Analysis Algorithm Overview

Defibrillation with RHYTHMx®

CARDIAC science™

Introduction

Every year, approximately 295,000 people in the U.S. die from Sudden Cardiac Arrest (SCA).[1] Sudden Cardiac Arrest is typically caused by rapid and chaotic heart rhythms, and manifests in the unexpected stopping of the heart pumping blood. For each minute that passes after the onset of SCA, a person's chance of survival goes down by approximately 10 percent. The most important determinant in the survival of victims who suffer a cardiac arrest is the length of time between onset of the event and delivery of the defibrillation shock.

The American Heart Association (AHA) recommends defibrillation response within 5 minutes for out-of-hospital events, and 3 minutes for in-hospital events. This is why the AHA has identified a treatment strategy called the "Chain of Survival" which consists of four links: early access to 9-1-1, early CPR, early defibrillation and early advanced care. Automated External Defibrillators (AED) were invented specifically to address the third and weakest link in the chain, early defibrillation. Currently, the response time from onset of SCA to first defibrillation shock varies greatly, with out-of-hospital survival rates averaging around 5 percent.[2]

When Cardiac Science introduced the Powerheart® AECD® fully automatic external cardioverter monitor-defibrillator for in-hospital use in 2000, clinicians for the first time, had a highly accurate device that offered continuous monitoring, instant detection and immediate treatment of life-threatening arrhythmias, all without human intervention. The foundation for the advanced technology of the Powerheart AECD is the patented RHYTHMx® software algorithm, which offers the unique ability of filtering noise and artifact from the patient's ECG signal without compromising its ability to correctly identify abnormal heart rhythms. This allows for the Powerheart to safely monitor patients while they are conscious, breathing, and ambulatory. Based on clinical studies and thousands of patient attachments in hospitals worldwide, RHYTHMx has been proven to be highly reliable.

By incorporating the RHYTHMx technology into the Powerheart® AED, the benefits of this advanced technology are now available to first responders and lay people. The Powerheart AED is designed to continuously monitor the patient's heart rhythm, significantly increase the accuracy of detecting abnormal cardiac arrhythmias and advise for external shocks when appropriate.

This paper will describe the Powerheart AED and its response to abnormal heart rhythms associated with SCA such as ventricular tachycardia (VT), ventricular fibrillation (VF), as well as supraventricular tachycardia (SVT). It will also describe the RHYTHMx technology and discuss clinical results from studies conducted with Cardiac Science's in-hospital device, the Powerheart AECD.

Automated External Defibrillators (AEDs)

AEDs were designed to be widely deployed in the hands of minimally trained rescuers to reduce critical response time to a SCA victim. The first AEDs were severely limited in their use because of their size, cost, and complexity. Today, AEDs are smaller, less expensive, and easier to use. The AHA, ERC, other industry groups, and countless communities now promote Public Access Defibrillation (PAD) programs where AEDs are placed in easily accessible public places as well as carried by police, fire fighters, emergency medical personnel, and other first responders be equipped and trained in the use of AEDs.

All AEDs are designed to acquire and analyze the heart's electrical activity or electrocardiogram (ECG, see figure 1). This information is gathered from a set of adhesive electrodes or pads that are placed on the victim's bare chest.
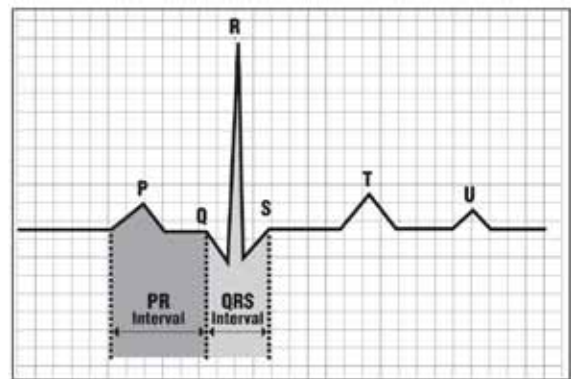

Fig. 1: Normal ECG Segment

The patient's ECG is assessed by the AED using a software algorithm that evaluates ECG characteristics (amplitude, frequency, and slope, as illustrated in figure 2). From the information gathered by the AED, a decision to advise the delivery of a shock, or not, is recommended by the device. All AED manufacturers use proprietary analysis algorithms, which are extensively tested by the manufacturer. AEDs are Class III medical devices and as such are regulated by the U.S. Food and Drug Administration (FDA) and other international regulatory agencies.

Fig. 2: ECG Characteristics

| Amplitude | Frequency (rate) | Slope |
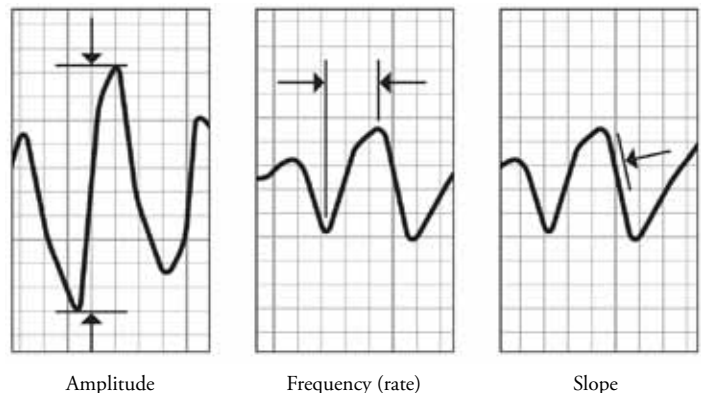
RHYTHMx Technology

The Powerheart AED is powered by the RHYTHMx technology. This patented software algorithm technology properly filters ECG signal for noise rejection, appropriately detects the heart's QRS complexes, calculates the heart rate, and classifies cardiac rhythms as life-threatening – "Shockable", or non-life threatening, – "Non-Shockable", based on programmed parameters. *(Note – Heart ECG signals contain wave-shapes that are referred to as P-QRS-T waves. A normal heartbeat contains each of these wave shapes. Abnormally fast rhythms, in particular ventricular fibrillation is a chaotic and disorganized rhythm where these wave shapes are absent or indistinguishable.)*
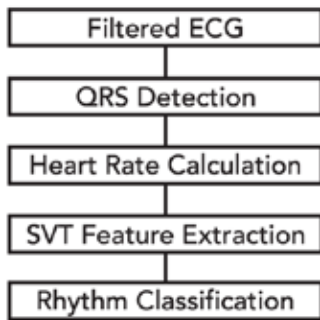
RHYTHMx Algorithm Overview

The patient's ECG signal is filtered to reduce noise artifacts and wandering baseline. The rate between two adjacent QRS complexes is calculated in beats per minute, then six of the last eight consecutive QRS rates are averaged, and the two outliers are discarded. If the running heart rate average is greater than the programmed VF/VT Rate, then the rhythm is classified as Shockable. If a Shockable rhythm persists, a defibrillation shock is advised. If the running average is lower than the VF/VT Rate, the rhythm is considered Non-Shockable and a shock will not be advised.

The "shock" or "no shock" decision made by the Powerheart AED is non-committed. This is a very important safety feature. Non-committed means that if the patient's heart rhythm suddenly reverts back to normal after the device has determined that the rhythm is Shockable, the AED will withhold the shock energy and will inform the operator via a voice prompt that the rhythm has changed and a shock is no longer warranted.

In the event of a Shockable rhythm, the Powerheart AED will always attempt synchronization of the shock to the patient's R-wave for a maximum of 1 second. This automatic synchronization feature allows the safe delivery of synchronous shock to a patient exhibiting a life threatening, high rate ventricular tachycardia or supraventricular tachycardia, and reduces the possibility that the electrical shock might induce the patient in ventricular fibrillation. If the Powerheart AED fails to identify appropriate ECG complexes, the heart rhythm is very likely ventricular fibrillation and the Powerheart AED will then deliver an asynchronous defibrillation shock. The Powerheart AED will deliver a synchronously only if necessary; however, the device will not delay its advisement of a defibrillation shock if the patient is exhibiting a Shockable rhythm.

Powerheart AED Rhythm Classification

If a person is experiencing the symptoms of a sudden cardiac arrest (not breathing, unconscious, no signs of circulation), by the time a first responder arrives on the scene, the most common ECG rhythm the person is exhibiting is most often a rapid and chaotic lethal arrhythmia called ventricular fibrillation (VF).[3] VF is expressed as the random absence of identifiable QRS complexes on the ECG (see figure 3). The Powerheart AED considers VF a Shockable rhythm.

Another rhythm that a SCA victim may experience is ventricular tachycardia (VT, see figure 4). VT is generally characterized by a very fast, abnormal heartbeat at rates exceeding 150 beats per minute.[4] The AHA treatment guidelines for cardiac arrest patients with an underlying VT rhythm state that this rhythm should be treated as if it were VF.[5] The Powerheart AED classifies VT as a Shockable rhythm, and a shock will be advised when the heart rate exceeds the programmed VF/VT Rate.
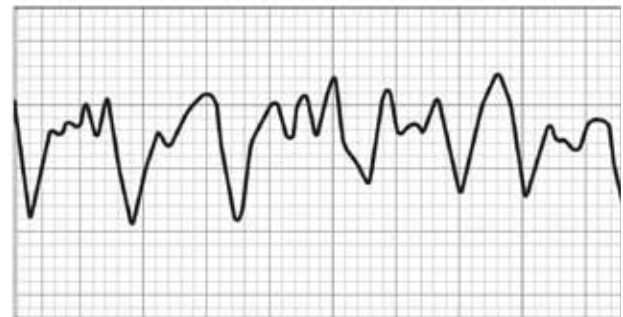

Fig. 3: Segment of Ventricular Fibrillation (VF)

The Powerheart AED provides significant improvement over current AEDs on the market, since all other AEDs currently use a single, fixed detection rate to treat VF/VT. The Powerheart AED is the first AED that allows a medical director to program detection rates for VF/VT, as well as supraventricular tachycardia (SVT), using Cardiac Science's MDLink® software. By providing the ability to adjust the VF/VT and SVT rates, a medical director can select detection rates based on his/her AED program. The detection rate for VF/VT can be set from 120-240 bpm, with factory default setting of 160 bpm. The SVT rate can be set from 160-240 bpm, with factory default setting of 200 bpm.
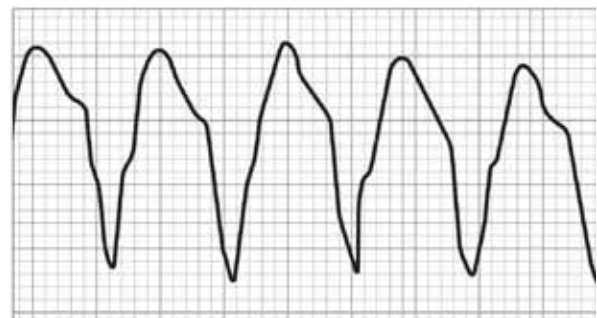

Fig. 4: Segment of Ventricular Tachycardia (VT)

Surpraventricular Tachycardia (SVT)

The AHA also recommends defibrillation therapy for supraventricular tachycardia (SVT, see figure 5).[6] SVT can be broadly defined as any rapid heart rhythm, originating in the atrium (the upper chambers of the heart). Many people experience short periods of SVT and have no symptoms. These short episodes of SVT are not life threatening. However, SVT is of concern when it lasts for extended periods of time and produces symptoms such as palpitations, light-headedness, and chest pain. In some severe cases, SVT may also lead to a loss of consciousness and the risk of sudden cardiac death.
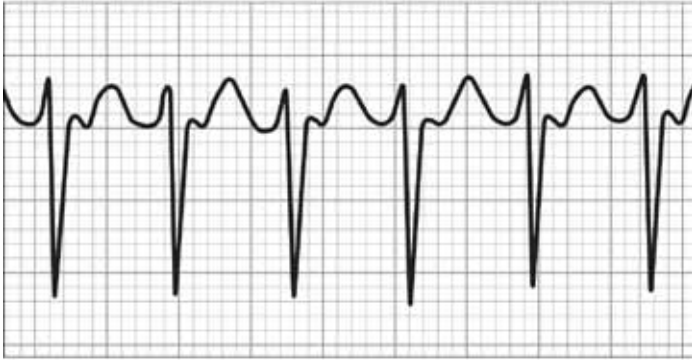

Fig. 5: Segment of Supraventricular Tachycardia (SVT)

There is some confusion and misinformation regarding shocking patients who exhibit SVT with an AED device. First, important to note that patients experiencing the symptoms of a sudden cardiac arrest (not breathing, unconscious, no signs of circulation), very rarely present an SVT rhythm. In fact, anecdotal evidence suggests that many clinicians or emergency medical personnel rarely, if ever, have even seen such a patient. Most of the SVT patients seen by clinicians are conscious, breathing and have a pulse. In these situations, AHA Advanced Cardiac Life Support (ACLS) training instructs that medications be administered to treat and reverse SVT.

Some persons however, may present an SVT rhythm and be clinically unstable, meaning that the person is exhibiting symptoms of a sudden cardiac arrest (not breathing, unconscious, no signs of circulation). In these cases, it is impossible for a first responder to make any distinctions.

In a clinical setting or if ACLS trained emergency medical technicians (EMT) are on the scene, the physician, nurse or EMT, may elect to deliver synchronized cardioversion, performed with a manual defibrillator.[7] Manual defibrillators are equipped to provide a trained clinician the choice of delivering a defibrillation shock or a synchronized cardioversion shock that is timed with the patient's ECG rhythm. This synchronization reduces the chance that the electrical shock might induce the patient into VF.[8] Confusion about SVT treatment usually occurs when a physician or ACLS-trained EMT is asked how an AED should be used to treat a SCA patient in SVT. In most cases, they would state that it is necessary to synchronously cardiovert the patient with a manual defibrillator.

Until the introduction of the Powerheart AED, this capability was not possible for AEDs. This feature is now available for the first responder, or lay rescuer.

The Powerheart AED has a built-in automatic synchronization feature. The Powerheart AED will deliver a synchronized cardioversion shock that is timed with the patient's ECG rhythm in order to convert the person's rhythm back to normal.

SVT Discrimination Function™

Powerheart AED includes a patented algorithm feature called SVT Discrimination Function™. The SVT Discrimination Function examines the unique characteristics, (i.e., the morphology shape, amplitude, duration, etc.) of the waveform and has the ability to accurately differentiate SVT from VT/VF. With the SVT Discrimination Function, RHYTHMx technology analyzes the cardiac arrhythmia in the same manner, except when the patient's heart rate falls between the programmed Detection Rate and the programmed maximum SVT Rate. The maximum SVT rate is as a rule always set higher than the Detection Rate. The Powerheart AED differentiates VT/VF from SVT as follows:

- If the average heart rate is between the Detection Rate and the maximum SVT Rate, therapy is advised only if the rhythm is classified as Shockable (i.e., the QRS complex begins to widen). For example, the Detection Rate on the Powerheart AED is programmed at 180 BPM, and the SVT Rate is programmed at 200 BPM. If the SVT occurs at 187 BPM, the rhythm will be classified as Non-Shockable.

- If the average heart rate is greater than the maximum SVT rate, therapy is always advised. Thus, if a rhythm occurs at a rate higher than the maximum SVT Rate setting, a shock is always advised.

Powerheart AED Classification of Asystole fine VF and Artifact

Asystole is defined as cardiac standstill where the heart has no electrical activity and the patient is completely unresponsive. The Powerheart AED classifies a rhythm as Asystole if the ECG signal amplitude is less than 0.08 mV. According to AHA guidelines, the Powerheart AED classifies Asystole as a Non-Shockable rhythm.

Powerheart AED classifies Fine VF as a Shockable rhythm except when the device is in a continuous monitoring mode and the heart rhythm is preceded by a non-shockable rhythm. However, in most cases, fine ventricular fibrillation is the deterioration of the ECG amplitude of a VF rhythm with an ECG amplitude of less than 0.9

mV with no obvious baseline and an irregular heart rate.

When an ECG signal becomes saturated, that is, the signal exceeds preset frequency and amplitude thresholds, it is classified as Artifact by the Powerheart AED. Artifact is considered an unusable ECG signal, and is automatically rejected for analysis. This rejection capability helps prevent over-sensing and false detections.

Clinical Results With RHYTHMx Technology

Clinical results with the RHYTHMx technology demonstrated 100% sensitivity (correct identification of shockable rhythms) and 99.4% specificity (correct identification of non-shockable rhythms)[.9] Below is a summary of these results.

Arrhythmia Detection Performance

The objective of the study was to assess the performance of the RHYTHMx technology in patients undergoing placement of Implantable Cardioverter Defibrillators (ICDs). Ventricular Fibrillation (VF) was induced using the ICD and the Powerheart AED device equipped with RHYTHMx technology was used as a back-up defibrillator should the ICD fail to convert the induced arrhythmia.

The RHYTHMx technology was tested in 54 patients who were 70 ± 12 years old with a Left Ventricular Ejection Fraction (LVEF) of 31 ± 10 %. A total of 108 VF inductions (mean cycle length 207 msec) were performed in 54 patients. One episode out of 108 episodes was not detected by the Powerheart, resulting in a sensitivity of 99.1%. Twenty shocks were delivered by the Powerheart, with all shocks administered effective in treating VF.

SVT Discrimination Algorithm Performance

The SVT Discrimination Function algorithm has three features (Modulation Domain Function, Waveform Factor Analysis and Signal Variability Analysis), and is used in the Powerheart AED to differentiate Supraventricular Tachycardia (SVT) from VT or VF based on a pre-programmed SVT rate zone. The Powerheart AED will withhold recommendation of therapy delivery in response to tachycardia that is recognized as SVT within this zone and recommend therapy for faster tachyarrhythmia rates.

The SVT Discrimination Function algorithm was tested in 100 patients during routine diagnostic electrophysiology (EP) studies. Clinical SVT was induced in 50 patients during the study; the Powerheart was programmed with a Detection Rate that would result in this tachyarrhythmia falling within the SVT rate zone. For instances where clinical SVT could not be induced, atrial bipolar pacing was used to mimic sinus tachycardia. Consequently, the events studied consisted of clinical supraventricular arrhythmias as well as paced rhythms.

Results

Overall the SVT Discrimination Function demonstrated a sensitivity of 100% and a specificity of 95.6%.

A total of 64 clinical SVT events and 83 paced events were studied. The events studied had rates that fell within the SVT discrimination zone mentioned previously. Each event (whether clinical or paced) received a score based on the interpretation of rhythm in question by the SVT DF algorithm. If the RHYTHMx technology diagnosed a clinically non-shockable rhythm as shockable, the event was classified as a False Positive (FP), otherwise, the event was classified as a True Negative (TN). There were a total of 6 FP events and 131 TN events. Out of a total of 137 events (with rates falling in the SVT discrimination zone), 6 events were incorrectly classified by the RHYTHMx technology as Shockable events, resulting in specificity of 95.6%. Specificity is defined as the ratio of FPs to the sum of FPs and TNs, and is a measure of the SVT Discrimination Function algorithm's strength in discriminating shockable from non-shockable rhythms.

Sensitivity is a measure of how sensitive the RHYTHMx technology is to detect shockable rhythms. If a clinically shockable rhythm is detected by the algorithm as shockable, the event is classified as True Positive (TP), otherwise, the event is classified as False Negative (FN). Sensitivity is defined as the ratio of TPs to the sum of TPs and FNs. In this study, there were 18 TPs and no FNs. These results demonstrate the RHYTHMx technology recognized all clinically shockable events with 100% sensitivity.

Artifact Rejection Robustness

The performance of RHYTHMx technology was assessed in ambulatory patients in a worse case scenario. Accordingly, 50 participants of a cardiac rehabilitation program were attached to the Powerheart during strenuous exercise. The goal was to allow patients to exercise on a treadmill while attached to Powerheart and reach heart rates within the Supraventricular Tachycardia/ Ventricular Tachycardia (SVT/VT) zone to assess discrimination capability as well as artifact (noise) rejection.

The Powerheart was programmed to detect any rate greater than 120 bpm as VT, and discriminate SVT from VT with rates up to 200 bpm. Patients were allowed to exercise until limited by symptoms. Self-adhesive defibrillation electrodes were placed on the patient's chest in a sternum-to-apex configuration that was also used as the sensing channel.

Five patients receiving beta-blockers did not achieve a heart rate greater than 120 bpm and were excluded from analysis; there were no false positive (FP) detections in this patient group. The remaining 45 patients achieved a mean peak heart rate of 136 bpm (range =120-186 bpm). There were 3 FP tachycardia detections (Specificity 93.3%). The first FP episode occurred in a female at a heart rate of 124 bpm; this patient had a small thoracic area that required the electrode to be placed over breast tissue, which resulted in non-contact areas under the sternum pad. The second FP episode occurred in a 32 y/o female at a peak heart rate of 186 bpm when pad detachment occurred secondary to excessive perspiration and body motion. The third FP episode occurred in

an obese female at a heart rate of 122 bpm in the setting of low frequency signal that was felt secondary to breast motion. Heart rate was accurately detected in all patients throughout exercise (Sensitivity 100%). It can be concluded that the RHYTHMx technology demonstrated accurate monitoring and was reliable in detecting motion noise even in the worse case scenario with monitoring of ambulatory patients during exercise.

Powerheart AED represents a considerable leap forward in the science and usability of public access defibrillators. The Powerheart AED incorporates for the first time into an AED, Cardiac Science's patented RHYTHMx technology. RHYTHMx helps make the Powerheart AED device highly accurate in the detection and treatment of patients suffering life-threatening abnormal heart rhythms, and provides for new capabilities and expanded applications.

As a result, Cardiac Science has been granted FDA clearance for new indications for use which eliminate the need for the rescuer to determine whether or not the cardiac arrest victim has a pulse prior to attaching the defibrillator device. In addition, the Powerheart AED is cleared for continuous monitoring of a conscious victim's heart rhythm after they have been revived, thereby protecting the victim against the reoccurrence of a post-resuscitation life-threatening arrhythmia, until they can be admitted to a hospital.

In addition to the patented Rescue Ready® features found in its predecessor device, the Survivalink® AED, such as one-button operation, pre-connected disposable pads, automatic self-test and

escalating variable low-energy biphasic defibrillation technology, new capabilities further distinguish the Powerheart AED from its competition. The Powerheart AED is the only AED that differentiates between shockable life-threatening ventricular arrhythmias (VT/VF) and other non-shockable cardiac arrhythmias events such as supraventricular tachyarrhythmias (SVT) and allows for synchronized shock when possible, by automatically synchronizing shock delivery with the patient's electrocardiogram R-wave.

The Powerheart AED has the ability to continuously analyze a victim's heart rhythm after charging and during CPR and is capable of sensing a change of rhythm after a shock decision has been made up until the time the shock button is pushed by the user. Upon recognition of a rhythm change, the Powerheart AED (if armed) automatically disarms, informs the user that the rhythm has changed, and reanalyzes the victims heart rhythm.

In addition, post-resuscitation monitoring of the victim's heart rhythm allows the Powerheart AED to instantly detect the reoccurrence of a life-threatening arrhythmia. If cardiac arrest recurs, the device will charge automatically and advise the operator to deliver a defibrillation shock. Powerheart AED also facilities easy medical oversight. VF/VT and SVT detection criteria and biphasic defibrillation variable energy settings are programmable by qualified medical personnel via Cardiac Science's proprietary MDLink® software.

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