



assure

Cardiac Recovery System

assure[®]

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 sale by or on the order of a physician.

Version History

This document describes the initial release of the ASSURE system and Charger.

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During the Warranty Period, Kestra will, at its cost and at its option, repair or replace any part of the ASSURE system as deemed reasonably necessary by Kestra, to ensure it performs to the standards for safety and effectiveness dictated by the Food and Drug Administration (FDA). This is the sole and exclusive remedy under this Limited Warranty. This Limited Warranty is non-transferable and is exclusive to you throughout the duration of your prescription period. Your acknowledgment of the instructions for use, risks, and your obligations with respect to the safe and effective use of the ASSURE system as outlined in your Patient Agreement and the *ASSURE Wearable Defibrillator Patient Handbook* are ongoing. Kestra shall not be responsible for any defect, failure to perform any specified function, or any other non-conformance, caused by or attributable to any modification, use, or misuse of the ASSURE system by you or others that is inconsistent with the instructions specified in the labeling, *ASSURE Wearable Defibrillator Patient Handbook* or *ASSURE Wearable Defibrillator Quick Start Guide*.

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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.

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.

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.

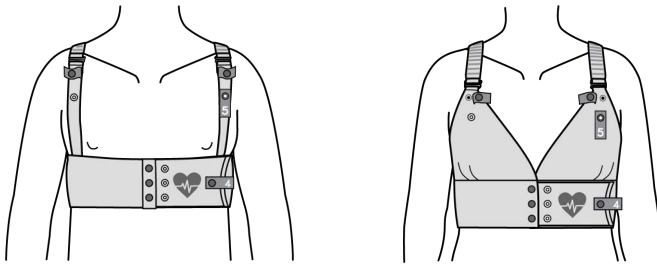
1.9 Part Descriptions

This section provides descriptions of the ASSURE system.

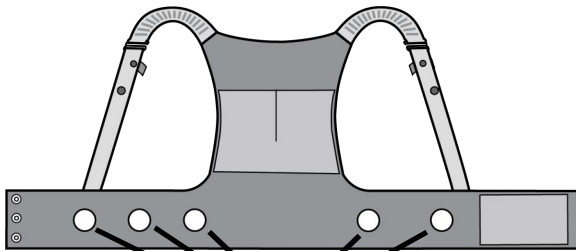
1.9.1 Garment Description

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.

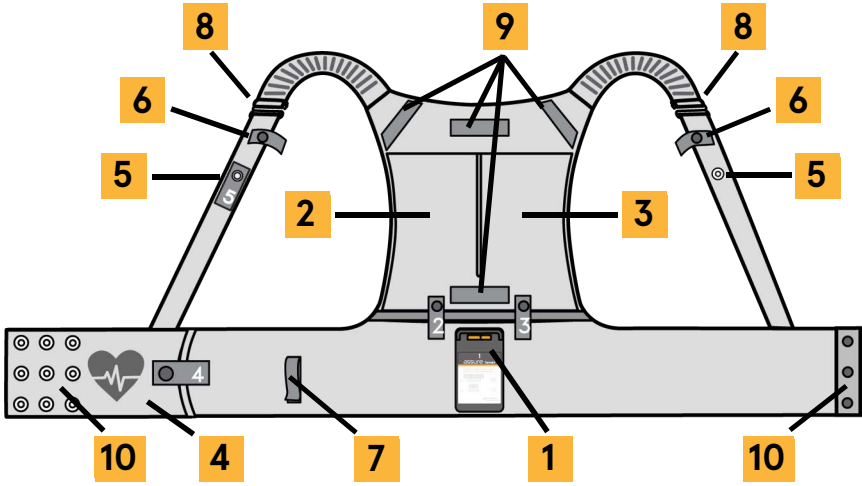


Garment Style A (left) and Style B (right)



Garment Inside View

Item	Name
1	Sensors



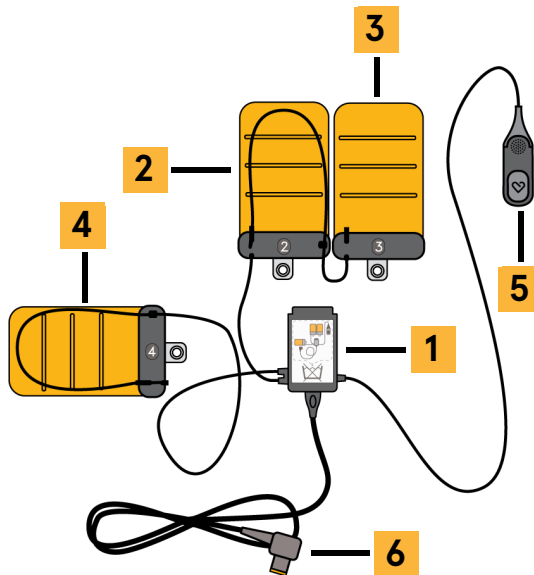
Garment Outside View

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.

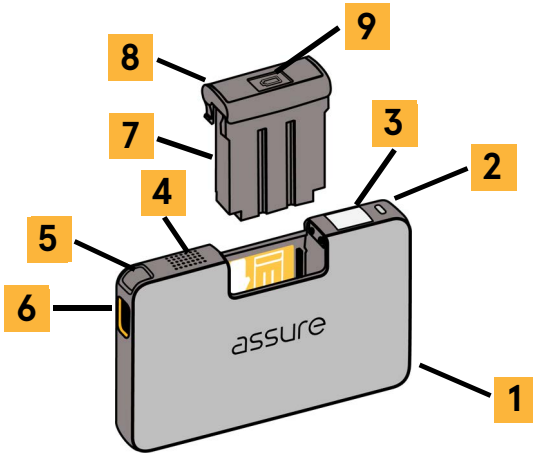
Note: The entire Therapy Cable is a single assembly. The cords connected to the Hub cannot be removed.



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

1.9.3 Monitor and Battery Description

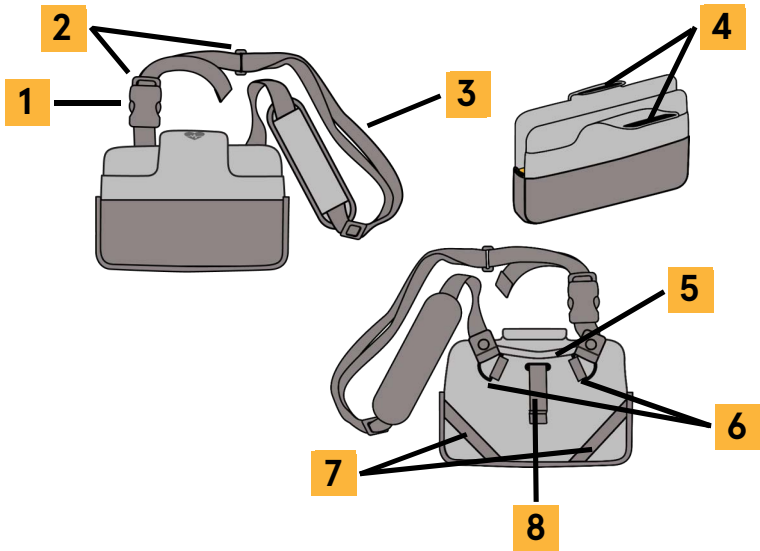
The Monitor is the main electronic part of the ASSURE system. The rechargeable Battery inserts into the Monitor and provides power to the system.



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

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 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.

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.

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.

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 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.*
- *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.

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.

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:

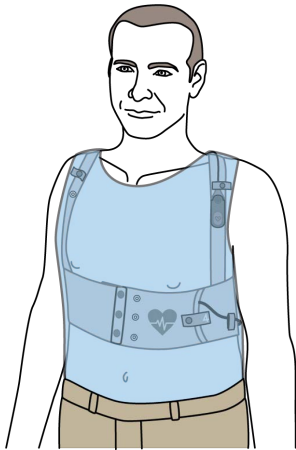
- Wearing the ASSURE system
- Checking the system status
- Sleeping while wearing the ASSURE system
- Taking a shower or bath
- Traveling with the system

3.1 Wearing the ASSURE System

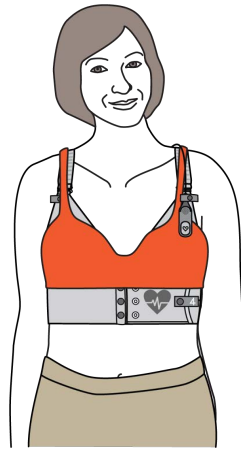
The ASSURE system is designed to be worn all the time, except while showering or bathing. You can wear it in a variety of public settings, like going to a grocery store, attending a sporting event, or dining out.

Guidelines while wearing the system:

- **Wear any clothing over the Garment.**
 - Do not wear or place anything between the Garment and your body.
 - Undershirts and bras may only be worn over 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:

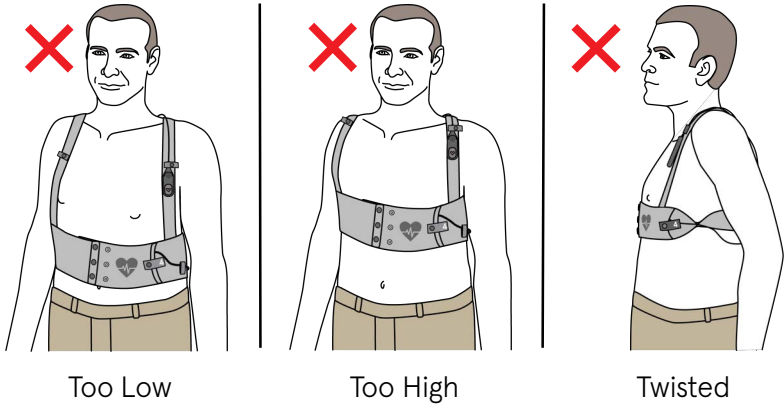
- *The Garment contains the following materials:*
 - > *Body fabric: 59% Polyamide, 41% Elastane (spandex)*
 - > *Inner lining: 73% Polyamide, 27% Elastane*
 - > *Therapy Pad pockets: 100% Silver-plated Nylon*
- *The Carry Pack is 100% Polyester and the strap is 100% Nylon.*

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.

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

Improper Garment Fit

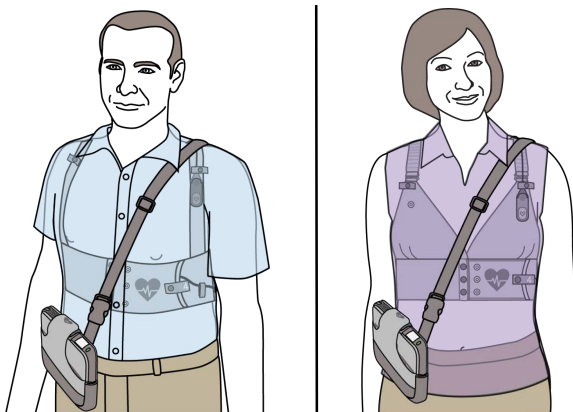


3.1.2 Using the Carry Pack

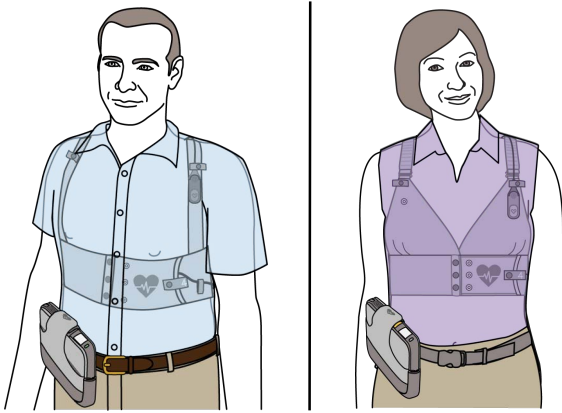
You can wear the Carry Pack in different ways depending on your preference.

Over the shoulder with the strap lengthened.

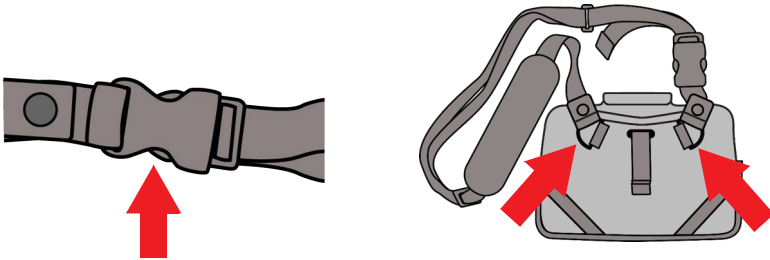
- Across the body or over the shoulder.



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 Carry Pack strap connectors and connect together using a buckle.



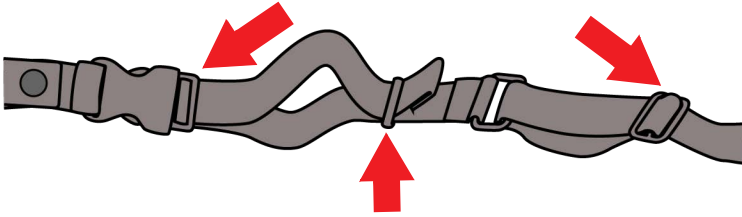
Buckle (Left) and Strap Connectors (Right)

- 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

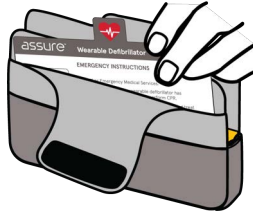
- Slide the adjuster along the strap to lengthen or shorten the strap.
- Use the strap adjuster near the buckle to tighten the strap when wearing the Carry Pack around the waist. You can insert any extra strap length through the elastic band on the strap.

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

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

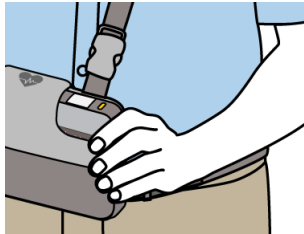
When you receive an alert, follow these three general steps:

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:

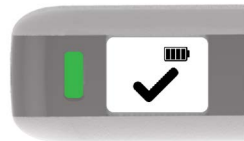
Press the Alert Button



What you will...

See

- Solid green Monitor light
- System Ready icon on Monitor screen



Hear

Three-note guitar strum

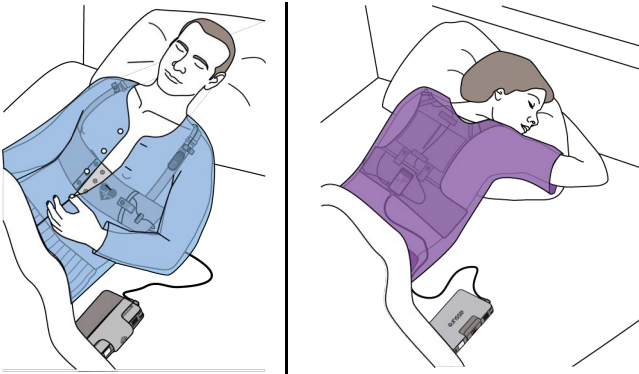
Feel

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.

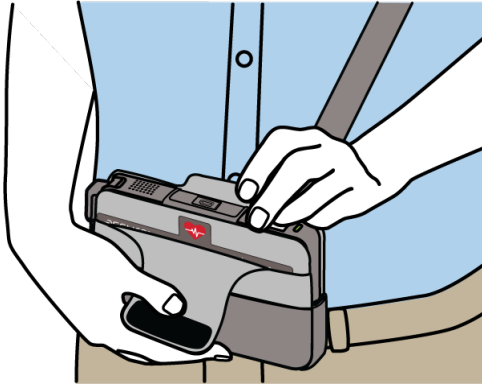
After taking a shower or bath and drying off, put on the system.

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

3.6.1 Removing the ASSURE System

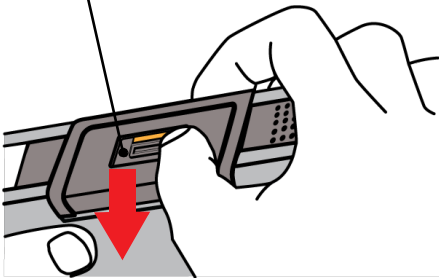
To take off the ASSURE system:

Step 1 - Open the Carry Pack flaps

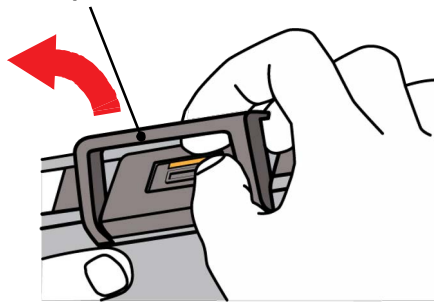


Step 2 - Slide the Battery lock until you see the yellow line and lift the Battery handle

Battery Lock

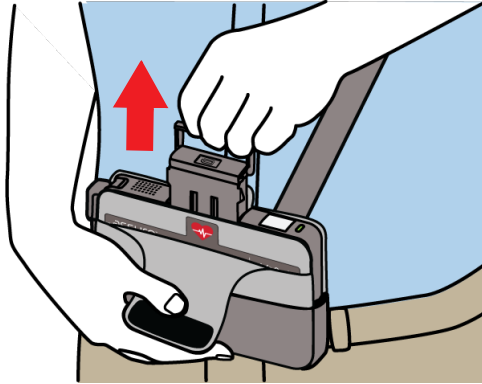


Battery Handle



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

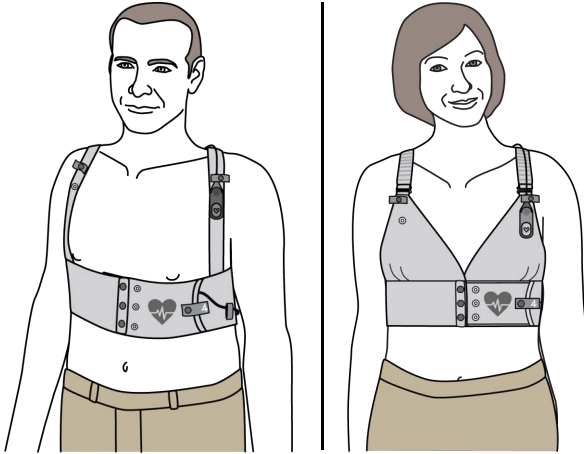


- Removing the Battery turns off the system.
- To avoid setting off alerts, always remove the Battery before taking off the ASSURE system.

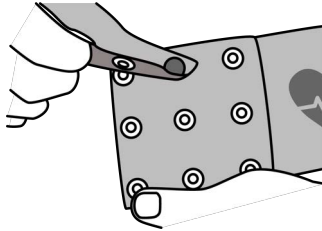
Step 4 - Take off the Carry Pack

- 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.

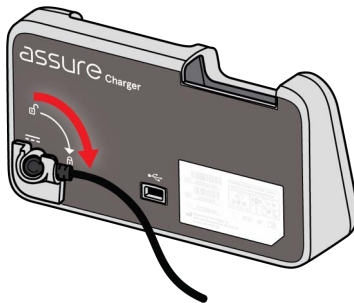
To plug in the Charger:

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.

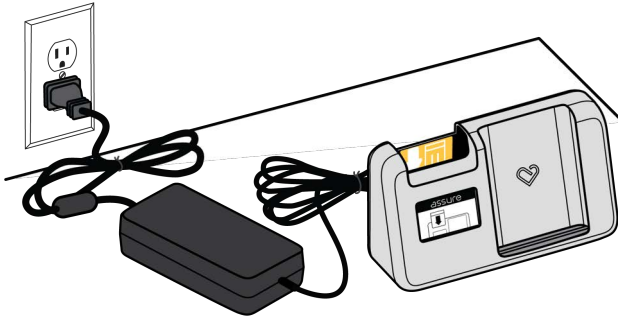


Note: Properly secure the cord in the clip. This prevents the cord from being accidentally removed from the Charger.

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.*

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.

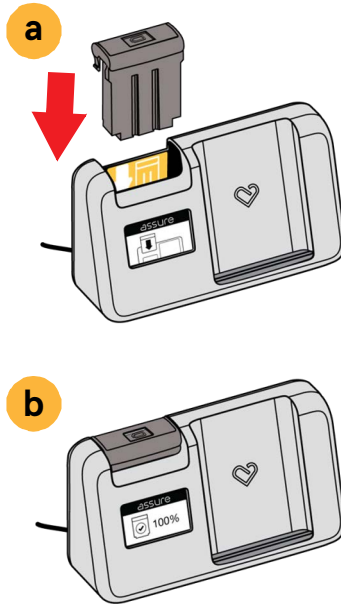
Notes:

- *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.


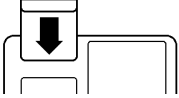

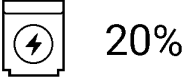

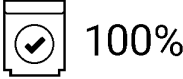





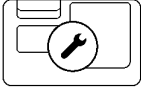


Step 2 - Check the Charger screen to confirm that the Battery is charging

- See the next page for more information.

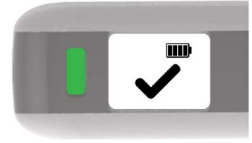
4.2.1 Viewing the Charger Screen






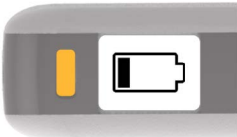
The Charger screen displays the Battery's current charge status.

Screen Display	Description
 	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.

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.

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

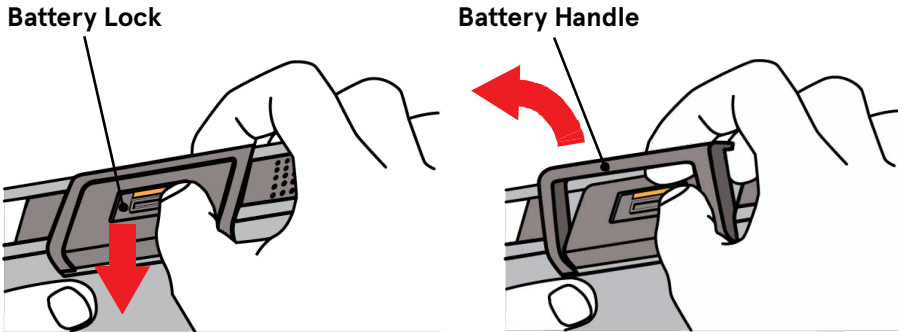
- The Charger screen shows the Battery status.



Step 2 - Open the flaps on the Carry Pack

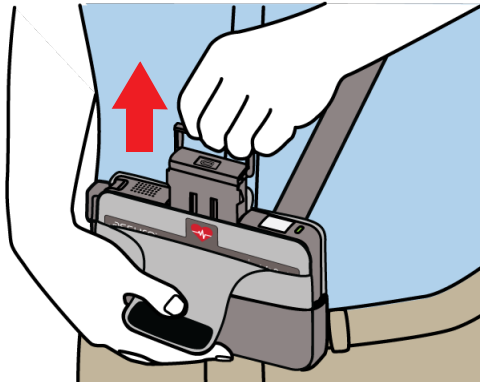


Step 3 - Slide the Battery lock until you see the yellow line and lift the Battery handle



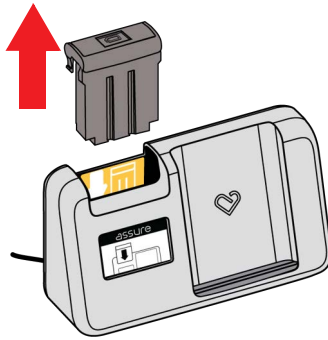
Note: If you need help with this task, see page 144 or watch the patient video at kestramedical.com/patients.

Step 4 - Pull up to remove the Battery from the Monitor



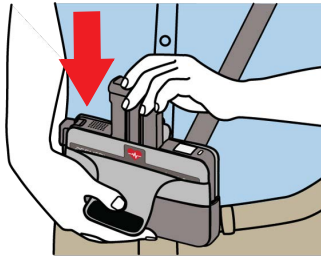
- Removing the Battery turns off the system.
- Damaged Batteries may leak and cause personal injury or equipment damage. Handle damaged or leaking Batteries with extreme care. Call the ASSURE Helpline at 1.833.692.7787 to report any equipment damage.

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

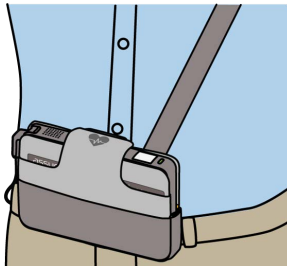


Step 6 - Insert the fully charged Battery into the Monitor

- 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.

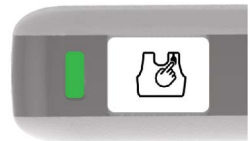
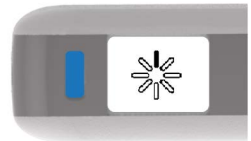
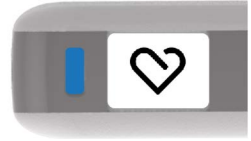


Step 7 - Close the flaps on the Carry Pack



Step 8 – Wait a few minutes while the ASSURE system 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 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

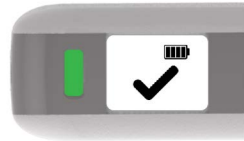
Note: If you press the Alert Button and the System Ready icon does not immediately appear on the Monitor screen, call the ASSURE Helpline at 1.833.692.7787. There may be an issue with the Alert Button.



What you will...

See

- Solid green Monitor light
- System Ready icon on Monitor screen



Hear

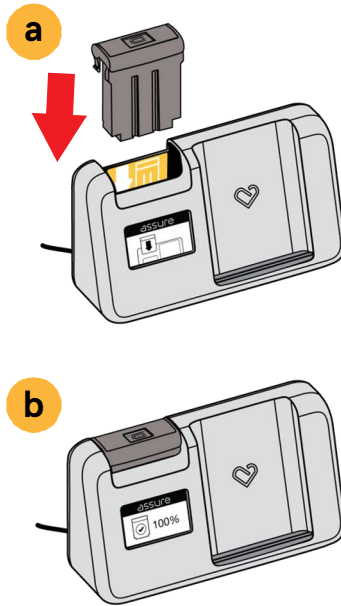
Three-note guitar strum

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

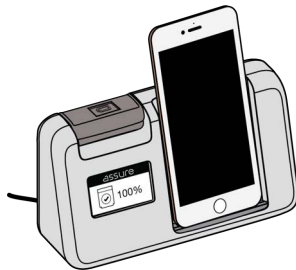
The Charger includes a wireless charging well for mobile devices. The well provides a standard 5W charging speed and supports mobile devices up to 6.3 x 3.3 x 0.49 inches (including a case).

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:

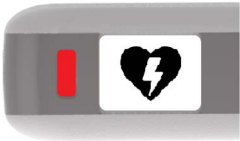

- Heart alerts – The ASSURE system has detected a heart rhythm that is either too fast or too slow. These alerts are critical and must be responded to immediately.
- System alerts – The ASSURE system has found a problem with the system equipment that needs your attention.

What you will...	Heart Alert	System Alert
See	<ul style="list-style-type: none"> ● Flashing red Monitor light ● Alert icon on Monitor screen 	<ul style="list-style-type: none"> ● Blinking yellow Monitor light ● Alert icon on Monitor screen
Hear	<ul style="list-style-type: none"> ● Harsh, alternating low-high alarm ● Voice message 	<ul style="list-style-type: none"> ● 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.

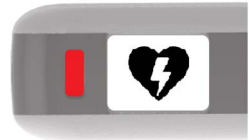
5.2.1 Shock Alert



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.

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 Seek Medical 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.

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.

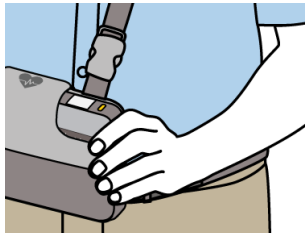
When you receive a System alert, follow these three general steps:

Step 1 - Press the Alert Button

- Press once to quiet the alert.
- Press again to replay the voice message.

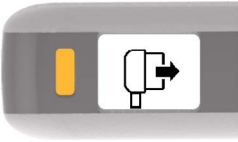
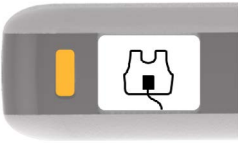
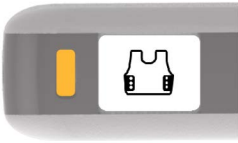
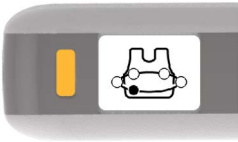
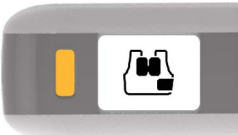


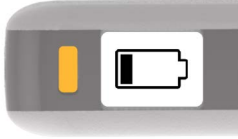



Step 2 - Look at the Monitor screen and light



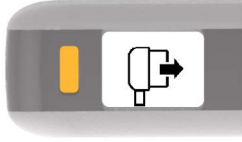

Step 3 – Respond

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).

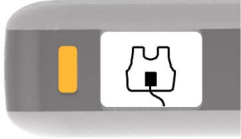
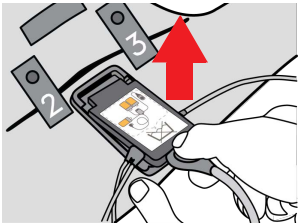
Alert Name	Light and Icon	Reference
Connect Plug to Monitor		See page 89.
Connect Hub to Garment		See page 90.
Put on Garment <i>Note: This alert uses a series of icons. The displayed icon will vary.</i>		See page 91.
Check Sensors <i>Note: The displayed icon will vary depending on which sensor has lost contact.</i>		See page 92.
Check Therapy Pads		See page 94.

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

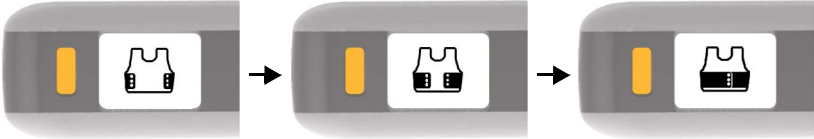
Monitor Icon	
Description	<p>The Plug is not inserted properly into the Monitor.</p>
Voice Message	<p>“Connect the Plug to your Monitor.”</p>
Actions	<p>To respond to this alert:</p> <p style="text-align: center;">Insert the Plug into the Monitor</p> <p>If the Plug is already inserted into the Monitor, try re-inserting it:</p> <p style="text-align: center;">Step 1 – Press and hold the Monitor’s Plug Release button and then remove the Plug from the Monitor</p> <p style="text-align: center;">Step 2 – Insert the Plug back into the Monitor</p> <ul style="list-style-type: none"> - A “click” sound means the Plug is securely inserted. <p><i>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.</i></p> <p> WARNING</p> <p><i>If the alert continues to play, remove the Battery from the Monitor and re-insert it to restart the ASSURE system.</i></p>

5.3.2 Connect Hub to Garment Alert

Monitor Icon	
Description	<p>The Hub is not properly inserted into the Garment.</p>
Voice Message	<p>“Connect the Hub to your Garment.”</p>
Actions	<p>To respond to this alert:</p> <p>Step 1 - Press the Alert Button</p> <p>Step 2 - Insert the Hub into the Garment</p> <p>If the Hub is already inserted into the back of the Garment, try re-inserting it:</p> <p>Step 1 - Use both hands to remove the Hub from the Garment</p> <ul style="list-style-type: none"> - 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.  <p>Step 2 - Insert the Hub back into the Garment</p> <ul style="list-style-type: none"> - A “click” sound means the Hub is securely inserted.

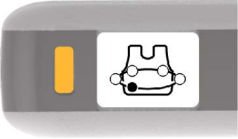
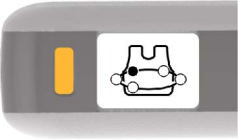
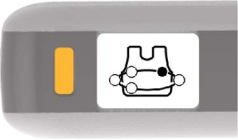
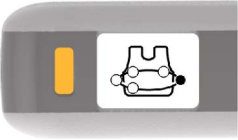
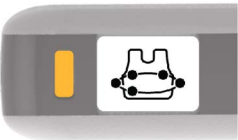
5.3.3 Put on Garment Alert

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	<p>To respond to this alert:</p> <p>Step 1 - Press the Alert Button to quiet the alert</p> <p>Step 2 - Put on the Garment</p> <p>If you are already wearing the Garment:</p> <ul style="list-style-type: none"> - 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.

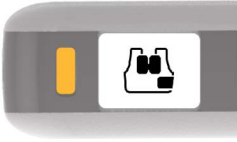
5.3.4 Check Sensors Alert

Note: The displayed Monitor screen icon will vary depending on which sensor has lost contact (see the examples below).

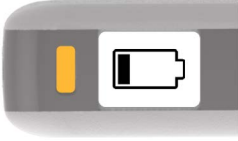
Monitor Icons	
	Right front sensor has lost contact.
	Right back sensor has lost contact.
	Left back sensor has lost contact.
	Left front sensor has lost contact.
	The Right Middle Sensor or multiple Sensors have lost contact, or the ASSURE system cannot sense your heart rhythm.
Description	One or more 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.”

<p>Actions</p>	<p>To respond to this alert:</p> <p>Step 1 – Press the Alert Button to quiet the alert</p> <p>Step 2 – Try the following actions:</p> <ul style="list-style-type: none"> - Adjust the Garment so the Sensors are flat and touching bare skin. <ul style="list-style-type: none"> > 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. <p><i>Note: Female patients may wear a bra over the Garment to provide more support.</i></p> <ul style="list-style-type: none"> - 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. <p>If the alert continues, try the following:</p> <ul style="list-style-type: none"> - 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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5.3.5 Check Therapy Pads Alert

Monitor Icon	
Description	<p>One or more of the Therapy Pads are not touching bare skin.</p>
Voice Message	<p>“Check the Therapy Pads. The pads must touch your skin.”</p>
Actions	<p>To respond to this alert:</p> <p>Step 1 - Press the Alert Button to quiet the alert</p> <p>Step 2 - Try the following actions:</p> <ul style="list-style-type: none"> - Confirm the Therapy Pads are flat and touching bare skin. <ul style="list-style-type: none"> > 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	<p>The Battery has less than two hours of power left. Replace the Battery now.</p>
Voice Message	<p>“Replace your Battery now.”</p>
Actions	<p>To respond to this alert:</p> <p>Step 1 - Press the Alert Button to quiet the alert</p> <p>Step 2 - Insert a fully charged Battery into the Monitor</p> <ul style="list-style-type: none"> - A “click” sound means the Battery is securely inserted. <p>Step 3 - When the Alert Button icon appears on the Monitor screen, press the Alert Button</p> <p><i>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.</i></p> <p>Step 4 - Place the used Battery into the Charger</p> <p>Step 5 - Check the Charger screen to confirm that the Battery is charging</p>

5.3.7 Shock Delivered – Seek Medical Attention Alert


Monitor Icon	
Description	<p>You have received a shock and the dangerous heart rhythm is no longer detected.</p>
Voice Message	<p>“Call 911 now. You have received a shock. Continue to wear your ASSURE system.”</p>
Actions	<ul style="list-style-type: none"> ● Continue to wear the ASSURE system. <ul style="list-style-type: none"> - 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. <p><i>Note: The ASSURE system will not call 911 for you. You or someone nearby must call 911.</i></p> ● Your chest area and back will be wet and covered with gel. <ul style="list-style-type: none"> - 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	<p>There is a problem with the ASSURE system that requires immediate attention. Service Required alerts use an “R” error code.</p> <p><i>Note: This alert will repeat every five minutes.</i></p>
Voice Message	<p>“Call the ASSURE Helpline now. Your device needs service.”</p>
Actions	<p>To respond to this alert:</p> <p>Call the ASSURE Helpline at 1.833.692.7787 immediately</p> <ul style="list-style-type: none"> - Provide the ASSURE representative with the error code that appears on the Monitor screen.

5.3.9 Service Needed Alert

<p>Monitor Icon</p>	
<p>Description</p>	<p>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.</p>
<p>Voice Message</p>	<p>“Call the ASSURE Helpline now. Your device needs service. Continue to wear your ASSURE system.”</p>
<p>Actions</p>	<p>To respond to this alert:</p> <p>Step 1 - Press the Alert Button to quiet the alert</p> <p>Step 2 - Call the ASSURE Helpline at 1.833.692.7787</p> <ul style="list-style-type: none"> - Provide the ASSURE representative with the error code that appears on the Monitor screen. <p>Step 3 - Continue to wear the ASSURE system</p>

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:

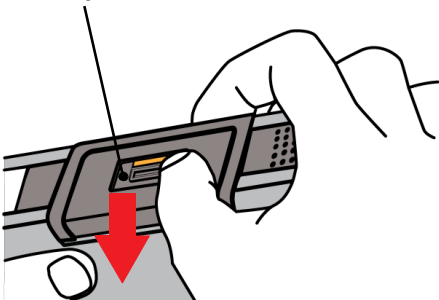
- Read through the following steps before attempting this task.
- If you need additional help, watch the patient video on the Kestra website at kestramedical.com/patients or call the ASSURE Helpline at 1.833.692.7787.

Step 1 - Open the Carry Pack flaps

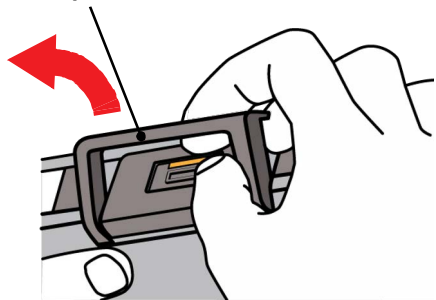


Step 2 - Slide the Battery lock until you see the yellow line and lift the Battery handle

Battery Lock

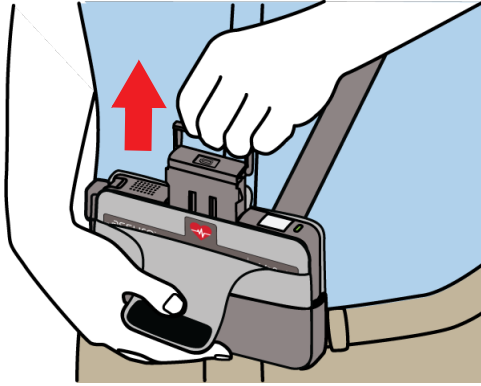


Battery Handle



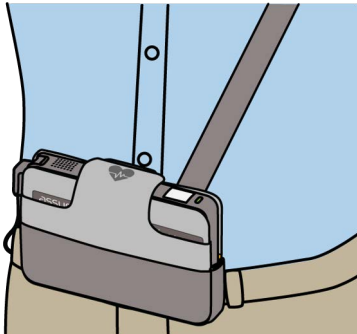
Note: If you need help with this task, see page 144 or watch the patient video at kestramedical.com/patients.

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



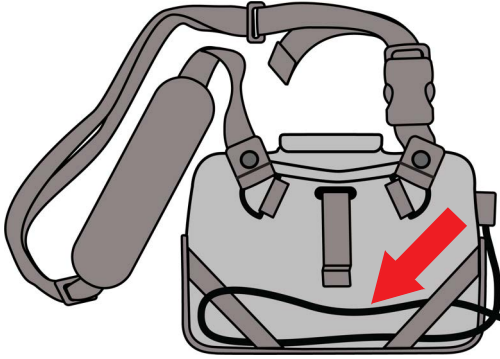
- Removing the Battery turns off the system.
- To avoid setting off alerts, always remove the Battery before taking off the ASSURE system.

Step 4 - Close the Carry Pack flaps

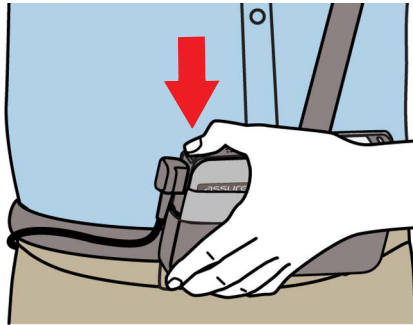


Step 5 - Remove any cable length tucked into the Carry Pack

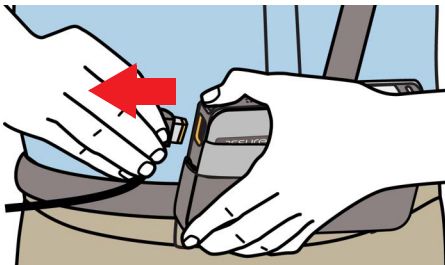
- The cabling may be inside the Carry Pack pockets or in the elastic corner straps on the back.



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

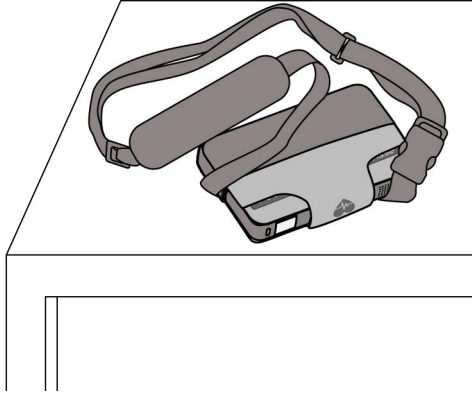


Step 7 - Remove the Plug from the Monitor

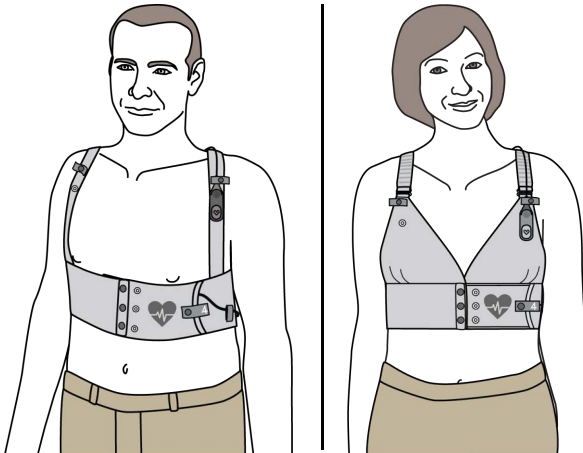


Step 8 - Take off the Carry Pack

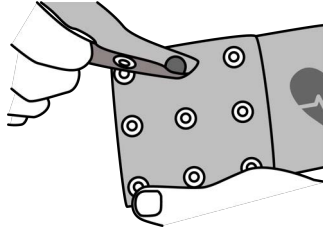
- Place the Carry Pack on a nearby flat surface to avoid dropping the Monitor.



Step 9 - Remove any clothing above the waist



Step 10 - Unsnap the front closure



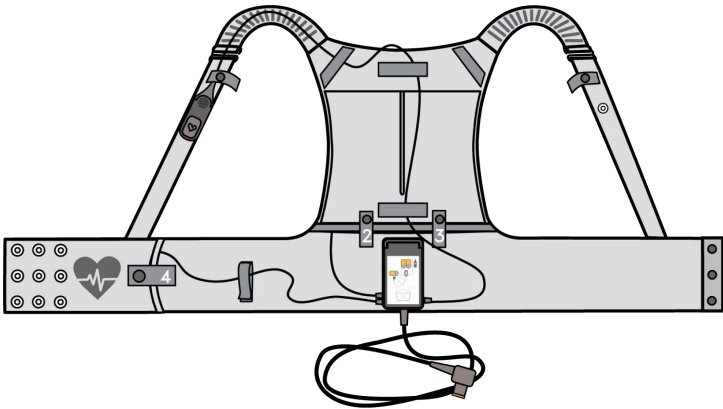
Step 11 - Take off the Garment

6.2 Removing the Therapy Cable from the Garment

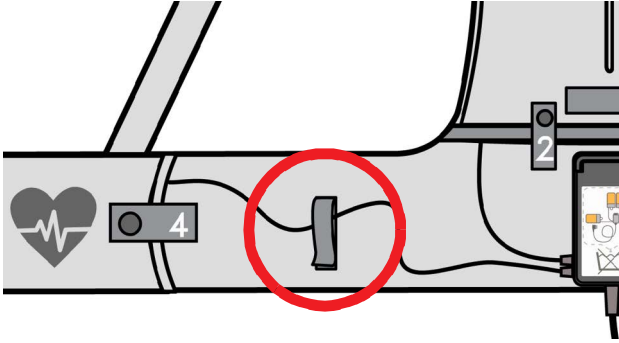
Notes:

- *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.*

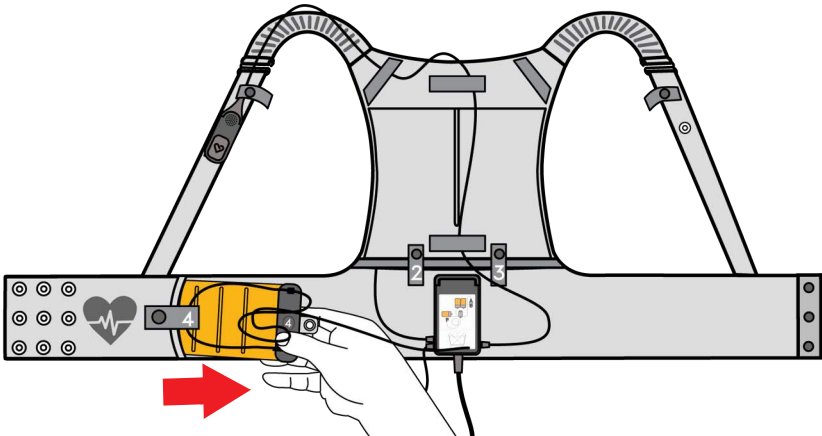
Step 1 – Take off the Garment and place it on a flat surface, like a table or desk



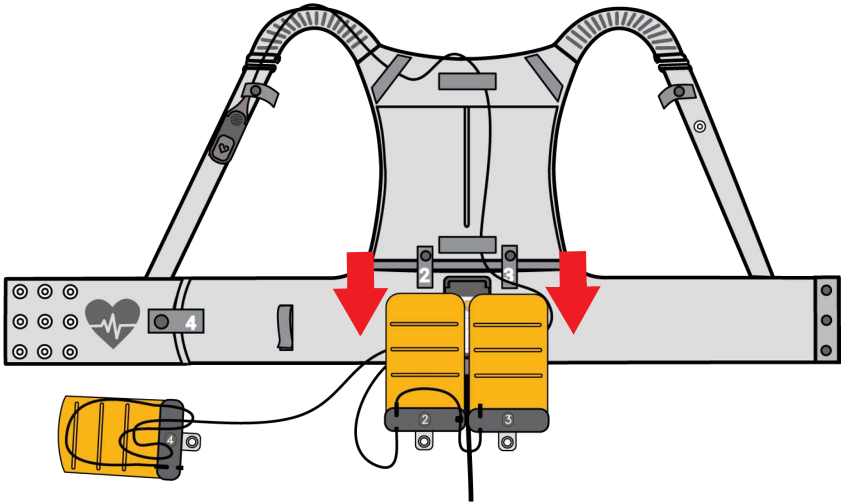
Step 2 - Open the cord wrap near pocket 4



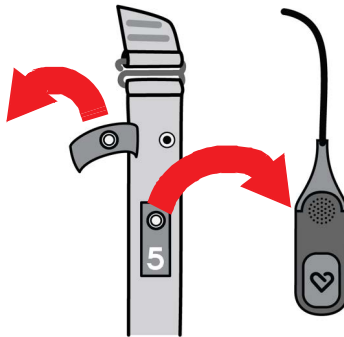
Step 3 - Unsnap and remove the Therapy Pad from pocket 4



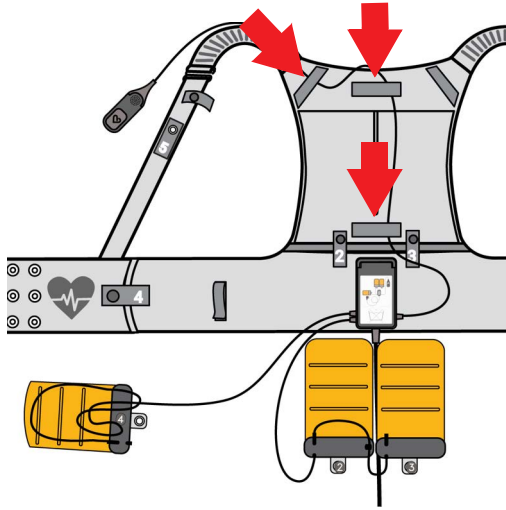
Step 4 - Unsnap and remove the Therapy Pads from pockets 2 and 3



Step 5 - Unsnap and remove the Alert Button from the shoulder strap

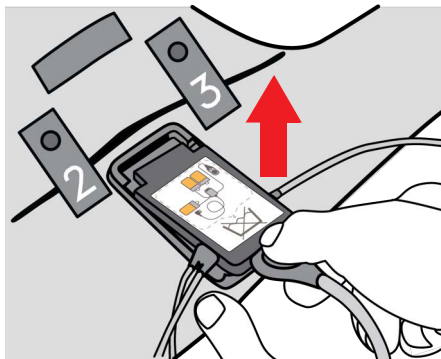


Step 6 - Gently pull the Alert Button cord through the loops on the back of the Garment until the cord is free



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.



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.

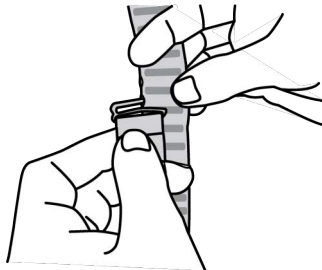
Follow these steps to assemble and put on the ASSURE system.

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).

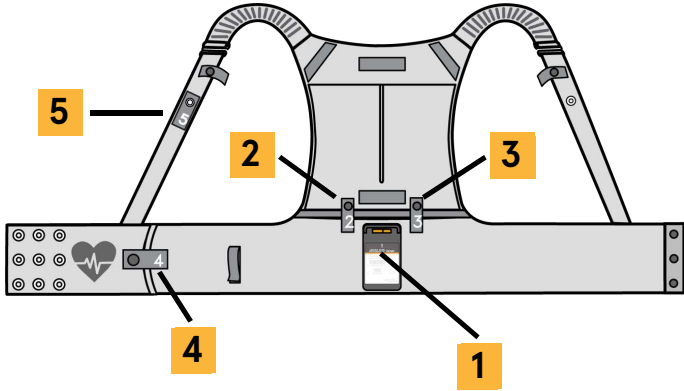
Notes:

- Additional adjustments to the shoulder strap settings may be 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 numbers facing up

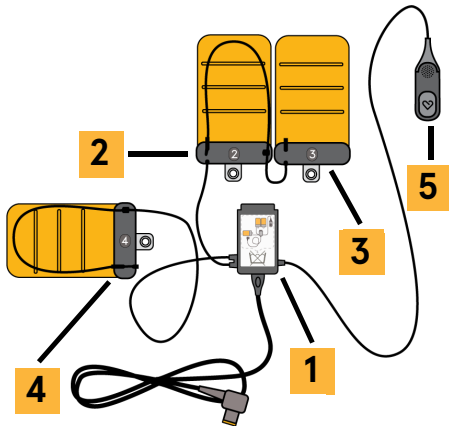
- Find the hub receptacle (number 1) and snaps (numbers 2-5) on the Garment.



Step 3 – Lay the Therapy Cable near the Garment with the yellow side of the Therapy Pads facing up

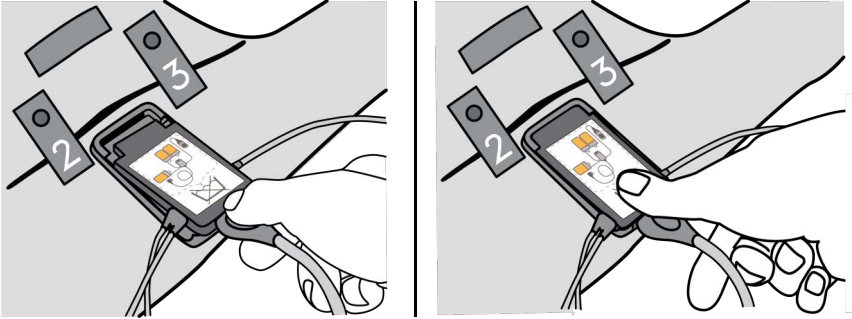
- Untangle any cords.
- Use the numbers on the Therapy Cable and the Garment to guide you through the assembly process.

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



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

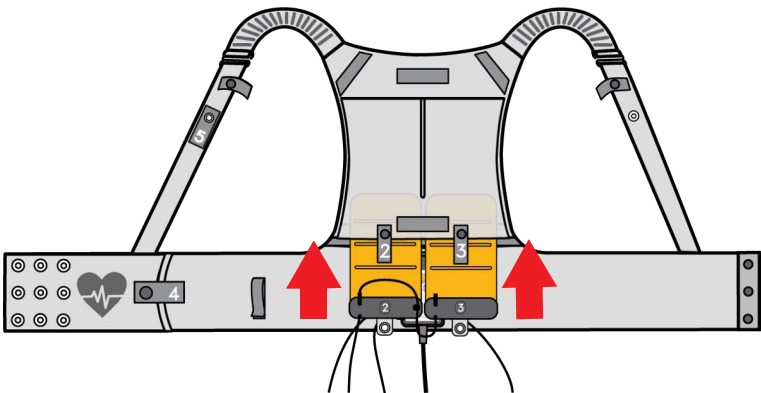
- Insert the Hub at a slight angle so it fits under the lip of the Hub Receptacle.



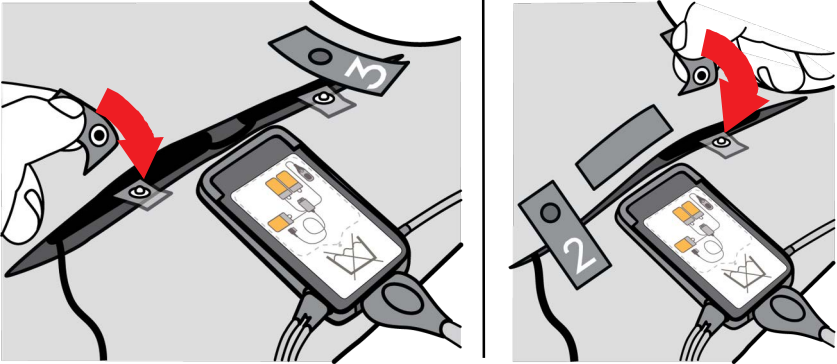
Step 5 - Insert Therapy Pads 2 and 3 into the back pockets

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.

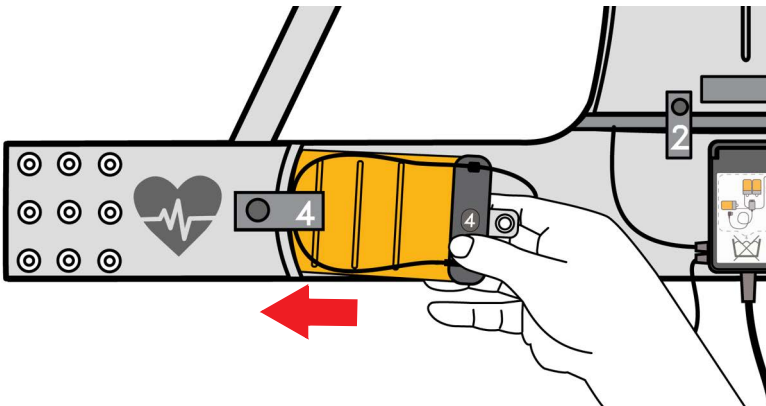


Step 6 - Snap Therapy Pads 2 and 3 to the pocket tabs

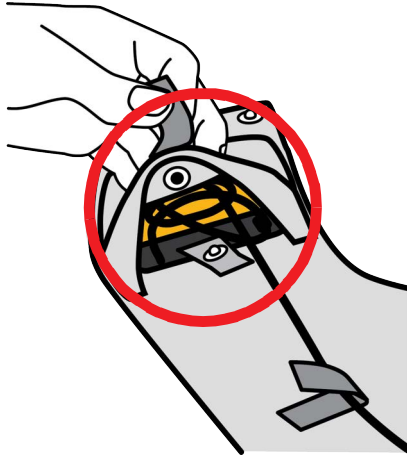


Step 7 - Insert Therapy Pad 4 into the front pocket

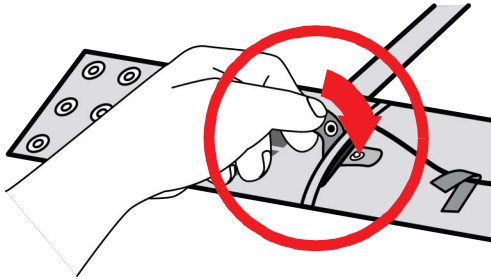
- Make sure the yellow side is facing up.
- The loop of cord should lie flat on top of the pad inside pocket 4.



Step 8 - Loop any extra length of cord and place it on top of the pad inside pocket 4

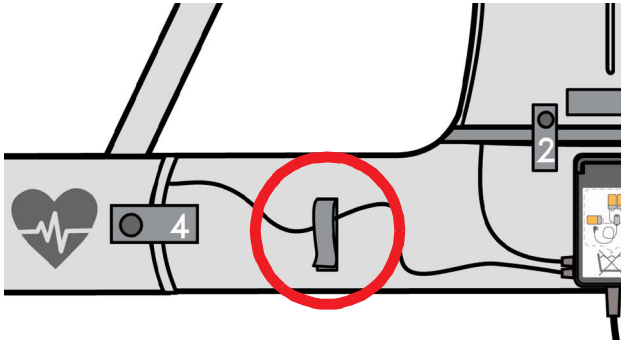


Step 9 - Snap Therapy Pad 4 to the pocket tab



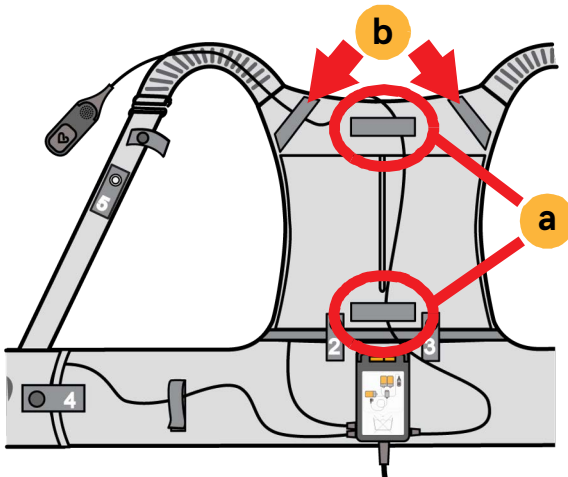
Step 10 - Fasten the cord wrap around the Therapy Pad 4 cord

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



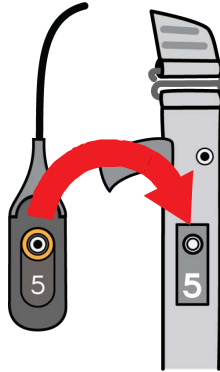
Step 11 - Pull the Alert Button and cord through the loops on the back of the Garment

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

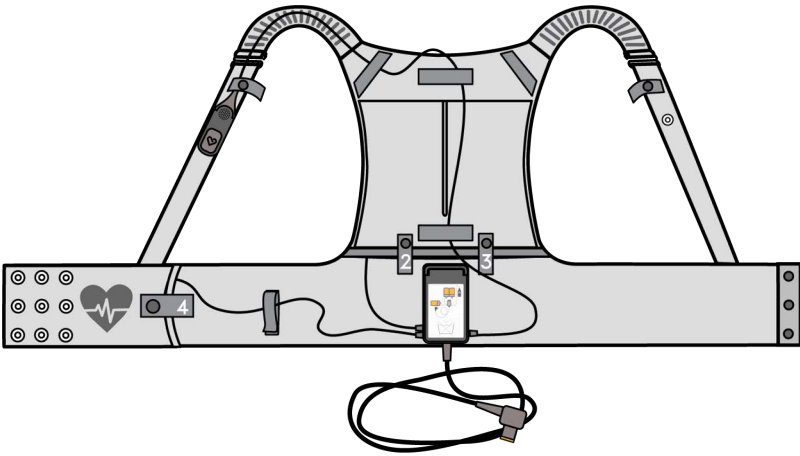


Step 13 – Place the cord wrap over the Alert Button cord and snap it to the shoulder strap

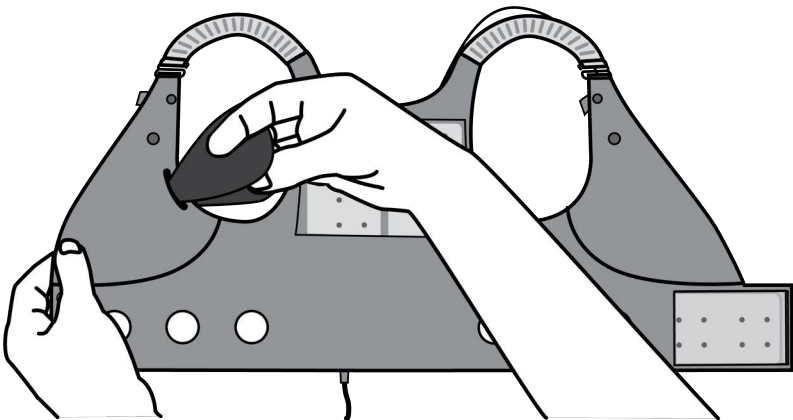


Note: There may be some extra Alert Button cord length after threading the cord through the Garment and fastening it to the shoulder strap properly. This allows for flexibility while wearing the assembled Garment.

The assembled Garment should look like the picture below.

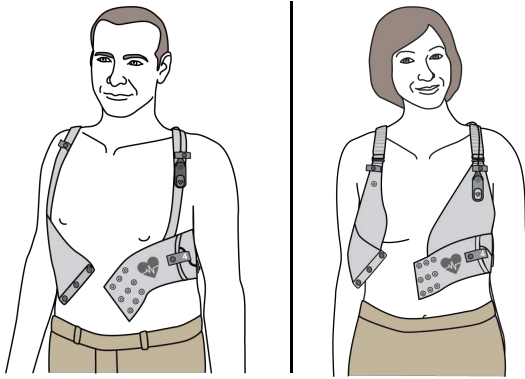


Step 14 - (Optional) Insert a bra pad (provided) into the opening between the fabric layers of each cup in the Style B Garment



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.

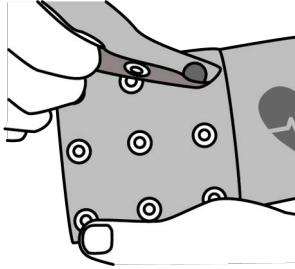


Notes:

- *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*

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

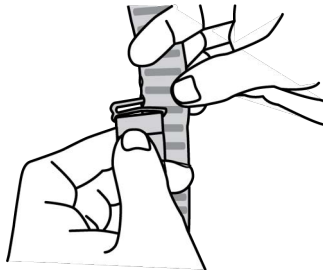
Note: The Garment must have a snug fit to keep the Sensors in contact with bare skin.



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.

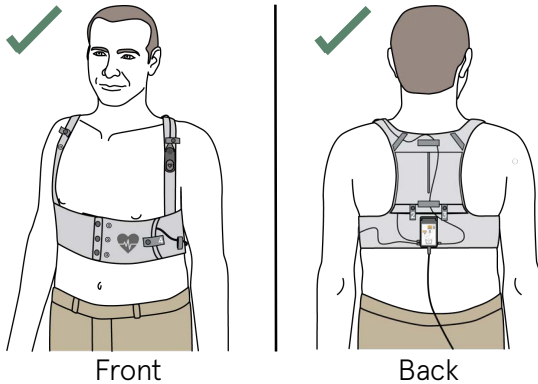


Step 18 - Check the Garment's fit

- 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 Therapy Pad or Sensors.

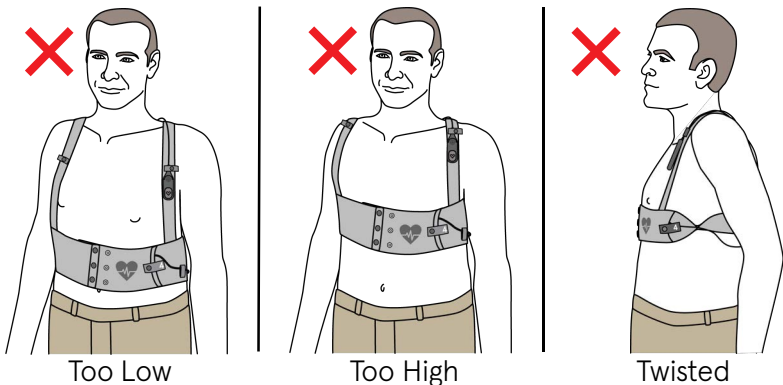
Proper Garment Fit



Front

Back

Improper Garment Fit



Too Low

Too High

Twisted

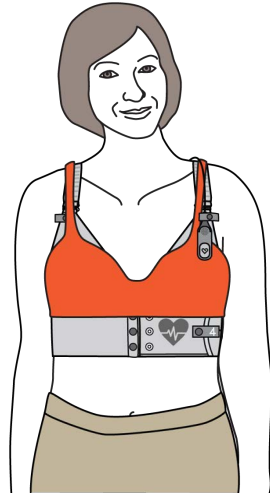
Step 19 - Put on clothes over the Garment

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 over the Garment (as shown below).



Undershirt Over the Garment

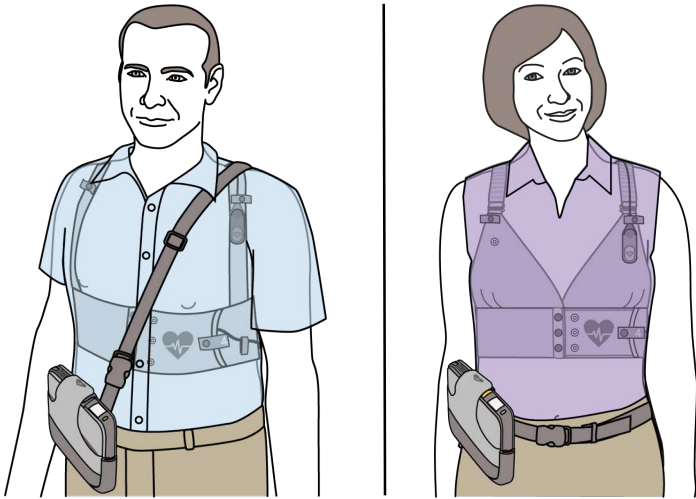


Bra Over the Garment

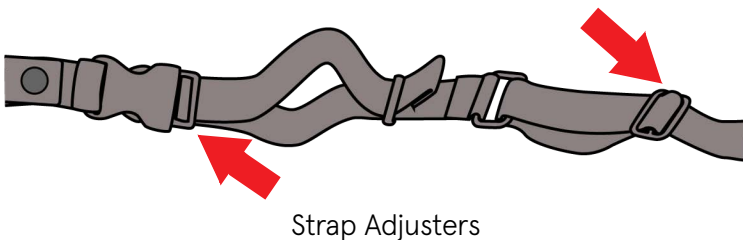
Step 20 - Put on the Carry Pack with the Monitor inside

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)



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

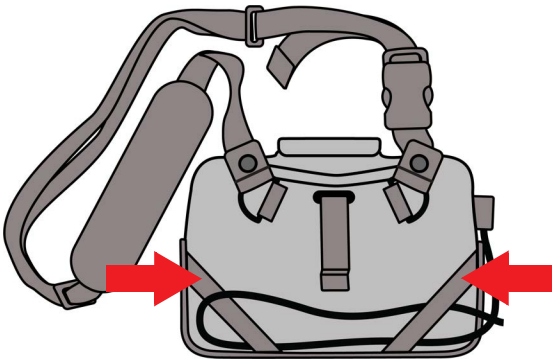
Step 22 - Insert the Plug into the Monitor

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

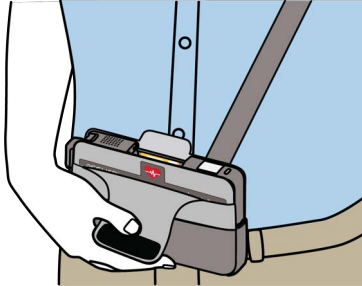


Step 23 - Manage the extra cable length to avoid catching the cable on anything

- 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.

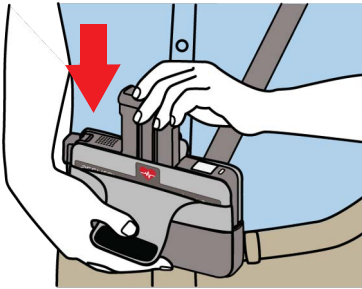


Step 24 - Open the flaps on the Carry Pack

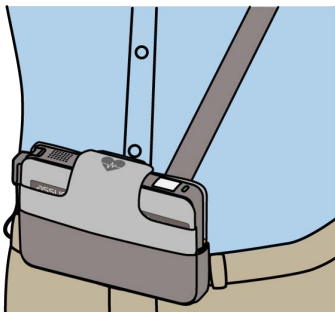


Step 25 - Insert a fully charged Battery into the Monitor

- A “click” sound means the Battery is securely inserted.

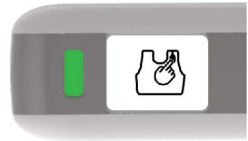
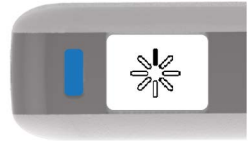
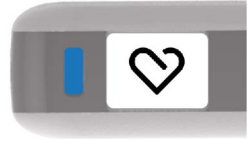


Step 26 - Close the Carry Pack flaps



Step 27 – Wait a few minutes while the ASSURE system 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 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

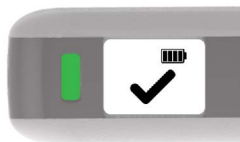
Note: If you press the Alert Button and the System Ready icon does not immediately appear on the Monitor screen, call the ASSURE Helpline at 1.833.692.7787. There may be an issue with the Alert Button.



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**

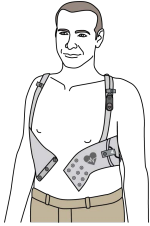


6.4 Washing the Garment

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:

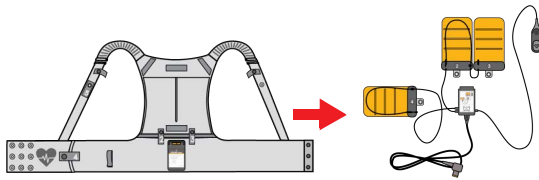
1. Take off the system.



For instructions

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.



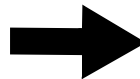
See section 6.2, Removing the Therapy Cable from the Garment, on page 105 for instructions.

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**

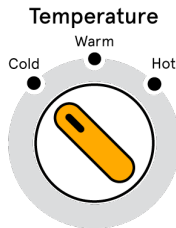
Always remove the Therapy Cable before washing the Garment.

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.

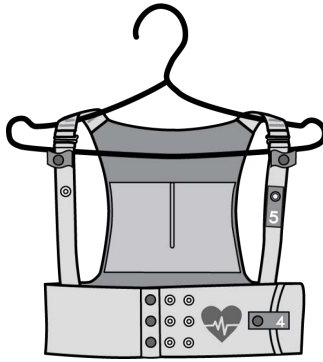
- If you prefer, you may hand wash the Garment.

**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 air dry

- 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.*

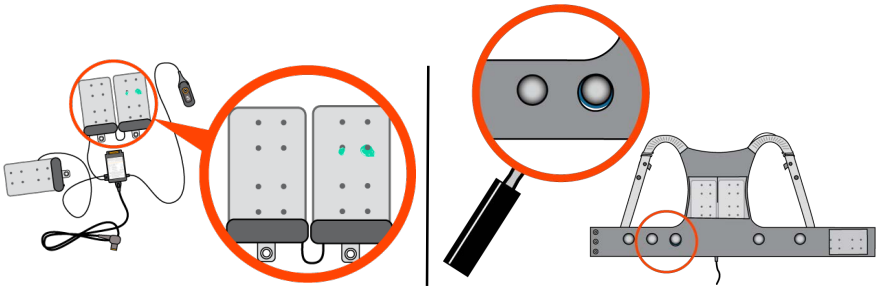
6.6 Checking for Equipment Damage

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).

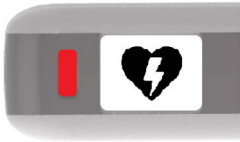
The following information is available:

- 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.

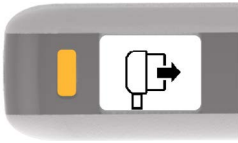
Note: The ASSURE system will not call 911 for you. You or someone nearby must call 911 during Heart alerts.

See "Seek Medical Attention Alert" on page 84 for more information.

Alert Icon

Actions

System Alerts



Insert the Plug into the Monitor.

- or -

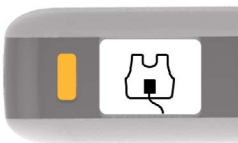
Remove the Plug from the Monitor and then re-insert it.

**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:

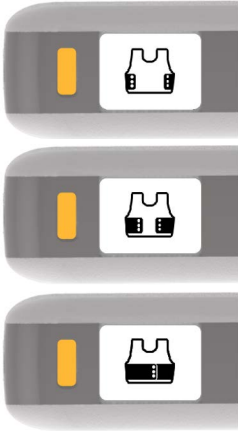
- **Insert** the Hub into the Garment.
- **Remove** the Hub from the Garment and then re-insert it.

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

Alert Icon

Actions

System Alerts



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.

Alert Icon	Actions
System Alerts	



Press the Alert Button to quiet the alert.

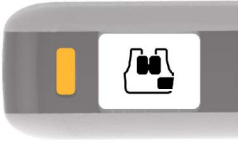
Then try the following:

- **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.

Alert Icon

Actions

System Alerts

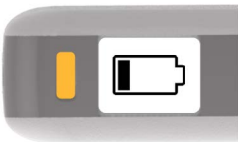


Press the Alert Button to quiet the alert.

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.


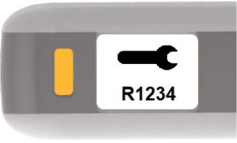

See "Check Therapy Pads Alert" on page 94 for more information.




Press the Alert Button to quiet the alert.

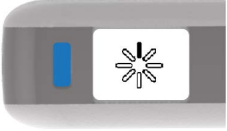
Insert a fully charged Battery into the Monitor.

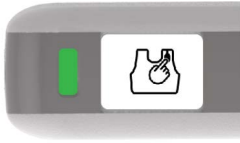
See "Low Battery Alert" on page 95 for more information.

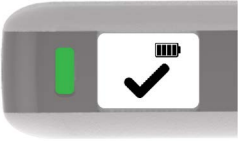
Alert Icon	Actions
System Alerts	
	<p>Press the Alert Button to quiet the alert.</p> <p>Then do the following:</p> <ul style="list-style-type: none"> ● Call 911 or seek medical attention. <i>Note: The ASSURE system will not call 911 for you. You or someone nearby must call 911 during Heart alerts.</i> ● Continue to wear the ASSURE system. <p>See "Shock Delivered – Seek Medical Attention Alert" on page 96 for more information.</p>
 <p>WARNING When the Service Required alert is active, the system is not operational and cannot protect you.</p>	<ul style="list-style-type: none"> ● Call the ASSURE Helpline at 1.833.692.7787 immediately. ● Provide the error code that appears on the Monitor screen to the ASSURE representative. <p>See "Service Required Alert" on page 97 for more information.</p>
	<p>Press the Alert Button to quiet the alert.</p> <ul style="list-style-type: none"> ● 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. <p>See "Service Needed Alert" on page 98 for more information.</p>

7.2 System Status Icons

	<h3>7.2.1 System Welcome</h3>
<p>Description</p>	<p>The Battery has been inserted into the Monitor to turn on the ASSURE system.</p>
<p>Notifications</p>	<ul style="list-style-type: none"> ● Blue Monitor light ● Icon displayed on the Monitor screen
<p>Action</p>	<p>Wait for the System Busy icon to appear on the Monitor screen.</p>

	<h2>7.2.2 System Busy</h2>
<p>Description</p>	<p>The ASSURE system is powering up.</p>
<p>Notifications</p>	<ul style="list-style-type: none"> ● Blue Monitor light ● Icon displayed on the Monitor screen
<p>Action</p>	<p>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.</p> <p><i>Notes:</i></p> <ul style="list-style-type: none"> ● <i>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.</i> ● <i>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.</i>

	<h2>7.2.3 Alert Button</h2>
<p>Description</p>	<p>The ASSURE system has finished powering up and is operational.</p> <p>Press the Alert Button to confirm it is operating properly.</p>
<p>Notifications</p>	<ul style="list-style-type: none"> ● 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.”
<p>Actions</p>	<p>Press the Alert Button</p> <p>After pressing the Alert Button, the System Ready icon appears on the Monitor screen. See section 7.2.4, System Ready, on page 142.</p>

	<h2>7.2.4 System Ready</h2>
<p>Description</p>	<p>The ASSURE system is working properly (normal operating mode).</p>
<p>Notifications</p>	<ul style="list-style-type: none"> ● Green Monitor light <i>Note: The light turns on for the first five seconds and then turns off.</i> ● Icon displayed on the Monitor screen ● Single-pulse vibration from the Alert Button ● Three-note guitar strum
<p>Action</p>	<p>None. You can press the Alert Button to check the system status at any time.</p>

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:

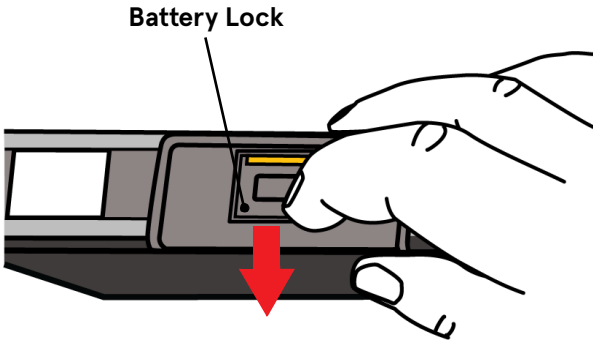
- Continue to wear the ASSURE system.
- Call your doctor.

How do I remove the Battery from the Monitor?

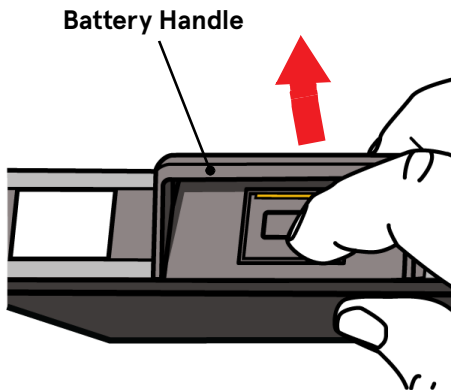
The Battery includes a lock on the top that locks the battery into the Monitor to avoid accidentally removing the Battery. If you are having issues with removing the Battery from the Monitor, try following the instructions below.

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

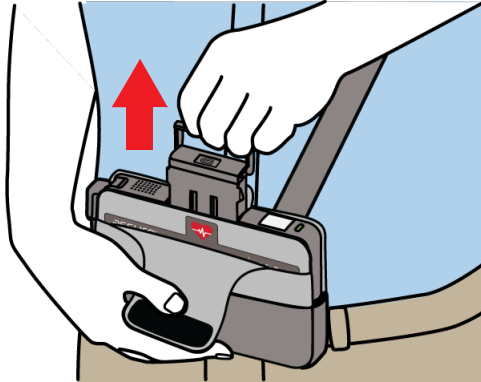
1. Slide the Battery lock until you see the yellow line.



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?

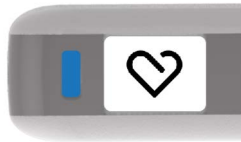
When you insert a Battery into the Charger, the Charger screen will display its status. See section 4.2.1, Viewing the Charger Screen, on page 66 for an explanation of what the different screens mean.

You can also check the following:

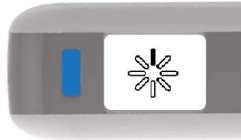
- The Charger is plugged into an electrical wall outlet.
- The Charger cord is plugged into the back of the Charger.
- The Battery is properly inserted into the Charger.

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.



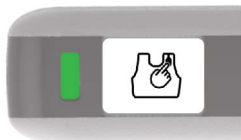
After a few seconds, the System Busy icon appears on the screen.



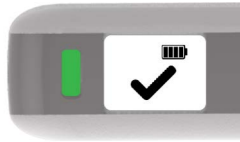
The System Busy icon can appear for a few minutes while the system is powering up.

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.

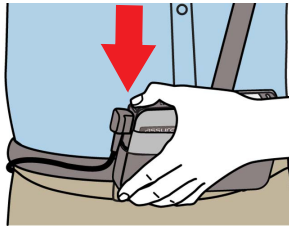


An alert icon appears on the Monitor screen when the system needs your attention. Use the reference charts at the beginning of this chapter (see page 132) to identify the alert and what actions you can take.

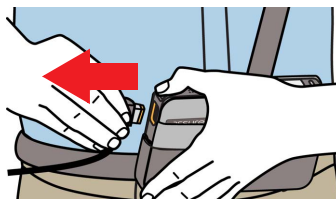
How do I disconnect the cable from the Monitor?

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.









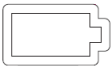
How do I clean the ASSURE system?









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


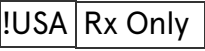






See chapter 6, General Care and Cleaning, on page 99 for more information.










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
	<p>Consult instructions for use. IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 1641</p>
	<p>Follow the instructions for use IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol ISO 7010-M002</p>
	<p>Do not dispose of in fire. IEC 60086-4, Primary batteries – Part 4: Safety of lithium batteries. Symbol C</p>
	<p>Do not deform or damage. IEC 60086-4, Primary batteries – Part 4: Safety of lithium batteries. Symbol B</p>
	<p>Do not open or dismantle. IEC 60086-4, Primary batteries – Part 4: Safety of lithium batteries. Symbol H</p>
 	<p>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</p>
	<p>Recommended storage temperature (from low to high) IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 0632</p>
	<p>Battery ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 5001B</p>

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

Symbol	Description and Reference Document
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
	For USA audiences only 21 CFR 801.109, Labeling: Prescription Devices
	Serial number IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2498
	Catalogue number IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2493
	Batch code IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2492
	Rechargeable battery IEC 60417, Graphical symbols for use on equipment. Symbol 5639
	Recognized component mark for Canada and the United States.
	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

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

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 parts per IEC 60601-2-4.
Operation Mode	Continuous; automatic detection and treatment of dangerously fast heart rhythms, automatic detection of dangerously slow heart rhythms, collection of 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) <i>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 not exceed skin temperature.</i>
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°C 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)
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)	IP21
Temperature Range: Operating	32°F to 113°F (0°C to 45°C)
Temperature Range: Storage and Transport	-4°F to 122°F (-20°C 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	<p>Alert notifications may include audio tones and instructions.</p> <p>Alert notifications and tones play through the Monitor and Alert Button speakers.</p> <ul style="list-style-type: none"> - Heart alert tone volume range is 70 ±5 dBA. - System alert tone volume range is 58 ±5 dBA. <p>The time between first notification and instructions is approximately six seconds.</p> <p>Alert volume is non-adjustable.</p> <p>The tone assignments for each type of alert include:</p> <ul style="list-style-type: none"> - 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.
Visual Notifications	<p>Alerts are indicated by an alert icon on the Monitor screen and the color of the Monitor light.</p> <ul style="list-style-type: none"> - 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.
Vibration Notifications	<p>Alerts are indicated by a vibration through the Alert Button.</p> <ul style="list-style-type: none"> - 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	<p>The following System alerts have a delay time to allow the system to confirm the alert condition before notifying the patient.</p> <ul style="list-style-type: none"> - Check Sensors alert (1-15 minutes) - Check Therapy Pads alert (15 minutes) <p><i>Note: The time between the first detection and instructions is approximately six seconds.</i></p>
System Alert Replay Delays	<p>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.</p>
System Alert Silence Delays	<p>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.</p>
Alert and System Status Priorities	<p>The lists below show the priorities from highest (1) to lowest.</p> <ol style="list-style-type: none"> 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	<p>The ASSURE detection algorithm uses ECG signals to analyze the rhythm and to detect shockable rhythms (ventricular tachycardia and ventricular fibrillation).</p> <p><i>Note: The default VT rate threshold is 170 BPM.</i></p> <p>The ASSURE detection algorithm automatically initiates analysis without requiring any input from the patient.</p>

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 872 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	Test Sample Size (Minimum Required ¹)	Performance Goal	Observed Performance ¹	90% One-sided LCL (Minimum LCL ¹)
Shockable				
Coarse VF ²	204 (200)	>90% sensitivity	99.0%	97.4% (87%)
Rapid VT ³	62 (50)	>75% sensitivity	98.4%	93.9% (67%)
Non-Shockable				
Normal Sinus Rhythm (NSR) ⁴	132 (100)	>99% specificity	100%	98.3% (97%)
AF, Sinus Bradycardia, SVT, Heart Block, idioventricular, PVCs	219 (30)	>95% specificity	96.3%	94.1% (88%)
Asystole ⁵	169 (100)	>95% specificity	97.6%	95.3% (92%)
Intermediate				
Fine VF ⁶	28 (n/a)	Report Only	75.0% sensitivity	61.6% (n/a)
Other VT ⁷	22 (n/a)	Report Only	95.5% sensitivity	83.4% (n/a)
Slow VT ⁸	36 (n/a)	Report Only	97.2% specificity	89.6% (n/a)

1. ASSURE system nominal therapy zone settings (VT 170 bpm, VF 200 bpm)
2. Disorganized ventricular rhythm with peak-to-peak amplitude $\geq 200\mu\text{V}$, and 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 $\geq 100 \mu\text{V}$ and $\leq 200 \mu\text{V}$
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)

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.

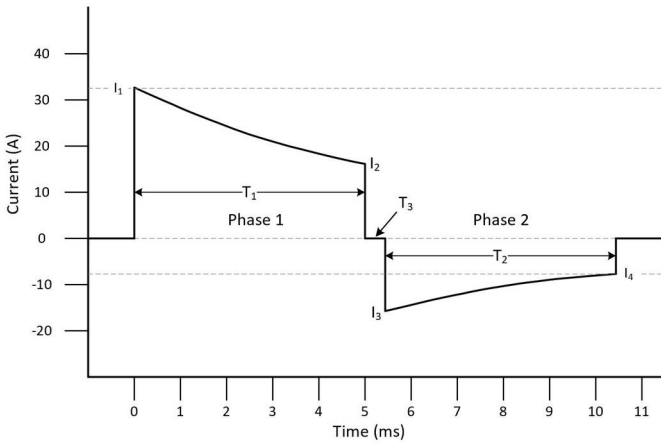
9.1.6 Defibrillation

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	<p>With a new Battery:</p> <ul style="list-style-type: none"> - 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. <p>At a Low Battery alert indication:</p> <ul style="list-style-type: none"> - Provides three 170J defibrillation shocks or two hours of operation time.
Shock Ready Time	<p>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.</p> <p>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.</p>
Maximum Charging Time After 6 Shocks	Within 20 seconds
Maximum Time from Initiation of Rhythm Analysis to Readiness for Discharge After 6 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.

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.

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 if 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.

	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 <i>Bluetooth</i> ® 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	<p><5% U_T (>95% dip in U_T) for 0.5 cycle</p> <p>40% U_T (60% dip in U_T) for 5 cycles</p> <p>70% U_T (30% dip in U_T) for 25 cycles</p> <p><5% U_T (>95% dip in U_T) for 5 sec</p>	Complies	<p>Mains power quality should be that of a typical home environment.</p> <p>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.</p>
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
			<p>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.</p>
<p>Conducted RF IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz outside ISM bands¹</p>	<p>3 Vrms</p>	<p>Recommended separation distance $d = 1.2\sqrt{P}$</p>
	<p>6 Vrms 150 kHz to 80 MHz in ISM bands¹</p>	<p>6 Vrms</p>	<p>$d = 1.2\sqrt{P}$</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: 

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.

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

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 (2.5mW) 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.



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