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A wearable cardioverter defibrillator with a low false alarm rate

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Abstract

Introduction: A wearable cardioverter defibrillator (WCD) is indicated in appropriate patients to reduce the risk for sudden cardiac death. Challenges for patients wearing a WCD have been frequent false shock alarms primarily due to electrocardiogram noise and wear discomfort. The objective of this study was to test a contemporary WCD designed for reduced false shock alarms and improved comfort.

Methods: One hundred and thirty patients with left ventricular ejection fraction ≤40% and an active implantable cardioverter defibrillator (ICD) were fitted with the ASSURE WCD (Kestra Medical Technologies) and followed for 30 days. WCD detection was enabled and shock alarm markers recorded, but shocks and shock alarms were disabled. All WCD episodes and ICD ventricular tachycardia/ventricular

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fibrillation (VT/VF) episodes were adjudicated. The primary endpoint was the false-positive shock alarm rate with a performance goal of 1 every 3.4 days (0.29 per patient-day).

Results: Of 163 WCD episodes, 4 were VT/VF and 159 non-VT/VF (121 rhythms with noise, 32 uncertain with noise, 6 atrial flutter without noise). Only three false-positive shock alarm markers were recorded; one false-positive shock alarm every 1333 patient-days (0.00075 per patient-day, 95% confidence interval: 0.00015–0.00361; $p < .001$). No ICD recorded VT/VF episodes meeting WCD detection criteria (≥170 bpm for ≥20 s) were missed by the WCD during 3501 patient-days of use. Median wear was 31.0 days (interquartile range [IQR] 2.0) and median daily use 23.0 h (IQR 1.7). Adverse events were mostly mild: skin irritation (19.4%) and musculoskeletal discomfort (8.5%).

Conclusion: The ASSURE WCD demonstrated a low false-positive shock alarm rate, low patient-reported discomfort, and no serious adverse events.

KEYWORDS
defibrillator, sudden cardiac death, ventricular arrhythmia

1 | INTRODUCTION

The wearable cardioverter defibrillator (WCD) provides automatic defibrillation therapy for patients at risk of sudden cardiac death who are not immediate candidates for implantable cardioverter defibrillator (ICD) therapy.[1] Such patients include those with reduced left ventricular ejection fraction (LVEF) and recent myocardial infarction, recent coronary revascularization, or new-onset heart failure (HF) to allow for optimization of medical therapy and re-evaluation of cardiac function. Additional indications include ICD explant due to infection, postponed ICD implant, and pending heart transplant.[1,2]

The only commercially available WCD in the market at the time this study was conducted was the LifeVest® (ZOLL® Medical Corporation), hereafter referred to as the C-WCD. Conversion efficacy of ventricular tachycardia/ventricular fibrillation (VT/VF) for the C-WCD is reported to be high (range 94%–100%) for detected events.[3–8] However, compliance with wearing the C-WCD has been challenging for many patients. Several factors may contribute to this observation, including frequent alarms, inappropriate shocks, and device discomfort.[5,9–12] Noise artifact has been reported to be the most common cause of false alarms in the C-WCD.[10,13]

Advances in electronics and mobile technology, signal processing techniques, and textiles have enabled the design of a contemporary WCD, the ASSURE® WCD System (Kestra Medical Technologies, Inc.), hereafter referred to as the A-WCD. In addition to designing a more comfortable device, a primary goal of the A-WCD design was to reduce the false alarm rate via effective noise immunity while maintaining high sensitivity for VT/VF. The preclinical evidence for safety and effectiveness included an extensive series of engineering verification tests and animal studies. VT/VF sensitivity and specificity performance was evaluated in accordance with the AHA recommendations using a recorded electrocardiogram (ECG) database that included a wide range of rhythm samples. Sensitivity for VF was 99.0% and 98.4% for VT (Table 1). The primary purpose of this study (ACE-DETECT, NCT 03887052) was to evaluate the A-WCD false alarm rate, wear compliance, and adverse events (AEs) in ambulatory patients. Shock efficacy of the A-WCD including preclinical studies and human study is the focus of a separate report.

2 | METHODS

2.1 | Study design and patient selection

ACE-DETECT was a multicenter prospective, nonrandomized study. The target population was adult patients who had an active ICD. These patients were chosen because they are representative of the WCD intended use population and are at high risk for ventricular

TABLE 1 A-WCD detection algorithm performance using an ECG database during preclinical evaluation

Rhythm	Test sample size (minimum required[a])	Performance goal[a]	Observed performance[b]	90% One-sided lower confidence limit (minimum)
Shockable				
Coarse VF	204 (200)	>90% sensitivity	99.0%	97.4% (87%)
Rapid VT	62 (50)	>75% sensitivity	98.4%	93.9% (67%)
Nonshockable				
Normal sinus rhythm	132 (100)	>99% sensitivity	100%	98.3% (97%)
AF, sinus bradycardia, SVT, heart block, idioventricular, PVCs	219 (30)	>95% specificity	96.3%	94.1% (88%)
Asystole	169 (100)	>95% specificity	97.6%	95.3% (92%)

Note: Preclinical determination of VT/VF sensitivity and specificity was performed in accordance with the AHA recommendations for AED performance (sensitivity/specificity) as required by IEC 60601-2-4. A rich ECG database included rhythm segments derived from a variety of sources including spontaneous cardiac arrest from Emergency Medical System recordings, previously recorded ECGs from an EP lab, and prospective EP lab recordings with electrodes in the ASSURE WCD locations. Rhythm samples with noise greater than 25% of the QRS amplitude were excluded from the database as per the recommendations outlined by the AHA to test rhythm segments free of substantial noise.

Abbreviations: AED, automatic external defibrillator; AHA, American Heart Association; A-WCD, ASSURE® WCD System; ECG, electrocardiogram; EP, electrophysiology; PVCs, premature ventricular complexes; SVT, supraventricular tachycardia; VF, ventricular tachycardia; VT, ventricular fibrillation.

[a]American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Efficacy.[14]

[b]ASSURE system nominal therapy zone settings (VT 170 bpm, VF 200 bpm).

tachyarrhythmias. The A-WCD was programmed with detection enabled, shock alarm event markers recorded, but auditory and vibratory shock alarms and shock therapy disabled. This approach allowed for evaluation of A-WCD detection performance (stored episodes including shock alarm event markers), patient-reported evaluation of comfort, AEs, and wear compliance.

The enrollment goal was 130 patients from ten sites across the United States. Enrollment at each site was limited to a maximum of 18 patients to ensure balanced sample distribution. Eligible patients were adults (≥18 years old) with LVEF ≤ 40% and an active ICD (transvenous or S-ICD™). Eligibility criteria allowed enrollment of patients with a variety of QRS morphologies including narrow QRS, bundle branch block, and paced rhythms. To avoid selection bias toward patients who would be predominantly paced, candidates with a cardiac resynchronization therapy defibrillator were excluded. Candidates were also excluded if they were using any other external medical device that might interfere with the proper fit of the A-WCD or if they had skin disorders on the upper body that would be exacerbated by wearing the A-WCD. A complete listing of the eligibility criteria is found in Table S1.

The study was approved by the governing international review boards for each institution as a nonsignificant risk device study subject to abbreviated Investigational Device Exemption (IDE) requirements. All patients provided written informed consent before participation.

2.2 | Study conduct

Patients were considered enrolled after they had completed training on the use of the A-WCD, were successfully fitted with a garment, and the system was powered ON. Training was performed in-person by sponsor representatives using a standardized procedure. Standardized training materials included a printed patient handbook, a quick start guide, and an instructional video. Baseline data included clinical and arrhythmia history. A-WCD parameters were programmed to nominal settings (VT zone rate threshold ≥170 bpm and VF zone rate threshold ≥200 bpm). Per the protocol, ICD programmed parameters were left to the discretion of the investigator, except for a request to set monitor rate zones to 150 bpm to facilitate the recording of rhythms that were below the A-WCD VT rate threshold. ICD and A-WCD internal clocks were synchronized to the current time and time zone to facilitate the comparison of episodes.

Patients were provided with a modest stipend for study participation and were asked to wear the A-WCD as much as possible for 30 days, except for showering/bathing. Clinical follow-up was conducted weekly via phone. Patients returned for final follow-up at the end of the 30-day participation period. Both the A-WCD and ICD were interrogated to collect all stored arrhythmia episodes. A-WCD data also included minutes of wear per day. Patients reported their perceived discomfort using the Borg CR10 scale for each of eight anatomical regions on the torso at baseline and final follow-up.[15–17] In addition, a two-question survey (5-point Likert scale) was provided to patients who had prior experience wearing the C-WCD to assess comfort and ease of use compared to the A-WCD.

2.3 | Study endpoints

The primary endpoint was the false-positive shock alarm rate compared to a prespecified objective performance goal of 0.29 per patient-day (2.0 per patient week). This comparator rate was based on the false arrhythmia declarations (false alarms) reported by the C-WCD manufacturer.[18] Other outcome measures included a summary of A-WCD and

ICD detected episodes, patient-reported outcomes including perceived comfort, AEs determined to be at least possibly related to use of the A-WCD, and patient wear compliance.

2.4 | Spontaneous episode adjudication

A Clinical Events Committee (CEC) was formed to adjudicate all arrhythmia episodes recorded by the A-WCD and all ICD episodes detected as VT/VF. The CEC was composed of an independent panel of board-certified electrophysiologists experienced in the interpretation of device-detected arrhythmias. The use of an ICD population allowed the CEC to examine ICD recorded VT/VF episodes and identify those episodes that met the A-WCD pre-defined study detection criteria for VT/VF (≥170 bpm for ≥20 s). The 20-s duration is based upon the A-WCD initial detection (15 s) and confirmation (5 s) criteria in the VF zone. The prespecified adjudication protocol included adjudication of detected rhythm type, heart rate, and rhythm duration. In addition, the CEC assessed the presence or absence of noise on any ECG channel. The rhythm types were ventricular arrhythmia (VT/VF), other physiologic (e.g., sinus rhythm, supraventricular tachycardia (SVT), atrial fibrillation/flutter, bradycardia, asystole), or uncertain. Results of the episode adjudications were then used by the study statistician to classify the episodes and alarms as defined below:

- *True-positive detection* was a stored A-WCD episode adjudicated as VT/VF.
- *False-positive detection* was a stored A-WCD episode adjudicated as other than VT/VF.
- *True-positive shock alarm* was an A-WCD shock alarm ECG event marker for a rhythm adjudicated as VT/VF.
- *False-positive shock alarm* was an A-WCD shock alarm ECG event marker for a rhythm adjudicated as other than VT/VF.
- *Missed event* was VT/VF that met all the following criteria: (1) detected by the ICD that was sustained for ≥20 s with a rate of ≥170 bpm, (2) not stored by the A-WCD, and (3) it was confirmed by stored data in the A-WCD that the patient was wearing the A-WCD at the time the ICD recorded the event.

2.5 | Statistical analysis

The primary endpoint was performed as a one-sided test with a 0.025 significance level of the null hypothesis (H_0) that the A-WCD false-positive shock alarm rate per patient-day for the study device was equal to or greater than the comparator rate (0.29). A random-effects Poisson regression model was fit with the number of false-positive shock alarms for each patient as the outcome, the logarithm of days of wear as an offset, and random site effect. An additional random-effects Poisson regression model was planned with patient characteristics (age, sex, body mass index, baseline QRS width, and ICD type) as covariates; however, due to the very small number of events and poor model fit the results are not reported.

The sample size required to ensure 90% power with a one-sided significance level of 0.025 to detect a 50% reduction in the false-positive shock alarm rate (primary endpoint) over 30 days of follow-up assuming an average wear time of 14 h per day was 105 patients. The enrollment goal was established at 130 patients to increase the likelihood of recording at least two A-WCD detected true VT/VF events. Data were pooled across study centers and data from all 130 patients were used for analysis. Cumulative days of use was calculated as the sum of all patients' total minutes of use recorded by their A-WCD, divided by 1440 min per day.

A-WCD wear compliance by a patient was calculated both as the number of days of use and daily hours of use. The first and last wear days were excluded from the number of days and daily hours calculations as they were less than a full day due to study visit scheduling. The day period was 12:00:00 a.m. to 11:59:59 p.m.

An AE was defined as any untoward medical occurrence in a patient during the study that in the opinion of the investigator was at least possibly related to the use of the A-WCD. An independent physician medical monitor adjudicated all AEs, assessing seriousness, severity, and relatedness to the study device and whether any were reportable as Unanticipated Adverse Device Effects (UADEs) per investigational device exemption regulations. Detailed definitions are included in the Supporting Information.

Reported discomfort data were treated as continuous and analyzed for each of the eight anatomical regions on the torso. Borg scale ratings (0–10) reported at baseline were compared to those reported at end of wear using a Wilcoxon's signed-rank test. Relative comparison of comfort and ease of use for those patients who previously had worn the C-WCD was summarized by Likert category.

2.6 | A-WCD detection and noise management

The most common cause of inappropriate detection, false alarms, and inappropriate shocks in a WCD is noise due primarily to motion artifact and inadequate electrode contact. Examples of raw signals illustrating various types of noise encountered by the A-WCD during this study are shown in Figure S1. Numerous design features were incorporated to increase noise immunity and consequently decrease false alarms and prevent inappropriate shocks. The A-WCD noise management strategy is summarized in Figure 1.

2.6.1 | Minimize noise

The A-WCD garment is made from a lightweight, breathable fabric that is available in two different styles designed for female and male body habitus, and multiple sizes (Figure S2). A well-fitting garment will minimize poor ECG electrode contact. If this should occur, the patient receives an alert instructing them to adjust their garment. The resistive ECG electrodes are cushioned and securely bonded to the fabric (Figure 2), all cables are shielded to reduce electrostatic noise, and an isolated, DC-coupled preamplifier with a wide dynamic range

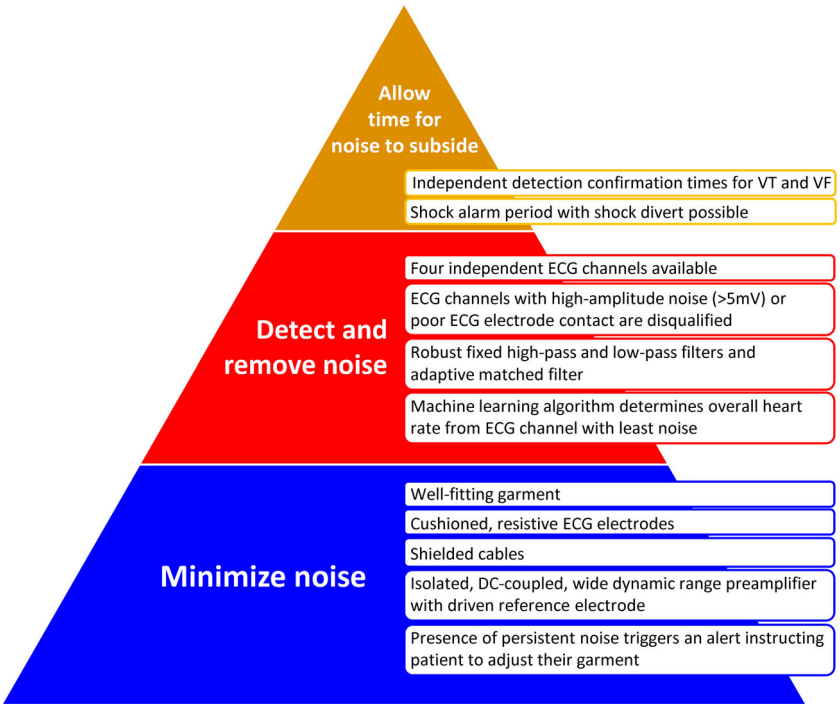

FIGURE 1 ASSURE® WCD System (A-WCD) noise management. The A-WCD employs three levels of protection to achieve a low false alarm rate due to noise. Level 1 (blue)—minimize noise; Level 2 (red)—detect and remove noise that does occur; and Level 3 (yellow)—allow time for remaining noise to subside before alarming

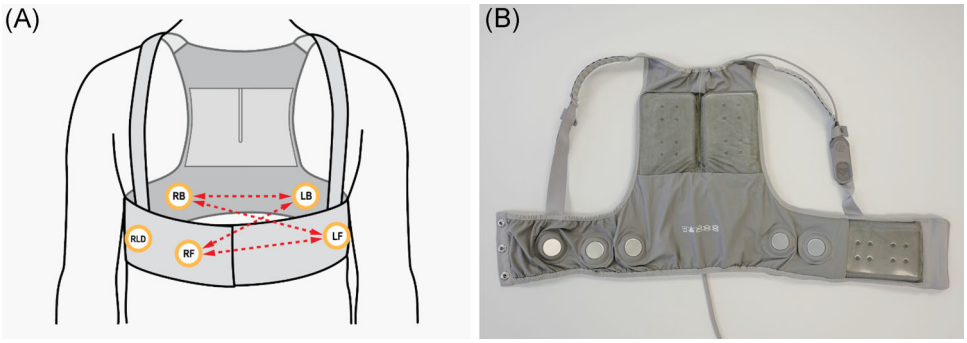

FIGURE 2 Electrocardiogram (ECG) sensing. (A) Five ECG electrodes are positioned circumferentially around the torso at the level of the subxiphoid process, labelled left front (LF), right front (RF), left back (LB), right back (RB), and right leg drive (RLD). Red arrows represent the four differential ECG vectors derived using RLD as a ground reference. (B) Garment interior depicting five embedded, cushioned ECG electrodes and defibrillation pads (two posterior and one anterior)

minimizes common-mode noise and enables the use of high-performance digital filters in the proprietary ASSURE Detection Algorithm (ADA).

2.6.2 | Detect and remove noise

The ECG is acquired from four independent vectors (channels) (Figure 2A). All four ECG channels are filtered with a high-pass filter designed to remove baseline wander and a low-pass filter to reduce high-frequency artifact and noise. The high-pass and low-pass filters are finite impulse response (FIR) filters—a filter type that minimizes distortion that might alter the shape of the QRST complexes. The ADA also includes an adaptive matched filter that learns the patient's specific QRS morphology. Unlike a template that is used by some ICDs to distinguish SVT from VT, a matched filter helps to distinguish QRS complexes from noise. A matched filter such as this provides the theoretical optimum signal-to-noise ratio when detecting a known signal when noise is present. The filter memory is implemented as a kernel. At power-on, the matched filter starts with a default kernel that contains a generic QRS morphology. During the first few minutes of wear, the kernel for each channel gradually adapts to match the patient's QRS morphology (Figure 3). Once the filter is trained it has increased sensitivity for the stored morphology and additional attenuation for other shapes. The kernel adaptation process slowly continues over time to match morphology or rhythm changes the patient may experience. Examples of ECG segment filtering and analysis are included in Figure 4 and Figures S3 and S4. Channels with high-amplitude noise (>5 mV) or poor ECG electrode contact are disqualified from further analysis.

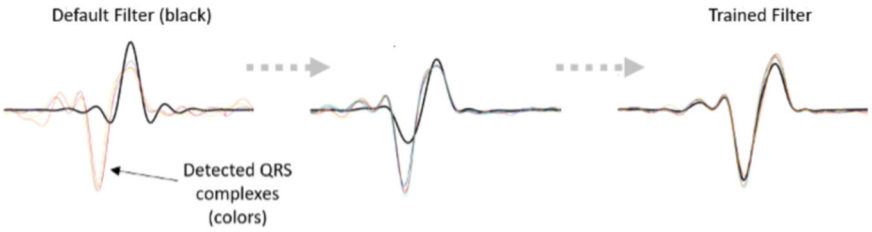

FIGURE 3 Matched filter training. The black line shows the filter kernel. The colored lines show detected complexes

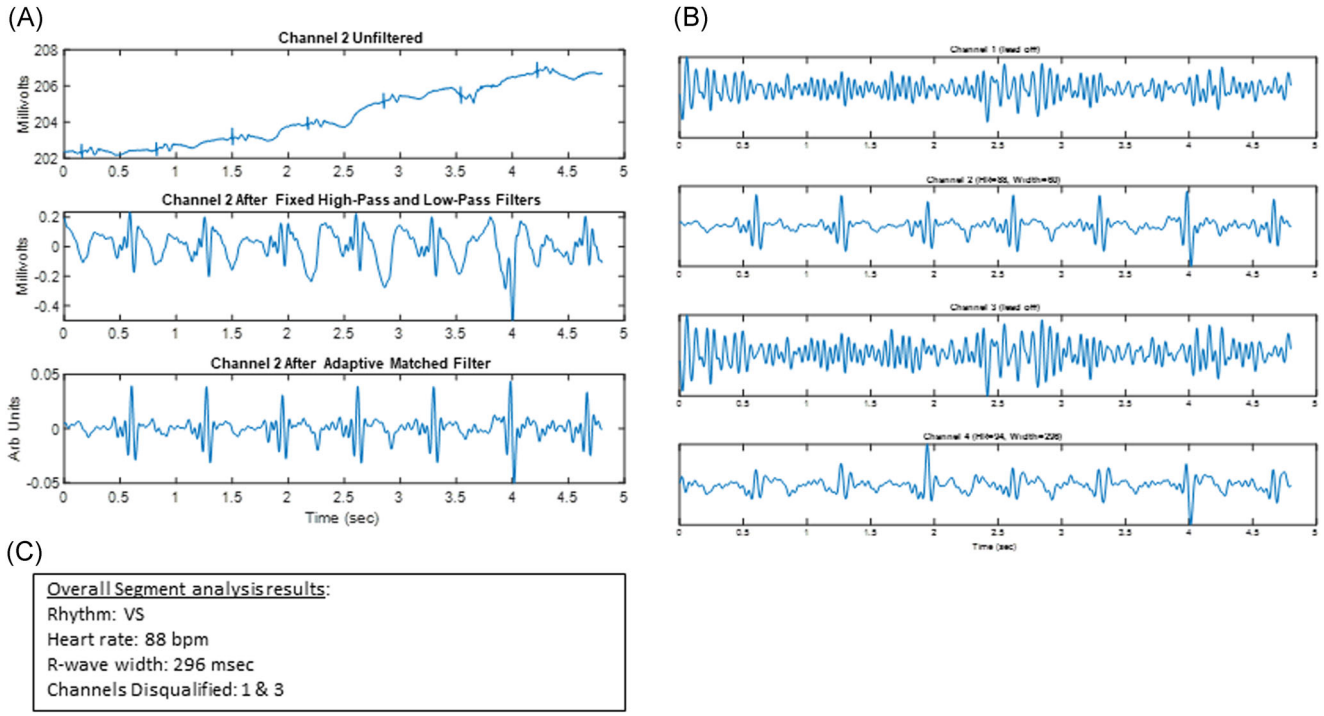

FIGURE 4 ASSURE® WCD System (A-WCD) segment with successful noise filtering. Example electrocardiogram segment from a 43-year-old female with dual-chamber implantable cardioverter defibrillator (ICD) implanted for secondary prevention. ICD interrogation at the final 30-day follow-up revealed 3% atrial pacing and 99% ventricular pacing. (A) Signal contains baseline wander that is successfully removed by the algorithm filters. (B) Two channels were disqualified from segment analysis due to poor electrode contact (lead off). (C) This segment was categorized by the algorithm as normal sinus rhythm with a heart rate of 88 bpm and wide R-wave. The episode was closed without a shock alarm event marker recorded

2.6.3 | Rhythm detection

Data from each channel is divided into 4.8 s segments (50% overlap) and each segment is assigned a rhythm classification. Persistent detection of segments classified as VT/VF leads to an alarm and potential shock (Figure 5). Rhythm classification for each segment is based on heart rate and R-wave width measurements. These measurements are made using detected QRS complexes on each channel. The R-wave width is not a measurement of the total QRS width, but is derived from specific fiduciary points within the complex and is less noise-sensitive. A machine learning algorithm estimates the heart rate error for each channel, and the heart rate from the channel with the least error is selected for rhythm classification. The R-wave width for each channel is measured using signal-averaged QRS complexes, and the channel with the widest value is selected for rhythm classification. This channel selection process in combination with channel disqualification as described above provides substantial noise immunity. A segment is classified as VT or VF if the selected R-wave width is ≥80 ms and the selected heart rate meets the programmable zone rate threshold (nominal 170 bpm for VT and 200 bpm for VF). The initial detection criterion is met when five of six consecutive segments are classified as VT or VF. The rhythm is classified as SVT if the selected R-wave width is <80 ms and the selected heart rate is above the VT rate threshold. An overview of the rhythm detection process including segment analysis is provided in Figure S5.

2.6.4 | VT/VF confirmation

While initial detection is the same for each rate zone, VT and VF have separate confirmation criteria resulting in different lengths of time that VT or VF must be sustained before alarming (Figure 5). This allows VT to

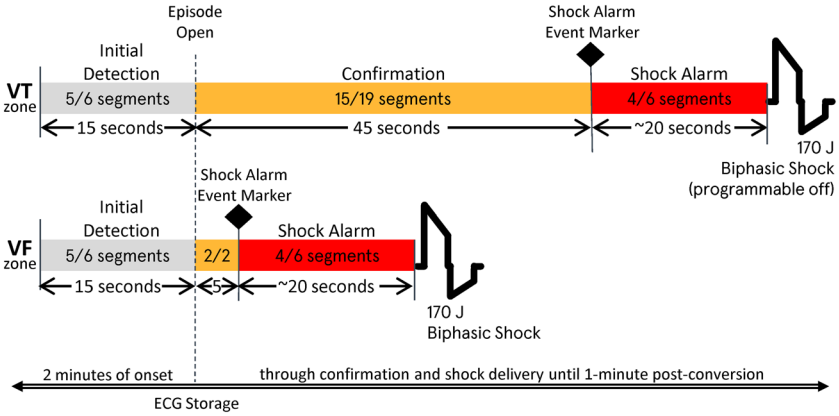

FIGURE 5 Initial detection and therapy timeline. The ASSURE® WCD System has two independently programmable therapy zones. Initial detection (gray) is the same for each zone (5/6 overlapping 4.8-s segments of ventricular tachycardia [VT] or ventricular fibrillation [VF]). Confirmation (yellow) is dependent on zone; 2/2 segments for VF and 15/19 segments for VT. VT that is determined to be disorganized will be treated as slow VF requiring 2/2 segments for confirmation. Once VT or VF is confirmed, a shock alarm event marker is recorded, and the shock alarm sequence (red) is initiated. If 4/6 segments during the shock alarm period are VT or VF, a shock will be delivered. Four out of five non-VT or VF segments will close an episode. After shock delivery, if an additional 3/5 VT or VF segments are detected, another shock will be delivered (up to five consecutive shocks) and the episode closed if 6/12 non-VT or VF segments are detected. Electrocardiogram episode storage includes 2 min of onset before episode open, through confirmation and shock delivery and 1-min post conversion. The shock alarm sequence consists of a triple-sensory indicator: (1) a flashing red light and shock icon on the monitor, (2) an intense vibration from the alert button, and (3) siren and voice prompts. The rate thresholds are programmable down to 130 bpm for VT and 180 bpm for VF. For this study, the heart rate thresholds were set at nominal (VT at 170 bpm and VF at 200 bpm), and the shock alarm sequence was programmed off

spontaneously terminate or for transient noise to subside. If VT/VF continues throughout the respective confirmation periods, an alarm is initiated notifying the patient and bystanders that a shock is about to be delivered (shock therapy and alarms were inactivated for this study). If VT/VF detection criteria continue to be met and the patient does not divert the shock using the alert button, gel is released from the defibrillation pads and a 170 Joule synchronous biphasic truncated exponential shock is delivered. Up to five shocks may be delivered within one episode. The episode is closed if four out of five segments are classified as non-VT/VF or the shock is diverted by the patient.

2.6.5 | Rhythm storage

Four channels of ECG data are stored when initial detection criteria are met and an episode is opened. Storage includes 2 min of onset before episode open, through confirmation and shock delivery, and 1 min post conversion. Arrhythmia episodes and use data are transmitted via a mobile application to a remote monitoring system for clinician review.

3 | RESULTS

3.1 | Study cohort

A total of 130 patients were enrolled between March 20, 2019 and May 13, 2019. The majority (121, 93.1%) fully completed the study (Figure S6). Investigational sites were geographically dispersed throughout the United States and included five academic and five nonacademic centers (Table S2). Baseline patient characteristics including demographics, medical, and arrhythmia history are summarized in Table 2. The mean age was 61.2 ± 11.4 years. The majority were male (69%) and predominantly white (64%). Black/African Americans represented 27%. The most common indication for the ICD was primary prevention. All patients had been diagnosed with cardiomyopathy, most having severely reduced ejection fraction. Common comorbidities included hypertension, any degree of coronary artery disease, and diabetes mellitus. A history of atrial fibrillation or atrial flutter was present in 51 patients (39.2%), and 71 patients (55%) had at least one episode of VT or VF previously detected by their ICD. A total of 21 patients reported previous use of the C-WCD. Nine patients (6.9%) were reported to have a history of bradycardia requiring pacing support. Of note, based on ICD interrogations at study exit, atrial pacing was used by 36% of patients at an average of 29.6% of the time, and ventricular pacing was used by 48% of patients at an average of 9.2% of the time.

3.2 | Primary safety endpoint: False-positive shock alarm rate

The primary endpoint performance goal was achieved. The analysis was based on the cohort of 130 patients with three false-positive shock alarms occurring over a total of 3501 patient-days (500 weeks), or 0.0060 false-positive shock alarms per patient-week. Using the Poisson distribution to model the results, the false-positive shock alarm rate was 0.00075 per patient-day (95% confidence interval [CI]: 0.00015–0.00361) (one false-positive shock every 1333 patient-days).

TABLE 2 Baseline patient characteristics

Characteristics	Value (*n* = 130)
Demographics	
Age (years), mean ± SD (range)	61.2 ± 11.4 (29–89)
Female sex, *n* (%)	40 (30.8)
Race, *n* (%)	
White	83 (63.8)
Black/African American	35 (26.9)
Not reported	11 (8.5)
Other	1 (0.8)
Medical history	
Indication for an ICD, *n* (%)	
Primary prevention	105 (80.8)
Secondary prevention	25 (19.2)
Cardiomyopathy, *n* (%)	
Ischemic	75 (57.7)
Nonischemic	44 (33.8)
Mixed ischemic/nonischemic	1 (0.8)
Primary valvular	2 (1.5)
Arrhythmogenic right ventricular cardiomyopathy	0 (0.0)
Hypertrophic cardiomyopathy	3 (2.3)
Congenital	0 (0.0)
Sarcoidosis	0 (0.0)
Other	5 (3.8)
Primary electrical disorder, *n* (%)	0 (0.0)
Left ventricular ejection fraction %, mean ± SD	28.2 ± 7.1
Comorbidities[a], *n* (%)	
Hypertension	96 (73.8)
History of heart failure	125 (96.2)
History of coronary artery disease	95 (73.1)
Diabetes	41 (31.5)
Chronic obstructive pulmonary disease	28 (21.5)
Chronic kidney disease	31 (23.8)
Body mass index, mean ± SD kg/m^2 (range)	31.4 ± 5.9 (20.5–54.4)
Arrhythmia history	
Prior ICD-detected VT/VF, *n* (%)	71 (54.6)
Atrial fibrillation/flutter, *n* (%)	51 (39.2)
Bradycardia requiring pacing support, *n* (%)	9 (6.9)
Previous LifeVest use, *n* (%)	21 (16.2)
QRS duration, mean ± SD (ms) (range)	113.8 ± 24.7 (71.0–198.0)

TABLE 2 (Continued)

Characteristics	Value (n = 130)
Left bundle branch block, *n* (%)	7 (5.9)
Right bundle branch block, *n* (%)	14 (11.8)
Intraventricular conduction delay, *n* (%)	13 (10.9)
Paced, *n* (%)	11 (8.5)

Abbreviations: ICD, implantable cardioverter defibrillator; VF, ventricular fibrillation; VT, ventricular tachycardia.
[a]Categories not mutually exclusive.

TABLE 3 Summary of 163 WCD recorded episodes in 18 patients

CEC adjudicated rhythm type	WCD episodes, *n* (% of 163)	WCD patients[a], *n* (% of 130)	WCD shock alarm event marker
VT/VF	**4 (2.5%)**	**3 (2.3%)**	**1—True**
Other rhythm with noise[b]	**121 (74.2%)**	**16 (12.3%)**	
Atrial fibrillation	1 (0.6%)	1 (0.7%)	0
Atrial flutter	0 (0.0%)	0 (0.0%)	0
Paced rhythm[c]	29 (17.8%)	4 (3.1%)	2—False
Sinus rhythm[c]	85 (52.1%)	11 (8.5%)	1—False
SVT[d]	6 (3.7%)	2 (1.5%)	0
Uncertain rhythm with noise	**32 (19.6%)**	**7 (5.4%)**	**0**
Atrial flutter without noise[e]	**6 (3.7%)**	**1 (0.7%)**	**0**

Abbreviations: CEC, Clinical Events Committee; SVT, supraventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia.
[a]Patients may have had one or more episodes.
[b]Although noise was present, the underlying rhythm could be discerned.
[c]In all episodes, the heart rate was ≤120 bpm in the presence of substantial noise.
[d]SVT was defined as a non-VT/VF rhythm with a heart rate >100 bpm. In one patient, a single episode was initially detected as VT, but following resolution of noise, no longer met the criteria for VT/VF. The other patient had five episodes in which substantial noise was present throughout. The underlying rhythm was adjudicated as SVT between 166 and 172 bpm.
[e]Detection was due to oversensing of large amplitude atrial flutter waves.

The upper bound of the 95% CI for the observed false-positive shock alarm rate was well below the prespecified performance goal of 0.29 per patient-day ($p < .001$).

3.3 | Summary of A-WCD and ICD detected episodes

A total of 163 A-WCD episodes and 237 ICD episodes were recorded over 3501 cumulative days of wear. All recorded episodes were adjudicated by the CEC.

3.3.1 | A-WCD detected episodes

The 163 A-WCD episodes were recorded in 18 patients (13.8% of 130) (Table 3). Four of these episodes in three patients were adjudicated as VT/VF (true-positive detections) with one lasting long enough to generate a shock alarm marker (true-positive shock alarm). All four VT/VF episodes were also detected by the ICD. Two episodes of VF in one patient were each converted by a single ICD shock. In a second patient, VT was terminated following antitachycardia pacing, and in the third patient, VT self-terminated (Figures S8–S11).

The 159 non-VT/VF A-WCD episodes occurred in 17 patients and were adjudicated as other physiologic rhythm with noise (121), uncertain rhythm with noise (32), or atrial flutter without noise (6). The six atrial flutter episodes in one patient were due to oversensing of high amplitude flutter waves. The majority (156) closed before a shock alarm event marker was recorded because the noise resolved or the rhythm was determined to be nonshockable. The resulting inappropriate detection rate was one every 22.0 patient-days in 17 (13.1%) patients, most of which (96%) were due to noise. Only three of the 159 non-VT/VF episodes were sustained long enough to record a shock alarm event marker (false-positive shock alarm). For all three, substantial noise was present on all ECG channels. The

underlying rhythm was adjudicated as sinus rhythm in one patient (Figure S12) and ventricular pacing (two episodes) in another patient, one of which is shown in Figure S13. No other false-positive shock alarms were recorded during the study, including in any patient with a history of atrial and/or ventricular pacing.

3.3.2 | ICD episodes detected as VT/VF

The 237 ICD detected VT/VF episodes were recorded in 51 patients (39.2% of 130). Of these, 106 were true VT/VF and 131 were inappropriate detections. The true VT/VF episodes included the four A-WCD true-positive detections and 102 that did not meet the A-WCD detection criteria (rate and duration). Therefore, there were no A-WCD missed events.

The 131 inappropriate ICD detections included 50 episodes of atrial fibrillation in four patients, 80 episodes of other SVT in 18 patients, and one episode of sinus rhythm with noise. Only one of these inappropriate ICD detections was also falsely detected by the A-WCD (SVT with noise), whereas 123 did not meet the rate and/or duration criteria of the A-WCD to open an episode. The remaining seven inappropriate ICD detections were appropriately rejected by the A-WCD as nonshockable. A summary of ICD detected episodes is included in Table S3.

3.4 | Patient-reported outcomes

Of 130 patients enrolled, 127 completed the Borg CR-10 scale at both baseline (Visit 1) and end of wear (Visit 2 or early withdrawal). Of these 127, 113 patients (89.0%) reported the highest discomfort rating (8 anatomical regions) of *none* or *slight discomfort* at baseline, and 106 patients (83.5%) reported the highest discomfort rating of *none* or *slight discomfort* at end of wear (Table S4 and Figure S14). Comfort results according to specific torso regions are summarized in Table S5. The mean discomfort score for each of the eight anatomical regions on the torso at end of wear was below 1 (*very slight discomfort*). No statistically significant change in comfort from baseline to end of wear was observed for seven of eight regions. For the one region that showed a statistically significant decrease in comfort, the mean score at end of wear was 0.34 (scale 0–10). Twenty-one patients (5 female and 16 male) had previous experience wearing the C-WCD. Of these, 16 (76.2%) rated the A-WCD more comfortable and 16 (76.2%) rated the A-WCD easier to use (Figures S15 and S16). All five of the female patients rated the A-WCD much more comfortable than the C-WCD.

3.5 | Adverse events

None of the observed AEs was classified as serious or UADEs. The most frequently reported AEs were mild skin irritation, followed by musculoskeletal-related complaints such as muscle strain related to carrying the monitor. One patient reported severe musculoskeletal pain related to wearing the A-WCD. AEs are summarized in Tables S6 and S7.

3.6 | Patient wear compliance

Patients wore the A-WCD for a median of 31.0 days (interquartile range, 2.0) and a median daily use of 23.0 h (interquartile range, 1.7). Most patients (123, 94.6%) had a median daily use of at least 22.0 h. No differences were found by age ($p = .47$) or by sex ($p = .97$). Summary of compliance metrics is included in Table S8 and Figure S7.

4 | DISCUSSION

We report initial study results for a contemporary WCD, the ASSURE WCD System, with a primary purpose to evaluate A-WCD false-positive shock alarms in HF patients with ICDs. The use of this population allowed independent confirmation that there were no VT/VF events missed by the A-WCD. In addition, information regarding patient-reported outcomes including comfort, AEs and wear compliance were collected. Key findings include a low false-positive shock alarm rate, low inappropriate detection rate, no missed true VT or VF events, high comfort with wearing the A-WCD, and mostly mild AEs.

4.1 | False-positive shock alarm rate (primary endpoint)

Wearable devices with surface ECG electrodes face substantial rhythm discrimination challenges due to noise artifacts created by motion and nonadhesive electrodes. Inappropriate detection of either noise or SVT may result in false alarms and inappropriate shocks. The A-WCD false alarm rate is fundamentally determined by the rate of inappropriate detections and the timing of alarm initiation. The A-WCD delays alarms until confirmation of VF (5 s) or VT (45 s) is complete. In comparison, the C-WCD initiates alarms immediately after detection and thus the inappropriate detection rate is equivalent to the false alarm rate.[18] In our study, both the false alarm rate and inappropriate detection rate were substantially lower than that reported for the C-WCD.[10,13,19] For instance, in a study by Odeneg et al. the inappropriate detection rate was one every 2.9 patient-days in 64.7% of 448 patients, whereas we reported an inappropriate detection rate of one every 22.0 patient days in 13.1% of 130 patients.[19] All of these inappropriate detections had substantial noise except for six episodes in one patient that were SVT (atrial flutter with high amplitude "flutter" waves). Despite the substantial noise present in these episodes, only three false-positive shock alarm event markers occurred providing evidence of an effective noise management strategy implemented in the A-WCD.

Multiple studies of the C-WCD have reported high false alarm rates with low inappropriate shock rates. The presence of shock alarms allows a conscious patient time to divert a shock preventing inappropriate detections from becoming inappropriate shocks. For instance, in a study by Zylla et al.,[10] 73% of 106 patients experienced false shock alarms, but only two patients had inappropriate shocks,

both due to sensing of ventricular pacing. In another study by Erath et al.,[13] 57% of 102 patients experienced false shock alarms due to noise artifact, but only two had inappropriate shocks, both for high-rate atrial fibrillation. In larger prospective studies, inappropriate shock rates have also been reported to be low.[3,4,8,20] Although shocks were disabled in our study, only three false-positive shock alarms occurred. In clinical use, the patient would have the opportunity to divert a shock and therefore we would predict that the A-WCD inappropriate shock rate would be lower than our reported false alarm rate (one every 1333 patient-days).

While C-WCD inappropriate shock rates may be low, shock alarms occur frequently and have been reported as a source of sleep disturbance, anxiety, and early discontinuation of WCD use.[9,10,21] Recent studies have attempted to correlate the impact of alarms on average daily use.[10,22] These studies suggest that in patients *motivated* to wear their WCD, alarms may not negatively affect average daily use. However, the impact of alarms on those patients who chose to discontinue using the WCD remains unclear.

4.2 | Detection of VT and VF events

Preclinical testing using an ECG database demonstrated high sensitivity for detection of true ventricular arrhythmia events (Table 1). In this study, as expected, there was a low incidence of sustained true VT/VF. Four VT/VF episodes in three patients (2.3%) met the A-WCD detection criteria—a rate similar to that reported for the C-WCD in clinical use (2.1%–3.1%).[4,8] Importantly, no VT/VF events identified by the ICD were missed by the A-WCD using the prespecified rate and duration criteria.

4.3 | Supraventricular rhythm discrimination

While noise is the primary cause of inappropriate detections in a WCD, discrimination of supraventricular tachyarrhythmias remains important to reduce false alarms and inappropriate shocks. Preclinical testing of the A-WCD detection algorithm demonstrated high specificity (>95%) for rejection of nonshockable rhythms (Table 1). In ACE-DETECT, we report a low rate of inappropriate AF/SVT detections due to a combination of factors including the rate and duration criteria and the effectiveness of the A-WCD discrimination algorithm.

4.4 | Wear compliance

The serious consequences of poor WCD compliance were demonstrated in the recent randomized Vest Prevention of Early Sudden Death Trial (VEST).[20] The authors noted that 75% of the deaths in the treatment group were among patients who were not wearing the device at the time of death. Thirty-four percent of all patients enrolled had a median wear-time of zero hours, and 30% of the enrolled patients discontinued use within one month of randomization.[22] A structured WCD program including a comfortable device, effective training, and remote monitoring capability may improve patient compliance and therefore save lives. For instance, in the Austrian Registry of 448 patients by Odeneg et al.,[19] nurse-led training and fitting, as well as remote monitoring contributed to higher compliance than prior studies. We attribute the high compliance in this study to multiple factors including a comfortable well-fitting garment, effective training, remote follow-up, and a motivated patient population.

5 | LIMITATIONS

The primary purpose of this study was to assess the false-positive shock alarm rate; however, our results may not translate to the results of a larger study with a longer wear time. Because auditory/vibratory alarms and shocks were disabled in this study, reported wear compliance may not reflect clinical use when this functionality is enabled. Further prospective large studies will enable assessment of overall A-WCD performance and patient compliance.

6 | CONCLUSIONS

This study evaluated ICD patients who wore the ASSURE WCD with shocks disabled. We observed a substantially lower false-positive shock alarm rate than the objective performance goal. In addition, we observed no true VT or VF events missed by the ASSURE WCD, low patient-reported discomfort, high wear compliance, and almost exclusively mild adverse events over a 30-day follow-up.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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