What is SMART Analysis?

Introduction

HeartStart Automated External Defibrillators (AEDs) are small, rugged, and virtually maintenance free. These characteristics make wide deployment of these defibrillators practical by a broad range of emergency responders, who may be medical professionals, EMTs, fire department personnel, police officers, security guards, flight attendants, corporate emergency response teams, or ordinary laypeople. In order for responders with minimal medical training to use it safely, a defibrillator must be able to accurately detect the victim's life-threatening heart arrhythmia and deliver therapy appropriately. If these requirements are met, anyone with minimal defibrillator training can deliver time-critical defibrillation therapy to victims of sudden cardiac arrest (SCA).

The HeartStart FR2 series, OnSite, and Home Defibrillators use a sophisticated computer algorithm — SMART Analysis — to rapidly and automatically assess the victim's heart rhythm and decide whether defibrillation is appropriate. This proprietary electrocardiogram (ECG) analysis system is exceptionally accurate.

This Application Note provides answers to questions about the SMART Analysis algorithm and its use in HeartStart Defibrillators.

What is an algorithm?

A crucial factor in the safety and performance of a defibrillator is the device's ability to accurately assess the cardiac state of the patient and make an appropriate therapy decision. The defibrillator performs this evaluation by sensing electrical signals from the patient's heart via adhesive pads and using a computerized algorithm to interpret the signals and make a therapy decision.

A defibrillation algorithm is a mathematical process used to interpret and analyze sensed ECG information.

Are all defibrillation algorithms the same?

No, all defibrillation algorithms are not the same. The SMART Analysis system simultaneously looks at four key indicators to determine whether a heart rhythm is shockable or non-shockable. These four indicators are rate, conduction, stability, and amplitude.

- Rate is determined by how many times the heart beats per minute (bpm). A healthy adult heart rate typically ranges from 60 to 100 bpm.
- Conduction is determined by examining the R-wave segment of the QRS complex, which is the electrical signature of a heart beat. With the defibrillation pads correctly positioned, a healthy R-wave appears on the ECG as a tall, narrow spike. This indicates that the conduction through the heart is rapid and well organized. A wide, rounded R-wave indicates possible problems with the conduction.

ECG of a normal, healthy heart.

- Stability is a measure of how repeatable the QRS complexes are. The ECG of a healthy heart shows a similar, stable signal for each heartbeat. In an unhealthy heart, the ECG typically reveals varying signal shapes that are not stable from one heart beat to the next.
- Amplitude is a measure of the strength of the heart's electrical activity. In a healthy heart, each beat, or contraction, is strong and results in a large, high-amplitude signal. Unhealthy heart rhythms are typically low in amplitude.

ECG of a heart in ventricular fibrillation, a life-threatening arrhythmia.

What are sensitivity and specificity?

The performance of a defibrillation algorithm is evaluated on two criteria, sensitivity and specificity.

- Sensitivity refers to the device's ability to detect life-threatening ventricular arrhythmias.
- Specificity refers to the device's ability to detect normal rhythms or arrhythmias that should not be shocked.

HeartStart Defibrillators, with SMART Analysis, exceed the performance requirements for sensitivity and specificity of both the American Heart Association (AHA) and the Association for the Advancement of Medical Instrumentation (AAMI).

How was SMART Analysis tested?

The SMART Analysis system was tested against a database of more than 3,000 ECG rhythms. Recorded from hospital and pre-hospital patients, the database comprised a wide variety of rhythms, including cardiac arrests of varying durations. All ECGs were reviewed and classified as shockable or non-shockable by three independent, board-certified cardiologists.

The results of the validation process illustrate the conservative nature of the SMART Analysis algorithm. In the few cases where the cardiologists disagreed with SMART Analysis, they chose to shock a rhythm that SMART Analysis chose not to shock. In every instance that SMART Analysis determined a rhythm was appropriate for defibrillation, the cardiologists agreed.

In addition, in a study of the first 100 uses of the HeartStart ForeRunner defibrillators, the devices used SMART Analysis to correctly identify all patients who required a shock (100% sensitivity) and all patients who did not require a shock (100% specificity).

What is artifact?

Artifact is an electrical signal present in the ECG that is unrelated to the heart signal. Artifact can cause an incorrect analysis of the patient's heart rhythm and lead to an inappropriate shock/no-shock decision.

Sources of artifact can be characterized as controllable or non-controllable by the responder.

- Controllable artifact includes signals resulting from directly touching the pads, moving the patient, radio transmissions, and ground transport.
- Non-controllable artifact may be caused by electrical interference, patient seizures or gasping (agonal respiration) or an implantable pacemaker, for example.

Since the responder cannot eliminate non-controllable sources of artifact, a well-designed defibrillator should be capable of correctly discriminating between the actual cardiac signal and artifact in order to make the correct treatment decision. It is important that the defibrillator recognize the difference between a signal generated by the heart and an artifact signal, regardless of its source, in order to minimize the effect of the artifact on the accuracy of the analysis of the heart rhythm.

How does SMART Analysis deal with artifact?

SMART Analysis can "see through" many kinds of non-controllable artifact signals and correctly assess the signal from the heart. Using SMART Analysis, the HeartStart Defibrillator is designed to detect many non-cardiac artifact signals — for example, agonal respiration and pacemaker artifact — while reliably analyzing the underlying cardiac rhythm.

When it does encounter artifact that corrupts the ECG signal sufficiently to interfere with analysis, the HeartStart Defibrillator uses artifact detection and comprehensive voice prompts to alert the user and assist in troubleshooting the problem. For example, the defibrillator will give a voice prompt saying "Analyzing interrupted. Do not touch the patient." or "Analyzing interrupted. Stop all motion." This helps the user identify the possible source of the artifact so that corrective action can be taken swiftly, saving valuable time.

In contrast, some defibrillators have no artifact detection. Others simply look for motion, which may or may not be associated with significant artifact. This can lead to unnecessary delay of rhythm analysis and treatment. In addition, some defibrillators may be susceptible to non-controllable artifact such as that caused by seizures or implanted pacemakers; this can result in delivery of inappropriate shocks or failure to deliver necessary shocks.

Why SMART Analysis?

To help save the life of an SCA victim, timely and effective defibrillation is required. To realize the goal of providing access to defibrillators for use by non-traditional responders without extensive medical training, the device used must be able to accurately detect life-threatening arrhythmias and deliver appropriate therapy.

SMART Analysis gives HeartStart Defibrillators an exceptional level of accuracy, greatly reducing the possibility of inappropriate shock delivery, increasing user confidence, and enhancing patient safety. This technology helps make widespread deployment of defibrillators a welcome reality.

POWER TO SAVE A LIFE

HEARTSTART®
DEFIBRILLATORS

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