PROTOCOL TITLE:	ASSURE WCD Clinical Evaluation - Detection and Safety Study (ACE-DETECT)
PROTOCOL NUMBER:	3324582_B
INVESTIGATIONAL DEVICE:	ASSURE™ WCD (Wearable Cardioverter-Defibrillator)
DEVICE REGULATORY CLASSIFICATION:	Non-Significant Risk (NSR) Medical Device; 21 CFR 812.2 (b) Abbreviated Investigational Device Exemption (IDE) requirements apply
INDICATION:	Adult Patients at Risk for Sudden Cardiac Arrest
DEVELOPMENT PHASE:	Validation
STUDY DESIGN:	Multicenter single arm open label evaluation
SPONSOR:	Kestra Medical Technologies, Inc. 3933 Lake Washington Blvd NE Kirkland, WA 98033
DATE OF PROTOCOL:	08/17/2018

NCT03887052

1 SPONSOR SIGNATURE PAGE

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Approved by:

Laura Gustavson

8/17/18

Laura Gustavson
Vice President, Clinical Marketing
Kestra Medical Technologies, Inc.

Date

17 AUG 2018

Robert McNutt, PhD
Biostatistician
RCRI, Inc.

Date

2 KEY ROLES AND CONTACTS

Key roles may be updated by written notification to the clinical sites without a protocol amendment.

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3 PROTOCOL SUMMARY

Protocol Number:	3324582_B
Protocol Title:	ASSURE WCD Clinical Evaluation - Detection and Safety Study (ACE-DETECT)
Study Objectives	Primary: To evaluate ambulatory detection performance of the ASSURE Wearable Cardioverter Defibrillator (WCD) Secondary: To evaluate arrhythmia detection performance and safety of the ASSURE WCD
Study Population:	Adult cardiac patients at risk for sudden cardiac arrest
Study Design:	Multicenter single arm open label evaluation
Number of Subjects:	At least 130 subjects (maximum 135) with at least 35 of each sex, male and female
Study Sites:	Subjects will be enrolled at approximately 10 clinical sites in the United States, with each site enrolling a maximum of 18 subjects.
Eligibility Criteria:	Candidates are eligible for participation if they meet all Inclusion Criteria and none of the Exclusion Criteria. **Inclusion Criteria**: 1. Males or females, age ≥ 18 years 2. Patients with an active Implantable Cardioverter Defibrillator (ICD) 3. Left Ventricular Ejection Fraction (LVEF) ≤ 40%, measured within the past year (12 months) by echocardiography, nuclear imaging (including MRI), or left ventricular angiography 4. Able and willing to provide written informed consent before undergoing any study-related procedures

	Exclusion Criteria: 1. 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 2. Any known skin allergy or sensitivity to the study garment materials that will be next to the skin 3. Any breached or compromised skin on the upper body that would be exacerbated by wearing the study garment 4. Work with or are frequently around equipment that produces high electromagnetic fields, for example magnetic resonance imaging devices, power supply facilities, or welding equipment 5. 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 6. Any planned air travel during the participation period 7. Pregnancy 8. Use of mechanical circulatory support, including but not limited to Left Ventricular Assist Device (LVAD) or Total Artificial Heart 9. Implanted Cardiac Resynchronization Therapy Defibrillator (CRT-D) 10. Simultaneous plan/prescription for Holter monitor, mobile cardiac outpatient telemetry (MCOT), Event Recorder, or in-hospital telemetry 11. 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 (SpO_2) monitor. 12. Under bust chest circumference greater than 52 inches or less than 28 inches 13. Current hospital inpatient
Device:	ASSURE™ WCD with shock alarms and shock functionality disabled. Shock Alarm Event *Markers* are recorded by the WCD and will be used for analysis of the primary outcome measure.
Study Procedures:	At Visit 1 subjects will be fitted with the WCD and will be trained and provided written instructions for use, including safety precautions and adverse event reporting. Demographic data and limited medical history will be collected and subjects will be asked to complete a baseline comfort scale. Subjects will wear the device for approximately 30 days during normal daily activities including sleep. Research Coordinators will conduct weekly phone interviews with the subjects during the participation period to address subject questions, review potential adverse events, and review usage. Subjects will return for a final visit, Visit 2, at the end of the wear period. At Visit 2 subjects will be interviewed

	regarding any adverse events they may have experienced since the most recent phone follow up, and status of any adverse events that were recorded during the participation period. They will be asked to complete a Device Usability Survey. The device will be removed and returned. They will be asked to complete a follow up comfort survey. All episodes recorded by the ASSURE WCD and/or the subject's ICD will be reviewed by independent clinical experts.
Study Endpoints:	
Primary:	WCD False Positive Alarm Rate (False Positive Alarms per subject-day)
Secondary:	Summary of WCD True Positive Detections and Missed Events (False Negative Detections) Estimated Inappropriate Shock Rate Adverse Events
Study Duration:	Individual subject participation is approximately 30 days. Total study duration from first subject in to last subject out is approximately 4 Months.

4 TABLE OF CONTENTS

LIST OF IN-TEXT FIGURES

5 GLOSSARY OF ABBREVIATIONS AND DEFINITION OF TERMS

ABBREVIATION	TERM
AADE	Anticipated Adverse Device Effect
AE	Adverse Event
BMI	Body Mass Index
CFR	Code of Federal Regulations
CIED	Cardiovascular Implantable Electronic Device
CPAP	Continuous Positive Airway Pressure (Sleep Apnea Therapy)
CRF	Case Report Form
CRT-D	Cardiac Resynchronization Therapy Defibrillator
ECG	Electrocardiogram
FDA	Food and Drug Administration
GDR	General Document Record
ICD	Implantable Cardioverter-Defibrillator
ICF	Informed Consent Form
IDE	Investigational Device Exemption
IRB	Institutional Review Board
ITT	Intent-to-Treat
LVAD	Left Ventricular Assist Device
LVEF	Left Ventricular Ejection Fraction
MCOT	Mobile Cardiac Outpatient Telemetry
MI	Myocardial Infarction
NSR	Non-Significant Risk (Medical Device)
PP	Per Protocol
RC	Research Coordinator
SAE	Serious Adverse Event
SAF	Safety (set of subjects for statistical analysis)
SAP	Statistical Analysis Plan
SCA	Sudden Cardiac Arrest
SID	Subject Identification Number
SpO2	Pulse Oximeter Oxygen Saturation
SVT	Supraventricular Tachycardia
UADE	Unanticipated Adverse Device Effect
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia
WCD	Wearable Cardioverter Defibrillator

6 INTRODUCTION

Background

The Wearable Cardioverter-Defibrillator (WCD) is indicated for adult patients who are at risk or at perceived risk of sudden cardiac arrest (SCA) and are not immediate candidates for or refuse an implantable defibrillator.

These patients are defined by two populations. The first population includes those patients for whom there may be optimism for clinical improvement, for example, patients soon after revascularization or those with a recent diagnosis of myocardial infarction (MI) or cardiomyopathy in whom guideline directed medical therapy is being initiated. The optimal management of these patients during the waiting period before ICD implantation is currently unknown. The second population includes those patients who have a clear indication for an ICD but also have a contraindication to immediate ICD placement, for example, active infection or unknown prognosis. (Piccini JP)

The study Sponsor has developed a new wearable defibrillator, the ASSURE WCD, to address this need. This study is part of a comprehensive set of tests which has been proposed to establish safety and effectiveness of the ASSURE WCD and will be included in support of the Premarket Approval (PMA) application for the ASSURE WCD.

Previous Clinical Studies

Second Generation Prototypes:

- Protocol 3322262: Single-center non-randomized study to evaluate Electrocardiogram (ECG) signal quality, comfort and usability; 5-day wear period; 6 healthy normal adult subjects (Sponsor employees, 4 males, 2 females) enrolled; 2 non-serious minor severity adverse events (AEs) observed (skin irritation) after five days of wear. ECG signal analysis and comfort/usability data used to improve various aspects of garment and electrode design in the next generation prototype.
- Protocol 3325053: Multi-center (Seattle and Florida) non-randomized study to evaluate ECG signal quality, comfort and usability enrolling adult subjects from the community with age and body-habitus representative of device intended use; 5-day wear period; 12 healthy normal adult subjects (8 females, 4 males) enrolled; 5 non-serious minor AEs and 1 non-serious moderate severity AE observed (all skin irritation) after five days of wear. The moderate severity AE was minor severity skin irritation due to the garment wear that was then

exacerbated by the subject scratching the area. ECG signal analysis and comfort/usability data were used to improve various aspects of garment and electrode design in the next generation prototype.

- Protocol 3321770: Single-center (University of Washington Medical Center) non-randomized study to evaluate ECG signal quality, comfort and usability enrolling adult cardiac subjects with low ejection fraction (≤ 40%), age and body-habitus representative of device intended use; 2-day wear period; 50 subjects enrolled (30 males, 20 females, average age 58, age range 34-90); 1 non-serious minor severity AE observed (skin irritation) after two days of wear. ECG signal analysis and comfort/usability data were used to improve various aspects of garment and electrode design in the next generation prototype. ECG and accelerometer signals were used to support Rhythm Analysis Algorithm (RAA) development.
- Protocol 3324914: Usability, non-randomized, study to evaluate comfort of WF2 prototypes and subject responses to simulated WF2 prototype system notification (alert) messages (low critical battery, adjust garment, and therapy) for 48 hours in subjects' home environments. A total of 10 subjects were enrolled from the general population (5 females, 5 males, average age 64.8, age range 56-74) each received 20 alert messages during the 48-hour study duration. No AEs were reported during the 48-hour study duration and subjects responded to simulated system notification messages during the day and night.

Third Generation Prototypes:

- Protocol 3330766: Multi (6)-center non-randomized study to collect ECG and accelerometer signals to support RAA development and assess comfort and usability; enrolling adult cardiac patients with low ejection fraction, age and body-habitus representative of device intended use; 5-day wear period; 117 subjects enrolled (40 females, 76 males, average age 60.1 age range 30-82). Nine (9) AEs were reported that were all related to skin irritation; 8 minor severity and 1 originally minor severity that was exacerbated to moderate severity after the subject scratched the area of irritation.
- Protocol 3333597: Single center (Swedish Sleep Medicine Sleep Lab) randomized study to assess subject response time to high priority alerts (shock alarms) during one night's sleep. Subjects were randomized at enrollment to one of 12 simulated alarm scenarios. 12 subjects from the general population were enrolled (5 males/ 7 females) with average age of 69 (range 43-73). 24 shock alarms were issued (2 to each subject). Mean response time to shock alarm

during sleep was (7.0 ± 2.5 seconds). There was one shock alarm that was "missed" (subject failed to respond in 20 seconds or less). No AEs were reported.

- Protocol 3334121: Single center randomized study to assess subject response time to high priority alerts (shock alarms) during normal daily activities. Subjects were randomized to one of three simulated alarm scenarios implemented over a 7-day wear period. 20 subjects from the general population were enrolled (9 males/11 females) with average age of 57 (range 41-71). 55 shock alarms were issued. Mean response time to shock alarm during normal daily activities was 13.3 ± 10.1 seconds. There were eleven shock alarms that were "missed" (subject failed to respond in 20 seconds or less). One minor AE reported (skin irritation).

Fourth Generation Prototypes:

- Protocol 3335586: Multicenter (3) non-randomized study to evaluate safety and detection performance of the ASSURE wearable cardioverter defibrillator (WCD) device during a typical 30-day prescription period; 32 subjects enrolled in the US from the general population (16 females, 16 males, average age 61.7, age range 40-73). This was a pilot study for the pivotal clinical study (ACE-DETECT). 8 AEs were reported in 6 subjects (2 subjects experienced 2 AEs each). 7 AEs were related to skin irritation and 1 was scratches from the garment seam; All 8 were minor severity.

Study Rationale

A WCD provides continuous arrhythmia monitoring with detection of potentially fatal ventricular arrhythmias and automatic defibrillation. The ASSURE WCD incorporates an automatic Rhythm Analysis Algorithm (RAA) that uses patient ECG to determine if a patient should be treated with a defibrillation shock. The device also provides vibratory, audible, and visual alerts to the patient when a shockable rhythm is detected and before a shock is delivered. If the patient is conscious during this "shock alarm", they will be able to defer a shock using a divert button on the WCD.

Because shockable rhythms occur infrequently in the target population, RAA sensitivity to shockable rhythms and specificity to non-shockable rhythms has been validated in the final ASSURE device using a robust, statistically-valid dataset of previously acquired rhythms.

False shock alarms are another important WCD performance metric. Medical device alarms in general have been recognized as a top health technology risk. Excessive alarms, particularly those for conditions that aren't clinically significant or for conditions that could be avoided, such as alarms that result from poor contact between an ECG electrode and the patient's skin, can lead to alarm fatigue and ultimately patient harm (ECRI Institute). In the case of the WCD, excessive alarms also contribute to lack of compliance (Duncker T). The LifeVest® 4000 Operator's manual (ZOLL Medical Corporation) indicates that false alarms occur at a rate of 2.0 per patient week of use (one every 3.4 days). Similarly, high alarm rates are reported in several other published and un-published studies of the LifeVest (Dillon K); (Schuhmann CG); (Duncker T); (Hucker W). Signal interference (ECG noise) is reported as the primary cause of false alarms.

7 INVESTIGATIONAL DEVICE

Description

The WCD used for this study will be controlled by the Sponsor from managed inventory designated for clinical evaluations only. The devices will be production-equivalent systems with shock alarms disabled (Shock Alarm Event Markers will be recorded by the device for analysis purposes), defibrillation therapy programmed OFF, and detection parameters at default settings. Detection parameter default settings include Ventricular Tachycardia (VT) rate threshold at 170 bpm and Ventricular Fibrillation (VF) rate threshold at 200 bpm.[1]

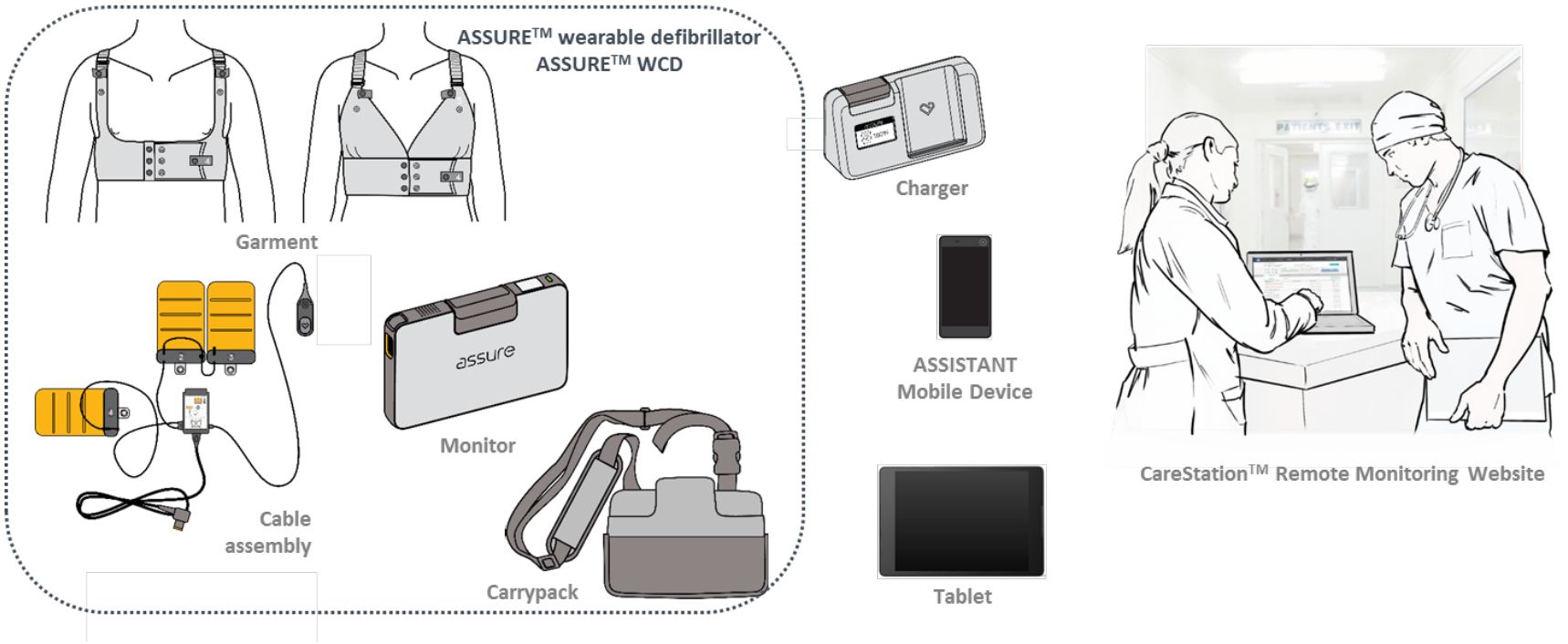
The ASSURE™ Cardiac Recovery System is comprised of several components:

- A WCD including a Garment with embedded ECG sensors that is worn on the body next to the skin, a Monitor which houses the battery and the graphic user interface, Cable Assembly which connects the Garment to the Monitor, and a Carry Pack
- A Charger that allows recharging of the monitor batteries
- A Tablet that allows the WCD to be programmed via wireless connection to the Monitor
- CareStation™ website which allows users to view WCD data associated with study subjects
- An ASSISTANT™ mobile device that allows data uploads from the WCD to CareStation website

The ASSURE Cardiac Recovery System is illustrated in Figure 1.

[1] Accuracy of the ASSURE WCD heart rate measurement for tachyarrhythmias is +/- 10%

Figure 1 ASSURE Cardiac Recovery System



Device Regulatory Classification

The Sponsor has assessed this as a minimal risk study using a Non-Significant Risk Device. The study will be governed by the abbreviated Investigational Device Exemption (IDE) Requirements [21 CFR 812.2(b)]. The rationale for this assessment is based on the configuration with shock alarms disabled and shock functionality programmed OFF.

Safety and Accountability

Risks have been identified through systematic hazard analysis. The Sponsor has documented risk mitigation in a controlled Risk Management Report. Each component of the WCD is assigned a unique serial number that is included on the labeling. Labeling also includes "CAUTION: Investigational Device. Limited by Federal (USA) law to investigational use", and the Sponsor's name and address in accordance with 21 CFR 812.5. The Sponsor will maintain tracking records for all system components.

Sizes and Fitting

Multiple sizes of the garment will be available for this study. In addition, there are two garment styles: one more suitable for male subjects, and one with support more suitable for female subjects. Subjects will be measured to select an appropriate size, then the garment fit will be adjusted while on the subject to ensure it is adequate for reliable data collection. Each subject will be assigned two garments so when they wash one, they can continue wearing the system using the other garment.

Reuse of System Components

The Garment, which is the component of the system that will come in direct contact with the study subject and includes the dry-contact electrodes, and the Carry Pack, will ***not*** be re-used for other study subjects. All other components of the system will be cleaned and disinfected by the Sponsor and will undergo safety testing before reuse.

Devices will be stored at ambient room temperature in a secure location. Access should be strictly limited to the Investigators and their designees. Neither the Investigators nor any designees may provide devices to any individual not participating in this protocol.

Device Accountability

Sites will maintain accurate records of inventory and dates of receipt of all devices.

For regulatory requirements regarding device accountability, all device accountability will be reconciled during study monitoring. Study devices must be returned to the Sponsor according to applicable state and federal regulations.

All Study System components returned by the site must be accompanied by a copy of the Product Accountability Log for the respective kit dispensed. No devices or device components should be destroyed.

8 INVESTIGATIONAL PLAN

This is a multicenter single arm open label study enrolling adult patients at risk for sudden cardiac arrest.

Number of Subjects

At least 130 subjects (maximum 135) will be enrolled with at least 35 of each sex, male and female.

Study Sites

Approximately 10 sites in the United States are planned to participate in this study, with each site enrolling a maximum of 18 subjects.

Participation Period

Subjects will wear the device for approximately 30 days. This period was selected to correspond to the WCD prescription period[2] while providing sufficient data to test the performance hypothesis.

Study Objectives and Endpoints

Primary Objective: To evaluate ambulatory detection performance of the ASSURE WCD.

Primary Endpoint: WCD False Positive Alarm Rate (FPA) calculated as False Alarms per subject-day.

Secondary Objectives: To evaluate arrhythmia detection performance and safety of the ASSURE WCD.

Secondary Endpoints: Summary of WCD True Positive Detections and Missed Events (False Negative Detections), estimated inappropriate shock rate, and summary of adverse events determined to be at least possibly related to the device.

[2] Medicare classifies the WCD as capped rental Durable Medical Equipment (DME) with a monthly payment. A Written Order Prior to Delivery (WOPD) is required to initiate the prescription, and continued use requires documentation justifying continued medical need such as by a prescription refill or completion of Certificate of Medical Necessity (CMN). The WCD is described by Healthcare Common Procedures Code Set (HCPCS) K0606, Automatic external defibrillator, with integrated electrocardiogram analysis, garment type.

Target Population

Adult cardiac patients at risk for sudden cardiac arrest

Eligibility Criteria

Candidates are eligible for participation if they meet all Inclusion Criteria and none of the Exclusion Criteria.

Inclusion Criteria

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

Exclusion Criteria

1. 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
2. Any known skin allergy or sensitivity to the study garment materials that will be next to the skin
3. Any breached or compromised skin on the upper body that would be exacerbated by wearing the study garment
4. Work with or are frequently around equipment that produces high electromagnetic fields, for example magnetic resonance imaging devices, power supply facilities, or welding equipment
5. 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
6. Any planned air travel during the participation period
7. Pregnancy
8. Use of mechanical circulatory support, for example Left Ventricular Assist Device (LVAD) or Total Artificial Heart
9. Implanted Cardiac Resynchronization Therapy Defibrillator (CRT-D)

10. Simultaneous plan/prescription for Holter monitor, mobile cardiac outpatient telemetry (MCOT), Event Recorder, or in-hospital telemetry.
11. 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 (SpO_2) monitor.
12. Under bust chest circumference greater than 52 inches or less than 28 inches
13. Current hospital inpatient

9 GENERAL STUDY PROCEDURES

Screening

Research Coordinators (RCs) will work in conjunction with the site investigators to identify patients who meet eligibility criteria at their respective site. Candidates will be initially screened either in person or by phone. For eligible candidates who express interest in participating, a Screening and Enrollment Visit will be scheduled (Visit 1). These candidates may be provided a copy of the informed consent along with supplemental materials that illustrate the device to review prior to Visit 1.

Enrollment and Screen Failures

At Visit 1, subject eligibility will be reviewed. Subjects who are still eligible and have provided written informed consent by signing the Informed Consent Form (ICF) will be considered for enrollment. Subjects will be provided a copy of the signed ICF.

Subjects will be considered enrolled in the study when they have completed training, are successfully fitted with a WCD System, the Monitor is connected to the Garment and the System is powered ON. Subjects who are consented but not enrolled per this definition will be classified as screen failures.

Subject Identification Numbers

Each enrolled subject will be assigned a unique subject identification (SID) number. The first three characters of the SID will reflect the study site number (e.g. S01, S02, …, S10). The Sponsor will inform each site of its designated site number before the site is opened for enrollment. The last two digits will be assigned based on the enrollment sequence (e.g. the first subject enrolled at each site will be assigned 01) and will be separated from the site designation by a hyphen e.g. S01-05 is subject 05 enrolled at site 01. This number will be used on the Case Report Form (CRF) and on the CareStation website data uploads. The Sponsor will not collect Protected Health Information that would allow specific subject identification (e.g. date of birth, name, initials, medical record number) on the CRF or in the WCD system data.

Unscheduled Visits

Unscheduled visits may be necessary due to AEs or other reasons. The Investigator may examine a subject as often as is medically necessary while the subject is enrolled in the study. Assessments performed at unscheduled visits are at the discretion of the Investigator and will be documented in the CRFs.

Phone Calls

Research Coordinators will conduct weekly phone interviews with the subjects during the participation period to address subject questions, review potential adverse events, and review usage. Unscheduled Study-related phone calls to or from the subjects may also occur.

Subject Withdrawals

Subjects may be withdrawn from the study for any reason including the following:

- Adverse Events (The Medical Monitor will consult with the Site Investigator)
- Investigator/Sponsor decision to withdraw subject from study
- Subject withdrawal of consent

Subjects who require temporary hospitalization (less than 72 hours) for non-study related complications are not required to withdraw from the study but may interrupt use of the WCD during this period at the Investigator's discretion.

When a subject is withdrawn from the study, the reason(s) for withdrawal will be recorded in the case report form (CRF). For any subject who withdraws due to an AE, the reason for withdrawal must be recorded as an AE. Whenever possible, all subjects who are being withdrawn from the study prematurely will undergo assessments listed for the Early Withdrawal visit. Every effort will be made to perform the same procedures at an Early Withdrawal Visit as the Study Exit Visit.

A subject who fails to return for any scheduled visit will be contacted by the site personnel with every effort made to have the subject comply with the protocol. After enrollment, if a subject cannot be contacted with a minimum of 3 telephone calls or emails over a period of 2 weeks (+/- 4 days) including a certified letter, the reason for withdrawal will be recorded as "lost to follow-up". If no response is received, the study withdrawal date will be documented as the date the certified letter was mailed. Every effort will be made to retrieve all study system components regardless of the reason for end of study participation.

In the event of a subject death during the study, the date of death (as listed on the death certificate) will be used as the date of study withdrawal.

AEs deemed by the investigator to be at least possibly related to the use of the ASSURE WCD system persisting at the time of the subject's study exit will be followed by the investigator until the events are resolved, the subject is lost to follow-up or the adverse events are otherwise explained. If further evaluations are required, the investigator will ensure that relevant additional information is documented in the CRF.

Medical Monitor

The Medical Monitor (an independent physician not participating as a clinical investigator in the clinical study) will review and assess in conjunction with the Sponsor all AEs considered by the investigator to be at least possibly related to the use of the ASSURE WCD System to determine if they are reportable to the FDA as Unanticipated Adverse Device Effects (UADEs) per the definition in Section 11. The Medical Monitor will also review all Serious Adverse Events considered by the investigator to be at least possibly related to the use of the ASSURE WCD System to verify relatedness and the Serious classification.

Endpoint Review Committee

An independent panel of board-certified electrophysiologists (physicians not participating as clinical investigators in the clinical study) will review all episodes recorded by the ASSURE WCD and/or the subject's ICD in accordance with the *Endpoint Review Committee (ERC) Charter for ASSURE WCD Clinical Evaluation - Detection and Safety Study (ACE-DETECT)* (3334131). These annotations will then be used in the statistical analysis to classify the episodes to calculate the study outcome measures.

Replacements

Subjects who are withdrawn from the study will not be replaced.

Sponsor or Regulatory Agency Termination of the Study

Although the Sponsor intends to complete the study, the right is reserved to discontinue the study at any time for clinical or administrative reasons, or if required by the local regulatory authority.

End of Study

The end of study will be defined as the date of the last visit of the last subject. A summary of the End of Study report will be sent to relevant regulatory authorities and Institutional Review Boards (IRBs) within 6 months of the end of the study.

10 STUDY VISIT PROCEDURES

The Schedule of Events is presented in Appendix A. A detailed description of assessments performed at each study visit is presented below.

Visit 1 (Day 0): Screening and Enrollment

The ASSURE System Training Manual provides detailed instructions for WCD fitting, programming, and System power ON. The following process will be followed at Visit 1.

- Review eligibility criteria
- Explain the purpose and conduct of the study visits to the subject, answer the subject's questions, and obtain written informed consent. This consent process can be performed in advance of Visit 1 at the discretion of the site Investigator.
- Provide the subject with a copy of the signed informed consent
- Obtain demographic data
- Collect ICD Baseline Documentation:
    - Perform a full interrogation of the ICD on the Day of enrollment prior to WCD garment fitting.
    - Synchronize the ICD internal clock to the current time and time zone.
    - If current programmed parameters do not include detection as low as 150 bpm, the Sponsor requests that a monitoring zone at 150 bpm be programmed at the approval of the subject's physician. (ICD data will be used to identify WCD Missed Events (False Negative Detections)).
    - Print the ICD report as part of the source documentation. The report shall include the programmed parameters and arrhythmic episode history.
- Obtain abbreviated limited medical history as specified in the Case Report Form (CRF).
- Perform Wearability Assessment as specified in the CRF. If there is any question regarding skin condition e.g. eczema, the site investigator shall use medical judgement to determine if it disqualifies the subject from participating.
- Obtain urine pregnancy test for women of childbearing potential. If positive, subject is ineligible to participate.
- Perform subject training, including overview of study procedures, hands-on assembly and disassembly of the garment and cable assembly, use and care of the

WCD, and review of manuals. Sponsor representative(s) may be available to assist.

- Have the subject complete the BORG Comfort Scale before they are fit with the Garment. This provides a baseline comfort level to which the follow up BORG Scale scores (obtained at Visit 2 after the subject has worn the WCD) can be compared.
- Fit Garment to subject in accordance with the sizing chart and instructions provided in the System Training Manual. *Subjects with an under bust chest circumference greater than 52 inches or less than 28 inches are not eligible to be enrolled.*
- Photograph Garment fit (torso only, not subject's head) from both lateral views, the anterior view and the posterior view.
- Set up the WCD including subject ID entry, and synchronization of the WCD internal clock to the current time and time zone. VT/VF detection parameters will remain at default settings. (Refer to the System Training Manual).
- Register the study subject on the CareStation remote monitoring website (Add New Patient) using their study subject ID number.
- Verify Garment fit per System Training Manual using the tablet. Save tablet screen images of the Patient Management, Device Status and WCD Settings screens including the ECG signals.
- Schedule subject to return for follow up (Visit 2)
- Notify the subject that they will receive phone calls on Days 7 +/- 2, 14 +/-2, 21+/- 2, and 28 +/- 2 during which they can ask questions, and during which they will be asked about usage (how long they have been wearing the system), and if they experienced any discomfort or injury. Schedule these weekly phone calls with the subject.

Weekly Phone Calls to Study Subject

On each of Day 7 +/- 2, Day 14 +/- 2, Day 21 +/- 2, and Day 28 +/- 2 the site RC will call the study subject. In preparation for the call, the RC will review daily usage using the CareStation website and will record the usage data in the CRF.

- Record subject questions and responses in the CRF, noting any questions that require additional follow up and when the subject was called again with the answer(s).

- Record subject's explanation for any usage less than 22 hours per day[3] since the previous call.
- Ask the subject if they have experienced any discomfort or injury during the previous week. If yes, and the investigator determines that the symptoms are at least possibly related to use of the system, record as an AE in the CRF and gather supporting documentation as appropriate, e.g. description, photograph.

Visit 2: Study Exit Visit

At Visit 2 the following will be performed:

- Photograph garment fit (torso only) from both lateral views, the anterior view and the posterior view.
- Remove the Garment.
- Record WCD System Return (all components).
- Perform Wearability Assessment after system removal as indicated in the CRF.
- Ask the subject if they have experienced any discomfort or injury since the last phone call. If yes, and the investigator determines that the symptoms are at least possibly related to use of the device, record as an AE in the CRF.
- Have the subject complete the follow up BORG Comfort Scale.
- Have the subject complete the Usability Survey.
- Record subject explanation for usage less than 22 hours per day since the last weekly phone call.
- Obtain ICD summary report via the ICD remote management system or direct interrogation (model number, current programmed parameters, episode detail and any stored electrograms that are available from all new episodes recorded since Visit 1). De-identify and label with subject ID.
- Release the subject from the Visit.

[3] Average WCD wear time reported in WEARIT-II Registry Trial (Kutyifa V)

Following the Study Visit:

- Follow up requirements for subjects with ongoing AEs are specified in Section 11.
- If follow-up is needed after the Study Exit visit, it should occur as an unscheduled visit at the Investigator's discretion.

11 STUDY ASSESSMENTS

This section describes the study assessments. For timing of study assessments, see the Schedule of Events (Appendix A).

Demographic Data

Demographic data, such as age, sex, race, and ethnicity will be collected on the CRF

Abbreviated Medical History

An abbreviated medical history as specified in the CRF, including but not limited to cardiac diagnosis and skin allergies will be obtained for each subject at screening and updated any time the Investigator learns of information that might affect the subject's eligibility to continue participation in the study or to identify AEs.

ICD Interrogation and Report Generation

ICD Interrogation at Visit 1 (collect Baseline ICD Documentation via direct interrogation) and at Visit 2 (Obtain ICD summary report via the ICD remote management system or direct interrogation) must be done by qualified site personnel.

BORG Comfort Scale

Subjects will be asked by the research coordinator at baseline and again at the follow up visit to locate and grade the severity of any discomfort they experience on their upper body. This will be recorded on a BORG comfort scale/map as specified in CRFs.

Wearability Assessment

A Wearability Assessment (as specified in the CRF), including a review of skin abnormalities on the upper body and/or musculoskeletal conditions, and measurement of height and weight, will be performed by study personnel. Abnormal findings at Visit 1 will be used to reassess eligibility. If the subject is enrolled, then the findings will be recorded in the CRFs as baseline conditions. The Wearability Assessment will also be performed at Visit 2 after the System has been removed. Height will not be measured or recorded at Visit 2. Abnormal findings that were not present at baseline or have worsened from baseline and are determined by the investigator to be at least possibly related to use of the WCD will be recorded in the CRFs as AEs.

Concomitant Medical Devices and Equipment

Use of allowed concomitant medical devices and durable medical equipment will be recorded in the CRFs (e.g. CPAP, walker, wheelchair).

Clinical Laboratory Tests

Pregnancy testing by urinalysis will be performed for women of child bearing potential to verify eligibility prior to enrollment. Test sticks will be provided by the Sponsor.

Evaluation of Adverse Events

Adverse events (AEs) as defined below will be monitored continuously during the study from the time the subject is considered enrolled through resolution. Subjects will be instructed to report all AEs during the study, and study personnel will interview the subjects regarding new AEs during each weekly phone call follow up. AEs may be reported by the subject, discovered by Investigator questioning, or detected through physical examination or other means at the study exit visit.

Device Usability Survey

A device Usability Survey will be administered at Visit 2.

Definitions

For the purposes of this study, an **AE** is defined as any untoward medical occurrence in a subject during the study that in the opinion of the investigator is at least possibly-related to use of the ASSURE WCD System.

A **serious adverse event (SAE)** is defined as any adverse event that:

- Leads to death
- Leads to serious deterioration in the health of a subject that:
    - Results in a life-threatening illness or injury, or
    - Results in a permanent impairment of a body structure or a body function, or
    - Requires in inpatient or prolonged hospitalization ≥ 24 hours, or
    - Results in medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or function, or
    - Leads to fetal distress, fetal death or a congenital anomaly or birth defect.

Adverse Device Effect (ADE) is an adverse event related to the use of an investigational medical device.

Anticipated Adverse Device Effects (AADE) are those events related to the use of the device that are reasonably expected to occur as a result of the subject's participation in

the study. The following are AADEs based on results from the series of previous feasibility studies listed in Section 6 and the system engineering hazard analysis:

- Mild to moderate skin irritation
- Muscle Strain
- Emotional discomfort e.g. anxiety, uncomfortable or claustrophobic feelings
- Fall Injury
- Bruising
- Pinched Fingers
- Shoulder discomfort
- Skin Infection (bacterial or yeast)
- ICD System Infection

An **Unanticipated Adverse Device Effect (UADE)** is any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with the device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in this protocol; or any other unanticipated serious problem associated with the device that relates to the rights, safety, or welfare of subjects.

All AEs will be assessed by the investigator according to:

- Whether the event is serious (SAE);
- The severity of the event (mild, moderate, severe); and
- The relationship of the event to device use (possibly, probably, or definitely related)
    - Possibly Related – There is a reasonable possibility that the AE may have been primarily caused by device use. The AE has a reasonable temporal relationship to the use of the device and follows a known or expected response pattern to device, but alternative etiology is equally or more likely compared to the potential relationship to the use of the device.
    - Probably Related – There is a reasonable probability that the AE may have been primarily caused by device use. The AE has a reasonable temporal relationship to the use of the device and follows a known or expected response pattern to device. Note: this definition assumes no

alternative etiology is equally or more likely compared to the potential relationship to the use of the device.

- Definitely Related – The AE has a strong causal relationship to device use. The AE follows a strong temporal relationship to the use of the device, follows a known response pattern to the device, and cannot be reasonably explained by known characteristics of the subject's clinical state or other therapies.

Whenever possible, the Investigator should group signs or symptoms that constitute a single diagnosis under a single AE term (e.g. redness and swelling can be combined under skin irritation).

Baseline conditions e.g. mild eczema, and AEs identified at Visit 1 following enrollment will be documented during the Wearability Assessment. Baseline conditions are not considered adverse events unless the condition worsens because of study device use.

Adverse Event Reporting Procedures

SAEs deemed at least possibly related to the use of the ASSURE WCD system will reviewed by the investigator and will be recorded on the CRF. The following information about each AE will be collected: description, severity, onset and resolution dates, seriousness, relationship to study device, action taken, and outcome.

Upon awareness of a SAE, the study site must enter the data into the eCRF within 2-3 business days. If the eCRF is not accessible, the Sponsor or Sponsor representative must be notified of any SAE via telephone (1-866-694-7476).

UADEs must be reported by the investigator to the approving IRB as soon as possible, but not later than 10 working days after the investigator first learns of the effect.

Reporting UADEs to Regulatory Agencies

The Sponsor is responsible for the ongoing safety evaluation of the device. The Sponsor should promptly notify all concerned Investigators/Institutions and the FDA of findings that could adversely affect the safety of subjects, impact the conduct of the study, or alter IRB approval to continue the study. The Sponsor will report UADEs to the Food and Drug Administration (FDA) and other IRBs within ten days of the Sponsor's learning of them.

Follow-up of Adverse Events

Resolution means the subject has returned to the baseline state of health or the Investigator does not expect any further improvement in the subject's condition or does not expect worsening of the AE.

AEs deemed at least possibly related to the use of the ASSURE WCD system persisting at the time of the subject's study exit will be followed by the investigator until the events are resolved, the subject is lost to follow-up or the adverse events are otherwise explained. If further evaluations are required, the investigator will ensure that relevant additional information is documented in the CRF.

12 STATISTICAL OVERVIEW

Data Sources

Outcome measures for the primary and secondary endpoints will be obtained by board-certified electrophysiologist review of Episodes recorded during the study period by the subject's ICD and/or the ASSURE WCD per the definitions and instructions identified in the *Endpoint Review Committee (ERC) Charter for ASSURE WCD Clinical Evaluation - Detection and Safety Study (ACE-DETECT)* (3334131). Cumulative wear time, which is also required to calculate the primary endpoint is recorded by the ASSURE WCD as "Usage" data and accessible via the CareStation website. The estimated inappropriate shock rate will be calculated as the product of the False Positive Alarm Rate (primary outcome measure) and the missed shock alarm rate obtained from prior usability studies (described in Section 6) conducted by the sponsor.

Determination of Sample Size

The sample size for this study is determined based on the primary endpoint.

Approximately 130 subjects will be enrolled. It is anticipated that 10 sites will participate and that a maximum of 18 subjects will be enrolled at each site. This sample size will provide approximately 90% power, at a significance level of 2.5%, to detect a difference between the study false alarm rate and the comparator rate if the true false alarm rate for the study device is at least 50% lower than the comparator rate. Power was calculated using the R statistical package. The comparator rate was chosen to be 0.29 false alarms per subject-day (one alarm every 3.43 days), which is the performance reported for the currently marketed ZOLL LifeVest® Model 3000[4]. A more detailed description of this calculation is provided in the Statistical Analysis Plan (SAP) (3338311).

Data sets to be analyzed

The primary and secondary endpoints will be analyzed using the Intent-to-Treat (ITT) and Per-Protocol (PP) sets of subjects, and all safety variables will be analyzed using the Safety (SAF) set of subjects. These data sets are defined below. Additional data sets may be defined in the Statistical Analysis Plan (SAP).

[4] LifeVest Model 3000 Clinical Study (as reported in LifeVest 4000 operator's manual pg. 7-5.)

- The ITT set of subjects will include the data from all enrolled subjects. No subjects will be excluded from this data set for any reason (e.g., protocol deviation, study device not used, etc.).
- The PP set of subjects will include all subjects enrolled who met the eligibility criteria and were appropriately fitted with a WCD (correct Garment size based on the sizing chart in the ASSURE System Training Manual). The determination of subjects excluded from the PP set will be made prior to locking the final database.
- The SAF set of subjects will include all subjects who used the device for at least two hours. No subjects (or data) will be excluded from this data set because of protocol deviations that occur during the study.

Subject Disposition

Subject disposition including the number of subjects enrolled and number of subjects completing the study (and completing each study visit) will be tabulated. The percentage of subjects completing the study will be based on the total number enrolled. Protocol deviations will also be summarized. Subject withdrawals and the reasons for withdrawal will also be summarized.

Analysis of Demographic and Baseline Data

Subject demographic and baseline data will be summarized by treatment arm for the ITT set of subjects. Continuous variables will be summarized using descriptive statistics (number of subjects, mean, standard deviation, median, minimum and maximum), and categorical variables will be summarized using the count and percentage of subjects in each category.

Endpoint Analysis

It is planned that the data from all clinical sites that participate in this study will be combined, so that the target sample size will be available for analysis. Further details of the statistical methods will be included in the Statistical Analysis Plan (SAP).

The primary endpoint in this study will be based on the assessment of performance in comparison to published performance for a comparative currently marketed device.

The endpoint analyses will be performed after all subjects have either completed the final visit or withdrawn early from the study, the study database has been cleaned, verified and locked, and adjudication/reconciliation of all Episodes is complete as specified in the Episode Annotation Protocol for *ASSURE WCD Clinical Evaluation - Detection and Safety Study ACE - DETECT* (GDR 3334131).

Alarm Definitions (for the Primary Endpoint)

When initial arrhythmia detection criteria are met, the ASSURE WCD opens an Episode and begins storage of ECG signals. If the rhythm is sustained for the confirmation period, a Shock Alarm Event Marker is recorded. Each Shock Alarm Event Marker will be reviewed and annotated per the definitions and instructions in the *Endpoint Review Committee (ERC) Charter for ASSURE WCD Clinical Evaluation - Detection and Safety Study (ACE-DETECT)* (3334131). Each Shock Alarm Event Marker will be classified for the primary endpoint as follows:

- **True Positive Alarm**: The presence of a WCD Shock Alarm Event Marker within a recorded Episode where the Shock Alarm has been annotated as:
    - Rhythm Type **VT/VF** with HR ≥ 153 bpm (170 bpm - 10%)

- **False Positive Alarm**: The presence of a WCD Shock Alarm Event Marker within a recorded Episode where the Shock Alarm has been annotated as:
    - Rhythm Type **Other**

      OR
    - Rhythm Type **Uncertain (presumed non-shockable)**

      OR
    - Rhythm Type **VT/VF** with HR < 153 bpm (170 bpm - 10%)

Episode Detection (for the secondary Endpoint)

All WCD Episodes, and ICD Episodes for which there is not a corresponding WCD Episode, will be reviewed and annotated per the definitions and instructions in the *Endpoint Review Committee (ERC) Charter for ASSURE WCD Clinical Evaluation - Detection and Safety Study (ACE-DETECT)* (3334131). These annotation results will be used to classify the detections according to the following definitions:

- **True Positive Detection**: A WCD recorded Episode (with or without a Shock Alarm Event Marker) annotated as Rhythm Type **VT/VF** with **HR** ≥ 153 bpm (170 - 10%)
- **Missed Event (False Negative Detection)**: An Episode recorded by the ICD but not by the WCD when it is confirmed that the WCD was being worn, and where

the ICD Episode is annotated as Rhythm Type **VT/VF** with **HR** ≥ 187 bpm (170 + 10%) and Duration ≥ 20 seconds.

Analysis of Primary Endpoint

The primary endpoint analysis will be a one-sided test with significance level 0.025 of the null hypothesis H_0 that the WCD False Positive Alarm Rate for the study device is equal to or greater than the comparator rate. The alternative hypothesis H_1 is that the study device False Positive Alarm Rate is lower than the comparator rate.

A random effects Poisson regression model will be fitted with the number of false alarms for each subject as the outcome variable. An additional random effects Poisson regression model will be fit including subject characteristics (including age, sex, height and weight) as covariates. Model assumptions will be checked, and a sensitivity analysis will be performed using the bootstrap if substantive violations of model assumptions are suspected. Further details of the statistical methods will be included in the SAP.

Analysis of Secondary Endpoints

Secondary endpoints are exploratory and do not have specific performance criteria requirements.

Summary of WCD True Positive Detections and Missed Events (False Negative Detections)

Shockable (VT/VF) events are estimated to occur at a rate of 24 per 100 patient-years based on reported appropriate shock and non-sustained VT rates in contemporary ICD trials[5]. Based on this, we estimate approximately two shockable events during the study. While all ASSURE WCD devices will be programmed to nominal settings during the study, ICD detection schemes and programmed parameters including rate threshold and duration will differ across the study population. This may be due to a variety of factors including but not limited to manufacturer, model, physician preference and unique subject conditions. Due to these differences, it is anticipated that all shockable events may not be simultaneously detected by the ICD and the ASSURE WCD. For example, it is foreseeable that the ICD may miss lower rate shockable rhythms if the ICD is programmed to a high rate cutoff (e.g. VF>200 bpm). It is also foreseeable that the

[5] MADIT-RIT, ADVANCE III, ALTITUDE REDUCES

WCD may miss rhythms that are treated quickly by the ICD (e.g. anti-tachycardia pacing programmed) and are not sustained long enough to fulfill WCD detection criteria.

Given the anticipated low incidence of shockable events, the incidence of True Positive Detections and Missed Events for each adjudicated Episode will be summarized.

Estimated Inappropriate Shock Rate

An estimate of the inappropriate shock rate will be calculated as the product of the WCD False Positive Alarm Rate (the Primary Outcome measure of this study) and the Missed Shock Alarm Rate. The Missed Shock Alarm Rate was derived from two prior studies during which high priority alarms (shock alarms) were delivered randomly to study subjects. A "Missed Shock Alarm" was one during which the subject failed to respond to the shock alarm within 20 seconds following alarm activation. Data was obtained both during sleep (GDR 3333597 ASSURE UISim Sleep Study) and during normal daily activities (GDR 3334121 ASSURE UISim 7-day study).

Adverse Events

AEs will be summarized using the SAF subject set. Separate summaries of AEs at least possibly related to device use and by severity (as reported by the Investigator and reviewed by the Medical Monitor) will be prepared. UADEs will also be summarized. AEs leading to withdrawal from the study will be listed and tabulated.

Subgroup Analysis

Subgroup analyses are exploratory and will be specified in the Statistical Analysis Plan.

13 DATA HANDLING AND QUALITY ASSURANCE

Case Report Forms

As part of the responsibilities assumed by participating in the study, the Investigator agrees to maintain adequate case histories for the subjects treated as part of the research under this protocol. The Investigator agrees to maintain an accurate CRF and source documentation as part of the case history for each subject. Source documentation may include chart notes, laboratory reports, ECG strips, and photographs.

All requested information is to be filled in on the CRF. If an item is not available or is not applicable, this should be indicated. Blank data fields should not be present unless otherwise directed.

CRFs must be reviewed, signed, and dated by the Investigator as required in a timely manner.

Study Monitoring

The Sponsor or Sponsor representative, will follow the study closely and will maintain necessary email, telephone, fax, and/or mail contact with the Investigators and study site and will visit the study sites at periodic intervals. The study monitor will maintain current personal knowledge of the study through observation, review of study records and source documentation, and discussion of the conduct of the study with the Investigators and study site staff. During those visits, the study monitor will compare the subject data recorded in the Case Report Form against source documents at the clinical site.

All aspects of the study will be carefully monitored by the Sponsor or its designee for compliance with applicable government regulations.

Inspection of Records

Investigators and institutions involved in the study will permit study-related monitoring, audits, IRB review, and regulatory inspection(s) by providing direct access to all study records. The Investigator or study site may be audited by the Sponsor or its representatives and/or regulatory agencies at any time. In the event of an audit, the Investigator agrees to allow the Sponsor, representatives of the Sponsor, the Food and Drug Administration (FDA), or other regulatory agency access to all study records.

The Sponsor will review case report form data and perform electronic edit checks on the data.

The Investigator should promptly notify the Sponsor of any audits scheduled by any regulatory authorities and promptly forward copies of any audit reports received to the Sponsor.

Study Record Retention

Government agency regulations and directives require that all study documentation pertaining to the conduct of a clinical study in the subject files as original source documents for the study must be retained by the Investigator until notified by the Sponsor in writing that retention is no longer necessary. Study documentation includes records of laboratory tests, clinical notes, and subject medical records. It is the responsibility of the Sponsor to inform the Investigator/institution as to when this documentation no longer needs to be retained.

Records containing subject medical information must be handled in accordance with the requirements of the applicable privacy rules and consistent with the terms of the subject authorization contained in the ICF for the study. Care should be taken to ensure that such records are not shared with any person or for any purpose not described by the ICF. Furthermore, the CRF and other documents to be transferred to the Sponsor should be completed in strict accordance with the instructions provided by the Sponsor, including the instructions regarding the coding of subject identities. Should the Investigator wish to assign the study records to another party or move them to another location, written agreement must be obtained from the Sponsor. If requested, the Investigator will provide the Sponsor, applicable regulatory agencies, and applicable IRB with direct access to original source documents.

Investigators shall maintain all study-related documentation for a period of two (2) years following completion of the study, or the date of marketing approval or as per the local regulatory authority's guidelines and practices, whichever is longer. The Investigator should contact the Sponsor prior to destroying any study related documents.

14 STUDY ETHICAL CONSIDERATIONS

Ethical Conduct of the Study

The Investigator agrees that the study will be conducted according to the applicable FDA regulations 21CFR 812.2(b). The Investigator will conduct all aspects of this study in accordance with all national, state, and local laws or regulations.

Informed Consent

Written informed consent in compliance with Title 21 of the CFR Part 50 shall be obtained from each subject prior to entering the study or performing any unusual or non-routine procedure that involves risk to the subject. An ICF template may be provided by the Sponsor or designee to investigative sites. The ICF will be submitted by the Investigator to his or her IRB for review and approval prior to the start of the study. If any institution-specific modifications to study-related procedures are proposed or made by the site, the ICF should be reviewed by the Sponsor and/or its designee, if appropriate, prior to IRB submission.

Before recruitment and enrollment, each prospective subject will be given a full explanation of the nature of the study and the action of the study device. The subject will be informed that participation is voluntary and that they can withdraw from the study at any time. The subject will be allowed to read the approved ICF. Once the Investigator is assured that the subject agrees to participate in the study, the subject will be asked to give consent by signing the ICF. This consent process can be performed in advance of Visit 1 at the discretion of the site Investigator.

The Investigator shall provide a copy of the signed and dated ICF to the subject. The original shall be maintained in the subject's medical records at the site.

Institutional Review Board

Federal regulations require that approval be obtained from an IRB prior to participation of subjects in research studies. Prior to subject enrollment, a signed copy of the IRB approval letter must be submitted to the sponsor. In addition, the protocol, informed consent form, advertisements to be used for subject recruitment, and any other written information regarding this study to be provided to the subject must be approved by the IRB. Documentation of all IRB approvals will be maintained by the site and will be available for review by the sponsor or its designee.

All IRB approvals should be signed by the IRB chairperson or designee and must identify the IRB by name and address, the clinical protocol by title and/or protocol number, and the date approval was granted.

The Investigator is responsible for submitting and obtaining initial and continuing review of the study at intervals not exceeding 1 year or as otherwise directed by the IRB. The investigator must supply the Sponsor or its designee written documentation of continued review of the study.

The Investigator will notify the Sponsor or Sponsor representative within 5 working days of withdrawal of IRB approval or if device use occurs without prior subject informed consent.

15 ADMINISTRATIVE CONSIDERATIONS

Confidentiality

All laboratory specimens, evaluation forms, reports, and other records will be identified in a manner designed to maintain subject confidentiality. All records will be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the subject, except as necessary for monitoring and auditing by the Sponsor, its designee, the FDA, or the IRB.

The Investigator and all employees and coworkers involved with this study may not disclose or use for any purpose other than performance of the study any data, record, or other unpublished confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

Modification of the Protocol

The Investigator may implement a change from the protocol without prior Sponsor and IRB approval only to eliminate an immediate hazard to a subject, in which case, Sponsor and IRB must be notified of the change within 24 hours.

Amendments to the protocol must be submitted in writing to the IRB and approved prior to subjects being enrolled into an amended protocol.

Protocol Deviations

A protocol deviation occurs when the Investigator or subject has failed to adhere to significant protocol requirements. Important deviations related to study inclusion or exclusion criteria, conduct of the trial, subject management or subject assessment should be documented. Specific categories to be documented include but are not limited to:

- Subjects who enter the study even though they do not satisfy the entry criteria
- Subjects who develop withdrawal criteria during the study but are not withdrawn
- Subjects who receive an excluded concomitant therapy or treatment

Other protocol deviations to be considered include non-adherence to the protocol that results in a significant additional risk to the subject.

The Investigator must document and explain any protocol deviation in the subject's source documentation. The IRB should be notified of important protocol deviations in a timely manner. Protocol deviations should be reported to the IRB periodically, according to their requirements. Protocol deviations may also be documented by the

clinical monitor during monitoring visits and those observations will be reviewed with the Investigator.

The Investigator is responsible for enrolling subjects who have met protocol eligibility criteria. If the Investigator has a question concerning a subject who may not meet an entry criterion, they should contact the Sponsor to discuss the specifics. Waivers for protocol eligibility will not be granted in this study.

Study Reporting Requirements

By participating in this study, the Investigator agrees to submit reports of SAEs according to the time line and method outlined in the protocol. In addition, the Investigator agrees to submit periodic reports to his/her IRB as appropriate.

Financial Disclosure

Principal Investigators and Sub-Investigators are required to provide financial disclosure information to allow the Sponsor to submit the complete and accurate certification or disclosure statements required under Title 21 CFR 54. In addition, the Investigator must provide to the Sponsor a commitment to update this information promptly, if any relevant changes occur during the investigation and at the completion of the trial.

Financial Obligations

The Sponsor is not financially responsible for further testing/treatment of any medical condition that may be detected during the screening process. In addition, in the absence of specific arrangements, the Sponsor is not financially responsible for further treatment of the subject's disease.

Investigator Documentation

Prior to beginning the study, the Investigator will be asked to comply with 21CFR812.2(b) by providing the following essential documents, including but not limited to:

- An Investigator-signed Investigator Agreement page of the protocol
- An IRB -approved ICF, samples of site advertisements for recruitment for this study, and any other written information regarding this study that is to be provided to the subject
- IRB approval of the Investigator, the Protocol, and the subject-facing materials
- Curricula vitae for the Principal Investigator and each Sub investigator listed. Current licensure must be noted on the curricula vitae or a copy of the license provided. The curricula vitae must be signed and dated by the Principal

Investigators and Sub investigators within 1 year of study start-up, indicating that they are accurate and current.

- Financial disclosure information to allow the Sponsor to submit complete and accurate certification or disclosure statements required under Title 21 CFR 54. In addition, the Investigators must provide to the Sponsor a commitment to promptly update this information if any relevant changes occur during the investigation, at the completion of the trial and 1 year following the completion of the study.

Clinical Trial Agreement

Payments by the Sponsor to Investigators and institutions conducting the study, requirements for Investigators' insurance, and other requirements are specified in the Clinical Trial Agreement.

Policy for Publication and Presentation of Data

Following completion of the study at all sites, data may be considered for reporting at a scientific meeting and/or for publication in a scientific journal. Draft manuscripts of any public disclosure shall be provided to the Sponsor 60 days prior to presentation or publication to enable the Sponsor to review and comment and take any steps necessary to protect its intellectual property rights, consistent with the Clinical Trial Agreement.

16 INVESTIGATOR AGREEMENT

I agree to conduct the study as outlined in the protocol entitled, "ASSURE WCD Clinical Evaluation - Detection and Safety Study (ACE-DETECT)", and in accordance with all applicable guidelines and government regulations including Title 21 CFR 54. I agree to provide the Sponsor with accurate financial information to allow the Sponsor to submit complete and accurate certification and disclosure statements as required by applicable regulations.

I have read and understand all sections of the protocol, including the section on study ethical considerations (Section 14) and administrative considerations (Section 15).

Principal Investigator's Name

Principal Investigator's Signature Date

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18 APPENDIX A: SCHEDULE OF EVENTS

Assessment	**Visit 1 (Day 0) Screening and Enrollment**	**Weekly Phone Calls**	**Visit 2 Study Exit**	**Early Withdrawal Visit[6]**
Study Day ± window (days)	**0**	**Days 7, 14, 21, and 28 each +/-2**	**Day 30 +5/-0**	
Informed Consent	X			
Inclusion/Exclusion Criteria	X			
Demographics	X			
Collect ICD Baseline Documentation	X	X	X	X
Synchronize the ICD Internal Clock to Current Time	X			
Abbreviated Medical History	X		X	X
Wearability Assessment[7]	X		X	X
BORG Comfort Scale[7]	X		X	X
Urine Pregnancy Test (as required)	X			
Subject Training on WCD	X			
Fit, Program and Initiate Device Use	X			
Photograph Garment Fit (torso only) – both lateral views, anterior and posterior views	X		X	X
Set up WCD per System Training Manual • Subject ID entry • Time zone setting and Synchronization of internal clock to current time • Leave VT/VF detection criteria at default	X			
Verify Garment Fit • Refer to System Training Manual • Save Tablet screen images of device status screen and WCD Settings	X			
Schedule Visit 2 and Weekly Calls with Subject	X			
Review Usage on CareStation • Record explanations for any daily usage less than 22 hours		X	X	X
Obtain ICD Report for all new Episodes since Visit 1			X	X
Adverse Events (at least possibly device-related)	X	X	X	X
Retrieve all WCD System Components			X	X
Device Usability Survey			X	X

[6] If the subject is withdrawn early, schedule as soon as possible following the time the study device use is stopped.

[7] Perform before the Garment is fitted at Visit 1, and after the Garment is removed at Visit 2 or the Early Withdrawal Visit.