

# Patient Handbook

**ASSURE Wearable ECG**





**assure<sup>®</sup>**

Cardiac Recovery System

**ASSURE Wearable ECG  
Patient Handbook**

**Kestra Medical Technologies, Inc.**

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

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# Chapter 1 Overview

Your doctor has prescribed the ASSURE<sup>®</sup> wearable ECG system (ASSURE wearable ECG) as a follow-up to your ASSURE wearable defibrillator prescription. Although it uses the same SensorFit™ Garment(s) as the ASSURE wearable defibrillator, the ASSURE wearable ECG will only record heart rhythms for later review by your doctor, it will not treat fast heart rhythms.

## **CAUTION**

*This device will not deliver a shock for fast heart rhythms and is not a substitute for emergency medical care. You should seek medical attention if you feel unwell.*

The ASSURE wearable ECG is designed to be worn all the time, except while showering, bathing, or washing the Garment. A typical ASSURE wearable ECG prescription lasts for about 30 days.

*Note: Read this manual before using the ASSURE wearable ECG.*

For questions or help with the ASSURE wearable ECG, call the ASSURE Helpline at (833) 692-7787 (Toll free).

# Clinical Information

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## Indications for Use

The ASSURE wearable ECG is indicated for adult patients who have been prescribed this device by a medical professional, who were previously prescribed the ASSURE wearable defibrillator, and who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, presyncope, syncope, fatigue, or anxiety. The signal acquired by the ASSURE wearable ECG is not intended and should not be used for automated or semi-automated analysis. The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements, or provide for any life support.

## Intended Use

The ASSURE wearable ECG continuously monitors heart rate information. Event data, which is automatically stored for low and high heart rates and patient-triggered events, is intended to aid medical professionals as they monitor various clinical conditions, events, and trends.

The ASSURE wearable ECG 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.

## Contraindications

The ASSURE wearable ECG is contraindicated for use in patients with an active implantable pacemaker or defibrillator.

## Essential Performance

The accurate recording and reproduction of electrocardiogram signals is essential for the ASSURE wearable ECG to perform its intended function.



# Safety Information

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## WARNINGS

- *The ASSURE wearable ECG is magnetic resonance (MR) unsafe. Do not wear or use the system near MR imaging (MRI) equipment.*
- *Do not alter, drop, or abuse any part of the ASSURE wearable ECG or Battery. Attempting to alter the equipment in any way may cause the system to malfunction or fail. If service is required, call the ASSURE Helpline at (833) 692-7787 (Toll free).*
- *During use, do not stack or place the ASSURE wearable ECG 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 wearable ECG 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 wearable ECG. 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.*

 **CAUTIONS**

- *Federal Law restricts this device to sale by or on the order of a physician.*
- *This device will not deliver a shock for fast heart rhythms and is not a substitute for emergency medical care. You should seek medical attention if you feel unwell.*
- *Always wear the ASSURE wearable ECG when instructed to do so by a doctor or other medical professional. If available, a second Garment can be worn while washing the used Garment.*
- *Always remove the System Cable before washing the Garment.*
- *Do not place the System Cable or Battery in water or other liquids. Avoid spilling any liquids on these parts. Liquids entering these parts may cause them to malfunction or fail. Follow the instructions in this document to properly clean these parts.*
- *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.*
- *When the Service Required alert is active, the ASSURE wearable ECG is not operational. Call the ASSURE Helpline at (833) 692-7787 (Toll free) for assistance.*

# Kit Contents

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The ASSURE wearable ECG kit includes the following items:

- System Cable (includes the Hub, HeartPoint™ Alert Button, and Battery connector)
- Battery (spare Battery also included)
- Battery band
- Charging adapter and cord
- *ASSURE Wearable ECG Patient Handbook* (this manual)
- *ASSURE Wearable ECG Quick Start Guide*
- *ASSURE Wearable ECG Return Instructions*
- *ASSURE Wearable ECG Travel Card*

The ASSURE wearable ECG reuses the Garment(s) from the ASSURE wearable defibrillator.

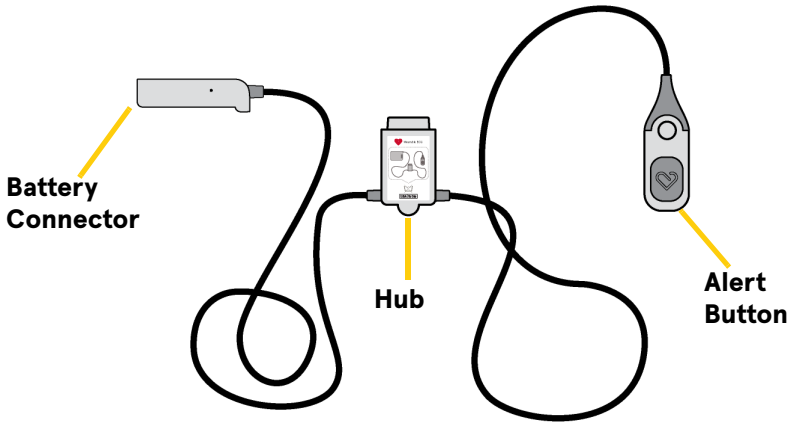
*Note: If you do not have the Garment(s), call the ASSURE Helpline at (833) 692-7787 (Toll free).*

## System Cable

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The System Cable contains the Hub, HeartPoint Alert Button, and the Battery connector. The System Cable inserts into the SensorFit Garment and connects to the Battery.

*Note: The System Cable cords cannot be removed from the Hub.*



The Hub is the central part of the System Cable that connects the Battery and the Garment to allow the ASSURE wearable ECG to monitor your heart rhythms.

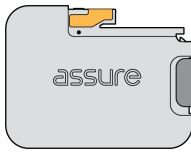
The Alert Button is an oval-shaped button that interacts with the ASSURE wearable ECG. Press this button to start the system or to respond to alerts. If you feel unwell, press and hold this button to record your heart rhythm.

The Battery connector slides onto the Battery to provide power to the ASSURE wearable ECG. The System Status light on the Battery connector displays the status of the ASSURE wearable ECG. See System Status Displays on page 53 for more information on the different colors and their meaning.

# Battery

The Battery connects to the System Cable to provide power to the ASSURE wearable ECG. The system comes with two rechargeable Batteries. A fully charged Battery will power the system for at least 24 hours.

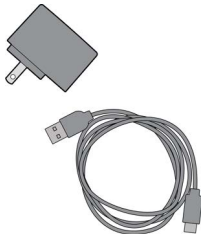
The Battery includes a charging adapter, a charging cord, and a Battery band, which is an optional, flexible fabric band that wraps around the Battery to secure it in the back pockets.



**Battery**



**Battery Band**



**Charging Adapter and Cord**

The light on the Battery displays its charging status.

Charging Status Light	Description
Orange	Battery is charging.
Green	Battery is fully charged.
Blinking	An error has occurred with the Battery. Call the ASSURE Helpline at (833) 692-7787 (Toll free).

## Glossary

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Term	Definition
Alert	A message from the ASSURE wearable ECG notifying you that there is a problem with the device that you need to fix.
Alert Button	An oval-shaped button that interacts with the ASSURE wearable ECG. Press this button to start the system or to respond to alerts. If you feel unwell, press and hold this button to record your heart rhythm. Also referred to as the HeartPoint Alert Button.
Battery	A rechargeable battery that connects to the System Cable and provides power to the ASSURE wearable ECG.
Battery connector	The part of the System Cable that slides onto the Battery.
Battery lock	A locking mechanism on the side of the Battery used to disconnect the Battery from the System Cable.
Battery band	An optional, flexible fabric band that wraps around the Battery to secure it in pockets 2 or 3 on the back of the Garment.
Charging Adapter	A USB 2.0 medical AC adapter that plugs into a power outlet.
Charging Cord	A USB-C cord that connects the Battery to the charging adapter.
Charging Status light	A light on the Battery that displays the current charging status of the Battery.
Cord loops	Fabric loops on the back of the Garment that hold the System Cable.

<b>Term</b>	<b>Definition</b>
Cord wraps	Fabric loops on the Garment that wrap around the System Cable and secure it to the Garment.
ECG	Electrocardiogram. Records the heart's electrical signal to detect different heart conditions.
Garment	A fabric top that contains the Sensors that track heart rhythm. It is worn directly on the body against bare skin. Also referred to as the SensorFit Garment.
Hub	The central part of the System Cable that connects the Battery and the Garment.
Hub Receptacle	The plastic housing on the back of the Garment where the Hub is inserted.
MRI	Magnetic resonance imaging
Presyncope	Medical term for the feeling that you are about to faint.
Sensors	Round metal ECG electrodes in the Garment that track heart rhythm.
Syncope	Medical term for fainting.
System Cable	A cable that contains the Hub, HeartPoint Alert Button, and Battery connector. The System Cable inserts into the SensorFit Garment and connects to the Battery.
System Status light	A light located on the System Cable's Battery connector that displays the status of the ASSURE wearable ECG.
USB	Universal Serial Bus

<b>Term</b>	<b>Definition</b>
Wearable defibrillator	A device 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.
Wearable ECG	A device worn by patients that records fast and slow heart rhythms for later review by a physician. It does not provide a shock for fast heart rhythms.



# Chapter 2 Set Up

When you receive the kit, open the kit and remove the items, and then do the following:

1. Connect the ASSURE patient application (optional)
2. Set up the SensorFit Garment
3. Put on the ASSURE wearable ECG
4. Charge the spare Battery

## Connecting the ASSURE Patient Application (OPTIONAL)

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The ASSURE patient app is an optional smartphone application that sends data to a remote patient data platform for later review by your physician.

To transfer the ASSURE patient app from the ASSURE wearable defibrillator to the ASSURE wearable ECG, scan the code below and follow the instructions.



## Setting Up the ASSURE Wearable ECG

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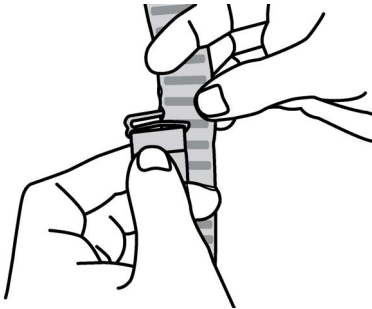
These instructions describe how to insert the System Cable into the Garment from the ASSURE wearable defibrillator.

**Notes:**

- *If you do not have the Garment(s) from the ASSURE wearable defibrillator, call the ASSURE Helpline at (833) 692-7787 (Toll free).*
- *Read the following steps before attempting this task. If you need additional help, call the ASSURE Helpline at (833) 692-7787 (Toll free).*

**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).

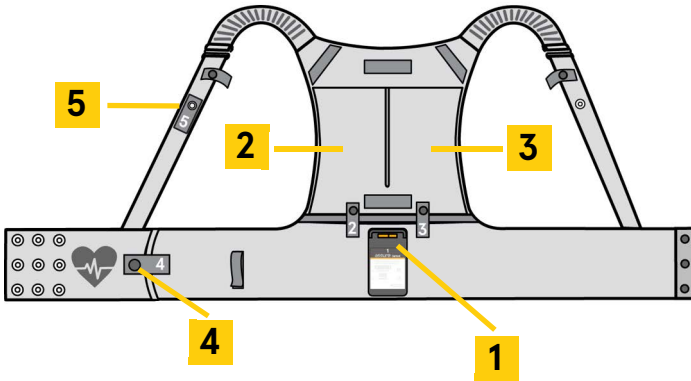


**Notes:**

- *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.*

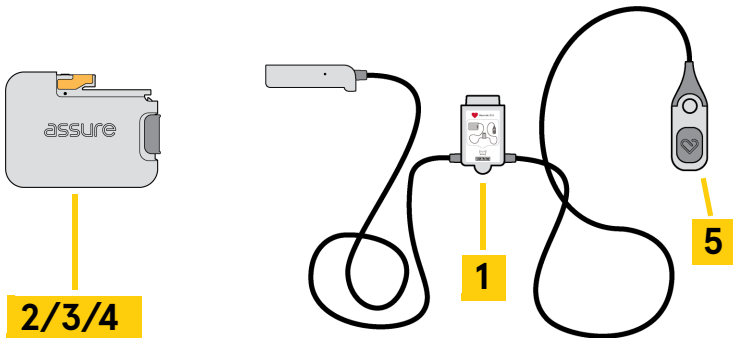
## Step 2 - Place the Garment on a flat surface with the numbers facing up

- Find the hub receptacle (number 1), pockets (numbers 2, 3, and 4), and HeartPoint Alert Button (number 5) on the Garment.



## Step 3 - Lay the System Cable near the Garment

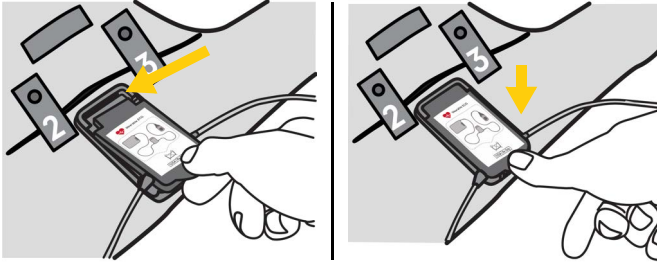
- Untangle any cords.
- Use the numbers on the System Cable, Battery, and Garment to guide you through the assembly process.



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

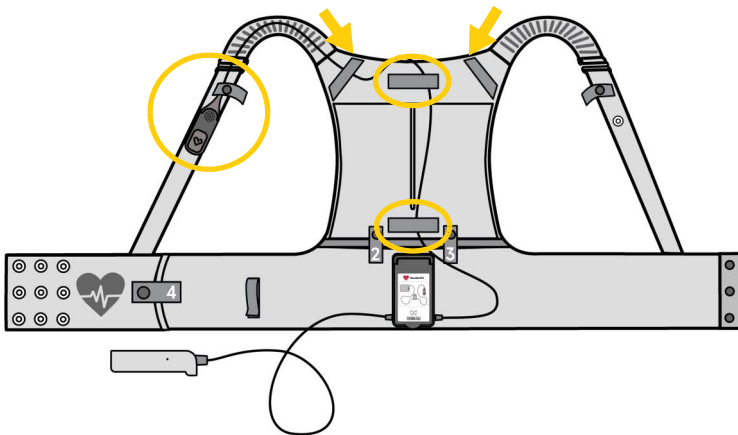
### Step 4 - Insert the Hub into the Garment and press down firmly until the Hub clicks into the Hub Receptacle

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



### Step 5 - Fasten the Alert Button to the Garment using the cord loops and shoulder snap

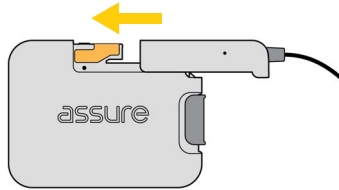
- Thread the Alert Button through the center loops on the back of the Garment.
- Thread the Alert Button through the angled loop on the left or right side.
- Snap the Alert Button to the shoulder strap and fasten the cord wrap over the Alert Button cord.



*Note: The left shoulder snap is labeled 5 on the Garment. The right shoulder snap is not labeled but may still be used.*

## Step 6 – Connect the System Cable to the Battery to turn on the system

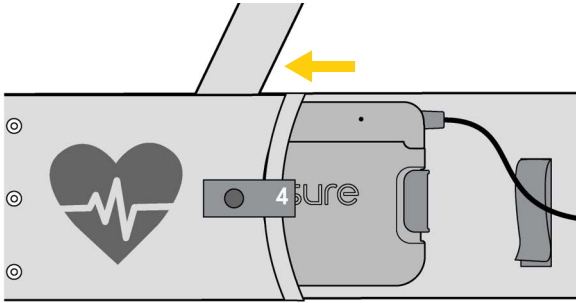
- You should hear a “click” when the Battery connector is secured to the Battery.



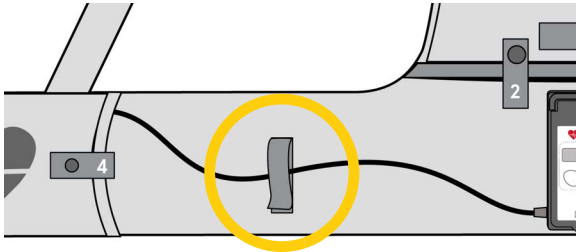
- The System Cable includes a System Status light on the Battery connector that indicates the status of the ASSURE wearable ECG.

System Status Light	Description
<b>Blue</b>	The system is powering up.
<b>Yellow (blinking)</b>	The system has found a problem that needs your attention.
<b>Green (blinking)</b>	<p>The system has finished powering up and is operational. Press the Alert Button to confirm it is operating properly.</p> <p>-or-</p> <p>The system is recording your heart rhythm.  <i>Note: It takes about one minute to record your heart rhythm.</i></p>
<b>Green (solid)</b>	<p>The system is working properly (normal operating mode).</p> <p><i>Note: The light turns on for the first five seconds and then turns off.</i></p>

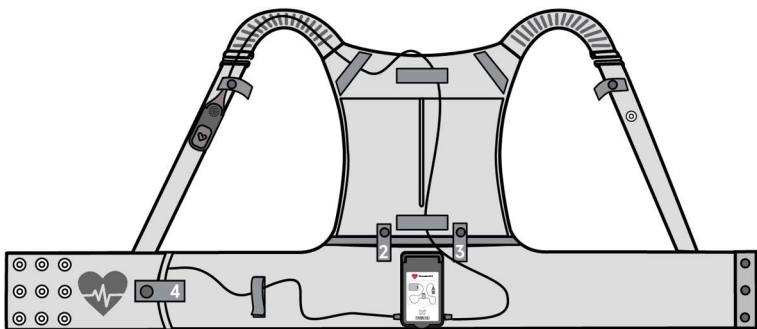
### Step 7 - Insert the Battery into pocket 4 of the Garment



- (Optional) Fasten the cord wrap around the System Cable.



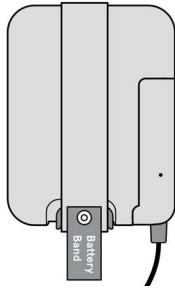
The assembled Garment should look like the picture below.



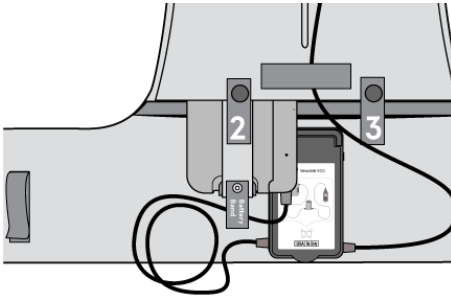
For improved comfort while wearing or sleeping, you can also place the Battery in pockets 2 or 3 on the back of the Garment. See the next page for instructions.

## Using the Battery Band for Pockets 2 or 3 (OPTIONAL)

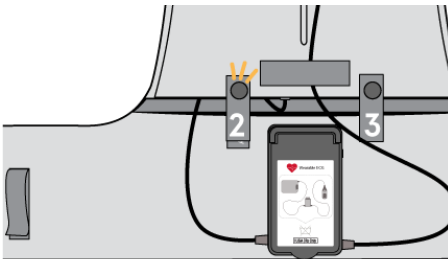
**Step 1 - Wrap the Battery band around the Battery with the snap positioned over the Battery lock**



**Step 2 - Insert the Battery into pocket 2 or pocket 3**



**Step 3 - Fasten the pocket snap to the Battery band to secure the Battery in the pocket**

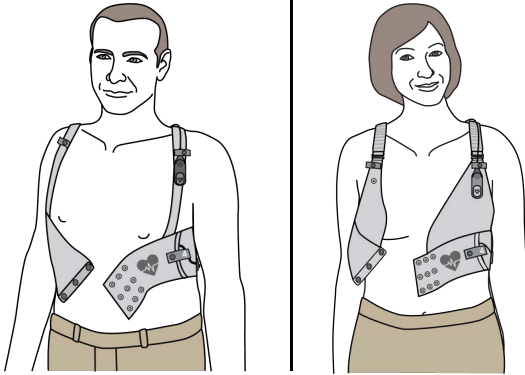


## Putting On the ASSURE Wearable ECG

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### Step 1 - Put on the Garment with the Sensors against bare skin

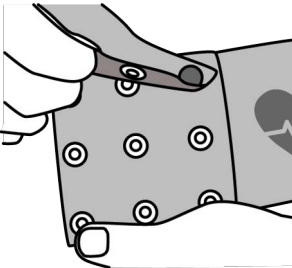
- Remove all clothing, including bras and undershirts, from your upper body.



*Note: The Garment contains the following materials:*

- *Body fabric: 59% Polyamide, 41% Elastane (spandex)*
- *Inner lining: 73% Polyamide, 27% Elastane (spandex)*
- *Therapy Pad pockets: 100% Silver-plated Nylon*

### Step 2 - Pull the Garment snug around your rib cage and then fasten the front closure snaps

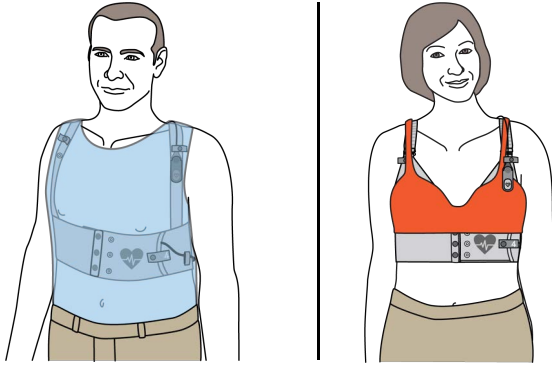


*Note: The Garment must have a snug fit to keep the Sensors in contact with bare skin.*





## Step 4 - Wear clothes over the Garment



Undershirt Over the Garment

Bra 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).

## Step 5 - Wait for confirmation from the ASSURE wearable ECG

- Power up may take a few minutes. The system will notify you when it is ready.

### What you will...

<b>See</b>	System Status light is blinking green
------------	---------------------------------------

<b>Hear</b>	Voice message stating, "Press your Alert Button now"
-------------	------------------------------------------------------

<b>Feel</b>	Single-pulse vibration from the Alert Button
-------------	----------------------------------------------

- If there is an alert, listen to the alert message and respond to the alert.
  - See chapter 4, Alerts and Status, on page 47 for a list of alerts.

## Step 6 - Press the Alert Button

### What you will...

<b>See</b>	System Status light is solid green. <i>Note: The light turns on for the first five seconds and then turns off.</i>
<b>Hear</b>	Three-note guitar strum
<b>Feel</b>	Single-pulse vibration from the Alert Button

*Note: If you press the Alert Button and there is no indication from the ASSURE wearable ECG, call the ASSURE Helpline at (833) 692-7787 (Toll free). There may be an issue with the Alert Button.*



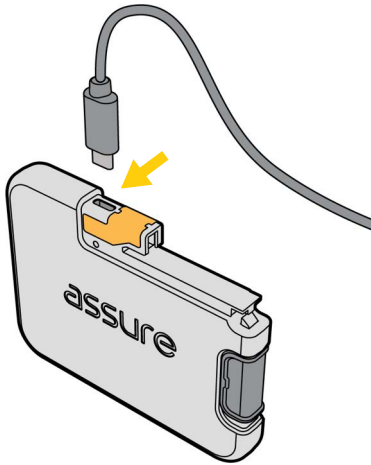
You are now wearing the ASSURE wearable ECG.

## Charging the Spare Battery

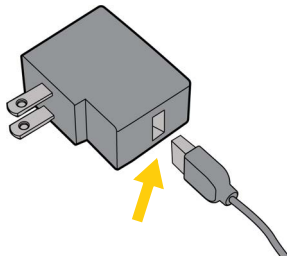
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The ASSURE wearable ECG uses a rechargeable Battery that lasts for at least 24 hours and charges in about 4 hours. The system comes with two rechargeable Batteries.

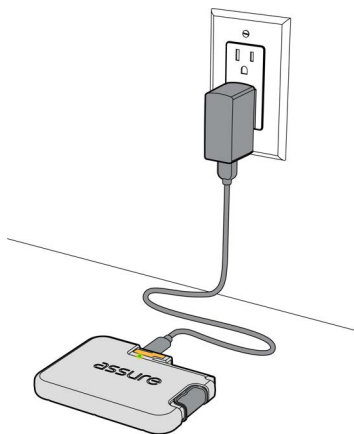
### Step 1 - Insert the charging cord into the Battery



### Step 2 - Connect the charging cord to the charging adapter



### Step 3 - Plug the charging adapter into a power outlet



The light on the Battery displays its charging status.

Charging Status Light	Description
Orange	Battery is charging.
Green	Battery is fully charged.
Blinking	An error has occurred with the Battery. Call the ASSURE Helpline at (833) 692-7787 (Toll free).

#### Notes:

- *Replace the Battery at the same time every day, so you do not forget.*
- *Do not connect line voltages, power banks, or other devices to the USB port on the Battery.*
- *Do not place the charging adapter and cord in a position or location that makes it difficult to connect or remove the Battery or unplug the charging cord.*
- *Unplug the charging adapter from the power outlet to stop charging the Battery for any reason.*

- *Check the Battery for wear or damage once or twice a week. To report any damage or concerns, call the ASSURE Helpline at (833) 692-7787 (Toll free).*
- *Use only the accessories provided with the ASSURE wearable ECG. This includes the Battery and charging adapter and cord.*

# Chapter 3 Wear and Care

## CAUTION

*This device will not deliver a shock for fast heart rhythms and is not a substitute for emergency medical care. You should seek medical attention if you feel unwell.*

## Guidelines

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Follow these guidelines while wearing the ASSURE wearable ECG:

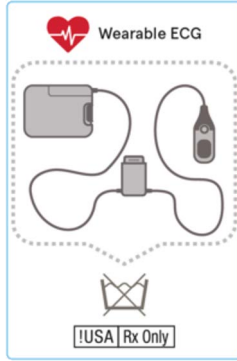
- **Always remove the ASSURE wearable ECG before taking a bath or shower or participating in any water-based activity, like swimming.**
  - Before taking a shower or bath, take off the system, remove the Battery from the SensorFit Garment pocket, and disconnect the Battery from the System Cable.
  - After taking a shower or bath and drying off, connect the Battery to the System Cable, place the Battery in a Garment pocket, and put on the system.



Never Wear the ASSURE Wearable ECG in the Bath or Shower

**! CAUTION**

*Do not place the System Cable or Battery in water or other liquids. Avoid spilling liquids on these parts. Liquids entering these parts may cause them to malfunction or fail. Follow the instructions in this document to properly clean these parts.*



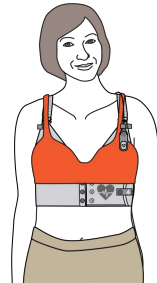
Do Not Wash the System Cable and Battery

● **Wear clothing over the SensorFit 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.**

If there is any damage to the equipment, call the ASSURE Helpline at (833) 692-7787 (Toll free).

*Notes:*

- *A damaged Battery may leak and cause personal injury or equipment damage. Handle a damaged or leaking Battery with extreme care.*
- *Use only the accessories provided with the ASSURE wearable ECG. This includes the Battery and charging adapter and cord.*

- **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 wearable ECG and call your doctor.**

*Note: The Garment contains the following materials:*

- *Body fabric: 59% Polyamide, 41% Elastane (spandex)*
- *Inner lining: 73% Polyamide, 27% Elastane (spandex)*
- *Pockets: 100% Silver-plated Nylon*

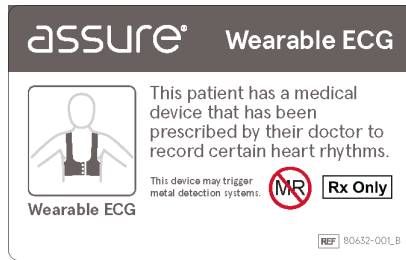
- **Keep the ASSURE wearable ECG out of the reach of children or pets.**

- **Traveling with the ASSURE wearable ECG:**

- You can wear the system while traveling, even on an airplane.

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

- A travel card is provided in the box with your system. This card can be used to identify the system as a medical device when traveling.



- Avoid walking through security screening equipment commonly found in airports, court buildings, and sporting events. Instead, show the security staff your travel 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.
- When traveling outside of North America, a power converter or different charging adapter may be required to charge the Battery.

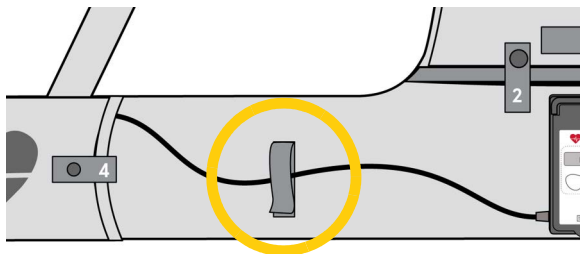
## Replacing the Battery

A fully charged Battery will power the ASSURE wearable ECG for at least 24 hours. See "Charging the Spare Battery" on page 28 for instructions on how to charge the Battery.

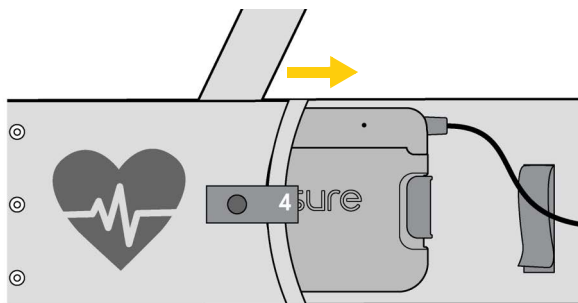
*Note: Replace the Battery at the same time every day, so you do not forget.*

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

### Step 1 - Open the cord wrap and remove the System Cable



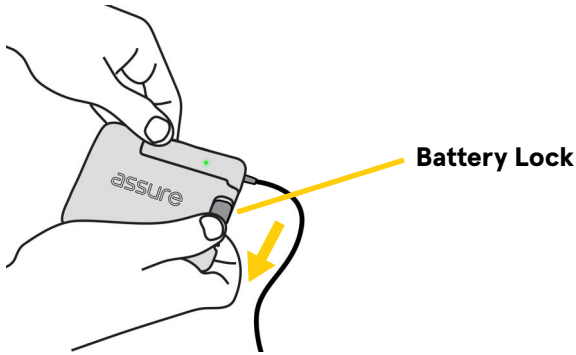
### Step 2 - Remove the Battery from the Garment



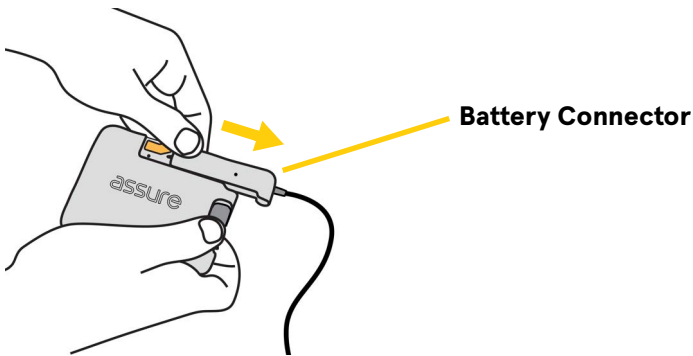
- If the Battery was in pockets 2 or 3, remove the Battery snap band.

### **Step 3 – Disconnect the Battery from the System Cable to turn off the ASSURE wearable ECG**

- Pull down on the Battery lock.

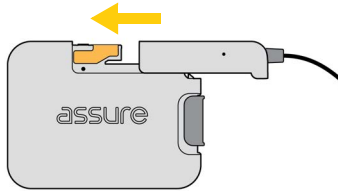


- Slide the Battery connector off the Battery.

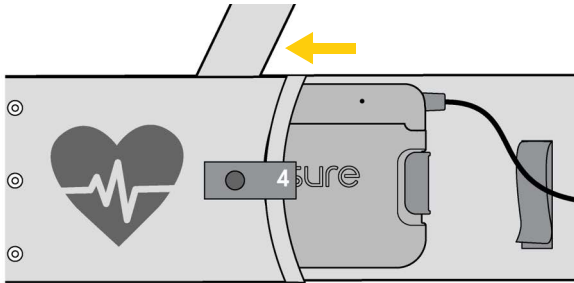


#### Step 4 - Connect the replacement Battery to the System Cable to turn on the ASSURE wearable ECG

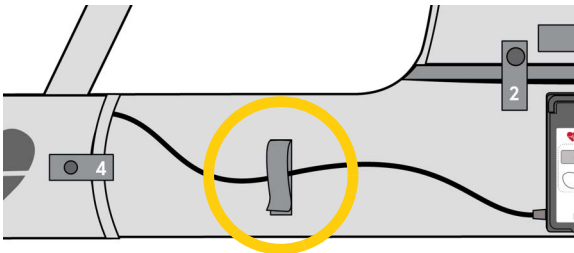
- You should hear a “click” when the Battery connector is secured to the Battery.



#### Step 5 - Insert the Battery into pocket 4 of the Garment



- It may take a few minutes for the system to power up.
- (Optional) Fasten the cord wrap around the System Cable.



## Step 6 – Wait for confirmation from the ASSURE wearable ECG

- The system will notify you when it is ready.

### What you will...

<b>See</b>	System Status light is blinking green
------------	---------------------------------------

<b>Hear</b>	Voice message stating, “Press your Alert Button now”
-------------	------------------------------------------------------

<b>Feel</b>	Single-pulse vibration from the HeartPoint Alert Button
-------------	---------------------------------------------------------

- If there is an alert, listen to the alert message and respond to the alert.
  - See chapter 4, Alerts and Status, on page 47 for a list of alerts.

## Step 7 – Press the Alert Button

### What you will...

<b>See</b>	System Status light is solid green.
------------	-------------------------------------

*Note: The light turns on for the first five seconds and then turns off.*

<b>Hear</b>	Three-note guitar strum
-------------	-------------------------

<b>Feel</b>	Single-pulse vibration from the Alert Button
-------------	----------------------------------------------

*Note: If you press the Alert Button and there is no indication from the ASSURE wearable ECG, call the ASSURE Helpline at (833) 692-7787 (Toll free). There may be an issue with the Alert Button.*

## Checking Device Status

---

To check the status of the ASSURE wearable ECG at any time:

### Press the Alert Button

#### What you will...

<b>See</b>	System Status light is solid green. <i>Note: The light turns on for the first five seconds and then turns off.</i>
<b>Hear</b>	Three-note guitar strum
<b>Feel</b>	Single-pulse vibration from the Alert Button



#### Notes:

- *If you press the Alert Button and there is no indication from the ASSURE wearable ECG, call the ASSURE Helpline at (833) 692-7787 (Toll free). There may be an issue with the Alert Button.*
- *If an alert is active, pressing the Alert Button will replay the voice message.*

## Recording Your Heart Rhythm

---

The ASSURE wearable ECG automatically records your heart rhythm. If you are experiencing symptoms, you can record a specific event. This recording can then be reviewed later by your doctor.

### Step 1 – Press and hold the Alert Button for two seconds

#### What you will...

<b>See</b>	System Status light is blinking green
<b>Hear</b>	<ul style="list-style-type: none"> <li>● Three-note guitar strum</li> <li>● Voice message stating, “Saving your heart rhythm”</li> </ul>
<b>Feel</b>	Single-pulse vibration from the Alert Button

### Step 2 – Release the Alert Button

- It takes about one minute to record your heart rhythm.

#### Notes:

- *The recording function is not a substitute for emergency medical care. Seek medical attention if you continue to feel unwell.*
- *The recording function is not available if you are not wearing the system (or not wearing it properly).*
- *If the recording function is interrupted, the voice message may not play, but the recording is still saved.*
- *If you press the Alert Button during an ongoing recording, you will hear the voice message “Saving your heart rhythm” again.*
- *If an existing System alert is present, the voice message for that System alert may repeat instead of the three-note guitar strum and single-pulse vibration.*



# Preparing the Garment for Washing

---

## CAUTION

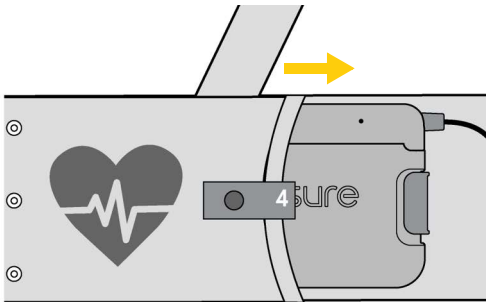
*Do not place the System Cable or Battery in water or other liquids. Avoid spilling any liquids on these parts. Liquids entering these parts may cause them to malfunction or fail. Follow the instructions in this document to properly clean these parts.*

### Notes:

- *The cords cannot be removed from the System Cable.*
- *If you need help with washing the Garment, call the ASSURE Helpline at (833) 692-7787 (Toll free).*

## Step 1 - Remove any clothing above the waist

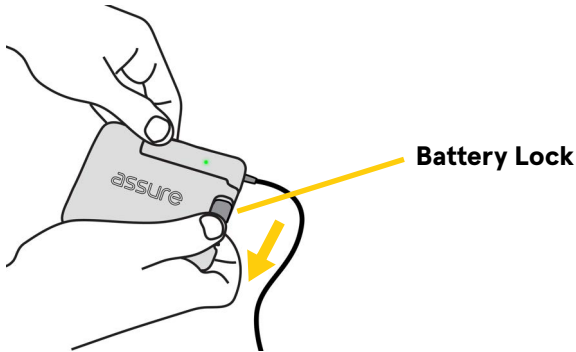
## Step 2 - Remove the Battery from the Garment



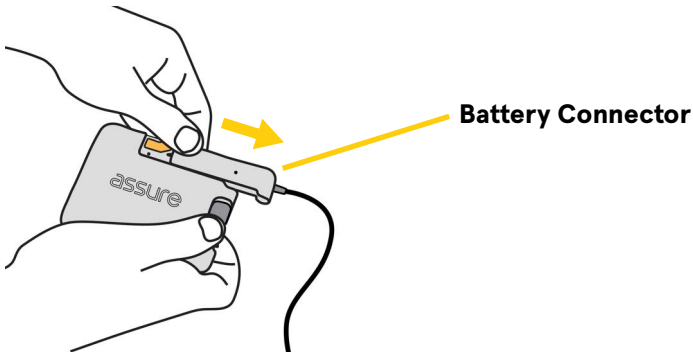
- If the Battery was in pockets 2 or 3, remove the Battery snap band.

### **Step 3 - Disconnect the Battery from the System Cable to turn off the ASSURE wearable ECG**

- Pull down on the Battery lock.

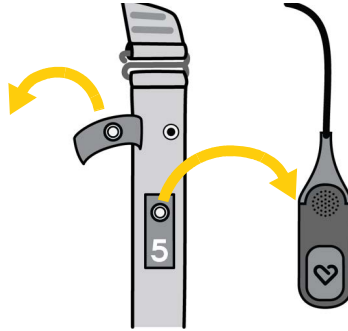


- Slide the Battery connector off the Battery.



### **Step 4 - Unsnap the front closure and take off the Garment**

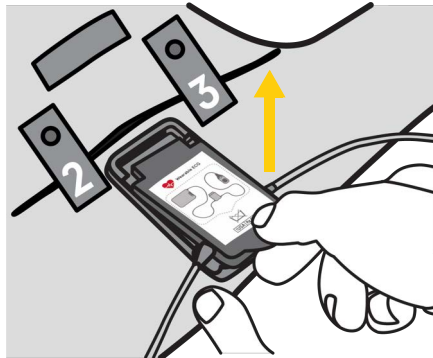
**Step 5 - Unsnap and remove the Alert Button from the shoulder strap**



**Step 6 - Gently pull the Alert Button cord through the back loops on the Garment**

**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 tab on the Hub with your other hand.



**Step 8 - Place the System Cable, Battery, and Battery snap band in a safe location**

## Washing the Garment

---

Wash the Garment as needed. If you have two Garments, you can wash one Garment while continuing to wear the ASSURE wearable ECG with the other Garment. If not, wash the single Garment and let it air dry before replacing the System Cable and putting on the Garment.

<b>Before washing the Garment:</b>	<b>For instructions</b>
1. Take off the system and remove the System Cable from the Garment.	See "Preparing the Garment for Washing" on page 41 for instructions.
2. If you have two Garments, place the System Cable into the spare Garment and put on the device.	See "Setting Up the ASSURE Wearable ECG" on page 18 and "Putting On the ASSURE Wearable ECG" on page 24 for instructions.

### CAUTIONS

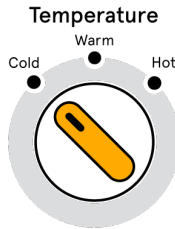
- *Always remove the System Cable before washing the Garment.*
- *Do not use chlorine bleach, bleach alternatives, fabric softeners, or anti-static sprays. Also, do not use detergents or detergent "pods" that include bleach or fabric softener additives.*

To wash the Garment:

### Step 1 - Place the Garment in the washing machine

*Note: The five round metal Sensors and the Hub receptacle are permanent parts of the Garment and may be washed.*

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



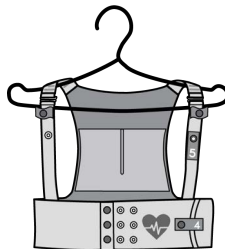
- Use a mild laundry detergent only, such as all<sup>®</sup> free clear or Tide Free and Gentle<sup>™</sup>.

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

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

### 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.



## **Cleaning the System Cable and Battery**

---

### **CAUTION**

*Do not place the System Cable or Battery in water or any other liquids. Avoid spilling any liquids on these parts. Liquids entering these parts may cause them to malfunction or fail.*

**The Garment has specific cleaning instructions, see "Washing the Garment" on page 44.**

In general, the System Cable, Batteries, and their accessories do not require maintenance, other than cleaning as needed. If there appears to be any damage, call the ASSURE Helpline at (833) 692-7787 (Toll free).

To clean the System Cable or Battery:

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

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

**Step 3 - Make sure the part is clean (repeat steps 1 and 2 if needed)**

*Notes:*

- *Avoid wiping the Hub connectors and pins.*
- *Do not allow any liquid or moisture to remain on the part or its connectors and pins after cleaning.*

# Chapter 4 Alerts and Status

The ASSURE wearable ECG monitors itself for proper function. When the system detects a problem, it creates an alert to let you know there is a problem.

When an alert occurs:

- The System Status light is yellow and blinking.
- A repeating, double tone and voice message plays.
- A triple-pulse vibration is felt from the HeartPoint Alert Button.

*Notes:*

- *The System Status light may not be visible depending on the Battery's location.*
- *The Put on Garment and Check Sensors alerts may correct themselves automatically due to changes in the SensorFit Garment's position or movement. If this occurs, the system will return to normal operation.*

## Responding to Alerts

---

When you receive an alert, follow these general steps:

### Step 1 - Listen to the alert voice message

- Press the Alert Button again to replay the voice message.

### Step 2 - Respond to the alert

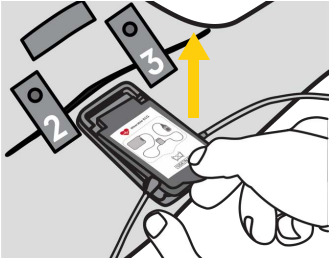
## Alert Descriptions

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Alert Name	Voice Message	Reference
Connect Hub to Garment	"Connect the Hub to your Garment."	See page 49.
Put on Garment	"Put on your Garment now."	See page 50.
Low Battery	"Replace your Battery now."	See page 50.
Check Sensors	"Adjust your Garment now. The Sensors must touch your skin."	See page 51.
Service Needed	"Call the ASSURE Helpline now. Your device needs service. Continue to wear your ASSURE system."	See page 52.
Service Required	"Call the ASSURE Helpline now. Your device needs service."	See page 52.



## Connect Hub to Garment Alert

<b>Voice Message</b>	"Connect the Hub to your Garment."
<b>Description</b>	The Hub is not properly inserted into the Garment.
<b>Actions</b>	<p>To respond to this alert:</p> <p><b>Insert the Hub into the Garment</b></p> <p>If the Hub is already inserted into the back of the Garment, try re-inserting it:</p> <p><b>Remove the Hub from the Garment and re-insert it into the Garment</b></p> <ul style="list-style-type: none"> <li>- To remove the Hub, press down on the Garment near the bottom of the Hub Receptacle with your thumb and pull up on the plastic tab on the Hub with your other hand.</li> </ul>  <ul style="list-style-type: none"> <li>- When re-inserting the Hub, a "click" sound means the Hub is securely inserted.</li> </ul>

## Put on Garment Alert

<b>Voice Message</b>	“Put on your Garment now.”
<b>Description</b>	You are not wearing the Garment properly.
<b>Actions</b>	<p>To respond to this alert:</p> <p><b>Put on the Garment</b></p> <p>If you are already wearing the Garment:</p> <ul style="list-style-type: none"> <li>- <b>Check</b> that the Garment is not twisted, there is nothing under it, and the Hub is inserted correctly.</li> <li>- <b>Moisten</b> the skin under the Sensors with water or lotion.</li> </ul>

## Low Battery Alert

<b>Voice Message</b>	“Replace your Battery now.”
<b>Description</b>	The Battery has less than two hours of power left. Replace the Battery now.
<b>Actions</b>	<p>To respond to this alert:</p> <p><b>Step 1 - Replace the drained Battery with a fully charged Battery</b></p> <p><b>Step 2 - When you hear the voice message stating, “Press your Alert Button now”, press the Alert Button</b></p>

## Check Sensors Alert

<b>Voice Message</b>	“Adjust your Garment now. The Sensors must touch your skin.”
<b>Description</b>	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.
<b>Actions</b>	<p>To respond to this alert:</p> <p><b>Try the following actions:</b></p> <ul style="list-style-type: none"> <li>- <b>Adjust</b> the Garment so the Sensors are flat and touching bare skin. <ul style="list-style-type: none"> <li>&gt; The Sensors should be snug around your rib cage, just below your breast area and nipples.</li> <li>&gt; Make sure your breasts are not under the front band or Sensors.</li> </ul> </li> </ul> <p><i>Note: Female patients may wear a bra over the Garment to provide more support.</i></p> <ul style="list-style-type: none"> <li>- <b>Check</b> that the Garment is not twisted and there is nothing under it.</li> <li>- <b>Stop</b> all movement and count to 10 slowly to allow the system to sense your heart rhythm.</li> </ul> <p>If the alert continues, try the following:</p> <ul style="list-style-type: none"> <li>- <b>Moisten</b> the skin under the Sensors with water or lotion.</li> <li>- <b>Tighten</b> the Garment by adjusting the front closure snaps and shoulder straps.</li> <li>- <b>Call</b> the ASSURE Helpline at (833) 692-7787 (Toll free).</li> </ul>

## Service Needed Alert

<b>Voice Message</b>	“Call the ASSURE Helpline now. Your device needs service. Continue to wear your ASSURE system.”
<b>Description</b>	There is a problem with the ASSURE wearable ECG. The system is still operational.
<b>Actions</b>	To respond to this alert:  <b>Step 1 - Call the ASSURE Helpline at (833) 692-7787 (Toll free)</b>  <b>Step 2 - Continue to wear the ASSURE wearable ECG</b>

## Service Required Alert



### CAUTION

*When the Service Required alert is active, the ASSURE wearable ECG is not operational. Call the ASSURE Helpline at (833) 692-7787 (Toll free) for assistance.*

<b>Voice Message</b>	“Call the ASSURE Helpline now. Your device needs service.”
<b>Description</b>	There is a problem with the ASSURE wearable ECG that <b>requires immediate attention</b> .  <i>Note: This alert will repeat every 30 seconds.</i>
<b>Actions</b>	To respond to this alert:  <b>Call the ASSURE Helpline at (833) 692-7787 (Toll free)</b>

## System Status Displays

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*Note: The System Status light on the System Cable displays the status of the ASSURE wearable ECG. This light may or may not be visible depending on the Battery's location.*

<b>Connecting/Power On</b>	
<b>System Status Light</b>	Blue
<b>Description</b>	The ASSURE wearable ECG is powering up.
<b>Actions</b>	None

<b>System Busy</b>	
<b>System Status Light</b>	Yellow and blinking
<b>Description</b>	The ASSURE wearable ECG has found a problem with the system that needs your attention.
<b>Actions</b>	<p>Wait for the Alert Button voice message to play (this may take a few minutes). See Alert Button on page 54.</p> <p><i>Note: If you do not hear the Alert Button voice message after more than five minutes, try reconnecting the Battery to the System Cable. If this does not work, call the ASSURE Helpline at (833) 692-7787 (Toll free).</i></p>

<b>Alert Button</b>	
<b>System Status Light</b>	Green and blinking
<b>Notifications</b>	<ul style="list-style-type: none"> <li>● Voice messaging stating, "Press your Alert Button now."</li> <li>● Single-pulse vibration from Alert Button</li> </ul>
<b>Description</b>	The ASSURE wearable ECG has finished powering up and is operational. Press the Alert Button to confirm operation.
<b>Actions</b>	<b>Press the Alert Button</b>

<b>System Ready</b>	
<b>System Status Light</b>	Green
<b>Notifications</b>	<ul style="list-style-type: none"> <li>● Single-pulse vibration from Alert Button</li> <li>● Three-note guitar strum</li> </ul>
<b>Description</b>	The ASSURE wearable ECG is working properly (normal operating mode).
<b>Action</b>	None. You can press the Alert Button to check the system status at any time.

<b>Recording Heart Rhythm</b>	
<b>System Status Light</b>	Green and blinking
<b>Description</b>	The ASSURE wearable ECG is recording your heart rhythm.
<b>Notifications</b>	<ul style="list-style-type: none"> <li>● Single-pulse vibration from Alert Button</li> <li>● Three-note guitar strum</li> <li>● Voice message: “Saving your heart rhythm.”</li> </ul> <p><i>Notes:</i></p> <ul style="list-style-type: none"> <li>● <i>It takes about one minute to record your heart rhythm.</i></li> <li>● <i>The recording function is not available if you are not wearing the system (or not wearing it properly).</i></li> <li>● <i>If the recording function is interrupted, the voice message may not play, but the recording is still saved.</i></li> <li>● <i>If you press the Alert Button during an ongoing recording, the voice message “Saving your heart rhythm” will repeat.</i></li> <li>● <i>If an existing alert is present, the voice message for that alert may repeat instead of the tone and vibration.</i></li> </ul>
<b>Action</b>	None.

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# Chapter 5 Help

For questions or help with the ASSURE wearable ECG, call the ASSURE Helpline at (833) 692-7787 (Toll free).



## **CAUTION**

*This device will not deliver a shock for fast heart rhythms and is not a substitute for emergency medical care. You should seek medical attention if you feel unwell.*

## Replacement Parts

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If any part of the ASSURE wearable ECG is not working properly or is damaged, call the ASSURE Helpline at (833) 692-7787 (Toll free) to order a replacement.

## Returning the ASSURE Wearable ECG

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After your physician has determined that you no longer need to wear the ASSURE wearable ECG, you must return the system as soon as possible.

1. Affix the return shipping label (provided on the Return Instructions card) over the original shipping label on the box.
2. Place the system in the box:

Top tray:

- Batteries (x2)
- System Cable
- Charging adapter and cord
- Battery band
- Documentation

Bottom tray:

- SensorFit Garment(s)
  - ASSURE mobile device from Kestra (if you have one)
3. Close and seal the box lid, and then drop off the box at any FedEx location (or call the ASSURE Helpline to arrange for FedEx pick up).

If you need help, call the ASSURE Helpline at (833) 692-7787 (Toll free).

## Frequently Asked Questions

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### Where can I get help with the ASSURE wearable ECG?

If you have any questions or need help with the system, call the ASSURE Helpline at (833) 692-7787 (Toll free).

### What can I do if I experience discomfort while wearing the ASSURE wearable ECG?

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

*Note: The Garment contains the following materials:*

- *Body fabric: 59% Polyamide, 41% Elastane (spandex)*
- *Inner lining: 73% Polyamide, 27% Elastane*
- *Therapy Pad pockets: 100% Silver-plated Nylon*

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

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

### Do I need to clean the ASSURE wearable ECG?

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

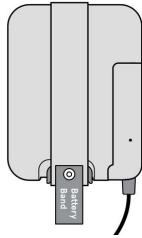
See *Cleaning the System Cable and Battery* on page 46 for more information.

## How do I use the Battery in Garment pockets 2 or 3?

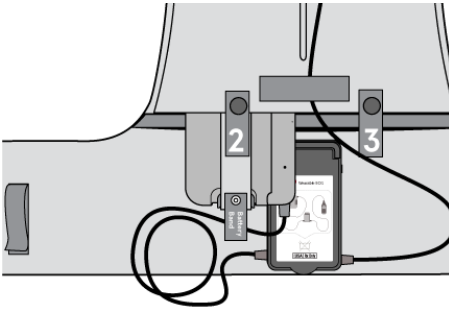
To place the Battery in pocket 2 or pocket 3 of the Garment, use the included Battery band.

### Step 1 - Wrap the Battery band around the Battery

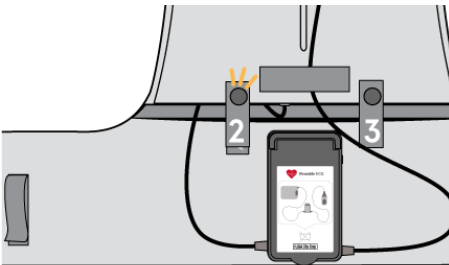
- Position the snap over the Battery lock.



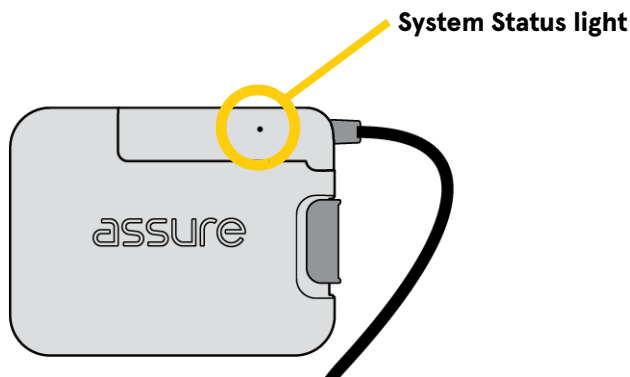
### Step 2 - Insert the Battery into pocket 2 or pocket 3



### Step 3 - Fasten the pocket snap to the Battery band to secure the Battery in the pocket

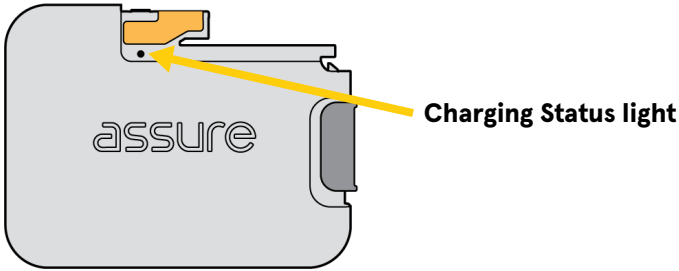


## What do the colors of the System Status light mean?



System Status Light	Description
<b>Blue</b>	The system is powering up.
<b>Yellow (blinking)</b>	The system has found a problem that needs your attention.
<b>Green (blinking)</b>	<p>The system has finished powering up and is operational. Press the HeartPoint Alert Button to confirm it is operating properly.</p> <p>-or-</p> <p>The system is recording your heart rhythm.</p> <p><i>Note: It takes about one minute to record your heart rhythm.</i></p>
<b>Green (solid)</b>	<p>The system is working properly (normal operating mode).</p> <p><i>Note: The light turns on for the first five seconds and then turns off.</i></p>

## What do the colors of the Charging Status light mean?
















Charging Status Light	Description
Orange	Battery is charging.
Green	Battery is fully charged.
Blinking	An error has occurred with the Battery. Call the ASSURE Helpline at (833) 692-7787 (Toll free).

## What should I do if the ASSURE wearable ECG does not turn on when I connect the Battery?





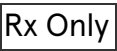



- Make sure the Battery is properly connected to the System Cable. Detach and reattach the Battery connector.
- Make sure the Battery is fully charged.
- Try the spare Battery. If the spare Battery works, charge the other Battery.
- If the problem persists, call the ASSURE Helpline at (833) 692-7787 (Toll free).





# Chapter 6 Symbols Glossary

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

Symbol	Description and Reference Document
	<p>Recommended storage temperature (from low to high)</p> <p>IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 0632</p>
	<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>



Symbol	Description and Reference Document
	<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>
IPxx	<p>Enclosure ingress protection code</p> <p>IEC 60529, Degrees of protection provided by enclosures (IP Code)</p>
	<p>Type BF applied part</p> <p>IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 5333</p>
	<p>For USA audiences only</p> <p>21 CFR 801.109, Labeling: Prescription Devices</p>
	<p>By prescription only</p> <p>21 CFR 801.109, Labeling: Prescription Devices</p>
	<p>Serial number</p> <p>IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2498</p>
	<p>Catalogue number</p> <p>IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2493</p>
	<p>Batch code</p> <p>IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2492</p>

Symbol	Description and Reference Document
	<p>Rechargeable battery IEC 60417, Graphical symbols for use on equipment. Symbol 5639</p>
	<p>Battery direct current IEC 60417, Graphical symbols for use on equipment. Symbol 5031.</p>
	<p>Do not use this device in a bathtub, shower, or water-filled reservoir. ISO 7010, Graphical symbols – Safety colours and safety signs – Registered safety signs. Symbol P026</p>
	<p>Recognized safety certification mark for the United States.</p>

# Chapter 7 Device Information

## Specifications

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The ASSURE wearable ECG was tested according to the recommendations of IEC TR 60601-4-2: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

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

### ASSURE Wearable ECG

Item	Detail
Classification	Internally powered equipment per IEC 60601-1 (Group 1, Class B per IEC 60601-1-2), transportable, body-worn
Electrical Protection	ECG electrodes are type BF applied parts per IEC 60601-1
Operation Mode	Continuous; automatic detection of fast and slow heart rhythms, collection of patient data and current system status
Heart Rate Measurement	Filtered heart rate data across all four ECG channels is analyzed by the algorithm in 4.8 second segments. The 1-minute heart rate is the median value of the heart rate data gathered each minute.
Defibrillation Protection	The system fully complies with IEC 60601-1 clauses 8.5.5.1 and 8.5.5.2 for defibrillation recovery and energy reduction. Full ECG functionality will resume in less than 5 seconds following a defibrillation pulse.
System Temperature Range: Operating	50°F to 113°F (10°C to 45°C) <i>Note: The SensorFit 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>
System Temperature Range: Storage and Transport	-13°F to 41°F (-25°C to 5°C) without relative humidity control 41°F to 95°F (5°C to 35°C) at a relative humidity up to 90%, non-condensing >95°F to 158°F (>35°C to 70°C) at a water vapor pressure up to 50hPa

Item	Detail
Relative Humidity	10 to 95% (non-condensing)
Operating Altitude	-1253 to 9878 feet (-382 to 3011 meters) above sea level 700 to 1060 hPa (atmospheric pressure)
Communications	<i>Bluetooth®</i> Classic and Bluetooth Low Energy (BLE) <i>Note: This device has not undergone the Bluetooth SIG certification process and no claim is made that the device is certified by the Bluetooth SIG.</i>
Liquid and Solid Ingress (per IEC 60529)	IP22 (System Cable)
Weight (including, System Cable, Battery, and Garment)	Approximately 1.19 lbs (0.54 kg) <i>Note: Weight may vary depending on Garment size. Stated weight uses the largest Garment size.</i>
Part Numbers	System Cable – 80500 Garment (Style A) – 80015 Garment (Style B) – 80016

## Battery

Item	Detail
Classification	Secondary rechargeable battery per IEC 62133
Type	Single Lithium Ion rechargeable battery
Power Supply	CUI SMM12-5-NB-I38-C1 2.4A charging adapter, AC-DC, 5V DC out, 12W, single output USB Rated supply voltage range: 100-240 V Rated supply frequency range: 50-60 Hz Rated supply input current: 1A max Standard 3A USB-C charging cord
Voltage	Typical: 3.8 V Operating Range: 3.3 V – 4.35 V
Capacity	3.81 Ah, 14.47 Wh rated capacity
Temperature Range: Operating	50°F to 113°F (10°C to 45°C)
Temperature Range: Charging	50°F to 113°F (10°C to 45°C)
Relative Humidity	10 to 95% (non-condensing)
Operating Altitude	-1253 to 9878 feet (-382 to 3011 meters) above sea level 700 to 1060 hPa (atmospheric pressure)
Temperature Range: Storage and Transport	-4°F to 41°F (-20°C to 5°C) without relative humidity control 41°F to 95°F (5°C to 35°C) at a relative humidity up to 90%, non-condensing >95°F to 140°F (>35°C to 60°C) at a water vapor pressure up to 50hPa
Liquid and Solid Ingress (per IEC 60529)	IP22
Part Numbers	Battery – 80499 Battery band – 80658 Charging adapter – 80159 Charging cord – 80158

## Voice Prompts

The ASSURE wearable ECG uses the following voice prompts.

Alert	Voice Prompt	Description
<b>Connect Hub to Garment Alert</b>	Connect the Hub to your Garment.	The device cannot detect that the Hub is inserted into the Garment.
<b>Put on Garment Alert</b>	Put on your Garment now.	The device cannot detect that the patient is wearing the Garment.
<b>Low Battery Alert</b>	Replace your Battery now.	The Battery has less than two hours of power left.
<b>Check Sensors Alert</b>	Adjust your Garment now. The Sensors must touch your skin.	The device has lost contact with one or more Sensors in the Garment.
<b>Service Required Alert</b>	Call the ASSURE Helpline now. Your device needs service.	The device has detected a problem and the system is not operational.
<b>Service Needed Alert</b>	Call the ASSURE Helpline now. Your device needs service. Continue to wear your ASSURE system.	The device has detected a problem, but the system is still operational.
System Status Message	Voice Prompt	Description
<b>Alert Button</b>	Press your Alert Button now.	Press the HeartPoint Alert Button to confirm device operation.
<b>Recording Heart Rhythm</b>	Saving your heart rhythm,	The device is recording your heart rhythm for 60 seconds.

## Wireless Interference

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If there is any indication of interference between a wireless device and the ASSURE wearable ECG, move away from the wireless device or turn it off, if possible. Call the ASSURE Helpline at (833) 692-7787 (Toll free) if you continue to have interference problems.

## Federal Communications Commission (FCC) Declaration

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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.

*Note: "Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.*

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.*

## Radio Frequency (RF) Transmissions

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The ASSURE wearable ECG 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.

The system also transmits using Bluetooth Low Energy with 6 dBm maximum output power. The frequency of operation is 2.400 to 2.4835 GHz including guard bands. It uses Gaussian Frequency Shift Keying, GFSK modulation, and frequency hopping spread spectrum over 40 channels spaced at 2 MHz.

*Note: This device has not undergone the Bluetooth SIG certification process and no claim is made that the device is certified by the Bluetooth SIG.*

## Electromagnetic Compatibility

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The ASSURE wearable ECG 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 common 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 system around equipment that could potentially produce uncommonly high electromagnetic interference. These types of devices generate electromagnetic fields that may interfere with normal system operation.

System recovery times vary depending on the type of exposure:

- Temporary exposure to equipment that might cause ECG noise is acceptable if it lasts for less than 60 seconds (for example, while walking past the equipment). Normal operation will resume within a few seconds of leaving the exposure.
- Temporary exposure to equipment that might cause Bluetooth connectivity issues is acceptable if it lasts for less than one hour. Normal operation will resume within a few minutes of leaving the exposure.
- If exposed to an unusually high electrostatic discharge (ESD), normal operation may take up to 60 seconds to recover.



*Note: Interference may occur in the vicinity of equipment marked with this symbol .*

## Known EMI Equipment to Avoid

- Communication equipment (for example, microwave transmitters and high-powered two-way radios)
- Arc welding equipment
- Large electric motors and generators
- Power tools
- High voltage transmissions lines and wireless power transfer (WPT) systems
- Medical equipment in hospitals and clinics:
  - Magnetic resonance imaging (MRI) equipment
  - Advanced imaging technology equipment
  - Electrocautery systems, Electrosurgical units (ESU), and Diathermy equipment

*Note: Remove the ASSURE wearable ECG before undergoing any imaging scans.*

## Airport or Security Screening Equipment

Avoid walking through security screening equipment commonly found in airports, court buildings, and sporting events. Instead, show the security staff your travel 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.

## Resolving EMI Issues

Going near equipment that is generating an electromagnetic field may cause issues with the ASSURE wearable ECG.

Always maintain a safe distance from any equipment that may cause potential interference with the 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 system.
  - If the 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 (833) 692-7787 (Toll free).

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

Only use equipment that is in good condition and make sure the equipment is used in a way intended by its original manufacturer.

## Electromagnetic Emissions – Guidance and Manufacturer's Declaration

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

<b>Emissions Test</b>	<b>Compliance</b>	<b>Electromagnetic Environment – Guidance</b>
RF emissions CISPR 11	Group 1	The ASSURE wearable ECG transmits RF energy only for low power <i>Bluetooth</i> <sup>®</sup> 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 wearable ECG 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.

## Electromagnetic Immunity – Guidance and Manufacturer's Declaration

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

<b>Immunity Test</b>	<b>IEC 60601-1-2 Test Level (Safety)</b>	<b>IEC/TR 60601- 4-2 Test Level (Performance)</b>	<b>Electromagnetic Environment – Guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±4 kV contact ±8 kV air	No precautions necessary
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	30 A/m	3 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.*

<b>Immunity Test</b>	<b>IEC 60601-1-2 Test Level (Safety)</b>	<b>IEC/TR 60601- 4-2 Test Level (Performance)</b>	<b>Electromagnetic Environment - Guidance</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands <sup>1</sup>  6 Vrms 150 kHz to 80 MHz in ISM bands <sup>1</sup>	3 Vrms 150 kHz to 80 MHz	No precautions necessary
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	No precautions necessary

**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.

## IEC 61000-4-3 Enclosure Port Immunity to RF Wireless Communications Equipment

Test Frequency (MHz)	Band (MHz)	Service	IEC 60601-1-2 Immunity Test Level (Safety) (V/m)	IEC/TR 60601-4-2 Immunity Test Level (Performance) (V/m)
385	380 to 390	TETRA 400	27	6
450	430 to 470	GMRS 460, FRS 460	28	9
710 745 780	704 to 787	LTE Band 13, 17	9	3
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28	9
1720 1845 1970	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	28	9
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28	9
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	9	6

*Note: No deviations or allowances to the standards have been used.*

## IEC 61000-4-39 Enclosure Port Immunity to Proximity Magnetic Fields

Test Frequency	Source	Immunity Test Level (A/m)
30 kHz	Induction cooking appliances	8
134.2 kHz	RFID	65
13.56 MHz	RFID	7.5

**Notes:**

- *The Immunity Test Levels stated are for both 60601-1-2 (Safety) and 60601-4-2 (Performance).*
- *No deviations or allowances to the standards have been used.*

## Limited Warranty

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Subject to the limitation and exclusions set forth below, Kestra Medical Technology Services, Inc., and its affiliated companies (collectively “Kestra”), hereby warrant to you that your ASSURE wearable ECG (including the Battery, SensorFit Garment, and System Cable), used in accordance with instructions and under prescription, will be free from defects in material and workmanship appearing under normal service and use, and Kestra will provide reasonable and customary support and services to Kestra patients for three (3) years from the date of your first use (the “Warranty Period”).

During the Warranty Period, Kestra will, at its cost and at its option, repair or replace any part of the ASSURE wearable ECG 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 wearable ECG as outlined in your Patient Agreement and the *ASSURE Wearable ECG 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 device by you or others that is inconsistent with the instructions specified in the labeling (*ASSURE Wearable ECG Patient Handbook*).

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You agree you will only use the ASSURE wearable ECG as prescribed by your physician. By using the device, you acknowledge that ownership of the device, software, documentation, and the intellectual property remains with Kestra, and you agree you will only use the device, software, documentation, and the intellectual property for the prescribed period of use and keep them confidential at all times.

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## Open Source Software

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**For assistance, call the ASSURE Helpline  
at (833) 692-7787 (Toll free).**

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