
assure®
Cardiac Recovery System
Modern
Wearable
Defibrillation

# Introducing the ASSURE WCD

The ASSURE® Wearable Cardioverter Defibrillator (WCD) system from Kestra Medical Technologies provides important advantages based on patient-focused design and advanced technology.

WCDs work when patients wear them, with over 90% survival after an appropriate shock.[1, 2, 3] Yet providers report challenges when it comes to patient compliance.

Now, there is a modern approach.

Kestra designed the ASSURE system to enhance comfort, provide greater clarity to care teams, and increase patient confidence during their recovery after a cardiac event—because compliance matters.

**Welcome to ASSURE.**


1 Wäßnig, N.K., et al. Experience With the Wearable Cardioverter-Defibrillator in Patients at High Risk for Sudden Cardiac Death. Circulation. 2016;134(9):635-43.

2 Ellenbogen, K.A., et al. Benefit of the Wearable Cardioverter-Defibrillator in Protecting Patients After Implantable-Cardioverter Defibrillator Explant: Results From the National Registry. JACC. 2017;3(3):243-250/.

3 Chung, M.K., et al. Aggregate National Experience With the Wearable Cardioverter-Defibrillator Vest: Event Rates, Compliance And Survival. Journal of the American College of Cardiology. 2010;56:194-203.

assure®
Cardiac Recovery System

# Comfortable Protection for Patients, Clear Insights for You

**ASSURE WCD**
Wearable device for patients at risk of sudden cardiac arrest that can provide automatic detection and defibrillation for ventricular arrhythmias.

**ASSURE Patient App**
Mobile app that transmits patient heart rhythm data securely and lets patients monitor their usage time, track activity, and learn more about using the system.

**Kestra CareStation®**
Remote patient data platform provides configurable notifications for clinical events and trending of physiologic and device data at any time.


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# Designed for Comfort and Compliance

**1. SensorFit™ Garments**
Made of breathable, lightweight fabrics with nonadhesive, embedded, and cushioned ECG sensors that are designed to move with the patient and capture high-fidelity ECG signals.

**2. HeartPoint™ Alert Button**
Enables the patient to interact easily with the WCD—by hearing, feeling, and touching—all from an intuitive location on the body.

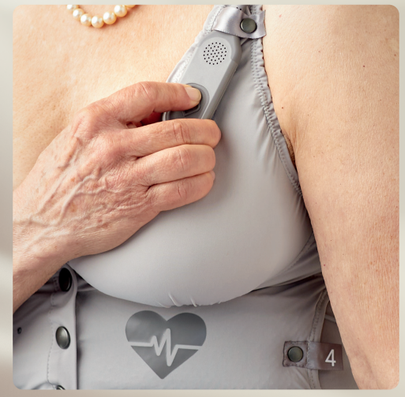
**3. ASSURE Detection Algorithm**
Quad Channel Processing™ utilizes four channels of high-fidelity ECG to determine the patient's heart rate and rhythm. Only one noise-free channel is required for rhythm analysis.

Adaptive Patient Intelligence™ is a proprietary technology that adapts to the patient's heart rhythm to filter out artifacts caused by patient motion.

# Easy to Use

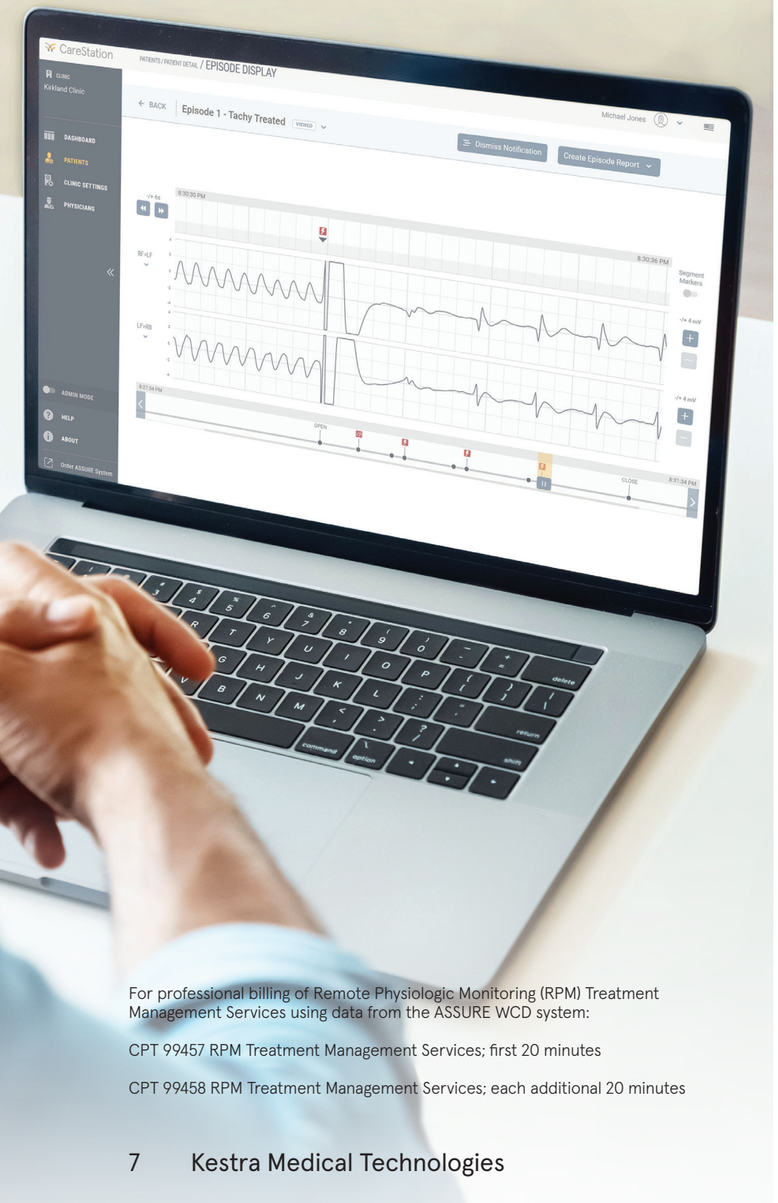

Therapy Pads are numbered and matched to the Garment to make inserting and removing them quick and straightforward.

# Freedom to Move




Styled and engineered by leading athletic and sportswear designers, SensorFit Garments are tailored in two styles and a wide range of sizes, feature nonadhesive cushioned ECG sensors, and can be washed.

# Clear Patient Information




## Kestra CareStation

The Kestra CareStation remote patient data platform offers intuitive, efficient tools for managing patient care, including:

Clear patient reports that include VT, VF, SVT, bradycardia, asystole, patient triggered episodes, and non-sustained ventricular arrhythmia episodes.

WCD usage, physical activity trends, and heart rate trends and histogram.

Population dashboard with configurable notifications.

Scan to review a Kestra CareStation report.

For professional billing of Remote Physiologic Monitoring (RPM) Treatment Management Services using data from the ASSURE WCD system:

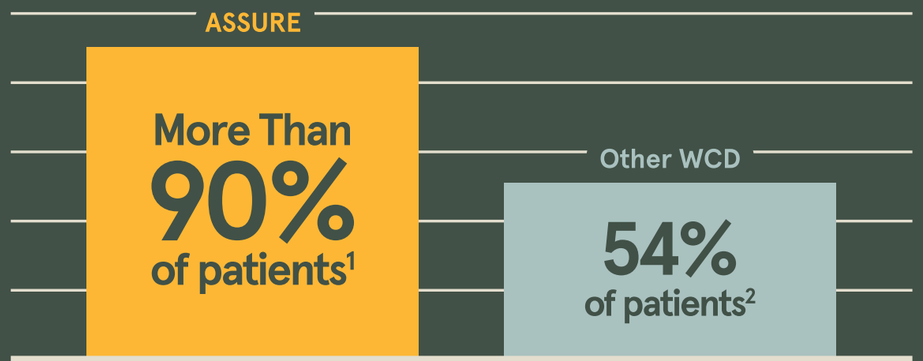
CPT 99457 RPM Treatment Management Services; first 20 minutes

CPT 99458 RPM Treatment Management Services; each additional 20 minutes



# Redefining WCDs for the Modern World

## Freedom from False Positive Shock Alarms




## >90% of ASSURE system patients never experience a false alarm

Disclaimer: A controlled, head-to-head study evaluating the comparative performance of these devices has not been done.


**SensorFit™ Garment design helps optimize patient protection, resulting in median wear time >23 hours/day[1]**


**First shock success rate is >95%[1]**

Scan to read published studies.[3,4]

1 ACE-PAS (NCT05135403, N = 1,651). Data on file.

2 Arkles, J. et al. J Interv Card Electrophysiol. 2023;66(7):1723-1728.

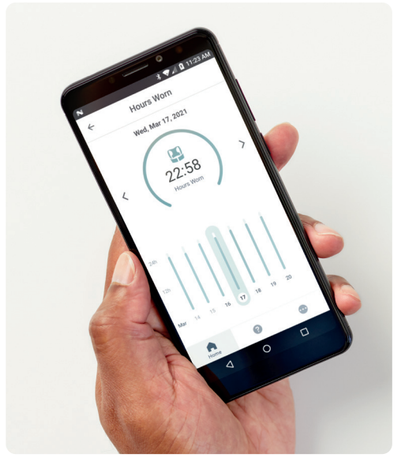
3 Poole JE, Gleva MJ, Birgersdotter-Green U, et al. A wearable cardioverter defibrillator with a low false alarm rate. J Cardiovascular Electrophysiol. 2022;1-12. doi:10.1111/jce.15417

4 Gleva MJ, Sullivan J, Crawford TC, et al. (2023) Defibrillation effectiveness and safety of the shock waveform used in a contemporary wearable cardioverter defibrillator: Results from animal and human studies. PLoS ONE 18(3): e0281340. https://doi.org/10.1371/journal.pone.0281340.

# Assurance When Needed

## ASSURE Assist Service

The ASSURE Assist® service[1] is designed to connect patients to the assistance they need after a shock event. An Emergency Medical Services (EMS) operator attempts to contact the patient to determine if additional help is needed. If the patient cannot be reached, the EMS operator attempts to contact the patient's emergency contact. If both the patient and the emergency contact cannot be reached, or if either request additional help, EMS may be dispatched to the patient's location.




## ASSURE Patient App

Can automatically transmit patient heart rhythm data and lets patients monitor their usage time, track activity, record symptoms, and learn more about using the system.




### Important Information About the ASSURE Assist Service

1 The ASSURE Assist service requires the mobile device with the ASSURE patient app to be connected to the Internet and or Wi-Fi®, powered on, location services enabled with location permissions granted and within 30 feet of the ASSURE system for proper operation. In the event of an emergency, the ASSURE Patient App is not a substitute for appropriate medical attention and should not be relied on to contact emergency services. Kestra Medical Technologies Inc. (KMT) does not represent or warrant that the ASSURE Assist service prevents death, bodily or personal injury, or damage to you. KMT makes no representation of warranty as to the promptness of the ASSURE Assist service or emergency services. See important information about your ASSURE system at kestramedical.com/patients or the ASSURE Patient Application User Manual for a full explanation of service conditions and requirements.

### Important Information About the ASSURE System

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

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

**Intended Use:** The ASSURE system is intended for patients who have been prescribed this device by their physician.

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

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

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

The ASSURE system is magnetic resonance (MR) unsafe. Do not wear or use this device near MR imaging equipment.

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

Do not alter, drop, or abuse any part of the ASSURE system. Attempting to alter the equipment in any way may cause the device to malfunction or fail. Do not take apart the Monitor. Dangerous high voltages may be present. If service is required, call the ASSURE Helpline at (833) 692-7787 (toll free).

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

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

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MEDICAL TECHNOLOGIES

Kestra Medical Technologies, Inc. is a wearable medical device and digital healthcare company that helps protect cardiac patients with diagnostic monitoring and therapeutic products that are intuitive, intelligent, and mobile. Kestra innovations empower providers and patients to collaborate toward better care and improved outcomes.

kestramedical.com



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