assure
Cardiac Recovery System

Instructions for Use

ASSURE Wearable ECG System

assure®

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Instructions for Use

Kestra Medical Technologies, Inc.

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

Marks

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Publication Date: 2024-07

REF 80667-001 Rev. D

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Chapter 1 Overview

The ASSURE® wearable ECG system (ASSURE wearable ECG) is a patient-worn device designed to assess an electrocardiogram (ECG) and record certain heart rhythms for later physician review.

The typical length of wear is 30 days following ASSURE Wearable Cardioverter Defibrillator (WCD) system prescription and uses the same Garment and (optional) ASSURE patient application from the ASSURE WCD system. The ASSURE wearable ECG is intended to be worn continuously except while showering, bathing, or washing the SensorFit™ Garment.

If the ASSURE wearable ECG detects low or high heart rates, it can record the information about the detected rhythms in the form of discrete episodes including four channels of electrogram data and a marker channel. The system also allows the patient to record their heart rhythm if they are experiencing symptoms while wearing the system and store that information as an episode. Episodes are retrievable from the ASSURE wearable ECG over a wireless link and can be transmitted to a remote data management server for viewing and printing.

Physicians and clinical staff should read this document before prescribing the ASSURE wearable ECG for a patient.

1.1 Clinical Information

1.1.1 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 WCD system, 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.

1.1.2 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.

1.1.3 Contraindications

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

1.1.4 Essential Performance

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

1.2 Safety Information

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 is not a therapeutic device and not a substitute for emergency medical care. Patients should seek medical attention if they 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.*
- *The device should be returned to the manufacturer between patients. Reuse without factory reset will cause data to be incorrectly combined.*

1.3 Potential Complications

Below is a list of potential adverse effects (e.g., complications) associated with the use of ASSURE wearable ECG:

- Improper, ineffective, or non-operation of the device due to external causes such as electromagnetic interference.
- Failure resulting from random component failure.
- Mild to moderate skin irritation or allergic dermatitis due to sensitivity to the materials used in the construction of the Garment.
- Skin infection (bacterial or yeast) secondary to continuous skin contact by electrodes or Garment.

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Chapter 2 Device Description

The ASSURE wearable ECG includes the following components that are provided to the patient:

- System Cable (includes the Hub, HeartPoint™ Alert Button, and Battery connector)
- Battery (spare Battery also included)
- Battery band
- Charging adapter and cord

The ASSURE wearable ECG reuses the SensorFit Garment(s) from the ASSURE WCD system. For more information about the Garment, see the *ASSURE Wearable Cardioverter Defibrillator (WCD) System Instructions for Use*.

Note: If the patient does not have the Garment(s) from the ASSURE WCD system, they should call the ASSURE Helpline at (833) 692-7787 (Toll free).

2.1 System Components

2.1.1 System Cable

The System Cable connects with the Garment and Battery. It consists of the following:

- Alert Button – Provides tones, voice prompts, and vibratory alerts. The patient can press the Alert Button to check system status or to respond to system alerts. If the patient feels unwell, they can press and hold this button to record their heart rhythm.

  Note: The recording function is not a substitute for emergency medical care. The patient should seek medical attention if they continue to feel unwell.

- Hub – The main component of the System Cable that inserts into the Garment and connects to the Battery.
- Battery connector – Connects to the Battery to provide power to the ASSURE wearable ECG. The System Status light on the Battery connector displays the current status of the ASSURE Wearable ECG.

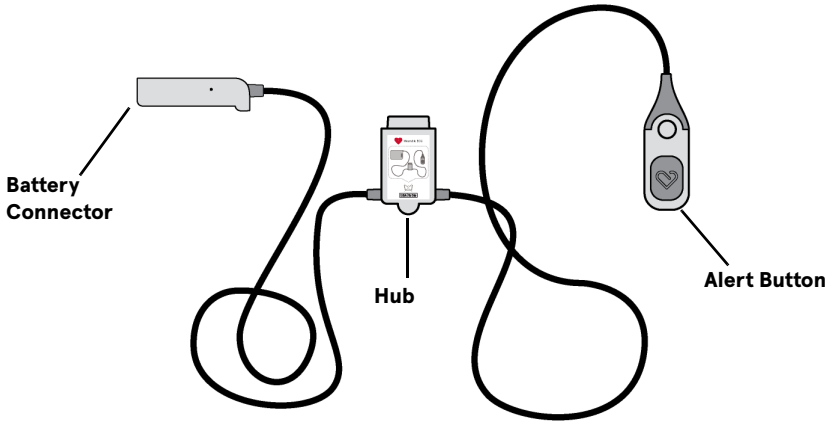


Figure 1: System Cable

The System Cable is inserted into the Garment during use and is removed before laundering the Garment. The length of the System Cable is designed to allow for range of motion and relocation of the Battery during activities of daily living.

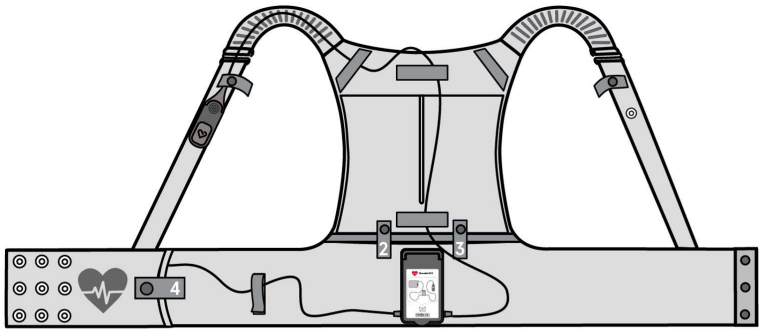


Figure 2: System Cable Inserted into Garment

The Alert Button provides system feedback and a patient-actuated user interface for the ASSURE wearable ECG. The Alert Button contains the following features:

1. A vibration motor for tactile feedback.
2. A speaker for auditory feedback.
3. A pressure-sensitive mechanical button for patient input.
4. A mechanical snap to secure the Alert Button to the proper location on the Garment.

These features were located together by design to facilitate the patient being able to hear, feel and touch all from the same, consistent location (at the shoulder and close to the ear).

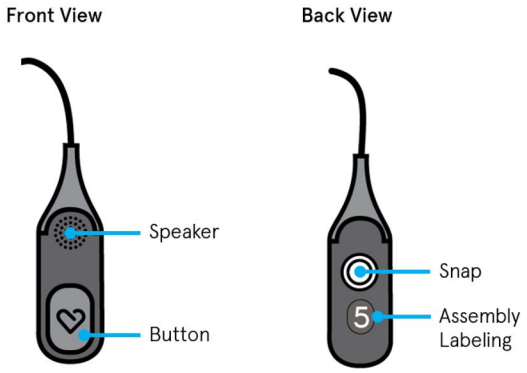


Figure 3: Location of the Speaker, Button, Snap, and Assembly Labeling on the Alert Button

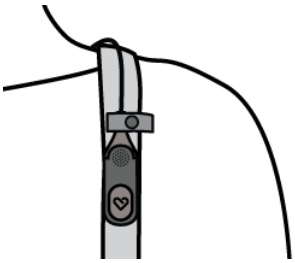


Figure 4: Alert Button Location on the Shoulder Strap of an Assembled ASSURE wearable ECG

The Hub is the central part of the System Cable. The Hub is inserted in the Hub Receptacle of the Garment and snapped into place by the patient.

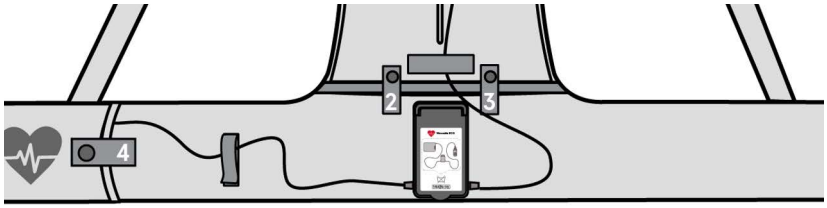
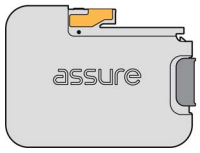


Figure 5: Hub Location in an Assembled Garment

Figure 6: Inserting the Hub into the Hub Receptacle

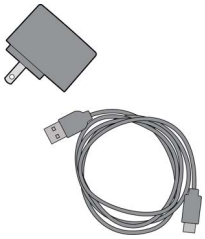
2.1.2 Battery

The Battery is a rechargeable power source that is connected to the System Cable. Two Batteries are provided to the patient so one Battery can charge while the other Battery is in use. 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 for placement in one of the back pockets.



Battery

Battery Band



Charging Adapter and Cord

The Battery includes a locking mechanism to prevent inadvertent or accidental disconnection. To disconnect the Battery from the System Cable, pull down on the Battery lock and slide the Battery connector off of the Battery at the same time.

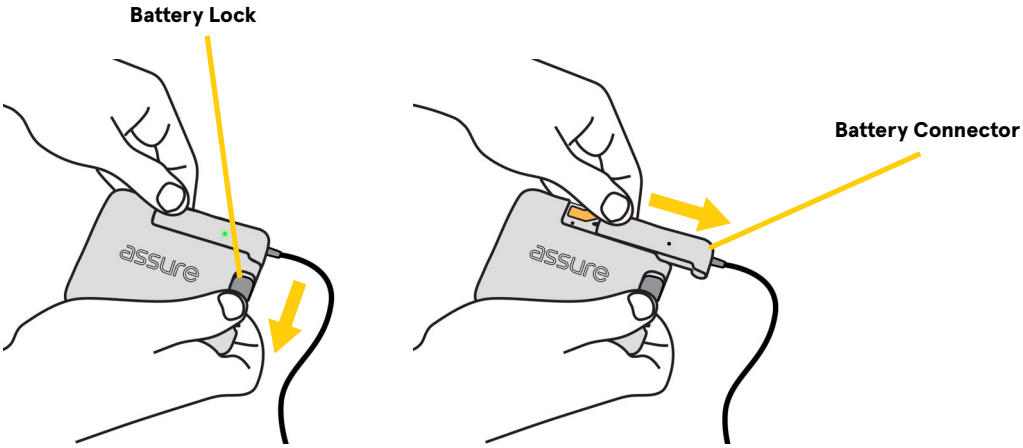


Figure 7: Battery Removal from System Cable

The Charging Status light on the Battery displays the current charging status of the Battery. When fully charged, the Battery can power the ASSURE wearable ECG for at least 24 hours. When Battery power is depleted, the patient will be alerted to replace it with a fully charged Battery.

2.2 System Operation

The ASSURE wearable ECG is a microprocessor-based wearable electrocardiogram recording device. When the ASSURE wearable ECG detects low or high heart rates, or a patient-initiated event, it can record those heart rhythms for later physician review.

The ASSURE wearable ECG communicates its status to the patient through voice messages, the System Status light, audio tones, and vibration.

The ASSURE wearable ECG stores information for detected rhythms in the form of discrete episodes and collects other patient information. All stored data can be retrieved from the system, during or after the patient prescription, over a wireless link for transmission to a remote data management server.

2.3 Accompanying Material

The following instructional material is provided with the ASSURE wearable ECG for patients:

- *ASSURE Wearable ECG Quick Start Guide*
- *ASSURE Wearable ECG Patient Handbook* (complete instructions on the assembly, wear, and maintenance of the system)
- *ASSURE Wearable ECG Return Instructions* (located in the shipping box with a return shipping label)
- *ASSURE Wearable ECG Travel Card* (medical device ID information)
- Patient setup video (available on the Kestra website at www.kestramedical.com/Wearable-ECG-Video).

2.4 Replacement Parts

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

2.5 Returning the ASSURE Wearable ECG

At the end of the prescription or after the physician has determined the patient no longer needs to use the ASSURE wearable ECG, the patient must return the system as soon as possible. Return instructions and a return shipping label are provided in the original shipping box. The box can be dropped off at any FedEx location, or the patient can call the ASSURE Helpline at (833) 692-7787 (Toll free) to arrange for FedEx to pick up the box.

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Chapter 3 Event Detection and Storage

This section describes how the ASSURE wearable ECG detects and stores event information.

3.1 Sensing Configuration

The ASSURE wearable ECG uses integrated electrodes in the SensorFit Garment for ECG signal acquisition. The electrodes are distributed around the patient's torso on level with the subxyphoid process. The ASSURE wearable ECG collects four channels of ECG signals (Quad Channel Processing™) with only a single noise-free channel required for analysis.

- A proprietary algorithm further attenuates noise through a series of fixed high- and low-pass filters and an adaptive match filter (Adaptive Patient Intelligence™).
- Noisy and low amplitude channels are automatically excluded by the algorithm.
- If a single electrode is off or noisy, channels using that electrode are disqualified. ECG analysis is still possible using the remaining channels.
- If two or more electrodes are off or all four channels are noisy, ECG analysis is not possible. The ASSURE wearable ECG notifies the patient to correct the situation.

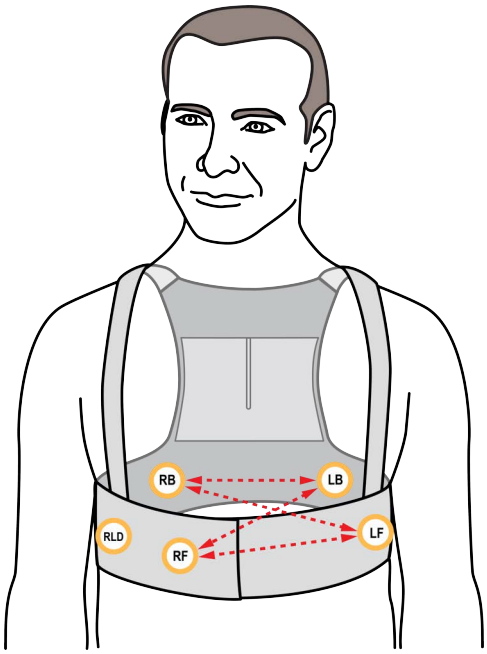

Figure 8: ASSURE Wearable ECG Differential ECG Vectors

3.2 Automatic Event Detection

The ASSURE wearable ECG analyzes the patient's heart rate for the following rhythms:

- Very slow rhythms (Bradycardia/Asystole)
  - Asystole is detected when there is no detected heart rate for more than 20 seconds (with heart rate at 0 bpm or peak-peak amplitude of less than 100 µV).
  - Prolonged, slow heart rates (below 20 bpm for 60 seconds) may be detected as bradycardia.
- Very fast rhythms (Tachyarrhythmias)
  - Tachycardia is detected when complexes are detected with a heart rate greater than 170 bpm for between 15–30 seconds.

Note: The ASSURE wearable ECG uses fixed (non-programmable) rates for event detection.

3.3 Episode Storage

The ASSURE wearable ECG stores data for arrhythmic events and records these events as episodes within device memory. After episode data has been transferred to a remote data management server (either during the prescription period or at the end of the prescription), it is available for prescriber use including viewing and printing.

Episodes are stored for two event types: device-determined events and patient triggered events.

3.3.1 Device-Determined Episodes

Device-determined events include the following arrhythmias:

- Tachy
- Bradycardia (Brady)
- Asystole

The ASSURE wearable ECG automatically detects and stores episodes for events without alerting the patient.

There are three significant areas included in stored episode data:

1. **Onset Data** – Up to 120 seconds of data prior to event detection.

   Note: When multiple episodes occur in a row, the onset data for the second episode is included in the previous episode's data.

2. **Confirmation Data** – Up to 120 seconds of data between event detection and the Episode Closure event.
3. **Post-Closure Data** – Up to 60 seconds of stored data after the detection of rate recovery.

3.3.2 Patient Triggered Events

The ASSURE wearable ECG allows the patient to record their heart rhythm while wearing the ASSURE wearable ECG. The episode recording is approximately 120 seconds in duration:

- Up to 60 seconds of data prior to the patient triggering the recording of the event.
- Up to 60 seconds of data after the patient triggers the recording of the event.

Notes:

- *The recording function is not a substitute for emergency medical care. The patient should seek medical attention if they feel unwell.*
- *The recording function is not available if the patient is not wearing the ASSURE wearable ECG (or not wearing it properly).*
- *The patient triggered episode captures ECG data, even if the signal is noisy.*
- *There is a two-second delay between when the patient triggers the event and the actual start of the event.*

See the figure below for a data storage diagram for an example patient triggered episode.

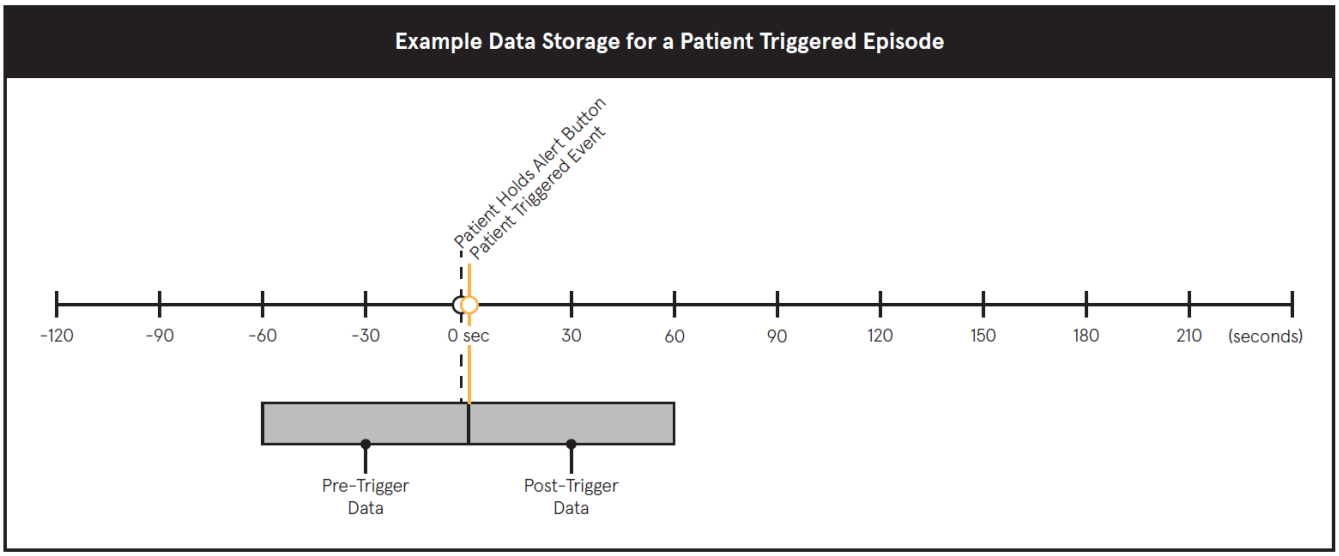

Figure 9: Example Data Storage for a Patient Triggered Episode

In this example, there are two significant events included in two blocks of stored episode data:

1. **Pre-Trigger Data** – Up to 60 seconds of data prior to the patient pressing the Alert Button to start recording the event.
2. **Post-Trigger Data** – Approximately 60 seconds of stored data after the patient presses the Alert Button to start recording the event.

3.4 Statistics

The ASSURE wearable ECG stores patient activity, usage, and heart rate measurements within device memory.

Patient activity is tracked by counting the number of steps the patient takes every day using an accelerometer located in the Hub component of the System Cable, which is situated in the middle of the patient's back.

Daily usage of the ASSURE wearable ECG is recorded in one-minute increments whenever the system sensors are in contact with the patient's skin.

Heart rate is measured continuously, and the data can be displayed as a trend or histogram.

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Chapter 4 Alerts

The ASSURE wearable ECG monitors the system components for proper function. When the system detects a problem, it creates an alert to notify the patient that there is a problem with the system equipment that requires the patient's attention, like the SensorFit Garment not fitting correctly or a low Battery.

What the patient will...	Alert
See	Blinking yellow System Status light *Note: The System Status light is only visible if the Battery is outside the Garment pocket.*
Hear	• Repeating, double tone • Voice message
Feel	Triple-pulse vibration from the HeartPoint Alert Button

Note: The Put on Garment and Check Sensors alerts may correct themselves automatically due to changes in Garment position or movement. If this occurs, the ASSURE wearable ECG will return to normal operation (indicated by the green System Status light, guitar strum, and vibration).

When the patient receives an alert, they should follow two 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

The following system alerts are available for the ASSURE wearable ECG:

Alert Name	Voice Message
Connect Hub to Garment	“Connect the Hub to your Garment.”
Put on Garment	“Put on your Garment now.”
Check Sensors	“Adjust your Garment now. The Sensors must touch your skin.”
Low Battery	“Replace your Battery now.”
Service Needed	“Call the ASSURE Helpline now. Your device needs service. Continue to wear your ASSURE system.”
Service Required	“Call the ASSURE Helpline now. Your device needs service.”

⚠ CAUTION

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

See the *ASSURE Wearable ECG Patient Handbook* for specific system alert information.

Chapter 5 Appendix

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

- Technical specifications
- Electromagnetic Compatibility (EMC) compliance
- Symbols glossary

5.1 Technical Specifications

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

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.

5.1.1 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) *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.*
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
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	*Bluetooth*® Classic and Bluetooth Low Energy *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.*
Liquid and Solid Ingress (per IEC 60529)	IP22 (System Cable)
Weight (including System Cable, Battery, and Garment)	Approximately 1.19 lbs (0.54 kg) *Note: Weight may vary depending on Garment size. Stated weight uses the largest Garment size.*
Part Numbers	System Cable – 80500-003 Garment (Style A) – 80015 Garment (Style B) – 80016

5.1.2 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

5.2 Wireless Interference

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.

5.3 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.

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.

5.4 Radio Frequency (RF) Transmissions

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 ASSURE wearable ECG 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.

5.5 Electromagnetic Compatibility

The ASSURE wearable ECG is shielded to protect it against electromagnetic interference (EMI) and prevent it from interfering with common electronic items. The ASSURE wearable ECG 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 wearable ECG around household equipment that could potentially produce uncommonly high electromagnetic interference. These types of devices generate electromagnetic fields that may interfere with the normal operation of the ASSURE wearable ECG.

ASSURE wearable ECG 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

Patients should avoid walking through security screening equipment commonly found in airports, court buildings, and sporting events. Instead, they should show the security staff their travel card, explain that they are wearing a medical device, and ask for a different screening method, such as a hand-held device or physical hand search.

5.5.1 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 ASSURE wearable ECG should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The ASSURE wearable ECG transmits RF energy only for low power *Bluetooth*® communication. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ASSURE 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.

5.5.2 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 ASSURE wearable ECG should ensure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level (Safety)	IEC/TR 60601-4-2 Test Level (Performance)	Electromagnetic Environment – Guidance
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.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[1] 6 Vrms 150 kHz to 80 MHz in ISM bands[1]	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	704 to 787	LTE Band 13, 17	9	3
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28	9
870				
930				
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	28	9
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28	9
5240	5100 to 5800	WLAN 802.11 a/n	9	6
5500				
5785				

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.*

5.6 Symbols Glossary

This section defines the symbols used on the ASSURE wearable ECG labels and packaging.

Symbol	Description and Reference Document
	Consult instructions for use. IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 1641
	Follow the instructions for use. IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol ISO 7010-M002
	Do not dispose of in fire. IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries. Symbol C
	Do not deform or damage. IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries. Symbol B
	Do not open or dismantle. IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries. Symbol H
	MR unsafe – Keep away from magnetic resonance imaging (MRI) equipment IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 62570-7.3.3
	Recommended storage temperature (from low to high) IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 0632
	Do not wash. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3123
	Wash in cold or mildly warm water with a maximum temperature of 104°F (40°C) on a gentle or delicate setting. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3089
	Do not use bleach. ASTM D5489-14, Standard Guide for Care Symbols for Care Instructions on Textile Products.
	Do not iron. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3113
	Do not dry clean. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3114
	Do not tumble dry. ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3109

Symbol	Description and Reference Document
	Manufacturer IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 3082
	Date of manufacture: YYYY-MM-DD IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2497
IPxx	Enclosure ingress protection code IEC 60529, Degrees of protection provided by enclosures (IP Code)
	Type BF applied part IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 5333
!USA	For USA audiences only 21 CFR 801.109, Labeling: Prescription Devices
Rx Only	By prescription only 21 CFR 801.109, Labeling: Prescription Devices
SN	Serial number IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2498
REF	Catalogue number IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2493
LOT	Batch code IEC/TR 60878, Graphical symbols for electrical equipment in medical practice. Symbol 2492
	Rechargeable battery IEC 60417, Graphical symbols for use on equipment. Symbol 5639
	Battery direct current IEC 60417, Graphical symbols for use on equipment. Symbol 5031.
	Do not use this device in a bathtub, shower, or water-filled reservoir. ISO 7010, Graphical symbols – Safety colours and safety signs – Registered safety signs. Symbol P026
	Recognized safety certification mark for the United States.

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

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Publication Date: 2024-07

REF 80667-001 Rev. D

80667-001