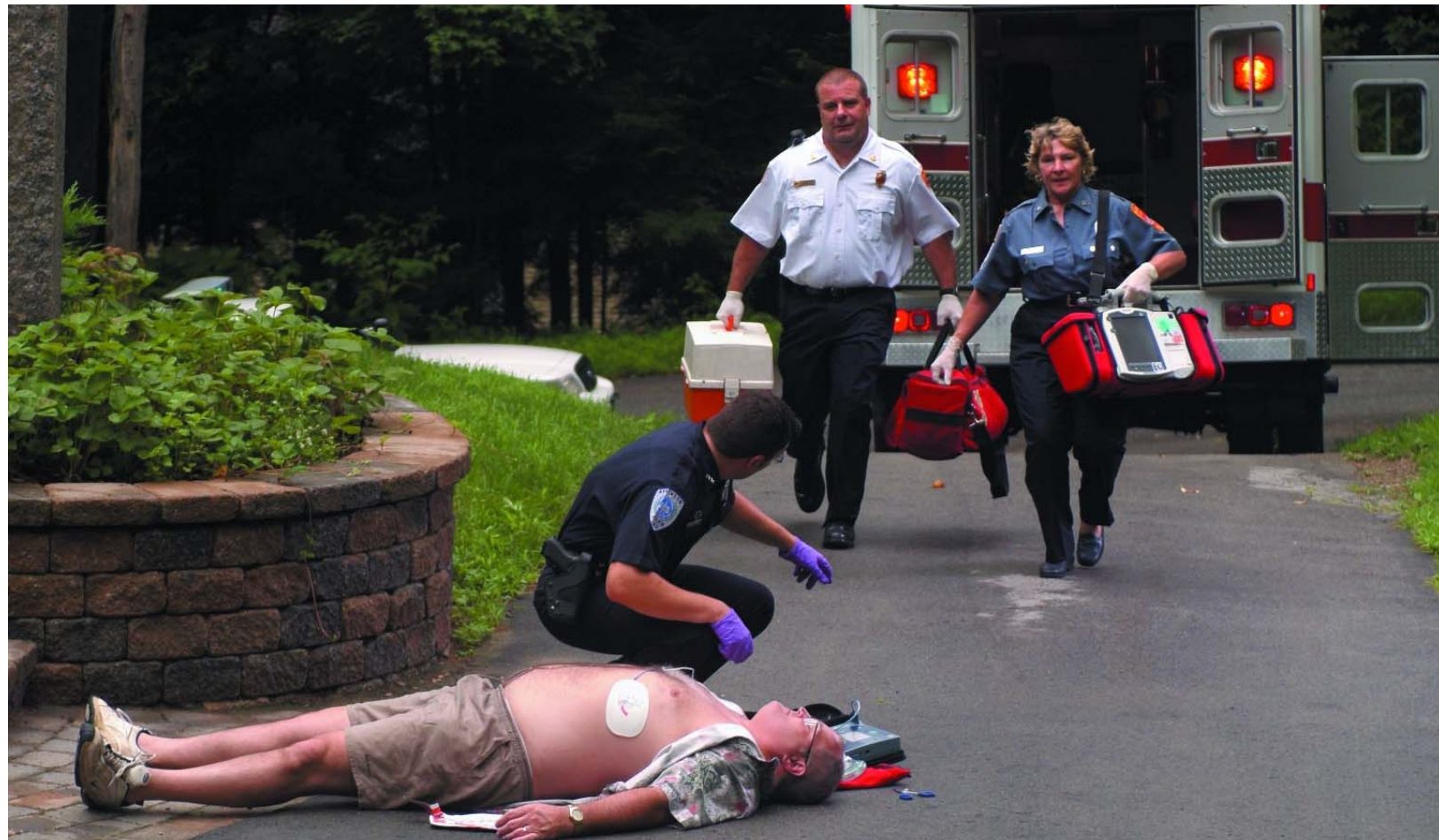


AED Algorithm

Application Note



Introduction

Philips Medical Systems' ALS Defibrillator/Monitors offer automatic external defibrillation (AED) mode. AED mode can be used to analyze a patient's ECG and determine if a shock is advised. Analysis is performed by internal microprocessors that use an algorithm to interpret the heart's electrical signals. Life-threatening arrhythmias are quickly and accurately detected, and the correct therapy is recommended.

This application note explains how the computerized AED algorithm successfully filters artifact and accurately identifies features of morphology associated with shockable rhythms. It also describes which rhythms are considered shockable and discusses the algorithm's effectiveness.

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What is an Algorithm?

An algorithm is a sophisticated, mathematical process of interpreting information. In AED mode, the defibrillator/monitor uses an algorithm to interpret electrical signals received from the patient’s heart, via multifunction defib 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 assess the cardiac state 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.

AED Algorithm Components

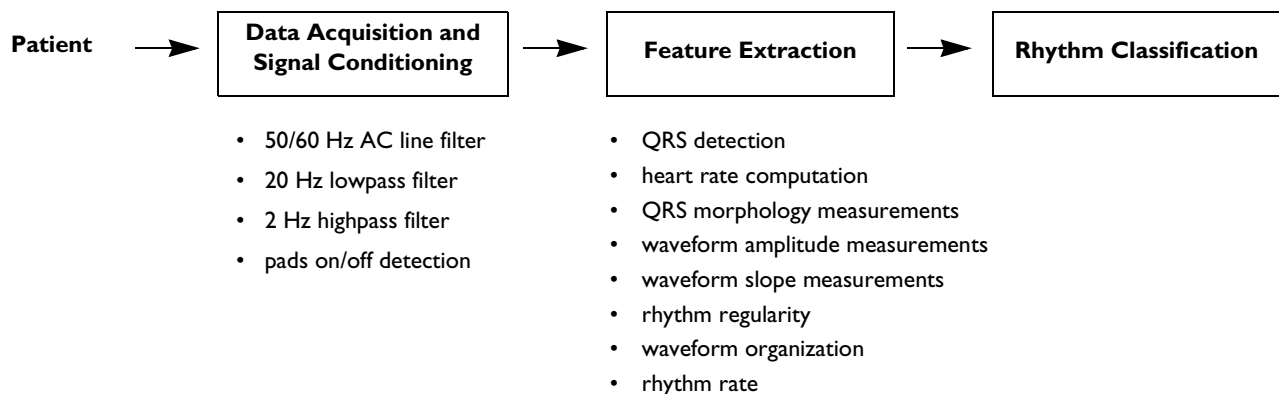
The AED algorithm is comprised of three components, as shown in Figure 1:

- ▶ Data acquisition and signal conditioning
- ▶ Feature extraction
- ▶ Rhythm classification

These components work together to produce an algorithm that is highly sensitive to shockable rhythms and highly specific to nonshockable rhythms.

The data acquisition and signal conditioning component acquires the ECG signal and removes unwanted artifact. This “clean” ECG signal is then passed on to the feature extraction component. The feature extraction component yields measurements of the various rhythm characteristics that are used to differentiate between shockable and non-shockable rhythms. Finally, the rhythm classification component of the algorithm uses these measurements to produce a shock/no-shock decision.

Figure 1 AED Algorithm Components



Data Acquisition and Signal Conditioning

The patient's ECG is acquired through the multifunction defib electrode pads that are attached to the patient's chest (anterior-anterior placement). The signal is digitized and processed to remove or reduce the effects of certain types of electrical interference, often referred to as artifact or noise. In addition, impedance between pads is monitored to detect conditions that could compromise the algorithm's results. The goal of this signal conditioning is to provide the feature extraction component with a signal that is a clean representation of the patient's ECG—a signal that is free of artifact.

What is Artifact?

Artifact is an electrical signal present in the ECG that is unrelated to the heart's signal. If artifact is not removed or sufficiently reduced, it can cause an incorrect analysis of the patient's heart rhythm, leading to an inappropriate shock/no-shock decision.

Sources of artifact can be characterized as either controllable or uncontrollable by the clinician. Directly touching the electrode pads, moving the patient, and transport are examples of artifact that can be controlled. Conversely, electrical interference, muscle tremor, and patient movement are sources of artifact that are generally not within the control of the clinician.

The AED algorithm detects artifact and handles it in several ways. If the artifact corrupts the ECG to the point that analysis is compromised, the clinician is directed to the source of the problem and prompted with the appropriate corrective action. Otherwise, the ECG signal is passed through a number of filters that remove or attenuate artifact.

Filters

Several filters help to remove common types of interference caused by sources such as AC power, and muscle tremor. AC power line interference may contaminate the ECG with a 50 or 60 Hz signal.

This interference is attenuated by a narrow stopband filter called a notch filter, which is tuned to remove the 50 or 60 Hz signals and higher harmonics. A 2 Hz high-pass filter is used to reduce low-frequency baseline wander that can be caused by pad offset drift or patient movements.

Muscle tremor may contaminate the ECG with high-frequency baseline noise. A low-pass filter can remove much of the noise. Unfortunately, the frequency spectrum overlaps the ECG frequency, so it is not possible to remove all of it without destroying ECG data. The AED algorithm applies a 20 Hz low-pass filter to minimize artifact from muscle tremor.

Impedance Monitoring

By monitoring the impedance between the electrodes, the AED algorithm can detect conditions that could compromise the algorithm's results. For example, a pad that is not making good contact with the patient interferes with ECG data acquisition. The impedance data in this case suddenly changes to very high values and back again. Similarly, when a pad comes off completely, the impedance data suddenly changes. The AED algorithm monitors the impedance data for this type of change and alerts the responder to reattach pads, if necessary.

Feature Extraction

Shockable rhythms have certain characteristics that can be used to distinguish them from non-shockable rhythms. The feature extraction component of the AED algorithm measures these key characteristics and provides the measurements to the rhythm classification component of the algorithm. Some rhythm types may have a single measurement that is good at distinguishing that rhythm from all others. Other rhythms require a number of measurements to finally distinguish the rhythm.

The features that are measured can be grouped into two categories: beat features and rhythm features.

Beat features are associated with the detection of a QRS complex. QRS morphology features are used to characterize the relative organization of the waveform. A rhythm is deemed organized if there are recurring QRS complexes of a similar morphology. The rate of QRS detection, heart rate, is a feature primarily used to decide when wide complex tachycardia is shockable.

Rhythm features measure properties of the waveform unrelated to the QRS beats. These features are particularly useful for rhythm types that do not contain true QRS complexes, such as asystole and ventricular

fibrillation. Rhythm features include average waveform amplitude, measures of isoelectric baseline content, waveform rate, and waveform rhythm regularity.

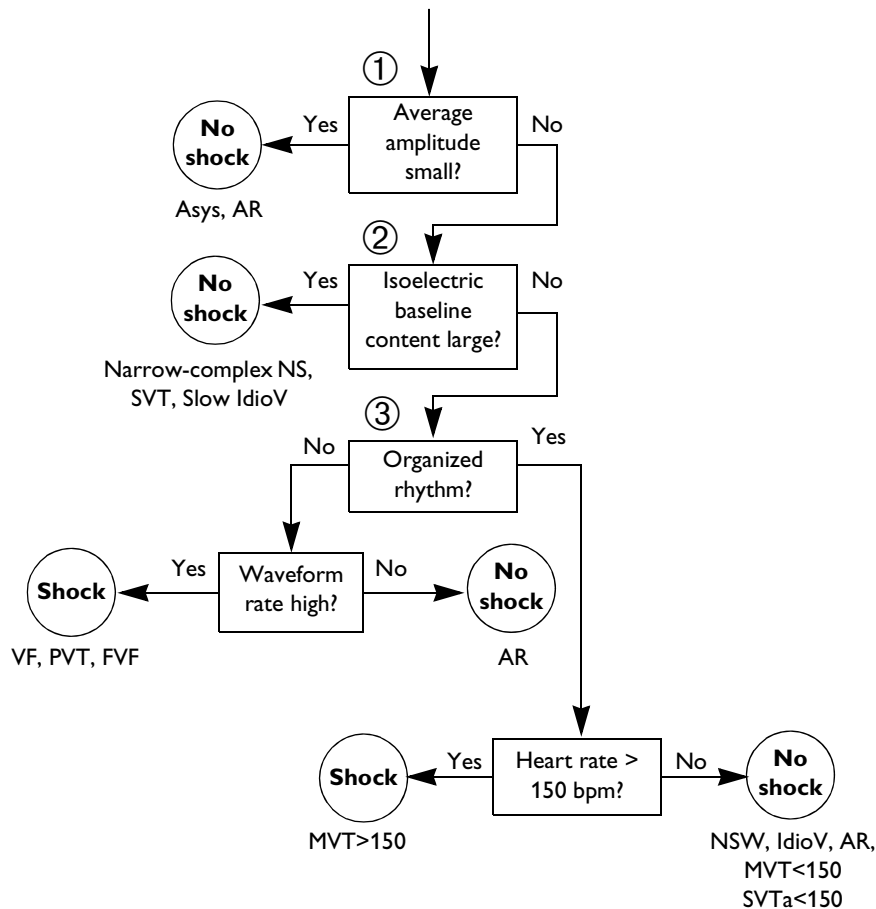
All of these features are combined in the rhythm classifier to yield the final shock/no-shock decision.

Rhythm Classification

The rhythm classification component of the algorithm combines the many measurements acquired during feature extraction into a single binary decision: shock or no-shock. To do this successfully, the algorithm must distinguish between a wide variety of ECG rhythms. Figure 2 shows the criteria used to make this decision. Refer to Table 1 for rhythm classification labels.

First, the average waveform amplitude is used to identify very small rhythms, such as asystole and agonal rhythms, as nonshockable. Then, isoelectric baseline content is used to identify narrow QRS-complex or slow rhythms as non-shockable. Finally, QRS morphology features are used to identify rhythms which are organized or disorganized. For the disorganized rhythms such as ventricular fibrillation and agonal rhythm, measures of waveform rate and regularity help distinguish slow, wide-complex nonshockable rhythms from fast, wide-complex shockable rhythms. Organized rhythms such as monomorphic ventricular tachycardia and other wide-QRS tachycardias of unknown origin are then deemed shockable if their QRS rate is greater than 150 beats per minute.

Figure 2 Rhythm Classification



Rhythm Classifications

Table 1 summarizes the key criteria used by the AED algorithm to classify a rhythm as shockable or non-shockable.

Table 1 Rhythm Classifications

Label ^a	Rhythm	Criteria	Shock Classification
VF	Ventricular Fibrillation	amplitude > 0.2 mV	Shockable
FVF	Fine Ventricular Fibrillation	0.1 mV < amplitude < 0.2 mV	Shockable
MVT, PVT	Ventricular Tachycardia (Monomorphic or Polymorphic)	QRS > 120 ms, ventricular or unknown origin: <ul style="list-style-type: none"> • rate > 150 bpm • rate < 150 bpm ^b 	<ul style="list-style-type: none"> • Shockable • Not Shockable
SVTa	Supraventricular Tachycardia with Aberrant Conduction	QRS > 120 ms, supraventricular origin	Not Shockable
IdioV	Idioventricular Rhythm	QRS > 120 ms, ventricular origin, rate < 100 bpm	Not Shockable
NSW	Other Non-shockable Rhythms with Wide QRS	QRS > 120 ms, unknown or supraventricular origin, rate < 100 bpm	Not Shockable
Asys	Asystole	amplitude < 0.1 mV	Not Shockable
AR	Agonal Rhythm	rate < 20 bpm	Not Shockable
SVT	Supraventricular Tachycardia with Narrow QRS	QRS < 120 ms, rate > 100 bpm, supraventricular origin	Not Shockable
AFF	Atrial Fibrillation or Flutter	atrial fib, or flutter waves, irregular rhythm	Not Shockable
VER	Ventricular Ectopic Rhythm	frequent ventricular ectopics	Not Shockable
BLK	Blocked Rhythm	AV or bundle branch block rhythms	Not Shockable
NS	Other Non-shockable Rhythms with Narrow QRS	QRS < 120 ms, unknown or supraventricular origin, rate < 100 bpm	Not Shockable
Paced	Paced Rhythm		Not Shockable

a. The rhythm labels shown are for algorithm classification purposes only.

b. Polymorphic Ventricular Tachycardia may be treated as VF and shocked.

Ventricular Fibrillation

Ventricular fibrillation (VF) is the most common cardiac arrest rhythm that can be terminated by a defibrillation shock. When VF is present, the heart cannot pump blood to the rest of the body. A patient with VF has no pulse, and the ECG is rapid and irregular with no QRS complexes.

Coarse VF has an amplitude greater than 0.2 mV. Fine VF has an amplitude between 0.1 mV and 0.2 mV. Below 0.1 mV, the algorithm recognizes the rhythm as asystole.

Shock is advised for VF. Fine VF and asystole can sometimes be difficult to differentiate. Asystole is not a shockable rhythm (see the “Asystole” section).

Figure 3 Coarse Ventricular Fibrillation

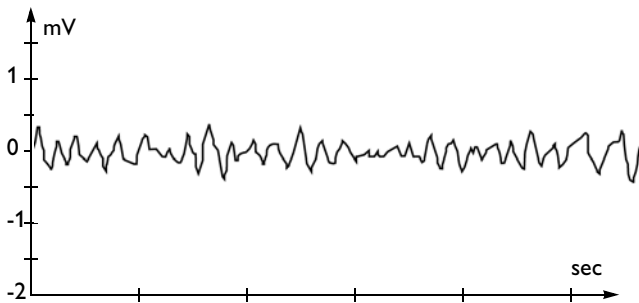
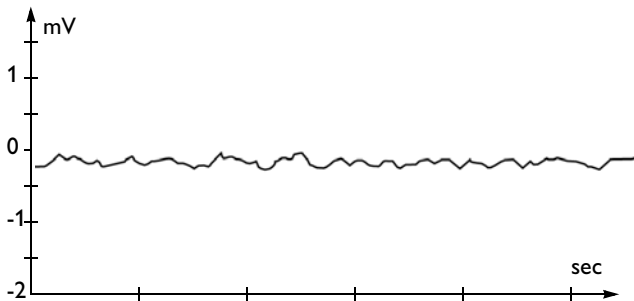


Figure 4 Fine Ventricular Fibrillation



Shock classification: Ventricular fibrillation is a shockable rhythm.

Ventricular Tachycardia

Ventricular tachycardia (VT) consists of three or more ventricular beats at a rate of more than 100 beats per minute (bpm). The QRS complexes are wide—greater than 120 ms—and may be of a single morphology (monomorphic VT) or of several morphologies (polymorphic VT).

Ventricular tachycardia with a rate greater than 150 bpm and sustained for six seconds is shockable. Some very irregular forms of polymorphic VT are treated like VF and are shockable regardless of rate. Assuming that the victim has no pulse (which is a condition for using the AED algorithm), VT may be treated with unsynchronized shocks.

Wide QRS tachycardia of unknown origin with a rate greater than 150 bpm and sustained for six seconds is also shockable. Clinicians sometimes find it difficult to distinguish VT from other wide-QRS tachycardias of unknown origin, and the same treatment is advised for both.

Figure 5 Monomorphic Ventricular Tachycardia

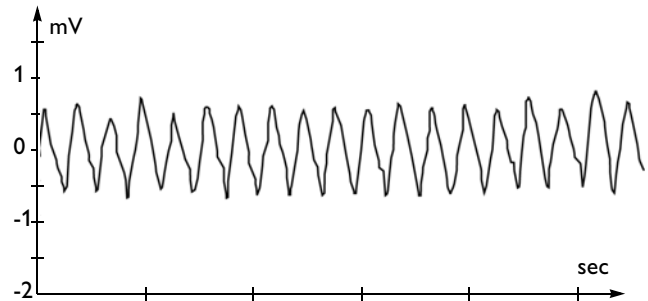
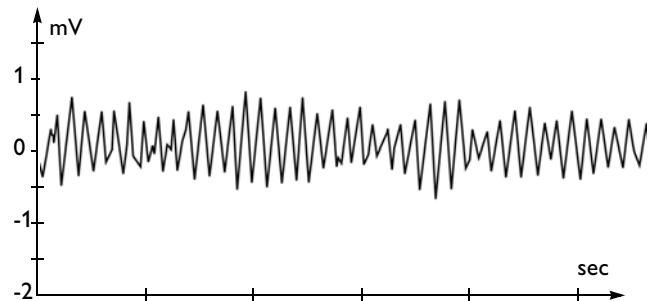


Figure 6 Polymorphic Ventricular Tachycardia



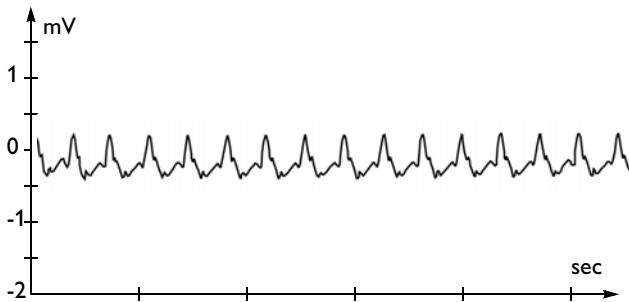
Shock classification: Ventricular tachycardia and wide-QRS tachycardia of unknown origin with a rate greater than 150 bpm is shockable. VT with a rate less than 150 bpm is not shockable.

Supraventricular Tachycardia with Aberrant Conduction

A rhythm originating above the ventricles with aberrant conduction and at a rate greater than 100 bpm is known as supraventricular tachycardia with aberrancy (SVTa).

Wide QRS complexes result from abnormal conduction paths within the ventricles.

Figure 7 Supraventricular Tachycardia with Aberrant Conduction



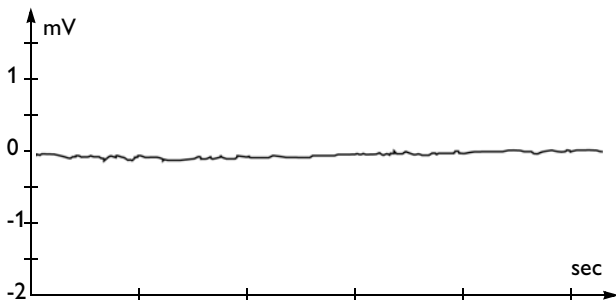
Shock classification: SVTa is not shockable.

Asystole

Ventricular asystole is the absence of ventricular depolarization and contraction. Interpreters of the ECG may have some difficulty distinguishing between asystole and fine VF. The algorithm defines asystole as a rhythm with an average amplitude less than 0.100 mV.

A person with asystole has no pulse and should not be shocked because shocks can inhibit any natural pacemakers.

Figure 8 Asystole

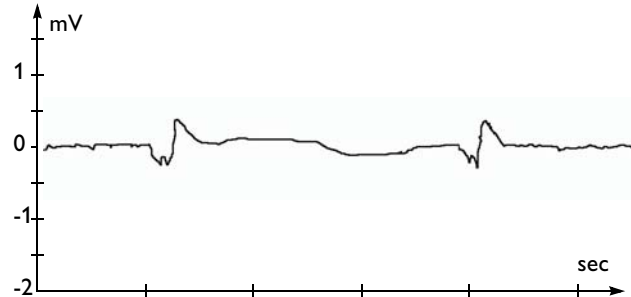


Shock classification: Asystole is not shockable.

Wide-Complex Idioventricular Rhythms

Wide ventricular beats, greater than 120 ms, at a rate of less than 100 bpm, often occur as a post-defibrillation-shock escape rhythm. This is not a shockable rhythm.

Figure 9 Idioventricular Rhythms



Shock classification: Wide-complex idioventricular rhythms are not shockable.

Other Non-Shockable Rhythms

Many rhythms exist for which a shock is not indicated. Some of these rhythms are not associated with cardiac arrest or will respond adversely. Such rhythms include:

- ▶ supraventricular tachycardia with narrow QRS morphology
- ▶ atrial fibrillation and flutter
- ▶ sinus rhythms
- ▶ rhythms with frequent PVCs
- ▶ blocked rhythms
- ▶ junctional rhythms
- ▶ paced rhythms

Transitional Rhythms

If the ECG changes from a non-shockable rhythm to a shockable rhythm, the algorithm's response may vary, depending upon how quickly the change occurred, how much of the shockable rhythm is included in the analyzed data, and the nature of the rhythms.

Clinical Performance

The algorithm was developed and validated using two large databases of ECG rhythms made up of data from 564 patients. The data was from two sources. One was created from tapes of primarily pre-hospital usages of AEDs. The other was collected using a CodeMaster XL+ defibrillator monitor with special software installed to record and save patient ECG data. This data was collected in a variety of clinical settings, both in and out of hospital. ECG rhythms were annotated by clinical experts according to the classifications shown in Table 1 “Rhythm Classifications” on page 5. All of the data was split in half into a training and a testing database.

The training data was used to develop the algorithm. The testing data was used to validate the algorithm’s performance, and was not used for development. There were 2337 total ECG strips in the testing database. The results on the testing data are shown in Tables 2 and 3.

Table 2 Shockable Rhythm Data

Rhythm Category	Sensitivity	Analyzed Strips #
Ventricular Fibrillation amplitude > 0.2 mV	97%	313
Fine Ventricular Fibrillation 0.1 mV < ampl. < 0.2 mV	76%	96
Ventricular Tachycardia rate ≥ 150 bpm	84%	43
Total		452

The overall sensitivity is 91%.

Table 3 Non-Shockable Rhythm Data

Rhythm Category	Specificity	Analyzed Strips #
Asystole /Agonal	96%	395
Ventricular Tachycardia 100 bpm < rate < 150 bpm	88%	206
Idioventricular	95%	438
All Other Non-Shockable Rhythms	100%	846
Total		1885

The overall specificity is 96%.

Performance Parameters

The following four parameters were 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 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.

Calculating Sensitivity and Specificity

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:

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

AED Algorithm Safety

The AED mode includes the following measures to ensure operator and patient safety:

- ▶ development in accordance with ANSI/AAMI Standard DF39-1/93
- ▶ does not shock automatically
- ▶ provides user with 1-2-3 step defibrillation
- ▶ easy-to-read messages and error tones alert the user to possible problems

- ▶ recorder strips are provided for medical records

It is important to note that the algorithm is not designed to handle erratic spiking problems caused by a pacemaker, or to detect pediatric cardiac arrhythmias.

NOTE: Prior to using the Philips Healthcare ALS defibrillator/monitor, review the indications for use defined in the Instructions for Use.



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