Introducing the ASSURE WCD

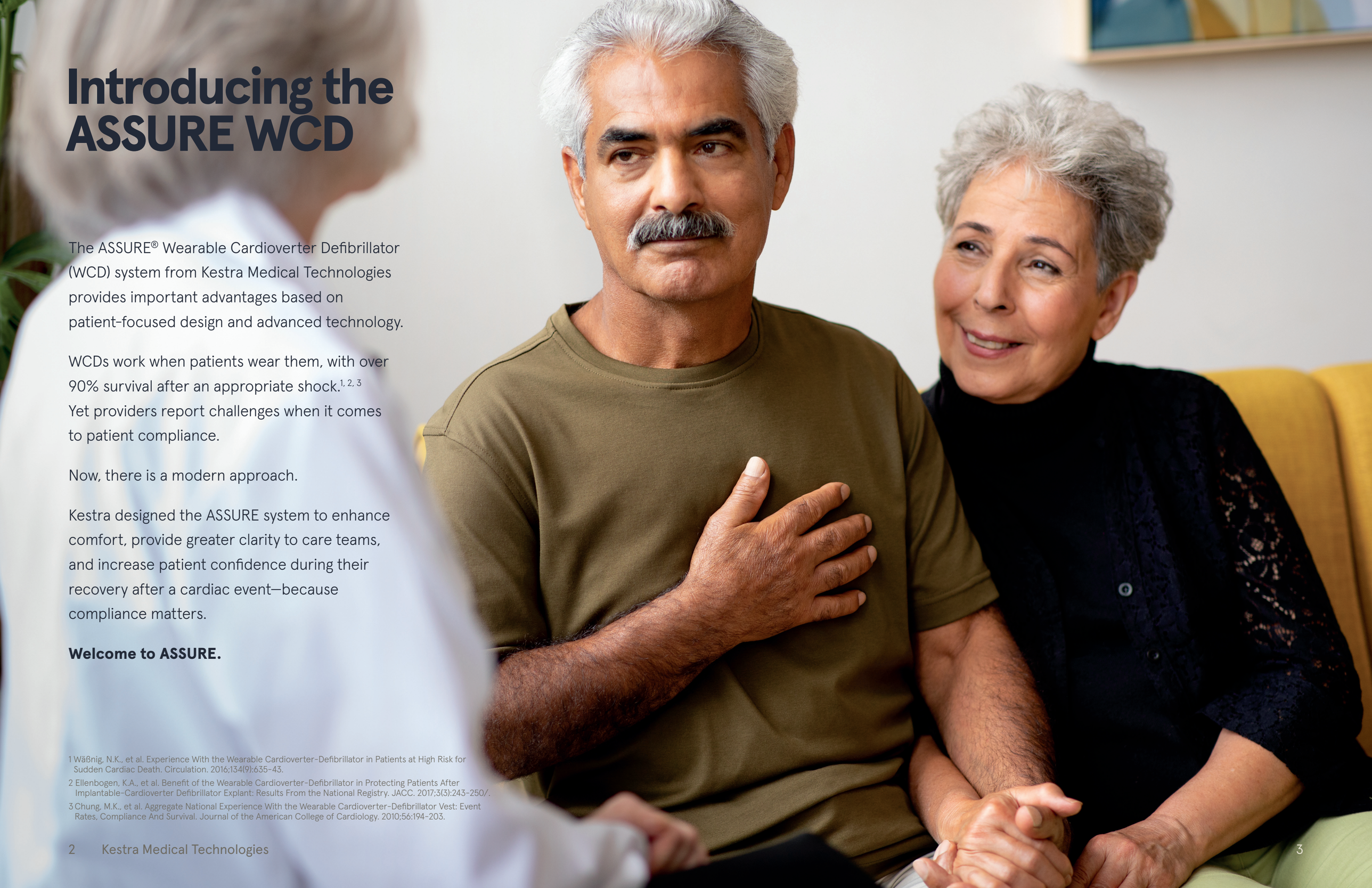
The ASSURE® Wearable Cardioverter Defibrillator (WCD) system from Kestra Medical Technologies provides important advantages based on patient-focused design and advanced technology.

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. 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.

2. 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.

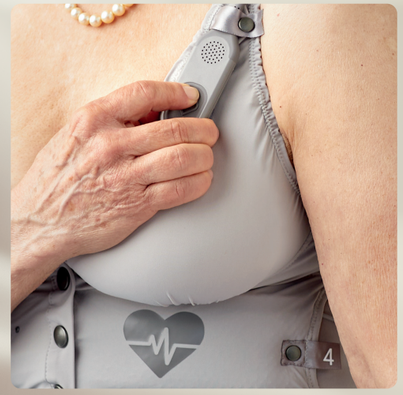
3. ASSURE Detection Algorithm
Quad Channel Processing™ utilizes four channels of high-fidelity ECG to determine the patient's heart rate and rhythm. Only one noise-free channel is required for rhythm analysis.

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.

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.

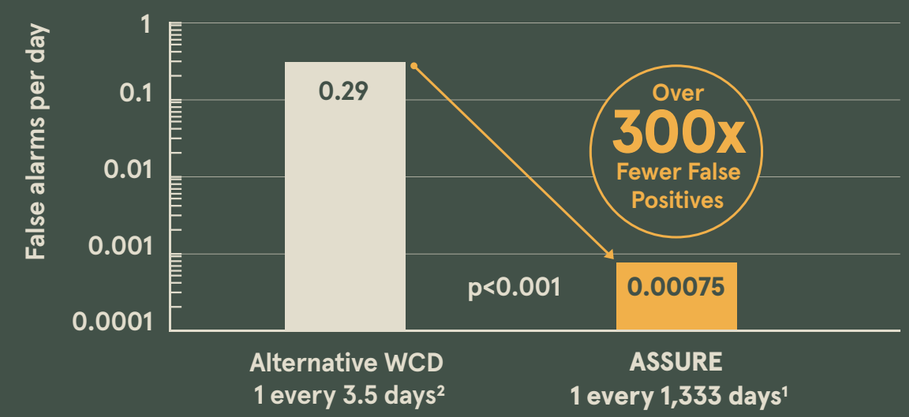
Do not alter, drop, or abuse any part of the ASSURE system. Attempting to alter the equipment in any way may cause the device to malfunction or fail. Do not take apart the Monitor. Dangerous high voltages may be present. If service is required, call the ASSURE Helpline at (833) 692-7787 (toll free).

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.

Performance Backed by Clinical Data

The ASSURE system has significantly fewer false positive shock alarms



The ASSURE system detection performance exceeds performance goals for arrhythmia analysis for external defibrillators.[3]

99.0% VF sensitivity[1]
(202/204)

98.4% VT sensitivity[1]
(61/62)

The ASSURE system uses a biphasic waveform delivering 170 joules.[4]

Scan here to read the published studies.

1 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

2 ZOLL Medical Corporation. (2016) LifeVest Model 4000: Operator's Manual, Rev E: Pittsburgh.

3 Link M, Atkins D, Passman R, et al. Part 6: electrical therapies: automated external defibrillators, defibrillation, cardioversion, and pacing: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2010;122(suppl 3):S706-S719.

4 ACE-CONVERT Pivotal Clinical Trial (NCT04132466).

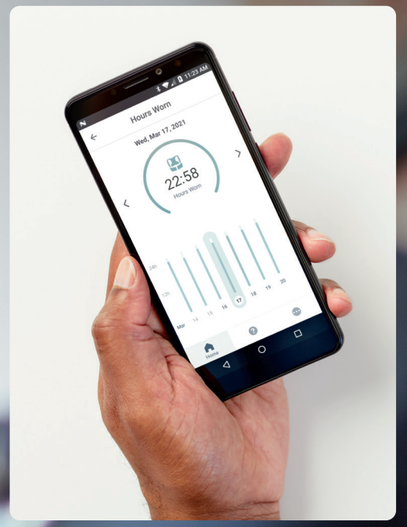
Clear Patient Information Anytime, Anywhere

Scan here to review an actual CareStation report.

Kestra CareStation

A remote patient data platform that offers efficient tools for managing patient cardiac care. As a provider, you need to see patient information clearly without being inundated by irrelevant data. Kestra CareStation accomplishes this by delivering valuable insight into patient heart rhythms:

- Clear patient reports that include VT, VF, bradycardia, asystole, and non-sustained ventricular arrhythmia episodes.
- WCD usage and physical activity trends.
- Population dashboard with configurable notifications.



ASSURE Patient App

Automatically transmits patient heart rhythm data and lets patients monitor their usage time, track activity, and learn more about using the system.

kestra
MEDICAL TECHNOLOGIES

Kestra Medical Technologies, Inc. is a wearable medical device and digital healthcare company that protects 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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