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Cardiac Recovery System

ASSURE Wearable Defibrillator Patient Handbook

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Cardiac Recovery System™

ASSURE® Wearable Defibrillator Patient Handbook

Kestra Medical Technologies, Inc.

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Important Information

!USA | Rx Only | Caution: Federal Law restricts this device to saleby or on the order of a physician.

Version History

This document describes the initial release of the ASSURE systemand Charger.

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1. Overview

This section provides general information about the ASSURE wearable defibrillator (ASSURE system) including:

- Introduction
- Using this manual
- How to get help
- Information for family and caregivers
- ASSURE System Clinical Studies Summary
- System kit contents
- Returning the system
- Part descriptions
- Glossary

1.1 Introduction

The ASSURE wearable defibrillator (or ASSURE system) monitors you for a potentially dangerous heart rhythm and provides therapy, in the form of an electrical shock, if needed.

If the ASSURE system detects a dangerously fast heart rhythm, it notifies you with an alert before delivering a shock. After delivering a shock, the system checks your heart rhythm to determine if it has returned to normal or if more shocks are needed.

This manual provides instructions for using the ASSURE system. See chapter 2, Safety Information, on page 35 for warnings and precautions.

1.1.1 Indications for Use

The ASSURE system is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for, or refuse, an implantable defibrillator.

1.1.2 Contraindications

The ASSURE system is contraindicated for use on patients with an active implantable defibrillator.

1.1.3 Intended Operator, Use, and Location

The ASSURE system is intended for patients who have been prescribed this device by their physician. The patient is the primary operator. A Kestra patient service representative (PSR) fits and trains the patient on proper use and care of the system.

The ASSURE system is intended for use by a patient during their normal daily activities primarily in the home or community setting, but also hospitals, medical clinics, healthcare facilities and transport. The Charger is intended to be used in the home environment.

1.1.4   Essential Performance

The ASSURE system monitors the patient for dangerous heart rhythms and determines if therapy, in the form of electrical shocks, is required. Unacceptable risks include the loss of detection and therapy.

1.2   Getting Help

For questions or help with the ASSURE system or Charger, call the toll-free ASSURE Helpline at 1.833.MYASSURE (1.833.692.7787).

You can also watch the patient video on the Kestra website at kestramedical.com/patients.

1.3   Using this Manual

Note: Read this manual before using the ASSURE system.

The manual includes the following information:

- Description of the ASSURE system
- Safety information
- Using the Charger and charging the Batteries
- Garment assembly and putting on the ASSURE system
- Alerts and how to respond to them
- Cleaning instructions

1.4   Information for Family and Caregivers

A doctor has prescribed the ASSURE system for your family member, friend, or patient. The ASSURE system monitors them for potentially dangerous heart rhythms and provides treatment in the form of an electrical shock, if needed.

Family and caregivers should read this manual to understand the ASSURE system and how it works. If you do not understand how to use or take care of the system, you may cause potential damage to the system or injury to the patient.

Some key points that family and caregivers should remember:

- Only the patient should wear the ASSURE system. Do not allow children or pets to play with or wear the ASSURE system.
- The patient is the only one who should press the Alert Button. You should NOT press the Alert Button for them.
- The Battery should be replaced in the Monitor every day.
- Keep the spare Battery in the Charger.
- The system may issue alerts.
    - System alerts (yellow) – correct an issue with the ASSURE system.
    - Heart alerts (red) – call 911 immediately.
- Wash the Garment as needed.
    - Remove the Therapy Cable from the Garment.
    - Use cold water and a mild laundry detergent:
        - > Such as all® free clear or Tide Free and Gentle™.
          Note: Follow the detergent manufacturer's warnings and cautions listed on the packaging.
    - Air dry the Garment.

For more information, read this handbook, call the ASSURE Helpline at 1.833.692.7787, or watch the patient video on the Kestra website at kestramedical.com/patients.

Emergency Instructions

⚠️ **CAUTION**

Bystanders should avoid touching the patient, any liquids or fluids, and any metal objects at the same time when a shock is delivered. Otherwise, the bystander may receive an unintentional shock.

The patient has a heart condition and is wearing a medical device. The ASSURE system will alert when it detects a dangerous heart rhythm.

Step 1 - Call 911 or Emergency Medical Services

Step 2 - Follow the voice messages from the ASSURE system Step 3 - If

directed to do so by the ASSURE system, begin CPR
if the patient is unconscious

IMPORTANT

- Do not press the Alert Button for the patient.

- Do not take the Battery out of the Monitor.

- Do not remove the Garment from the patient.

- Do not touch the patient or the system while a shock is being delivered.

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1.5   ASSURE System Clinical Studies Summary

The ASSURE system was tested in two clinical studies in the United States. Subjects included patients who were at risk for sudden cardiac arrest.

The first study tested the ability of the ASSURE system to sense heart rhythms. 130 patients took part in the study. Patients wore the system for a month. 93% of the patients finished the study. The average daily wear time was over 22 hours. During this time, the system issued very few false shock alerts and the system sensed dangerously fast heart rhythms properly. The most reported issues were mild skin irritation, muscle strain, and bruising. Overall, the ASSURE system was well-tolerated in a broad range of adult patients.

The second study assessed the ability of the ASSURE system to return a heart rhythm to normal when providing a shock for a dangerously fast heart rhythm. This study included 13 patients. All patients had their heart rhythm restored to normal. The only reported issue was mild skin irritation under the shock pads.

For more information, go to www.clinicaltrials.gov and search for NCT03887052 and NCT04132466.

1.6   System Kit Contents

Note: You will receive two Garments during your patient training session.

The ASSURE system kit includes the following items:

- Monitor
- Batteries (2)
- Therapy Cable
- Charger, AC adapter, and power cord
- Carry Pack
- Garment laundry bag and laundry detergent
- *ASSURE Wearable Defibrillator Patient Handbook* (this manual)
- *ASSURE Wearable Defibrillator Quick Start Guide*

See section 1.9, Part Descriptions, on page 23 for descriptions of the individual parts of the ASSURE system.

1.7   Ordering Replacement Parts

If any part of the ASSURE system is not working properly or is damaged, call the ASSURE Helpline at 1.833.692.7787 to order a replacement.

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1.8   Returning the System

Your doctor will decide when you no longer need to use the ASSURE system. When you are finished with the system, you must do the following:

- Remove the Battery from the Monitor.
- Take off the ASSURE system.
- Find the original system kit box and follow the repacking instructions on the inside of the lid.
- Pack up the complete system, including all accessories, the second Garment, Charger, and both Batteries, into the provided system kit box.
- Seal the lid on the system kit box according to the instructions on the inside of the lid.
- Return the system kit box to Kestra Medical Technologies. The box should have a prepaid return shipping label already on it.

If you have any questions, call the ASSURE Helpline at 1.833.692.7787.

1.9   Part Descriptions

This section provides descriptions of the ASSURE system.

1.9.1   Garment Description

The Garment is worn on the body and contains the Sensors. It holds both the Sensors and Therapy Pads against your bare skin.

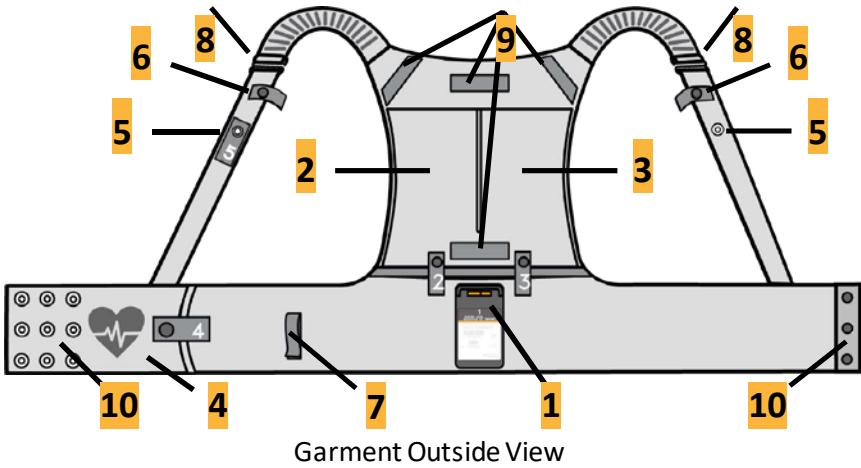There are two Garment styles (style A and style B), and each style is available in a range of sizes.
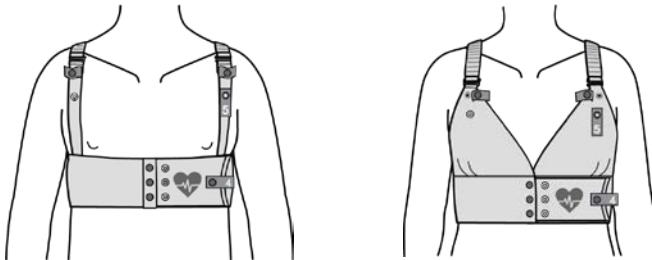
Garment Style A (left) and Style B (right)
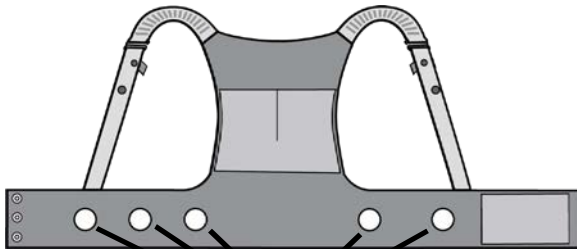

Garment Inside View

Item	Name
1	Sensors

Garment Outside View

Item	Name
1	Hub Receptacle
2	Therapy Pad 2 Pocket (back)
3	Therapy Pad 3 Pocket (back)
4	Therapy Pad 4 Pocket (front)
5	Alert Button Snap
6	Alert Button Cord Wrap
7	Therapy Pad 4 Cord Wrap
8	Shoulder Strap Hooks
9	Alert Button Cord Loops (back)
10	Front Closure Snaps

1.9.2   Therapy Cable Description

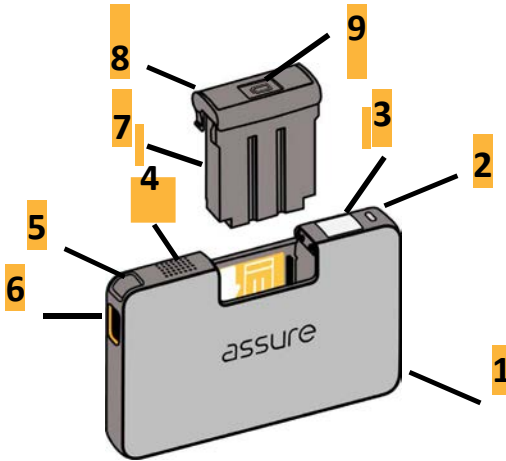The Therapy Cable provides the connection between the Garment and the Monitor.

> Note: The entire Therapy Cable is a single assembly. The cords connected to the Hub cannot be removed.
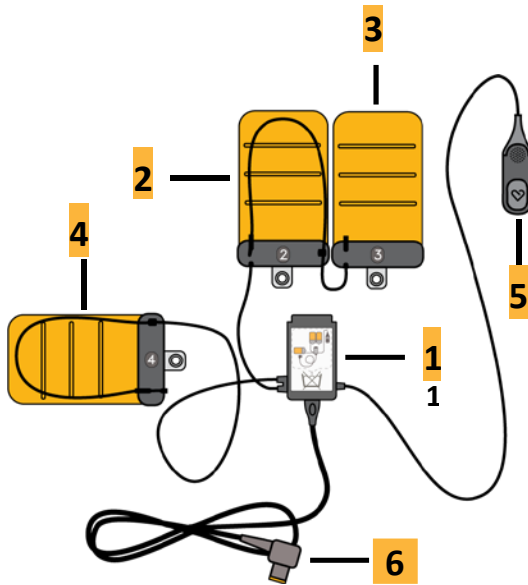
Item	Name
1	Hub
2	Therapy Pad 2 (back)
3	Therapy Pad 3 (back)
4	Therapy Pad 4 (front)
5	Alert Button
6	Plug and Cable

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1.9.3   Monitor and Battery Description

The Monitor is the main electronic part of the ASSURE system. The rechargeable Battery inserts into the Monitor and provides power to the system.

Item	Name
1	Monitor
2	Monitor Light
3	Monitor Screen
4	Speaker
5	Plug Release Button
6	Plug Receptacle
7	Battery
8	Battery Handle
9	Battery Lock

1.9.4   Carry Pack Description

The Carry Pack holds the Monitor while wearing the system.

Item	Name
1	Buckle
2	Strap Adjusters
3	Strap
4	Flaps
5	Handle
6	Strap Connectors
7	Corner Straps
8	Belt Clip

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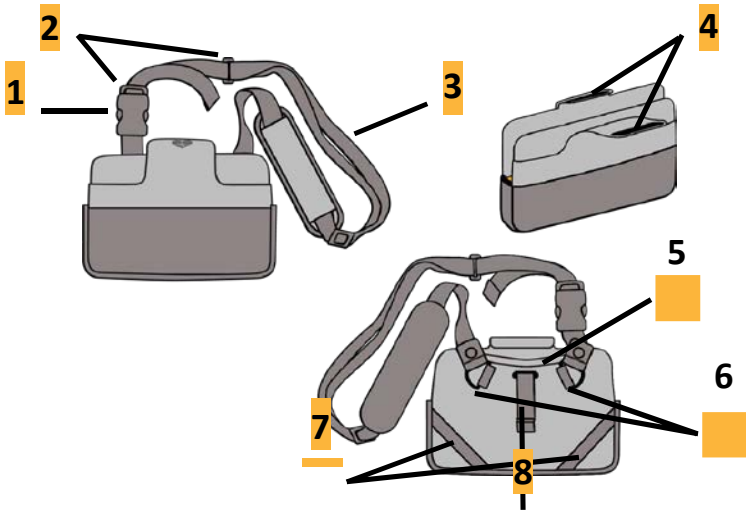
1.9.5 Charger Description

The Charger is a separate device that charges the spare Battery.
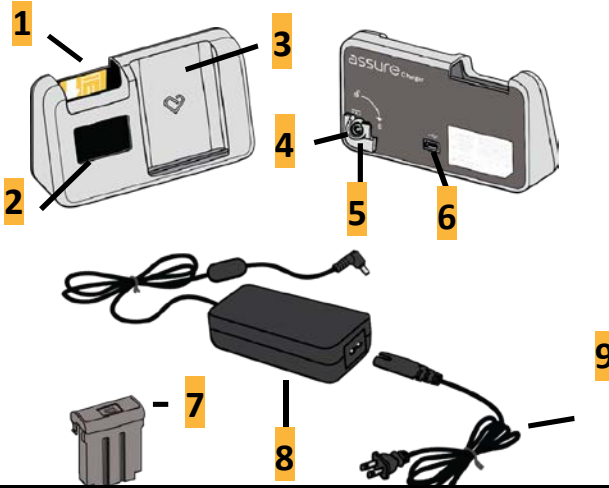
Item	Name
1	Battery Slot
2	Charger Screen
3	Wireless Charging Well
4	Power Port
5	Charger Cord Clip
6	USB Port (output only)
7	Battery
8	AC Adapter with Charger Cord and Plug
9	AC Adapter Power Cord with Connector and Plug

1.10   Glossary

Term	Definition
AC Adapter	The power supply for the Charger.
AC Adapter Power Cord	The cord that connects the AC adapter to an electrical wall outlet.
AC Adapter Power Cord Connector	The end of the AC adapter power cord that plugs into the AC adapter.
AC Adapter Power Cord Plug	The end of the AC adapter power cord that plugs into an electrical wall outlet.
Alert	A message from the ASSURE system that a condition exists that requires attention. There are two types of alerts – Heart and System.
Alert Button	An oval-shaped button on the Therapy Cable. Press this button to start the ASSURE system or to respond to alerts.
Alert Button Back Cord Loops	Fabric loops that hold the Alert Button cord on the back of the Garment.
Alert Button Shoulder Wraps	Fabric loops with snaps that hold the Alert Cord Button cord on the Garment shoulder straps.
Alert Button Snap	A connector on the Garment's shoulder strap that attaches to the back of the Alert Button.
ASSURE System	Also known as the ASSURE wearable defibrillator.
Battery	A rechargeable battery in the Monitor that powers the ASSURE system.

Term	Definition
Battery Handle	A lever on the top of the Battery. Slide the Battery lock and lift the handle. Pull up on the handle to remove the Battery from the Monitor. Leave the handle down when inserting the Battery into the Monitor or Charger.
Battery Lock	Locking mechanism on top of the Battery. Slide the lock until you see the yellow line and lift the Battery handle. Pull up on the handle to remove the Battery from the Monitor.
Battery Slot	The opening in the Charger where you insert the Battery to charge it.
Carry Pack	A portable case that holds the Monitor while wearing the ASSURE system.
Carry Pack Belt Clip	A clasp on the back of the Carry Pack that holds it on a belt.
Carry Pack Buckle	Plastic pieces on the ends of the Carry Pack straps that connect together.
Carry Pack Corner Straps	Elastic straps located on the back of the Carry Pack. May be used to hold any extra length of the cable running from the Garment to the Monitor.
Carry Pack Flaps	A big flap and a small flap that fasten together to secure the Monitor in the Carry Pack.
Carry Pack Handle	A fabric handle on the back of the Carry Pack.
Carry Pack Strap	An adjustable two-piece strap that attaches to the Carry Pack and fastens with a buckle.

Term	Definition
Carry Pack Strap Adjusters	Used to lengthen or shorten the Carry Pack strap. There is an adjuster on the strap and another one in the buckle.
Carry Pack Strap Connectors	Plastic loops on the back of the Carry Pack. Connect the strap ends to the loops.
Charger	A separate device that charges the Battery.
Charger Cord	The cord that connects the AC adapter to the Charger.
Charger Cord Clip	A plastic clip on the back of the Charger that holds the Charger cord.
Charger Cord Plug	The end of the Charger cord that plugs into the Charger.
Charger Screen	The visual display on the Charger that shows the Battery's charging status.
CPR	Cardiopulmonary resuscitation
Front Closure Snaps	Connectors on the front of the Garment that fasten together to close it.
Garment	A fabric top that contains the Sensors that track heart rhythm. It is worn directly on the body against bare skin.
Garment Shoulder Strap Hooks	Adjustable hooks on the Garment's shoulder straps.
Heart Alert	A critical alert that notifies you that the system has detected a dangerous heart rhythm and is taking action.

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Term	Definition
Hub	The central part of the Therapy Cable that connects the Therapy Pads, Alert Button, and cable.
Hub Receptacle	The plastic housing on the back of the Garment where the Hub is inserted.
ICD	Implantable Cardioverter Defibrillator
Monitor	The part of the ASSURE system that provides power and displays system status information.
Monitor Light	The multi-colored light on the Monitor that displays the current system status.
Monitor Screen	The visual display on the Monitor that provides system status information.
MRI	Magnetic resonance imaging
Plug	The connector at the end of the Therapy Cable that inserts into the Monitor.
Plug Receptacle	The side opening on the Monitor where the Plug inserts.
Plug Release Button	A button on the Monitor that is pressed and held down to remove the Plug from the Monitor.
Power Port	An opening on the back of the Charger where the AC adapter cord is inserted to provide power to the Charger.
Sensors	Round metal ECG electrodes in the Garment that track heart rhythm.

Term	Definition
Snaps 2-4	Connectors on the Therapy Pads and on the Garment's pockets that fasten together to keep the Therapy Pads inside the Garment.
Speaker	An enclosed speaker in the Monitor and Alert Button that delivers audio voice messages and alert tones.
System Alert	An alert that notifies you that there is a problem with the ASSURE system that you need to fix.
Therapy	An electrical shock provided by the ASSURE system for a potentially life-threatening heart rhythm.
Therapy Cable	A group of connected parts consisting of the Hub, Therapy Pads, Alert Button, and a cable that connects to the Monitor. The Therapy Cable is inserted into the Garment.
Therapy Pad 4 Cord Wrap	A fabric loop located near the Therapy Pad 4 pocket that fastens the Therapy Pad 4 cord to the Garment.
Therapy Pad Pockets	Fabric pockets in the Garment that hold the Therapy Pads. There are two back pockets and one front pocket.
Therapy Pads	Front and back Therapy Pads attached to the Therapy Cable that deliver an electrical shock to the heart when needed. The Therapy Pads contain gel that is dispersed before a shock is delivered.

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Term	Definition
USB Port	A Universal Serial Bus 2.0 dedicated charging port on the back of the Charger. This port is output only, so it can only charge USB-compatible devices.
Wearable Defibrillator	A system worn by patients at risk of sudden cardiac arrest that detects dangerously fast heart rhythms and delivers a shock to restore a normal heart rhythm.
Wireless Charging Well	A slot in the Charger that can recharge a mobile device that supports wireless charging.

2. Safety Information

This section provides warnings, cautions, and electromagnetic interference (EMI) information for the ASSURE wearable defibrillator (ASSURE system) and Charger.

See chapter 8, Symbols Glossary, on page 149 for a list of symbols that appear on the ASSURE system and Charger labels and packaging.

2.1 Safety Labels

The following safety labels and terms appear in this manual:

⚠️ **WARNING**

Hazards or unsafe practices that may result in serious personal injury or death.

⚠️ **CAUTION**

Hazards or unsafe practices that may result in minor or moderate personal injury, product damage, or property damage.

2.2 Places to Avoid

⚠️ **WARNINGS**

- *Keep the ASSURE system, Charger, and all accessories away from open flame, flammable gases, or other potential fire sources. Shock delivery in these environments may pose an explosion or fire hazard risk.*

- *The ASSURE system is magnetic resonance (MR) unsafe. Do not wear or use the system near MR imaging equipment.*

2.3   Wear

⚠️ **WARNINGS**

- *Always wear the ASSURE system when instructed to do so by a doctor or other medical professional. A second Garment is provided so the system can be worn while washing the used Garment.*

- *Operating a motorcycle, boat, riding lawnmower, or other noisy vehicle, or any vehicle or equipment that emits heavy vibrations, while wearing the ASSURE system may prevent you from realizing an alert is happening.*

- *Do not alter, drop, or abuse any part of the ASSURE system. Attempting to alter the equipment in anyway may cause the system to malfunction or fail. Do not take apart the Monitor. Dangerous high voltages may be present. If service is required, call the ASSURE Helpline at 1.833.692.7787.*

- *When the Service Required alert is active, the ASSURE system is not operational and cannot protect you. Call the ASSURE Helpline at 1.833.692.7787 immediately for assistance.*

2.4   Use

⚠️ **WARNINGS**

- *Do not place the Monitor, Therapy Cable, Charger, or Battery in water or other liquids. Avoid spilling any liquids on these devices. Liquids entering these devices may cause them to malfunction or fail. Follow the instructions in this document to properly clean these devices.*

- *If you will be away from home for longer than 24 hours, take the spare, fully charged Battery and Charger with you.*

- *During use, do not stack or place the ASSURE system near other equipment. Doing so may cause the system to malfunction or fail due to EMI exposure from the other equipment. If such use is necessary, the ASSURE system and the other equipment should be observed to verify that they are operating normally.*

- *Only use portable RF communications equipment that is included with or intended for use with the ASSURE system. Do not use any other portable RF communications equipment (including antenna cables and external antennas) any closer than 12 inches (30 cm) to any part of the system. Otherwise, equipment performance may suffer.*

- *When washing the Garment, do not use chlorine bleach, bleach alternatives, fabric softeners, or anti-static sprays. In addition, do not use detergents or detergent "pods" that include bleach or fabric softener additives.*

- *Do not connect line voltages, power banks, or other devices that may attempt to use the USB port on the Charger as an input port. The Charger's USB port is a dedicated charging port that is output only and can only charge connected devices.*

- *Always remove the Therapy Cable before washing the Garment.*

- *If the Plug is removed from the Monitor and then re- inserted while the ASSURE system is operational, the system may issue the Connect Plug to Monitor alert repeatedly. This alert will continue to play even if the Plug is removed and re-inserted into the Monitor. If this occurs, remove the Battery from the Monitor and then re-insert it to restart the ASSURE system.*

⚠ **CAUTION**

Bystanders should avoid touching the patient, any liquids or fluids, and any metal objects at the same time when a shock is delivered. Otherwise, the bystander may receive an unintentional shock.

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2.5   Electromagnetic Interference

The ASSURE system is shielded to protect it against electromagnetic interference (EMI) and prevent it from interfering with common electronic items. The system should operate normally around most electronic household items, such as microwave ovens, televisions, computers, kitchen appliances, mobile phones, and garage door openers.

See chapter 9, Technical Information, on page 155 for more detailed information regarding electromagnetic compatibility (EMC).

Household Equipment to Avoid

Some household items can generate electromagnetic fields that may interfere with the ASSURE system. To prevent this, avoid going near the following types of household equipment:

- Communication equipment (for example, microwave transmitters or high-powered two-way radios)
- Arc welding equipment
- Large electric motors and generators
- Power tools
- High voltage transmissions lines

Hospital and Clinic Equipment to Avoid

Certain medical equipment in hospitals and clinics can produce uncommonly high EMI that may interfere with ASSURE system. To prevent this, avoid going near the following equipment:

- Magnetic resonance imaging (MRI) equipment
- Advanced imaging technology equipment
- Electrocautery systems

Note: Remove the Battery from the Monitor and take off the ASSURE system before undergoing any imaging scans.

Airport or Security Screening Equipment

Avoid walking through security screening equipment commonly found in airports, courthouses, and sporting events. Instead, show the security staff your patient information card, explain that you are wearing a medical device, and ask for a different screening method, such as a hand-held device or physical hand search.

Retail Store Product Security Stands

Passing through the product security stands commonly found at the entrances and exits of retail stores should not cause any issues with the ASSURE system. Pass through the security stands at a normal speed and get clear of them. Do not stand around the security stands for a long time.

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2.5.1　　Resolving EMI Issues with the System

Going near an item that is generating an electromagnetic field may cause issues with the ASSURE system.

Always maintain a safe distance from any item that may cause potential interference with the ASSURE system.

Follow the steps below to fix EMI issues with the system:

1. Check for any electronic devices nearby that could be causing interference.
2. Move away from those devices and check the ASSURE system.
    - If the ASSURE system returns to normal operation, one or more of those devices is likely the cause.
    - If the issue persists, go to the next step.
3. Move to a different room or area and see if that fixes the issue.
4. If the issue still occurs, call the ASSURE Helpline at 1.833.692.7787.

Avoid touching or coming into contact with any item that is not in proper working condition or wired properly. Items that have not been properly maintained, or have been altered from their original intended use, may pose an electrical shock risk.

Only use items that are in good condition and make sure those items are used in a way intended by their original manufacturer.

3. Daily Life Routine

This section describes how to make the ASSURE wearable defibrillator (ASSURE system) a part of your daily life, including:

- Wearing the ASSURE system
- Checking the system status
- Sleeping while wearing the ASSURE system
- Taking a shower or bath
- Traveling with the system

3.1   Wearing the ASSURE System

The ASSURE system is designed to be worn all the time, except while showering or bathing. You can wear it in a variety of public settings, like going to a grocery store, attending a sporting event, or dining out.

Guidelines while wearing the system:

- **Wear any clothing <u>over</u> the Garment.**
  - Do not wear or place anything between the Garment and your body.
  - Undershirts and bras may only be worn <u>over</u> the Garment (as shown below).
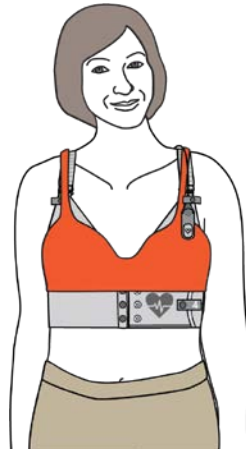
Undershirt Over the Garment   Bra Over the Garment

- **Check for any wear or damage once or twice a week.** To report any damage or concerns, call the ASSURE Helpline at 1.833.692.7787. See section 6.6, Checking for Equipment Damage, on page 130 for more information.
- **If you will be going out into heavy rain or snow, keep the Monitor and Carry Pack covered as much as possible.**

- **The Carry Pack strap and Therapy Cable are potential hazards for getting strangled.** To reduce this risk:
    - Never wrap the Carry Pack around your neck.
    - Keep the Monitor and Carry Pack at or below waist level.
    - Manage any extra length of cable between the Hub and Monitor.
    - Remove the Carry Pack strap if sleeping with the Monitor inside the Carry Pack.
- **Do not allow children or pets to play with the ASSURE system.**
- **If you have any skin issues underneath the Garment, like redness, bumps, inflammation, irritation, skin breakdown, blistering, or a cut, continue to wear the ASSURE system and call your doctor.**

    Notes:

    - *The Garment contains the following materials:*
        - > *Body fabric: 59% Polyamide, 41% Elastane (spandex)*
        - > *Inner lining: 73% Polyamide, 27% Elastane*
        - > *Therapy Pad pockets: 100% Silver-plated Nylon*
    - *The Carry Pack is 100% Polyester and the strap is 100% Nylon.*

You should temporarily remove the ASSURE system for the following situations only:

- **When you need to take a shower or bath, or when you will be actively participating in a water-based activity, like swimming.** See section 3.6, Taking a Shower or Bath, on page 55 for more information.
- **When moving the Therapy Cable from one Garment to the other Garment.** See section 6.4, Washing the Garment, on page 126 for more information.

3.1.1 Proper Garment Fit

The Garment must be worn against bare skin to analyze your heart rhythm. To keep the Sensors in contact with your body, the Garment must be fastened securely.

Check the fit of the Garment:

- The shoulder straps should lie flat against your chest and shoulders and not be loose.
- The Therapy Pads should lie flat against your back.
- The Garment should not be twisted around the sides or back. Use a mirror to check or have another person help check.
- The front Therapy Pad should be snug around your rib cage, below your breast area and nipples, but above your stomach.

Note: Make sure your breasts are not underneath the front TherapyPad or Sensors.

The pictures below show examples of a Garment that fits properly.

Proper Garment Fit

Front   Back

The following pictures show examples of a Garment that does NOT fit properly.

Improper Garment Fit
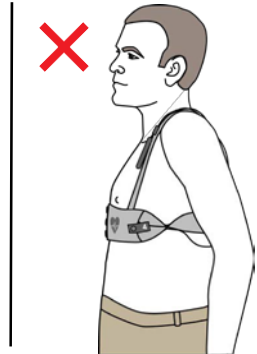
Too Low   Too High   Twisted

3.1.2   Using the Carry Pack

You can wear the Carry Pack in different ways depending on your preference.

Over the shoulder with the strap lengthened.

- Across the body or over the shoulder.

Around the waist with the strap shortened or attached to a belt using the belt clip.
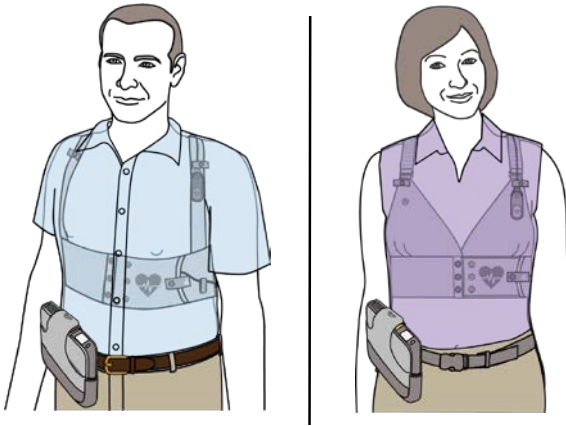
The Carry Pack strap includes two pieces that attach to the CarryPack strap connectors and connect together using a buckle.
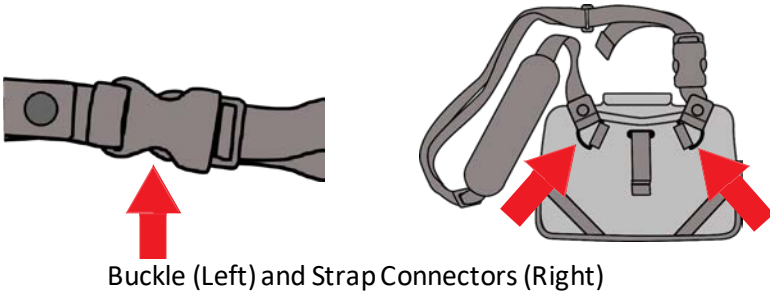
Buckle (Left) and Strap Connectors (Right)

● To connect the buckle, press the two sides together until you hear a "click".

● To detach the buckle, squeeze the buckle sides until they unlock and then pull them apart.

You can lengthen or shorten the Carry Pack strap using the two strap adjusters.
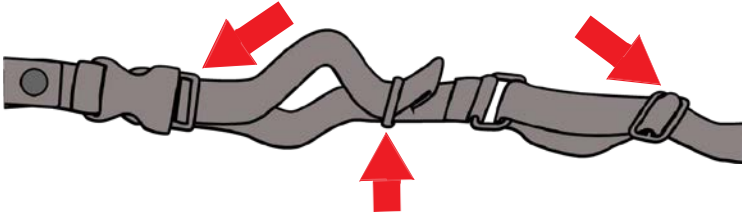
Strap Adjusters and Elastic Band

- Slide the adjuster along the strap to lengthen or shorten the strap.
- Use the strap adjuster near the buckle to tighten the strap when wearing the Carry Pack around the waist. You can insert any extra strap length through the elastic band on the strap.

Note: The inside of the Carry Pack (the side with the belt clip and corner straps) should always face towards your body.

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3.2   Patient Information Card

The information card provides emergency instructions for first responders or bystanders and it includes emergency contact information. The patient information card is also useful when traveling. See section 3.7, Traveling with the ASSURE System, on page 59 for more information.

The information card should have been filled out during your patient training session. Make sure to place the card in the front pocket of the Carry Pack.

To replace a lost card, call the ASSURE Helpline at 1.833.692.7787.

3.3   Responding to Alerts

When you receive an alert, follow these three general steps:

Step 1 - Press the Alert Button

- Press once to quiet the alert.
- For System alerts, press the Alert Button again to replay the voice message.

Step 2 - Look at the Monitor screen and light

Step 3 - Respond to the alert

- See chapter 5, Alerts, on page 77 for more information.

3.4 Checking System Status

To check the status of the ASSURE system at any time:

Press the Alert Button

What you will...	
See	● Solid green Monitor light ● System Ready icon on Monitor screen
Hear	Three-note guitar strum
Feel	Single-pulse vibration from the Alert Button

Note: If a System alert is active, pressing the Alert Button will replay the voice message.

3.5   Sleeping in the ASSURE System

Wear the ASSURE system while you sleep so it can monitor and protect you during that time.

Proper Monitor Position While Sleeping

Note: The Carry Pack strap and Therapy Cable are potential hazards for getting strangled, especially when sleeping. To reduce this risk:

- – *Never place the Monitor or Carry Pack near your head or neck.*
- – *Keep the Monitor or Carry Pack at or below waist level.*
- – *Remove the Carry Pack strap if sleeping with the Monitor inside the Carry Pack.*

3.5.1   Responding to Alerts While Sleeping

An alert may occur at any time, even while you are sleeping. To

respond to alerts during sleep:

Step 1 - Press the Alert Button

Note: For System alerts, press the Alert Button again to replay the audio message.

Step 2 - Look at the Monitor screen and light Step 3 -

Respond to the alert

● See chapter 5, Alerts, on page 77 for more information.

3.6   Taking a Shower or Bath

⚠ **WARNING**

Do not place the Monitor, Therapy Cable, Charger, or Battery in water or other liquids. Avoid spilling liquids on these devices.
Liquids entering these devices may cause them to malfunction or fail.
Follow the instructions in this document to properly clean these devices.

You must always remove the ASSURE system before taking a bath or shower or participating in any water-based activity, like swimming.

Note: You will not be protected while you are not wearing the system. Try to limit the activity to the least amount of time as possible.

Never Wear the ASSURE System in the Bath or Shower

Before taking a shower or bath, remove the system.

- See section 3.6.1, Removing the ASSURE System, on the next page for instructions.

After taking a shower or bath and drying off, put on the system.

- See section 6.3, Assembling and Putting on the System, on page 109 for instructions.

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3.6.1   Removing the ASSURE System

To take off the ASSURE system:

Step 1 - Open the Carry Pack flaps

Step 2 - Slide the Battery lock until you see the yellow line and lift the Battery handle

Note: If you need help with this task, see page 144 or watch the patient video at kestramedical.com/patients.

Step 3 - Pull up to remove the Battery from the Monitor
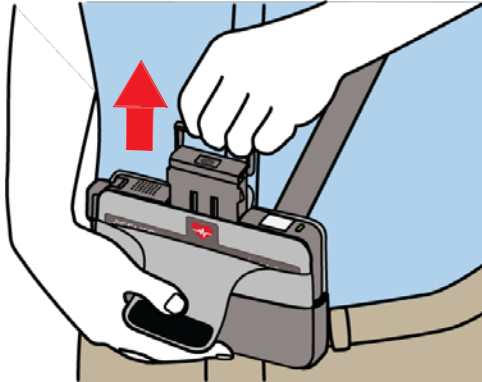
- Removing the Battery turns off the system.
- To avoid setting off alerts, always remove the Battery before taking off the ASSURE system.

Step 4 - Take off the Carry Pack

- Place the Carry Pack on a nearby flat surface to avoid dropping the Monitor.

Step 5 - Remove any clothing above the waist
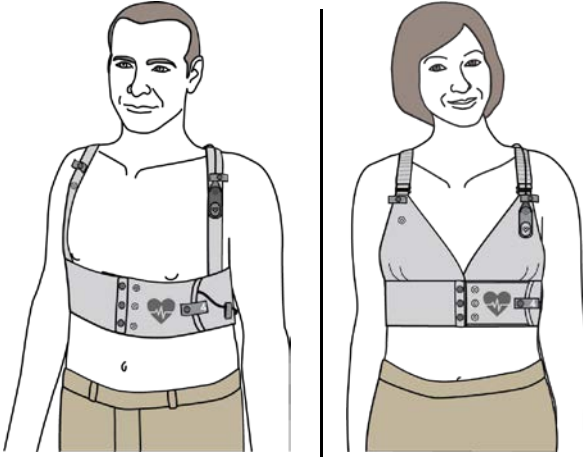
Step 6 - Unsnap the front closure

Step 7 - Take off the Garment

Step 8 - Place the Garment and Carry Pack in a safe place to avoid dropping the Monitor, getting it wet, or getting tangled in the cables

3.7   Traveling with the ASSURE System

⚠️ **WARNING**

If you will be away from home for longer than 24 hours, take the spare, fully charged Battery and Charger with you.

Air Travel

You should always wear the ASSURE system while traveling. It is safe to wear and use the ASSURE system on an airplane.

Never place the ASSURE system in checked baggage.

Refer to the Transportation Security Administration (TSA) website at www.tsa.gov/travel/special-procedures for information on traveling with medical devices.

Electronic Security Check Points at the Airport

Avoid walking through security screening equipment commonly found in airports, courthouses, and sporting events. Instead, show the security staff your patient information card, explain that you are wearing a medical device, and ask for a different screening method, such as a hand-held device or physical hand search.

International Travel

If you are traveling outside of North America, you may need to purchase a power converter or adapter for the Charger to work properly in that country.

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4. Battery and Charger

This section describes how to manage the Battery and Charger, including:

- Plugging in the Charger
- Charging the Battery
- Viewing the Charger screen
- Viewing the Battery status on the Monitor
- Replacing the Battery
- Using the Wireless Charging Well
- Using the USB port on the Charger

4.1 Plugging in the Charger

Note: Use only the accessories provided with the ASSURE system. This includes the Batteries and Charger.

To plug in the Charger:

Step 1 - Insert the Charger cord plug from the AC adapter into the Charger

- Insert the plug with the cord straight up.

- Turn the cord to the right to secure it in the clip.

Note: Properly secure the cord in the clip. This prevents the cord from being accidentally removed from the Charger.

Step 2 - Connect the power cord to the AC adapter

Step 3 - Plug the power cord into an electrical wall outlet
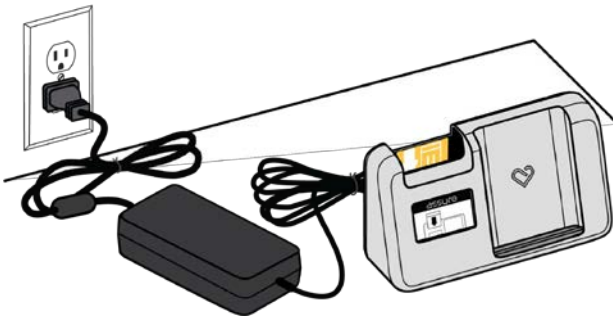
Notes:

- *Do not place the Charger in a position or location that makes it difficult to insert or remove the Battery or unplug the AC adapter power cord.*
- *Always leave the Charger plugged into an electrical outlet to keep the spare Battery fully charged.*
- *If you must turn off the Charger for any reason, unplug the AC Adapter power cord from the electrical wall outlet.*

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4.2 Charging the Battery

The ASSURE system comes with two Batteries. You should replace the Battery at the same time every day.

An empty Battery charges in about four hours.

Notes:

- *Check the Charger and Batteries for any wear or damage once or twice a week. To report any damage or concerns, call the ASSURE Helpline at 1.833.692.7787. See section 6.6, Checking for Equipment Damage, on page 130 for more information.*
- *Use only the accessories provided with the ASSURE system. This includes the Batteries and Charger.*

To charge the Battery in the Charger:

Step 1 - Insert the Battery into the Charger

- Do not force the Battery into the Charger. There is only one way to insert the Battery.
- Keep the fully charged spare Battery in the Charger until you need to replace the Battery in the Monitor.
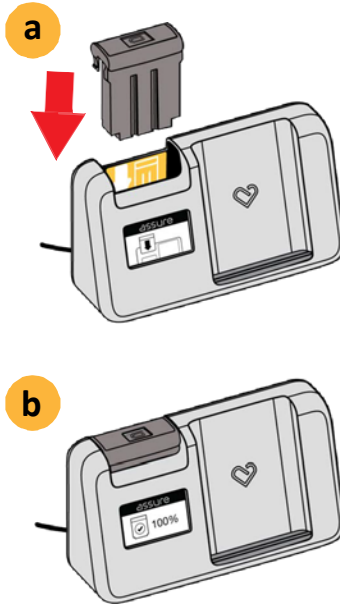
Step 2 - Check the Charger screen to confirm that the Battery is charging

- See the next page for more information.

4.2.1   Viewing the Charger Screen

The Charger screen displays the Battery's current charge status.

Screen Display	Description
assure	Insert a Battery into the Charger.
assure 20%	The Battery is charging. The charging symbol flashes and the screen displays the current progress from 0–100% in 5% increments.
	The Battery is fully charged.
assure 100%	There is a problem with the Battery. Remove the Battery and re-insert it into the Charger. If the problem still occurs, call the ASSURE Helpline at 1.833.692.7787.
assure	The Battery is too hot. Remove the Battery from the Charger. Allow the Battery to cool down to room temperature before using it or putting it back in the Charger.
assure	There is a problem with the Charger. Unplug the power cord and then plug it back in. If the problem still occurs, call the ASSURE Helpline at 1.833.692.7787.
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4.3   Viewing Battery Status on the Monitor

A full Battery lasts at least 24 hours. The Monitor screen displays the current Battery status with the System Ready icon.

Screen Display	Description
	The Battery is fully charged (more than 24 hours of remaining charge).
	The Battery has 18 to 24 hours of remaining charge.
	The Battery has 12 to 18 hours of remaining charge.
	(Solid bar) The Battery has 6 to 12 hours of remaining charge.
	(Blinking bar) The Battery has 2 to 6 hours of remaining charge.
	(Blinking) Low Battery alert – The Battery has less than two hours of remaining charge. See the Low Battery Alert on page 95.

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4.4   Replacing the Battery in the Monitor

A fully charged Battery will power the ASSURE system for at least 24 hours. Replace the Battery at the same time every day, so you do not forget.

⚠️ **WARNING**

If you will be away from home for more than 24 hours, take the spare, fully charged Battery and Charger with you.

To replace the Battery:

Step 1 - Check that the Battery in the Charger is fully charged

- The Charger screen shows the Battery status.

Step 2 - Open the flaps on the Carry Pack

Step 3 - Slide the Battery lock until you see the yellow line and lift the Battery handle

Battery Lock

Battery Handle
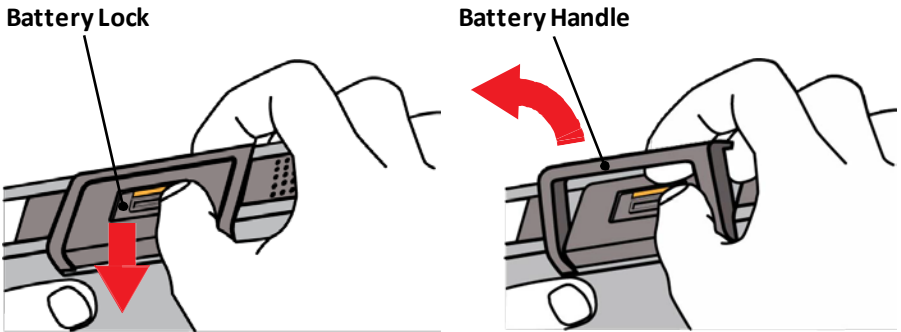
Note: If you need help with this task, see page 144 or watch the patient video at kestramedical.com/patients.

Step 4 - Pull up to remove the Battery from the Monitor
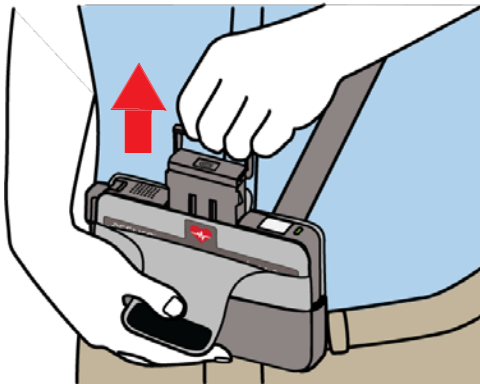
- Removing the Battery turns off the system.
- Damaged Batteries may leak and cause personal injury or equipment damage. Handle damaged or leaking Batteries with extreme care. Call the ASSURE Helpline at 1.833.692.7787 to report any equipment damage.

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Step 5 - Take the fully charged Battery out of the Charger

Step 6 - Insert the fully charged Battery into the Monitor

- A "click" sound means the Battery is securely inserted.
- Do not force the Battery into the Monitor. There is only one way to insert the Battery.
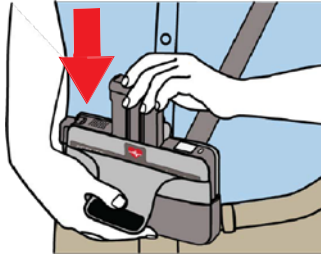
Step 7 - Close the flaps on the Carry Pack

Step 8 - Wait a few minutes while the ASSURE system powersup

- The Monitor light turns blue right away and the Monitor screen displays the Welcome icon.

- The System Busy icon then appears.

- Wait for the Alert Button icon to appear on the Monitor screen (this may take a few minutes).

If a different icon appears on the Monitor screen, check the alert icon andrespond to the alert.

- See section 5.1, Identifying Alerts, on page 78 for a list of the alert icons.
- After responding to the alert, the Alert Button icon should appear on the Monitor screen.

Step 9 - Press the Alert Button

Note: If you press the Alert Button and the System Ready icon does not immediately appear on the Monitor screen, call the ASSURE Helpline at 1.833.692.7787. There may be an issue with the Alert Button.

What you will...	
See	● Solid green Monitor light ● System Ready icon on Monitor screen
Hear	Three-note guitar strum
Feel	Single-pulse vibration from the Alert Button

Note: The green light and the screen backlight turn off after five seconds.

Step 10 - Insert the used Battery into the Charger
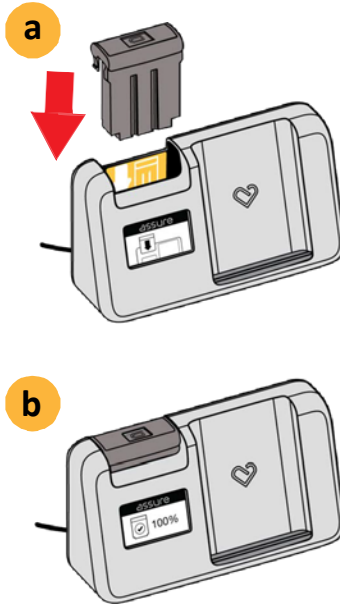
Step 11 - Check the Charger screen to confirm that the Battery is charging

4.5   Using the Wireless Charging Well

The Charger includes a wireless charging well for mobile devices. The well provides a standard 5W charging speed and supports mobile devices up to 6.3 x 3.3 x 0.49 inches (including a case).

Notes:
- *Check with your mobile device manufacturer to confirm your device supports wireless charging.*
- *The Charger may not be compatible with all wireless-charging mobile devices.*
- *If your mobile device case holds items that may contain magnetic strips or RFID chips, like credit cards or passports, remove the case from the device before placing it in the well.*

To use the wireless charging well:

Step 1 - Place the mobile device into the wireless charging well with the device's screen facing outwards
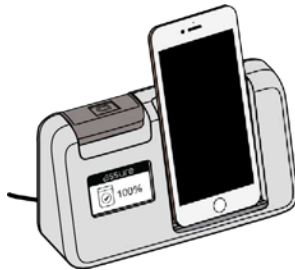
Step 2 - Check the mobile device to make sure it is charging

- The device's screen should display an indication that the mobile device is charging.

Note: If there is no indication that the device is charging, you may need to remove the device case, if one is installed. Remove the case and then repeat steps 1 and 2 above.

4.6 Using the USB Port on the Charger

The Charger's USB port can charge any USB-compatible device using a USB cable with a type A connector. The USB port is located on the back of the Charger.

⚠️ **WARNING**

Do not connect line voltages, power banks, or other devices that may attempt to use the USB port as an input port. The USB port is a dedicated charging port that is output only and can only charge connected devices.

To plug in a USB-compatible device to the Charger:

Step 1 - Insert one end of the USB cable into the device Step 2 -

Insert the USB cable's type A connector into the USB port on the Charger

Step 3 - Check the connected device to make sure it is charging

4.7 **What to Do During a Power Outage**

You must keep the Batteries charged for the ASSURE system to operate properly.

If a power outage occurs, follow these guidelines:

- Call your electrical company to report the outage. Tell them that you have a medical device that requires power.
- Call or visit your local emergency services to see if they can help. Tell them that you have a medical device that requires power to charge its Batteries.
- A fully charged Battery provides at least 24 hours of operation. If the power is out for more than 24 hours, try to find a place with power, like a family member or friend's house. Take the spare Battery and Charger with you and charge the Batteries there.

  Note: The Charger can recharge an empty Battery in about four hours.

The U.S. Food & Drug Administration (FDA) provides a booklet on their website (www.fda.gov) titled, "Home Use Devices: How to Prepare for and Handle Power Outages for Medical Devices that Require Electricity".

After power is restored, return the Charger to its usual charging location and follow the 24-hour Battery charging schedule.

5. Alerts

This section describes how to identify and respond to the alerts issued by the ASSURE wearable defibrillator (ASSURE system).

5.1 Identifying Alerts

⚠️ **WARNING**

Operating a motorcycle, boat, riding lawnmower, or other noisy vehicle, or any vehicle or equipment that emits heavy vibrations, while wearing the ASSURE system may prevent you from realizing an alert is happening.

The ASSURE system monitors you for dangerous heart rhythms and itself for proper function. When the system detects a problem, it creates an alert to let you know there is something that needs your attention.

There are two alert types:

- Heart alerts – The ASSURE system has detected a heart rhythm that is either too fast or too slow. These alerts are critical and must be responded to immediately.
- System alerts – The ASSURE system has found a problem

What you will...	Heart Alert	System Alert
See	• Flashing red Monitor light • Alert icon on Monitor screen	• Blinking yellow Monitor light • Alert icon on Monitor screen
Hear	• Harsh, alternating low-high alarm • Voice message	• Repeating, double tone • Voice message
Feel	Four gentle pulses followed by an intense, triple-buzz vibration from the Alert Button	Triple-pulse vibration from the Alert Button

Note: The vibration continues throughout a Shock alert.

5.2   Heart Alerts

There are two types of Heart alerts:

Alert Name	Light and Icon	Reference
Shock		See page 80.
Seek Medical Attention		See page 84.

The ASSURE system will not call 911 for you. You or someone nearby must call 911 during Heart alerts.

5.2.1 Shock Alert

⚠️ **WARNING**

No one should touch the patient or equipment when a shock is being delivered. The ASSURE system delivers a large amount of electrical energy during shock delivery.

After the ASSURE system detects and confirms a dangerously fast heart rhythm, it issues a Shock alert to tell you that a shock will be delivered.
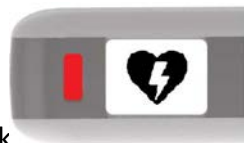
Do not remove the Battery from the Monitor or take off the Garment during a Shock alert. Doing so will prevent the ASSURE system from analyzing your heart rhythm and providing a shock if needed.

Responding to a Shock Alert

Before delivering a shock, the following voice messages play:

- "Preparing to shock. Do not touch the patient."
- "Do not touch the patient."
- "Preparing to shock in 3, 2, 1."

If you notice the Shock alert:

- Press the Alert Button immediately to cancel shock delivery.

  – You are the only person who should press the Alert Button.
  – Pressing the Alert Button cancels the shock.
  – The ASSURE system will confirm the shock was canceled with a voice message and a vibration from the Alert Button.
- Continue to wear the ASSURE system unless a medical professional tells you to remove it.
- Call 911 or seek medical attention if you feel dizzy or unwell.

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If you do not press the Alert Button:

- The ASSURE system will automatically provide a shock, if needed.
- The ASSURE system will instruct anyone nearby to call 911.

Notes:

- *The ASSURE system will not call 911 for you. You or someone nearby must call 911 during Heart alerts.*
- *You are the only one who should press the Alert Button. If you are unconscious, no one should press the Alert Button for you.*

After delivering a shock, the following voice messages play:

- "Shock delivered."
- "Call 911 now. Do not touch the patient."
- "Preparing to shock. Do not touch the patient."

The ASSURE system will continue to analyze your heart rhythm, and it will instruct anyone nearby to call 911.

Notes:

- *The ASSURE system will not call 911 for you. You or someone nearby must call 911 during Heart alerts.*
- *If at any time you hear the Shock alert again, press the Alert Button. If you are unconscious, the ASSURE system will provide up to five shocks, if needed.*
- *The voice messages will repeat as needed.*

After a Shock Alert

- After the Shock alert is over, the following voice messages play:
    - "Call 911 now."
    - "You have received a shock."
    - "Continue to wear your ASSURE system."
- Continue to wear the ASSURE system.
    - It will continue to analyze your heart rhythm.
    - Press the Alert Button if you notice another Shock alert.
    - If you are unconscious, the system will provide additional shocks if needed.
- Call 911 or seek medical attention.
- Your chest area and back will be wet and covered with gel.
    - This gel was released by the Therapy Pads as part of the shock delivery.
    - Leave the gel under the Therapy Pads. Do not wipe off the gel, unless directed by a medical professional.
- You may experience some discomfort or soreness around your chest.
- If the Battery is removed and replaced after a shock has been delivered, the alert will change to a Service Needed alert. Call the ASSURE Helpline at 1.833.692.7787.

5.2.2 Seek Medical Attention Alert

When the ASSURE system detects that you have a dangerously slow heart rhythm, or it can no longer deliver a shock, it issues a SeekMedical Attention alert.

Notes:

- *The ASSURE system cannot treat slow heart rhythms.*
- *The ASSURE system can deliver up to five shocks. If another fast heart rhythm is detected, the ASSURE system will deliver another five shocks, if needed.*

The following voice message plays during this alert: "Call

911 now. Begin CPR if patient is unconscious."

Responding to a Seek Medical Attention Alert

If you notice this alert:

- Press the Alert Button.
    - Pressing the Alert Button quiets the alert.

- Continue to wear the ASSURE system unless a medical professional tells you to remove it.
- Call 911 or seek medical attention if you feel dizzy or unwell.

If you do not press the Alert Button:

- The ASSURE system will instruct anyone nearby to call 911 and begin CPR.

  Note: The ASSURE system will not call 911 for you. You or someone nearby must call 911 during Heart alerts.

After a Seek Medical Attention Alert

- Continue to wear the ASSURE system.
  - It will continue to analyze your heart rhythm.
  - Press your Alert Button if you notice another Seek Medication Attention alert.
- Call 911 or seek medical attention if you feel dizzy or unwell.

  Note: You should also call your doctor to report the event.

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5.3   System Alerts

This section describes the alerts that the ASSURE system uses to let you know there is a problem with the system equipment that you need to fix.

When you receive a System alert, follow these three general steps:

Step 1 - Press the Alert Button

- Press once to quiet the alert.
- Press again to replay the voice message.
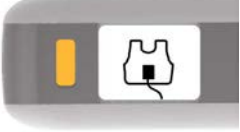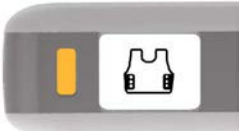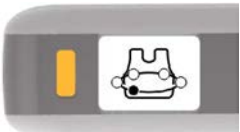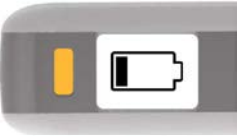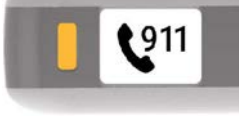
Step 2 - Look at the Monitor screen and light
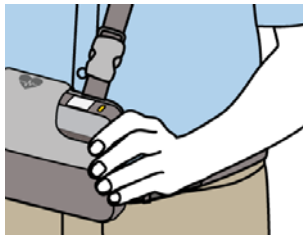
Step 3 - Respond
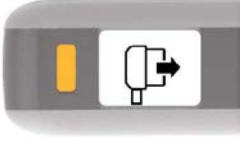
Note: The Put on Garment, Check Sensors, and Check Therapy Pads alerts may correct themselves automatically due to changes in Garment positioning or movement. If this occurs, the ASSURE system will return to normal operation (indicated by the System Ready icon).

Alert Name	Light and Icon	Reference
Connect Plug to Monitor		See page 89.
Connect Hub to Garment		See page 90.
Put on Garment *Note: This alert uses a series of icons. The displayed icon will vary.*		See page 91.
Check Sensors *Note: The displayed icon will vary depending on which sensor has lost contact.*		See page 92.
Check Therapy Pads		See page 94.
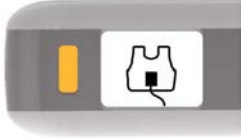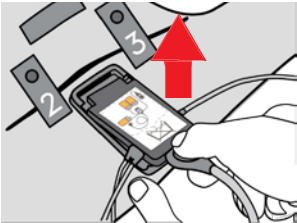
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Alert Name	Light and Icon	Reference
Low Battery		See page 95.
Shock Delivered – Seek Medical Attention		See page 96.
Service Required		Call the ASSURE Helpline at 1.833.692.7787. See page 97.
Service Needed		See page 98.

5.3.1   Connect Plug to Monitor Alert
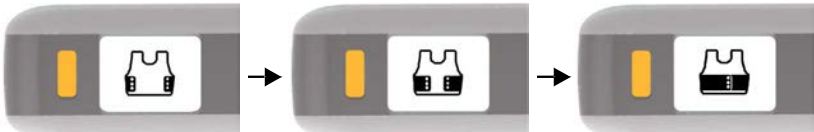
Monitor Icon	
Description	The Plug is not inserted properly into the Monitor.
Voice Message	"Connect the Plug to your Monitor."
Actions	To respond to this alert: **Insert the Plug into the Monitor** If the Plug is already inserted into the Monitor, try re-inserting it: **Step 1 - Press and hold the Monitor's Plug Release button and then remove the Plug from the Monitor** **Step 2 - Insert the Plug back into the Monitor** - A "click" sound means the Plug is securely inserted. *Note: The System Busy icon will appear on the Monitor screen with a yellow Monitor light when the Monitor detects a Plug insertion. This check may take up to a minute to complete.* ⚠️ **WARNING** *If the alert continues to play, remove the Battery from the Monitor and re-insert it to restart the ASSURE system.*

5.3.2 Connect Hub to Garment Alert

Monitor Icon	
Description	The Hub is not properly inserted into the Garment.
Voice Message	"Connect the Hub to your Garment."
Actions	To respond to this alert: **Step 1 - Press the Alert Button** **Step 2 - Insert the Hub into the Garment** If the Hub is already inserted into the back of the Garment, try re-inserting it: **Step 1 - Use both hands to remove the Hub from the Garment** - Press down on the Garment near the bottom of the Hub Receptacle with your thumb. - Pull up on the cable handle at the bottom of the Hub with your other hand. **Step 2 - Insert the Hub back into the Garment** - A "click" sound means the Hub is securely inserted.
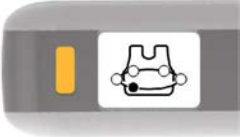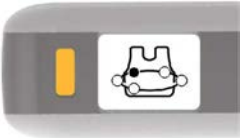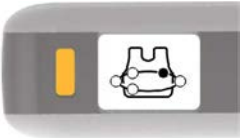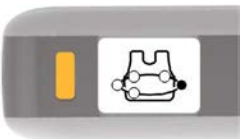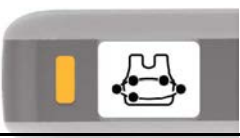
5.3.3   Put on Garment Alert

Note: This alert uses a series of icons. The displayed Monitor screen icon will vary (see the examples below).

Monitor Icons	
Description	You are not wearing the Garment properly.
Voice Message	"Put on your Garment now."
Actions	To respond to this alert: **Step 1 - Press the Alert Button to quiet the alert** **Step 2 - Put on the Garment** If you are already wearing the Garment: - **Check** that the Garment is not twisted, there is nothing under it, and the Therapy Pads are assembled correctly. - **Moisten** the skin under the Sensors with water or lotion.

5.3.4 Check Sensors Alert

Note: The displayed Monitor screen icon will vary depending on which sensor has lost contact (see the examples below).
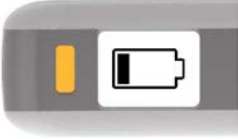
Monitor Icons	
	Right front sensor has lost contact.
	Right back sensor has lost contact.
	Left back sensor has lost contact.
	Left front sensor has lost contact.
	The Right Middle Sensor or multiple Sensors have lost contact, or the ASSURE system cannot sense your heart rhythm.
Description	One or more of the Sensors are not touching bare skin, there is poor skin contact, your skin may be too dry, or the sensors cannot get a clear signal from your heart.
Voice Message	"Adjust your Garment now. The Sensors must touch your skin."

Actions	To respond to this alert:
	Step 1 - Press the Alert Button to quiet the alert
	Step 2 - Try the following actions:
	- **Adjust** the Garment so the Sensors are flat and touching bare skin.
	> The Sensors should be snug around your rib cage, just below your breast area and nipples.
	> Make sure your breasts are not under the front Therapy Pad or Sensors.
	Note: Female patients may wear a bra over the Garment to provide more support.
	- **Check** that the Garment is not twisted and there is nothing under it.
	- **Stop** all movement and count to 10 slowly to allow the system to sense your heart rhythm.
	If the alert continues, try the following:
	- **Moisten** the skin under the Sensors with water or lotion.
	- **Tighten** the Garment by adjusting the front closure snaps and shoulder straps.
	- **Call** the ASSURE Helpline at 1.833.692.7787.

5.3.5 Check Therapy Pads Alert

Monitor Icon	
Description	One or more of the Therapy Pads are not touching bare skin.
Voice Message	"Check the Therapy Pads. The pads must touch your skin."

Actions	To respond to this alert:
	
	Step 1 - Press the Alert Button to quiet the alert
	
	Step 2 - Try the following actions:
	
	- **Confirm** the Therapy Pads are flat and touching bare skin.
	   > The front Therapy Pad should be snug around your rib cage, just below your breast area and nipples.
	   > Make sure your breasts are not under the front Therapy Pad or Sensors.
	- **Check** that the Garment is not twisted and there is nothing under it.
	- **Moisten** the skin under the Therapy Pads with water or lotion.
	- **Change** the front closure snaps and shoulder strap settings for a snug Garment fit. The shoulder straps should be comfortable but not loose.
	- **Verify** the Therapy Pads are correctly inserted and snapped in the pockets.

5.3.6   Low Battery Alert

Monitor Icon	
Description	The Battery has less than two hours of power left. Replace the Battery now.
Voice Message	"Replace your Battery now."
Actions	To respond to this alert: **Step 1 - Press the Alert Button to quiet the alert** **Step 2 - Insert a fully charged Battery into the Monitor** - A "click" sound means the Battery is securely inserted. **Step 3 - When the Alert Button icon appears on the Monitor screen, press the Alert Button** *Note: If a different icon appears on the Monitor screen, there is likely an alert condition on the ASSURE system. You must respond to the alert. See section 5.1, Identifying Alerts, on page 78 for a list of the alert icons.* **Step 4 - Place the used Battery into the Charger** **Step 5 - Check the Charger screen to confirm that the Battery is charging**

5.3.7 Shock Delivered – Seek Medical Attention Alert

Monitor Icon	
Description	You have received a shock and the dangerous heart rhythm is no longer detected.
Voice Message	"Call 911 now. You have received a shock. Continue to wear your ASSURE system."
Actions	- Continue to wear the ASSURE system. - The system will continue to analyze your heart rhythm. - Press your Alert Button if you notice another Shock alert. - If you are unconscious, the system will provide additional shocks if needed. - Call 911 or seek medical attention. *Note: The ASSURE system will not call 911 for you. You or someone nearby must call 911.* - Your chest area and back will be wet and covered with gel. - This gel was released by the Therapy Pads as part of the shock delivery. - Leave the gel under the Therapy Pads. Do not wipe off the gel, unless directed by a medical professional. - You may experience some discomfort or soreness around your chest. - If the Battery is removed and replaced after a shock has been delivered, the alert will change to a Service Needed alert. Call the ASSURE Helpline at 1.833.692.7787.

5.3.8   Service Required Alert

⚠️ **WARNING**

When the Service Required alert is active, the ASSURE system is not operational and cannot protect you. Call the ASSURE Helpline at 1.833.692.7787 immediately for assistance.

Monitor Icon	
Description	There is a problem with the ASSURE system that **requires immediate attention**. Service Required alerts use an "R" error code. *Note: This alert will repeat every five minutes.*
Voice Message	"Call the ASSURE Helpline now. Your device needs service."
Actions	To respond to this alert: **Call the ASSURE Helpline at 1.833.692.7787 immediately** - Provide the ASSURE representative with the error code that appears on the Monitor screen.

5.3.9   Service Needed Alert

Monitor Icon	
Description	There is a problem with the ASSURE system. Service Needed alerts use an "N" error code. The ASSURE system is still operational and can still provide therapy.
Voice Message	"Call the ASSURE Helpline now. Your device needs service. Continue to wear your ASSURE system."
Actions	To respond to this alert: **Step 1 - Press the Alert Button to quiet the alert** **Step 2 - Call the ASSURE Helpline at 1.833.692.7787** - Provide the ASSURE representative with the error code that appears on the Monitor screen. **Step 3 - Continue to wear the ASSURE system**

6. General Care and Cleaning

This section describes how to care for and clean the ASSURE wearable defibrillator (ASSURE system) and its accessories, including:

- Taking off the system
- Removing the Therapy Cable from the Garment
- Assembling and putting on the system
- Washing the Garment
- Cleaning the system
- Checking for equipment damage

6.1 Taking Off the System to Wash the Garment

Notes:

- *Read through the following steps before attempting this task.*
- *If you need additional help, watch the patient video on the Kestra website at kestramedical.com/patients or call the ASSURE Helpline at 1.833.692.7787.*

Step 1 - Open the Carry Pack flaps

Step 2 - Slide the Battery lock until you see the yellow line and lift the Battery handle

Battery Lock   **Battery Handle**

Note: If you need help with this task, see page 144 or watch the patient video at kestramedical.com/patients.

Step 3 - Pull up to remove the Battery from the Monitor

- Removing the Battery turns off the system.
- To avoid setting off alerts, always remove the Battery before taking off the ASSURE system.

Step 4 - Close the Carry Pack flaps
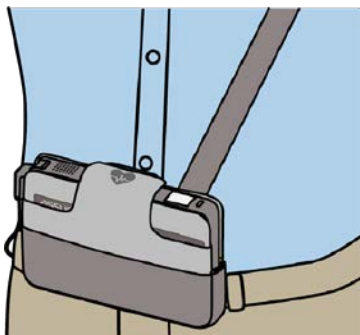
Step 5 - Remove any cable length tucked into the Carry Pack

- The cabling may be inside the Carry Pack pockets or in the elastic corner straps on the back.

Step 6 - Press and hold the Plug Release button on the Monitor

Step 7 - Remove the Plug from the Monitor

Step 8 - Take off the Carry Pack

- Place the Carry Pack on a nearby flat surface to avoid dropping the Monitor.

Step 9 - Remove any clothing above the waist

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Step 10 - Unsnap the front closure

Step 11 - Take off the Garment

6.2   Removing the Therapy Cable from the Garment

Notes:

- *The Therapy Cable is a complete assembly. The cords and cable cannot be removed from the Hub.*
- *Read through the following steps before attempting this task.*
- *If you need additional help, watch the patient video on the Kestra website at kestramedical.com/patients or call the ASSURE Helpline at 1.833.692.7787.*

Step 1 - Take off the Garment and place it on a flat surface, like a table or desk
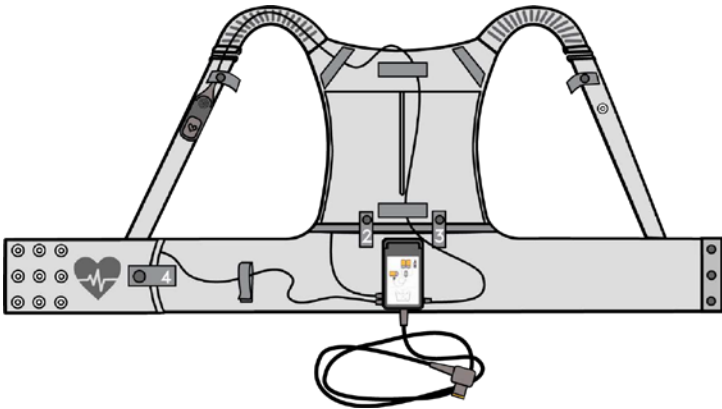
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Step 2 - Open the cord wrap near pocket 4
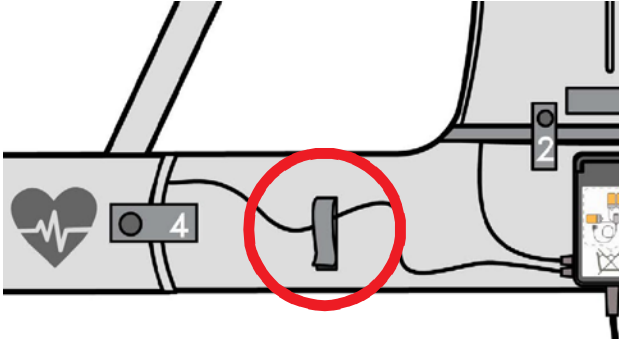
Step 3 - Unsnap and remove the Therapy Pad from pocket 4
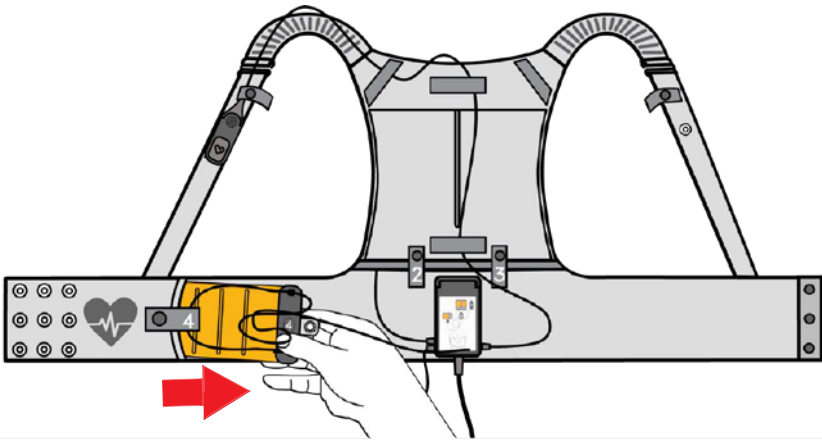
Step 4 - Unsnap and remove the Therapy Pads from pockets 2and 3

Step 5 - Unsnap and remove the Alert Button from theshoulder strap
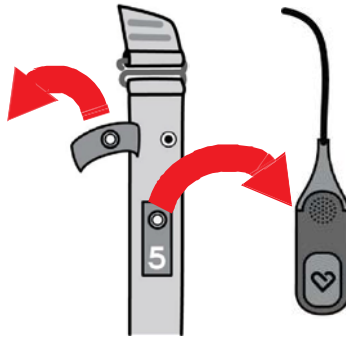
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Step 6 - Gently pull the Alert Button cord through the loops on the back of the Garment until the cord is free

Step 7 - Use both hands to remove the Hub from the Garment

- Press down on the Garment near the bottom of the Hub Receptacle with your thumb.
- Pull up firmly on the cable handle at the bottom of the Hub with your other hand.

6.3   Assembling and Putting on the System

Notes:

- *See chapter 1, Part Descriptions, on page 23 for the names and descriptions of the ASSURE system parts.*
- *Read through the following steps before attempting this task.*
- *If you need additional help, watch the patient video on the Kestra website at kestramedical.com/patients or call the ASSURE Helpline at 1.833.692.7787.*

The ASSURE system comes with two Garments, so you can wash one Garment while continuing to wear the system with the other Garment. Before washing the used Garment, assemble and put on the clean Garment so you will continue to be protected.

Follow these steps to assemble and put on the ASSURE system.

Step 1 - If needed, connect each end of the shoulder strap by inserting the adjustable hook into a slot on the strap

- The shoulder straps should be comfortable but not loose.
- Place any extra shoulder strap length behind the strap (as shown below).

Notes:

- *Additional adjustments to the shoulder strap settings maybe necessary after putting on the Garment.*
- *Make sure the shoulder straps are not twisted when you connect them.*
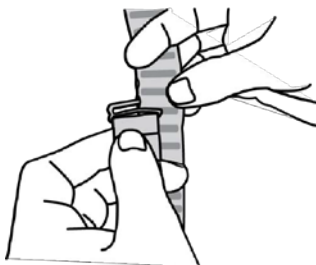
Step 2 - Place the Garment on a flat surface with the numbersfacing up

● Find the hub receptacle (number 1) and snaps (numbers 2-5) on the Garment.
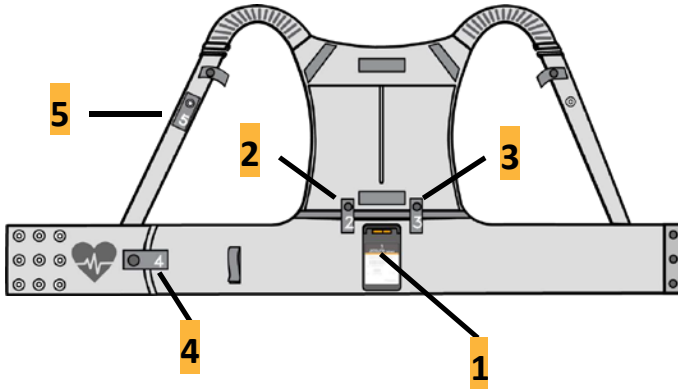
**Step 3 - Lay the Therapy Cable near the Garment with theyellow side of the Therapy Pads facing up**

● Untangle any cords.
● Use the numbers on the Therapy Cable and the Garment to guide you through the assembly process.

Note: The Hub and Alert Button numbers are located on the back.

1
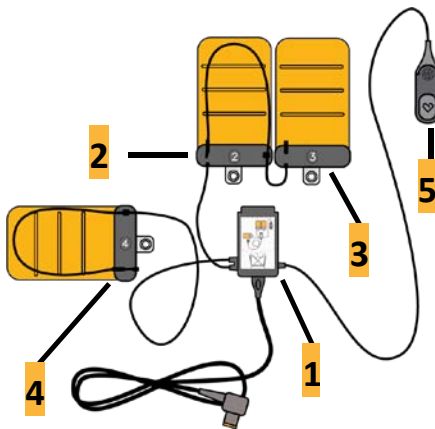
Step 4 - Insert the Hub into the Garment and press down firmly until the Hub clicks into the Hub Receptacle

- Insert the Hub at a slight angle so it fits under the lip of the Hub Receptacle.
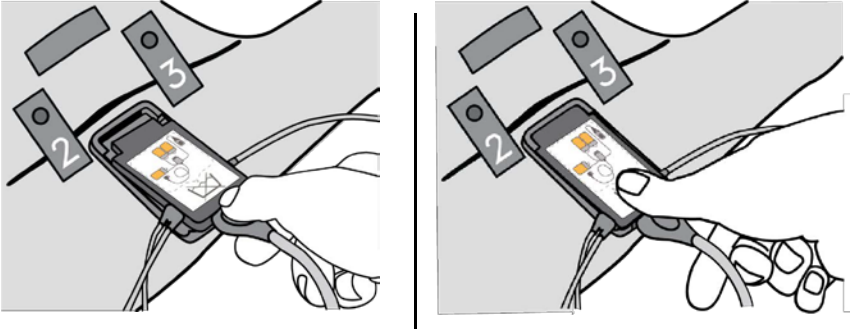
Step 5 - Insert Therapy Pads 2 and 3 into the back pockets

Note: There is a divider between the pockets.

- Make sure the yellow side is facing up.
- Make sure the Therapy Pads are on each side of the divider and completely inside their pockets.

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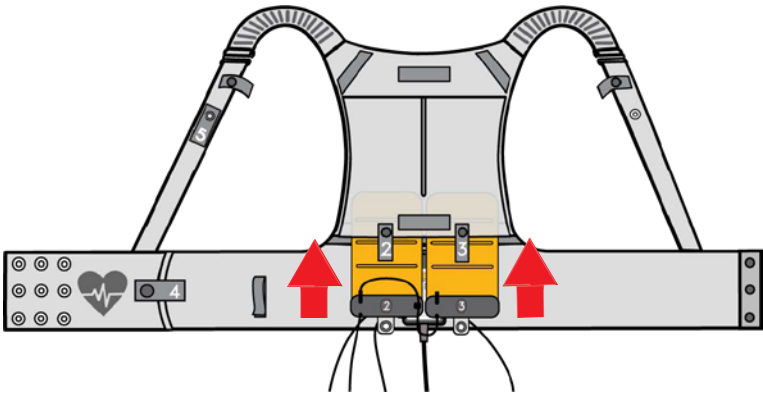
Step 6 - Snap Therapy Pads 2 and 3 to the pocket tabs
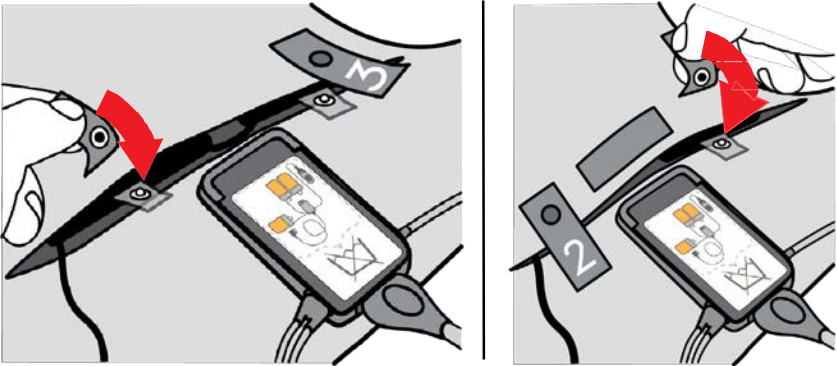
Step 7 - Insert Therapy Pad 4 into the front pocket

- Make sure the yellow side is facing up.
- The loop of cord should lie flat on top of the pad inside pocket 4.
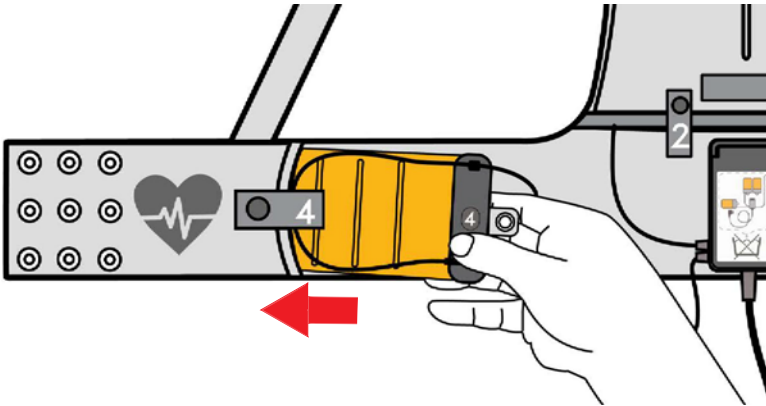
Step 8 - Loop any extra length of cord and place it on top of the pad inside pocket 4
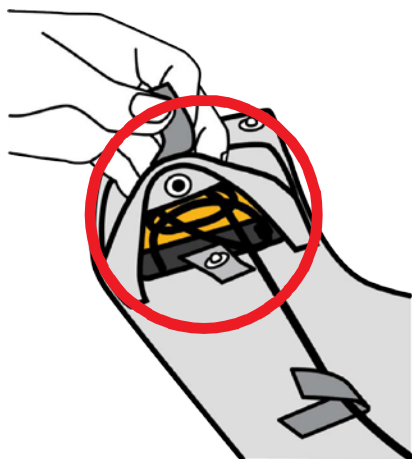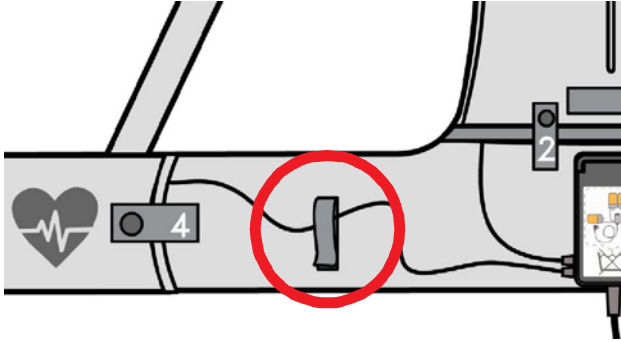

**Step 9 - Snap Therapy Pad 4 to the pocket tab**

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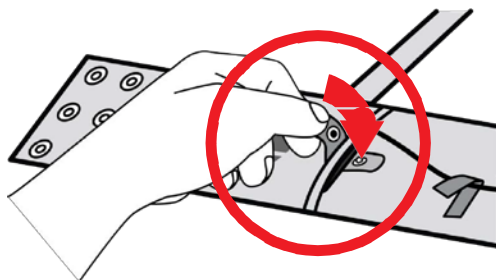
Step 10 - Fasten the cord wrap around the Therapy Pad 4 cord

*Note: If there is extra cord length, open the pocket and repeat steps 8 and 9.*

Step 11 - Pull the Alert Button and cord through the loops on the back of the Garment

a. Thread the Alert Button through the center loops on the back of the Garment (above the Hub Receptacle).

b. Select the left or right side, and then thread the Alert Button through the angled loop for that side.
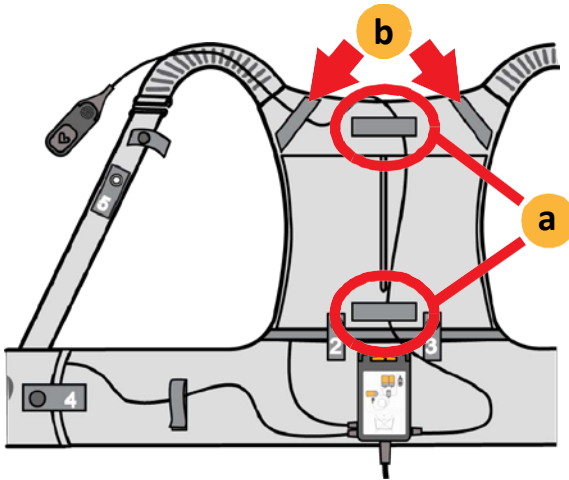
Step 12 - Snap the Alert Button (number 5) to the shoulder strap

Note: The right shoulder strap does not have a label number, but the snap is in the same location as on the left side.
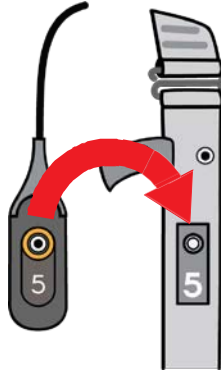

Step 13 - Place the cord wrap over the Alert Button cord and snap it to the shoulder strap

Note: There may be some extra Alert Button cord length after threading the cord through the Garment and fastening it to the shoulder strap properly. This allows for flexibility while wearing the assembled Garment.

The assembled Garment should look like the picture below.
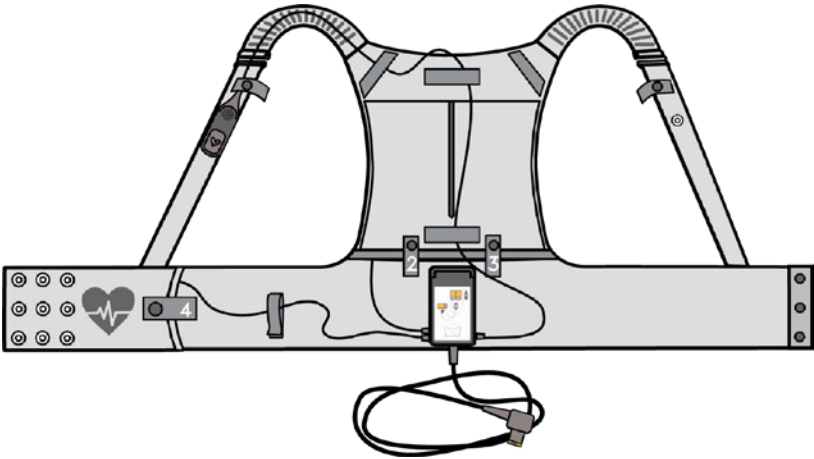
Step 14 - (Optional) Insert a bra pad (provided) into the opening between the fabric layers of each cup in the Style B Garment
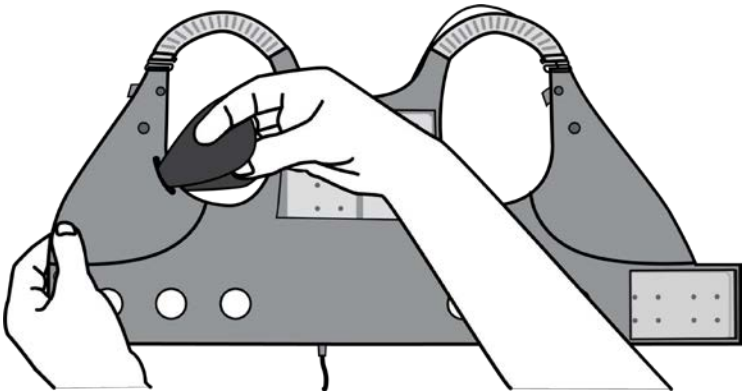
Step 15 - Put on the assembled Garment with the Sensors against bare skin

- Remove all clothing, including bras and undershirts, from your upper body.
- Insert your arms between the shoulder straps and the back of the Garment.
- Pull the straps over your shoulders.
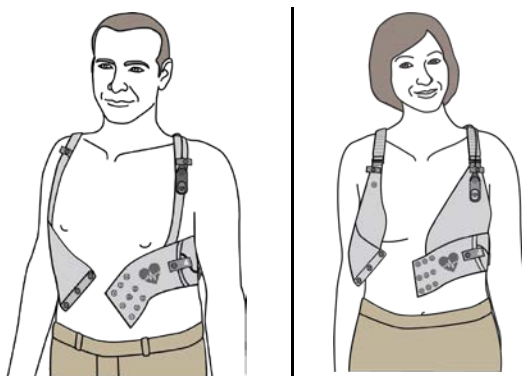
Notes:

- *Always wear the Garment against bare skin.*
- *The Garment contains the following materials:*
  - *Body fabric: 59% Polyamide, 41% Elastane (spandex)*
  - *Inner lining: 73% Polyamide, 27% Elastane*
  - *Therapy Pad pockets: 100% Silver-plated Nylon*

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**Step 16 - Pull the Garment snug around your rib cage and then fasten the front closure snaps**

Note: The Garment must have a snug fit to keep the Sensors in contact with bare skin.
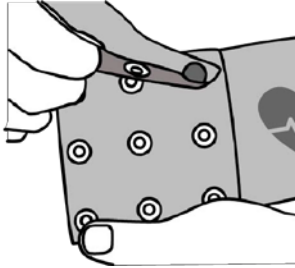
Step 17 - Adjust the shoulder straps to lie flat against the chest and shoulders

- The shoulder straps should be comfortable but not loose.
- Any extra upper strap length should go behind the lower strap (as shown below).

Note: Remove the Garment before adjusting the shoulder straps using the adjustable hooks.
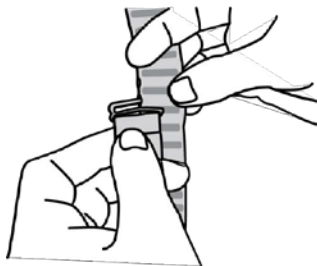
Step 18 - Check the Garment's fit

- The straps should lie flat against the chest and shoulders.
- The Therapy Pads should lie flat against the back.
- Check that the Garment is not twisted around the sides or back. Use a mirror or have another person help check.
- The front Therapy Pad should be snug around your rib cage, below your breast area and nipples but above your stomach.

Note: Make sure your breasts are not underneath the front TherapyPad or Sensors.

Proper Garment Fit

Front   Back

Improper Garment Fit

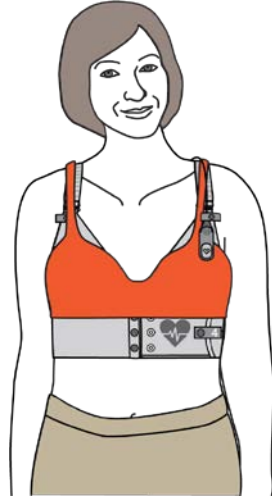Too Low   Too High   Twisted

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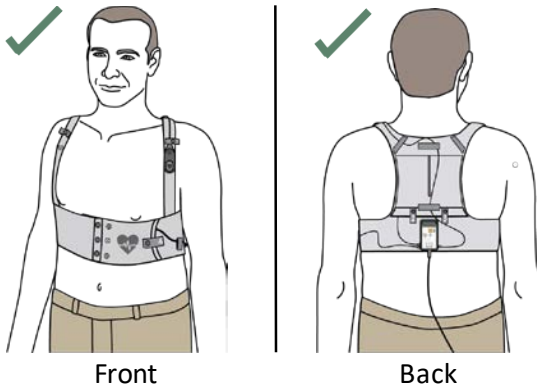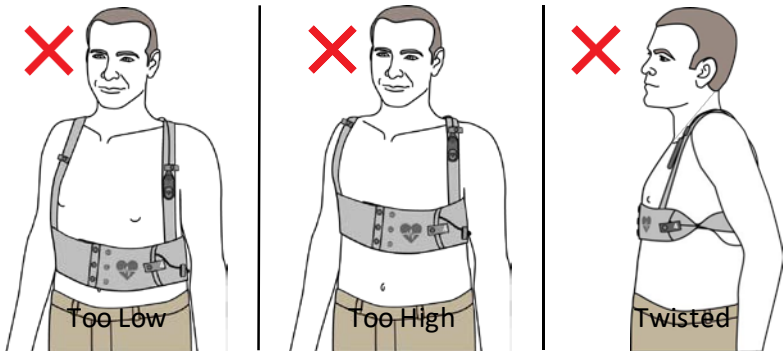
Step 19 - Put on clothes <u>over</u> the Garment

Notes:

- *Do not wear or place anything between the Garment and your body. The Sensors must touch bare skin.*
- *Undershirts and bras may only be worn <u>over</u> the Garment (as shown below).*

Undershirt Over the Garment   Bra Over the Garment

Step 20 - Put on the Carry Pack with the Monitor inside

Note: The inside of the Carry Pack (the side with the belt clip and corner straps) should always face towards your body. This prevents the cable from getting snagged or caught on something.

- See section 3.1.2, Using the Carry Pack, on page 47 for more information on how to wear and use the Carry Pack.
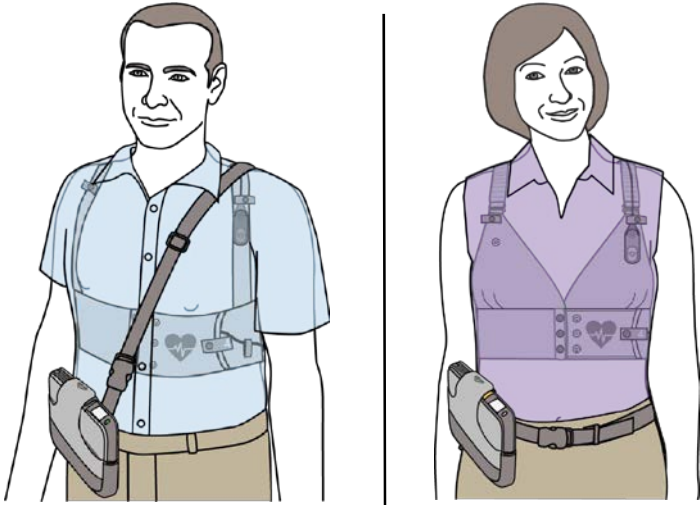
Step 21 - Adjust the Carry Pack strap (if necessary)
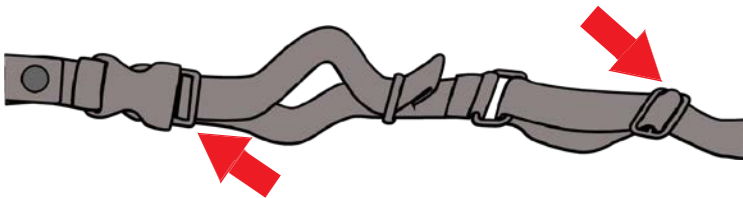
Strap Adjusters

- Slide the adjuster along the strap to lengthen or shorten the strap.

Step 22 - Insert the Plug into the Monitor

- The Plug can be inserted in one direction only.
- A "click" sound means the Plug is securely inserted.

Step 23 - Manage the extra cable length to avoid catching the cable on anything

- Options for managing extra cable length:
    - Use the back corner straps of the Carry Pack.
    - Place it in the Carry Pack pocket.
    - Tuck it into your pants or pocket.
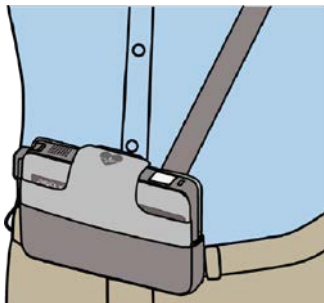
Step 24 - Open the flaps on the Carry Pack

Step 25 - Insert a fully charged Battery into the Monitor

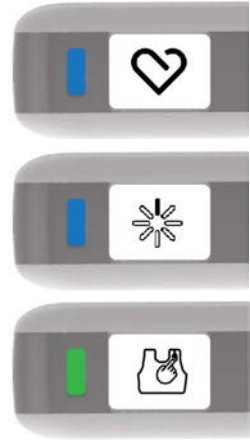- A "click" sound means the Battery is securely inserted.

Step 26 - Close the Carry Pack flaps

Step 27 - Wait a few minutes while the ASSURE system powersup

- The Monitor light turns blue right away and the Monitor screen displays the Welcome icon.

- The System Busy icon then appears.

- Wait for the Alert Button icon to appear on the Monitor screen (this may take a few minutes).

If a different icon appears on the Monitor screen, check the alert icon andrespond to the alert.

- See section 5.1, Identifying Alerts, on page 78 for a list of the alert icons.
- After responding to the alert, the Alert Button icon should appear on the Monitor screen.

Step 28 - Press the Alert Button

Note: If you press the Alert Button and the System Ready icon does not immediately appear on the Monitor screen, call the ASSURE Helpline at 1.833.692.7787. There may be an issue with the Alert Button.

What you will...

See	● Solid green Monitor light
	● System Ready icon on Monitor screen

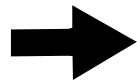| **Hear**	Three-note guitar strum
Feel	Single-pulse vibration from the Alert Button

Note: The green light and the screen backlight turn off after five seconds.

Go to the next page for the Garment washing instructions

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6.4   Washing the Garment

Wash the Garment as needed. The ASSURE system comes with two Garments, so you can wash one Garment while continuing to wear the system with the other Garment.
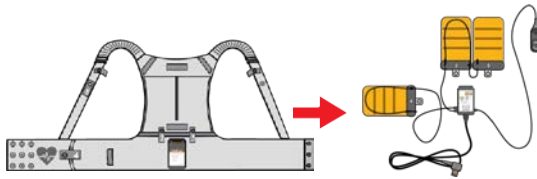
Before washing the Garment:	For instructions
1. Take off the system.	See section 6.1, Taking Off the System to Wash the Garment, on page 100 for instructions.
2. Remove the Therapy Cable from the used Garment.	See section 6.2, Removing the Therapy Cable from the Garment, on page 105 for instructions.
3. Place the Therapy Cable into the clean Garment and put on the system.	See section 6.3, Assembling and Putting on the System, on page 109 for instructions.

Go to the next page

⚠️ **WARNING**

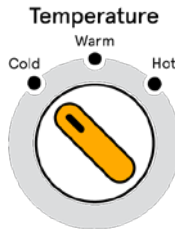*Always remove the Therapy Cable before washing the Garment.*

To wash the Garment:

Step 1 - Place the Garment in the washing machine

> *Notes:*
>
> - *The five round metal Sensors and the Hub receptacle are permanent parts of the Garment and may be washed.*
> - *A laundry bag is provided in the system kit if you want to use it.*

Step 2 - Machine wash in cold water on a gentle cycle

- Use a mild laundry detergent only, such as all® free clear or Tide Free and Gentle™.

  Note: Follow the detergent manufacturer's warnings and cautions listed on the packaging.

- If you prefer, you may hand wash the Garment.

⚠️ **WARNING**

Do not use chlorine bleach, bleach alternatives, fabric softeners, or anti-static sprays. Also, do not use detergents or detergent "pods" that include bleach or fabric softener additives.

Step 3 - Hang the Garment or place it on a flat surface to airdry

- Make sure that the Garment is dry before using it.
- Do not dry clean or iron the Garment.
- Do not dry the Garment in a clothes dryer, microwave oven, or any other oven.
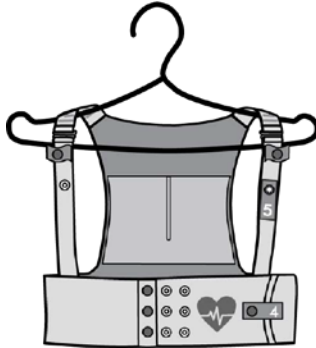
6.5   Cleaning the ASSURE System

The Garment has specific cleaning instructions, see section 6.4, Washing the Garment, on page 126.

In general, the ASSURE system parts and accessories do not require maintenance, other than cleaning as needed. If there appears to be any damage or if you have any concerns about the equipment, call the ASSURE Helpline at 1.833.692.7787.

⚠️ **WARNING**

Do not place the Monitor, Therapy Cable, Batteries, or Charger in water or any other liquids. Avoid spilling any liquids on these devices. Liquids entering these devices may cause them to malfunction or fail.

To clean the equipment:

Step 1 - Gently wipe the equipment with a clean, soft cloth dampened slightly with water only

Step 2 - Use a separate dry, soft cloth to dry the equipment before using it

Notes:

- *Avoid wiping the Hub connectors and pins.*
- *Do not allow any liquid or moisture to remain on the equipment or its connectors and pins after cleaning.*
- *Do not dry clean the Carry Pack.*
- *Do not dry the Carry Pack in a clothes dryer, microwave oven, or any other oven.*

6.6 Checking for Equipment Damage

You should check the ASSURE system for any wear or damage once or twice a week.

Some examples of potential damage or improper use include:

- Gel leaking from the Therapy Pads (see below)
- Sensors peeling off from the Garment (see below)
- Worn cables or cords
- Cracked or broken Monitor case
- Broken snaps on Garment
- Tamper-evident seal on Monitor (below the Plug Receptacle) shows "VOID" and "KESTRA" markings

If there appears to be any damage or if you have any concerns about the equipment, call the ASSURE Helpline at 1.833.692.7787.
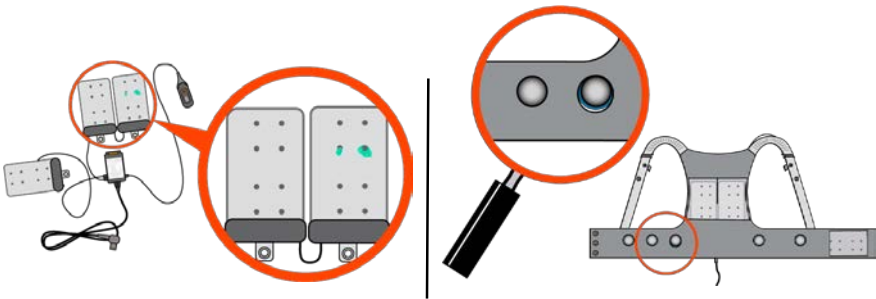
Examples of Potential Damage to the ASSURE System

7. Help

This section provides help with wearing and using the ASSURE wearable defibrillator (ASSURE system).
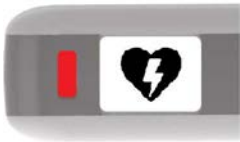
The following information is available:

- Alerts quick reference chart
- System status icon descriptions
- Frequently-Asked Questions (FAQs)

If you need help, call the ASSURE Helpline at 1.833.692.7787.

7.1 Alerts Quick Reference

Alert Icon	Actions
Heart Alerts	
	If you notice this alert: ● Press the Alert Button to cancel shock delivery. ● Continue to wear the system unless a medical professional tells you to remove it. ● Call 911 or seek medical attention if you feel dizzy or unwell. **If you do not press the Alert Button:** ● The ASSURE system will automatically provide a shock, if needed. ● The ASSURE system will instruct anyone nearby to call 911. *Note: The ASSURE system will not call 911 for you. You or someone nearby must call 911 during Heart alerts.* See "Shock Alert" on page 80 for more information.

| Alert Icon	Actions
Heart Alerts	

If you notice this alert:

- Press the Alert Button.
- Continue to wear the system unless a medical professional tells you to remove it.
- Call 911 or seek medical attention if you feel dizzy or unwell.

If you do not press the Alert Button:

- The ASSURE system will instruct anyone nearby to call 911 and begin CPR.

  Note: The ASSURE system will not call 911 for you. You or someone nearby must call 911 during Heart alerts.

See "Seek Medical Attention Alert" on page 84 for more information.
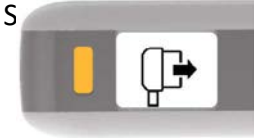
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Insert the Plug into the Monitor.
- or -
**Remove** the Plug from the Monitor and then re-insert it.

⚠️ **WARNING**

If the alert continues to play, remove the Battery from the Monitor and re-insert it to restart the ASSURE system.

See "Connect Plug to Monitor Alert" on page 89 for more information.

Note: The System Busy icon will appear on the Monitor screen with a yellow Monitor light when the Monitor detects a Plug insertion. This check may take up to a minute to complete.

Press the Alert Button to quiet the alert.
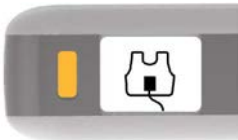
Then try the following:
- **Insert** the Hub into the Garment.
- **Remove** the Hub from the Garment and then re-insert it.

See "Connect Hub to Garment Alert" on page 90 for more information.

Press the Alert Button to quiet the alert.
Then try the following:

- **Put on** the Garment.
- **Check** that the Garment is not twisted, there is nothing under it, and the Therapy Pads are assembled correctly.
- **Moisten** the skin under the Sensors and Therapy Pads with water or lotion.

See "Put on Garment Alert" on page 91 for more information.

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System Alerts

Press the Alert Button to quiet the alert.

Then try the following:

- **Adjust** the Garment so the Sensors are flat and touching bare skin.
- **Check** that the Garment is not twisted, there is nothing under it, and the Therapy Pads are assembled correctly.
- **Stop** all movement and count to 10 slowly to allow the system to sense your heart rhythm.
- **Moisten** the skin under the Sensors with water or lotion.
- **Tighten** the Garment by adjusting the front closure snaps and shoulder straps.
- **Call** the ASSURE Helpline at 1.833.692.7787.
- See "Check Sensors Alert" on page 92 for more information.

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Press the Alert Button to quiet the alert.
Then try the following:

- **Confirm** the Therapy Pads are flat and touching bare skin.
- **Check** that the Garment is not twisted and there is nothing under it.
- **Moisten** the skin under the Therapy Pads with water or lotion.
- **Change** the front closure snaps and shoulder strap settings for a snug Garment fit. The shoulder straps should be comfortable but not loose.
- **Verify** the Therapy Pads are correctly inserted and snapped in the pockets.

See "Check Therapy Pads Alert" on page 94 for more information.
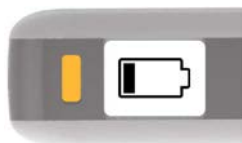
Press the Alert Button to quiet the alert.

Insert a fully charged Battery into the Monitor.

See "Low Battery Alert" on page 95 for more information.

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Press the Alert Button to quiet the alert.
Then do the following:
- **Call 911** or seek medical attention.
  *Note: The ASSURE system will not call 911
  for you. You or someone nearby must call
  911 during Heart alerts.*
- Continue to wear the ASSURE system.

See "Shock Delivered – Seek Medical Attention
Alert" on page 96 for more information.

- **Call** the ASSURE Helpline at 1.833.692.7787
  immediately.
- **Provide the error code** that appears on the
  Monitor screen to the ASSURE representative.

See "Service Required Alert" on page 97 for
more information.

⚠️ **WARNING**
*When the Service
Required alert is
active, the system is
not operational and
cannot protect you.*

Press the Alert Button to quiet the alert.
- **Call** the ASSURE Helpline at 1.833.692.7787.
- **Provide the error code** that appears on the
  Monitor screen to the ASSURE representative.
- Continue to wear the ASSURE system.

See "Service Needed Alert" on page 98 for
more information.

7.2   System Status Icons

	### 7.2.1 System Welcome
Description	The Battery has been inserted into the Monitor to turn on the ASSURE system.
Notifications	● Blue Monitor light ● Icon displayed on the Monitor screen
Action	Wait for the System Busy icon to appear on the Monitor screen.

	### 7.2.2 System Busy
Description	The ASSURE system is powering up.
Notifications	● Blue Monitor light ● Icon displayed on the Monitor screen
Action	Wait for the Alert Button icon to appear on the Monitor screen (this may take a few minutes). See section 7.2.3, Alert Button, on page 141. *Notes:* ● *If the System Busy icon displays for more than five minutes, try re-inserting the Battery into the Monitor. If this does not work, call the ASSURE Helpline at 1.833.692.7787.* ● *The System Busy icon will appear on the Monitor screen with a yellow Monitor light when the Monitor detects a Plug insertion. This check may take up to a minute to complete.*

	### 7.2.3 Alert Button
Description	The ASSURE system has finished powering up and is operational. Press the Alert Button to confirm it is operating properly.
Notifications	● Blinking, green Monitor light ● Icon displayed on the Monitor screen ● Single-pulse vibration from the Alert Button ● Voice message stating, "Press your Alert Button now."
Actions	**Press the Alert Button** After pressing the Alert Button, the System Ready icon appears on the Monitor screen. See section 7.2.4, System Ready, on page 142.

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	7.2.4 System Ready
Description	The ASSURE system is working properly (normal operating mode).
Notifications	● Green Monitor light *Note: The light turns on for the first five seconds and then turns off.* ● Icon displayed on the Monitor screen ● Single-pulse vibration from the Alert Button ● Three-note guitar strum
Action	None. You can press the Alert Button to check the system status at any time.

7.3   Frequently-Asked Questions

Where can I get help with the ASSURE system?

If you have any questions or need help related to the ASSURE system, call the ASSURE Helpline at 1.833.692.7787.

You can also watch the patient video on the Kestra website at kestramedical.com/patients.

What can I do if I experience discomfort while wearing the ASSURE system?

- Try adjusting the Garment or Carry Pack to improve comfort and fit.
- Check for any skin issues underneath the Garment, like redness, bumps, inflammation, irritation, skin breakdown, blistering, or a cut.

Notes:

- *The Garment contains the following materials:*
  - *Body fabric: 59% Polyamide, 41% Elastane (spandex)*
  - *Inner lining: 73% Polyamide, 27% Elastane*
  - *Therapy Pad pockets: 100% Silver-plated Nylon*
- *The Carry Pack is 100% Polyester and the strap is 100% Nylon.*

If you still have a problem or if you need to report a skin issue:

- Continue to wear the ASSURE system.
- Call your doctor.

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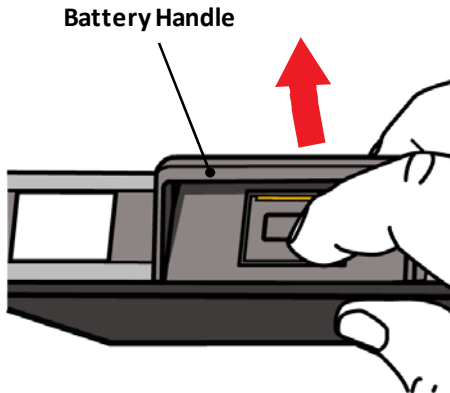## How do I remove the Battery from the Monitor?

The Battery includes a lock on the top that locks the battery into the Monitor to avoid accidentally removing the Battery. If you are having issues with removing the Battery from the Monitor, try following the instructions below.

Note: When removing the Battery from the Monitor, it is important to remember to perform the following steps at the same time.

1. Slide the Battery lock until you see the yellow line.
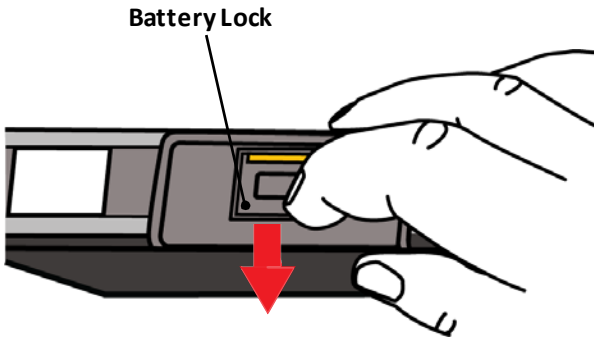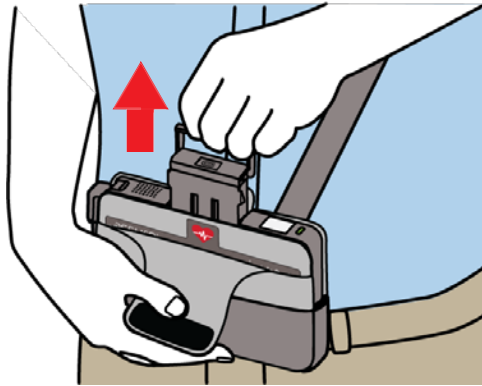

2. With the Battery unlocked (yellow line is shown), lift the Battery handle.

3. Pull up to remove the Battery from the Monitor.

Note: If you still need help, watch the patient video at kestramedical.com/patients or call the ASSURE Helpline at 1.833.692.7787.

What should I do if the Charger does not charge the Battery?

When you insert a Battery into the Charger, the Charger screen will display its status. See section 4.2.1, Viewing the Charger Screen, on page 66 for an explanation of what the different screens mean.

You can also check the following:

- The Charger is plugged into an electrical wall outlet.
- The Charger cord is plugged into the back of the Charger.
- The Battery is properly inserted into the Charger.

What does the symbol on the Monitor screen mean?

When you insert the Battery into the Monitor to turn on the ASSURE system, the System Welcome icon appears on the Monitor screen.

After a few seconds, the System Busy icon appears on the screen.
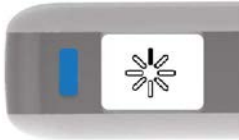
The System Busy icon can appear for a few minutes while the system is powering up.

> *Note: If the System Busy icon displays for more than five minutes, try re-inserting the Battery into the Monitor. If this does not work, call the ASSURE Helpline at 1.833.692.7787.*

After the system is operational, the Alert Button icon appears. Press the Alert button to confirm that the Alert Button is working properly.

When the ASSURE system is working properly, the System Ready icon appears on the Monitor screen.

An alert icon appears on the Monitor screen when the system needs your attention. Use the reference charts at the beginning of this chapter (see page 132) to identify the alert and what actions you can take.

How do I disconnect the cable from the Monitor?

The Plug is designed to not come out of the Monitor easily. To remove the Plug from the Monitor, follow these steps:

1. Press and hold down the Monitor's Plug Release button.
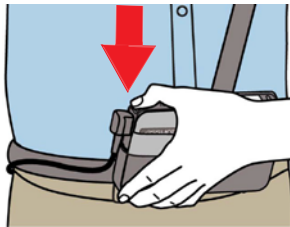
2. Remove the Plug from the Monitor.

What should I do if the ASSURE system does not turn on when I insert the Battery?

- Make sure the Battery is properly seated in the Monitor. When you insert the Battery, you should hear a "click" sound. This means the Battery is securely inserted.
- Make sure the Battery you are using is fully charged. Place the Battery into the Charger to check its current charge status. See section 4.2.1, Viewing the Charger Screen, on page 66 for more information.
- Try inserting the spare Battery into the Monitor. If the spare Battery works, place the other Battery in the Charger to check its status.

What should I do if the Connect Plug to Monitor alert keeps playing after removing and re-inserting the Plug into the Monitor while the ASSURE system is on?

- Remove the Battery from the Monitor and then re-insert it to restart the ASSURE system.

What should I take with me when I travel, or when I will be away from home for more than 24 hours?

If you will be away from home for longer than 24 hours, take the spare, fully charged Battery and Charger with you.

How do I clean the ASSURE system?

Other than washing the Garment, you should not have to clean the ASSURE system very often.

See chapter 6, General Care and Cleaning, on page 99 for more information.

8. Symbols Glossary

This section defines the symbols used on the ASSURE wearable defibrillator (ASSURE system) and Charger labels and packaging.

Symbol	Description and Reference Document
	Consult instructions for use. IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 1641
	Follow the instructions for use IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol ISO 7010-M002
	Do not dispose of in fire. IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries. Symbol C
	Do not deform or damage. IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries. Symbol B
	Do not open or dismantle. IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries. Symbol H
	MR unsafe – Keep away from magnetic resonance imaging (MRI) equipment IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 62570-7.3.3
	Recommended storage temperature (from low to high) IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 0632
	Battery ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 5001B

Symbol	Description and Reference Document
	Do not wash. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3123
	Wash in cold or mildly warm water with a maximum temperature of 104°F (40°C) on a gentle or delicate setting. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3089
	Do not use bleach. ASTM D5489-14, Standard Guide for Care Symbols for Care Instructions on Textile Products.
	Do not iron. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3113
	Do not dry clean. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3114
	Do not tumble dry. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3109
	Manufacturer IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 3082
	Date of manufacture: YYYY-MM-DD IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2497

Symbol	Description and Reference Document
IPxx	Enclosure ingress protection code IEC 60529, Degrees of protection provided by enclosures (IP Code)
Type BF applied part symbol	Type BF applied part IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 5333
!USA Rx Only	For USA audiences only 21 CFR 801.109, Labeling: Prescription Devices
SN	Serial number IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2498
REF	Catalogue number IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2493
LOT	Batch code IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2492
Rechargeable battery symbol	Rechargeable battery IEC 60417, Graphical symbols for use on equipment. Symbol 5639
cULus mark	Recognized component mark for Canada and the United States.
USB symbol	USB port ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3650

Symbol	Description and Reference Document
	Charger power port IEC 60417, Graphical symbols for use on equipment. Symbol 5031
	Lock ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 1656
	Unlock ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3305
	Wireless charging No applicable standard
	Class II equipment IEC 60417, Graphical symbols for use on equipment. Symbol 5172
	Input IEC 60417, Graphical symbols for use on equipment. Symbol 5034
	Output IEC 60417, Graphical symbols for use on equipment. Symbol 5035
	Rated power output, direct current IEC 60417, Graphical symbols for use on equipment. Symbol 6048
	Polarity of Direct Current Power Connector IEC 60417, Graphical symbols for use on equipment. Symbol 5926

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Symbol	Description and Reference Document
	Do not use this device in a bathtub, shower or water-filled reservoir. ISO 7010, Graphical symbols – Safety colours and safety signs – Registered safety signs. Symbol P026
	Recognized UL Classification Marking for Canada and the United States.
	Recognized safety certification mark for the United States.

9. Technical Information

This section is provided in compliance with European standards. The following information is provided:

- Technical specifications
- Voice prompts
- Electromagnetic Compatibility (EMC) compliance

9.1   Specifications

This section provides technical specifications and performance characteristics for the ASSURE system.

All specifications are at 68°F (20°C) unless otherwise stated.

9.1.1   ASSURE System

Item	Detail
Classification	Internally powered equipment per IEC 60601-1 (Group 1, Class B per IEC 60601-1-2), transportable, body-worn, infrequent use AED
Electrical Protection	Therapy Pads are type BF applied parts. ECG electrodes are type CF applied partsper IEC 60601-2-4.
Operation Mode	Continuous; automatic detection and treatment of dangerously fast heart rhythms, automatic detection of dangerously slow heart rhythms, collectionof patient data and current system status
Accessible Parts (per IEC 60601-1)	Monitor's Plug Receptacle Hub Connector
Communications	Near Field Communication (NFC) 13.56 MHz RFID, ASK Modulation, 124 dBuV/m, 0.12 in (3 mm) communication range 802.11 wireless networking
System Temperature Range: Operating	32°F to 122°F (0°C to 50°C) *Note: The Garment, which is worn directly on the skin, operates to a maximum of 105.8°F (41°C). The Garment does not generate additional heat. When the Garment is on the body, the Sensors will notexceed skin temperature.*
Relative Humidity	5 to 95% (non-condensing)
Operating Altitude	-1253 to 9878 feet (-382 to 3011 meters) above sea level 700 to 1060 hPa (atmospheric pressure)
System Temperature Range: Storage and Transport	-4°F to 122°F (-20 to 50°C)
Liquid and Solid Ingress (per IEC 60529)	IP22 (Monitor and Therapy Cable)
Monitor Weight (including Battery)	1.8 lb (0.82 kg)

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Item	Detail
Part Numbers	Garment (Style A) – 80015
	Garment (Style B) – 80016
	Monitor – 80008
	Therapy Cable – 80004
	Carry Pack – 3326502

9.1.2   Battery

Item	Detail
Classification	Secondary rechargeable battery per IEC 62133
Type	Single Lithium Ion rechargeable battery
Voltage	Typical: 10.8 V
	Operating Range: 7.5 V – 12.6 V
Capacity	3.2 Ah, 34.5 Wh rated capacity
Temperature Range: Operating	32°F to 131°F (0°C to 55°C)
Temperature Range: Charging	32°F to 113°F (0°C to 45°C)
Relative Humidity	5 to 95% (non-condensing)
Operating Altitude	-1253 to 9878 feet (-382 to 3011 meters) above sea level
	700 to 1060 hPa (atmospheric pressure)
Liquid and Solid Ingress (per IEC 60529) IP55	
Part Number	3322882

9.1.3 Charger

Item	Detail
Classification	Class II ME Equipment per IEC 60601-1, Portable, Continuous Operation (CISPR 11 Group 1, Class B per IEC 60601-1-2), Type BF applied part
Charging Capacity	One Lithium Ion battery with up to a 2 A charge current in the Battery slot.
Battery Charge Time (from empty to fully charged)	Approximately 4 hours
Power Supply	Delta MDS-060BAS19 A 15-20 VDC, Class II
Wireless Charging	Power output: 5W Wireless charging well - maximum device dimensions including case: Height: 6.3 in (160.02 mm) Width: 3.33 in (84.58 mm) Depth: 0.49 in (12.45 mm)
USB Dedicated Charging Port	USB 2.0 Standard Type A Output voltage and current: 5VDC at 1.5A
AC Adapter	Class II, Line Voltage 100-240V AC, 50-60Hz
Power Jack Diameter and Polarity	Diameter 2.1mm or 2.5mm Support for up to 3A output current to Charger
UL Rating	94-V0
Liquid and Solid Ingress (per IEC 60529)	IP2
Temperature Range: Operating	32°F to 113°F (0°C to 45°C)
Temperature Range: Storage and Transport	-4°F to 122°F (-20 to 50°C)
Operating Humidity	15 to 90% non-condensing
Operating Altitude	-1253 to 9878 feet (-382 to 3011 meters) above sea level 700 to 1060 hPa (atmospheric pressure)
Part Numbers	Charger – 3326633 AC Adapter – 3337063 Power Cord – 3336093

9.1.4 Alerts

Item	Detail

Audible Notifications	Alert notifications may include audio tones and instructions.
	Alert notifications and tones play through the Monitor and Alert Button speakers.
	
	  - Heart alert tone volume range is 70 ±5 dBA.
	  - System alert tone volume range is 58 ±5 dBA.
	The time between first notification and instructions is approximately six seconds.
	
	Alert volume is non-adjustable.
	
	The tone assignments for each type of alert include:
	  - The Heart alert tone is used to indicate that there is a rhythm issue with the patient. The tone is 2 low-high chords repeated twice a second.
	  - The System alert tone is used to indicate that there is an equipment or system issue. The tone is a single chord played twice at a low volume, then automatically repeated at a slightly increased volume with a total play time of 2.45 seconds for the set of paired chords.

Vibration Notifications	Alerts are indicated by a vibration through the Alert Button.

Visual Notifications	Alerts are indicated by an alert icon on the Monitor screen and the color of the Monitor light.
	
	  - Heart alerts display a flashing red Monitor light and an alert icon on the Monitor screen.
	  - System alerts display a blinking yellow Monitor light and an alert icon on the Monitor screen.

	- Heart alerts – Four gentle pulses followed by an intense, triple-buzz vibration from the Alert Button. - System alerts – Triple-pulse vibration from the Alert Button.

Item	Detail
System Alert Detection Delays	The following System alerts have a delay time to allow the system to confirm the alert condition before notifying the patient. - Check Sensors alert (1–15 minutes) - Check Therapy Pads alert (15 minutes) *Note: The time between the first detection and instructions is approximately six seconds.*
System Alert Replay Delays	If a System alert is not silenced, there is a delay time before the System alert is replayed ranging from 30 seconds to 30 minutes depending on the specific alert.
System Alert Silence Delays	If the System alert is silenced, there is a delay time before the System alert is replayed ranging from 5 minutes to 30 minutes depending on the specific alert.
Alert and System Status Priorities	The lists below show the priorities from highest (1) to lowest. 1. Service Required alert 2. Check Sensors alert (with a 1–2-minute delay) 3. Shock and Seek Medical Attention alerts 4. Check Therapy Pads alert 5. Low Battery alert 6. Check Sensors alert (with a 15-minute delay) 7. Shock Delivered – Seek Medical Attention alert 8. Service Needed alert

9.1.5 Detection

Note: This section provides information regarding the ASSURE detection algorithm's performance and test methods per IEC 60601-2-4.

Item	Detail
Detection	The ASSURE detection algorithm uses ECG signals to analyze the rhythm and to detect shockable rhythms (ventricular tachycardia and ventricular fibrillation).
	Note: The default VT rate threshold is 170 BPM.
	The ASSURE detection algorithm automatically initiates analysis without requiring any input from the patient.

Performance of the ASSURE detection algorithm has been evaluated using a Test Dataset of electrocardiogram (ECG) segments. The Test Dataset was adjudicated by cardiac electrophysiology experts using manual methods to determine the heart rate. The Test Dataset includes a total of 1,287 ECG segments from a variety of sources. Each ECG segment is at least 6 seconds in duration. Sources for the Test Dataset include:

- Prospective data collection from electrophysiology (EP) labs using a commercial data acquisition system and standard adhesive electrodes placed in ASSURE ECG lead locations
- University of Alabama Birmingham Medical Center EP Lab 12-lead ECG recordings
- Los Angeles Fire Department LIFEPAK12 and LIFEPAK15 12-lead ECG recordings
- Resuscitation Outcomes Consortium (ROC) single-lead ECG recordings
- A series of single-lead ECG recordings gathered from emergency medical services with locations in North America and Europe in which patients were treated with a LIFEPAK 1000 or a LIFEPAK 12
- Amsterdam emergency medical services spontaneous VF single-lead ECG recordings

The ASSURE detection algorithm's performance meets or exceeds the American Heart Association (AHA) recommendations for performance as required by IEC 60601-2-4.

Rhythm Classification	Min. Sample Size	Test Sample Size	Performance Goal	Observed Performance[1]
Shockable Rhythm: Coarse VF[2]	200	211	>90% sensitivity	Met
Shockable Rhythm: Rapid VT[3]	50	107	>90% sensitivity	Met
Non-Shockable Rhythm: Normal Sinus Rhythm (NSR)[4]	100	248	>99% specificity	Met
Non-Shockable AF, Sinus Bradycardia, SVT, Heart Block, idioventricular, PVCs Rhythm:	30	397	>95% specificity	Met
Non-Shockable Asystole[5]	100	117	>95% specificity	Met
Intermediate Rhythm: Fine VF[6]	25	28	Report Only	> 74% sensitivity
Intermediate Rhythm: Other VT[7]	25	37	Report Only	> 89% sensitivity
Slow VT[8]	-	142	Report Only	> 97% specificity

Overall Test Results

Sensitivity			>90% sensitivity	Met
Specificity			>95% specificity	Met
Positive Predictive Value			- Report Only	> 93%
False Positive Rate			Report Only	< 3%

1. ASSURE system nominal therapy zone settings (VT 170 bpm, VF 200 bpm)

without consistently identifiable QRS complexes

3. Ventricular rhythm (Monomorphic/Polymorphic/Pleomorphic VT) adjudicated heart rate > 187 bpm (nominal VT rate threshold + 10%)

4. Heart rate > 60 bpm and < 100 bpm, and p-waves consistent with sino-atrial origin

5. Rhythms with peak-to-peak amplitude < 75 μV
6. Disorganized ventricular rhythm with a peak-to-peak amplitude ≥ 100 μV and ≤ 200 μV
7. Ventricular rhythm (Monomorphic/Polymorphic/Pleomorphic VT) adjudicated heart rate ≥ 170 bpm (nominal VT rate threshold) and ≤ 187 bpm (nominal VT rate threshold + 10%)
8. Ventricular rhythm (Monomorphic/Polymorphic/Pleomorphic VT) adjudicated heart rate < 170 bpm (nominal VT rate threshold)

Notes:

- *American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Efficacy. "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety." Circulation 95, no. 6 (1997): 1677–82.*
- *The studies and data cited above are the result of extremely challenging rhythms that deliberately test the limits of AEDs. Clinically, the actual sensitivity and specificity may be equal or better.*

9.1.6 Defibrillation

Note: This section provides information regarding defibrillation per IEC 60601-2-4.

Item	Detail
Shock Waveform	A Biphasic Truncated Exponential (BTE) waveform that provides synchronous cardioversion defibrillation therapy.
Device Capacity	With a new Battery: - Provides up to 25 170J defibrillation shocks (per IEC 60601-2-4 for an infrequent use AED) or at least 24 hours of operation time. At a Low Battery alert indication: - Provides three 170J defibrillation shocks or two hours of operation time.
Shock Ready Time	There is a delay of approximately 20 seconds from the Shock alert notification to the actual shock delivery. This allows time for the patient to press the Alert Button to divert the shock. If rate recovery or a non-shockable rhythm occurs after the initial Shock alert notification, the system will cancel the shock sequence and issue a "No shock needed" message within 30 seconds.
Maximum Charging Time After Shocks	Within 20 seconds6
Maximum Time from Initiation of Rhythm Analysis to Readiness for Discharge After6 Shocks	Within 35 seconds
VF Shock Delivery Time	A shock is delivered within approximately 40 seconds of the onset of VF, unless a conscious patient diverts therapy by pressing the Alert Button or the rhythm returns to normal.
VT Shock Delivery Time	A shock is delivered within approximately 80 seconds of the onset of VT, unless a conscious patient diverts therapy by pressing the Alert Button or the rhythm returns to normal.

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Item	Detail
Shock Energy Output and Accuracy	The shock energy output is 170 joules (non-configurable). The energy accuracy for shock energy delivered into a 50Ω resistor is equal to 170 joules ± 8%.
Impedance at which the shock is not delivered	A shock is delivered regardless of the impedance reading.

The complete ASSURE system biphasic waveform is shown below.
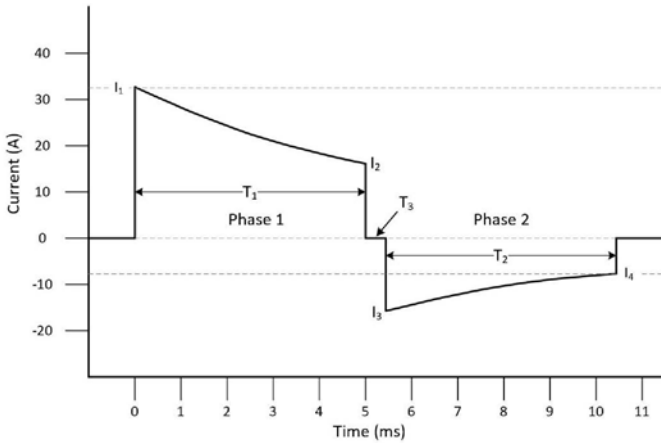
Current flow is maintained during phase 1 for a time T1, after which there is a short 400µS pause between phases (T3). Current flow is then reversed for phase 2.

The peak current (I1) is determined by the charge voltage/patient resistance.

The phase durations (T1 and T2) are microprocessor-controlled and are adjusted based on the patient impedance. Patient impedance is derived from the rate of decay of the capacitor voltage.

The waveform "tilt" is a measure of the amount the capacitor voltage has decayed during a shock. It is calculated with the formula Tilt = (I1 - |I4|)/I1. For the ASSURE system's defibrillation waveform, the tilt is greatest at low impedances and less at high impedances.

Nominal shock waveform parameters are provided in the following table.

Patient Resistance	Peak Current (I1)	Phase 1 (T1)	Phase 2 (T2)	Tilt	Measured Energy Output
25	63 A	3.54 ms	3.54 ms	86.2%	156 to 184 joules
50	32 A	4.96 ms	4.96 ms	75.7%	156 to 184 joules
75	21 A	6.33 ms	6.33 ms	70.2%	156 to 184 joules
100	16 A	8.08 ms	5.60 ms	63.6%	143 to 168 joules
125	13 A	8.85 ms	5.28 ms	55.7%	136 to 158 joules
150	11 A	9.50 ms	5.08 ms	50.4%	126 to 148 joules
175	9 A	10.07 ms	5.02 ms	46.3%	117 to 138 joules
200	8 A	10.58 ms	5.01 ms	43.0%	109 to 128 joules

Shocks per Sequence

The ASSURE system can deliver up to five shocks in a row for a single event (or episode). If the ASSURE system detects a rate recovery after a shock, additional shocks are canceled and the ASSURE system resets. If a new episode occurs, the shock sequence begins again.

Synchronized Defibrillation Shock Delivery

The ASSURE system will deliver a synchronous defibrillation shock after charging under the following conditions:

- If an R-wave is detected within three seconds after the ASSURE system finishes charging, the maximum time delay from the peak of the R-wave to the peak of the ASSURE system output waveform is 60 ms.
- If an R-wave is not detected within three seconds after the ASSURE system finishes charging, the ASSURE system delivers the defibrillation shock asynchronously.

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9.2 Voice Prompts

This section lists the voice prompts that are used by the ASSURE system.

	Voice Prompt	Description
Heart Alerts		
Shock Alert		
Before the shock:	Preparing to shock. Do not touch the patient.	The device is charging for defibrillation.
	Do not touch the patient.	Instructs anyone nearby not to touch the patient as a shock is imminent.
	Preparing to shock in 3, 2, 1.	The device provides a warning that the shock is about to be delivered.
After the shock:	Shock delivered.	The device has successfully delivered a shock.
	Call 911 now. Do not touch the patient.	Instructs anyone nearby to call 911 and not touch the patient because additional shocks may occur.
	Preparing to shock. Do not touch the patient.	The device is charging for defibrillation.
Seek Medical Attention Alert	Call 911 now. Begin CPR is patient is unconscious.	Instructs anyone nearby to call 911 and begin CPR if the patient is unconscious.
System Alerts		
Connect Plug to Monitor Alert	Connect the Plug to your Monitor.	The device cannot detect that the Plug is connected to the Monitor.
Connect Hub to Garment Alert	Connect the Hub to your Garment.	The device cannot detect that the Hub is inserted into the Garment.
Put on Garment Alert	Put on your Garment now.	The device cannot detect that the patient is wearing the Garment.

	Voice Prompt	Description
Low Battery Alert	Replace your Battery now.	The battery has less than two hours of power left.
Check Sensors Alert	Adjust your Garment now. The Sensors must touch your skin.	The device has lost contact with one or more Sensors in the Garment.
Check Therapy Pads Alert	Check the Therapy Pads. The pads must touch your skin.	The device has lost contact with one or more of the Therapy Pads.
Shock Delivered – Seek Medical Attention Alert	Call 911 now. You have received a shock. Continue to wear your ASSURE system.	The device has successfully delivered a shock and the dangerous heart rate is no longer detected.
Service Required Alert	Call the ASSURE Helpline now. Your device needs service.	The device has detected a problem with the system and the device is not operational.
Service Needed Alert	Call the ASSURE Helpline now. Your device needs service. Continue to wear your ASSURE system.	The device has detected a problem with the system, but the system is still operational.
System Status Messages		
Alert Button	Press your Alert Button now.	The device is requesting interaction with the Alert Button to confirm operation.
Shock Diverted (shock not delivered)	Shock has been canceled.	The Alert Button was pressed to cancel the shock delivery.
Shock Diverted (shock delivered)	Shock has been canceled. Call 911 now. You have received a shock. Continue to wear your ASSURE system.	The device successfully delivered a shock. However, a dangerously fast heart rhythm was still detected so another shock sequence started, and the patient pressed the Alert Button to cancel the shock delivery.

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	Voice Prompt	Description
Shock Not Delivered	No shock was needed.	The ASSURE system has detected a rate recovery, so the shock was canceled.
Therapy Depleted (additional shocks still available)	You have reset the system. Call 911 now. You have received a shock. Continue to wear your ASSURE system.	The device successfully delivered five shocks. The device has been reset and an additional five shocks are available if a dangerously fast heart rhythm is detected again.

9.3   Wireless Interference

If there is any indication of interference between a wireless device and the ASSURE system, move away from the wireless device or turn it off, if possible. Call the ASSURE Helpline at 1.833.692.7787 if you continue to have interference problems.

9.4   Electromagnetic Compatibility

The ASSURE wearable defibrillator is shielded to protect it against electromagnetic interference (EMI) and prevent it from interfering with common electronic items. The ASSURE system should operate normally around most electronic household items, such as microwave ovens, televisions, computers, kitchen appliances, mobile phones, and garage door openers.

However, the patient should always use caution when wearing the ASSURE system around household equipment that could potentially produce uncommonly high electromagnetic interference, such as high-powered two-way radios, arc welding equipment, high voltage transmission lines, large electric motors and generators, and power tools. These types of devices generate electromagnetic fields that may interfere with the normal operation of the ASSURE system.

9.4.1 Electromagnetic Emissions - Guidance and Manufacturer's Declaration

The ASSURE system is intended for use in the electromagnetic environment specified below. The patient or the user of the ASSURE system should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The ASSURE system transmits RF energy only for low power *Bluetooth*® communication. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ASSURE system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

9.4.2 Federal Communications Commission (FCC) Declaration

This device complies with Part 15 of the FCC rules, and its operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device contains:

- Transmitter Module FCC ID: YKP1024119

⚠ **CAUTION**

Changes or modifications to this device not expressly approved by Kestra Medical Technologies, Inc. could void the patient's authority to operate the device.

9.4.3 Electromagnetic Immunity - Guidance and Manufacturer's Declaration

The ASSURE system is intended for use in the electromagnetic environment specified below. The patient or the user of the ASSURE system should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Monitor, Battery, Garment, and Charger: ±8 kV contact ±15 kV air Therapy Cable: ±6 kV contact ±15 kV air	No precautions necessary
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Complies	Mains power quality should be that of a typical home environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Complies	Mains power quality should be that of a typical home environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Complies	Mains power quality should be that of a typical home environment. If the user of the ASSURE system requires continued operation during power mains interruptions, the ASSURE system's Charger should be connected to an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home environment.

Note: U_T is the AC Mains voltage prior to application of the test level.

The ASSURE system is intended for use in the electromagnetic environment specified below. The patient or the user of the ASSURE system should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the defibrillator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[1]	3 Vrms	$d = 1.2\sqrt{P}$
	6 Vrms 150 kHz to 80 MHz in ISM bands[1]	6 Vrms	$d = 1.2\sqrt{P}$

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[2] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[3], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: $((\underset{\blacktriangle}{\cdot}))$

Notes:
- *At 80 MHz and 800 MHz, the higher frequency range applies.*
- *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*
- *No deviations or allowances to the standards have been used.*

1. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

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2. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
3. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ASSURE system is used exceeds the applicable RF compliance level above, the ASSURE system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as increasing the distance between the ASSURE system and the RF transmitter.

9.4.4 Recommended Separation Distances

The ASSURE system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The patient or the user of the ASSURE system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ASSURE system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:
- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9.4.5   Radio Frequency (RF) Transmissions

The ASSURE system transmits using *Bluetooth®* Classic with Class 2 power management, 4 dBm (2.5 mW) maximum output power. The frequency of operation is 2.400 to 2.4835 GHz including guard bands 2 MHz wide at the bottom end and 3.5 MHz wide at the top. It uses Gaussian Frequency Shift Keying, GFSK modulation, and frequency hopping over 79 channels.

Note: The Monitor has not undergone the Bluetooth SIG certification process and no claim is made that the Monitor is certified by the Bluetooth SIG.

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For assistance, call the ASSURE Helpline at 1.833.692.7787.

![Kestra Medical Technologies logo]

Kestra Medical Technologies, Inc.
3933 Lake Washington Blvd. NE, Suite 200
Kirkland, WA 98033 USA

assure

Quick Start Guide

Quick Start Guide

When You Get Home

1. Insert the Charger cord plug from the AC adapter into the Charger and rotate the cord to secure it
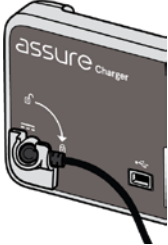
2. Connect the power cord to the AC adapter and plug the Charger into an electrical outlet
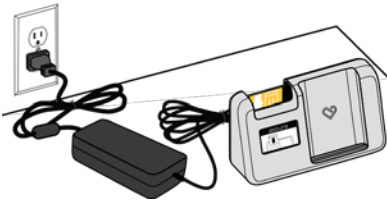
3. Insert the spare Battery into the Charger
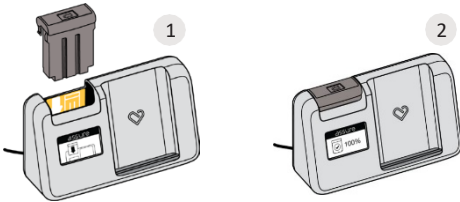
Need help?

- Read the *ASSURE Wearable Defibrillator Patient Handbook*.
- Watch the patient video on the Kestra website at kestramedical.com/patients.
- Call the toll-free ASSURE Helpline at 1.833.MYASSURE (1.833.692.7787).

Your Daily Routine

1. Wear the ASSURE® Wearable Defibrillator, even while you sleep
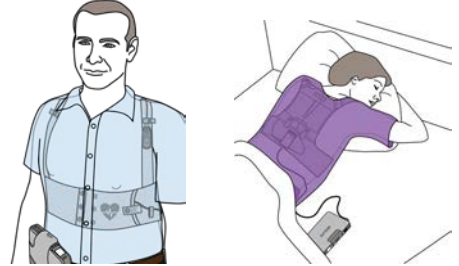
2. Replace the Battery daily

3. Remove the ASSURE system before taking a shower or bath

4. Check the system status at any time by pressing the Alert Button

- You should see a green light and the System Ready icon on the Monitor.
- You should hear a guitar strum.

Note:
If a System alert is active, pressing the Alert Button will replay the alert.

Note:

See the *ASSURE Wearable Defibrillator Patient Handbook* for product label and packaging symbol descriptions.

Responding to a System Alert

1. PATIENTS ONLY: Press the Alert Button to quiet the alert

2. Look at the Monitor Light and Screen
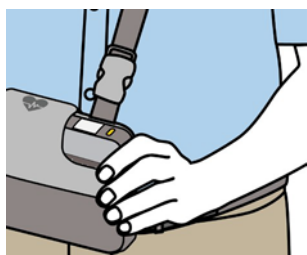
3. Respond to the alert

   Note:
   Press the Alert Button again to replay the alert.

Responding to a Shock Alert

When the ASSURE system detects and confirms a dangerously fast heart rhythm, it issues a Shock alert.

If you notice the Shock alert:

- PATIENTS ONLY: Press the Alert Button immediately to cancel shock delivery.
- Continue to wear the system unless a doctor tells you to remove it.
- Call 911 or seek medical attention if you feel dizzy or unwell.

If you do not press the Alert Button:

- The system will deliver a shock, if needed.
- CAREGIVERS/FAMILY:
  - After a shock, the system will instruct anyone nearby to call 911. The system will not call 911 for you.
  - The patient is the only one who should press the Alert Button. Do not press the Alert Button for them.

Other Important Alerts

Icon	Description	Response
	The Battery has less than two hours remaining.	Replace the Battery in the Monitor.
	Emergency help is needed.	Call 911 and continue to wear the ASSURE system.
	Service is required.	Immediately call the ASSURE Helpline at 1.833.692.7787.
	Check the Sensors.	Adjust the Garment or moisten your skin.

ASSURE
Cardiac Recovery System

For assistance, call the ASSURE
Helpline at 1.833.692.7787.

Kestra Medical Technologies, Inc.
3933 Lake Washington Blvd. NE, Suite 200
Kirkland, WA 98033 USA

REF 80023-001 Rev. C

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Cardiac Recovery System

ASSURE Wearable Defibrillator Training Manual

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Cardiac Recovery System™

ASSURE® Wearable Defibrillator Training Manual

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Important Information

Version History

This document is based on the initial release of the ASSURE system and Charger.

Trademarks

ASSURE, KESTRA, and the ASSURE heart logo are registered trademarks and Cardiac Recovery System is a trademark of Kestra Medical Technologies, Inc. or its affiliates. All other product and company names herein are trademarks or registered trademarks of their respective owners.

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The ASSURE system documentation provided to the patient service representative (PSR) for training, programming, fitting, maintaining, and troubleshooting (including the Training Manual) are confidential and proprietary information of Kestra Medical Technologies, Inc. or its affiliates (collectively "Kestra"). By accepting the documentation the PSR agrees to the following:

    (i) the PSR will not share the documentation with third parties;

    (ii) the PSR will not make copies of the documentation;

    (iii) the PSR will keep the documentation under their direct control and confidential when using the documentation; and

    (iv) the PSR will store the documentation in a secure manner when they are not using the documentation.

License

The ASSURE system, including the ASSURE Charger and Tablet, its proprietary software, documentation, and certain intellectual property associated with the system are owned by Kestra. The system, software, and documentation provided to the PSR must be returned to Kestra after completing the term of their agreement with Kestra. Kestra grants the PSR a nonexclusive license to use the system, software, and intellectual property solely for use during the term of their agreement with Kestra.

The PSR agrees they will only use the ASSURE system as authorized in their agreement with Kestra. By using the ASSURE system, the PSR acknowledges that ownership of the system, software, and documentation remains with Kestra, and the PSR agrees they will use the system, software, documentation, and intellectual property only during the term in their agreement with Kestra.

Further, except as expressly permitted under applicable law that cannot be waived, the PSR agrees they will NOT perform, aid, or condone any party in performing any of the following:

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(ii) removing or destroying any proprietary copyright notices or other legends and labeling that are part of the system including the software and documentation;

(iii) removing or downloading the software from the system;

(iv) reverse engineering the system including the software (reverse engineering as used herein includes but is not limited to modifying, decompiling, sniffing, or reconstructing the system software).

Open Source Software

Certain software components (referred to herein as "Open Source Components") that are used with or in the ASSURE system are not owned Kestra but are licensed to Kestra under various open source license agreements. As required by the terms of these open source license agreements, Kestra offers to make the source code corresponding to the Open Source Components available upon request.

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For more information on open-source application licenses for the ASSURE system, go to www.kestramedical.com/oss-attribution-notice.

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1. Overview

This section provides general information about the ASSURE wearable defibrillator (ASSURE system) including:

- Introduction
- Using this manual
- How to get help
- Information for family and caregivers
- System kit contents
- Returning the ASSURE system
- Part descriptions
- Glossary

1.1   Introduction

Note: The PSR should be familiar with the ASSURE Wearable Defibrillator Patient Handbook, the ASSURE system, and its components.

The ASSURE wearable defibrillator (or ASSURE system) is used to treat Sudden Cardiac Arrest (SCA). SCA is when the heart stops pumping without warning and typically results in death because there is insufficient time to seek treatment. The ASSURE system analyzes and treats patients for a potentially life-threatening heart rhythm. In order for the ASSURE system to work properly, it must be properly fitted and programmed for each patient.

The ASSURE system has two main wearable components: the Garment and the Carry Pack. The patient services representative (PSR) is responsible for fitting the patient with these components and demonstrating how the patient should wear them. The ASSURE system is designed to be worn on the body at all times, can be used by many different types of users, and can be discreetly worn in public settings (for example, going to a grocery store, attending a football game, or eating at a restaurant).

The ASSURE system is worn by the patient and provides continuous electrocardiogram (ECG) acquisition and rhythm analysis and, if necessary, delivers a therapeutic shock to the patient without the assistance of another person. The ASSURE system provides ongoing detection of the following arrhythmias: Ventricular Fibrillation (VF), Ventricular Tachycardia (VT), Bradycardia, and Asystole. The ASSURE system provides synchronous and asynchronous defibrillation therapy using a Biphasic Truncated Exponential (BTE) waveform and is able to deliver up to 170J energy. The ASSURE system supports configurable rate zone management of ventricular arrhythmias.

When the ASSURE system detects a dangerously fast heart rate, it alerts the patient through a series of vibrations, visual, and audio notifications (called a Heart alert). If therapy is required, the ASSURE system notifies bystanders that a shock is going to be delivered and to not touch the patient. The ASSURE system will then deliver a defibrillating shock and continue analyzing the patient. If the patient is conscious and realizes a Heart alert is occurring, they must immediately press the Alert Button. Doing so notifies the ASSURE system that the patient is conscious and diverts therapy to the patient. The ASSURE system continually analyzes the patient's ECG rhythm and determines if additional therapy is required. After therapy is delivered, the ASSURE system instructs the patient or bystanders to call emergency services.

During the patient session, the PSR uses the Tablet to communicate with the ASSURE system and fit and train the patient. The Tablet connects to the main electronics unit of the ASSURE system, the Monitor, via a secure wireless link. The ASSURE application enables the PSR to determine proper functionality of ASSURE system components, program the ASSURE system according to the patient's prescription, and verify fit of the ASSURE system. For more information on the Tablet, see chapter 3, Using the Tablet, on page 33.

Note: The Tablet is not intended to be used for patient diagnosis or treatment.

1.1.1 Indications for Use

The ASSURE system is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for, or refuse, an implantable defibrillator.

1.1.2 Contraindications

The ASSURE system is contraindicated for use on patients with an active implantable defibrillator.

1.1.3 Intended Use, Operators, and Location

The ASSURE system is intended for patients who have been prescribed this device by their physician. The patient is the primary operator. A Kestra patient service representative (PSR) fits and trains the patient on proper use and care of the system.

The ASSURE system is intended for use by a patient during their normal daily activities primarily in the home or community settings, but also hospitals, medical clinics, healthcare facilities, and transport. The Charger is intended to be used in the home environment.

1.1.4 Essential Performance

The ASSURE system monitors the patient for dangerous heart rhythms and determines if therapy, in the form of electrical shocks, is required. Unacceptable risks include the loss of detection and therapy.

1.2 Using this Manual

This manual is intended for Kestra Medical Technologies employees, Patient Service Representatives (PSRs), and other contracted representatives, who are responsible for fitting and training patients with the ASSURE system.

This manual includes the following information:

- Description of the ASSURE system and its components
- Safety information
- An overview of the Tablet and its features
- Instructions for preparing for the initial patient session
- Instructions for fitting the patient with a Garment and how to assemble the ASSURE system
- Instructions for training the patient on the ASSURE system
- A checklist for performing the patient fitting and training tasks
- A patient comprehension test

1.3 Product Assistance

For questions or help concerning the ASSURE system, Charger, or patient set up and training, call the toll-free ASSURE Helpline at 1.833.MYASSURE (1.833.692.7787).

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1.4   System Kit Contents

The ASSURE system is packaged in a sealed system kit box from the factory.

Note: In addition to the system kit, the PSR will also provide the patient with two Garments after the fitting.

The system kit includes the following items:

- Monitor
- Batteries (2)
- Therapy Cable
- Charger, AC adapter, and power cord
- Carry Pack
- Garment laundry bag and laundry detergent
- *ASSURE Wearable Defibrillator Patient Handbook*
- *ASSURE Wearable Defibrillator Quick Start Guide*

Note: If any part of the ASSURE system is not working properly or is damaged, the patient should call the ASSURE Helpline at 1.833.692.7787 to order a replacement.

1.5   Kit Return after Prescription Completion

The prescriber will determine when the patient no longer needs to wear or use the ASSURE system. When the patient is finished with the system, they should do the following:

- Remove the Battery from the Monitor.
- Take off the ASSURE system.
- Find the original system kit box and follow the repacking instructions on the inside of the lid.
- Pack up the complete system, including all accessories, the second Garment, Charger, and both Batteries, into the provided system kit box.
- Seal the lid on the system kit box according to the instructions on the inside of the lid.
- Return the system kit box to Kestra Medical Technologies. The box should have a prepaid return shipping label already on it.

If the patient has any questions, they can call the ASSURE Helpline at 1.833.692.7787.

1.6   Patient Training Video

A video is available to assist with training patients on how to use the ASSURE system. Have the patient watch this video prior to assembling the ASSURE system. The video is approximately 15 minutes long and is available at www.kestramedical.com.

The video includes the following topics:

- Chapter 1 – Your ASSURE System
- Chapter 2 – Putting your ASSURE System Together
- Chapter 3 – Putting on your ASSURE System
- Chapter 4 – Turning on your ASSURE System
- Chapter 5 – Wearing your ASSURE System
- Chapter 6 – Caring for your ASSURE System
- Chapter 7 – Therapy from your ASSURE System

Note: Encourage patients to pause the video for any comments or questions.

1.7   Patient Information Card

The information card provides emergency instructions for first responders or bystanders and it includes emergency contact information.

Instructions:

Step 1   The PSR should ensure the patient contact information is completed

- Patient name
- Emergency contact name
- Emergency contact phone number

Step 2   The patient should insert the card into the Carry Pack's front pocket

Note: To replace a lost card, the patient should call the ASSURE Helpline at 1.833.692.7787.

1.8   Information for Family and Caregivers

Note: If possible, caregivers or family members who live with the patient should attend the patient training session.

Family members and caregivers are encouraged to read the *ASSURE Wearable Defibrillator Patient Handbook* or watch the patient video (available at www.kestramedical.com) to understand the ASSURE system and how it works.

Responding to Heart Alerts for Family and Caregivers

During an emergency event, the family member or caregiver must remember the following:

- Do not press the Alert Button for the patient.
- Do not take the Battery out of the Monitor.
- Do not remove the Garment from the patient.
- Do not touch the patient or the system while a shock is being delivered. The

family member or caregiver should follow these instructions:

Step 1   Call 911 or Emergency Medical Services

Step 2   Follow the voice messages from the ASSURE system

Step 3   If directed to do so by the ASSURE system, begin CPR if the patient is unconscious

1.9   Part Descriptions

This section provides descriptions of the ASSURE system, Charger, and Tablet.

1.9.1   Garment Description

The Garment is worn on the body and contains the Sensors. It holds both the Sensors and Therapy Pads against the patient's bare skin.

There are two Garment styles (style A and style B), and each style is available in a range of sizes.
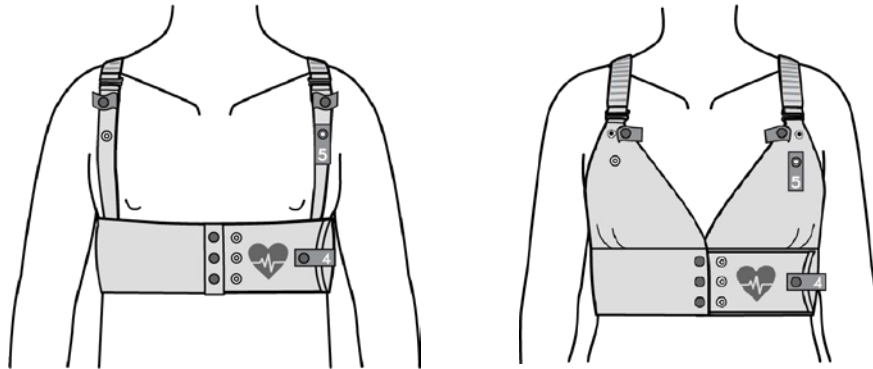
Garment Style A (left) and Style B (right)
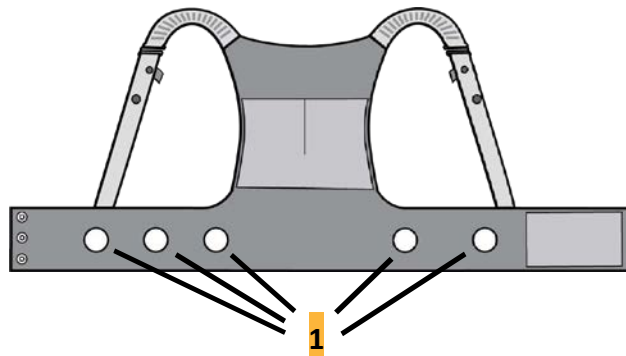
Garment (Interior)

Item	Name
1	Sensors
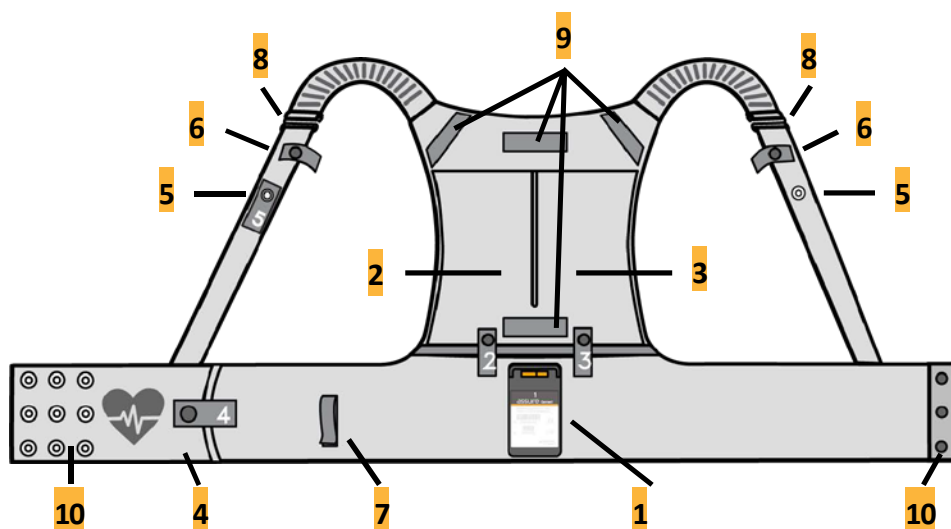
Garment (Exterior)

Item	Name
1	Hub Receptacle
2	Therapy Pad 2 Pocket (back)
3	Therapy Pad 3 Pocket (back)
4	Therapy Pad 4 Pocket (front)
5	Alert Button Snap
6	Alert Button Cord Wrap
7	Therapy Pad 4 Cord Wrap
8	Shoulder Strap Hooks
9	Alert Button Cord Loops (back)
10	Front Closure Snaps

1.9.2 Therapy Cable Description

The Therapy Cable provides the connection between the Garment and the Monitor. The Therapy Pads contain gel that is dispersed prior to delivering a shock.

Note: The entire Therapy Cable is a single assembly. The cords connected to the Hub cannot be removed.
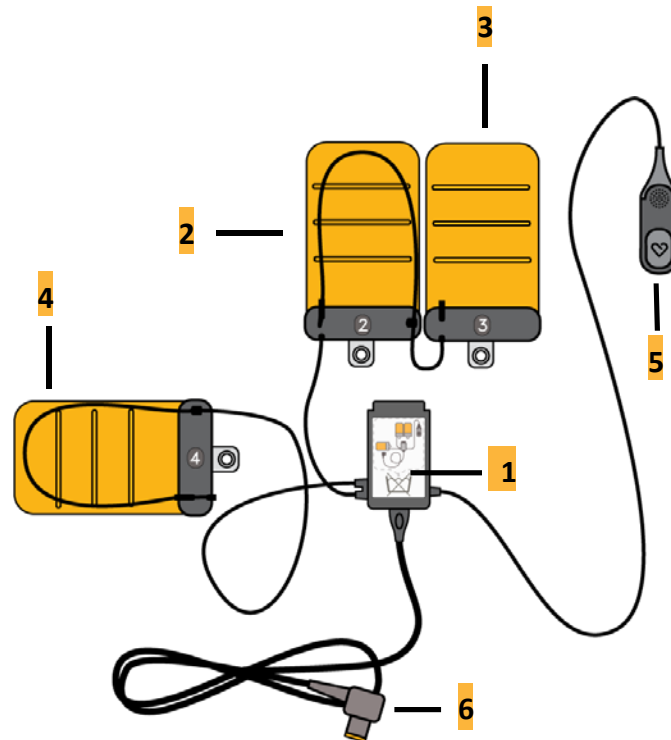
Item	Name
1	Hub
2	Therapy Pad 2 (back)
3	Therapy Pad 3 (back)
4	Therapy Pad 4 (front)
5	Alert Button
6	Plug and Cable

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1.9.3   Monitor and Battery Description

The Monitor is the primary electronic component of the ASSURE system. The rechargeable Battery inserts into the Monitor and provides power to the system.
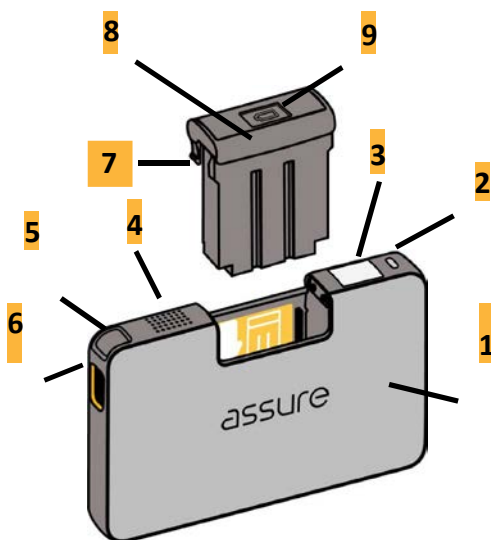
Item	Name
1	Monitor
2	Monitor Light
3	Monitor Screen
4	Speaker
5	Plug Release Button
6	Plug Receptacle
7	Battery
8	Battery Handle
9	Battery Lock

1.9.4 Carry Pack Description

The Carry Pack holds the Monitor while the patient is wearing the system.
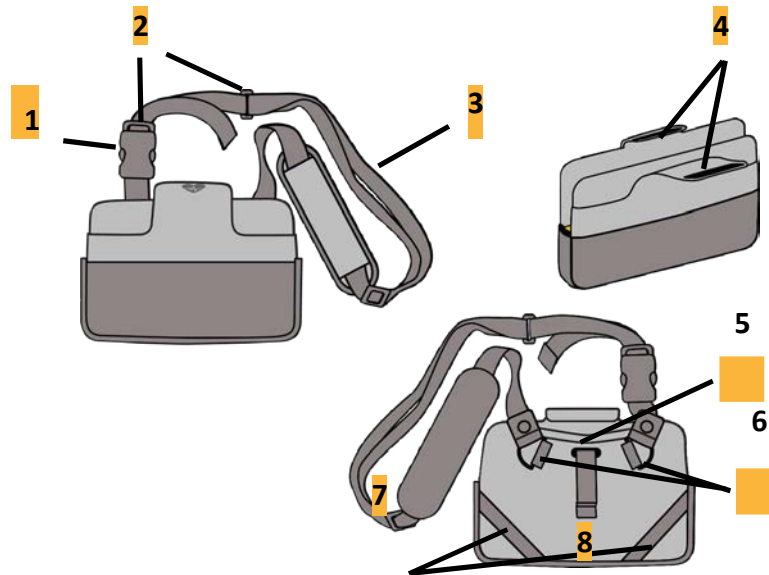
Item	Name
1	Buckle
2	Strap Adjusters
3	Strap
4	Flaps
5	Handle
6	Strap Connectors
7	Corner Straps
8	Belt Clip

1.9.5 Charger

The Charger is a separate device that charges the spare Battery.
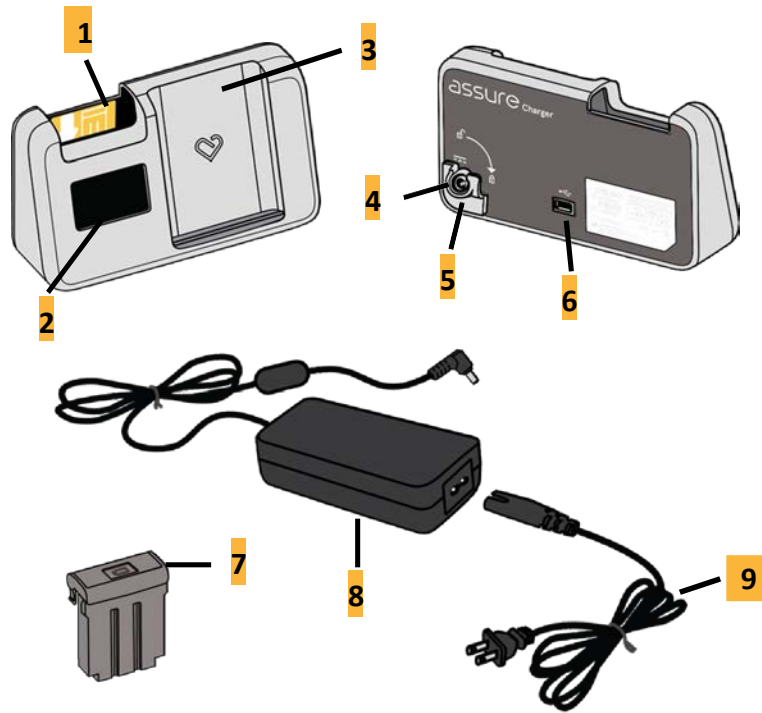
Item	Name
1	Battery Slot
2	Charger Screen
3	Wireless Charging Well
4	Power Port
5	Charger Cord Clip
6	USB Port (output only)
7	Battery
8	AC Adapter with Charger Cord and Plug
9	AC Adapter Power Cord with Connector and Plug

1.10   Tablet Description

The Tablet is a mobile wireless device that uses custom applications to program the ASSURE system for the patient.
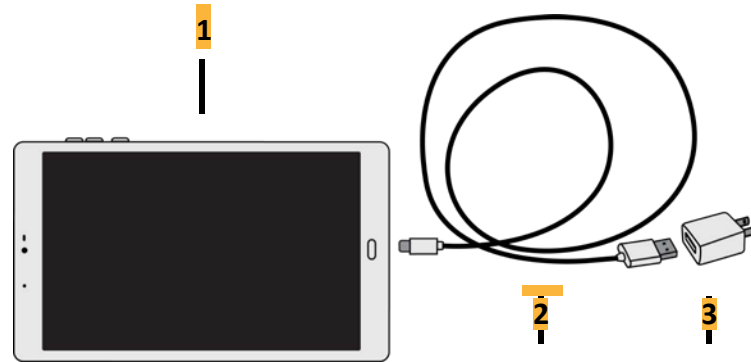
Item	Name
1	Tablet
2	Tablet USB Type C to Type A Cable
3	Tablet USB Charger

Note: The Tablet also includes a protective case (not shown).

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1.11   ASSURE Application Screen Description

ASSURE Application Screen
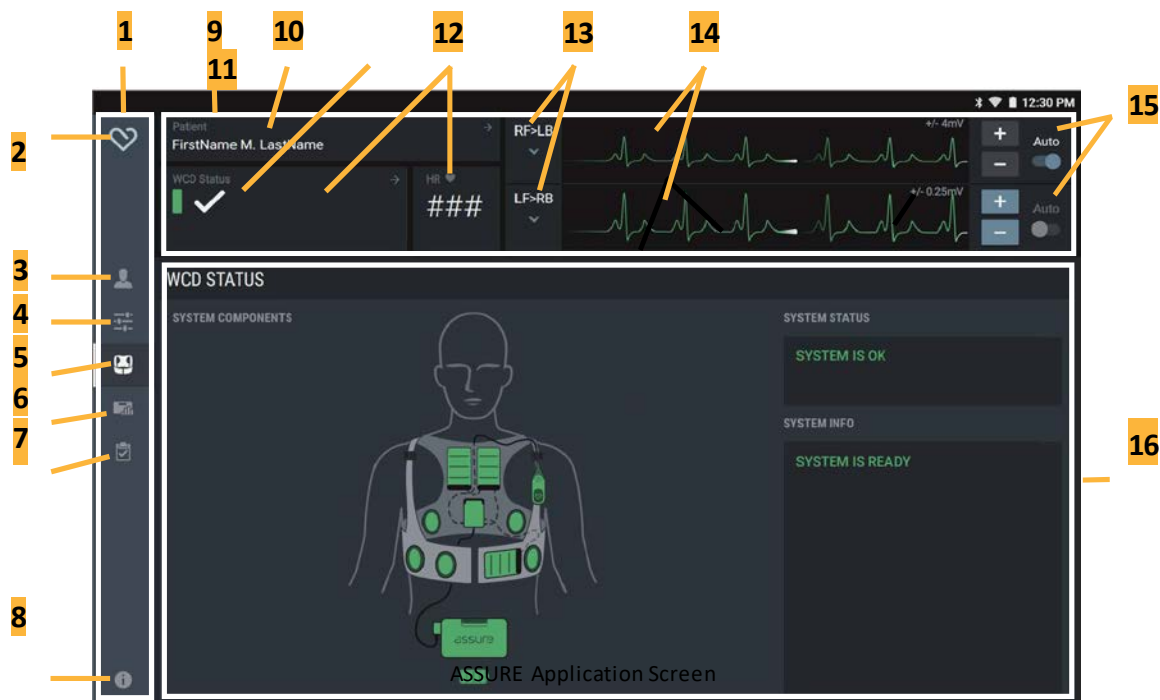
Item	Name
1	Navigation Menu (Highlighted icon information appears in the Screen Content section)
2	• ASSURE Heart Logo (Tap or slide to expand the menu, or exit the application)
3	• Patient Information Screen
4	• WCD Settings Screen
5	• WCD Status Screen
6	• Clinical Data Screen
7	• Session Report Screen
8	• About Screen
9	Tablet Screen Header
10	• Patient Name
11	• WCD Status Summary (Mirrors the status on the Monitor)
1	• Segment-Based Algorithm Results and Heart Rate (As measured by the ASSURE system)
13	• ECG Channel Selection
14	• ECG Display (6-second strips of ECG data)
15	• Scaling Controls
16	Screen Content

1.12   Glossary

Term	Definition
AC Adapter	The power supply for the Charger.
AC Adapter Power Cord	The cord that connects the AC adapter to an electrical wall outlet.
AC Adapter Power Cord Connector	The end of the AC adapter power cord that plugs into the AC adapter.
AC Adapter Power Cord Plug	The end of the AC adapter power cord that plugs into an electrical wall outlet.
Alert	A message from the ASSURE system that a condition exists that requires attention. There are two types of alerts – Heart and System.
Alert Button	An oval-shaped button on the Therapy Cable. The patient presses this button to start the ASSURE system or to respond to alerts.
Alert Button Back Cord Loops	Fabric loops that hold the Alert Button cord on the back of the Garment.
Alert Button Shoulder Cord Wraps	Fabric loops with snaps that hold the Alert Button cord on the Garment shoulder straps.
Alert Button Snap	A connector on the Garment's shoulder strap that attaches to the back of the Alert Button.
ASSURE System	Also known as the ASSURE wearable defibrillator.
Battery	A rechargeable battery in the Monitor that powers the ASSURE system.
Battery Handle	A lever on the top of the Battery. Slide the Battery lock and lift the handle. Pull up on the handle to remove the Battery from the Monitor. Leave the handle down when inserting the Battery into the Monitor or Charger.
Battery Lock	Locking mechanism on top of the Battery. Slide the lock until you see the yellow line and lift the Battery handle. Pull up on the handle to remove the Battery from the Monitor.
Carry Pack	A portable case that holds the Monitor while wearing the ASSURE system.
Battery Slot	The opening in the Charger where the Battery is inserted to charge it.
Carry Pack Belt Clip	A clasp on the back of the Carry Pack that holds it on a belt.
Carry Pack Buckle	Plastic pieces on the ends of the Carry Pack straps that connect together.
Carry Pack Corner Strap	Elastic straps located on the back of the Carry Pack. May be used to hold any extra length of the cable running from the Garment to the Monitor.
Carry Pack Flaps	A big flap and a small flap that fasten together to secure the Monitor in the Carry Pack.
Carry Pack Handle	A fabric handle on the back of the Carry Pack.
Carry Pack Strap	An adjustable two-piece strap that attaches to the Carry Pack and fastens with a buckle.

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Term	Definition
Carry Pack Strap Adjusters	Used to lengthen or shorten the Carry Pack strap. There is an adjuster on the strap and another one in the buckle.
Carry Pack Strap Connectors	Plastic loops on the back of the Carry Pack. Connect the strap ends to the loops.
Charger	A separate device that charges the Battery.
Charger Cord	The cord that connects the AC adapter to the Charger.
Charger Cord Clip	A plastic clip on the back of the Charger that holds the Charger cord.
Charger Cord Plug	The end of the Charger cord that plugs into the Charger.
Charger Screen	The visual display on the Charger that shows the Battery's charging status.
CPR	Cardiopulmonary resuscitation
ECG	Electrocardiogram
Front Closure Snaps	Connectors on the front of the Garment that fasten together to close it.
Garment	A fabric top that contains the Sensors that track heart rhythm. It is worn directly on the body against bare skin.
Garment Shoulder Strap Hooks	Adjustable hooks on the Garment's shoulder straps.
Heart Alert	A critical physiological alert that notifies the patient that the system has detected a dangerous heart rhythm and is taking action.
Hub	The central part of the Therapy Cable that connects the Therapy Pads, Alert Button, and cable.
Hub Receptacle	The plastic housing on the back of the Garment where the Hub is inserted.
ICD	Implantable Cardioverter Defibrillator
Monitor	The part of the ASSURE system that provides power and displays system status information.
Monitor Light	The multi-colored light on the Monitor that displays the current system status.
Monitor Screen	The visual display on the Monitor that provides system status information.
MRI	Magnetic resonance imaging
Plug	The connector at the end of the Therapy Cable that inserts into the Monitor.
Plug Receptacle	The side opening on the Monitor where the Plug inserts.
Plug Release Button	A button on the Monitor that is pressed and held down to remove the Plug from the Monitor.
Power Port	An opening on the back of the Charger where the AC adapter cord is inserted to provide power to the Charger.
PSR	Patient Service Representative

Term	Definition
SCA	Sudden Cardiac Arrest
Sensors	Round metal ECG electrodes in the Garment that track heart rhythm.
Snaps 2-4	Connectors on the Therapy Pads and on the Garment's pockets that fasten together to keep the Therapy Pads inside the Garment.
Speaker	An enclosed speaker in the Monitor and Alert Button that delivers audio voice messages and alert tones.
System Alert	An alert that notifies the patient that there is a problem with the ASSURE system that they need to fix.
Tablet	An electronic device used to program the ASSURE system and assist in patient fitting and training.
Tablet Case	The protective cover for the Tablet.
Tablet USB Cable	The cable that connects the Tablet to the USB charger.
Tablet USB Port	The USB cable plugs into this standard connection on the Tablet to charge or provide power to the device.
Tablet USB Charger	The part that plugs into an electrical wall outlet and, when connected with the USB cable, charges the Tablet.
Therapy	A defibrillating electrical shock provided by the ASSURE system for a potentially life-threatening heart rhythm.
Therapy Cable	A group of connected parts consisting of the Hub, Alert Button, Therapy Pads, and a cable that connects to the Monitor. The Therapy Cable is inserted into the Garment.
Therapy Pad 4 Cord Wrap	A fabric loop located near the Therapy Pad 4 pocket that fastens the Therapy Pad 4 cord to the Garment.
Therapy Pad Pockets	Fabric pockets in the Garment that hold the Therapy Pads. There are two back pockets and one front pocket.
Therapy Pads	Front and back pads attached to the Therapy Cable that deliver an electrical shock to the heart when needed. The Therapy Pads also contain gel that is dispersed prior to delivering a shock.
USB Port	A Universal Serial Bus 2.0 dedicated charging port on the back of the Charger. This port is output only, so it can only charge USB-compatible devices.
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia
WCD	Wearable Cardioverter Defibrillator
Wearable Defibrillator	A system worn by patients at risk of SCA that detects dangerously fast heart rhythms and delivers a defibrillating shock to restore a normal heart rhythm.
Wireless Charging Well	A slot in the Charger that can recharge a mobile device that supports wireless charging.

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2. Safety Information

This section provides warnings, cautions, and electromagnetic interference (EMI) information that are applicable to PSRs, or other Kestra representatives, while using or training with the ASSURE wearable defibrillator (ASSURE system), Charger, and Tablet.

See chapter 9, Symbols Glossary, on page 131 for a list of symbols that appear on the ASSURE system and Charger labels and packaging.

2.1   Safety Labels

The following safety labels and terms appear in this manual:

⚠️ **WARNING**

Hazards or unsafe practices that may result in serious personal injury or death.

⚠️ **CAUTION**

Hazards or unsafe practices that may result in minor or moderate personal injury, product damage, or property damage.

2.2   ASSURE System Safety Information

⚠️ **WARNINGS**
- *Keep the ASSURE system, Charger, and all accessories away from open flame, flammable gases, or other potential fire sources. Shock delivery in these environments may pose an explosion or fire hazard risk.*
- *The ASSURE system is magnetic resonance (MR) unsafe. Do not wear or use the device near MR imaging equipment.*
- *Do not place the Monitor, Therapy Cable, Charger, or Battery in water or other liquids. Avoid spilling any liquids on these devices. Liquids entering these devices may cause them to malfunction or fail.*
- *Do not alter, drop, or abuse any part of the ASSURE system. Attempting to alter the equipment in any way may cause the system to malfunction or fail. Do not take apart the Monitor. Dangerous high voltages may be present. If service is required, call the ASSURE Helpline at 1.833.692.7787.*
- *During use, do not stack or place the ASSURE system near other equipment. Doing so may cause the system to malfunction or fail due to EMI exposure from the other equipment. If such use is necessary, the ASSURE system and the other equipment should be observed to verify that they are operating normally.*
- *Only use portable RF communications equipment that is included with or intended for use with the ASSURE system. Do not use any other portable RF communications equipment (including antenna cables and external antennas) any closer than 12 inches (30 cm) to any part of the system. Otherwise, equipment performance may suffer.*

2.3   Implantable Pacemakers

⚠️ **WARNING**

The ASSURE system is not intended for use on patients with an implantable pacemaker that produces a pacemaker pulse artifact greater than 0.5 mV on any ASSURE system ECG channel. This artifact may interfere with the system's ability to detect dangerous heart rhythms and prevent shock delivery.

2.4   Tablet Safety Information

Safety information for the Tablet can be found in section 11.4, User Information, on page 143.

2.5 Federal Communications Commission (FCC) Declaration

The ASSURE system and Tablet comply with Part 15 of the FCC rules, and their operation is subject to the following two conditions: (1) these devices may not cause harmful interference, and (2) these devices must accept any interference received, including interference that may cause undesired operation.

⚠ **CAUTION**

Changes or modifications to these devices not expressly approved by Kestra Medical Technologies, Inc. could void the user's authority to operate the devices.

2.6 Electromagnetic Interference

ASSURE System

Refer to the *ASSURE Wearable Defibrillator Patient Handbook* for more information on electromagnetic interference, what type of equipment to avoid, and how to resolve potential EMI issues while wearing the ASSURE system.

Tablet

Refer to section 11.4, User Information, on page 143 for more information on potential electromagnetic interference while using the Tablet.

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3. Using the Tablet

This section provides information and instructions for:

- Charging the Tablet
- Turning on the Tablet
- Unlocking the Tablet
- Viewing the Home screen
- Opening applications
- Restarting the Tablet
- Turning off the Tablet
- General care and cleaning

For device specifications and additional information, see chapter 11, Tablet Specifications and User Information, on page 139.

3.1 Charging the Tablet

Read the following information before charging the Tablet:

- After receiving the Tablet, plug in and charge the Tablet for at least 30 minutes before turning on the Tablet for the first time.
- Use only the accessories provided with the Tablet. This includes the USB cable and charger. To

charge the Tablet:

Step 1   **Connect the USB cable to the Tablet Step 2**

Connect the USB cable to the USB charger

Step 3   **Plug the USB charger into an electrical outlet**
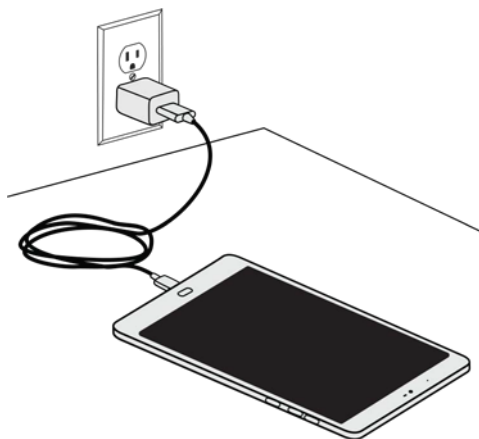
3.1.1 Charging Status

While the Tablet is charging, the charging status is displayed on the Lock screen and in the Status Bar.

Note: To keep the Tablet fully charged, leave it connected to the USB charger when it is not in use.

3.2   Changing the Access Code
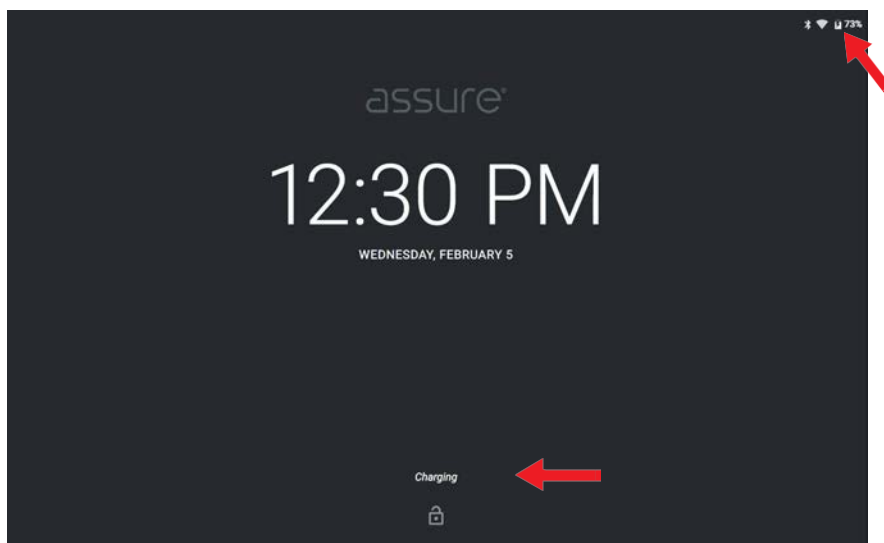
The Tablet requires you to enter an access code (or PIN) to unlock it. The default access code is provided to you by KestraMedical Technologies. When you receive your Tablet, make sure it is charged and then follow the instructions below to change the access code.

Step 1   Turn on the Tablet by pressing and holding the power button for a few seconds

- The Tablet vibrates and then displays a start up screen.
- The Tablet is ready when the Lock screen appears.

Step 2   Unlock the Tablet by swiping up on the screenStep

3   Enter the default access code

- Call the ASSURE Helpline at 1.833.692.7787 if you forgot or lost the default access code.
- After unlocking the Tablet, the Home screen appears.

Step 4   Tap Settings on the Home screen

Step 5   Scroll to the Personal section and tap SecurityStep

6   Tap Screen Lock

Step 7   Enter the default access code

Step 8   Tap the PIN option

Step 9   When prompted to use the PIN to secure start up, tap No ThanksStep

10 Enter the new access code (PIN)

- Call the ASSURE Helpline at 1.833.692.7787 to report the new access code.

Step 11 Enter the new access code (PIN) again to confirm itStep 12

Return to the Home screen

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3.3   Basic Operation

This section describes the basic functionality of the Tablet.

*Note: The Tablet meets electrical safety requirements when used or stored in temperatures of 41°F to 95°F (5°C to 35°C). The Tablet should only be used or stored within this range.*

3.3.1   Turning On the Tablet

To turn on the Tablet:

Press and hold the power button for a few seconds

- The Tablet vibrates and then displays a start up screen.
- The Tablet is ready when the Lock screen appears.
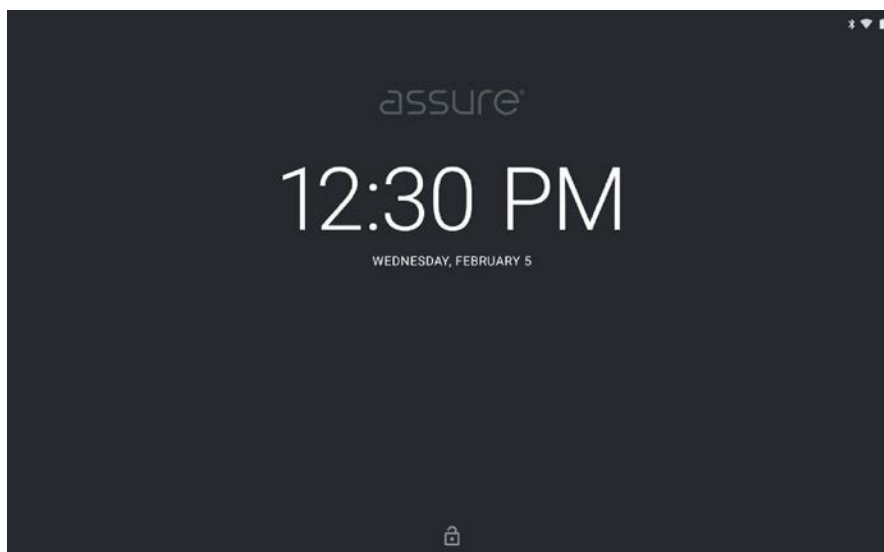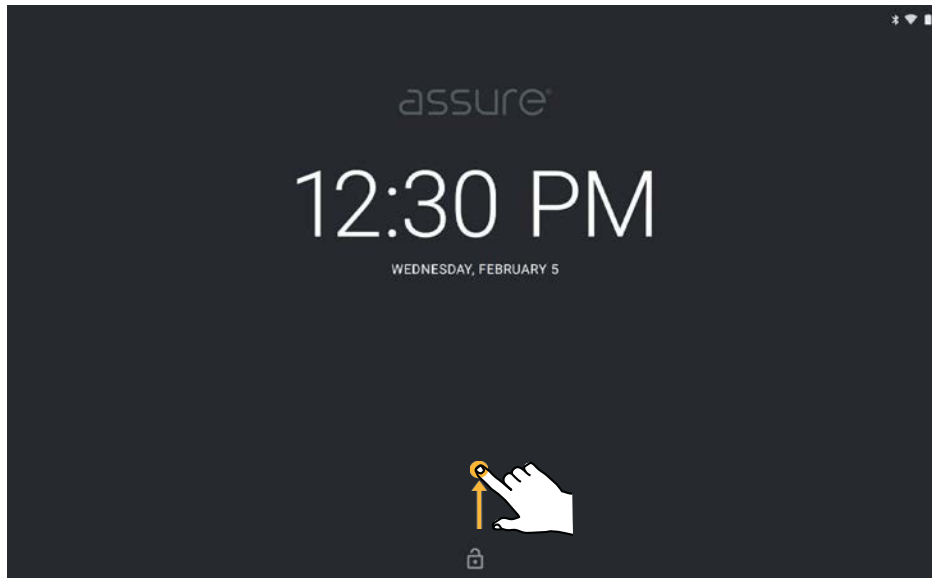
3.3.2   Unlocking the Tablet

The Lock screen appears after turning on the Tablet or when the Tablet wakes up from Standby mode.

Note: See section 3.3.5, Entering Standby Mode, on page 39 for more information on Standby mode.

The Lock screen displays the time and date, battery charge status, and connectivity status. A lock icon is displayed at the bottom of the Lock screen to indicate that the Tablet is locked.
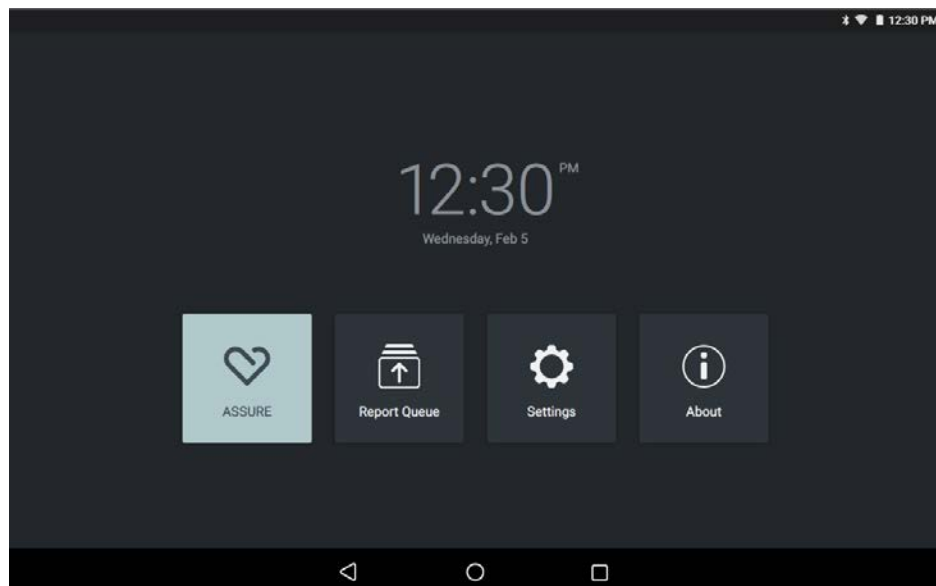
To unlock the Tablet:

Step 1   Swipe up on the screen

Step 2   Enter the access code

- The access code is specific to the Tablet and cannot be changed. Call the ASSURE Helpline at 1.833.692.7787 if the access code has been lost or forgotten.
- After unlocking the Tablet, the Home screen appears.

3.3.3   Viewing the Home Screen

After starting up and unlocking the Tablet, the Home screen is displayed. The Home screen is divided into multiple sections.
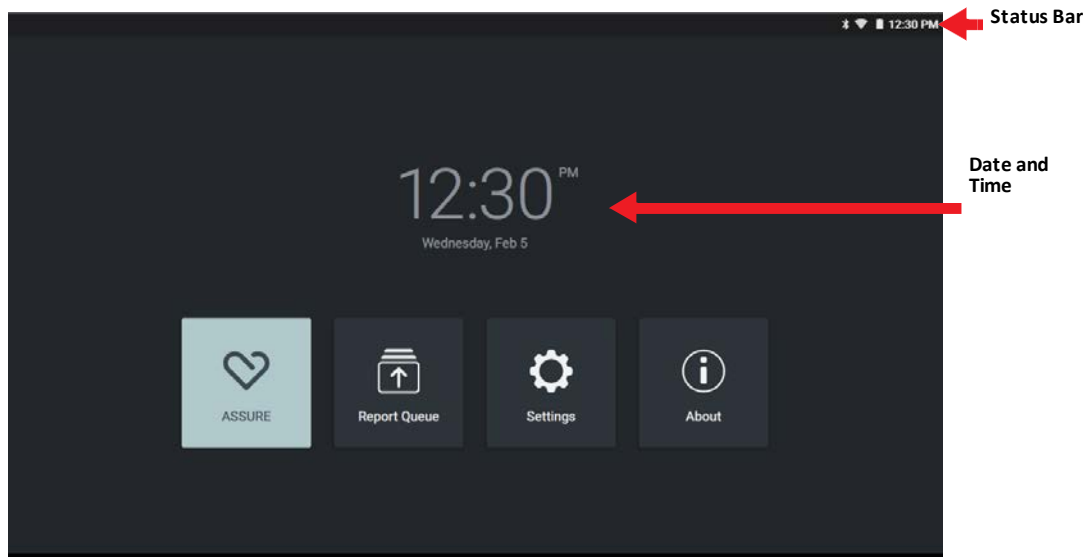
Name	Description
Status bar	Appears at the top of the screen and displays the time, battery charge status, and connectivity status.
Date and Time	Displays the current date and time
ASSURE	Opens the ASSURE application
Report Queue	Opens the Report Queue application
Settings	Opens the Settings screen to configure the date, time, and other device settings.
About	Displays license, software, and legal information

3.3.4   Viewing and Opening Applications

The Home screen displays the applications installed on the Tablet.
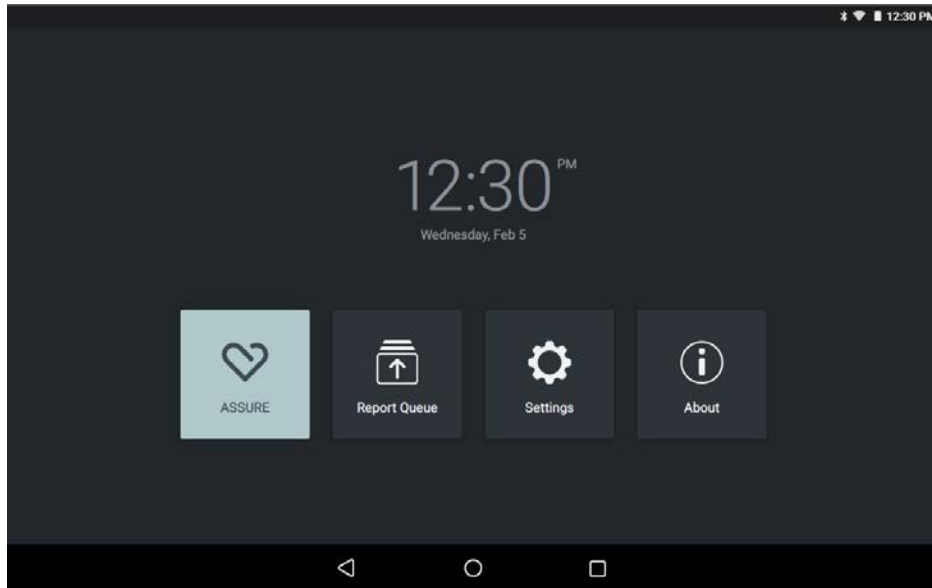
To open an application on the Home screen, tap the specific application icon.

Note: After exiting an application, the Home screen appears.

3.3.5   Entering Standby Mode

If the ASSURE application is not open, the Tablet enters Standby mode after a period of no activity. When the Tablet is in Standby mode, it is locked and the screen is off.

Note: Place the Tablet into Standby mode at any time to conserve battery life, as long as the ASSURE application is not open.

To place the Tablet into Standby mode:

Press the power button on the Tablet

To wake up the Tablet from Standby mode:

Press the power button

Note: Plugging in the Tablet to a power source will also bring the Tablet out of Standby mode.

3.3.6 Restarting the Tablet

To restart the Tablet:

Step 1 Press and hold the power button for 1-2 seconds
- A menu appears.

Step 2 Tap Reboot
- The Tablet turns off and then turns back on.

3.3.7 Turning Off the Tablet

To turn off the Tablet:

Step 1 Press and hold the Power button for 1-2 seconds
- A menu appears.

Step 2 Tap Power off
- The Tablet turns off.

3.3.8 Changing the Date and Time

To change the date and time on the Tablet:

Step 1 Tap the Settings application on the Home screen

Step 2 Under Settings, go the System section and tap Date & time
- Select whether to set the date and time automatically using the network-provided information, or set it manually.

3.3.9 Connecting to a Wireless Network

A wireless network connection is required to transmit a Session Report to the remote server. To

connect to a wireless network:

Step 1 Tap the Settings application on the Home screen

Step 2 Under Settings, go the Wireless & networks section and tap WLAN
- Select the wireless network to connect to or add a network if one is not shown.
  Note: A password may be required when connecting to a wireless network.

3.4 Starting the ASSURE Application

After starting the ASSURE application, a connection must be established between the Tablet and the ASSURE system's Monitor. After connecting the Tablet and Monitor, the ASSURE system and Tablet are in a "session". Each session is independent, so patient data from one session does not exist in another session.

Instructions:

Step 1   Ensure the ASSURE system's Monitor is turned on and has completed the power up process Step 2

Ensure the Tablet is powered on and unlocked

Step 3   Tap ASSURE on the Home screen
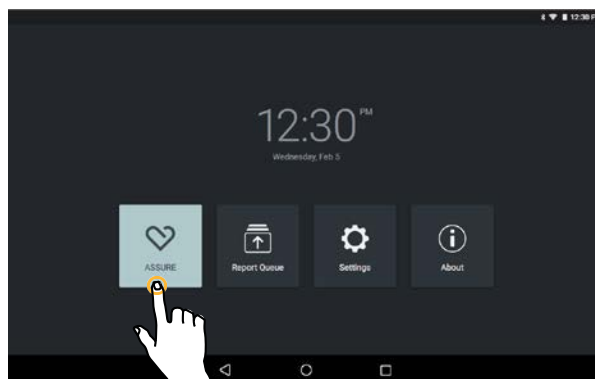
- The Connect Devices screen appears showing how to align the Tablet to the Monitor.
- If help is needed with connecting the Tablet and ASSURE system, tap **Help** on the Connect Devices screen.

Step 4   Align the top left corners of the Tablet and Monitor as shown on the screen.

- When the Tablet and ASSURE system connect, an audio tone plays (if the volume is on) and a "Connecting/Connected" animation appears on the screen.

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Step 5 **After connecting the Monitor to the Tablet, the System Setup screen appears**

Note: If the ASSURE system is already connected to the
Monitor, the Patient Information screen appears.

- See section 4.3.2, Creating a New Patient Record, on page 48 for instructions on how to set up the ASSURE system.

3.5 General Tablet Care and Cle

The Tablet should be kept clean and its battery should stay fully charged on a daily basis. See the cleaning instructions below. For battery charging instructions, see section 3.1, Charging the Tablet, on page 34.

Check the Tablet and its accessories for any damage (for example, a cracked screen or a frayed cable) prior to use. Contact Kestra Medical Technologies for assistance with repairing or replacing the Tablet if it appears damaged.

3.5.1 Tablet Cleaning Instructions

The Tablet is intended for use by a Kestra Medical Technologies representative in a clinic or hospital environment. During the Tablet's service life, the Tablet may be exposed to dirt, fluids, environmental contaminants, or other substances and may require cleaning. This section provides instructions and requirements for cleaning the Tablet and its accessories.

Note: Do not clean any part of the Tablet or its accessories with bleach, bleach dilution, or phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not attempt to sterilize the Tablet or its accessories. Follow the cleaning instructions provided in this document.

To clean the Tablet screen:

Gently wipe the screen with a clean soft cloth or microfiber towel

To clean the back of the Tablet and its accessories:

Step 1 **Unplug the USB power cord (if connected) from the Tablet and remove the USB charger from the electrical outlet**

Step 2 **Gently wipe the Tablet and accessories with a clean, slightly dampened, soft cloth**

- Do not use harsh chemicals, cleaning solvents, or aerosols to clean the Tablet or its accessories.
- Do not allow any liquid or moisture to remain in the connectors or openings after wiping the Tablet and accessories.

Step 3 **Allow the Tablet or accessories to air dry or use a dry soft cloth to wipe them down**

Step 4 **Reconnect the USB cable to the Tablet and plug the USB charger back into the electrical outlet**

4. Initial Patient Session Preparation

This section provides the following information and instructions:

- Starting the ASSURE application
- Setting up the ASSURE wearable defibrillator (ASSURE system)

Note: The PSR should be familiar with the ASSURE Wearable Defibrillator Patient Handbook, the ASSURE system, and its components.

4.1 Overview

⚠️ **WARNINGS**

- *The ASSURE system is not intended for use on patients with an implantable pacemaker that produces a pacemaker pulse artifact greater than 0.5 mV in any ECG channel. This artifact may interfere with the system's ability to detect dangerous heart rhythms and prevent shock delivery.*

Complete the following tasks before the patient session:

- Start the ASSURE application.
- Set up the ASSURE system.
    - Verify the ASSURE system date and time.
    - Create a new patient in the ASSURE application.
    - Write down the patient code, as it is required to enroll the patient in the remote server.

4.2 Starting the ASSURE Application

After starting the ASSURE application, a connection must be established between the Tablet and the ASSURE system's Monitor. After connecting the Tablet and Monitor, the ASSURE system and Tablet are in a "session". Each session is independent, so patient data from one session does not exist in another session.
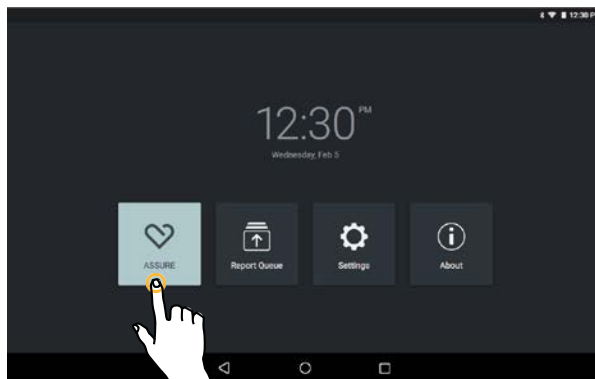
Instructions:

Step 1   Ensure the ASSURE system's Monitor is turned on and has completed the power up process Step 2 If

the Monitor is in the Carry Pack, remove the Monitor from the Carry Pack and lay it on a flat surface

Step 3   Ensure the Tablet is powered on and unlocked Step

4   Tap ASSURE on the Home screen

- The Connect Devices screen appears showing how to align the Tablet to the Monitor.
- If help is needed with connecting the Tablet and ASSURE system, tap **Help** on the Connect Devices screen.

Step 5   Align the top left corners of the Tablet and Monitor

- When the Tablet and ASSURE system connect, an audio tone plays (if the volume is on) and a "Connecting/Connected" animation appears on the screen.

Step 6   After connecting the Monitor to the Tablet, the System Setup begins to configure the first session

- See section 4.3, Setting Up the ASSURE System, on page 46 for more information.

4.3   Setting Up the ASSURE System

When the Tablet initially connects with a Monitor that has not been programmed, the system setup appears. A new system setup can also be initiated on a Monitor that has already been programmed by selecting **Create a New Patient** on the Patient Management screen. Completing the system setup ensures the Patient Code is generated with the correct date and time for accuracy of data collection, and ensures the ASSURE system is configured properly and operational.

The system setup consists of the following steps:

1. Verifying the basic ASSURE system settings.
2. Entering patient information and creating the patient's record.

The initial System Setup screen appears when the Tablet connects to a Monitor for the first time. For instructions on how to connect the Tablet with the Monitor, see section 4.2, Starting the ASSURE Application, on page 44.

Note: If the Monitor has already been programmed, the initial System Setup screen will appear after selecting Create a New Patient on the Patient Management screen.


The initial System Setup screen provides confirmation of the date, time, and time zone on the ASSURE system.

4.3.1 Verifying the ASSURE System Date and Time

The ASSURE system date, time, and time zone settings must be verified, so the patient data is stored properly. If the ASSURE system's date and time settings are incorrect, synchronize the ASSURE system with the Tablet's date and time settings, or manually set the date and time settings from the System Setup screen.

To synchronize the ASSURE system time with the Tablet

Step 1 Tap Sync WCD to Tablet on the System Setup screen
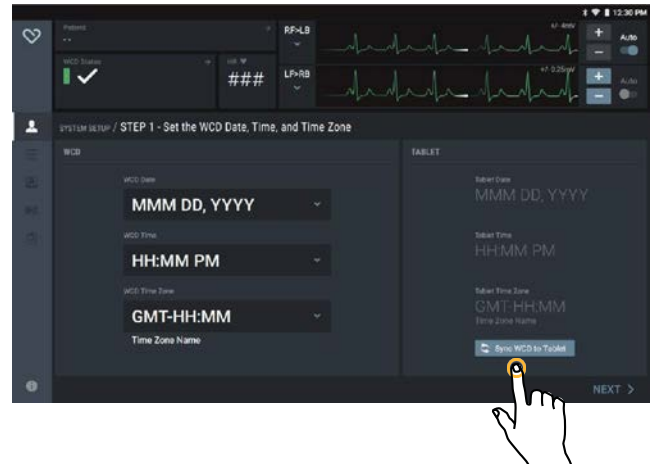
Step 2 After setting up the WCD Date and Time, tap Next to proceed

- The System Setup – Step 2 screen appears. See section 4.3.2, Creating a New Patient Record, on page 48 for more information.

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4.3.2   Creating a New Patient Record

When a new patient record is created for the ASSURE system, any existing patient data on the ASSURE system is deleted.

Note: Always create a new patient on the Monitor before fitting the patient. Otherwise, a Service Needed alert will appear when the Battery is inserted into the Monitor for the first time.

To create a new patient record on the Tablet:

Step 1   Enter the patient's information

- Tap in a field to display a virtual keyboard on the screen.
- To hide the keyboard, tap the keyboard icon

   .

- Enter the relevant patient information.
- To enter the date of birth, tap the field to display the Date of Birth screen.
    - Select the appropriate month, day, and year.
    - When finished, tap **OK**.

Step 2   After entering the information, tap SAVE

- A Programming Successful message appears after saving the changes.
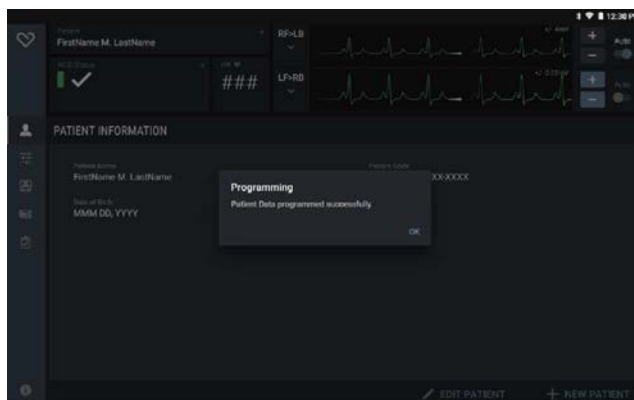
Step 3   Tap OK to close the screen

4.3.3   Recording the Patient Code

After creating a new patient, write down the Patient Code. The Patient Code is required to enroll the patient in the remote server.

To find the Patient Code:

Step 1   **Tap the Patient Information icon on the Navigation menu**

- The Patient Information screen appears.
- The Patient Code is located on the right side.

Step 2   **Record the Patient Code to activate the patient on th**

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5. Patient Fit

The patient must wear the ASSURE wearable defibrillator (ASSURE system) all the time, except while showering or bathing, for the prescribed duration. The ASSURE system must fit the patient properly and comfortably. In addition, the patient should feel comfortable using the ASSURE system in their everyday life.

This section provides the following patient session information and instructions:

- Fitting the patient with the ASSURE system
- Starting the ASSURE system
- Using the Carry Pack
- Starting the ASSURE application
- Confirming proper fit of the Garment on the patient
- Programming the ASSURE system
- Creating a Session Report
- Viewing the Report Queue application

5.1 Fitting the Patient with the ASSURE System

This section includes:

- Measuring the patient for proper Garment fit
- Assembling the Garment with the patient
- Putting the assembled Garment on the patient

5.1.1 Measuring for Proper Garment Fit

Required item:

- Flexible measuring tape

Instructions:

Step 1   Ask the patient to remove any outer wear (jacket, sweater, pullover)

- Patient should be wearing a t-shirt, bra, or thin top only.

Step 2   Instruct the patient to stand with their arms down at their sides

Step 3   Measure the patient's underbust chest circumference over their clothing

- Wrap the measuring tape tightly around the patient's rib cage at the lower border of the sternum.
- Measure to the nearest half-inch. Round down all measurements.
- Proper fit must be made according to the underbust measurement, regardless of bust or shoulder size.
- For certain body types, both Garment styles may be considered regardless of gender.
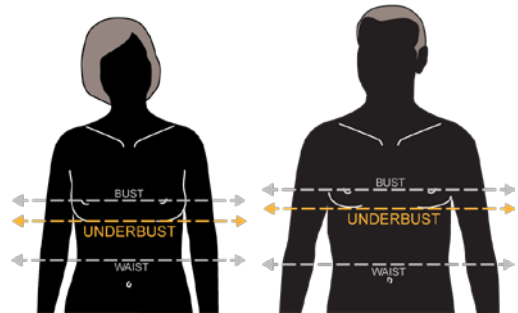
Step 4   Determine the appropriate size Garment for the patient
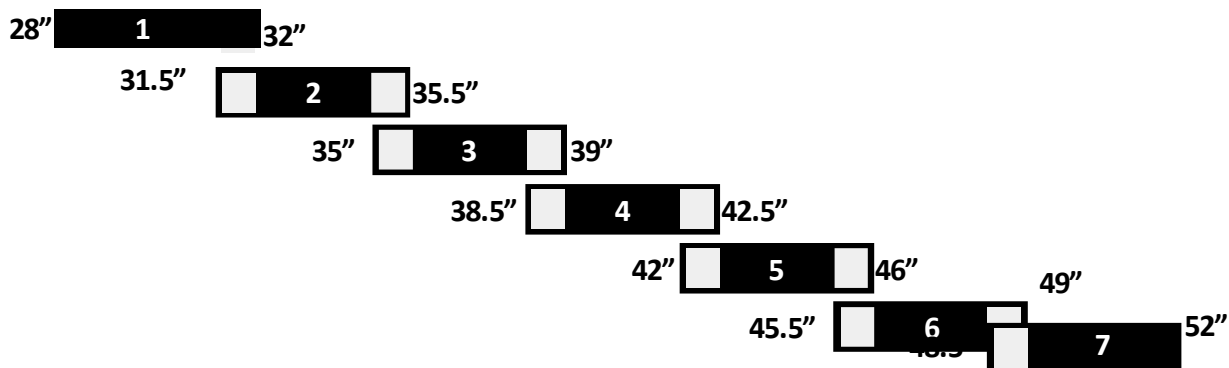
28" [1] 32"
31.5" [2] 35.5"
35" [3] 39"
38.5" [4] 42.5"
42" [5] 46"
45.5" [6] 49"
48.5" [7] 52"

- If the patient falls in between two sizes, attempt to fit the patient with the smaller-sized Garment.
- If the patient falls outside the size range (less than 28" or more than 52"), do not proceed. Contact the prescriber.

5.1.2　　Helping the Patient Assemble the Garment

Note: Before assembling the Garment, introduce the ASSURE system kit to the patient, reassure them that they will be taught how to use the system, and have the patient watch the training video. Encourage patients to pause the video for any comments or questions. For more information on the patient training video, see section 1.6, Patient Training Video, on page 15.

Use the following instructions to assist the patient with inserting the Therapy Cable into the Garment.

The PSR should encourage family members and caregivers to read the *ASSURE Wearable Defibrillator Patient Handbook* or watch the patient video (available at www.kestramedical.com) to understand how to assemble and use the ASSURE system.

Required Items:

- Garment fitted for the patient
- Therapy Cable
- Flat, clean surface to lay out the Garment and Therapy Cable

Instructions:

Step 1　　If necessary, help the patient connect the shoulder straps on the Garment

- Using your best judgment, place the shoulder strap hooks in a suitable setting for the patient's body size.

- For taller patients, place the hooks in a lower setting. For average-sized patients, place the hooks in a middle setting.

- For Style B Garments, placing the straps in a higher setting provides more support.

- The shoulder straps should be comfortable but not loose. Extra shoulder strap length should go behind the strap (as shown to the right).
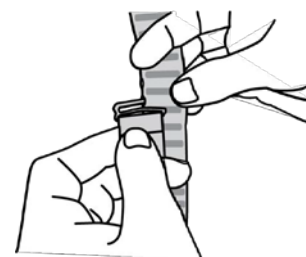
Step 2　　The patient should place the Garment on a flat surface with the numbers facing up

- Show the patient the assembly sequence numbers on the Garment.

- Point out the hub receptacle (number 1) and snaps (numbers 2-5).
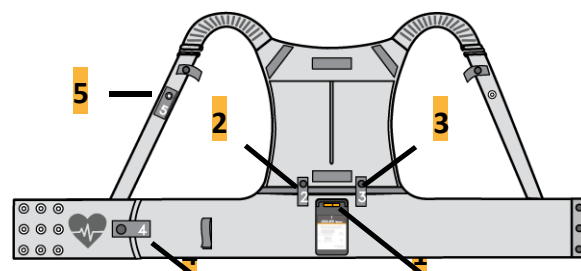
Step 3   The patient should lay the Therapy Cable near the Garment with yellow side of the Therapy Pads facing up

- Untangle any cords.

- Point out the numbering on the Therapy Cable and show how it correlates to the numbering on the Garment.

Note: Ensure the patient understands that the Hub and Alert Button numbers are on the back of the parts.
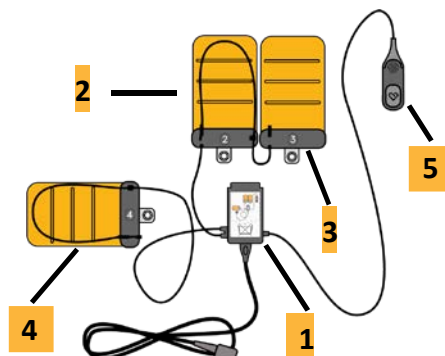
Step 4   The patient should insert the Hub into the Garment and press down firmly until the Hub clicks into the Hub Receptacle

- The patient should insert the Hub at a slight angle so it fits under the lip of the Hub Receptacle.

  Note: Have the patient practice inserting and removing the Hub.
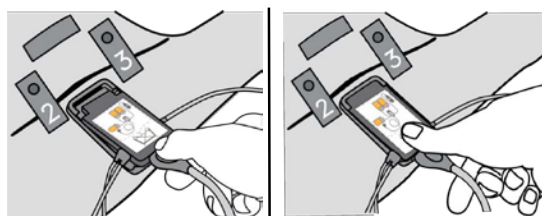
Step 5   The patient should insert Therapy Pads 2 and 3 into the back pockets

Note: There is a divider between the pockets.

- Make sure the yellow side is facing up.

- Show the patient how to use the tabs to open the pockets on the Garment.

- Make sure the Therapy Pads are on each side of the divider and completely inside their pockets.
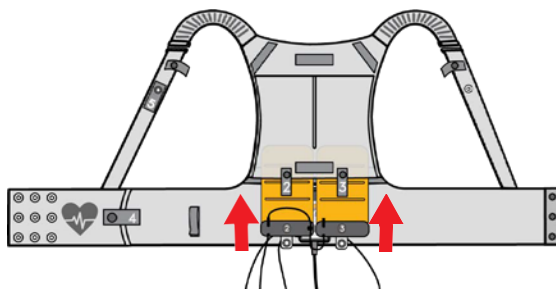
Step 6   The patient should snap Therapy Pads 2 and 3 to the pocket tabs
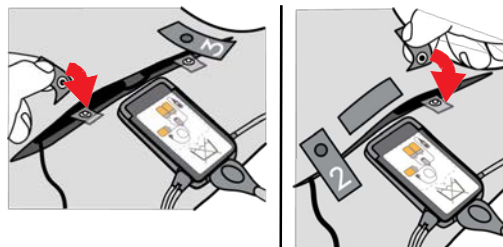
Step 7   The patient should insert Therapy Pad 4 into the front pocket

- Make sure the yellow side is facing up.
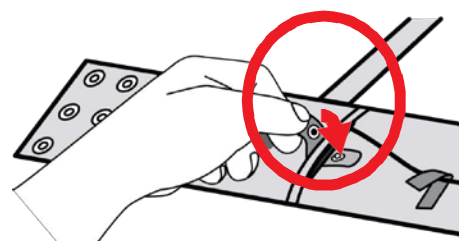- The loop of the cord should lie flat on top of the pad inside the pocket.
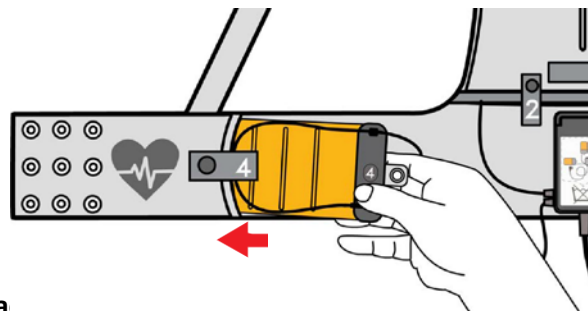
Step 8   The patient should loop any extra length of cord and pla

- Remind the patient that the looped cord should go on TOP of the Therapy Pad in the pocket, not underneath it (between the pad and the pocket mesh).
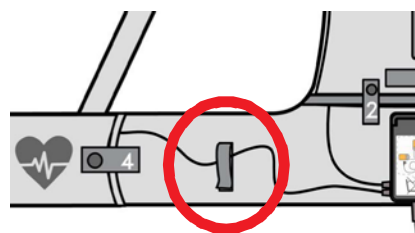

Step 9   The patient should snap Therapy Pad 4 to the pocket tab

Step 10 The patient should fasten the cord wrap around the Therapy Pad 4 cord

Note: If there is extra cord length, the patient should open the pocket and repeat steps 8 and 9.

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Step 11 The patient should pull the Alert Button and cord through the loops on the back of the Garment

a. Determine the side on which the patient wants to wear the Alert Button. There are Alert Button snaps on both sides of the Garment.

   Note: If the patient has an implanted device, like a pacemaker, the Alert Button may be more comfortable on the opposite shoulder.

b. Have the patient thread the Alert Button through the center loops on the back of the Garment (above the Hub Receptacle).

c. The patient should pull the Alert Button through the angled loop for the side they selected.
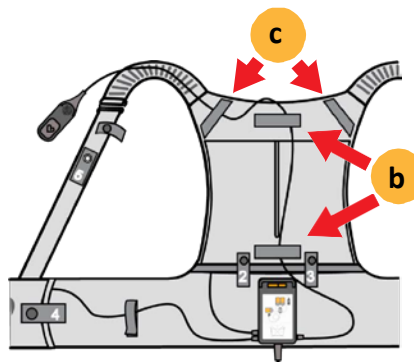
Step 12 The patient should snap the Alert Button (number 5) to the shoulder strap

• Show the patient that the right shoulder strap does not have a number on it, but the snap is in the same location as on the left side.
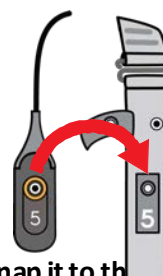
Step 13 The patient should place the cord wrap over the Alert Button cord and snap it to the shoulder strap

Note: There may be some extra Alert Button cord length after threading the cord through the Garment and fastening it to the shoulder strap properly. This allows for flexibility while wearing the assembled Garment.
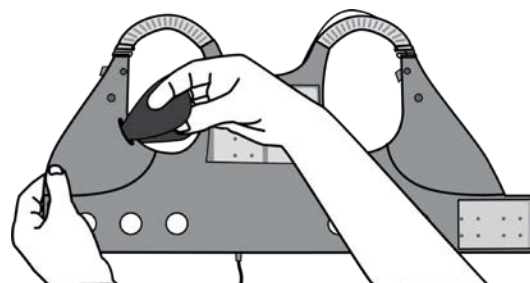
• The assembled Garment should look like the picture below.
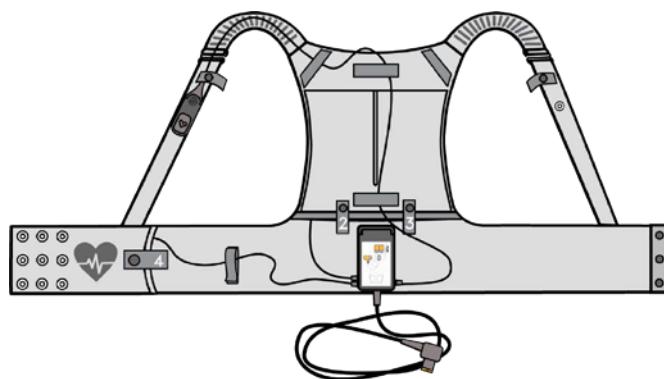
Step 14 **(Optional) Insert a bra pad (provided) into the opening between the fabric layers of each cup in the Style B Garment**

5.1.3 Helping the Patient Put on the Assembled Garment

Use the following instructions to assist the patient with putting on the assembled Garment. After completing these steps, the patient should be wearing the assembled Garment.

Instructions:

Step 1 **Ask the patient to remove their shirt and any undergarments (including bras)**

Step 2 **Examine the patient's torso for any skin abnormalities that may become an issue when wearing the Garment for an extended length of time**

>   *Note: Do not place the ASSURE system on a patient if they have an open wound that will come in contact with the ASSURE system.*

Step 3 **Help the patient put on the assembled Garment with the Sensors against their bare skin**

- The patient should:
    - Insert their arms through the shoulder straps and the back of the Garment.
    - Pull the straps over their shoulders.
- Point out the Sensors to the patient and explain that the Sensors must touch their bare skin at all times.

>   *Note: The Garment contains the following materials:*
>   - *Body fabric: 59% Polyamide, 41% Elastane (spandex)*
>   - *Inner lining: 73% Polyamide, 27% Elastane*
>   - *Therapy Pad pockets: 100% Silver-plated Nylon*
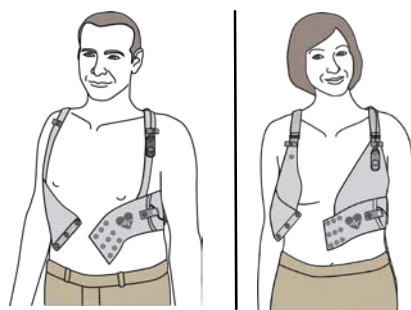
Step 4 **The patient should pull the Garment snug around their rib cage and then fasten the front closure snaps**

- The Garment must have a snug fit to keep the Sensors in contact with bare skin.
- Ensure the superior aspect of the Garment band (Style A), or the bottom edge of the bra cup (Style B), is below either the top of the areola or the inframammary fold, whichever is higher.
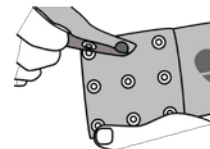
Step 5 **The patient should adjust the shoulder straps to lie flat against their chest and shoulders**

- The shoulder straps should be comfortable but not loose.
- Demonstrate to the patient that any extra upper strap length goes behind the lower strap (as shown to the right).

>   *Note: It may be easier to adjust the shoulder straps if the Garment is removed.*
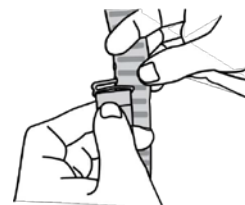
**Step 6   Teach the patient how to assess Garment fit**

- Use the Garment Fit images to emphasize that the front Therapy Pad should be snug around the patient's rib cage, below their breast area and nipples, but above the patient's stomach.

- The shoulder straps should lie flat against the patient's chest and shoulders.

- The Therapy Pads should lie flat against their back.

- Check that the Garment is not twisted around the sides or back. Use a mirror if one is available or have another person help check.

  Note: Patients should make sure their breast tissue is not underneath the front Therapy Pad or Sensors.

Proper Garment Fit

Improper Garment Fit

Too High   **Too Low**

Twisted
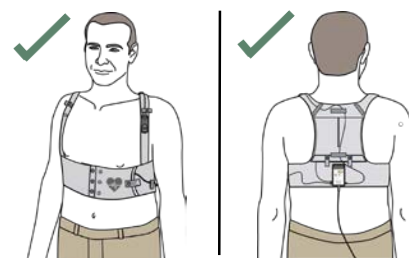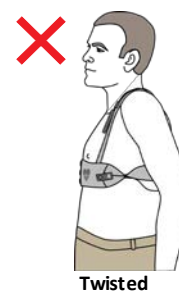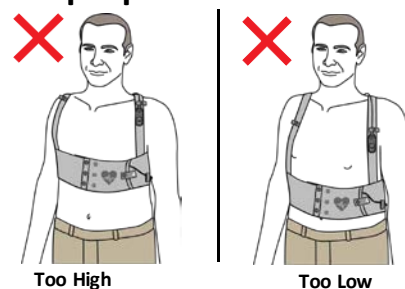
Step 7   After confirming the Garment's fit, the patient can put their clothes on <u>over</u> the Garment

- Ensure that the patient understands the following:
  - The patient must not place anything between the Garment and their body, even if they want to increase their comfort. The Sensors must touch bare skin.
  - Undershirts and bras may only be worn <u>over</u> the Garment (as shown).
  - If the patient has any comfort issues with the Garment, they should try adjusting the Garment or call the ASSURE Helpline at 1.833.692.7787.
  - It will take a little time to get used to wearing the Garment. If the patient has ongoing comfort issues, they should call the ASSURE Helpline at 1.833.692.7787.
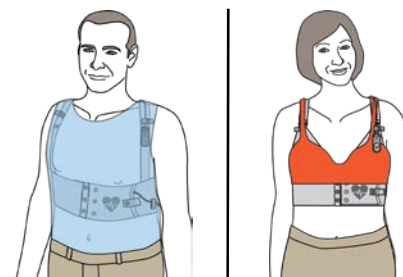
Step 8   Set up the shoulder straps on the second Garment using the settings from the first Garment

- Explain the purpose of the second Garment, including that it may be worn while washing a used Garment.
- Place the second Garment in the system kit

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5.1.4   Starting the ASSURE System

Use the following instructions to assist the patient with starting the ASSURE system.
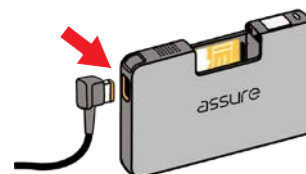
Required Items:

- Assembled Garment (worn by patient)
- Monitor
- Carry Pack
- Battery

Instructions:

Step 1   The patient should insert the Plug into the Monitor

- The Plug can be inserted in one direction only.
- A "click" sound means the Plug is securely inserted.

Note: Have the patient practice inserting and removing the Plug.

Step 2   The patient should insert a fully charged Battery into the Monitor

- Demonstrate that the Battery can only be properly inserted one way.
- A "click" sound means the Battery is securely inserted.

Note: Have the patient practice inserting and removing the Battery.
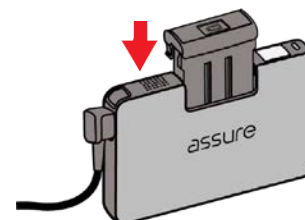
Step 3   Wait a few minutes while the ASSURE system powers up

- Explain the start up Monitor icons to the patient.
- The Monitor light turns blue right away and the Monitor screen displays the Welcome icon.

- The System Busy icon then appears.

- Wait for the Alert Button icon to appear on the Monitor screen (this may take a few minutes).

Notes:

- *This time may be used to explain how to charge the Battery. See section 6.2, Managing the Battery and Charger, on page 79".*
- *Always create a new patient on the Monitor before fitting the patient. Otherwise, a Service Needed alert will appear when the Battery is inserted into the Monitor for the first time.*

- **If a different icon appears on the Monitor screen**, check the alert icon and respond to the alert.
  - See section 6.7, Alerts, on page 102 for a list of the alert icons.
  - After responding to the alert, the Alert Button icon should appear on the Monitor screen.

  Note: This is an opportunity to discuss the different alerts and how to press the Alert Button to respond to alerts.

Step 4   The patient should press the Alert Button to finish setup

- If the system is working properly, the patient will:
  - See a solid green Monitor light and the System Ready icon on the Monitor screen (shown at right).
  - Hear a three-note guitar strum.
  - Feel a single-pulse vibration from the Alert Button.

  Note: The green light and the screen backlight turn off after five seconds.

5.1.5   Using the Carry Pack

Use the following instructions to explain how to wear the Carry Pack and how to insert the Monitor into the Carry Pack. After completing these steps, the patient will be wearing the complete ASSURE system.

Required Items:

- Patient wearing the assembled Garment
- Monitor and Carry Pack

Instructions:

Step 1   Help the patient put on the Carry Pack

Demonstrate how the patient can wear the Carry Pack:

- Over the shoulder (with the strap lengthened)
  - Across the body or over the shoulder

- Around the waist
  - With the strap shortened or attached to a belt using the belt clip.

Note: The inside of the Carry Pack (the side with the belt clip and corner straps) should always face towards the patient's body.
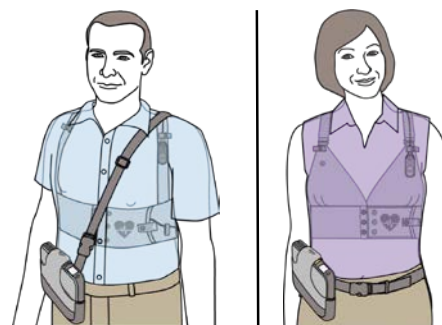
Step 2   Demonstrate Carry Pack strap adjustments

- The Carry Pack strap includes a buckle, two strap adjusters, and an elastic band.
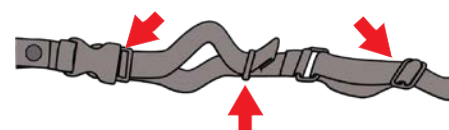
Using the buckle

- – To connect the buckle, press the two sides together until there is a "click".
- – To detach the buckle, squeeze the buckle sides until they unlock and then pull them apart.

Adjusting the strap

- – Slide the adjuster along the strap to lengthen or shorten the strap.
- – Use the buckle's strap adjuster to tighten the strap when wearing the Carry Pack around the waist.
- – Insert the strap through the elastic band.

Step 3   The patient should open the flaps on the Carry Pack

Step 4   The patient should insert the Monitor into the Carry Pack

Step 5   Show the patient how to manage the extra cable length to avoid catching the cable on anything

- • Options for managing extra cable length:
  - – Use the back corner straps of the Carry Pack.
  - – Place it in the Carry Pack pocket.
  - – Tuck it into their pants or pocket.
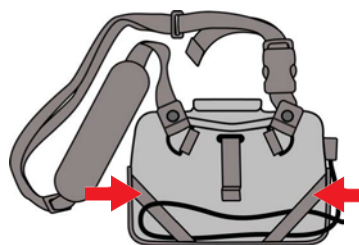
After completing all the steps, ensure that the Carry Pack with the Monitor inside fits comfortably on the patient. Make any adjustments as necessary.

Note: Ensure patients understand that they can change how they wear the Carry Pack as needed throughout the day.

5.2 Starting the ASSURE Application

After starting the ASSURE application, a connection must be established between the Tablet and the ASSURE system's Monitor. After connecting the Tablet and Monitor, the ASSURE system and Tablet are in a "session". Each session is independent, so patient data from one session does not exist in another session.
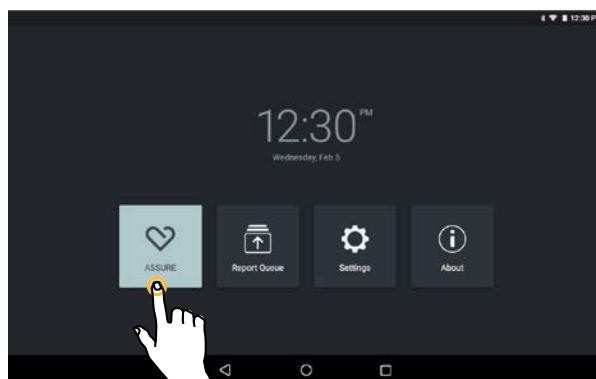
Instructions:

Step 1 **Ensure the ASSURE system's Monitor is turned on and has completed the power up process Step 2**

Remove the Monitor from the Carry Pack and lay it on a flat surface

Step 3 **Ensure the Tablet is powered on and unlocked**

Step 4 **Tap ASSURE on the Home screen**

- The Connect Devices screen appears showing how to align the Tablet to the Monitor.
- If help is needed with connecting the Tablet and ASSURE system, tap **Help** on the Connect Devices screen.

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Step 5   **Align the top left corners of the Tablet and Monitor as shown on the screen**

- When the Tablet and ASSURE system connect, an audio tone plays (if the volume is on) and a "Connecting/Connected" animation appears on the screen.

Step 6   **After connecting the Monitor to the Tablet, the Pa[...] continues the patient session**

5.3   Viewing the ECG

Note: Display of the ECG is not intended to be used as a diagnostic tool.

The ECG displays two waves of streaming ECG data or the amount of motion (measured by the built-in accelerometer) acquired through the currently connected ASSURE system. Select from four available waveforms or the motion option. The waveforms display the most recent six seconds of data.

To select a specific ECG waveform:

Step 1   Tap the down arrow icon under the electrode setting

Step 2   Select one of the following options:

- Right Front > Left Back (default selection)
- Left Front > Right Back (default selection)
- Right Front > Left Front
- Left Back > Right Back
- Motion

Note: The same waveform or motion cannot be selected to display in both fields at the same time.

The waveforms use automatic scaling by default. To

manually scale the waveforms:

Step 1   Tap Auto to turn off automatic scaling

Step 2   Tap the "+" or "-" buttons to scale the waveform up or down

Note: Scaling the waveforms may be useful to assess the presence of pacemaker spikes.

5.4   Confirming Fit with the Tablet

During a patient session, confirm the fit of the ASSURE system using the Tablet. The Tablet displays the current ASSURE system status information on the Device Status screen. Use the patient avatar on the Device Status screen to verify that the patient is wearing the Garment correctly. If the system is ready and the Garment is in contact with the skin, all indicators on the patient avatar will be highlighted in green. Otherwise, any issues will be indicated in yellow.

To view the WCD Status screen:

Tap the WCD Status icon on the Navigation menu

- The WCD Status screen appears.

Note: The WCD Status screen can also be viewed by tapping in the WCD

To confirm the fit of the ASSURE system on the patient:

Step 1   Make sure the patient has pressed the Alert Button Step

2   Tap the WCD Status icon on the Navigation menu

- The WCD Status screen appears.

Step 3   Verify there are no Sensors or Therapy Pads off (the Sensors and Therapy Pads will appear yellow if there is an issue)

Note: Patient avatar status is near real-time and does not include the latency built into the header's WCD Status Summary.

- Ensure the patient avatar is solid green with no intermittent yellow indicators.
- Verify contact with the patient's skin. All indicators should remain green even with patient movement.
- If any of the patient avatar indicators are yellow (even intermittently), try the following: For

  Sensors:

  – Adjust the Garment so the Sensors are flat and touching bare skin.
  – Check that the Garment is not twisted, there is nothing under it, and the Therapy Pads are assembled correctly.
  – Moisten the skin under the Sensors with water or lotion.
  – Tighten the Garment by adjusting the front closure snaps and shoulder straps.

For Therapy Pads:

- Confirm the Therapy Pads are flat and touching bare skin.
- Check that the Garment is not twisted and there is nothing under it.
- Moisten the skin under the Therapy Pads with water or lotion.
- Change the front closure snaps and shoulder strap settings for a snug Garment fit. The shoulder straps should be comfortable but not loose.
- Verify the Therapy Pads are correctly inserted and snapped in the pockets.

Step 4   Verify both channels of the ECG signal are clean in the top right portion of the screen

- See section 5.3, Viewing the ECG, on page 65 for more information.

Step 5   Address any other issues highlighted in yellow

- Refer to section 8.1, Alerts Quick Reference, on page 124 for how to respond to the System alerts.

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5.5   ASSURE System Programming

The ASSURE system includes settings that are programmable using the Tablet. These settings allow customization of the device behavior according to the patient's prescription.

The following settings can be programmed:

- ASSURE system's time zone setting (if the time zone setting was not set properly during the new patient creation process)
- VT Rate Threshold setting and the VF Rate Threshold setting – Program the rates specified in the patient's prescription, and select whether the VT Zone will be monitored or will deliver therapy.

Any changes to the settings are highlighted in yellow to identify them as proposed settings. These settings will not take effect until they are programmed into the Monitor. See the following sections for more information on changing the settings and programming the ASSURE system.

5.5.1   Viewing ASSURE System Settings

A summary of the current ASSURE system settings can be viewed on the WCD Settings screen. The WCD Settings screen allows for changes to the settings.

To view the ASSURE system settings on the WCD Settings screen:

Step 1   Tap the WCD Settings icon on the Navigation menu

- The WCD Settings screen appears.
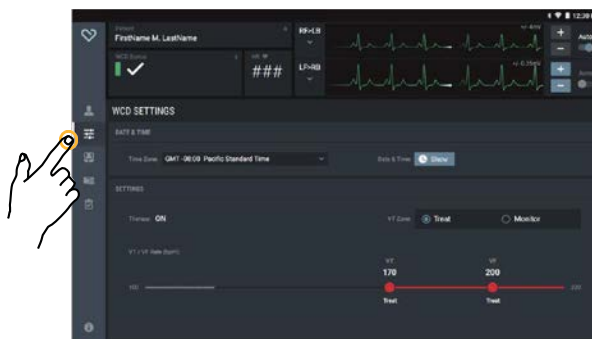
Step 2   Verify the current ASSURE system settings

The following options are available from the WCD Settings screen:

- View the date and time on the ASSURE system
- Set the time zone on the ASSURE system
- Adjust the VT/VF rate thresholds for the ASSURE system and select the VT Zone operation (monitor or deliver therapy)
- Identify proposed changes to the settings
- Program the settings on the ASSURE system

5.5.1.1 Viewing the ASSURE System's Date and Time Settings

To check the date and time settings on the ASSURE system:

Step 1   Tap the Show button next to Date & Time

- The date and time are displayed for about five seconds before the Show button re-appears.
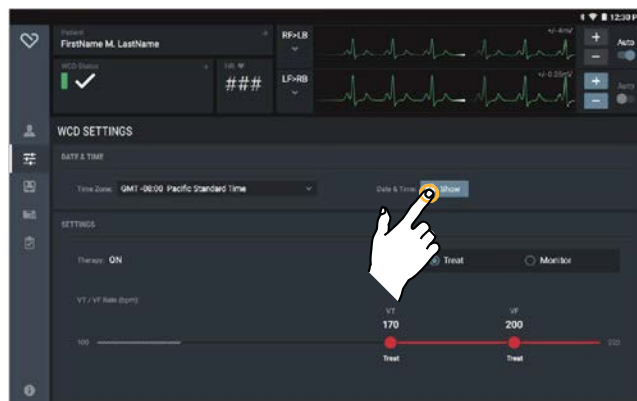
5.5.1.2 Setting the Time Zone

To set the ASSURE system's time zone:

Step 1   Tap the Time Zone drop-down list
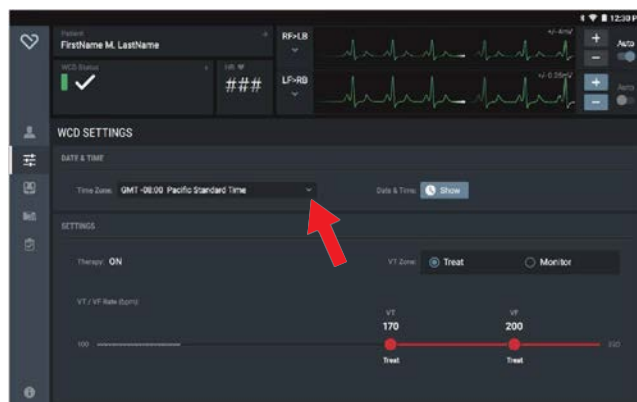
Step 2   Select the appropriate time zone for the desired location

Step 3   When finished, program the proposed changes into the ASSURE system

- See section 5.5.3, Programming Changes to Settings, on page 71.

5.5.1.3   Adjusting the VF and VT Rate Settings

Set the VT/VF rate thresholds to values according to the patient's prescription. If the prescription does not include the threshold values, use the default values for the rate thresholds or contact the prescriber.

Note: Programming changes are not effective until the programming is confirmed using the Tablet.

To set the VT Zone setting:

Select the appropriate VT Zone setting

- Set to **Treat** to enable Therapy in the VT zone range.
- Set to **Monitor** to disable Therapy in the VT zone range.

   Note: Episode information will still be stored when the VT Zone is set to Monitor.
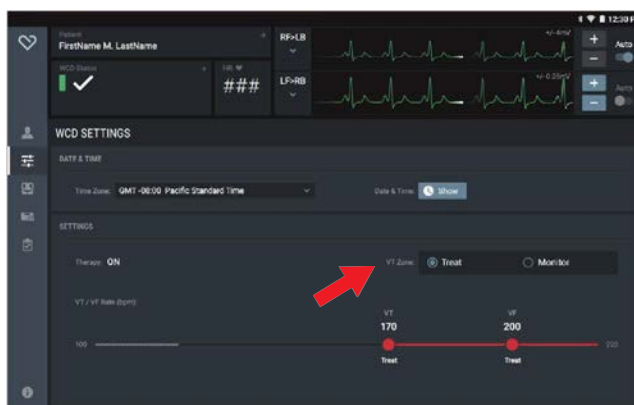
To set the rate threshold:

Step 1   **Tap the VT Rate slider or the VF rate slider on the Rate Bar**
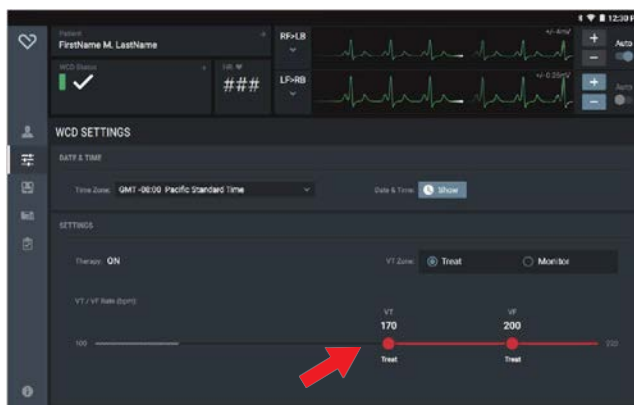
Step 2   **Move the slider to the left or right to select the appropriate rate**

- The VT rate range is 130 to (VF rate - 10) bpm in 10 bpm intervals. The default setting is 170 bpm.
- The VF rate range is 180 to 220 bpm in 10 bpm intervals. The default setting is 200 bpm.

Notes:

- *The VF Rate Threshold value must be higher than the VT Rate Threshold value.*
- *The sliders cannot cross over each other. To increase the VT Rate Threshold value, move the VF Rate Threshold slider to the right before moving the VT Rate Threshold slider. Conversely, to decrease the VF Rate Threshold value, move the VT Rate Threshold slider to the left before moving the VF Rate Threshold slider.*

5.5.2   Identifying Pending Changes to WCD Settings

Any pending changes to the ASSURE system settings are indicated by highlighting those changes in yellow in the Settings section on the WCD Settings screen. A yellow dot indicator also appears next to the WCD Settings icon in the Navigation menu.
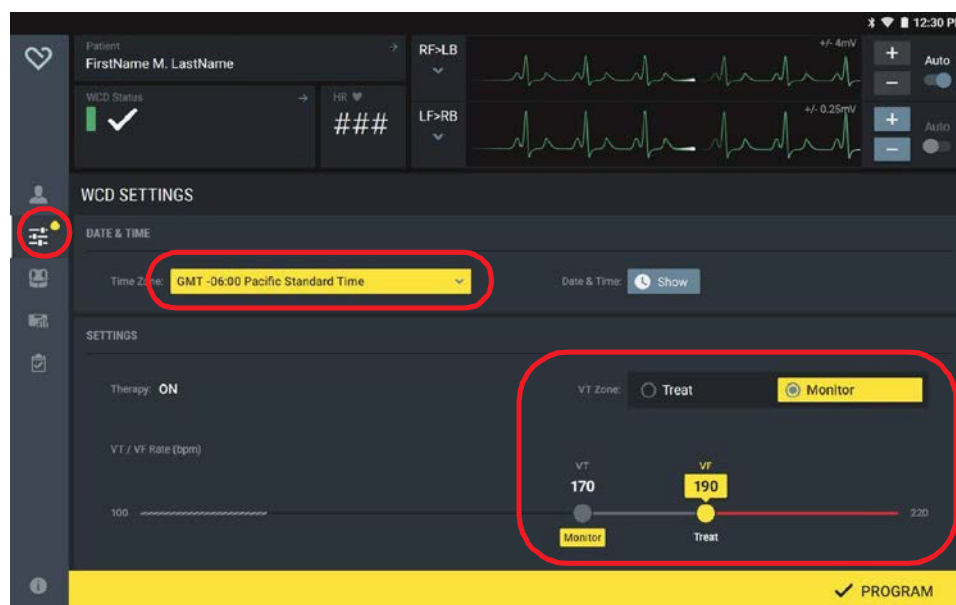
Pending Changes Indicators

5.5.3   Programming Changes to Settings

After making changes to the ASSURE system settings, program those changes into the Monitor. *Note:*

Programming changes are not effective until the programming is confirmed using the Tablet. To program

any changes into the Monitor:

Step 1   Tap Program on the WCD Settings screen
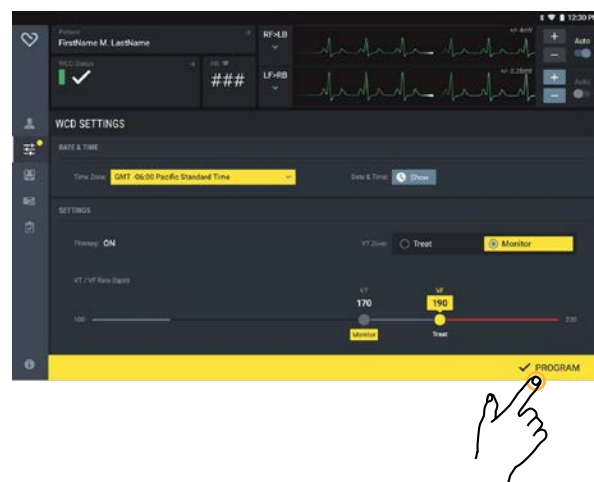
- A message screen appears while the Tablet programs the ASSURE system.

Step 2   **Tap Program on the message screen**

- A confirmation screen appears after the changes have been successfully programmed.

Step 3   **Tap OK to close the confirmation screen**
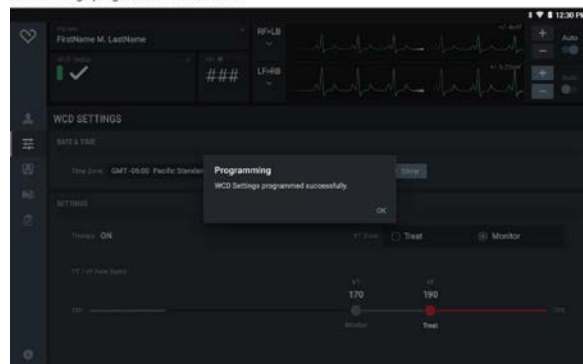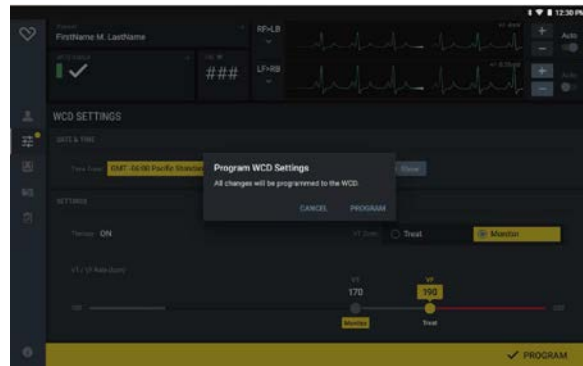
5.6   Creating a Session Report

After fitting the patient, generate a report for the current session. The session report contains a summary of the patient's information and identifies what changes were made to the ASSURE system during the session.

To create a Session Report:

Step 1   Tap the Session Report icon on the Navigation menu

- The Session Report screen appears.

Step 2   Tap Create Report to proceed

- The session report is created and sent to the remote server when the Tablet has a wireless network connection.
- Check the Report Queue application for the session report's delivery status.

    Note: Session reports can be viewed and printed from the remote server only.

5.7 Viewing the Report Queue Application

The Report Queue application is available on the Home screen. The application displays a list of generated reports, their current transmission status to the remote server, and provides an option to delete reports from the Tablet.

5.7.1 Starting the Report Queue Application

To launch the Report Queue application:

Tap the Report Queue icon on the Home screen
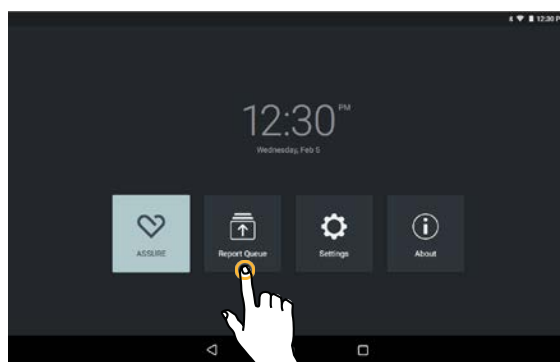
- The Report Queue screen appears.

The Report Queue screen displays the following information:

- Date and time the report was created
- Patient name
- Patient code
- Transmission status
  - Sent
  - Not Sent

The following options are available from the Report Queue screen:

- Manually upload reports from the Tablet to the remote server
- Delete a report in the Report Queue
- Return to the Home screen

5.7.2   Manually Uploading to the Remote Server

Note: The Tablet requires access to a wireless connection to communicate with the remote server.

The Tablet automatically performs regular background transmissions of all reports to the remote server. To

force the Tablet to synchronize with the remote server, tap the **Sync** icon on the Report Queue screen.

5.7.3   Removing a Report from the Report Queue

A report can be removed from the Report Queue. If a report has not been successfully transmitted to the remote server, the Report Queue application will provide a notification that the report has not been transmitted and request confirmation to continue with the removal of the report.

Note: Removing a report that has not been sent to the remote server is irreversible. After a report has been deleted, it cannot be recovered.

To remove a report:

Step 1   Find the desired report on the Report Queue screen

Step 2   Tap the Remove Report icon

 • A confirmation screen appears.

Step 3   Tap Remove on the confirmation screen

5.7.4   Returning to the Home Screen

To return to the Home screen, tap the **Back** icon on the screen.

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6. Patient Training

This section provides information and training for teaching the patient how to incorporate the ASSURE wearable defibrillator (ASSURE system) into their daily routine, including:

- Daily Routine Checklist
- Charging the Battery and replacing the Battery in the Monitor
- Taking a shower or bath
- Wearing the ASSURE system while sleeping
- General care and cleaning instructions
- Alerts

Note: In addition to the training provided in this section, it is important to review the chapter 2, Safety Information, on page 29 with the patient.

6.1   Patient Daily Routine Checklist

Assist the patient with understanding the daily procedures for wearing and using the ASSURE system. Review the Safety Information section in the *ASSURE Wearable Defibrillator Patient Handbook* with the patient.

☐ **Wear the ASSURE system**

- The patient must wear the ASSURE system all the time, except when they need to take a shower or bath or participate in water-based activities, like swimming.
- The patient should wear the ASSURE system while they sleep.

☐ **Charge the Battery**

- The patient should replace the Battery at the same time every day to ensure the ASSURE system has adequate power.

☐ **Respond to any alerts**

When an alert happens, the patient should:

1. Press the Alert Button to quiet the alert
   - Press once to quiet the alert.
   - For System alerts, press the Alert Button again to replay the voice message.
2. Look at the Monitor light and screen
3. Respond to the alert

☐ **Wash the Garment when necessary**

- Use cold water and a mild laundry detergent, like:
  - all® free clear
  - Tide Free and Gentle™

  Note: The patient should follow the detergent manufacturer's warnings and cautions listed on the packaging.

- Hang the Garment to air dry.
- Review the following safety information with the patient:

⚠️ **WARNINGS**
- *Always remove the Therapy Cable before washing the Garment.*
- *Do not use chlorine bleach, bleach alternatives, fabric softeners, or anti-static sprays. Also, do not use detergents or detergent "pods" that include bleach or fabric softener additives.*

☐ **Remove the ASSURE system before taking a shower or bath**

Review the following warning text with the patient:

⚠️ **WARNING**
Do not place the Monitor, Therapy Cable, Charger, or Battery in water or other liquids. Avoid spilling any liquids on these devices. Liquids entering these devices may cause them to malfunction or fail.

6.2 Managing the Battery and Charger

The ASSURE system comes with a Charger and two Monitor batteries. One Battery should remain in the Charger while the other Battery is in the Monitor.

6.2.1 Plugging in the Charger

Note: The patient should use only the accessories provided with the ASSURE system, including the Batteries and Charger.

Instructions:

Step 1   Instruct the patient to insert the Charger cord plug from the AC adapter into the Charger

- The patient should insert the plug with the cord straight up.

- Turn the cord to the right to secure it in the clip.

  Note: Properly secure the cord in the clip. This prevents the cord from being accidentally removed from the Charger.

Step 2   Connect the power cord to the AC adapter

Step 3   Plug the power cord into an electrical wall outlet

Notes:

- *Do not place the Charger in a position or location that makes it difficult to insert or remove the Battery or unplug the AC adapter power cord.*
- *If the patient must turn off the Charger for any reason, unplug the power cord from the electrical wall outlet.*
- *Always leave the Charger plugged into an electrical outlet to keep the spare Battery fully charged.*
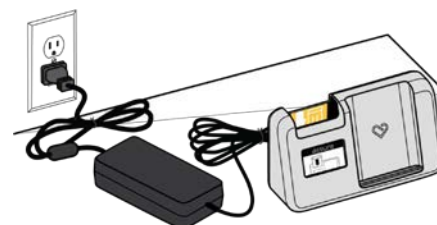
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6.2.2   Charging the Battery

The ASSURE system comes with two Batteries. The patient should replace the Battery at the same time every day. An

empty Battery charges in about four hours.

Notes:

- *The patient should check the Charger and Batteries for any wear or damage once or twice a week. To report any damage or concerns, the patient should call the ASSURE Helpline at 1.833.692.7787. See section 6.6, Checking for Equipment Damage, on page 101 for more information.*
- *The patient should use only the accessories provided with the ASSURE system. This includes the Batteries and Charger.*

Instructions:

Step 1   Insert the Battery into the Charger

- Do not force the Battery into the Charger. There is only one way to insert the Battery.
- Keep the fully charged spare Battery in the Charger until you need to replace the Battery in the Monitor.
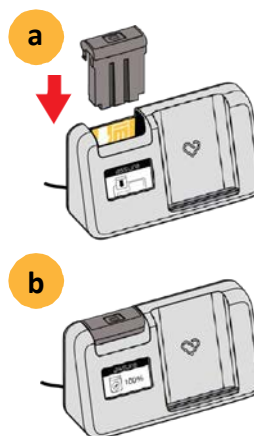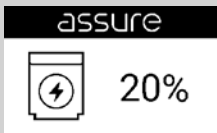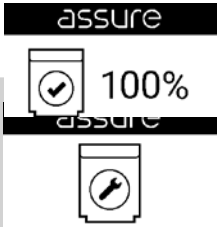
Step 2   Check the Charger screen to confirm that the Battery is charging

- See the next page for more information.

6.2.2.1   Charger Screen

The Charger screen displays the Battery's current charge status.

Screen Display	Description
	Insert a Battery into the Charger.
	The Battery is charging. The charging symbol flashes and the screen displays the current progress from 0–100% in 5% increments.
	The Battery is fully charged.
	There is a problem with the Battery. Remove the Battery and re-insert it into the Charger. If the problem still occurs, call the ASSURE Helpline at 1.833.692.7787.
	The Battery is too hot. Remove the Battery from the Charger. Allow the Battery to cool down to room temperature before using it or putting it back in the Charger.
	There is a problem with the Charger. Unplug the power cord and then plug it back in. If the problem still occurs, call the ASSURE Helpline at 1.833.692.7787.

6.2.3   Viewing Battery Status on the Monitor

A full Battery lasts at least 24 hours. The Monitor screen displays the current Battery status with the System Ready icon.

Screen Display	Description
	The Battery is fully charged (more than 24 hours of remaining charge).
	The Battery has 18 to 24 hours of remaining charge.
	The Battery has 12 to 18 hours of remaining charge.
	(Solid bar) The Battery has 6 to 12 hours of remaining charge.
	(Blinking bar) The Battery has 2 to 6 hours of remaining charge.
	(Blinking) Low Battery alert – The Battery has less than two hours of remaining charge. See section 6.7.2.6, Low Battery Alert, on page 113.

6.2.4   Replacing the Battery in the Monitor

A fully charged Battery will power the ASSURE system for a minimum of 24 hours. The patient should replace the Battery at the same time every day.

Review the following warning text with the patient:

⚠️ **WARNING**

If you will be away from home for longer than 24 hours, take the spare, fully charged Battery and Charger with you.

Instructions:

Step 1   Check that the Battery in the Charger is fully charged

- The Charger's screen shows the Battery status.

Step 2   Open the flaps on the Carry Pack

Step 3   Slide the Battery lock until you see the yellow line and lift the Battery handle

- Remind the patient that they can also watch the patient video at kestramedical.com/patients, if they need assistance with this task after they go home.
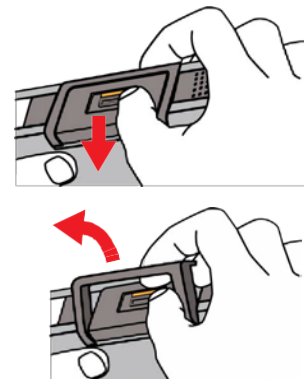
Step 4   Pull up to remove the Battery from the Monitor

- Removing the Battery turns off the system.

- Damaged Batteries may leak and cause personal injury or equipment damage. Handle damaged or leaking Batteries with extreme care. Call the ASSURE Helpline at 1.833.692.7787 to report any equipment damage.

Step 5   Take the fully charged Battery out of the Charger
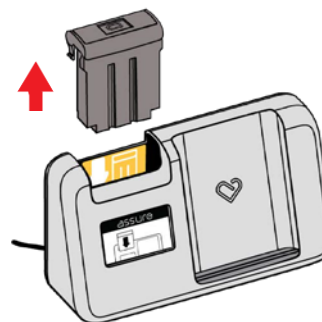
Step 6   Insert the fully charged Battery into the Monitor

- A "click" sound means the Battery is securely inserted.

- The patient should not force the Battery into the Monitor. There is only one way to insert the Battery.
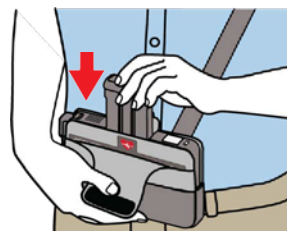
Step 7   Close the flaps on the Carry Pack

Step 8   Wait a few minutes while the system powers up

- The Monitor light turns blue right away and the Monitor screen displays the Welcome icon.

- The System Busy icon then appears.

- Wait for the Alert Button icon to appear on the Monitor screen (this may take a few minutes).

- **If a different icon appears on the Monitor screen**, check the alert icon and respond to the alert.
  - See section 6.7, Alerts, on page 102 for a list of the alert icons.
  - After responding to the alert, the Alert Button icon should appear on the Monitor screen.

Step 9   The patient should press the Alert Button

- If the system is working properly, the patient will:
  - See a solid green Monitor light and the System Ready icon on the Monitor screen (shown at right).
  - Hear a three-note guitar strum.
  - Feel a single-pulse vibration from the Alert Button.

Note: The green light and the screen backlight turn off after five seconds.

Step 10 Insert the used Battery into the Charger
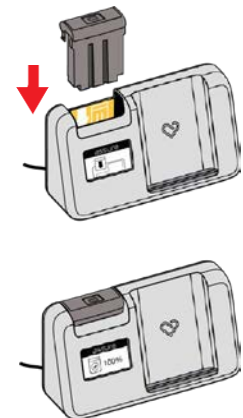
Step 11 Check the Charger screen to confirm that the Battery is charging

6.2.5   Using the Wireless Charging Well

The Charger includes a wireless charging well for mobile devices. The well provides a standard 5W charging speed and supports mobile devices up to 6.3 x 3.3 x 0.49 inches (including a case).

Notes:

- *Check with your mobile device manufacturer to confirm your device supports wireless charging.*
- *The Charger may not be compatible with all wireless-charging mobile devices.*
- *If your mobile device case holds items that may contain magnetic strips or RFID chips, like credit cards or passports, remove the case from the device before placing it in the well.*

Instructions:

Step 1   **Place the mobile device into the wireless charging well with the device's screen facing outwards**
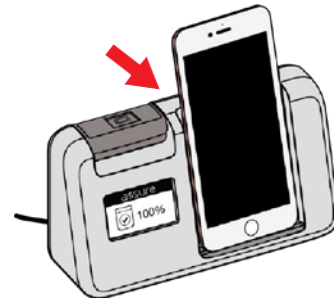
Step 2   **Check the mobile device to make sure it is charging**

- The device screen should display an indication that the mobile device is charging.

Note: If there is no indication that the device is charging, you may need to remove the device case, if one is installed. Remove the case and then repeat steps 1 and 2 above.

6.2.6　Using the USB Port on the Charger

The Charger's USB port can charge any USB-compatible device using a USB cable with a type A connector. The USB port is located on the back of the Charger.

⚠️ **WARNING**

Do not connect line voltages, power banks, or other devices that may attempt to use the USB port as an input port. The USB port is a dedicated charging port that is output only and can only charge connected devices.

Instructions:

Step 1　**Insert one end of the USB cable into the device**

Step 2　**Insert the USB cable's type A connector into the USB port on the Charger**

Step 3　**Check the connected device to make sure it is charging**

6.2.7　Loss of Power or Power Outage

The patient must keep the batteries charged for the ASSURE system to operate properly. If a

power outage occurs, the patient should follow these guidelines:

- Contact their electrical company to report the outage. The patient should inform the electrical company that they have a medical device that requires power.
- The patient should call or visit their local emergency services to see if they can help. The patient should inform the emergency services personnel that they have a medical device that requires power to charge its batteries.
- A fully charged Battery provides at least 24 hours of operation. If the power is out for more than 24 hours, the patient should try to find a place with power, like a family member or friend's house. The patient should take the spare Battery and Charger with them to charge the batteries there.

  Note: The Charger can recharge an empty Battery in about four hours.

The U.S. Food & Drug Administration (FDA) provides a booklet on their website (www.fda.gov) titled, "Home Use Devices: How to Prepare for and Handle Power Outages for Medical Devices that Require Electricity".

After power is restored, the patient should return the Charger to its usual charging location and follow the 24-hour Battery charging schedule.

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6.3   Wearing the ASSURE System

The ASSURE system is designed to be worn all the time, except while showering or bathing. The patient can wear it in a variety of public settings, like going to a grocery store, attending a sporting event, or dining out.

The patient should follow these guidelines while wearing the ASSURE system:

- **Wear any clothing <u>over</u> the Garment**
    – The patient should not wear or place anything between the Garment and their body.
    – Undershirts and bras may only be worn <u>over</u> the Garment.
- **Check for any wear or damage once or twice a week.**
- **If the patient needs to go out in heavy rain or snow, they should keep the Monitor and Carry Pack covered as much as possible.**
- **The Carry Pack strap and Therapy Cable are potential hazards for getting strangled.**

    To reduce this risk, the patient should:

    – Never wrap the Carry Pack around their neck.
    – Keep the Monitor and Carry Pack at or below waist level.
    – Manage any extra length of cable between the Hub and Monitor.
    – Remove the Carry Pack strap if sleeping with the Monitor inside the Carry Pack.
- **Do not allow children or pets to play with the ASSURE system.**
- **If the patient has any skin issues underneath the Garment, like redness, bumps, inflammation, irritation, skin breakdown, blistering, or a cut, the patient should continue to wear the system and seek medical attention.**
    Notes:
    – *The Garment contains the following materials:*
        • *Body fabric: 59% Polyamide, 41% Elastane (spandex)*
        • *Inner lining: 73% Polyamide, 27% Elastane*
        • *Therapy Pad pockets: 100% Silver-plated Nylon*
    – *The Carry Pack is 100% Polyester and the strap is 100% Nylon.*

The patient should temporarily remove the ASSURE system for the following situations only:

- When the patient needs to take a shower or bath, or when they will be actively participating in a water-based activity, like swimming.
- When moving the Therapy Cable from one Garment to the other Garment.

6.3.1   Checking the ASSURE System Status

To check the status of the ASSURE system at any time:

Press the Alert Button

What the patient will…	
See	• Solid green Monitor light • System Ready icon on Monitor screen
Hear	Three-note guitar strum
Feel	Single-pulse vibration from the Alert Button

Notes:
- *The green light and the screen backlight turn off after five seconds.*
- *If a System alert is active, pressing the Alert Button will replay the voice message.*

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6.3.2　　Sleeping in the ASSURE System

The patient must wear the ASSURE system while they are sleeping to ensure they are monitored and protected during that time.

Notes:
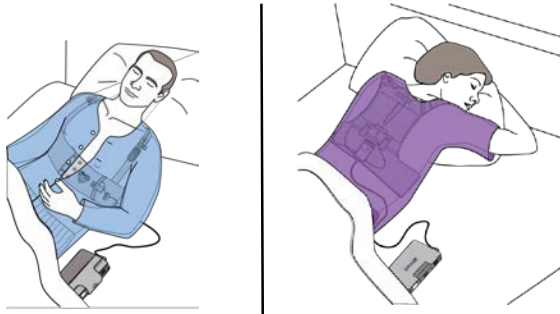
Proper Monitor Position While Sleeping

- *Keeping the Monitor in the Carry Pack while sleeping is recommended to protect the Monitor and Battery.*
- *The Carry Pack strap and Therapy Cable are potential hazards for getting strangled, especially when sleeping. To reduce this risk, the patient should:*
    - *Never place the Monitor or Carry Pack near their head or neck.*
    - *Keep the Monitor or Carry Pack at or below waist level.*
    - *Remove the Carry Pack strap if sleeping with the Monitor inside the Carry Pack.*

6.3.3　　Responding to Alerts While Sleeping

Instructions:

Step 1　　Press the Alert Button

- Press once to quiet the alert.
- For System alerts, press the Alert Button again to replay the voice message.

Step 2　　Look at the Monitor screen and light

Step 3　　Respond

- Refer the patient to the *ASSURE Wearable Defibrillator Patient Handbook* for alert information
- For System alert information see section 6.7.2, System Alerts, on page 106.

6.3.4   Taking a Shower or Bath

Review the following warning text with the patient:

⚠️ **WARNING**

Do not place the Monitor, Therapy Cable, Charger, or Battery in water or other liquids. Avoid spilling any liquids on these devices. Liquids entering these devices may cause them to malfunction or fail. Follow the instructions in the ASSURE Wearable Defibrillator Patient Handbook to properly clean these devices.

The patient must always remove the ASSURE system before taking a bath or shower or participating in a water-based activity, like swimming.

Note: The patient will not be protected while they are not wearing the ASSURE system. The patient should try to limit the activity to the least amount of time as possible.

Never Wear the ASSURE System in the Bath or Shower

Before taking a shower or bath, the patient must remove the system.

- See section 6.3.4.1, Removing the ASSURE System, on the next page for instructions.

After taking a shower or bath and drying off, the patient must put on the system.

- See the instructions in sections 5.1.3-5.1.4 starting on page 58.

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6.3.4.1   Removing the ASSURE System

Instructions:

Step 1   **Open the Carry Pack flaps**

Step 2   **Slide the Battery lock until you see the yellow line and lift the Battery handle**

- Remind the patient that they can also watch the patient video at kestramedical.com/patients, if they need assistance with this task after they go home.
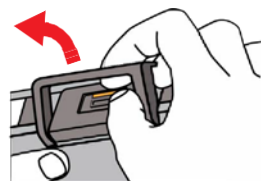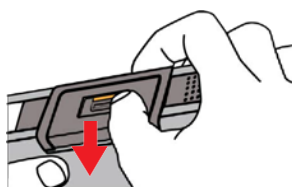
Step 3   **Pull up to remove the Battery from the Monitor**

Notes:

- *Removing the Battery turns off the system.*
- *To avoid setting off alerts, the patient should always remove the Battery before taking off the system.*

Step 4   **Take off the Carry Pack**

- Place the Carry Pack on a nearby flat surface to avoid dropping the Monitor.

Step 5   **Remove any clothing above the waist**
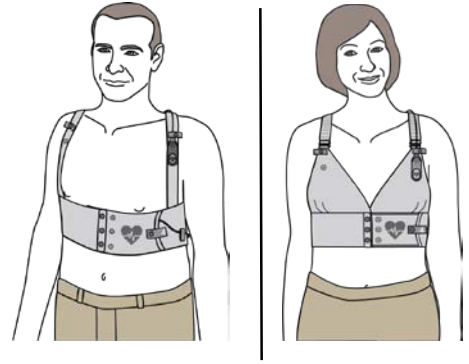
Step 6   **Unsnap the front closure**
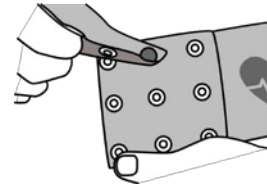
Step 7   **Take off the Garment**

Step 8   **Place the Garment and Carry Pack in a safe place to avoid dropping the Monitor, getting it wet, or getting tangled in the cables**

6.4 Traveling with the ASSURE System

Review the following warning text with the patient:

⚠️ **WARNING**

If you will be away from home for longer than 24 hours, take the spare, fully charged Battery and Charger with you.

6.4.1 Air Travel

Before making reservations, the patient should speak to an airline representative about any specific restrictions for wearing medical electronic equipment on the airplane.

Refer the patient to the Transportation Security Administration (TSA) website at www.tsa.gov/travel/special-procedures for information on traveling with medical devices.

6.4.2 Electronic Security Check Points at the Airport

Patients should avoid walking through security screening equipment commonly found in airports, courthouses, and sporting events. Instead, the patient should show the security staff their patient information card, explain that they are wearing a medical device, and request an alternate screening method, like a hand-held device or physical hand search.

6.4.3 International Travel

If the patient will be traveling outside of North America, they may need to purchase a power converter or adapter so the Charger will work in that particular country.

6.5 General ASSURE System Care and Cleaning Instructions

This section provides an overview of the care and cleaning instructions for the ASSURE system and its components. The PSR

should encourage family members and caregivers to read the *ASSURE Wearable Defibrillator Patient Handbook* or watch the patient video (available at www.kestramedical.com) to understand how to wash the Garment and clean the ASSURE system.

Patient Information:

- Review the information in the *ASSURE Wearable Defibrillator Patient Handbook* with the patient.
- The patient should wash the Garment as needed. The ASSURE system comes with two Garments, so the patient can wash the used Garment while continuing to wear the ASSURE system.
- Before washing the Garment, the patient must do the following:
    1. Take off the ASSURE system.
        - See section 6.5.1, Taking Off the System to Wash the Garment, on page 96 for instructions.
    2. Remove the Therapy Cable from the used Garment.
        - See section 6.5.2, Removing the Therapy Cable from the Garment, on page 99 for instructions.
    3. Place the Therapy Cable into the clean Garment and put on the system.
        - See sections 5.1.2-5.1.3 starting on page 53 for instructions.
- After washing the Garment, the patient should hang the Garment or place it on a flat surface to air dry.
    - The patient should NOT dry clean or iron the Garment.
    - The patient should NOT dry the Garment in a clothes dryer, microwave oven, or any other oven.
- To clean the other equipment:
    1. Gently wipe the equipment with a clean, soft cloth dampened slightly with water only.
    2. Use a separate dry, soft cloth to dry the equipment before using it.
    Notes:
    - *Avoid wiping the Hub connectors and pins.*
    - *Do not allow any liquid or moisture to remain on the equipment or its connectors and pins after cleaning.*
    - *Do not dry clean the Carry Pack.*
    - *Do not dry the Carry Pack in a clothes dryer, microwave oven, or any other oven.*

Review the following safety information with the patient:

⚠️ **WARNINGS**
- *Do not use chlorine bleach, bleach alternatives, fabric softeners, or anti-static sprays. Also, do not use detergents or detergent "pods" that include bleach or fabric softener additives.*
- *Do not place the Monitor, Therapy Cable, Charger, or Battery in water or other liquids. Avoid spilling any liquids on these devices. Liquids entering these devices may cause them to malfunction or fail.*
- *Always remove the Therapy Cable before washing the Garment.*

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6.5.1   Taking Off the System to Wash the Garment

Instructions:

Step 1   Open the Carry Pack flaps

Step 2   Slide the Battery lock until you see the yellowline and lift the Battery handle
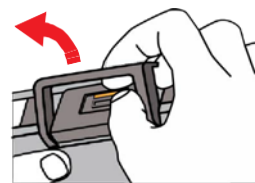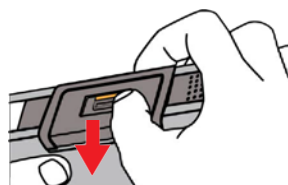
Step 3   Pull up to remove the Battery from the Monitor

- Lift up the Battery handle and pull up.

Notes:

- *Removing the Battery turns off the system.*
- *To avoid setting off alerts, the patient should always remove the Battery before taking off the system.*

Step 4   Close the Carry Pack flaps

Step 5   Remove any cable length tucked into the Carry Pack

- The cabling may be inside the Carry Pack pockets or in the elastic corner straps on the back.

Step 6   Press and hold the Plug Release button on the Monitor

Step 7   Remove the Plug from the Monitor

Step 8   Take off the Carry Pack

- Place the Carry Pack on a nearby flat surface to avoid dropping the Monitor.

Step 9   Remove any clothing above the waist

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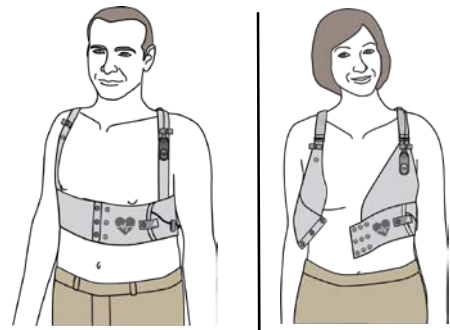
Step 10 Unsnap the front closure
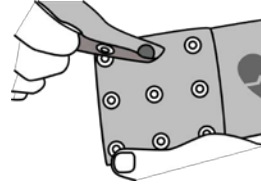
Step 11 Take off the Garment

- See section 6.5.2, Removing the Therapy Cable from the Garment, on page 99 for the next steps.

6.5.2   Removing the Therapy Cable from the Garment

Note: The Therapy Cable is a complete assembly. The cords and cable cannot be removed from the Hub.

Instructions:

Step 1   Take off the Garment and place it on a flat surface, like a table or desk
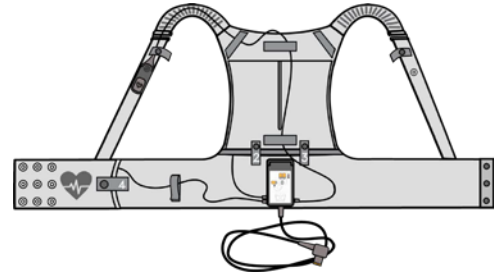
Step 2   Open the cord wrap near pocket 4
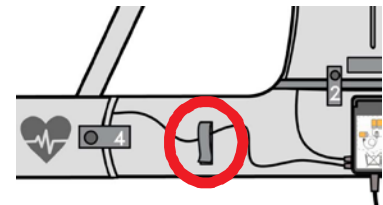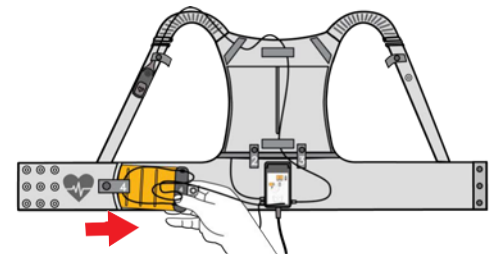
Step 3   Unsnap and remove the Therapy Pad from pocket 4

Step 4   Unsnap and remove the Therapy Pads from pockets 2 and 3

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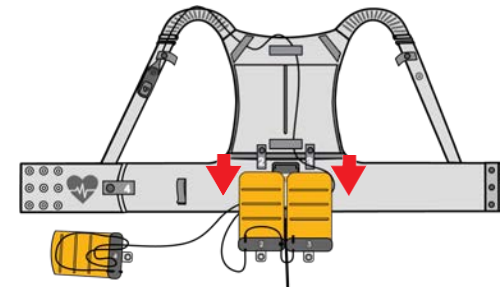
Step 5 **Unsnap and remove the Alert Button from the shoulder strap**
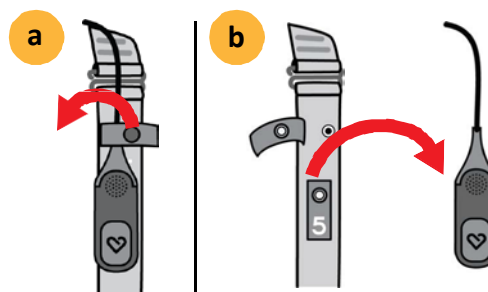
Step 6 **Gently pull the Alert Button cord through the loops on the back of the Garment until the cord is free**
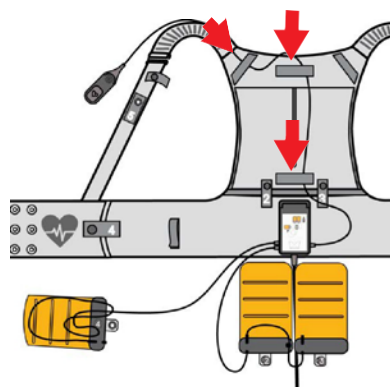
Step 7 **Use both hands to remove the Hub from the Garment**

- Press down on the Garment near the bottom of the Hub Receptacle with your thumb.
- Pull up firmly on the cable handle at the bottom of the Hub with your other hand.
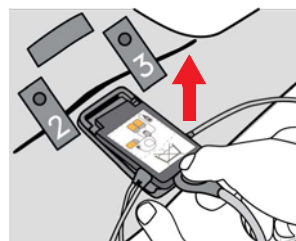
After the patient has removed the Therapy Cable from the used Garment, they must place it into the clean Garment and put on the ASSURE system before washing the used Garment. See section 5.1.2, Helping the Patient Assemble the Garment, on page 53 for instructions.

6.6　Checking for Equipment Damage

The patient should check the ASSURE system for any wear or damage once or twice a week. Some

examples of potential damage or improper use include:

- Gel leaking from the Therapy Pads (see below)
- Sensors peeling off from the Garment (see below)
- Worn cables or cords
- Cracked or broken Monitor case
- Broken snaps on Garment
- Tamper-evident seal on Monitor (below the Plug Receptacle) shows "VOID" and "KESTRA" markings

If there appears to be any damage, or if the patient has any concerns about the equipment, the patient should call the ASSURE Helpline at 1.833.692.7787.
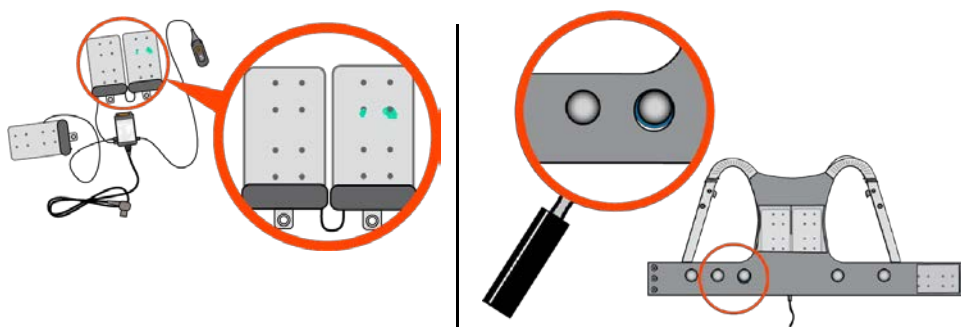
Examples of Potential Damage to the ASSURE System

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6.7 Alerts

Note: Use the ASSURE Wearable Defibrillator Quick Start Guide to ensure patients understand the following important alerts:

- *Low Battery*
- *Service Required*
- *Shock*
- *Check Sensors*

Review the following information and warning text with the patient to ensure the patient understands how to respond to alerts.

⚠️ **WARNING**

Operating a motorcycle, boat, riding lawnmower, or other noisy vehicle, or any vehicle or equipment that emits heavy vibrations, while wearing the ASSURE system may prevent you from realizing an alert is happening.

The ASSURE system analyzes the patient for dangerous heart rhythms and itself for proper function. When the system detects a problem, it creates an alert to notify the patient that there is something that needs their attention.

There are two alert types:

- Heart alerts – The ASSURE system has detected a heart rhythm that is either too fast or too slow. These alerts are critical and the patient must respond to them immediately.
- System alerts – The ASSURE system has discovered a problem with the system equipment that requires the patient's attention, like the Garment not fitting correctly or a low Battery.

What the patient will...	Heart Alert	System Alert
See	• Flashing red Monitor light • Alert icon on Monitor screen	• Blinking yellow Monitor light • Alert icon on Monitor screen
Hear	• Harsh, alternating low-high alarm • Voice message	• Repeating, double tone • Voice message
Feel	• Four gentle pulses followed by an intense, triple-buzz vibration from the Alert Button	• Triple-pulse vibration from the Alert Button

Notes:

- *The Heart alert vibration continues throughout the Shock alert.*
- *For more information on Heart alerts, see section 6.7.1, Heart Alerts, on page 103.*
- *For more information on System alerts, see section 6.7.2, System Alerts, on page 106.*

6.7.1   Heart Alerts

There are two types of Heart alerts:

Alert Name	Light and Icon	Reference
Shock		See page 103
Seek Medical Attention		See page 105

6.7.1.1   Shock Alert

Review the following information and warning text with the patient to ensure the patient understands how to respond to a Shock alert.

⚠️ **WARNING**

No one should touch the patient or equipment when a shock is being delivered. The ASSURE system delivers a large amount of electrical energy during shock delivery.

After the ASSURE system detects and confirms a dangerously fast heart rate in the patient, it issues a Shock alert to tell the patient that an electrical shock will be delivered.

The patient should not remove the Battery from the Monitor or take off the Garment during a Shock alert. Doing so will prevent the ASSURE system from analyzing the patient's heart rhythm and providing a shock if needed.

Responding to a Shock Alert

Before delivering shock, the following voice messages play:

- "Preparing to shock. Do not touch the patient."
- "Do not touch the patient."
- "Preparing to shock in 3, 2, 1."

If the patient notices the Shock alert:

- The patient must immediately press the Alert Button to cancel shock delivery.
    - The patient is the only person who should press the Alert Button.
    - Pressing the Alert Button cancels the shock.
    - The ASSURE system will confirm the shock was canceled with a voice message and a vibration from the Alert Button.
- The patient should continue to wear the ASSURE system unless a medical professional tells them to remove it.
- The patient should call 911 or seek medical attention if they feel dizzy or unwell.

If the patient does not press the Alert Button:

- The ASSURE system will automatically provide a shock, if needed.
- The ASSURE system will instruct anyone nearby to call 911.

Note: The patient is the only person who should press the Alert Button. If the patient is unconscious, no one should press the Alert Button for them.

After delivering a shock, the following voice messages play:

- "Shock delivered."
- "Call 911 now. Do not touch the patient."
- "Preparing to shock. Do not touch the patient."

The ASSURE system will continue to analyze the patient's heart rhythm, and it will instruct anyone nearby to call 911. The system can deliver up to five shocks in a row for a single episode.

Notes:

- *If at any time the patient hears the Shock alert again, they should press the Alert Button.*
- *The voice messages will repeat as needed during the episode.*

After a Shock Alert

- After the Shock alert is over, the following voice messages play:
  - "Call 911 now."
  - "You have received a shock."
  - "Continue to wear your ASSURE system."
- The patient should continue to wear the ASSURE system.
  - It will continue to analyze the patient's heart rhythm.
  - If the patient notices another Shock alert, they should press the Alert Button
  - If the patient is unconscious, the ASSURE system will provide up to five shocks per episode (if needed) for up to five episodes.
- The Shock Delivered - Seek Medical Attention alert is displayed so the patient understands that they received therapy and are encouraged to seek medical attention or call 911.
- After a shock is delivered, gel remains viable for at least an hour.
- The patient's chest and back will be wet and covered with gel.
  - This gel was released by the Therapy Pads as part of the shock delivery.
  - The patient should leave the gel under the Therapy Pads. They should not wipe off the gel, unless directed by a medical professional.
- The patient may experience some discomfort or soreness around their chest.
- Remind the patient that they will still receive additional therapy (if needed) while these other alert icons are displayed.
- If the battery is removed and replaced after a shock has been delivered, the alert will change to a Service Needed alert.

6.7.1.2   Seek Medical Attention Alert

When the ASSURE system detects that the patient has a low heart rate, or it can no longer deliver a shock during this episode, it issues a Seek Medical Attention alert.

Notes:
- *The ASSURE system can deliver up to five shocks per a single episode. If a new episode is detected, the ASSURE system can deliver an additional five shocks, if needed. The ASSURE system will continue to shock (when necessary) until the battery runs out of power.*
- *The ASSURE system cannot treat low heart rates.*

The following voice message plays during this alert: "Call

911 now. Begin CPR if patient is unconscious."

Note: The ASSURE system does not call 911 for the patient. The patient or someone nearby must call 911.

Responding to a Seek Medical Attention Alert

If the patient notices this alert:

- The patient should press the Alert Button.
    - Pressing the Alert Button quiets the alert.
- The patient should continue to wear the ASSURE system unless a medical professional tells them to remove it.
- The patient should call 911 or seek medical attention if they feel dizzy or unwell.

If the patient does not press the Alert Button:

- The ASSURE system will instruct anyone nearby to call 911 and begin CPR.

    Note: The ASSURE system does not call 911 for the patient. The patient or someone nearby must call 911.

After a Seek Medical Attention Alert

- The patient should continue to wear the ASSURE system.
    - It will continue to analyze their heart rhythm.
    - If the patient hears another Seek Medical Attention alert, they should press the Alert Button.
- The patient should call 911 or seek medical attention if they feel dizzy or unwell.

6.7.2   System Alerts

This section describes the alerts that the ASSURE system uses to notify the patient that there is a problem with the system equipment that they need to fix.

Note: The Put on Garment, Check Sensors, and Check Therapy Pads alerts may correct themselves automatically due to changes in Garment positioning or movement. If this occurs, the ASSURE system will return to normal operation (indicated by the green Monitor light, System Ready icon, guitar strum, and vibration).

When the patient receives a System alert, they should follow three general steps.

Instructions:

Step 1   Press the Alert Button

- Press once to quiet the alert.
- Press again to replay the voice message.
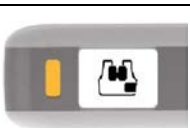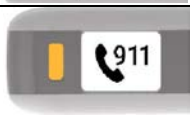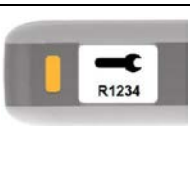
Step 2   Look at the Monitor screen and light
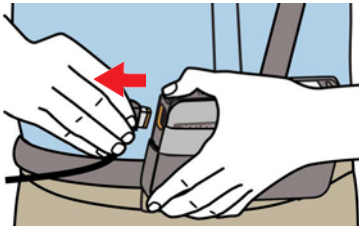
Step 3   Respond

- Refer the patient to the *ASSURE Wearable Defibrillator Patient Handbook* for System alert information.
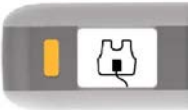
Alert Name	Light and Icon	Reference
Connect Plug to Monitor		See page 108
Connect Hub to Garment		See page 109

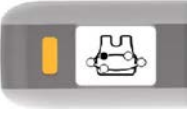| Alert Name	Light and Icon	Reference
Put on Garment *Note: This alert uses a series of icons. The displayed icon will vary (see examples).*		See page 110
Check Sensors *Note: The displayed icon will vary depending on which Sensor has lost contact.*		See page 111
Check Therapy Pads		See page 112
Low Battery		See page 113
Shock Delivered – Seek Medical Attention		See page 113
Service Required		Call the ASSURE Helpline at 1.833.692.7787. See page 114
Service Needed		See page 114

6.7.2.1   Connect Plug to Monitor Alert

Monitor Icon	
Description	The Plug is not inserted properly into the Monitor.
Voice Message	"Connect the Plug to your Monitor."
Instructions	To respond to this alert: **Insert the Plug into the Monitor** If the Plug is already inserted into the Monitor, try re-inserting it: **Step 1 Press and hold the Monitor's Plug Release button and then remove the Plug from the Monitor** **Step 2 Insert the Plug back into the Monitor** • A "click" sound means the Plug is securely inserted. *Note: The System Busy icon will appear on the Monitor screen with a yellow Monitor light when the Monitor detects a Plug insertion. This check may take up to a minute to complete.* ⚠️ **WARNING** *If the alert continues to play, remove the Battery from the Monitor and re-insert it to restart the ASSURE system.*

6.7.2.2   Connect Hub to Garment Alert

Monitor Icon	
Description	The Hub is not properly inserted into the Garment.
Voice Message	"Connect the Hub to your Garment."

Instructions	To respond to this alert:
	
	Step 1 Press the Alert Button to quiet the alert
	
	Step 2 Insert the Hub into the Garment
	
	If the Hub is already inserted into the back of the Garment, try re-inserting it:
	
	Step 1 Use both hands to remove the Hub from the Garment
	   • Press down on the Garment near the bottom of the Hub Receptacle with your thumb.
	   • Pull up on the cable handle at the bottom of the Hub with your other hand.
	
	Step 2 Insert the Hub back into the Garment
	   • A "click" sound means the Hub is securely inserted.

6.7.2.3 Put on Garment Alert

Note: This alert uses a series of icons. The displayed Monitor screen icon will vary (see the examples below).

Monitor Icons	
Description	The patient is not wearing the Garment properly.
Voice Message	"Put on your Garment now."
Instructions	To respond to this alert: **Step 1 Press the Alert Button to quiet the alert** **Step 2 Put on the Garment** If the patient is already wearing the Garment, they should follow these suggestions: • **Check** that the Garment is not twisted, there is nothing under it, and the TherapyPads are assembled correctly. • **Moisten** the skin under the Sensors with water or lotion.

6.7.2.4   Check Sensors Alert

Note: The displayed Monitor screen icon will vary depending on which Sensor has lost contact (see the examples below).
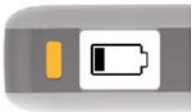
Monitor Icons	
	Right front Sensor has lost contact.
	Right back Sensor has lost contact.
	Left back Sensor has lost contact.
	Left front Sensor has lost contact.
	The Right Middle Sensor or multiple Sensors have lost contact, or the system cannot sense the patient's heart rhythm.
Description	One or more Sensors are not touching bare skin, there is poor skin contact, the patient's skin may be too dry, or the sensors cannot get a clear signal from the patient's heart.
Voice Message	"Adjust your Garment now. The Sensors must touch your skin."

Instructions	To respond to this alert:
	
	Step 1 Press the Alert Button to quiet the alert
	
	Step 2 Try the following actions:
	• **Adjust** the Garment so the Sensors are flat and touching bare skin.
	  – The Sensors should be snug around the patient's rib cage, just below their breast area and nipples.
	  – Patients should make sure their breast tissue is not under the front Therapy Pad or Sensors.
	  Note: Female patients may wear a bra over the Garment for more support.
	• **Check** that the Garment is not twisted and there is nothing under it.
	• **Stop** all movement for 15 seconds to allow the system to sense a heart rhythm. If the alert continues, try the following:
	• **Moisten** the skin under the Sensors with water or lotion.
	• **Tighten** the Garment by adjusting the front closure snaps and shoulder straps.
	• **Call** the ASSURE Helpline at 1.833.692.7787.

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6.7.2.5   Check Therapy Pads Alert

Monitor Icon	
Description	One or more of the Therapy Pads are not touching bare skin.
Voice Message	"Check the Therapy Pads. The pads must touch your skin."

Instructions	To respond to this alert:
	
	Step 1 Press the Alert Button to quiet the alert
	
	Step 2 Try the following actions:
	• **Confirm** the Therapy Pads are flat and touching bare skin.
	  – The front Therapy Pad should be snug around the patient's rib cage, just below their breast area and nipples.
	  – Patients should make sure their breast tissue is not under the front Therapy Pad or Sensors.
	• **Check** that the Garment is not twisted and there is nothing under it.
	• **Moisten** the skin under the Therapy Pads with water or lotion.
	• **Change** the front closure snaps and shoulder strap settings for a snug Garment fit. The shoulder straps should be comfortable but not loose.
	• **Verify** the Therapy Pads are correctly inserted and snapped in the pockets.

6.7.2.6   Low Battery Alert

Monitor Icon	
Description	The Battery has less than two hours of power left. Replace the Battery now.
Voice Message	"Replace your Battery now."
Instructions	To respond to this alert: **Step 1 Press the Alert Button to quiet the alert Step 2** **Insert a fully charged Battery into the Monitor** • A "click" sound means the Battery is securely inserted. **Step 3 After the Alert Button icon appears on the Monitor screen, press the Alert Button** *Note: If a different icon appears on the Monitor screen, there is likely an alert condition on the ASSURE system. See section 6.7.2, System Alerts, on page 106 for a list of alert icons and respond to the alert.* **Step 4 Place the used Battery into the Charger** **Step 5 Check the Charger screen to confirm the Battery is charging**

6.7.2.7   Shock Delivered – Seek Medical Attention Alert

Monitor Icon	
Description	The patient has received a shock and the dangerous heart rate is no longer detected.
Voice Message	"Call 911 now. You have received a shock. Continue to wear your ASSURE system."
Instructions	• The patient should continue to wear the ASSURE system. • It will continue to analyze the patient's heart rhythm. • If the patient hears another Shock alert, they should press the Alert Button. • If the patient is unconscious, the ASSURE system will provide additional shocks if needed. • The patient should call 911 or seek medical attention. • The patient may experience some discomfort or soreness around their chest. • The patient's chest and back may be wet and covered with gel. • This gel was released by the Therapy Pads as part of the shock delivery. • The patient should leave the gel under the Therapy Pads. The patient should not wipe off the gel, unless directed by a medical professional.

6.7.2.8   Service Required Alert

⚠️ **WARNING**

When the Service Required alert is active, the ASSURE system is not operational and cannot protect the patient. The patient must immediately call the ASSURE Helpline at 1.833.692.7787 for assistance.
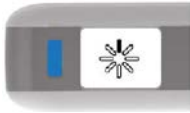
Monitor Icon	
Description	There is a problem with the ASSURE system that **requires immediate attention**. Service Required alerts are designated by an "R" error code. *Note: This alert will repeat every five minutes.*
Voice Message	"Call the ASSURE Helpline now. Your device needs service."
Instructions	To respond to this alert: **Call the ASSURE Helpline at 1.833.692.7787** • Provide the ASSURE representative with the error code that appears on the Monitor screen.

6.7.2.9   Service Needed Alert

Monitor Icon	
Description	There is a problem with the ASSURE system. Service Needed alerts are designated by an "N" error code. The ASSURE system is still operational and can still provide therapy.
Voice Message	"Call the ASSURE Helpline now. Your device needs service. Continue to wear your ASSURE system."
Instructions	To respond to this alert: **Step 1 Press the Alert Button** **Step 2 Call the ASSURE Helpline at 1.833.692.7787** • Provide the ASSURE representative with the error code that appears on the Monitor screen. **Step 3 Continue to wear the ASSURE system**

6.8   System Status Icons

This section identifies the system status icons that are displayed when the system is powering on or operational.

System Status Icon Name	Light and Icon	Reference
System Welcome		See page 116
System Busy		See page 116
Alert Button		See page 117
System Ready		See page 117

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6.8.1   System Welcome

Monitor Icon	
Description	The Battery has been inserted into the Monitor to turn on the ASSURE system.
Notification	• Blue Monitor light • Icon displayed on the Monitor screen
Instructions	Wait for the System Busy icon to appear on the Monitor screen.

6.8.2   System Busy

Monitor Icon	
Description	The ASSURE system is powering up.
Notification	• Blue Monitor light • Icon displayed on the Monitor screen
Instructions	Wait for the Alert Button icon to appear on the Monitor screen (may take a few minutes). *Notes:* • *If the System Busy icon displays for more than five minutes, try re-inserting the Battery into the Monitor. If this does not work, call the ASSURE Helpline at 1.833.692.7787.* • *The System Busy icon will appear on the Monitor screen with a yellow Monitor light when the Monitor detects a Plug insertion. This check may take up to a minute to complete.*

6.8.3 Alert Button

Monitor Icon	
Description	The ASSURE system has finished powering up and is operational. The patient should press the Alert Button to confirm it is operating properly.
Notifications	• Blinking green Monitor Light • Icon displayed on the Monitor screen • Single-pulse vibration from the Alert Button • Voice message stating, "Press your Alert Button now."
Instructions	**Press the Alert Button** After pressing the Alert Button, the System Ready icon appears on the Monitor screen.

6.8.4 System Ready

Monitor Icon	
Description	The system is in working properly (normal operating mode).
Notifications	• Green Monitor Light *Note: The light turns on for the first five seconds and then turns off.* • Icon displayed on the Monitor screen • Single-pulse vibration from the Alert Button • Three-note guitar strum
Instructions	None. The patient can press the Alert Button to check the system status at any time.

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7. Concluding the Patient Session

This section provides instructions for administering the Patient Comprehension Test.

7.1　Overview

Before concluding the patient session, the PSR must administer the Patient Comprehension Test to the patient to ensure they understand how to wear and use the ASSURE system.

Note: Prescribers should ensure the patient is willing and capable of using the ASSURE system before prescribing it. This includes the consideration of any cognitive, visual, physical, or auditory limitations that the patient may have that could affect their use of the ASSURE system.

Note: The Tablet is not intended to be used for patient diagnosis or treatment.

7.2　Administering the Patient Comprehension Test

The Patient Comprehension Test evaluates the patient's understanding of the ASSURE system and how to use and wear it after receiving training.

To administer the Patient Comprehension Test:

Step 1　Have a printed copy of the test available for the patient session

Step 2　Administer the test to the patient at the end of the patient session

- If the patient answers incorrectly to any question, reteach that point and confirm the patient understands. If there's any doubt regarding the patient's understanding of the ASSURE system and how to use it, contact the prescriber.

7.3   Patient Comprehension Test

Circle one or more appropriate responses to the following questions about your ASSURE system

1. What should you do when you get a Heart alert?

    A.   Pull the battery out to stop the alarm.

    B.   Ask someone else to press the Alert Button.

    C.   Press the Alert Button to cancel the shock.

2. What will happen if there is a Heart alert but **you do not notice** it because you are asleep?

    A.   The ASSURE system will notify EMS of your location.

    B.   The ASSURE system will deliver a shock if needed.

    C.   The ASSURE system will turn off.

3. What should you do when **you get** a System alert?

    A.   Pull the battery out to stop the alert.

    B.   **Press** the Alert Button. **Look** at the Monitor screen. **Respond** to the alert to fix the problem.

    C.   Wait until it stops on its own.

4. When should **you wear** the ASSURE system?

    A.   Only if I don't feel well.

    B.   Only when I'm home alone.

    C.   All the time, except when I take a bath, shower, or swim.

5. How often should **you change** the Battery in the ASSURE system's Monitor?

    A.   Every day.

    B.   Once per week.

    C.   Never.
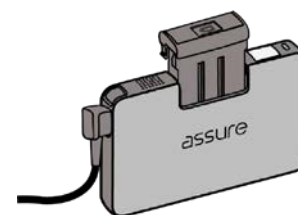
6. How should the Garment fit?

    A.   Loose.

    B.   Snug around my rib cage.

    C.   Over my undershirt (or bra).

Patient signature and date: _____

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8. Troubleshooting

This section provides help with wearing and using both the ASSURE wearable defibrillator (ASSURE system) and Tablet. The following information is available:

- Alerts quick reference chart
- System status icon descriptions
- Frequently-Asked-Questions (FAQs)

For assistance, call the ASSURE Helpline at 1.833.692.7787.

8.1   Alerts Quick Reference

Alert Icon	Actions
Heart Alerts	
	If the patient hears this alert: • The patient should press the Alert Button to cancel shock delivery. • The patient should continue to wear the system unless a medical professional tells them to remove it. • The patient or anyone nearby should call 911. • The patient should seek medical attention if they feel dizzy or unwell. **If the patient does not press the Alert Button:** • The ASSURE system will automatically provide a shock, if needed. • The ASSURE system will instruct anyone nearby to call 911. See section 6.7.1.1, Shock Alert, on page 103 for more information.
	If the patient hears this alert: • The patient should press the Alert Button. • The patient should continue to wear the system unless a medical professional tells them to remove it. • The patient or anyone nearby should call 911. • The patient should seek medical attention if they feel dizzy or unwell. **If the patient does not press the Alert Button:** • The ASSURE system will instruct anyone nearby to call 911 and begin CPR. See section 6.7.1.2, Seek Medical Attention Alert, on page 105 for more information.
System Alerts	
	The patient should try the following: • **Insert** the Plug into the Monitor. - or - • **Remove** the Plug from the Monitor and then re-insert it. ⚠️ **WARNING** *If the alert continues to play, remove the Battery from the Monitor and re-insert it to restart the ASSURE system.* *Note: The System Busy icon will appear on the Monitor screen with a yellow Monitor light when the Monitor detects a Plug insertion. This check may take up to a minute to complete.* See section 6.7.2.1, Connect Plug to Monitor Alert, on page 108 for more information.
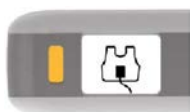
Alert Icon	Actions
System Alerts	

The patient should press the Alert Button to quiet the alert. Then,
the patient should try the following:

- **Insert** the Hub into the Garment.

  - or -

- **Remove** the Hub from the Garment and then re-insert it.

See section 6.7.2.2, Connect Hub to Garment Alert, on page 109 for more information.

The patient should press the Alert Button to quiet the alert. Then,
the patient should try the following:

- **Put on** the Garment.
- **Check** that the Garment is not twisted, there is nothing under it, and the Therapy Pads are assembled correctly.
- **Moisten** the skin under the Sensors and Therapy Pads with water or lotion. See

section 6.7.2.3, Put on Garment Alert, on page 110 for more information.
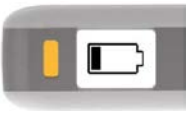
The patient should press the Alert Button to quiet the alert. Then,
the patient should try the following:

- **Adjust** the Garment so the Sensors are flat and touching bare skin.
- **Check** that the Garment is not twisted, there is nothing under it, and the Therapy Pads are assembled correctly.
- **Stop** all movement for 15 seconds to allow the system to sense a heart rhythm.
- **Moisten** the skin under the Sensors with water or lotion.
- **Tighten** the Garment by adjusting the front closure snaps and shoulder straps.
- **Call** the ASSURE Helpline at 1.833.692.7787.

See section 6.7.2.4, Check Sensors Alert, on page 111 for more information.

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Alert Icon	Actions

System Alerts

The patient should press the Alert Button to quiet the alert. Then, the patient should try the following:

- **Confirm** the Therapy Pads are flat and touching bare skin.
- **Check** that the Garment is not twisted and there is nothing under it.
- **Moisten** the skin under the Therapy Pads with water or lotion.
- **Change** the front closure snaps and shoulder strap settings for a snug Garment fit. The shoulder straps should be comfortable but not loose.
- **Verify** the Therapy Pads are correctly inserted and snapped in the pockets.

See section 6.7.2.5, Check Therapy Pads Alert, on page 112 for more information. The

patient should press the Alert Button to quiet the alert.
Then, the patient should **insert a fully charged Battery into the Monitor**. See

section 6.7.2.6, Low Battery Alert, on page 113 for more information.

1. The patient should press the Alert Button to quiet the alert.
2. The patient should **continue to wear the system**.
3. The patient should **call 911 or seek medical attention**.

See section 6.7.2.7, Shock Delivered – Seek Medical Attention Alert, on page 113 for more information.

1. The patient should **call the ASSURE Helpline at 1.833.692.7787 immediately**.
2. The patient should provide the error code that appears on the Monitor screen to the ASSURE representative.

See section 6.7.2.8, Service Required Alert, on page 114 for more information.

⚠️ **WARNING**
When the Service Required alert is active, the system is not operational and cannot protect the patient.

1. The patient should press the Alert Button to quiet the alert.
2. The patient should **call the ASSURE Helpline at 1.833.692.7787**.
3. The patient should provide the error code that appears on the Monitor screen to the ASSURE representative.
4. The patient should **continue to wear the ASSURE system**.

See section 6.7.2.9, Service Needed Alert, on page 114 for more information.

8.2 Frequently-Asked Questions

Who do I call for help?

For questions or assistance with the ASSURE system or patient training, call the ASSURE Helpline at 1.833.692.7787.

Where can I find the patient code if I forgot to write it down?

If a Session Report was generated for the patient visit, look in the Report Queue application.

If the patient is still present, connect the Tablet to the Monitor again and check for the Patient Code on the Patient Information screen.

If the patient has left and a Session Report was not generated, another patient visit will be necessary. See "How do I create a Session Report if I forgot to do it during the patient visit?" on page 129 for information on generating a new Session Report.

What should I do if the Tablet does not respond when I try to connect to the Monitor using the ASSURE application?

If the Connect Devices screen is displayed but the Tablet is not responding when you place it in the proper pairing location, you may need to perform the following steps:

1. Tap **Settings** on the Home screen.
2. Under **Wireless & networks**, select **More** > **NFC** > tap to toggle **On**.
3. Return to the ASSURE application and try connecting to the Monitor again.

What should I do if the data transmission from the Tablet to the remote server fails?

If the Tablet has access to the remote server through a Wi-Fi connection but the transmission fails, the Tablet will attempt to transmit the information again.

Check the transmission status of any reports in the Report Queue application. If any reports have not been sent, check the Tablet's wireless network connection. If the Tablet has a wireless network connection, verify that the password is correct using another device connected to the same wireless network.

Note: The Tablet cannot connect to a wireless network that requires a web-based authentication method.

What should I do if the Tablet does not turn on?

1. Press and hold the Power button for a few seconds. If nothing appears on the screen, the battery may be very low.
2. Charge the Tablet with the Tablet USB charger for 1-2 hours and then try to turn on the Tablet. Continue charging the Tablet until it is fully charged.

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What can I do if the Tablet is not charging?

If the Tablet is not charging despite being plugged into an electrical wall outlet, try the following suggested actions:

- Make sure that the electrical wall outlet is not controlled by a switch that is currently turned off. If it is, moving the Tablet's USB charger to a wall outlet not controlled by a switch is advised. If that is not possible, turn on the switch.
- Try plugging the Tablet's USB charger into a different electrical wall outlet.
- Confirm the USB charger that came with the Tablet is being used. Use only the accessories that came with the Tablet.
- Try connecting the USB cable that came with the Tablet to the Tablet and a computer. If the Tablet starts charging, the Tablet's USB charger may be defective.
- If the Charger is available, try plugging the Tablet's USB cable into the USB port on the back of the Charger.

Note: If the Tablet battery life is very low (almost zero), it may take several hours of charging before the Tablet indicates that it is being charged. To prevent this, charge the Tablet when the battery life falls below 25%.

What can I do if the Tablet's battery life seems shorter than normal?

The Tablet requires approximately four hours of continuous charge time to reach a fully charged battery when connected to an electrical wall outlet. Charge times for USB connections to computers or other devices may be longer.

Ensure the Tablet is charging with the supplied USB charger. Use only the accessories that came with the Tablet.

What should I do if I get an error or WARNING message while using the Tablet with the Monitor?

- For the "Unable to connect to the ASSURE system" error message, follow these steps:
  - Exit out of the ASSURE application. Wait five seconds and then try again.
  - If that does not work, try restarting the ASSURE system by removing and re-inserting the Battery. You can also restart the Tablet while the ASSURE system is powering up.
- For the following error messages, call the ASSURE Helpline at 1.833.692.7787:
  - The ASSURE system is not compatible with this Tablet.
  - The NFC tag of this ASSURE system is not valid.
  - Unable to authenticate the connection to the ASSURE system.
- A WARNING message appears when you attempt to leave a patient session before saving any programming changes. The WARNING message will inform you that settings have not been programmed to the ASSURE system.
  - If you want to save the changes to the settings, tap **CANCEL**, save the programming changes, and then exit the ASSURE application.
  - If you do not want to save the changes, tap **EXIT**.
- If a WARNING message appears during a patient session, it may indicate that the Tablet or ASSURE system has malfunctioned. To respond:
  1. Tap **OK** to close the WARNING message in the ASSURE application.
  2. If another Tablet is available, connect that device to the ASSURE system and continue the patient session.
  3. If the issue persists with the new Tablet then the ASSURE system may have an issue:
     - Do not dispense that ASSURE system to the patient.
     - Open a new System Kit and set up that system for the patient.
     - Call the ASSURE Helpline at 1.833.692.7787 to initiate a service request for the malfunctioning Tablet or ASSURE system.

The Tablet screen does not recognize my taps or gestures, or incorrect selections are being made on the screen. What should I do?

Most likely, the Tablet screen is dirty. Clean the screen of any dirt, smudges, or water that may be present using a dry microfiber cloth.

Do not wear gloves or any other protective handwear.

Try restarting the Tablet and see if the issue goes away. If not, call the ASSURE Helpline at 1.833.692.7787.

How do I create a Session Report if I forgot to do it during the patient visit?

The only way to generate a new Session Report for that patient is to have a second patient visit. During the second visit, you can connect the Tablet to the Monitor and create a Session Report.

If a patient needs a follow-up visit, where can I find patient information, such as their activity or episode information?

In the ASSURE application, tap the Clinical Data icon on the Navigation menu. The Clinical Data screen appears.
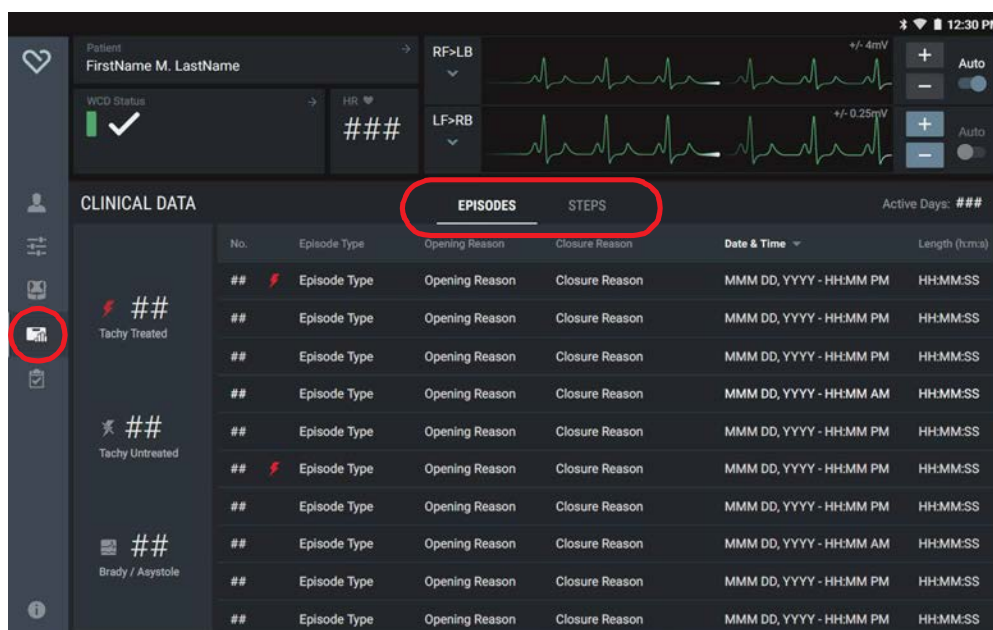
Clinical Data Screen

The default tab is the Episodes tab. This screen displays any episode information for the patient, including:

- Number of Treated Tachy episodes
- Number of Untreated Tachy episodes
- Number of Brady/Asystole episodes
- A list of episodes for the patient that includes the following information:
    - Episode number
    - Episode type

    Note: Any Treated Tachy episode is indicated by a red shock icon between the Episode number and the Episode type.

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- Opening reason
- Closure reason
- Date and time – The date and time of the earliest data for this episode.
- Length – The duration of the episode based on the date and time when the episode open and closed.

Sort the episode list by tapping on the specific column heading.

Patient Activity (Steps)

To view patient activity, tap the Steps tab at the top of the Clinical Data screen. The Steps screen appears.

Clinical Data – Steps Screen

The Steps screen displays a trend chart for the total steps per day for the last 30 days (default setting). The horizontal scale of the chart measures in days, while the vertical scale measures the number of steps. The trend chart shows all database d on the actual patient time.

The number of steps can be viewed in a single day, week, month, 60 days, or 90 days range. The

number of steps for a specific day can be viewed by tapping on the bar for that specific day.

Note: Days in which a time zone change occurs may have more or less than 24 hours in a day. Those days are indicated with a clock icon at the top of the column.

9.   Symbols Glossary

This section defines the symbols used on the ASSURE wearable defibrillator (ASSURE system) and Charger labels and packaging.

Symbol	Description and Reference Document
	Consult instructions for use.
	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 1641
	Follow the instructions for use
	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol ISO 7010-M002
	Do not dispose of in fire.
	IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries. Symbol C
	Do not deform or damage.
	IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries. Symbol B
	Do not open or dismantle.
	IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries. Symbol H
	MR unsafe – Keep away from magnetic resonance imaging (MRI) equipment
	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 62570-7.3.3
	Recommended storage temperature (from low to high)
	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 0632
	Battery
	ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 5001B
	Do not dispose of this product in the unsorted municipal waste stream. Contact the ASSURE Helpline at 1.833.692.7787 for instructions on returning this product. Disposal will be performed by the manufacturer.
	BS EN 50419, Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of the European Community Directive 2002/96/EC (WEEE)
	Do not wash.
	ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3123
	Wash in cold or mildly warm water with a maximum temperature of 104°F (40°C) on a gentle or delicate setting.
	ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3089
	Do not use bleach.
	ASTM D5489-14, Standard Guide for Care Symbols for Care Instructions on Textile Products.
	Do not iron.
	ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3113

Symbol	Description and Reference Document
	Do not dry clean. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3114
	Do not tumble dry. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3109
	Manufacturer IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 3082
	Date of manufacture: YYYY-MM-DD IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2497
IPxx	Enclosure ingress protection code IEC 60529, Degrees of protection provided by enclosures (IP Code)
	Type BF applied part IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 5333
IUSA	For USA audiences only 21 CFR 801.109, Labeling: Prescription Devices
Rx Only	By prescription only 21 CFR 801.109, Labeling: Prescription Devices
	Part number No applicable standard
PN	Serial number IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2498
SN	Catalogue number IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2493
REF	Batch code IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2492
LOT	Rechargeable battery IEC 60417, Graphical symbols for use on equipment. Symbol 5639Recognized component mark for Canada and the United States.
	Federal Communications Commission compliance mark FCC 784748 D01 Labeling Part 15 18 Guidelines, Section 2.5
	USB port ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3650

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Symbol	Description and Reference Document
− − −	Charger power port IEC 60417, Graphical symbols for use on equipment. Symbol 5031
🔒	Lock ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 1656
🔓	Unlock ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3305
«⚡»	Wireless charging No applicable standard
▢	Class II equipment IEC 60417, Graphical symbols for use on equipment. Symbol 5172
⊖→	Input IEC 60417, Graphical symbols for use on equipment. Symbol 5034
⊖→	Output IEC 60417, Graphical symbols for use on equipment. Symbol 5035
⊖⇒	Rated power output, direct current IEC 60417, Graphical symbols for use on equipment. Symbol 6048
⊖–⊙–⊕	Polarity of Direct Current Power Connector IEC 60417, Graphical symbols for use on equipment. Symbol 5926
🚫	Do not use this device in a bathtub, shower or water-filled reservoir. ISO 7010, Graphical symbols – Safety colours and safety signs – Registered safety signs. Symbol P026
c(UL)us CLASSIFIED	Recognized UL Classification Marking for Canada and the United States.
(ETL)us LISTED Intertek	Recognized safety certification mark for the United States.

10.Fit and Train Checklist

This section provides a summary of the required steps to fit and train the patient on the proper wearing and use of the ASSURE wearable defibrillator (ASSURE system).

10.1   ASSURE System Setup Checklist

Use this checklist to set up the ASSURE system for a patient.

☐ **Step 1   Prepare for patient session**
- In the ASSURE application, connect the Tablet to the Monitor.
  - See section 4.2, Starting the ASSURE Application, on page 44 for instructions.
- To create a new patient in the ASSURE application, follow the steps on the screen (this must be the same day as the fitting).
  - See section 4.3, Setting Up the ASSURE System, on page 46 for more information.
  - The patient code is displayed on the Patient Management screen. Write down the Patient Code, as it is required to enroll the patient in the remote server.
  - _____ – _____ – _____ – _____

☐ **Step 2   Measure the patient for proper Garment fit:**

a.   Measure the patient's underbust chest circumference over light clothing with their arms down at their sides.
- Wrap the measuring tape tightly around the patient's rib cage at the lower border of the sternum.
- Measure to the nearest half-inch. Round down all measurements.
- Proper fit must be made according to the underbust measurement, regardless of bust or shoulder size.
- For certain body types, both Garment styles may be considered regardless of gender.

Underbust Measurement _____ inches
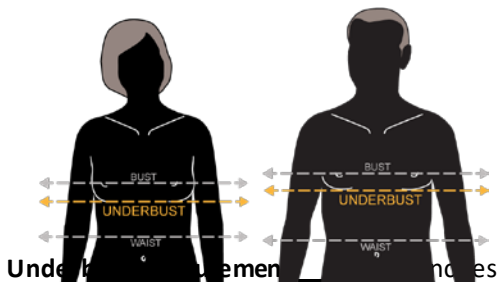
b.   Select the appropriate size Garment for the patient.
- If the patient falls in between two sizes, attempt to fit the patient with the smaller-sized Garment.
- If the patient falls outside the size range (less than 28" or more than 52"), do not fit them with a Garment.

Garment Style (circle one):   A   -or-   B

28" **1** 32"
31.5" **2** 35.5"
35" **3** 39"
38.5" **4** 42.5"
42" **5** 46"
45.5" **6** 49"
7 52"

☐ **Step 3   Introduce the ASSURE system kit to the patient**
- Reassure the patient that they will be taught how to use the system.

☐ **Step 4   Have the patient watch the training video**
- Encourage patients to pause the video for any comments or questions.

☐ **Step 5   Have the patient assemble the Garment**
- See section 5.1.2, Helping the Patient Assemble the Garment, on page 53 for instructions.
- Allow the patient to practice inserting and removing the Hub.
- Familiarize the patient with the *ASSURE Wearable Defibrillator Patient Handbook*.

☐ **Step 6 Have the patient put on the Garment and place the Battery in the Monitor**
- See section 5.1.3, Helping the Patient Put on the Assembled Garment, on page 58 for instructions.
- Allow the patient to practice inserting and removing the Plug and the Battery.
- Have the patient press the Alert Button when the Alert Button icon appears.

☐ **Step 7 Connect the Tablet to the Monitor**
- See section 4.2, Starting the ASSURE Application, on page 44 for instructions.

☐ **Step 8 Have the patient put on the Carry Pack and insert the Monitor**

☐ **Step 9 Confirm ASSURE system programming and check Garment fit**
- Confirm the WCD Settings are programmed according to the prescription.
- Check proper Garment fit on the patient:
    - Confirm that the Sensors are making good contact with the patient's skin. See section 5.4, Confirming Fit with the Tablet, on page 66.
    - If there is an issue with Garment fit, try the following:
        - **Adjust** the Garment so the Sensors are flat and touching bare skin.
        - **Check** that the Garment is not twisted and there is nothing under it.
        - **Moisten** the skin under the Sensors with water or lotion.
        - **Tighten** the Garment by adjusting the front closure snaps and shoulder straps.

☐ **Step 10 Create a Session Report prior to exiting the ASSURE application**

☐ **Step 11 Train the patient on wearing the ASSURE system during their normal day**
- Go over how to charge the Battery using the Charger.
- Review where to place the Monitor while sleeping.
- Discuss the required actions before and after taking a bath or shower.
- Review the Garment washing instructions.
    - Remind the patient to remove the Therapy Cable before washing the Garment.
    - As necessary, show the patient where to find information in the *ASSURE Wearable Defibrillator Patient Handbook.*

☐ **Step 12 Train the patient on alerts using the *ASSURE Wearable Defibrillator Patient Handbook*, *ASSURE Wearable Defibrillator Quick Start Guide*, and training video**
- Discuss what the patient should do if a Shock Alert occurs (replay the Shock Alert portion of the training video (Chapter 7) and have the patient practice pressing the Alert Button).
- Discuss what the patient should do if a System alert occurs.
- Discuss skin moisturizing procedures to resolve Garment-related System alerts.

☐ **Step 13 Encourage the patient to have their family members or caregivers read the *ASSURE Wearable Defibrillator Patient Handbook***

☐ **Step 14 Complete the patient information card and insert it into the Carry Pack's front pocket**

☐ **Step 15 Administer the patient comprehension test**
- Have the patient complete the patient comprehension test to verify the patient understands how to wear and use the ASSURE system.
- See chapter 7, Concluding the Patient Session, on page 119 for more information.

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11.Tablet Specifications and User Information

This section provides device specifications and information on the Mason G450 Tablet.

11.1   Specifications

Item	Detail
Size	6.03 x 10.32 x 0.36 in (153.2 x 262 x 9.2 mm)
Battery type	Lithium-ion (non-removable)
Battery power	8500 mAh
Operating system	Android 7.1.2
Screen size (resolution)	10.1 in (1920 x 1200 pixels)
Wireless interfaces	NFC, *Bluetooth*® 4.2, IEEE 802.11b/g/n 2.4G/5G
Ports	USB-C 3.5mm audio jack
Operating and storage temperature	41°F to 95°F (5°C to 35°C)
Relative humidity	8 to 80% (non-condensing)
Manufacturer Name	Mason America, Inc.
Manufacturer Address	2101 4th Avenue Suite 1550 Seattle, WA 98121 USA

11.2   Wireless Specifications

The Tablet meets the following specifications for wireless transmission and reception.

Frequency range:	WCDMA Band I: Uplink: 1920-1980 MHz, Downlink: 2110-2170 MHz
	WCDMA Band VIII: Uplink: 880-915 MHz, Downlink: 925-960 MHz LTE
	FDD Band 1: Uplink: 1920-1980 MHz, Downlink: 2110-2170 MHz LTE FDD
	Band 3: Uplink: 1710-1785 MHz, Downlink: 1805-1880 MHz LTE FDD Band
	7: Uplink: 2500-2570 MHz, Downlink: 2620-2690 MHz LTE FDD Band 8:
	Uplink: 880-915 MHz, Downlink: 925-960 MHz LTE FDD Band 20: Uplink:
	832-862 MHz, Downlink: 791-821 MHz LTE FDD Band 28: Uplink: 703-748
	MHz, Downlink: 758-803 MHz
	IEEE 802.11: 2412-2472 MHz, 5180-5240 MHz, 5260-5320 MHz, 5500-5700 MHz
	Short Range Devices: 5745-5825 MHz
	Bluetooth: 2402-2480 MHz
	RFID: 12.56 MHz GPS:
	1575.42 MHz (RX)

Transmit power	WCDMA Band I / WCDMA Band VIII: 0.25 Watts / 0.25 Watts
	LTE FDD Band 1 / LTE FDD Band 3: 0.2 Watts / 0.2 Watts LTE
	FDD Band 7 / LTE FDD Band 8: 0.2 Watts / 0.2 Watts LTE FDD
	Band 20 / LTE Band 28: 0.2 Watts / 0.2 Watts
	IEEE 802.11: 2412-2472 MHz: 0.05 Watts (EIRP), 5180-5240 MHz: 0.061 Watts (EIRP) 5260-5320 MHz: 0.066 Watts (EIRP), 5500-5700 MHz: 0.053 Watts (EIRP)
	Short Range Devices: 0.02 Watts (EIRP)
	Bluetooth: 0.0046 Watts (EIRP)
	RFID: -5.68 dBuA/m@3m

Modulation type:	WCDMA Band I / WCDMA Band VIII: QPSK[1]
	LTE FDD Band 1 / LTE FDD Band 3: QPSK, 16QAM[2] LTE
	FDD Band 7 / LTE FDD Band 20: QPSK, 16QAM
	IEEE 802.11: DSSS[3], OFDM[4], BPSK[5], QPSK, 16QAM, 64QAM
	Short Range Devices: BPSK, QPSK, 16QAM, 64QAM
	Bluetooth: GFSK[6], π/4QPSK[7], 8DPSK[8]
	RFID: ASK[9] GPS:
	BPSK[10]

1. Quadrature Phase Shift Keying
2. Quadrature Amplitude Modulation
3. Direct Sequence Spread Spectrum
4. Orthogonal Frequency-Division Multiplexing
5. Binary Phase Shift Keying
6. Gaussian Frequency Shift Keying
7. Pi/4 Quadrature Phase Shift Keying
8. Eight Differential Phase Shift Keying
9. Amplitude Shift Keying
10. Binary Phase Shift Keying

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11.3   Standards Conformance

The Tablet conforms to the following standards:

Protection of Health and Safety	EN 62368-1:2014+A11:2017
	EN 50360:2017, EN 50566:2017, EN 50663:2017EN
	62209-11:2016, EN 62209-2:2010
Electromagnetic Compatibility (EMC)	Draft ESTI EN 301 489-1 V2.2.1, ETSI EN 301 489-3 V2.1.1
	Draft ESTI EN 301 489-17 V3.2.0, Draft ETSI EN 301 489-19 V2.1.0Draft
	ETSI EN 301 489-52 V1.1.0
Radio Spectrum Use	ETSI EN 303 413 V1.1.1, ETSI EN 300 328 V2.1.1
	ETSI EN 301 908-1 V11.1.1, ETSI EN 300 330V2.1.1
	ETSI EN 301 908-2 V11.1.2, ETSI EN 301 908-13 V11.1.2
	ETSI EN 301 893 V2.2.1, ETSI EN 300 440V2.1.1

11.4   User Information

Note: The following information is provided from the manufacturer.

MASON

USER INFO

G450

8LMW QEVOMRK SR XLI FEXXIV], QERYEP, SV TEGOEKMRK MRHMGEXIW XLI FEXXIVMIW MR XLMW TVSHYGX WLSYPH RSX FI HMWTSWIH SJ [MXL SXLIV LSYWILSPH [EWXI.

SAFETY INFORMATION

Read all safety information before using the device to ensure safe and proper use.

*EMPYVI XS JSPPS[WEJIX] ERH [EVRMRK KYMHIPMRIW GER VIWYPX MR MRNYV] ERH HIEXL.

▶ (S RSX I\TSWI XLI HIZMGI XS TL]WMGEP MQTEGX SV HEQEKI.

▶ 3RP] YWI QERYJEGXYVIV- ETTVSZIH FEXXIVMIW, GLEVKIVW, ERH EGGIWWSVMIW.

▶ 4VIZIRX XLI QYPXMTYVTSWI NEGO ERH FEXXIV] XIVQMREPW JVSQ GSRXEGXMRK GSRHYGXMZI IPIQIRXW WYGL EW QIXEP SV PMUYMHW.

▶ -J ER] TEVX SJ XLI HIZMGI MW GVEGOIH SV FVSOIR, SV MJ XLI HIZMGI FIGSQIW ZIV] LSX, WXST YWMRK XLI HIZMGI MQQIHMEXIP].

▶ Do not turn on or use the device when the FEXXIV] GSQTEVXQIRX MW I\TSWIH.

▶ (S RSX FMXI SV WYGO SR XLI HIZMGI ERH ER] EGGIWWSVMIW EXXEGLIH XS XLI HIZMGI.

▶ Do not insert the device or any attached accessories MRXS XLI IEVW, QSYXL, SV I]IW.

▶ (S RSX YWI XLI GEQIVE sEWL GPSWI XS XLI I]IW SJ ER] ERMQEPW SV LYQERW.

▶ (S RSX WXSVI]SYV HIZMGI MR ZIV] LSX SV ZIV] GSPH EQFMIRX XIQTIVEXYVI EVIEW. 6IGSQQIRHIH STIVEXMRK XIQTIVEXYVI VERKI MW FIX[IIR 5°* XS 35°*.

▶ Do not store your device near high heat sources MRGPYHMRK LIEXIVW, QMGVS[EZIW, GSSOMRK IUYMTQIRX, SV LMKL TVIWWYVI GSRXEMRIVW.

▶ /IIT]SYV HIZMGI HV]. (S RSX XSYGL XLI HIZMGI [MXL [IX LERHW.

▶ %ZSMH XLI YWI SJ XLI HIZMGI MR LYQMH IRZMVSRQIRXW WYGL EW VIWXVSSQW, ERH HYVMRK [EXIV-FEWIH EGXMZMXMIW.

▶ Do not use your device outdoors HYVMRK E XLYRHIVWXSVQ.

▶ /IIT XLI HIZMGI EX E QMRMQYQ HMWXERGI SJ 15GQ E[E] JVSQ ER EGXMZI IPIGXVSRMG QIHMGEP MQTPERXIH HIZMGI.

▶ 'SQTP] [MXL EPP WEJIX] [EVRMRKW ERH VIKYPEXMSRW VIKEVHMRK HIZMGI HIZMGI YWEKI [LMPI STIVEXMRK E ZILMGPI.

CORRECT DISPOSAL

Do not dispose your device and/or battery in 5VI SV ER] sEQQEFPI WSYVGIW.

Do not dispose your device and/or battery [MXL VIKYPEV LSYWILSPH [EWXI.

*SV TVSTIV HMWTSWEP TPIEWI GSRXEGX GYWXSQIV WIVZMGI.

⚠

8LMW QEVOMRK SR XLI TVSHYGX, QERYEP, EGGIWWSVMIW SV TEGOEKMRK MRHMGEXIW XLI TVSHYGX ERH MXW IPIGXVSRMG EGGIWWSVMIW (I.K. GLEVKIV, LIEHWIX, ERH 97& GEFPI) WLSYPH RSX FI HMWTSWIH SJ [MXL SXLIV LSYWILSPH [EWXI. 8LMW TVSHYGX MW 6S,7 GSQTPMERX.

📠 1.866.217.5164

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SPECIFIC ABSORPTION RATE (SAR) CERTIFICATION INFORMATION

8S TVIZIRX TSWWMFPI LIEVMRK HEQEKI [LIR
YWMRK E LIEHWIX, HS RSX PMWXIR EX LMKL ZSPYQI
JSV PSRK TIVMSHW SJ XMQI.

This device meets international guidelines for exposure to radio waves.

=SYV HIZMGI HIZMGI MW HIWMKRIH RSX XS I\GIIH XLI PMQMXW
JSV I\TSWYVI XS VEHMS [EZIW VIGSQQIRHIH F]
MRXIVREXMSREP KYMHIPMRIW. 8LI KYMHIPMRIW [IVI HIZIPSTIH
F] ER MRHITIRHIRX WGMIRXMJMG SVKERM^EXMSR ('2-64) ERH
MRGPYHIW E WYFWXERXMEP WEJIX] QEVKMR HIWMKRIH XS
EWWYVI XLI WEJIX] SJ EPP TIVWSRW VIKEVHPIWW SJ EKI
ERH LIEPXL. 8LI VEHMS [EZI I\TSWYVI KYMHIPMRIW YWIW
E YRMX SJ QIEWYVIQIRX ORS[R EW XLI 7TIGMJMG
%FWSVTXMSR 6EXI, SV 7%6.

8LI 7%6 PMQMX JSV HIZMGI HIZMGIW MW 1.6;//K [MXL
E WITEVEXMSR HMWXERGI EW JSPPS[W:

,IEH: 0QQ; &SH]: 10QQ.

8LI QE\MQYQ 7%6 JSV XLMW QSHIP QIEWYVIH
SZIV SRI KVEQ SJ XMWWYI:

,IEH: 0.22;//K; &SH]: 1.0 ;//K

FCC STATEMENT

%R] 'LERKIW SV QSHMJMGEXMSRW RSX I\TVIWWP] ETTVSZIH
F] XLI TEVX] VIWTSRWMFPI JSV GSQTPMERGI GSYPH ZSMH XLI
YWIVbW EYXLSVMX] XS STIVEXI XLI IUYMTQIR X.

8LMW HIZMGI GSQTPMIW [MXL TEVX 15 SJ XLI *'' 6YPIW.
3TIVEXMSR MW WYFNIGX XS XLI JSPPS[MRK X[S GSRHMXMSRW:

(1) 8LMW HIZMGI QE] RSX GEYWI LEVQJYP MRXIVJIVIRGI,
ERH

(2) 8LMW HIZMGI QYWX EGGITX ER] MRXIVJIVIRGI
VIGIMZIH, MRGPYHMRK MRXIVJIVIRGI XLEX QE] GEYWI
YRHIWMVIH STIVEXMSR.

FCC RADIATION EXPOSURE STATEMENT:

8LMW IUYMTQIRX GSQTPMIW [MXL *'' VEHMEXMSR
I\TSWYVI PMQMXW WIX JSVXL JSV ER YRGSRXVSPPIH
IRZMVSRQIRX. 8LMW IUYMTQIRX WLSYPH FI MRWXEPPIH
ERH STIVEXIH [MXL QMRMQYQ HMWXERGI 20GQ
FIX[IIR XLI VEHMEXSV &
]SYV FSH].

FCC CAUTION

15.19 Labeling requirements

8LMW HIZMGI GSQTPMIW [MXL TEVX 15 SJ XLI *' 6YPIW.
3TIVEXMSR MW WYFNIGX XS XLI GSRHMXMSR XLEX XLMW HIZMGI
HSIW RSX GEYWI LEVQJYP MRXIVJIVIRGI.

15.21 Information to user

%R] 'LERKIW SV QSHMJMGEXMSRW RSX I\TVIWWP] ETTVSZIH
F]

XLI TEVX] VIWTSRWMFPI JSV GSQTPMERGI GSYPH ZSMH XLI YWIVbW
EYXLSVMX] XS STIVEXI XLI IUYMTQIRX.

15.105 Information to the user

2SXI: 8LMW IUYMTQIRX LEW FIIR XIWXIH ERH JSYRH XS
GSQTP] [MXL XLI PMQMXW JSV E 'PEWW & HMKMXEP HIZMGI,
TYVWYERX XS TEVX 15 SJ XLI *'' 6YPIW. 8LIWI PMQMXW EVI
HIWMKRIH XS TVSZMHI VIEWSREFPI TVSXIGXMSR EKEMRWX
LEVQJYPMRXIVJIVIRGI MR E VIWMHIRXMEP MRWXEPPEXMSR. 8LMW
IUYMTQIRX KIRIVEXIW YWIW ERH GER VEHMEXI VEHMS
JVIUYIRG] IRIVK] ERH, MJ RSX MRWXEPPIH ERH YWIH MR
EGGSVHERGI [MXL XLI MRWXVYGXMSRW, QE] GEYWI LEVQJYP
MRXIVJIVIRGI XS VEHMS GSQQYRMGEXMSRW. ,S[IZIV,
XLIVI MW RS KYEVERXII XLEX MRXIVJIVIRGI [MPP RSX SGGYV MR E
TEVXMGYPEV MRWXEPPEXMSR. -J XLMW IUYMTQIRX HSIW GEYWI
LEVQJYP MRXIVJIVIRGI XS VEHMS SV XIPIZMWMSR
VIGITXMSR, [LMGL GER FI HIXIVQMRIH F] XYVRMRK XLI
IUYMTQIRX SJJ ERH SR, XLI YWIV MW IRGSYVEKIH XS XV] XS
GSVVIGX XLI MRXIVJIVIRGI F] SRI SV QSVI SJ XLI
JSPPS[MRK QIEWYVIW:

6ISVMIRX SV VIPSGEXI XLI VIGIMZMRK ERXIRRE.

-RGVIEWI XLI WITEVEXMSR FIX[IIR XLI IUYMTQIRX
ERH VIGIMZIV.

'SRRIGX XLI IUYMTQIRX MRXS ER SYXPIX SR E
GMVGYMX HMJJIVIRX JVSQ XLEX XS [LMGL XLI VIGIMZIV
MW GSRRIGXIH.

'SRWYPX XLI HIEPIV SV ER
I\TIVMIRGIH VEHMS/8= XIGLRMGMER JSV
LIPT.

SPECIFIC ABSORPTION RATE (SAR) INFORMATION:

8LMW XEFPIX QIIXW XLI KSZIVRQIRXbW VIUYMVIQIRXW
JSV I\TSWYVI XS VEHMS [EZIW. 8LI KYMHIPMRIW EVI
FEWIH SR WXERHEVHW XLEX [IVI HIZIPSTIH F]
MRHITIRHIRX WGMIRXMJMG SVKERM^EXMSRW XLVSYKL TIVMSHMG
ERH XLSVSYKL IZEPYEXMSR SJ WGMIRXMJMG WXYHMIW. 8LI
WXERHEVHW MRGPYHI E WYFWXERXMEP WEJIX] QEVKMR
HIWMKRIH XS EWWYVI XLI WEJIX] SJ EPP TIVWSRW
VIKEVHPIWW SJ EKI SV LIEPXL. *'' 6* I\TSWYVI
-RJSVQEXMSR ERH 7XEXIQIRX 8LI 7%6 PMQMX SJ 97%
(*'') MW 1.6 ;/OK EZIVEKIH SZIV SRI KVEQ SJ XMWWYI.
(IZMGI X]TIW: 8EFPIX (*'' -(:2%.>4-+450%1) LEW
EPWS FIIR XIWXIH EKEMRWX XLMW 7%6 PMQMX. 8LMW HIZMGI
[EW XIWXIH JSV X]TMGEP FSH]-[SVR STIVEXMSRW [MXL XLI
FEGO SJ XLI LERHWIX OITX 10QQ JSV FSH] [SVR ERH
10QQ JSV LSXWTSX. 8S QEMRXEMR GSQTPMERGI [MXL
'' 6 I\TSWYVI VIUYMVIQIRXW, YWI EGGIWWSVMIW
XLEX QEMRXEMR E 10QQ JSV FSH] [SVR ERH 10QQ JSV
LSXWTSX. 8LI YWI SJ FIPX GPMTW, LSPWXIVW ERH WMQMPEV
EGGIWWSVMIW WLSYPH RSX GSRXEMR QIXEPPMG GSQTSRIRXW MR
MXW EWWIQFP]. 8LI YWI SJ EGGIWWSVMIW XLEX HS RSX
WEXMWJ] XLIWI VIUYMVIQIRXW QE] RSX GSQTP] [MXL
'' 6 I\TSWYVI VIUYMVIQIRXW, ERH WLSYPH FI EZSMHIH.

BODY-WORN OPERATION

8LMW HIZMGI [EW XIWXIH JSV X]TMGEP FSH]-[SVR STIVEXMSRW.
8S GSQTP] [MXL 6* I\TSWYVI VIUYMVIQIRXW, E
QMRMQYQ WITEVEXMSR HMWXERGI SJ 10QQ JSV FSH]
[SVR ERH 10QQ JSV LSXWTSX QYWX FI QEMRXEMRIH
FIX[IIR XLI YWIVbW FSH] ERH XLI LERHWIX, MRGPYHMRK XLI
ERXIRRE. 8LMVH-TEVX] FIPX- GPMTW, LSPWXIVW, ERH WMQMPEV
EGGIWWSVMIW YWIH F] XLMW HIZMGI WLSYPH RSX GSRXEMR
ER] QIXEPPMG GSQTSRIRXW. &SH]-[SVR EGGIWWSVMIW
XLEX HS RSX QIIX XLIWI VIUYMVIQIRXW QE] RSX GSQTP]
[MXL 6* I\TSWYVI VIUYMVIQIRXW ERH WLSYPH FI
EZSMHIH. 9WI SRP] XLI WYTTPMIH SV ER ETTVSZIH
ERXIRRE.

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Publication Date: 2021-05

REF 80026-001 Rev. H