SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Automated Insulin Dosing System

Device Trade Name: MiniMed 770G System

Device Procode: OZP

Applicant's Name and Address: Medtronic MiniMed, Inc.
18000 Devonshire Street
Northridge, CA 91325

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P160017/S076

Date of FDA Notice of Approval: 8/31/2020

Breakthrough Device: Granted breakthrough device status on July 2, 2019 because the device is expected to provide more effective treatment of type 1 diabetes mellitus, an irreversibly debilitating disease, in the 2-6 years old population for which no approved or cleared alternatives exist.

The MiniMed 670G System (identical to the current MiniMed 770G System except for the lack of bluetooth communication capability) was first approved on September 28, 2016 for use in ages 14 years. The Indications for Use for the MiniMed 670G System were later expanded to include users 7 to 13 years and up and was approved on June 21, 2018. The SSEDs for the original approval (P160017) and the 7-13 years old expansion (P160017/S031) can be found on the CDRH website. The current Panel Track Supplement was to expand the Indications for Use for the MiniMed 770G System to include the 2 to 6 years of age user population (in addition to the previously approved indications of 7 years and older for the MiniMed 670G System); and as well as a change to the pump's wireless protocol from a proprietary approach to Bluetooth Low Energy (BLE).

II. INDICATIONS FOR USE

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 sensor glucose 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).

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 14 and older	Abdomen and Buttocks Abdomen and Arm
MiniMed 670G System	7-13 14 and older	Abdomen and Buttocks 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 it is not intended for multiple-patient use.

Guardian Link (3) Transmitter
The Guardian Link (3) Transmitter is intended for use with the 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.

III. CONTRAINDICATIONS

A prominent boxed warning is included in the labeling regarding use of the device in users with a total daily insulin dose of less than 8 units:

"Medtronic performed an evaluation of the 770G closed loop system and determined that it may not be safe for use in patients who require less than a total daily insulin dose of 8 units per day because the device requires a minimum of 8 units per day to operate safely."

The following contraindications for this device are also described in the labeling:

- Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms.
- Do not use serter on products other than the GuardianSensor (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, blood glucose (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.
- SmartGuard Auto Mode cannot be used for people who require less than eight units or more than 250 units of total daily insulin dose per day.

- Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional.

IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the MiniMed 770G System labeling.

V. DEVICE DESCRIPTION

The MiniMed 770G System is a Bluetooth Low Energy (BLE)-enabled version of the previously approved MiniMed 670G System (P160017). The MiniMed 770G System has similar interface scheme as the MiniMed 670G System, with the exception that the devices communicate via BLE (2.4 GHz) wireless communication protocols instead of the Tel-D protocol. The use of BLE in the MiniMed 770G System allows the user to optionally use an off-the-shelf suitable consumer electronic device to assist with the management of their therapy. The MiniMed Mobile App provide a secondary display to wirelessly receive data from the pump and to wirelessly transfer pump data to CareLink. Pump data uploaded into CareLink can be used to track patterns and in addition the pump data from CareLink is also remotely viewable via the CareLink Connect App. The CareLink Connect App allows Care Partner (i.e. care giver or health care provider) to remotely monitor glucose levels of a patient via a mobile app.

The MiniMed 770G system is comprised of the following devices:

MiniMed 770G Pump (MMT-1880)

The MiniMed 770G pump (model MMT-1880) is an ambulatory, battery operated, rate programmable micro infusion pump designed to deliver insulin from a reservoir. The reservoir is driven by a motor to deliver determined basal rate profiles and user selected bolus amounts of insulin into the subcutaneous tissue through an infusion set.

The MiniMed 770G pump is offered in one model (MMT-1880). The pump houses electronics, a pumping mechanism, a user interface, and a medication reservoir within the same physical device. The reservoir is attached to a tube that connects to the user's infusion site on their body. It is intended to deliver insulin through a diffusion mechanism. Model MMT-1880 is compatible with a 3.0 mL reservoir. The pump only displays blood glucose level units in mg/dL and cannot be reconfigured by the user.

In addition to its delivery of insulin, the MiniMed 770G pump is designed to receive and display real-time interstitial fluid glucose values via the Guardian Link (3) Transmitter. When used in combination with Guardian Sensor (3), the transmitter sends sensor signals to the MiniMed 770G pump via BLE wireless communication protocol every five minutes. The 770G Pump can operate in Manual Mode or Auto Mode, and each mode includes various features and capabilities. These features and capabilities are described in detail in the MiniMed 770G System user guide. A summary of these features and capabilities is provided in Table 1 below.

Table 1: Summary of the Features of the MiniMed 770G System

Mode	Description	When is it Active?	Will I receive Alerts?
Manual Mode: Insulin Infusion Pump	This mode is when the device is functioning as a pump that can deliver insulin, but the device does not have a sensor connected, is not in Auto Mode and the insulin suspend features are	This is the default mode and the user does not have to specifically turn this mode on.	There are alerts if the pump has any issues with delivering insulin (e.g. suspended delivery) or low reservoir.
Manual Mode: Sensor Augmented Pump	This mode is when the device is functioning as a sensor and pump, but the device is not in Auto Mode and the insulin suspend features are not turned on.	This user has to be wearing a CGM that will be communicating to the pump in order to receive sensor glucose alerts.	There is a mandatory severe low alarm at 50 mg/dL; The user can also set optional high and low alerts to sound on or before set sensor glucose levels.
Manual Mode: Suspend On Low	When this feature is active the device detects that your sensor glucose level has reached a pre-set sensor glucose value and it automatically suspends basal insulin delivery when that value is reached.	The user has to turn this feature on. It is not available when Auto Mode is turned on, and it cannot be turned on if Suspend before Low is turned on.	There is a mandatory severe low alarm at 50 mg/dL and at the pre-set low level. The user can also set optional high alerts to sound on or before set sensor glucose levels, and an optional
Manual Mode: Suspend Before Low	When this feature is active the device detects when your sensor glucose is predicted to reach a pre-set value and it automatically suspends basal insulin delivery before that value is reached.	The user has to turn this feature on. It is not available when Auto Mode is turned on, and it cannot be turned on if Suspend before Low is turned on.	There is a mandatory severe low alarm at 50 mg/dL and at the pre-set low level. The user can also set optional high alerts to sound on or before set sensor glucose levels, and an optional alarm before low alert.
Auto Mode	When this mode is active, the device can automatically adjust basal insulin by increasing, decreasing, or turning off basal insulin delivery based on sensor glucose levels.	The user has to turn this mode on and certain pre-defined conditions have to be met.	There is a mandatory severe low alarm at 50 mg/dL; The user can also set optional high and low alerts to sound on or before set sensor glucose levels.

Mode	Description	When is it Active?	Will I receive Alerts?
Auto Mode: Safe Basal Delivery	When this feature is active, the device will deliver basal insulin at a patient-specific safe basal or safe basal low rate for no longer than 90 minutes. If the fault condition resolves within 90 minutes, the system will begin to automatically adjust basal insulin again. If the fault does not resolve within 90 minutes, the system will switch to Manual Mode.	This feature turns on when the system determines that either the sensor data is not adequate for Auto Mode or delivery at the minimum or maximum limit for a set amount of time has elapsed.	There is a mandatory alert before this feature turns on when the sensor glucose accuracy check fails. The user can also set optional alerts to sound before this feature turns on when minimum or maximum insulin delivery times out or when the sensor has been under-reading for too long. There is a mandatory severe low alarm at 50 mg/dL; The user can also set optional high and low alerts to sound on or

Guardian Link (3) Transmitter(MMT-7911)

The Guardian Link (3) Transmitter is a portable, electrical current meter intended to process, store, and transmit glucose sensor values to the compatible insulin pump. The transmitter sends sensor glucose (SG) values and sensor integrity (SI) data from the Guardian Sensor (3) to the compatible insulin pumps via BLE wireless communication protocol.

The transmitter interfaces directly with the glucose sensor assembly, provides power to the glucose sensor, and measures the sensor signal current from the glucose sensor. The sensor signal current is an electrical current level that is proportional to the glucose level in the user's subcutaneous interstitial fluid. The sensor signal current is converted to a digital signal, which is filtered to reduce noise artifacts. This digital signal is sent to the MiniMed 770G pump every 5 minutes via BLE wireless communication.

Guardian Sensor (3) (MMT-7020)

The Guardian Sensor (3) is a sterile, single-use, single patient glucose sensing component for continuous monitoring of glucose levels in the user's interstitial fluid for up to seven days. The Sensor is inserted into the subcutaneous tissue using the One-Press Serter and is taped to the user's skin. It connects to the Guardian Link (3) Transmitter, which in turn communicates with the MiniMed 770G Pump.

When making treatment decisions, such as determining insulin dose for meals, the MiniMed 770G continuous glucose monitor (CGM) values should not be used, as they are not intended to be used to make such treatment decisions. The MiniMed 770G CGM does

not replace a blood glucose meter. Users should always use the values from a blood glucose meter for treatment decisions. Blood glucose values may differ from sensor glucose values. Using the sensor glucose readings for treatment decisions could lead to unwanted high or low blood glucose.

Users should calibrate the Guardian Sensor (3) at least every 12 hours using meter blood glucose values. Calibration is necessary for sensor function, and more frequent calibration can help increase the accuracy of the sensor. The system requires a minimum of two calibrations per day, and four calibrations per day are recommended. The system is contraindicated for patients unwilling or unable to do frequent blood glucose meter measurements.

If the user obtains blood glucose values using the Accu-Chek Guide™ Link Meter, the user may transmit blood glucose values via BLE communication to the MiniMed 770G pump to be used for sensor calibrations. If the user uses a different FDA cleared blood glucose meter to calibrate the Guardian Sensor (3), the user must manually input the blood glucose values into the pump to be used for sensor calibration. Additionally, users who use the Accu-Chek Guide™ Link Meter should calibrate with values obtained from measurements of fresh capillary whole blood from the fingertip only. Alternative site testing (i.e., palm or upper arm) should be done only during steady-state times (when glucose is not changing rapidly) and should not be used for calibrating the CGM sensor.

One-Press Serter

The One-Press serter is a sensor insertion device which aids the user in inserting the Guardian Sensor (3). The serter was also previously reviewed and approved under P120010/S070. The user must use the One-Press Serter in order to insert the Guardian Sensor (3).

Accu-Chek Guide™ Link Blood Glucose Meter

The Accu-Chek Guide™ Link Blood Glucose Meter can be used with the MiniMed 770G system. The meter sends blood glucose values to the insulin pump for sensor calibration via BLE wireless communication protocol. This meter is a modified version of the Accu-Chek Guide™ Blood Glucose Meter, which was previously cleared under k160944.

Specifications and performance requirements were previously established for the meter used with the MiniMed 670G system and evaluated as part of the original PMA, P160017. The sponsor validated the Accu-Chek Guide™ Link Blood Glucose Meter and the Accu-Chek Guide™ test strips against the previously established performance requirements. The sponsor provided blood glucose meter specifications, rationale for requirements for the meter, and impact of error on the sensor, predictive low alerts, threshold glucose suspend, and the predictive low glucose management and hybrid closed loop features in the submission. The sponsor carried out error impact analysis in order to determine the lot release criteria for the test strips. The sponsor verified and validated the specifications, performance requirements, and lot release criteria of the Accu-Chek Guide™ Link Blood glucose

meter and the Accu-Chek Guide™ test strips for use with the MiniMed 770G System. Based on the information provided, the specifications meet the clinical needs of the MiniMed 770G system.

Additional System Accessories

The following additional accessory devices are compatible with the MiniMed 770G Insulin Pump:

Table 2: Accessory Devices

Device	Model
Reservoirs and Infusion Sets	**Model Numbers**
MiniMed Quick Set Infusion Set	MMT-386, MMT-387, MMT-394, MMT-396, MMT-397, MMT-398, MMT-
MiniMed Silhouette Infusion Set	MMT-368, MMT-369, MMT-370, MMT-377, MMT-378, MMT-381, MMT-382, MMT-
MiniMed Mio Infusion Set	MMT-921, MMT-923, MMT-925, MMT-941, MMT-943, MMT-945, MMT-961, MMT-963,
MiniMed Sure-T Infusion Set	MMT-862, MMT-864, MMT-866, MMT-874, MMT-876, MMT-884, MMT-
MiniMed Mio Advance	MMT-211, MMT-212, MMT-213, MMT-231, MMT-232, MMT-233, MMT-242, MMT-243, MMT-244, MMT-247, MMT-248, MMT-242T,
MiniMed Pro-set	MMT-280, MMT-281, MMT-280T
Paradigm Reservoir	MMT-332A
Optional Devices	**Model Numbers**
MiniMed Mobile Application (Android)	MMT-6101
MiniMed Mobile Application (iOS)	MMT-6102
CareLink Connect Application (Android)	MMT-6111
CareLink Connect Application (iOS)	MMT-6112
Blue Adapter	ACC-190
CareLink Online (Personal)	MMT-7333
CareLink Pro	MMT-7335

This medical device product has functions subject to FDA premarket review as well as functions (e.g., the MiniMed Mobile Applications) that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the management of diabetes. Control of diabetes can be achieved through a combination of various behaviors and methods.

Self-behaviors include healthy eating, taking the clinically indicated medications, and being active. Persons with diabetes may also administer insulin by injection or using other insulin infusion pumps as prescribed by their physician. An insulin pump is an alternative to multiple daily insulin injections (via insulin syringe or an insulin pen). Periodic self-glucose monitoring using home-use blood glucose meters provides information regarding variations in glucose levels.

Methods of monitoring glycemic control include periodic measurement of Hemoglobin A1c (HbA1c) which reflects blood glucose control over a three-month period. Self- monitoring of blood glucose using glucose meters and test strips provides quantitative measurements of blood glucose at a single point in time for users and their healthcare providers. This helps to monitor the effectiveness of glycemic control, as well as make more immediate treatment modifications.

Currently, cleared or approved insulin infusion pumps may be used for continuous subcutaneous insulin infusion. Additionally, commercially available sensor-augmented insulin infusion pumps or continuous glucose monitoring systems may be used to record continuous interstitial glucose information and provide real-time hypoglycemia and hyperglycemia alerts.

Each alternative method for monitoring glycemic control has its own advantages and disadvantages. A user should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

VII. MARKETING HISTORY

The MiniMed 770G System has not been marketed in the United States or any foreign country.

The MiniMed 770G System is an iteration of the MiniMed 670G System. The MiniMed 670G System was originally approved for marketing in the United States on September 28, 2016 (P160017), and received approval for marketing with a pediatric indication (ages 7-13 years) on June 21, 2018 (P160017/S031). In addition to the device name change, this Panel Track Supplement expands the Indications for Use to include users ages 2-6 years old and updated the communications protocol to BLE. The MiniMed 670G System has not been withdrawn from the market for any reason related to its safety or effectiveness..

The insulin reservoirs and infusion sets used with the MiniMed 770G System are also the same as those currently used with the MiniMed 530G System (P120010), the MiniMed 630G System (P150001), and the MiniMed 670G System (P160017). These devices have not been withdrawn from commercial distribution for any reason, related to either safety or effectiveness.

VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Potential device-related serious adverse events include

- Diabetic ketoacidosis (DKA) resulting from high blood glucose due to suspension of insulin elivery or inadequate insulin delivery (which may result from catheter occlusion, hardware or software malfunction, erroneous CGM readings in Auto Mode or suspend mode, or inadequate insulin dosing).
- Severe hypoglycemia resulting from over-delivery of insulin (which can result from hardware or software malfunction, erroneous CGM readings in Auto Mode, or erroneous insulin dosing), which may lead to seizure, unconsciousness, and rarely death.

Potential device related non-serious events include:

- Skin irritiation or redness
- Infection
- Pain or discomfort
- Bruising
- Edema
- Rash
- Bleeding
- Induration of skin
- Allergic reaction to adhesive

Sensor breakage with fragments retained under the skin is a potential adverse event related to use of the CGM component of the 770G system, but this was not observed during these studies. Based on post-market experience with similar devices and the results observed in these clinical studies, the occurrence and severity of these events are low.

Infection at the insulin pump infusion set insertion site and sensor insertion site is a potential complications related to insertion of the CGM or the insulin pump infusion set. Based on post-market experience with similar devices, and the results observed in these clincal studies, the occurrence and severity of these events are not expected to be different from other approved infusion sets and CGM devices.

Use of insulin pumps are known to carry an increased risk of DKA. However, FDA has received information indicating some patients are willing to accept an increased risk of DKA or ketosis and hyperglycemia (severe hyperglycemia) because of the benefits of pump use (see also Section XII below).

Like other insulin pumps, there is an inherent risk that users of the device who do not use the 770G system as intended could harm themselves. Therefore, the device is for prescription use only and contraindicated for people unwilling or unable to perform a minimum of four fingerstick blood glucose meter tests per day and for people unwilling or unable to maintain contact with their healthcare professional.

As demonstrated under P120010/S046 for the MiniMed 530G System (which has the same 'suspend on low' feature, where the insulin delivery will suspend for two hours after the low glucose threshold has been reached), two hour suspension of insulin delivery is unlikely to lead to clinically sifnificant ketosis or ketoacidosis even if the pump inappropriately suspends when the blood sufar is normal or elevated, and should respond to insulin therapy and hydration within a few hours.

There is a theoretical risk of insulin over-delivery due to device malfunction which has a risk of leading to severe hypoglycemia due to malfunction of the 770G System. This even did not occur during the pivotal study or the continuation phase of the pivotal study. If insulin over-delivery were to occur, there are several mechanisms in placed designed to help detect and mitigate the risk of impending and/or current hypoglycemia, including the presence of alarms/alerts and the suspension/reduction of insulin delivery.

There is a theorectical risk of insulin under-delivery (due to a hardware or software malfunction) which may lead to severe hyperglycemia or DKA due to malfunction of the 770G system. This event did not occur during the pivotal study or the continuation phase of the pivotal study. If insulin under-delviery were to occur, there are mechanisms in place to help detect impending and/or current hyperglycemia, including the presence of alerts and alarms.

The consequences of falsely high glucose reading on the continuos glucose monitor would be potential over-delivery of insulin via automated insulin delivery and missed low glucose suspensions and alerts/alarms, which have the potential to lead to servere hypoglycemia. The consequences of falsely low glucose reading on the continuous glucose monitor would be potential under-delivery of insulin and missed high glucose alerts, which have the potential to lead to severe hyperglycemia or DKA.

IX. SUMMARY OF NONCLINICAL STUDIES

A. Laboratory Studies

Pre-clinical testing was performed on the MiniMed 770G Pump and the Guardian Link (3) Transmitter for the BLE component and functionality and for other specifications which were impacted by the BLE feature. Some previous pre-clinical testing of the MiniMed 670G hardware and the associated Guardian Link (3) Transmitter supports the safe use of the 770G pump as the corresponding pumps and transmitters contain similar hardware. Please see the SSED for P160017 for all other pre-clinical testing.

Pre-clinical and performance testing of the Accu-Chek Guide™ Link Meter to support safe use of the meter with the MiniMed 770G System was submitted and reviewed to support approval.

The Guardian Sensor (3) and One-Press Serter have not changed. Please see the SSED for P160017 for descriptions of the pre-clinical testing of the Guardian Sensor (3) and One-Press Serter.

MiniMed 770G Pump (MMT-1880)

Pumps were subjected to the following functional and environmental tests to ensure that the devices will continue to function normally even when exposed to extreme environmental conditions.

Table 3: Pump Testing

Test	Purpose	Acceptance Criteria Summary	Pass/Fail
Patient Leakage Current per **EN 60601-1**	Verifies the ability of the NGP's (Next Generation Pump) electrical isolation to provide protection against electric shock of current flowing through	The leakage current shall not exceed 100 µAac (equivalent to 100 mVac) and 10 µAdc (equivalent to 10 mVdc) in normal conditions as described in Table 3 of EN 60601 1 section 8.7.3	Passed
Battery Life	Demonstrates the Alkaline LR6 AA battery's lasting capacity while being used by a Bluetooth enabled NGP during normal everyday use including continuous glucose monitoring	The NGP is operational for a minimum of 7 days while being subjected to the nominal use model with CGM Provides a warning 10 hours ± 2 hours before cessation of delivery due to depletion of battery	Passed
Self Test Power Empty Reset	Verifies that the pump can complete a self-test, generate an alarm when a fault in electrical power occurs, and detect an empty reservoir	The NGP shall be able to perform a Self-Test The NGP shall detect an empty reservoir during delivery The NGP shall generate an alarm when it detects a fault in electrical power The NGP shall perform a hard reset of the device when the battery is removed, and back button is held	Passed
Mechanical Vibration per **EN 60601-1-11**	Determines ability of the NGP to withstand mechanical vibration that the device may encounter during normal use or in excess of normal use	The NGP shall be able to maintain basic safety and essential performance after exposure to mechanical vibration exposure	Passed
Shipment Test per **ASTM D4169**	Determines the durability of the NGP packaging to withstand shipping conditions	Packaging shall be intact Packaging shall protect the product and package contents in such a manner that they are usable by the customer	Passed

		All labels and barcodes shall be legible and intact	
AA Compatibility	Verifies the ability of the NGP to Operate with Lithium and Nickel-Metal Hydride	The pump shall Operate with Lithium, Nickel-Metal Hydride, and alkaline AA batteries. Alkaline batteries are the standard battery tested in all other functional cases, so that battery chemistry is covered outside of this protocol	Passed
Forced Occlusion	Verifies that the NGP can detect an occlusion condition and generate an alarm to notify the user	The NGP shall detect occlusion during bolus delivery. The NGP shall detect an occlusion within 0.05 mL (5 U) of missed delivery. The NGP shall notify the user with an alarm (audio, tactile or visual) whenever it detects conditions that stop delivery of insulin.	Passed
Storage Temperature Humidity	Verifies the ability of the NGP BLE pump to withstand the effects of temperature and humidity during storage	All NGP BLE pumps Operate after exposure to the temperature/humidity Shipping & Storage Environments: -20°C to +50°C and 5% to 95% RH	Passed
Mechanical Shock per **EN 60601-1-11**	Determines ability of the NGP to withstand mechanical shock that the device may encounter during normal use or in excess of normal use	The NGP BLE Pump shall be able to maintain basic safety and essential performance after exposure to mechanical shock exposure	Passed
Temperature Shock	Verifies the ability of the NGP to withstand the effects of extreme and rapid temperature changes during shipping or storage	All pumps can Operate after exposure to 10 cycles of temperature extremes between -20°C and +60°C with a 0.5 hour dwell time at each temperature plateau, and with a minimum rate of change of 10°C per minute, non-operating	Passed
Mechanical Drop per **EN 60601-1** and **EN 60601-1-11**	Determines the ability of the pump hardware to meet drop requirements	Pump maintains basic safety Cessation of delivery must be accompanied by an alarm	Passed

Protection Excessive Temp per **EN 60601-1**	Verifies the ability of the NGP BLE pump and its accessories to not produce an excessive temperature when operating in worst case normal use conditions	The NGP and its accessories do not produce excessive temperatures when operating in worst case normal use conditions	Passed
Operating Temperature Humidity	Determines the ability of the NGP to Operate while withstanding the effects of exposure to temperature and humidity	The pump and its associated consumables shall Operate when exposed to Operating Environments: 5°C to +40°C and 20% to 90% RH	Passed
Dielectric Strength	Verifies the NGP maintains its electrical insulation by withstanding the test voltage	The NGP shall withstand the test voltage of 1000 Volts and maintain its electrical insulation. The Hipot Safety Tester generates a PASSED notification and the PASS light illuminates upon completion of the program	Passed
Standby Current	Determines the ability of the NGP to consume a maximum current of 1 mA in Standby Mode with a AA battery voltage of 1.5V	The NGP in Standby Mode shall draw a maximum current of 1 mA from a AA battery voltage of 1.5 V	Passed
Bolus Delivery	Verifies that the NGP can program a bolus, accurately deliver a bolus, and store bolus information	The motor slide displacement shall be within ±5% of 0.08719 inches (value within 0.08283 inches - 0.09155 inches) the calculated distance traveled to deliver a 25 U Bolus pump shall be able to program and store bolus information	Passed

Guardian Link (3) Transmitter (MMT-7911)

Pre-clinical testing of the Guardian Link (3) Transmitter leveraged testing performed for Guardian Connect Transmitter (approved under P160007) as the two transmitters contain identical hardware. Please see the SSED for P160007 for descriptions of the pre-clinical testing of the Guardian Link (3) Transmitter. The following regression functional testing was performed to ensure that the devices will continue to function normally. Battery testing was performed since the change of communication protocol has potential to impact battery life and transmission of alerts.

Table 4: Transmitter Testing

Test	Purpose	Acceptance Criteria Summary	Pass/Fail
Battery Life	Demonstrates the battery life and memory capacity of the glucose sensor transmitter (GST)	The GST battery operates the device for the duration of 1 sensor use (a minimum of 7 days and 2 hours or 170 hours total) while being subject to the Nominal Use Model. The GST can also record operation data for the duration of 1 sensor use while being subject to the Nominal Use Model. The time between when the GST advertises the low battery alert to the depleted battery alert is at least 1-day (24 hours) while being subject to the Nominal Use Model.	Passed

MiniMed 770G System

The MiniMed 770G System with all components operating together, including the Guardian Link (3) Transmitter and Accu-Chek Guide™ Link Meter, was subjected to the following functional and environmental tests to ensure that these devices will continue to function normally when exposed to extreme environmental conditions.

Electromagnetic compatibility (EMC) testing of the Guardian Link (3) Transmitter at the device level leveraged testing performed for Guardian Connect Transmitter (approved under P160007) as the two transmitters contain identical hardware configurations. Please see the SSED for P160007 for descriptions of the EMC testing of the Guardian Link (3) Transmitter.

Table 5: System Testing

Test	Purpose	Acceptance Criteria Summary	Pass/Fail
EMC/EMI Testing per EN 60601-1-2: 2015	Demonstrate ability of the system to operate in environments with Electromagnetic Interference (EMI) which meet the standard of EN 60601-1-2	The NGP shall maintain Essential Performance during and after the exposure. Cessation of delivery must be accompanied with an alarm. Isig values recorded during exposure must be within the value specified for the tester unit (TUT) or test plug (TPT) (49.93 – 56.70 nA)	Passed

Test	Purpose	Acceptance Criteria Summary	Pass/Fail
		Idle/Alarm Mode - total displacement is less than 0.00348759 inches. Delivery Mode - the motor slide displacement shall be within ±5% of the expected displacement (For examples: 0.0818975 inches is the expected displacement measured at 25.0 U/hr Basal rate in 1 hour).	
Wireless Coexistence per AAMI TIR 69	Determines the ability of the NGP to coexist with other devices operating in the 2.4 GHz frequency band	The NGP shall maintain Essential Performance during and after the exposure. Cessation of delivery must be accompanied with an alarm. Isig values recorded during exposure must be within the value specified for the TUT or TPT (49.93 – 56.70 nA) Idle/Alarm Mode - total displacement is less than 0.00348759 inches. Delivery Mode - the motor slide displacement shall be within ±5% of the expected displacement (For examples: 0.0818975 inches is the expected displacement measured at 25.0 U/hr Basal rate in 1 hour).	Passed
FCC Testing	Demonstrate compatibility with FCC regulation	Emitted levels must be per FCC CFR 47 Part 15.247. It is acceptable that the pump pay lose RF communication with the transmitter. In this case the pump will alarm “Lost Sensor” to notify the user. Pump operating mode shall not be affected. BG Meter commanded bolus amount matches pump displayed delivered amount. No interruption of pump alarms, and no change in pump operating mode or programmed settings.	Passed
FAA Testing per **RTCA DO-160G** Section 20.5 Category R	Determines the ability of the NGP to withstand RF disturbances radiated by external sources	The NGP shall maintain Basic Safety. Cessation of delivery must be accompanied with an alarm Isig values recorded during exposure must be within the value	Passed

Test	Purpose	Acceptance Criteria Summary	Pass/Fail
		specified for the TUT or TPT (49.93 – 56.70 nA) Idle/Alarm Mode - total displacement is less than 0.00348759 inches Delivery Mode - the motor slide displacement shall be within ±5% of the expected displacement (For examples: 0.0818975 inches is the expected displacement measured at 25.0 U/hr Basal rate in 1 hour).	
MRI Immunity	Determines the ability of the NGP to maintain Basic Safety when exposed to electromagnetic fields which exceed the intended use environments	The NGP shall maintain Basic Safety. Cessation of delivery must be accompanied with an alarm.	Passed
Electromagnetic Disturbances	Determines the ability of the NGP to withstand radiated electromagnetic energy by external sources.	The NGP shall maintain Essential Performance during and after the exposure. Cessation of delivery must be accompanied with an alarm. Isig values recorded during exposure must be within the value specified for the TUT or TPT (49.93 – 56.70 nA) Idle/Alarm Mode - total displacement is less than 0.00348759 inches Delivery Mode - the motor slide displacement shall be within ±5% of the expected displacement (For examples: 0.0818975 inches is the expected displacement measured at 25.0 U/hr Basal rate in 1 hour).	Passed
RF Transmission	Verifies the NGP can receive radio frequency (RF) transmissions of sensor glucose (SG) from the Glucose Sensor Transmitter (GST).	The NGP BLE shall receive sensor glucose (SG) values from an associated GST	Passed

Test	Purpose	Acceptance Criteria Summary	Pass/Fail
ESD Immunity	Verifies that the NGP can maintain Essential Performance in an environment with high level of electrostatic discharge (ESD) at ±22 kV and ±30 kV, with a low relative humidity of 1-5 %.	The NGP shall maintain Basic Safety. Cessation of delivery must be accompanied with an alarm. Isig values recorded during exposure must be within the value specified for the TUT or TPT (49.93 – 56.70 nA)	Passed
Security Device Immunity	Determines the ability of the NGP to withstand RF disturbances radiated by external sources such as Electronic Article Surveillance, RFID, metal detectors, and tag deactivators	The NGP shall maintain Basic Safety. Cessation of delivery must be accompanied with an alarm. Isig values recorded during exposure must be within the value specified for the TUT or TPT (49.93 – 56.70 nA) Idle/Alarm Mode - total displacement is less than 0.00348759 inches. Delivery Mode - the motor slide displacement shall be within ±5% of the expected displacement (For examples: 0.0818975 inches is the expected displacement measured at 25.0 U/hr Basal rate in 1 hour).	Passed

Packaging

The MiniMed 770G Pump was tested under conditions of simulated shipping per ASTM D4169, *Standard Practice for Performance Testing of Shipping Containers and Systems*. Testing included environmental conditioning, manual handling, vehicle stacking, loose load vibration, low pressure testing, vehicle vibration, concentrated impact, and final inspection of samples. The MiniMed 770G Insulin Pump (MMT-1880) has a shelf life of 1095 days (3 years) based on the internal backup battery, which requires regular recharging.

Please see the SSED for P160017 for descriptions of the pre-clinical testing of the Guardian Link (3) Transmitter and Guardian Sensor (3) packaging validation.

Software

Comprehensive verification and validation testing was conducted to confirm that the software used in the MiniMed 770G System meets all specified requirements and that the software will operate reliably and safely under normal or abnormal use conditions.

The software verification and validation were carried out in accordance with the FDA Guidance Document, "*General Principles of Software Validation: Final Guidance for Industry and FDA Staff*." Software development activities included establishing detailed software requirements, linking requirements with associate verification tests, software code reviews, unit testing, system level testing and defect tracking and dispositioning to ensure the software conforms to user needs and intended uses. The pump has the capability to securely receive and install firmware over the air (FOTA) updates from an external server (which is not yet available). Verification of the FOTA functionality in the pump software is included in the supplement.

Human Factors Testing

Human Factors usability validation studies were conducted in accordance with EN62366, *Medical Devices – Application of Usability Engineering to Medical Devices* and the FDA Guidance Document "*Applying Human Factors and Usability Engineering to Medical Device: Guidance for Industry and Food and Drug Administration Staff*".

The sponsor previously conducted usability validation studies to evaluate use of the MiniMed 670G System by Type 1Diabetes Melitus (T1DM) patients ages 14 years and older (submitted under P160017) and by T1DM patients ages 7 to 13 years of age with assistance from an adult caregiver (submitted under P160017/S031).

The sponsor also conducted two usability validation studies to evaluate the MiniMed 670G System, with continuous glucose monitoring and auto mode (hybrid closed loop, or HCL) function, to provide evidence that caregivers of younger children (2 to 6 years of age) diagnosed with T1DM can safely and effectively use the MiniMed 670G System. These usability validation studies are applicable to the MiniMed 770G System because the user interface functions of both the 670G and 770G pumps are similar.

In the first study, users representing caregivers of both novice and experienced pediatric pump users participated performed critical tasks associated with using the MiniMed 670G system in both Manual and Auto Modes with the continuous glucose monitoring system. Task Analysis was used to determine critical tasks.The two user groups were defined as follows:

- Novice Insulin Pump Users: Users in this group were not currently external pump users, had less than 6 months of experience with a Medtronic pump, or were currently using a competitor pump.

- Experienced Insulin Pump Users: Users in this group currently were using a Medtronic external insulin pump for more than 6 months.

A second study was performed that focused only on novice pediatric pump users.
All use errors, close calls and use difficulties observed during completion of critical tasks were analyzed, and the root causes and impacts were assessed. For any use errors and close calls, a residual risk analysis was performed to determine whether design changes would

further reduce the risks and to assess the residual risks related to the benefits to the patient. It was determined that no design changes were necessary. However, it was concluded that the current pump training program should be enhanced to address the usability issues identified in the human factors studies especially for novice pump users for this age group. The training program has been updated based on the findings from the human factors study. Some key areas that have been modified include the addition of proactive training measures to address user errors encountered during the human factors studies, new touchpoints to assure that user device training is scheduled with optional touch points to reinforce key concepts or training on items for patients that may need additional help, and a plan for validating training effectiveness in the post-market stage. Training is required for the use of the 770G System and a warning has been added to the device labeling to emphasize that users should not use the device until having received the appropriate training.

B. Animal Studies

None

C. Additional Studies

None

X. SUMMARY OF PRIMARY CLINICAL STUDY(IES)

In addition to the clinical studies that established the safety and effectiveness of the MiniMed 670G System in users 7 years of age and older (see in the SSEDs for P160017 and P160017/S031), the sponsor performed clinical studies of the 670G System in pediatric subjects ages 2-6 years. These studies establish a reasonable assurance of the safety and effectiveness of the MiniMed 770G System because the underlying therapy in the 670G system, and the associated Guardian Sensor (3), are identical to that of the 770G System. Other changes to the device, which include the change of the communication protocol to BLE and the change of the blood glucose monitoring system component to the Accu-Check Guide Link Blood Glucose Monitoring System, do not impace the clinical study results. A summary of the clinical studies is presented below.

Table 6: Summary of P160017/S076 Clinical Studies

Clinical Study	IDE	Patient Population	Study Design/Objective
Safety Evaluation of the Hybrid Closed Loop (HCL) System in Pediatric Subjects with Type 1 Diabetes	G150247	2-6 years*	Multi-center, single-arm, home and hotel clinical study. The study evaluated the safety of the 670G System and its algorithm with the Guardian Sensor in subjects aged 2 13 years.

A Performance Evaluation of the Enlite® and Enlite 3 Glucose Sensor to Support Use in Children; Phase 2 (Enlite 3)	G120262	2-6 years*	Multi-center, prospective, single-sample correlational design without controls. The study demonstrated the measurement performance of the Guardian Sensor (3) (commercial name of Enlite 3) in subjects aged 2 to 18 years.

*Note: These studies were designed for broader pediatric patient populations (2-13 years for G150247 and 2-18 years for G120262). However, only data for the patient population aged 2-6 years, from G150247 was provided in support of this PMA supplement. Therefore, data for the matching patient population from G120262 was reviewed. Only data for this 2-6-year-old population from both studies are presented in this SSED document.

Pivotal study: Safety Evaluation of the Hybrid Closed Loop (HCL) System in Pediatric Subjects with Type 1 Diabetes (G150247):

A. Study Design

Subjects were treated between April 10, 2017 and November 28, 2018 and included 46 patients. There were 7 investigational sites.

The pivotal study was a multi-center, single-arm home and hotel clinical evaluation in subjects with type 1 diabetes on insulin pump therapy. The sponsor enrolled 52 subjects (ages 2-6 years) at 7 investigational centers (see subject accountability below).

Of the 52 subjects that enrolled, 47 entered the run-in period. One subject withdrew prior to the start of the study period. Therefore, 46 subjects entered the study period. The 46 study subjects wore the MiniMed 670G pump with the Guardian Link (3) Transmitter, the Guardian Sensor (3) and infusion sets for approximately 3.5 months and participated in all three study phases: a two-week run-in period, a three-month at-home use period, and an out-of-home study for 5 consecutive days occurring during the at-home use period. Subjects were instructed to use the device in Auto Mode for the duration of the 3-month at home study. One subject withdrew during the study period. Therefore, 45 subjects completed the study period.

Run-in period

During the two-week run-in period, subjects used the study pump (670G) with only the sensor augmented pump function activated (all automated features were off).

Prior to wearing study devices, all subjects and their companions were trained on the devices as well as diabetes management principles, such as the treatment of hyperglycemia and hypoglycemia. In addition, there was training regarding the need to have access to oral glucose in case of hypoglycemia. Subjects were instructed to monitor blood glucose using self-monitoring of blood glucose (SMBG) 4-6 times a day. As a precaution, subjects were told that they should keep their own insulin pump

supplies in case they were asked during the study to revert back to using their own pump. Subjects were also instructed that they should always have insulin and syringes or pens, in case they encountered problems with the study pump (e.g., infusion set occlusion with high glucose).

At-Home Study Period
Following the two-week run-in period, a total of 46 subjects participated in a 3-month at-home study period. Prior to entry into Auto Mode, subjects used the pump in Manual Mode during the first 6 days of the study period in order to collect data on insulin utilization and sensor glucose levels. After this 6-day period, the subjects were allowed to enter Auto Mode.

Subjects were required to have a companion with them during the night for the duration of the study period. Companions, who had to be at least 18 years of age, were instructed to be under the same roof (i.e. within range and able to hear sensor alarms), but not necessarily in the same bedroom as the study subject. Subjects were also required to upload their pump data daily for the first 14 days after entering into Auto Mode to facilitate remote monitoring by the study sponsor.

The required device settings for the study are below unless otherwise stated as optional:

- Manual Mode:
    - High Sensor Glucose Alert was recommended to be set at 300 mg/dL
    - Low Sensor Glucose Alert was recommended to be set at 80 mg/dL
    - Low Sensor Glucose Alert could not be set lower than 70 mg/dL
        - It was recommended (optional) to have the *Suspend before Low* feature turned ON
- Auto Mode:
    - Adjustable Sensor Glucose Settings
    - High alert was recommended to be set at 300 mg/dL
    - Low sensor glucose alert recommended was to be set at 80 mg/dL
        - Low sensor glucose alert could not be set lower than 70 mg/dL
- The Temp Target was recommended to be used when subject exercises
- Alarms that were fixed (not able to be adjusted or turned OFF) in Auto Mode:
    - When sensor glucose is at or below 50 mg/dL
    - When sensor glucose is at or above 300 mg/dL for one hour
    - When sensor glucose is at or above 250 mg/dL for 3 hours

Out-of-Home Study Period
All 46 subjects participated in the out-of-home portion of the study period which lasted for 5 consecutive days, 4 – 6 hours per day. The purpose of the out-of-home portion of the study was to stress the system with sustained daily exercise.

During the out-of-home study, subjects engaged in significant activity/exercise, including use of gym play areas appropriate for toddlers and young children,

swimming, and playground games. Subjects underwent 4 – 6 hours of daytime frequent sample testing on one of the days of the out-of-home study period, with sampling occurring every 30 minutes. With respect to meals, subjects were allowed to eat as they normally would at home.

The study was a multi-center, single arm observational at home and hotel clinical study with no controls. There were no statistically powered endpoints in the Auto Mode study (G150247). This was a descriptive study to evaluate the safe use of the 670G System.

1. Clinical Inclusion and Exclusion Criteria
   Subjects were considered for enrollment in the study if they met all of the following criteria:

   General Inclusion Criteria

   1. Subject is age 2 – 6 years at time of screening
   2. Subject age 2 – 6 years has a clinical diagnosis of type 1 diabetes for 3 months or more as determined via medical record or source documentation by an individual qualified to make a medical diagnosis

   Study-Specific Inclusion Criteria

   3. Subject must have a minimum daily insulin requirement (Total Daily Dose) of greater than or equal to 8 units
   4. Subject 2-6 years of age and their parent(s)/guardian(s) are willing to participate in an extended visit during the study period to perform Frequent Sample Testing.
   5. Subject must have companion 18 years or older who will sleep in the same dwelling place every night during the Study period. This requirement may be verified by subject report at screening visit.
   6. Subject is willing to perform ≥ 4 finger stick blood glucose measurements daily
   7. Subject is willing to perform required sensor calibrations
   8. Subject is willing to wear the system continuously throughout the study
   9. Subject has a Glycosylated hemoglobin (HbA1c) value less than 10.0% (as processed by Central Lab) at time of screening visit
      Note: All HbA1C blood specimens will be sent to and tested by a NGSP certified Central Laboratory. HbA1c testing must follow National Glycohemoglobin Standardization Program (NGSP) standards.
   10. Subject has thyroid stimulating hormone (TSH) in the normal range **OR** if the TSH is out of normal reference range the Free T3 is below or within the lab's reference range and Free T4 is within the normal reference range.
   11. Subject 2-6 years of age has had pump therapy for greater than 90 days prior to screening (with or without CGM experience)
   12. Subjects and their parent(s)/guardian(s) are willing to upload data from the study pump; must have Internet access and a computer system that meets the requirements for uploading the study pump

13. If subject has celiac disease, it has been adequately treated as determined by the investigator
14. Subjects and their parent(s)/guardian(s) are willing to take one of the following insulins and can financially support the use of either of the 2 insulin preparations throughout the course of the study (i.e. co-payments for insulin with insurance or able to pay full amount)
    - Humalog® (insulin lispro injection)
    - NovoLog® (insulin aspart)
15. Subjects and their parent(s)/guardian(s)/companions must be able to speak and be literate in English as verified by the investigator

Subjects were <u>not</u> permitted to enroll in the pivotal study if they met any of the following exclusion criteria:

1. Subject has a history of 2 or more episodes of severe hypoglycemia, which resulted in any the following during the 6 months prior to screening:
    a. Medical assistance (i.e. Paramedics, Emergency Room (ER) or Hospitalization)
    b. Coma
    c. Seizures
2. Subject is unable to tolerate tape adhesive in the area of sensor placement
3. Subject has any unresolved adverse skin condition in the area of sensor placement (e.g., psoriasis, dermatitis herpetiformis, rash, Staphylococcus infection)
4. Females who are sexually active and able to conceive will be excluded if they are not using an effective method of contraception and do not agree to continue using an effective method of contraception for the duration of the study as determined by investigator.
5. Subject has a cardiovascular condition which the investigator determines should exclude the subject, i.e. ventricular rhythm disturbance, hypertrophic cardiomyopathy
6. Subject is being treated for hyperthyroidism at time of screening
7. Subject has diagnosis of adrenal insufficiency
8. Subject 2-6 years of age has had DKA in the 3 months prior to screening visit.
9. Subject has taken any oral, injectable, or intravenous (IV) glucocorticoids within 8 weeks from time of screening visit, or plans to take any oral, injectable, or IV glucocorticoids during the course of the study
10. Subject is actively participating in an investigational study (drug or device) wherein he/she has received treatment from an investigational study drug or investigational study device in the last 2 weeks

Subject 2-6 years of age has been hospitalized or has visited the ER in the 3 months prior to screening resulting in a **<u>primary diagnosis</u>** of uncontrolled diabetes

11. Subject is currently abusing illicit drugs
12. Subject is currently abusing marijuana.
13. Subject is currently abusing prescription drugs
14. Subject is currently abusing alcohol

15. Subject is using pramlintide (Symlin), DPP-4 inhibitor, liraglutide (Victoza or other GLP-1 agonists), metformin, canagliflozin (Invokana or other SGLT2 inhibitors) at time of screening
16. Subject has a history of visual impairment which would not allow subject to participate in the study and perform all study procedures safely, as determined by the investigator
17. Subject has elective surgery planned that requires general anesthesia during the course of the study
18. Subject has a sickle cell disease, hemoglobinopathy; or has received red blood cell transfusion or erythropoietin within 3 months prior to time of screening
19. Subject plans to receive red blood cell transfusion or erythropoietin over the course of study participation
20. Subject diagnosed with current eating disorder such as anorexia or bulimia
21. Subject has been diagnosed with chronic kidney disease that results in chronic anemia
22. Subject has a hematocrit that is below the normal reference range of lab used.
23. Subject is on dialysis
24. Subject has serum creatinine of >2 mg/ dL.

2. Follow-up Schedule

Throughout the study period there were a number of scheduled telephone calls. These calls were meant to make sure that the subject was healthy and to remind them about adherence to study requirements, for example uploading the study pump data to CareLink.

During the final study visit, subjects were asked to complete some questionnaires about their experience and also had blood collected for an HbA1c test.

Out-of-Home Study Phase

A staff member who was a healthcare professional supervised subjects during the 4-6 hours of each day of the out-of-home study phase.

Clinical Endpoints

There were no statistically powered endpoints in the pivotal study, nor was there any hypothesis testing. This was a descriptive study to evaluate the safe use of the Auto Mode.

Descriptive Endpoints

- The mean change in HbA1c is presented from baseline to end of study
- Change of Total Daily Dose (TDD) of insulin from baseline to end of study
- Change of weight from baseline to end of study
- Time spent in Auto Mode versus time spent in Manual Mode
- Time in different range (% of sensor glucose): sensor glucose ≤ 50 mg/dL, ≤ 54 mg/dL, ≤60 mg/dL, ≤ 70 mg/dL, 71 mg/dL – ≤180

mg/dL, sensor glucose > 180 mg/dL, > 250 mg/dL, > 350 mg/dL

- Number of Events, AUC and Time in the hyperglycemic range: sensor glucose (SG) > 180 mg/dL,> 250 mg/dL, >350 mg/dL
- Number of Events, AUC and Time in the hypoglycemic range: sensor glucose ≤ 50 mg/dL, ≤ 54 mg/dL, ≤ 60 mg/dL, and ≤ 70 mg/dL

Safety Data Summarized

- Serious Adverse Events (SAE), Serious Adverse Device Effects (SADE)
- Unanticipated Adverse Device Effects (UADE)
- Incidence of Severe Hypoglycemia
- Incidence of DKA

B. Accountability of PMA Cohort

A total of 47 subjects entered the run-in period, 1 subject withdrew during the run-in period and 46 subjects entered the study period. One subject withdrew during the study period, therefore 45 subjects completed the study period.

The demographics of the study population are typical for studies performed in the Type 1 diabetes population performed in the US.

C. Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for studies performed in the Type 1 diabetes population performed in the US.

Table 7: Study Demographics

Characteristic	Number of Subjects = 46
Age (Years)	
n	46
Mean (SD)	4.6 (1.4)
Median	5.0
Min, Max	2.0, 6.0
Gender N(%)	
Female	20 (43.5%)
Male	26 (56.5%)
Race N(%)	
American Indian/Alaska Native	1 (2.2%)

Characteristic	Number of Subjects = 46
Black/African American	4 (8.7%)
Other	3 (6.5%)
White	38 (82.6%)
Ethnicity N(%)	
Hispanic/Latino	5 (10.9%)
Non-Hispanic/Non-Latino	41 (89.1%)
Diabetes History(Years)	
n	46
Mean (SD)	2.9 (1.4)
Median	2.5
Min, Max	0.8, 5.5
Height(cm)	
n	46
Mean (SD)	110.7 (10.6)
Median	111.8
Min, Max	86.0, 130.7
Weight (kg)	
n	46
Mean (SD)	20.6 (4.0)
Median	20.3
Min, Max	11.3, 28.2
BMI (kg/m^2)	
n	46
Mean (SD)	16.7 (1.7)
Median	16.0
Min, Max	14.0, 22.0
Baseline HbA1c (%)	
n	46
Mean (SD)	8.0 (0.9)
Median	8.1
Min, Max	6.0, 9.9

D. Safety and Effectiveness Results

1. Safety Results

The safety of the 670G System was assessed by evaluation of the incidence of all serious Adverse Events, Adverse Device Effects (ADEs), Serious Adverse Device Events (SADEs), and Unanticipated Adverse Device Effects (UADEs) experienced by study subjects. Adverse events (AEs) were listed in terms of severity and relationship to the device.

There was one report of a serious adverse event. This event was an episode of altered mental status after a fall that occurred prior to the subject beginning use of the 670G system and therefore the event was adjudicated as not related to the study device.

There were no reports of unanticipated serious adverse device effects.

There were no reports of unanticipated non-serious adverse device/procedural effects.

There were no reports of diabetic ketoacidosis events.

There were no reports of severe hypoglycemia events.

There were 86 severe hyperglycemia events reported.

Severe hyperglycemia was defined in the protocol as a glucose concentration >300 mg/dL with blood ketones >0.6mmol/L or accompanied by symptoms of nausea, vomiting or abdominal pain.

Of the 86 reported severe hyperglycemia events, 49 were thought to be device-related. The majority (39) of the device-related severe hyperglycemia events were believed to be due to infusion set issues (occlusion, bent cannula or cannula pull out).

Adverse effects that occurred in the PMA clinical study:

There were no reports of unanticipated serious adverse device effects.
There were no reports of unanticipated non-serious adverse device/procedural effects.
There were no reports of diabetic ketoacidosis events.
There were no reports of severe hypoglycemia events.

2. Effectiveness Results

The data below describe how the device performed during the HCL pivotal study. The study was not designed to determine the effectiveness of the device compared

to alternative treatments such as manual daily injections or non-automated insulin pump therapy.

The table below provides an overall summary of the run-in phase and study phase (home and hotel) for all subjects in the study. The data presented in this table includes information about subjects' glucose levels, insulin delivered and weight during run-in versus study phases.

Table 8: Percent of Time within Glucose Ranges, Mean Insulin Delivery, and Mean Weight of Subjects during Run-in and Study Phases

Parameter	Age 2-6 Years (46)	
	Run-In	Study
Sensor glucose, mean ± SD (median, interquartile range) mg/dL	172.8±24.5 (172.8, 157.1-191.8)	161.2±16.2 (161.5, 148.5-171.1)
Sensor Glucose Range (mg/dL)	Percent of Time with Glucose Level in Range Mean ± SD (95% CI), %	
≤ 50 mg/dL	0.5±0.6 (0.3, 0.7)	0.5±0.4 (0.4, 0.6)
≤ 54 mg/dL	0.8±0.8 (0.6, 1.1)	0.8±0.6 (0.6, 1.0)
≤ 60 mg/dL	1.6±1.4 (1.1, 2.0)	1.5±0.9 (1.2, 1.8)
≤ 70 mg/dL	3.6±2.6 (2.8, 4.4)	3.5±1.6 (3.0, 3.9)
71 − ≤ 180 mg/dL	55.4±13.3 (51.4, 59.3)	63.6±9.4 (60.8, 66.4)
> 180 mg/dL	41.0±14.7 (36.7, 45.4)	33.0±9.9 (30.0, 35.9)
> 250 mg/dL	14.6±9.4 (11.8, 17.4)	10.7±5.9 (8.9, 12.4)
> 300 mg/dL	5.2±4.9 (3.7, 6.7)	3.7±2.9 (2.9, 4.6)
> 350 mg/dL	1.7±2.1 (1.0, 2.3)	1.2±1.1 (0.8, 1.5)
Within-day SD of glucose – mean ± SD (median, interquartile range) mg/dL	58.4±9.7 (59.3, 52.3-65.0)	57.0±8.5 (57.8, 49.8-61.9)
Within-day coefficient of variation of glucose (%) – mean ± SD (median, interquartile range) mg/dL	34.2±3.6 (34.1, 31.2-36.7)	35.3±2.6 (34.7, 33.2-37.8)
Glycated hemoglobin – mean ± SD (median, interquartile range), %	8.0±0.9 (8.1, 7.3-8.7)	7.5±0.6 (7.5, 7.1-7.9)
Total daily dose of insulin – mean ± SD (median, interquartile range), U	15.4±4.0 (15.6, 12.4-17.7)	16.1±4.7 (16.4, 12.5-18.3)

Parameter	Age 2-6 Years (46)	
	Run-In	Study
Total daily dose/Weight – mean ± SD (median, interquartile range), U/kg/day	0.8±0.1 (0.8, 0.7-0.8)	0.8±0.2 (0.7, 0.6-0.9)
Basal insulin as a % of total daily insulin – mean ± SD (median, interquartile range)	41.6±10.1 (42.2, 33.4-47.8)	39.8±10.7 (40.6, 35.4-46.7)
Weight – mean ± SD (median, interquartile range), kg	20.6±4.0 (20.3, 17.7-23.4)	21.3±4.0 (21.4, 18.0-24.4)

The subjects' baseline HbA1c value was collected at the first office visit during the study period. The end-of-study HbA1c was collected at the last visit of the study period. The change in mean HbA1c from the first visit and last visit was analyzed and found to be -0.5% (with 95% confidence intervals of -0.7 to -0.3). A summary of HbA1c data is provided in the table below.

Table 9: Percent Change in HbA1c from Baseline to End of Study

	Baseline (SD)	End of Study (SD)	Change from Baseline to End of Study (SD)
Number of Subjects	46	44*	44*
HbA1c, %, Mean (SD)	8.0 (0.9)	7.5 (0.6)	-0.5 (0.7)
HbA1c %, Median	8.1	7.5	-0.5
95% Confidence Interval	(7.7, 8.2)	(7.4, 7.7)	(-0.7, -0.3)
HbA1c, %, Min, Max	6.0, 9.9	6.2, 8.8	-1.6, 1.0

* The end-of-study A1c for Subject 302007001 was not collected and the deviation was reported. The end-of-study A1c for Subject 302008001 was not collected due to early withdrawal, per protocol.

The table below provides data regarding the subject baseline HbA1c collected at the beginning of the study and the number of subjects who experienced a decrease, no change, or increase in HbA1c values at the end of the study.

Table 10: Number of subjects with change in HbA1C at different baselines

HbA1c Change Range (%)	Number (%) of Subjects with Change in HbA1c				
	Decrease > 1%	Decrease > 0 to 1%	No Change	Increase > 0 to 1%	Increase > 1%
5%≤ **HbA1c** <6%*	-	-	-	-	-
6%≤ **HbA1c** <7%	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (13.0%)	0 (0.0%)
7%≤ **HbA1c** <8%	2 (4.3%)	7 (15.2%)	0 (0.0%)	4 (8.7%)	0 (0.0%)
8%≤ **HbA1c** <9%	4 (8.7%)	11 (23.9%)	1 (2.2%)	2 (4.3%)	0 (0.0%)

9%≤ **HbA1c**<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%)

The table below provides the average time the subjects spent in a specific glucose range in both the run-in and study phases.

Table 11: Time spent in specific glucose ranges during the run-in and study phases by all subjects

Glucose Range (mg/dL)	**Run-In Time in Glucose Range (mins) Mean ± SD (Median, Interquartile Range)**	**Study Time in Glucose Range (mins) Mean ± SD (Median, Interquartile Range)**
≤50	7.5±8.8 (5.8, 1.6-9.6)	7.4±6.5 (5.1, 3.3-9.2)
≤60	22.4±20.2 (17.0, 8.5-30.2)	21.4±13.6 (16.9, 13.4-23.9)
≤70	51.9±37.7 (50.0, 26.8-61.7)	49.7±23.7 (42.7, 33.0-57.0)
>70 to 180	797.6±191.6 (796.1, 659.5-890.0)	915.5±134.8 (886.7, 833.3-1038.4)
>180	590.5±211.1 (607.1, 455.2-742.1)	474.8±142.6 (483.1, 360.4-574.4)
>250	210.6±136.0 (182.9, 104.3-304.0)	153.5±85.4 (160.9, 77.1-204.1)
>300	75.0±70.8 (49.5, 22.1-107.6)	53.5±41.2 (45.7, 17.4-77.2)
>350	23.9±30.8 (12.8, 2.6-33.7)	16.6±16.4 (11.0, 2.9-27.2)

The table below provides the average time subjects spent in a specific glucose range while in Auto Mode during the study phase.

Table 12: Time spent in auto mode at different glucose ranges during the study phase

CGM Glucose Range (mg/dL)	**Study Period Time in Glucose Range (mins) Mean ± SD (95% CI)**
≤50	6.2±5.4 (4.6, 7.8)

CGM Glucose Range (mg/dL)	Study Period Time in Glucose Range (mins) Mean ± SD (95% CI)
≤60	18.1±11.4 (14.7, 21.4)
≤70	42.4±19.8 (36.5, 48.3)
>70 to 180	805.1±139.8 (763.6, 846.6)
>180	371.9±106.1 (340.4, 403.4)
>250	107.7±56.5 (90.9, 124.4)
>300	32.3±23.9 (25.2, 39.3)
>350	7.7±7.5 (5.5, 9.9)
All	1219.4±93.0 (1191.8, 1247.0)

The table below summarizes time spent in Auto Mode and summary of sensor wear, from start of Auto-Mode (Day 7 of the Study Phase) until the end of the study period.

Table 13: Summary of Sensor Wear and Time Spent in Auto Mode, From Start of Auto-Mode to End of the Study Period

Category	Percentage of Time
Time spent wearing sensor	96.2%
Time spent not wearing sensor	3.8%
Auto Mode (core algorithm)	77.8%
Auto Mode (safe basal)	7.1%
Time spent in Manual Mode	15.1%

Guardian Sensor Performance Study - A Performance Evaluation of the Enlite® and Enlite 3 Glucose Sensor to Support Use in Children; Phase 2 (Enlite 3) (G120262):

A. Study Design

This study was performed to assess the analytical performance of the Guardian

Sensor (3). It ran between May 12, 2015 and December 13, 2016 and included 21 subjects (different from subjects who participated in the pivotal study above). There were 11 investigational sites.

This study was a prospective, single arm, multi-center, in-clinic study. All subjects wore one receiver, one transmitter, one transmitter used as a recorder, and two sensors. All subjects were assigned to complete frequent sample testing (FST).

Subjects wore the Guardian Sensor (3) for a 7-day training period (that included a minimum of 6 days of sensor wear), followed by a 7-day study period. During the study period, each subject participated in one in-clinic FST intervention. FST occurred at the beginning (Day 1), middle (Day 3) or end (Day 7) of the Guardian sensor (3) use. During these FST sessions, if tolerated by the patient, intravenous (IV) blood samples were drawn every 5 to 15 minutes and analyzed for plasma blood glucose levels using the comparator method (CM); otherwise, blood glucose levels were measured using a blood glucose meter at the same time intervals. The CM in this study was the Yellow Springs Instrument (YSI) 2300 Stat Plus Glucose Lactate Analyzer or the Bayer CONTOUR Next Link RF blood glucose meter. FST with the CM lasted approximately 6 hours during the in-clinic visit.

Subjects were randomized to one of 10 groups that determined when they participated in the in-clinic FST.

Subjects continued with their current diabetes regimen independent of the study devices. Subjects were instructed by the investigational center that they were not to use the investigational devices for the management of their diabetes.

There was no control group as this study was an observational study to determine the accuracy and precision of the Guardian sensor. Accuracy was assessed by comparing the sensor values to the CM, and precision of the sensor system was assessed by comparing sensor values to each other in subjects wearing two sensors.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the Guardian sensor study was limited to subjects who met the following inclusion criteria:

   1. Subject is 2-6 years of age at time of screening (which was a subset of the entire study population)
   2. Subject has been diagnosed with insulin requiring diabetes mellitus for at least one year.
   3. Subject is willing to perform greater than or equal to 4 finger stick blood glucose measurements daily
   4. Subject is willing to perform required sensor calibrations
   5. Subject is willing to wear the system continuously throughout the study

   Inclusion Criteria Specific to Study

6. Adequate venous access for subjects requiring IV for their FST, as assessed by investigator or appropriate staff

Subjects were not permitted to enroll in the Guardian sensor study if they met any of the following exclusion criteria:

1. Subject is unable to tolerate tape adhesive in the area of sensor placement
2. Subject has any unresolved adverse skin condition in the area of sensor or device placement (e.g., psoriasis, rash, Staphylococcus infection)
3. Subject is actively participating in an investigational study (drug or device) wherein they have received treatment from an investigational study (drug or device) in the last 2 weeks
4. Subjects with hematocrit lower than the normal age specific reference range per central or local lab testing

2. Follow-up Schedule

At the end of the study, subjects removed all study devices. Upon removal, all the Sensor insertion sites were examined and evaluated by the study staff. Sensors were visually inspected at the site. Study investigators documented any Adverse Device Effects (including skin irritations) and evaluated safety issues related to system use during the study. No long-term follow up was included in this study protocol.

3. Clinical Endpoints

Because this was an observational study, it did not include traditional analysis of clinical endpoints. The data were presented using multiple analyses as described in the Study Results section below.

Safety of the sensor was determined by skin and insertion site reactions.

B. Accountability of Study Cohort

Of the 21 subjects that entered the study, all participated in Phase 2 (Enlite 3 Phase) of the study. No subjects withdrew before entering Phase 2 (Enlite 3 phase).

All 21 subjects underwent FST and completed the study. Six (6) subjects completed the first FST on Day 1, 7 subjects completed FST on Day 3, and 8 subjects completed FST on Day 7.

C. Study Population Demographics and Baseline Parameters

Table 14: Study Demographics

Characteristic	All Subjects N = 21
Age (Years)	

Characteristic	All Subjects N = 21
Number of Subjects	21
Mean (SD)	5.3 (0.90)
Median	6
Min, Max	3.0, 6.0
Gender, Number (%)	
Female not of child bearing potential	9 (42.9%)
Male	12 (57.1%)
Race, Number (%)	
Black/African American	1 (4.8%)
White	20 (95.2%)
Ethnicity, Number (%)	
Hispanic/Latino	4 (19.0%)
Non-Hispanic/Non-Latino	17 (81.0%)
Height (cm)	
Number of subjects	21
Mean (SD)	116.6 (8.89)
Median	118.5
Min, max	95.2, 131.0
Weight (kg)	
Number of subjects	21
Mean (SD)	24.5 (7.28)
Median	22.5
Min, max	14.2, 48.4
Body Mass Index (kg/m^2)	
Number of subjects	21
Mean (SD)	17.9 (4.56)
Median	16.7
Min, max	14.4, 35.7
A1C (%)	
Number of subjects	20*
Mean (SD)	7.8 (0.85)
Median	7.9
Min, max	6.5, 9.3
Hematocrit (%)	
Number of subjects	20*
Mean (SD)	39.9 (2.96)
Median	39.7
Min, max	34.7, 46.9

* Subject 249002037 did not have an HbA1c test result, and Subject 249007008 did not have a hematocrit test result.

D. Safety and Effectiveness Results

1. Safety Results

The safety of the Guardian Sensor (3) was assessed by evaluation of the incidence of all adverse events, Adverse Device Effects (ADEs), Serious Adverse Device Events (SADEs), and Unanticipated Adverse Device Effects (UADEs) experienced by study subjects. Adverse events (AEs) were listed in terms of severity and relationship to device. Sensor insertion site and adhesive area were examined for erythema, edema and infection. The local skin reactions from the insertion site or the adhesive were also evaluated.

There were 8 adverse events reported during the study as summarized below. All adverse events were resolved and subjects recovered completely without residual sequelae.

There were no reports of device-related serious adverse events (SAEs).

There were no reports of non-device-related SAEs.

There was one report of a device-related adverse event. This event was the occurrence of mild contact dermatitis, likely related to a tape allergy in the area of sensor placement.

There was one report of severe hypoglycemia. This event was not device-related.

There was one report of severe hyperglycemia. This event was not device-related.

There were no reports of subject death.

There were no reports of DKA.

There were no reports of procedure-related adverse events.

The following adverse events were reported for the study that were neither device-related nor procedure related:

- One report of hand, foot and mouth disease
- Two reports of cough
- One report of food allergy: shellfish positive (food-protein-induced enterocolitis syndrome)
- One report of upper respiratory infection

The incidence of adverse events directly related to the CGM in the intended use population is not expected to differ significantly from the event rate observed during the Guardian Sensor (3) accuracy study for the 14 years and older

population (G140053) or those observed for other approved CGM devices. Based on (FDA-analyzed) post-market adverse event reports for similar CGM devices, no additional concerns regarding adverse events were raised for CGMs.

2. Effectiveness Results

Study results from the Guardian sensor study are presented in Tables 15 to 82. Results are presented below by abdominal insertion site followed by buttock insertion site.

The sensor must be calibrated at least twice per day (every 12 hours). However, the sponsor recommends users calibrate more often for best results (3 to 4 times per day). Most tables below represent data for minimal calibration (every 12 hours). Please see table headers to understand calibration frequency for each analysis.

1. Abdomen Insertion Site

Tables 15 and 16 below provide the Guardian sensor values and the percent difference with respect to comparator method (CM) values when the sensor worn in the abdomen was calibrated every 12 hours and three to four times per day, respectively.

Tables 17 and 18 below provide the Guardian sensor values and the percent difference with respect to CGM values when the sensor worn in the abdomen was calibrated every 12 hours and three to four times per day, respectively.

Table 15. CGM Difference to CM within CM Glucose Ranges, Calibrating Every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

CM Glucose Ranges (mg/dL)	Number of Subjects	Number of Paired CGM-CM Pairs	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	5	62	10.7	9.29
61-80*	1	1	7	7
81-180	4	26	10.12	8.19
181-300	5	30	11.9	11.84
301-350	2	5	6.73	6.31

**For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*
Note: Sensor glucose readings are within 40-400 mg/dL.

Table 16. CGM Difference to CM within CM Glucose Ranges, Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

CM Glucose Ranges (mg/dL)	Number of Subjects	Number of Paired CGM-CM Pairs	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	5	62	10.96	9.84
61-80*	1	1	7	7
81-180	4	26	10.12	8.19
181-300	5	30	11.98	11.91
301-350	2	5	9.46	6.5

**For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*
Note: Sensor glucose readings are within 40-400 mg/dL.

Table 17. CGM Difference to CM within CGM Glucose Ranges, Calibrating Every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

CGM Glucose Ranges (mg/dL)	Number of Subjects	Number of Paired CGM-CM Pairs	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	5	62	11.09	8.5
61-80*	1	1	7	7
81-180	4	25	13.16	8.5
181-300	5	27	10.01	8.98
301-350	3	8	7.61	5.38
351-400	1	1	18.19	18.19

**For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*
Note: Sensor glucose readings are within 40-400 mg/dL.

Table 18. CGM Difference to CM within CGM Glucose Ranges, Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

CGM Glucose Ranges (mg/dL)	Number of Subjects	Number of Paired CGM-CM Pairs	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	5	62	11.34	8.96
61-80*	1	1	7	7
81-180	4	25	12.72	8.5
181-300	5	28	10.74	10.58
301-350	3	7	8.15	5.94
351-400	1	1	18.19	18.19

**For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%).*

Note: Sensor glucose readings are within 40-400 mg/dL.

Tables 19 and 20 below provide the Guardian Sensor (3) values and the percentage of data points that fell within 15, 20, 30, 40, and >40 mg/dL or percent of a specific CM glucose range when the sensor worn in the abdomen was calibrated every 12 hours after: Days 1, 3, and 7 (Table 19); Day 1 only (Table 20), respectively.

Tables 21 and 22 below provide the Guardian Sensor (3) values and the percent of data points that fell within 15, 20, 30, 40, and >40 mg/dL or percent of a specific CM glucose range when the sensor worn in the abdomen was calibrated three to four times per day, after: Days 1, 3, and 7 (Table 21); Day 1 only (Table 22), respectively.

Table 19. Agreement (%) of Sensor-CM Paired Points (15/15%- greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CM Glucose Ranges (mg/dL)	**Number of Subjects**	**Number of CGM-CM Pairs**	**Percent of CGM Within XX mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (*where XX signifies the values in header below*)**				
			15/15%	**20/20%**	**30/30%**	**40/40%**	**>40/40%**
Overall	5	62	72.6	85.5	96.8	100	0
>60-80*	1	1	100	100	100	100	0
>80-180	4	26	80.8	88.5	96.2	100	0
>180-300	5	30	60	80	96.7	100	0
>300-350	2	5	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 20. Agreement (%) of Sensor-CM Paired Points (15/15%- greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, ***Day 1***

CM Glucose Ranges (mg/dL)	**Number of Subjects**	**Number of CGM-CM Pairs**	**Percent of CGM Within XX mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (*where XX signifies the values in header below*)**				
			15/15%	**20/20%**	**30/30%**	**40/40%**	**>40/40%**
Overall	1	11	72.7	100	100	100	0
>80-180	1	1	100	100	100	100	0
>180-300	1	10	70	100	100	100	0

Table 21. Agreement (%) of Sensor-CM Paired Points (15/15%-greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CM Glucose Ranges (mg/dL)	Number of Subjects	Number of CGM-CM Pairs	Percent of CGM Within XX mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (where XX signifies the values in header below)				
			15/15%	20/20%	30/30%	40/40%	>40/40%
Overall	5	62	71	83.9	98.4	100	0
>60-80*	1	1	100	100	100	100	0
>80-180	4	26	80.8	88.5	96.2	100	0
>180-300	5	30	60	80	100	100	0
>300-350	2	5	80	80	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 22. Agreement (%) of Sensor-CM Paired Points (15/15%-greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, ***Day 1***

CM Glucose Ranges (mg/dL)	Number of Subjects	Number of CGM-CM Pairs	Percent of CGM Within XX mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (where XX signifies the values in header below)				
			15/15%	20/20%	30/30%	40/40%	>40/40%
Overall	1	11	72.7	100	100	100	0
>80-180	1	1	100	100	100	100	0
>180-300	1	10	70	100	100	100	0

Tables 23 to 26 show the percentage of concurring CGM readings compared to CM values for sensors worn in the abdomen. With ideal performance, the CGM readings would match the CM values. For example, with perfect concurrence, the shaded boxes in the tables below would be 100 percent.

Tables 23 and 24 show the concurrence of the CGM values compared to CM values when calibrating every 12 hours, after Days 1, 3, and 7; and Day 1 only, respectively.

Tables 25 and 26 show the concurrence of the CGM values compared to CM values when calibrating three to four times per day, after Days 1, 3, and 7; and Day 1 only, respectively.

Table 23. Concurrence of CM values and CGM readings using CM glucose ranges; Calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CGM Glucose Range for Each CM Glucose Range												
	CGM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
C) >60-80	1	1	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	3	11	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	63.6% (7/11)	36.4% (4/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	4	10	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (2/10)	60.0% (6/10)	20.0% (2/10)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	4	11	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.2% (2/11)	63.6% (7/11)	18.2% (2/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	4	6	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.7% (1/6)	0.0% (0/0)	33.3% (2/6)	50.0% (3/6)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	4	19	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	21.1% (4/19)	47.4% (9/19)	21.1% (4/19)	5.3% (1/19)	5.3% (1/19)
I) >300-350	2	5	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (1/5)	80.0% (4/5)	0.0% (0/0)	0.0% (0/0)

Table 24. Concurrence of CM values and CGM readings using CM glucose ranges; Calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, ***Day 1***

CM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CGM Glucose Range for Each CM Glucose Range												
	CGM (mg/dL)												
	Number of Subjects	**Number of Paired CGM-CM***	**<40**	**≥40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
E) >120-160	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	1	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (2/4)	50.0% (2/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	1	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (1/2)	50.0% (1/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	1	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	75.0% (3/4)	25.0% (1/4)	0.0% (0/0)	0.0% (0/0)

Table 25. Concurrence of CM values and CGM readings using CM glucose ranges; Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CM Glucose Ranges (mg/dL)	**Percent of Matched Pairs-in Each CGM Glucose Range for Each CM Glucose Range**												
	CGM (mg/dL)												
	Number of Subjects	**Number of Paired CGM-CM**	**<40**	**≥40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
C) >60-80	1	1	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	3	11	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	63.6% (7/11)	36.4% (4/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	4	10	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (2/10)	60.0% (6/10)	20.0% (2/10)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	4	11	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.2% (2/11)	63.6% (7/11)	18.2% (2/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	4	6	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.7% (1/6)	0.0% (0/0)	33.3% (2/6)	50.0% (3/6)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	4	19	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	26.3% (5/19)	42.1% (8/19)	21.1% (4/19)	5.3% (1/19)	5.3% (1/19)
I) >300-350	2	5	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (1/5)	20.0% (1/5)	60.0% (3/5)	0.0% (0/0)	0.0% (0/0)

Table 26. Concurrence of CM values and CGM readings using CM glucose ranges; Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, ***Day 1***

CM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CGM Glucose Range for Each CM Glucose Range												
	CGM (mg/dL)												
	Number of Subjects	**Number of Paired CGM-CM***	**<40**	**≥40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
E) >120-160	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	1	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (2/4)	50.0% (2/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	1	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (1/2)	50.0% (1/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	1	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	75.0% (3/4)	25.0% (1/4)	0.0% (0/0)	0.0% (0/0)

Tables 27 through 30 show the percentage of concurring CM readings compared to CGM values for sensors worn in the abdomen. With ideal performance the CGM readings would match the CM values. For example, with perfect concurrence, the shaded boxes would be 100 percent.

Tables 27 and 28 show the concurrence of the CM values compared to CGM values when calibrating every 12 hours, after Days 1, 3, and 7 and Day 1 only, respectively.

Tables 29 and 30 show the concurrence of the CM values compared to CGM values when calibrating three to four times per day, after Days 1, 3, and 7 and Day 1 only, respectively.

*Table 27. Concurrence of CGM readings and CM values using CGM glucose ranges; Calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, **Days 1, 3, and 7 combined***

CGM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range												
	CM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM Values	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
C) >60-80	1	1	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	3	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	77.8% (7/9)	22.2% (2/9)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	3	13	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	30.8% (4/13)	46.2% (6/13)	15.4% (2/13)	7.7% (1/13)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	4	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	22.2% (2/9)	77.8% (7/9)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	3	8	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	25.0% (2/8)	25.0% (2/8)	50.0% (4/8)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	4	13	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	23.1% (3/13)	69.2% (9/13)	7.7% (1/13)	0.0% (0/0)	0.0% (0/0)
I) >300-350	3	8	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (4/8)	50.0% (4/8)	0.0% (0/0)	0.0% (0/0)
J) >350-400	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
K) >400	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

*Table 28. Concurrence of CGM readings and CM values using CGM glucose ranges; Calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, **Day 1***

CGM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range												
	CM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM Values	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
F) >160-200	1	3	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	33.3% (1/3)	66.7% (2/3)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	1	3	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	66.7% (2/3)	33.3% (1/3)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	1	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	25.0% (1/4)	75.0% (3/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
I) >300-350	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Table 29. Concurrence of CGM readings and CM values using CGM glucose ranges; Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CGM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range												
	CM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM Values	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
C) >60-80	1	1	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	3	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	77.8% (7/9)	22.2% (2/9)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	3	13	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	30.8% (4/13)	46.2% (6/13)	15.4% (2/13)	7.7% (1/13)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	4	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	22.2% (2/9)	77.8% (7/9)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	3	10	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (2/10)	20.0% (2/10)	50.0% (5/10)	10.0% (1/10)	0.0% (0/0)	0.0% (0/0)
H) >250-300	4	12	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	25.0% (3/12)	66.7% (8/12)	8.3% (1/12)	0.0% (0/0)	0.0% (0/0)
I) >300-350	3	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	57.1% (4/7)	42.9% (3/7)	0.0% (0/0)	0.0% (0/0)
J) >350-400	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
K) >400	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

*Table 30. Concurrence of CGM readings and CM values using CGM glucose ranges; Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age, **Day 1***

CGM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range												
	CM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM Values	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
F) >160-200	1	3	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	33.3% (1/3)	66.7% (2/3)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	1	3	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	66.7% (2/3)	33.3% (1/3)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	1	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	25.0% (1/4)	75.0% (3/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
I) >300-350	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)

Tables 33 and 34 show sensor stability in the abdomen by comparing the CM values collected during frequent sample testing days 1, 3, and 7 to their paired sensor points. The tables stratify the paired CM-sensor data by 15/15, 20/20, 30/30, 40/40 and >40/40 mg/dL and percent, respectively.

Table 31. Sensor Stability (accuracy over time) for Calibration every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

Day of Wear	Number of Subjects	Number of Paired CGM-CM Values	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)	Percent Within XX /mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (*where XX signifies the values in header below*)				
					15/15%	20/20%	30/30%	40/40%	>40/40%
1	1	11	8.7	7.2	72.7	100.0	100.0	100.0	0.0
3	2	26	8.2	6.9	88.5	96.2	100.0	100.0	0.0
7	2	25	14.2	14.0	56.0	68.0	92.0	100.0	0.0

Table 32. Sensor Stability (accuracy over time) for Calibration three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

Day of Wear	Number of Subjects	Number of Paired CGM-CM Values	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)	Percent Within XX /mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (*where XX signifies the values in header below*)				
					15/15%	20/20%	30/30%	40/40%	>40/40%
1	1	11	8.7	7.2	72.7	100.0	100.0	100.0	0.0
3	2	26	8.2	6.9	88.5	96.2	100.0	100.0	0.0
7	2	25	14.9	15.0	52.0	64.0	96.0	100.0	0.0

Tables 33 and 34 below provide the percent agreement of Guardian Sensor (3) and the comparator method (CM) within a specific time range after calibration.

Table 33. Agreement Rates for Every 2 Hour Period Post Calibration, Calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

Time After Calibration	Number of Subjects	Number of Paired CGM-CMValues	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	4	20	65	85	100	100	0
2–4 hours	4	16	68.8	93.8	100	100	0
4–6 hours	4	11	90.9	90.9	100	100	0
6–8 hours	2	8	62.5	62.5	87.5	100	0
8–10 hours	2	6	100	100	100	100	0
10–12 hours	1	1	0	0	0	100	0

Table 34. Agreement Rates for Every 2 Hour Period Post Calibration, Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

Time After Calibration	Number of Subjects	Number of Paired CGM-CMValues	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	5	24	62.5	79.2	100	100	0
2-4 hours	4	13	61.5	92.3	100	100	0
4-6 hours	4	11	90.9	90.9	100	100	0

6-8 hours	2	8	62.5	62.5	87.5	100	0
8-10 hours	2	6	100	100	100	100	0

Tables 35 and 36 below provide data representing sensor accuracy in the abdomen over specific glucose rates of change. The concurrence tables below provide the percent of matched CM pairs to CGM values over specific glucose rates of change for sensors worn in the abdomen calibrated every 12 hours and three to four times per day, respectively.

Table 35. Percent of Matched Pairs in Each CM Rate Range for Each CGM Rate Range, Calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

CGM Rate Ranges (mg/dL/min)	**Percent of Matched Pairs-in Each CM Rate Range for Each CGM Rate Range**							
	CM (mg/dL/min)							
	Number of Subjects	**Number of Paired CGM-CM**	**<-2**	**[-2, -1)**	**[-1, 0)**	**[0, 1]**	**(1, 2]**	**>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)	2	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)	2	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]	3	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]	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	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 36. Percent of Matched Pairs in Each CM Rate Range for Each CGM Rate Range, Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

CGM Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each CM Rate Range for Each CGM Rate Range							
	CM (mg/dL/min)							
	Number of Subjects	Number of Paired CGM-CM	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>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)	2	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)	2	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]	3	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]	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	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)

Tables 37 and 38 below provide the number and percentage of CM measurements collected while the continuous glucose monitor read ‘low’ (< 40 mg/dL), or ‘high’ (> 400 mg/dL) for sensors worn in the abdomen calibrated every 12 hours.

Tables 39 and 40 below provide the number and percentage of CM measurements collected while the continuous glucose monitor read ‘low’ (< 40 mg/dL), or ‘high’ (> 400 mg/dL) for sensors worn in the abdomen calibrated three to four times per day.

Table 37. The Number and Percentage of CM values collected when CGM readings displayed 'Low' (less than 40 mg/dL); calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

CGM Readings	CGM-CM pairs	<55	<60	<70	<80	>80	Total
'LOW'	Cumulative, n	0	0	0	0	0	0
	Cumulative %	0%	0%	0%	0%	0%	

Table 38. The Number and Percentage of CM values collected when CGM readings displayed 'High' (more than 400 mg/dL); calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

CGM Readings	CGM-CM pairs	>340	>320	>280	>240	<240	Total
'HIGH'	Cumulative, n	0	0	1	1	0	1
	Cumulative %	0%	0%	100%	100%	0%	

Table 39. The Number and Percentage of CM values collected when CGM readings displayed 'Low' (less than 40 mg/dL); calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

CGM Readings	CGM-CM pairs	<55	<60	<70	<80	>80	Total
'LOW'	Cumulative, n	0	0	0	0	0	0
	Cumulative %	0%	0%	0%	0%	0%	

Table 40. The Number and Percentage of CM values collected when CGM readings displayed 'High' (more than 400 mg/dL); calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

CGM Readings	CGM-CM pairs	>340	>320	>280	>240	<240	Total
'HIGH'	Cumulative, n	0	0	1	1	0	1
	Cumulative %	0%	0%	100%	100%	0%	

2. <u>Pump Alert Performance using the Abdomen Sensor Insertion Site</u>

Alert performance was evaluated to obtain 'true alert' and 'false alert' rates, and 'correctly detected' and 'missed alert' rates. The descriptions and tables below describe the alert rate performance of the device within this clinical study:

<u>True alert rates</u>
The true alert rate is the rate at which the blood glucose value confirmed that the continuous glucose monitor alert was triggered correctly. For example:

- True Threshold Hypoglycemic alert rate alerted when the continuous glucose monitor read that the user was below the low threshold and the user's blood glucose was actually below that low threshold (within +/- 15 or 30 minutes of the alert)
- True Threshold Hyperglycemic alert rate alerted when the continuous glucose monitor read that the user was above the high threshold and the user's blood glucose was actually above that high threshold (within +/- 15 or 30 minutes of the alert)
- True Predictive Hypoglycemic alert rate alerted when the continuous glucose monitor 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 following the alert
- True Predictive Hyperglycemic alert rate alerted when the continuous glucose monitor 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 minutes following the alert.
-

Table 41. Glucose TRUE Alert Performance, Calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose True Alert Rate: Low glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	N/A	N/A	**55**	0.0%(0/1, 1)	0.0%(0/1, 1)	**55**	0.0%(0/1, 1)	0.0%(0/1, 1)
	60	N/A	N/A	**60**	0.0%(0/1, 1)	0.0%(0/1, 1)	**60**	0.0%(0/1, 1)	0.0%(0/1, 1)
	70	0.0%(0/1, 1)	0.0%(0/1, 1)	**70**	0.0%(0/4, 2)	0.0%(0/4, 2)	**70**	0.0%(0/5, 2)	0.0%(0/5, 2)
	80	25.0%(1/4, 2)	25.0%(1/4, 2)	**80**	16.7%(1/6, 3)	0.0%(0/6, 3)	**80**	20.0%(2/10, 3)	10.0%(1/10, 3)
	90	50.0%(2/4, 2)	50.0%(2/4, 2)	**90**	50.0%(3/6, 3)	33.3%(2/6, 3)	**90**	50.0%(5/10, 3)	40.0%(4/10, 3)
Glucose True Alert Rate: High glucose Alerts	**300**	60.0%(3/5, 4)	60.0%(3/5, 4)	**300**	40.0%(2/5, 5)	40.0%(2/5, 5)	**300**	50.0%(5/10, 5)	50.0%(5/10, 5)
	250	100.0%(5/5, 4)	100.0%(5/5, 4)	**250**	83.3%(5/6, 5)	83.3%(5/6, 5)	**250**	90.9%(10/11, 5)	90.9%(10/11, 5)
	220	100.0%(4/4, 4)	100.0%(4/4, 4)	**220**	50.0%(5/10, 5)	50.0%(5/10, 5)	**220**	61.5%(8/13, 5)	61.5%(8/13, 5)
	180	100.0%(7/7, 5)	100.0%(7/7, 5)	**180**	80.0%(8/10, 5)	70.0%(7/10, 5)	**180**	85.7%(12/14, 5)	78.6%(11/14, 5)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Table 42. Glucose TRUE Alert Performance, Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose True Alert Rate: Low glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	N/A	N/A	**55**	0.0%(0/1, 1)	0.0%(0/1, 1)	**55**	0.0%(0/1, 1)	0.0%(0/1, 1)
	60	N/A	N/A	**60**	0.0%(0/1, 1)	0.0%(0/1, 1)	**60**	0.0%(0/1, 1)	0.0%(0/1, 1)
	70	N/A	N/A	**70**	0.0%(0/4, 2)	0.0%(0/4, 2)	**70**	0.0%(0/4, 2)	0.0%(0/4, 2)
	80	25.0%(1/4, 2)	25.0%(1/4, 2)	**80**	16.7%(1/6, 3)	0.0%(0/6, 3)	**80**	20.0%(2/10, 3)	10.0%(1/10, 3)
	90	50.0%(2/4, 2)	50.0%(2/4, 2)	**90**	50.0%(3/6, 3)	33.3%(2/6, 3)	**90**	50.0%(5/10, 3)	40.0%(4/10, 3)
Glucose True Alert Rate: High glucose Alerts	**300**	50.0%(2/4, 4)	50.0%(2/4, 4)	**300**	40.0%(2/5, 5)	40.0%(2/5, 5)	**300**	44.4%(4/9, 5)	44.4%(4/9, 5)
	250	100.0%(5/5, 4)	100.0%(5/5, 4)	**250**	83.3%(5/6, 5)	83.3%(5/6, 5)	**250**	90.9%(10/11, 5)	90.9%(10/11, 5)
	220	100.0%(4/4, 4)	100.0%(4/4, 4)	**220**	50.0%(5/10, 5)	50.0%(5/10, 5)	**220**	61.5%(8/13, 5)	61.5%(8/13, 5)
	180	100.0%(8/8, 5)	100.0%(8/8, 5)	**180**	80.0%(8/10, 5)	70.0%(7/10, 5)	**180**	86.7%(13/15, 5)	80.0%(12/15, 5)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

False Alert Rates

The glucose false alert rate is the rate at which the blood glucose value did not confirm that the continuous glucose monitor alert was triggered correctly. For example:

- False Threshold Hypoglycemic alert rate the alarm alerted when the continuous glucose monitor read that the user was below the low threshold but the users blood glucose was actually above that low threshold (within +/- 15 or 30 minutes of the alert).
- False Threshold Hyperglycemic alert rate the alarm alerted when the continuous glucose monitor read that the user was above the high threshold but the user's blood glucose was actually below that high

threshold (within +/- 15 or 30 minutes of the alert).

- False Predictive Hypoglycemic alert rate the alarm alerted when the continuous glucose monitor 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 following the alert.
- False Predictive Hyperglycemic alert rate the alarm alerted when the continuous glucose monitor 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 following the alert.

Table 43. Glucose FALSE Alert Performance, Calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			**Predictive Only**			**Threshold & Predictive**		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose False Alert Rate: Low Glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	N/A	N/A	**55**	100.0%(1/1, 1)	100.0%(1/1, 1)	**55**	100.0%(1/1, 1)	100.0%(1/1, 1)
	60	N/A	N/A	**60**	100.0%(1/1, 1)	100.0%(1/1, 1)	**60**	100.0%(1/1, 1)	100.0%(1/1, 1)
	70	100.0%(1/1, 1)	100.0%(1/1, 1)	**70**	100.0%(4/4, 2)	100.0%(4/4, 2)	**70**	100.0%(5/5, 2)	100.0%(5/5, 2)
	80	75.0%(3/4, 2)	75.0%(3/4, 2)	**80**	83.3%(5/6, 3)	100.0%(6/6, 3)	**80**	80.0%(8/10, 3)	90.0%(9/10, 3)
	90	50.0%(2/4, 2)	50.0%(2/4, 2)	**90**	50.0%(3/6, 3)	66.7%(4/6, 3)	**90**	50.0%(5/10, 3)	60.0%(6/10, 3)
Glucose False Alert Rate: High Glucose Alerts	**300**	40.0%(2/5, 4)	40.0%(2/5, 4)	**300**	60.0%(3/5, 5)	60.0%(3/5, 5)	**300**	50.0%(5/10, 5)	50.0%(5/10, 5)
	250	0.0%(0/5, 4)	0.0%(0/5, 4)	**250**	16.7%(1/6, 5)	16.7%(1/6, 5)	**250**	9.1%(1/11, 5)	9.1%(1/11, 5)
	220	0.0%(0/4, 4)	0.0%(0/4, 4)	**220**	50.0%(5/10, 5)	50.0%(5/10, 5)	**220**	38.5%(5/13, 5)	38.5%(5/13, 5)
	180	0.0%(0/7, 5)	0.0%(0/7, 5)	**180**	20.0%(2/10, 5)	30.0%(3/10, 5)	**180**	14.3%(2/14, 5)	21.4%(3/14, 5)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Table 44. Glucose FALSE Alert Performance, Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose False Alert Rate: Low Glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	N/A	N/A	**55**	100.0%(1/1, 1)	100.0%(1/1, 1)	**55**	100.0%(1/1, 1)	100.0%(1/1, 1)
	60	N/A	N/A	**60**	100.0%(1/1, 1)	100.0%(1/1, 1)	**60**	100.0%(1/1, 1)	100.0%(1/1, 1)
	70	N/A	N/A	**70**	100.0%(4/4, 2)	100.0%(4/4, 2)	**70**	100.0%(4/4, 2)	100.0%(4/4, 2)
	80	75.0%(3/4, 2)	75.0%(3/4, 2)	**80**	83.3%(5/6, 3)	100.0%(6/6, 3)	**80**	80.0%(8/10, 3)	90.0%(9/10, 3)
	90	50.0%(2/4, 2)	50.0%(2/4, 2)	**90**	50.0%(3/6, 3)	66.7%(4/6, 3)	**90**	50.0%(5/10, 3)	60.0%(6/10, 3)
Glucose False Alert Rate: High Glucose Alerts	**300**	50.0%(2/4, 4)	50.0%(2/4, 4)	**300**	60.0%(3/5, 5)	60.0%(3/5, 5)	**300**	55.6%(5/9, 5)	55.6%(5/9, 5)
	250	0.0%(0/5, 4)	0.0%(0/5, 4)	**250**	16.7%(1/6, 5)	16.7%(1/6, 5)	**250**	9.1%(1/11, 5)	9.1%(1/11, 5)
	220	0.0%(0/4, 4)	0.0%(0/4, 4)	**220**	50.0%(5/10, 5)	50.0%(5/10, 5)	**220**	38.5%(5/13, 5)	38.5%(5/13, 5)
	180	0.0%(0/8, 5)	0.0%(0/8, 5)	**180**	20.0%(2/10, 5)	30.0%(3/10, 5)	**180**	13.3%(2/15, 5)	20.0%(3/15, 5)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Correct Detection Rates

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 (within +/- 15 or 30 minutes for the threshold alerts, and within 15 or 30 minutes following predictive alerts).

Table 45. Glucose Correct Detection Alert Performance, Calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose Correct Detection Rate: Low Glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	N/A	N/A	**55**	N/A	N/A	**55**	N/A	N/A
	60	N/A	N/A	**60**	N/A	N/A	**60**	N/A	N/A
	70	N/A	N/A	**70**	N/A	N/A	**70**	N/A	N/A
	80	100.0%(1/1, 1)	100.0%(1/1, 1)	**80**	100.0%(1/1, 1)	0.0%(0/1, 1)	**80**	100.0%(1/1, 1)	100.0%(1/1, 1)
	90	66.7%(2/3, 3)	66.7%(2/3, 3)	**90**	100.0%(3/3, 3)	66.7%(2/3, 3)	**90**	100.0%(3/3, 3)	100.0%(3/3, 3)
Glucose Correct Detection Rate: High Glucose Alerts	**300**	100.0%(4/4, 2)	100.0%(4/4, 2)	**300**	100.0%(4/4, 2)	75.0%(3/4, 2)	**300**	100.0%(4/4, 2)	100.0%(4/4, 2)
	250	100.0%(8/8, 4)	100.0%(8/8, 4)	**250**	100.0%(8/8, 4)	87.5%(7/8, 4)	**250**	100.0%(8/8, 4)	100.0%(8/8, 4)
	220	100.0%(8/8, 4)	100.0%(8/8, 4)	**220**	100.0%(8/8, 4)	87.5%(7/8, 4)	**220**	100.0%(8/8, 4)	100.0%(8/8, 4)
	180	84.6%(11/13, 5)	84.6%(11/13, 5)	**180**	92.3%(12/13, 5)	84.6%(11/13, 5)	**180**	92.3%(12/13, 5)	84.6%(11/13, 5)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Table 46. Glucose Correct Detection Alert Performance, Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose Correct Detection Rate: Low Glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	N/A	N/A	**55**	N/A	N/A	**55**	N/A	N/A
	60	N/A	N/A	**60**	N/A	N/A	**60**	N/A	N/A
	70	N/A	N/A	**70**	N/A	N/A	**70**	N/A	N/A
	80	100.0%(1/1, 1)	100.0%(1/1, 1)	**80**	100.0%(1/1, 1)	0.0%(0/1, 1)	**80**	100.0%(1/1, 1)	100.0%(1/1, 1)
	90	66.7%(2/3, 3)	66.7%(2/3, 3)	**90**	100.0%(3/3, 3)	66.7%(2/3, 3)	**90**	100.0%(3/3, 3)	100.0%(3/3, 3)
Glucose Correct Detection Rate: High Glucose Alerts	**300**	75.0%(3/4, 2)	75.0%(3/4, 2)	**300**	100.0%(4/4, 2)	75.0%(3/4, 2)	**300**	100.0%(4/4, 2)	75.0%(3/4, 2)
	250	100.0%(8/8, 4)	100.0%(8/8, 4)	**250**	100.0%(8/8, 4)	87.5%(7/8, 4)	**250**	100.0%(8/8, 4)	100.0%(8/8, 4)
	220	100.0%(8/8, 4)	100.0%(8/8, 4)	**220**	100.0%(8/8, 4)	87.5%(7/8, 4)	**220**	100.0%(8/8, 4)	100.0%(8/8, 4)
	180	92.3%(12/13, 5)	92.3%(12/13, 5)	**180**	92.3%(12/13, 5)	84.6%(11/13, 5)	**180**	100.0%(13/13, 5)	92.3%(12/13, 5)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Missed Detection Rates

The Missed Detection Rate is the rate that the device did not alert when it should have (within +/- 15 or 30 minutes for the threshold alerts, and within 15 or 30 minutes following predictive alerts). 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.

Table 47. Glucose Missed Detection Alert Performance, Calibrating every 12 hours, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose Missed Detection Rate: Low Glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	N/A	N/A	**55**	N/A	N/A	**55**	N/A	N/A
	60	N/A	N/A	**60**	N/A	N/A	**60**	N/A	N/A
	70	N/A	N/A	**70**	N/A	N/A	**70**	N/A	N/A
	80	0.0%(0/1, 1)	0.0%(0/1, 1)	**80**	0.0%(0/1, 1)	100.0%(1/1, 1)	**80**	0.0%(0/1, 1)	0.0%(0/1, 1)
	90	33.3%(1/3, 3)	33.3%(1/3, 3)	**90**	0.0%(0/3, 3)	33.3%(1/3, 3)	**90**	0.0%(0/3, 3)	0.0%(0/3, 3)
Glucose Missed Detection Rate: High Glucose Alerts	**300**	0.0%(0/4, 2)	0.0%(0/4, 2)	**300**	0.0%(0/4, 2)	25.0%(1/4, 2)	**300**	0.0%(0/4, 2)	0.0%(0/4, 2)
	250	0.0%(0/8, 4)	0.0%(0/8, 4)	**250**	0.0%(0/8, 4)	12.5%(1/8, 4)	**250**	0.0%(0/8, 4)	0.0%(0/8, 4)
	220	0.0%(0/8, 4)	0.0%(0/8, 4)	**220**	0.0%(0/8, 4)	12.5%(1/8, 4)	**220**	0.0%(0/8, 4)	0.0%(0/8, 4)
	180	15.4%(2/13, 5)	15.4%(2/13, 5)	**180**	7.7%(1/13, 5)	15.4%(2/13, 5)	**180**	7.7%(1/13, 5)	15.4%(2/13, 5)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Table 48. Glucose Missed Detection Alert Performance, Calibrating three to four times per day, Abdominal Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose Missed Detection Rate: Low Glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	N/A	N/A	**55**	N/A	N/A	**55**	N/A	N/A
	60	N/A	N/A	**60**	N/A	N/A	**60**	N/A	N/A
	70	N/A	N/A	**70**	N/A	N/A	**70**	N/A	N/A
	80	0.0%(0/1, 1)	0.0%(0/1, 1)	**80**	0.0%(0/1, 1)	100.0%(1/1, 1)	**80**	0.0%(0/1, 1)	0.0%(0/1, 1)
	90	33.3%(1/3, 3)	33.3%(1/3, 3)	**90**	0.0%(0/3, 3)	33.3%(1/3, 3)	**90**	0.0%(0/3, 3)	0.0%(0/3, 3)
Glucose Missed Detection Rate: High Glucose Alerts	**300**	25.0%(1/4, 2)	25.0%(1/4, 2)	**300**	0.0%(0/4, 2)	25.0%(1/4, 2)	**300**	0.0%(0/4, 2)	25.0%(1/4, 2)
	250	0.0%(0/8, 4)	0.0%(0/8, 4)	**250**	0.0%(0/8, 4)	12.5%(1/8, 4)	**250**	0.0%(0/8, 4)	0.0%(0/8, 4)
	220	0.0%(0/8, 4)	0.0%(0/8, 4)	**220**	0.0%(0/8, 4)	12.5%(1/8, 4)	**220**	0.0%(0/8, 4)	0.0%(0/8, 4)
	180	7.7%(1/13, 5)	7.7%(1/13, 5)	**180**	7.7%(1/13, 5)	15.4%(2/13, 5)	**180**	0.0%(0/13, 5)	7.7%(1/13, 5)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

3. Abdomen Sensor Life

After the first successful calibration, 50.0% 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 142.1 hours, with a median functional life of 163.2 hours.

4. Buttock Insertion Site

Tables 49 and 50 below provide the Guardian sensor values and the percent difference with respect to comparator method (CM) values when the sensor worn in the buttocks was calibrated every 12 hours and three to four times per day, respectively.

Tables 51 and 52 below provide the Guardian sensor values and the percent difference with respect to CGM values when the sensor worn in the buttocks was calibrated every 12 hours and three to four times per day, respectively.

Table 49. CGM Difference to CM within CM Glucose Ranges, Calibrating Every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

CM Glucose Ranges (mg/dL)	Number of Subjects	Number of Paired CGM-CM Pairs	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	14	195	10.1	7.62
40-60*	2	2	21.5	21.5
61-80*	4	12	14.76	13.58
81-180	14	99	10.72	8.82
181-300	14	73	7.09	5.21
301-350	5	8	6.63	6.24
351-400	1	1	7.71	7.71

**For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%). Note: Sensor glucose readings are within 40-400 mg/dL.*

Table 50. CGM Difference to CM within CM Glucose Ranges, Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

CM Glucose Ranges (mg/dL)	Number of Subjects	Number of Paired CGM-CM Pairs	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	12	159	10.05	7.14
40-60*	2	2	23	23
61-80*	4	12	11.51	13
81-180	11	78	11.54	8.62
181-300	12	60	6.03	4.06
301-350	5	7	7.5	7.3

**For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%). Note: Sensor glucose readings are within 40-400 mg/dL.*

Table 51. CGM Difference to CM within CGM Glucose Ranges, Calibrating Every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

CGM Glucose Ranges (mg/dL)	Number of Subjects	Number of Paired CGM-CM Pairs	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	14	195	9.71	7.38
40-60*	1	4	12.5	14.5
61-80*	2	4	6.24	5.33
81-180	13	103	10.57	8.6
181-300	13	78	8.08	5.5
301-350	3	4	4.86	3.97
351-400	1	2	9.71	9.71

**For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%). Note: Sensor glucose*

readings are within 40-400 mg/dL.

Table 52. CGM Difference to CM within CGM Glucose Ranges, Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

CGM Glucose Ranges (mg/dL)	Number of Subjects	Number of Paired CGM-CM Pairs	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)
Overall	12	159	9.4	7.17
40-60*	1	4	11.75	13
61-80*	4	6	7.66	7.95
81-180	10	75	10.33	7.8
181-300	12	70	7.64	5.31
301-350	2	3	5.57	5.19
351-400	1	1	12.26	12.26

**For glucose ranges ≤ 80 mg/dL, the differences in mg/dL are included instead of percent difference (%). Note: Sensor glucose readings are within 40-400 mg/dL.*

Tables 53 and54 below provide the Guardian sensor values and the percent of data points that fell within 15, 20, 30, 40, and >40 mg/dL or percent of a specific CM glucose range when the sensor worn in the buttocks was calibrated every 12 hours after: Days 1, 3, and 7 (Table 53); Day 1 only (Table 54), respectively.

Tables 55 and 56 below provide the Guardian sensor values and the percent of data points that fell within 15, 20, 30, 40, and >40 mg/dL or percent of a specific CM glucose range when the sensor worn in the buttocks was calibrated three to four times per day, after: Days 1, 3, and 7 (Table 55); Day 1 only (Table 56), respectively.

Table 53. Agreement (%) of Sensor-CM Paired Points (15/15%- greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CM Glucose Ranges (mg/dL)	**Number of Subjects**	**Number of CGM- CM Pairs**	**Percent of CGM Within XX mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (*where XX signifies the values in header below*)**				
			15/15%	**20/20%**	**30/30%**	**40/40%**	**>40/40%**
Overall	14	195	81.5	88.7	97.4	98.5	1.5
≥40-60*	2	2	50	50	50	100	0
>60-80*	4	12	75	83.3	91.7	91.7	8.3
>80-180	14	99	78.8	85.9	97	98	2
>180-300	14	73	84.9	93.2	100	100	0
>300-350	5	8	100	100	100	100	0
>350-400	1	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 54. Agreement (%) of Sensor-CM Paired Points (15/15%- greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, ***Day 1***

CM Glucose Ranges (mg/dL)	**Number of Subjects**	**Number of CGM- CM Pairs**	**Percent of CGM Within XX mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (*where XX signifies the values in header below*)**				
			15/15%	**20/20%**	**30/30%**	**40/40%**	**>40/40%**
Overall	6	93	71	83.9	96.8	97.8	2.2
≥40-60*	1	1	100	100	100	100	0
>60-80*	3	10	70	80	90	90	10
>80-180	6	46	63	78.3	95.7	97.8	2.2
>180-300	6	31	77.4	90.3	100	100	0
>300-350	3	4	100	100	100	100	0
>350-400	1	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 55. Agreement (%) of Sensor-CM Paired Points (15/15%-greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CM Glucose Ranges (mg/dL)	Number of Subjects	Number of CGM- CM Pairs	Percent of CGM Within XX mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (where XX signifies the values in header below)				
			15/15%	20/20%	30/30%	40/40%	>40/40%
Overall	12	159	84.3	88.7	96.2	97.5	2.5
≥40-60*	2	2	50	50	50	50	50
>60-80*	4	12	75	91.7	100	100	0
>80-180	11	78	78.2	83.3	93.6	96.2	3.8
>180-300	12	60	93.3	95	100	100	0
>300-350	5	7	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 56. Agreement (%) of Sensor-CM Paired Points (15/15%-greater than 40/40%) Stratified by Different CM Glucose Ranges, Calibrated three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, ***Day 1***

CM Glucose Ranges (mg/dL)	**Number of Subjects**	**Number of CGM- CM Pairs**	**Percent of CGM Within XX mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (*where XX signifies the values in header below*)**				
			15/15%	**20/20%**	**30/30%**	**40/40%**	**>40/40%**
Overall	5	70	74.3	81.4	94.3	97.1	2.9
≥40-60*	1	1	100	100	100	100	0
>60-80*	3	10	80	90	100	100	0
>80-180	4	37	59.5	70.3	89.2	94.6	5.4
>180-300	5	19	94.7	94.7	100	100	0
>300-350	3	3	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*

Tables 57 to 60 show the percentage of concurring CGM readings compared to CM values for sensors worn in the buttocks. With ideal performance, the CGM readings would match the CM values. For example, with perfect concurrence, the shaded boxes in the tables below would be 100 percent.

Tables 57 and 58 show the concurrence of the CGM values compared to CM values when calibrating every 12 hours, after Days 1, 3, and 7 and Day 1 only, respectively.

Table 59 and 60 show the concurrence of the CGM values compared to CM values when calibrating three to four times per day, after Days 1, 3, and 7 and Day 1 only, respectively.

Table 57. Concurrence of CM values and CGM readings using CM glucose ranges; Calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CM Glucose Ranges (mg/dL)	**Percent of Matched Pairs-in Each CGM Glucose Range for Each CM Glucose Range**												
	CGM (mg/dL)												
	Number of Subjects	**Number of Paired CGM-CM**	**<40**	**≥40-60**	**>60-80**	**>80-120**	**>120-160**	**>160-200**	**>200-250**	**>250-300**	**>300-350**	**>350-400**	**>400**
B) ≥ 40-60	2	2	0.0% (0/0)	50.0% (1/2)	0.0% (0/0)	50.0% (1/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	4	12	0.0% (0/0)	25.0% (3/12)	33.3% (4/12)	41.7% (5/12)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	11	31	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	87.1% (27/31)	12.9% (4/31)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	13	45	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	17.8% (8/45)	60.0% (27/45)	22.2% (10/45)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	13	41	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	17.1% (7/41)	65.9% (27/41)	17.1% (7/41)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	12	31	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	16.1% (5/31)	77.4% (24/31)	6.5% (2/31)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	9	24	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.2% (1/24)	16.7% (4/24)	70.8% (17/24)	8.3% (2/24)	0.0% (0/0)	0.0% (0/0)
I) >300-350	5	8	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	62.5% (5/8)	25.0% (2/8)	12.5% (1/8)	0.0% (0/0)
J) >350-400	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)

*Table 58. Concurrence of CM values and CGM readings using CM glucose ranges; Calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, **Day 1***

CM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CGM Glucose Range for Each CM Glucose Range												
	CGM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM*	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	1	1	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	3	10	0.0% (0/0)	30.0% (3/10)	40.0% (4/10)	30.0% (3/10)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	5	14	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	78.6% (11/14)	21.4% (3/14)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	6	21	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	14.3% (3/21)	47.6% (10/21)	38.1% (8/21)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	6	19	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	31.6% (6/19)	47.4% (9/19)	21.1% (4/19)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	6	11	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.2% (2/11)	72.7% (8/11)	9.1% (1/11)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	4	12	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	8.3% (1/12)	16.7% (2/12)	58.3% (7/12)	16.7% (2/12)	0.0% (0/0)	0.0% (0/0)
I) >300-350	3	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (2/4)	25.0% (1/4)	25.0% (1/4)	0.0% (0/0)
J) >350-400	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)

Table 59. Concurrence of CM values and CGM readings using CM glucose ranges; Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CGM Glucose Range for Each CM Glucose Range												
	CGM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	2	2	0.0% (0/0)	50.0% (1/2)	0.0% (0/0)	50.0% (1/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	4	12	0.0% (0/0)	25.0% (3/12)	33.3% (4/12)	41.7% (5/12)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	9	23	0.0% (0/0)	0.0% (0/0)	8.7% (2/23)	73.9% (17/23)	13.0% (3/23)	4.3% (1/23)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	10	36	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (4/36)	61.1% (22/36)	27.8% (10/36)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	10	33	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	6.1% (2/33)	72.7% (24/33)	18.2% (6/33)	3.0% (1/33)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	10	27	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	18.5% (5/27)	70.4% (19/27)	11.1% (3/27)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	8	19	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.5% (2/19)	78.9% (15/19)	10.5% (2/19)	0.0% (0/0)	0.0% (0/0)
I) >300-350	5	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	71.4% (5/7)	14.3% (1/7)	14.3% (1/7)	0.0% (0/0)

Table 60. Concurrence of CM values and CGM readings using CM glucose ranges; Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, ***Day 1***

CM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CGM Glucose Range for Each CM Glucose Range												
	CGM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM*	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	1	1	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	3	10	0.0% (0/0)	30.0% (3/10)	40.0% (4/10)	30.0% (3/10)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	4	13	0.0% (0/0)	0.0% (0/0)	7.7% (1/13)	69.2% (9/13)	15.4% (2/13)	7.7% (1/13)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	4	16	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	6.3% (1/16)	50.0% (8/16)	43.8% (7/16)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	4	13	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	69.2% (9/13)	23.1% (3/13)	7.7% (1/13)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	4	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	14.3% (1/7)	71.4% (5/7)	14.3% (1/7)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	3	7	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	71.4% (5/7)	28.6% (2/7)	0.0% (0/0)	0.0% (0/0)
I) >300-350	3	3	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	66.7% (2/3)	0.0% (0/0)	33.3% (1/3)	0.0% (0/0)

Tables 61 through 64 show the percentage of concurring CM readings compared to CGM values for sensors worn in the buttocks. With ideal performance the CGM readings would match the CM values. For example, with perfect concurrence, the shaded boxes would be 100 percent.

Tables 61 and 62 show the concurrence of the CM values compared to CGM values when calibrating every 12 hours, after Days 1, 3, and 7.

Tables 63 and 64 show the concurrence of the CM values compared to CGM values when calibrating three to four times per day, after Days 1, 3, and 7.

Table 61. Concurrence of CGM readings and CM values using CGM glucose ranges; Calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CGM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range												
	CM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	1	4	0.0% (0/0)	25.0% (1/4)	75.0% (3/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	2	4	0.0% (0/0)	0.0% (0/0)	100.0% (4/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	11	41	0.0% (0/0)	2.4% (1/41)	12.2% (5/41)	65.9% (27/41)	19.5% (8/41)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	12	38	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.5% (4/38)	71.1% (27/38)	18.4% (7/38)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	13	43	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	23.3% (10/43)	62.8% (27/43)	11.6% (5/43)	2.3% (1/43)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	12	35	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (7/35)	68.6% (24/35)	11.4% (4/35)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	9	24	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	8.3% (2/24)	70.8% (17/24)	20.8% (5/24)	0.0% (0/0)	0.0% (0/0)
I) >300-350	3	4	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (2/4)	50.0% (2/4)	0.0% (0/0)	0.0% (0/0)
J) >350-400	1	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (1/2)	50.0% (1/2)	0.0% (0/0)

Table 62. Concurrence of CGM readings and CM values using CGM glucose ranges; Calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, ***Day 1***

CGM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range												
	CM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	1	4	0.0% (0/0)	25.0% (1/4)	75.0% (3/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	2	4	0.0% (0/0)	0.0% (0/0)	100.0% (4/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	5	17	0.0% (0/0)	0.0% (0/0)	17.6% (3/17)	64.7% (11/17)	17.6% (3/17)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	5	19	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	15.8% (3/19)	52.6% (10/19)	31.6% (6/19)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	6	20	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	40.0% (8/20)	45.0% (9/20)	10.0% (2/20)	5.0% (1/20)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	6	14	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	28.6% (4/14)	57.1% (8/14)	14.3% (2/14)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	4	10	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	10.0% (1/10)	70.0% (7/10)	20.0% (2/10)	0.0% (0/0)	0.0% (0/0)
I) >300-350	2	3	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	66.7% (2/3)	33.3% (1/3)	0.0% (0/0)	0.0% (0/0)
J) >350-400	1	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	50.0% (1/2)	50.0% (1/2)	0.0% (0/0)

Table 63. Concurrence of CGM readings and CM values using CGM glucose ranges; Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, ***Days 1, 3, and 7 combined***

CGM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range												
	CM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	1	4	0.0% (0/0)	25.0% (1/4)	75.0% (3/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	4	6	0.0% (0/0)	0.0% (0/0)	66.7% (4/6)	33.3% (2/6)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	9	27	0.0% (0/0)	3.7% (1/27)	18.5% (5/27)	63.0% (17/27)	14.8% (4/27)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	9	27	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (3/27)	81.5% (22/27)	7.4% (2/27)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	10	40	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	2.5% (1/40)	25.0% (10/40)	60.0% (24/40)	12.5% (5/40)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	10	27	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	22.2% (6/27)	70.4% (19/27)	7.4% (2/27)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	10	24	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	4.2% (1/24)	12.5% (3/24)	62.5% (15/24)	20.8% (5/24)	0.0% (0/0)	0.0% (0/0)
I) >300-350	2	3	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	66.7% (2/3)	33.3% (1/3)	0.0% (0/0)	0.0% (0/0)
J) >350-400	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)

*Table 64. Concurrence of CGM readings and CM values using CGM glucose ranges; Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age, **Day 1***

CGM Glucose Ranges (mg/dL)	Percent of Matched Pairs-in Each CM Glucose Range for Each CGM Glucose Range												
	CM (mg/dL)												
	Number of Subjects	Number of Paired CGM-CM	<40	≥40-60	>60-80	>80-120	>120-160	>160-200	>200-250	>250-300	>300-350	>350-400	>400
B) ≥40-60	1	4	0.0% (0/0)	25.0% (1/4)	75.0% (3/4)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
C) >60-80	3	5	0.0% (0/0)	0.0% (0/0)	80.0% (4/5)	20.0% (1/5)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
D) >80-120	4	13	0.0% (0/0)	0.0% (0/0)	23.1% (3/13)	69.2% (9/13)	7.7% (1/13)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
E) >120-160	3	10	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	20.0% (2/10)	80.0% (8/10)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
F) >160-200	4	18	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	5.6% (1/18)	38.9% (7/18)	50.0% (9/18)	5.6% (1/18)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
G) >200-250	4	8	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	37.5% (3/8)	62.5% (5/8)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
H) >250-300	5	9	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	11.1% (1/9)	11.1% (1/9)	55.6% (5/9)	22.2% (2/9)	0.0% (0/0)	0.0% (0/0)
I) >300-350	1	2	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (2/2)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)
J) >350-400	1	1	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	0.0% (0/0)	100.0% (1/1)	0.0% (0/0)	0.0% (0/0)

Tables 65 and 66 show sensor stability in the buttocks by comparing the CM values collected during frequent sample testing days 1, 3, and 7 to their paired sensor points. The tables stratify the paired CM-sensor data by 15/15, 20/20, 30/30, 40/40 and >40/40 mg/dL and percent, respectively.

Table 65. Sensor Stability (accuracy over time) for Calibration every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

Day of Wear	Number of Subjects	Number of Paired System CM	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)	Percent Within XX /mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (*where XX signifies the values in header below*)				
					15/15%	20/20%	30/30%	40/40%	>40/40%
1	6	93	12.8	10.5	71.0	83.9	96.8	97.8	2.2
3	5	67	7.6	5.4	94.0	95.5	98.5	100.0	0.0
7	3	35	7.6	5.3	85.7	88.6	97.1	97.1	2.9

Table 66. Sensor Stability (accuracy over time) for Calibration three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

Day of Wear	Number of Subjects	Number of Paired System CM	Mean Absolute Percent Difference (%)	Median Absolute Percent Difference (%)	Percent Within XX /mg/dL/XX Percent of CM Glucose Ranges (mg/dL) (*where XX signifies the values in header below*)				
					15/15%	20/20%	30/30%	40/40%	>40/40%
1	5	70	12.8	10.3	74.3	81.4	94.3	97.1	2.9
3	4	54	7.6	5.2	94.4	98.1	98.1	98.1	1.9
7	3	35	8.2	5.3	88.6	88.6	97.1	97.1	2.9

Tables 67 and 68 below provide the percent agreement of Guardian Sensor (3) and the comparator method (CM) within a specific time range after calibration.

Table 67. Agreement Rates for Every 2-hour Period Post Calibration, Calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

Time After Calibration	Number of Subjects	Number of Paired CM-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	14	64	85.9	92.2	98.4	100	0
2–4 hours	13	60	78.3	86.7	95	96.7	3.3
4–6 hours	12	52	75	84.6	98.1	98.1	1.9
6–8 hours	8	11	90.9	90.9	100	100	0
8–10 hours	1	4	100	100	100	100	0
10–12 hours	1	4	100	100	100	100	0

Table 68. Agreement Rates for Every 2hour Period Post Calibration, Calibration three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

Time After Calibration	Number of Subjects	Number of Paired CM-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	12	84	86.9	90.5	97.6	98.8	1.2
2–4 hours	11	46	87	91.3	93.5	93.5	6.5
4–6 hours	6	22	63.6	72.7	95.5	100	0
6–8 hours	2	5	100	100	100	100	0
8–10 hours	1	2	100	100	100	100	0

Tables 69 and 70 below provide data to representing sensor accuracy in the buttocks over specific glucose rates of change. The concurrence tables below provide the percent of matched CM pairs to CGM values over specific glucose rates of change for sensors worn in the buttocks calibrated every 12 hours and three to four times per day, respectively.

Table 69. Calibration every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

CGM Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each CM Rate Range for Each CGM Rate Range							
	CM (mg/dL/min)							
	Number of Subjects	Number of Paired CGM-CM	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2
<-2	1	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)	3	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)	4	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]	5	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]	4	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	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 70. Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

CGM Rate Ranges (mg/dL/min)	Percent of Matched Pairs-in Each CM Rate Range for Each CGM Rate Range							
	CM (mg/dL/min)							
	Number of Subjects	Number of Paired CGM-CM	<-2	[-2, -1)	[-1, 0)	[0, 1]	(1, 2]	>2
<-2	1	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)	3	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)	5	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]	4	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]	4	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	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)

Tables 71 and 72 below provide the number and percentage of CM measurements collected while the continuous glucose monitor read 'low' (< 40 mg/dL), or 'high' (> 400 mg/dL) for sensors worn in the buttocks calibrated every 12 hours.

Tables 73 and 74 below provide the number and percentage of CM measurements collected while the continuous glucose monitor read 'low' (< 40 mg/dL), or 'high' (> 400 mg/dL) for sensors worn in the buttocks calibrated three to four times per day.

Table 71. The Number and Percentage of CM values collected when CGM readings displayed 'Low' (less than 40 mg/dL); calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

CGM Readings	CGM-CM pairs	<55	<60	<70	<80	>80	Total
'LOW'	Cumulative, n	0	0	0	0	0	0
	Cumulative %	0%	0%	0%	0%	0%	

Table 72. The Number and Percentage of CM values collected when CGM readings displayed 'High' (more than 400 mg/dL); calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

CGM Readings	CGM-CM pairs	>340	>320	>280	>240	<240	Total
'HIGH'	Cumulative, n	0	0	0	0	0	0
	Cumulative %	0%	0%	0%	0%	0%	

Table 73. The Number and Percentage of CM values collected when CGM readings displayed 'Low' (less than 40 mg/dL); calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

CGM Readings	CGM-CM pairs	<55	<60	<70	<80	>80	Total
'LOW'	Cumulative, n	0	0	0	0	0	0
	Cumulative %	0%	0%	0%	0%	0%	

Table 74. The Number and Percentage of CM values collected when CGM readings displayed 'High' (more than 400 mg/dL); calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

CGM Readings	CGM-CM pairs	>340	>320	>280	>240	<240	Total
'HIGH'	Cumulative, n	0	0	0	0	0	0
	Cumulative %	0%	0%	0%	0%	0%	

5. Pump Alert Performance using the Buttock Sensor Insertion Site

Alert performance was evaluated to obtain 'true alert' and 'false alert' rates, and 'correctly detected' and 'missed alert' rates. The descriptions and tables below describe the alert rate performance of the device within this clinical study:

True alert rates

The true alert rate is the rate at which the blood glucose value confirmed that the continuous glucose monitor alert was triggered correctly. For example:

- True Threshold Hypoglycemic alert rate alerted when the continuous glucose monitor read that the user was below the low threshold and the user's blood glucose was actually below that low threshold (within +/- 15 or 30 minutes of the alert)
- True Threshold Hyperglycemic alert rate alerted when the continuous glucose monitor read that the user was above the high threshold and the user's blood glucose was actually above that high threshold (within +/- 15 or 30 minutes of the alert)
- True Predictive Hypoglycemic alert rate alerted when the continuous glucose monitor 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 following the alert
- True Predictive Hyperglycemic alert rate alerted when the continuous glucose monitor 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 minutes following the alert.

Table 75. Glucose TRUE Alert Performance, Calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose True Alert Rate: Low glucose Alerts	**50**	0.0%(0/1, 1)	0.0%(0/1, 1)	**50**	0.0%(0/1, 1)	0.0%(0/1, 1)	**50**	0.0%(0/2, 1)	0.0%(0/2, 1)
	55	100.0%(1/1, 1)	100.0%(1/1, 1)	**55**	33.3%(1/3, 3)	33.3%(1/3, 3)	**55**	50.0%(2/4, 3)	50.0%(2/4, 3)
	60	100.0%(1/1, 1)	100.0%(1/1, 1)	**60**	25.0%(1/4, 4)	25.0%(1/4, 4)	**60**	40.0%(2/5, 4)	40.0%(2/5, 4)
	70	100.0%(2/2, 2)	100.0%(2/2, 2)	**70**	40.0%(2/5, 4)	40.0%(2/5, 4)	**70**	57.1%(4/7, 4)	57.1%(4/7, 4)
	80	40.0%(2/5, 3)	40.0%(2/5, 3)	**80**	33.3%(3/9, 6)	22.2%(2/9, 6)	**80**	35.7%(5/14, 6)	28.6%(4/14, 6)
	90	100.0%(8/8, 6)	100.0%(8/8, 6)	**90**	81.8%(9/11, 8)	63.6%(7/11, 8)	**90**	88.9%(16/18, 8)	77.8%(14/18, 8)
Glucose True Alert Rate: High glucose Alerts	**300**	66.7%(4/6, 5)	66.7%(4/6, 5)	**300**	35.0%(7/20, 12)	30.0%(6/20, 12)	**300**	42.3% (11/26, 12)	38.5% (10/26, 12)
	250	80.0%(12/15, 9)	73.3%(11/15, 9)	**250**	65.2% (15/23, 13)	56.5% (13/23, 13)	**250**	70.3% (26/37, 13)	62.2% (23/37, 13)
	220	90.0% (18/20, 12)	85.0% (17/20, 12)	**220**	62.1% (18/29, 14)	55.2% (16/29, 14)	**220**	70.5% (31/44, 14)	63.6% (28/44, 14)
	180	89.7%(26/29, 14)	89.7%(26/29, 14)	**180**	84.8%(28/33, 14)	81.8%(27/33, 14)	**180**	85.7% (48/56, 14)	83.9% (47/56, 14)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Table76. Glucose TRUE Alert Performance, Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose True Alert Rate: Low glucose Alerts	**50**	0.0%(0/1, 1)	0.0%(0/1, 1)	**50**	0.0%(0/1, 1)	0.0%(0/1, 1)	**50**	0.0%(0/2, 1)	0.0%(0/2, 1)
	55	100.0%(1/1, 1)	100.0%(1/1, 1)	**55**	50.0%(1/2, 2)	50.0%(1/2, 2)	**55**	66.7%(2/3, 2)	66.7%(2/3, 2)
	60	100.0%(1/1, 1)	100.0%(1/1, 1)	**60**	33.3%(1/3, 3)	33.3%(1/3, 3)	**60**	50.0%(2/4, 3)	50.0%(2/4, 3)
	70	100.0%(2/2, 2)	100.0%(2/2, 2)	**70**	33.3%(2/6, 5)	33.3%(2/6, 5)	**70**	50.0%(4/8, 5)	50.0%(4/8, 5)
	80	80.0%(4/5, 4)	80.0%(4/5, 4)	**80**	50.0%(4/8, 6)	37.5%(3/8, 6)	**80**	61.5% (8/13, 6)	53.8%(7/13, 6)
	90	100.0%(8/8, 6)	87.5%(7/8, 6)	**90**	90.0% (9/10, 7)	60.0%(6/10, 7)	**90**	94.1% (16/17, 7)	70.6% (12/17, 7)
Glucose True Alert Rate: High glucose Alerts	**300**	80.0%(4/5, 4)	80.0%(4/5, 4)	**300**	35.0% (7/20, 12)	30.0% (6/20, 12)	**300**	44.0% (11/25, 12)	40.0% (10/25, 12)
	250	84.6%(11/13, 10)	76.9%(10/13, 10)	**250**	60.0% (12/20, 12)	60.0% (12/20, 12)	**250**	68.8% (22/32, 12)	65.6% (21/32, 12)
	220	88.9%(16/18, 11)	83.3%(15/18, 11)	**220**	60.0% (15/25, 12)	56.0% (14/25, 12)	**220**	68.4% (26/38, 12)	63.2% (24/38, 12)
	180	91.7%(22/24, 12)	91.7%(22/24, 12)	**180**	84.6% (22/26, 12)	80.8% (21/26, 12)	**180**	86.7% (39/45, 12)	84.4% (38/45, 12)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

False Alert Rates

The glucose false alert rate is the rate at which the blood glucose value did not confirm that the continuous glucose monitor alert was triggered correctly. For example:

- False Threshold Hypoglycemic alert rate the alarm alerted when the continuous glucose monitor read that the user was below the low threshold but the users blood glucose was actually above that low threshold (within +/- 15 or 30 minutes of the alert)
- False Threshold Hyperglycemic alert rate the alarm alerted when the continuous glucose monitor read that the user was above the high threshold but the user's blood glucose was actually below that high threshold (within +/- 15 or 30 minutes of the alert)
- False Predictive Hypoglycemic alert rate the alarm alerted when the continuous glucose monitor 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 following the alert.

- False Predictive Hyperglycemic alert rate the alarm alerted when the continuous glucose monitor 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 following the alert.

Table 77. Glucose FALSE Alert Performance, Calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose False Alert Rate: Low Glucose Alerts	**50**	100.0%(1/1, 1)	100.0%(1/1, 1)	**50**	100.0%(1/1, 1)	100.0% (1/1, 1)	**50**	100.0%(2/2, 1)	100.0%(2/2, 1)
	55	0.0%(0/1, 1)	0.0%(0/1, 1)	**55**	66.7%(2/3, 3)	66.7%(2/3, 3)	**55**	50.0%(2/4, 3)	50.0%(2/4, 3)
	60	0.0%(0/1, 1)	0.0%(0/1, 1)	**60**	75.0%(3/4, 4)	75.0%(3/4, 4)	**60**	60.0%(3/5, 4)	60.0%(3/5, 4)
	70	0.0%(0/2, 2)	0.0%(0/2, 2)	**70**	60.0%(3/5, 4)	60.0%(3/5, 4)	**70**	42.9%(3/7, 4)	42.9%(3/7, 4)
	80	60.0%(3/5, 3)	60.0%(3/5, 3)	**80**	66.7%(6/9, 6)	77.8%(7/9, 6)	**80**	64.3%(9/14, 6)	71.4% (10/14, 6)
	90	0.0%(0/8, 6)	0.0%(0/8, 6)	**90**	18.2%(2/11, 8)	36.4% (4/11, 8)	**90**	11.1%(2/18, 8)	22.2%(4/18, 8)
Glucose False Alert Rate: High Glucose Alerts	**300**	33.3%(2/6, 5)	33.3%(2/6, 5)	**300**	65.0% (13/20, 12)	70.0% (14/20, 12)	**300**	57.7% (15/26, 12)	61.5% (16/26, 12)
	250	20.0%(3/15, 9)	26.7%(4/15, 9)	**250**	34.8%(8/23, 13)	43.5% (10/23, 13)	**250**	29.7% (11/37, 13)	37.8% (14/37, 13)
	220	10.0%(2/20, 12)	15.0%(3/20, 12)	**220**	37.9% (11/29, 14)	44.8% (13/29, 14)	**220**	29.5% (13/44, 14)	36.4% (16/44, 14)
	180	10.3%(3/29, 14)	10.3%(3/29, 14)	**180**	15.2%(5/33, 14)	18.2% (6/33, 14)	**180**	14.3%(8/56, 14)	16.1% (9/56, 14)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Table 78. Glucose FALSE Alert Performance, Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose False Alert Rate: Low Glucose Alerts	**50**	100.0%(1/1, 1)	100.0%(1/1, 1)	**50**	100.0%(1/1, 1)	100.0% (1/1, 1)	**50**	100.0%(2/2, 1)	100.0%(2/2, 1)
	55	0.0%(0/1, 1)	0.0%(0/1, 1)	**55**	50.0%(1/2, 2)	50.0%(1/2, 2)	**55**	33.3%(1/3, 2)	33.3%(1/3, 2)
	60	0.0%(0/1, 1)	0.0%(0/1, 1)	**60**	66.7%(2/3, 3)	66.7%(2/3, 3)	**60**	50.0%(2/4, 3)	50.0%(2/4, 3)
	70	0.0%(0/2, 2)	0.0%(0/2, 2)	**70**	66.7%(4/6, 5)	66.7%(4/6, 5)	**70**	50.0%(4/8, 5)	50.0%(4/8, 5)
	80	20.0%(1/5, 4)	20.0%(1/5, 4)	**80**	50.0%(4/8, 6)	62.5%(5/8, 6)	**80**	38.5%(5/13, 6)	46.2%(6/13, 6)
	90	0.0%(0/8, 6)	12.5%(1/8, 6)	**90**	10.0%(1/10, 7)	40.0% (4/10, 7)	**90**	5.9%(1/17, 7)	29.4%(5/17, 7)
Glucose False Alert Rate: High Glucose Alerts	**300**	20.0%(1/5, 4)	20.0%(1/5, 4)	**300**	65.0% (13/20, 12)	70.0% (14/20, 12)	**300**	56.0% (14/25, 12)	60.0% (15/25, 12)
	250	15.4%(2/13, 10)	23.1%(3/13, 10)	**250**	40.0% (8/20, 12)	40.0% (8/20, 12)	**250**	31.3% (10/32, 12)	34.4% (11/32, 12)
	220	11.1%(2/18, 11)	16.7%(3/18, 11)	**220**	40.0% (10/25, 12)	44.0% (11/25, 12)	**220**	31.6% (12/38, 12)	36.8% (14/38, 12)
	180	8.3%(2/24, 12)	8.3%(2/24, 12)	**180**	15.4%(4/26, 12)	19.2% (5/26, 12)	**180**	13.3%(6/45, 12)	15.6% (7/45, 12)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Correct Detection Rates

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 (within +/- 15 or 30 minutes for the threshold alerts, and within 15 or 30 minutes following predictive alerts).

Table 79. Glucose Correct Detection Alert Performance, Calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose Correct Detection Rate: Low Glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	50.0%(1/2, 2)	50.0%(1/2, 2)	**55**	50.0%(1/2, 2)	50.0%(1/2, 2)	**55**	50.0%(1/2, 2)	50.0%(1/2, 2)
	60	50.0%(1/2, 2)	50.0%(1/2, 2)	**60**	50.0%(1/2, 2)	50.0%(1/2, 2)	**60**	50.0%(1/2, 2)	50.0%(1/2, 2)
	70	66.7%(2/3, 3)	66.7%(2/3, 3)	**70**	66.7%(2/3, 3)	66.7%(2/3, 3)	**70**	66.7%(2/3, 3)	66.7%(2/3, 3)
	80	40.0%(2/5, 4)	40.0%(2/5, 4)	**80**	60.0%(3/5, 4)	40.0%(2/5, 4)	**80**	60.0%(3/5, 4)	40.0%(2/5, 4)
	90	80.0%(8/10, 7)	80.0%(8/10, 7)	**90**	90.0%(9/10, 7)	60.0% (6/10, 7)	**90**	90.0% (9/10, 7)	80.0%(8/10, 7)
Glucose Correct Detection Rate: High Glucose Alerts	**300**	62.5%(5/8, 5)	62.5%(5/8, 5)	**300**	100.0%(8/8, 5)	87.5%(7/8, 5)	**300**	100.0% (8/8, 5)	100.0%(8/8, 5)
	250	84.0%(21/25, 11)	84.0%(21/25, 11)	**250**	96.0% (24/25, 11)	84.0% (21/25, 11)	**250**	96.0% (24/25, 11)	88.0% (22/25, 11)
	220	91.7%(33/36, 12)	86.1%(31/36, 12)	**220**	97.2% (35/36, 12)	86.1% (31/36, 12)	**220**	100.0% (36/36, 12)	94.4% (34/36, 12)
	180	100.0% (58/58, 14)	98.3%(57/58, 14)	**180**	100.0% (58/58, 14)	91.4% (53/58, 14)	**180**	100.0% (58/58, 14)	100.0% (58/58, 14)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect

actual use performance

Table 80. Glucose Correct Detection Alert Performance, Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose Correct Detection Rate: Low Glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	50.0%(1/2, 2)	50.0%(1/2, 2)	**55**	50.0%(1/2, 2)	50.0%(1/2, 2)	**55**	50.0%(1/2, 2)	50.0%(1/2, 2)
	60	50.0%(1/2, 2)	50.0%(1/2, 2)	**60**	50.0%(1/2, 2)	50.0%(1/2, 2)	**60**	50.0%(1/2, 2)	50.0%(1/2, 2)
	70	66.7%(2/3, 3)	66.7%(2/3, 3)	**70**	66.7%(2/3, 3)	66.7%(2/3, 3)	**70**	66.7%(2/3, 3)	66.7%(2/3, 3)
	80	80.0%(4/5, 4)	80.0%(4/5, 4)	**80**	80.0%(4/5, 4)	60.0%(3/5, 4)	**80**	100.0%(5/5, 4)	80.0%(4/5, 4)
	90	100.0%(7/7, 6)	100.0%(7/7, 6)	**90**	100.0%(7/7, 6)	71.4%(5/7, 6)	**90**	100.0%(7/7, 6)	100.0%(7/7, 6)
Glucose Correct Detection Rate: High Glucose Alerts	**300**	57.1%(4/7, 5)	57.1%(4/7, 5)	**300**	100.0%(7/7, 5)	85.7%(6/7, 5)	**300**	100.0%(7/7, 5)	100.0%(7/7, 5)
	250	95.0%(19/20, 10)	95.0% (19/20, 10)	**250**	100.0% (20/20, 10)	95.0% (19/20, 10)	**250**	100.0% (20/20, 10)	100.0% (20/20, 10)
	220	100.0% (29/29, 11)	93.1% (27/29, 11)	**220**	96.6% (28/29, 11)	89.7% (26/29, 11)	**220**	100.0% (29/29, 11)	96.6% (28/29, 11)
	180	100.0% (46/46, 12)	100.0% (46/46, 12)	**180**	100.0% (46/46, 12)	95.7% (44/46, 12)	**180**	100.0% (46/46, 12)	100.0% (46/46, 12)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Missed Detection Rates

The Missed Detection Rate is the rate that the device did not alert when it should have (within +/- 15 or 30 minutes for the threshold alerts, and within 15 or 30 minutes following predictive alerts). 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.

Table 81. Glucose Missed Detection Alert Performance, Calibrating every 12 hours, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose Missed Detection Rate: Low Glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	50.0%(1/2, 2)	50.0%(1/2, 2)	**55**	50.0%(1/2, 2)	50.0%(1/2, 2)	**55**	50.0%(1/2, 2)	50.0%(1/2, 2)
	60	50.0%(1/2, 2)	50.0%(1/2, 2)	**60**	50.0%(1/2, 2)	50.0%(1/2, 2)	**60**	50.0%(1/2, 2)	50.0%(1/2, 2)
	70	33.3%(1/3, 3)	33.3%(1/3, 3)	**70**	33.3%(1/3, 3)	33.3%(1/3, 3)	**70**	33.3%(1/3, 3)	33.3%(1/3, 3)
	80	60.0%(3/5, 4)	60.0%(3/5, 4)	**80**	40.0%(2/5, 4)	60.0%(3/5, 4)	**80**	40.0%(2/5, 4)	60.0%(3/5, 4)
	90	20.0%(2/10, 7)	20.0%(2/10, 7)	**90**	10.0%(1/10, 7)	40.0% (4/10, 7)	**90**	10.0%(1/10, 7)	20.0%(2/10, 7)
Glucose Missed Detection Rate: High Glucose Alerts	**300**	37.5%(3/8, 5)	37.5%(3/8, 5)	**300**	0.0%(0/8, 5)	12.5%(1/8, 5)	**300**	0.0%(0/8, 5)	0.0% (0/8, 5)
	250	16.0%(4/25, 11)	16.0%(4/25, 11)	**250**	4.0%(1/25, 11)	16.0% (4/25, 11)	**250**	4.0%(1/25, 11)	12.0% (3/25, 11)
	220	8.3%(3/36, 12)	13.9%(5/36, 12)	**220**	2.8%(1/36, 12)	13.9% (5/36, 12)	**220**	0.0%(0/36, 12)	5.6%(2/36, 12)
	180	0.0%(0/58, 14)	1.7%(1/58, 14)	**180**	0.0%(0/58, 14)	8.6% (5/58, 14)	**180**	0.0%(0/58, 14)	0.0%(0/58, 14)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

Table 82. Glucose Missed Detection Alert Performance, Calibrating three to four times per day, Buttock Insertion Site, Data From Subjects 2-6 Years of Age

	Threshold Only			Predictive Only			Threshold & Predictive		
	mg/dL	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**	**mg/dL**	**±30 Min (n/N of Events, # of Subjects)**	**±15 Min (n/N of Events, # of Subjects)**
Glucose Missed Detection Rate: Low Glucose Alerts	**50**	N/A	N/A	**50**	N/A	N/A	**50**	N/A	N/A
	55	50.0%(1/2, 2)	50.0%(1/2, 2)	**55**	50.0%(1/2, 2)	50.0%(1/2, 2)	**55**	50.0%(1/2, 2)	50.0%(1/2, 2)
	60	50.0%(1/2, 2)	50.0%(1/2, 2)	**60**	50.0%(1/2, 2)	50.0%(1/2, 2)	**60**	50.0%(1/2, 2)	50.0%(1/2, 2)
	70	33.3%(1/3, 3)	33.3%(1/3, 3)	**70**	33.3%(1/3, 3)	33.3%(1/3, 3)	**70**	33.3%(1/3, 3)	33.3%(1/3, 3)
	80	20.0%(1/5, 4)	20.0%(1/5, 4)	**80**	20.0%(1/5, 4)	40.0%(2/5, 4)	**80**	0.0%(0/5, 4)	20.0%(1/5, 4)
	90	0.0%(0/7, 6)	0.0%(0/7, 6)	**90**	0.0%(0/7, 6)	28.6%(2/7, 6)	**90**	0.0%(0/7, 6)	0.0%(0/7, 6)
Glucose Missed Detection Rate: High Glucose Alerts	**300**	42.9%(3/7, 5)	42.9%(3/7, 5)	**300**	0.0%(0/7, 5)	14.3%(1/7, 5)	**300**	0.0%(0/7, 5)	0.0%(0/7, 5)
	250	5.0%(1/20, 10)	5.0%(1/20, 10)	**250**	0.0%(0/20, 10)	5.0% (1/20, 10)	**250**	0.0% (0/20, 10)	0.0%(0/20, 10)
	220	0.0%(0/29, 11)	6.9%(2/29, 11)	**220**	3.4%(1/29, 11)	10.3% (3/29, 11)	**220**	0.0% (0/29, 11)	3.4%(1/29, 11)
	180	0.0%(0/46, 12)	0.0%(0/46, 12)	**180**	0.0%(0/46, 12)	4.3% (2/46, 12)	**180**	0.0% (0/46, 12)	0.0%(0/46, 12)

Note: Given the small sample size of data available, the alert performance should be interpreted with caution and may not reflect actual use performance

6. Buttock Sensor Life

After the first successful calibration, 72.2% 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 buttock insertion site over the course of the study was 146.4 hours, with a median functional life of 166.8 hours.

7. Precision Analysis

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 in the abdomen/abdomen insertion locations 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 in the abdomen/buttock insertions location provided 108 pairs of CGM measurements, with a mean 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 in the buttock/buttock insertions location provided 754 pairs of CGM measurements, with a mean PARD during the study of 5.98% and a coefficient of variation (%CV) of 4.2%.

3. Subgroup Analyses

   Guardian Sensor (3) performance and 670G System performance was evaluated within study population subgroups, such as age, gender, ethnicity, body mass index (BMI), baseline HbA1c, prior CGM experience, and exercise activity (during in-clinic portions of the study).

   Although the studies were not powered for analysis of subpopulations, no significant differences in performance were noted based on these subgroup analyses. However, it should be noted that the system was not evaluated in pump-naïve users.

E. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included (hybrid closed loop pediatric study (G150247))

included 9 principal investigators. The sensor performance study (G120262, the Guardian Sensor (3) study) included 11 principal investigators. The following clinical investigators had disclosable financial interests/arrangements as defined in sections 54.2(a), (b), (c), and (f).

G150247

- Dr. Bruce Bode
- Dr. Kevin Kaiserman

G120262

- Dr. Jennifer Sherr
- Dr. Kevin Kaiserman
- Dr. Bruce Bode

The information provided does not raise any questions about the reliability of the data.

XI. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Continued Access Study

Subjects in the HCL pediatric pivotal study were given the opportunity to extend the use of their 670G systems study devices for a period of up to 3 years after the end of the study period or until the device is available commercially (if approved). During the continued access period, subjects were scheduled to come in for office visits every 3 months. At each of the quarterly visits, subjects were asked about the occurrence of adverse events and device complaints. The purpose of the continued access study was to obtain additional safety information regarding the device.

The data provided for the continued access study was collected for 2-6-year-old subjects through December 14, 2018.

Forty-three subjects opted to participate in the continued access phase of the study. As of December 14, 2018, two subjects withdrew from the study because the subjects' legal representative reported device issues or preferences.

There were a total of 99 adverse events reported from September 1, 2017 through December 14, 2018 for the continued access phase. The majority (64) of adverse events during the continued access phase involved severe hyperglycemia.

Of the 99 adverse events reported during the continued access phase, 41 were device-related. Of the 41 device-related adverse events, 34 involved severe hyperglycemia, and 7 were from other device-related events.

There were no episodes of severe hypoglycemia and one serious adverse events reported

during the continued access phase. The serious adverse event was a case of severe hyperglycemia and was considered possibly device-related.

XII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Clinical Chemistry and Clinical Toxicology Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XIII. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

A. Effectiveness Conclusions

Note: The clinical studies which were carried out to support this approval were conducted using the 670G System. These clinical studies support the use of the 770G System as there is no difference in clinical performance, usibility, or overall components compared to the 670G System. The only differences between the 770G and 670G Systems is the communication protocol and the blood glucose meter; the 770G System uses BLE and the Accu-Check Guide Link Blood Glucose Monitoring System. Please see the information in the above sections for more details.

The clinical study was not designed to evaluate clinical effectiveness endpoints (e.g., reduction of hypoglycemia, etc.), and only limited observational information about safety and effectiveness of device function (insulin delivery) were collected.

The results of the clinical studies performed to support this submission establish a reasonable assurance of effectiveness that the MiniMed 770G System can automatically adjust basal insulin rates based on CGM values.

Additionally, a reasonable assurance has been demonstrated tha the system can detect trends and track patterns and temporarily suspend and resume the delivery of insulin when used as intended, as an adjunct to blood glucose testing in subjects with type 1 diabetes mellitus.

The effectiveness of the Guardian Sensor (3) component was based on the performance evaluatation of the Guardian Sensor compared to the blood glucose values measured by the CM during in-clinic sessions spanning the wear period of the sensor (7 days). The performance data presented above (tables 15-82) established the sensor across the claimed measuring range (40-400 mg/dL glucose), the precison, and the calibration frequency (calibrate minimally every 12 hours or 3-4 times a day) of the 7 day wear period for the Guardian Sensor (3). The performance data presented above also established the performance of the alarms and alerts of the Guardian sensor. It should be noted that although the accuracy study is small, the hybrid closed loop system pediatric pivotal study (G150247) and its continuation phase provides

additional performance information for the sensor specifically in the context of use within the 770G System.

The results of the clinical studies performed to support approval establish a reasonable assurance that the MiniMed 770G system is effective for its intended use.

B. Safety Conclusions

An understanding of the risks of the device are based on nonclinical laboratory data as well as on data collected in the clinical studies conducted to support PMA approval that are described above.

The following events are possible adverse device effects of inserting as sensor into your skin: local infection, inflammation, pain or discomfort, bleeding at the glucose sensor insertion site, bruising, itching, scarring or skin discoloration, hematoma, tape irritation, sensor or needle fracture during insertion, wear or removal.

Potential device related non serious events include:

- Skin irritation or redness
- Infection
- Pain or discomfort
- Bruising
- Edema
- Rash
- Bleeding
- Induration of skin
- Allergic reaction to adhesives
- Hyperglycemia following inadequate or suspension of insulin delivery (which can result from catheter occlusion, hardware or software malfunction, or erroneous CGM readings)
- Ketosis following inadequate or suspension of insulin delivery (which can result from catherter occlusion, hardware or software malfunction, or erroneous CGM readings)
- Hypoglycemia resulting from insulin over-delivery (which can result from catheter occlusion, hardware or software malfunction, or erroneous CGM readings)

A higher incidence of severe hyperglycemia was reported during the pediatric (2-6 year age group) HCL study (and continuation phase to date) compared with the 14 years and above age group. It is possible that the 2-6 year age group could have a higher risk of severe hyperglycemia compared to the 14 years and above population.

Based on the data provided, it is possible that the reported alert performance for the 2-6 year age group could result in an increased risk of hypoglycemia in the 2-6 year age group, compared to the 14 years and above population.

Sensor breakage with fragments retained under the skin is a potential adverse event related to use of the CGM component of the System, but this was not observed during these studies. Based on postmarket experience with similar devices and the results observed in these clinical studies, the occurrence and severity of these events do not raise major concerns.

Infection at the insulin pump infusion set insertion site and sensor insertion site is a potential complication related to insertion of the CGM or the insulin pump infusion set. Based on post-market experience with similar devices, and the results observed in these clinical studies, the occurrence and severity of these events are not expected to be different from other approved infusion sets and CGM devices, and so do not pose an unreasonable risk.

The CGM readings (together with blood glucose meter readings) are used by the System to determine automated insulin delivery, including insulin suspension and insulin dosing, and are the basis for alerts for hypoglycemia and hyperglycemia. The continuous glucose sensor readings are also to be used by the patient for tracking and trending, when in Manual Mode. While in manual mode, the continuous glucose sensor readings are intended to be used adjunctively (i.e., confirmatory blood glucose meter readings should be used for diabetes treatment decisions) for tracking and trending of blood sugars.

The consequences of a false positive (falsely high) glucose reading on the continuous glucose meter would be potential over-delivery of insulin via automated insulin delivery, which has the potential to lead to severe hypoglycemia or even death. The consequences of a false negative (falsely low) glucose reading on the continuous glucose meter would be potential under-delivery of insulin, which has the potential to lead to severe hyperglycemia or DKA.

A confirmatory blood glucose meter reading has the potential to mitigate some of the risk of falsely high or falsely low glucose sensor readings, as the patient could choose to override the settings of the system in some cases (i.e., decline to take additional bolus of insulin as recommended by the System in setting of falsely high continuous glucose reading or exit Auto Mode).

The results of the clincal studies performed and described in section IX and X above to support approval establish a reasonable assurance that the MiniMed 770G system is safe for its intended use.

C. Benefit-Risk Determination

Summary of Benefits

The MiniMed 770G System (previously approved as the MiniMed 670G System in persons with Type 1 Diabetes ages 7 years of age and older) features, in addition to

sensor- augmented insulin pump therapy; an automated insulin delivery (Auto Mode) feature, as well as a predictive low glucose management feature ('Suspend before low').

Compared to the run-in period for the pivotal study, results from the pivotal study period demonstrated the following:

- Suggested a potential for improvement in overall glycemic control based on change in HbA1c values
- Less time and number of events with sensor glucose <70 mg/dL, particularly overnight.
- Less time and number of events with sensor glucose >250 mg/dL
- More time with sensor glucose in the 70-180 range.
- Longer sensor life compared to prior generation approved Medtronic CGMs (should benefit users since less insertions are required, reducing the risks associated with the process (pain, bruising, bleeding)).

The use of the continuous glucose monitor gives patients and healthcare providers glucose tracking and trending information not feasible using traditional blood glucose monitoring as blood glucose meters only provide information about discrete, intermittent blood glucose levels. Patients, caregivers, and healthcare providers can review the tracking and trending data by day and time of day such as daytime, or night time when fewer fingersticks are usually performed. The CGM includes a software package to aid in the evaluation of glucose trends over several days to detect patterns which may indicate a need to adjust therapy such as changes to basal rates and bolus dose instructions.

Further, the continuous glucose monitors provide real time knowledge of interstitial glucose levels that can be displayed on the insulin pump screen. The system can be set to provide notifications based on sensor trends or threshold, adding information not available by traditional discrete monitoring.

Interstitial glucose trending information can be used to provide rate of change alerts that notify the patient that interstitial glucose is increasing or decreasing at a rate that raises concern for hyperglycemia or hypoglycemia. Threshold and Predictive alert settings allow for high alerts, low alerts, and alerts regarding insulin delivery suspension. With the guidance of their healthcare provider the patient can set predictive or threshold high or low alerts to provide notifications that sensor glucose is approaching (the case of the predictive) or has reached (in the case of the threshold) level of concern. These alerts and alarms may be particularly helpful for individuals with hypoglycemia unawareness (these individuals may develop sequelae of severe hypoglycemia without the normal warning symptoms), or during the night when patients may have prolonged hypoglycemia that does not awaken them and could proceed to severe hypoglycemia if not treated in time. Traditional blood glucose testing is not able to automatically alert users to these potentially dangerous episodes of asymptomatic hypoglycemia.

The Predictive Low Glucose Management (PLGM) feature is an optional tool (not available when Auto Mode is activated), which (when activated) is intended to suspend insulin delivery (for up to 2 hours) when the sensor glucose value is predicted to reach a preset value between 50 to 90 mg/dL. The PLGM feature also resumes insulin delivery based on feedback from the CGM system after 2 hours or earlier, based on a pre-set glucose value. The user has the option to choose between suspending on a sensor glucose threshold ('suspend on low') or suspending based on a prediction ('suspend beforelow').

The potential ability to automatically suspend insulin when the user is unaware of and/or unable to treat a low blood sugar with carbohydrate is a desirable feature given the risk of severe hypoglycemia and its potential complications (seizures, unconsciousness and death). The potential ability to automatically resume insulin is also a desired feature as it reduces the risk of hyperglycemia, ketoacidosis and DKA from prolonged insulin suspension. The degree of prevention of hypoglycemia could not be determined in the previously conducted predictive suspend study (G140052) because of the limitations of study design. Nevertheless, if used as intended and not as the primary method for preventing hypoglycemia, the predictive suspend feature is likely to provide more benefit than risk.

The Auto Mode feature is an optional tool to automate insulin delivery within the System. The automated insulin delivery is based on sensor glucose readings. There is no automated insulin-delivery system currently approved for this age group (2-6 years). Auto Mode, when activated, will calculate the insulin dose at five-minute intervals, based on CGM data, in order to achieve a target glucose threshold (120 mg/dL) throughout the day and night. Meal boluses are the responsibility of the user. Blood glucose meter readings will be used for any correction boluses, as well as when the user elects to take a reading prior to their meal bolus (while in Auto Mode).

There are several different options (Modes) within Auto Mode:

1) Temp Target - The user can set a temporary target glucose of 150 mg/dL for a period of time within "Temp Target" mode
2) Safe Basal Mode (or Safe Basal Low Mode) - The Auto Mode algorithm initiates a "safe basal mode" or "safe basal low" when the safeguards within the system algorithm determine that either the sensor data is not adequate for Auto Mode (sensor under- reading or no sensor data), or delivery at the minimum or maximum limit for a set amount of time has elapsed. The Auto Mode algorithm will determine when to deliver safe basal or safe basal low, depending on the patient's sensor glucose value. The various safe basal rates are defined as:
    - Safe basal is the calculated rate of insulin [U/h] that will bring the fasting blood glucose to the value of 120 [mg/dL].
    - Safe Basal Low is the calculated rate of insulin [U/h] that will bring the fasting blood glucose to the value of 200 [mg/ dL].

The ability to automate insulin delivery based on sensor glucose values (Auto Mode feature) is a desirable feature given the risk of severe hypoglycemia and DKA associated with insulin pump therapy, especially when patients are unable to adjust insulin doses or monitor their blood glucose (e.g., when sleeping). In addition, automated insulin delivery has the potential to be convenient to the user.

There is residual uncertainty about the benefits of use of the 770G System. In particular:

- The 770G System was not used in the pivotal clinical study (the 670G System was used). Therefore, although use of the 770G System is not thought to adversely impact safety and/or effectiveness with respect to glycemic indices, there is uncertainty about the degree of potential benefits associated with 770G System

- The pivotal clinical study did not utilize the Roche Accu-Chek Guide™ Link BGM System. Therefore, there is residual uncertainty about if and how safety and/or effectiveness measures are impacted through use of the 770G System.

- The pivotal clinical study design lends itself to some residual uncertainty about the performance (potential benefits) of the 770G System. The pivotal clinical study comprised a 3 month, uncontrolled study, in 45 study participants 2-6 years of age, with Type 1 Diabetes, so considering the relatively small sample size, relatively short study duration, and lack of control group, there remains residual uncertainty about performance of the System. The study results support the safety of the 770G System, but there is some residual uncertainty about the benefits of use, particularly relating to the durability of the reported potential benefits

Summary of Risks

Although the overall risks of use of the 770G System in the 2-6 year population with Type 1 Diabetes are similar to the risks of use of the 670G System in the currently approved population, the clinical consequences to individuals of these risks likely result in increased harm, considering the relative vulnerability of this patient population.

Two specific potential differences in risk (severe hyperglycemia and well as alert performance for alerts at the low sensor glucose values - particularly 50, 55 and 60 mg/dL) were noted based on the HCL Study and sensor accuracy study, respectively:

- There is a general paucity of alert performance data reported for low sensor glucose alerts (particularly in the 50, 55 and 60 mg/dL) in this 2-6 year age group for the Guardian Sensor (3). Although challenging to interpret the reported alert performance (given the general paucity of data for this assessment), the alert performance (particularly at the abdomen insertion site) raises uncertainty with respect to alert performance. Therefore, the sponsor has proposed risk mitigations (already present for the 7-13 year age group), including warnings in the labeling (including in the package insert) with respect to use of the low sensor glucose warnings, and additional postmarket assessment of alert performance seem adequate to inform and mitigate potential risks associated with use and overreliance on these

specific alerts, as well as further confirm the safety of the sensor performance. Given that there were no reports of severe hypoglycemia during the HCL Study, as well as that sensor performance data during the HCL study demonstrated comparable to decreased sensor glucose time (compared to run-in) in the low sensor glucose ranges (< 50 mg/dL, <60 mg/L, and < 70 mg/dL), the reported alert performance does not seem to translate into an increased risk of severe hypoglycemia. Further uncertainty about the reported sensor performance for the low sensor glucose alerts arises from small sample size, relatively small number of datasets from the study, as well as that the relevant datasets constitute a subanalysis of a subgroup of the Sensor Accuracy Study data.

- A higher incidence of severe hyperglycemia was reported during the pediatric (2-6 year age group) HCL study (and continuation phase to date) compared with the 14 years and above age group. It is possible that the 2-6 year age group could have a higher risk of severe hyperglycemia compared to the 14 years and above population. The majority of the severe hyperglycemia episodes reported were related to potential occlusions. Given that there were no events of DKA that were device related during the HCL study, as well as that sensor performance data during the HCL study (compared to run-in) reported decreased sensor glucose time >180 mg/dL, >250 mg/dL, >300 mg/dL, and > 350 mg/dL, the reported higher incidence of severe hyperglycemia reported does not seem to translate into an increased clinical risk of severe hyperglycemia. The sponsor has proposed (already present for the 7-13 year age group) risk mitigations relating to the reported increased incidence of severe hyperglycemia, including labeling mitigations. The postmarket confirmatory study already includes an assessment of severe hyperglycemia and DKA events, and additional considerations relating to severe hyperglycemia and/or occlusion are already incorporated into the existing postmarket confirmatory study.

The general risks for the proposed indication for use of the Auto Mode (hybrid closed loop) feature include the following:

- The insulin pump may inappropriately suspend or decrease insulin delivery due to software error or erroneous CGM data.
- The insulin pump may inappropriately increase insulin delivery or suggest that the user administer additional insulin due to software error or erroneous CGM data.
- Hyperglycemia and ketosis from automatic insulin suspension or decrease in insulin delivery.
- Hypoglycemia from automatic increase in insulin delivery.
- Hyperglycemia, ketosis, ketoacidosis, hypoglycemia due to willing or unwilling off label use of the device.
- Inappropriate use of Auto Mode can result in an increased risk of the above risks

Risks of the PLGM feature include the following:

- The PLGM may inappropriately suspend insulin due to a software defect or erroneous CGM data, which inaccurately detects impending hypoglycemia or a threshold glucose

- The PLGM may inappropriately resume insulin due to a software defect or erroneous CGM data, which inaccurately detects resolution of hypoglycemia or a threshold glucose
- The PLGM may not appropriately suspend insulin due to a software defect or erroneous CGM data, which does not detect impending hypoglycemia or a threshold glucose.
- The PLGM may not appropriately resume insulin due to a software defect or erroneous CGM data, which does not detect resolution of hypoglycemia or a threshold glucose
- Hyperglycemia and ketosis from automatic insulin suspension.
- Inappropriate reliance on PLGM can result in an increased risk of the above risks.

Risks of the pump hardware problems include the following:
- Hypoglycemia from excessive pump delivery due to a hardware defect
- Hyperglycemia and ketosis possibly leading to ketoacidosis due to inappropriate insulin suspension or pump failure resulting in cessation of all insulin delivery due to either a hardware defect or software anomaly.

Risks of the CGM and sensor include:
- Sensor error resulting in incorrect tracking and trending or threshold detection; increased false negative and false positive low threshold alerts and alarms or high threshold alerts, and incorrect rate of change calculations that could adversely affect treatment decisions, and result in an increased risk of hypoglycemia or hyperglycemia.
- Non-adjunctive use of CGM data for meal bolusing decisions could result in an increased risk of hypoglycemia or hyperglycemia.

Potential device-related non-serious events include:
- Skin irritation or redness
- Infection
- Pain or discomfort
- Bruising
- Edema
- Rash
- Bleeding
- Induration of skin,
- Allergic reaction to adhesives
- Hematoma
- Unnecessary fingersticks
- Hyperglycemia following insulin suspension
- Ketosis following insulin suspension
- Sensor may break leaving a sensor fragment under the skin

Potential device-related serious adverse events include:

- DKA resulting from suspension of insulin delivery or inadequate insulin delivery (which can result from catheter occlusion, hardware or software malfunction, or erroneous CGM readings),

- Severe hypoglycemia resulting from over-delivery of insulin (which can result from hardware or software malfunction or erroneous CGM readings), which may lead to seizure, unconsciousness, and rarely, death

The pivotal study to evaluate safety and performance of the System in the 2-6 year age group did not have a dedicated control group. Rather, the data obtained from the clinical study was compared to the data from subjects from prior to the run-in phase. Therefore, there is residual uncertainty due to the study design (lack of control group) about the risks of the device.

During the 3 month phase of the HCL pivotal clinical study (and the continuation phase of the pivotal study is currently still ongoing):

- There were no reports of unanticipated serious adverse device effects.
- There were no reports of unanticipated non-serious adverse device/procedural effects.
- There were no reports of diabetic ketoacidosis events.
- There were no reports of severe hypoglycemia events.

- There is a high amount of residual uncertainty about the risks relating to usability of the System. The human factors (usability) study results indicated that there were usability issues, particularly for novice pump users. In addition, available post-market information suggests that there may be issues with the existing training program; which include complaints regarding not receiving training or receiving insufficient training. Some of these complaints have also been reported to be associated with hypo- and hyperglycemic events and even hospitalization.

- There is residual uncertainty about the risks specific to use of the 770G System (which has a different communication protocol and remote monitoring capabilities for parents/caregivers, as the 770G System was not used in the pivotal clinical study. The sponsor provided adequate (non-clinical) information relating to cybersecurity and the related software validation of the 770G System.

- In addition, there is residual uncertainty about the risks specific to use of the 770G System due to the blood glucose meter (BGM)) change compared to the 670G System. The BGM is an important component of use of the 770G System, as the BGM is used for (mandatory) calibration, as well as for diabetes treatment decisions in use of the 770G System, as the Guardian Sensor (3) does not have a non-adjunctive claim, or a standalone sensor use claim in this (2-6 year age group) population, at this time. Use of the new BGM was not validated in the clinical study, as the 770G System was not used in the pivotal clinical study. The sponsor provided adequate (non-clinical) information to support the use of the new (Accu-Chek Guide™ Link) BGM with use of the 770G System.

Therefore, considering the relative vulnerability of this population (2-6 year age group with Type 1 Diabetes), and that the clinical sequelae of the above discussed potential risks are potentially amplified in this population, as well as the information available at this time, it was not possible to reach a favorable benefit-risk conclusion and it was necessary to take into account additional relevant considerations, risk mitigation strategies and postmarket actions in the benefit-risk assessment.

Additional Relevant Considerations

There are currently no marketed automated insulin delivery (AID) systems in this specific unique and vulnerable patient population (2-6 years of age with Type 1 Diabetes). Considering the considerable residual uncertainty (see assessment of risk section above), this device (the 770G System) presents the potential for benefits of accessibility of this device for this population.

Further, the 770G system allows for remote monitoring capabilities, as discussed above, which presents the potential for benefits, as well as the potential for mitigations to risk by allowing parental/caregiver remote monitoring capabilities.

However, considering the significant resulting uncertainty discussed above (see Summary of Assessment of Benefit-Risk) about the potential risks, and the resulting uncertainty to the benefit-risk profile of 770G System use, it was not possible to reach a favorable benefit-risk assessment, even taking into account the additional relevant considerations. Therefore, it was necessary to take additional risk mitigation strategies into consideration in the benefit risk assessment.

Risk Mitigation Strategies

Additional risk mitigation strategies are currently incorporated into this submission. Specifically, there are significant labeling mitigations relating to the reported CGM performance as well as severe hyperglycemia events reported in the HCL pivotal study results (warnings, including in the package insert, descriptions of limitations of information in the performance section of the labeling, limitation to adjunctive use of the CGM System).

There is a high amount of residual uncertainty relating to safe use (usability), as discussed above (Summary of the Assessment of Benefit-Risk). In addition, there is information to suggest that there are postmarket signals indicating potential problems with the effectiveness of end-user (patient and caregiver) training, as well as reports of difficulty of users obtaining training.

The sponsor proposed to enhance their end-user training, and specifically, to incorporate training about the critical usability tasks to improve their training. The sponsor provided adequate information about proposed enhancements to their training program, to help mitigate risks relating to usability. In addition, the sponsor has committed to including a warning in the labeling emphasizing the necessity of training to ensure safe use of the 770G System.

However, there is residual uncertainty relating to the effectiveness of the proposed enhancements to the training program for end-users of the device, and a favorable benefit-risk balance was not possible to achieve, even considering risk mitigation strategies. Therefore, it was necessary to consider the use of postmarket actions in the benefit-risk assessment.

Postmarket Actions

There is a postmarket confirmatory study currently in progress, that includes the 2-6 year age group (G160046). The sponsor has clarified during this review that they plan for the 770G System to be utilized for new enrollees in that study, if approved. As discussed above (see Summary of Assessment of Risks), additional assessment of areas of significant residual uncertainty of risk are incorporated into the postmarket confirmatory study (including alert performance, severe hyperglycemia event rate, as well as use of the 770G System), in order to confirm safety and/or effectiveness.

As discussed above, there is significant residual uncertainty relating to the adequacy of the enhanced training proposed to mitigate risks relating to safe usability of the 770G System. The sponsor proposes to conduct an assessment to retrospectively to confirm the effectiveness of the enhanced training in the postmarket setting. The sponsor plans to incorporate this assessment into the existing post approval study, through a focused assessment of usability elements, in reported adverse events.

The proposed collection of this additional information relating to usability, as well as the enhanced training in the postmarket setting, as well as the warning in the labeling about the necessity of training to ensure safe use, is adequate to relieve the uncertainty relating to usability to an acceptable level, as well as to mitigate risks to a more acceptable level.

Therefore, considering postmarket actions, it is possible to conclude that the benefits associated with the intended use of the 770G System, in the intended use population, most likely outweigh the potential risks.

Patient Perspectives

Patient perspectives considered during the review included:
Patients want a variety of devices that provide information and aid in managent of their glucose control to inform decision maining with their health care proivders on lifestyle changes and treatment decisions. Patients have also expressed in personal conversations with FDA staff, on social media outlets, and at patient centered public conferences that they want devices that privode features that enable automated insulin delivery, and are willing to accept reasonable risks related to such devices. This information was gathered during patient oriented conferences and face-to-face meetings with patients.

D. Overall Conclusions

The data in this application support a reasonable assurance of safety and effectiveness for this device when used in accordance with the indications for use. The benefits of using the MiniMed 770G system, as discussed above, outweigh the risks.

XIV. CDRH DECISION

CDRH issued an approval order on August 31, 2020. The final conditions of approval cited in the approval order are described below.

In addition to the Annual Report requirements, the applicant must provide the following data in post-approval study (PAS). The Multi-Center, Randomized, Parallel, Adaptive, Controlled Trial in Adult and Pediatric patients with Type 1 Diabetes Using Hybrid Closed Loop System and Control (CSII, MDI, and SAP study arms) at Home is a 6 month, multi- center, randomized, parallel, adaptive study in adult and pediatric subjects ages 2-80 years with type 1 diabetes with a 6 month continuation period. Up to 1500 subjects will be enrolled in order to have 1120 subjects who enter the study period. Up to 70 investigational centers in the US and Canada, as well as in the Medtronic EMEA region, that is comprised of Europe, the Middle East and Africa, will be enrolled. The purpose of this study is to demonstrate the safety and effectiveness of the Hybrid Closed Loop system (HCL) in adult and pediatric patients with type 1 diabetes in the home setting. The study population will have a large range for duration of diabetes and glycemic control, as measured by glycosylated hemoglobin (A1C). Follow-up visits are scheduled throughout the study period up to 6 months and throughout the continuation period up to 6 months. Safety endpoints include Diabetic Ketoacidosis, severe hyperglycemia, severe hypoglycemia, serious adverse events, and unanticipated adverse device effects.

XV. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Post-approval Requirements and Restrictions: See approval order.

XVI. REFERENCES

None.