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Enhancing Wearable Cardioverter Defibrillator Performance: Comparative Validation of a Revised Algorithm to Reduce False Positive Alarms

David Finch
Kestra Medical Technologies, Inc., Kirkland, WA, USA
Jaeho Kim
Kestra Medical Technologies, Inc., Kirkland, WA, USA
Maurie Wiswell
Kestra Medical Technologies, Inc., Kirkland, WA, USA
Karl Hibler
Kestra Medical Technologies, Inc., Kirkland, WA, USA
Pamela Breske
pamela.breske@kestramedical.com

Kestra Medical Technologies, Inc., Kirkland, WA, USA https://orcid.org/0009-0000-8380-8467

Research Article

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Authors: David Finch, Jaeho Kim, Maurie Wiswell, Karl Hibler, Pamela Breske*

Kestra Medical Technologies, Inc., Kirkland, WA, USA

*Corresponding author: Pamela Breske, pamela.breske@kestramedical.com, ORCID: 0009-0000-8380-8467

Abstract

Background:

The ASSURE® wearable cardioverter defibrillator (WCD) is designed to protect patients at risk of sudden cardiac death while minimizing false positive shock alarms (FPAs), which can undermine confidence and reduce adherence. Although the original ASSURE Detection Algorithm (ADA) demonstrated robust performance, post-market experience identified opportunities to further reduce FPAs without compromising ventricular tachycardia/fibrillation (VT/VF) sensitivity. This study included development and comparative validation of a revised ADA designed to reduce FPAs while preserving VT/VF sensitivity using stored ECG episodes from ASSURE WCD patients.

Results:

Development of a revised ADA incorporated a high-fidelity virtual model for rapid iteration, and validation was performed using a physical WCD device model. The controlled comparative approach enabled evaluation of arrhythmia classification performance using the same ECG recordings across algorithm versions. Sensitivity, and per-episode and per-patient FPA rates as measures of specificity, were assessed using a real-world ECG dataset and corroborated with datasets used for original algorithm testing. Algorithm refinements focused on improved supraventricular tachycardia discrimination, enhanced noise management, and more accurate QRS identification. The revised algorithm detected 100% of shockable VT/VF rhythms (137 episodes) in the Field Episode test dataset. In >8,000 non-VT/VF Field Episodes, the revised ADA reduced per-patient total FPAs by 51.9% (95% CI 43.8–60.0) and sustained FPAs by 69.4%

(95% CI 59.2–78.3). Testing with legacy datasets confirmed continued compliance with standard performance criteria.

Conclusions:

Using a controlled, comparative development and validation methodology, the revised ADA demonstrated substantial reductions in FPAs while maintaining high VT/VF sensitivity. These findings support the ability of the revised ADA to reduce false alarm burden and the opportunity for inappropriate therapy, with further evaluation needed to confirm performance following clinical implementation.

Keywords: wearable cardioverter defibrillator (WCD); detection algorithm; false positive alarms; signal quality; comparative validation.

Background

The ASSURE® wearable cardioverter defibrillator (WCD) is designed to protect patients at risk of sudden cardiac death while optimizing comfort and minimizing false positive shock alarms (FPAs). Near continuous wear is essential for timely detection and treatment of life-threatening ventricular arrhythmias; however, prior studies of other FDA approved WCDs have identified adherence challenges often linked to discomfort and frequent FPAs [1-3].

Central to ASSURE system performance is the ASSURE Detection Algorithm (ADA), engineered to maintain high sensitivity in detecting ventricular arrhythmias with sufficient specificity to keep FPAs low. FPAs are clinically important because they reflect rhythm misclassification that can lead to inappropriate therapy; even when nonsustained or diverted, FPAs can provoke anxiety and diminish patient quality of life. In bench testing and an early human trial, ADA performance was robust [1 FPA per 1,333 patient days with no missed episodes] [4], supporting Food and Drug Administration Pre-Market Approval in July 2021. Post market surveillance further corroborated these findings. In the ASSURE WCD Clinical Evaluation – Post Approval Study (ACE-PAS, NCT05135403), FPAs occurred in only 6% of patients [5], comparing favorably to other WCD systems that reported FPAs in 46% [3] and 38% [2] of patients.

Despite this superior performance, analysis of residual FPAs revealed opportunities to further increase specificity and minimize inappropriate shock risk without compromising VT/VF sensitivity. The intended clinical benefit is improved patient safety, experience, and adherence, while reinforcing provider confidence in prescribing the ASSURE system.

This paper describes the comparative testing methodology used to develop and validate a revised ADA with results presented relative to the original algorithm. Additional details are available in the Supplemental Materials. This methodology focuses on the measurement reliability of physical and virtual WCD models to evaluate arrhythmia classification performance using stored ECG episodes from ASSURE WCD patients that reflect the signal quality variability inherent to wearable systems. The results establish a benchmark for expected real-world benefits.

Methods

ASSURE WCD – Design and Operational Summary

A brief overview is provided here to contextualize subsequent sections; full details of product design, detection logic, and noise discrimination have been previously reported [4]. The ASSURE WCD system consists of two styles of patient-worn garments with integrated ECG electrodes and a monitor that houses the capacitors, electronics, removable battery, and software, including the ADA. A therapy cable connects the monitor to the garment and delivers therapy through anterior and posterior electrode pads positioned within dedicated garment pockets and secured via a snap-in connector. The ADA integrates per channel adaptive matched filtering to enhance R-wave identification; device determined R-wave width analysis and signal organization metrics for rhythm discrimination; and cross channel machine learning for heart rate determination. The R-wave width is not a measurement of the total QRS width but rather is derived by the device using specific fiduciary points within a portion of the complex [4]. Confirmation of an arrhythmia requires persistence beyond initial detection for 5 seconds in the VF zone or 45 seconds in the VT zone. If confirmed, the device enters a reconfirmation phase at which time audible, visual, and tactile alarms are activated to alert the patient of impending therapy. Reconfirmation requires an additional 15 seconds of sustained arrhythmia, providing time for patient intervention via alert button press. Once reconfirmed, the

device initiates a 5 second preshock warning, releases conductive gel, and delivers a synchronized 170 J shock unless interrupted by the alert button. If VT/VF persists, up to four additional 170 J shocks can be delivered per episode. Failure to confirm a sustained arrhythmia at any point, or patient activation of the alert button, aborts therapy and returns the device to a monitoring state.

Datasets

Three datasets were used and each organized into independent development and validation sets: Arrhythmia Rich, Ambulatory, and Field Episodes. The Arrhythmia Rich and Ambulatory datasets were used during development and testing of the original ADA and served as controls to ensure that the revised algorithm maintained VT/VF detection sensitivity and monitoring performance. The Arrhythmia Rich dataset was used to ensure detection compliance with American Heart Association (AHA) performance requirements [6] and is comprised of artifact-free ECG segments of shockable and nonshockable rhythms collected from electrophysiology labs and other clinical environments. The Ambulatory dataset consisted of continuous ECG recordings (equivalent to 295 patient-days of wear) gathered during development using WCD prototypes without a shock function. The Field Episode datasets comprised real-world data collected from consecutive patients fitted across the United States within the ASSURE WCD Registry. Episodes from November 2021 through July 2023 were used for development; episodes collected from August 2023 through April 2024 were used for validation testing. The episodes in the Field Episode test dataset were independently reviewed by experts in arrhythmia analysis (Supplemental Materials), and unanimously adjudicated as VT/VF (VF, monomorphic VT, or polymorphic VT) or non-VT/VF prior to comparative analysis. Each Field Episode dataset included more than 8,000 non-VT/VF episodes from more than 650 patients. The validation datasets remained locked and unavailable to the algorithm team throughout development.

False Positive Alarms

The majority of episodes in the non-VT/VF portion of the Field Episode dataset represent false detections that were stored by the WCD, but most were short in duration and did not progress to an FPA. Those that resulted in an FPA were categorized as nonsustained (progressed to reconfirmation but spontaneously terminated prior to shock delivery) or sustained (progressed through the detection sequence to therapy

delivery). In the development set, the predominant cause of FPAs was SVT accounting for 59% of non-sustained FPAs and 69% of sustained FPAs. Noise contributed to 32% of non-sustained FPAs and 23% of sustained FPAs. Other factors, such as physiologic oversensing, represented 9% and 8% of the non-sustained and sustained FPAs, respectively.

WCD Device Models

Two objective, repeatable models were developed to compare the performance of the original ADA and revised ADA: a physical WCD Device Model and a virtual WCD Device Model. Strict controls included manufacturer default programming (170 bpm VT zone rate, 200 bpm VF zone rate); system restart before playback of each ECG to avoid adaptive matched filtering carryover; and deactivation of the alert button so alarms and pending shocks proceeded without interruption, removing variability due to patient behavior and enabling objective assessment of the full detection sequence. The physical model consisted of WCD systems (without garments) connected to a custom patient simulator that provided ECG and defibrillation interfaces, managed ECG playback, and monitored device state. The virtual model used in development was a high-fidelity MATLAB [7] implementation replicating WCD behavior and hosting multiple algorithm versions, including the original ADA and prototype revisions. ECG recordings from development datasets were replayed into algorithm versions, and results were compared against the original ADA. This model served as the primary development environment, enabling rapid iteration and direct, paired comparisons. The physical WCD Device Model was used for validation.

Algorithm Changes

Prototype algorithm revisions were assessed against two competing priorities: improved specificity (FPA reduction) and preserved VT/VF sensitivity. The final candidate selected for validation balanced strong FPA reduction without compromising VT/VF sensitivity. To improve SVT specificity, the device determined R-wave width (not equivalent to total QRS width) threshold for classifying rhythms as SVT in the VT rate zone was increased from 80 ms to 90 ms, while the VF rate zone conservatively retained the 80 ms threshold. A heart rate stability metric was added in the VT rate zone to better distinguish VT from atrial fibrillation with rapid ventricular response. Noise discrimination was strengthened by simplifying the matched filter adaptation logic and refining QRS identification and cross-channel heart rate determination

to reduce false detections from motion artifact or electromagnetic interference. Further improvements to QRS identification included updated processing and windowing within the matched filter for more reliable QRS capture, and preservation of noise-free, lower amplitude signals to support more accurate rate determination across diverse ECG conditions. Finally, the required durations for VT/VF detection during reconfirmation and post-shock redetection were extended by 5 seconds to allow more time for noise to subside or patients to divert. These changes extend the time to therapy by 5 seconds but maintain therapy delivery within the established treatment time for WCD therapy. To aid interpretation, Figure 1 illustrates the integrated system design and key functional elements of the revised ADA.

Figure 1: Integrated system design and key functional elements of the revised detection algorithm

Three interdependent levels collectively reduce noise and support reliable rhythm detection.

Noise minimization forms the foundation with a combination of garment design, electrode configuration, shielded cabling, and patient alerts that promote continued signal integrity.
Signal processing builds on this foundation using four channels for ECG sensing, dynamic channel qualification, high and low pass filtering, adaptive matched filtering, and a machine-learning based heart rate determination.
Rhythm classification incorporates this conditioned signal information to accurately detect VT/VF using rate zone logic, R-wave width analysis, heart rate stability metrics, and adaptive confirmation periods for slower rhythms or noisy conditions to preserve detection accuracy and reduce false positive alarms.

Figure 1 is adapted from a figure published in Poole et al, 2022 [4].

Abbreviations: ADA, arrhythmia detection algorithm; AF, atrial fibrillation; DC, direct current; ECG, electrocardiogram; HR, heart rate; SVT, supraventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia; WCD, wearable cardioverter defibrillator.

An exploratory analysis comparing FPA performance of the final prototype ADA with that of the original ADA using the Field Episode Development Dataset (not the locked validation dataset) and the WCD models, demonstrated total FPAs due to SVTs with wide QRS and RVR were reduced by 76% on a per episode basis; sustained FPAs by 97%. Total FPAs due to Noise were reduced by 72%; sustained FPAs by 71%.

Validation and Statistical Analysis

Validation used the physical WCD Device Model to compare performance of the original ADA and revised ADA. The legacy Arrhythmia Rich test dataset was used to evaluate shockable rhythm sensitivity and

against AHA performance thresholds [6] and statistically compared using one-sided 90% lower exact binomial confidence limits (Clopper-Pearson).

The non-VT/VF recordings from the Field Episode test dataset were used to measure specificity as per-episode and per-patient FPA rates (nonsustained, sustained, and total) for both ADA versions. Field Episode VT/VF recordings were used to measure sensitivity; numerical results were reported. Percent reduction in FPA between the original ADA and revised ADA were calculated along with 95% exact binomial confidence intervals using the Clopper-Pearson method. All statistical analyses were conducted using IBM SPSS Statistics, version 29.0.2.0 (20).

Results

VT/VF Sensitivity

Comparative performance for the original and revised ADA using the VT/VF portion of the Field Episode test dataset demonstrated identical VT/VF sensitivity for both algorithms; 100% of shockable rhythms (137 episodes) were detected by the revised ADA (Table 1). Evaluation using the Arrhythmia Rich test dataset exceeded AHA performance goals [6] and demonstrated no reduction in observed VT/VF sensitivity with the revised algorithm.

Specificity Measured as False Positive Alarm Performance

Comparative FPA results are summarized in Table 2 (per-episode) and Table 3 (per-patient) for the Field Episode test dataset. On a per-episode basis, total FPAs with the revised ADA were reduced by 64.2% (95% CI 60.8–67.6); sustained FPAs were reduced by 79.9% (95% CI 75.4–84.0). On a per-patient basis, the revised ADA reduced the number of patients with 1 or more FPAs by 51.9% (95% CI 43.8%-60.0%); patients with 1 or more sustained FPAs were reduced by 69.4% (95% CI 59.2%-78.3%). Two representative six-second ECG recordings from the non-VT/VF Field Episode development dataset are presented in Figure 2. They illustrate atrial fibrillation with rapid ventricular response and noise, respectively, which were misclassified by the original ADA causing FPAs. In the real-world episodes, patients diverted therapy using the alert button. When these same recordings were replayed through the

virtual WCD Device Model, the revised ADA correctly classified both rhythms as non-VT/VF and did not generate episodes or FPAs.

Figure 2: Example False Positive Alarm Episodes using the Original ADA and Correct Classification by the Revised ADA
Two representative six-second ECG recordings from the non-VT/VF Field Episode development dataset illustrate atrial fibrillation with rapid ventricular response and noise, respectively, which were misclassified by the original ADA causing FPAs. In both episodes, the onset of the FPA is indicated by the "HEART ALERT" notification with additional information in the associated segment detection metrics. In the real-world episodes, patients diverted therapy using the alert button. When these same episodes were replayed through the virtual WCD Device Model, the revised ADA correctly classified both episodes as non-VT/VF and did not record episodes or generate FPAs.

2a. Episode excerpt illustrating FPA caused by atrial fibrillation with rapid ventricular response, with segment-level detection markers (e.g., S44, S45) displayed above the ECG waveform and detection information on the right side.

2b. Episode excerpt demonstrating an FPA produced by noise artifact, where motion- or interference-related distortion resulted in erroneous rhythm detection by the original ADA.

Abbreviations: ADA, arrhythmia detection algorithm; FPA, false positive alarm; VT/VF, ventricular tachycardia/ventricular fibrillation; WCD, wearable cardioverter defibrillator.

Discussion

The ASSURE system employs an integrated hardware and software strategy for sensing and artifact reduction, enabling high sensitivity to life-threatening ventricular arrhythmias and a competitively low FPA rate. Post-market experience, however, revealed limitations in distinguishing supraventricular tachyarrhythmias, most notably atrial fibrillation and SVT with rapid rates, from true VT due to overlap in QRS morphology and ventricular rate. Noise artifact and other factors, such as physiologic oversensing, also contributed to FPAs leaving patients exposed to FPAs and possible inappropriate therapies.

Importantly, real-world WCD ECG episodes were incorporated into the development of the revised ADA, were used for a direct, comparative validation of both sensitivity and FPAs as a measure of specificity, and results were generated using a controlled test methodology.

The revised ADA retains the core architecture of the original algorithm and fully preserves its ability to detect VT/VF, as demonstrated by the 100% detection of shockable rhythms in the Field Episode test dataset. Inclusion of these field episodes was critical for identifying the specific factors that limited the original algorithm's specificity and guided targeted refinements. These revisions resulted in focused

enhancements to SVT discrimination and more accurate QRS detection in the presence of noise artifact and challenging QRS morphologies.

The Field Episode datasets include real-world ECD recordings from a broad population of U.S. WCD patients across demographics, regions, rhythms, and signal characteristics. Consequently, the 51.9% relative reduction in per-patient total FPAs is expected to provide a close estimate of what will occur in the real-world experience with the revised ADA. Although the per-patient sustained FPA rate is not equivalent to the inappropriate shock rate (given the potential for patients to divert), it represents the potential for inappropriate therapy. The 69.4% relative reduction in per-patient sustained FPAs with the revised ADA indicates a substantial reduction in exposure to potential inappropriate shocks. Collectively, these findings indicate that the revised ADA delivers a clinically meaningful enhancement in specificity while maintaining the high sensitivity required for a lifesaving WCD system. The controlled, comparative testing methodology may also be applicable to any wearable system requiring controlled validation independent of patient behavior. Real-world evaluation following implementation of the revised ADA will be needed to determine whether the reductions in FPAs predicted by the comparative validation are observed in clinical use.

Clinical Implications

By reducing both total and sustained FPAs, the revised ADA is expected to lessen alarm fatigue and anxiety, improve sleep and daily wear adherence, and reduce exposure to potential inappropriate therapy. When the comparative validation results are applied to the existing ACE-PAS registry data, only an estimated 3% of patients are projected to experience any FPA with the revised ADA, and the opportunity for inappropriate therapies is estimated to be less than 0.4%. Although promising, these projections should be interpreted cautiously until the predicted reductions in FPAs are confirmed following real-world implementation of the revised ADA.

Limitations

Differentiating SVT with wide QRS morphology and rapid ventricular response from true VT remains challenging. Although the revised ADA improves specificity for these rhythms, some overlap in morphology and rate characteristics is unavoidable. The testing environment differs from clinical use in

that alert button use is effectively disabled to remove variability due to patient behavior, so in the presence of a sustained FPA, test episodes proceeded to the committed shock state. Consequently, absolute sustained FPA counts in testing cannot be equated directly to inappropriate shock rates in the field; patient diverts may make the inappropriate shock rate lower. However, while the WCD alert button function provides an important safety mechanism, symptomatic or anxious patients may be less likely to intervene, underscoring the need to minimize both FPA frequency and reliance on patient diversion. Algorithm development, device-model implementation, and validation were conducted by the manufacturer; although testing used predefined datasets and adjudicated rhythms, independent external validation would further strengthen confidence in the findings. Finally, the present evaluation is retrospective, based on prerecorded datasets rather than a prospective clinical study. Although the Field Episode dataset is extensive, well-annotated, and representative of real-world WCD use, the present evaluation is retrospective and based on prerecorded episodes. Evaluation following implementation of the revised ADA will be needed to confirm algorithm performance.

Conclusions

The revised ASSURE Detection Algorithm was evaluated using real-world ECG data replayed into software simulations of the ASSURE WCD and actual ASSURE WCD hardware. This controlled, comparative development and validation methodology demonstrated that the revised ADA maintained high sensitivity for detecting shockable ventricular arrhythmias while substantially increasing specificity as measured by the reduction in FPAs and opportunity for inappropriate therapy. Reduced FPA burden has the potential to improve patient experience, decrease unnecessary clinical interventions, and support WCD adherence.

Declarations

Ethics Approval and Consent to Participate

The registry protocol (ACE-PAS, NCT05135403) and retrospective analyses were approved by the WCG IRB, protocol ID 20213046, with a waiver of informed consent for analysis of de-identified data. The study complied with the Declaration of Helsinki.

Consent for Publication

Not applicable

Availability of data and materials

The datasets generated and analyzed during the current study are proprietary and therefore are not publicly available. Limited de-identified data may be shared by the corresponding author upon reasonable request and subject to data-use agreements.

Competing Interests

DF, JK, MW, and PB are or have been employees of Kestra Medical Technologies, Inc. and KH is a paid consultant for Kestra Medical Technologies, Inc.

Funding

Kestra Medical Technologies, Inc. funded this algorithm project in its entirety including registry data collection, analysis, and interpretation; writing of the report; and the decision to submit the article for publication.

Authors' contributions

DF and JK designed the algorithm revisions. DF, JK, and MW designed the validation testing, and MW performed the testing. KH conducted the statistical analyses. DF and PB drafted the manuscript. All authors reviewed and approved the final manuscript.

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Tables

Table 1: Field Episode Test Dataset Detection Results (n=48 patients with 137 VT/VF episodes)

Rhythm Classification	Episode Sample Size (n)	Original ADA Detections (n)	Revised ADA Detections (n)
Shockable: VF	26	26	26
Shockable: Rapid VT	61	61	61
Intermediate: Other VT[1]	50	50	50
Totals	137	137	137

[1] Ventricular rhythm (Monomorphic/Polymorphic/Pleomorphic VT) adjudicated heart rate ≥170 bpm (nominal VT rate threshold) and ≤187 bpm (nominal VT rate threshold +10%).

Abbreviations: ADA, arrhythmia detection algorithm; VT, ventricular tachycardia; VF, ventricular fibrillation.

Table 2: Field Episode Test Dataset Per-episode FPA Reduction Results (n=8,155 non-VT/VF episodes)

	# Episodes with FPAs, Original ADA	# Episodes with FPAs, Revised ADA	FPA Reduction (%)	FPA Reduction (95% CI)
All FPAs	811	290	64.2%	60.8% – 67.6%
Sustained FPAs	359	72	79.9%	75.4% – 84.0%

Abbreviations: ADA, arrhythmia detection algorithm; FPA, false positive alarm.

Table 3: Field Episode Test Dataset Per-patient FPA Reduction Results (n=688 patients with non-VT/VF episodes)

	# Patients with ≥1 FPA, Original ADA	# Patients with ≥1 FPA, Revised ADA	FPA Reduction (%)	FPA Reduction (95% CI)
All FPAs	156	75	51.9%	43.8% – 60.0%
Sustained FPAs	98	30	69.4%	59.2% – 78.3%

Abbreviations: ADA, arrhythmia detection algorithm; FPA, false positive alarm.

Figures

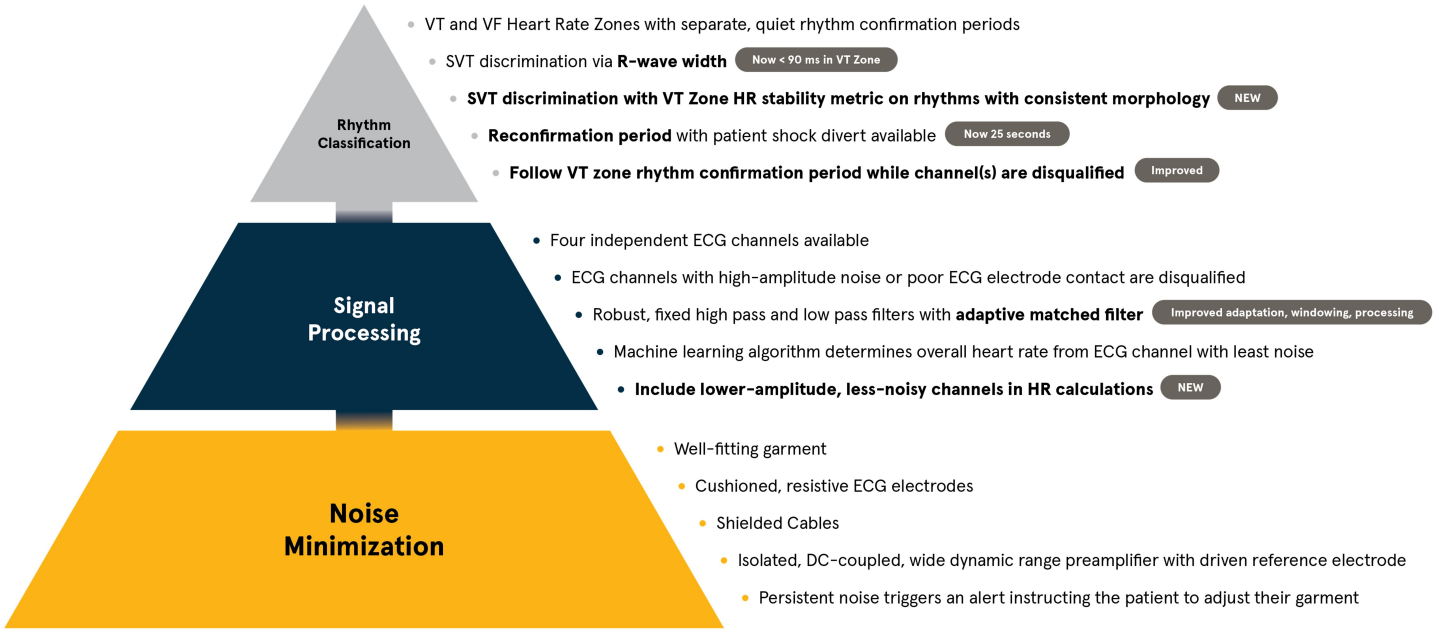


Figure 1

Integrated system design and key functional elements of the revised detection algorithm

Three interdependent levels collectively reduce noise and support reliable rhythm detection.

Noise minimization forms the foundation with a combination of garment design, electrode configuration, shielded cabling, and patient alerts that promote continued signal integrity.

Signal processing builds on this foundation using 4-independent channels for ECG sensing, dynamic channel qualification, high and low pass filtering, adaptive matched filtering, and a machine-learning based heart-rate determination.

Rhythm classification incorporates this conditioned signal information to accurately detect VT/VF using rate-zone logic, R-wave width analysis, heart-rate stability metrics, and adaptive confirmation periods for slower rhythms or noisy conditions to preserve detection accuracy and reduce false positive alarms.

Figure 1 is adapted from a figure published in Poole et al., J Cardiovasc Electrophysiol, 2022 [4]

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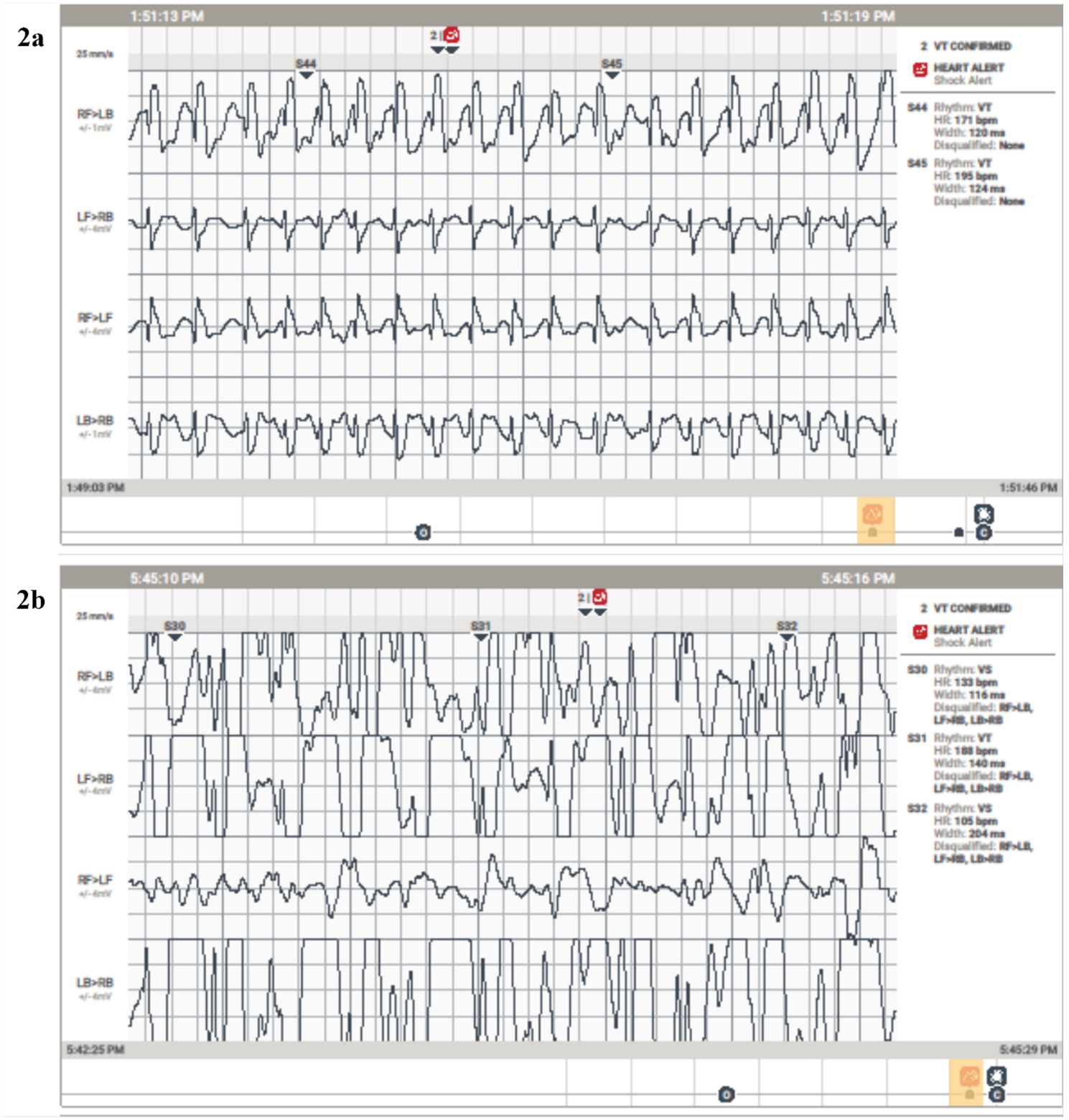


Figure 2

Example False Positive Alarm Episodes using the Original ADA and Correct Classification by the Revised ADA

Two representative six-second ECG recordings from the non-VT/VF Field Episode development dataset illustrate atrial fibrillation with rapid ventricular response and noise, respectively, which were

misclassified by the original ADA causing FPAs. In both episodes, the onset of the FPA is indicated by the “HEART ALERT” notification with additional information in the associated segment detection metrics. In the real-world episodes, patients diverted therapy using the alert button. When these same episodes were replayed through the virtual WCD Device Model, the revised ADA correctly classified both episodes as non-VT/VF and did not record episodes or generate FPAs.

2a. Episode excerpt illustrating FPA caused by atrial fibrillation with rapid ventricular response, with segment-level detection markers (e.g., S44, S45) displayed above the ECG waveform and detection information on the right side.

2b. Episode excerpt demonstrating an FPA produced by noise artifact, where motion- or interference-related distortion resulted in erroneous rhythm detection by the original ADA.

Abbreviations: ADA, arrhythmia detection algorithm; FPA, false positive alarm; VT/VF, ventricular tachycardia/ventricular fibrillation; WCD, wearable cardioverter defibrillator.