assure

Cardiac Recovery System

ASSURE Wearable Cardioverter Defibrillator (WCD) System
Instructions for Use

assure®

Cardiac Recovery System™

ASSURE® Wearable Cardioverter Defibrillator (WCD) System Instructions for Use

Kestra Medical Technologies, Inc.

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Important Information

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

Trademarks

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Contents

1. Introduction

This section provides an overview of the ASSURE Wearable Cardioverter Defibrillator (WCD) system (or ASSURE system) for physicians and clinical staff who will prescribe this device to their patients.

1.1 Overview

The ASSURE Wearable Cardioverter Defibrillator (WCD) system (or ASSURE system) is a patient-worn device designed to assess an electrocardiogram (ECG) and automatically deliver therapy in the form of a defibrillating shock. The ASSURE system is intended to be worn continuously except while bathing/showering. If the ASSURE system detects life-threatening ventricular arrhythmias, specifically, ventricular tachycardia (VT) or ventricular fibrillation (VF) above a programmable heart rate threshold, it can deliver a defibrillating shock to the heart to restore an effective rhythm without further interaction from the patient or bystander. When the device detects an arrhythmia, it issues an alert notifying the patient that they are about to receive a shock while providing the patient the opportunity to divert it if they are still conscious by pressing the Alert Button. Information about detected rhythms are stored in the form of discrete episodes including four channels of electrogram data and a marker channel that identifies algorithm detection decisions. Episodes are retrievable from the Monitor 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 system to a patient.

1.2 Indications for Use

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

1.3 Contraindications

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

1.4 Intended Operator, Use, and Location

The ASSURE system is intended for patients who have been prescribed this device by their physician. The patient is the primary operator. A Kestra patient service representative (PSR) fits and trains the patient on proper use and care of the system.

The ASSURE system is intended for use by a patient during their normal daily activities primarily in the home or community setting, but also hospitals, medical clinics, healthcare facilities and transport. The Charger is intended to be used in the home environment.

1.5 Safety Information

The following safety labels appear in this manual:

WARNING

Hazards or unsafe practices that may result in serious personal injury or death.

CAUTION

Hazards or unsafe practices that may result in minor or moderate personal injury, product damage, or property damage.

1.5.1 Warnings

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 1.833.692.7787.*
- *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.*

1.6 Potential Complications

Below is a list of potential adverse effects (e.g., complications) associated with the use of a Wearable Cardioverter Defibrillator:

- Failure to sense and detect a treatable ventricular arrhythmia resulting in death.
- Unsuccessful cardioversion or defibrillation resulting in death or disability.
- Inappropriate shock causing abnormal heart rhythms, including fatal rhythms.
- Improper, ineffective, or non-operation of the device due to external causes such as electromagnetic interference.
- Failure resulting from random component failure.
- Damage to or reset of a pacemaker due to a shock.
- Superficial skin burns resulting from defibrillation.
- Pain from conscious shock.
- 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.
- Bystander shock from patient contact during a treatment event.
- Fire hazard in the presence of a high oxygen concentration.
- Muscle strain or shoulder discomfort.
- Bruising from monitor striking a body part.
- Trip hazard or fall

1.7 Clinical Studies

Kestra Medical Technologies, Inc. performed two clinical studies in the United States. The first of which was to evaluate ambulatory and arrhythmia detection performance and safety of the device. The second study evaluated conversion effectiveness and safety of the ASSURE defibrillation waveform, under IDE # G190232. These studies, in combination with animal studies, establish a reasonable assurance of safety and effectiveness of defibrillation with the ASSURE Wearable Cardioverter Defibrillator (WCD) System (ASSURE system) for adult patients who are at risk for sudden cardiac arrest and are not candidates for, or refuse, an implantable defibrillator.

The clinical data that demonstrate a reasonable assurance of safety and effectiveness of the ASSURE system came from the following trials:

- ACE-DETECT (section 1.7.1, Pivotal U.S. Clinical Study: ACE-DETECT, on page 13)
- ACE-CONVERT (section 1.7.2, Pivotal U.S. Clinical Study: ACE-CONVERT, on page 24)

A summary of each study is presented in Table 1.

Table 1 Summary of ASSURE Clinical Studies

	ACE-DETECT (NCT03887052)	ACE-CONVERT (NCT04132466)
Objectives	Evaluate ambulatory and arrhythmia detection performance and safety	Evaluate conversion effectiveness and safety
Study Design	Prospective, non randomized	Prospective, non randomized
Patient Population	Patients at risk for sudden cardiac arrest who had an active, implantable cardioverter defibrillator (ICD)	Patients at risk for sudden cardiac arrest and undergoing noninvasive programmed stimulation (NIPS) or ICD pulse generator replacement
Endpoints	Primary: WCD False Positive Alarm rate calculated as False Positive Alarms per subject-day Secondary: • Summary of WCD True Positive Detections and Missed Events (False Negative Detections) • Estimated inappropriate shock rate • Summary of adverse events determined to be at least possibly related to the device	Primary effectiveness: Estimated cumulative first and second shock VT/VF conversion effectiveness ≥ 94% Secondary effectiveness: First shock VT/VF conversion effectiveness Safety: Summary of adverse events that are at least possibly related to use of the investigational Test System, including classification of Unanticipated Adverse Device Effects
Number of Patients Enrolled	130	13
Follow-up	Study complete 3,501 subject-days (9.6 years)	Study complete Acute, intra-procedural testing only

1.7.1 Pivotal U.S. Clinical Study: ACE-DETECT

1.7.1.1 Study Design

Patients were enrolled between March 20, 2019 and June 18, 2019. The database for this PMA reflected data collected through June 18, 2019 and included 130 patients enrolled at 10 investigational sites in the U.S.

The study was a prospective, non-randomized, single arm, multi-center open label study in patients at risk for sudden cardiac arrest who had an active, implantable cardioverter defibrillator (ICD) implanted for either primary or secondary indications.

A sample size of 105 was required to show that the False Positive Alarm rate per subject-day (primary endpoint) for the ASSURE system was statistically significantly lower than the comparator rate of 0.29 at a one-sided 0.025 significance level with at least 90% power. A total of 130 subjects, with at least 35 of each sex, were planned to be enrolled to meet the sample size requirement for the primary endpoint while also achieving the goal of recording approximately two shockable events. A Statistical Analysis Plan (SAP) for the ACE-DETECT study was generated to guide the analyses for the defined endpoints.

The ASSURE systems used in this study were production-equivalent with defibrillation therapy programmed OFF, shock alarms disabled (Shock Alarm Event Markers were recorded by the device for analysis purposes), and detection parameters at nominal settings [Ventricular Tachycardia (VT) rate threshold at 170 bpm and Ventricular Fibrillation (VF) rate threshold at 200 bpm]. As such, ventricular arrhythmias with a heart rate greater than 170 bpm sustained for at least 20 seconds should be detected in this study. When initial arrhythmia detection criteria are met, the ASSURE system opens an Episode and begins storage of ECG signals. If the rhythm is sustained for the confirmation period (5 seconds for VF, 45 seconds for VT), a Shock Alarm Event Marker is recorded. Any Episode that is opened is retained in device memory regardless of the presence of a Shock Alarm Event Marker.

An independent panel of board-certified electrophysiologists reviewed all ventricular tachyarrhythmia episodes recorded by the ASSURE system and/or ICD. The panel was established prior to study commencement and consisted of three voting members with broad experience with clinical trials and no vested interest in the ASSURE system.

An independent Medical Monitor reviewed all adverse events. The Medical Monitor had no financial, scientific, or other conflict of interest with the study.

Clinical Inclusion and Exclusion Criteria

Enrollment in the ACE-DETECT study was limited to patients who met the following inclusion criteria:

- Males or females, age ≥ 18 years
- Patients with an active Implantable Cardioverter Defibrillator (ICD)
- Left Ventricular Ejection Fraction (LVEF) ≤ 40%, measured within the past year (12 months) by echocardiography, nuclear imaging (including MRI), or left ventricular angiography
- Able and willing to provide written informed consent before undergoing any study-related procedures

Patients were not permitted to enroll in the ACE-DETECT study if they met any of the following exclusion criteria:

- Any condition that by the judgement of the physician investigator precludes the subject's ability to comply with the study requirements, including cognitive and/or physical limitations that would prevent the subject from interacting with the device as intended
- Any known skin allergy or sensitivity to the study Garment materials that will be next to the skin
- Any breached or compromised skin on the upper body that would be exacerbated by wearing the study Garment
- Work with or are frequently around equipment that produces high electromagnetic fields, for example magnetic resonance imaging devices, power supply facilities, or welding equipment
- Any planned surgical or medical procedures during the participation period that would require the subject to remove the study device for more than 12 hours
- Any planned air travel during the participation period.
- Pregnancy

- Use of mechanical circulatory support, for example Left Ventricular Assist Device (LVAD) or Total Artificial Heart
- Implanted Cardiac Resynchronization Therapy Defibrillator (CRT-D)
- Simultaneous plan/prescription for Holter monitor, mobile cardiac outpatient telemetry (MCOT), Event Recorder, or in-hospital telemetry
- Use of any electronic medical device that is worn on or near the body requires Sponsor approval, other than continuous positive airway pressure (CPAP), continuous blood glucose monitor, or pulse oximeter oxygen saturation (SpO2) monitor
- Under bust chest circumference greater than 52 inches (132 cm) or less than 28 inches (71 cm)
- Current hospital inpatient

Follow-up Schedule

After consent, a visit was performed to fit the Garment and instruct the subject on how to wear and manage the ASSURE system. Subjects were asked to wear the ASSURE system as much as possible for approximately 30 days. Weekly phone calls were conducted to address subject questions, review any potential adverse events, and review usage information.

Detected arrhythmias were stored in the ASSURE system and/or ICD. At the end of the 30-day period, the subject returned for the exit visit and ended participation in the study.

Adverse events (at least possibly device-related) were reported at all scheduled and unscheduled visits throughout the study.

Clinical Endpoints

Primary Endpoint

The primary endpoint analysis was based on the Intent to Treat cohort and was performed as a one-sided test with 0.025 significance level of the null hypothesis (H_0) that the WCD False Positive Alarm rate per subject-day for the study device is equal to or greater than the comparator rate (0.29). The alternative hypothesis (H_1) was that the WCD False Positive Alarm rate is lower than (superior to) the comparator rate. A random effects Poisson regression model was fit with the number of false positive alarms for each subject as the outcome variable, the logarithm of days of wear as an offset term, and random site effect. An additional random effects Poisson regression model was fit that included subject characteristics (age, sex, height, and weight) as covariates.

Secondary Endpoints

The secondary endpoint analyses were exploratory and did not have specific performance criteria requirements. No formal tests of hypotheses were planned. Summary statistics were provided for True Positive Detections, Missed Events, and Adverse Events.

The estimate of the Inappropriate Shock Rate was calculated as the product of the WCD False Positive Alarm rate (the primary endpoint of this study) and the Missed Shock Alarm Rate. The Missed Shock Alarm Rate (23.1%) was derived from the upper limit of the 95% confidence interval of the missed alarm rate observed in two prior feasibility studies during which shock alarms were delivered randomly to study subjects during sleep and normal daily activities. In those studies, a “missed shock alarm” was one during which the subject failed to respond to the shock alarm (press the Alert Button) within 20 seconds following alarm activation. The analysis assumes that detected ECG signals persist during the entire alarm period and likely over-estimates the Inappropriate Shock Rate.

A summary of AEs at least possibly related to device use and by severity (as reported by the Investigator and reviewed by the Medical Monitor) was prepared.

1.7.1.2 Accountability of PMA Cohort

At the time of database lock, a total of 130 patients enrolled in the PMA study, 93% (121) patients were available for analysis at the completion of the study, the 30-day study exit visit. The disposition of all study subjects is summarized below.

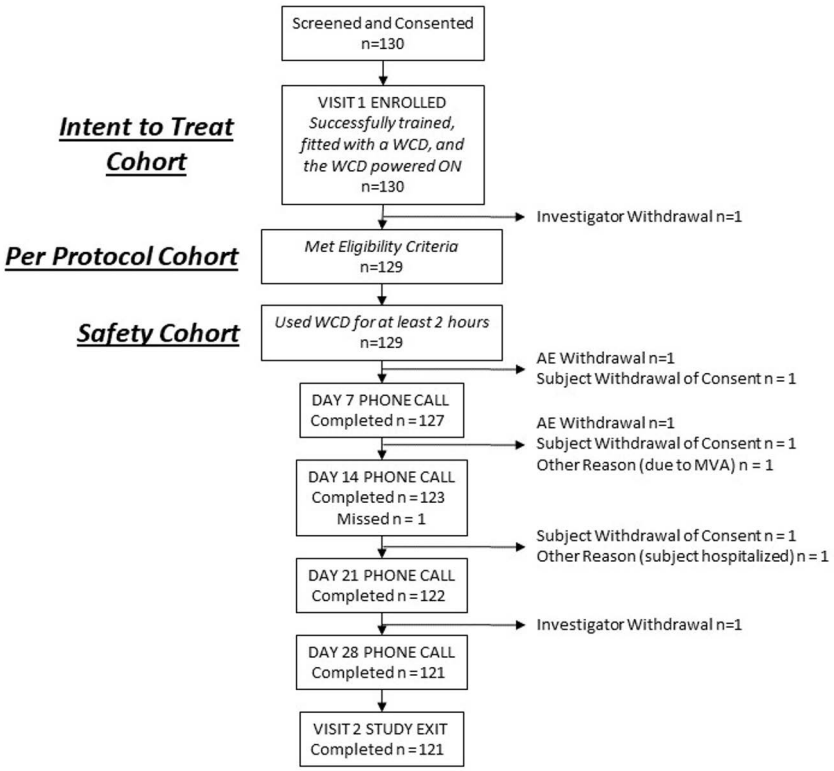

Figure 1: Study Cohort

1.7.1.3 Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for an ICD study performed in the U.S. This approach allowed evaluation of the ASSURE system in patients similar to those currently indicated for a WCD and in whom spontaneous occurrence of both ventricular and supraventricular arrhythmias were likely to occur.

ACE-DETECT subjects were enrolled from disparate geographic areas, were of variable body habitus, and included 30.8% female and 28% non-Caucasian participants. Subjects were reflective of a chronic heart failure population, including both an ischemic (57.7%) and non-ischemic (33.8%) etiology, with a median LVEF of 30% and mean LVEF of 28%, similar to other published studies of the commercially available WCD. Patient demographics and clinical characteristics are summarized in Table 2 and Table 3 on page 17, respectively. Body habitus is shown in the figure after the tables.

Table 2 Baseline Demographic Characteristics

Baselines Characteristics	Enrolled Subjects N = 130
Age (years)	
N	130
Mean ± SD	61.2 ± 11.4
Median	62.0
IQR	15.0
Min, Max	29.0, 89.0
Sex	
Male	90 (69.2%)
Female	40 (30.8)
Race (not mutually exclusive)	
American Indian or Alaska Native	0 (0.0%)
Asian	0 (0.0%)
Black or African American	35 (26.9%)
Native Hawaiian or Other Pacific Islander	1 (0.8%)
White	83 (63.8%)
Other	0 (0.0%)
Not Reported	11 (8.5%)
Ethnicity	
Hispanic or Latino	2 (1.5%)
Not Hispanic or Latino	124 (95.4%)
Unknown or Not Reported	4 (3.1%)

Table 3 Cardiovascular and Other Medical History

Medical History	Enrolled Subjects N = 130
Etiology of Cardiovascular Disease (Primary)	
Ischemic	75 (57.7%)
Nonischemic (not primarily valvular)	44 (33.8%)
Mixed ischemic/nonischemic	1 (0.8%)
Primary valvular	2 (1.5%)
Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC)	0 (0.0%)
Hypertrophic Cardiomyopathy	3 (2.3%)
Congenital	0 (0.0%)
Sarcoidosis	0 (0.0%)
Other	5 (3.8%)
NYHA Classification	
I	9 (6.9%)
II	52 (40.0%)
III	43 (33.1%)
IV	2 (1.5%)
Unknown	19 (14.6%)
LVEF (%)	
N	130
Mean ± SD	28.2 ± 7.1
Median	30.0
IQR	12.0
Min, Max	11.0, 40.0
Method of LVEF Determination	
Echocardiogram	122 (93.8%)
Nuclear, including SPECT and cMR	6 (4.6%)
Left Ventricular Angiography	1 (0.8%)
Other	1 (0.8%)

Table 3 Cardiovascular and Other Medical History (Continued)

Medical History	Enrolled Subjects N = 130
Medical History (not mutually exclusive)	
Coronary Artery Disease	95 (73.1%)
Prior Myocardial Infarction (MI)	75 (57.7%)
Prior Coronary Artery Bypass Graft (CABG)	26 (20.0%)
Prior Percutaneous Coronary Intervention (PCI)	57 (43.8%)
Heart Failure	125 (96.2%)
Diabetes	41 (31.5%)
Type I	2 (1.5%)
Type II	39 (30.0%)
Hypertension	96 (73.8%)
Chronic Obstructive Pulmonary Disease (COPD)	28 (21.5%)
Chronic Kidney Disease	31 (23.8%)
End Stage Renal Disease	4 (3.1%)
Dialysis Dependent	3 (2.3%)
Current Smoker	23 (17.7%)
Use of Concomitant Medical Devices	
Yes	32 (24.6%)
No	98 (75.4%)
Type of Concomitant Medical Device (not mutually exclusive)	
Implantable Loop Recorder (ILR)	1 (0.8%)
Cane	5 (3.8%)
CardioMEMs	1 (0.8%)
Continuous Positive Airway Pressure (CPAP)	21 (16.2%)
Walker	3 (2.3%)
Other	3 (2.3%)
Subject Has Worn a Life Vest Previously	
Yes	21 (16.2%)
No	109 (83.8%)

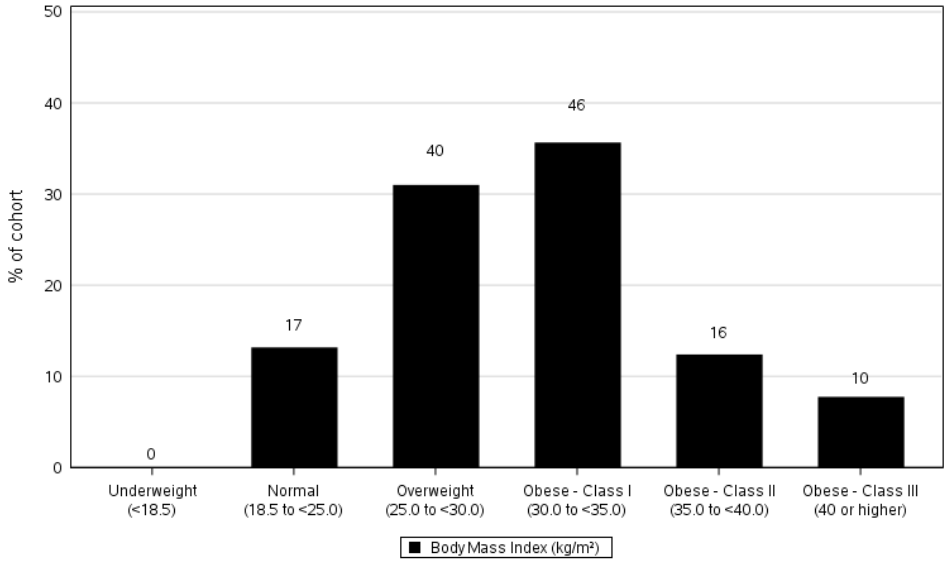

Figure 2: Body Habitus

Compliance

Enrolled subjects achieved cumulative device usage of 3,501 subject-days (9.6 years). Average usage was 29.4 ± 6.9 days and average daily usage was 22.7 ± 1.7 hours (Table 4). Most subjects (114, 88.4%) achieved an average daily use of at least 20 hours. No differences were found in usage by gender, age, or use of concomitant medical devices (Table 5 on page 20).

Table 4 WCD Usage

	Enrolled Subjects N = 130
Total Usage (hours)[1]	
N	130
Mean ± SD	646.4 ± 164.0
Median	694.5
IQR	57.5
Min, Max	0.6, 789.5
Cumulative Usage Across All Subjects (hours)	84,028
Cumulative Usage Across All Subjects (days)	3,501
Cumulative Usage Across All Subjects (years)	9.6
WCD Use Days ≥1 Hour Per Day[2]	
N	130
Mean ± SD	29.4 ± 6.9
Median	31.0
IQR	1.0
Min, Max	0.0, 35.0

Table 4 WCD Usage (Continued)

	Enrolled Subjects N = 130
Average Daily Usage (hours)[3]	
N	128
Mean ± SD	22.7 ± 1.7
Median	23.1
IQR	1.1
Min, Max	12.4, 24.0

1. Total Usage (hours) is calculated as the sum of hours of device usage by each subject across all study days.
2. WCD Use Days with ≥1 Hour Per Day is calculated as the number of days the subject used the device for at least 1 hour.
3. Average Daily Usage (hours) is calculated as the sum of hours of device usage, excluding any days with <1 hour of use and the first and the last wear days, divided by the number of WCD use days with ≥1 hour per day, excluding the first and the last wear days.

Table 5 WCD Usage Stratified by Age, Gender, and Concomitant Device Use

	N	Mean	SD	P-value (t-test)
Sex				
Male	90	22.7	1.8	
Female	40	22.5	1.6	p = 0.47
Age				
≥62 years	66	22.7	1.8	
<62 years	64	22.7	1.7	p = 0.97
Concomitant Device				
Yes	32	22.8	1.0	
No	98	22.6	1.9	p = 0.56

Note: Average Daily Usage (hours) is calculated as the sum of hours of device usage, excluding any days with <1 hour of use and the first and the last wear days, divided by the number of WCD use days with ≥1 hour per day, excluding the first and the last wear days.

Stored Episodes

ICD Episodes Recorded as Ventricular Tachyarrhythmias

A total of 237 ICD episodes were recorded as ventricular tachyarrhythmias in 51 (39.2%) of subjects. These episodes are summarized in Table 6. 106 were adjudicated as Rhythm Type VT/VF (44.7%). The majority (91) of these VT/VF episodes were non-sustained lasting less than 20 seconds. 15 VT/VF episodes were sustained for at least 20 seconds. The remaining episodes were adjudicated as SVT (33.8%), Atrial Fibrillation (21.1%), or Sinus Rhythm (0.4%).

Table 6 Summary of ICD Episodes

Rhythm	Subjects (n = 51)	Episodes (n = 237)
VT/VF	**40**	**106 (44.7%)**
Sustained (≥ 20 seconds)	5	15 (6.3%)
Non-sustained (< 20 seconds)	38	91 (38.4%)
Other Physiologic	**23**	**131 (55.3%)**
Atrial Fibrillation	4	50 (21.1%)
Atrial Flutter	0	0 (0%)
Paced Rhythm	0	0 (0%)
Sinus Rhythm	1	1 (0.4%)
SVT	18	80 (33.8%)
	0	**0 (0%)**

WCD Episodes Recorded as Ventricular Tachyarrhythmias

A total of 163 WCD episodes were recorded in 18 subjects (Table 7). Four (4) episodes (2.5%) in three subjects were adjudicated as Rhythm Type VT/VF. Six (6) episodes (3.7%) in a single subject were adjudicated as Atrial Flutter without artifact. The remaining 153 episodes (93.9%) in 24 subjects had noise artifact on the recorded electrogram and were adjudicated as Other Physiologic rhythms (74.2%) or Uncertain and presumed non-shockable (19.6%). Mean adjudicated heart rate for Other Physiologic rhythms was 92.2 bpm (50-172) and was Indeterminate for all Uncertain and presumed non-shockable rhythms. None of the episodes adjudicated as Other Physiologic or Uncertain and presumed non-shockable had corresponding ICD episodes.

Table 7 Summary of WCD Episodes by Adjudicated Rhythm

Rhythm	Subjects (n = 18)	Episodes (n = 163)
VT/VF	3	4 (2.5%)
Other rhythms with artifact	16	121 (74.2%)
Atrial Fibrillation	1	1 (0.6%)
Atrial Flutter	0	0 (0.0%)
Paced Rhythm	4	29 (17.8%)
Sinus Rhythm	11	85 (52.1%)

Table 7 Summary of WCD Episodes by Adjudicated Rhythm (Continued)

Rhythm	Subjects (n = 18)	Episodes (n = 163)
SVT	2	6 (3.7%)
Uncertain rhythm with artifact	7	32 (19.6%)
Atrial Flutter without artifact	1	6 (3.7%)

1.7.1.4 Safety and Effectiveness Results

Safety Results

The analysis of safety was based on the Intent to Treat cohort of 130 patients available for evaluation. The key safety outcomes for this study are presented below in Table 8 and Table 9. Adverse effects are reported in Table 10 on page 23.

The False Alarm Rate (primary endpoint) was 0.00075 per subject-day and the upper bound of the 95% confidence interval was 0.00361 per subject-day (Table 8), well below the pre-specified objective performance goal of 0.29 per subject-day (This comparator rate is based on reported false alarms in the LifeVest 4000 Operators Manual[1]). The null hypothesis associated with the primary endpoint was rejected. The observed False Positive Alarm rate per subject-day is equivalent to one False Positive Alarm every 1,333 days.

A total of four (4) WCD episodes were sustained long enough that a shock alarm event marker was recorded. One of these episodes was adjudicated as VT/VF and was therefore a True Positive Alarm and a True Positive Detection. The other three episodes, which occurred in two subjects (1.5%), were adjudicated as Other Physiologic rhythms with noise artifact, and were therefore False Positive Alarms.

Table 8 Results of Primary Endpoint Poisson Regression Analysis

Coefficient	Value	95% CI	t	p-Value
Intercept	0.00075	0.00015, 0.00361	-10.33	< 0.001

The Estimated Inappropriate Shock Rate (secondary endpoint) was based on the Intent-to-Treat cohort of 130 subjects. The incidence of inappropriate shocks is estimated to be 0.00017 per subject-day, or 0.00527 per subject-month (Table 9), based on a Missed Shock Alarm rate of 23.1% as pre-specified in the Statistical Analysis Plan. In the worst-case scenario, assuming either that all false positive alarms result in a shock if not diverted by a patient or the arrhythmia spontaneously terminated, the incidence of inappropriate shocks equals the False Positive Alarm rate (0.00075 per subject-day).

Table 9 Estimated Inappropriate Shock Rate

	Enrolled Subjects (n = 130)
Estimated Inappropriate Shock Rate (assuming 23.1% Missed Shock Alarm Rate)	0.00017 per subject-day 0.00527 per subject-month
Worst Case Estimated Inappropriate Shock Rate (assuming 100% Missed Shock Alarm Rate)	0.00075 per subject-day 0.02283 per subject-month

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

Adverse effects that occurred in the PMA clinical study:

Adverse Events (AE) determined to be at least possibly related to the device (secondary endpoint) were based on the Safety cohort of 129 subjects. A total of 55 AEs occurred in 44 subjects (34.1%). None of the AEs were determined to be Serious by the Medical Monitor and none were classified as Unanticipated Adverse Device Effects. A summary of AEs is presented in Table 10 on page 23. The average time to onset for skin-related AEs was 11.8 days and 14.7 days for musculoskeletal AEs. All adverse events were noted as either recovered/resolved (42 events) or recovering/resolving (13 events) at the end of study participation.

Table 10 Adverse Events by Severity

	Mild		Moderate		Severe	
	Events n	Subjects (N=129*) n (%)	Events n	Subjects (N=129*) n (%)	Events n	Subjects (N=129*) n (%)
All Adverse Events	**44**	**35 (27.1%)**	**10**	**10 (7.8%)**	**1**	**1 (0.8%)**
Skin-related	29	25 (19.4%)	7	7 (5.4%)	0	0 (0.0%)
Skin Infection (bacterial or yeast)	0	0 (0.0%)	2	2 (1.6%)	0	0 (0.0%)
Mild to moderate skin irritation	29	25 (19.4%)	5	5 (3.9%)	0	0 (0.0%)
Musculoskeletal-related	14	11 (8.5%)	2	2 (1.6%)	1	1 (0.8%)
Muscle Strain	4	4 (3.1%)	0	0 (0.0%)	0	0 (0.0%)
Bruising	3	3 (2.3%)	0	0 (0.0%)	0	0 (0.0%)
Other Musculoskeletal-related	7	5 (3.9%)	2	2 (1.6%)	1	1 (0.8%)
Other	1	1 (0.8%)	1	1 (0.8%)	0	0 (0.0%)
Fall	0	0 (0.0%)	1	1 (0.8%)	0	0 (0.0%)
Device hit ankle	1	1 (0.8%)	0	0 (0.0%)	0	0 (0.0%)

Effectiveness Results

The analysis of effectiveness of the ASSURE system was assessed by arrhythmia detection performance (True Positive Detections and Missed Events) and was based on the Intent-to-Treat Cohort of 130 evaluable patients at the 30-day time point. Of the 15 sustained (≥ 20 seconds) VT/VF episodes detected by the ICD, four were also detected by the WCD (True Positive Detections). There were no Missed Events.

The four True Positive Detections occurred in three subjects and were all adjudicated as VT/VF with heart rates above the WCD nominal VT threshold of 170bpm. The ASSURE system did not detect any of the remaining 11 episodes because either the rate of the arrhythmia was below the nominal VT threshold of 170 bpm or the ASSURE system was not being worn.

Subgroup Analyses

Subgroup analysis was not feasible due to the low incidence of False Positive Alarms.

Pediatric Extrapolation

Existing clinical data was not leveraged to support approval of a pediatric patient population.

1.7.2 Pivotal U.S. Clinical Study: ACE-CONVERT

1.7.2.1 Study Design

Patients were enrolled between November 25, 2019 and March 3, 2019. The database for this PMA reflected data collected through March 3, 2019 and included 13 patients enrolled at two investigational sites in the U.S.

The study was a prospective, non-randomized, single arm, multi-center open label study in patients undergoing any of the medically necessary electrophysiology procedures in Inclusion Criterion 3.

After consent, subjects had two pairs of commercially available disposable adhesive defibrillation pads applied. One pair was placed in defined locations and used to deliver the ASSURE defibrillation waveform using a Test System. The other pair was located on the subject's torso according to physician preference and was attached to a commercially available external defibrillator for backup rescue defibrillation. Commercially available ECG monitoring electrodes were positioned as needed. The ASSURE Monitor was configured to Manual Shock mode, which allowed the experimental shock to be delivered on command of the physician Investigator.

A single sustained episode of rapid VT or VF was induced during an electrophysiologic study from a catheter or an implanted defibrillator. If the Arrhythmia was > 150bpm, then a 170J shock was delivered from the Test System to convert the arrhythmia. A second shock at 170J was delivered from the Test System if the first shock was unsuccessful. Further rescue shocks could be delivered via an internal or external defibrillator at the Investigator's discretion

An independent Medical Monitor reviewed all AEs. The Medical Monitor had no financial, scientific, or other conflict of interest with the study.

Clinical Inclusion and Exclusion Criteria

Enrollment in the ACE-CONVERT study was limited to patients who met the following inclusion criteria:

- Males or females, age ≥ 18 years
- Able and willing to provide written informed consent before undergoing any study-related procedures
- Scheduled for any of the following procedures:
  - Electrophysiology study for induction of ventricular arrhythmias
  - Non-invasive electrophysiology testing using an existing implantable defibrillator
  - ICD replacement procedure during which induction of a ventricular arrhythmia is planned
  - Ablation of ventricular tachycardia (patients undergoing ventricular tachycardia ablation in which ONLY a substrate modification approach is planned, with no intention of inducing a ventricular arrhythmia, should not be included)

Patients were not permitted to enroll in the ACE-CONVERT study if they met any of the following exclusion criteria:

- Any condition that by the judgement of the physician investigator precludes the subject's ability to comply with the study requirements
- Pregnancy
- Use of mechanical circulatory support (e.g. LVAD, Total Artificial Heart, intra-aortic balloon pump or Impella)
- Documented nonchronic cardiac thrombus
- Atrial fibrillation or atrial flutter without therapeutic systemic anticoagulation
- Critical aortic stenosis
- Unstable coronary artery disease (CAD)
- Recent stroke or transient ischemic attack (TIA)
- Hemodynamic instability
- Currently implanted Boston Scientific S-ICD (due to location of implant relative to test system)
- Unstable angina
- New York Heart Association (NYHA) Class IV

- Left Ventricular Ejection Fraction (LVEF) < 20%
- Any medical condition that by the judgement of the physician investigator, patient participation in this study is not in the best interest of the patient
- History of difficulty of ventricular arrhythmia induction
- Amiodarone use within 3 months before the study procedure

Follow-up Schedule

Individual subject participation was during acute intra-procedural testing only.

Adverse events that persisted at the time of the subject's study exit were followed by the investigator until the event was resolved or otherwise explained.

Clinical Endpoints

Primary Effectiveness Endpoint

The primary endpoint analysis was based on the Per Protocol cohort. The primary endpoint was calculated as the ratio of the number of subjects with successful (first or second shock) arrhythmia conversion using the Test System to the number of total inductions attempted with shocks delivered by the Test System in the respective data set. A successful arrhythmia conversion was defined as termination of an induced ventricular rhythm (>150 bpm) by first or second shock from the Test System to a non-shockable rhythm (rhythms other than VT or VF). Performance criteria were based on comparison to the published conversion effectiveness point estimate of 94% reported for a commercially available WCD.

Secondary Effectiveness Endpoint

The secondary endpoint analysis was exploratory and did not have pre-specified performance criteria. Data was summarized for both the Intention-to-Treat and Per-Protocol cohorts.

Safety Endpoint

Safety was analyzed based on the Intention-to-Treat cohort. The assessment of safety was based on the summary of AEs, vital signs, physical examination findings, and ECGs. The Medical Monitor's assessment of seriousness and relatedness was used for summarizing and analyzing safety data. The Medical monitor also evaluated AEs to determine if they were Unanticipated Adverse Device Effects. Separate summaries of AEs related to use of the Test System and by severity were prepared. Continuous variables were summarized by descriptive statistics, and categorical variables were summarized using the count and percentage of subjects in each category.

1.7.2.2 Accountability of PMA Cohort

At the time of database lock, a total of 13 patients enrolled in the PMA study, 100% (13) patients were available for analysis at the completion of the study, the medically necessary electrophysiology procedure. The disposition of all study subjects is summarized in the figure below.

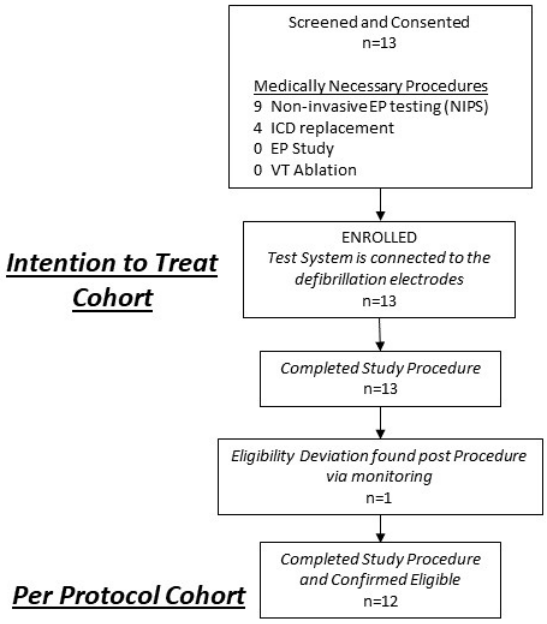

Figure 3: Study Cohort

1.7.2.3 Study Population Demographics and Baseline Parameters

The demographics of the study population are typical for patients at high risk of sudden cardiac arrest and undergoing noninvasive programmed stimulation (NIPS) or ICD pulse generator replacement in the U.S. (Table 11).

ACE-CONVERT subjects had differing primary etiologies of cardiovascular disease including ischemic (2), non-ischemic (3), mixed ischemic/nonischemic (1), congenital (3), sarcoidosis (3) and long QT syndrome (1). The mean left ventricular ejection fraction (LVEF) was 46.8% ranging from 24% to 62%, and all but one had a history of heart failure (New York Heart Association class I to III). All 13 subjects had comorbidities including heart failure (11), hypertension (9), coronary artery disease (7), hyperlipidemia (7), diabetes (4), COPD (4), and kidney disease (2). Three subjects were current smokers (Table 12 on page 28).

Most study subjects were on guideline-directed heart failure medical therapy, including angiotensin-converting enzyme (ACE) inhibitors (5), angiotensin II receptor blocker (3) or sacubitril-valsartan (Entresto) (2), beta blockers (11), and aldosterone antagonists (4). None of the subjects was taking antiarrhythmic drugs (Table 13 on page 30).

The mean BMI in this study population was 31.5 (range 23.7–46.1). Most subjects were obese (53.8%) or overweight (38.5%) as shown in the figure after the tables.

Table 11 Baseline Demographic Characteristics

Baselines Characteristics	Enrolled Subjects N = 13
Age (years)	
N	13
Mean ± SD	55.3 ± 11.3
Median	57
IQR	15
Min, Max	37, 71
Sex	
Male	7 (53.8%)
Female	6 (46.2%)
Race (not mutually exclusive)	
American Indian or Alaska Native	0 (0.0%)
Asian	0 (0.0%)
Black or African American	3 (23.1%)
Native Hawaiian or Other Pacific Islander	0 (0.0%)
White	10 (76.9%)
Other	0 (0.0%)
Not Reported	0 (0.0%)
Ethnicity	
Hispanic or Latino	0 (0.0%)
Not Hispanic or Latino	13 (100.0%)
Unknown or Not Reported	0 (0.0%)

Table 12 Cardiovascular and Other Medical History

Medical History	Enrolled Subjects N = 13
Etiology of Cardiovascular Disease (Primary)	
Ischemic	2 (15.4%)
Nonischemic (not primarily valvular)	3 (23.1%)
Mixed ischemic/nonischemic	1 (7.7%)
Primary valvular	0 (0.0%)
Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC)	0 (0.0%)
Hypertrophic Cardiomyopathy	0 (0.0%)
Congenital	3 (23.1%)
Sarcoidosis	3 (23.1%)
Other	1 (7.7%)
NYHA Classification	
I	1 (7.7%)
II	7 (53.8%)
III	3 (23.1%)
IV	0 (0.0%)
Unknown	0 (0.0%)
LVEF (%)	
N	13
Mean ± SD	47.1 ± 11.9
Median	49
IQR	1918
Min, Max	24.0, 62.0
Method of LVEF Determination	
Echocardiogram	10 (76.9%)
Nuclear, including SPECT and cMR	3 (23.1%)
Left Ventricular Angiography	0 (0.0%)
Other	0 (0.0%)

Table 12 Cardiovascular and Other Medical History (Continued)

Medical History	Enrolled Subjects N = 13
Right Ventricular Function	
Normal	8 (61.5%)
Mildly reduced	1 (7.7%)
Moderately reduced	2 (15.4%)
Severely reduced	2 (15.4%)
Medical History (not mutually exclusive)	
Coronary Artery Disease	7 (53.8%)
Prior Myocardial Infarction (MI)	3 (23.1%)
Prior Coronary Artery Bypass Graft (CABG)	1 (7.7%)
Prior Percutaneous Coronary Intervention (PCI)	3 (23.1%)
Heart Failure	11 (84.6%)
Diabetes	4 (30.8%)
Type I	0 (0.0%)
Type II	4 (30.8%)
Hypertension	9 (69.2%)
Hyperlipidemia	7 (53.8%)
Prior Stroke/TIA	1 (7.7%)
Chronic Obstructive Pulmonary Disease (COPD)	4 (30.8%)
Chronic Kidney Disease	2 (15.4%)
End Stage Renal Disease	0 (0.0%)
Dialysis Dependent	0 (0.0%)
Current Smoker	3 (23.1%)

Table 13 Baseline Medications

Baselines Medications	Enrolled Subjects N = 13
ACE Inhibitors	5 (38.5%)
Beta Blockers	11 (84.6%)
Angiostensin II Receptor Blocker (ARB)	3 (23.1%)
Aldosterone Antagonist	4 (30.8%)
Combination Drug (Sacubitril-Valsartan)	2 (15.4%)
Digoxin	1 (7.7%)
Antiarrhythmic Drugs	0 (0.0%)

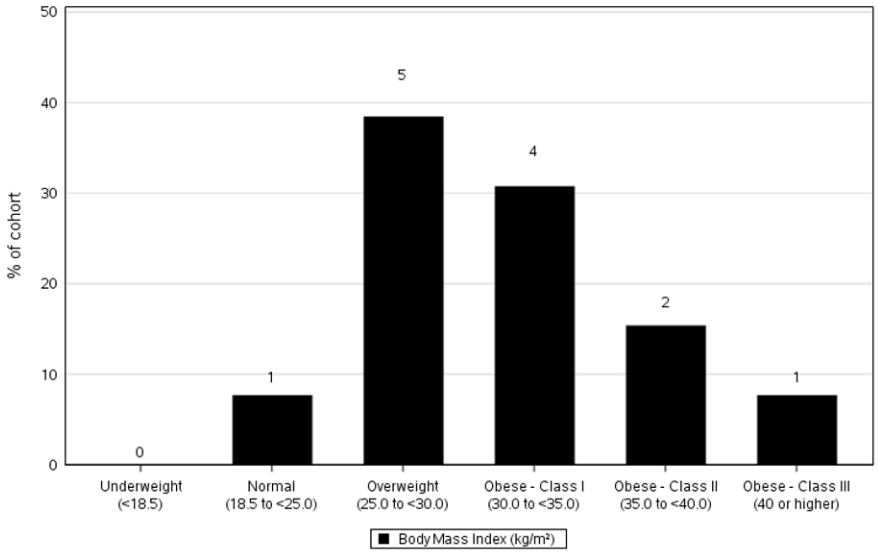

Figure 4: Body Habitus

1.7.2.4 Safety and Effectiveness Results

Safety Results

The analysis of safety was based on the Intent to Treat cohort of 13 patients available for evaluation. The key safety outcomes for this study are presented as a summary of Adverse Events (AE).

A total of three AEs occurred in three subjects (23.1%). All three were mild irritation to the skin under the adhesive defibrillation pads. None were determined to be Serious by the Medical Monitor nor were any classified as Unanticipated Adverse Device Effects. The AEs were noted as either recovered/resolved (2) or recovering/resolving (1) at the end of study participation.

Table 14 Adverse Events

AE ID	AE Description	Serious	Severity	Time from Enrollments to Event Onset (days)	Description
1	Skin irritation	No	Mild	0	Skin irritation on back, left side, square patch mark, noticed the following day after the procedure.
2	Redness of skin	No	Mild	1	Faint red outline at the edge of anterior and posterior patch
3	Skin irritation	No	Mild	1	Subject developed skin irritation and redness where the patches were placed for the defibrillation threshold test.

Effectiveness Results

The analysis of primary effectiveness endpoint using both the Intention-to-Treat cohort (13 subjects) and Per-Protocol cohort (12 subjects) was met. Key effectiveness outcomes are presented in Table 15. The cumulative first and second shock VT/VF conversion effectiveness was 100% exceeding the performance criteria point estimate of 94% (Table 8 on page 22). For the Per Protocol cohort, the lower bound of the 95% confidence interval was 73.5%.

The secondary endpoint, first shock VT/VF conversion effectiveness, was 83.3% and 84.6% determined using the Per Protocol and Intention to Treat cohorts respectively.

Table 15 ASSURE Defibrillation Waveform Conversion Effectiveness

	Per Protocol Analysis Population (n = 12)	Intention-to-Treat Analysis Population (n = 13)
Primary Effectiveness Endpoint: Cumulative first and second shock VT/VF conversion effectiveness	12 out of 12 100.0% (73.5%, 100.0%)	13 out of 13 100.0% (75.3%, 100.0%)
Secondary Effectiveness Endpoint: First shock VT/VF conversion effectiveness	10 out of 12 83.3% (51.6%, 97.9%)	11 out of 13 84.6% (54.6%, 98.1%)

Subgroup Analyses

No subgroup analyses were planned or performed.

1.8 Animal Studies

Kestra performed a series of pre-clinical studies to test the safety and effectiveness of the ASSURE WCD shock waveform. Swine were used as the animal model for these studies because their thoracic anatomy, coronary arteries, and thoracic impedance are similar to humans and they have been used in numerous other defibrillation studies. Animal care complied with the Guide for Animal Care and Use of Laboratory Animals (NIH), the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the USDA Animal Welfare Act and Regulations, and IACUC Standard Operating Procedures and the facility animal care program.

The ASSURE waveform was developed and tested through nine pre-clinical studies, seven specifically evaluating effectiveness and two evaluating safety. The following table provides a chronological listing of the seven effectiveness studies. Initial studies (studies 1–5) with prototype waveforms facilitated selection of the final pulse widths and energy. Studies 6 and 7 were statistical studies to evaluate the final ASSURE waveform. Study 6 tested the waveform shape at three different impedance levels using an energy level near the estimated 50% defibrillation threshold. Study 7 tested the waveform at full energy. Two additional studies were performed to establish waveform safety.

1.8.1 Effectiveness Study Descriptions

The objective of the Reduced Energy Effectiveness Study was to provide scientifically rigorous evidence that the ASSURE defibrillation waveform was non-inferior to a commercially available WCD waveform at three impedances. Shock success rates were compared at reduced energy levels (~50% probability of success). Over 2,100 shocks were delivered to 36 pigs. This study showed with 95% confidence that the ASSURE system shock success rate is non-inferior to a commercially available WCD's shock success rate at the 50-, 85- and 125-ohm impedance levels.

Effectiveness Study 1: Original Pilot Study

Background: This study compared the effectiveness of two prototype ASSURE waveforms with the V waveform. The purpose of this study was to compare the effectiveness of the prototype ASSURE shock waveforms to the V shock waveform in swine.

Methods: A programmable waveform generator was used to generate attenuated shock waveforms that simulated the waveshape that was delivered into 25Ω, 50Ω, and 100Ω. Shock success rates were recorded for each waveform at each impedance level in ten swine. The tested prototype waveforms were considered non-inferior to V waveform at a given impedance if the lower 95% confidence bound for the difference in success rate (i.e., ASSURE waveform - V) was greater than -10%.

Results: The prototype ASSURE waveforms were non-inferior to the V shock waveform at all three impedances. Prototype ASSURE2 success rates were numerically greater than prototype ASSURE1 but the difference was not statistically significant.

Conclusions: The prototype ASSURE2 shock waveform was chosen for further study.

Effectiveness Study 2: Non-inferiority Study with prototype ASSURE Waveform

Background: The Original Pilot Study provided evidence that the prototype ASSURE2 waveform was non-inferior to the V waveform when the shocks were generated with a programmable waveform generator. This second effectiveness study sought to compare the prototype ASSURE2 shock success rate to the V shock success rate at 50Ω, 85Ω, and 125Ω using an ASSURE prototype system.

Methods: Prototype ASSURE shock waveforms were attenuated to achieve approximately 50% success rate and the V shock waveforms were attenuated by the same percentage. The prototype ASSURE2 waveform was considered non-inferior to V at a given impedance if the lower 95% confidence bound for the difference in success rate (i.e., ASSURE waveform - V) was greater than -10%. Thirty-six swine were planned for this study.

Results: The study was terminated after 20 swine because the ASSURE2 waveform was unlikely to meet non-inferiority objectives.

Conclusions: The prototype ASSURE2 waveform effectiveness was lower than V at all three impedance levels, especially at 125Ω. Further investigation was undertaken to improve the performance of the prototype ASSURE shock waveform.

Effectiveness Study 3: WOW 125 Ohm Study

The WOW 125 Ohm Study compared the Walcott Optimized Waveform (WOW) to the prototype ASSURE2 waveform at 125Ω. This informal study used six animals, a sample size that had previously been adequate to provide meaningful results. The results indicated that the Walcott Optimized Waveform was about 10% more effective than the original prototype ASSURE2 waveform at 125Ω.

Effectiveness Study 4: WOW 50 Ohm Study

The WOW 50 Ohm Study compared the effectiveness of the Walcott Optimized Waveform at two different charge voltages to V at 50Ω. The results from this study indicated that the WOW waveform was slightly less effective than the ASSURE2 waveform at the same charge voltage at 50Ω. If the charge voltage was increased slightly, the WOW waveform was about equivalent to the ASSURE2 waveform. These results led to the development of a 'blended' waveform - a shock waveform that used the ASSURE2 waveform below 85Ω and used the WOW waveform above 85Ω.

Effectiveness Study 5: Blended Pilot Study

The Blended Pilot Study tested the Final ASSURE Waveform (the blended waveform with slightly higher charge voltage resulting in 170J) at 50Ω and 125Ω. The purpose of this final study was to gather data for sample size estimation before initiation of a formal non-inferiority study. Nine swine were tested at 50Ω and six swine at 125Ω. The results from this study suggested that this Final ASSURE Waveform was more effective than any of the previous shock waveforms.

Effectiveness Study 6: Non-inferiority Study with Attenuated Energy

Background: This study sought to provide scientifically rigorous evidence that the Final ASSURE Waveform was non-inferior to the V waveform at three impedances (50, 85, and 125Ω).

Methods: Thirty-six pigs were shocked with the Final ASSURE Waveform and the V waveform at three impedances ASSURE shock waveforms were attenuated to achieve approximately 50% success rate and V shock waveforms were attenuated by the same percentage. The ASSURE waveform was considered non-inferior to the V waveform at a given impedance if the lower 95% confidence bound for the difference in success rate (i.e., ASSURE waveform - V) was greater than -10%.

Results: A total of 2,160 ventricular fibrillation (VF) inductions were performed in 36 swine.

Table 16 Percent Difference in Success Rate (ASSURE Waveform – V)

	% Success ASSURE Waveform	% Success V Waveform	Difference
50 ohms	56%	55%	1%
85 ohms	53%	46%	7%
125 ohms	53%	41%	12%

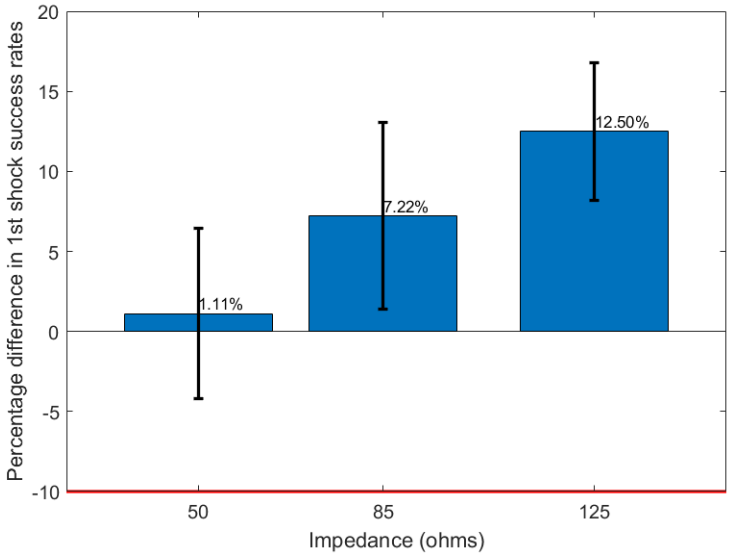

Figure 5: Differences in Success Rate (ASSURE-V)

Conclusions: This study demonstrated that an attenuated ASSURE shock waveform was non-inferior to an equally-attenuated V shock waveform.

Effectiveness Study 7: Full Energy Effectiveness Study

Background: While previous studies compared shock waveforms at reduced energy levels, the Full-Energy Effectiveness Study compared the Final ASSURE waveform at 170J to the V waveform at 150J. The goal of the study was to demonstrate that the ASSURE waveform was non-inferior to the V waveform at clinically relevant energy levels.

Methods: Six pigs 27–33 kg were induced into VF and shocked with either a 170J ASSURE waveform or 150J V waveform Ten shocks with each waveform were given to each pig. The ASSURE waveform was considered non-inferior to V at a given impedance if the lower 95% confidence bound for the difference in success rate (i.e., ASSURE waveform - V) was greater than -10%.

Results: All shocks succeeded, giving 100% shock success rate for each device. Because there were no shock failures for either waveform the difference in success rates was zero. The lower 95% confidence interval of the difference was zero, which met the definition of non-inferiority.

Conclusions: This study demonstrated that a full-energy ASSURE shock waveform is non-inferior to a full-energy V shock waveform.

1.8.2 Safety Studies

The objective of the Full Energy Effectiveness Study was to demonstrate that the ASSURE defibrillation waveform was non-inferior to a commercially available WCD waveform at clinically relevant energy levels. Shock success rates were compared at full energy (ASSURE system at 170J versus commercially available WCD at 150J). Ten shocks with each waveform were given to each of six pigs. All shocks delivered using both waveforms were successful, giving 100% first shock effectiveness for both waveforms and demonstrating that the ASSURE defibrillation waveform was non-inferior to a commercially available WCD waveform at full energy.

Safety Study 1

Background: The study aimed to show that the ASSURE WCD shock waveform did not cause more injury than another commercially available external defibrillator.

Methods: Eight 62–76 kg swine were split into two groups of four. One group was shocked with five 170J ASSURE WCD shocks, while the other group was shocked with five 200J external defibrillator shocks. All shocks were delivered synchronously into a normal sinus rhythm. Pre- and post-shock values of Troponin I, CPK, CK-MM, and CK-MB were compared to look for signs of injury. Pre- and post-shock ECG recordings were also compared. Post-shock blood draws and ECG recordings were taken at 6 hours and 24 hours. In addition, tissue samples were evaluated for injury at the macro and microscopic level by a board-certified pathologist. Tissue injury was evaluated on a scale of 0–3, where 0 is normal and 3 represents significant injury. An injury score difference (ASSURE WCD minus external defibrillator) of 0.4 or greater was considered significant.

Results: None of the blood tests demonstrated a significant difference between the two devices.

Table 17 Troponin I Results (mean ± std dev)

	ASSURE WCD	External Defibrillator	P-Value	Pass/Fail
6-hour delta	0.7275 ± 0.97	0.2725 ± 0.40	0.4522	Pass
24-hour delta	0.0875 ± 0.15	0.0750 ± 0.11	0.8893	Pass

Table 18 CK-MM Results (mean ± std dev)

CK-MM Results (mean ± std dev)				
	ASSURE WCD	External Defibrillator	P-Value	Pass/Fail
6-hour delta	40800 ± 15500	23200 ± 32000	0.1178	Pass
24-hour delta	35500 ± 7900	10500 ± 6200	0.2678	Pass

The histology results showed that the difference in injury scores were below the predetermined threshold of 0.4 in all tissue samples.

Table 19 Histology Injury Results (mean ± std dev)

Tissue Section	ASSURE WCD Average	External Defibrillator Average	Difference	Pass/Fail
Myocardium	0.75 ± 0.5	0.50 ± 0.6	0.25	Pass
Lung	0.0 ± 0	0.5 ± 0	-0.5	Pass

Table 19 Histology Injury Results (mean ± std dev)

Tissue Section	ASSURE WCD Average	External Defibrillator Average	Difference	Pass/Fail
Skin and Skeletal Muscle	1.5 ± 0.5	1.5 ± 0.6	0.0	Pass

The ECG evaluation showed that although transient post-shock ECG changes were observed in both groups, no significant changes persisted at the one-hour mark or six-hour mark post-shock. Overall, there were no significant differences between the two groups.

Conclusions: The ASSURE WCD shocks did not cause significantly more injury than the External Defibrillator shocks in this study.

Safety Study 2: V and 360J External Defibrillator Safety Study

Background: While Safety Study 1 found no significant difference in the mean values of the ASSURE WCD and an external defibrillator, there were outliers in the ASSURE WCD's CPK results. This study sought to explain these outliers by gathering additional data under more controlled conditions.

Methods: Fourteen swine (38–52 kg) were split into four groups. The 170J ASSURE WCD group (N=5), the 150J V group (N=5), and the 360J external defibrillator group (N=3) all received five synchronous shocks in normal sinus rhythm with the corresponding defibrillator. The final group was a sham animal (N=1) to explore the effect of the test procedure on CPK values. Pre- and post-shock values of Troponin I, CPK, CK-MM, and creatinine were compared to look for signs of injury. Post-shock blood draws were taken at 1 hour, 6 hours, and 24 hours. Pre-shock ECG recordings were compared to those taken at 1 hour and 6 hours.

Results: No significant ($p<.05$) differences between the ASSURE WCD and V in Troponin I, CPK, CK-MM, and creatinine were found. Statistically significantly differences between the ASSURE WCD and the external defibrillator were found in Troponin I, CPK, and CK-MM.

Table 20 Troponin I Results (mean ± std dev)

	ASSURE WCD	V Waveform	P-Value	External Defibrillator	P-Value
1-hour delta	0.00 ± 0.01	-0.01 ± 0.01	0.51	0.03 ± 0.03	0.07
6-hour delta	0.12 ± 0.04	0.05 ± 0.06	0.06	0.46 ± 0.23	0.01
24-hour delta	0.08 ± 0.05	0.05 ± 0.04	0.27	0.29 ± 0.35	0.27

Table 21 CK-MM Results (mean ± std dev)

	ASSURE WCD	V Waveform	P-Value	External Defibrillator	P-Value
1-hour delta	1,134 ± 1,401	321 ± 147	0.23	1,532 ± 385	0.66
6-hour delta	7,508 ± 3,417	7,108 ± 5,242	0.85	13,181 ± 623	0.03
24-hour delta	14,745 ± 7,932	20,888 ± 15,698	0.45	32,860 ± 10,203	0.03

Table 22 Creatinine Results (mean ± std dev)

	ASSURE WCD	V Waveform	P-Value	External Defibrillator	P-Value
1-hour delta	0.14 ± 0.25	0.06 ± 0.11	0.57	0.10 ± 0.10	0.68
6-hour delta	0.23 ± 0.13	0.20 ± 0.19	0.13	0.53 ± 0.59	0.92
24-hour delta	0.32 ± 0.34	0.04 ± 0.21	0.15	0.23 ± 0.12	0.67

The sham animal showed no increase in Troponin I and a small increase in CPK and CK-MM, as well as a creatinine change that was comparable to the shocked animals.

Conclusions: This study found no significant differences in injury markers for swine shocked with the ASSURE WCD versus V. The ASSURE WCD shocks caused less injury than the 360J external defibrillator shocks.

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2. Device Description

This section provides a description of the ASSURE system and its components.

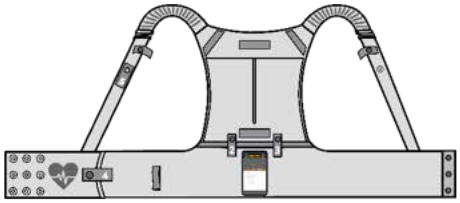
2.1 System Components

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

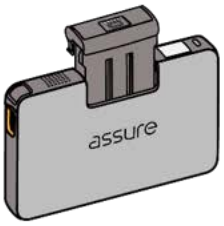
- Garment (2)
- Monitor
- Batteries (2)
- Therapy Cable
- Carry Pack
- Charger

ASSURE System

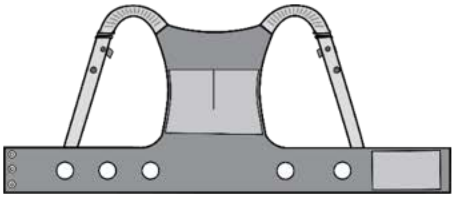
Garment Exterior



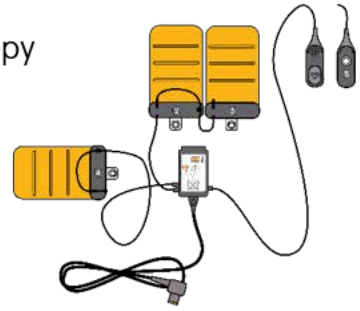
Monitor and Battery



Garment Interior



Therapy Cable



Accessories to the ASSURE System

Charger

Carry Pack

2.1.1 Garment

The Garment includes integrated ECG Sensors, pockets to hold the Therapy Pads, and a snap to attach the Alert Button. The Garment is designed to position the ECG Sensors and the Therapy Pads in the appropriate locations against the patient's skin, and it is intended to be worn continuously, except while bathing or swimming.

The Garment is available in two styles and a range of sizes. The patient is fitted with the appropriate size Garment based on their underbust measurement. Adjustable straps and front closure snaps provide the ability to optimize fit and provide stable contact for the ECG Sensors and Therapy Pads.

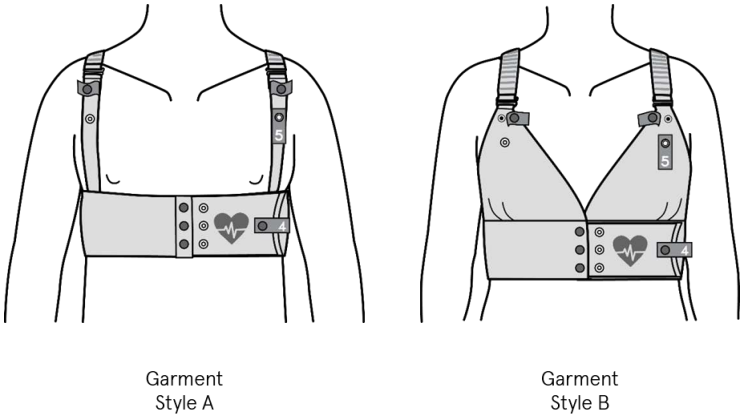


Figure 6: Garment Styles A and B

The Garment includes pockets for the front and back Therapy Pads. These pockets enable proper placement and containment of the Therapy Pads. The inside of the Therapy Pad pockets in contact with the skin consist of a conductive mesh fabric that allows for:

- Monitoring of the contact status of the Therapy Pads against the patient's skin
- Gel dispersion from the Therapy Pads to the patient’s skin in preparation for shock delivery
- Electrical current conduction from the Therapy Pads to the patient upon delivery of a therapeutic shock

2.1.2 Therapy Cable

The Therapy Cable connects the Garment to the Monitor. It consists of the following:

- Alert Button (A) - Provides tones, voice prompts, and vibratory alerts when determined appropriate by the Monitor. The patient can press the Alert Button to check system status or provide input when requested by the ASSURE system, including diverting therapy delivery.
- Hub (B) - The central piece of the Therapy Cable that connects the Therapy Pads, Alert Button, and cable.
- Therapy Pads (C) - Three (3) yellow defibrillation pads that are inserted into the pockets in the front and back of the Garment. The Therapy Pads contain a small quantity of electrolyte gel that is released in preparation for shock delivery.
- Cable (D) - Connects the Hub to the Monitor. The Plug at the end of the cable inserts into the Monitor.

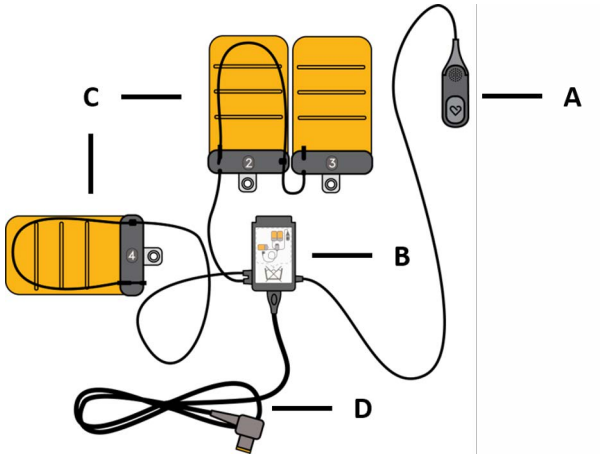


Figure 7: Therapy Cable

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

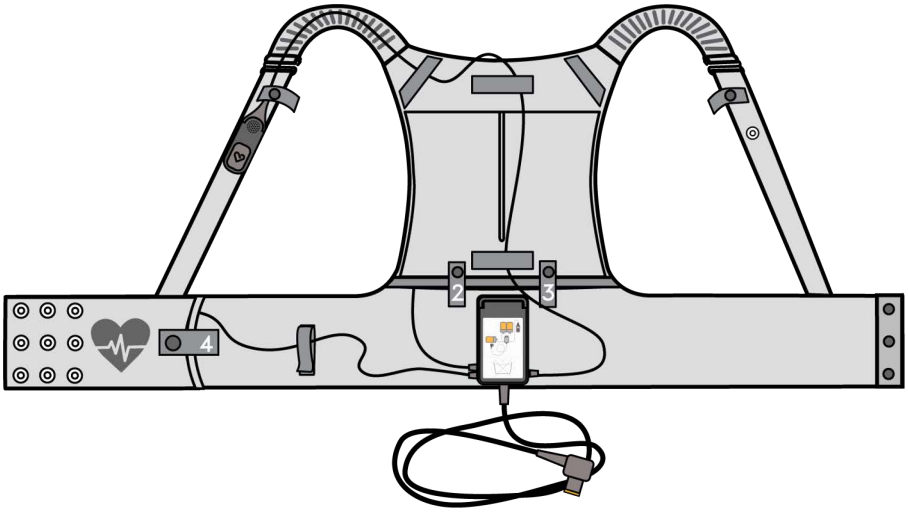


Figure 8: Garment Style A with Therapy Cable

The Alert Button provides system feedback and a patient-actuated user interface for the ASSURE system. 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).

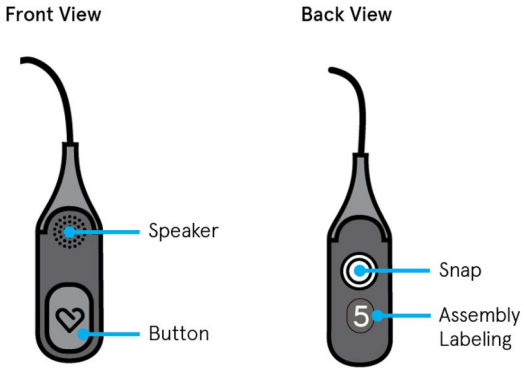


Figure 9: Location of the Speaker, Button, Snap, and Assembly Labeling on the Alert Button

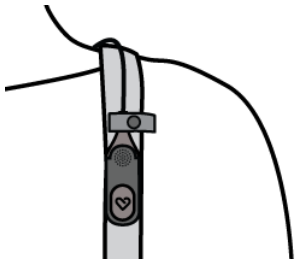


Figure 10: Alert Button Location on the Shoulder Strap of an Assembled ASSURE System

The Hub is the central part of the Therapy Cable and is the interface between the Monitor and the Garment. The Hub is inserted in the Hub Receptacle of the Garment and snapped into place by the patient.

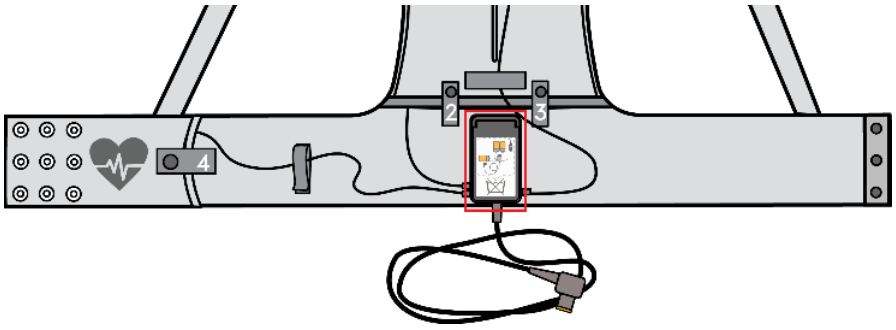


Figure 11: Hub Location in an Assembled Garment

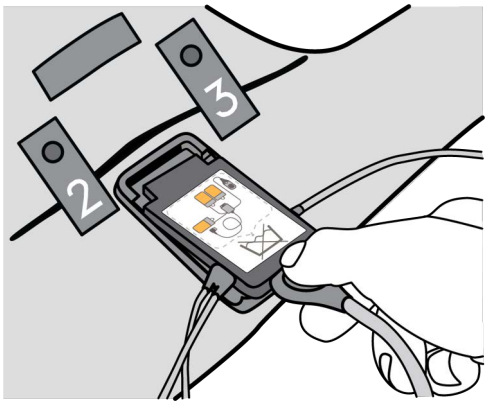
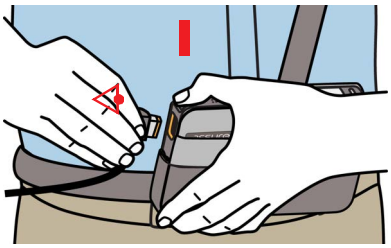


Figure 12: Inserting the Hub into the Hub Receptacle

The Therapy Cable's Plug connects the cable to the Monitor via the Plug release button, which is intended to prevent inadvertent disconnection of the Therapy Cable from the Monitor. To disconnect the Plug, the patient must push the release button while simultaneously pulling the Plug out of the Monitor.

Plug Connected to the Monitor



Actuation of the Release Button to Remove the Plug

Figure 13: Plug Connection to the Monitor

2.1.3 Battery

The Battery is a rechargeable power source that is inserted into the Monitor. Two Batteries are provided to the patient so one Battery can charge while the other battery is in use. When fully charged, the Battery can power the ASSURE system for at least 24 hours while providing a minimum of 25 full-energy shocks.

When Battery power is depleted, the patient removes the Battery from the Monitor and replaces it with the fully charged Battery from the Charger. The Battery is keyed to insert into the Monitor in one direction only.

The Battery includes a locking mechanism to prevent inadvertent or accidental removal. To remove the Battery from the Monitor, slide the lock until the yellow line is visible and lift up the Battery handle at the same time.

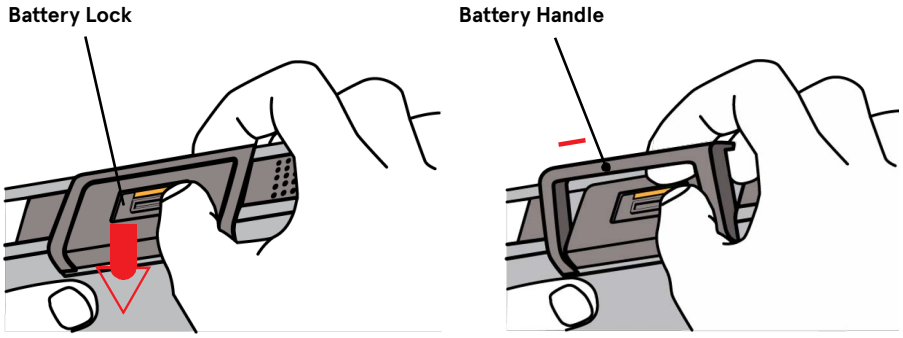


Figure 14: Battery Removal from Monitor

2.1.4 Monitor

The Monitor is the primary electronic component of the ASSURE system that controls overall system operation. It houses the capacitor for therapy delivery, provides system power using the rechargeable Battery, and includes a speaker for auditory tones and voice messages, a liquid crystal display (LCD) for graphical information, and a multicolored LED for system status information.

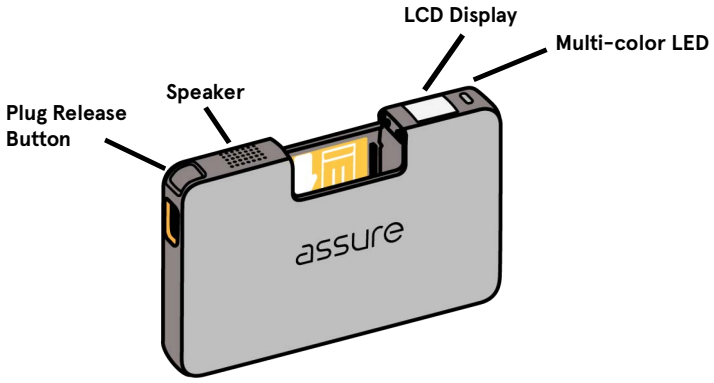


Figure 15: Monitor

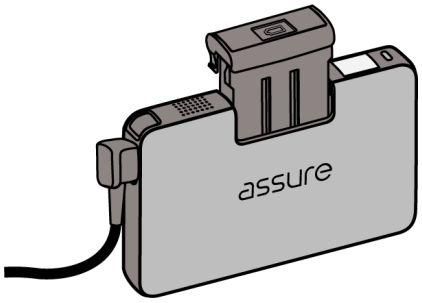


Figure 16: Monitor with Battery

2.1.5 Carry Pack

The Carry Pack is designed to hold the Monitor and provides a method of carrying the Monitor while the ASSURE system is being worn.

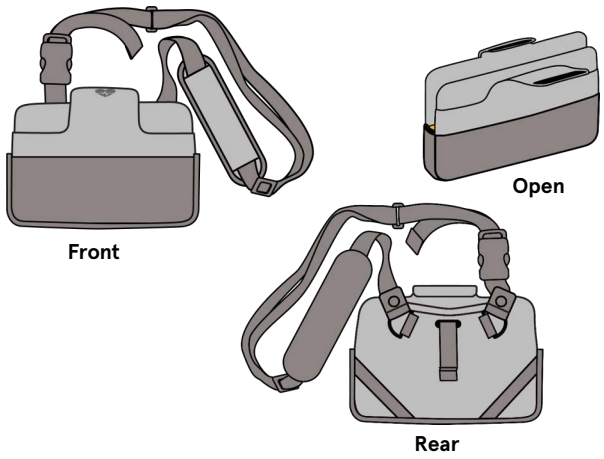


Figure 17: Carry Pack

2.1.6 Charger

The Charger is provided to the patient to use at home for Battery charging. This accessory is intended to be plugged into the home AC wall outlet. The Charger has a monochromatic LCD display to provide status of the Battery charge (0-100%) as well as indication for Battery and Charger conditions.

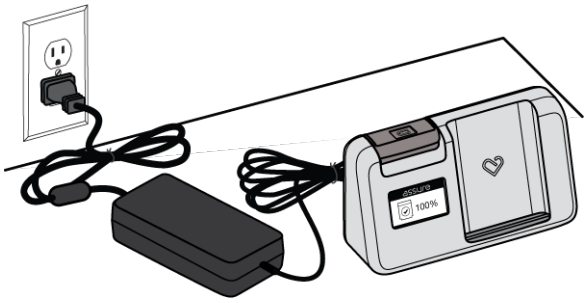


Figure 18: Charger for Monitor Battery

2.2 Tablet (Programming Tool)

The Kestra patient service representative (PSR), an agent of Kestra Medical Technologies who has received training on the use of the ASSURE system, uses the Tablet to program the ASSURE system for patient use. After establishing a wireless connection with the ASSURE Monitor, the PSR can use the Tablet to assess proper functionality of the ASSURE system, program the ASSURE system according to the patient's prescription, and assess fit of the ASSURE system prior to dispensing it to the patient. The Tablet may also be used during the prescription for follow-up visits to confirm current system settings and status.

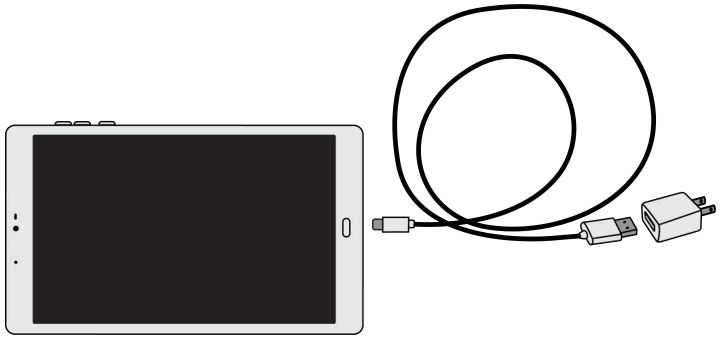


Figure 19: Tablet and Accessories

2.2.1 Programming Parameters

The physician can prescribe specific VT and VF ranges for the patient.

- The VT rate range is 130 to (VF rate - 10) bpm in 10 bpm intervals. The default setting is 170 bpm.
- The VF rate range is 180 to 220 BPM in 10 bpm intervals. The default setting is 200 bpm.

Therapy is always enabled in the VF zone. Therapy in the VT zone is programmable [Treat (default) or Monitor].

Note: The VF Rate Threshold value must be higher than the VT Rate Threshold value.

2.3 System Operation

The ASSURE system is a microprocessor-based wearable AED designed to analyze an electrocardiogram (ECG) and automatically deliver therapy, in the form of a defibrillation shock. If the ASSURE system detects life-threatening ventricular tachyarrhythmias, specifically, ventricular tachycardia (VT) or ventricular fibrillation (VF) above a programmable heart rate threshold, it can deliver a defibrillation shock to the heart to restore an effective rhythm without further interaction from the patient or bystander.

The ASSURE system communicates its status to the patient through voice messages, display icons and LEDs, audio tones, and vibration. When the device detects an arrhythmia, it issues a voice prompt notifying the patient that they are about to receive a shock. This provides the patient the opportunity to avoid receiving a shock while conscious by pressing the Alert Button.

The ASSURE system automatically delivers a defibrillation shock, unless a conscious patient diverts the shock by pressing the Alert Button. The ASSURE system can deliver up to five shocks during an arrhythmic episode. The heart rate threshold above which an arrhythmia is detected and treated is set using the Tablet per the physician prescription during the device fitting by a PSR. The ASSURE system stores information for detected rhythms in the form of discrete episodes and collects other patient information. All stored data can be retrieved from the Monitor over a wireless link for transmission to a remote data management server.

2.4 Accompanying Material

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

- *ASSURE Wearable Defibrillator Quick Start Guide*
- *ASSURE Wearable Defibrillator Patient Handbook* (complete instructions on assembly, wearing, and maintaining the system)
- Patient Information card (emergency instructions and contact information)
- Patient training video (available on the Kestra website at kestramedical.com/patients)

3. Detection and Therapy

This section provides information on the ASSURE system's detection and defibrillation specifications.

3.1 Sensing Configuration

The ASSURE system uses integrated electrodes in the Garment for superior ECG signal acquisition. The electrodes are distributed around the patient's torso on level with the subxyphoid process. The ASSURE system collects four channels of ECG signals with only a single noise-free channel required for analysis.

- 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 system notifies the patient to correct the situation.

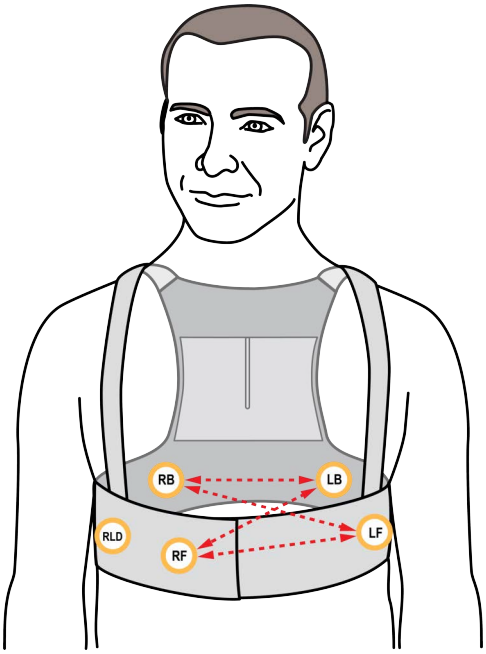


Figure 20: ASSURE System Differential ECG Vectors

3.2 Arrhythmia Detection

The ASSURE system uses two parameters to make a shock decision:

- Heart rate
- R-wave duration

The initial criteria consists of both a heart rate above the programmed rate threshold and the R-wave duration. The R-wave duration is used to discriminate supraventricular from ventricular arrhythmias when the patient's heart rate is above the VT threshold.

The ASSURE system also uses a numerical measurement of the QRS organization in the VT zone to distinguish VT from slow VF or polymorphic VT. This enables the time to therapy to be accelerated for unstable rhythms.

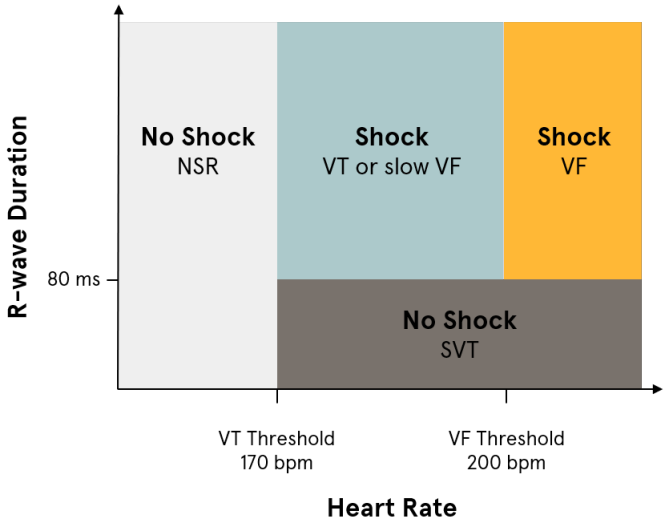


Figure 21: Arrhythmia Detection Parameters

3.2.1 ASSURE Detection Algorithm

The ASSURE detection algorithm uses three main components: the Gatekeeper, Main Algorithm, and State Machine.

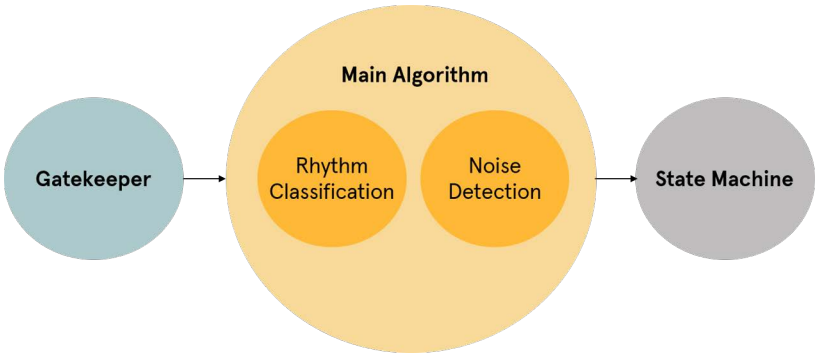


Figure 22: Detection Algorithm Components

The Gatekeeper is a highly sensitive heart rate detector that runs continuously and triggers the Main Algorithm for further analysis, if required.

The Main Algorithm is a segment-based rhythm analyzer that is activated once per minute or immediately upon notification by the Gatekeeper. The Main Algorithm is activated by the Gatekeeper when one of the following conditions occurs:

- Heart rate above 135 bpm or 10 bpm below the programmed VT rate zone, whichever is lower (indicates possible tachyarrhythmia)
- No QRS complexes detected for two seconds (indicates possible asystole)
- Five QRS complex amplitudes less than 100µV (indicates possible asystole)

The Main Algorithm performs the following functions for each 4.8-second ECG analysis segment:

- Calculates the heart rate, R-wave duration, and QRS organization
- Classifies the overall rhythm (VF, VT, Slow VF, SVT, Asystole, Bradycardia, or Noise)
- Renders a segment therapy decision (Shock, No Shock, Noise)

The ECG segments continuously overlap by 2.4 seconds allowing the algorithm to classify rhythms by looking both forward and backward.

The State Machine aggregates the Main Algorithm's overlapping, segment-based rhythm analyses and shock decisions over time to determine device behavior. When a string of segment results meets the criteria for a ventricular tachyarrhythmia and is sustained for a period of time, the State Machine causes the device to store an episode with ECGs, generate a shock alert with voice messages, and, if necessary, deliver a shock.

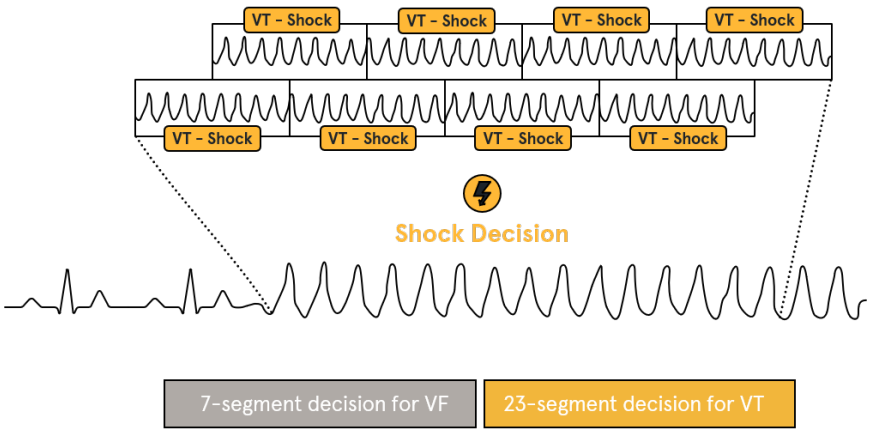


Figure 23: Segment-based Rhythm Analyses

3.3 Therapy Zones

The ASSURE system analyzes the patient's heart rate in two independently programmable therapy zones – one for ventricular tachycardia (VT) and another for ventricular fibrillation (VF). The therapy zones are defined by the following programmable rate ranges:

- The VT rate range is 130 to (VF rate - 10) bpm in 10 bpm intervals. The default setting is 170 bpm.
- The VF rate range is 180 to 220 BPM in 10 bpm intervals. The default setting is 200 bpm.

Therapy is always enabled in the VF zone. Therapy in the VT zone is programmable [Treat (default) or Monitor].

Note: The VF Rate Threshold value must be higher than the VT Rate Threshold value.

Initial detection is the same for each zone: 5 out of 6 segments of VT or VF are required to satisfy the initial detection criteria (approximately 15 seconds).

Confirmation is dependent on the specific zone:

- VF requires 2 out of 2 segments (approximately 5 seconds)
- VT requires 15 out of 19 segments (approximately 45 seconds)

The first and last segments must be in the specific treatment zone.

When therapy is required, the ASSURE system can deliver up to five 170J shocks per episode. While therapy may be programmed off in the VT zone (episode storage only), it cannot be programmed off in the VF zone.

The figure below depicts the VF and VT shock timelines.

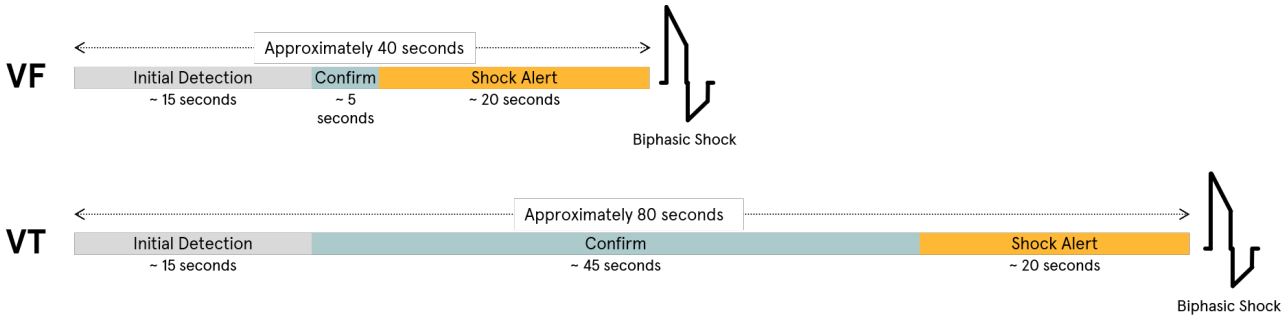


Figure 24: VF and VT Shock Timelines

3.3.1 Shock Alert Sequence

After VT or VF has been detected and confirmed, the ASSURE system initiates the shock alert sequence. The shock alert sequence consists of a triple-sensory alert that includes:

- A flashing red light and Shock icon on the Monitor
- An intense vibration from the Alert Button
- A harsh siren alarm and voice prompts

During the alert period (approximately 20 seconds), confirmation continues and the arrhythmia must be sustained for 4 out of 6 segments. After this, a shock can only be diverted by pressing the Alert Button.

Note: The patient must press the Alert Button within 20 seconds or a shock will be delivered.

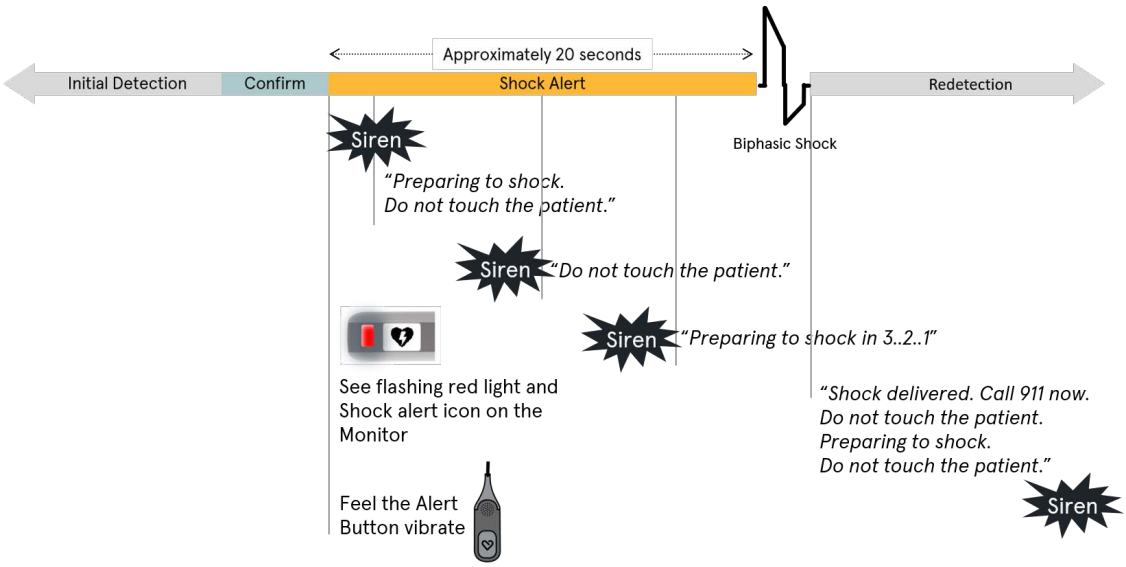


Figure 25: ASSURE System Shock Alert Sequence

3.4 Therapy Delivery

The ASSURE system uses a biphasic truncated exponential (BTE) waveform and delivers a non-programmable 170J electrical shock.

A shock is delivered within approximately 40 seconds of the onset of VF (approximately 80 seconds for VT), unless a conscious patient diverts therapy by pressing the Alert Button or the rhythm slows to below the programmed rates.

Shocks are delivered synchronously, unless a 3-second time out expires without an event being detected for synchronization, at which time the shock is delivered asynchronously.

3.5 Post Shock

After delivering a shock to the patient, the ASSURE system continues to perform rhythm analysis while the alert continues to sound.

- If 3/5 segments remain above the programmed therapy rate, another shock will be delivered.

  Note: If a shock fails to convert the arrhythmia, up to five total shocks may be delivered within one episode.

- If the patient presses the Alert Button, or the rate falls below the programmed VT threshold for 6/12 segments (approximately 15 seconds), the alert stops and a post-therapy message is initiated that instructs the patient to call 911 and to continue to wear the ASSURE system.
- If the rhythm converts to a rhythm with a rate that still falls in the VT zone:
  - Shocks will continue to be delivered if therapy is programmed on.
  - If therapy is programmed off in the VT zone, the episode will close and a new episode will begin storage.

3.6 Bradycardia/Asystole

The ASSURE system also analyzes the patient's heart rate for very slow rhythms.

- Asystole is detected when there is no detected heart rate for more than 20 seconds (5 out of 7 segments with heart rate at 0 bpm or peak-peak amplitude of less than 100 µV).
- Prolonged slow heart rates (below 30bpm) may be detected as bradycardia rather than asystole.

When bradycardia or asystole is detected, an episode is opened and a loud alarm sequence is initiated to attract bystander attention and instruct them to call 911 and perform CPR. The Seek Medical Attention alert can be silenced by pressing the Alert Button, or it will resolve when a heart rate > 30 bpm is detected for more than 30 seconds.

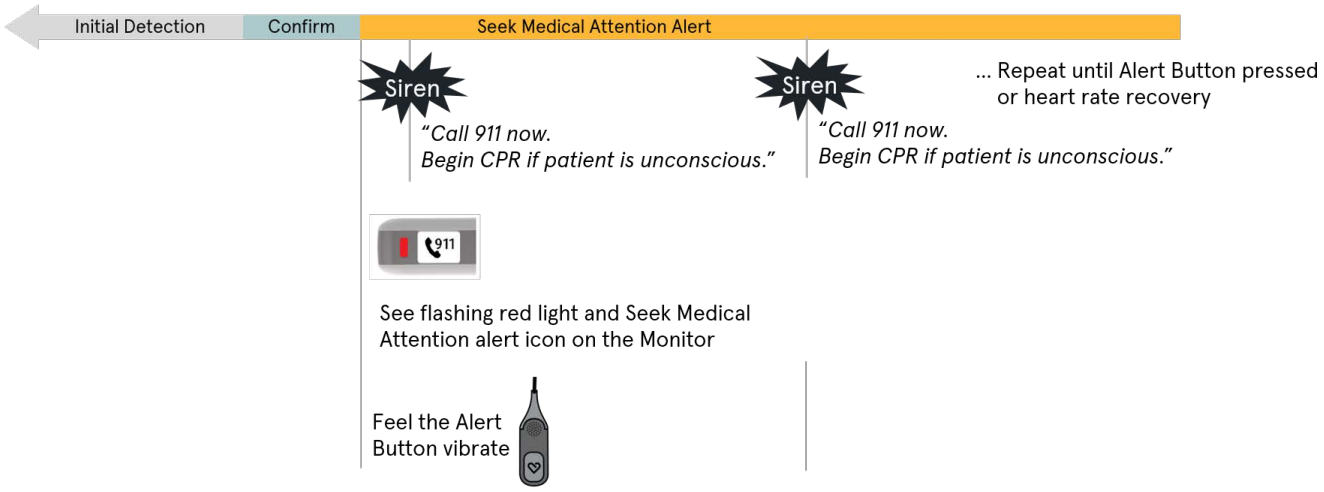


Figure 26: Bradycardia/Asystole Alert Sequence

3.7 Episode Storage

The ASSURE system stores data for arrhythmic events and records these events as episodes within device memory. Episodes are stored for the following device-determined VT, VF, and bradycardia/asystole events:

- Tachy-treated (shock)
- Tachy-untreated (non-sustained and not treated)
- Brady/Asystole

The ASSURE system will deliver up to five shocks per episode. Refer to the following figure for an episode storage diagram for arrhythmia detection and delivery of a single shock.

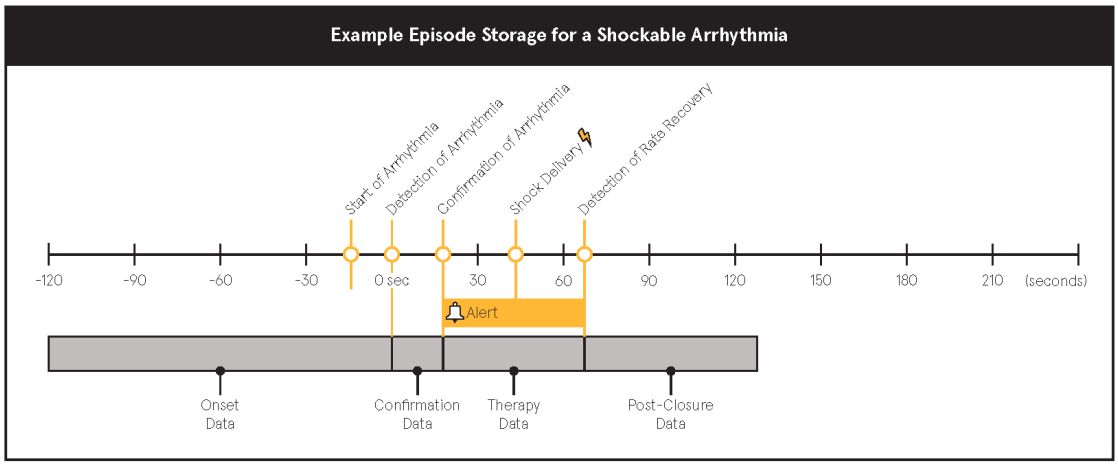


Figure 27: Example Episode Storage for a Shockable Arrhythmia

In this example, there are five significant events that are stored in four blocks of episode data: (indicated in gray in the diagram):

1. **Onset Data** – Up to 120 seconds of data prior to arrhythmia detection.
2. **Confirmation Data** – Data between arrhythmia detection and confirmation of the arrhythmia.
3. **Therapy Data** – All data between the confirmation of the arrhythmia and the detection of rate recovery/ conversion.
4. **Post-Closure Data** – Up to 60 seconds of stored data after the detection of rate recovery/conversion.

Refer to the following figure for an episode storage diagram in which five shocks were delivered. Note that additional shocks are available for subsequent episodes after the system is reset by an Alert Button press or the patient's rate falls below the programmed rate cutoff.

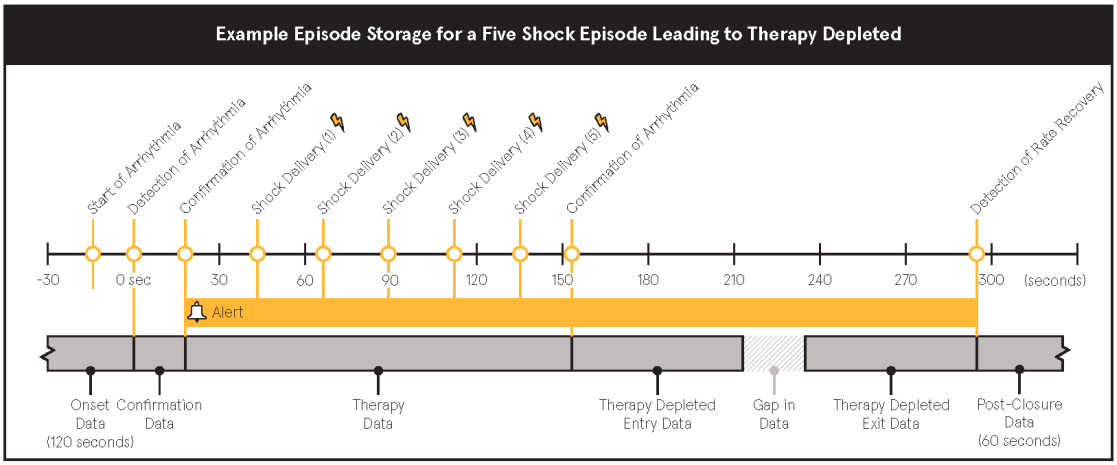


Figure 28: Example Episode Storage for a Five-shock Episode Leading to Therapy Depleted

In this example, there are ten significant events that are stored in five blocks of episode data:

1. **Onset Data** – Up to 120 seconds of data prior to arrhythmia detection.
2. **Confirmation Data** – Data between arrhythmia detection and confirmation of the arrhythmia.
3. **Therapy Data** – Data between the confirmation of the arrhythmia and the entry into Therapy Depleted.
4. **Therapy Depleted Data** – Up to 120 seconds of data between the entry to Therapy Depleted and the Episode Closure event. In this example, the 120 seconds is split into two blocks with a time gap indicated since data exceeded the 120-second limit:
   - **Therapy Depleted Entry Data** – The first 60 seconds after entry to Therapy Depleted.
   - **Therapy Depleted Exit Data** – The final 60 seconds leading up to the detection of rate recovery/conversion.
5. **Post-Closure Data** – Up to 60 seconds of stored data after the detection of rate recovery/conversion.

The ASSURE system may detect and store episodes for non-sustained arrhythmias without alerting the patient. Episodes are stored upon detection of an arrhythmia, while Shock Alerts are not issued until confirmation of the arrhythmia. See the figure below for an episode storage diagram (without alerts) for a non-sustained arrhythmia.

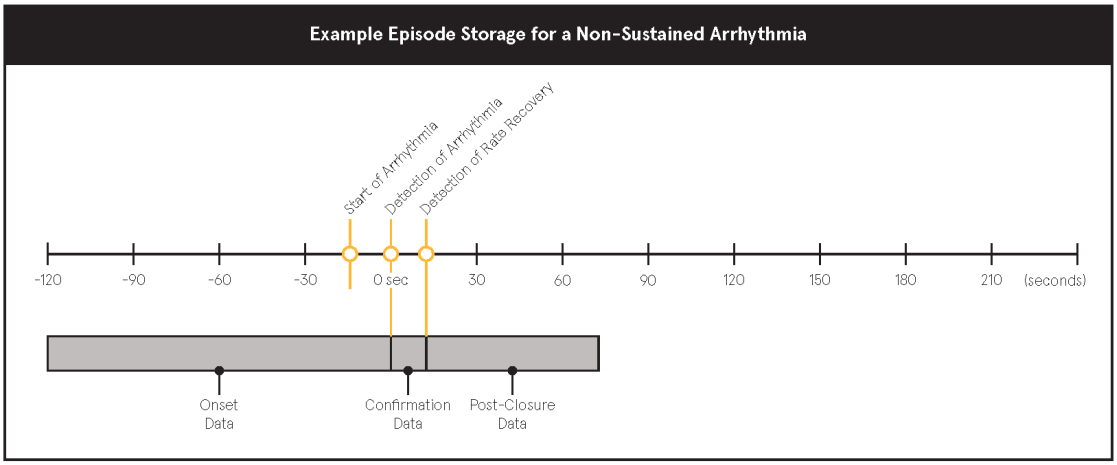


Figure 29: Example Episode Storage for a Non-sustained Arrhythmia with No Shock Alert

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

1. **Onset Data** – Up to 120 seconds of data prior to arrhythmia detection.
2. **Confirmation Data** – Data between arrhythmia detection and the detection of rate recovery/spontaneous conversion.
3. **Post-Closure Data** – Up to 60 seconds of stored data after the detection of rate recovery/conversion.

3.8 Trends

The ASSURE system stores patient activity and usage trends 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 Therapy Cable, which is situated in the middle of the patient's back. Daily usage of the ASSURE system is recorded in one-minute increments whenever the system sensors are in contact with the patient's skin.

4. Patient Training

This section describes the processes for fitting and training, the patient with the ASSURE system.

4.1 Patient Fit and Training Session

During the Patient Fit and Training session, the best Garment fit for the patient to maximize the wear and use of the ASSURE system is determined. During this session, the patient is measured and fitted with a suitable Garment style and size (see section 2.1.1, Garment, on page 41 for more information). The patient is provided with two Garments.

The PSR then plays the patient training video and walks the patient through common daily tasks while providing the patient with hands-on activities to improve their understanding of how the ASSURE system operates and how to maintain it.

Note: If possible, caregivers or family members who live with the patient should attend the patient training session.

Topics covered include:

- Assembling the ASSURE system
- Putting on the ASSURE system
- Starting the ASSURE system
- Verifying proper Garment fit
- Setting up the Charger
- Charging the Battery in the Charger
- Replacing the Battery in the Monitor
- Sleeping with the ASSURE system
- When and how to remove the ASSURE system

  Note: Patients will need to temporarily remove the ASSURE system for bathing, showering, swimming. Occasionally, they may also need to remove it to accomplish other activities or undergo procedures. Advise the patient to have another person present, if possible, when they are not wearing the system and to limit the amount of time they are not protected by the ASSURE system.
- Removing the Therapy Cable from one Garment and placing it into another Garment
- Washing the Garment
- Responding to alerts
- How to get help if needed

After completing the Patient Fit and Training session, the PSR administers a Patient Comprehension Test to evaluate the patient's understanding of how to wear and use the ASSURE system in their daily life.

4.2 Patient Comprehension Test

The Patient Comprehension Test evaluates the patient's understanding of the ASSURE system and how to use and wear it after receiving training.

Note: Clinicians should ensure the patient is willing and capable of using the ASSURE system before prescribing it. This includes the consideration of any cognitive, visual, physical, or auditory limitations that the patient may have that could affect their use of the ASSURE system.

If the patient misses any questions, the PSR is instructed to reteach that point. If after reteaching the patient does not demonstrate understanding, the PSR is instructed to contact the prescriber for prescription re-assessment.

4.2.1 Patient Comprehension Test

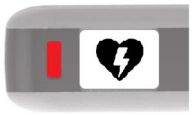
Circle one or more appropriate responses to the following questions about your ASSURE system.

1. What should you do when you get a Heart alert?

   A. Pull the battery out to stop the alarm.

   B. Ask someone else to press the Alert Button.

   C. Press the Alert Button to cancel the shock.

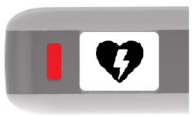


2. What will happen if there is a Heart alert but **you do not notice** it because you are asleep?

   A. The ASSURE system will notify EMS of your location.

   B. The ASSURE system will deliver a shock if needed.

   C. The ASSURE system will turn off.

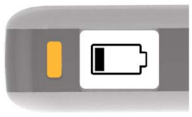


3. What should you do when **you get** a System alert?

   A. Pull the battery out to stop the alert.

   B. **Press** the Alert Button. **Look** at the Monitor screen. **Respond** to the alert to fix the problem.

   C. Wait until it stops on its own.



4. When should **you wear** the ASSURE system?

   A. Only if I don't feel well.

   B. Only when I'm home alone.

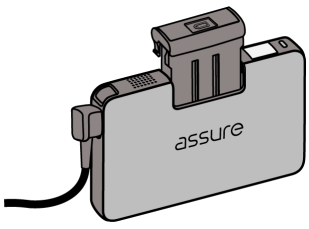
   C. All the time, except when I take a bath, shower, or swim.

5. How often should **you change** the Battery in the ASSURE system's Monitor?

   A. Every day.

   B. Once per week.

   C. Never.



6. How should the Garment fit?

   A. Loose.

   B. Snug around my rib cage.

   C. Over my undershirt (or bra).

Patient signature and date: _____

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5. Alerts

This section describes the alerts used in the ASSURE system.

5.1 Overview

The ASSURE system analyzes the patient's heart rate for dangerous heart rhythms and itself for proper function. When the system detects a problem, it creates an alert to notify the patient that there is something that needs their attention.

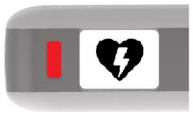
There are two alert types:

- Heart alerts – The ASSURE system has detected a heart rhythm that is either too fast or too slow. These alerts are critical and the patient must respond to them immediately.
- System alerts – The ASSURE system has discovered a problem with the system equipment that requires the patient's attention, like the Garment not fitting correctly or a low Battery.

What the patient will...	Heart Alert	System Alert
See	· Flashing red Monitor light · Alert icon on Monitor screen	· Blinking yellow Monitor light · Alert icon on Monitor screen
Hear	· Harsh, alternating low-high alarm · Voice message	· Repeating, double tone · Voice message
Feel	Four gentle pulses followed by an intense, triple-buzz vibration from the Alert Button	Triple-pulse vibration from the Alert Button

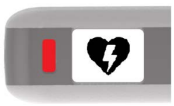
5.2 Heart Alerts

There are two types of Heart alerts:

Alert Name	Light and Icon	Reference
Shock		See page 65
Seek Medical Attention		See page 67

5.2.1 Shock Alert

After the ASSURE system detects and confirms a dangerously fast heart rhythm, it issues a Shock alert to tell the patient that an electrical shock will be delivered.



Responding to a Shock Alert

Before delivering shock, the following voice messages play:

- "Preparing to shock. Do not touch the patient."
- "Do not touch the patient."
- "Preparing to shock in 3, 2, 1."

Note: The Heart alert vibration continues throughout the Shock alert.

If the patient notices the Shock alert:

- The patient must immediately press the Alert Button to cancel shock delivery.
  - The patient is the only person who should press the Alert Button.
  - Pressing the Alert Button cancels the shock.
  - The ASSURE system will confirm the shock was canceled with a voice message and a vibration from the Alert Button.
- The patient should continue to wear the ASSURE system unless a medical professional tells them to remove it.
- The patient should call 911 or seek medical attention if they feel dizzy or unwell.

If the patient does not press the Alert Button:

- The ASSURE system will automatically provide a shock, if needed.
- The ASSURE system will instruct anyone nearby to call 911.

Note: The patient is the only person who should press the Alert Button. If the patient is unconscious, no one should press the Alert Button for them.

After delivering a shock, the following voice messages play:

- "Shock delivered."
- "Call 911 now. Do not touch the patient."
- "Preparing to shock. Do not touch the patient."

The ASSURE system will continue to analyze the patient's heart rhythm, and it will instruct anyone nearby to call 911. The system can deliver up to five shocks in a row for a single episode.

Notes:

- *If at any time the patient hears the Shock alert again, they should press the Alert Button.*
- *The voice messages will repeat as needed during the episode.*

After a Shock Alert

- After the Shock alert is over, the following voice messages play:
  - "Call 911 now."
  - "You have received a shock."
  - "Continue to wear your ASSURE system."
- The patient should continue to wear the ASSURE system.
  - It will continue to analyze the patient's heart rhythm.
  - If the patient notices another Shock alert, they should press the Alert Button
  - If the patient is unconscious, the ASSURE system will provide up to five shocks per episode (if needed).

- The Shock Delivered – Seek Medical Attention alert is displayed so the patient understands that they received therapy and are encouraged to seek medical attention or call 911.
- After a shock is delivered, the patient's chest and back will be wet and covered with gel.
  - This gel was released by the Therapy Pads as part of the shock delivery.
  - The patient should leave the gel under the Therapy Pads. They should not wipe off the gel, unless directed by a medical professional.
  - The gel remains viable for at least an hour.
- The patient may experience some discomfort or soreness around their chest.

5.2.2 Seek Medical Attention Alert

When the ASSURE system detects that the patient has a dangerously slow heart rhythm that may be bradycardia or asystole, or it can no longer deliver a shock during an episode, it issues a Seek Medical Attention alert.

Notes:

- *The ASSURE system can deliver up to five shocks. If another fast heart rhythm is detected, the ASSURE system will deliver another five shocks, if needed. The ASSURE system will continue to shock (when necessary) for up to five episodes or until the battery runs out of power.*
- *The ASSURE system cannot treat slow heart rhythms.*

The following voice message plays during this alert:

"Call 911 now. Begin CPR if patient is unconscious."

Note: The ASSURE system does not call 911 for the patient. The patient or someone nearby must call 911.

Responding to a Seek Medical Attention Alert

If the patient notices this alert:

- The patient should press the Alert Button.
  - Pressing the Alert Button quiets the alert.
- The patient should continue to wear the ASSURE system unless a medical professional tells them to remove it.
- The patient should call 911 or seek medical attention if they feel dizzy or unwell.

If the patient does not press the Alert Button:

- The ASSURE system will instruct anyone nearby to call 911 and begin CPR.

Note: The ASSURE system does not call 911 for the patient. The patient or someone nearby must call 911.

After a Seek Medical Attention Alert

- The patient should continue to wear the ASSURE system.
  - It will continue to analyze their heart rhythm.
  - If the patient hears another Seek Medical Attention alert, they should press the Alert Button.
- The patient should call 911 or seek medical attention if they feel dizzy or unwell.

5.3 System Alerts

This section describes the alerts that the ASSURE system uses to notify the patient that there is a problem with the system equipment that they need to fix.

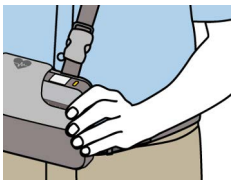
Note: The Put on Garment, Check Sensors, and Check Therapy Pads alerts may correct themselves automatically due to changes in Garment positioning or movement. If this occurs, the ASSURE system will return to normal operation (indicated by the green Monitor light, System Ready icon, guitar strum, and vibration).

When the patient receives a System alert, they should follow three general steps.

Step 1 Press the Alert Button

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

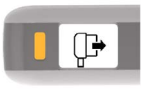
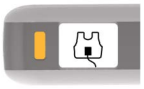
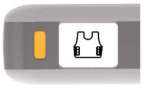
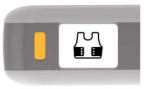
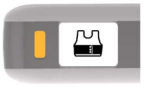
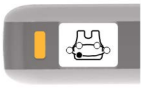
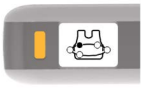
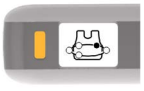
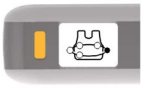
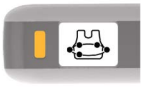
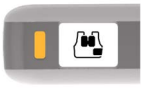
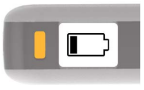
Step 2 Look at the Monitor screen and light



Step 3 Respond

A list of the System Alerts is available on the following page. See the *ASSURE Wearable Defibrillator Patient Handbook* for specific System alert information.

The following System alerts are available for the ASSURE system:

Alert Name	Light and Icon
Connect Plug to Monitor	
Connect Hub to Garment	
Put on Garment *Note: This alert uses a series of icons. The displayed icon will vary (see examples).*	  
Check Sensors *Note: The displayed icon will vary depending on which Sensor has lost contact.*	    
Check Therapy Pads	
Low Battery	
Shock Delivered – Seek Medical Attention	
Service Required	
Service Needed	

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6. Appendix

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

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

6.1 Specifications

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

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

6.1.1 ASSURE System

Item	Detail
Classification	Internally powered equipment per IEC 60601-1 (Group 1, Class B per IEC 60601-1-2), transportable, body-worn, infrequent use AED
Electrical Protection	Therapy Pads are type BF applied parts. ECG electrodes are type CF applied parts per IEC 60601-2-4.
Operation Mode	Continuous; automatic detection and treatment of dangerously fast heart rhythms, automatic detection of dangerously slow heart rhythms, collection of patient data and current system status
Accessible Parts (per IEC 60601-1)	Monitor's Plug Receptacle Hub Connector
Communications	Near Field Communication (NFC) 13.56 MHz RFID, ASK Modulation, 124 dBuV/m, 0.12 in (3 mm) communication range 802.11 wireless networking
System Temperature Range: Operating	32°F to 122°F (0°C to 50°C) *Note: The Garment, which is worn directly on the skin, operates to a maximum of 105.8°F (41°C). The Garment does not generate additional heat. When the Garment is on the body, the Sensors will not exceed skin temperature.*
Relative Humidity	5 to 95% (non-condensing)
Operating Altitude	-1253 to 9878 feet (-382 to 3011 meters) above sea level 700 to 1060 hPa (atmospheric pressure)
System Temperature Range: Storage and Transport	-4°F to 122°F (-20 to 50°C)
Liquid and Solid Ingress (per IEC 60529)	IP22 (Monitor and Therapy Cable)
Monitor Weight (including Battery)	1.8 lb (0.82 kg)
Part Numbers	Garment (Style A) – 80015 Garment (Style B) – 80016 Monitor – 80008 Therapy Cable – 80004 Carry Pack – 3326502

6.1.2 Battery

Item	Detail
Classification	Secondary rechargeable battery per IEC 62133
Type	Single Lithium Ion rechargeable battery
Voltage	Typical: 10.8 V Operating Range: 7.5 V – 12.6 V
Capacity	3.2 Ah, 34.5 Wh rated capacity
Temperature Range: Operating	32°F to 131°F (0°C to 55°C)
Temperature Range: Charging	32°F to 113°F (0°C to 45°C)
Relative Humidity	5 to 95% (non-condensing)
Operating Altitude	-1253 to 9878 feet (-382 to 3011 meters) above sea level 700 to 1060 hPa (atmospheric pressure)
Liquid and Solid Ingress (per IEC 60529)	IP55
Part Number	3322882

6.1.3 Charger

Item	Detail
Classification	Class II ME Equipment per IEC 60601-1, Portable, Continuous Operation (CISPR 11 Group 1, Class B per IEC 60601-1-2), Type BF applied part
Charging Capacity	One Lithium Ion battery with up to a 2 A charge current in the Battery slot.
Battery Charge Time (from empty to fully charged)	Approximately 4 hours
Power Supply	Delta MDS-060BAS19 A 15-20 VDC, Class II
Wireless Charging	Power output: 5W Wireless charging well - maximum device dimensions including case: Height: 6.3 in (160.02 mm) Width: 3.33 in (84.58 mm) Depth: 0.49 in (12.45 mm)
USB Dedicated Charging Port	USB 2.0 Standard Type A Output voltage and current: 5VDC at 1.5A
AC Adapter	Class II, Line Voltage 100-240V AC, 50-60Hz
Power Jack Diameter and Polarity	Diameter 2.1 mm or 2.5 mm Support for up to 3A output current to Charger
UL Rating	94-V0
Liquid and Solid Ingress (per IEC 60529)	IP21
Temperature Range: Operating	32°F to 113°F (0°C to 45°C)
Temperature Range: Storage and Transport	-4°F to 122°F (-20 to 50°C)
Operating Humidity	15 to 90% non-condensing
Operating Altitude	-1253 to 9878 feet (-382 to 3011 meters) above sea level 700 to 1060 hPa (atmospheric pressure)
Part Numbers	Charger – 3326633 AC Adapter – 3337063 Power Cord – 3336093

6.1.4 Alerts

Item	Detail
Audible Notifications	Alert notifications may include audio tones and instructions. Alert notifications and tones play through the Monitor and Alert Button speakers. · Heart alert tone volume range is 70 ±5 dB. · System alert tone volume range is 58 ±5 dB. The time between first notification and instructions is approximately six seconds. Alert volume is non-adjustable. The tone assignments for each type of alert include: · The Heart alert tone is used to indicate that there is a rhythm issue with the patient. The tone is 2 low-high chords repeated twice a second. · The System alert tone is used to indicate that there is an equipment or system issue. The tone is a single chord played twice at a low volume, then automatically repeated at a slightly increased volume with a total play time of 2.45 seconds for the set of paired chords.
Visual Notifications	Alerts are indicated by an alert icon on the Monitor screen and the color of the Monitor light. · Heart alerts display a flashing red Monitor light and an alert icon on the Monitor screen. · System alerts display a blinking yellow Monitor light and an alert icon on the Monitor screen.
Vibration Notifications	Alerts are indicated by a vibration through the Alert Button. · Heart alerts – Four gentle pulses followed by an intense, triple-buzz vibration from the Alert Button. · System alerts – Triple-pulse vibration from the Alert Button.
System Alert Detection Delays	The following System alerts have a delay time to allow the system to confirm the alert condition before notifying the patient. · Check Sensors alert (1–15 minutes) · Check Therapy Pads alert (15 minutes) *Note: The time between the first detection and instructions is approximately six seconds.*
System Alert Replay Delays	If a System alert is not silenced, there is a delay time before the System alert is replayed ranging from 30 seconds to 30 minutes depending on the specific alert.
System Alert Silence Delays	If the System alert is silenced, there is a delay time before the System alert is replayed ranging from 5 minutes to 30 minutes depending on the specific alert.
Alert and System Status Priorities	The lists below show the priorities from highest (1) to lowest. 1. Service Required alert 2. Check Sensors alert (with a 1–2-minute delay) 3. Shock and Seek Medical Attention alerts 4. Check Therapy Pads alert 5. Low Battery alert 6. Check Sensors alert (with a 15-minute delay) 7. Shock Delivered – Seek Medical Attention alert 8. Service Needed alert

6.1.5 Detection

Note: This section provides information regarding the ASSURE detection algorithm's performance and test methods per IEC 60601-2-4.

Item	Detail
Detection	The ASSURE detection algorithm uses ECG signals to analyze the rhythm and to detect shockable rhythms (ventricular tachycardia and ventricular fibrillation). *Note: The default VT rate threshold is 170 BPM.* The ASSURE detection algorithm automatically initiates analysis without requiring any input from the patient.

Performance of the ASSURE detection algorithm has been evaluated using a Test Dataset of electrocardiogram (ECG) segments. The Test Dataset was adjudicated by cardiac electrophysiology experts using manual methods to determine the heart rate. The Test Dataset includes a total of 872 ECG segments from a variety of sources. Each ECG segment is at least 6 seconds in duration. Sources for the Test Dataset include:

- Prospective data collection from electrophysiology (EP) labs using a commercial data acquisition system and standard adhesive electrodes placed in ASSURE ECG lead locations
- University of Alabama Birmingham Medical Center EP Lab 12-lead ECG recordings
- Los Angeles Fire Department LIFEPAK12 and LIFEPAK15 12-lead ECG recordings
- Resuscitation Outcomes Consortium (ROC) single-lead ECG recordings
- A series of single-lead ECG recordings gathered from emergency medical services with locations in North America and Europe in which patients were treated with a LIFEPAK 1000 or a LIFEPAK 12
- Amsterdam emergency medical services spontaneous VF single-lead ECG recordings

The ASSURE detection algorithm's performance meets or exceeds the American Heart Association (AHA) recommendations for performance as required by IEC 60601-2-4.

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

1. ASSURE system nominal therapy zone settings (VT 170 bpm, VF 200 bpm)
2. Disorganized ventricular rhythm with peak-to-peak amplitude ≥ 200μV, and without consistently identifiable QRS complexes
3. Ventricular rhythm (Monomorphic/Polymorphic/Pleomorphic VT) adjudicated heart rate > 187 bpm (nominal VT rate threshold + 10%)
4. Heart rate > 60 bpm and < 100 bpm, and p-waves consistent with sino-atrial origin
5. Rhythms with peak-to-peak amplitude < 75 μV
6. Disorganized ventricular rhythm with a peak-to-peak amplitude ≥ 100 μV and ≤ 200 μV
7. Ventricular rhythm (Monomorphic/Polymorphic/Pleomorphic VT) adjudicated heart rate ≥ 170 bpm (nominal VT rate threshold) and ≤ 187 bpm (nominal VT rate threshold + 10%)
8. Ventricular rhythm (Monomorphic/Polymorphic/Pleomorphic VT) adjudicated heart rate < 170 bpm (nominal VT rate threshold)

Notes:

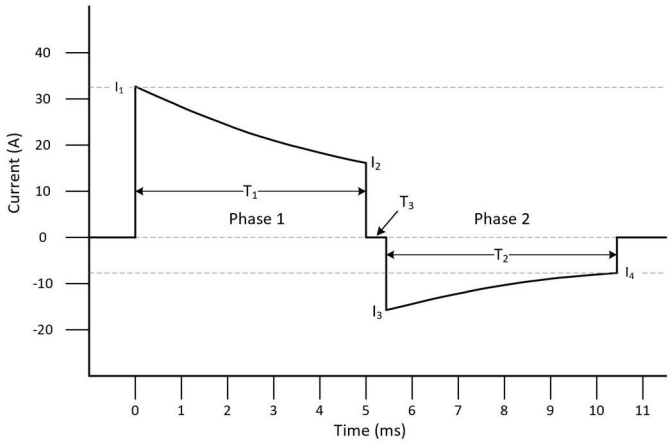
- *American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Effectiveness. "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety." Circulation 95, no. 6 (1997): 1677–82.*
- *The studies and data cited above are the result of extremely challenging rhythms that deliberately test the limits of AEDs. Clinically, the actual sensitivity and specificity may be equal or better.*

6.1.6 Defibrillation

Note: This section provides information regarding defibrillation per IEC 60601-2-4.

Item	Detail
Shock Waveform	A Biphasic Truncated Exponential (BTE) waveform that provides synchronous cardioversion defibrillation therapy.
Device Capacity	With a new Battery: • Provides up to 25 170J defibrillation shocks (per IEC 60601-2-4 for an infrequent use AED) or at least 24 hours of operation time. At a Low Battery alert indication: • Provides three 170J defibrillation shocks or two hours of operation time.
Shock Ready Time	There is a delay of approximately 20 seconds from the Shock alert notification to the actual shock delivery. This allows time for the patient to press the Alert Button to divert the shock. If rate recovery or a non-shockable rhythm occurs after the initial Shock alert notification, the system will cancel the shock sequence and issue a "No shock needed" message within 30 seconds.
Maximum Charging Time After 6 Shocks	Within 20 seconds
Maximum Time from Initiation of Rhythm Analysis to Readiness for Discharge After 6 Shocks	Within 35 seconds
VF Shock Delivery Time	A shock is delivered within approximately 40 seconds of the onset of VF, unless a conscious patient diverts therapy by pressing the Alert Button or the rhythm returns to normal.
VT Shock Delivery Time	A shock is delivered within approximately 80 seconds of the onset of VT, unless a conscious patient diverts therapy by pressing the Alert Button or the rhythm returns to normal.
Shock Energy Output and Accuracy	The shock energy output is 170 joules (non-configurable). The energy accuracy for shock energy delivered into a 50Ω resistor is equal to 170 joules ± 8%.
Impedance at which the shock is not delivered	A shock is delivered regardless of the impedance reading.

The complete ASSURE system biphasic waveform is shown in the figure below.



Current flow is maintained during phase 1 for a time T1, after which there is a short 400µS pause between phases (T3). Current flow is then reversed for phase 2.

The peak current (I1) is determined by the charge voltage/patient resistance.

The phase durations (T1 and T2) are microprocessor-controlled and are adjusted based on the patient impedance. Patient impedance is derived from the rate of decay of the capacitor voltage.

The waveform "tilt" is a measure of the amount the capacitor voltage has decayed during a shock. It is calculated with the formula Tilt = (I1 - |I4|)/I1. For the ASSURE system's defibrillation waveform, the tilt is greatest at low impedances and less at high impedances.

Nominal shock waveform parameters are provided in the following table.

Patient Resistance	Peak Current (I1)	Phase 1 (T1)	Phase 2 (T2)	Tilt	Measured Energy Output
25	63 A	3.54 ms	3.54 ms	86.2%	156 to 184 joules
50	32 A	4.96 ms	4.96 ms	75.7%	156 to 184 joules
75	21 A	6.33 ms	6.33 ms	70.2%	156 to 184 joules
100	16 A	8.08 ms	5.60 ms	63.6%	143 to 168 joules
125	13 A	8.85 ms	5.28 ms	55.7%	136 to 158 joules
150	11 A	9.50 ms	5.08 ms	50.4%	126 to 148 joules
175	9 A	10.07 ms	5.02 ms	46.3%	117 to 138 joules
200	8 A	10.58 ms	5.01 ms	43.0%	109 to 128 joules

Shocks per Sequence

The ASSURE system can deliver up to five shocks in a row for a single event (or episode). If the ASSURE system detects a rate recovery after a shock, additional shocks are canceled and the ASSURE system resets. If a new episode occurs, the shock sequence begins again.

Synchronized Defibrillation Shock Delivery

The ASSURE system will deliver a synchronous defibrillation shock after charging under the following conditions:

- If an R-wave is detected within three seconds after the ASSURE system finishes charging, the maximum time delay from the peak of the R-wave to the peak of the ASSURE system output waveform is 60 ms.

If an R-wave is not detected within three seconds after the ASSURE system finishes charging, the ASSURE system delivers the defibrillation shock asynchronously.

6.2 Wireless Interference

If there is any indication of interference between a wireless device and the ASSURE system, move away from the wireless device or turn it off, if possible. Call the ASSURE Helpline at 1.833.692.7787 if you continue to have interference problems.

6.3 Electromagnetic Compatibility

The ASSURE system is shielded to protect it against electromagnetic interference (EMI) and prevent it from interfering with common electronic items. The ASSURE system should operate normally around most electronic household items, such as microwave ovens, televisions, computers, kitchen appliances, mobile phones, and garage door openers.

However, the patient should always use caution when wearing the ASSURE system around household equipment that could potentially produce uncommonly high electromagnetic interference, such as high-powered two-way radios, arc welding equipment, high voltage transmission lines, large electric motors and generators, and power tools. These types of devices generate electromagnetic fields that may interfere with the normal operation of the ASSURE system.

6.3.1 Electromagnetic Emissions – Guidance and Manufacturer's Declaration

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

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The ASSURE system transmits RF energy only for low power *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 system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

6.3.2 Federal Communications Commission (FCC) Declaration

This device complies with Part 15 of the FCC rules, and its operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device contains:

- Transmitter Module FCC ID: YKP1024119

⚠ CAUTION

Changes or modifications to this device not expressly approved by Kestra Medical Technologies, Inc. could void the patient's authority to operate the device.

6.3.3 Electromagnetic Immunity – Guidance and Manufacturer's Declaration

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

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Monitor, Battery, Garment, and Charger: ±8 kV contact ±15 kV air Therapy Cable: ±6 kV contact ±15 kV air	No precautions necessary
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Complies	Mains power quality should be that of a typical home environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Complies	Mains power quality should be that of a typical home environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Complies	Mains power quality should be that of a typical home environment. If the user of the ASSURE system requires continued operation during power mains interruptions, the ASSURE system's Charger should be connected to an uninterruptible power supply.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home environment.

Note: U_T is the AC Mains voltage prior to application of the test level.

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

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the defibrillator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[1]	3 Vrms	$d = 1.2\sqrt{P}$
	6 Vrms 150 kHz to 80 MHz in ISM bands[1]	6 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[2] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[3], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Notes:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- No deviations or allowances to the standards have been used.

1. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
2. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
3. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ASSURE system is used exceeds the applicable RF compliance level above, the ASSURE system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as increasing the distance between the ASSURE system and the RF transmitter.

6.3.4 Recommended Separation Distances

The ASSURE system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The patient or the user of the ASSURE system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ASSURE system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

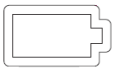
6.3.5 Radio Frequency (RF) Transmissions

The ASSURE system transmits using *Bluetooth*® Classic with Class 2 power management, 4 dBm (2.5mW) maximum output power. The frequency of operation is 2.400 to 2.4835 GHz including guard bands 2 MHz wide at the bottom end and 3.5 MHz wide at the top. It uses Gaussian Frequency Shift Keying, GFSK modulation, and frequency hopping over 79 channels.

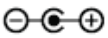
Note: The Monitor has not undergone the Bluetooth SIG certification process and no claim is made that the Monitor is certified by the Bluetooth SIG.

6.4 Symbols Glossary

This section defines the symbols used on the ASSURE wearable defibrillator (ASSURE system) and Charger labels and packaging.

Symbol	Description and Reference Document
	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
	Battery ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 5001B
	Do not dispose of this product in the unsorted municipal waste stream. Contact the ASSURE Helpline at 1.833.692.7787 for instructions on returning this product. Disposal will be performed by the manufacturer. BS EN 50419, Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of the European Community Directive 2002/96/EC (WEEE)
	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

Symbol	Description and Reference Document
	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
	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
PN	Part number No applicable standard
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
	Recognized component mark for Canada and the United States.

Symbol	Description and Reference Document
	Federal Communications Commission compliance mark FCC 784748 D01 Labeling Part 15 18 Guidelines, Section 2.5
	USB port ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3650
	Charger power port IEC 60417, Graphical symbols for use on equipment. Symbol 5031
	Lock ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 1656
	Unlock ISO 7000, Graphical symbols for use on equipment – Registered symbols. Symbol 3305
	Wireless charging No applicable standard
	Class II equipment IEC 60417, Graphical symbols for use on equipment. Symbol 5172
	Input IEC 60417, Graphical symbols for use on equipment. Symbol 5034
	Output IEC 60417, Graphical symbols for use on equipment. Symbol 5035
	Rated power output, direct current IEC 60417, Graphical symbols for use on equipment. Symbol 6048
	Polarity of Direct Current Power Connector IEC 60417, Graphical symbols for use on equipment. Symbol 5926
	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 UL Classification Marking for Canada and the United States.
	Recognized safety certification mark for the United States.

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