduce the number of false alerts, but does not provide a warning before reaching a high or low limit.

Predictive alerts notify users that their sensor glucose level may soon reach a high or low limit setting. Users may select how early they would like to be notified before their sensor glucose level reaches a high limit setting. The earliest warning is 30 minutes before reaching a high, but users can reduce the amount of warning time down to 5 minutes. Users will receive a warning approximately 30 minutes prior to when their sensor glucose level is predicted to reach their low limit setting. In general, the earlier the warning, the more time a user will have to react to a potential high or low, but this also increases the potential for false alerts.

A predictive alert is simply an estimation of a future sensor glucose level compared to the high or low limit setting. If the predicted sensor glucose value is above the high limit or below the low limit, then a predictive alert is sounded even though

the current sensor glucose level has not crossed the high or low limit. The predicted sensor glucose level is calculated using the current sensor glucose level, the derivative of previous sensor glucose readings (the trend or slope of the sensor glucose readings) and the amount of early warning duration the user selects.

The device will always alert the user when the CGM reads that the user is below 50 mg/dL, regardless of the high/low threshold and/or predictive alerts that the user sets.

Glucose TRUE Alert Rate

The glucose true alert rate is the rate at which the blood glucose confirmed that the CGM alert was triggered correctly. For example:

True Threshold Hypoglycemic alert rate alerted when the CGM read that the user was below the low threshold and the user's blood glucose was actually below that low threshold.

True Threshold Hyperglycemic alert rate alerted when the CGM read that the user was above the high threshold and the user's blood glucose was actually above that high threshold.

True Predictive Hypoglycemic alert rate alerted when the CGM predicted that the user would reach below the low threshold and the user's blood glucose was actually below that low threshold within 15 or 30 minutes.

True Predictive Hyperglycemic alert rate alerted when the CGM predicted that the user would reach above the high threshold and the user's blood glucose was actually above that high threshold within 15 or 30 min.

The true alert rate is important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high true alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, when wearing the sensor in the Buttocks, the low glucose alerts would have correctly indicated that the user was below (i.e. threshold only), or predicted to reach below the threshold (i.e. predictive only) or both (predictive and threshold) 100%, 40%, or 57.1 % of the time within 30 minutes (or 100%, 40% or 57.1% of the time within 15 minutes) when the user had blood glucose values lower than 70 mg/dL.

		Glucose TRUE Alert Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
mg/dL	Insertion Site	30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	-	-	-	-	-	-
	Buttock	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/2)	0.0% (0/2)
60	Abdomen	-	-	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)
	Buttock	100.0% (1/1)	100.0% (1/1)	25.0% (1/4)	25.0% (1/4)	40.0% (2/5)	40.0% (2/5)
70	Abdomen	0.0% (0/1)	0.0% (0/1)	0.0% (0/4)	0.0% (0/4)	0.0% (0/5)	0.0% (0/5)
	Buttock	100.0% (2/2)	100.0% (2/2)	40.0% (2/5)	40.0% (2/5)	57.1% (4/7)	57.1% (4/7)
80	Abdomen	25.0% (1/4)	25.0% (1/4)	16.7% (1/6)	0.0% (0/6)	20.0% (2/10)	10.0% (1/10)
	Buttock	40.0% (2/5)	40.0% (2/5)	33.3% (3/9)	22.2% (2/9)	35.7% (5/14)	28.6% (4/14)
90	Abdomen	50.0% (2/4)	50.0% (2/4)	50.0% (3/6)	33.3% (2/6)	50.0% (5/10)	40.0% (4/10)
	Buttock	100.0% (8/8)	100.0% (8/8)	81.8% (9/11)	63.6% (7/11)	88.9% (16/18)	77.8% (14/18)
180	Abdomen	100.0% (7/7)	100.0% (7/7)	80.0% (8/10)	70.0% (7/10)	85.7% (12/14)	78.6% (11/14)
	Buttock	89.7% (26/29)	89.7% (26/29)	84.8% (28/33)	81.8% (27/33)	85.7% (48/56)	83.9% (47/56)
220	Abdomen	100.0% (4/4)	100.0% (4/4)	50.0% (5/10)	50.0% (5/10)	61.5% (8/13)	61.5% (8/13)
	Buttock	90.0% (18/20)	85.0% (17/20)	62.1% (18/29)	55.2% (16/29)	70.5% (31/44)	63.6% (28/44)
250	Abdomen	100.0% (5/5)	100.0% (5/5)	83.3% (5/6)	83.3% (5/6)	90.9% (10/11)	90.9% (10/11)
	Buttock	80.0% (12/15)	73.3% (11/15)	65.2% (15/23)	56.5% (13/23)	70.3% (26/37)	62.2% (23/37)
300	Abdomen	60.0% (3/5)	60.0% (3/5)	40.0% (2/5)	40.0% (2/5)	50.0% (5/10)	50.0% (5/10)
	Buttock	66.7% (4/6)	66.7% (4/6)	35.0% (7/20)	30.0% (6/20)	42.3% (11/26)	38.5% (10/26)

Table I-1. Glucose TRUE Alert Performance using Calibration every 12 hours

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Note: For the blank cells (-), there are no evaluable events in this reference range.

Glucose FALSE Alert Rate

The glucose false alert rate is the rate at which the blood glucose did not confirm that the CGM alert was triggered correctly. For example:

False Threshold Hypoglycemic alert rate alerted when the CGM read that the user was below the low threshold but the users blood glucose was actually above that low threshold.

False Threshold Hyperglycemic alert rate alerted when the CGM read that the user was above the high threshold but the user's blood glucose was actually below that high threshold.

False Predictive Hypoglycemic alert rate alerted when the CGM predicted that the user would be below the low threshold but the user's blood glucose was actually above that low threshold within 15 or 30 minutes.

False Predictive Hyperglycemic alert rate alerted when the CGM predicted that the user would be above the high threshold but the user's blood glucose was actually below the high threshold within 15 or 30 minutes.

The false alert rate is important because it is necessary that users be correctly notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A low false alert rate indicates that when the CGM says that their glucose values are, or will reach a specified threshold, the user's blood glucose is likely to be at or approaching that threshold.

For example, per the following table, when wearing the sensor in the buttock, the high glucose threshold alerts would have incorrectly indicated that the user was above (i.e. threshold only), or predicted to reach above the threshold (i.e. predictive only), or both (threshold and predictive) 10.3%, 15.2% or 14.3% of the time within 30 minutes (or 10.3%, 18.2%, or 16.1% of the time within 15 minutes) when the user had blood glucose less than 180 mg/dL.

Table I-2. Glucose FALSE Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose FALSE Alert Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	-	-	-	-	-	-
	Buttock	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (2/2)	100.0% (2/2)
60	Abdomen	-	-	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
	Buttock	0.0% (0/1)	0.0% (0/1)	75.0% (3/4)	75.0% (3/4)	60.0% (3/5)	60.0% (3/5)
70	Abdomen	100.0% (1/1)	100.0% (1/1)	100.0% (4/4)	100.0% (4/4)	100.0% (5/5)	100.0% (5/5)
	Buttock	0.0% (0/2)	0.0% (0/2)	60.0% (3/5)	60.0% (3/5)	42.9% (3/7)	42.9% (3/7)
80	Abdomen	75.0% (3/4)	75.0% (3/4)	83.3% (5/6)	100.0% (6/6)	80.0% (8/10)	90.0% (9/10)
	Buttock	60.0% (3/5)	60.0% (3/5)	66.7% (6/9)	77.8% (7/9)	64.3% (9/14)	71.4% (10/14)
90	Abdomen	50.0% (2/4)	50.0% (2/4)	50.0% (3/6)	66.7% (4/6)	50.0% (5/10)	60.0% (6/10)
	Buttock	0.0% (0/8)	0.0% (0/8)	18.2% (2/11)	36.4% (4/11)	11.1% (2/18)	22.2% (4/18)
180	Abdomen	0.0% (0/7)	0.0% (0/7)	20.0% (2/10)	30.0% (3/10)	14.3% (2/14)	21.4% (3/14)
	Buttock	10.3% (3/29)	10.3% (3/29)	15.2% (5/33)	18.2% (6/33)	14.3% (8/56)	16.1% (9/56)
220	Abdomen	0.0% (0/4)	0.0% (0/4)	50.0% (5/10)	50.0% (5/10)	38.5% (5/13)	38.5% (5/13)
	Buttock	10.0% (2/20)	15.0% (3/20)	37.9% (11/29)	44.8% (13/29)	29.5% (13/44)	36.4% (16/44)
250	Abdomen	0.0% (0/5)	0.0% (0/5)	16.7% (1/6)	16.7% (1/6)	9.1% (1/11)	9.1% (1/11)
	Buttock	20.0% (3/15)	26.7% (4/15)	34.8% (8/23)	43.5% (10/23)	29.7% (11/37)	37.8% (14/37)
300	Abdomen	40.0% (2/5)	40.0% (2/5)	60.0% (3/5)	60.0% (3/5)	50.0% (5/10)	50.0% (5/10)
	Buttock	33.3% (2/6)	33.3% (2/6)	65.0% (13/20)	70.0% (14/20)	57.7% (15/26)	61.5% (16/26)

Table I-2. Glucose FALSE Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose FALSE Alert Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.							
Note: For the blank cells (-), there are no evaluable events in this reference range.							

Glucose Correct Detection Rate

Glucose Correct Detection Rate is the rate that the device alerted when it should have alerted. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device sounded an alert.

Glucose detection rates are important because it is necessary that users be notified when their blood glucose is low (or high) so that they can correct the low (or high) blood glucose. A high glucose correct detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose is low or high.

For example, per the following table, when wearing the sensor in the buttock, the threshold alert, the predictive alert, or both (threshold and predictive) notified the user 50.0%, 50.0% or 50.0% of the time within 30 minutes (or 50.0%, 50.0% or 50.0% within 15 minutes) when the user had blood glucose less than 60 mg/dL.

Table I-3. Glucose Correct Detection Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose Correct Detection Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	-	-	-	-	-	-
	Buttock	-	-	-	-	-	-
60	Abdomen	-	-	-	-	-	-
	Buttock	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)
70	Abdomen	-	-	-	-	-	-
	Buttock	66.7% (2/3)	66.7% (2/3)	66.7% (2/3)	66.7% (2/3)	66.7% (2/3)	66.7% (2/3)
80	Abdomen	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)	100.0% (1/1)
	Buttock	40.0% (2/5)	40.0% (2/5)	60.0% (3/5)	40.0% (2/5)	60.0% (3/5)	40.0% (2/5)
90	Abdomen	66.7% (2/3)	66.7% (2/3)	100.0% (3/3)	66.7% (2/3)	100.0% (3/3)	100.0% (3/3)
	Buttock	80.0% (8/10)	80.0% (8/10)	90.0% (9/10)	60.0% (6/10)	90.0% (9/10)	80.0% (8/10)
180	Abdomen	84.6% (11/13)	84.6% (11/13)	92.3% (12/13)	84.6% (11/13)	92.3% (12/13)	84.6% (11/13)
	Buttock	100.0% (58/58)	98.3% (57/58)	100.0% (58/58)	91.4% (53/58)	100.0% (58/58)	100.0% (58/58)

Table I-3. Glucose Correct Detection Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose Correct Detection Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
220	Abdomen	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	87.5% (7/8)	100.0% (8/8)	100.0% (8/8)
	Buttock	91.7% (33/36)	86.1% (31/36)	97.2% (35/36)	86.1% (31/36)	100.0% (36/36)	94.4% (34/36)
250	Abdomen	100.0% (8/8)	100.0% (8/8)	100.0% (8/8)	87.5% (7/8)	100.0% (8/8)	100.0% (8/8)
	Buttock	84.0% (21/25)	84.0% (21/25)	96.0% (24/25)	84.0% (21/25)	96.0% (24/25)	88.0% (22/25)
300	Abdomen	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	75.0% (3/4)	100.0% (4/4)	100.0% (4/4)
	Buttock	62.5% (5/8)	62.5% (5/8)	100.0% (8/8)	87.5% (7/8)	100.0% (8/8)	100.0% (8/8)

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Note: For the blank cells (-), there are no evaluable events in this reference range.

Glucose Missed Detection Rate

The Missed Detection Rate is the rate that the device did not alert when it should have. For example, the blood glucose was below the hypoglycemic threshold, or above the hyperglycemic threshold, and the device did not sound a threshold or predictive alert.

Missed detection rates are important because it is necessary that users be notified when their blood glucose is low (or high), so that they can correct the low (or high) blood glucose. A low missed detection rate indicates that users can have confidence that they will be notified by the device if their blood glucose is low or high.

For example, per the following table, when wearing the sensor in the buttocks, the threshold alert, predictive alert, or both alert (threshold and predictive) did not sound 50.0%, 50.0% or 50.0% of the time within 30 minutes (or 50.0%, 50.0% or 50.0% within 15 minutes) when the user had blood glucose less than 60 mg/dL.

Table I-4. Glucose Missed Detection Alert Performance using Calibration every 12 hours							
mg/dL	Insertion Site	Glucose Missed Detection Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
50	Abdomen	-	-	-	-	-	-
	Buttock	-	-	-	-	-	-
60	Abdomen	-	-	-	-	-	-
	Buttock	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)	50.0% (1/2)
70	Abdomen	-	-	-	-	-	-
	Buttock	33.3% (1/3)	33.3% (1/3)	33.3% (1/3)	33.3% (1/3)	33.3% (1/3)	33.3% (1/3)

mg/dL	Insertion Site	Glucose Missed Detection Rate					
		Threshold Only		Predictive Only		Threshold & Predictive	
		30 min	15 min	30 min	15 min	30 min	15 min
80	Abdomen	0.0% (0/1)	0.0% (0/1)	0.0% (0/1)	100.0% (1/1)	0.0% (0/1)	0.0% (0/1)
	Buttock	60.0% (3/5)	60.0% (3/5)	40.0% (2/5)	60.0% (3/5)	40.0% (2/5)	60.0% (3/5)
90	Abdomen	33.3% (1/3)	33.3% (1/3)	0.0% (0/3)	33.3% (1/3)	0.0% (0/3)	0.0% (0/3)
	Buttock	20.0% (2/10)	20.0% (2/10)	10.0% (1/10)	40.0% (4/10)	10.0% (1/10)	20.0% (2/10)
180	Abdomen	15.4% (2/13)	15.4% (2/13)	7.7% (1/13)	15.4% (2/13)	7.7% (1/13)	15.4% (2/13)
	Buttock	0.0% (0/58)	1.7% (1/58)	0.0% (0/58)	8.6% (5/58)	0.0% (0/58)	0.0% (0/58)
220	Abdomen	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	12.5% (1/8)	0.0% (0/8)	0.0% (0/8)
	Buttock	8.3% (3/36)	13.9% (5/36)	2.8% (1/36)	13.9% (5/36)	0.0% (0/36)	5.6% (2/36)
250	Abdomen	0.0% (0/8)	0.0% (0/8)	0.0% (0/8)	12.5% (1/8)	0.0% (0/8)	0.0% (0/8)
	Buttock	16.0% (4/25)	16.0% (4/25)	4.0% (1/25)	16.0% (4/25)	4.0% (1/25)	12.0% (3/25)
300	Abdomen	0.0% (0/4)	0.0% (0/4)	0.0% (0/4)	25.0% (1/4)	0.0% (0/4)	0.0% (0/4)
	Buttock	37.5% (3/8)	37.5% (3/8)	0.0% (0/8)	12.5% (1/8)	0.0% (0/8)	0.0% (0/8)

Table I-4. Glucose Missed Detection Alert Performance using Calibration every 12 hours

Note: Given the small sample size of data available in the low range, the alert performance in the 50 mg/dL and 60 mg/dL should be interpreted with caution and may not reflect actual use performance.

Note: For the blank cells (-), there are no evaluable events in this reference range.

Appendix A: Open Source Software disclosure

Open Source Software disclosure

Open Source Software disclosure

This document identifies the Open Source Software that may be separately called, executed, linked, affiliated, or otherwise utilized by this product.

Such Open Source Software is licensed to users subject to the terms and conditions of the separate software license agreement for such Open Source Software.

Use of the Open Source Software by you shall be governed entirely by the terms and conditions of such license.

The source and object code, and applicable license for any Open Source Software can be obtained at the following site(s):

- LZ4–compression library (v1.9.1): http://www.lz4.org
- SWIG (v3.0.12): http://www.swig.org
- FNV-1 hash algorithm (v5.1): http://www.isthe.com/chongo/tech/comp/fnv/ and http://www.isthe.com/chongo/src/fnv/fnv64.c
- CRC32 algorithm: https://opensource.apple.com/source/xnu/xnu-792.13.8/bsd/libkern/crc32.c

Glossary

active insulin	Bolus insulin that has been delivered by the pump and is still working to lower your BG levels.
active insulin adjustment	The amount of insulin that is subtracted from your BG correction bolus to account for the active insulin that is tracked by the Bolus Wizard feature.
Active Insulin Time	A Bolus Wizard setting that lets you set the length of time that bolus insulin is tracked as active insulin.
Activity Guard	An attachment that can be used to ensure that the reservoir stays secure during activity, or when the pump is worn by a child.
alarm	An audible beep or vibration with a message to inform you that the pump is no longer delivering insulin. Alarms require immediate action.
Alarm History	A feature that stores information about recent alarms and alerts.
alert	An audible beep or vibration with a message to inform you of a situation that may require your attention.
Alert before high	An alert that occurs when you are approaching your high limit.
Alert before low	An alert that occurs when you are approaching your low SG value.
Alert Limits	The values that you set to determine when low and high glucose alerts are triggered.

Alert on high	An alert that occurs when your SG value reaches or rises above your high limit.
Alert on low	An alert that occurs when your SG value reaches or falls below your low limit.
Auto Basal	The automatically adjusted basal insulin delivered by Auto Mode based on your SG values.
Auto Mode	Auto Mode is an insulin delivery feature that automatically controls basal insulin delivery to regulate BG levels to a target SG value.
Auto Mode Bolus feature	The Auto Mode Bolus feature assists the user in calculating a recommended bolus amount based on optional carbohydrate intake and optional BG measurement. The user may enter one or both of the two optional inputs. This feature utilizes the Carb Ratio setting to compute the bolus.
Auto Suspend	An alarm that you set to suspend insulin delivery and trigger an alarm if no buttons are pressed for a specified period of time. Clearing the alarm resumes basal insulin delivery.
Awake mode	A state in which the pump screen is on. Unless you are actively using another screen, your Home screen appears.
basal insulin	Insulin that is continuously delivered by the pump to meet your individual insulin needs between meals and during sleep.
basal pattern	A set of one or more basal rates that covers a 24-hour period.
basal rate	The amount of continuous basal insulin that you program your pump to automatically deliver per hour.
BG	Abbreviation for blood glucose. See *blood glucose (BG)*.
BG meter	A device that measures glucose levels in the blood.
BG Targets	The high and low values to which your BG is corrected when using the Bolus Wizard feature.
Block Mode	A feature that restricts the ability to change all settings. You can still perform certain functions, such as

	suspending insulin delivery, reviewing history, testing your pump, or clearing alarms and alerts.
blood glucose (BG)	Glucose that is present in the blood, commonly measured by a BG meter.
Bolus BG Check reminder	A reminder that you set just after you program a bolus. The reminder tells you to check your BG when the time period that you specified has passed.
bolus insulin	Insulin used to cover an expected rise in BG levels due to carbohydrates, or to lower a high BG value down to your target range.
Bolus Speed	A feature that lets you choose the speed at which your device delivers bolus insulin.
Bolus Wizard feature	A feature that uses your individual Bolus Wizard settings to calculate an estimated bolus amount based on the BG values and carbs that you enter. These settings include Carb Ratio, Insulin Sensitivity Factor, BG Target range, and Active Insulin Time.
calibrate	The process of using a meter BG reading to calculate SG values.
Calibration reminder	Set the Calibration reminder to notify you when your next calibration is due.
cannula	Short, thin, and flexible tube placed in the tissue below the skin. Insulin is delivered through the cannula into the body.
carb ratio	The number of grams of carbohydrates covered by one unit of insulin. The carb ratio is used to calculate bolus amounts.
CGM	Abbreviation for continuous glucose monitoring. See *continuous glucose monitoring (CGM)*.
continuous glucose monitoring (CGM)	A monitoring tool that uses a glucose sensor placed below the skin to continuously measure the amount of glucose in your interstitial fluid.
correction bolus	Insulin used to lower a high BG value down to your target range.

Daily History	A feature that displays the actions that you performed using your device.
diabetic ketoacidosis (DKA)	A serious condition that occurs when the insulin levels are low, BG levels are elevated, and the body uses fat for energy. This process produces ketones which upset the body's acid-base balance, leading to a potentially life threatening situation.
Dual Wave bolus	A type of bolus that provides a dose of insulin delivered as a combination of a Normal Bolus followed by a Square Wave bolus.
Easy Bolus feature	A feature that lets you deliver a Normal Bolus in preset increments using only audio or vibrate confirmation.
Event Marker	A feature that lets you record events, such as BG readings, injections, carbohydrates, and exercise.
food bolus	A dose of insulin you give to cover an expected rise in glucose levels from carbohydrates.
High limit	The value you set to determine when the pump will alert you of a high SG condition.
infusion set	Tubing that connects to the reservoir on one end, and has a needle or cannula on the other end, that you insert into your body. Insulin travels from the pump through the infusion set into your body.
infusion site	The location on the body where the infusion set is inserted.
insulin sensitivity factor	The amount that BG is reduced by one unit of insulin. The insulin sensitivity factor is used to calculate correction bolus amounts.
interstitial fluid	The fluid that surrounds the cells in the body.
ISIG	The signal created by the sensor that is used to calculate your SG value. Typically used by Medtronic technical support representatives when troubleshooting.
lock	A pump feature that prevents accidental button presses.

Low limit	The value you set to determine when the pump will alert you of a low SG condition, and also used for determining if insulin delivery should be suspended.
Manual Bolus	A feature that lets you enter and deliver a dose of insulin in the amount that you have determined is necessary.
Manual Mode	Manual Mode refers to system functions other than Auto Mode. In other words, if Auto Mode is not active, the system is in Manual Mode.
Max Basal Rate	A feature that lets you set the maximum amount of basal insulin that can be delivered per hour.
Max Bolus	A feature that lets you set the maximum bolus amount that can be delivered in one dose.
meter	A term for any BG meter.
Missed Meal Bolus reminder	A reminder that a bolus was not delivered during time periods that you specify, often set around your meal times.
Normal Bolus	A type of bolus that provides an entire dose of insulin immediately.
notifications	All notifications are designed to get your attention and convey different types of information. They include alarms, alerts, reminders, and messages.
occlusion	A blockage or crimp of the cannula or tubing that prevents proper insulin flow.
piston	The part of the insulin pump that engages the reservoir and moves insulin through the tubing.
Power save mode	A state in which your pump is fully functional, but the screen goes dark to save power. You can set how long it takes for your screen to enter power save mode with the Backlight setting.
Preset Bolus	A feature that lets you set up and save a bolus for specific meals or snacks that you frequently eat or drink.
Preset Temp Basal	A feature that lets you set up and save temporary basal rates for repeated use.

reminder	A type of notification that you can set to help you remember to do something.
reservoir	The small container that you fill with insulin and insert into your delivery device.
Resume basal alert	An alert that can be set to occur when your pump has automatically resumed basal insulin delivery after a Suspend before low or Suspend on low event because your SG values have met the necessary criteria. This alert always occurs if basal insulin delivery has resumed because the two-hour maximum suspend time has elapsed.
Rewind	A feature used when you change a reservoir. It returns the piston to its start position and lets a new reservoir be placed into the pump.
Rise Alert	An alert that tells you if your SG value is rising rapidly.
sensitivity	See *insulin sensitivity factor*.
sensor (glucose sensor)	The small part of the continuous glucose monitoring system that you insert just below your skin to measure glucose levels in your interstitial fluid.
sensor glucose (SG)	Glucose that is present in the interstitial fluid and is measured by a glucose sensor.
Set Change reminder	A reminder that you can set to change your infusion set.
SG	Abbreviation for sensor glucose. See *sensor glucose (SG)*.
Sleep mode	A state in which your pump is fully functional, but the screen is dark. Your pump automatically enters sleep mode when you have not pressed any buttons for about two minutes.
SmartGuard suspend	SmartGuard suspend features include Suspend before low and Suspend on low.
SmartGuard technology	A feature that can automatically stop and resume basal insulin delivery based on your SG values and low limit. SmartGuard Auto Mode can automatically adjust basal insulin delivery based on SG values.

Square Wave bolus	A bolus delivered evenly over a specified time period.
Suspend before low	A feature that suspends insulin delivery when the sensor predicts the SG value is approaching your low limit.
Suspend Delivery	This feature stops all insulin delivery until you resume it. Only the basal insulin restarts when delivery is resumed.
Suspend on low	A feature that suspends insulin delivery when your SG value reaches or falls below your low limit.
Temp Basal rate (temporary basal rate)	A feature that lets you temporarily increase or decrease your current basal rate for a duration of time that you specify.
transfer guard	The plastic piece that comes attached to the reservoir. It is used to connect the reservoir to the insulin vial while the reservoir fills with insulin.
transmitter	A device that connects to a glucose sensor. The transmitter collects data measured by the sensor and wirelessly sends this data to monitoring devices.

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Medtronic

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MiniMed™ 770G

ATT R1 - Accu-Chek Guide Link Blood Glucose Monitoring System Labeling Changes

Changed From…	To…
ATT R2 - Accu-Chek Guide Link User Manual	
Pages 1, 3, 83, 84: Changed the phrase "compatible MiniMed pump"	"the MiniMed 770G system"
Page 3: Changed "The system includes:"	"The Accu-Chek Guide Link Blood Glucose Monitoring System includes:"
Pages 84, 90, 105: Changed "the MiniMed System User Guide"	"the MiniMed 770G System User Guide"
ATT R3 - Accu-Chek Guide Link Quick Start Guide	
Front panel: Changed "For use with a compatible MiniMed pump"	"For use with the MiniMed 770G system"
Under section "Pair the Meter and Insulin Pump": Changed "compatible MiniMed pump"	"the MiniMed 770G system"
ATT R4 - Accu-Chek Guide Link Kit Carton	
Side Panel, in the Contents section: Changed "Accu-Chek Guide Link meter with batteries"	"Accu-Chek Guide Link blood glucose meter with batteries included
Side Panel, in the Contents section: Changed "Accu-Chek FastClix lancing device"	"Accu-Chek FastClix lancing device with 6 lancets (1 drum)"
Side Panel, in the Contents section: Changed "For use with a compatible MiniMed pump with Bluetooth wireless technology."	"For use with the MiniMed 770G system with Bluetooth wireless technology."
ATT R5 - Accu-Chek Guide Test Strip Insert	
Intended Use for the Accu-Chek Guide Link Meter: No statement regarding MiniMed system	Added "The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used to wirelessly transmit glucose values to the MiniMed 770G system with Bluetooth wireless technology through the use of Bluetooth low energy communication."
ATT R6 - Accu-Chek Guide Test Strip Carton	
Changed color of the carton from blue to red. Marketing messaging was simplified. Added image of Guide test strip vial and close up image of dosing end of the test strip for marketing purposes.	

ACCU-CHEK® Guide Link
Blood Glucose Monitoring System

User's Manual
for Single Patient Use Only
Blood Glucose Meter

For use with the MiniMed™ 770G system with *Bluetooth*® wireless technology

ACCU-CHEK®
Guide Link

OK

Medtronic   Roche

Contents

The Accu-Chek Guide Link System

The Accu-Chek Guide Link Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Link meter and the Accu-Chek Guide test strips.*

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended for in vitro diagnostic single-patient use by people with diabetes.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosing or screening of diabetes mellitus and not for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly)

The Accu-Chek Guide control solutions are for use with the Accu-Chek Guide Link Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used to wirelessly transmit glucose values to the MiniMed™ 770G system with Bluetooth® wireless technology through the use of Bluetooth low energy communication.

The Accu-Chek Guide Link Blood Glucose Monitoring System includes:

Accu-Chek Guide Link meter with batteries, Accu-Chek Guide test strips,* Accu-Chek Guide control solutions,* Accu-Chek FastClix lancing device,* Accu-Chek FastClix lancet drums.*

*Some items may not be included in the kit. They are a separate purchase.

WARNING

- Choking hazard. Small parts. Keep away from children under the age of 3 years.
- Keep new and used batteries away from children. Ingestion or insertion into the body may cause chemical burns, perforation of soft tissues, and death. Severe burns may occur within 2 hours of swallowing. If you think a battery might have been swallowed or placed inside any part of the body, seek medical attention immediately.
- If the battery compartment does not close securely, stop using the product and keep it away from children. Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Important Safety Information

Limitations

• Do not use the meter at high hematocrit levels above 65 % or low hematocrit levels below 10 %.

• Not for use in diagnosis or screening of diabetes mellitus.

• Not for neonatal use.

• Abnormally high concentrations of ascorbic acid (vitamin C) resulting in blood concentrations in excess of 5 mg/dL may cause inaccurate test results. If you are not sure please check with your doctor.

• Do not use the meter system to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.

• Do not use this system during xylose absorption test.

• Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients.

• This system has not been tested at altitudes higher than 10,150 feet.

WARNING

• Do not use Alternative Site Testing to calibrate a continuous glucose monitoring system.

• Do not use Alternative Site Testing to make insulin dosing calculations.

• Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Important Safety Information

Need Help?

For questions, contact the Accu-Chek Customer Care Service Center toll-free at 1-800-858-8072. Hours of operation are Monday through Friday between 8:00 am and 8:00 pm eastern standard time (EST). We offer assistance in many languages. You can also visit accu-chek.com for diabetes management tools and product demonstrations.

Please register your warranty online at accu-chek.com/register, so you receive the best customer service possible and product update news.

About Testing Yourself or Others

WARNING

- DO NOT CHANGE YOUR THERAPY BASED ON A TEST RESULT THAT DOES NOT MATCH HOW YOU FEEL OR IF YOU BELIEVE THAT YOUR TEST RESULT COULD BE INCORRECT.
- It is strongly recommended to have a back-up testing method available. Failure to test could cause a delay in therapy decisions and lead to a serious medical condition. Examples of back-up testing methods include a back-up meter and test strips. Ask your healthcare professional or pharmacist about other possible back-up methods.
- If your blood glucose result does not match how you feel and you have followed the instructions in this User's Manual, follow your healthcare professional's instructions, or contact your healthcare professional.

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Important Safety Information

WARNING

- During normal testing, any blood glucose meter or lancing device may come in contact with blood. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from bloodborne pathogens, even after you have performed cleaning and disinfecting.[1,2]

- The meter and lancing device should never be used by more than one person. Do not share the meter and lancing device with anyone, including family members, due to the risk of infection from bloodborne pathogens.[1,2] Do not use on multiple patients!

- Cleaning and disinfecting the meter and lancing device destroys most, but not necessarily all, bloodborne pathogens.[3]

- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.

- Disinfect the meter and lancing device before allowing anyone else to handle them. Do not allow anyone else to test with the meter or lancing device.

- It is important to keep the meter and lancing device clean and disinfected. For instructions on how to clean and disinfect the meter and lancing device, see the chapter Meter and Lancing Device Cleaning and Disinfecting.

- Wash hands and dry thoroughly before and after handling the meter, lancing device, or test strips.

NOTE

- Perform a control test when you open a new test strip box or if you think that a test result is incorrect. Performing a control test lets you know that the meter and test strips are working properly.
- Refer to the test strip and control solution package inserts for additional health-related information.
- Blood glucose and BG are interchangeable and mean the same thing.

Special Information for Caregivers

- Consult your healthcare professional to determine if it is appropriate for your child to be taught how to use the meter system or any other medical products.
- Some people with diabetes do not experience symptoms of low blood glucose (hypoglycemia). Others, such as children or people who are unconscious or have certain disabilities, may not be able to communicate their symptoms to caregivers. For these reasons, do not change any therapy without first talking to a healthcare professional.

Important Safety Information

Before You Start Testing

WARNING

- Carefully read and follow the instructions in the User's Manual and package inserts for the test strips and control solutions. It is very important to follow the instructions in order to avoid an incorrect test result that leads to improper therapy.
- Inspect the test strip container before using the test strips for the first time. If you see any damage to the container cap or if anything prevents the cap from closing properly, do not use the test strips. Contact the Accu-Chek Customer Care Service Center. Damaged test strips can cause inaccurate results, which could lead to improper therapy.
- The meter, test strips, and control solution are only for use outside the body (in vitro). Do not eat the test strips. Do not swallow or inject the control solution or use the control solution for any purpose other than testing the Accu-Chek Guide Link Blood Glucose Monitoring System.

NOTE

- The meter may prompt you to choose a language the first time you turn it on.

The Accu-Chek Guide Link Meter

Front View   **Back View**   **Side View**

1. **Display**
   Shows results, messages, and test results stored in memory.

2. **Back Button**
   Returns to a previous display or field.

3. **Up Arrow and Down Arrow Buttons**
   Press to move between menu options or to increase or decrease numbers.

4. **Power/Set/OK Button**
   Turns meter on or off and sets options.

5. **Test Strip Slot with Light**
   Insert test strip here.

6. **Battery Door**
   Flip open to replace batteries.

7. **Micro USB Port**
   USB functionality is not available for this meter.

8. **Test Strip Ejector**
   Press to remove test strip.

1 Your New Meter
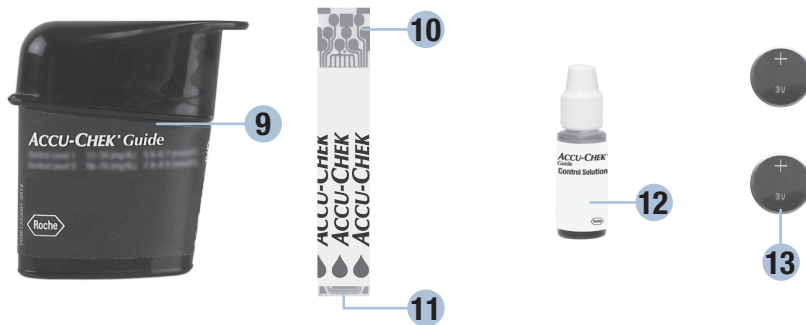
9. **Test Strip Container***

10. **Test Strip* – Metallic End**
    Insert this end into meter.

11. **Test Strip* – Yellow Edge**
    Touch blood drop or control solution here.

12. **Control Solution Bottle***

13. **Batteries**

*Some items may not be included in the kit. They are a separate purchase. Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

The Accu-Chek FastClix Lancing Device
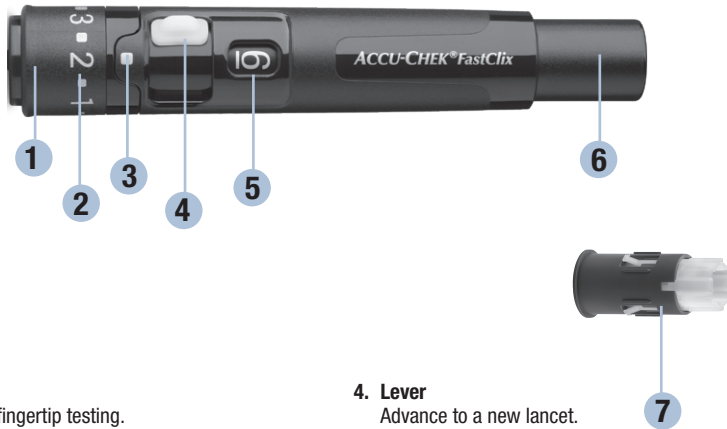
1. **Cap**
   For fingertip testing.

2. **Comfort Dial with Depth Selection**
   Select penetration depth.

3. **Penetration Depth Indicator**
   Points to depth setting.

4. **Lever**
   Advance to a new lancet.

5. **Lancet Counter Window**
   Shows number of available lancets.

6. **Release Button**
   Press to prime and prick.

7. **Lancet Drum**
   Contains 6 lancets.

NOTE

Some items may be sold separately.

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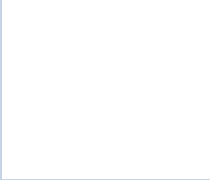
1 | Your New Meter

Button Functions

Here are the functions of the back, arrow, and Power/Set/OK buttons on the meter. These functions are used throughout this manual. See the chapter Meter Settings for specific instructions on setting up the meter.

Button	Function
Back Button	Return to the previous display. Return to the previous field.
Up Arrow and Down Arrow Buttons	Navigate up and down in a menu. Increase or decrease a number.
Power/Set/OK Button	Press briefly to turn the meter on. Press and **hold** to turn the meter off. Press to select an option. Press to move to the next field or display. Press to save an option. With the meter off, press and **hold** to check the meter display.

Display Check

NOTE

Before you begin testing, turn the meter on by briefly pressing ⏻ so the meter can synchronize its time and date with the paired pump.
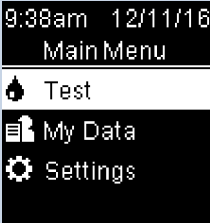
Meter Menus
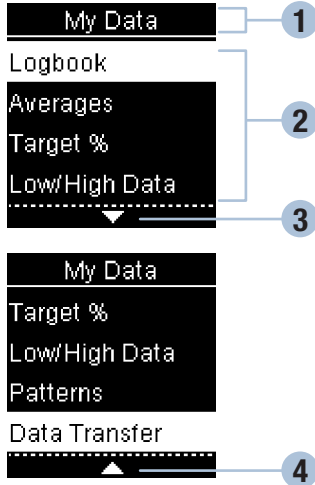
❶ Title of display or menu
❷ Menu options
❸ Scroll down
❹ Scroll up

Display	Description
▼	There are more menu options listed beneath the last option. Press ▼ on the meter to view the options.
▲	There are more menu options listed above the first option. Press ▲ on the meter to view the options.
▲▼	There are more menu options listed above and below the options. Press ▼ or ▲ on the meter to view the options.

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1 | Your New Meter

Display	Description
9:38am 12/11/16 Main Menu ◆ Test 🗐 My Data ⚙ Settings	Highlighted option (**Test**) Press 🆗 to enter the **Test** menu.
Time/Date HH MM A/P **9** : 38 am DD MM YY 11 / 12 / 16	Highlighted field (**HH**=Hour) Press ⬇ or ⬆ to increase or decrease the hour. Press 🆗 to set the hour and move to the minutes field.

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Symbols

Here is a list of the symbols on the meter display.

Symbols	Description
⬆	Above target range
	After meal
🌙	Bedtime
🍎	Before meal
⬇	Below target range
⬤	Blood glucose test
✔	Checkmark / Control test OK / Selected option or setting
C	Control bottle
✖	Control test not OK
✏	Edit
⊗	Error
⊘	Fasting

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1 | Your New Meter

Symbols	Description
✈	Flight mode
?	Help
🔋	Low battery
📇	My data
— -	No comment
✳	Other
⊙	Overall
⚙	Settings
🔔	Test reminder
⚠	Warning
↕	Within target range

Set the Language

The meter may prompt you to choose a language the first time you turn it on.

1	2
Language ✓ English Български Česky Dansk ▼	9:38am 12/11/16 Main Menu 🔥 Test 📋 My Data ⚙ Settings
Turn the meter on by briefly pressing 🆗. **Language** appears. Press 🔽 or 🔼 to highlight the language.	Press 🆗 to set the desired language and continue.

NOTE

If you select the wrong language and cannot correct it, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

1 Your New Meter

Using the Accu-Chek FastClix Lancing Device

	• The black cap is for fingertip testing only. • Remember that the opening where the lancet comes out is not in the center of the cap. • Remove the cap by pulling it straight off. Do not twist the cap.
	• A new lancet drum is dark gray with a white end.
	• A used lancet drum has a visible red stripe on the white end. • You cannot reuse a used lancet drum. • Do not remove the lancet drum until you have used all 6 lancets.
	• The penetration depth indicator on the comfort dial shows the current depth setting. The higher the number, the deeper the penetration. The best depth setting is the lowest number that lets you get enough blood for a test. Try different depth settings to find the one that is right for you. • For soft skin, we suggest a depth setting of 2. For thick skin, try a higher depth setting.

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2 | The Accu-Chek FastClix Lancing Device

Inserting a Lancet Drum

You must first load the lancet drum into the lancing device to get it ready for use.

1	2	3
Remove the cap. Insert a new lancet drum, white end first, until it clicks firmly into place.	Slide the cap on until it stops by aligning the notch on the cap with the notch on the lancing device.	You are now ready to use the first lancet. The lancet counter shows a number 6, meaning you have 6 new lancets remaining.
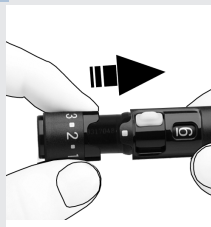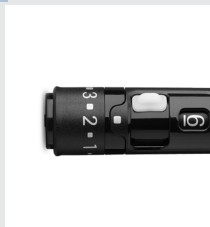
NOTE

Once the lancet drum is inserted into the lancing device, do not remove the lancet drum until completely used. The lancet drum cannot be reused once it has been removed from the lancing device.

WARNING

You must not insert the lancet drum into the lancing device and simultaneously press the release button or hold the lancing device with the release button resting on a surface such as a table top. This could release a lancet and inadvertently cause injury.

Using the Accu-Chek FastClix Lancing Device

1	2	3
Adjust the lancet depth by turning the comfort dial.	Obtain a blood drop. See the chapter Blood Glucose Tests.	Advance to the next lancet by sliding the lever forward and back all the way.
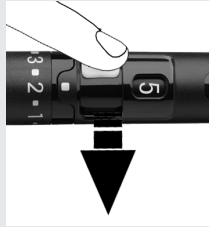
Advance to the next lancet by sliding the lever forward and back all the way.

The number in the lancet counter decreases by 1.

The lancet counter window shows the number of remaining lancets.

NOTE

- NEVER reuse a lancet.
- ALWAYS use a new, sterile lancet each time you test to avoid infection.
- For safety reasons, once you advance to a new lancet, you cannot go back to a used lancet.

WARNING

NEVER share your lancing device with anyone.

2 | The Accu-Chek FastClix Lancing Device

Changing the Lancet Drum

When you have used the sixth and last lancet, change the lancet drum.

1
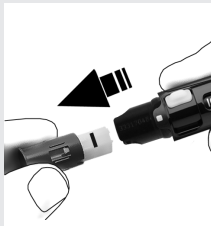
Remove the cap.

Hold the lancet drum between your thumb and index finger and pull it straight out.

A red stripe is visible on the white part, indicating that the lancet drum has been used.

2

Throw the old lancet drum away.

Always discard according to local regulations.

3
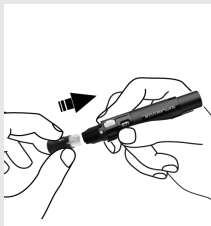
Slide the cap back on until it stops by aligning the notch on the cap with the notch on the lancing device.

Insert a new lancet drum, white end first, until it clicks firmly into place.

WARNING

- The meter and lancing device should never be used by more than one person. Do not share the meter and lancing device with anyone, including family members, due to the risk of infection from bloodborne pathogens.1,2 Do not use on multiple patients!
- Blood glucose results can be displayed in either mg/dL or mmol/L. The back label of the meter shows the unit of measurement. If the meter shows the wrong unit, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072. The correct unit of measure in the US is mg/dL. If you do not know which unit of measurement is correct for you, contact your healthcare professional. Using the wrong unit of measurement may cause misinterpretation of your actual blood glucose level and may lead to improper therapy.

mg/dL or mmol/L is printed here
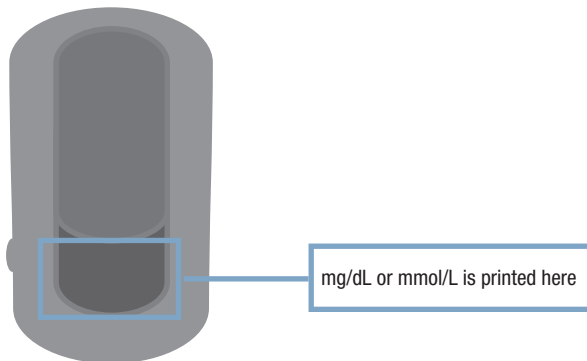
3 | Blood Glucose Tests

Using the Accu-Chek Guide Link Meter System

- The Accu-Chek Guide test strips are for testing fresh capillary whole blood.

- Use only Accu-Chek Guide test strips.

- Use the test strip immediately after removing it from the test strip container.

- Do not apply blood or control solution to the test strip before inserting it into the meter. If you applied blood or control solution before inserting the test strip into the meter, retest with a new test strip. If a result appears before applying blood or control solution, do not act on that result.

- Close the test strip container tightly immediately after removing a test strip. Moisture can damage the test strips and produce incorrect results.

- Store the unused test strips in their original container with the cap tightly closed.

- Discard the test strips if they are past the **Use By** date printed on the test strip container. If the **Use By** date is missing or cannot be read, do not use the test strips. Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

- Refer to the test strip package insert for test strip storage and system operating conditions.

- Do not remove test strips from the test strip container and put them into another container, such as a plastic bag, pocket, purse, wallet, etc.

- Do not reuse test strips. Once control solution or blood has been applied to a test strip, discard it. If a retest is necessary, use a new test strip.

- Perform a control test every time you open a new test strip box.

WARNING

To prevent inaccurate results:

- If you drop the meter or drop the meter with a test strip inserted, the meter and/or test strip could be damaged. Discard the test strip and perform a control test with control solution and a new, unused test strip to ensure the meter and test strips are both working properly. Then repeat the blood glucose test with a new test strip.

- DO NOT remove test strips from the test strip container and put them into another container, such as a plastic bag, pocket, purse, wallet, etc. Storing test strips outside of the test strip container can damage the test strips and lead to inaccurate results. It is important that the test strips remain in their original container until the time of use.

- DO NOT expose test strips to heat, moisture, or humidity. Temperatures outside the required range, as well as moisture and humidity, can damage the test strips and lead to inaccurate results.

- DO NOT bend, cut, or alter the test strips.

- DO NOT get dirt, food, or other material on the test strip.

- When performing a blood glucose test, remove your finger from the test strip after the test strip is dosed and Analyzing appears on the meter. Failure to move your finger away from the test strip during measurement could give inaccurate results.

3 | Blood Glucose Tests

Representation of Accuracy for Home Use

Your Accu-Chek Guide Link meter result may vary slightly from your actual blood glucose value. This is due to slight differences in technique and the natural variation in the test technology. The table and chart below show the results of a study where 120 typical users used the meter to test their blood glucose level. The system exceeds the FDA requirement of at least 95 % of results to be within ±15 % of the reference value across the entire measuring range.

Accu-Chek Guide System User Performance:
Subject Versus Reference – Total System Capillary Accuracy

Difference range between true blood glucose level and meter result:	Meter Results Within			
	±5 %	±10 %	±15 %	±20 %
Number (and percentage) of meter results that match the true blood glucose level:	70 of 120 (58.3 %)	111 of 120 (92.5 %)	119 of 120 (99.2 %)	120 of 120 (100.0 %)

Accurate Results
(within ±15 % of laboratory)

119 of 120 results (99.2 %)

More Accurate Results
(within ±10 % of laboratory)

111 of 120 results (92.5 %)

Most Accurate Results
(within ±5 % of laboratory)

70 of 120 results (58.3 %)

Performing a Blood Glucose Test with Blood from Your Fingertip

Refer to the Important Safety Information section at the beginning of this manual.

NOTE
• Before you perform your first blood glucose test, set up the meter correctly.
• You need the meter, a test strip, and a lancing device with a lancet drum loaded to perform a blood test.
• A blood glucose test cannot be performed while the meter is connected to a PC with a USB cable.
• There are 2 ways to start a blood glucose test.
• Insert a test strip into the meter.
• Turn the meter on by briefly pressing ⬚. Select **Test** > ⬚.

3 | **Blood Glucose Tests**

1
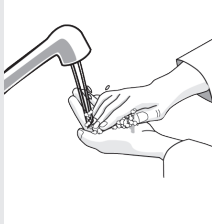
Wash your hands with warm soapy water and dry thoroughly. Dirty or wet hands could affect test results.

2
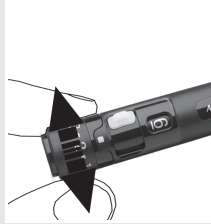
Rotate the comfort dial until the desired penetration depth lines up with the indicator.

3

Use By: 0000-00-00

Check the **Use By** date on the test strip container.

Do not use test strips past the **Use By** date.

4

Remove a test strip from the test strip container.
Close the cap tightly.

5
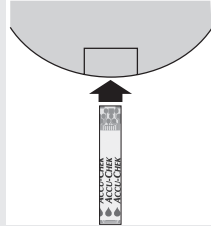
Insert the metallic end of the test strip into the meter.
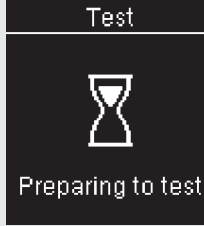
Test

Preparing to test

The meter turns on. **Preparing to test** appears.

6

When **Apply drop** appears, obtain a blood drop.

7
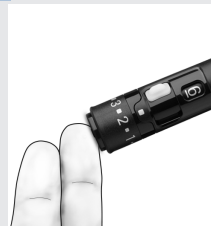
Press the lancing device firmly against the side of your fingertip.

Press the release button all the way down to prick your finger.

8
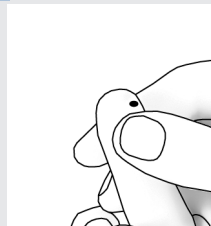
Gently squeeze your finger to assist the blood flow. This helps you get a blood drop.

Blood Glucose Tests
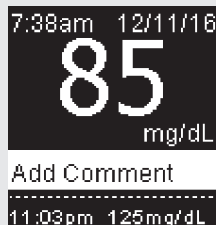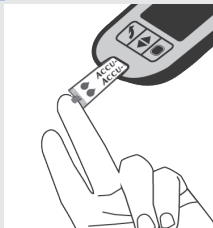
Touch the **yellow edge** of the test strip to the blood drop. Remove your finger from the test strip when **Analyzing** appears. Failure to move your finger away from the test strip could give inaccurate results. Do not put blood on top of the test strip.

The test result appears on the display.

Note: Press ⬛ to automatically send result to a paired pump. If ⬛ is not pressed, there will be a delay seeing the blood glucose result on the paired pump.

You have the option of adding a comment to the test result by pressing ⬛ OR proceed to Step 12 to complete the test.

10

Add Comment appears. Press ▼ to highlight a comment. Press 🆗 to set the comment for the test result and send the blood glucose result to the paired pump. See the Adding Comments to Blood Glucose Results section of this chapter for details.

11

The final result appears. Press 🆗 or ◤ to set the comment and return to **Main Menu**. Or to change the comment, press ▼ to select the comment.

Press 🆗 to return to **Add Comment**.

12

Press here to eject test strip

Remove and discard the used test strip by pulling the test strip out of the meter or by pushing the test strip ejector on the side of the meter.

13
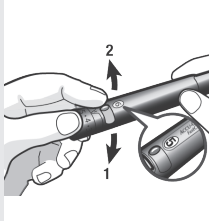
Advance to the next lancet by sliding the lever forward and back all the way.

14
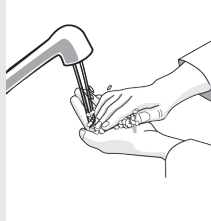
Wash hands thoroughly with soap and water.

Blood Glucose Warnings

If your blood glucose result is outside the measuring range of the meter, a warning is displayed. Press ▣ to acknowledge the LO or HI warning, OR the meter automatically moves to the LO or HI result display.

⚠WARNING LO Result Retest BG. Contact your healthcare professional.	9:38am 12/11/16 LO Add Comment	Blood glucose may be lower than the measuring range of the system. See the Unusual Blood Glucose Results section of this chapter.
⚠WARNING HI Result Consider checking BG, ketones, and insulin.	9:38am 12/11/16 HI Add Comment	Blood glucose may be higher than the measuring range of the system. See the Unusual Blood Glucose Results section of this chapter.

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3 | Blood Glucose Tests

Adding Comments to Blood Glucose Results

NOTE

Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results.

WARNING

CAUTION – Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is On.

Overview

It is very important to have the correct time and date set in the meter. Having the correct time and date setting helps ensure accurate interpretation of information by you and your healthcare professional.

• You may add comments to blood glucose results to help you and your healthcare professional analyze patterns detected by the meter (see the Patterns section in the chapter Meter Settings for details).

• If Patterns is set to **On**, once a pattern is detected you may NOT change the comment attached to a blood glucose result (see the Patterns section in the chapter Meter Settings for details).

• Adding a comment saves the comment and the symbol with the blood glucose result.

NOTE

If paired with a pump, the meter time and date are automatically set to the pump's time and date during communication.

Here is a list of comment symbols that can be added to a blood glucose result.

Symbols	Name	Description
🍎	Before meal	If Patterns is **On**, select Before breakfast, lunch, dinner, or snack (see the following page for adding comments with Patterns **On**).
🍎	After meal	If Patterns is **On**, select After breakfast, lunch, dinner, or snack (see the following page for adding comments with Patterns **On**).
🚫	Fasting	Select Fasting for no caloric intake for at least 8 hours.*
🌙	Bedtime	
✳	Other comment	You can use this comment to mark an event such as an AST result or exercise.
━ ━	No entry	1. You do not want to add a comment. 2. You want to remove a comment for the current blood glucose result.

*American Diabetes Association: Standards of Medical Care in Diabetes-2016.

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1

After performing a blood glucose test, the test result is displayed on the screen with **Add Comment** highlighted. Press to add a comment.

2

The **Add Comment** menu appears. Press to select the desired comment (the example here is **Before meal**). Press to set the comment.

If Patterns is On:

If **Patterns** is on and you select **Before meal** or **After meal**, press to select a specific meal (**Breakfast, Lunch, Dinner,** or **Snack**). Press to set the selected meal for the test result.

The final result appears with the comment symbol. When automatically sending results to a paired pump, press ⊡ or ◥ to set the comment, send the result, and return to **Main Menu**.

To change the comment, press ⊡ to select the comment. Press ⊡ to return to **Add Comment**.

PRECAUTION

When using a test result for calibrating a continuous glucose monitoring system or to make insulin dosing calculations, confirm that the result displayed on the pump matches the result displayed on the meter.

3 | Blood Glucose Tests

Performing a Blood Glucose Test with Blood from Your Palm or Upper Arm (Alternative Site Testing, AST)

WARNING
• Do not use alternative site testing to calibrate a continuous glucose monitoring system.
• Do not use alternative site testing to make insulin dosing calculations.
• Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

You have the option of obtaining a blood sample from other sites on your body besides the fingertip. Alternative sites include the palm and upper arm.

Blood obtained from the fingertip can be used at any time to test blood glucose.

If blood from an alternative site is used, there are certain times when testing is not appropriate. This is because your blood glucose level changes faster in your fingertip than in the alternative sites. These differences may cause you to misinterpret your actual blood glucose level, leading to improper therapy and potential adverse health effects.

Read the next section before you try testing from alternative sites.

You may perform a palm or upper arm test	• immediately before a meal. • while fasting.
You may NOT perform a palm or upper arm test	• up to 2 hours following a meal, when blood glucose values can rise quickly. • after injecting bolus insulin, when blood glucose values can decrease rapidly. • after exercise. • if you are sick. • if you think your blood glucose is low (hypoglycemia). • if you sometimes do not notice when your blood glucose is low.

If you are interested in AST, talk to your healthcare professional first.

To obtain an AST cap and detailed AST instructions, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Unusual Blood Glucose Results

If your blood glucose result does not match how you feel, follow these steps:

1. Perform a control test. See the chapter Control Tests.

2. Repeat the blood glucose test.

If your blood glucose result still does not match how you feel, follow your healthcare professional's instructions or call your healthcare professional immediately.

NOTE
Always follow your healthcare professional's instructions. For example, if your healthcare professional has advised you to immediately treat a low blood glucose result (such as by eating something), then do that first.

WARNING
• Do not change your treatment because of one blood glucose result. • NEVER ignore symptoms of low or high blood glucose.

3 | Blood Glucose Tests

Symptoms of Low or High Blood Glucose

The meter is designed to provide a numerical value for blood glucose in the range of 20–600 mg/dL.

WARNING

Being aware of the symptoms of low or high blood glucose can help you understand your test results and decide what to do if they seem unusual.

Low blood glucose (hypoglycemia): Symptoms of hypoglycemia may include, but are not limited to, anxiety, shakiness, sweating, headache, increased hunger, dizziness, pale skin color, sudden change in mood or irritability, fatigue, difficulty concentrating, clumsiness, palpitations, and/or confusion.

High blood glucose (hyperglycemia): Symptoms of hyperglycemia may include, but are not limited to, increased thirst, frequent urination, blurred vision, drowsiness, and/or unexplained weight loss.

If you are experiencing any of these symptoms, or other unusual symptoms, test your blood glucose from the fingertip. If your blood glucose result is displayed as LO or HI, follow your healthcare professional's instructions or contact your healthcare professional immediately. If your blood glucose result does not match how you feel, follow the steps in the Unusual Blood Glucose Results section of this chapter.

Comparing Your Meter Result to a Laboratory Result

A common question is how the blood glucose results on the meter compare to the laboratory results. Your blood glucose can change quickly, especially after eating, taking medication, or physical activity. If you test yourself in the morning, then go to your healthcare professional's office for a blood glucose test, your test results will probably not match, even if you are fasting. This is typically not a problem with the meter, it just means that time has elapsed and your blood glucose level has changed.

Although you always apply fresh capillary whole blood to the test strip, the system has been calibrated to deliver plasma-like values for easier comparison to laboratory results.

If you want to compare your meter result to the laboratory result, **you must be fasting**. Take the meter to your healthcare professional's office and test yourself by fingerstick within 5 minutes of having blood drawn from your arm by a healthcare professional. Keep in mind that the laboratory uses different technology than the meter and that blood glucose meters for self-testing generally read somewhat lower than the laboratory result.

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When to Perform a Control Test

Performing a control test lets you know the meter and test strips are working properly. You should perform a control test when:

• you open a new test strip box.

• you left the test strip container open.

• you think the test strips are damaged.

• you want to check the meter and test strips.

• the test strips were stored in extreme temperatures, humidity, or both.

• you dropped the meter.

• your test result does not match how you feel.

• you want to check if you are performing the test correctly.

About the Control Solutions

• Use only Accu-Chek Guide control solutions.

• Close the control solution bottle tightly after use.

• Write the date you open the control solution bottle on the bottle label. The control solution must be discarded 3 months from the date the control solution bottle was opened (discard date) or on the **Use By** date on the bottle label, whichever comes first.

• Do not use control solution that is past the **Use By** or discard date.

• Refer to the control solution package insert for control solution storage conditions.

• The meter automatically recognizes the difference between the control solution and blood.

• The control results are not displayed in memory.

• The control solution can stain fabric. Remove stains by washing with soap and water.

• Control solution is available for purchase. To order the control solution, talk to your pharmacist or visit accu-chek.com to order online.

4 | Control Tests

Performing a Control Test

You need the meter, a test strip, and control solution Level 1 or Level 2.

1

Use By: 0000-00-00

Check the **Use By** date on the test strip container. Do not use test strips past the **Use By** date.

2

Remove a test strip from the test strip container.

Close the cap tightly.

3
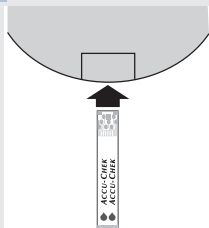
Insert the metallic end of the test strip into the meter. Place the meter on a flat surface.
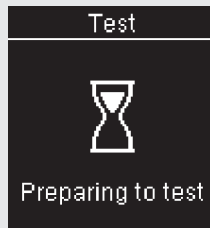
Test

Preparing to test

The meter turns on. **Preparing to test** appears.

Test

Apply drop

Apply drop appears.

4

Select the control solution to test. You will enter the level later in the test.

5

Remove the bottle cap. Wipe the tip of the bottle with a tissue. Squeeze the bottle until a tiny drop forms at the tip.

6
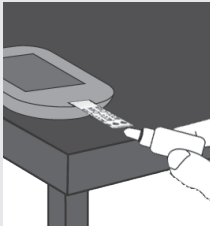
Touch the drop to the **yellow edge** of the test strip. Do not put control solution on top of the test strip.

Analyzing appears when there is enough control solution in the test strip.

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7

Control Result and the control bottle symbol appear. Press ▼ or ▲ to select the control level you tested. If you do not select a level, the control result is saved without a control level.

Press OK.

8

 or
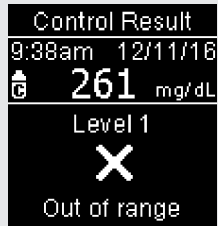
Within range and ✔ appear if the control result is within range.

Out of range and ✘ appear if the control result is out of range.

9

Wipe the tip of the bottle with a tissue. Cap the bottle tightly.

Remove and discard the used test strip.

PRECAUTION

Control results are not transmitted to the pump.

• Do not calibrate your continuous glucose monitoring device from a control result.

• Do not calculate a bolus based on a control result.

NOTE

• Most people just test the Level 1 control. If you wish, you can also test a Level 2 control. A set of Level 1 and Level 2 control solutions is available for purchase.

• The ranges for Level 1 and Level 2 control solutions are printed on the test strip container label.

• The meter turns off 90 seconds after a successful test or 15 seconds after the test strip is removed, provided no other action is taken.

4 | Control Tests

Understanding Out-of-Range Control Results

WARNING

The control range applies only to a control result. It only indicates that the test strips and meter are working properly. Do not use a control result to interpret blood glucose results.

If the control result is out of range, do not use the meter until you solve the problem. Check this list to help solve the problem.

Troubleshooting Checks	Action
Were the test strips or control solutions expired?	Discard the test strips or control solution if either is past the **Use By** date. If the control solution was opened more than 3 months ago, discard it. Repeat the control test with an unexpired test strip and an unexpired control solution.
Did you wipe the tip of the control solution bottle before use?	Wipe the tip of the bottle with a tissue. Repeat the control test with a new test strip and a fresh drop of control solution.
Were the caps on the test strip container and the control solution bottle always closed tightly?	Replace the test strips or control solution if you think either was uncapped for some time. Repeat the control test.
Was the test strip used immediately after it was removed from the test strip container?	Repeat the control test with a new test strip and a fresh drop of control solution.
Were the test strips and control solutions stored in a cool, dry place?	Repeat the control test with a properly stored test strip or control solution.
Did you follow the directions?	Read the chapter Control Tests and repeat the control test.
Did you choose the correct control solution level, either 1 or 2, when you performed the test?	If you chose the wrong control solution level, you can still compare the control result to the range printed on the test strip container.
Are you still unsure of the problem?	Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Overview

You can adjust the following settings in the meter for your personal preferences. Refer to the sections later in this chapter for details and how to set the options.

Setting	Options	Function
Time/Date	Time / Date	Set the time and date.
		NOTE
		Feature is only available if the meter is not paired with a pump. If paired with a pump, the meter time and date are automatically set to the pump's time and date during communication.
Beeper	On / Off	Select On or Off.
Wireless	Select wireless communication settings. See the chapter Wireless Communication and Meter Pairing.	

5 | Meter Settings

Setting	Options	Function
Target Ranges	Off / Single Range / 2 Ranges	Select the blood glucose target range appropriate for you.
		NOTE
		Consult your healthcare professional for the appropriate target range for you.
		Off – no target range arrow symbols appear with blood glucose result. Patterns is **Off** (see the Patterns section of this chapter for details).
	70–160 mg/dL (pre-set target range)	Single Range – blood glucose results are marked as above, within, or below range based on the single target range set in the meter.
	Before Meal Range 70–110 mg/dL (pre-set target range) After Meal Range 70–160 mg/dL (pre-set target range)	2 Ranges – set Before Meal and After Meal ranges. Blood glucose results are marked as above, within, or below range based on the 2 target ranges (Before Meal and After Meal) set in the meter.
Patterns	On / Off	On – a pattern is detected when 2 below-target or 3 above-target results with the same comment are detected within a 7-day period.
Reminders	On / Off / Edit time	On – set up to 4 reminders per day to remind you to test.
Post Meal	On / Off / Edit time	On – reminds you to perform an after meal blood glucose test.

Setting	Options	Function
Last Result	On / Off	Select whether the previous blood glucose result (within the past 24 hours) appears with the current blood glucose result.
		On – the previous blood glucose result appears with the current blood glucose result.
		Off – only the current blood glucose result appears.
Language		Select the language for the meter.
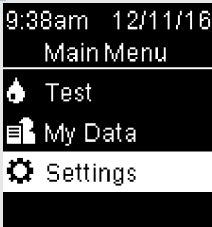
Time/Date
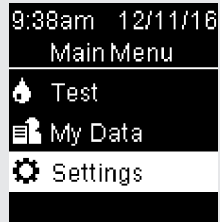
> **NOTE**
>
> Feature is only available if the meter is not paired with a pump. If paired with a pump, the meter time and date are automatically set to the pump's time and date during communication.

1

9:38am   12/11/16
Main Menu
🩸 Test
📑 My Data
⚙ Settings

Turn the meter on by briefly pressing ▨. From **Main Menu**, press ▾ to highlight **Settings**. Press ▨.

2

Settings
Time/Date
Beeper
Wireless
More Options

Time/Date is highlighted. Press ▨.

3

Time/Date
HH   MM   A/P
9 : 38   am
DD   MM   YY
11 / 12 / 16

Press ▾ or ▴ to adjust each field. Press ▨ to set and proceed to the next field. Set **am** or **pm** if necessary.

Press ▨ to save and return to the previous menu.

Beeper

The beeper prompts you:

• when a test strip is inserted.

• to apply blood or control solution to the test strip.

• when enough blood or control solution is drawn into the test strip.

• when the blood glucose or control test is complete.

• when the meter is turned on.

• when a button is pressed.

• when it is time to perform a test (if Reminders or Post Meal reminders are **On**).

• when the batteries are inserted.

• when there are no stored blood glucose results or there is an invalid record in the logbook.

• when there are no errors in the error log.

• if an error occurred (even if the beeper is off, it still beeps for an error).
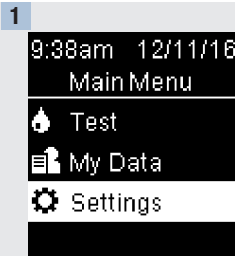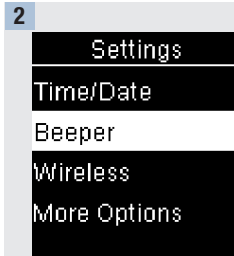
1	2	3
9:38am 12/11/16 Main Menu ♠ Test ▤ My Data ✿ Settings	Settings Time/Date Beeper Wireless More Options	Beeper ✔ On Off
Turn the meter on by briefly pressing 🔲. From **Main Menu**, press 🔽 to highlight **Settings**. Press 🔲.	Press 🔽 to highlight **Beeper**. Press 🔲.	Press 🔽 or 🔼 to highlight **On** or **Off**. Press 🔲 to move ✔ to the option. Press 🔲 to set the option and return to the previous menu.
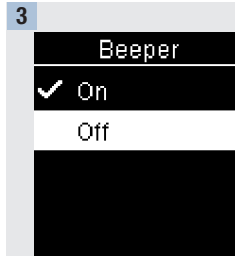
51

Target Ranges

Your healthcare professional can tell you what blood glucose range is appropriate for you. It is very important to stay within your target range.

Target Ranges can be set from a lower limit of 60–100 mg/dL to an upper limit of 101–300 mg/dL.

Options	Function
Off	Arrow symbols for above, within, or below target ranges do not appear with the blood glucose results.
Single Range	Set lower limit and upper limit for the target range. You will be prompted to turn on Patterns if desired (see the Patterns section of this chapter for details).
2 Ranges	Set lower limits and upper limits for Before meal and After meal target ranges. You must mark your blood glucose results with a comment for the meter to detect above, within, or below Before Meal or After Meal test results (see the Adding Comments to Blood Glucose Results section in the chapter Blood Glucose Tests for details). You will be prompted to turn on Patterns if desired (see the Patterns section of this chapter for details).

When Target Ranges is **On**, the following symbols appear with blood glucose results.

Symbol	Meaning
↧	The blood glucose result is below the target range.
↕	The blood glucose result is within the target range.
↥	The blood glucose result is above the target range.

WARNING
This function is no substitute for hypoglycemia training by your healthcare professional.

1
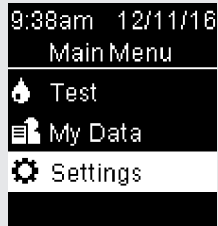
9:38am   12/11/16
Main Menu
🔥 Test
📊 My Data
⚙ Settings

Turn the meter on by briefly pressing 🆗. From **Main Menu**, press ⬇ to highlight **Settings**. Press 🆗.

2

Settings
Time/Date
Beeper
Wireless
More Options

Press ⬇ to highlight **More Options**. Press 🆗.

3

More Options
Target Ranges
Patterns
Reminders
Post Meal
▼

Target Ranges is highlighted. Press 🆗.

4
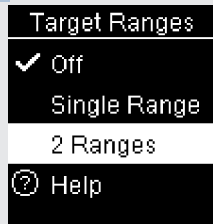
Press ⬇ or ⬆ to highlight **Off**, **Single Range**, or **2 Ranges**. Press 🆗 to select an option (the example here is **2 Ranges**).

5

Press ⬇ or ⬆ to adjust the lower limit of the **Before Meal** target range. Press 🆗 to set and move to the next field.

Continue to set the upper limit for the **Before Meal** target range and the lower and upper limits for the **After Meal** target range. Press 🆗.

6
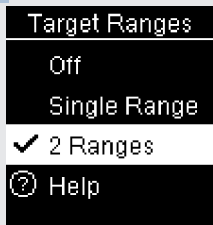
The ✔ appears next to the option you selected.

Press ◀ to return to the previous menu.
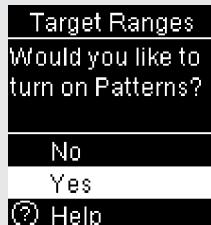
The meter may prompt you to turn on Patterns.

Press ⬇ or ⬆ to highlight **Yes** or **No**.

Press 🆗 to set the option and return to the previous menu (see the Patterns section of this chapter for details).

> **NOTE**
>
> Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results. Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is **On**.

Patterns

A Pattern is detected by the meter when 2 below-target (Low Pattern) or 3 above-target (High Pattern) test results with the same comment are detected within a 7-day period.

• The meter does NOT detect a pattern for the "Other" comment added to blood glucose results.

• It is very important to have the correct time and date set in the meter. Having the correct time and date setting helps ensure accurate interpretation of information by you and your healthcare professional.

• Only blood glucose results marked with comments will be included in Patterns. If LO or HI test results are marked with comments, the test results become part of Patterns (see the chapter Blood Glucose Tests for more details).

• Target Ranges must be set in the meter to use Patterns. If Target Ranges are not set, the meter prompts you to set them.

> **NOTE**
>
> If paired with a pump, the meter time and date are automatically set to the pump's time and date during communication.

5 Meter Settings

1

9:38am   12/11/16
Main Menu

🔥 Test
📊 My Data
⚙ Settings

Turn the meter on by briefly pressing ⏺. From **Main Menu**, press ⏷ to highlight **Settings**. Press ⏺.

2

Settings
Time/Date
Beeper
Wireless
More Options

Press ⏷ to highlight **More Options**. Press ⏺.

3

More Options
Target Ranges
Patterns
Reminders
Post Meal

Press ⏷ to highlight **Patterns**. Press ⏺.

56

4

Patterns

Off

✓ On

? Help

Press ▼ to highlight **On**. Press ▣ to move ✓ to the option. Press ▣.

Patterns

Target ranges must be set up. Set up now?

No

Yes
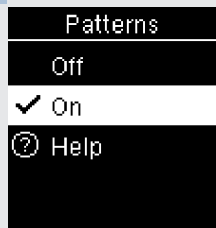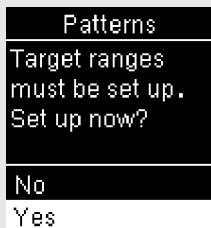
This message appears if Target Ranges is Off:
Press ▼ to highlight **Yes**. Press ▣.

(To turn Patterns **Off**, select **No**. Press ▣ to return to **Patterns**.)

Target Ranges

Choose an option.

Single Range
2 Ranges

? Help
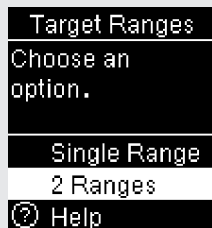
Target Ranges appears on the display (see the Target Ranges section of this chapter for details on setting target ranges).

5 Meter Settings

NOTE

When automatically sending results to a paired pump, select the **View later** option to send the test result without delay or press ◤ to automatically send result to a paired pump.

If Patterns is **On** and a new pattern is detected with a blood glucose result, a message appears on the display.

or
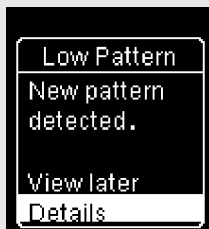
Press ◢ to select **Details** to view the blood glucose results that make up that pattern.
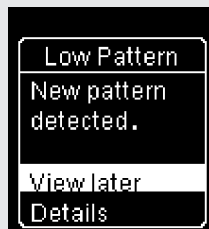
Press ▥ to highlight **View Later**.

Press ▥ to return to the previous screen.

Reminders

You can set up to 4 general test Reminders per day to remind you to test. A series of beeps sound and △ is displayed for Reminders set in the meter.

Reminders:

• turn off by inserting a test strip or pressing any button.

• are postponed until the next test reminder if a test was performed within 15 minutes of a test reminder.

• do not appear/beep if the meter is on at the test reminder time.

• do not appear/beep if the meter is connected and communicating to the paired pump.

• do not beep if the meter's beeper is set to off.

• do not appear/beep if the batteries need to be replaced.

Set Reminders

• Reminder times are pre-set in the meter for 8:00 am, 12:00 pm, 6:00 pm, and 10:00 pm. You may change reminder times by following the instructions below.

• If a general test Reminder is set for the same time as a Post Meal reminder, the Post Meal reminder will appear/beep instead of the general Reminder (see the Post Meal Reminders section of this chapter for details).
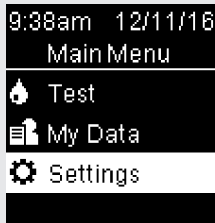
Meter Settings

1

9:38am   12/11/16
Main Menu
♦ Test
▤ My Data
⚙ Settings

Turn the meter on by briefly pressing 🆗. From **Main Menu**, press ⬇ to highlight **Settings**. Press 🆗.

2

Settings
Time/Date
Beeper
Wireless
More Options

Press ⬇ to highlight **More Options**. Press 🆗.

3

More Options
Target Ranges
Patterns
Reminders
Post Meal
▼

Press ⬇ or ⬆ to highlight **Reminders**. Press 🆗.

4

Reminders
☐ 8:00am
☐ 12:00pm
☐ 6:00pm
☐ 10:00pm
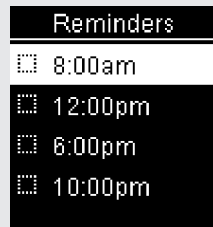
Pre-set reminder times appear on the display. Press ⬇ to highlight a reminder time. Press 🆗.

5
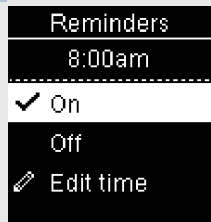
The pre-set reminder time appears. Press ⬇ or ⬆ to select **On** or **Off**. Press 🆗 to move ✔ to the option.
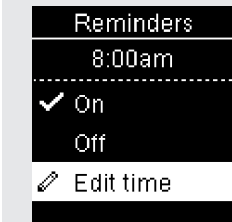
To change the Reminder time shown:

Press ⬇ to highlight **Edit time**. Press 🆗.
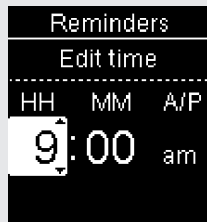
Press ⬇ or ⬆ to adjust each field. Press 🆗 to move to the next field. Press 🆗 to return to the previous menu.

6
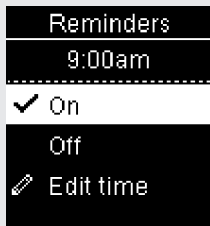
A ✔ indicates the Reminder is set for the time shown and automatically set to **On**.

To turn the reminder off, press ⬇ to highlight **Off**. Press 🆗.

Press 🆗 to return to **Reminders**.

7
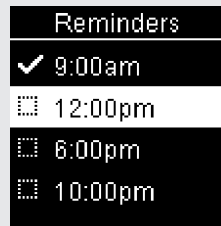
The reminder time appears.

Press ⬇ to continue to set additional reminders or press ◤ to return to **More Options**.

Post Meal Reminders

Post Meal reminders can be set to remind you to test again later when you add a Before Meal comment to a blood glucose result. When a reminder occurs, a series of beeps sound and ⌂ is displayed.

Post Meal reminders:

• turn off by inserting a test strip or pressing any button.

• are postponed until the next test reminder if a test was performed within 15 minutes of a test reminder.

• do not appear/beep if the meter is on at the test reminder time.

• do not appear/beep if the meter is connected and communicating to the paired pump.

• do not beep if the meter's beeper is set to off.

• do not appear/beep if the batteries need to be replaced.

Set Post Meal Reminders

• Adding a Before Meal comment to a blood glucose result sets a Post Meal reminder in the meter.

• Marking blood glucose results with a Post Meal comment provides more information about your test results to help you and your healthcare professional in the management of your diabetes.

• Talk to your healthcare professional to determine your Post Meal test time.

• Select 1 hour, 1.5 hours, or 2 hours for Post Meal reminders to occur.
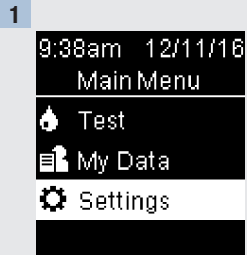
1

9:38am   12/11/16
Main Menu
🔥 Test
📇 My Data
⚙ Settings

Turn the meter on by briefly pressing ▣. From **Main Menu**, press ▼ to highlight **Settings**. Press ▣.

2

Settings
Time/Date
Beeper
Wireless
More Options

Press ▼ to highlight **More Options**. Press ▣.

3
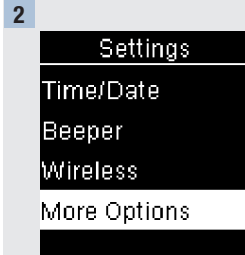
More Options
Target Ranges
Patterns
Reminders
Post Meal
▼

Press ▼ to highlight **Post Meal**. Press ▣.

4

Post Meal
✓ On
Off
✏ Edit time
⑦ Help

Press ▼ or ▲ to highlight **On**. Press 🆗 to move ✓ to the option.

5

Post Meal
✓ On
Off
✏ Edit time
⑦ Help

Press ▼ to highlight **Edit time**. Press 🆗.

6

Post Meal
Remind after:
1 hour
✓ 1.5 hours
2 hours

Press ▼ or ▲ to highlight **1 hour**, **1.5 hours**, or **2 hours** after a meal for **Post Meal** reminders to occur.

Press 🆗 to move ✓ to the option.

Press 🆗 to set and return to the previous menu.

Last Result

Select whether the previous blood glucose result appears with the current blood glucose result. **Test results older than 24 hours do not appear.**

Off – only the current blood glucose result ❶ appears.
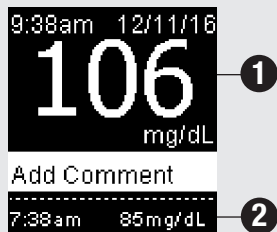
On – the previous blood glucose result ❷ appears with the current blood glucose result.
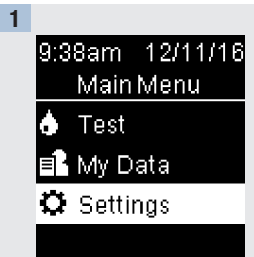
1

Turn the meter on by briefly pressing 🆗. From **Main Menu**, press ⬇ to highlight **Settings**. Press 🆗.

2

Settings
Time/Date
Beeper
Wireless
More Options

Press ⬇ to highlight **More Options**. Press ▥.

3

More Options
Patterns
Reminders
Post Meal
Last Result

Press ⬇ to highlight **Last Result**. Press ▥.

4
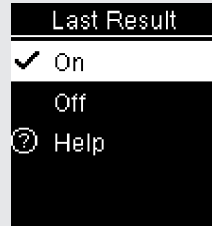
Last Result
✔ On
Off
⑦ Help

Press ⬇ or ⬆ to highlight **On** or **Off**. Press ▥ to move ✔ to the option.

Press ▥ to set the option and return to the previous menu.

Language

Choose the language that appears on the meter.

1
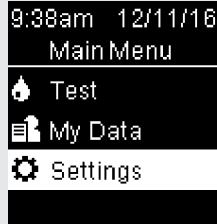
9:38am 12/11/16
Main Menu
🩸 Test
📑 My Data
⚙ Settings

Turn the meter on by briefly pressing 🆗. From **Main Menu**, press 🔽 to highlight **Settings**. Press 🆗.

2

Settings
Time/Date
Beeper
Wireless
More Options

Press 🔽 to highlight **More Options**. Press 🆗.

3
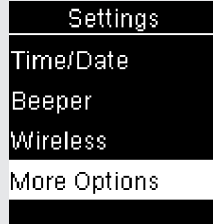
More Options
Reminders
Post Meal
Last Result
Language

Press 🔽 to highlight **Language**. Press 🆗.

4

Language
✓ English
Български
Česky
Dansk
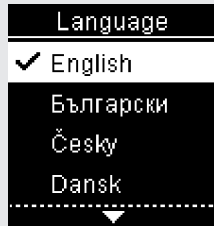
Press 🔽 or 🔼 to highlight the desired language. Press 🆗 to move ✓ to the option.

Press 🆗 to set the language and return to the previous menu.

5 Meter Settings

Overview

- Blood glucose results are stored from the newest to the oldest.
- The meter automatically stores up to 720 blood glucose results in memory with the time and date of the test and any test result comments.
- Once 720 blood glucose results are in memory, adding a new blood glucose result deletes the oldest blood glucose result.
- Only test results that have been marked with a fasting, before meal, after meal, or bedtime comment are included in the average for that comment.
- All test results are included in the overall 7, 14, 30, and 90-day averages regardless of what comment is added.
- Control results are not included in the averages or blood glucose reports.

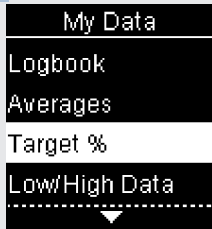| WARNING |
| --- |
| Do not change your therapy based on an individual test result in memory. Talk to your healthcare professional before changing therapy based on test results in memory. |
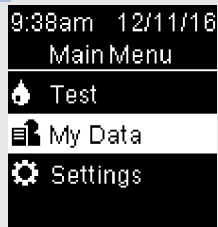
Logbook

1

9:38am   12/11/16
Main Menu

🔴 Test

📊 My Data

⚙ Settings

Turn the meter on by briefly pressing 🆗. From **Main Menu**, press ⬇ to highlight **My Data**. Press 🆗.

2

My Data

Logbook

Averages

Target %

Low/High Data
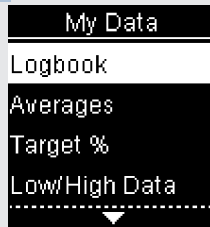
Logbook is highlighted. Press 🆗.

3

Logbook
11/10/16   mg/dL
2:30pm 🔴 145 ——❶
12:00pm 🍴 65 ——❷
9:38am ◐ 106
7:38am ☾ 85
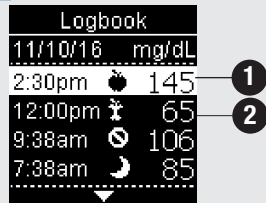
Press ⬇ or ⬆ to scroll through **Logbook**.

The most recent test result ❶.

The 2nd most recent test result ❷.

4 To view details about a test result, press ⬇ or ⬆ to highlight the test result. Press ⬛. Test result details shown below only appear if **Target Ranges** is On or comments were added to a test result.
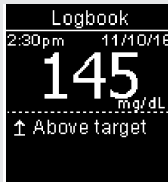
❶

The most recent test result.

❷

The 2nd most recent test result.

Averages

1

9:38am 12/11/16
Main Menu
🔥 Test
▤ My Data
⚙ Settings

Turn the meter on by briefly pressing 🆗. From **Main Menu**, press ▼ to highlight **My Data**. Press 🆗.

2
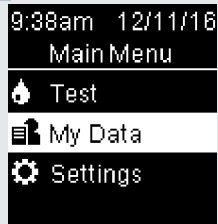
My Data
Logbook
Averages
Target %
Low/High Data
▼
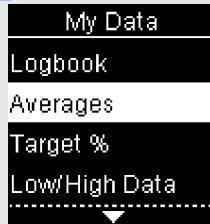
Press ▼ to highlight **Averages**. Press 🆗.

3

Averages
😊 Overall
🍎 Before meal
🍴 After meal
🚫 Fasting
▼

Press ▼ to highlight a category (the example here is **Overall**). Press 🆗.

4

Average
😊 Overall
7 days
14 days
30 days
90 days

Press ▼ to highlight a time period (the example here is **90 days**). Press 🆗.

5

Average
😊 Overall
90 days
106
mg/dL
Tests: 720
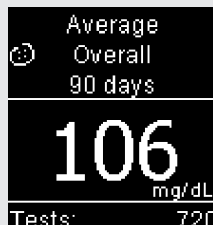
Press ◀ to return to the previous menu if you want to review a different time period OR press ▼ or ▲ to move through different averages.

72
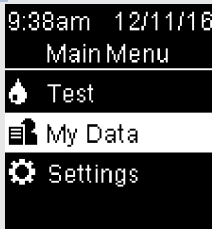
Target Percent (%)

Target Percent (%) allows you to view the percentage of your Overall, Before meal, After meal, Fasting, and Bedtime blood glucose results that are above, within, or below your target ranges.

• Target % results can be viewed for 7, 14, 30, or 90-day time periods.

• Target Ranges must be set in the meter to review Target % results.

1

9:38am 12/11/16
    Main Menu
♦ Test
▤ My Data
⚙ Settings

Turn the meter on by briefly pressing 🆗. From **Main Menu**, press ⬇ to highlight **My Data**. Press 🆗.

2

    My Data
Logbook
Averages
Target %
Low/High Data

Press ⬇ to highlight **Target %**. Press 🆗.

3

    Target %
☺ Overall
♦ Before meal
⚡ After meal
⊘ Fasting

Press ⬇ to highlight a category (the example here is **Before meal**). Press 🆗 to select the option.

4

Press ⌄ to highlight a time period (the example here is **90 days**). Press OK.

5

The **Target %** appears (for the **Before meal** example). The number of total tests included in the Target % appears at the bottom of the display.

Press ◤ to return to the previous menu.

NOTE
Analyzing your blood glucose results stored in the meter is an effective way for you and your healthcare professional to determine how well you are controlling your diabetes. This analysis is a valuable tool for making improvements to your diabetes management. Use care when adding comments to blood glucose results. Incorrect comments can cause inaccurate patterns to be detected by the meter if Patterns is **On**.

Low/High Data

Your healthcare professional can tell you what blood glucose range is appropriate for you. It is very important to stay within your target range.

• Target Ranges must be set in the meter to track Low/High Data test results (see the Target Ranges section in the chapter Meter Settings for details).

• Low BG or High BG Data includes only test results that fall above or below the target ranges set in the meter.

• Low BG or High BG Data is tracked in the meter for 30 days.

6 Review Your Data

You can select Low BG and High BG results for Overall, Before meal, After meal, Fasting, or Bedtime blood glucose results.

Symbol	Name	Description
⊙	Overall	Includes low and high blood glucose results based on Target Ranges set in the meter.
🍎	Before meal	You may view low or high test results marked with a Before Meal comment for Overall, Before breakfast, Before lunch, Before dinner, and Before snack blood glucose results.*
🍏	After meal	You may view low or high test results marked with an After Meal comment for Overall, After breakfast, After lunch, After dinner, and After snack blood glucose results.*
🚫	Fasting	Includes low or high fasting blood glucose results marked as Fasting in comments.
🌙	Bedtime	Includes low or high bedtime blood glucose results marked as Bedtime in comments.

*Test results for Before and After specific meals are only available if Patterns is set to **On**.
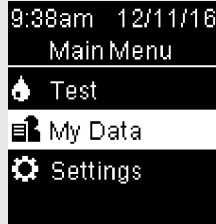
76

1

9:38am   12/11/16
Main Menu

♦ Test

🗎 My Data

⚙ Settings

Turn the meter on by briefly pressing ▣. From **Main Menu**, press ▾ to highlight **My Data**. Press ▣.

2

My Data

Logbook

Averages

Target %

Low/High Data

▾

Press ▾ to highlight **Low/High Data**. Press ▣.

3

Low/High Data

↧ Low BG Data

↥ High BG Data

or

Low/High Data

No data available. Enable target ranges to track low/high BG data.
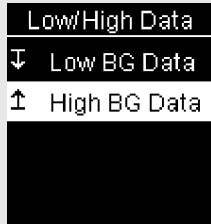
If Target Ranges is set to On:

Press ▾ to select **Low** or **High BG Data** (the example here is **High BG Data**). Press ▣.
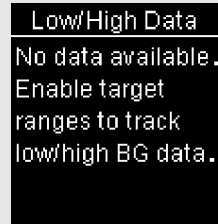
If Target Ranges have NOT been On within the last 30 days:

This message appears on the meter (to turn on Target Ranges see the **Target Ranges** section in the chapter **Meter Settings** for details).

4

Press ▼ to highlight a category (the example here is **Before meal**). Press ᴼᴷ.

If results with detailed meal comments are saved in the Logbook:

The meter may prompt you to select detailed categories to view. Press ▼ to highlight a category (the example here is **Before breakfast**). Press ᴼᴷ.

5
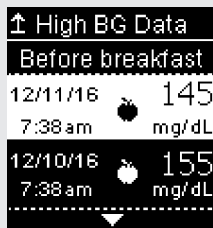
The selected data appears (the example here is **High BG Data**). Press ▼ to scroll through the test results.

Press ◥ to return to the previous menu.

Patterns

• Patterns displays only active Low Patterns or High Patterns based on comments added to blood glucose results within the last 7 days.

• A Pattern is generated when 2 below-target or 3 above-target test results with the same comment are detected within a 7-day period.

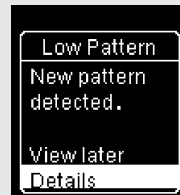Patterns may be viewed on the meter in 3 ways:

9:38am 12/11/16		9:38am 12/11/16		Low Pattern
Main Menu		Main Menu		New pattern detected.
Test		Test		
My Data	or	My Data	or	View later
Settings		Settings		Details
Patterns				
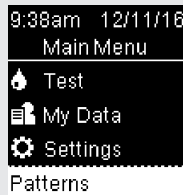
when a Patterns option is displayed at the bottom of **Main Menu**.
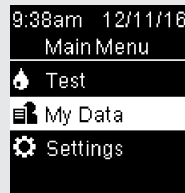
from **My Data** on **Main Menu.**

if a **New pattern detected** message appears on the display when performing a blood glucose test.

Patterns detected by the meter may be displayed on the Main Menu as:

|		
Patterns	High and low patterns have been detected	Patterns may include the following blood glucose results marked with comments:
High Pattern(s)	One or more high patterns have been detected	
Low Pattern(s)	One or more low patterns have been detected	
No Patterns	No active pattern based on test results from last 7 days	Before breakfast, After breakfast, Before lunch, After lunch, Before dinner, After dinner, Before snack, After snack, Fasting, or Bedtime (see the Adding Comments to Blood Glucose Results section in the chapter Blood Glucose Tests).
Blank	Patterns feature is set to **Off**	

1

9:38am   12/11/16
Main Menu
🔴 Test
📑 My Data
⚙ Settings
Patterns
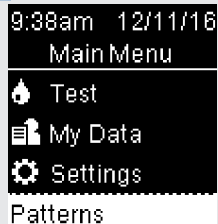
Turn the meter on by briefly pressing ⬛. From **Main Menu**, press ⬇ to highlight the Patterns option at the bottom of the screen (the example here is **Patterns**). Press ⬛.

2

Patterns
⬇ Low Patterns
⬆ High Patterns
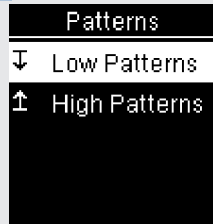
Press ⬆ or ⬇ to highlight **Low Patterns** or **High Patterns** (the example here is **Low Patterns**). Press ⬛ to select the option.

3

⬇ Low Patterns
Before breakfast
Before lunch
Before dinner
Before snack
▼
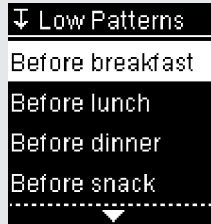
Press ⬇ to highlight a category to review (the example here is **Before breakfast**). Press ⬛.

4

⬇ Low Pattern
Before breakfast
12/11/16   85
7:38am   mg/dL
12/10/16   84
7:38am   mg/dL
▼
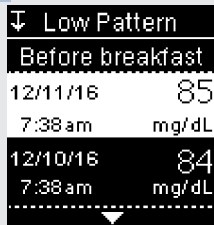
Press ⬇ to scroll through test results.

Press ◤ to return to the previous menu.

6 Review Your Data

Overview

You can wirelessly and automatically synchronize your diabetes information with the MiniMed™ 770G system with Bluetooth® wireless technology. The process of creating a connection between the meter and the pump is called pairing.

Setting	Options	Function
Pairing	Pair To Pump / Delete Pairing	Select whether to pair a pump or to delete the paired pump.
Flight Mode	On / Off	Select whether wireless communication is available. On – wireless communication is not available. Off – wireless communication is available.
Auto-Send	On / Off	Select whether data is automatically sent to the paired pump after each test. On – data is automatically sent to the pump. Off – data is not automatically sent to the pump.

83

Pairing

The meter can automatically send blood glucose results to the MiniMed™ 770G system with Bluetooth® wireless technology. This feature eliminates the need to manually enter your blood glucose result on the pump. Before the meter can send blood glucose results to a pump, the meter and pump must be paired. Refer to the MiniMed™ 770G System User Guide for pairing instructions.

Once the meter and pump are paired, the pairing settings are stored in both devices so that you do not have to repeat the pairing. If communication between the meter and pump is stopped or interrupted for any reason, they will automatically resume communication when both devices are in communication range.

The meter can only be paired with the MiniMed™ 770G system. The meter can only be paired with 1 pump at a time. It is not necessary to delete the existing pump ID when pairing with a new pump. The previous pairing will be replaced by the new pairing. If re-pairing with the same pump, delete the existing pump ID first. Any blood glucose results stored on the meter prior to pairing cannot be transferred from the meter to the pump.
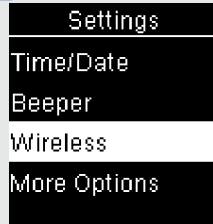
Flight Mode

Select whether wireless communication is available or not. When **Flight Mode** is on, ✈ appears in the title bar and wireless communication is not available.
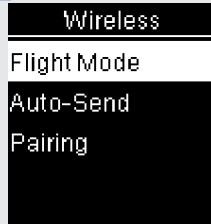
1
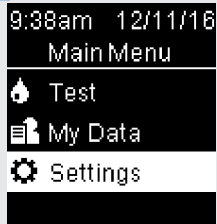
Turn the meter on by briefly pressing 🆗. From **Main Menu**, press ⬇ to highlight **Settings**. Press 🆗.
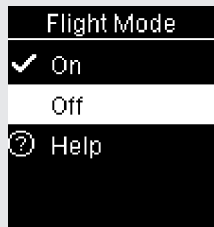
2

Press ⬇ to highlight **Wireless**. Press 🆗.

3

Flight Mode is highlighted. Press 🆗.

4

Press ⬇ or ⬆ to highlight **On** or **Off**. Press 🆗 to move ✔ to the option.

Press 🆗 to set the option and return to the previous menu.

Main Menu with meter in Flight Mode.

85

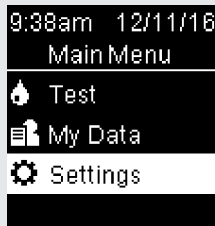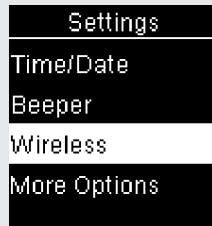## Auto-Send

Select whether blood glucose results are automatically sent to the paired pump after each test. Results sent using Auto-Send can be used by the pump system to calibrate a continuous glucose monitoring system or make insulin dosing calculations.

1

9:38am   12/11/16
Main Menu
🩸 Test
📑 My Data
⚙ Settings

Turn the meter on by briefly pressing 🆗. From **Main Menu**, press ▾ to highlight **Settings**. Press 🆗.

2

Settings
Time/Date
Beeper
Wireless
More Options

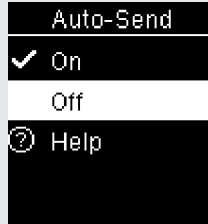Press ▾ to highlight **Wireless**. Press 🆗.

WARNING

- Do not use alternative site testing to calibrate a continuous glucose monitoring system.
- Do not use alternative site testing to make insulin dosing calculations.
- Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

3

Wireless

Flight Mode
Auto-Send
Pairing
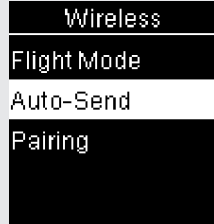
Press ▼ to highlight **Auto-Send**. Press 🆗.

4

Auto-Send

✔ On
Off
⑦ Help

Press ▼ or ▲ to highlight **On** or **Off**. Press 🆗 to move ✔ to the option.
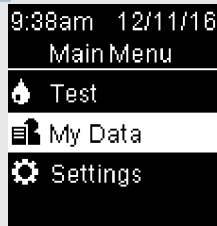
Press 🆗 to set the option and return to the previous menu.

Data Transfer

This feature allows you to transfer data wirelessly from your meter to a paired pump. This feature can be used after the meter and paired pump have not been communicating for a period of time, such as when Flight Mode has been enabled or Auto-Send has been disabled. In this case, there may be blood glucose results that have not been sent to the pump.
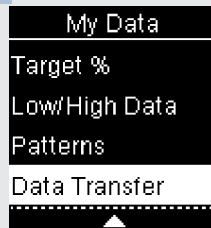
Results sent using Data Transfer cannot be used by the pump system to calibrate a continuous glucose monitoring system or to make insulin dosing calculations.
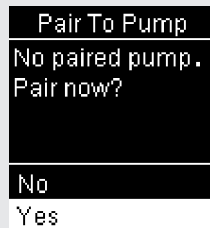
1

```
9:38am   12/11/16
   Main Menu
♦ Test
▤ My Data
⚙ Settings
```

Turn the meter on by briefly pressing 🆗. From **Main Menu**, press 🔽 to highlight **My Data**. Press 🆗.

2

```
   My Data
Target %
Low/High Data
Patterns
Data Transfer
      ▲
```

Press 🔽 to highlight **Data Transfer**. Press 🆗.

```
  Pair To Pump
No paired pump.
Pair now?

No
Yes
```

If a pump is not paired with your meter:

The meter prompts you to pair a pump to the meter (see the Pairing section in the chapter Wireless Communication and Meter Pairing for details).
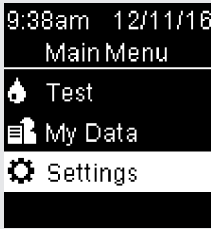
3

The meter transfers the data to the pump.

Delete Pairing

This procedure is to delete the pump ID from the meter, which ends communication between the meter and the pump. For instructions on deleting the pairing information on the pump, refer to the MiniMed™ 770G System User Guide.

The meter can only be paired with 1 pump at a time. It is not necessary to delete the existing pairing when pairing with a new pump.
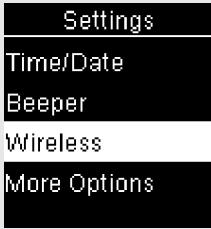
1

9:38am   12/11/16
Main Menu
◆ Test
🗐 My Data
⚙ Settings

Turn the meter on by briefly pressing ▦. From **Main Menu**, press ▼ to highlight **Settings**. Press ▦.

2

Settings
Time/Date
Beeper
Wireless
More Options

Press ▼ to highlight **Wireless**. Press ▦.

3
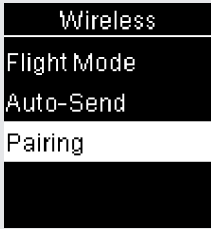
Wireless
Flight Mode
Auto-Send
Pairing

Press ▼ to highlight **Pairing**. Press ▦.

4

Pairing

Pair To Pump

Delete Pairing

⑦ Help
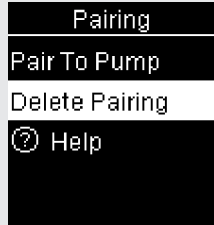
Press ▼ or ▲ to highlight
Delete Pairing. Press 🆗.

5

Delete Pairing

pump 1234567B

Press 🆗 to confirm.

Delete Pairing

Deleted:
pump 1234567B

✓

The meter shows the deleted
pairing.

7 | Wireless Communication and Meter Pairing

What is the difference between cleaning and disinfecting?

Cleaning is the removal of dirt from the meter or lancing device.[3]

Disinfecting is the removal of most, but not all, disease-causing and other types of microorganisms (bloodborne pathogens) from the meter or lancing device.[3]

Approved Cleaning and Disinfecting Product

The following product has been approved for cleaning and disinfecting the meter and lancing device:

Super Sani-Cloth (EPA* reg. no. 9480-4)

Super Sani-Cloth can be purchased from Amazon.com, Officedepot.com, and Walmart.com.

- Do not use any other cleaning or disinfecting solutions. Using solutions other than the Super Sani-Cloth could result in damage to the meter and lancing device.
- The effect of using more than one product interchangeably to clean and disinfect the meter and lancing device has not been tested. Always use Super Sani-Cloth to clean and disinfect the meter and lancing device.
- Roche has demonstrated that the product is good for 5-year use, after testing in a total of 260 disinfection cycles (equal to cleaning and disinfecting once per week for 5 years).

*Environmental Protection Agency

8 | Meter and Lancing Device Cleaning and Disinfecting

NOTE

For technical assistance or questions on cleaning and disinfecting, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Cleaning and Disinfecting the Meter

WARNING

If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be cleaned and disinfected prior to use by the second person.

To clean and disinfect without damaging the meter, follow these procedures carefully.

When to Clean and Disinfect the Meter

• Clean the meter to remove visible dirt or other material prior to disinfecting.

• Clean and disinfect the meter at least once per week and when blood is present on the surface of the meter.

• Clean and disinfect the meter before allowing anyone else to handle the meter. Do not allow anyone else to use the meter on themselves for testing purposes.

NOTE

Using cleaning and disinfecting products could result in damage to the meter. If you notice any of the following signs of deterioration after cleaning and disinfecting your meter, stop using your meter and contact the Accu-Chek Customer Care Service Center at 1-800-858-8072: residue around buttons, clouding of display, button malfunction, out-of-range control results.

What to Clean and Disinfect

The following parts of the meter should be cleaned and disinfected:

• The area around slots and openings (do not get any moisture in slots or openings)

• The meter display

• The entire meter surface

How to Clean and Disinfect the Meter

WARNING

Failure to follow these instructions will damage the meter and stop it from working properly.

- DO NOT clean or disinfect the meter while performing a blood glucose or control test.
- DO NOT get any moisture in slots or openings.
- DO NOT spray anything onto the meter.
- DO NOT immerse the meter in liquid.
- Always use the same product for both cleaning and disinfecting.

1
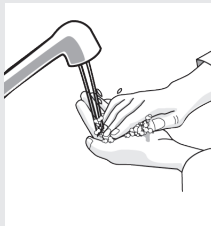
Wash hands thoroughly with soap and water.

2
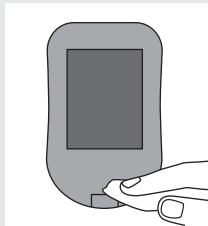
Turn the meter off and wipe the entire meter surface with a Super Sani-Cloth. Carefully wipe around the test strip slot and other openings.

Make sure that no liquid enters any slot or opening.

3

A separate Super Sani-Cloth should be used for cleaning and disinfection. For disinfecting the meter, get a new cloth and repeat step 2, making sure the surface stays wet for 2 minutes.

Make sure that no solution is seen in any slot or opening.

95

4

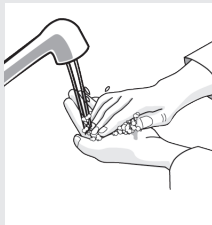Wash hands thoroughly with soap and water.

Cleaning and Disinfecting the Lancing Device

To clean and disinfect without damaging the lancing device, follow these procedures carefully.

When to Clean and Disinfect the Lancing Device

- Clean the lancing device to remove visible dirt or other material prior to disinfecting.
- Clean and disinfect the lancing device at least once per week to remove visible dirt or other material for safe handling.
- Clean and disinfect the lancing device before allowing anyone else to handle the lancing device, for instance, if you have someone assisting you. Do not allow anyone else to use the lancing device.

NOTE

- Do not throw away the cap after each use. Use the approved cleaning and disinfecting product on the cap.
- Always remove the lancet drum before cleaning or disinfecting the lancing device.
- Using cleaning and disinfecting products could result in damage to the lancing device. If you notice any of the following signs of deterioration after cleaning and disinfecting your lancing device, stop using your lancing device and contact the Accu-Chek Customer Care Service Center at 1-800-858-8072: residue around buttons, difficulty in priming the device, difficulty in inserting the lancet drum.
- You might observe a slight discoloration of the lancing device after multiple cleaning and disinfecting cycles. This does not affect the functionality of the lancing device.

What to Clean and Disinfect

The following parts of the lancing device should be cleaned and disinfected:

- The entire lancing device surface
- The cap

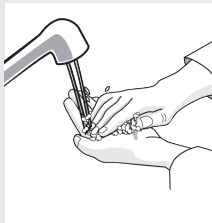## 8 | Meter and Lancing Device Cleaning and Disinfecting

How to Clean and Disinfect the Lancing Device

WARNING

Failure to follow these instructions may damage the lancing device and stop it from working properly.
- DO NOT get any moisture into any openings.
- Always use the same product for both cleaning and disinfecting.

1

Wash hands thoroughly with soap and water.

2

Wipe the entire surface of the lancing device and the inside of the cap with a Super Sani-Cloth.

3

A separate Super Sani-Cloth should be used for cleaning and disinfection. For disinfecting the lancing device, use a new cloth and repeat step 2 making sure the surface stays wet for 2 minutes.

4
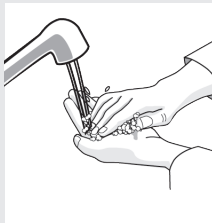
Wash hands thoroughly with soap and water.

Meter and Lancing Device Cleaning and Disinfecting | 8

8 Meter and Lancing Device Cleaning and Disinfecting

Meter Maintenance

The meter automatically tests its own systems every time you turn it on and lets you know if something is wrong. See the Error Messages section of this chapter.

If you have problems with the meter or think the results are not accurate, perform a control test with an unexpired test strip and control solution. If the control result is not within the acceptable range, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

WARNING
Keep new and used batteries away from children. See the warning in the Important Safety Information section of this User's Manual for additional information.

Changing the Batteries

1	2	3
	Press	
Open the battery door on the back of the meter by pushing the tab in the direction of the arrow and pulling the door up.	Release the old batteries by pressing the 🔋 button. Remove the old batteries.	Slide the new batteries under the black tabs and 🔋 button, with the **(+) side facing up**. Put the battery door back in place and snap it closed.

NOTE

- If the E-7 or E-9 error code still appears on the display after you have changed the batteries, remove the batteries again, press and hold the Power/Set/OK button for at least 2 seconds, then reinsert the batteries.
- Always have a spare set of batteries.
- Battery life may vary due to factors such as temperature and battery manufacturer.
- The meter uses two 3-volt lithium batteries, coin cell type CR2032. This type of battery can be found in many stores.
- Always replace both batteries at the same time and with the same brand.
- The logbook data is saved when you replace the batteries.

Error Messages

WARNING

• Never make therapy decisions based on an error message.

• If you have any concerns or see any other error message, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

The meter will not turn on or the display is blank.

• Batteries are dead.

Insert new batteries.

• Display is damaged. / Meter is defective.

Contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

• Extreme temperatures.

Move the meter to a location within the stated temperature limits.

⚠ Test Not Allowed
Remove USB cable to perform test.

The meter is connected to a USB cable and a test cannot be performed.

Remove the USB cable and perform a test.

⚠ Transfer Failed
Ensure pump is within range.
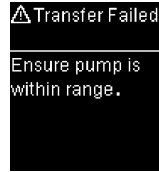
Blood glucose results were not transferred to the paired pump.

Make sure the paired pump is within range of the meter.

Data cannot be sent to the paired pump because the meter is in Flight Mode.

Retry the data transfer when the meter is not in Flight Mode.

USB functionality is not available for this meter.

Remove the USB cable.

One or more blood glucose results are excluded from the selected averages because the results are invalid or outside the system measuring range.

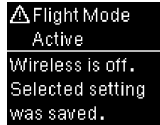One or more blood glucose results are excluded from the selected target % data because the test results are invalid.

One or more blood glucose results are excluded from the selected low/high data because the test results are invalid.

The date entered is not valid.

Enter the correct date.
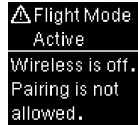
⚠ Flight Mode
Active
Wireless is off.
Selected setting
was saved.

A meter setting was changed while in Flight Mode.
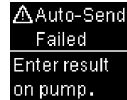
The setting change will not take effect until Flight Mode is turned off.

⚠ Flight Mode
Active
Wireless is off.
Pairing is not
allowed.

Pairing to a pump cannot be performed while in Flight Mode.

Retry pairing when the meter is not in Flight Mode.

⚠ Auto-Send
Failed
Enter result
on pump.

The blood glucose result has not been sent to the pump.

Manually enter the result on the pump. For instructions, refer to the MiniMed™ 770G System User Guide.

⚠ Pairing Failed

Retry pairing.

The meter was unable to pair with a pump.

Retry the pairing.

The test strip may be damaged, not properly inserted, or was previously used.

Remove and reinsert the test strip or replace it if damaged or previously used.
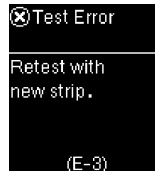
A meter or test strip error has occurred.

This error message could appear if the cap on the test strip container was not closed tightly. The test strips may have been damaged due to improper storage or handling.

Never make therapy decisions based on an error message.

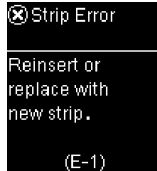Repeat the blood glucose test. If a second E-3 error message appears, perform a control test with the control solution and a new test strip. See the section Performing a Control Test in the chapter Control Tests. If you continue to receive an E-3 error message, use an alternate method for testing your blood glucose, such as a back-up meter and test strip. If the alternate method gives an extremely high blood glucose result, or if an alternate method is not available, **contact your healthcare professional immediately**.

In rare cases, an E-3 error message may indicate that your blood glucose is extremely high and above the system's measuring range. **See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests for other possible causes of the error message.**

(E-4)

Not enough blood or control solution was drawn into the test strip for measurement or was applied after the test had started.

Discard the test strip and repeat the blood glucose or control test.

(E-6)

Blood or control solution was applied to the test strip before **Apply drop** appeared.

Discard the test strip and repeat the blood glucose or control test.

(E-7)

An electronic error occurred.

Remove the batteries, press and hold the Power/Set/OK button for at least 2 seconds, and reinsert the batteries. Perform a blood glucose or control test.

(E-8)

The temperature is above or below the proper range for the system.

Refer to the test strip package insert for system operating conditions. Move to an area with the appropriate conditions and repeat the blood glucose or control test. Do not artificially heat or cool the meter.

(E-9)

The batteries may be out of power.

Turn the meter back on. **If you are in a cold environment, move to a location with a more moderate temperature and retest.** If the message continues to appear after several attempts, replace the batteries. If the message reappears after the batteries have been replaced, remove the batteries, press and hold the Power/Set/OK button for at least 2 seconds, then reinsert the batteries

Time/Date Error
Correct time/date if necessary.
(E-10)

The time and date setting may be incorrect.

Make sure the time and date are correct and adjust, if necessary.

Time/Date Error
Ensure pump is within range.
(E-10)

The time and date setting may be incorrect.

Make sure the pump is in communication range of the meter to update the time and date.

Test Error
Retest with new strip.
(E-11)

The test strip may be damaged.

Retest with a new test strip.

High Ascorbate
Contact your healthcare professional.
(E-12)

Your blood sample may contain a high level of ascorbate.

Contact your healthcare professional.

Strip Error
Reinsert or replace with new strip.
(E-13)

Fluid or foreign material may be present in the test strip slot.

Remove and reinsert the test strip or repeat the blood glucose or control test with a new test strip. If the problem persists, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Electronic
Error
Contact Roche.

(E-14)

(E-14)
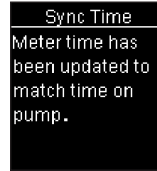
An electronic error has occurred.

Contact the Accu-Chek Customer Care Service Center at
1-800-858-8072.
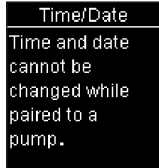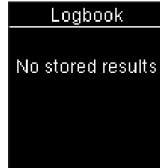
Sync Time
Meter time has
been updated to
match time on
pump.

The meter time and date have
been changed to match the
paired pump.

Time/Date
Time and date
cannot be
changed while
paired to a
pump.

When paired to a pump, the
meter time and date cannot be
changed using the meter.

Logbook
No stored results

There are no results in the
Logbook.

There is an invalid result in the Logbook.
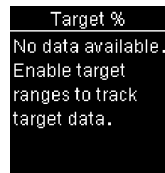
There are no test results in range for the selected data.

Target Ranges is **Off** and there are no results for the Target % data stored in the meter.

Low/High Data		↑ High BG Data	↓ Low BG Data
No data available. Enable target ranges to track low/high BG data.		No high BG data available	No low BG data available

Target Ranges is **Off** and there are no results for the low/high data stored in the meter.

There are no results stored in the meter for the selected data.

Patterns		Patterns	Patterns
No active patterns based on last 7 days of data.		No data available. Turn on Patterns in Settings to show patterns for results marked ▼	with comments. ⬍

Patterns is **On** but there are no active patterns stored in the meter.

Patterns is **Off**.
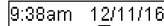
9:38am 12/11/16	9:38am 12/11/16	
HI	LO	
Add Comment	Add Comment	

Blood glucose may be higher than the measuring range of the system.

See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests.

Blood glucose may be lower than the measuring range of the system.

See the Unusual Blood Glucose Results section in the chapter Blood Glucose Tests.
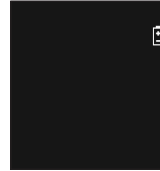
The batteries are almost out of power.

Change the batteries now. If the symbol reappears after the batteries have been replaced, remove the batteries again, press and hold the Power/Set/OK button for at least 2 seconds, then reinsert the batteries.

Product Limitations

See the literature packaged with the test strips and control solutions for the latest information on product specifications and limitations.

Specifications	
Blood volume Sample type Measuring time Measuring range Test strip storage conditions System operating conditions	Refer to the test strip package insert.
Meter storage conditions	Temperature: -13–158 °F
Memory capacity	720 blood glucose results and 32 control results with time and date
Automatic off	90 seconds
Power supply	Two 3-volt lithium batteries (coin cell type CR2032)
Display	LCD
Dimensions	80 × 47 × 20 mm (LWH)
Weight	Approx. 40 g (with batteries)
Construction	Hand-held
Protection class	III
Meter type	The Accu-Chek Guide Link meter is suitable for continuous operation.

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10 | Technical Information

Control solution storage conditions	Refer to the control solution package insert.
Interfaces	Bluetooth low energy technology; USB: micro-B connector (functionality not available)
Radio frequency connectivity	Bluetooth low energy technology operating in the frequency band of 2.4 GHz (2.402 GHz to 2.480 GHz) with a maximum transmitted power of 0 dBm (1 mW).

Bluetooth Wireless Technology –The meter uses Bluetooth low energy wireless technology to communicate and transfer information to the pump. Bluetooth wireless technology is a form of radio frequency (RF) technology that operates in the unlicensed industrial, scientific, and medical band at 2.4 to 2.485 GHz.

Electromagnetic Compatibility – The meter meets the electromagnetic emission requirements as per EN ISO 15197. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. In addition, the meter meets the electromagnetic emissions requirements as per EN 61326-2-6 / EN 60601-1-2. Its electromagnetic emission is thus low. Interference from the meter to other electrically-driven equipment is not anticipated.
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
1. This device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

In the event there is interference from another device, it is recommended that you increase the distance between the meter and that device. You can also turn off the interfering device. In addition, you can turn off Bluetooth low energy wireless technology on the meter.
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment is in direct contact with the body of the user under normal operating conditions. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

Changes or modifications not expressly approved by the party responsible for compliance (i.e., the manufacturer) could void the user's authority to operate the equipment.

Performance Analysis – Refer to the test strip package insert.

Test Principle – Refer to the test strip package insert.

Product Safety Information

WARNING

- This meter meets IEC 61010-1 and IEC 61010-2-101 safety standards.
- Strong electromagnetic fields may interfere with the proper operation of the meter. Do not use the meter close to sources of strong electromagnetic radiation.
- To avoid electrostatic discharge, do not use the meter in a very dry environment, especially one in which synthetic materials are present.

Travel Documentation

If you are traveling on a commercial airline, you may be required to provide documentation certifying that this meter meets environmental conditions and test procedures for Airborne Equipment (RTCA DO-160) section 21 Emission of Radio Frequency Energy. Visit accu-chek.com or contact the Accu-Chek Customer Care Service Center at 1-800-858-8072 to obtain a copy of the document.

10 | Technical Information

Discarding the Meter, Test Strips, Lancing Devices, Lancets, and Batteries

> **WARNING**
>
> - Any product coming in contact with blood is considered contaminated (potentially infectious).*
> - During normal testing, any blood glucose meter may come in contact with blood.
> - Lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions.

Roche is committed to recycling and sustainability. Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used meters, used test strips, used lancets, and used batteries.

Consider the following points when discarding used testing materials: Consider recycling the meters and batteries at an appropriate facility. Be aware the meter is potentially hazardous electronics scrap (e-scrap) and should be disposed of accordingly. The batteries are potentially hazardous also and should be discarded accordingly.

Disinfect the meter before recycling or discarding.

*29 CFR 1910.1030 – Bloodborne pathogens

Explanation of Symbols

⚠	Caution, refer to safety-related notes in the instructions for use accompanying this product.
☣	Biological risks – used meters carry a risk of infection.
FC FCC ID: WX3-401	This device complies with Part 15 of the FCC Rules.
⧗	Use by
🏭	Manufacturer
LOT	Batch code
GTIN	Global Trade Item Number
SN	Serial number
⊟+⊟	3-volt coin cell type CR2032
🚫	Keep new and used batteries away from children.

10 | Technical Information

Additional Supplies

Test Strips: Accu-Chek Guide test strips

Control Solutions: Accu-Chek Guide control solutions

Lancets: Accu-Chek FastClix 102-ct. lancet drums (17-6 ct. drums)

References

[1] FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). Update 11/29/2010." http://wayback.archive-it.org/7993/20161022010458/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. Accessed January 17, 2018.

[2] CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010)." http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html. Accessed January 17, 2018.

[3] Centers for Disease Control and Prevention (CDC): "Guideline for Disinfection and Sterilization in healthcare Facilities, 2008." Update: May 2019. William A. Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC). https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf. Accessed September 23, 2019.

Warranty

Accu-Chek Guide Link Meter 30-day Money-back Guarantee for Qualifying Consumers

Roche offers qualifying consumers that purchase an Accu-Chek Guide Link meter, a 30-day money back guarantee. If you are not fully satisfied with your Accu-Chek Guide Link meter, contact the Accu-Chek Customer Care Service Center toll-free at 1-800-858-8072 to determine whether you qualify to receive a full refund within 30 days of purchase. If you are covered under Medicare, Medicaid, other federal/state programs, or private insurance you are NOT eligible for this money-back offer. Consumers affected by this exclusion may instead request a different Accu-Chek meter/system. The refund will be limited to the amount paid by you net of any rebates. You must have a copy of the dated itemized purchase receipt and the original packaging to obtain this refund.

Accu-Chek Guide Link Meter Limited 3-Year Warranty

Roche warrants to the original purchaser of the meter that your Accu-Chek Guide Link meter will be free from defects in materials and workmanship for three years from the date of purchase. If, during this 3-year period, the meter does not work properly because of a defect in materials or workmanship, Roche will replace it with a new Accu-Chek Guide Link meter or equivalent product free of charge. The warranty on the replacement meter will expire on the date of the original warranty expiration or 90 days after the shipment of a replacement system, whichever period is longer. The purchaser's exclusive remedy with respect to the Accu-Chek Guide Link meter shall be replacement.

This warranty does not apply to the performance of an Accu-Chek Guide Link meter that has been damaged by accident or has been altered, misused, tampered with, or abused in any way. Roche will handle meters that show damage or abuse according to its Non-Warranty Service Policy described on the following page.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR OPERATION OF THE METER OR ITS PARTS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FROM THE SALE OF THE METER, SHALL EXTEND FOR A LONGER DURATION THAN THREE YEARS FROM THE DATE OF PURCHASE.

Some states do not allow limitations on how long an implied warranty will last or the exclusion of incidental or consequential damages, so the above limitation and exclusion may not apply to you. This warranty gives you specific legal rights, which vary from state to state.

11 | License and Warranty

Non-Warranty Service Policy

Roche Non-Warranty Service Policy applies to meters where the above warranty has not become effective, has become inapplicable, or has expired. Roche will replace, at its option, meters returned to it for a service charge (not to exceed $35).

Replacement will be with the same or similar product. Replacement meters will be warranted for a period of 90 days from shipment under a limited warranty providing for replacement of parts and labor at no charge.

Warranty and Service Instructions

All requests for return of Accu-Chek Guide Link meters under the above warranty or service policy must be made to the Accu-Chek Customer Care Service Center. You will be mailed a return authorization label, which must be affixed to your carton for shipping the system to Roche. Cartons received without this label will be returned to you at your expense.

Customers experiencing difficulties should review the troubleshooting information in the Meter Maintenance and Troubleshooting chapter of this manual. Further inquiries should be directed to the Accu-Chek Customer Care Service Center.

Be sure to register your warranty online at accu-chek.com/register for the Accu-Chek Guide Link system.

Limited License

CAUTION – A RESTRICTED LICENSE LIMITS USE OF THE ACCU-CHEK GUIDE LINK SYSTEM (meter and test strips) IN THE UNITED STATES – READ CAREFULLY THE LIMITATIONS RECITED BELOW.

The ACCU-CHEK Guide Link system (meter and test strips) and its use are protected by U.S. Patent Nos. 7,276,146 (expires 4-October-2022); 7,276,147 (expires 4-October-2022); 8,298,401 (expires 4-October-2022); 8,303,801 (expires 4-October-2022); 8,329,026 (expires 4-October-2022); 7,407,811 (expires 9-May-2020); 7,452,457 (expires 2-May-2026); 7,488,601 (expires 1-February-2026); 7,494,816 (expires 29-December-2019); 7,569,126 (expires 28-December-2026); and 7,604,721 (expires 12-August-2026). A license to use the ACCU-CHEK Guide Link system is required until the expiration of the last-to-expire patent listed above and is only granted when the ACCU-CHEK Guide Link meter is used with the ACCU-CHEK Guide test strips.

Accu-Chek Guide test strips are specifically manufactured for operation with the Accu-Chek Guide Link meter. Use of other test strips supplied by another manufacturer may prevent or impair the proper function of the Accu-Chek Guide Link system.

Using the ACCU-CHEK Guide Link system indicates your acceptance of the restricted license to use the ACCU-CHEK Guide Link meter only with ACCU-CHEK Guide test strips. If you do not agree to the terms and conditions of the restricted license, you may return, at the place of purchase, the unused ACCU-CHEK Guide Link system for a full refund. If you have any questions, contact the ACCU-CHEK Customer Care Services Center at 1-800-858-8072.

Except where prohibited by statute, all warranties covering the ACCU-CHEK Guide Link system are voided by use of the ACCU-CHEK Guide Link meter with any test strips other than ACCU-CHEK Guide test strips.

11 | License and Warranty

CAUTION - A RESTRICTED LICENSE LIMITS USE OF THE ACCU-CHEK FASTCLIX SYSTEM (lancing device and lancet drums) IN THE UNITED STATES. READ CAREFULLY THE LIMITATIONS RECITED BELOW.

The Accu-Chek FastClix system (device and lancet drums) and its use are protected by U.S. Patent Nos. 7,322,998 (expires 3-March-2020); and 7,785,338 (expires 5-January-2026). A license to use the Accu-Chek FastClix system is required until the expiration of the last-to-expire patent listed above and is only granted when Accu-Chek FastClix lancet drums are used with the Accu-Chek FastClix device.

Accu-Chek FastClix lancet drums are high precision components that are produced to the close tolerances required for satisfactory operation with the Accu-Chek FastClix device. Use of other lancet drums with the Accu-Chek FastClix device may prevent or impair proper function of the Accu-Chek FastClix device.

Using the Accu-Chek FastClix device indicates your acceptance of the restricted license to use the Accu-Chek FastClix device only with Accu-Chek FastClix lancet drums. If you do not agree to the terms and conditions of the restricted license, you may return, at the place of purchase, the unused Accu-Chek FastClix device for a full refund. If you have any questions, please call the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Except where prohibited by statute, all warranties covering the Accu-Chek FastClix device are voided by use of the Accu-Chek FastClix device with any lancet drums other than Accu-Chek FastClix lancet drums.

Patent Information
U.S. Pat.: http://www.roche-diagnostics.us/patents

Index

Notes

ACCU-CHEK® Guide Link
Blood Glucose Monitoring System

ENGLISH

Start Here
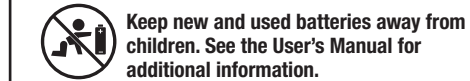
Quick Start Guide

For in vitro diagnostic use only

For use with the MiniMed™ 770G system with Bluetooth® wireless technology

Medtronic **Roche**

WARNING

Keep new and used batteries away from children. See the User's Manual for additional information.

- This Quick Start Guide does not replace the User's Manual for your Accu-Chek Guide Link blood glucose meter. The User's Manual contains important cleaning and disinfecting procedures and additional information.
- The meter and lancing device are for single patient use. Do not share them with anyone, including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from bloodborne pathogens, even after you have performed cleaning and disinfecting.
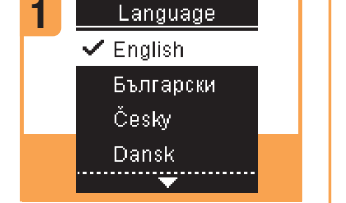
NOTE

- Always have a spare set of batteries.
- Battery life may vary due to factors such as temperature and battery manufacturer.
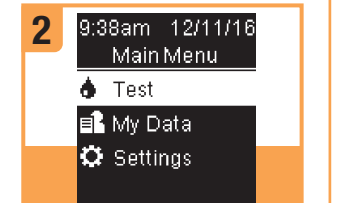

Meter Overview

1. Display
2. Back Button ⬅
3. Up Arrow and Down Arrow Buttons ▲ ▼
4. Power/Set/OK Button ●
5. Test Strip Slot with Light
6. Battery Door
7. Micro USB Port*
8. Test Strip Ejector

*USB functionality is not available for this meter.

Set the Meter Language

1

Language
✓ English
Български
Česky
Dansk

Turn the meter on by briefly pressing ●. Language appears.
Press ▲ or ▼ to highlight the desired language.

2

9:38am 12/11/18
Main Menu
🩸 Test
📋 My Data
⚙ Settings

Press ● to set the language and return to Main Menu.


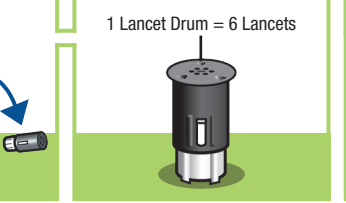## Pair the Meter and Insulin Pump

The Accu-Chek Guide Link meter can automatically send blood glucose results to the MiniMed™ 770G system with Bluetooth® wireless technology.
This feature eliminates the need to manually enter your blood glucose result on the insulin pump.
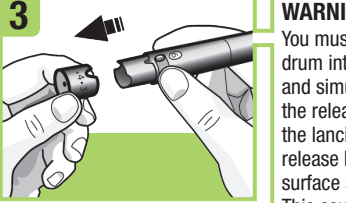Refer to the MiniMed™ 770G System User Guide for pairing instructions.

Set up the Lancing Device

1

Release button
Penetration depth
Cap
Number of lancets remaining
Lever to advance lancet
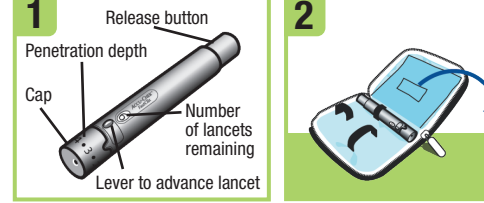
Familiarize yourself with the Accu-Chek FastClix lancing device and the lancet drum.

2

Get the lancet drum from the pocket in the carry case.

3

1 Lancet Drum = 6 Lancets

Remove the cap by pulling it straight off. Do not twist the cap.

NOTE
Each lancet drum contains 6 sterile lancets. You can perform 6 tests before replacing it.

WARNING
You must not insert the lancet drum into the lancing device and simultaneously press the release button or hold the lancing device with the release button resting on a surface such as a table top. This could release a lancet and inadvertently cause injury.

4

Insert the lancet drum, white end first, into the lancing device. Push the drum all the way in until it clicks firmly into place.
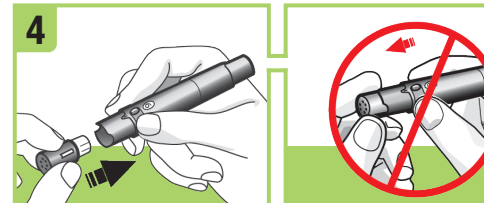
NOTE
Do not remove the lancet drum until all 6 lancets are used since the drum cannot be reused once it has been removed from the lancing device.

5

Place the cap back on the lancing device. Make sure the notch on the cap lines up with the notch on the lancing device.

6
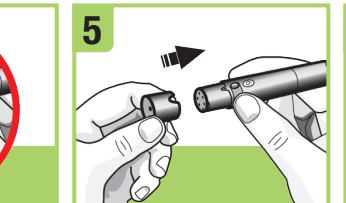
Adjust the lancet depth to a comfortable penetration level. Start at 2. For tougher skin, dial to a higher number.

When ready to test…
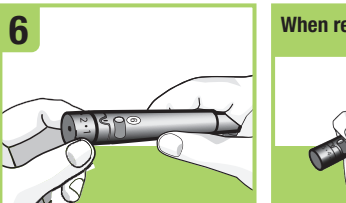
Using the lancing device: By pressing the release button all the way down, the lancing device primes and pricks with 1 click.

Perform a Blood Glucose Test

1
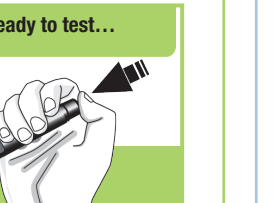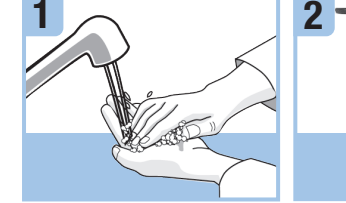
Wash and dry your hands thoroughly **before** and **after** you perform a blood glucose test.
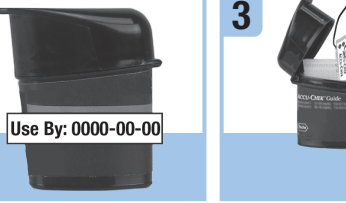
2

Use By: 0000-00-00

Check the **Use By** date on the test strip container. Do not use test strips past the **Use By** date.

3

Remove a test strip from the test strip container. Close the cap tightly.

4

Test
⏳
Preparing to test

Insert the metallic end of the test strip into the meter.

The meter turns on. **Preparing to test** appears.

5
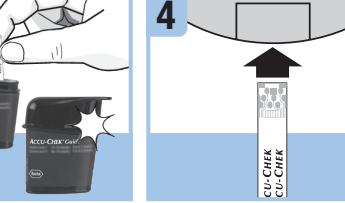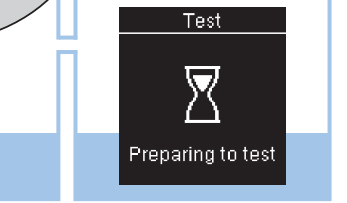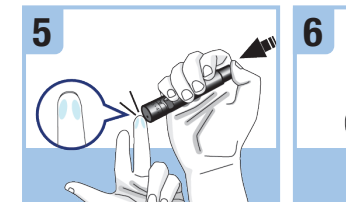
Press the lancing device firmly against the side of your fingertip and press the release button all the way down to prick your finger.
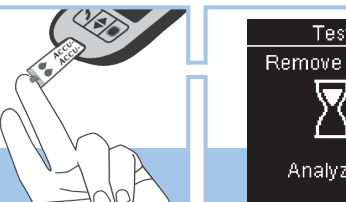
6

Test
Remove finger
⏳
Analyzing

Touch the **yellow edge** of the test strip to the blood drop. Do not put blood on top of the test strip. Remove your finger from the test strip when **Analyzing** appears. Failure to move your finger away from the test strip could give inaccurate test results.

9:38am 12/11/18
106
mg/dL
Add Comment
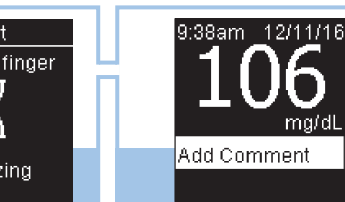
The test result appears on the display in less than 4 seconds. Press 🔄 to automatically send result to a paired pump. If 🔄 is not pressed, there will be a delay seeing the blood glucose result on the paired pump.

Before you finish…

Prepare the lancing device for the next test. Slide the lever over and back once to advance to the next lancet. The window shows the number of lancets remaining.

Roche Diabetes Care, Inc.
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Indianapolis, IN 46256
www.accu-chek.com

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XXXXXXXXXXX-0820

05939-GuideLink-qsg-fc-FDA.indd   1   4/24/2020 4:24:49 PM

ID-No.
Dimensions

158,8 x 134,9 x 67 Var. C

8000779

10 mm

10mm

10mm

PMS-8000779 OOBE DIE
WITH LATCH

| Roche – 01031 V5/1 – GuideLink-meter-kit-FDA – Black 8000779 |
| Roche – 01031 V5/2 – GuideLink-meter-kit-FDA – Cyan 8000779 |
| Roche – 01031 V5/3 – GuideLink-meter-kit-FDA – Magenta 8000779 |
| Roche – 01031 V5/4 – GuideLink-meter-kit-FDA – Yellow 8000779 |
| Roche – 01031 V5/5 – GuideLink-meter-kit-FDA – PMS 2382 C 8000779 |
| Roche – 01031 GuideLink-meter-kit-FDA – die_cut 8000779_ |

Approved according to
SOP,04,07,GPL,0004

Master

The Signature will not be printed!

TW

GD/LAY

PROOF OF PURCHASE
Accu-Chek Guide Link Care Kit
Cat. No. XXXXXXXXXXX
NDC XXXXX-XXXXX-XX

XX-XXXX-XXXXX-XX

Code or Label

Attention: Control solution is available for purchase.
To order the control solution, talk to your pharmacist
or visit accu-chek.com to order online.

Theft tag may be included inside package.

U.S. Pat.: http://www.roche-diagnostics.us/patents

Manual before use.
drums) in the United States. Carefully read the User's
and the Accu-Chek FastClix system (device and lancet
Accu-Chek Guide Link system (meter and test strips)
CAUTION: A restricted license limits use of the

For Single Patient Use Only
Blood Glucose Monitoring System

ACCU-CHEK®
Guide Link

ACCU-CHEK®
Guide Link
Blood Glucose Monitoring System
For Single Patient Use Only

Get the help you need.

For questions, visit accu-chek.com/support
or call 1-800-858-8072.

Diabetes information, self-care tools,
product support, and demonstrations are
available at accu-chek.com.

Carefully read the User's Manual before use

For testing glucose in fresh capillary whole
blood

For single patient use only

For in vitro diagnostic use

Store between 39–86 °F

Use between 10–90 % relative humidity

Use of this device on multiple patients may lead to
transmission of Human Immunodeficiency Virus
(HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV),
or other bloodborne pathogens.

Roche Diabetes Care, Inc.
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Indianapolis, IN 46256
accu-chek.com

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Bluetooth SIG, Inc. and any use of such marks by Roche is under license.
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ACCU-CHEK®
Guide Link
Blood Glucose Monitoring System
For Single Patient Use Only

Medtronic   **Roche**

ACCU-CHEK®
Guide Link
Blood Glucose Monitoring System
For Single Patient Use Only

Contains:
- Accu-Chek Guide Link blood glucose meter with
  batteries included
- 10 Accu-Chek Guide test strips
- Accu-Chek FastClix lancing device with 6 lancets
  (1 drum)
- Carrying case
- Instructions for use

**For use with the MiniMed™ 770G system with
Bluetooth® wireless technology.**

Accu-Chek Guide Link System User Performance

Accurate Results	119 out of 120 (99.2 % of results)
More Accurate Results	111 out of 120 (92.5 % of results)
Most Accurate Results	70 out of 120 (58.3 % of results)

Accuracy key	% listed are meter result as compared to lab result
Accurate result	Meter result is +/- 15 % of lab result
More accurate result	Meter result is +/- 10 % of lab result
Most accurate result	Meter result is +/- 5 % of lab result

See the website, test strip package insert, and User's Manual
for more information.

Bluetooth

Medtronic   **Roche**

Medtronic

Code or Label

Board quality

supplier
markings

ACCU-CHEK® Guide

Test Strips

FOR SINGLE PATIENT USE ONLY
Cat. No. XXXXXXXX

Important Information

NOTE: In this package insert the term "blood glucose" is used when referring to "blood sugar."

Intended Use for the Accu-Chek Guide Meter

The Accu-Chek Guide Blood Glucose Monitoring System is comprised of the Accu-Chek Guide meter and Accu-Chek Guide test strips.

The Accu-Chek Guide Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Blood Glucose Monitoring System is intended for in vitro diagnostic single patient use by people with diabetes.

The Accu-Chek Guide Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Accu-Chek Guide control solutions are for use with the Accu-Chek Guide Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

Intended Use for the Accu-Chek Guide Link Meter

The Accu-Chek Guide Link Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Link meter and Accu-Chek Guide test strips.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended for in vitro diagnostic single patient use by people with diabetes.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Accu-Chek Guide control solutions are for use with the Accu-Chek Guide Link Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

The Accu-Chek Guide Link Blood Glucose Monitoring System is intended to be used to wirelessly transmit glucose values to the MiniMed™ 770G system with Bluetooth® wireless technology through the use of Bluetooth low energy communication.

Intended Use for the Accu-Chek Guide Me Meter

The Accu-Chek Guide Me Blood Glucose Monitoring System is comprised of the Accu-Chek Guide Me meter and Accu-Chek Guide test strips.

The Accu-Chek Guide Me Blood Glucose Monitoring System is intended to quantitatively measure glucose in fresh capillary whole blood from the fingertip, palm, and upper arm as an aid in monitoring the effectiveness of glucose control.

The Accu-Chek Guide Me Blood Glucose Monitoring System is intended for in vitro diagnostic single patient use by people with diabetes.

The Accu-Chek Guide Me Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

This system is not for use in diagnosis or screening of diabetes mellitus, nor for neonatal use.

Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Accu-Chek Guide control solutions are for use with the Accu-Chek Guide Me Blood Glucose Monitoring System to check that the meters and test strips are working together properly and that the test is performing correctly.

Introduction

Testing your blood glucose regularly may help you better manage your diabetes, which can prevent or slow the development of diabetes complications. Your healthcare professional can tell you what blood glucose range is appropriate for you. It is very important to stay in your target range. If your blood glucose is too low, you may experience anxiety, shakiness, sweating, headache, increased hunger, dizziness, pale skin color, sudden change in mood or irritability, fatigue, difficulty concentrating, clumsiness, palpitations, and/or confusion. If your blood glucose is too high, you may experience increased thirst, frequent urination, blurred vision, drowsiness, and/or unexplained weight loss.

Important Safety Information

- During normal testing any blood glucose meter or lancing device may come in contact with blood. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases from bloodborne pathogens, even after you have performed cleaning and disinfecting.[1,2]
- Meters and lancing devices should never be used by more than one person. Do not share them with anyone, including other family members, due to the risk of infection from bloodborne pathogens.[1,2] Do not use on multiple patients!
- Clean and disinfect the meter and the lancing device before allowing anyone

else to handle them. Do not allow anyone else to test with the meter or lancing device.
- It is important to keep the meter and lancing device clean and disinfected. Read and follow the meter and lancing device cleaning and disinfecting instructions found in the meter User's Manual.
- Wash and dry hands thoroughly using soap and water before and after handling the meter, lancing device, and test strips.

Warning
- Do not eat the test strips. They are only for use outside the body (in vitro).
- Choking hazard. Small parts. Keep away from children under the age of 3 years.
- Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

Limitations

- Do not use the meter at high hematocrit levels above 65 % or low hematocrit levels below 10 %.
- Not for use in diagnosis or screening of diabetes mellitus.
- Not for neonatal use.
- Abnormally high concentrations of ascorbic acid (vitamin C) resulting in blood concentrations in excess of 5 mg/dL may cause inaccurate results. If you are not sure please check with your doctor.
- Do not use the meter system to measure blood glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.
- Do not use this system during xylose absorption test.
- Not for use on critically ill patients, patients in shock, dehydrated patients, or hyperosmolar patients.
- This system has not been tested at altitudes higher than 10,150 feet.

Before You Start Testing

- Carefully read and follow all instructions in the package insert when testing your blood glucose.
- The Accu-Chek Guide test strips are for testing fresh capillary whole blood.
- Your hematocrit should be between 10–65 %. Ask your healthcare professional if you do not know your hematocrit.
- If you have poor circulation, testing your own blood glucose may not be right for you. Ask your healthcare professional.

Test Strip Storage and Handling

- Use the test strips at temperatures between 43–113 °F.
- Use the test strips between 10–90 % relative humidity. Humidity is the amount of dampness in the air.
- Do not expose the test strips to heat, moisture, or humidity. Temperatures outside the required range, as well as moisture and humidity, can damage the test strips and produce incorrect results.
- Use the test strip immediately after removing it from the container.
- Discard the test strips if they are past the **Use By** date printed on the test strip container. If the **Use By** date is missing or cannot be read, do not use the test strips.
- Store the test strip container at temperatures between 39–86 °F. Do not freeze. Do not store the test strip container in rooms where the air is humid such as the kitchen, laundry room, or bathroom.
- Store the test strips in their original container with the cap closed. Close the container tightly immediately after removing a test strip to protect the test strips from humidity.
- Store the test strip container between 10–90 % relative humidity.

STEP 1 Getting Ready to Test

1. Get your supplies together. You need the meter, a test strip, a lancing device, and a lancet.
2. Prepare the lancing device.
3. Check the **Use By** date on the test strip container. Do not use test strips past the **Use By** date.

STEP 2 Performing a Control Test

What control solution to use
Use the Accu-Chek Guide control solutions.

How the control solution works
The control solution contains a known amount of glucose that acts like blood when you apply it to the test strip. Performing a control test lets you know that the meter and test strips are working properly.

When to perform a control test
- You open a new test strip box
- You left the test strip container open
- You think the test strips are damaged
- You want to check the meter and test strips
- The test strips were stored in extreme temperatures, humidity, or both
- You dropped the meter
- Your test result does not match how you feel
- You want to check if you are performing the test correctly

How to perform a control test
Refer to the control solution package insert or User's Manual for instructions. If you need control solutions, talk to your pharmacist or visit accu-chek.com to order online.

What the control results mean
Compare the control result to the range on the label of the test strip container. If the control result is within the range, you know that the meter and test strips are working properly. You can now test your blood glucose.

If the control result is not within the range…
- Were the test strips or control solutions past the **Use By** or discard date?
- Did you wipe the tip of the control solution bottle before use?
- Were the caps on the test strip container and the control solution bottle always closed tightly?

- Was the test strip used immediately after it was removed from the test strip container?
- Were the test strips and control solutions stored in a cool, dry place?
- Did you follow the directions?
- Did you choose the correct control solution level, either 1 or 2, when you performed the control test?

For more information, refer to the control solution package insert or User's Manual.

For questions, contact the Accu-Chek Customer Care Service Center toll-free at 1-800-858-8072. We offer assistance in many languages.

STEP 3 Performing a Blood Glucose Test

You are now ready to test your blood glucose. Read the "Getting a good blood drop" section of this package insert if you have problems or are new to testing.

Procedure
1. Wash hands with warm soapy water and dry thoroughly.
2. Insert the metallic end of the test strip into the meter. The meter turns on.
   On the Accu-Chek Guide and Accu-Chek Guide Link meters, Preparing to test appears on the display.
   On the Accu-Chek Guide Me meter, a flashing drop appears on the display.
3. Check the **Use By** date on the test strip container. Do not use test strips past the **Use By** date.
4. Use the lancing device to get a blood drop.
5. Touch the yellow edge of the test strip to the blood drop. Do not put blood on top of the test strip.
   On the Accu-Chek Guide and Accu-Chek Guide Link meters, remove your finger from the test strip when **Analyzing** appears on the display.
   On the Accu-Chek Guide Me meter, remove your finger from the test strip when the flashing hourglass appears on the display.
   Failure to move your finger away from the test strip could give inaccurate results.
6. The test result appears on the display.
7. Take the test strip out of the meter. Put the lancet and the test strip in a puncture-proof container, such as a biohazard container.
8. Wash hands thoroughly with soap and water.

Getting a good blood drop
If you have trouble getting a good blood drop, here are some tips:

Fingertip testing
- Wash your hands in warm, soapy water, then rinse and dry thoroughly. (Warming your fingers can increase blood flow.)
- If you use an alcohol wipe, make sure the testing site is dry before getting a blood drop.
- Let your hand hang by your side. (This increases blood flow.)
- Squeeze your finger at the knuckle for 3 seconds, then let go. Repeat.
- Prick your finger, and then squeeze at the knuckle to form a blood drop. Do not squeeze too hard.

Alternative site testing–Rub the skin prior to lancing to increase blood flow.

Your Blood Glucose Results

The normal fasting glucose level for a non-diabetic adult is below 100 mg/dL. The normal glucose level for a non-diabetic adult 2 hours post 75 g Oral Glucose Tolerance Test (OGTT) is less than 140 mg/dL.[3,4] For people with diabetes: Consult your healthcare professional for the blood glucose range appropriate for you. You should treat your low or high blood glucose as recommended by your healthcare professional.

These test strips deliver results that correspond to blood glucose concentrations in plasma as per the recommendation of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Therefore, your meter displays blood glucose concentrations that refer to plasma although you always apply whole blood to the test strip.

Symptoms of low or high blood glucose
Being aware of the symptoms of low or high blood glucose can help you understand your blood glucose results and decide what to do if they seem unusual.

Low blood glucose (hypoglycemia): Symptoms of hypoglycemia may include, but are not limited to, anxiety, shakiness, sweating, headache, increased hunger, dizziness, pale skin color, sudden change in mood or irritability, fatigue, difficulty concentrating, clumsiness, palpitations, and/or confusion.

High blood glucose (hyperglycemia): Symptoms of hyperglycemia may include, but are not limited to, increased thirst, frequent urination, blurred vision, drowsiness, and/or unexplained weight loss.

If you are having any of these symptoms, test your blood glucose. If your blood glucose result is displayed as **LO** or **HI**, and you have symptoms of low or high blood glucose, follow your healthcare professional's instructions or contact your healthcare professional. For example, if your healthcare professional has advised you to immediately treat a low blood glucose result (such as by eating something), then do so.

Warning: Follow the advice of your healthcare professional before you change your therapy!

Unusual test results
If **LO** is displayed on the meter, blood glucose may be below 20 mg/dL.
If **HI** is displayed on the meter, blood glucose may be over 600 mg/dL.
If your blood glucose result does not match the way you feel, follow these steps:
1. Perform a control test.
2. Review the test procedure and repeat the test with a new test strip.
3. If your blood glucose result still does not match the way you feel, follow your healthcare professional's instructions or contact your healthcare professional immediately.

Do not change your treatment because of just one result.

NEVER ignore symptoms of low or high blood glucose.

For detailed information on error codes, refer to the User's Manual.

Testing from Alternative Sites with the Accu-Chek Guide, Accu-Chek Guide Link, and Accu-Chek Guide Me Meters

Warning: Do not use alternative site testing to calibrate a continuous glucose monitoring system or to make insulin dosing calculations.

Warning: Alternative site testing should be done only during steady-state times (when blood glucose is not changing rapidly).

Alternative site testing is ONLY approved for the Accu-Chek Guide test strips when used with the Accu-Chek Guide, Accu-Chek Guide Link, or Accu-Chek Guide Me meters.

You have the option of obtaining a blood sample from other sites on your body besides the fingertip. Alternative sites include the palm and upper arm. Blood obtained from the fingertip can be used at any time to test blood glucose. If blood from an alternative site is used, there are certain times when testing is not appropriate (see below). This is because your blood glucose level changes faster in your fingertip than in the alternative sites. These differences may cause you to make the wrong therapeutic decision, producing adverse health effects. Read the following section before you test from alternative sites.

IMPORTANT
- Talk to your healthcare professional before you test from alternative sites.
- Only fingertip samples should be used to calibrate a continuous glucose monitoring (CGM) device or to make insulin dosing calculations.

You may perform a test from the palm or upper arm:
- immediately before a meal.
- while fasting.

You may NOT perform a test from the palm or upper arm:
- up to 2 hours following a meal, when blood glucose values can rise quickly.
- after injecting bolus insulin, when blood glucose values can decrease rapidly.
- after exercise.
- if you are sick.
- if you think your blood glucose is low (hypoglycemia).
- if you sometimes do not notice when your blood glucose is low.

If your blood glucose does not match how you feel, perform a fingertip test to confirm your result. If the fingertip test result still does not match how you feel, contact your healthcare professional. For more information on testing from alternative sites, contact the Accu-Chek Customer Care Service Center at 1-800-858-8072.

Performance Characteristics

Test principle: The blood glucose monitoring systems are plasma calibrated to allow easy comparison of results with laboratory methods. Blood from your fingertip reacts with the chemicals in the test strip to create a harmless electrical current in the test strip. The meter reads the current and gives you the blood glucose result.

Sample size: 0.6 μL
Test time: <4 seconds
System measurement range: 20–600 mg/dL
User performance study: In a study conducted at 2 sites with capillary blood samples, the following results were obtained by untrained patients:

Results for glucose concentrations less than 75 mg/dL		
within ±5 mg/dL	within ±10 mg/dL	within ±15 mg/dL
8/12 (66.7 %)	12/12 (100 %)	12/12 (100 %)

Results for glucose concentrations greater than or equal to 75 mg/dL			
within ±5 %	within ±10 %	within ±15 %	within ±20 %
63/108 (58.3 %)	103/108 (95.4 %)	107/108 (99.1 %)	108/108 (100 %)

User performance study: In a study conducted at 1 site with Palm AST samples, the following results were obtained by untrained patients:

Results for glucose concentrations less than 75 mg/dL			
Alternative Site	within ±5 mg/dL	within ±10 mg/dL	within ±15 mg/dL
Palm	8/9 (88.9 %)	9/9 (100 %)	9/9 (100 %)

Results for glucose concentrations greater than or equal to 75 mg/dL				
Alternative Site	within ±5 %	within ±10 %	within ±15 %	within ±20 %
Palm	175/363 (48.2 %)	308/363 (84.8 %)	356/363 (98.1 %)	362/363 (99.7 %)

User performance study: In a study conducted at 1 site with Upper Arm AST samples, the following results were obtained by untrained patients:

Results for glucose concentrations less than 75 mg/dL			
Alternative Site	within ±5 mg/dL	within ±10 mg/dL	within ±15 mg/dL
Upper Arm	7/10 (70 %)	10/10 (100 %)	10/10 (100 %)

Results for glucose concentrations greater than or equal to 75 mg/dL				
Alternative Site	within ±5 %	within ±10 %	within ±15 %	within ±20 %
Upper Arm	156/355 (43.9 %)	281/355 (79.2 %)	337/355 (94.9 %)	351/355 (98.9 %)

Precision
Precision studies using control solutions (day-to-day precision) and blood (within-system precision) are shown below:

Control solutions	Low	Mid	High
N	300	300	300
mean [mg/dL]	44.9	116.6	297.4

SD [mg/dL]	1.4	2.8	6.8
CV [%]	3.1	2.4	2.3

Blood	1	2	3	4	5
N	300	300	300	300	300
mean [mg/dL]	40.5	81.7	132.1	206.7	330.2
SD [mg/dL]	1.4	2.0	2.8	5.4	8.6
CV [%]	3.5	2.4	2.1	2.6	2.6

Reagent composition†

Mediator	6.6 %
FAD-GDH enzyme	21.3 %
Buffer	22.6 %
Stabilizer	2.3 %
Non-reactive ingredients	47.2 %

†Minimum at time of manufacture

Warranty

Roche warrants that your Accu-Chek Guide test strips will be free from defects in materials and workmanship until the product expiration date printed on the label if the test strips are used and stored in the manner described in this package insert and in your Accu-Chek blood glucose meter User's Manual. If, prior to the expiration date of the test strips, there is a defect in materials or workmanship, Roche will replace the test strips free of charge. Your sole and exclusive remedy with respect to the test strips shall be replacement. Any warranty claim should be directed to the Accu-Chek Customer Care Service Center at 1-800-858-8072.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR USE OF THE TEST STRIPS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FOR THE SALE OF THE TEST STRIPS, SHALL EXTEND FOR A LONGER DURATION THAN THE EXPIRATION DATE OF THE TEST STRIPS.

Some states do not allow limitations on how long an implied warranty will last or the exclusion of incidental or consequential damages, so the above limitation and exclusion may not apply to you. This warranty gives you specific legal rights, which vary from state to state.

Additional Information

The User's Manual contains more information.

For questions, contact the Accu-Chek Customer Care Service Center toll-free at 1-800-858-8072. We offer assistance in many languages.

References
1. *FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication,* Update November 29, 2010. http://wayback.archive-it.org/7993/20161022010458/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm. Accessed April 22, 2019.
2. CDC website on "Infection Prevention During Blood Glucose Monitoring and Insulin Administration," http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html. Accessed July 11, 2019.
3. American Diabetes Association website; Diagnosing Diabetes and Learning about Prediabetes. http://www.diabetes.org/diabetes-basics/diagnosis/. Accessed April 22, 2019.
4. American Diabetes Association. 2. Classification and diagnosis of diabetes; Standards of Medical Care in Diabetes- 2019. *Diabetes Care* 2019; 42 (Suppl. 1): S13-S28.

Explanation of Symbols

GTIN	Global Trade Item Number
SN	Serial number

Problems or Questions?
For questions, contact the Accu-Chek Customer Care Service Center toll-free at 1-800-858-8072. We offer assistance in many languages.

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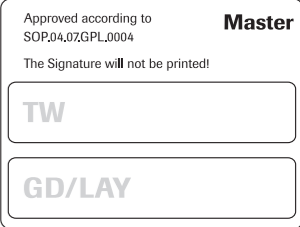U.S. Pat.: http://www.roche-diagnostics.us/patents

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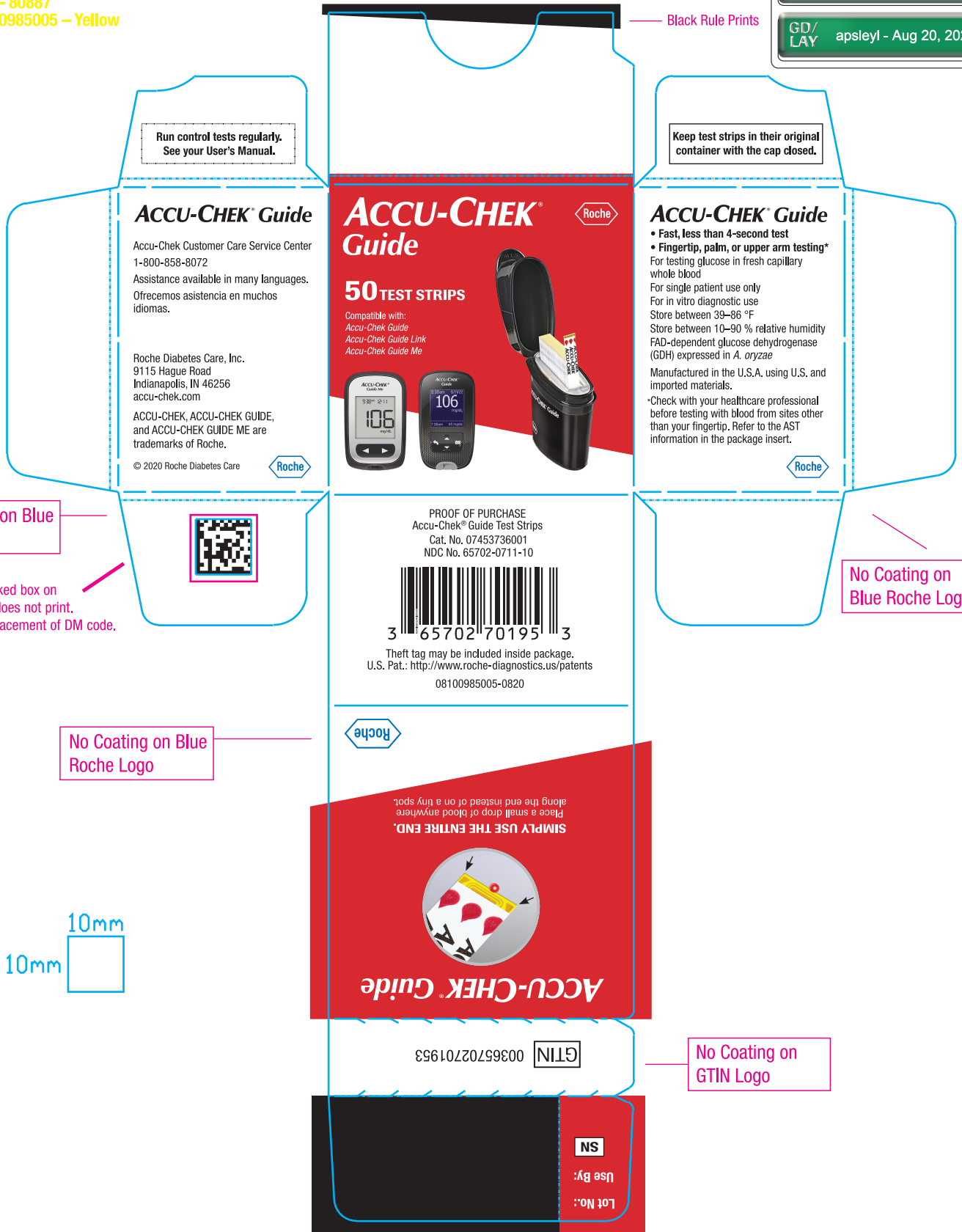
Black Rule Prints

Run control tests regularly.
See your User's Manual.

Keep test strips in their original
container with the cap closed.

ACCU-CHEK® Guide

Accu-Chek Customer Care Service Center
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Assistance available in many languages.
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**ACCU-CHEK®
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50 TEST STRIPS

Compatible with:
Accu-Chek Guide
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ACCU-CHEK® Guide
• Fast, less than 4-second test
• Fingertip, palm, or upper arm testing*
For testing glucose in fresh capillary
whole blood
For single patient use only
For in vitro diagnostic use
Store between 39–86 °F
Store between 10–90 % relative humidity
FAD-dependent glucose dehydrogenase
(GDH) expressed in A. oryzae

Manufactured in the U.S.A. using U.S. and
imported materials.

*Check with your healthcare professional
before testing with blood from sites other
than your fingertip. Refer to the AST
information in the package insert.

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Magenta stroked box on
callout layer does not print.
This shows placement of DM code.

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PROOF OF PURCHASE
Accu-Chek® Guide Test Strips
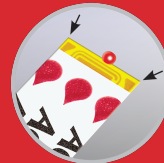Cat. No. 07453736001
NDC No. 65702-0711-10

3 65702 70195 3

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SIMPLY USE THE ENTIRE END.
Place a small drop of blood anywhere
along the end instead of on a tiny spot.

ACCU-CHEK® Guide

10mm

7010399   10mm

GTIN 00365702701953

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NS

Use By:
Lot No.:

106 mg/dL