

LifeVest® TruVector™ Arrhythmia Detection Algorithm

Overview	The LifeVest® wearable cardioverter defibrillator (WCD) is worn by patients at risk for sudden cardiac death (SCD). The TruVector™ arrhythmia detection algorithm has been designed specifically for LifeVest in order to accurately detect ventricular arrhythmias.
Method	Provide a technical review of the TruVector arrhythmia detection algorithm—including system overview, arrhythmia determination, signal quality, patient interaction, and timing sequence.
Results	The TruVector algorithm uses heart rate and a rhythm morphology vectorcardiogram template analysis in parallel with ECG signal discriminators to identify treatable ventricular arrhythmias. LifeVest detects 100% of VF with 100% specificity and 97% of VT with 100% specificity. In a meta-analysis of nearly 20,000 patients, LifeVest was 96% effective at terminating VT/VF. ¹
Summary	The TruVector arrhythmia detection algorithm is unique to LifeVest. The TruVector algorithm is highly effectively at identifying treatable ventricular arrhythmias.

Overview

The LifeVest® WCD is worn by patients at risk for sudden cardiac death (SCD), providing protection during their changing condition and while permanent SCD risk has not been established. LifeVest allows a patient's physician time to assess their long-term arrhythmic risk and make appropriate plans. LifeVest is lightweight and easy to wear, allowing patients to return to most of the common activities of daily living, while having the peace of mind that they have protection from SCD. LifeVest is non-invasive and consists of two main components—a garment and a monitor. The garment, worn under the clothing, detects arrhythmias and delivers treatment shocks. The monitor is worn around the waist or from a shoulder strap and continuously monitors the patient's heart. If a life-threatening rapid heart rhythm is detected, the device is designed to alert bystanders and delivers a treatment shock to restore normal heart rhythm. LifeVest is automatic and does not require bystander intervention.

The TruVector™ detection algorithm has been designed to continuously monitor signals from the electrode belt. The TruVector algorithm uses a variety of techniques for processing signals digitally, such as the filtering of signals to improve signal quality or to extract important information in real-time. The detection algorithm uses a combination of heart rate and morphology analysis, based on the baseline template of the patient's vectorcardiogram, and Advanced Arrhythmia Discrimination (AArD) to determine a treatable arrhythmia. The algorithm uses a four-electrode, two-lead system to assess heart rate. Morphology analysis is performed by comparing a baseline template to the patient's current vectorcardiogram. AArD further discriminates ECG patterns caused by physiological arrhythmias from patterns caused by non-physiological signals. The combination of these criteria provides a high degree of sensitivity and specificity in the detection of ventricular tachyarrhythmias and a low rate of inappropriate shocks.² (Table 1.) The TruVector detection algorithm includes a variety of features to identify and remove interference, reduce noise, and evaluate the quality of electrode signals.

	Sensitivity	Specificity
VT	97%	100%
VF	100%	100%

Table 1: Sensitivity and specificity within 60 seconds of event detection.²

Once a ventricular tachyarrhythmia has been declared, LifeVest determines if the patient is conscious through a series of vibration, voice and siren alerts. If the patient does not respond by pressing and holding the response buttons, the device automatically treats the patient. This patient interaction feature provides the unique advantage of potentially eliminating all inappropriate treatments.

Arrhythmia Determination

Heart Rate

A feature of the TruVector detection algorithm is that it is designed to evaluate several rate inputs simultaneously to determine the patient's heart rate. The TruVector algorithm uses two QRS detectors, one on each lead, to provide independent assessments of the heart rate. ECG signal frequencies are also analyzed using a fast fourier transform (FFT) algorithm, which decomposes an analog waveform into its frequency components and allows input signal analysis in the frequency domain. The FFT algorithm output is analyzed to determine the strongest frequency component indicative of heart rate. The FFT analysis often provides the best indication of heart rate, specifically during ventricular tachycardia (VT) or ventricular fibrillation (VF). Finally, the morphology analysis algorithm is also used to determine the heart rate.

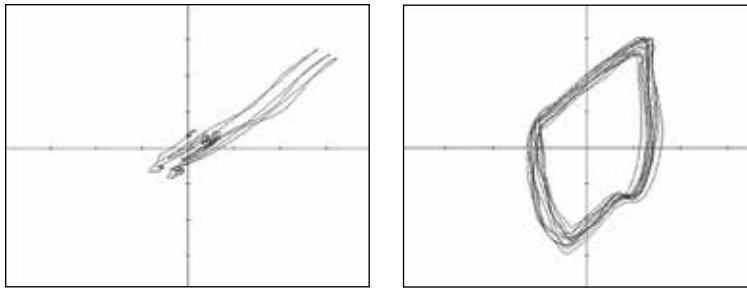
The TruVector detection algorithm then applies logical weights based on comparing leads, signal quality, and historic rate values in order to determine the best inputs to accurately monitor the patient's heart rate. For example, if the heart rate from the two QRS detectors do not match, less weight is applied to these inputs and greater weight is applied to other sources.

Once the TruVector detection algorithm determines the best combination of factors to assess heart rate, the heart rate is then categorized as below the VT threshold, above the VT threshold but below the VF threshold, or above the VF threshold. These thresholds are programmed for the patient during the setup of the device. If the rate exceeds the VT threshold, the algorithm then proceeds to a morphology analysis comparing the patient's normal rhythm baseline template obtained during device setup to the current QRS morphology.

Morphology

The TruVector detection algorithm uses two leads in normal operation. These orthogonal leads (front-to-back and side-to-side) are positioned circumferentially at the level of the xiphoid process. The vectorcardiogram formed from these signals is compared in real-time with the patient's normal rhythm baseline template (Figure 1). Failure to match the real-time vectorcardiogram and baseline morphology templates contributes to the device's determination that a treatable arrhythmia exists. If the current vectorcardiogram and the baseline template match, the treatment algorithm continues to monitor the patient.

If the signal quality from one of the leads is deemed unreliable or if the rate is above the VF threshold, morphology analysis is not used. Instead, the algorithm relies primarily on the heart rate, stability, and onset criteria. Stability criteria is measured by monitoring R-to-R wave intervals. Onset criteria is determined by rapid changes in the heart rate.



Baseline vectorcardiogram

VT vectorcardiogram

Figure 1: Vectorcardiogram of a normal ECG (left) is quite different from vectorcardiogram of VT or VF in the same patient.

Confidence Algorithms

The TruVector detection algorithm also applies a confidence level as part of the process for deciding to treat or not to treat an arrhythmia. The confidence level is the sum of the individually weighted input factors of heart rate, morphology, response button use, and signal quality. The input factors can contribute positively or negatively to the confidence. If an input factor is deemed unreliable, its weight can be lessened or redistributed entirely to other factors.

Once an arrhythmia is declared, the confidence algorithm must decide if the rhythm is treatable based on the duration or persistence of the arrhythmia. If the confidence level falls below a specified level, the treatment sequence is terminated and the system reverts to monitoring for a new arrhythmia.

For example, if a patient uses the response buttons after hearing the alerts and the heart rate slows, the confidence level would decrease. If the patient releases the response buttons and the heart rate increases or becomes abnormal, the treatment confidence would increase.

Advanced Arrhythmia Discriminator (AArD)

AArD operates in parallel with heart rate and the rhythm morphology vectorcardiogram to further discriminate ECG patterns caused by physiological arrhythmias from patterns caused by non-physiological signals. AArD performs signal analysis based on intensity, spectral characteristics, and machine learning developed pattern identification techniques constructed from a database of thousands of ECGs. AArD has demonstrated a reduction in inappropriate patient alerts by 51% and inappropriate therapies by 22% working in conjunction with TruVector algorithm.³

Time to Detection

Approximately 5 to 6 seconds are needed from the onset of a ventricular arrhythmia that exceeds the rate threshold to the time that the TruVector detection algorithm declares an arrhythmia to be present. The signal must continue to meet the criteria for an arrhythmia for an additional 10 seconds before the treatment sequence alerts begin. This arrhythmia confirmation time reduces the incidence of false arrhythmia alerts.

In less than 3% of events, AArD requires additional time to classify an arrhythmia as physiologic or non-physiologic.⁴ In this subset of events that required additional time to classify, the additional time required averaged 12 seconds. The maximum time that AArD has to determine if an arrhythmia is physiologic is 35 seconds for VF and 60 seconds for VT, still allowing for the patient to receive a treatment shock in a clinically acceptable period of time. If AArD is not able to discriminate an ECG signal as physiologic, the detection algorithm will determine if a treatment is required based on rate and the rhythm morphology vectorcardiogram.

Signal Quality

Surface ECG signals are frequently corrupted by skin distortion under the electrodes, movement of the electrodes, environmental electromagnetic interference (EMI), and non-cardiac electrical potentials from the body. The LifeVest WCD incorporates the following features to eliminate, reduce, or identify the potential presence of ECG signal disturbances:

Two-Lead System

The TruVector detection algorithm uses both leads for arrhythmia determination over 95% of the time.⁵ However, interference or poor electrode contact is monitored and may be identified on either ECG lead. If necessary, the TruVector detection algorithm ignores suspicious input from one lead and uses the remaining lead to determine the presence or absence of an arrhythmia.

Driven Ground

When LifeVest recognizes interference common to all of the electrodes (such as EMI, see Figure 2 below), the driven ground returns (or “drives”) a filtered result onto the skin, reducing or eliminating common-mode interference.

The driven ground is essential because living and working environments can be heavily polluted with EMI at line frequency (50 or 60 Hz) radiating from power lines, building wiring, and AC powered devices such as lights, televisions, radios, and computers.

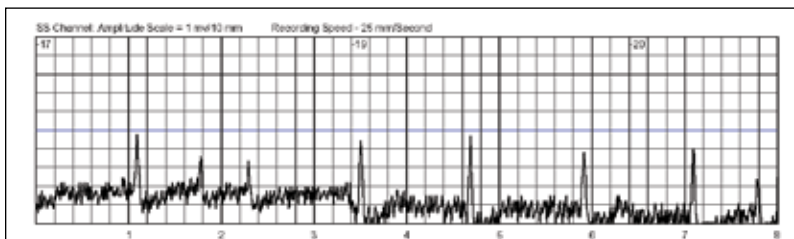


Figure 2: Example of line frequency electromagnetic interference.

ECG Signal Filtering

The TruVector detection algorithm filters out non-cardiac frequencies by both analog and digital means to attenuate frequencies outside of the range of the ECG.

Electrode Skin Contact Analysis

The falloff signal allows the TruVector detection algorithm to make a judgment regarding the quality of the skin contact of each electrode. The ground electrode places a low amplitude signal on the skin that can be detected at each electrode. If the signal is not detected or is lower than the expected amplitude for an electrode with good skin contact, the TruVector detection algorithm reacts by placing no diagnostic weight on the signal received from that ECG lead.

ECG Interference Analysis

In some situations, ECG signal corruption is easily recognizable. The TruVector detection algorithm reviews each lead for situations where signal voltages reach or exceed the algorithm's input capability, often referred to as clipping, and for the overwhelming presence of higher frequencies in the signal (Figure 3). Either of these conditions will cause the TruVector detection algorithm to place no reliance on that particular lead.

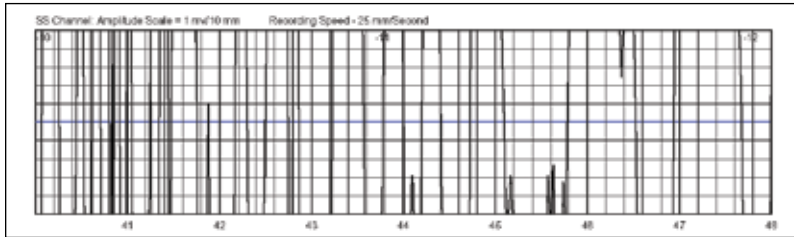


Figure 3: Example of clipping due to electrode movement.

Patient Interaction

LifeVest offers the unique advantage of patient interaction. After the TruVector detection algorithm has detected a treatable arrhythmia, the device tests the patient's level of consciousness by looking for a response to an escalating series of vibrating, audible, and visual alerts. The patient responsiveness test begins discretely with a silent vibration and illumination of the response buttons, providing the patient the opportunity to respond without disrupting the social environment. The expected conscious response is for the patient to press and hold the response buttons on the monitor (Figure 4). If there is no response after 5 seconds, a low-volume dual-tone siren begins. The siren then gets louder (about 100 decibels) to reach a volume that could awaken a potentially sleeping patient. If the patient still has not responded, voice prompts provide instructions to the patient and bystanders. These messages are interspersed with the high-volume siren.

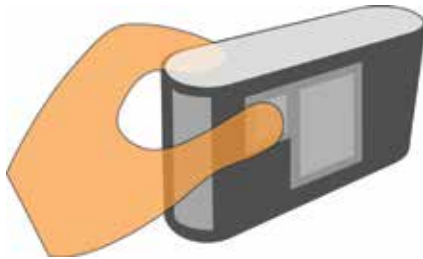
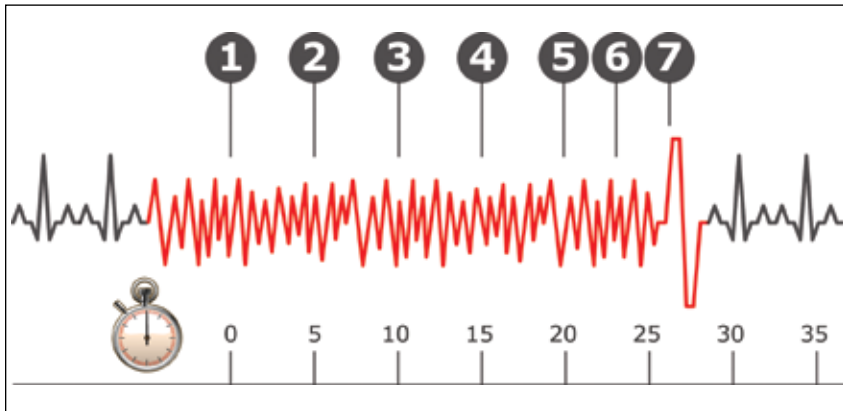


Figure 4: Location of response buttons on device.

Timing Sequence

The TruVector detection algorithm is designed to treat ventricular tachyarrhythmias. In a typical situation, treatment occurs in about one minute following arrhythmia detection. Below is an example of a VF treatment sequence in a typical situation.



1. Arrhythmia detected, activating vibration alert (continues throughout sequence).
2. Siren alerts begin (continues throughout sequence).
3. Siren alerts get louder.
4. Patient audible prompt: “Press response buttons to delay treatment.”
5. Blue™ gel release.
6. Bystander audible prompt: “Bystanders, do not interfere.”
7. Treatment shock.

Summary

The LifeVest WCD uses a proprietary and unique detection algorithm called TruVector that identifies a treatable ventricular arrhythmia by utilizing multiple analyses and factors focused both on heart rate and morphology. Once the heart rate is categorized above the VT threshold, the device compares the morphology of the patient’s current QRS complex to their baseline template. In parallel, AArD is discriminating between physiological and non-physiological patterns. The criteria work together to declare when an arrhythmia is present. LifeVest then utilizes patient interaction through a series of alerts to test the patient’s responsiveness in order to determine whether the patient is conscious. If the patient does not respond by pressing and holding the response buttons, a treatment shock will be delivered. The algorithm incorporates several features to evaluate signal quality, including identifying and reducing ECG signal corruption. The LifeVest TruVector detection algorithm results in a low risk of inappropriate shocks while maintaining a high sensitivity for detecting ventricular tachyarrhythmias.

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¹ Nguyen E, Weeda ER, Kohn CG, et al. Wearable Cardioverter-defibrillators for the Prevention of Sudden Cardiac Death: A Meta-analysis. The journal of Innovations in Cardiac Rhythm Management. 2018;9:3151-3162.

² Data on file at ZOLL as of April 2011.

³ Data on file at ZOLL as of October 2019.

⁴ Data on file at ZOLL as of October 2017.

⁵ Data on file at ZOLL as of April 2012.

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