Philips SMART Analysis AED algorithm

Introduction

This application note explains how Philips Automated External Defibrillators (AED) and ALS monitor/defibrillators,* with optional AED mode, utilize Philips proprietary SMART Analysis AED algorithm to analyze a patient's ECG and determine if a shock should be delivered.

In this application note AED will be used to refer to Philips Automated External Defibrillators (AED) and ALS monitor/defibrillators that have the optional AED mode installed.

* This application note does not apply to Philips HeartStart MRx and XL ALS monitor/defibrillators, with optional AED mode.

What is an algorithm?

An algorithm is a sophisticated, mathematical process of interpreting information. An AED uses an algorithm to interpret electrical signals received from the patient's heart, via multifunction defibrillation electrode pads. The algorithm determines if the patient has a life-threatening arrhythmia and makes a shock/no-shock decision.

An algorithm is a crucial factor in the safety and performance of an AED. The algorithm must accurately identify features of morphology associated with shockable rhythms and successfully remove artifacts to assess the cardiac rhythm of a patient and make an appropriate therapy recommendation.

Algorithm performance 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.

SMART Analysis algorithm components

The SMART Analysis algorithm consists of three parts:

• Pad contact quality

• Artifact detection

• Arrhythmia detection

These three parts work together to read an ECG and evaluate available information to determine if a shock is appropriate.

Pad contact quality
The analysis system continuously monitors the patient impedance to ensure that it remains within the appropriate range. If the measured impedance is too high, it may indicate that the pads are not properly applied or that there may be a problem with the skin contact. Unless this is corrected, the defibrillator will not be able to read the ECG effectively to determine whether a shock is advised. Poor pad connection can also cause a problem with the delivery of current to the patient. If the patient impedance is too high, then the AED issues voice prompts directing your attention to the pads, announcing that pads contact is poor and instructing you to apply pads or to press the pads firmly to correct the situation.

Artifact detection
Whenever any electrical signal (such as an ECG) is measured, there is always some electrical noise in the environment that can interfere with an accurate measurement. Artifact detection is important in ECG analysis because it allows filtering out or compensation for this electrical noise.

Any artifact that is undetected can lead to incorrect decisions by the algorithm and can cause incorrect or delayed treatment of the patient. Artifact may be caused by CPR, agonal breathing, transportation, patient handling, or the presence of a pacemaker in the patient. The SMART Analysis' action depends on how the artifact looks in relation to the ECG signal.

To detect artifact, the AED measures the transthoracic impedance, common mode current, and electrical potentials sensed by the pads and compares these values to the ECG signal. If these values correlate, then an artifact is detected and appropriate voice prompts and display messages signal you to take appropriate action. Otherwise, analysis proceeds, and the AED makes a shock / no-shock decision.

If the amplitude of the underlying ECG signal is smaller than an artifact signal, then the AED may be unable to accurately analyze the underlying ECG. Then it prompts you not to touch the patient or to stop all motion, and informs you that the analysis has been interrupted.

If the amplitude of the ECG signal is sufficiently high relative to the artifact signal, or if the artifact does not correlate with the ECG signal, then the artifact may not interfere with the normal operation of the AED. In these cases, the AED continues to make shock/no-shock decisions and prompts you to press the flashing Shock button if appropriate.

CPR artifacts

CPR during SMART Analysis can cause incorrect or delayed analysis. If analysis detects CPR, the AED interrupts the rescuer doing CPR and instructs to not touch the patient. However; not all artifact from CPR can be detected.

Figure 1 shows an example of rapid CPR done in such a way that it was not detected by the SMART Analysis. The second segment shows the underlying asystole present when CPR was stopped. The AED continually monitors the ECG and looks for changes in the rhythm; therefore, the unit was automatically disarmed when CPR was discontinued, and no-shock was delivered to the patient.

2 div/mV, 5 div/sec
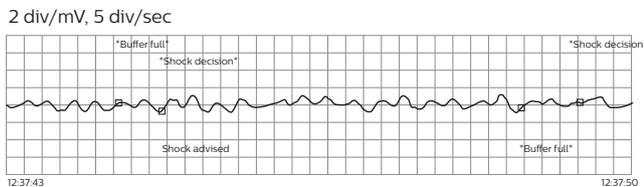
CPR artifact: underlying rhythm asystole

2 div/mV, 5 div/sec
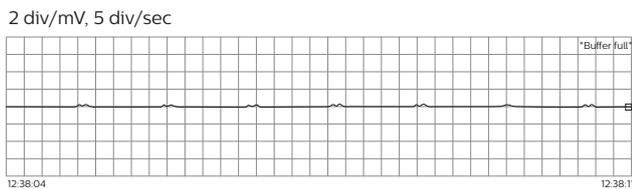
Post–CPR: underlying rhythm asystole

Figure 1: CPR artifact interference.

Pacemaker artifacts

If the patient has an internal pacemaker, then the AED filters attempt to remove the pacemaker artifact and, if appropriate, advises to shock the patient. The ECG shown on the display and ECG stored in the device memory still have the pacemaker spikes represented, but the ECG used by the algorithm has the spikes removed.

The two segments in Figure 2 represent the Ventricular Fibrillation (VF) ECG before and after the pacemaker artifact is filtered out.
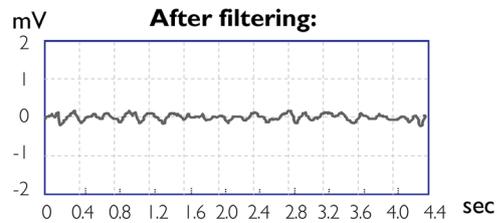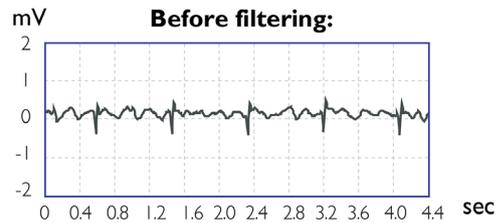

Figure 2: Pacemaker artifact removal.

Even with a sophisticated artifact detection system, not all artifact can be detected during the use of the AED; therefore, it is important to listen to the voice prompts and observe the display messages given by the AED and to not touch the patient while the algorithm is analyzing the ECG.

Caution: Due to differences between pacemaker therapy designs, artifact removal cannot be guaranteed. The SMART Analysis AED algorithm is not designed to handle erratic spiking problems caused by a properly or improperly functioning pacemaker. In patients with cardiac pacemakers, the AED may have reduced sensitivity and may not detect all shockable rhythms.

Arrhythmia detection

The patient's cardiac rhythm is crucial for its safety and performance in AED mode. The AED evaluates the cardiac rhythm by sensing electrical signals from the patient's heart via multifunction pads and using a software algorithm to interpret these signals and make a shock/no–shock decision. SMART Analysis was developed and tested to ensure that its sensitivity (ability to detect shockable rhythms) and specificity (ability to detect non–shockable rhythms) exceed the IEC60601–2–4 requirements.

To determine if a patient's rhythm is shockable, the SMART Analysis algorithm evaluates these four parameters of the ECG in 4.5 second segments:

· Rate

· Conduction (shape of the QRS complex)

· Stability of the rhythm (regularity of the waveform pattern)

· Amplitude.
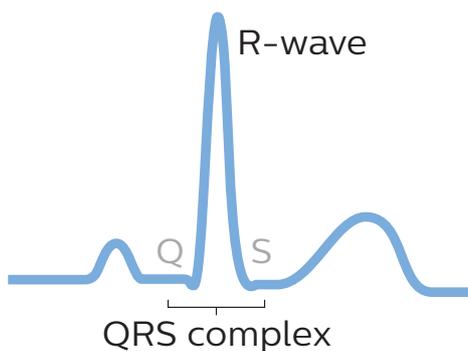
Figure 3: QRS complex.

Rate

Rate measures how many times the heart beats per minute (bpm). An adult heart beats approximately 60–100 bpm, but some normal rhythms can be very fast. Therefore, it is important to have additional indicators in the analysis system of an AED. Rate is used along with the other parameters to help determine whether the rhythm is shockable. The higher the rate, the more likely a rhythm is shockable. The lowest rate to be shocked is 135 bpm, and this applies to those rhythms that are most disorganized, such as VF. The more organized a rhythm is, the higher the rate must be in order to be shockable. However, rhythms with narrow QRS complexes, such as Supraventricular Tachycardia with Narrow QRS (SVT) will not be shocked, regardless of the heart rate.
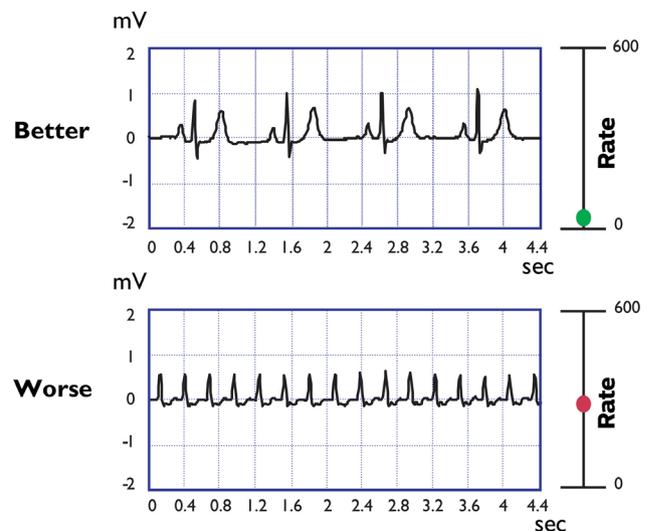

Figure 4: Rate in arrhythmia detection.

Conduction

Conduction is determined by examining the R-wave of the QRS complex. Conduction is related to the propagation of electrical impulses through the ventricles. In a healthy heart, the ventricles contract in unison, which is reflected in the ECG by narrow QRS complexes with sharp transitions. Non-perfusing rhythms are characterized by wide complexes with smooth transitions. Therefore, a rhythm with wide complexes and smooth transitions is more likely to be shocked.
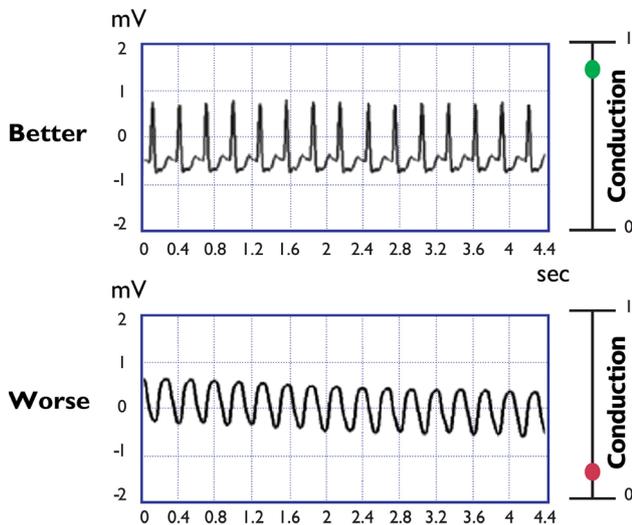

Figure 5: Conduction in arrhythmia detection.

Stability

Stability refers to the repeatability of the morphologies of the various waves of the ECG complexes, but does not depend on the consistency of the period between complexes. Thus NSR and atrial fibrillation both result in high stability. A heart in VF has chaotic, unstable complexes.
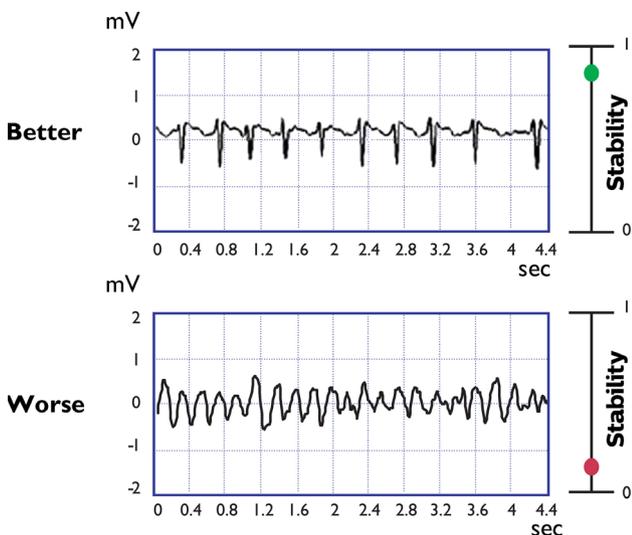

Figure 6: Stability in arrhythmia detection.

Amplitude

Amplitude is a measure of magnitude of the heart's electrical activity. A heart in asystole has a low amplitude ECG. Amplitude is dependent on the patient and pads placement. Amplitude is the least important of the four indicators.

SMART Analysis simultaneously measures the first three indicators over 4.5-second segments of ECG, and then classifies each segment of ECG as shockable or not. Amplitude is used as a gating check to determine if a segment is considered shockable; i.e. the 4.5-second segment of ECG must have at least a 0.1 mV peak-to-peak median amplitude in order for a segment to be considered VF. An ECG with amplitude below this threshold is considered asystole.
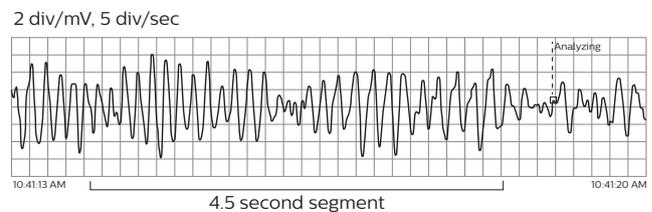
Figure 7: Amplitude measurement.

Analysis confirmation

Before the AED charges, the SMART Analysis algorithm must identify one or more ECG segments as shockable. The AED continues to monitor the ECG even after a shock/no-shock decision has been made and the unit has charged; this means that the SMART Analysis would react to a change in the heart rhythm and disarm if the rhythm becomes non-shockable after the device is charged.

Because artifact may be present and some rhythms have varying rates and morphologies, the device may review multiple segments before providing advice. If the device detects 2 non-shockable segments before detecting a shockable rhythm, it gives a voice and visual prompt that no-shock is advised and directs you to attend to the patient.

SMART Analysis algorithm in action

Analysis examples

This section reviews four different ECG examples. Each ECG is graphed based on its score for rate, conduction, and stability to determine if the SMART Analysis algorithm would or would not advise a shock. In Figures 8–12, the shock criteria surface is drawn in gray. According to the algorithm, any dot above the surface represents a shockable rhythm, and any dot below is a non-shockable rhythm. Green dots indicate a non-shockable rhythm for the Normal Sinus Rhythm (NSR) and Supraventricular Tachycardia (SVT), and red dots indicate a "shock advised" condition for the polymorphic Ventricular Tachycardia and Fibrillation (VT and VF) rhythms.

No shock advised: excellent stability, conduction, and rate
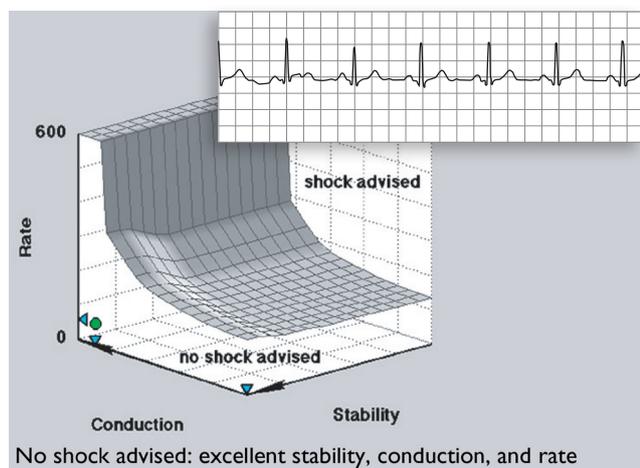
Figure 8: Normal sinus rhythm.

Shock advised: poor stability, very poor conduction, high rate
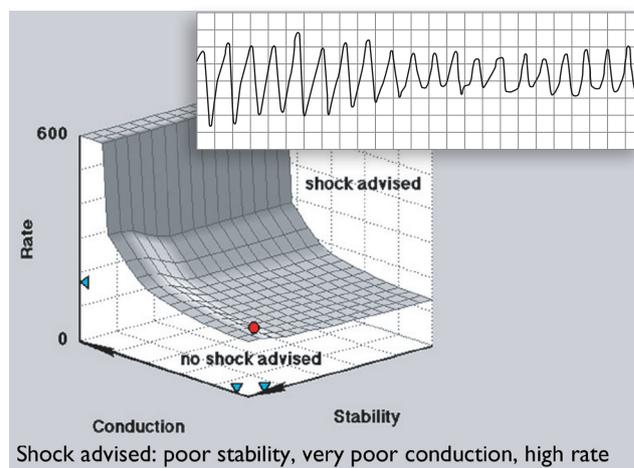
Figure 10: Polymorphic ventricular tachycardia.

No shock advised: excellent stability and conduction, high rate
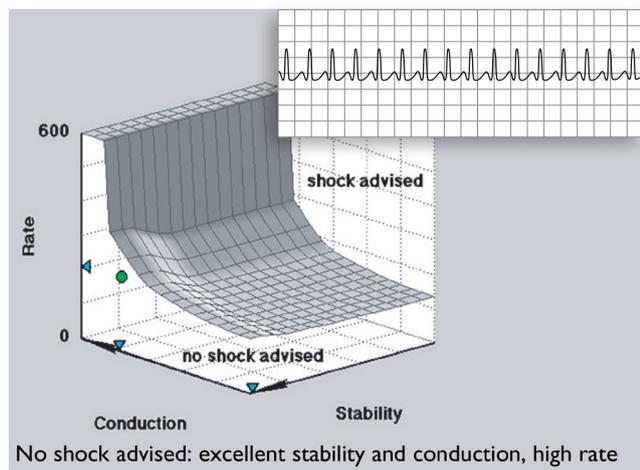
Figure 9: Supraventricular tachycardia.

Shock advised: very poor stability and conduction, high rate
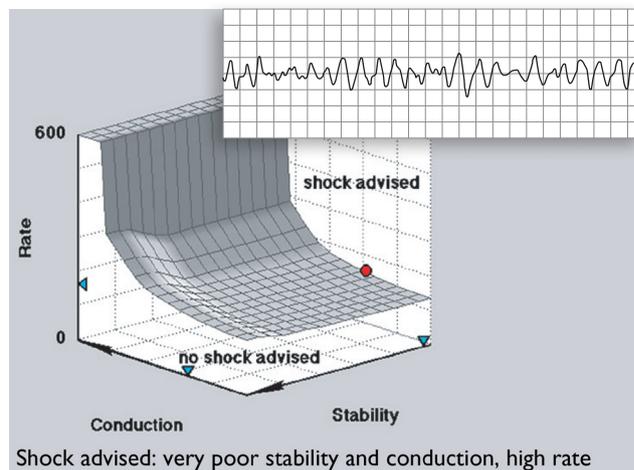
**Figure 11: Ventricular fibrillation.**

SMART Analysis approach

In 1997, the American Heart Association published a Scientific Statement that recommends a strategy for evaluating the accuracy of the arrhythmia analysis algorithms incorporated in AEDs.[1] Following the process described in this recommendation, over 3,000 ECG segments were collected into a database. This database included both shockable and non-shockable rhythms, which were randomly divided into design and validation databases. These databases allowed independent design and validation of the SMART Analysis system used in the Philips AEDs.

Each segment was reviewed by a group of three cardiologists to determine whether that segment should be considered shockable or non-shockable. If after review there was a disagreement on a particular segment, the majority opinion was used in calculating algorithm performance, and the disagreement was noted. By far, the most disagreements resulted from ventricular tachycardia (VT) segments and were related to whether it was appropriate for an AED to shock this type of VT.

Figure 12 shows the diagram of evaluated ECGs shock/no-shock decisions against the SMART Analysis parameters. In this diagram, each of the 3,000 segments is plotted according to their stability, conduction, and rate, as in the "Analysis Examples". If the dot is red, the cardiologists considered it a shockable rhythm; if it is green, it was considered a non-shockable rhythm.

Figure 12 shows some red dots that fall below the shock criteria surface. In these instances, the algorithm does not advise a shock, but the cardiologists concluded that a shock should be advised. These rhythms include low frequency or low amplitude VF, and some ventricular tachycardia, especially VT with sharp transitions that may be candidates for synchronized cardioversion.

If the shock criteria were changed so that the surface was shifted to try to catch more of the shockable rhythms below the surface, the algorithm would also advise a shock for a greater number of non-shockable rhythms.
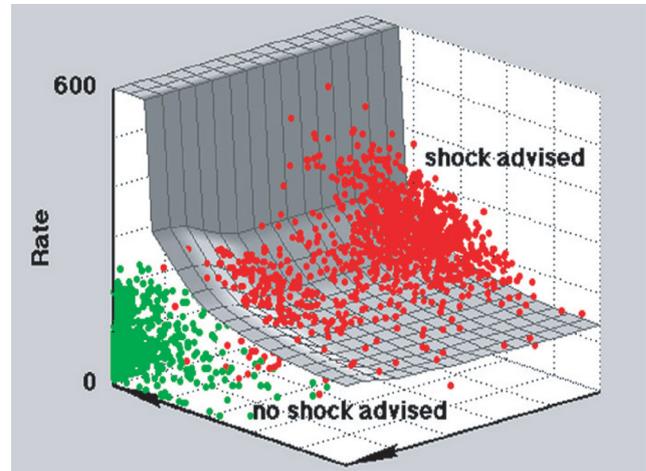

Figure 12: Evaluated ECGs plot.

The SMART Analysis algorithm is designed to make aggressive decisions about shocking VF rhythms and conservative decisions about shocking VT rhythms that may have an associated pulse. Figure 12 shows only red dots above the shock-criteria surface, indicating that a shock will be advised only if it is needed.

The SMART Analysis algorithm is designed to be conservative in this respect in order to increase the specificity of the AED.

While rate is a key factor, it is not the only factor. The more normal the conduction and stability of the QRS complexes, the greater the possibility of perfusion, and the less likely is the SMART Analysis to recommend a shock. For example, if an infant patient with a fast sinus rhythm has a heart rate of 250 bpm with excellent conduction and stability, the SMART Analysis would correctly not advise a shock.

Shockable rhythms

The SMART Analysis algorithm is designed to shock these most common rhythms associated with sudden cardiac arrest:

· Ventricular fibrillation (VF)

· Ventricular flutter

· Polymorphic ventricular tachycardia (VT)

In addition, it is designed to avoid shocking rhythms that are commonly accompanied by a pulse or rhythms that would not benefit from an electrical shock. The AHA states that rhythms accompanied by a pulse should not be shocked because no benefit will follow, and deterioration in rhythm may result.[1]

The shock/no-shock decision made by the AED may be different from a decision a clinician may make. AEDs and AED mode on ALS monitor/defibrillators is designed to be used by lay responders and rescuers trained in Basic Life Support (BLS). Manual defibrillation mode on an ALS monitor/defibrillator is designed to be used by qualified medical personnel trained in Advanced Cardiac Life Support (ACLS). Therefore, an AED is more conservative in shocking intermediate rhythms such as fine VF and VT that do not meet all criteria for inclusion in the shockable VT rhythm category, which includes polymorphic VT and ventricular flutter.

SMART Analysis is designed to be conservative for stable monomorphic tachycardias. The rate threshold for a shockable tachycardia varies from a minimum of about 165 bpm for rhythms with very slow ventricular like conduction to higher-rate thresholds for waveforms with more rapid transitions.

The AHA has issued a Scientific Statement identifying SVT as a non-shockable rhythm, and requiring a minimum defibrillator algorithm specificity of 95% for this rhythm, including SVT with bundle branch block.[2] The AED is designed to issue a no-shock recommendation for rhythms of supraventricular origin regardless of their rate, and has demonstrated 100% specificity when tested against a database containing 100 examples of SVT with rates as high as 255 bpm.

For rhythms that have poorer morphological stability, such as polymorphic VT and VF, the rate threshold varies in a similar manner. As morphological stability degrades, the rate threshold is progressively reduced, approaching a minimum rate threshold of about 135 bpm.

This adaptive design allows the rate threshold to be varied from a minimum level for the most lethal VF rhythms, providing very high sensitivity, to increasingly higher rate thresholds as the stability or conduction characteristics approach normal, providing very high specificity. Borderline rhythms, such as monomorphic tachycardias, are treated conservatively by AEDs, with the expectation that hemodynamically unstable rhythms will soon exhibits shockable characteristics.

Two samples of monomorphic tachycardia are shown in Figure 13 as examples of borderline rhythms that do not require shocks. Both rhythms are of known supraventricular origin. SMART Analysis gives a no-shock decision for these rhythms.
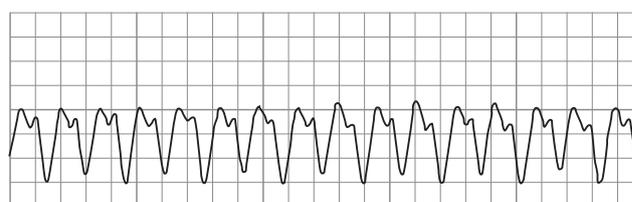
Rate = 192 bpm   **No shock advised**
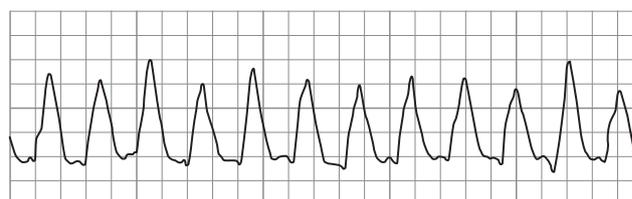
Rate = 144 bpm   **No shock advised**

Figure 13: Monomorphic tachycardia.

AHA guidelines recommend synchronized cardioversion for hemodynamically unstable monomorphic tachycardia, but allow unsynchronized cardioversion if the synchronized cardioversion is not available.[3] If SMART Analysis does not recommend a shock for monomorphic tachycardia, then consider using an ALS monitor/defibrillator in Manual mode with synchronized cardioversion if an ACLS clinician is present. The samples shown in Figure 14 are examples of polymorphic VT and flutter. These rhythms represent ECGs that are considered shockable forms of VT.
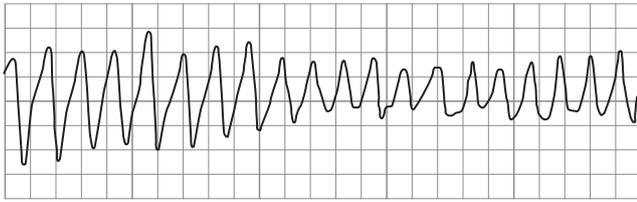
Rate = 240 bpm   **Shock advised**
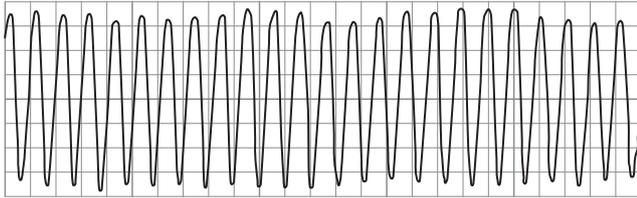
Rate = 288 bpm   **Shock advised**

Figure 14: Polymorphic VT and flutter.

For safety reasons, some very low–amplitude or low–frequency rhythms may not be interpreted as shockable VF rhythms. Also some VT rhythms may not be interpreted as shockable rhythms. As noted earlier in this chapter, what appears to be low–amplitude or low–frequency VF may sometimes be artifact resulting from patient handling, and some VT rhythms have been associated with a pulse.

The Figure 15 example of VF would not be considered a shockable rhythm because of its low frequency. In addition to the possibility of patient handling generating this type of rhythm, there are studies that indicate that a fine VF such as this would benefit from a minute or two of CPR before a shock is attempted. CPR tends to oxygenate the myocardium and increase the electrical activity of the heart, making it more susceptible to defibrillation.

10:19:20   10:19:27
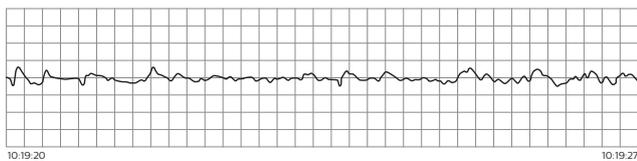
Fine VF   **No shock advised**

Figure 15: Low–frequency VF.

SMART Analysis algorithm validation

Algorithm performance is evaluated by its sensitivity and specificity. The SMART Analysis algorithm provides an exceptional level of sensitivity and specificity, and its validation results exceed AHA recommendations and international standards for adult defibrillation.

The studies cited above and Table 1 performance data are the result of testing the extremely challenging rhythm collection from the Philips Healthcare ECG rhythm databases that deliberately test the limits of Philips AEDs.[1,4,5]

Table 1: AHA recommendations and SMART Analysis test results.

Rhythm class shockable	AHA performance goal (min sample size)	Sensitivity
VF	Sensitivity > 90% (n=200 minimum)	99% (n=300)
VT	Sensitivity > 75% (n=50 minimum)	78% (n=100)

Rhythm class non-shockable	AHA performance goal (min sample size 300 total)	Specificity
Normal sinus rhythm	Specificity > 99% (n=100 minimum)	100% (n=300)
Asystole	Specificity > 95% (n=100 minimum)	100% (n=100)
All other non-shockable rhythms	Specificity > 95% includes AF, SB, SVT, heart block, idioventricular, PVCs (n=35 minimum)	100% (n=450)

AHA rhythm class intermediate	Specificity	Sensitivity	Strips analyzed
Fine VF (low rate/amplitude	100% (3/3)	54% (52/97)	100
Other VT	97% 58/60	24% (13/55)	115

Rhythm class	IEC 60601-2-4 requirements	Test result
Shockable course VF	Sensitivity > 90%	99%
Shockable VT	Sensitivity > 75%	78%
Non-shockable	Overall specificity > 95%	100%
Positive predictive value	Report only	100%
False positive rate	Report only	0%

Table 2: IEC 60601–2–4 requirements and AHA pediatric SMART Analysis test results.

Rhythm class shockable	AHA performance goal	Sensitivity
VF	Sensitivity > 90%	96% (n=73)

Rhythm class non-shockable	AHA performance goal	Specificity
Sinus rhythm	Specificity > 99%	100% (n=173)
Asystole	Specificity > 95%	100% (n=39)
All other non-shockable rhythms	Specificity > 95% includes AF, SB, SVT, heart block, idioventricular, PVCs	100% (n=251)

AHA rhythm class intermediate	Specificity	Sensitivity	Strips analyzed
Fine VF (low rate/amplitude	N/A	75% (3/4)	4
VT (polymorphic/flutter)	N/A	69% (40/58)	58
Other VT	96% (87/91)	29% (2/7)	98

Rhythm class	IEC 60601-2-4 requirements	Test result
Shockable course VF	Sensitivity > 90%	96%
Non-shockable	Overall specificity > 95%	100%
Positive predictive value	Report only	100%
False positive rate	Report only	0%

Note:
* Requirements for shockable VT are polymorphic VT and Ventricular Flutter
* Additional details are available upon request. A non-disclosure may be required.
* The studies and data cited above are the result of extremely challenging rhythms that deliberately test the limits of AEDs. In clinical situations, the actual sensitivity and specificity for the HeartStart AEDs have been equal or better, thereby confirming Philips rigorous premarket testing of its algorithm.
* American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Efficacy. Automatic External Defibrillators for Public Access Use: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporation of New Waveforms, and Enhancing Safety. Circulation 1997;95:1677–1682.
* From Philips ECG rhythm databases. The sample sizes in each category are mutually exclusive, that is, no sample overlap between categories. Total sample size is 1250.

* Although the AHA recommendations did not include performance goals for pediatric patients, the Performance Goals above are adapted from these recommendations.
* For pediatric patients, sinus rhythm is not limited to heart rate <100 beats/minute because of the higher heart rates associated with pediatric patients.
* VT is considered an Intermediate rhythm for pediatric patients because of the higher uncertainty of association of wide QRS supraventricular tachycardias with pediatric cardiac arrest.

In the original out-of-hospital study involving 100 patients,[6] the SMART Analysis system correctly identified all patients in VF (100% sensitivity, no false negatives) and correctly identified and did not shock all patients in non-VF rhythms (100% specificity, no false positives). For example, in preparation for introducing the pediatric defibrillation electrodes, a database was assembled that included 696 pediatric arrhythmias.

Sensitivity and specificity definitions

The following four parameters are used to assess the algorithm's performance:

A true positive (A) is a shockable rhythm associated with cardiac arrest that is classified as a shockable rhythm/condition.

A false positive (B) is an organized or perfusing non-shockable rhythm that has been incorrectly classified as a shockable rhythm/condition.

A false negative (C) is a shockable rhythm associated with cardiac arrest that has been incorrectly classified as a non-shockable rhythm/condition.

A true negative (D) is any non-shockable rhythm that is classified as a non-shockable rhythm/condition.

The sensitivity of the device is the number of true positive shockable rhythms, expressed as a percentage of the total number of shockable rhythms:

$$\text{sensitivity} = \frac{A}{A + C} \times 100\%$$

The specificity is the number of organized or perfusing rhythms that have been correctly classified as non-shockable rhythms/conditions by the algorithm, and is expressed as a percentage of the total number of non-shockable rhythms/conditions:

$$\text{specificity} = \frac{D}{B + D} \times 100\%$$

Example
Course VF sensitivity = (296/300) x 100% = 98.7%
Asystole sensitivity = (100/100) x 100% = 100%

Specific concerns for advanced users of AEDs

Simulator issues with SMART Analysis

ECG simulators are designed to train people to recognize different heart rhythms based on a visual analysis of the data and cannot be used to verify defibrillator analysis algorithms. Simulators contain simulated waveforms and typically have only one example of each type of rhythm. In addition, some devices only store a few seconds of ECG signal that is repeated over and over again. This apparent stability can cause the AED to not advise a shock even though the simulator-generated rhythm may appear shockable to the user.

The conduction and stability characteristics of a simulated VT waveform frequently appear to be high and repeatable. Also, the shape of the simulator's QRS complexes may be fairly sharp, indicating possible perfusion and causing the SMART Analysis algorithm to determine that the rhythm is not shockable. A monomorphic VT must have a relatively high rate and poor conduction to be considered shockable by the SMART Analysis. Polymorphic VTs are considered shockable at lower rates because there is variation in the shape of the QRS complexes.

Most simulated VF signals are interpreted as shockable by the SMART Analysis algorithm. However, most VT rhythms found in simulators are monomorphic VT and are not considered shockable because the shape and regularity of the waveform indicate that there may be a pulse associated with it.

AED features

Therapy delivery speed: Maximum time from initiation of rhythm analysis to readiness for discharge of AED with a fully charged battery is no more than 20 seconds (up to a maximum of 17 s for analysis and up to 3 s for charge).

Configurable resuscitation protocols: You have the flexibility to configure your AED to match your institution's resuscitation protocols.

- Customize the device for the number of shocks (1–4) in a series.

- Select the energy setting within a given shock series. Default: 150 J for adult; 50 J for infant/child (non-configurable).

- Set the CPR pause interval 1–3 minutes.

References

1. American Heart Association (AHA) AED Task Force, Subcommittee on AED Safety & Efficacy. Automatic External Defibrillators for Public Access Use: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporation of New Waveforms, and Enhancing Safety. *Circulation*, 1997; 95:1677–1682.

2. Ibid.

3. Link, M. S., Atkins, D. L., Passman, R. S., Halperin, H. R., Samson, R. A., White, R. D., . . . Kerber, R. E. (2010). Part 6: Electrical therapies: Automated external defibrillators, defibrillation, cardioversion, and pacing • 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*, 122(18_suppl_3), S706–S719.

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6. Poole, JE, et al. Low–energy impedance compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out–of–hospital cardiac arrest, *Journal of Cardiovascular Electrophysiology*, December 1997

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