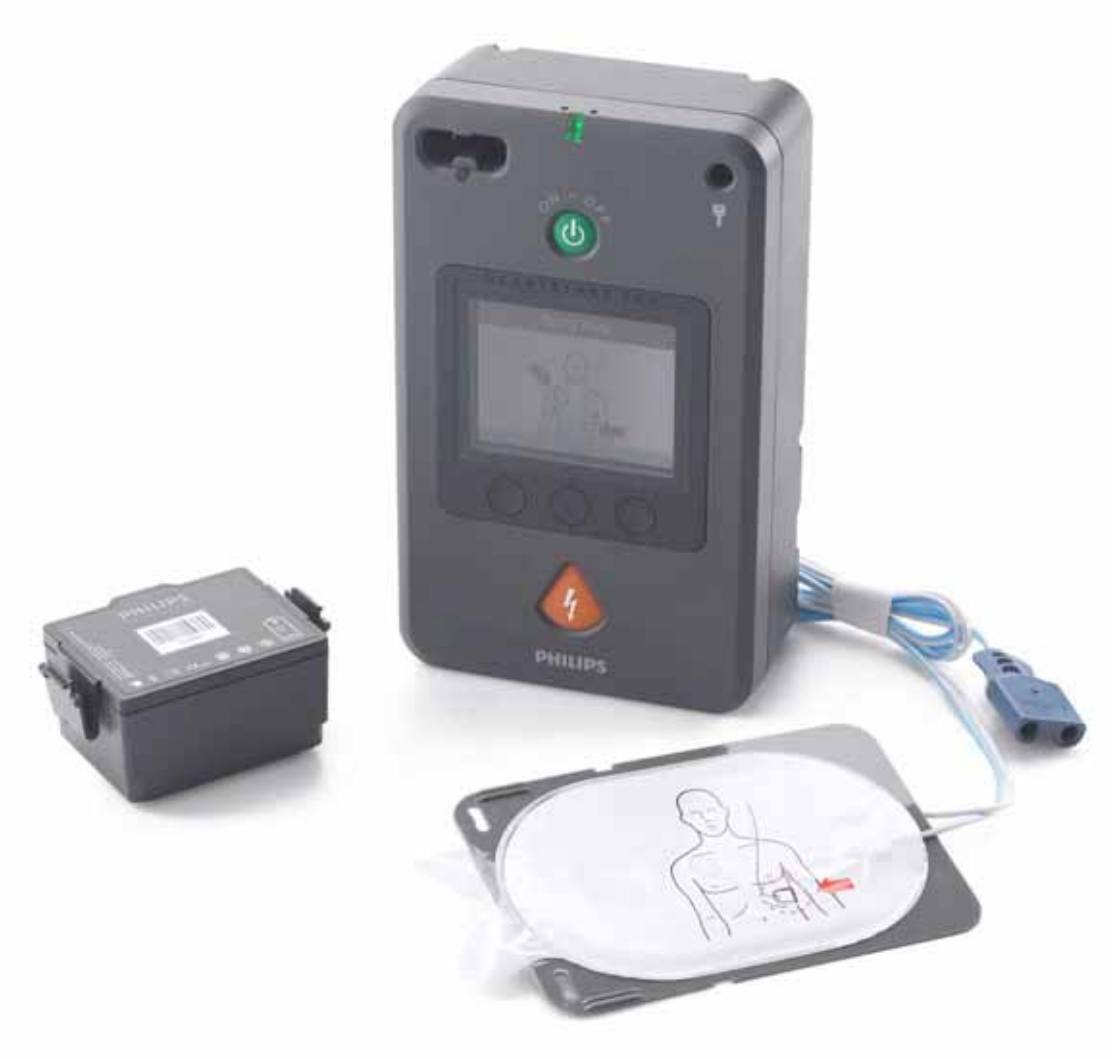
HeartStart FR3 Defibrillator

TECHNICAL REFERENCE MANUAL



PHILIPS

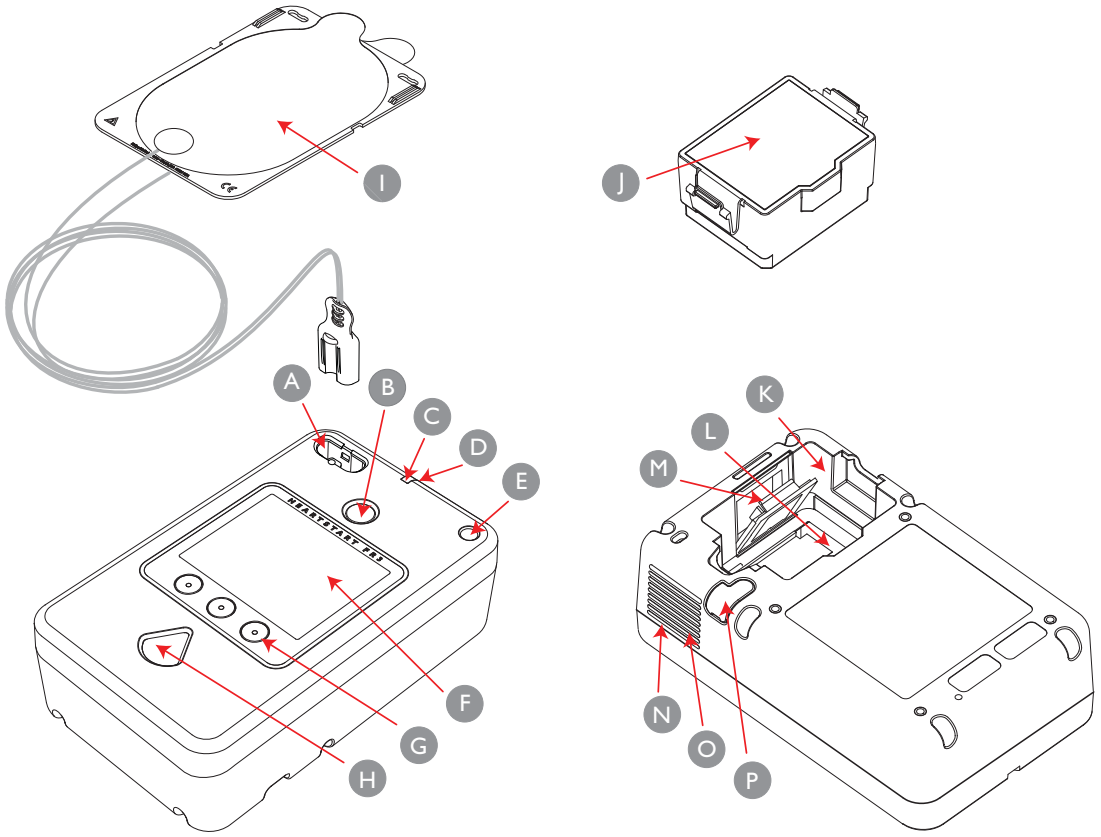


Diagram of the HeartStart FR3 Defibrillator

A **Defibrillator pads connector socket.** Receptacle for the defibrillator pads cable connector. A light on the socket flashes when the FR3 is turned on to show socket location.

B **Green On/Off button.** Turns on the FR3 and starts voice and text prompts. A second press brings up the status screen, and then turns off the FR3.

C **Green Ready light.** Shows the readiness status of the FR3.

D **Microphone.** Used optionally to record audio during an incident.

E **Infant/Child Key port.** Accommodates the optional FR3 Infant/Child Key accessory to enable pediatric treatment protocols for patients under 55 lbs (25 kg) or 8 years old.

F **Screen.** Displays text prompts, graphics, and incident data. The FR3 ECG model also displays the patient's ECG if enabled.

G **Option buttons (three).** When pressed, activates the function identified on the screen.

H **Orange Shock button.** Controls shock delivery. The button flashes when the FR3 is ready to deliver a shock.

I **SMART Pads III.** Self-adhesive pads supplied with attached cable and connector. If using the optional FR3 system case and/or the Pads Sentry, store pads in Pads Sentry and pre-connect pads to FR3 for automatic self-test.

J **Battery.** Long-life battery used to power the FR3.

K **Battery compartment.** Provides electrical connection for the installed battery and contains the data card slot and *Bluetooth*® wireless technology transceiver module compartment.

L **Data card slot.** Receptacle for the optional data card accessory. Located beneath the battery in the battery compartment.

M ***Bluetooth* wireless technology transceiver module compartment.** Accommodates the optional transceiver module accessory. Located behind a removable door in battery compartment.

N **Speaker.** Broadcasts FR3 voice prompts and alert tones when appropriate.

O **Beeper.** Broadcasts FR3 alert chirps when appropriate.

P **Accessory port.** Connection port for future use..

CONTENTS

6 THEORY OF OPERATION

7 HEARTSTART DATA MANAGEMENT SFTWARE

APPENDICES

A Technical Specifications

B Troubleshooting Information

C Pads, Batteries, and Display

D Use Environment

E Literature Summary for HeartStart AEDs

1 THE HEARTSTART FR3 DEFIBRILLATOR

SUDDEN CARDIAC ARREST AND THE AED

Each year in North America alone, approximately 350,000 people suffer sudden cardiac arrest (SCA).[1] Fewer than 5% of them survive. SCA is most often caused by an irregular heart rhythm called ventricular fibrillation (VF), for which the only effective treatment is defibrillation, an electrical shock. Often, a victim of SCA does not survive because of the time it takes to deliver the defibrillation shock. For every minute that passes between collapse and defibrillation, survival rates from witnessed VF SCA decrease 7% to 10% if no CPR is provided.[2] When bystander CPR is provided, the decrease in survival rates averages 3% to 4% per minute from collapse to defibrillation, so treating someone as quickly as possible is vital to survival.

DESIGN FEATURES OF THE FR3 DEFIBRILLATOR

The Philips HeartStart FR3 automated external defibrillator (AED) is available in two models, one with an ECG and text display screen (model 861389) and one with a text display screen only (model 861388). The FR3 can be configured to permit manual control of the analyze and, for the FR3 ECG model 861389 only, shock charge functions. This can be beneficial for transitioning the patient care from a first responder to more highly trained medical personnel.

RELIABILITY AND SAFETY

- FAIL-SAFE DESIGN — The FR3 AED is intended to detect a shockable rhythm and instruct the user to deliver a shock if needed. It will not allow a shock if the rhythm is not shockable.
- RUGGED MECHANICAL DESIGN — The FR3 AED is built with high-impact plastics, has few openings, and incorporates a rugged defibrillation pads connector and battery interface. Using the optional FR3 rigid carry case [REF: 989803149971] provides additional protection as well as storage for extra sets of pads, a spare battery, and the FR3 Fast Response Kit [REF: 989803150111].
- DAILY AUTOMATIC SELF-TEST — The FR3 AED performs daily, weekly, and monthly self-tests to help ensure it is ready to use when needed. An active status indicator (Ready light) shows at a glance that the unit has passed its last self-test and is therefore ready to use.
- ENVIRONMENTAL PARAMETERS — Extensive environmental tests were conducted to prove the ability of the FR3 to operate in expected conditions of use.

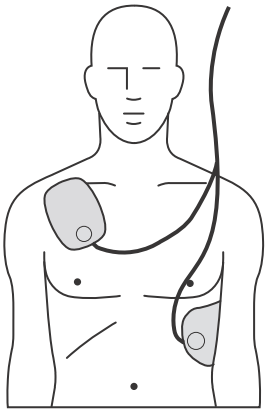
1. American Heart Association. 2010 Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science. *Circulation* 2010;122[suppl 3].
2. *Ibid*.

- LONG-LIFE LITHIUM BATTERY — The FR3 standard long-life battery [REF: 989803150161] was designed for use in an emergency environment. It is small, lightweight, and safe to use. It uses lithium manganese dioxide (Li/MnO_2) technology and does not contain pressurized sulfur dioxide, which has been know to "vent" violently on occasion. The battery pack meets the U.S. Environmental Protection Agency's Toxicity Characteristic Leaching Procedure. All battery cells contain chemicals and should be recycled at an appropriate recycling facility in accordance with local regulations.
- QUICK SHOCK — Minimizing the time from the end of CPR chest compressions to shock delivery can potentially improve the return of circulation. The FR3 AED takes less than 8 seconds from the end of the "Stop CPR" prompt to armed state for shock delivery.
- PRE-CONNECTED DEFIBRILLATOR PADS — The FR3 AED is designed for use with HeartStart SMART Pads III [REF: 989803149981], which can be pre-connected to the FR3 when stored in the optional Pads Sentry. When the pads are pre-connected and stored in the Pads Sentry, they are automatically tested for readiness as part of the FR3 periodic self-tests. The FR3 can also be used with HeartStart DP adult defibrillator pads [REF: 989803158211 and REF: 989803158221], which should *not* be pre-connected to the FR3.
- INFANT/CHILD KEY — With the optional FR3 Infant/Child Key [REF: 989803150031] installed, the FR3 automatically reduces the defibrillation therapy to a level more appropriate for infants and children less than 55 lbs (2.5 kg) or 8 years old.

EASE OF USE

- SMALL AND LIGHT — The FR3 AED is the smallest and lightest AED introduced by Philips to date. It can easily be carried and operated by one person.
- SELF-CONTAINED — The optional FR3 rigid system case [REF: 989803149971] accommodates all of the most common elements required for a successful rescue, including the AED with pre-connected SMART Pads III in a Pads Sentry, a set of spare pads, a spare battery, an Infant/Child Key, and an FR3 Fast Response Kit. The optional FR3 small soft case [REF: 989803173711] accommodates the AED with pre-connected SMART Pads III in a Pads Sentry, a set of spare pads, and an Infant/Child Key. The Pads Sentry is also available separately.
- AUTO ON CARRY CASE — The FR3 carry cases are designed to automatically activate the AED when the case is opened. If the FR3 is not stored in an FR3 carry case, the green On/Off button is used to turn on the device.

- VOICE INSTRUCTIONS — The FR3 AED provides audible voice instructions that guide the user through the process of using the device. The voice prompts reinforce the messages that appear on the display screen and allow the user to attend to the patient while receiving detailed instructions for each step of the rescue.
- FLASHING SHOCK BUTTON — The orange Shock button bears a lightning bolt symbol and flashes when the unit has charged for a shock. The FR3 directs the user to press the button to deliver a shock.
- EXTENSIVE CONFIGURABILITY — Under the authority of a Medical Director, the FR3 can be customized to comply with local protocols to enable features such as SMART CPR, CPR Coaching, and use of the Advanced Mode.
- CLEAR LABELING AND GRAPHICS — The FR3 AED is designed to enable fast response by the user. The pads placement icon displayed on the screen when the FR3 is turned on clearly indicates anterior-anterior pads placement on an adult. The pads themselves are labeled to specify where each one should be placed. The polarity of the pads does not affect the operation of the AED, but user testing has shown that people apply the pads more quickly and accurately if a specific position is shown on each pad. If the Infant/Child Key is inserted, the pads placement display shows anterior- posterior pads placement on a child.



- LCD SCREEN — The FR3 AED has a display screen that provides text instructions and illustrations to direct the user through each step of using the AED during an incident. On the ECG model FR3, the screen can also be configured to display the patient's ECG signal to help advanced users rapidly assess the patient's heart rhythm and prioritize initial patient care accordingly.
- PROVEN ANALYSIS SYSTEM — The SMART rhythm analysis system used in the FR3 AED analyzes the patient's ECG rhythm and determines whether or not a shock should be administered. The algorithm's decision criteria allow the AED to advise a shock only when appropriate.
- ARTIFACT DETECTION SYSTEM — An artifact detection system in the FR3 AED senses if the ECG is being corrupted by some form of artifact, including electrical "noise" in the surrounding environment, patient handling, other patient movement, or activity of an implanted pacemaker. If the artifact might inhibit or delay a shock decision, the AED filters out the noise from the ECG, prompts the user to stop patient movement, or

determines that the level of artifact does not pose a problem for the algorithm.

- PADS-ON DETECTION SYSTEM — The FR3 AED's pads-on detection system provides a voice prompt to alert the user if the pads are not making proper contact with the patient's skin.

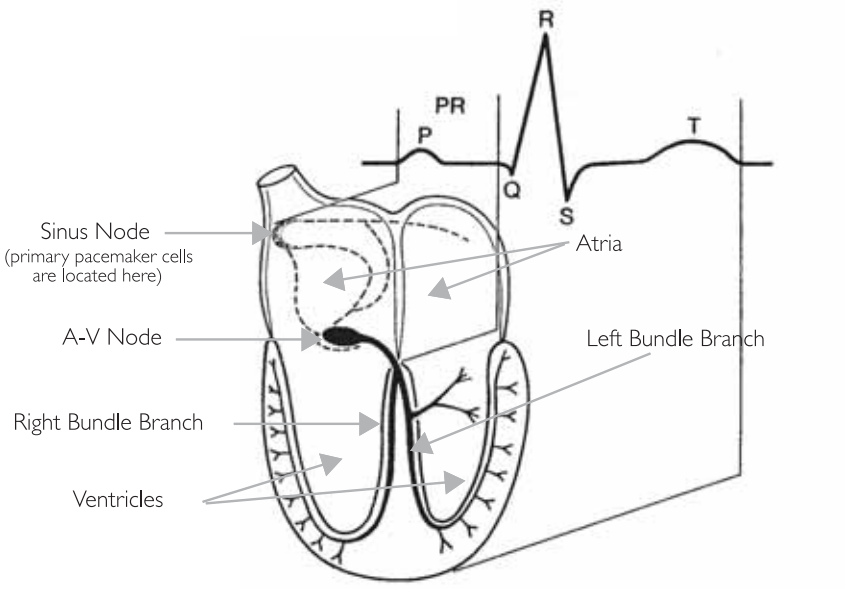
EASE OF OWNERSHIP

- AUTOMATIC DAILY/WEEKLY/MONTHLY SELF-TESTS — There is no need for calibration, energy verification, or manual testing with the FR3 series AEDs. Calibration and energy verification are automatically performed once a month as part of the AED self-test routine.
- ACTIVE STATUS INDICATOR — The status indicator (Ready light) in the upper center of the front panel of the FR3 AED shows whether or not the device has passed its last self-test. As long as the green Ready light is flashing, the AED is ready for use. The Ready light is on solid during use of the device and during self-tests. If the Ready light goes off and the FR3 is chirping, this means that the FR3 has detected a problem during a self-test and needs attention. If the Ready light is off, the FR3 is not chirping, and the display screen is blank, this means the battery is depleted or missing or the FR3 needs repair.
- BATTERY LEVEL INDICATOR — When the battery needs to be replaced, the FR3 AED prompts the user by sounding a periodic chirp and by turning off the Ready light.

2 DEFIBRILLATION AND ELECTRICITY

THE HEART'S ELECTRICAL SYSTEM

The heart muscle, or myocardium, is a mass of muscle cells. Some of these cells ("working" cells) are specialized for contracting, which causes the pumping action of the heart. Other cells ("electrical system" cells) are specialized for conduction. They conduct the electrical impulses throughout the heart and allow it to pump in an organized and productive manner. All of the electrical activity in the heart is initiated in specialized muscle cells called "pacemaker" cells, which spontaneously initiate electrical impulses that are conducted through pathways in the heart made up of electrical system cells. Although autonomic nerves surround the heart and can influence the rate or strength of the heart's contractions, it is the pacemaker cells, and not the autonomic nerves, that initiate the electrical impulses that cause the heart to contract.

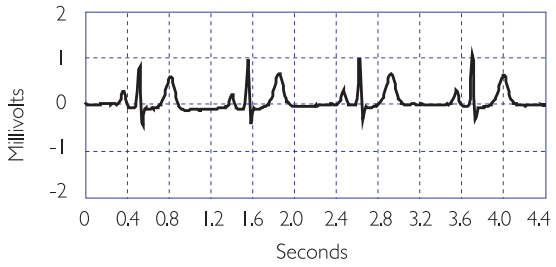


Relation of an ECG to the anatomy of the cardiac conduction system

The heart is made up of four chambers, two smaller, upper chambers called the atria, and two larger, lower chambers called the ventricles. The right atrium collects blood returning from the body and pumps it into the right ventricle. The right ventricle then pumps that blood into the lungs to be oxygenated. The left atrium collects the blood coming back from the lungs and pumps it into the left ventricle. Finally, the left ventricle pumps the oxygenated blood to the body, and the cycle starts over again.

The electrocardiogram (ECG) measures the heart's electrical activity by monitoring the small signals from the heart that are conducted to the surface of the patient's chest. The ECG indicates whether or not the heart is conducting the electrical impulses properly, which results in pumping blood throughout the body. In a healthy heart, the electrical impulse begins at the sinus node, travels down (propagates) to the A-V node, causing the atria to contract, and then travels down the left and right bundle branches before spreading out across the ventricles, causing them to contract in unison.

The "normal sinus rhythm" or NSR (so called because the impulse starts at the sinus node and follows the normal conduction path) shown below is an example of what the ECG for a healthy heart looks like.

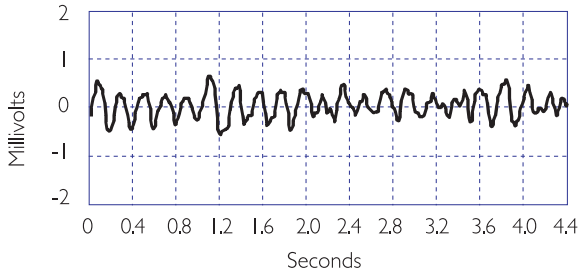


Normal sinus rhythm

Sudden cardiac arrest (SCA) occurs when the heart stops beating in an organized manner and is unable to pump blood throughout the body. A person stricken with SCA will lose consciousness and stop breathing within a matter of seconds. SCA is a disorder of the heart's electrical conduction pathway that prevents the heart from contracting in a manner that will effectively pump the blood.

Although the terms "heart attack" and "sudden cardiac arrest" are sometimes used interchangeably, they are actually two distinct and different conditions. A heart attack, or myocardial infarction (MI), refers to a physical disorder that is restricted in a certain area of the heart. This can be caused by a coronary artery that is obstructed with plaque and results in an area of tissue that doesn't receive any oxygen. This will eventually cause those cells to die if nothing is done. A heart attack is typically accompanied by pain, shortness of breath, and other symptoms, and is usually treated with drugs or angioplasty. Although sudden death is possible, it does not always occur. Many times, a heart attack will lead to SCA, which does lead to sudden death if no action is taken.

The most common heart rhythm in SCA is ventricular fibrillation (VF). VF refers to a condition that can develop when the working cells stop responding to the electrical system in the heart and start contracting randomly on their own. When this occurs, the heart becomes a quivering mass of muscle and loses its ability to pump blood through the body. The heart "stops beating", and the person will lose consciousness and stop breathing within seconds. If defibrillation is not successfully performed to return the heart to a productive rhythm, the person will die within minutes. The ECG below depicts ventricular fibrillation.



Ventricular fibrillation

Cardiopulmonary resuscitation, or CPR, allows some oxygen to be delivered to the various body organs (including the heart), but at a much-reduced rate. CPR will not stop fibrillation. However, because it allows some oxygen to be supplied to the heart tissue, CPR extends the length of time during which defibrillation is still possible. Even with CPR, a fibrillating heart rhythm will eventually degenerate into asystole, or "flatline," which is the absence of any electrical activity. If this happens, the patient has almost no chance of survival.

Defibrillation is the use of an electrical shock to stop fibrillation and allow the heart to return to a regular, productive rhythm that leads to pumping action. The shock is intended to cause the majority of the working cells to contract (or "depolarize") simultaneously. This allows them to start responding to the natural electrical system in the heart and begin beating in an organized manner again. The chance of survival decreases by about 10% for every minute the heart remains in fibrillation, so defibrillating someone as quickly as possible is vital to survival.

An electrical shock is delivered by a defibrillator, and involves placing two electrodes on an adult's chest in such a way that an electrical current travels from one pad to the other, passing through the heart muscle along the way. Since the electrodes typically are placed on the patient's chest, the current must pass through the skin, chest muscles, ribs, and organs in the area of the chest cavity, in addition to the heart. A person will sometimes "jump" when a shock is delivered, because the same current that causes all the working cells in the heart to contract can also cause the muscles in the chest to contract.

SIMPLIFYING ELECTRICITY

Energy is defined as the capacity to do work, and electrical energy can be used for many purposes. It can drive motors used in many common household appliances, it can heat a home, or it can restart a heart. The electrical energy used in any of these situations depends on the level of the voltage applied, how much current is flowing, and for what period of time that current flows. The voltage level and the amount of current that flows are related by impedance, which is basically defined as the resistance to the flow of current.[1]

If you think of voltage as water pressure and current as the flow of water out of a hose, then impedance is determined by the size of the hose. If you have a small garden hose, the impedance would be relatively large and would not allow much water to flow through the hose. If, on the other hand, you have a fire hose, the impedance would be lower, and much more water could flow through the hose given the same pressure. The volume of water that comes out of the hose depends on the pressure, the size of the hose, and the amount of time the water flows. A garden hose at a certain pressure for a short period of time works well for watering your garden, but if you used a fire hose with the same pressure and time, you could easily wash your garden away.

Electrical energy is similar. The amount of energy delivered depends on the voltage, the current, and the duration of its application. If a certain voltage is present across the defibrillator pads attached to a patient's chest, the amount of current that will flow through the patient's chest is determined by the impedance of the body tissue. The amount of energy delivered to the patient is determined by how long that current flows at that level of voltage.

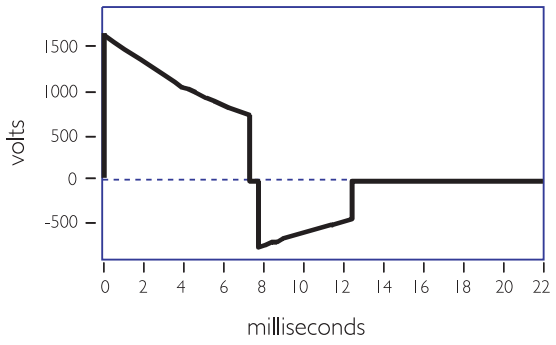
In the case of the biphasic waveforms shown in the following pages, energy (E) is the power (P) delivered over a specified time (t), or $E = P \times t$.

1. Voltage is measured in volts, current is measured in amperes (amps), and impedance is measured in ohms. Large amounts of electrical energy are measured in kilowatt-hours, as seen on your electric bill. Small amounts can be measured in joules (J), which are watt-seconds.

Electrical power is defined as the voltage (V) times the current (volts= joules/coulomb, amps = coulombs/sec):	$P = V \times I$
From Ohm's law, voltage and current are related by resistance (R) (impedance):	$V = I \times R$ or $I = V/R$
Power is therefore related to voltage and resistance by:	$P = V^2/R$ or $P = I^2R$
Substituting this back into the equation for energy means that the energy delivered by the biphasic waveform is represented by:	$E = V^2/R \times t$ or $E = I^2R \times t$

In determining how effective the energy is at converting a heart in fibrillation, how the energy is delivered -- or the shape of the waveform (the value of the voltage over time) -- is actually more important than the amount of energy delivered.

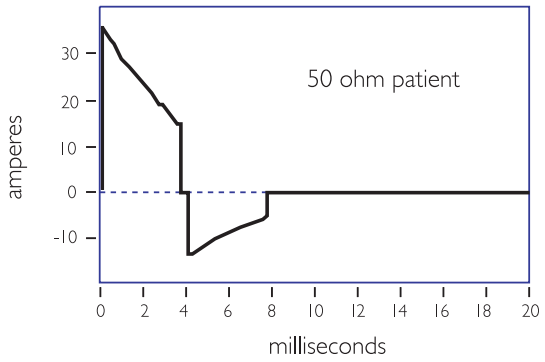
For the SMART Biphasic waveform, the design strategy involved starting with a set peak voltage stored on the capacitor that will decay exponentially as current is delivered to the patient. The SMART Biphasic waveform shown here is displayed with the voltage plotted versus time, for a patient with an impedance of 75 ohms. By changing the time duration of the positive and negative pulses, the energy delivered to the patient can be controlled.

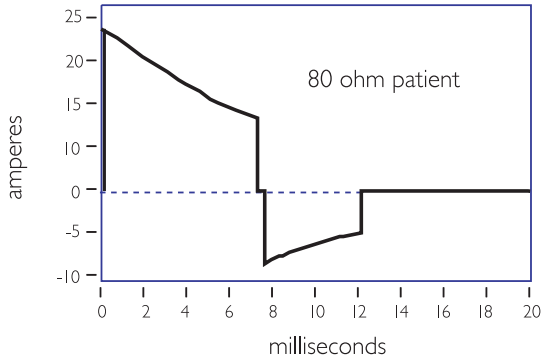


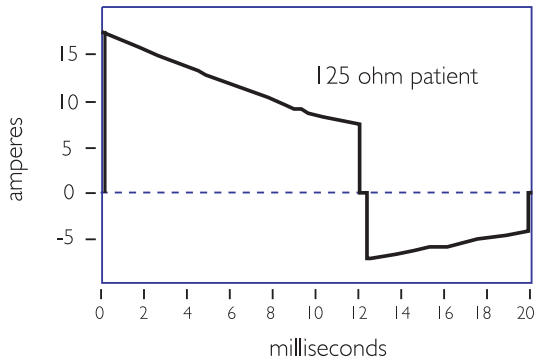
SMART Biphasic waveform

Although the relationship of voltage and energy is of interest in designing the defibrillator, it is actually the current that is responsible for defibrillating the heart.

The following three graphs demonstrate how the shape of the current waveform changes with different patient impedances. Once again, the SMART Biphasic waveform delivers the same amount of energy (150 J) to every patient, but the shape of the waveform changes to provide the highest level of effectiveness for defibrillating the patient at each impedance value.







With the SMART Biphasic waveform, the shape of the waveform is optimized for each patient. The initial voltage remains the same, but the peak current will depend on the patient's impedance. The tilt (slope) and the time duration are adjusted for different patient impedances to maintain approximately 150 J for each shock. The phase ratio, or the relative amount of time the waveform spends in the positive pulse versus the negative pulse, is also adjusted depending upon the patient impedance to insure the waveform remains effective for all patients. Adjusting these parameters makes it easier to control the accuracy of the energy delivered since they are proportionally related to energy, whereas voltage is exponentially related to energy.

The HeartStart Defibrillator measures the patient's impedance during each shock. The delivered energy is controlled by using the impedance value to determine what tilt and time period are required to deliver 150 J.

The average impedance in adults is 75 ohms, but it can vary from 25 to 180 ohms. Because a HeartStart Defibrillator measures the impedance and adjusts the shape of the waveform accordingly, it delivers 150 J of energy to the patient every time the shock button is pressed. Controlling the amount of energy delivered allows the defibrillator to deliver enough energy to defibrillate the heart, but not more. Numerous studies have demonstrated that the waveform used by HeartStart Defibrillator is more effective in defibrillating out-of-hospital cardiac arrest patients than the waveforms used by other defibrillators. Moreover, the lower energy delivered results in less post-shock dysfunction of the heart, resulting in better outcomes for survivors.[1]

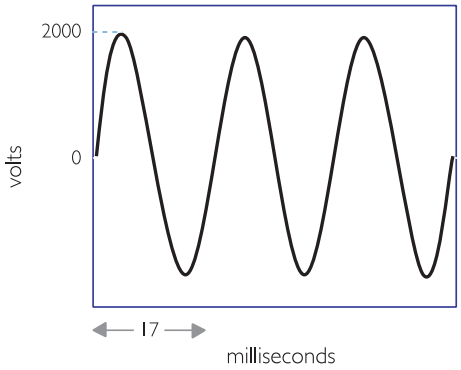
1. American Heart Association. Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care December 2005.

3 SMART BIPHASIC WAVEFORM

Defibrillation is the only effective treatment for ventricular fibrillation, the most common cause of sudden cardiac arrest (SCA). The defibrillation waveform used by a defibrillator determines how energy is delivered to a patient and defines the relationship between the voltage, current, and patient impedance over time. The defibrillator waveform used is critical for defibrillation efficacy and patient outcome.

A BRIEF HISTORY OF DEFIBRILLATION

The concept of electrical defibrillation was introduced over a century ago. Early experimental defibrillators used 60 cycle alternating current (AC) household power with step-up transformers to increase the voltage. The shock was delivered directly to the heart muscle. Transthoracic (through the chest wall) defibrillation was first used in the 1950s.

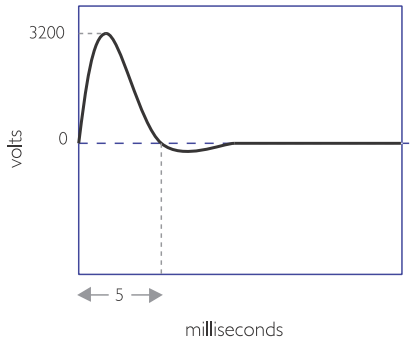


alternating current (AC) waveform

The desire for portability led to the development of battery-powered direct current (DC) defibrillators in the 1950s. At that time it was also discovered that DC shocks were more effective than AC shocks. The first "portable" defibrillator was developed at Johns Hopkins University. It used a biphasic waveform to deliver 100 joules (J) over 14 milliseconds. The unit weighed 50 pounds with accessories (at a time when standard defibrillators typically weighed more than 250 pounds) and was briefly commercialized for use in the electric utility industry.

Defibrillation therapy gradually gained acceptance over the next two decades. An automated external defibrillator (AED) was introduced in the mid-1970s, shortly before the first automatic internal cardioverter-defibrillator (AICD) was implanted in a human.

Historically, defibrillators used one of two types of monophasic waveforms: monophasic damped sine (MDS) or monophasic truncated exponential (MTE). With monophasic waveforms, the heart receives a single burst of electrical current that travels from one pad or paddle to the other.

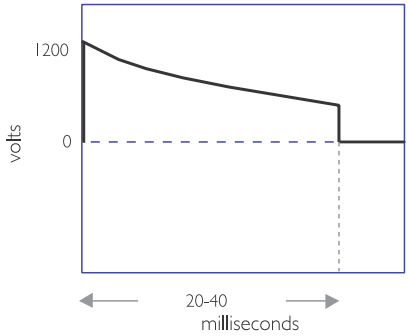


biphasic damped sine (MDS) waveform

The MDS waveform requires high energy levels, up to 360 J, to defibrillate effectively. MDS waveforms are not designed to compensate for differences in impedance — the resistance of the body to the flow of current — encountered in different patients. As a result, the effectiveness of the shock can vary greatly with the patient impedance.

Traditional MDS waveform defibrillators assume a patient impedance of 50 ohms, but the average impedance of adult humans is between 70 and 80 ohms. As a result, the actual energy delivered by MDS waveforms is usually higher than the selected energy.

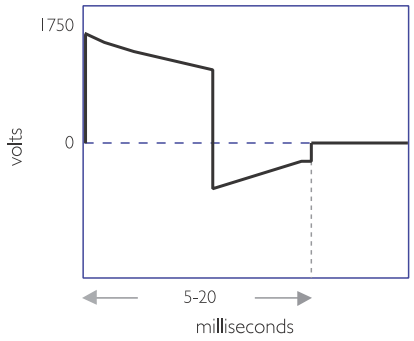
The monophasic truncated exponential (MTE) waveform also uses energy settings of up to 360 J. Because it uses a lower voltage than the MDS waveform, the MTE waveform requires a longer duration to deliver the full energy to patients with higher impedances. This form of impedance compensation does not improve the efficacy of defibrillation, but simply allows extra time to deliver the selected energy. Long-duration shocks (> 20 msec) have been associated with refibrillation.[1]



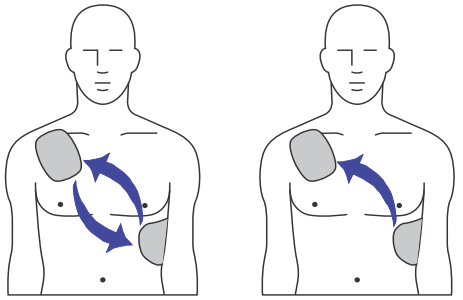
monophasic truncated exponential (MTE) waveform

Despite the phenomenal advances in the medical and electronics fields during the last half of the 20th century, the waveform technology used for external defibrillation remained the same until just recently. In 1992, research scientists and engineers at Heartstream (now part of Philips Medical Systems) began work on what was to become a significant advancement in external defibrillation waveform technology. Extensive studies for implantable defibrillators had shown biphasic waveforms to be superior to monophasic waveforms.[2,3,4] In fact, a biphasic waveform has been the standard waveform for implantable defibrillators for over a decade. Studies have demonstrated that biphasic waveforms defibrillate at lower energies and thus require smaller components that result in smaller and lighter devices.

Heartstream pursued the use of the biphasic waveform in AEDs because use of the biphasic waveform allows for smaller and lighter AEDs. The SMART Biphasic waveform has been proven effective at an energy level of 150 joules and has been used in HeartStart AEDs since they were introduced in 1996.



biphasic truncated exponential (BTE) waveform



defibrillation current flow

One of the main differences between monophasic and biphasic waveforms is the direction of current flow between the defibrillation pads. With a monophasic waveform, the current flows in only one direction. With a biphasic waveform, the current flows in one direction and then reverses and flows in the opposite direction. Looking at the waveforms, a monophasic waveform has one positive pulse, whereas a biphasic starts with a positive pulse that is followed by a negative one.

In the process of developing the biphasic truncated exponential waveform for use in AEDs, valuable lessons have been learned:

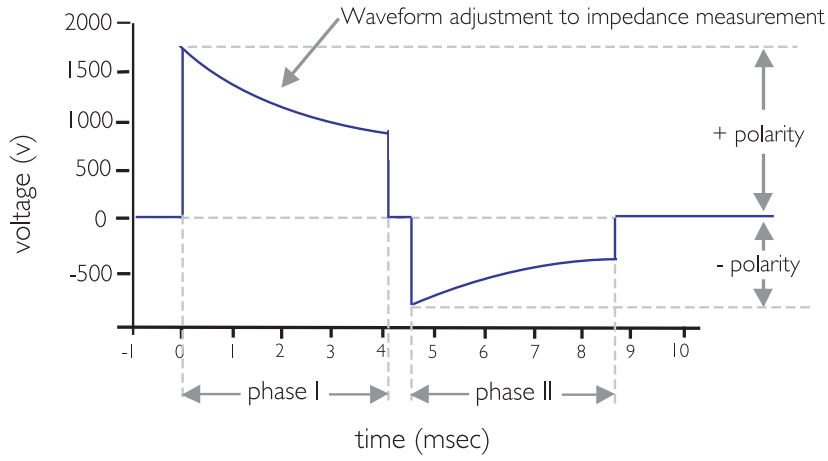
1. Not all waveforms are equally effective. How the energy is delivered (the waveform used) is actually more important than how much energy is delivered.
2. Compensation is needed in the waveform to adjust for differing patient impedances because the effectiveness of the waveform may be affected by patient impedance. The patient impedance can vary due to the energy delivered, electrode size, quality of contact between the electrodes and the skin, number and time interval between previous shocks, phase of ventilation, and the size of the chest.
3. Lower energy is better for the patient because it reduces post-shock dysfunction. While this is not a new idea, it has become increasingly clear as more studies have been published.

The characteristics for the monophasic damped sine and monophasic truncated exponential waveforms are specified in the AAMI standard DF80:2003; the result is that these waveforms are very similar from one manufacturer to the next.

There is no standard for biphasic waveforms, each manufacturer has designed their own. This has resulted in various wave-shapes depending on the design approach used. While it is generally agreed that biphasic waveforms are better than the traditional monophasic waveforms, it is also true that different levels of energy are required by different biphasic waveforms in order to be effective.

SMART BIPHASIC

SMART Biphasic is the patented waveform used by all HeartStart AEDs. It is an impedance-compensating, low energy (<200 J), low capacitance (100 µF), biphasic truncated exponential (BTE) waveform that delivers a fixed energy of 150 J for defibrillation. Heartstream was the first company to develop a biphasic waveform for use in AEDs.



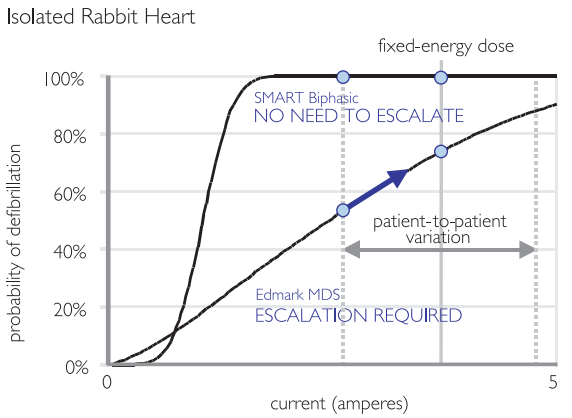
SMART Biphasic waveform

The SMART Biphasic waveform developed by Heartstream compensates for different impedances by measuring the patient impedance during the discharge and using that value to adjust the duration of the waveform to deliver the desired 150 joules. Since the starting voltage is sufficiently large, the delivered energy of 150 joules can be accomplished without the duration ever exceeding 20 milliseconds. The distribution of the energy between the positive and negative pulses was fine tuned in animal studies to optimize defibrillation efficacy and validated in studies conducted in and out of the hospital environment.

Different waveforms have different dosage requirements, similar to a dosage associated with a medication. "If energy and current are too low, the shock will not terminate the arrhythmia; if energy and current are too high, myocardial damage may result." (I-63)[5] The impedance compensation used in the SMART Biphasic waveform results in an effective waveform for all patients. The SMART Biphasic waveform has been demonstrated to be just as effective or superior for defibrillating VF when compared to other waveforms and escalating higher energy protocols.

UNDERSTANDING FIXED ENERGY

The BTE waveform has an advantage over the monophasic waveforms related to the shape of the defibrillation response curve. The following graph, based on Snyder et al., demonstrates the difference between the defibrillation response curves for the BTE and the MDS waveform.



Based on data from Snyder et al., *Resuscitation* 2002; 55:93 [abstract]

With the gradual slope of the MDS waveform, it is apparent that as current increases, the defibrillation efficacy also increases. This characteristic of the MDS response curve explains why escalating energy is needed with the MDS waveform; the probability of defibrillation increases with an increase in peak current, which is directly related to increasing the energy.

For a given amount of energy the resulting current level can vary greatly depending on the impedance of the patient. A higher-impedance patient receives less current, so escalating the energy is required to increase the probability of defibrillation.

The steeper slope of the BTE waveform, however, results in a response curve where the efficacy changes very little with an increase in current, past a certain current level. This means that if the energy (current) level is chosen appropriately, escalating energy is not required to increase the efficacy. This

fact, combined with the lower energy requirements of BTE waveforms,[16,18] means that it is possible to choose one fixed energy that allows any patient to be effectively and safely defibrillated.

EVIDENCE-BASED SUPPORT FOR THE SMART BIPHASIC WAVEFORM

Using a process outlined by the American Heart Association (AHA) in 1997,[6] the Heartstream team put the SMART Biphasic waveform through a rigorous sequence of validation studies. First, animal studies were used to test and fine-tune the waveform parameters to achieve optimal efficacy. Electrophysiology laboratory studies were then used to validate the waveform on humans in a controlled hospital setting. Finally, after receiving FDA clearance for the ForeRunner AED, the first AED to use the SMART Biphasic waveform, post-market studies were used to prove the efficacy of the waveform in the out-of-hospital, emergency-resuscitation environment.

Even when comparing different energies delivered with a single monophasic waveform, it has been demonstrated that lower-energy shocks result in fewer post shock arrhythmias.[7] Other studies have demonstrated that the biphasic waveform has several clinical advantages. It has equivalent efficacy to higher energy monophasic waveforms but shows no significant ST segment change from the baseline.[8] There is also evidence of less post shock dysfunction when the biphasic waveform is used.[9,10,11,27] There is evidence that the biphasic waveform has improved performance when anti-arrhythmic drugs are present,[12,13] and with long duration VF.[14,20] Another study has also demonstrated improved neurological outcomes for survivors defibrillated with SMART Biphasic when compared to patients defibrillated with monophasic waveforms.[15]

The bottom line is that the SMART Biphasic waveform has been demonstrated to be just as effective or superior to monophasic waveforms at defibrillating patients in VF. In addition, there are indications that patients defibrillated with the SMART Biphasic waveform suffer less dysfunction than those defibrillated with conventional escalating-energy monophasic waveforms. SMART Biphasic has been used in AEDs for over two decades, and there are numerous studies to support the benefits of this waveform, including out-of-hospital data with long-down-time VF.

SMART BIPHASIC SUPERIOR TO MONOPHASIC

Researchers have produced over 20 peer-reviewed manuscripts to prove the efficacy and safety of the SMART Biphasic waveform. Thirteen of these are out-of-hospital studies that demonstrated high efficacy of the SMART Biphasic waveform on long-down-time patients in emergency environments. No other waveform is supported by this level of research.

Using criteria established by the AHA in its 1997 Scientific Statement,[25] the data from the ORCA study[15,32] demonstrate that the 150J SMART Biphasic waveform is superior to the 200J - 360J escalating energy monophasic waveform in the treatment of out-of-hospital cardiac arrest. This is true for one-shock, two-shock, and three-shock efficacy and return of spontaneous circulation.

KEY STUDIES

year	waveforms studied	results
1992	low-energy vs. high-energy damped sine monophasic	**249 patients** (emergency resuscitation). Low-energy and high-energy damped sine monophasic are equally effective. Higher energy is associated with increased incidence of A-V block with repeated shocks.[7]
1994	biphasic vs. damped sine monophasic	**19 swine.** Biphasic shocks defibrillate at lower energies, and with less post-shock arrhythmia, than monophasic shocks.[16]
1995		**171 patients** (electrophysiology laboratory). First-shock efficacy of biphasic damped sine is superior to high-energy monophasic damped sine.[17]
1995	low-energy truncated biphasic vs. high-energy damped sine monophasic	**30 patients** (electrophysiology laboratory). Low-energy truncated biphasic and high-energy damped sine monophasic equally effectiveness.[18]
1996	115 J and 130 J truncated biphasic vs. 200 J and 360 J damped sine monophasic	**294 patients** (electrophysiology laboratory). Low-energy truncated biphasic and high-energy damped sine monophasic are equally effective. High-energy monophasic is associated with significantly more post-shock ST-segment changes on ECG.[8] This study of a 115 J and 130 J waveform contributed to the development of the 150 J, nominal, therapy that ships with Philips AEDs.
1997	SMART Biphasic vs. standard high-energy monophasic	**18 patients** (10 VF, emergency resuscitation). SMART Biphasic terminated VF at higher rates than reported damped sine or truncated exponential monophasic.[19]
1998		**30 patients** (electrophysiology laboratory). High-energy monophasic showed significantly greater post-shock ECG ST-segment changes than SMART Biphasic.[9]
1999		**286 patient**s (100 VF, emergency resuscitation). First-shock efficacy of SMART Biphasic was 86% (compared to pooled reported 63% for damped sine monophasic); three or fewer shocks, 97%; 65% of patients had organized rhythm at hand-off to ALS or emergency personnel.[20]
		116 patients (emergency resuscitation). At all post-shock assessment times (3 - 60 seconds) SMART Biphasic patients had lower rates of VF. Refibrillation rates were independent of waveform.[10]
1999	low-energy (150 J) vs. high-energy (200 J) biphasic	**20 swine.** Low-energy biphasic shocks increased likelihood of successful defibrillation and minimized post-shock myocardial dysfunction after prolonged arrest.[21]

year	waveforms studied	results
1999	low-capacitance biphasic vs. high-capacitance biphasic	**10 swine.** Five of five low-capacitance shock animals were resuscitated, compared to two of five high-capacitance at 200 J. More cumulative energy and longer CPR were required for high-capacitance shock animals that survived.[22]
1999	SMART Biphasic vs. escalating high-energy monophasic	**10 swine.** Stroke volume and ejection fraction progressively and significantly reduced at 2, 3, and 4 hours post-shock for monophasic animals but improved for biphasic animals.[11]
2000		**338 patients** (115 VF, emergency resuscitation). Demonstrated superior defibrillation performance in comparison with escalating, high-energy monophasic shocks in out-of hospital cardiac arrest (average time from call to first shock was 8.9 minutes). SMART Biphasic defibrillated at higher rates than MTE and MDS (96% first-shock efficacy vs. 59%), with more patients achieving ROSC. Survivors of SMART Biphasic resuscitation were more likely to have good cerebral performance at discharge, and none had coma (vs. 21% for monophasic survivors).[15]
2001		**338 patients** (115 VF, emergency resuscitation). Use of a low-energy impedance-compensating biphasic waveform device resulted in superior first-shock efficacy, in the first set of two or three shocks, time to shock, and first successful shock compared to traditional defibrillators using escalating energy monophasic truncated exponential and monophasic damped sine waveforms.[32]
2004	SMART Biphasic	**62 patients** (shockable rhythms; 41% of patients were classified as overweight, 24% as obese, and 4% as extremely obese). Overweight patients were successfully defibrillated by the 150 J SMART Biphasic waveform, without energy escalation.[33]
2005		**102 patients** (all presenting with shockable rhythms). SMART Biphasic successfully defibrillated high-impedance patients without energy escalation. Rapid defibrillation rather than differences in patient impedance accounted for resuscitation success.[34]

FREQUENTLY ASKED QUESTIONS

ARE ALL BIPHASIC WAVEFORMS ALIKE?

No. Different waveforms perform differently, depending on their shape, duration, capacitance, voltage, current, and response to impedance. Different biphasic waveforms are designed to work at different energies. As a result, an appropriate energy dose for one biphasic waveform may be inappropriate for a different waveform.

There is evidence to suggest that a biphasic waveform designed for low-energy defibrillation may result in overdose if applied at high energies (the Tang AHA abstract from 1999 showed good resuscitation performance for the SMART Biphasic waveform, but more shocks were required at 200 J than at 150 J[21]). Conversely, a biphasic waveform designed for high-energy defibrillation may not defibrillate effectively at lower energies. (The Tang AHA abstract from 1999 showed poor resuscitation performance for the

200 µF capacitance biphasic waveform at 200 J compared to the 100 µF capacitance biphasic waveform [SMART Biphasic] at 200 J.[22] The Higgins manuscript from 2000 showed that the 200 µF capacitance biphasic waveform performed better at 200 J than at 130 J.[23])

It is consequently necessary to refer to the manufacturer's recommendations and the clinical literature to determine the proper dosing for a given biphasic waveform. The recommendations for one biphasic waveform should not be arbitrarily applied to a different biphasic waveform. "It is likely that the optimal energy level for biphasic defibrillators will vary with the units' waveform characteristics. An appropriate energy dose for one biphasic waveform may be inappropriate for another."[24]

SMART Biphasic was designed for low-energy defibrillation, while some other biphasic waveforms were not. It would be irresponsible to use a waveform designed for high energy with a low-energy protocol.

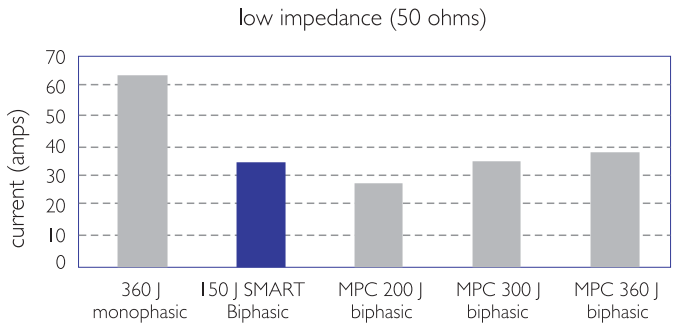
HOW CAN THE SMART BIPHASIC WAVEFORM BE MORE EFFECTIVE AT LOWER ENERGY?

The way the energy is delivered makes a significant difference in the efficacy of the waveform. Electric current has been demonstrated to be the variable most highly correlated with defibrillation efficacy. The SMART Biphasic waveform uses a 100 µF capacitor to store the energy inside the AED; other biphasic waveforms use a 200 µF capacitor to store the energy. The energy (E) stored on the capacitor is given by the equation:

$$E = \tfrac{1}{2} C V^2$$

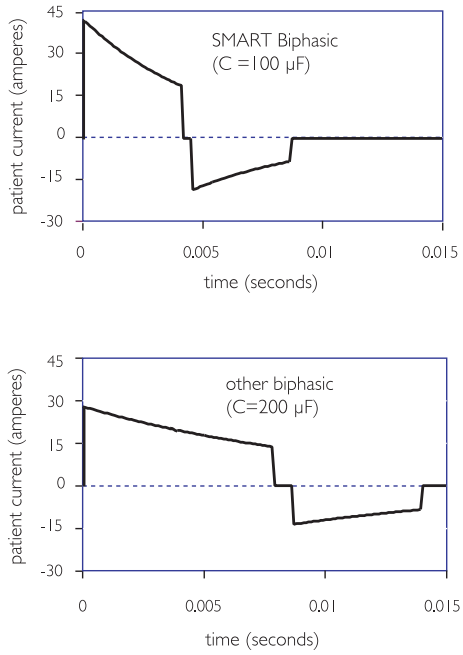
The voltage (V) and the current (I) involved with defibrillating a patient are related to the patient impedance (R) by the equation:

$$V = I R$$



Peak Current Levels

For the 200 µF capacitance biphasic waveform to attain similar levels of current to the SMART Biphasic (100 µF) waveform, it must apply the same voltage across the patient's chest. This means that to attain similar current levels, the 200 µF biphasic waveform must store twice as much energy on the capacitor and deliver much more energy to the patient; the graph of peak current levels demonstrates this relationship. This is the main reason why some biphasic waveforms require higher energy doses than the SMART Biphasic waveform to attain similar efficacy.



The illustrations to the left show the SMART Biphasic waveform and another biphasic waveform with a higher capacitance, similar to that used by another AED manufacturer. The low capacitance used by the patented SMART Biphasic waveform delivers energy more efficiently. In an animal study using these two waveforms, the SMART Biphasic waveform successfully resuscitated all animals and required less cumulative energy and shorter CPR time than the other biphasic waveform, which resuscitated only 40% of the animals.[22]

The amount of energy needed depends on the waveform that is used. SMART Biphasic has been demonstrated to effectively defibrillate at 150 J in out-of-hospital studies.[15] Animal studies have indicated that the SMART Biphasic waveform would not be more effective at higher energies[21] and this seems to be supported with observed out-of-hospital defibrillation efficacy of 96% at 150 J.[15]

IS ESCALATING ENERGY REQUIRED?

No, not with SMART Biphasic technology. In the "Guidelines 2010,"[35] the AHA states, "Energy levels vary by type of device" (page S708). The SMART Biphasic waveform has been optimized for ventricular defibrillation efficacy at 150 J. The Guidelines state, "Data from both out-of-hospital and in-hospital studies indicate that lower-energy biphasic waveform shocks have equivalent or higher success for termination of VF than either MDS or MTE monophasic waveform shocks" (page S708).

The Guidelines also state that "the optimal energy for first-shock biphasic waveform defibrillation has not been determined," noting that "multiple

prospective human clinical studies and retrospective studies have failed to identify an optimal biphasic energy level for first or subsequent shocks. … Different biphasic waveforms have not been compared in humans with regard to efficacy. Therefore, for biphasic defibrillators, providers should use the manufacturer's recommended energy dose (120 to 200 J) (Class I, LOE B)" (page S703).

Some have suggested that a patient may need more than 150 J with a BTE waveform when conditions like heart attacks, high-impedance, delays before the first shock, and inaccurate electrode pad placement are present. This is not true for the SMART Biphasic waveform, as the evidence presented in the following sections clearly indicates. On the other hand, the evidence does indicate that other BTE waveforms may require more than 150 J for defibrillating patients in VF.

HEART ATTACKS

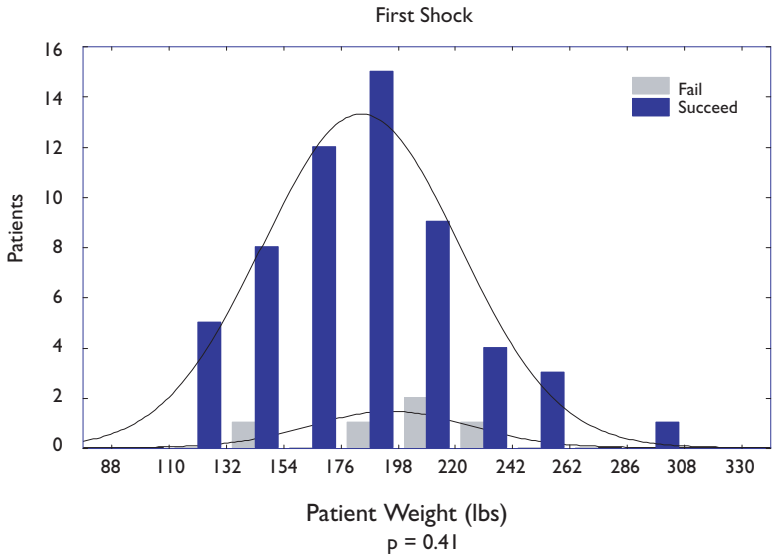
The SMART Biphasic waveform has been tested in the real world with real heart attack victims and has proven its effectiveness at terminating ventricular fibrillation (VF). In a prospective, randomized, out-of-hospital study, the SMART Biphasic waveform demonstrated a first shock efficacy of 96% versus 59% for monophasic waveforms, and 98% efficacy with 3 shocks as opposed to 69% for monophasic waveforms.[15] Fifty-one percent of the victims treated with the SMART Biphasic waveform were diagnosed with acute myocardial infarction. The published evidence clearly indicates that the SMART Biphasic waveform does not require more than 150 J for heart attack victims.

HIGH-IMPEDANCE OR LARGE PATIENTS

High impedance patients do not pose a problem with the low energy SMART Biphasic waveform. Using a patented method, SMART Biphasic technology automatically measures the patient's impedance and adjusts the waveform dynamically during each shock to optimize the waveform for each shock on each patient. As demonstrated in published, peer-reviewed clinical literature, the SMART Biphasic waveform is as effective at defibrillating patients with high impedance (greater than 100 ohms) as it is with low-impedance patients.[19] The bottom line is that the SMART Biphasic waveform does not require more than 150 J for high-impedance patients.

Data collected from a group of patients defibrillated by the Rochester, Minnesota, EMS organization during actual resuscitation attempts was examined to determine if patient weight affected the defibrillation effectiveness of the 150 J non-escalating SMART biphasic shock that was used. Of the patients for whom both weight and height data were available, 41% were overweight, 24% were obese, and 4% were extremely obese by BMI (Body Mass Index) standards. As shown in the graph below, the success and failure distributions were identical for the three groups. Thus,

defibrillation effectiveness on the first shock was in no way related to the weight of the patient. The cumulative two-shock success rate was 99%, and all patients were defibrillated by the third shock.



DELAYS BEFORE THE FIRST SHOCK

In a randomized out-of-hospital study comparing the low-energy SMART Biphasic waveform to high-energy escalating monophasic waveforms, the average collapse-to-first-shock time was 12.3 minutes. Of the 54 patients treated with the SMART Biphasic waveform, 100% were successfully defibrillated, 96% on the first shock and 98% with three or fewer shocks. With the monophasic waveforms, only 59% were defibrillated on the first shock and only 69% with three or fewer shocks. Seventy-six percent of the patients defibrillated with the SMART Biphasic waveform experienced a return of spontaneous circulation (ROSC), versus only 55% of the patients treated with high-energy monophasic waveforms.[15] In a post-market, out-of-hospital study of 100 VF patients defibrillated with the SMART Biphasic waveform, the authors concluded, "Higher energy is not clinically warranted with this waveform."[20] SMART Biphasic does not require more than 150 J when there are delays before the first shock.

INACCURATE ELECTRODE PAD PLACEMENT

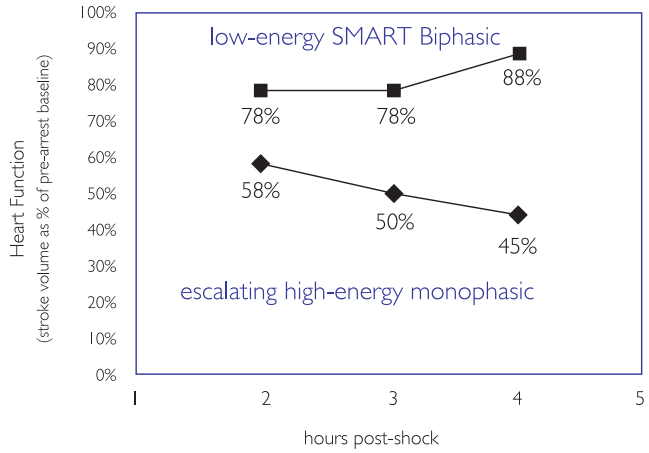
The claim that more energy is possibly required if the pads are not placed properly is a purely speculative argument with no basis in scientific evidence. However, common sense would suggest that if a given biphasic waveform needs more energy when pads are located properly, why would it perform any better if the pads were placed sub-optimally? Once again, the real world data demonstrates high efficacy with the SMART Biphasic waveform in out-of-hospital studies.[15,20] These studies included hundreds of AED users with a variety of different backgrounds.

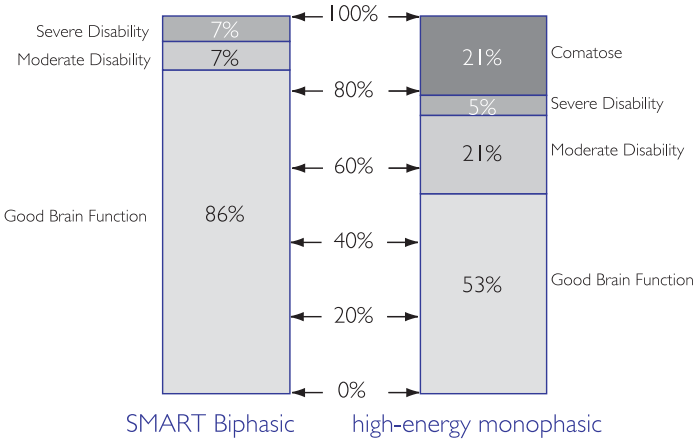
out-of-hospital studies.[15,20] These studies included hundreds of AED users with a variety of different backgrounds.

IS THERE A RELATIONSHIP BETWEEN WAVEFORM, ENERGY LEVEL, AND POST-SHOCK DYSFUNCTION?

Yes. Higher-energy defibrillation waveforms — whether monophasic or biphasic — are associated with increased post-shock cardiac dysfunction.

There is a difference between damage and dysfunction. In the context of post-shock cardiac assessment, "damage" can be defined as irreversible cell death, as measured by various enzyme tests. "Dysfunction" is reflected in reduced cardiac output as a result of reversible myocardial stunning. Dysfunction can result in significantly reduced cardiac output for many hours post-resuscitation. Waveforms that do not cause damage can cause dysfunction.





Evidence of this dysfunction includes electrocardiogram (ECG) abnormalities.[8,26] A study of escalating-energy monophasic waveforms found that increased levels of delivered energy were associated with increased

evidence of impaired myocardial contractility and perfusion failure. The authors conclude: "The severity of post-resuscitation myocardial dysfunction is related, at least in part, to the magnitude of electrical energy of the delivered shock."[27] Several other studies also provide data to support this conclusion for biphasic as well as monophasic waveforms.[21,28,29]

Post-resuscitation brain dysfunction is another important area that warrants further study. In a randomized study of 115 out-of-hospital SCA patients with VF, 54 were shocked with the SMART Biphasic waveform and the remainder with escalating high-energy monophasic devices. In this study, 87% of SMART Biphasic survivors had good brain function when discharged from the hospital, as opposed to only 53% of monophasic escalating-energy survivors. None of the SMART Biphasic patients experienced post-shock coma, while 21% of monophasic survivors did.[15]

HOW DOES SMART BIPHASIC COMPARE TO OTHER BIPHASIC WAVEFORMS?

While there is a large body of literature published about the SMART Biphasic waveform, there is very little published research about other biphasic defibrillation waveforms.

Comparing waveform results within a single, controlled study can yield meaningful information. However, comparing the results from separate studies can be extremely misleading, due to any number of uncontrolled differences from study to study. The same waveform can perform differently in different studies, depending on how each study is set up.

The results of an animal study comparing the SMART Biphasic waveform to a type of biphasic waveform used by another manufacturer establish that the SMART Biphasic waveform increases the likelihood of successful defibrillation, minimizes post-shock myocardial dysfunction, and requires less cumulative energy.[22]

IS THERE A STANDARD FOR BIPHASIC ENERGY LEVELS?

No. The data supporting low-energy biphasic defibrillation has been reviewed by the American Heart Association (AHA), which found the therapy to be "safe, effective, and clinically acceptable." As stated by the AHA, "A review of previous AHA guidelines for the [monophasic] energy sequence 200 J- 300 J-360 J reveals that the evidence supporting this reputed 'gold standard' is largely speculative and is based largely on common sense extrapolation… Multiple high energy shocks could easily result in more harm than good."[30]

Since there are differences between the biphasic waveforms available, the proper energy level for a particular biphasic waveform depends on how it was designed and should be specified by the manufacturer. The proper energy level for SMART Biphasic is 150 J, as demonstrated by the studies

completed. When referencing these studies and the SMART Biphasic waveform, the AHA states that, "The growing body of evidence is now considered sufficient to support a Class IIa recommendation for this low energy, BTE waveform."[5] The AHA defines a Class IIa as, "Good/very good evidence," "Considered standard of care," and "Considered intervention of choice by a majority of experts."[5]

In the same guidelines, the AHA also issued a similar recommendation for the general practice of low-energy biphasic defibrillation, but cautioned that, "at this time no studies have reported experience with other biphasic waveforms in long-duration VF in out-of-hospital arrest. When such data becomes available, it will need to be assessed by the same evidence evaluation process as used for the biphasic defibrillator and this guidelines process."

WHY USE SMART BIPHASIC?

Some waveforms may need more than 150 J for defibrillation, but the SMART Biphasic waveform does not. Published clinical evidence indicates that the SMART Biphasic waveform does not require more than 150 J to effectively defibrillate, even if the patient has experienced a heart attack, has a higher than normal impedance, or if there have been delays before the first shock is delivered. Published clinical evidence also indicates that there is increased dysfunction associated with high-energy shocks.[7,8,27,28,31]

REFERENCES

1. Jones JL and Jones RE. Postshock arrhythmias - a possible cause of unsuccessful defibrillation. *Critical Care Medicine* 1980;8(3):167-71.
2. Winkle RA, et al. Improved low energy defibrillation energy in man with the use of a biphasic truncated exponential waveform. *American Heart Journal* 1989;117:122-127.
3. Bardy GH et al. A prospective, randomized evaluation of biphasic vs monophasic waveform pulses on defibrillation efficacy in humans. *Journal of the American College of Cardiology* 1989;14:728-733.
4. Schwartz JF, et al. Optimization of biphasic waveforms for human nonthoracotomy defibrillation. *Circulation* 1993;33:2646-2654.
5. American Heart Association. *Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care* December 2005.
6. American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. AHA Scientific Statement. Automatic external defibrillators for public access defibrillation: Recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. *Circulation* 1997;95:1277-1281.
7. Weaver WD, et al. Ventricular defibrillation-A comparative trial using 175J and 320J shocks. *New England Journal of Medicine* 1982;307:1101-1106.
8. Bardy GH, et al. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. *Circulation* 1996;94:2507-2514.
9. Reddy RK, et al. Biphasic transthoracic defibrillation causes fewer ECG ST-segment changes after shock. *Annals of Emergency Medicine* 1997;30:127-134.
10. Gliner BE and White RD. Electrocardiographic evaluation of defibrillation shocks delivered to out-of-hospital sudden cardiac arrest patients. *Resuscitation* 1999;41:133-144.
11. Tang W, Weil MH, Sun Shijie, et al. Defibrillation with low-energy biphasic waveform reduces the severity of post-resuscitation myocardial dysfunction after prolonged cardiac arrest. *Journal of Critical Care Medicine* 1999;27:A43.
12. Ujhelyi, et al. *Circulation* 1995;92(6):1644-1650
13. Kopp, et al. *PACE* 1995;18:872
14. 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 Electrophysiology* 1997;8:1373-1385.
15. Schneider T, Martens PR, Paschen H, et al. Multicenter, randomized, controlled trial of 150-joule biphasic shocks compared with 200- to 360-joule monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. *Circulation* 2000;102:1780-1787.
16. Gliner BE, et al. Transthoracic defibrillation of swine with monophasic and biphasic waveforms. *Circulation* 1995;92:1634-1643.
17. Greene HL, DiMarco JP, Kudenchuk PJ, et al. Comparison of monophasic and biphasic defibrillating pulse waveforms for transthoracic cardioversion. *American Journal of Cardiology* 1995;75:1135-1139.
18. Bardy GH, Gliner BE, Kudenchuk PJ, et al. Truncated biphasic pulses for transthoracic defibrillation. *Circulation* 1995;64:2507-2514.
19. White RD. Early out-of-hospital experience with an impedance-compensating low-energy biphasic waveform automatic external defibrillator. *Journal of Interventional Cardiac Electrophysiology* 1997;1:203-208.
20. Gliner BE, et al. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. *Biomedical Instrumentation & Technology* 1998;32:631-644.
21. Tang W, et al, Effects of low- and higher-energy biphasic waveform defibrillation on success of resuscitation and post-resuscitation myocardial dysfunction after prolonged cardiac arrest. *Circulation* (supplement)1999:100(18):I-662 (abstract).
22. Tang W, et al, Low capacitance biphasic waveform shocks improve immediate resuscitation after prolonged cardiac arrest. *Circulation* (supplement)1999:100(18):I-663 (abstract).
23. Higgins SL, et al. A Comparison of Biphasic and Monophasic Shocks for External Defibrillation. *PreHospital Emergency Care* 2000; 4:305-313.

24. ECRI. External Biphasic Defibrillators, Should You Catch the Wave? *Health Devices*. June 2001, Volume 30, Number 6.

25. Kerber RE, et al. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. *Circulation* 1997; 95:1677-1682.

26. Reddy RK, et al. Biphasic transthoracic defibrillation causes fewer ECG ST-segment changes after shock. *Annals of Emergency Medicine* 1997;30:127-134.

27. Xie J, et al. High-energy defibrillation increases the severity of postresuscitation myocardial function. *Circulation* 1997;96:683-688.

28. Tokano T, et al. Effect of ventricular shock strength on cardiac hemodynamics. *Journal of Cardiovascular Electrophysiology* 1998;9:791-797.

29. Cates AW, et al. The probability of defibrillation success and the incidence of postshock arrhythmia as a function of shock strength. *PACE* 1994;117:1208-1217.

30. Cummins RO, et al. Low-energy biphasic waveform defibrillation: Evidence-based review applied to emergency cardiovascular care guidelines: A statement for healthcare professionals from the American Heart Association Committee on Emergency Cardiovascular Care and the Subcommittees on Basic Life Support, Advanced Cardiac Life Support, and Pediatric Resuscitation. *Circulation* 1998;97:1

31. Tang W, et al. Defibrillation with low-energy biphasic waveform reduces the severity of post-resuscitation myocardial dysfunction after prolonged cardiac arrest. *Journal of Critical Care Medicine*. (Abstract) 1999;27:A43.

32. Martens PR, Russell JK, Wolcke B, Paschen H, Kuisma D, Schneider T. Optimal response to cardiac arrest study: defibrillation waveform effects. *Resuscitation* 2001; 49:233-243.

33. White RD, Blackwell TH, Russell JK, Jorgenson DB. Body weight does not affect defibrillation, resuscitation or survival in patients with out-of-hospital biphasic waveform defibrillator. *Critical Care Medicine* 2004; 32(9) Supplement: S387-S392.

34. White RD, Blackwell TH, Russell JK, Snyder DE, Jorgenson DB. Transthoracic impedance does not affect defibrillation, resuscitation or survival in patients with out-of-hospital cardiac arrest treated with a non-escalating biphasic waveform defibrillator. *Resuscitation* 2005 Jan; 64(1):63-69.

35. American Heart Association. 2010 Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science. *Circulation* 2010;122[suppl 3].

4 SMART ANALYSIS

SMART Analysis refers to the proprietary analysis system used in HeartStart AEDs that analyzes a patient's ECG and determines whether a shock should be delivered. It consists of three parts: pad contact quality, artifact detection, and arrhythmia detection. These three parts work together to enable the defibrillator to read an ECG and evaluate the available information to determine if a shock is appropriate.

PAD CONTACT QUALITY

This part of the analysis system continuously monitors the patient impedance to ensure that it remains within the appropriate range. This impedance measurement is a low signal measurement made through the front-end circuitry of the defibrillator and is different from the impedance measurement made at the beginning of the SMART Biphasic waveform.

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 pad/skin interface. 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 above the appropriate range, the HeartStart AED will issue voice prompts directing the user's attention to the pads, announcing that pads contact is poor and instructing the user to apply pads or to press the pads firmly to correct the situation.

ARTIFACT DETECTION

OVERVIEW

Whenever any electrical signal (such as an ECG) is measured, there is invariably a certain amount of electrical noise in the environment that can interfere with an accurate measurement. Artifact detection is important in an ECG analysis system because it allows detection of this extraneous electrical noise so that it can either be filtered out or compensated for. Motion detection is one way of dealing with this noise, but it is only important if the motion produces artifact on the ECG signal. Any artifact that is undetected can lead to incorrect decisions by the algorithm and can cause incorrect or delayed treatment of the patient.

Artifact can be caused in a variety of ways, including CPR, agonal breathing, transportation, patient handling, and the presence of a pacemaker in the patient. The action taken depends on how the artifact looks in relation to the ECG signal.

Artifact detection in HeartStart AEDs is accomplished by measuring the amount of static electricity sensed by the pads; this static is considered to be artifact signal. This artifact signal is then compared to the ECG signal. If they correlate, then artifact is detected and appropriate voice prompts are given so the user can take appropriate action. However, if it does not correlate with the ECG, then analysis proceeds and the defibrillator makes shock/no-shock decisions.

If the amplitude of the underlying ECG signal is small compared to an artifact signal, then the HeartStart AED will respond by giving voice prompts that tell the user not to touch the patient, that analyzing has been interrupted, or to stop all motion. In this situation, the defibrillator can not accurately analyze the underlying ECG because the amount of electrical noise present has corrupted the ECG signal. The AED messages given in this situation are designed to prompt the user to take actions that will stop or minimize the artifact in the environment.

If the amplitude of the ECG signal is sufficiently high compared to the artifact signal or if the artifact does not correlate with the ECG signal, the artifact will not interfere with the normal operation of the AED. In these cases, the defibrillator recognizes that artifact is present, but the defibrillator can continue to make shock decisions and deliver a shock if appropriate.

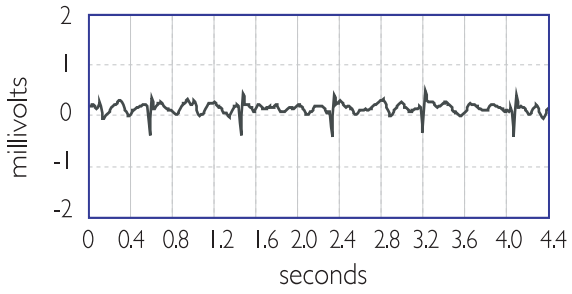
CPR AT HIGH RATES OF COMPRESSION

CPR rates significantly above 100 compressions per minute can cause incorrect or delayed analysis by the HeartStart AED. CPR performed with chest compressions of rates over 135/minute can sometimes mimic a shockable rhythm. In the presence of detected high CPR rates during ECG analysis, the AED will interrupt the rescuer doing CPR and give an instruction to not touch the patient. It is important to emphasize that CPR should be done at a reasonable rate in order to avoid unnecessary interruptions of patient treatment.

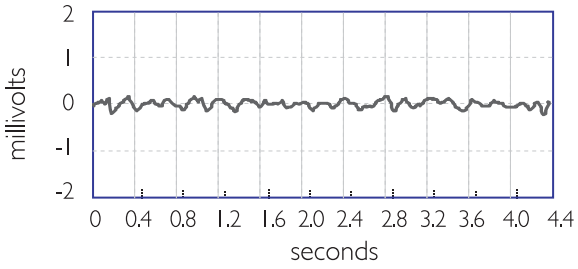
PACEMAKER DETECTION

In the event that the patient has an implanted pacemaker, HeartStart AEDs have special filters that remove the pacemaker artifact and allow the defibrillator to shock the patient if appropriate. The ECG shown on the AED's display and the ECG stored on the data card still have the pacemaker spikes represented, but the ECG used by the algorithm has the spikes removed.[1] The two strips in the following figure represent the ECG before and after the pacemaker artifact is filtered out.

1. Due to differences between pacemaker therapy designs, artifact removal cannot always be achieved.



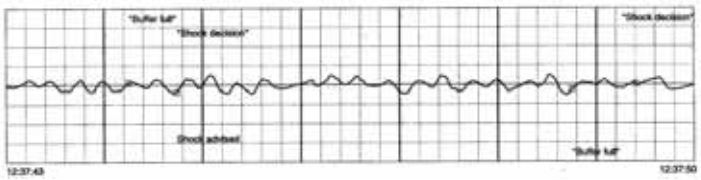
Before filtering: Underlying rhythm VF, pacemaker artifact



After filtering: Underlying rhythm VF, no pacemaker artifact

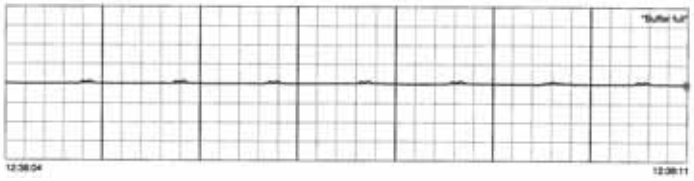
Even with a sophisticated artifact detection system, not all artifact can be detected during the use of the AED. This is why it is important to listen to the voice prompts given by the AED and to not touch the patient while it is analyzing the ECG. Below is an example of rapid CPR done in such a way that it was not detected by the analysis system. The second strip shows the underlying asystole present when CPR is stopped. Because HeartStart AEDs continually monitor the ECG and look for changes in the rhythm, the unit quickly disarmed automatically in this situation when CPR was discontinued and no shock was delivered to the patient. Asystole is not considered a shockable rhythm.

2 div/mV, 5 div/sec



CPR artifact: underlying rhythm asystole

2 div/mV, 5 div/sec



Post-CPR: underlying rhythm asystole

Delivering a shock to a patient in asystole will not return the heart to a normal rhythm and may actually prevent more appropriate therapies from being successful.

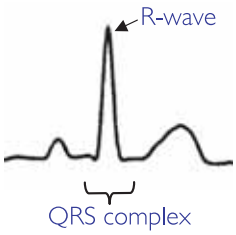
ARRHYTHMIA DETECTION

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

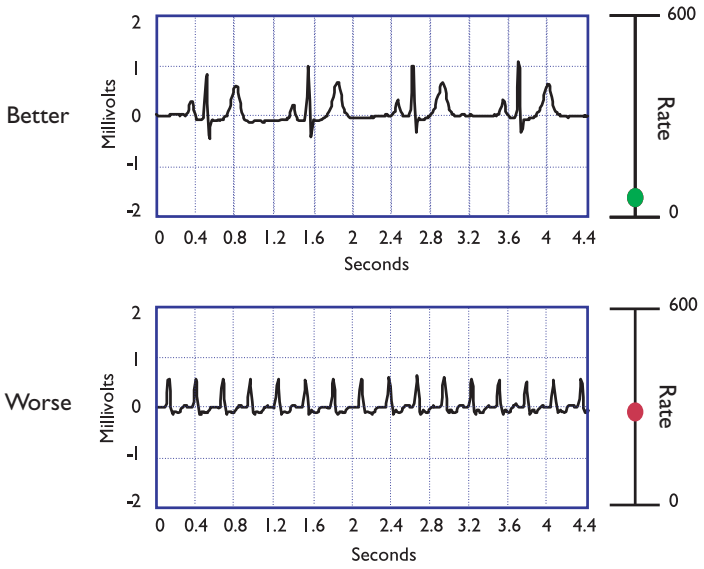
The HeartStart analysis system (SMART Analysis) was developed and tested to ensure that its sensitivity (ability to detect shockable rhythms) and the specificity (ability to detect non-shockable rhythms) exceeded the AHA and AAMI DF80 recommendations. The ECG strips contained in the development database represent hundreds of examples of various rhythms obtained from numerous clinical studies.

To determine if a patient's rhythm is shockable, the SMART Analysis system evaluates four parameters of the ECG in 4.5-second segments. The four parameters are the amplitude, rate, conduction (shape of the QRS complex), and stability of the rhythm (repeatability of the waveform pattern). A brief discussion of each of these parameters follows.

RATE



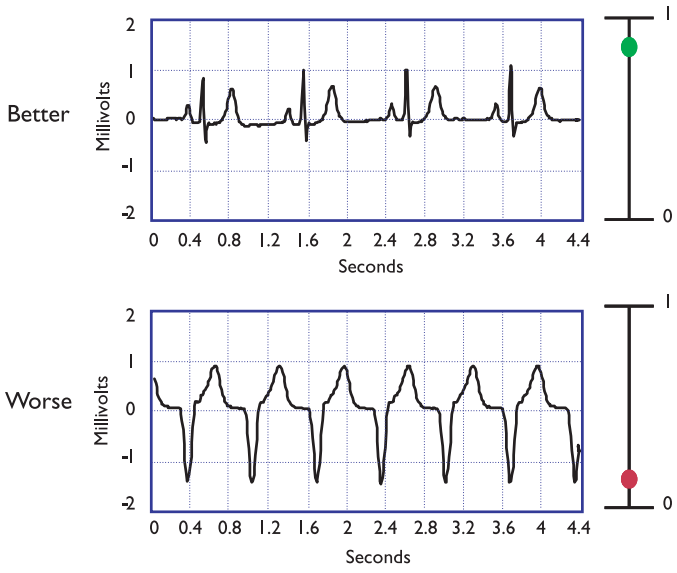
Rate is determined by how many times the heart beats per minute (bpm). A healthy heart beats 60-100 bpm. Some normal rhythms can be very fast. Therefore, it is important to have additional indicators in the analysis system of an AED. Rate is used along with the other parameters to help determine whether 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 SVT) will not be shocked, regardless of the rate.



Rate parameter

CONDUCTION

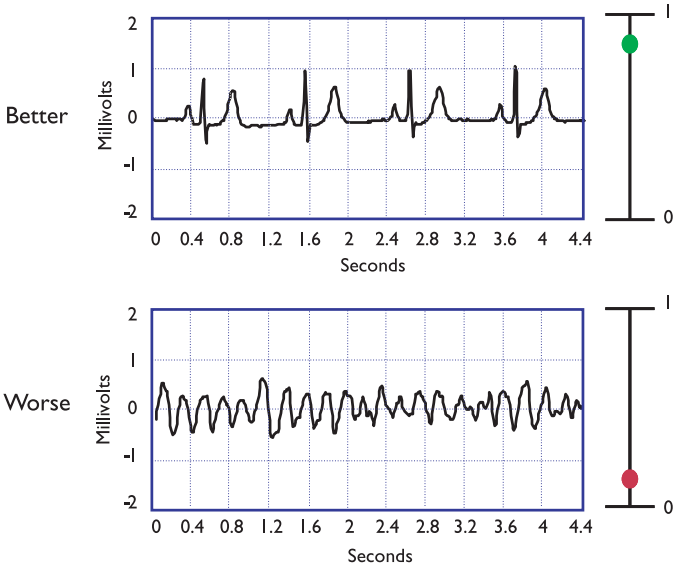
Conduction is determined by examining the R-wave of the QRS complex. Conduction is related to the propagation of electrical impulses through the ventricles. In a healthy heart, the ventricles contract in unison, which is reflected in the ECG by narrow QRS complexes with sharp transitions. Non-perfusing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



Conduction parameter

STABILITY

Stability refers to the repeatability of the morphologies of the various waves of the ECG complexes. The consistency of both the shape of the complex and the period between complexes also indicates whether a rhythm is perfusing. With a perfusing rhythm, the sequential complexes tend to be very similar in shape. A heart in ventricular fibrillation will have chaotic, unstable complexes.

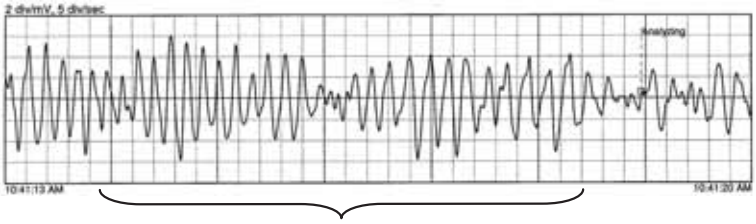


Stability parameter

AMPLITUDE

Amplitude is a measure of magnitude of the heart's electrical activity. A heart that is in asystole, or "flatline," will have a low-amplitude ECG. Amplitude is very dependent on the patient and pads placement and is therefore the least important of the four indicators.

SMART Analysis simultaneously measures the first three indicators above over 4.5 second segments of ECG, and then classifies each segment of ECG as shockable or non-shockable. Amplitude is used as a gating check to determine if a strip is considered shockable; i.e. the 4.5 second strip of ECG must have at least a 100 μV peak-to-peak median amplitude in order for a strip to be considered VF.



4.5 second strip

ANALYSIS CONFIRMATION

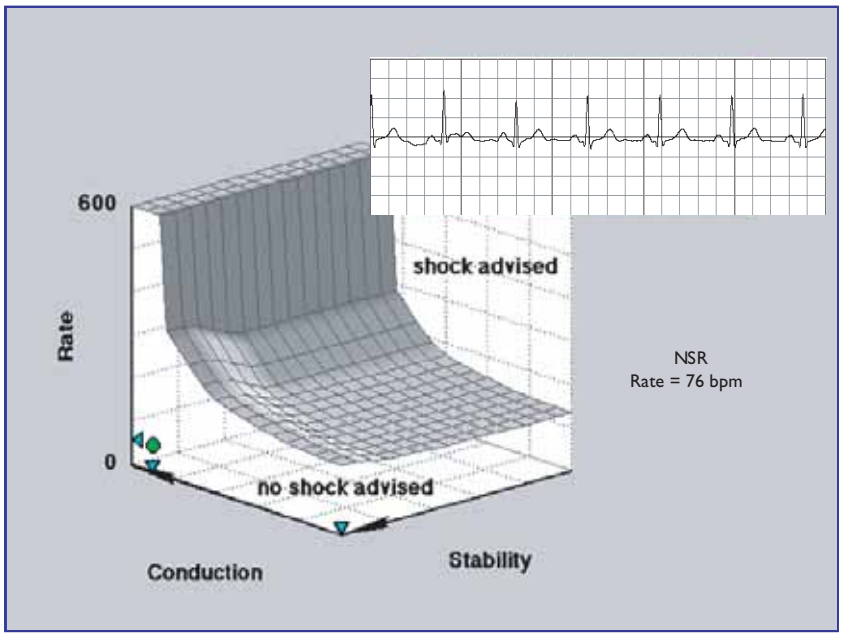
Except when Quick Shock is active, the AED must identify multiple ECG strips as shockable before it will allow the device to arm. The device must then continue to see shockable strips in order to allow a shock to be delivered. HeartStart AEDs differ from other AEDs in that they continue to monitor the ECG even after a shock decision has been made and the unit has charged; this means that the HeartStart AED will react to a change in rhythm and disarm if the rhythm becomes non- shockable.

If the device detects several consecutive strips that are non-shockable, it will give a voice prompt that no shock is advised, inform the user that it is safe to touch the patient, and then transition into "monitor" mode if so configured. The device continues to monitor the ECG, but it will give minimal voice prompts until it identifies another strip as shockable. At this point it will transition back into "analyze" mode where it will direct the user to stop touching the patient and make a decision to shock the patient if appropriate.

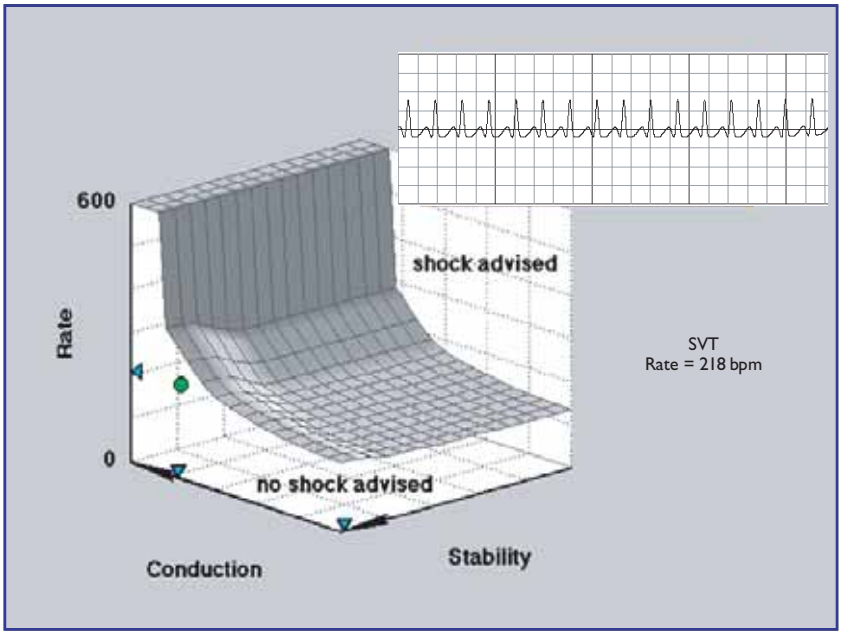
SPECIFIC ANALYSIS EXAMPLES

This method of analysis is applied to the four different ECG examples displayed on the following pages. Each ECG is graphed based on its score for stability, conduction, and rate to determine if a shock is advised or not advised by the algorithm. In the graph below, the shock criteria plane is drawn in grey; any dot above the plane represents a shockable rhythm according to the algorithm, and any dot below is considered a non-shockable

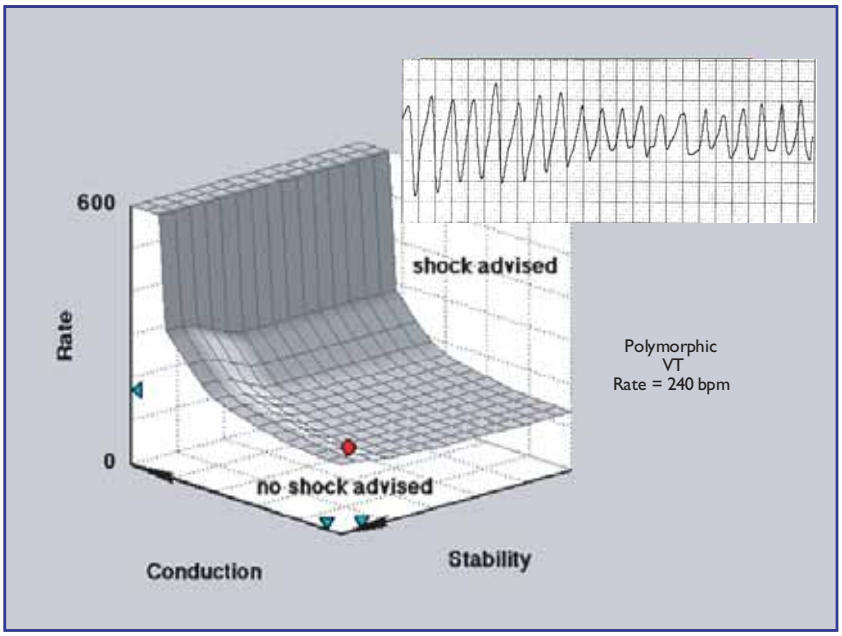
rhythm. Green dots indicate a non-shockable rhythm for the NSR and SVT rhythms, and red dots indicate a shock advised for the polymorphic VT and VF rhythms.



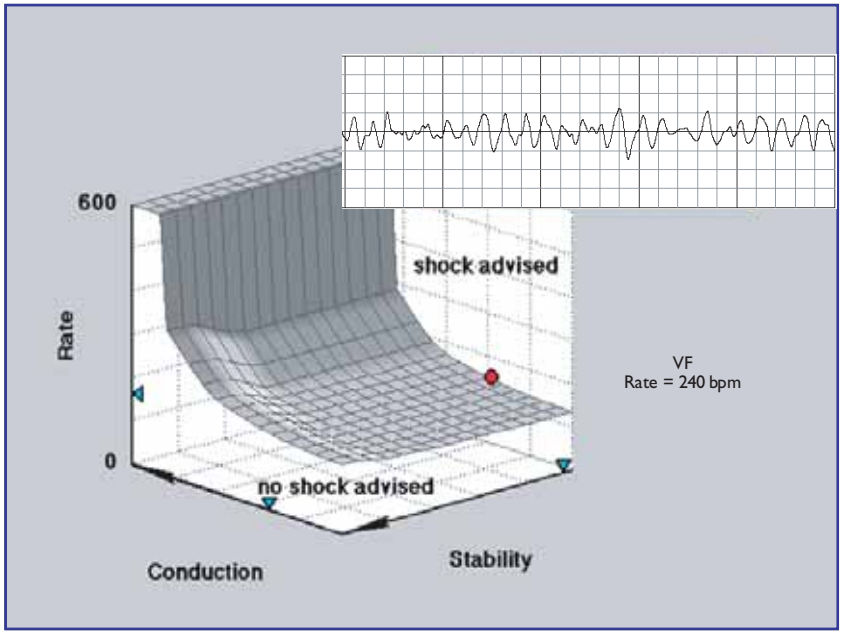
Normal Sinus Rhythm: No-shock advised - excellent stability, conduction, and rate



SVT: No-shock advised - excellent stability and conduction, high rate



Polymorphic VT: Shock advised - poor stability, very poor conduction, high rate



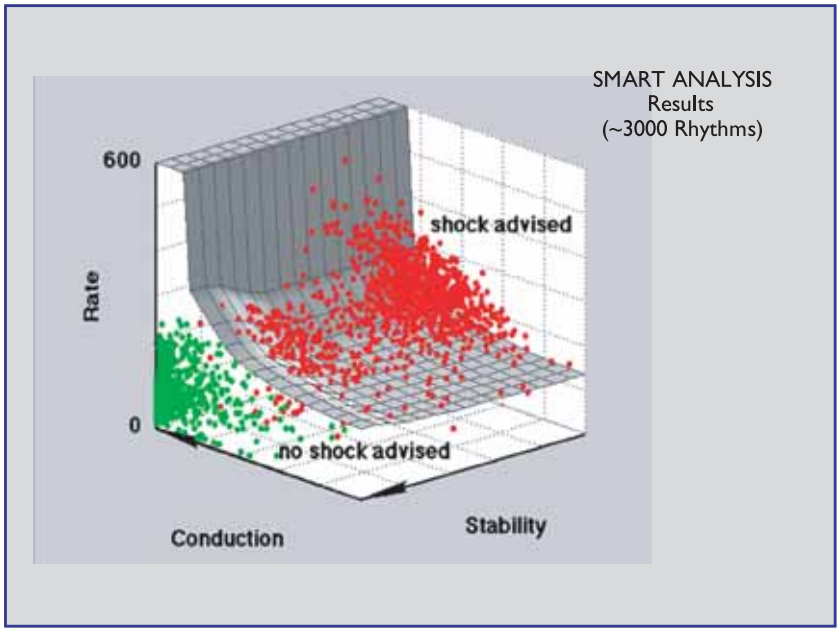
Ventricular fibrillation: Shock advised - very poor stability and conduction, high rate

SENSITIVITY AND SPECIFICITY

In 1997, the American Heart Association published a Scientific Statement[1] that recommends a strategy for evaluating the accuracy of the arrhythmia analysis algorithms incorporated in AEDs. Following the process described in this recommendation, over 3000 ECG strips were collected into a database. This database included both shockable and non-shockable rhythms, and was used to design and validate the SMART Analysis system used in the HeartStart AEDs.

Each strip was reviewed by a group of three cardiologists to determine whether that strip should be considered shockable or non-shockable. If there was disagreement on a particular strip, the cardiologists were asked to discuss the strip and come to a consensus on how to classify the strip. By far, the most disagreements resulted from ventricular tachycardia (VT) strips and were related to whether it was appropriate for an AED to shock this type of VT.

In the following graph, each of the 3000 strips was plotted according to the same criteria as the specific examples discussed above (stability, conduction and rate). If the dot is red, it was considered a shockable rhythm by the cardiologists; if it is green, it was considered a non-shockable rhythm.



Plot of evaluated ECGs shock/no shock decisions against the SMART Analysis parameters

The SMART Analysis algorithm was designed to make aggressive shock decisions concerning VF but to make conservative decisions about shocking

1. Automatic external defibrillators for public access defibrillation: recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. *Circulation.* 1997;95:1677-1682.

VT rhythms that may have an associated pulse. The graph above shows only red dots above the shock-criteria plane, indicating that a shock will be advised only if it is needed.

The figure shows some red dots that fall below the shock criteria plane. In these instances, the algorithm did not advise a shock, but the cardiologists concluded that a shock should be advised. These rhythms are typically intermediate VT that may have some perfusion associated with them. If they are non-perfusing rhythms, they will quickly degrade to the point that they will migrate above the shock-criteria plane and the SMART Analysis system will advise a shock. If the shock criteria were changed so that the plane was shifted to try to catch more of the shockable rhythms below the plane, the algorithm would also advise a shock for a greater number of non-shockable rhythms. The SMART Analysis system was intentionally designed to be conservative in this respect because the specificity of AED algorithms is required to be high.

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 the SMART Analysis system will be to recommend a shock. For example, if a patient, such as an infant with a fast normal sinus rhythm, should have a heart rate of 250 bpm with excellent conduction and stability, the SMART Analysis system would correctly not advise a shock.

SHOCKABLE RHYTHMS

SMART Analysis is designed to shock ventricular fibrillation (VF), ventricular flutter, and polymorphic ventricular tachycardia (VT). These are the most common rhythms associated with sudden cardiac arrest. 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 algorithm used in HeartStart AEDs is different from the algorithm used in the HeartStart manual defibrillators, such as the HeartStart XL and MRx. AEDs are designed to be used by lay rescuers, whereas manual defibrillators are designed to be used by trained medical personnel. The main difference is that the algorithm in an AED should try to differentiate between ventricular tachycardia that has a pulse and one without. The consequence of this is that the HeartStart AEDs are more conservative in shocking intermediate rhythms such as fine VF and VT that don't meet all criteria for inclusion in the shockable VT rhythm category.

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.

SMART Analysis has been designed to be conservative for stable monomorphic tachycardias. The rate threshold for a shockable tachycardia will vary from a minimum of about 160 bpm for rhythms with very slow ventricular-like conduction to a maximum threshold of 600 bpm for rhythms with healthy normal conduction. Thus, rhythms with normal conduction will not be shocked regardless of the rate.

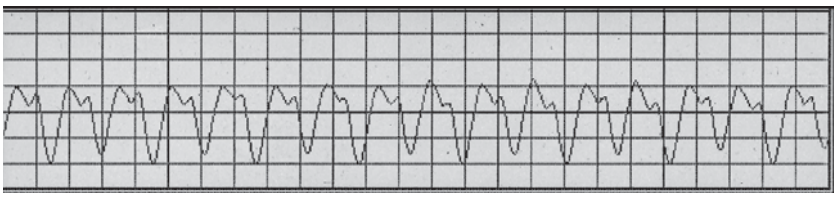
The AHA has issued a Scientific Statement clearly identifying SVT as a non-shockable rhythm, and requiring a minimum defibrillator algorithm specificity of 95% for this rhythm.[1] This high-specificity requirement assumes that a high-quality assessment of perfusion status has been made, thereby eliminating many SVTs from analysis by the defibrillator. The HeartStart 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 beats per minute.

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

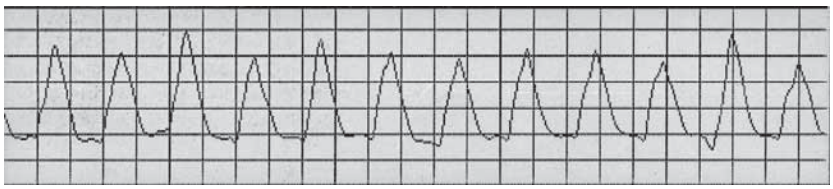
This adaptive design allows the rate threshold to be varied from a minimum level for the most lethal VF rhythms, providing very high sensitivity, to increasingly higher rate thresholds as the stability or conduction characteristics approach normal, providing very high specificity. Borderline rhythms,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

Two samples of monomorphic tachycardia are shown below as examples of borderline rhythms that do not require shocks. Both of these rhythms are of supraventricular origin, with one known to be accompanied by a pulse. SMART Analysis gives a no-shock recommendation for both of these rhythms.

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.

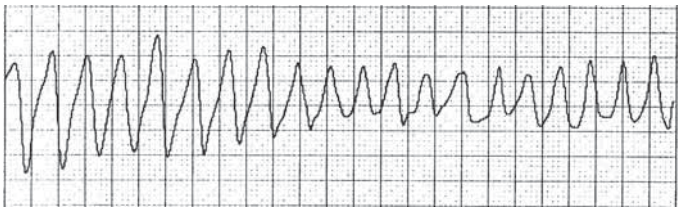


Rate ~ 192 bpm No Shock Advised

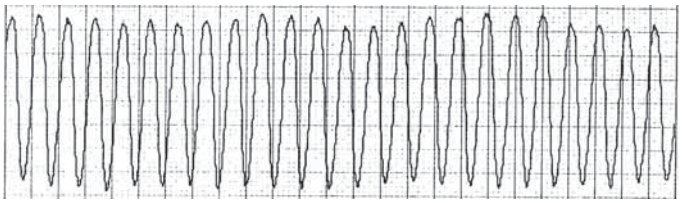


Rate ~ 144 bpm No Shock Advised

The next two samples are examples of polymorphic VT and flutter. These rhythms represent ECGs that are not associated with a pulse and are considered shockable forms of VT.



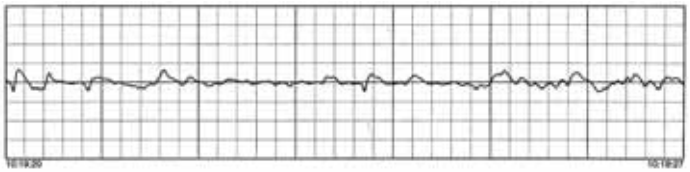
Rate ~ 240 bpm Shock Advised



Rate ~ 288 bpm Shock Advised

The FR3 *Instructions for Administrators* states that, 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 next example of VF shown 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. (See Chapter 5 for a discussion of CPR First in the FR3 AED.) CPR tends to oxygenate the myocardium and increase the electrical activity of the heart, making it more susceptible to defibrillation.



Fine VF No Shock Advised

VALIDATION OF ALGORITHM

Algorithm performance is evaluated by two criteria: sensitivity, which is the ability of the algorithm to detect life-threatening ventricular arrhythmias, and specificity, which is the ability of the algorithm to discriminate life-threatening arrhythmias from normal rhythms or arrhythmias that should not be shocked. Philips developed a proprietary electrocardiogram (ECG) analysis system that provides an exceptional level of sensitivity and specificity.

rhythm class	HeartStart AED validation results[a] meets AHA recommendations[b] for adult defibrillation				
	AAMI DEF80 requirement[b]	observed performance validation results[c]	artifact-free	artifact included	90% one-sided lower confidence limit[b]
Shockable Rhythm — Ventricular Fibrillation	Sensitivity >90%	97% (n=300)	99.1% (n=106)	97.3% (n=111)	(87%)
Shockable Rhythm — Ventricular Tachycardia	Sensitivity >75%	81% (n=100)	100% (n=9)	90% (n=10)	(67%)
Non-shockable Rhythm — Normal Sinus Rhythm	Specificity >99%	100% (n=300)	100% (n=15)	100% (n=17)	(97%)
Non-shockable Rhythm — Asystole	Specificity >95%	100% (n=100)	100% (n=53)	100% (n=64)	(92%)
Non-shockable Rhythm — All Other Non-shockable Rhythms	Specificity >95% includes: SVT (R>100), SVD (R≤100), VEB, Idioventricular, and Bradycardia	100% (n=450)	99% (n=101)	95.6% (n=114)	(88%)

a. 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 significantly better, thereby validating Heartstream's rigorous pre-market testing of its algorithm.
b. 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.
c. From Philips Medical Heartstream ECG rhythm databases.

In the original, out-of-hospital study involving 100 patients,[1] the SMART Analysis system correctly identified all patients in VF (100% sensitivity) and correctly identified and did not shock all patients in non-VF rhythms (100% specificity). Borderline rhythms are reviewed periodically to determine if the algorithm should be fine-tuned in future products.

For example, in preparation for introducing the pediatric defibrillation electrodes for the HeartStart FR2 AED, a database was assembled that included 696 pediatric arrhythmias. When the HeartStart SMART Analysis system was tested on the ECG strips in this database, the authors of the study concluded, "There was excellent AED rhythm analysis sensitivity and specificity in all age groups for ventricular fibrillation and non-shockable rhythms. The high specificity and sensitivity indicate that there is a very low risk of an inappropriate shock and that the AED correctly identifies shockable rhythms, making the algorithm both safe and effective for children."[2]

SPECIFIC CONCERNS FOR ADVANCED USERS OF HEARTSTART AEDS

HEARTSTART AED VS. HEARTSTART ALS DEFIBRILLATOR ALGORITHMS

The algorithm designed specifically for HeartStart AEDs differs somewhat from the algorithm designed for HeartStart ALS defibrillators, such as the XL and the MRx. AEDs are designed to be used by lay rescuers as well as trained EMS personnel and medical professionals, whereas manual defibrillators are designed to be used only by trained medical personnel. Because AEDs are designed to be used in circumstances that require delivery of therapy without the advice of a medical professional, the algorithm must differentiate between pulsed and pulseless tachycardia.

It is important for Medical Directors of defibrillator programs to be aware of these differences in rhythm analysis. HeartStart AEDs are 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. Therefore, HeartStart ALS defibrillators will advise a shock on some VT rhythms that the HeartStart AEDs consider non-shockable. This difference may affect decisions concerning the deployment of both AEDs and ALS defibrillators and the kind of training provided for their use.

1. Jeanne Poole, M.D., 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.
2. Cecchin F, et al. Is arrhythmia detection by automatic external defibrillator accurate for children? *Circulation*, 2001; 103:2483-2488.

ADVANCED MODE

For physicians, paramedics, and other advanced users who are qualified to evaluate intermediate rhythms (e.g., fine VF, monomorphic VT) and advise the delivery of a shock, the FR3 can be configured for Advanced Mode. For the FR3 ECG model 861389, Advanced Mode permits manual control of the analyze and shock charge functions. For the FR3 text model 861388, Advanced Mode permits manual control of the analyze function only. It is important that qualified users be trained in how to use these functions. The FR3 was designed to minimize access of these features for the lay user.

The FR3 should only be configured for advanced mode use if authorized by the Medical Director of the AED program, and configuration should be done under the supervision of the Medical Director. Changes to the default configuration of the FR3 requires use of HeartStart Configure software, available separately from Philips.

Directions for using Advanced Mode functions are provided in the *Instructions for Administrators* provided with the FR3 AED.

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, these devices only store a few seconds of ECG signal that is repeated over and over again. This apparent stability can cause the FR3 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 system 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 system. Polymorphic VTs are considered shockable at lower rates because there is variation in the shape of the QRS complexes.

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

USE OF EXTERNAL PACEMAKERS WITH INTERNAL LEADS

In some countries, it is common practice after open-heart surgery to leave internal leads on the heart to be used with an external pacing device if needed during recovery. These external pacers have different characteristics from implantable pacemakers and can, therefore, interfere with proper analysis of an AED algorithm.

External pacing and defibrillation are two different therapies and should not be performed at the same time. If an external pacer is being used on a patient who goes into cardiac arrest, the pacer should be turned off or disconnected from the patient before the AED is applied to the patient. Failure to do so may result in delayed or incorrect analysis by the AED.

5 OTHER FEATURES

OVERVIEW

The FR3 is intended mainly for lay rescuers and BLS providers, but it contains Advanced Mode features for use by ALS trained personnel. The AED is shipped with default parameter settings that comply with the Guidelines 2010. However, it is extensively configurable.

SELF-TESTS

The HeartStart FR3 AED is designed to minimize required maintenance by using extensive self-tests to simplify the maintenance process. The user is not required to perform calibration or energy verification, either before the AED is put into service or at regular intervals. Maintenance testing is not required, because the FR3 automatically monitors its performance during a use and automatically performs periodic self-tests while in standby mode. These include daily, weekly, and monthly self-tests of respectively increasing detail to verify readiness for use. By visually checking the Ready light daily, the user can verify that the AED has passed a self-test within the last 24 hours and is therefore ready for use.

USER-INITIATED TEST

AUTOMATIC USER-INITIATED TEST

- The first time you install a battery, the FR3 will automatically run a user-initiated test.[1]
- This detailed test will also run automatically anytime the battery is installed after having been out of the FR3 long enough that the clock time has been lost. This time period can range from 2 to 24 hours.
- The FR3 automatically runs the user-initiated test if the FR3 has a failure condition when the battery is installed.
- The FR3 automatically runs the user-initiated test when the last time the FR3 was turned on was to complete language and/or configuration loading.

MANUAL USER-INITIATED TEST

You can also run the user-initiated test at any time. However, as long as the green Ready light is flashing and the FR3 is not chirping, it is NOT necessary to test the defibrillator by initiating a test. This uses battery power and drains the battery prematurely.

1. This is the FR3 user-initiated equivalent of the automatic battery insertion test (BIT) used for HeartStart ForeRunner and FR2 defibrillators.

Philips recommends you initiate the test after each use of the device. The FR3 prompts you to run the test if it detects a problem during routine self-testing.

Directions for running the user-initiated test are provided in the *Instructions for Administrators* and in the *Guide to Setup, Operation, and Maintenance* provided with the FR3 AED.

READY LIGHT

The FR3's green Ready light is the primary indicator of device readiness for use. If the Ready light is flashing, the FR3 has passed its most recent self-test or user-initiated test and is therefore ready for use. If the Ready light is on steady, the FR3 is in use or is running a periodic self-test. The following table lists conditions where the Ready light is off, and recommended action.

INDICATOR	RECOMMENDED ACTION
Ready light is off and the FR3 is chirping	If the FR3 is emitting single chirps, press the On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen for information about the status of the FR3 and how to resolve the problem. If the FR3 is emitting triple chirps, press the On/Off button once. If an error message is displayed on the status screen, record the error, turn off the FR3, and remove it from service. Then contact Philips at www.philips.com/AEDSupport for technical support.
Ready light is off, the FR3 is not chirping, and the display screen is blank	The battery is depleted or missing, or the FR3 needs repair. Insert or replace a battery. The FR3 automatically runs a power-on self-test. If the green Ready light starts flashing, the FR3 has passed the self-test and is therefore ready for use. If not, contact Philips at www.philips.com/AEDSupport for technical support.

PERIODIC SELF-TESTS

As long as a battery is installed in the FR3 AED, the unit automatically performs a self-test at least once every 24 hours. An exception to this is when the unit is stored outside of its operating temperature range. The device should not be stored outside of its specified temperature range. In the event that it is, the AED will wait until its temperature is within specified limits before it resumes self-testing. This allows it to automatically reschedule self-testing to avoid, for example, a particularly cold time of night.

There are three different periodic self-tests: daily, weekly, and monthly. The main difference among these tests is the extent of front end and waveform delivery circuitry tested and the energy level used. The monthly periodic self-test is the equivalent of the user-initiated test, but without the user interactive part of the test. Test coverage is shown in Table 1, below.

During the tests, the various lights on the device will briefly light, the display will show various test patterns, and the unit may emit a soft click as its relays are tested. If the AED is stored within its carrying case, it is unlikely that any of this activity will be noticeable.

If the Ready light is flashing, the FR3 has passed its most recent self-test or user-initiated test and is therefore ready for use. If a written record of the periodic check is required, the visual check can be noted in an Operator's Checklist. A sample checklist is provided in the *Instructions for Administrators* shipped with the FR3. In addition, HeartStart Event Review Software, available from Philips, can be used to print a self-test report.

FR3 SUBSYSTEM	DAILY SELF-TEST	WEEKLY SELF-TEST	MONTHLY SELF-TEST	USER-INITIATED TEST
Battery	Battery Capacity Check - Measures remaining battery capacity to warn user when the battery becomes low or is temporarily low due to having been stored below its operating temperature range. The instrument will provide at least 15 minutes of monitoring and 9 shocks after the low battery indication is first displayed.			
Computer and Data Processing	Memory and Microprocessor Integrity Check - Checks the RAM, ROM, microprocessor and custom integrated circuits developed by Philips. The executable program in ROM is verified using a 32-Bit Cyclical Redundancy Check algorithm capable of detecting both single and multi-bit errors.			
Power Supplies and Measure-ment Standards	Voltage Reference Check - Cross checks two independent voltage reference standards. These voltage references are traceable to NIST (National Institute of Standards and Technology) when the instrument is manufactured, and they are checked against each other each day over the life of the instrument. Time Base Reference Check - Cross checks two independent system clocks. These time references are traceable to NIST when the instrument is manufactured, and they are checked against each other each day over the life of the instrument. System Power Supply Voltage Check - Checks the internal power supply voltages used to operate the instrument.			

FR3 SUBSYSTEM	DAILY SELF-TEST	WEEKLY SELF-TEST	MONTHLY SELF-TEST	USER-INITIATED TEST
ECG Rhythm Analysis System	Patient ECG Front End Functional Test — Verifies the integrity of the ECG front end signal path.	Patient ECG Front End Calibration — Measures 24 different parameters of the ECG front end circuitry including gain, bandwidth, phase error, offset voltage, and internal system noise.		
AED biphasic waveform delivery system	Biphasic Waveform Delivery System Functional Test — Performs a functional low-energy test shock and verifies all 16 possible states of the biphasic waveform control circuitry. Also, it checks the functionality of the high voltage solid state switches, the high voltage charger, and the patient isolation relay.		Biphasic Waveform Delivery System Calibration — Performs a calibrating test shock (full 150 J) into an internal test load and measures 16 parameters of the Biphasic Waveform Delivery System. Measurements include: energy storage capacitance, full charge voltage, capacitor leakage power, maximum and minimum shockable patient impedance limits, internal dynamic impedance, and patient impedance sense accuracy.	
User Interface				User Interactive Tests — FR3 prompts the user to verify the buttons, LCD display, LED indicators, and speaker.

"POWER ON" AND "IN USE" SELF-TESTS

When the FR3 AED is first turned on, it executes a test to help ensure that the device is ready to use. This test checks the battery to ensure that there is at least enough energy for a typical patient use. It also verifies that the software has not been corrupted and that the system timing is correct. In

addition to this initial power on test, the device periodically checks a number of other parameters while the AED is in use to confirm the unit is functioning properly. These tests are summarized in the table below.

FR3 SUBSYSTEM	POWER ON SELF-TEST	IN-USE SELF-TEST
Battery	Battery Capacity Check — Measures remaining battery capacity to warn user when the battery becomes low. The instrument will provide at least 15 minutes of monitoring and 9 shocks after the low battery indication is first displayed.	
Computer and Data Processing	Program Code Verification — Verifies the executable program in ROM before allowing use of the instrument.	Program Sanity Monitor — Verifies that the computer is executing its program in a controlled manner. If the program ever becomes unsafe, the instrument will shut down.
Power Supplies and Measure-ment Standards	Time Base Reference Check — Cross checks two independent system clocks. These time references are traceable to NIST when the instrument is manufactured, and they are checked against each other each day over the life of the instrument.	System Power Supply Voltage Check — Checks internal power supply voltages used to operate the instrument.
ECG Rhythm Analysis System		Voltage Reference Check — Cross checks two independent voltage reference standards. These references are traceable to NIST when the instrument is manufactured, and they are checked against each other each day over the life of the instrument. Patient ECG Front End Functional Check — Verifies the integrity of the ECG front end signal path.
AED Biphasic Waveform Delivery System		Biphasic Waveform Delivery System Safety Check — Verifies that the biphasic waveform delivery system is functioning safely. Uses redundant energy monitoring to ensure correct energy.

FR3 SUBSYSTEM	POWER ON SELF-TEST	IN-USE SELF-TEST
User Interface		Shock Button Safety Test — Tests the Shock button through two independent signal paths to ensure that the paths are consistent and that the Shock button is not stuck.

CUMULATIVE DEVICE RECORD

The Cumulative Device Record (CDR) contains a list of the events that the FR3 AED has experienced during the life of the device. The first event is stored when the software is loaded during the manufacturing process. Each time the device is turned on, one or more events are appended to this list.

The CDR was designed primarily for troubleshooting purposes and stores the results of each self-test in non-volatile memory in the AED. The CDR stores information from each use of the device such as the presenting ECG, elapsed time of the use, number of shocks delivered, pads condition, and the number of shock and no-shock decisions made during each use. It does not store audio recording.

This information is relatively easy to download, but was not designed for interpretation by the user. In the troubleshooting process, Philips will occasionally ask a customer to download the information on a data card and send it back to Philips to be analyzed by Philips personnel.

SUPPLEMENTAL MAINTENANCE INFORMATION FOR TECHNICAL PROFESSIONALS

CALIBRATION REQUIREMENTS AND INTERVALS

The FR3 AED does not require user calibration or verification of energy delivery prior to placing it in service. Further, the FR3 does not require user calibration at regular intervals, including annual intervals.

MAINTENANCE TESTING

Maintenance testing is unnecessary because the FR3 automatically perform daily self-tests and correct operation is verified during user-initiated tests. When the green Ready light is flashing, this means that daily, weekly and monthly self-tests are operating as scheduled and that the unit has passed the most recently scheduled self-test.

VERIFICATION OF ENERGY DISCHARGE

The FR3 does not require manual verification of energy delivery because monthly automatic self-tests verify the waveform delivery system. However, if desired, a qualified technical professional can test FR3 AED energy delivery, using instructions found on page B-12 of this document. Improper testing can seriously damage the AED and render it unusable.

SERVICE/MAINTENANCE AND REPAIR MANUAL

The FR3 AED has no user-serviceable parts, and Philips is the sole repair facility for the unit. As a result, Philips does not publish Service/ Maintenance and Repair Manuals for these products.

CONFIGURATION

The FR3 defibrillator comes with a factory default configuration designed to meet the needs of most users. If desired, your Medical Director can revise the setup. There are several ways to change the setup of the HeartStart FR3. All of them require use of products or accessories available separately from Philips.

For directions on how to modify the FR3 configuration, see the *Instructions for Administrators* shipped with the FR3.

The following table provides an overview of the modifications you can make using the FR3 administration mode, an FR3 language card,[1] and/or the HeartStart Configuration software.

MODIFICATION	FR3 only, in Admin. Mode	FR3 Language Card[a]	HeartStart Configure	Wireless Trans-ceiver Module
Change device operation *(except primary language and bilingual option)*: self-test options, patient care, defibrillation, and advanced mode parameters	✓		✓	✓
Change primary language only		✓		

1. The FR3 language card is provided with certain versions of the FR3 and is also available separately. If parameter configuration changes other than language are desired, an FR3 data card can be used instead of the language card.

MODIFICATION	FR3 only, in Admin. Mode	FR3 Language Card[a]	HeartStart Configure	Wireless Trans-ceiver Module
Enable bilingual option and select secondary language		✓	✓	
Set FR3 date and time	✓		✓	✓
Use computer date and time for FR3			✓	✓

a The FR3 language card is provided with certain versions of the FR3 and is also available separately. If parameter configuration changes other than language are desired, an FR3 data card can be used instead of the language card.

Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.

NOTE: The configuration features discussed here are for FR3 software version 1.0. The following tables present the settings for configuration parameters that are not directly related to the patient care protocol. Default settings are indicated by an asterisk (*).

LANGUAGE SELECTION PARAMETERS

The FR3 can operate in any of several available languages. If you want to configure the FR3 to a non-default language, you must have the FR3 language card. The FR3 language card is provided with certain versions of the FR3 and is also available separately. If parameter configuration changes other than language are desired, an FR3 data card can be used instead of the language card. If you want to enable bilingual operation and/or make other configuration changes, you need both the language card and the HeartStart Configure software.

For detailed information about device operation for these parameters, see the *Instructions for Administrators* provided with the FR3. Default settings are identified with an asterisk in the following tables.

PARAMETER	SETTINGS	DESCRIPTION
Primary Language	* U.S. English, U.K. English, or Japanese (depending on model) • any on language card	Sets the language used for FR3 text and voice prompts.

PARAMETER	SETTINGS	DESCRIPTION
Bilingual Option	* off • any on language card	Disables (OFF) or enables (ON) use of a secondary language for optional activation by a responder in an emergency. *NOTE: To select the bilingual option, the FR3 language card must be installed in a computer equipped with HeartStart Configure.*

DEVICE OPERATION PARAMETERS

The device operation parameter settings determine the basic setup of the FR3, irrespective of the selected patient care parameters.

PARAMETER	SETTINGS	DESCRIPTION
Volume	* loud • medium • soft	Sets the FR3 speaker volume.
ECG Display (FR3 model 861389 only)	* on • off	Enables (ON) or disables (OFF) display of the patient's ECG on the FR3 screen.[a]
Record Audio	• on * off	Enables (ON) or disables (OFF) audio recording on the data card during use. *NOTE: Metronome audio beats, if enabled, will mask ambient sounds during CPR in the Record Audio data.*
Wireless PIN	* 2071 • custom	Sets use of default *Bluetooth* wireless technology personal identification number (PIN) or a custom PIN created by Administrator using HeartStart Configure. Activation of a custom PIN requires turning the FR3 off and then on. *NOTE: Required for use with the optional wireless transceiver module.* *NOTE: For security reasons, the FR3 does not display the PIN. In the Administration mode's VIEW SETUP, the PIN is shown as "Default" if never changed, or "****" if customized.*

a Even if ECG display is disabled in the FR3 model 861389, if the advanced use mode is selected, the FR3 screen displays the ECG.

SELF-TEST OPTIONS PARAMETERS

The FR3 can be configured to test for the presence of certain pre-connected accessories during its periodic self-tests (PST) and user-initiated test (UIT). The default setting is OFF; if the accessory is not detected, the self-test does not fail. However, if the self-test for an accessory is configured to ON and the FR3 does *not* detect the accessory, it provides alert chirps.

NOTE: The FR3 automatically tests the functional integrity of any detected accessory during the PST, even if the test for its *presence* is configured to OFF. This gives Administrators a tool that helps ensure the accessories they want used are in place and ready for use.

PARAMETER	SETTINGS	DESCRIPTION
Test Pads	• on * off	Enables (ON) or disables (OFF) testing for the presence of pre-connected pads during each self-test.
Test Data Card	• on * off	Enables (ON) or disables (OFF) testing for the presence of an installed data card during each self-test.

PATIENT CARE PARAMETERS

The FR3 is designed to follow a patient care protocol defined by the parameters in the following tables. The default settings are optimized for compliance with Guidelines 2010. Changes to the FR3 configuration should be done by or under the supervision of a Medical Director, using the HeartStart Configure software.

Because many of the patient care protocol parameters interact with each other, it is important to understand how each parameter affects the protocol. The description of each parameter identifies any interacting parameters, indicated by underlined text.

TYPES OF CPR PROTOCOLS

The FR3 provides three kinds of separately configurable CPR protocols. The kind of CPR protocol applied depends on its context in the patient care cycle.

- Basic CPR — *Upon completion of a shock series*[1], *or upon use of a configured CPR option button during rhythm analysis*, the FR3 provides a CPR protocol.
- CPR First — The FR3 provides a CPR protocol *before defibrillation therapy*, based on the selected SMART CPR algorithm or the User setting.

1. FR3 default shock series is one shock.

- NSA CPR — *After a no shock advised (NSA) decision,* the FR3 provides an attend-to-patient period with a CPR option button or, if NSA CPR is configured ON, an NSA CPR protocol.

Each of these three protocol types can also be configured separately for adult and infant/child applications, for a total of six distinct CPR protocols.

CPR PROTOCOL PARAMETERS

The CPR protocol parameters for the FR3 are either "general" or "specific." General CPR parameters apply to all CPR protocols. Specific CPR parameters apply to each CPR protocol individually.

The following tables present the available settings, default setting, and a description of each general and specific CPR protocol parameter. Default settings are indicated by an asterisk (*).

GENERAL CPR PARAMETERS

Unless otherwise noted, these parameters pertain to *all* adult and infant/child CPR protocols (Basic CPR, CPR First, and NSA CPR) initiated by the FR3. If you change a general CPR parameter setting, it will be applied to every CPR protocol.

NOTE: CPR protocols are time-based, using the selected CPR duration setting.

PARAMETER	SETTINGS	DESCRIPTION
Metronome	• on * off	Enables (ON) and disables (OFF) audio beats for CPR compressions. *NOTE: Metronome audio beats, if enabled, will mask ambient sounds during CPR in the Record Audio data.*
CPR First	* off • SMART CPR auto1 • SMART CPR auto2 • user	Sets whether the FR3 provides an interval for CPR prior to defibrillation, in the first rhythm analysis in a use. For details on settings, selection criteria, and device operation for this parameter, see Appendix D, "SMART CPR," of the *Instructions for Administrators* provided with the FR3. NOTE: The **Analyze option button** is always available in any CPR First protocol. Press the button to initiate FR3 analysis of heart rhythm.

PARAMETER	SETTINGS	DESCRIPTION
CPR Option Button	• on * off	Enables (ON) or disables (OFF) ability to initiate a Basic CPR protocol, by pressing the designated option button, when active during rhythm analysis or a shock-related sequence, on the front panel of the FR3.
Analyze Option Button	• on * off	Enables (ON) or disables (OFF) ability to interrupt a CPR protocol, NSA monitoring, or attend-to-patient period and resume rhythm analysis, by pressing the designated option button on the front panel of the FR3.
NSA Action	* NSA CPR • NSA monitor	Sets FR3 available behavior during the attend-to-patient period that follows any NSA (no shock advised) decision. During this period, the responder may perform CPR or otherwise attend to the patient, as needed. For details on settings, selection criteria, and device operation for this parameter, see Appendix E, "NSA Action," of the *Instructions for Administrators* provided with the FR3. *NOTE: When configured to NSA CPR, the FR3 enables configuration of NSA CPR Coaching for use during the attend-to-patient period. NSA CPR Coaching settings are ALWAYS and USER.*
NSA CPR Coaching	* User • Always	Available only when NSA Action is configured to NSA CPR. Allows selection of NSA CPR Coaching following an NSA decision, either at user discretion (USER) or ALWAYS. For details on settings, selection criteria, and device operation for this parameter, see Appendix E, "NSA Action," of the *Instructions for Administrators* provided with the FR3.
NSA Monitor Prompt Repeat Rate (minutes)	* 1.0 • 2.0 • 3.0 • infinite	Sets the repeat rate for patient care prompts provided by the FR3 during monitoring, only when NSA action is set to MONITOR. *NOTE: Selection of INFINITE means that no repeat prompting will be provided during background monitoring.*

PROTOCOL-SPECIFIC CPR PARAMETER

The CPR Duration parameter can be configured separately for each adult and infant/child CPR protocol.

PARAMETER	SETTINGS	DESCRIPTION
Adult Basic CPR Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the CPR protocol for adult Basic CPR.
Adult CPR First Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the CPR protocol for adult CPR First.
Adult NSA CPR Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the adult attend-to-patient period for the adult NSA CPR protocol.
Infant/Child Basic CPR Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the CPR protocol for infant/child Basic CPR.
Infant/Child CPR First Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the CPR protocol for infant/child CPR First.
Infant/Child NSA CPR Duration (minutes)	• 1.0 • 1.5 * 2.0 • 2.5 • 3.0	Sets the length of the attend-to-patient period for the infant/child NSA CPR protocol.

DEFIBRILLATION PARAMETERS

These parameters govern the number of and time between defibrillation shocks in a shock series. The FR3 uses a biphasic shock waveform. The shock therapy level is not configurable. When you insert the optional Infant/Child Key in the FR3, the FR3 reduces the therapy dose to a level more appropriate for infants and children.

PARAMETER	SETTINGS	DESCRIPTION
Shock Series (number of shocks per stack)	* 1 • 2 • 3 • 4	Sets the number of shocks in a series that must be delivered before the FR3 automatically activates a Basic CPR protocol. A new shock series begins when a shock is delivered: • after the FR3 is turned on • after a completion of any CPR protocol • if the time since the previous shock exceeds the shock series interval setting (when the shock series setting is more than one).
Shock Series Interval (minutes)	* 1.0 • 2.0 • infinite	Sets the time interval used to determine if a delivered shock should be counted as part of the current shock series. This parameter applies only when the shock series setting is greater than 1. *NOTE: Selection of infinite means that the shock protocol will not time out until the configured number of shocks per stack (shock series) has been delivered.*

ADVANCED MODE PARAMETERS

The advanced mode is intended for use by authorized operators only. When configured to ON, advanced mode use allows manual override of certain FR3 functions and configuration of the prompt repeat rate. See the *Instructions for Administrators* provided with the FR3 for instructions on using the advanced mode.

PARAMETER	SETTINGS	DESCRIPTION
Advanced Mode Use	• analyze • charge * off	Enables (ANALYZE and CHARGE) or disables (OFF) advanced mode. ANALYZE — The FR3 permits user-initiated rhythm analysis when the advanced mode is entered by pressing the ANALYZE option button. CHARGE — The FR3 permits user-initiated rhythm analysis, plus charge, shock delivery, and disarm when the advanced mode is entered, by pressing the CHARGE option button. *NOTE: The CHARGE setting is available for FR3 ECG model only.*
Advanced Use Prompt Repeat Rate (minutes)	* 0.5 • 1.0 • 2.0	Sets the repeat rate for patient care prompts provided by the FR3 when advanced mode use is configured to ANALYZE or CHARGE.

QUICK SHOCK

The HeartStart FR3 is able to deliver a shock in less than 8 seconds, typical, from the end of the "Stop CPR" prompt to armed state for shock delivery.

It is now well known that for longer down time patients, e.g., longer than 5 minutes, good CPR prior to defibrillation shock can help restore a normal heartbeat in more patients.[1,2] The beneficial effect of CPR disappears very rapidly once it is stopped, so time to shock is very important.[3,4]

Quick Shock helps by reducing the interruption of CPR chest compressions and increasing the chance that a shock will result in a successful return to spontaneous circulation. Two independent articles published in *Circulation* support Quick Shock. In one article, Dr. Yu et al, concluded, "Interruptions of precordial compression for rhythm analyses that exceed 15 seconds before each shock compromise the outcome of CPR and increase the severity of post resuscitation myocardial dysfunction."[3] A second study by Dr. Eftestol et al., similarly concluded "The interval between discontinuation of chest compressions and delivery of a shock should be kept as short as possible."[4] Simply put, getting a shock to the heart as soon as possible after CPR can save more lives.

1. Cobb LA, Fahrenbruch CE, Walsh TR, et al. Influence of cardiopulmonary resuscitation prior to defibrillation in patients with out-of-hospital ventricular fibrillation. *JAMA*. 1999 Apr 7; 281(13):1182-8.
2. Wik L, Hansen TB, Fylling F, et al. Delaying defibrillation to give basic cardiopulmonary resuscitation to patients with out-of-hospital ventricular fibrillation: A randomized trial. *JAMA*. 2003 Mar 19; 289(11):1389-95
3. Yu T, Weil MH, Tang W. Adverse outcomes of interrupted precordial compression during automated defibrillation. *Circulation.* 2002; 106:368-372.
4. Eftestol T, Sunde K, Steen PA. Effects of interrupting precordial compressions in the calculated probability of defibrillation success during out-of-hospital cardiac arrest. *Circulation*. 2002;105:2270-2273.

SMART CPR

Philips has augmented the HeartStart AED's well proven patient analysis logic with SMART CPR, a feature that provides a tool for Medical Directors and Administrators to implement existing or emerging protocols using the CPR First parameter. Currently, some emergency response protocols incorporate a CPR interval prior to applying the AED. Although this provides for initial CPR treatment, since the device is not attached to the patient it cannot collect data or provide the responder with prompts or an initial CPR interval.

Until recently, immediate defibrillation with an automated external defibrillator (AED) was the general rule. However studies now show the benefit of providing one to two minutes of quality CPR prior to a defibrillation shock if the response time to the patient is greater than five minutes.[1,2,3] Unfortunately, it is often not possible for responders to determine on arrival how long the patient has been down.

When the CPR First setting is configured to SMART CPR AUTO1 or AUTO2 in the FR3, the defibrillator uses a separate, more refined treatment algorithm to evaluate key attributes of the patient's presenting heart rhythm and advises whether to initially treat shockable rhythms such as ventricular fibrillation (VF) with a shock, or with CPR immediately followed by a shock. (See discussion of settings on following pages.)

If a patient in VF is likely to experience a return of circulation with a shock (as is typical of short duration VF), the FR3 advises an immediate shock. Otherwise, the FR3 advises CPR prior to a shock. SMART CPR is designed to help responders make better-informed, more refined customized treatment decisions. It supports an emerging response protocol that current scientific literature suggests may improve survival for more patients.

Patients with some VF rhythms respond well to a shock and achieve a return of circulation. If the VF rhythm is of high frequency and amplitude — in other words, if the VF rhythm is coarse, spiky, and energetic — the heart is likely to return to circulation with an immediate shock (Figure 1a). For these rhythms, an immediate shock is beneficial.

Other VF rhythms are indicative of a heart that is not receptive to a shock. If the frequency and amplitude of the VF rhythm is low — if the rhythm is weak, fine, rather flat, and shapeless — it indicates that the heart's energy is depleted and a return to circulation is unlikely (Figure 1b). For these rhythms,

1. Wik L, Hansen TB, Fylling F, Steen T, Vaagenes P, Auestad B, Steen PA. Delaying Defibrillation to Give Basic Cardiopulmonary Resuscitation to Patients with Out-of-Hospital Ventricular Fibrillation: A Random Trial, *JAMA* March 19, 2003, 289:111389-1395.
2. Cobb LA, Fahrenbruch CE, Walsh TR, Copass MK, Olsufka M. Breskin M, Hallstrom AP. The Influence of Cardiopulmonary Resuscitation Prior to Defibrillation in Patients with Out-of-Hospital Ventricular Fibrillation. *JAMA, April* 7, 1999, 281:13:1182-1188.
3. Weisfeldt ML, Becker LB. Resuscitation After Cardiac Arrest: A 3-phase Time-sensitive Model. *JAMA*, December 18, 2002. 288:23:3035-3038.

an initial interval of CPR prior to a shock can be beneficial. Properly applied CPR oxygenates the heart, which can cause a weak VF to become more coarse and energetic and make the heart more receptive to a shock.

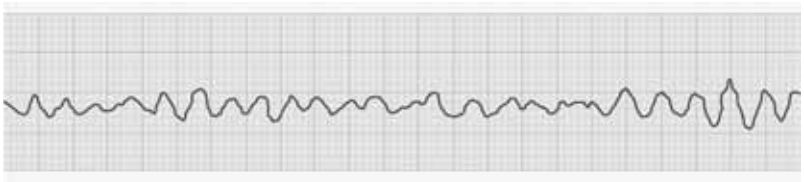


Figure 1a: Short-term VF rhythm with high frequency and amplitude, characteristic of a heart receptive to a defibrillation shock

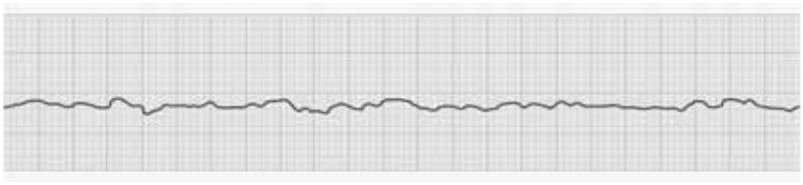


Figure 1b: Long-term VF rhythm with low frequency and amplitude, characteristic of a heart that is unlikely to return to circulation with a shock. CPR prior to a shock may improve the outcome.

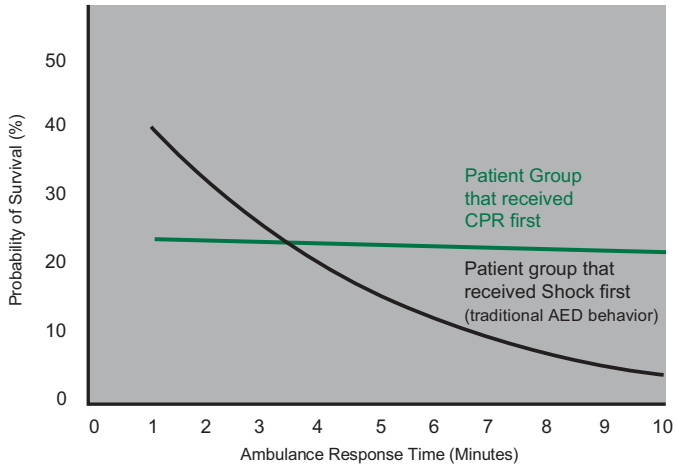
At the onset of cardiac arrest, VF typically starts out quite coarse and energetic. As minutes pass without treatment, however, the heart depletes its fuel reserves, and the VF rhythm progressively weakens, getting flatter and finer. Note that time is not the only contributor to a weak VF. Other factors include the degree of underlying heart disease and the cause of the arrest.

It is not surprising, therefore, that recent studies are showing that patients with rhythms typical of short-duration VF respond better when they receive an initial treatment of defibrillation, while patients with rhythms typical of long-duration VF (> 5 minutes) have higher survival rates when they receive an initial interval of CPR prior to defibrillation shocks.

One such study, by Wik et al.,[1] looked at cardiac arrest patients in an EMS system. Patients were divided into two groups. One group received shocks as the initial treatment. In this group, the patients with short-duration VF had markedly higher survival if they received immediate shocks. However, survival rates with this protocol dropped precipitously the longer the patients were in VF. The other group received an interval of CPR followed by shocks. Figure 2 shows the survival curve over time for that group of patients. Of particular interest is that the figure also shows that, among

1. Wik L, Hansen TB, Fylling F, Steen T, Vaagenes P, Auestad BH, Steen PA. Delaying defibrillation to give basic cardiopulmonary resuscitation to patients with out-of-hospital ventricular fibrillation a randomized trial. *JAMA*. 2003 Mar 19; 289(11)1389

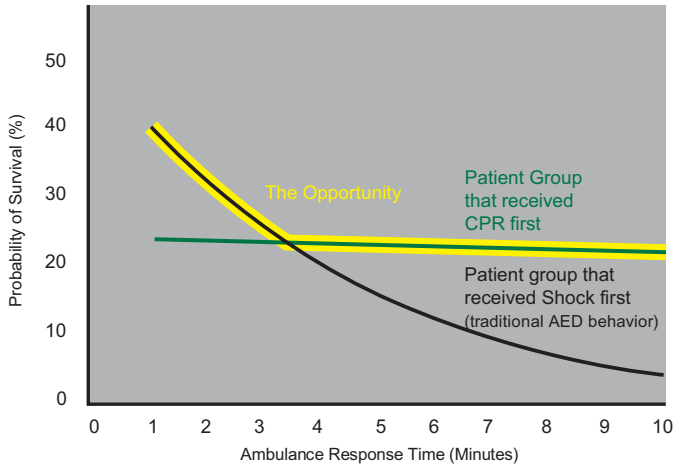
patients with longer-duration VF, those in the group receiving an interval of CPR prior to a shock had significantly better survival.



Wik et al. JAMA, 2003, 289;1389-1395.

Figure 2: Patients with short-duration VF had good survival rates when they received immediate shocks. Those with long-duration VF had higher survival rates when receiving CPR prior to a shock.

This data suggests an opportunity to improve survival of cardiac arrest with a simple change in response protocol: provide immediate shocks to patients in short-duration VF, but provide initial CPR to patients in long-duration VF (Figure 3). Indeed, the current literature proposes such a protocol – and using AEDs that support it – as a way to improve survival.



Wik et al. JAMA, 2003, 289;1389-1395.

Figure 3: The opportunity to improve survival of SCA with a change in response protocol.

The EMS responder faces a dilemma when, as is often the case, there is insufficient information upon arrival to determine the best course of treatment: Did EMS witness the arrest? How long has the patient been in

arrest? How long after the victim's collapse was it before emergency response was called? Was bystander CPR performed prior to arrival of EMS? If so, was it effective CPR? What is the underlying condition of this individual patient's heart? What should the arriving responder do—shock first or perform CPR first? The choice may not be obvious.

The HeartStart FR3 with SMART CPR enabled assesses the initial heart rhythm to determine if it is shockable. If it is, SMART CPR determines if the rhythm has the specific attributes of a heart likely to benefit from an initial defibrillation shock. If this is the case, the FR3 will advise a shock. Otherwise, it will advise a period of CPR first, followed quickly by a shock, anticipating that CPR may render the heart more receptive to that shock (Figure 4). Either way, the FR3 adjusts its voice instructions accordingly.

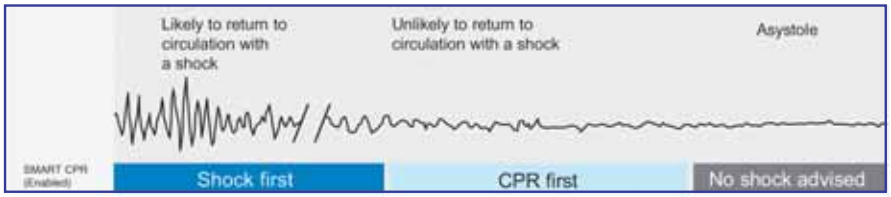


Figure 4: A conceptual representation of the progression of VF over time, showing SMART CPR's response.

In deciding whether to enable SMART CPR in the FR3, the Medical Director should consider the overall impact the selected setting would have on the SCA emergency response system, and train responders accordingly. Other factors to be considered include:

- Emergency system response times
- Responder skill level
- Prevailing protocols and time and cost for training
- Expected changes in response protocols

Based on a consideration of these factors, the Medical Director can configure the FR3 to any of four CPR First settings: OFF, SMART CPR AUTO1, SMART CPR AUTO2, and USER. These are defined in greater detail below.

OFF SETTING

The OFF setting means the FR3 will not provide an initial CPR interval prior to defibrillation of a shockable rhythm. Thus, once the FR3 is attached, it will advise an immediate shock for all SCA patients presenting with a shockable rhythm — even those who may benefit from CPR first — before it provides a CPR interval. This setting represents the historical behavior of AEDs, including the ForeRunner and FR2+. It is therefore the default setting for CPR First.

SMART CPR AUTO1 AND AUTO2 SETTINGS

It is often not possible for the responder to know whether an individual patient in SCA might benefit from CPR first or defibrillation first. When set to AUTO1 or AUTO2, the FR3 analyzes the patient's initial rhythm and automates the decision as to whether an individual shockable patient will receive an initial shock or CPR first. Based on a comprehensive database of ECG recordings of actual resuscitation attempts,[1] the SMART CPR algorithm evaluates the initial ECG's amplitude and frequency characteristics — both known predictors of shock success — and calculates the likelihood of the return of spontaneous circulation (ROSC) following a defibrillation shock. If the likelihood is low, the FR3 will provide a CPR interval prior to defibrillation in an effort to increase the likelihood of successful defibrillation. If high, the device will advise immediate defibrillation. In either case, the device adjusts its voice and text prompts appropriately.

WARNING: Although SMART CPR can be used for adults and children, the performance of the SMART CPR AUTO1 and AUTO2 settings has not been established in patients under 8 years or 55 lb. (25 kg).

SMART CPR AUTO1. Provides immediate defibrillation for more than 90%†[2] of shockable patients who are likely to achieve ROSC (less than 10% receive CPR first). Of those shockable patients who are unlikely to achieve ROSC, more than 50% will receive CPR first.

SMART CPR AUTO2. Provides immediate defibrillation for more than 80%† of shockable patients who are likely to achieve ROSC (less than 20% receive CPR first). Of those shockable patients who are unlikely to achieve ROSC, more than 60% will receive CPR first.

USER SETTING

The USER setting provides the responder with a means to manually initiate a CPR interval, based on either a patient assessment or standing orders from the Medical Director. The FR3 can thus be applied immediately to the patient, enabling the device to collect data and provide reminder text prompts that the CPR Pause key is available. The responder presses the CPR Pause key to start a CPR interval. The FR3 will continue with rhythm analysis unless the CPR Pause key is pressed.

With the FR3 CPR First setting set to USER, the FR3 provides an opportunity for the responder to initiate a CPR interval for all patients — even those who may benefit from immediate defibrillation.

1. Data collected from multi-center, multi-national out-of-hospital and in-hospital adult sudden cardiac arrest rhythms. The SMART CPR algorithm was developed based on VF, polymorphic VT, and ventricular flutter rhythms.
2. Based on observed performance. ROSC was determined by several parameters, including patient assessment, ECG analysis, and/or patient impedance cardiography.

Information on how to upgrade an FR3 defibrillator to permit configuration for the SMART CPR feature is provided in Appendix E.

PEDIATRIC DEFIBRILLATION

The HeartStart FR3 defibrillator can be used with the FR3 Infant/Child Key [REF: 989803150031] to treat children under 8 years of age or 55 pounds (25 kg). With the Key in place, the FR3 automatically decreases the defibrillation therapy delivered from the adult dose to a level more appropriate for these patients and implements the configured infant/child CPR protocols.

WARNING: Most cardiac arrests in children are not caused by heart problems. When responding to cardiac arrest in an infant or child:

- Provide infant/child CPR while a bystander calls EMS and brings the FR3.
- If no bystander is available, provide 1-2 minutes of CPR before calling EMS and retrieving the FR3.
- If you witnessed the child's collapse, call EMS *immediately* and *then* get the FR3.

Alternatively, follow your local protocol.

If the victim is under 55 pounds or 8 years old, but you do not have the Infant/Child Key, do not delay treatment. Place one pad in the center of the chest between the nipples, and the other in the center of the back (anterior-posterior).

If the victim is over 55 pounds or 8 years old, or if you are not sure of the exact weight or age, do not delay treatment. Place the pads as illustrated on each pad (anterior-anterior). Make sure the pads do not overlap or touch each other.

TRAINER OPTIONS

TRAINING PADS AND FR3

The HeartStart FR3 AED can be used for training purposes with the HeartStart FR3 Training Pack [REF: 989803150191]. The Training Pack comprises a rechargeable FR3 training battery, one pair of HeartStart Training Pads III, an interconnect cable, and an external manikin adapter. See the *Instructions for Use* provided with the Training Pack for directions for using the Training Pack with the FR3.

When used with the Training Pack, the FR3 provides the following three training scenarios. The training behavior described below assumes factory default configuration. Changes to device configuration may result in different

training behavior. In the training scenarios, "conversion" means a change from a shockable to a non-shockable rhythm.

SCENARIO NUMBER AND OVERVIEW	SCENARIO DETAILS
Scenario 1  Shockable rhythm, one shock needed for conversion	• The FR3 detects a shockable rhythm, tells user to deliver a shock. • The FR3 provides a Basic CPR protocol. • The FR3 detects a non-shockable rhythm (no shock advised; NSA). • The FR3 provides an NSA CPR protocol.
Scenario 2  Shockable rhythm, conversion, return to shockable rhythm, conversion*	• The FR3 detects a shockable rhythm, tells user to deliver a shock. • The FR3 provides a Basic CPR protocol. • The FR3 detects a non-shockable rhythm (no shock advised; NSA). • The FR3 provides an NSA CPR protocol. • The FR3 detects a shockable rhythm, tells user to deliver a shock. • The FR3 provides a Basic CPR protocol. • The FR3 detects a non-shockable rhythm.
Scenario 3  Non-shockable rhythm	• The FR3 detects a non-shockable rhythm throughout; alternates between rhythm analysis and providing an NSA CPR protocol.

AED TRAINER 3

The AED Trainer 3 [REF: 861467] resembles the FR3 defibrillator but does not have an active display and operates on four replaceable AA size alkaline batteries. See the *Directions for Use* provided with the AED Trainer 3 for detailed instructions on using the Trainer.

The AED Trainer 3 provides eight training scenarios that simulate realistic episodes of sudden cardiac arrest (SCA) and help responders become familiar with use of the HeartStart FR3 AED in an emergency. These scenarios are compatible with training programs developed by internationally recognized responder programs.

The AED Trainer 3 can be used with an optional infrared remote control. The remote control gives the instructor the ability to alter training scenarios while in progress, to test student response.

The Trainer 3 provides simulated shock delivery. It has no high-voltage capabilities, ensuring safety during training. The Trainer 3 is designed for use with HeartStart Training Pads III and, for training in pediatric defibrillation, a Training Infant/Child Key. When used with the AED Little Anne and Resusci Anne manikins with Laerdal Link Technology, it gives realistic responses to

pad placement on the manikins. It can also be used with any other manikin. Realistic responses to pad placement feature is only available when used together with the AED Little Anne or Resusci Anne manikins with Laerdal Link Technology.

The Trainer 3 can be connected to the serial port or USB port of a PC (generally labeled "COM1"). The optional PC software lets you configure custom training scenarios, set-up various protocol parameters and change language output. Connection to a PC serial port requires a standard 1:1 9-pin D-sub serial cable.

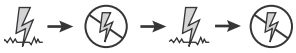
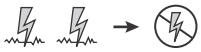
The following eight training scenarios are available when using the Trainer 3. The training behavior described below assumes factory default configuration. Changes to device configuration may result in different training behavior. After each shock/no shock advised decision, the defibrillator provides a CPR interval. In the training scenarios, "conversion" means a change from a shockable to a non-shockable rhythm.

The training scenario symbols used are defined below.

	Shockable rhythm detected by AED Trainer 3.
	Non-shockable rhythm detected by AED Trainer 3.
	Pads problem detected by AED Trainer 3.
	CPR First protocol initiated by AED Trainer 3.

The following training scenarios are available for use with the AED Trainer 3:

SCENARIO	SYMBOL	DESCRIPTION
1	 One shock for conversion	• Shockable rhythm • One shock needed for conversion • Non-shockable rhythm
2	 One shock for conversion	• Non-shockable rhythm • Shockable rhythm • One shock needed for conversion • Non-shockable rhythm
3	 Troubleshooting pads, one shock for conversion	• Poor pads contact • Shockable rhythm • One shock needed for conversion • Non-shockable rhythm

SCENARIO	SYMBOL	DESCRIPTION
4	 Refibrillation after conversion	• Shockable rhythm • One shock needed for conversion • Non-shockable rhythm • Return to shockable rhythm after three minutes • One shock needed for conversion • Non-shockable rhythm
5	 Non-shockable rhythm	• Non-shockable rhythm throughout
6	 Two shocks for conversion	• Shockable rhythm • Two shocks needed for conversion • Non-shockable rhythm
7	 CPR first, one shock for conversion	• Shockable rhythm • CPR First • Shockable rhythm • One shock needed for conversion • Non-shockable rhythm
8	 Shockable rhythm	• Shockable rhythm throughout

6 THEORY OF OPERATION

IMPORTANT NOTE: The internal construction of all HeartStart AEDs is extremely sophisticated. These devices require special fixtures for assembly in order to achieve their compact size and shape while ensuring a durable environmental seal. The AEDs also contain high-voltage circuits that can present a safety risk if improperly handled. As a result, HeartStart AEDs are not designed to be opened in the field; they must be returned to the factory for any repair. All service for the AED is done via an exchange program with the factory.

OVERVIEW

The theory of operation presented here in brief is provided solely to give the user a better understanding of how a HeartStart automated external defibrillator (AED) works.

The HeartStart FR3 AED monitors the patient's electrocardiogram (ECG) and advises the user to deliver a shock when appropriate. In order to do this, the AED has to perform a number of functions, including:

- Input the ECG signal and convert it into a digital format that the microprocessor can analyze.
- Analyze the ECG and determine if the device should charge and allow a shock to be delivered.
- Charge the internal capacitor to a voltage high enough to effectively defibrillate the patient.
- Instruct the user to deliver the shock.
- Provide the proper switching inside the device to deliver a controlled shock when the shock button is pressed.
- Repeat this process if necessary.

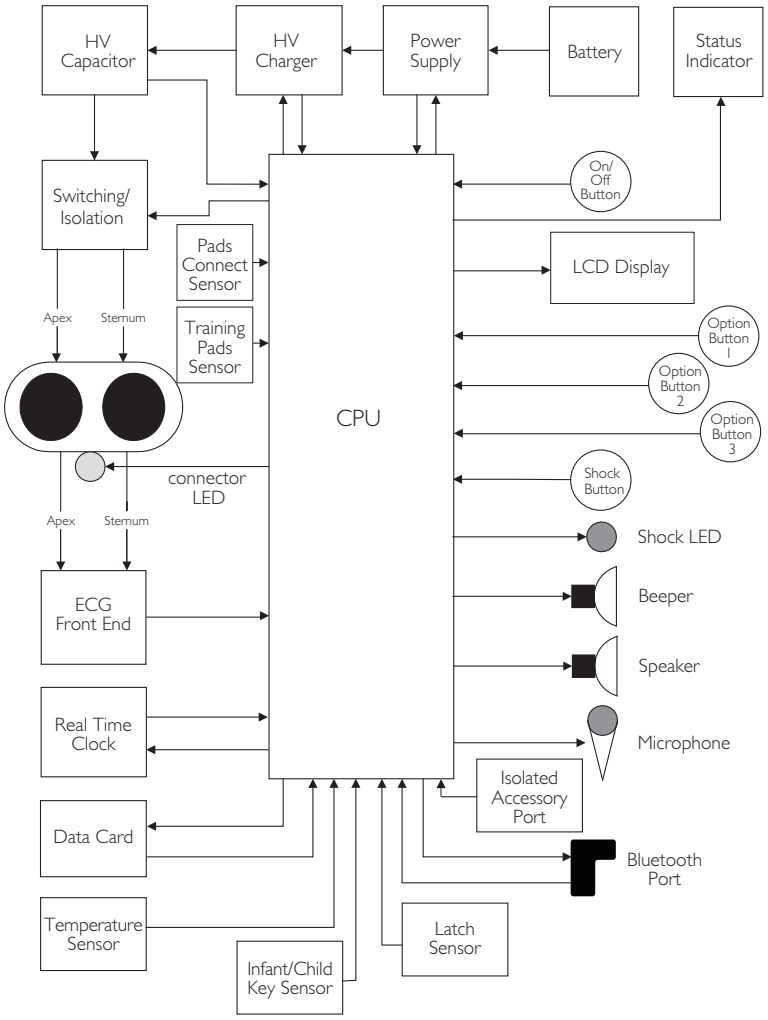
Because HeartStart FR3 AED is designed to permit use by rescuers who are not trained to read ECGs and to distinguish between shockable and non-shockable rhythms, the devices must also:

- Supply text messages and voice prompts to instruct the user and help in the process of assisting the patient.
- Provide audio and visual indicators to call attention to various parts of the device at appropriate times (pads connector port or Shock button light, Ready light, low battery warning, charge-done tone).
- Automate the maintenance process to ensure the device is ready to use when needed.

- Store the ECG and event data to be reviewed at a later time.

The block diagram shown below indicates the major components of the HeartStart FR3 AED as an example. These include:

- User interface
- CPU
- Battery
- Power supply
- ECG Front End
- Patient Circuit (high-voltage charger, high-voltage capacitor, switching/isolation circuitry)
- Recording (microphone, data card)



HeartStart FR3 block diagram

USER INTERFACE

The user interface of the FR3 consists of the main LCD display, the on/off button, the shock button, the three option buttons, the pads connector port light and Shock button light, the beeper, the speaker, and the Ready light.

OPERATION

In normal operation, text prompts are displayed on the HeartStart FR3 LCD screen, and voice prompts are provided through the speaker. These prompts guide the rescuer in the use of the device and give warnings (such as low battery) to call the user's attention to certain parts of the device that may need attention. The connector light blinks when the unit is turned on to draw attention to the connector port as an aid in guiding the user in connecting the defibrillation pads to the FR3. If the FR3 advises a shock and charges, the shock button light will flash to help guide the user's attention to the shock button and indicate that it is ready to deliver a shock to the patient. The beeper is also used to draw the user's attention to the FR3 with different tones that let the user know that the unit is ready to deliver a shock or that the battery is low and needs to be replaced.

MAINTENANCE

As discussed on page 5-6, maintenance for the HeartStart FR3 defibrillator primarily consists of the user checking the Ready light regularly to verify that the unit is working and ready to be used. The FR3 will perform an automatic self-test every 24 hours that verifies that the unit is functioning properly. Once a month, this automatic self-test does a full functional check of the unit that includes verifying full energy discharge internally and self-calibration. If the unit fails to pass one of these self-tests, the green Ready light will go off and the FR3 will emit single or triple alarm chirps, depending on the criticality of the problem.

TROUBLESHOOTING

The display screen, beeper, and Ready light are also used for troubleshooting the HeartStart FR3. The main troubleshooting tool is the user-initiated test. See the *Instructions for Administrators* or the *Guide to Setup, Operation, and Maintenance* provided with the FR3 for directions on running the test. The user-initiated test begins with an interactive test that allows the user to verify that all the buttons, the beeper, and the displays are working. This is followed by a comprehensive functional test of the system ending with a screen that displays either "Test Passed, Ready for Use" or "Test Failed, Not Ready for Use," along with other information about the revision of the hardware and software and status of the FR3.

CONFIGURATION

The LCD display and option buttons are used in adminisistration mode to set the clock or customize the configuration of the HeartStart FR3. The lower option button is used to scroll through the various parameters displayed on the main display, while the upper option button is used to select the highlighted value.

CPU

The CPU holds the main processor and all of the circuitry required to control the real time functions of the HeartStart FR3. The real time control handles the processing needed to sample the ECG data, store ECG and voice data onto the data card, send data to the display, play the voice prompts on the speaker, turn on warning tones, charge the high-voltage capacitor, and deliver the shock to the patient. In addition, the processor on the CPU runs all of the data processing for the analysis system.

BATTERY

The 989803150161 is a 12 V, 4.7 Ah battery pack containing 12 $LiMnO_2$ battery cells, similar to those used in cameras. This battery is non-rechargeable and can be disposed of with regular waste when depleted.

POWER SUPPLY

The power supply is used to convert the battery voltage to the various voltages needed by the electronic components within the HeartStart FR3.

ECG FRONT END

The front end of the HeartStart FR3 amplifies and filters the ECG signal input from the electrodes and feeds this signal into the analog-to-digital (A/D) converter. The sampled data is further filtered and downsampled to 200 Hz, and this digital data is fed into the CPU to be used by the analysis system and stored onto the data card.

PATIENT CIRCUIT

This circuitry includes all components (high-voltage charger, high-voltage capacitor, switching/isolation circuitry) needed for the HeartStart FR3 to deliver the defibrillation waveform to the patient. A large amount of energy is stored in the battery, however, this energy is stored in the battery at a low voltage (12 V in FR3) that is not effective for a defibrillation shock. In order for a patient to be defibrillated, enough energy for a shock must be transferred to the high-voltage (HV) capacitor at a voltage sufficiently high to make an effective defibrillation waveform (about 1800 VDC for the SMART Biphasic waveform).

When a decision to shock is made by the FR3, the high-voltage (HV) charger circuit transfers energy stored in the battery at a voltage of 12 VDC to energy stored in the high-voltage capacitor at about 1800 VDC. This voltage is maintained on the capacitor until the shock is delivered, ensuring that the device is ready to deliver the 150 J shock to the patient.

When the shock button is pressed, the HV capacitor is disconnected from the HV charger circuit and connected to the patient through the electrode pads. The switching circuitry then allows the current to flow in one direction, pad-to-pad through the patient, and then reverses the direction of the current flow for a preset period of time. The duration of the current flow in each direction through the patient is based on the measured patient impedance; it is this bi-directional flow of current that forms the SMART Biphasic waveform.

DATA CARD

When the HeartStart FR3 is turned on and the pads are applied to the patient, the AED continually records the ECG and the event summary onto the data card, if installed. The FR3 can also record all the audio information from the event through its microphone. The ECG and audio information can later be reviewed using HeartStart Event Review data management software. See the FR3 *Instructions for Administrators* for a complete description of the data available from the FR3 AED.

TEMPERATURE SENSOR

The HeartStart FR3 incorporates a temperature sensor that allows the CPU to determine the ambient temperature of the device. This sensor enables the AED to measure the temperature at the start of any self-test. If the temperature is outside the recommended storage range, the AED postpones the self-test until the following day, or in 8 hours over a 16 hour period. If the self-test is postponed three times in a row, an error is generated, which causes the Ready light to go off and the unit to begin chirping. This condition will be cleared once the unit returns to the recommended temperature range and an automatic daily self-test is passed. If the device is exposed to extreme temperatures for extended periods of time, permanent damage can occur to the electrode pads and/or the battery.

REAL-TIME CLOCK

The HeartStart FR3 contains a real-time clock that is the reference time for any patient use that occurs. Any patient use of the AED will have the time and date information annotated on the data recorded on the data card. The time and date can be set using the administration mode of the FR3 itself. Alternatively, using wireless transmission, you can to set the clock to match the clock of a computer running HeartStart Configure software.

7 HEARTSTART DATA MANAGEMENT SOFTWARE

OVERVIEW

HeartStart data management software allows the data from an FR3 AED use to be reviewed on a PC at a later time. With this software, the user can:

- Download ECG data collected in defibrillators
- Review ECG and event data
- Play back audio, if audio was stored, while watching the ECG trace across the screen
- Annotate the ECG
- Generate and print reports for analysis and record-keeping
- Print out the entire ECG of the event
- Merge, review, and archive ECG data recorded on multiple devices for a single patient
- Save the event data to a file
- Archive reports in a secure environment

The HeartStart data management software suite includes the following packages.[1]

HEARTSTART EVENT REVIEW is an application for electronically managing the ECG case data, including shocks and audio (if recorded) by your Philips or Laerdal defibrillator. It allows you to add case details by adding notes and completing basic data entry screens. Using Event Review, ECGs from multiple defibrillators can be integrated into one case for a complete event history. Case reports include ECG waveform, event log and case data. With Event Review, you can perform ad hoc queries of the database and e-mail cases to colleagues who are running Event Review or Event Review Pro for review. When available, it can be ordered in English, French, German, Spanish, Italian, and Japanese.

EVENT REVIEW PRO is a comprehensive application for electronically managing the case data recorded by Philips and Laerdal AEDs. HeartStart Event Review Pro helps the medical director or code team leader take a big-picture view of their resuscitation program in order to evaluate and optimize resuscitation response. It lets the Program Manager collect and review more comprehensive response and patient data than Event Review, including detailed BLS and ALS responder observations and interventions.

1. HeartStart Event Review version 4.2, Event Review Pro version 4.2, the upgrade for Event Review Pro version 4.2, and Data Messenger version 4.2 are expected to be available in 2011 to support the FR3.

ECGs from multiple defibrillators can be integrated into one case for a complete event history. Event Review Pro can be used to produce case reports, 12-lead reports, Utstein reports and overall system response time summaries. In addition, ad hoc queries of the database can be performed and cases emailed to colleagues who are running Event Review or Event Review Pro for review. Available in English, French, German, Spanish, Italian, and Japanese.

EVENT REVIEW DATA MESSENGER is a software product designed to receive downloaded defibrillator patient data, and print it out, save it, and/or forward it to the medical director or data administrator who then can review the data and perform quality assurance/improvement reviews of it using Event Review or Event Review Pro. HeartStart Data Messenger can also forward defibrillator patient data to other applications, such as electronic patient care reporting systems, that have been programmed to receive that data using HeartStart Data Software Developers Kit.[1]

Detailed information about the Event Review suite of data management software programs is available online at medical.philips.com.

SYSTEM REQUIREMENTS

In order for a PC to run Event Review, Event Review Pro, or Data Messenger revision 4.2 or higher software for managing data from the FR3 AED, it must be equipped as follows:

PC ELEMENT	REQUIREMENT
Operating System	Microsoft Windows: XP Professional SP 3 or later (32-bit) XP Tablet Edition (32-bit) Vista SP2 or later (32-bit and 64-bit) Windows 7 (32-bit and 64-bit)
Browser	Microsoft Internet Explorer 7.0 or later
Processor Speed	1 GHZ or higher
Display	1280 x 768 or higher
Memory	1 GB or larger
Disk Storage Space	40 GB or larger
File Transfer	Data card reader or *Bluetooth* wireless data transfer technology
Sound Card	100% Sound Blaster® compatible sound card
Card Reader	Secure Digital (SD) for FR3

1. Expected to be available in 2012.

DATA MANAGEMENT SOFTWARE VERSIONS

Following is a list of the data management software previously and currently offered and the AEDs supported by each software package.

SOFTWARE PACKAGE	AEDS SUPPORTED
Event Review Pro	Philips/Agilent/Hewlett-Packard: Heartstream ForeRunner, Heartstream FR2, HeartStart FR2, HeartStart FR2+, HeartStart Home, HeartStart OnSite, HeartStart HS1, HeartStart FRx, HeartStart FR3[a] Laerdal: Heartstart FR, Heartstart FR2, HeartStart FR2+, HeartStart, HeartStart FRx
Event Review	Philips/Agilent/Hewlett-Packard: Heartstream ForeRunner, Heartstream FR2, HeartStart FR2+, HeartStart Home, HeartStart OnSite, HeartStart HS1, HeartStart FRx, HeartStart FR3[a] Laerdal: Heartstart FR, Heartstart FR2, HeartStart FR2+, HeartStart, HeartStart FRx
HeartStart Configure	Philips: HeartStart Home, HeartStart OnSite, HeartStart HS1, HeartStart FRx, HeartStart FR3[b] Laerdal: HeartStart, HeartStart FRx
Data Messenger	Philips/Agilent/Hewlett-Packard: Heartstream FR2, HeartStart FR2+, HeartStart Home, HeartStart OnSite, HeartStart HS1, HeartStart FRx, HeartStart FR3 Laerdal: Heartstart FR2, HeartStart FR2+, HeartStart, HeartStart FRx, HeartStart FR3

a. The FR3 requires version 4.2 or higher.
b. The FR3 requires version 3.0 or higher.

COMPARISON OF EVENT REVIEW AND EVENT REVIEW PRO

	EVENT REVIEW	EVENT REVIEW PRO
Access	• For single-user PC-based computer workstations • Software loads and data resides on single-user PCs	• For data-sharing computer networks • Software loads and data resides on user's server, network, or stand-alone PC

	EVENT REVIEW	EVENT REVIEW PRO
Features	• Single-user access and data management control directly on PC; no Internet connection required for use • Allows data sharing via e-mail if Internet connection is available	• Accommodates instantaneous and simultaneous data management for multiple users from remote sites and satellite locations via the Internet • Allows networked data sharing for an unlimited number of users • Secures patient records and enables data sharing at varied access levels for different users
Reports	• Provides standard pre-defined report for each patient	• Provides detailed patient data report for each patient • Enables system-wide statistically-based reports drawn from a group of events for data trending • Provides six pre-defined event reports in Utstein format
Data Storage	• Stores ECG data on user's PC for direct review and reporting	• Stores ECG data within user's networked system on a Microsoft Access 2000 or SQL 7 database
Defibrillators Supported	• Heartstream or HeartStart: FR. ForeRunner. FR2 series, HS1, FRx, XL, XLT, 4000, MRx	• Heartstream or Heartstart: FR, ForeRunner, FR2 series, HS1, FRx, XL, XLT, 4000, MRx
Defibrillator Configuration	• Enables quick configuration of multiple HS1 or FRx defibrillators (standard time, audio option, etc.)	• Enables quick configuration of multiple defibrillators (standard time, audio option, etc.)
Technical Support	• Online and phone support	• Online and phone support
Languages	• English, French, German, Italian, Spanish, Japanese	• English, French, German, Italian, Spanish, Japanese

SYSTEM ANNOTATIONS

A variety of different event annotations appear on the ECG when the Event Review software prints it out. Some, like “shock advised” and “shock delivered,” are self-explanatory and relate directly to the treatment of the patient. Others, like “monitoring,” are less obvious and relate to the internal state of the defibrillator. Annotations that can appear on the ECG printout for current software are listed and defined below.

ANALYZING — The defibrillator is in analyze mode; it has started to actively analyze the patient's ECG and has given the voice prompts to instruct the user not to touch the patient. The internal capacitor is partially charged in this state, and the defibrillator will either (a) advise a shock and fully charge the capacitor or (b) give a no-shock advised prompt, disarm, and go into monitor mode.

ARMED — At this point, the defibrillator is fully charged, and the user can deliver a shock to the patient by pressing the shock button.

ARTIFACT — This indicates that the defibrillator has detected artifact corruption of the ECG within the previous five seconds.

MONITORING — The defibrillator has transitioned from analyze mode to monitor mode. While monitoring, the defibrillator is still reviewing the patient's ECG, but has informed the user that it is safe to touch the patient. If it detects a potentially shockable rhythm while in monitor mode, the defibrillator will go back to analyze mode and instruct the user to not touch the patient. The internal capacitor has no charge on it in monitor mode.

NEW USE — This indicates the point at which pads were connected to the patient and the defibrillator begins recording the ECG and tracking events.

NO SHOCK ADVISED — The defibrillator has determined that the patient's rhythm is not considered shockable.

PADS MARGINAL — The defibrillator has detected pads at this point, but the impedance measured is too high to obtain a good ECG reading or to deliver an effective shock if required. The defibrillator will give voice prompts (e.g., "press pads firmly") to alert the user that the defibrillation pads are not making good contact.

PADS OFF — The measured impedance has become too high and indicates that the defibrillation pads are no longer connected between the defibrillator and the patient's chest.

PADS ON — The measured impedance is low enough to indicate that the defibrillation pads are making good contact to the patient's chest, and the defibrillator can proceed to analyze the ECG.

RESUME ANALYSIS — The defibrillator has either detected a potentially shockable rhythm while in monitor mode or has transitioned back into analyze mode after completing a pause period.

SHOCK ABORT — The shock was aborted either because the defibrillator detected a change to a non-shockable rhythm or the user failed to press the Shock button.

SHOCK ADVISED — The defibrillator has determined that the patient's rhythm is considered shockable and begins to fully charge the internal capacitor so that a shock may be delivered.

SHOCK # DELIVERED — Indicates the point at which a given shock is delivered to the patient. ("#" will be the actual number of that shock.)

SHOCK INITIATED — Indicates the point at which the shock button was pressed by the user.

START OF AUDIO — If the defibrillator is configured to store the audio signal on the data card, this indicates when the audio recording began.

START OF ECG — This marks the point on the printout when the ECG recording begins on the data card. The defibrillator begins audio recording (if configured) when it is turned on and begins ECG recording when the pads are connected to the patient's chest.

START PAUSE — This indicates the beginning of a pause period. A pause occurs after a series of shocks are delivered (default is one shock) or if the unit is configured to pause after a no-shock advised. During a pause, the defibrillator will not react to changes in the patient's ECG and it will not give any voice prompts.

TECHNICAL SUPPORT FOR DATA MANAGEMENT SOFTWARE

The Event Review Help Desk covers all phases of installation and use of Event Review software and hardware. Questions posted to this technical support site are answered by the Event Review Team. Email your questions to: eventreview.support@philips.com.

For those customers who use Event Review and do not have an Internet connection, phone support in North America is available by calling (800) 263-3342.

CONFIGURATION SOFTWARE

HEARTSTART CONFIGURE software is for use by trained personnel. The software enables you to review and change the configuration of HeartStart FR3 defibrillators. With HeartStart Configure software installed on a PC, you can retrieve the current configuration from the defibrillator, reset the configuration to default values, or revise individual settings according to your Medical Director's directive, and transmit them to the defibrillator.

To more efficiently manage configuration for your defibrillator program, HeartStart Configure also lets you save FR3 settings to a file on your PC.

This lets you transmit the same configuration to all your AEDs as well as maintain a record of allowable settings.

NOTE: Federal Law (USA) restricts this product to sale by or on the order of a physician. Your defibrillator's configuration determines its behavior during an emergency. Changes must be made only by authorized personnel under the oversight of a medical professional. Software should not be shared and handheld security measures such as password protection should be taken.

A TECHNICAL SPECIFICATIONS

HeartStart AEDs have been environmentally tested to demonstrate conformance to numerous standards. In addition, stress testing and life testing has been conducted to provide a design that is rugged and reliable. To date, HeartStart AEDs have accumulated over a billion hours of powered service.

Except as otherwise noted, the information below applies to the HeartStart FR3 AEDs (models 861389 and 861388). These products are classified as Class IIb, Rule 9 of Annex IX of the MDD. All these devices meet the provisions of the council Directive 93/42/EEC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer, Philips Medical Systems.

STANDARDS APPLIED

- AAMI DF80:2003
- IEC 60601-1:1988 / EN 60601-1:1990
- EN 60601-1-2:1993 / IEC 60601-1-2:1993
- EN 61000-4-3:2006
- CAN/CSA-C22.2 No 601.1-M90
- CISPR 11:2004/ EN55011:1991
- RTCA/DO-160E:2004

In addition to the testing done for performance in hospital settings, HeartStart AEDs have been tested in numerous field environments where devices have been deployed. These field environments may subject the FR3 to environmental conditions involving much higher electric or magnetic field strengths than the specified tolerance for the FR3. When there is concern about using an AED in a particular environment, it is possible to test the FR3 on site to ensure that its performance will not be adversely affected by the environment or will not affect the performance of surrounding equipment if used in that environment.

HeartStart AEDs has been tested in the following environments, where it was demonstrated that the AED performed properly and did not adversely affect surrounding electronic equipment.

- Aircraft: Commercial airliners, corporate jets, helicopters
- Ships: Cruise ships, car ferries, small power boats
- Power Switching Station (high EMI field)
- Chemical Plant (high magnetic field)
- Hand-held metal detector
- Cell phone/hand-held transmitter factory environment

FR3 AED SPECIFICATIONS

PHYSICAL

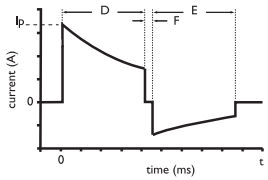
CATEGORY	SPECIFICATION
Size	2.7" high x 5.3" wide x 8.7" deep (6.9 cm x 13.5 cm x 22.1 cm).
Weight	3.5 lbs (1.6 kg) with FR3 standard clinical use battery installed.

ENVIRONMENTAL

CATEGORY	SPECIFICATION
Temperature and Relative Humidity	Operating (battery installed, pads connected): 32° to 122° F (0° to 50° C); 5% to 95% relative humidity (non-condensing). Standby/Storage (battery installed and defibrillator pads pre-connected): 32° to 122° F (0° to 50° C); 10% to 75% relative humidity (non-condensing). Transport: -4° to 140° F (-20° to 60° C); 0% to 85% relative humidity (non-condensing) for up to 2 days, thereafter 65% relative humidity maximum.
Altitude	Meets IEC 60601-1:5.3 (0 to 15,000 feet; 0 to 4,572 meters).
Shock/Drop Abuse Tolerance	Meets MIL-810F 516.4, Procedure IV (after a 1 meter drop to any edge, corner, or surface, in standby mode).
Vibration	Meets MIL-810F 514.5C-17.
Sealing	Meets IEC 529 class IP55.
Aircraft: Method	Meets RTCA/DO-160E:2004 Section 21 (Category M - Charging).

DEFIBRILLATOR

CATEGORY	SPECIFICATIONS
Charge Control	Controlled by SMART Analysis for automated operation. Can be programmed for manual initiation using advanced mode of the 861389.
Shock Cycle Timing	Shock delivery within 8 seconds, typical, following the prompt ending a CPR protocol using a new battery. Shock to shock, new battery, <20 seconds, typical, including analysis using a new battery. Shock to shock after 15 shocks, <30 seconds from analyzing to ready-to-shock. Shock to shock after 200 shocks,<40 seconds from initial power-on to ready-to-shock.
"Charge Complete" Indicator	Orange Shock button flashes, the FR3 gives a continuous tone and prompts user to deliver shock.
Waveform Parameters	Biphasic truncated exponential. Waveform parameters are automatically adjusted as a function of patient defibrillation impedance. In the diagram at left, D is the duration of phase 1 and E is the duration of phase 2 of the waveform, F is the interphase delay (500 ± 50µs), and Ip is the peak current. The HeartStart FR3 AED delivers shocks to load impedances from 25 to 180 ohms. The duration of each phase of the waveform is dynamically adjusted based on delivered charge, in order to compensate for patient impedance variations, as shown below:



adult defibrillation

load resistance (Ω)	phase 1 duration (ms)	phase 2 duration (ms)	peak current (A)	delivered energy (J)
25	2.8	2.8	55.2	128
50	4.5	4.5	32.3	150
75	6.3	5.0	22.8	155
100	8.0	5.3	17.6	157
125	9.7	6.4	14.4	159
150	11.5	7.7	12.1	160
175	12.0	8.0	10.5	158

pediatric defibrillation (using 989803150031 Infant/Child Key)

load resistance (Ω)	phase 1 duration (ms)	phase 2 duration (ms)	peak current (A)	delivered energy (J)
25	2.8	2.8	32.0	43.4
50	4.5	4.5	18.7	50.2
75	6.3	5.0	13.2	51.8
100	8.0	5.3	10.2	52.4
125	9.0	6.0	8.3	52.3
150	9.0	6.0	7.0	50.2
175	9.0	6.0	6.1	48.1

NOTE: The values given are nominal.

CATEGORY	SPECIFICATIONS
Disarm (AED mode)	Once charged, the FR3 will disarm if: • patient's heart rhythm changes to non-shockable rhythm. • a shock is not delivered within 30 seconds after the FR3 is armed. • the CPR button (if enabled) is pressed. • the On/Off button is pressed to turn off the FR3. • rhythm analysis has continued for 45 seconds but extended artifact prevents shock determination. • the battery is depleted. • the defibrillator pads are removed from the patient or the pads connector is disconnected from the FR3. • the Infant/Child Key is inserted.
Disarm (advanced mode)	Once charged, the FR3 will disarm if any of the AED disarm conditions (above) are met, or if: • the On/Off button is pressed to turn off the FR3 • a shock is not delivered within 30 seconds after charging. • the manual disarm button is pressed. • the defibrillator pads are removed from the patient or the pads connector is disconnected from the FR3. • in advanced mode analysis, the patient's heart rhythm changes to a non-shockable rhythm.
Shock Delivery Vector	Via defibrillator pads placed in the anterior-anterior (Lead II) position or, for infants and children under 55 lbs (25 kg) or 8 years old, via defibrillator pads placed in the anterior-posterior position.

ECG ANALYSIS SYSTEM

CATEGORY	SPECIFICATIONS
Function	Evaluates impedance of defibrillation pads for proper contact with patient skin, and evaluates the ECG rhythm and signal quality to determine if a shock is appropriate.
Protocols	Follows pre-programmed settings to match local EMS guidelines or medical protocols. The settings can be modified using the setup options.
Shockable Rhythms	Ventricular fibrillation (VF) and certain ventricular tachycardias, including ventricular flutter and polymorphic ventricular tachycardia (VT). The HeartStart AED uses multiple parameters to determine if a rhythm is shockable. NOTE: 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.

CATEGORY	SPECIFICATIONS
Asystole	On detection of asystole, provides CPR prompt at programmed interval.
Pacemaker Detection	Pacemaker artifact is displayed on the FR3 ECG model. In both the FR3 ECG and Text models, the FR3 rhythm analysis algorithm is designed to remove pacemaker artifact from the signal for analysis. However, due to differences between pacemaker therapy designs, artifact removal cannot always be achieved. In the advanced mode, upon detection of a pacemaker the FR3 provides screen display of PACEMAKER DETECTED alert.

ECG ANALYSIS PERFORMANCE

RHYTHM CLASS	ECG TEST SAMPLE[A] SIZE	MEETS AHA RECOMMENDATIONS[B] FOR ADULT DEFIBRILLATION	
		OBSERVED PERFORMANCE	90% ONE-SIDED LOWER CONFIDENCE LIMIT
Shockable Rhythm — Ventricular Fibrillation	300	sensitivity >90% (meets AAMI DF80 requirement)	(87%)
Shockable Rhythm — Ventricular Tachycardia	100	sensitivity >75% (meets AAMI DF80 requirement)	(67%)
Non-Shockable Rhythm — Normal Sinus Rhythm	300	specificity >99% (meets AAMI DF80 requirement)	(97%)
Non-shockable Rhythm — Asystole	100	specificity >95% (meets AAMI DF80 requirement)	(92%)
Non-Shockable Rhythm — All other non-shockable rhythms[c]	450	specificity >95% (meets AAMI DF80 requirement)	(88%)

a. From Philips Medical Systems ECG rhythm databases.
b. 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.
c. Supraventricular tachycardia (SVT) is specifically included in the non-shockable rhythm class, in accordance with AHA recommendations[†] and the AAMI standard DF80.

DISPLAY

CATEGORY	NOMINAL SPECIFICATIONS
Monitored ECG Lead	ECG information is received from defibrillator pads in anterior-anterior (Lead II) position or in anterior-posterior position. (Displayed on FR3 ECG model 861389 only.) NOTE: The ECG display provided by the FR3 is not intended to provide diagnostic or ST segment interpretation.
Screen Type and Resolution	High-resolution color liquid crystal display (LCD).
Screen Dimensions	2.8 in wide x 2.1in high (72 mm x 54 mm).
Sweep Speed (861389 only)	18 mm/sec, nominal.
ECG Display	4 second-segments displayed (861389 only).
Frequency Response (bandwidth)	Non-diagnostic rhythm monitor 1 Hz to 30 Hz (-3 dB), nominal.
Sensitivity	9 mm/mV, nominal.

CONTROLS AND INDICATORS

CATEGORY	NOMINAL SPECIFICATIONS
Display Screen	High-resolution color LCD screen. Displays graphics, text prompts, status messages, and 4-second segments of ECG (861389 only).
Controls	On/Off button Shock button Option buttons
Sensors	Alert FR3 when: • the system case has been opened. • the Infant/Child Key has been installed. • the therapy pads or training pads connector has been connected.
LED Indicators	Ready light LED flashes to show device readiness for use. Connector socket LED flashes to indicate socket location. (LED is covered when defibrillator pad connector is properly inserted.) Shock button LED flashes when defibrillator is armed.
Speaker	Provides voice prompts and tones (volume is adjustable via setup screen).
Beeper	Chirps to alert user to a problem; e.g., when a self-test has failed.

ELECTROMAGNETIC CONFORMITY

Guidance and manufacturer's declaration: The HeartStart FR3 is intended for use in the electromagnetic environment specified in the tables below. The customer or user of the HeartStart FR3 should assure that it is used in such an environment.

ELECTROMAGNETIC EMISSIONS

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF CISPR 11	Group 1 Class B	The FR3 uses RF energy only for its internal function, except when the optional *Bluetooth* module is installed. Even under these circumstances, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The FR3 AED is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

ELECTROMAGNETIC IMMUNITY

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	There are no special requirements with respect to electro-static discharge.[a]
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial/ hospital environment. There are no special requirements for non-commercial/non-hospital environments.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	20 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the HeartStart FR3 AED, including cables, than is absolutely necessary.[b,c] The recommended separation distances for various transmitters and the AED are shown in the following table. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1.At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2.These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Generally, AEDs are sometimes susceptible to interference generated by patient and/or responder motion in environments in which a high static electric field is present (e.g., low humidity, synthetic carpets, etc.). As a safety measure, Philips AEDs incorporate a patented method to sense possible corruption of the ECG signal by such interference and to respond by directing the user to stop all motion. In these cases, it is important to minimize movement in the vicinity of the patient during rhythm analysis in order to ensure that the signal being analyzed accurately reflects the patient's underlying heart rhythm.

b. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13, 567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HeartStart FR3 AED is used exceeds the applicable RF compliance level above, the HeartStart FR3 AED should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartStart.

PORTABLE AND MOBILE RF EQUIPMENT

The HeartStart FR3 AED is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FR3 AED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FR3 AED as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (M)	
	80 MHz to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.15\sqrt{P}$
0.01	0.06	0.115
0.1	0.19	0.36
1	0.6	1.15
10	1.9	3.64
100	6.0	11.5

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2. The ISM (industrial, scientific and medial) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13, 567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3. An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 5. Transmitters/antenna of this power-level are most likely mounted on an emergency vehicle chassis. The distances cited here are for open field. For an external antenna, the separation distance is most likely shorter.

ACCESSORIES SPECIFICATIONS

989803150161 CLINICAL USE BATTERY

CATEGORY	NOMINAL SPECIFICATIONS
Battery Type	Lithium manganese dioxide. Disposable, long-life primary cell.
Capacity	12 VDC, 4.7 AH, when new and stored at 77° F (25° C).
Battery Performance	Low Battery Indication • Configured for NSA monitoring: 12 hours operating time • Configured for NSA CPR: 7.5 hours operating time • Typical shock count: 300 shocks • Minimum remaining capacity after Low Battery warning: 9 shocks, 15 minutes of operating time.
Standby Life (after installation)	Minimum 3 years when stored under standby environmental conditions (battery installed, FR3 unused).
Status Indicators for Installed Battery	Battery status is displayed on FR3 status screen at shutdown. When appropriate, text and/or voice prompts during use.
Temperature and Relative Humidity	Operating: 32° to 122° F (0° to 50° C); 5% to 95% relative humidity (non-condensing). Standby/Storage: 32° to 122° F (0° to 50° C); 10% to 75% relative humidity (non-condensing). Transport: -4° to 140° F (-20° to 60° C); 0% to 85% relative humidity (non-condensing) for up to 2 days, thereafter 65% relative humidity maximum.
Battery Limitations	Never charge, short circuit, puncture, deform, incinerate, heat above 60° C, or expose contents to water. Remove the battery when discharged.

989803150191 RECHARGEABLE TRAINING BATTERY

CATEGORY	NOMINAL SPECIFICATIONS
Battery Type	Lithium ion, rechargeable, using the 861394 charger only.
Capacity	10.8 VDC, 4.5 AH, typical. When fully charged, provides 4 hours of operating time at 77° F (25° C).
Time to Full Charge	3 hours.
Temperature and Relative Humidity	Operating: 32° to 104° F (0° to 40° C) Standby/Storage: 32° to 122° F (0° to 50° C). Transport: -4° to 140° F (-20° to 60° C); 0% to 85% relative humidity (non-condensing) for up to 2 days, thereafter 65% relative humidity maximum.

861394 BATTERY CHARGER

CATEGORY	NOMINAL SPECIFICATIONS
Application	For use with FR3 rechargeable 989803150191 training battery only.
Power Requirements	100 to 240 VAC, 47 to 63 Hz, 30 Watts
Status Indicators for Connected Battery	Flashing green LED: The battery is charging. Steady green LED: The battery is fully charged. Red LED: Charging has stopped due to failure during the charge process.
Temperature and Relative Humidity	Operating: 32° to 104° F (0° to 40° C) Standby/Storage: 32° to 122° F (0° to 50° C). Transport: -4° to 140° F (-20° to 60° C); 0% to 85% relative humidity (non-condensing) for up to 2 days, thereafter 65% relative humidity maximum.
Conformance Testing	International: IEC 60601-1:1988+A1:1991+A2:1995 2nd Ed. North America: UL 60601-1, 1st Ed.

989803149981 AND 989803149991 HEARTSTART SMART PADS III

CATEGORY	NOMINAL SPECIFICATIONS
Application	Pads for defibrillation, pacing, monitoring, cardioversion. Pre-connectable to FR3; testable when preconnected and installed in Pads Sentry. Disposable, adhesive pads with a nominal active surface area of 80 cm^2 each, and an integrated 48 inch (122 cm), typical, cable. Set of two pads on liner are designed to fit into Pads Sentry for an FR3 system case. Provided as a single set (989803149981) or five sets (989803149991).
Pads Shelf Life	Pads package is labeled with an expiration date of at least 30 months from date of manufacture.
Storage/ Transport Temperature	32° to 122° F (0° to 50° C).

OTHER COMPATIBLE DEFIBRILLATOR PADS

CATEGORY	NOMINAL SPECIFICATIONS
Pre-connectable and Tested	HeartStart SMART Pads II 98980313926: Disposable, adhesive pads with a nominal active surface area of 80 cm^2 each, provided in a disposable plastic case, and an integrated 48 inch (122 cm), typical, cable. *Pre-connectable to FR3.* For adult and infant/child patient use with FR3.

CATEGORY	NOMINAL SPECIFICATIONS
Non-pre-connectable	HeartStart DP Series 989803158211 and 989803158221: Disposable, adheisve pads with a nominal active surface area of 85 cm^2 each, provided in a sealed package, and an integrated 48 inch (122 cm), typical, cable. *Not pre-connectable to FR3.* For adult and infant/child patient use with FR3.

989803149971 FR3 RIGID SYSTEM CASE

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores and secures the FR3 with pre-connected SMART Pads III and optional accessories (Infant/Child Key, spare pads, and spare battery). Includes top and bottom case inserts and Pads Sentry.
Dimensions	13.2 in x 10.3 in x 5.2 in (33.5 cm x 26.2 cm x 13.2 cm) including handle.
Weight	4.9 lbs (2.2 kg) including Pads Sentry.

989803150211 FR3 SYSTEM CASE BOTTOM INSERT

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores and secures the FR3 with pre-connected SMART Pads III and optional accessories (spare battery). Includes Pads Sentry.
Dimensions	10.6 in x 9.1 in x 2.8 in (26.9 cm x 23.1 cm x 7.1 cm).
Weight	0.8 lb (0.4 kg).

989803150221 FR3 SMALL SOFT CASE

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores and secures the FR3 with pre-connected SMART Pads III and optional accessories (Infant/Child Key and spare pads). Includes Pads Sentry.
Dimensions	4.8 in x 9.9 in x 7.7 in (12.2 cm x 25.1 cm x 19.5 cm).
Weight	1.3 lbs (0.6 kg).

989803150031 FR3 INFANT/CHILD KEY

CATEGORY	NOMINAL SPECIFICATIONS
Application	When installed in FR3, causes defibrillator to go into infant/child mode, deliver a lower therapy level more appropriate for infants and children, and to provide any configured infant/child CPR protocol and infant/child prompts.
Dimensions	2.09 in x 0.25 in (5.31 cm x 0.63 cm).
Weight	0.6 oz (17.0 g).

989803150061 FR3 DATA CARD

CATEGORY	NOMINAL SPECIFICATIONS
Application	Stores use data for download and subsequent review.
Minimum Capacity	8 hours of ECG, event, and voice recording.

989803150101 FR3 LANGUAGE CARD

CATEGORY	NOMINAL SPECIFICATIONS
Application	Enables change of FR3 primary language or, in conjunction with the HeartStart Configure software, enables bilingual option.
Minimum Capacity	When used as an FR3 data card: 4 hours of audio, ECG, event, and voice recording. NOTE: If used as a data card, the original language files on the language card will not be overwritten. As a result, the capacity for data recording on the language card is less than on a data card.

989803150081 *BLUETOOTH* WIRELESS TECHNOLOGY TRANSCEIVER MODULE

CATEGORY	NOMINAL SPECIFICATIONS
Compliance	V2.0 Core Specification *Bluetooth* Class II.
Frequency	2.402 to 2.48 GHz.
Storage Temperature	-4° F to 140 ° F (-20° C to 60° C).

CATEGORY	NOMINAL SPECIFICATIONS
Supported Profiles	SPP serial port profile with compatible Philips software products. FTP file transfer profile for file retrieval.

989803150111 FR3 FAST RESPONSE KIT

CATEGORY	NOMINAL SPECIFICATIONS
Application	Designed to snap into 989803149971 FR3 rigid system case.
Contents	A pocket mask, a disposable razor, 2 pairs of gloves, a pair of paramedics scissors, and an absorbent wipe.
Dimensions	4.8 in x 7.75 in x 1.6 in (12.1 cm x 19.7 cm x 4.0 cm).
Case Material	High-density polyethylene.
Weight	0.5 lb (0.2 kg).

861467 AED TRAINER 3

CATEGORY	NOMINAL SPECIFICATIONS
Application	Training in use of FR3 AED.
Dimensions	8.6” x 5.2” x 2.2” (21.8 mm x 133 mm x 57 mm).
Weight (with batteries)	1.3 lb (600 g).
Battery type and quantity	4 AA size alkaline batteries (LR6).
Battery capacity	> 10 hours.
Temperature and Relative Humidity	Operating temperature: 50° - 95° F (10° - 35° C). Storage temperature: 32° - 104° F (0° - 40° C). Relative humidity: 0 - 90% non-condensing.

ENVIRONMENTAL CONSIDERATIONS

By complying with your national or local regulations regarding disposal of electric, electronic, and battery waste, you can make a positive contribution to our shared environment.

PRODUCT	INFORMATION
Defibrillator	The defibrillator contains electronic components. Do not dispose of it as unsorted municipal waste. Collect such electronic waste separately and dispose of it at an appropriate recycling facility according to your country's or local regulations.
Battery	The battery cells contain chemicals. The chemistry used in each battery is identified by a symbol on the label; symbols are defined in the defibrillator *Instructions for Administrators*. Recycle the battery at an appropriate recycling facility.
Pads	The used pads may be contaminated with body tissue, fluid, or blood. Dispose of them as infectious waste. Recycle the case at an appropriate recycling facility.

B TROUBLESHOOTING INFORMATION

GENERAL TROUBLESHOOTING

The FR3's green Ready light is the primary indicator of device readiness for use. If the Ready light is flashing, the FR3 has passed its most recent self-test or user-initiated test and is therefore ready for use. If the Ready light is on steady, the FR3 is in use or is running a periodic self-test. The following table – which is also provided on page 5-2 of this document along with detailed information about the FR3 self-tests – lists conditions where the Ready light is off, and recommended action.

INDICATOR	RECOMMENDED ACTION
Ready light is off and the FR3 is chirping	If the FR3 is emitting single chirps, press the On/Off button to start the FR3. When voice prompts begin, press the button again to display the status screen for information about the status of the FR3 and how to resolve the problem. If the FR3 is emitting triple chirps, press the On/Off button once. If an error message is displayed on the status screen, record the error, turn off the FR3, and remove it from service. Then contact Philips at www.philips.com/AEDSupport for technical support.
Ready light is off, the FR3 is not chirping, and the display screen is blank	The battery is depleted or missing, or the FR3 needs repair. Insert or replace a battery. The FR3 automatically runs a power-on self-test. If the green Ready lights starts flashing, the FR3 has passed the self-test and is therefore ready for use. If not, contact Philips at www.philips.com/AEDSupport for technical support.

TROUBLESHOOTING DURING PATIENT USE

NOTE: The information in this section is provided for use by Administrators in training responders in operation of the FR3.

If the green Ready light is flashing, press on the On/Off button to turn on the FR3, then follow all voice and text prompts.

If the green Ready light is off and the FR3 is giving single chirps, the FR3 may still be able to be used to treat a victim of SCA. Press the On/Off button then follow all voice and text prompts.

In the unlikely event that the device becomes unresponsive during use, press the On/Off button once, wait one second, then press it again. If this does not

clear the problem, remove and reinstall the battery or replace it with a new FR3 battery, if available. If this still does not clear the problem, do not use the FR3.

If you are able to complete emergency use of the FR3, but cannot clear the problem as instructed on the status screen and the green Ready light is not flashing after the FR3 is put into standby, contact Philips at www.philips.com/AEDSupport for technical support.

NOTE: Perform CPR, if needed, any time there is a delay before applying or an interruption in using the FR3.

If the FR3 detects a condition during use that requires immediate attention, it provides voice and/or screen prompts that identify the condition and, in most cases, directs the user how to correct the condition. The following table lists sample troubleshooting prompts the FR3 may give during patient use, the possible cause, and recommended action for each.

FR3 PROMPT	POSSIBLE CAUSE	RECOMMENDED ACTION
Low battery	• The battery power is low or the FR3 does not recognize the battery.	• Install a new clinical battery as soon as possible. If a new battery is not available, attempt to complete use of the FR3.
Replace battery	• The battery is depleted or the FR3 does not recognize the battery and cannot use it.	• Install a new FR3 battery immediately. The FR3 will turn off unless a new battery is installed.
Training	• The training battery is installed.	• Install a clinical battery.
Remove training pads	• The training pads are connected to the FR3.	• Disconnect the training pads and connect a set of SMART Pads III.
Replace pads	• The FR3 does not detect pads application to the patient after extended prompting.	• Be sure pads are applied properly. If prompt persists, replace the original pads with new ones.
	• The pads are damaged.	• Check for pads damage and replace if necessary.

FR3 PROMPT	POSSIBLE CAUSE	RECOMMENDED ACTION
Plug in pads connector	• The pads connector is unplugged or not fully inserted.	• Plug in the pads connector firmly.
Insert connector firmly	• The pads connector is not fully inserted. • The pads are not correctly applied to the patient. • Only one pad is applied to the patient.	• Plug in the pads connector firmly. • Replace the pads and apply to patient to continue treatment. • Remove the second pad from the liner and apply it to the patient.
Press pads firmly to patient's bare skin Be sure pads connector is completely inserted Pads must not be touching clothing or each other If needed, remove hair from patient's chest	• The pads are not properly applied to the patient. • The pads connector is not fully inserted. • The pads are on the patient's clothing or touching each other. • The pads are not making good contact with the patient's bare chest because of moisture or excessive hair.	• Make sure that the pads are sticking completely to the patient's skin. • Make sure the pads connector is fully inserted. • Make sure pads are not on their liner or the patient's clothing; reposition the pads. • If the pads are not sticking, dry the patient's chest and shave or clip any excessive chest hair.

FR3 PROMPT	POSSIBLE CAUSE	RECOMMENDED ACTION
Analyzing interrupted … Stop all motion … Cannot analyze	• The patient is being moved or jostled, interfering with heart rhythm analysis.	• Stop CPR; do not touch the patient. Minimize patient motion. If the patient is being transported, stop the vehicle.
	• The environment is dry; movement around the patient is causing static electricity to interfere with ECG analysis.	• Responders and bystanders should minimize motion, particularly in dry environments that can generate static electricity.
	• Radio or electrical sources are interfering with ECG analysis.	• Check for possible sources of radio and electrical interference and turn them off or remove them from the area.
	• Radio or electrical sources are interfering with ECG analysis or there is excessive patient motion.	• Check for possible sources of radio and electrical interference and turn them off or remove them from the area. Minimize patient motion. Then press the ANALYZE option button if available.
No shock delivered	• The pads are not making good contact with the patient's skin.	• Press the pads firmly to the patient's bare chest.
	• The pads are touching each other.	• Make sure the adhesive pads are correctly positioned on the patient. For example, the pads may be touching each other if adult pads placement is used on a very small patient.
	• The pads are damaged or the adhesive dried out.	• Replace the pads if necessary.

FR3 PROMPT	POSSIBLE CAUSE	RECOMMENDED ACTION
Shock button not pressed	• Shock has been advised but the shock button has not been pressed within 30 seconds.	• When next prompted, press the Shock button to deliver shock.
Attend to patient	• A shock has been advised but the Shock button was not pressed within 30 seconds. • The AED has been unable to analyze for more than 45 seconds.	• Provide CPR if needed. When next prompted, press the Shock button to deliver a shock. • Provide CPR if needed or follow your local protocol.
Press Shock button or device will disarm	• The On/Off button has been pressed while the FR3 is armed.	• Press the Shock button to deliver shock.

INFORMATIONAL AND ERROR MESSAGES

The FR3 is designed to assist in troubleshooting any problems it detects in its operation and use. In addition to the Ready light and alert chirping indicators, the FR3 displays an informational or error text message to alert the user to situations requiring attention. The FR3 logs error messages in internal memory.

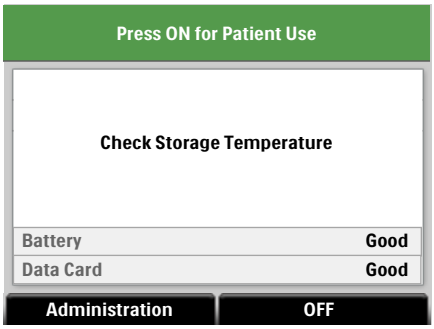
With the exception of service-required error messages, which are displayed for 60 seconds, informational and error messages are displayed for 15 seconds. If more than one message is appropriate, each screen is displayed for 15 seconds. Afterwards, the FR3 briefly displays the status screen before going to standby.

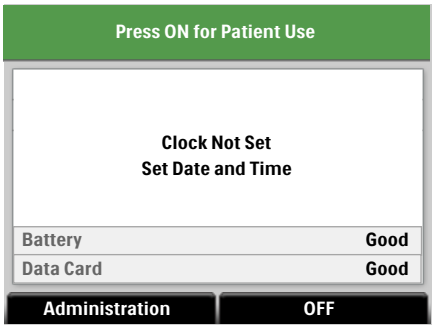
MESSAGES AT SHUTDOWN

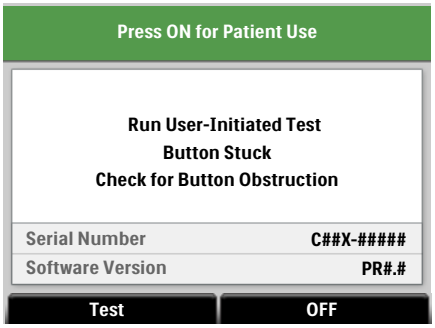
The FR3 provides informational and error messages at shutdown to identify conditions detected by the FR3 that *do not affect use of the FR3*. These conditions should be corrected so that the FR3 can pass its next self-test. In most cases, the messages include directions for resolving the issue. Follow the directions on the screen.

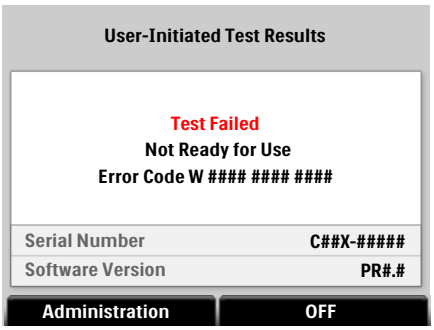
If the FR3 is already giving single chirps because it has failed a self-test, correct the problem identified, then run a user-initiated test to ensure that the defibrillator is ready for use. If an error code is displayed, please record the code and contact Philips at www.philips.com/AEDSupport to report the error.

Sample message-at-shutdown error screens are shown below.









The following table lists sample information and error messages that the FR3 may give at shutdown, the probable cause, and recommended action for each.

TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Check Storage Temperature	The FR3 has been stored outside its specified temperature range.	Make sure the FR3 is stored in a location within the specified storage temperature range.
Clock Not Set … Set Date and Time	The FR3 internal clock is not set or has lost its setting because the battery was removed for more than 2 hours.	Press the Administration option button and select DATE AND TIME from the SETUP menu. Set the date and time in the FR3 before shutting it down. The date and time may also be set using wireless data transfer and the HeartStart Configure software.
Replace Pads and Restart	The FR3 cannot detect pads attachment after five minutes of prompting.	Make sure pads are undamaged and are correctly applied to patient's bare chest. Clip or shave excess chest hair from pads placement areas. If necessary, connect a new set of pads.

TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Replace Pads Now	The pads are not ready for use.	Make sure pads are not damaged, expired, or dried out. If necessary, connect a new set of pads.
Button Stuck … Check for Button Obstruction	A button on the FR3 panel is stuck in the pressed position.	Ensure that all buttons are clear of obstruction when the carry case is closed.
Incomplete Self-Test	The FR3 has attempted to run an automatic periodic self-test three times and aborted each time due a problem.	Run a user-initiated test to identify the problem.
Remove Infant/Child Key	The Infant/Child Key has been left installed.	Remove the Infant/Child Key. The Infant/Child Key should be installed only during a pediatric use.
Data Card Full … Replace Data Card	The installed data card is full.	Remove the data card, download the data for analysis, then erase and reinstall the data card, or install a new data card. After reinstalling the battery, press the On/Off button to turn the FR3 on and then off again to clear the error.
Invalid Data Card … Replace Data Card	The installed data card is invalid.	Remove the invalid data card and install an appropriate data card. After reinstalling the battery, press the On/Off button to turn the FR3 on and then off again to clear the error.
Remove Training Pads	Training pads are connected.	Remove the training pads and replace them with appropriate clinical pads.
Plug in Pads Connector	The FR3 is configured to check pre-connected pads during self-test and does not detect the pads.	Make sure pads are pre-connected to the FR3.
No Data Card Detected … Install Data Card	The FR3 is configured to check the data card during self-test and does not detect a data card.	Install a data card in the FR3. After reinstalling the battery, press the On/Off button to turn the FR3 on and then off again to clear the error.

TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Button Test Incomplete	The user did not press the button(s) during the interactive portion of the user-initiated test.	Repeat the user-initiated test and be sure to press each button when instructed.
Replace Battery	The FR3 does not recognize the battery, or the battery power is low.	Remove the depleted or unrecognized battery and replace it with a new FR3 battery. *NOTE: If battery power is seriously depleted, the FR3 briefly displays a shutdown screen indicating the battery should be replaced, then goes to standby.*
Setup Lost … Reload Setup	The setup file is corrupt or lost and the FR3 has reverted to the default configuration. (This is extremely unlikely.)	Reload desired custom configuration using HeartStart Configure and the Administration mode. Contact Philips at www.philips.com/AEDSupport for technical support.
Test Failed … Run User-Initiated Test … Error Code W ##### ##### #####	The FR3 has encountered an error.	Record the error code number. Run the user-initiated test. Contact Philips at www.philips.com/AEDSupport for technical support.
User-Initiated Test Results …Test Failed … Not Ready for Use … Error Code W ##### ##### #####	The user-initiated test has failed.	Record the error code number. Contact Philips at www.philips.com/AEDSupport for technical support.

RESTART MESSAGES DURING PATIENT USE

In the unlikely event that the FR3 detects an error during patient use, the FR3 logs the error, records all data for the current use, and then displays the error message and shuts down. If the FR3 provides a pads problem message, replace the pads. If it provides an error code message, press the green On/Off button to turn on the defibrillator and complete the use. After the use, contact Philips at www.philips.com/AEDSupport to report the error.

Sample restart message screens are shown below.

NOTE: Perform CPR, if needed, any time there is a delay before or an interruption in using the FR3.

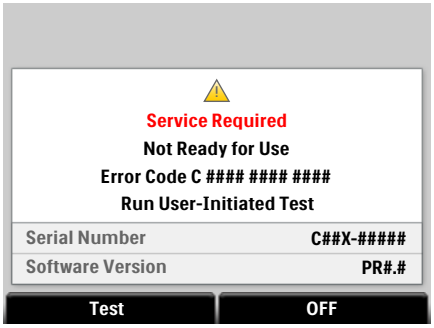
The following table presents sample restart error messages that the FR3 displays during use, probable cause, and recommended action.

TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
Error … Press ON button to Restart … Replace Pads and Restart	After three attempts, the FR3 was not able to deliver a shock through the pads and is shutting down.	Turn off the FR3, replace the pads, and turn on the FR3.
Error … Press ON button to Restart … Error Code N #####	The FR3 has encountered an error.	Press the On/Off button to clear. After the use, contact Philips at www.philips.com/AEDSupport for technical support.

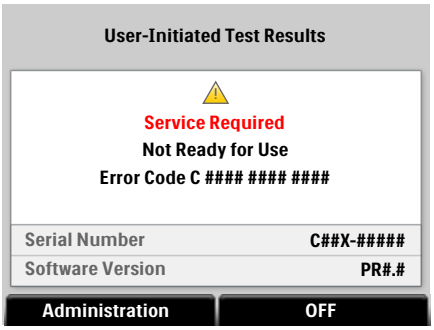
SERVICE-REQUIRED ERROR MESSAGES

When an FR3 self-test detects an error that renders the device not ready for use, it displays a service-required message with an error code for 60 seconds, then shuts down and gives triple chirps to alert you to the problem. *You cannot use the FR3 to deliver therapy until the error is cleared.*

To clear the error, first record the error code, software version, and device serial number. Then press the Test option button to run a user-initiated test. Follow the directions during the interactive portion of the user-initiated test.

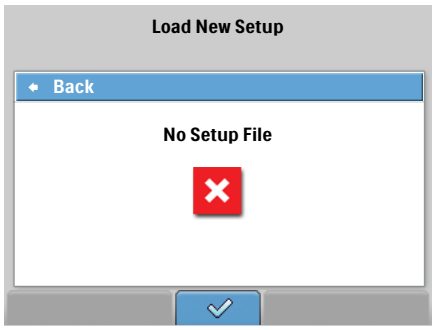


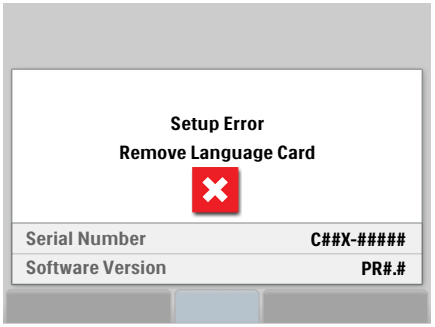
If the user-initiated test fails to clear the error, the FR3 displays a service-required error message. Record the error code, software version, and device serial number, and contact Philips at www.philips.com/AEDSupport for technical support.



ERROR MESSAGES DURING CONFIGURATION AND LANGUAGE LOADING

If the FR3 encounters an error during configuration or language loading, it displays an error message. Sample screens are shown below.





NOTE: If you encounter errors during wireless data transfer of a new device configuration file, see the HeartStart Configure software documentation.

The following table lists sample error messages that the FR3 may display during configuration and language loading, the probable cause, and recommended action for each.

TEXT MESSAGE	PROBABLE CAUSE	RECOMMENDED ACTION
No Setup File	While attempting to load a new setup, the FR3 detects that the data card is missing or does not contain a device configuration file.	Check to make sure the data card is installed and has the setup file from HeartStart Configure on it.
Invalid Setup	While loading a new setup, the FR3 detects that the setup file on the data card is corrupt.	Copy the setup file to another FR3 data card and retry or create a new setup file using the HeartStart Configure software.
Setup Error … Remove Language Card	Installation of the device configuration or new primary language has not completed successfully; configuration reverts to default settings.	Retry installing the configuration or language, or copy the file to another FR3 data card for use.
Setup Not Saved … Check Data Card	While saving a setup to a data card, the FR3 detects that a file cannot be created on a data card or there is no data card installed.	Make sure a data card is installed and has sufficient room for the device configuration file.
Language Unchanged … See Instructions for Administrators	While loading a new setup from a data card, the FR3 detects that the configuration contains language files for a new primary or selected secondary language.	The FR3 language card is required to make any changes to language. Language files cannot be loaded using the Load New Setup command on the ADMINISTRATION screen or via wireless data transfer. *NOTE: Configuration changes other than language can be loaded using either an FR3 data card or, for convenience, the FR3 language card.*

QUESTIONS ABOUT A SPECIFIC INCIDENT

If there are questions about why a HeartStart AED performed a particular way during a specific incident, please e-mail the COD file along with your questions to: AEDsupport@philips.com. This email address may also be used for general questions about HeartStart Defibrillators, their technology, or their use if you have not found sufficient answers in this manual.

VERIFICATION OF ENERGY DELIVERY

The FR3 defibrillator does not require manual verification of energy delivery, because monthly automatic self-tests verify the waveform delivery system. However, a qualified technical professional can test AED energy delivery, using the following instructions.

TEST EQUIPMENT REQUIRED

- Defibrillator Analyzer, Dynatech Nevada, Impulse 3000 with any software revision except 1.10 and Dynatech Nevada adapter cable # 3010-0537.

OR

- Defibrillator Analyzer, Dynatech Nevada, Impulse 4000 with any software revision and Dynatech Nevada adapter cable # 3010-0593.

OR

- Defibrillator Analyzer, Biotek, QED6. A cable can be fabricated from the appropriate HeartStart AED pads or cartridge and two banana plugs.

PROCEDURE WITH IMPULSE 3000

1. Connect the AED to the Impulse 3000 using the adapter cable.
2. Set up the Impulse 3000:
   - Set RANGE to Hi
   - Set POWER to On
   - Press ENERGY (F1)
   - Press VFIB (F3)
3. Press the AED On/Off button.
4. Wait for the AED to recommend a shock and when prompted, press the orange button.
5. Verify that the Impulse 3000 indicates 130-170 Joules.
6. Press the AED On/Off button and disconnect adapter cable

PROCEDURE WITH IMPULSE 4000

1. Connect the AED to the Impulse 4000 using the adapter cable.
2. Set up the Impulse 4000:
   - Set POWER to On
   - Press DEFIB (F1)
   - Press NO (F1)
   - Press ENERGY (F1)
   - Press HIGH (F2)
   - Press VFIB (F1)

3. Press the AED On/Off button.
4. Wait for the AED to recommend a shock and when prompted, press the orange button.
5. Verify that the Impulse 4000 indicates 130-170 Joules.
6. Press the AED On/Off button and disconnect adapter cable.

PROCEDURE WITH BIOTEK QED6

1. Connect the AED to the QED6 with the fabricated cable.
2. Setup the QED6 to measure the hi energy range, set the rhythm to VFIB.
3. Press the AED On/Off button.
4. Wait for the AED to recommend a shock and when prompted, press the orange button.
5. Verify that the QED6 indicates 130-170 Joules.
6. Press the AED On/Off button and disconnect adapter cable.

IMPORTANT NOTES

- If energy output is tested using any equipment other than described above, subsequent damage to the AED may occur and will invalidate product warranty.
- If questions arise, please contact Philips at 1.800.263.3342 for assistance or contact us by email at AEDsupport@philips.com.

C PADS, BATTERIES, AND DISPLAY

The supplemental information in this appendix is drawn from Application and Technical Notes relating to HeartStart defibrillators.

DEFIBRILLATOR PADS FOR FR3 AEDS

Each FR3 AED is shipped with a set of HeartStart SMART Pads III [REF: 989803149981]. These pads have an expiration date of two years from the date of manufacture and they should be checked and replaced as needed. These pads are designed to be pre-connected to the FR3 and are illustrated with pads placement instructions for lay rescuers, which makes the AED easier to use by people who are not highly trained medical personnel.

In conjunction with the FR3 Infant/Child Key, the SMART Pads III can be used for treating children under 55 pounds (25 kg) or less than 8 years old. When the Infant/Child Key is installed in the FR3, the device reduces the amount of energy delivered, so that the patient receives 50 J instead of the adult dose of 150 J.

The pediatric defibrillation solution is different for each AED model.

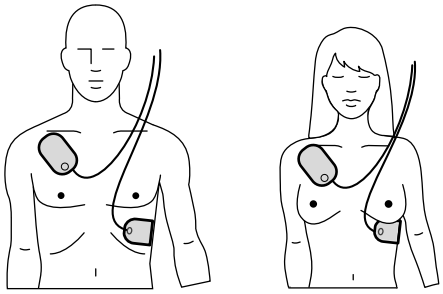
- Philips manual monitor/defibrillators must use the HeartStart manual pediatric pads (M3717A).
- The HeartStart FR2+ device requires the HeartStart Infant/Child pads (M3870A).
- The HeartStart HS1 devices (including the HeartStart OnSite and HeartStart Home) require the Infant/Child SMART Pads Cartridge (M5072A).
- The HeartStart FRx uses HeartStart SMART Pads II [REF: 989803139261] for adults with an Infant/Child Key (989803139311) for pediatric use.
- There are no pediatric pads available for the ForeRunner AED.

PADS PLACEMENT WITH THE FR3 AED

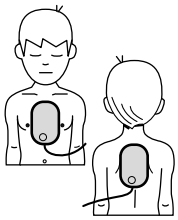
Proper pads placement for adult defibrillation with the HeartStart FR3 defibrillator is specified with an illustration on the FR3 display, on the pads themselves, and with a diagram in the *Guide to Setup, Operation, and Maintenance* and *Instructions for Administrators* provided with the FR3.

When the FR3 Infant/Child Key is inserted, the FR3 screen displays correct placement on patients younger than 8 years old or weighing less than 55 pounds (25 kg).

Where to place pads on adults and children over 55 pounds or 8 years old (anterior-anterior).



Where to place pads on infants or children under 55 pounds or 8 years old (anterior-posterior).



Use studies with the first Philips AED, the ForeRunner, demonstrated that users consistently took less time to apply the pads when the pads were labeled with a specific location. With this in mind, the pads themselves are labeled to show that one should be applied below the right clavicle and the other should be applied below the patient's left breast and in line with the axilla. While unpublished animal studies showed no difference in defibrillation efficacy if the pads are reversed, human factors studies showed that the pads are applied more quickly if specific locations are shown for each pad.

Polarity is also specified on the pads in order to normalize the ECG display. If the pads are reversed, the user will see an inverted QRS complex on the display. While this may be inconvenient for viewing the ECG, it does not reduce the performance of the AED's algorithm or the efficacy of the delivered energy in any way.

The HeartStart FR3 AED is designed to be as easy to use as possible. Labeling the pads with specific locations was just one of many design decisions made to reduce the variables present in using the device. Philips developed this pad labeling to reassure the user during a patient use and to speed up pad application. This allows delivery of the first shock as quickly as possible when needed.

BATTERIES FOR FR3 AED

There are several different lithium battery chemistries, each with its own set of characteristics that determine their suitability for different environments.

The standard non-rechargeable batteries used in the FR3 AED contain consumer grade lithium manganese dioxide ($LiMnO_2$) cells. The 989803150161 battery contains twelve "2/3A" size standard camera batteries built into a custom battery pack. The batteries used by Philips are designed and tested specifically for high-volume consumer applications, where safety is of the utmost importance. These same battery cells can be purchased individually at local camera stores or drugstores for use in consumer electronic devices.

The batteries chosen for HeartStart AEDs meet Philips high standard of quality and have been proven to be reliable and safe over many years of operation. These battery cells are recognized under the Component Program of Underwriters Laboratories, Inc. (UL) and have been extensively tested by exposing them to abusive environmental, mechanical, and electrical conditions. Additionally, a third-party testing laboratory has confirmed that the battery cells used in HeartStart AED battery packs satisfy international standards for safety.

DIFFERENCES IN BATTERY CHEMISTRIES UTILIZED BY AEDS

Lithium manganese dioxide ($LiMnO_2$) and lithium sulfur dioxide ($LiSO_2$) are two lithium chemistries currently used in non-rechargeable AED batteries. After evaluating both chemistries, Philips determined that $LiSO_2$ is unsuitable for its automated external defibrillator application. $LiSO_2$ batteries contain pressurized sulfur dioxide gas, which can present a serious health hazard if released into an enclosed area such as a car, a mine, or an aircraft. The evaluation also showed performance and stability problems associated with $LiSO_2$ batteries when the cells are periodically discharged over a prolonged period of time, such as what happens when daily self-tests are performed.

Millions of consumer-grade lithium manganese dioxide ($LiMnO_2$) battery cells are safely used in common consumer applications including cameras, portable electronic devices, and even wristwatches. Consumer-grade $LiMnO_2$ technology was chosen for the HeartStart AEDs, because it is safe to use in an AED application. The consumer-grade $LiMnO_2$ cells used in the HeartStart AEDs' battery packs are small, low-pressure cells that have built-in safety devices that prevent excessive current draw above a certain temperature; the result is a safer cell design that is appropriate for use by the general public.

DISPOSABLE VERSUS RECHARGEABLE BATTERIES

Rechargeable batteries have historically been a major source of failures in AEDs, particularly as a result of poor battery maintenance practices.[1] The use of non-rechargeable batteries eliminates the need for a controlled battery maintenance process and the personnel needed to implement it. The consumer grade non-rechargeable $LiMnO_2$ batteries were chosen because they provide the best balance of safety, reliability and performance and meet the requirement of a low level of maintenance.

AEDs need to be as maintenance free as possible. HeartStart AEDs are designed to monitor the battery and prompt the user by way of the Ready light and alert chirping if it needs to be replaced.

The battery cells contain chemicals. Recycle the battery at an appropriate recycling facility in accordance with local regulations.

1 American Heart Association. *Advanced Cardiac Life Support.* September 1997, pp. 4-15.

BATTERY USAGE

The 989803150161 battery is designed to provide a minimum of 300 shocks or from 7.5 to 12 hours of operating life (depending on configuration) or to last a minimum of 3 years, typical, in standby mode.

There are other activities, such as self-tests, the user-initiated test, and frequent power-ons, that use energy from the battery, and if these activities are performed frequently, they can lead to a reduction in the performance life of the FR3 battery.

TROUBLESHOOTING THE BATTERY

Anytime that a battery is suspected of being low or having problems, the first troubleshooting step should be to perform a user-initiated test using the suspect battery. See the *Instructions for Administrators* or the *Guide to Setup, Operation, and Maintenance* provided with the FR3 for directions on running the user-initiated test. If the FR3 passes the test with no indications of battery problems, the unit and battery are both ready for service. Other conditions, such as keeping the AED outside the recommended storage temperature can cause failure messages. These messages will be cleared out with a successful user-initiated test. If the AED does not pass the test, the test should be reattempted with a known good battery that has been stored within the specified temperature range, to determine if the battery is the cause of the failed test. If the unit again does not pass, contact Philips Customer Service. In the North America, contact Philips at 1.800.263.3342 for assistance.

ADVANCED BATTERY TROUBLESHOOTING

The FR3 has several advanced features to help the user determine battery health. The FR3 clinical battery (989803150161) contains electronics that record how much it has been used. This battery use information can be checked by reviewing the Battery History information available in the FR3. The information includes the following:

- Total operating time, including self-test time, for the battery
- Total number of full defibrillation charges that have been provided by the battery, including self-test and user-initiated test chargers
- Total number of days the installed battery has been in standby mode
- Total number of user-initiated tests that have been run using the battery
- The status of the battery
- The battery status code (for use by Philips technical support)

See the *Instructions for Administrators* provided with the FR3 for directions on accessing the battery history.

The FR3 also stores Device History information. This information includes the following:

- How many times the FR3 has been turned on and pads applied
- Total time the FR3 has been used with pads applied
- Total number of shocks the FR3 has delivered
- Total number of times the FR3 training battery has been installed to activate training
- Total time the FR3 has been used with a training battery
- Total number of daily self-tests the FR3 has run
- Total number of weekly self-tests the FR3 has run
- Total number of monthly self-tests the FR3 has run
- Total number of user-initiated tests of the FR3 that have been run

Note that to the FR3, shocks and charges are not equivalent. It is not uncommon for the number of monthly self-tests to be greater than the number of weekly self-tests. This is because monthly self-tests can occur during additional situations. For example, turning off the AED during a user-initiated test causes the unit to perform a monthly self-test two hours later.

See the *Instructions for Administrators* provided with the FR3 for directions on accessing the device history.

VALUE OF AN ECG DISPLAY ON THE FR3 AED

The ECG display on the FR3 AED was designed to provide a simple display of the ECG through Lead II. The HeartStart FR3 AED:

- Displays Lead II only - cardiac monitors typically display multiple leads (Lead I, II, and III)
- Has a bandwidth of 1 Hz - 20 Hz (typical of transport defibrillators)
- Displays 3 seconds of ECG

The display was not designed to meet the AAMI Standard for Cardiac Monitors, as the LCD screen does not provide the resolution required for diagnostic and ST segment interpretation, which require the use of a 12 lead ECG. However, the ECG display on the FR3 is useful to Advanced Live Support (ALS) providers when they arrive on scene. With this display, they are able to make a quick assessment of the patient's heart rhythm and determine if the rhythm is VF, organized or asystole. This ability to immediately see the patient's heart rhythm allows ALS rescuers to prioritize their initial care.

For instance, if ALS providers familiar with the HeartStart AED see an organized rhythm on the screen, they may choose to leave the AED on the patient while providing additional care, such as airway intubation and establishment of an intravenous line for administering medication. During this time, the HeartStart AED continues to monitor the patient's heart rhythm and will alert the ALS provider if an analysis and/or shock is necessary.

An ALS provider who does not have an ALS monitor/defibrillator, but does have ALS medications (e.g., on a commercial aircraft) may also find the HeartStart AED ECG screen helpful in determining appropriate care after the patient has been initially treated with the AED for SCA. Indications of a slow or fast heart rate, premature ventricular contractions (PVCs) or an irregular heart rhythm may be visualized on the screen. With this information, a physician or ALS provider can make treatment decisions to further stabilize and protect the patient until they can be transferred to fully equipped care providers.

Given these examples, it is evident that the ECG display has value for ALS providers and contributes to efficient and effective patient care. Even after a successful defibrillation, it is best to leave the HeartStart AED attached to the patient (unless an ALS provider has decided to transfer the patient to another monitor/defibrillator). In these cases, the HeartStart AED will continue to monitor the patient and prompt the rescuer in case of refibrillation.

D USE ENVIRONMENT

DEFIBRILLATION IN THE PRESENCE OF OXYGEN

The *Instructions for Administrators* and the *Guide to Setup, Operation, and Maintenance* provided with the FR3 AED contain the following warning:

> DANGER: IF THE FR3 IS USED TO GIVE A SHOCK IN THE PRESENCE OF FLAMMABLE ANESTHETICS OR CONCENTRATED OXYGEN, THERE IS A RISK OF EXPLOSION. MOVE SUPPLEMENTAL OXYGEN AND OXYGEN DELIVERY DEVICES AWAY FROM THE DEFIBRILLATION PADS. HOWEVER, IT IS SAFE TO USE THE FR3 ON SOMEONE WEARING AN OXYGEN MASK.

This warning refers to situations where a fire hazard is present. In these rare situations, a patient may be in an environment where a spark could ignite any combustibles present, such as clothes or bedding.

AEDs deliver an electrical current, so there are rare instances in which a spark may be generated between the AED and the patient during a discharge. This may occur from problems such as a faulty connection or improperly applied pads. If a spark is generated in the presence of flammable gases, it could result in a fire.

While this may be a problem in a hospital environment when an oxygen tent is in use, there is no problem when using an oxygen canister with a mask on the patient. In this situation there are not high concentrations of oxygen accumulating around the patient's chest that would pose a risk. EMS personnel and paramedics commonly administer oxygen while performing CPR and typically do not remove this equipment if the patient needs to be defibrillated. However, if practice is to remove the oxygen mask before defibrillating, care should be taken to ensure that oxygen is not flowing across the patient’s chest.

DEFIBRILLATION ON A WET OR METAL SURFACE

It is safe to defibrillate a patient on either a wet or metal surface as long as the appropriate safety precautions are taken. Specifically, care should be taken to ensure that no one is touching the patient when the shock button is pressed.

The FR3 defibrillator is designed to be easy to use and have clear text and voice prompts that reinforce the proper use of the product. When the HeartStart defibrillator is analyzing the ECG, it will announce, "Do not touch the patient." When it decides to shock and charges, it will tell the user to stay clear of the patient. It will also inform the user when it is safe to touch the patient. All these messages are intended to make the unit safer and easier to use.

BACKGROUND

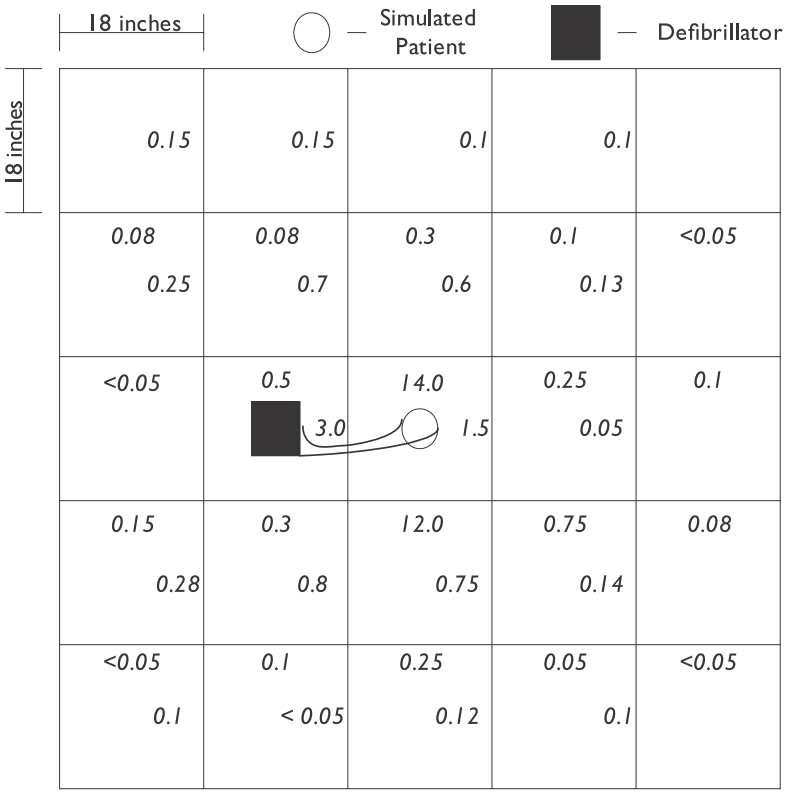
When a patient is externally defibrillated, the current that travels between the pads will always seek the path of least resistance. Some of this current will pass over the surface of the patient's skin, and if the patient is resting on an electrically insulating surface, all defibrillation energy is kept within the patient. If the user does not touch the patient during the discharge, there is no danger of their receiving a shock, as there is not a current path that would cause the user to experience a shock. However, if the patient is resting on a somewhat electrically conductive material, such as a wet surface, some of this energy may pass outside the patient. It is the presence of this energy near the patient that has prompted concern of electrical shock hazards to caregivers or bystanders during delivery of defibrillation.

Historically, patients have been defibrillated without harm on both insulating and conductive surfaces. For example, dry flooring (such as wood) does not conduct stray currents, hence inducing no potential gradient around the patient. At the other extreme, patients on metal surfaces (such as the floor of a helicopter) are also defibrillated safely, as the electricity is completely conducted through the metal and away from any bystanders. According to the American Heart Association (*Guidelines 2000*), metal surfaces "pose no shock hazard to either the victim or rescuer."

TESTING

To confirm there would be no effect on the user, Philips has simulated a 150J SMART Biphasic shock to a patient on a wet concrete surface using chlorinated pool water.[1] The voltages created in the water were tested at various points away from the simulated patient to verify that no danger existed to the user. This grid below shows the leading edge peak voltage (in Volts) recorded during a defibrillation shock measured at each location on the grid.

1. Vance et al. Automated External Defibrillation in a Wet Environment World Congress on Drowning 2002, Amsterdam, 26-28 June 2002, *Book of Abstracts,* p.169



Numbers in italics are voltages at locations.

The maximum peak voltage of 14 volts occurred at a distance of approximately six inches from the simulated patient. Fourteen (14) volts are unlikely to cause any operator or bystander sensation or risk in this environment.

The voltages quickly lowered as the distance from the patient increased. At a distance of approximately 2 feet away from the patient, the maximum voltage was only 0.28 volts. At this voltage, there is virtually no operator or bystander sensation or risk in this environment.

It should be noted that the voltage recorded on the Defibrillator Shock Button was 0.4 V or less when placed 18 inches from the simulated patient, resulting in no sensation or risk to the user when the button is pressed.

CONCLUSION

The simulation of patient defibrillation in a pool water environment demonstrated that an operator touching the defibrillator was at particularly low risk. Bystander risk in an actual defibrillation event is likely to be considerably less than the simulated bystander risk, because patient head and limbs will provide greater separation between the bystander and the defibrillation pad area. Operation of the defibrillator in a rainy environment should present no additional risks to the operator or bystanders, since the conductivity of rainwater will be less than the pool water.

PROTECTION AGAINST WATER AND PARTICLES

THE IP CODE

HeartStart defibrillators use an international standard to identify the level of protection provided by the defibrillator enclosures against solid particles and water. This standard is called "IEC 529, Degrees of protection provided by enclosures (IP Code)." This standard identifies the protection with two numbers. The first number designates the level of protection against solid particles, and the second designates the level of protection against water.

Higher numbers indicate a higher level of protection. The degrees of protection are listed in the tables below:

SOLID PARTICLE PROTECTION

FIRST NUMBER	DEGREE OF PROTECTION	
	USER PROTECTION FROM HAZARDS	SOLID OBJECT PROTECTION
0	Non-Protected	Non-Protected
1	Protected against access to hazardous parts with the back of the hand	Protected against solid foreign objects of 50 mm diameter and greater
2	Protected against access to hazardous parts with a finger	Protected against solid foreign objects of 12.5 mm diameter and greater
3	Protected against access to hazardous parts with a tool	Protected against solid foreign objects of 2.5 mm diameter and greater
4	Protected against hazardous parts with a 1mm diameter wire	Protected against solid foreign objects of 1.0 mm and greater
5	Protected against hazardous parts with a 1mm diameter wire	Dust protected
6	Protected against hazardous parts with a 1mm diameter wire	Dust-tight
X	Not Tested	Not Tested

WATER PROTECTION

SECOND NUMBER	DEGREE OF PROTECTION
	PROTECTION FROM WATER
0	Non-Protected
1	Protected against vertically falling water drops
2	Protected against vertically falling water drops when enclosure is tilted 15°
3	Protected against spraying water
4	Protected against splashing water
5	Protected against water jets
6	Protected against powerful water jets
7	Protected against the effects of temporary immersion in water
8	Protected against the effects of continuous immersion in water (special conditions)
X	Not tested

HEARTSTART DEFIBRILLATOR TESTING

Each level of protection requires that the product pass a predefined test. The FR3 AED meets the specifications for IEC 529 class IP55. The test procedure performed by Philips to meet this standard was as follows: The defibrillator was sprayed on all sides with pressurized water using a calibrated nozzle for 3 minutes. The defibrillator was then removed, inspected, and tested to ensure that the water had not accumulated enough to affect the performance or safety of the defibrillator.

EFFECTS OF EXTREME ENVIRONMENTS

The FR3 defibrillator has a recommended environmental range of:

ENVIRONMENT	RANGE
Operating Temperature	32° F to 122 °F (0° C to 50° C)
Operating Humidity	5% to 95% RH (Relative Humidity)
Standby/Storage temperature	32° F to 122° F (0° C to 50° C) - FR3
Standby Humidity	10% to 75% RH

These ranges are specified in the *Instructions for Use* for the defibrillator. The standby temperatures assume that a battery is installed and the unit is stored with defibrillator pads. When the defibrillator and accessories are exposed to environments outside the recommended temperature and humidity ranges, their performance can be affected. Some major effects are outlined below:

PADS

ABOVE STANDBY TEMPERATURE

The gel on the defibrillator pads contains large quantities of water. Over time, this water will evaporate out of the pads through the pads packaging. At standby temperatures, this evaporation will occur over a period of years. Increases in temperature will cause the water to evaporate faster. Storing the pads at temperatures above the suggested storage temperature may cause them to expire prematurely.

BELOW STANDBY TEMPERATURE

Although the pads contain water, they will not freeze when stored at temperatures below the recommended standby temperature. There are other components in the gel, such as salt, that prevent the water from freezing. Extremely low temperatures may affect pad adhesion and shock impedance. However, when cold pads are placed on a warm patient, they will warm up quickly and will be ready to use for therapy.

BATTERIES

ABOVE STANDBY TEMPERATURE

All batteries self-discharge over time, and the rate of this discharge increases as the storage temperature increases. Storing the batteries (in or out of the defibrillator) above the recommended standby temperature will cause the batteries to become depleted prematurely.

LCD DISPLAYS

ABOVE STANDBY TEMPERATURE

A combination of high humidity (above the recommended standby humidity of 75% RH) and high temperature (above the recommended standby temperature of 109°F) for long periods will permanently damage the polarizing layer of an LCD, creating a washed out appearance. A failure of the LCD polarizer does not inhibit or otherwise degrade defibrillator performance during patient use.

Note that high temperatures without high humidity can also cause this effect, but the effect is only temporary and the display will recover after returning to specified use temperatures. The combination of both high humidity and high temperature is required to permanently damage the screen.

BELOW STANDBY TEMPERATURE

Temperatures below the recommended standby temperature of 32° F (0° C) will temporarily cause the LCD display to react slowly and may not produce accurate prompts or ECG readings. This effect is temporary and the display will recover when returned to normal use temperatures.

SELF-TEST FAILURES

The FR3 will postpone its daily self-test if the temperature is below 32° F (0° C) or above 122° F (50° C). This is to prevent inaccurate results as the electronic components tested perform differently at temperatures outside of the recommended standby temperature ranges. Extended storage above or below these temperatures will cause the unit to begin chirping to warn the user that the test is not being performed and the FR3 may not be ready for use. A user-initiated test (initiated by removing and re-inserting the battery) will test the FR3 and typically clear the failure message.

SELF-TEST ABORTS DUE TO TEMPERATURE EXTREMES

BACKGROUND

HeartStart AEDs employ daily self-tests to ensure that the units are always ready for use. However, the units will not perform these tests during extreme temperature conditions. Because computer electronics perform differently at different temperatures, these self-tests are aborted above and below certain temperatures to ensure that the self-tests are producing accurate results.

TECHNIQUE

HeartStart Defibrillators have an electronic thermometer that measures the temperature of the defibrillator's immediate environment. If the temperature is measured below 32° F (0° C) or above 122° F (50° C) for the FR series (ForeRunner or FR), FR2 series (FR2 and FR2+), FRx series, and FR3 series; or below 32° F (0° C) or above 109° F (43° C) for the HS1 series (HeartStart Defibrillator, Home, and OnSite) defibrillators, the self-test will abort. The defibrillator will then attempt to perform the test again 8 hours later (instead of the standard 24 hours), to allow for the ambient temperature to either increase or decrease. If this test is aborted again, the unit will attempt to perform the self-test once again in another 8 hours. If the defibrillator aborts the self-test three times in a row (over a 16 hour period) it will issue a warning that the unit is being stored incorrectly and is not capable of accurately performing its self-tests, and may not be ready for service.

NOTIFICATION

HeartStart Defibrillators will announce the temperature-related aborts through a series of audible chirps and changes in the status indicator. The notification is very similar to, and can be easily confused with a low battery message. Take care not to discard an otherwise good battery when this occurs. The FRx and HS1Defibrillator will also flash the blue “i-button.” Pressing this button will inform the user that the defibrillator has been stored outside the acceptable temperature limits. The FR, FR2, and FR3 series will display a text message on the screen announcing that the defibrillator has been stored outside the acceptable temperature limits.

WHAT TO DO

When this notification or any similar notification occurs, a Battery Insertion Test (BIT), initiated by removing and re-inserting the battery, should be performed at room temperature. This will likely clear the failure and ensure that the defibrillator is ready for use. The unit will still attempt to operate in an emergency even though it has aborted the self-tests due to a temperature extreme, and it is recommended that the unit be used in such a situation. To prevent this issue from occurring again, the defibrillator should be stored within the specified standby temperatures — 32°-109° F (0°- 43° C) for the

FR2 series, 50°-109° F (10°-43° C) for the FR and HS1 series, and 32°-122° F (0°- 50° C) for the FRx and FR3 series — as noted in the Instructions for Use/Owner's Manual/User's Guide/Guide to Setup, Operation, and Maintenance.

E LITERATURE SUMMARY FOR HEARTSTART AEDS

INTRODUCTION

The following pages list references for numerous studies completed to demonstrate the validity and effectiveness of the HeartStart AED technology as well as use of HeartStart AEDs in clinical situations. A brief conclusion is listed next to the reference. There is also a citation of the actual source or abstract for additional details.

The Philips HeartStart SMART Biphasic waveform is set apart from other waveforms by the sheer volume of research data available to support it. There are currently over two dozen peer-reviewed manuscripts that have been published to support the SMART Biphasic waveform.

When reviewing studies on biphasic waveforms, it is important to understand which biphasic waveform or waveforms are being studied and in what environment. For example, the SMART Biphasic waveform uses a 100 μF capacitor in its design to store the energy that will be delivered to the patient, whereas some other manufacturers use 200 μF capacitors. The value of the capacitor makes a significant difference in the amount of energy and the waveform shape required in order to be effective. In addition, as was done for SMART Biphasic, defibrillation models developed for animal studies must be proven in out-of-hospital cardiac arrest human studies in order to validate the model. If the results of a defibrillation study with animals contradict the results of defibrillation studies with real people in sudden cardiac arrest, then the model is questionable and should be viewed with skepticism.

The following tables provide a glimpse into the cumulative literature on the technology used in HeartStart AEDs, presented chronologically within each category. All references are peer-reviewed manuscripts. The bulk of the literature presented deals with experimental and clinical studies of the biphasic waveform. These are followed by citations of publications on pediatric defibrillation, the respective roles of CPR and defibrillation, ease-of-use and user-interface studies, and research into the use of AEDs by first responders to treat victims of sudden cardiac arrest.

REFERENCES

DEFIBRILLATION WAVEFORM -- ANIMAL STUDIES	EXCERPTS/CONCLUSIONS
Gliner BE, Lyster TE, Dillion SM, Bardy GH. Transthoracic defibrillation of swine with monophasic and biphasic waveforms. *Circulation* 1995 Sep 15; 92(6):1634-43.	"This study demonstrates the superiority of truncated biphasic waveforms over truncated monophasic waveforms for transthoracic defibrillation of swine. Biphasic waveforms should prove as advantageous at reducing voltage and energy requirements for transthoracic defibrillation as they have for internal defibrillation."
Tang W, Weil MH, Sun S, Yamaguchi H, Povoas HP, Pernat AM, Bisera J. The effects of biphasic and conventional monophasic defibrillation on postresuscitation myocardial function. *J Am Coll Cardiol* 1999 Sep; 34(3):815-22.	"Lower-energy biphasic waveform shocks were as effective as conventional higher energy monophasic waveform shocks for restoration of spontaneous circulation after 4 and 7 min of untreated VF. Significantly better postresuscitation myocardial function was observed after biphasic waveform defibrillation."
Tang W, Weil MH, Sun S. Low-energy biphasic waveform defibrillation reduces the severity of postresuscitation myocardial dysfunction. *Crit Care Med* 2000 Nov; 28(11 Suppl):N222-4.	"We compared the effects of low-energy biphasic waveform defibrillation with conventional monophasic waveform defibrillation after a short (4 mins), intermediate (7 mins), or prolonged (10 mins) interval of untreated ventricular fibrillation. Biphasic waveform defibrillation with a fixed energy of 150 joules proved to be as effective as conventional monophasic damped sine waveform defibrillation for restoration of spontaneous circulation, with significantly lower delivered energy. This was associated with significantly less severity of postresuscitation myocardial dysfunction. The low-energy biphasic waveform defibrillation is, therefore, likely to be the future direction of transthoracic defibrillation in settings of cardiopulmonary resuscitation."

DEFIBRILLATION WAVEFORM -- ANIMAL STUDIES	EXCERPTS/CONCLUSIONS
Tang W, Weil MH, Sun S, Povoas HP, Klouche K, Kamohara T, Bisera J. A comparison of biphasic and monophasic waveform defibrillation after prolonged ventricular fibrillation. *Chest* 2001 Sep; 120(3):948-54.	"Lower-energy biphasic waveform shocks were as effective as conventional higher-energy monophasic waveform shocks for restoration of spontaneous circulation after 10 min of untreated VF. Significantly better postresuscitation myocardial function was observed after biphasic waveform defibrillation. Administration of epinephrine after prolonged cardiac arrest decreased the total energy required for successful resuscitation."
Tang W, Weil MH, Jorgenson D, Klouche K, Morgan C, Yu T, Sun S, Snyder D. Fixed-energy biphasic waveform defibrillation in a pediatric model of cardiac arrest and resuscitation. *Crit Care Med* 2002 Dec; 30(12):2736-41.	"An adaptation of a 150-J biphasic adult automated defibrillator in which energy-reducing electrodes delivered 50-J shocks successfully resuscitated animals ranging from 3.7 to 25 kg without compromise of postresuscitation myocardial function or survival."

DEFIBRILLATION WAVEFORM -- ANIMAL STUDIES	EXCERPTS/CONCLUSIONS
Yoon RS, DeMonte TP, Hasanov KF, Jorgenson DB, Joy ML. Measurement of thoracic current flow in pigs for the study of defibrillation and cardioversion. *IEEE Trans Biomed Eng* 2003 Oct; 50(10):1167-73.	"The current applied through surface electrodes followed a complex pathway through the body that has not been seen before. The high current density and the direction of streamlines along the chest wall indicate patterns of shunting current between the electrodes. Furthermore, the total amount of current flowing along the chest wall (58%-65% of the applied current) suggests that the majority of the current will travel through the chest wall. This pattern has been suggested by other researchers as a result of the chest wall having a more conductive pathway than the transthoracic pathways through the lung (σ_{muscle} = 0.3 S/m, σ_{lung} = 0.08 S/m)… Furthermore, asymmetry of the tissue composition (e.g., the presence of spine and the thickness of the chest wall) will also affect the current distribution. It is important to note that the majority of the current entering the heart was seen originating from these shunting currents along the precordial chest wall… "Although defibrillation has been in clinical use for more than 50 years, the complete current flow distribution inside the body during a defibrillation procedure has never been directly measured… In this study, CDI [current density imaging] was used to measure current density at all points within a postmortem pig torso during an electrical current application through defibrillation electrodes. Furthermore, current flow information was visualized along the chest wall and within the chest cavity using streamline analysis. As expected, some of the highest current densities were observed in the chest wall. However, current density distribution varied significantly from one region to another, possibly reflecting underlying heterogeneous tissue conductivity and anisotropy. Moreover, the current flow analysis revealed many complex and unexpected current flow patterns that have never been observed before. This study has, for the first time, noninvasively measured the volume current measurement inside the pig torso."

DEFIBRILLATION WAVEFORM -- ANIMAL STUDIES	EXCERPTS/CONCLUSIONS
Tang W, Weil MH, Sun S, Jorgenson D, Morgan C, Klouche K, Snyder D. The effects of biphasic waveform design on post-resuscitation myocardial function. *J Am Coll Cardiol* 2004 Apr 7;43(7):1228-35.	"It has been previously shown that a biphasic truncated exponential (BTE) waveform may be designed to minimize the defibrillation threshold in terms of either energy or peak current but that these two notions of optimization result in different waveform shapes. These waveform variants generally are achieved through the appropriate choice of the defibrillation capacitor (e.g., 100 μF for low-energy biphasic truncated exponential [BTEL] at 150 J vs. 200 μF for high-energy biphasic truncated exponential [BTEH] at 200 to 360 J). Low-energy biphasic truncated exponential waveforms are generally characterized by higher peak current but lower energy and average current than their BTEH counterparts. Although both waveform variants are commonly available in commercial products, the question remains as to which of these approaches might result in better outcome, as characterized by survival and post-resuscitation myocardial function… "This study confirmed the hypothesis that biphasic waveform defibrillation with a BTEL waveform at 150 J is as effective as the same waveform at 200 J for successful return of spontaneous circulation while it simultaneously minimizes post-resuscitation myocardial dysfunction. We also confirmed that BTEL waveform shocks at 150 J are as effective as BTEH shocks at 200 and 360 J for successful return of spontaneous circulation while they simultaneously minimize post-resuscitation myocardial dysfunction. We further demonstrated that these effects are attributable to specific characteristics of waveform design. In particular, higher peak current is positively associated with improved survival, whereas higher energy and higher average current are associated with increased post-resuscitation myocardial dysfunction. These observations argue for a damage mechanism related to cumulative, rather than instantaneous, electrical exposure." See Selected Clinical Studies at the end of this chapter for a more detailed discussion of this publication.

DEFIBRILLATION WAVEFORM -- ANIMAL STUDIES	EXCERPTS/CONCLUSIONS
Tang W, Snyder D, Wang J, Huang L, Chang YT, Sun S, Weil MH. One-shock versus three-shock defibrillation protocol significantly improves outcome in a porcine model of prolonged ventricular fibrillation cardiac arrest. *Circulation* 2006 Jun 13; 113(23):2683-9.	"The observation of different survival outcome despite similar defibrillation efficacy is readily understood in the context of the overall resuscitation process. When the duration of cardiac arrest is prolonged, continuous and good-quality CPR, especially chest compressions, is an extremely important determinant of successful resuscitation. Both experimental and clinical studies have demonstrated that interruption of chest compressions for as little as 10 seconds between each interval of CPR for rhythm analysis, ventilation, or patient assessment significantly reduces the number of chest compressions delivered to a patient. This, in turn, reduces coronary perfusion pressure and myocardial blood flow, decreases successful resuscitation, and increases the severity of postresuscitation myocardial and cerebral dysfunction. This is especially important with regard to AEDs, because most currently available AEDs require significantly longer than 10 seconds for rhythm analysis and charging. CPR interruptions are prolonged even further when the conventional (and recommended) 3-shock protocol is used. It is clear that the performance of a defibrillator must be viewed in a much larger context than its efficacy at terminating VF. An optimal defibrillator must minimize interruptions of CPR for voice prompts, rhythm analysis, and capacitor charging. In addition, the electrical therapy must provide high efficacy while simultaneously minimizing postresuscitation myocardial dysfunction." See Selected Clinical Studies at the end of this chapter for a more detailed discussion of this publication.

DEFIBRILLATION WAVEFORM -- CLINICAL STUDIES	EXCERPTS/CONCLUSIONS
Bardy GH, Gliner BE, Kudenchuk P J, Poole JE, Dolack GL, Jones GK, Anderson J, Troutman C, Johnson G. Truncated biphasic pulses for transthoracic defibrillation. *Circulation* 1995 Mar 15; 91(6):1768-74.	"The results of this study suggest that biphasic truncated transthoracic shocks of low energy (115 and 130 J) are as effective as 200-J damped sine wave shocks used in standard transthoracic defibrillators. This finding may contribute significantly to the miniaturization and cost reduction of transthoracic defibrillators, which could enable the development of a new generation of AEDs appropriate for an expanded group of out-of-hospital first responders and, eventually, layperson use." NOTE: This study of a 115J and 130J waveform contributed to the development of the 150 J, nominal, therapy that ships with Philips AEDs.
Bardy GH, Marchlinski FE, Sharma AD, Worley SJ, Luceri RM, Yee R, Halperin BD, Fellows CL, Ahern TS, Chilson DA, Packer DL, Wilber DJ, Mattioni TA, Reddy R, Kronmal RA, Lazzara R. Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. Transthoracic Investigators. *Circulation* 1996 Nov 15; 94(10):2507-14.	"We found that 130-J biphasic truncated transthoracic shocks defibrillate as well as the 200-J monophasic damped sine wave shocks that are traditionally used in standard transthoracic defibrillators and result in fewer ECG abnormalities after the shock."
White RD. Early out-of-hospital experience with an impedance-compensating low-energy biphasic waveform automatic external defibrillator. *J Interventional Cardiac Electrophysiology* 1997; 1:203-208.	"Impedance-compensating low-energy BTE waveforms incorporated into an AED terminated VF in OHCA [out-of-hospital cardiac arrest] patients with a conversion rate exceeding that reported with traditional higher energy monophasic waveforms. VF was terminated in all patients, including those with high impedance."
Reddy RK, Gleva MJ, Gliner BE, Dolack GL, Kudenchuk PJ, Poole JE, Bardy GH. Biphasic transthoracic defibrillation causes fewer ECG ST-Segment changes after shock *Ann Emerg Med* 1997; 30:127-34.	"Transthoracic defibrillation with biphasic waveforms results in less postshock ECG evidence of myocardial dysfunction (injury or ischemia) than standard monophasic damped sine waveforms without compromise of defibrillation efficacy."

DEFIBRILLATION WAVEFORM -- CLINICAL STUDIES	EXCERPTS/CONCLUSIONS
Poole JE, White RD, Kanz K-G, Hengstenberg F, Jarrard GT, Robinson JC, Santana V, McKenas DK, Rich N, Rosas S, Merritt S, Magnotto L, Gallagher JV, Gliner BE, Jorgenson DB, Morgan CB, Dillon SM, Kronmal RA, Bardy GH. Low-energy impedance-compensating biphasic waveforms terminate ventricular fibrillation at high rates in victims of out-of-hospital cardiac arrest. *J Cardiovasc Electrophysiol* 1997; 8:1373-1385.	"The low-energy impedance-compensating BTE waveform used in this study's AED consistently terminated long-duration VF as encountered in out-of-hospital cardiac arrest. The observed defibrillation rate exceeds that of published studies on higher energy monophasic waveforms. Higher energy is not clinically warranted with this [biphasic truncated exponential] waveform. The efficient user interface and high defibrillation efficacy of this low-energy biphasic waveform allows the AED to have device characteristics consistent with widespread deployment and early defibrillation."
Gliner BE, Jorgenson DB, Poole JE, White RD, Kanz K-G, Lyster TD, Leyde KW, Powers DJ, Morgan CB, Kronmal RA, Bardy GH. Treatment of out-of-hospital cardiac arrest with a low-energy impedance-compensating biphasic waveform automatic external defibrillator. *Biomedical Instrumentation & Technology* 1998; 32:631-644.	"It is concluded that low-energy impedance-compensating biphasic waveforms terminate long-duration VF at high rates in out-of-hospital cardiac arrest and provide defibrillation rates exceeding those previously achieved with high-energy shocks."
Gliner BE, White RD. Electrocardiographic evaluation of defibrillation shocks delivered to out-of-hospital sudden cardiac arrest patients. *Resuscitation* 1999 Jul;41(2):133-44.	"At each analysis time, there were more patients in VF following high-energy monophasic shocks than following low-energy biphasic shocks."
White RD and Blanton DM. Biphasic truncated exponential waveform defibrillation. *Prehosp Emerg Care* 1999 Oct-1999 Dec 31; 3(4):283-9.	"When defibrillation is defined as termination of ventricular fibrillation at 5 seconds postshock, whether to an organized rhythm or asystole, low-energy BTE [biphasic truncated exponential] shocks appear to be more effective than high-energy MDS [monophasic damped sine] shocks in out-of-hospital arrest. For future research, the terms associated with defibrillation should be standardized and used uniformly by all investigators. In particular, there should be an agreed-upon definition of shock efficacy.

DEFIBRILLATION WAVEFORM -- CLINICAL STUDIES	EXCERPTS/CONCLUSIONS
Schneider T, Martens PR, Paschen H, Kuisma M, Wolcke B, Gliner BE, Russell JK, Weaver WD, Bossaert L, Chamberlain D. Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 360-J monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. *Circulation* 2000 Oct 10; 102(15): 1780-7.	"In summary, the results of the present study show that an appropriately dosed low-energy impedance-compensating biphasic-waveform strategy results in superior defibrillation performance in comparison with escalating, high-energy monophasic shocks in out-of hospital cardiac arrest. Moreover, the 150-J biphasic waveform AED resulted in a higher rate of ROSC [return of spontaneous circulation] and better neurological status at the time of hospital discharge."
Martens PR, Russell JK, Wolcke B, Paschen H, Kuisma M, Gliner BE, Weaver WD, Gossaert L, Chamberlain D, Schneider T. Optimal response to cardiac arrest study: defibrillation waveform effects. *Resuscitation* 2001; 49:233-243.	"A low-energy impedance-compensating biphasic waveform strategy results in superior defibrillation performance, in terms of first shock efficacy and defibrillation in the first set of two or three shocks, when compared to traditional escalating energy monophasic defibrillators of both MTE [monophasic truncated exponential] and MDS [monophasic damped sine] design. The biphasic devices were also quicker to first shock and to first successful shock."
White RD, Hankins DG, Atkinson EJ. Patient outcomes following defibrillation with a low energy biphasic truncated exponential waveform in out-of-hospital cardiac arrest. *Resuscitation* 2001 Apr; 49(1):9-14.	"Low-energy (150 J) non-escalating biphasic truncated exponential waveform shocks terminate VF in out-of-hospital cardiac arrest with high efficacy; patient outcome is comparable with that observed with escalating high-energy monophasic shocks. Low-energy shocks, in addition to high efficacy, may confer the advantage of less shock-induced myocardial dysfunction, though this will be difficult to define in the clinical circumstance of long-duration VF provoked by a pre-existing diseased myocardial substrate."
Hess EP and White RD. Recurrent ventricular fibrillation in out-of-hospital cardiac arrest after defibrillation by police and firefighters: implications for automated external defibrillator users. *Crit Care Med* 2004 Sep; 32(9 Suppl):S436-9.	"VF [ventricular fibrillation] recurrence is frequent, variable in time of onset, and unrelated to the performance of bystander CPR. The prevalence and frequency of VF recurrence were unpredictable and do not adversely affect survival. Thus, vigilance for recurrent VF is essential to ensure the survival of patients who are in the care of first responders, even after initial restoration of pulses with shocks."

DEFIBRILLATION WAVEFORM -- CLINICAL STUDIES	EXCERPTS/CONCLUSIONS
White RD, Blackwell TH, Russell JK, Jorgenson DB. Body weight does not affect defibrillation, resuscitation or survival in patients with out-of-hospital cardiac arrest treated with a non-escalating biphasic waveform defibrillator. *Crit Care Med* 2004; 32(9) Supplement: S387-S392.	"Overweight patients were defibrillated by the biphasic waveform used in this study at high rates, with a fixed energy of 150 J, and without energy escalation."
White RD, Blackwell TH, Russell JK, Snyder DE, Jorgenson DB. Transthoracic impedance does not affect defibrillation, resuscitation or survival in patients with out-of-hospital cardiac arrest treated with a non-escalating biphasic waveform defibrillator. *Resuscitation* 2005 Jan; 64(1):63-9.	"High impedance patients were defibrillated by the biphasic waveform used in this study at high rates with a fixed energy of 150 J and without energy escalation. Rapid defibrillation rather than differences in patient impedance accounts for resuscitation success."
White RD and Russell JK. Refibrillation, resuscitation and survival in out-of-hospital sudden cardiac arrest victims treated with biphasic automated external defibrillators. *Resuscitation* 2002 Oct; 55(1):17-23.	"One hundred and sixteen of 128 shocks delivered under BLS care to 49 patients with witnessed cardiac arrests presenting with VF terminated VF. Most patients (61%) refibrillated while under BLS care, many (35%) more than once. Occurrence of and time to refibrillation were unrelated to achievement of return of spontaneous circulation (ROSC) under BLS care (BLS ROSC), to survival to hospital discharge and to neurologically intact survival."

RELATED PAPERS AND PUBLICATIONS	EXCERPTS/CONCLUSIONS
American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. AHA Scientific Statement. Automatic external defibrillators for public access defibrillation: Recommendations for specifying and reporting arrhythmia analysis algorithm performance, incorporating new waveforms, and enhancing safety. *Circulation* 1997;95:1277-1281.	"These recommendations are presented to enhance the safety and efficacy of AEDs intended for public access. The task force recommends that manufacturers present developmental and validation data on their own devices, emphasizing high sensitivity for shockable rhythms and high specificity for nonshockable rhythms. Alternate defibrillation waveforms may reduce energy requirements, reducing the size and weight of the device."

RELATED PAPERS AND PUBLICATIONS	EXCERPTS/CONCLUSIONS
Cummins R, et.al. Low-Energy Biphasic Waveform Defibrillation: Evidence-Based Review Applied to Emergency Cardiovascular Care Guidelines: A statement for healthcare professionals from the American Heart Association committee on emergency cardiovascular care and the subcommittees on basic life support, advanced cardiac life support, and pediatric resuscitation. *Circulation* 1998; 97:1654-1667.	"Positive evidence supports a statement that initial low-energy (150J), nonprogressive (150J-150J-150J), impedance-adjusted biphasic waveform shocks for patients in out-of-hospital VF arrest are safe, acceptable, and clinically effective."

RELATED PAPERS AND PUBLICATIONS	EXCERPTS/CONCLUSIONS
American Heart Association. 2010 Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science, *Circulation.* 2010;122[suppl 3].	"Energy levels vary by type of device … Data from both out-of-hospital and in-hospital studies indicate that lower-energy biphasic waveform shocks have equivalent or higher success for termination of VF than either MDS or MTE monophasic waveform shocks" (page S708) … "The optimal energy for first-shock biphasic waveform defibrillation has not been determined" … "Multiple prospective human clinical studies and retrospective studies have failed to identify an optimal biphasic energy level for first or subsequent shocks. … Commercially available biphasic AEDs provide either fixed or escalating energy levels. Multiple prospective human clinical studies and retrospective studies have failed to identify an optimal biphasic energy level for first or subsequent shocks. Human studies have not demonstrated evidence of harm from any biphasic waveform defibrillation energy up to 360 J, with harm defined as elevated biomarker levels, ECG findings, and reduced ejection fraction. Conversely, several animal studies have shown the potential for myocardial damage with much higher energy shocks. Therefore, it is not possible to make a definitive recommendation for the selected energy for subsequent biphasic defibrillation attempts. However, based on available evidence, we recommend that second and subsequent energy levels should be at least equivalent and higher energy levels may be considered, if available (Class IIb, LOE B). Different biphasic waveforms have not been compared in humans with regard to efficacy. Therefore, for biphasic defibrillators, providers should use the manufacturer's recommended energy dose (120 to 200 J) (Class I, LOE B)."

RELATED PAPERS AND PUBLICATIONS	EXCERPTS/CONCLUSIONS
ECRI. External Biphasic defibrillators: Should you catch the wave? *Health Devices* 2001;30:219-225.	"It is likely that the optimal energy level for biphasic defibrillators will vary with the units' waveform characteristics. An appropriate energy dose for one biphasic waveform may be inappropriate for another. … So it's necessary to refer to the supplier's recommendations to determine the proper energies to be used for a given waveform."
Jordan D. The fundamentals of automated external defibrillators. *Biomedical Instrumentation and Technology* 2003;37:55-59.	General article about automated external defibrillators and the technology used to design and build them.

ELECTROMAGNETIC INTERFERENCE AND AED USE	EXCERPTS/CONCLUSIONS
Fleischhackl R, Singer F, Nitsche W, Gamperl G, Roessler B, Arrich J, Fleischhackl S, Losert H, Sterz F, Mittlboeck M, Hoerauf K. Influence of electromagnetic fields on function of automated external defibrillators. *Acad Emerg Med* 2006 Jan; 13(1)1-6.	"ABSTRACT. OBJECTIVES In this study, the authors tested whether electro-magnetic interference (EMI) is able to impair correct electrocardiogram analysis and produce false-positive shock advice from automated external defibrillators (AEDs) when the true rhythm is sinus. METHODS Nineteen healthy subjects were used to test five AEDs available on the Austrian market in a prospective, open, and sequence-randomized study. The primary outcome variable was the absolute number of shocks advised in the presence of EMI. The secondary outcome was the number of impaired analyses caused by incorrectly detected patient movements or electrode failure. RESULTS Of 760 tests run, 18 (2.37%) cases of false-positive results occurred, and two of five AEDs recommended shocks in the presence of sinus rhythm. Of 760 tests run, no electrode failures occurred. There were 27 occurrences (3.55%) of motion detected by an AED in the presence of strong electromagnetic fields. CONCLUSIONS AED models differ in their response to EMI; it may be useful to consider specific safety requirements for areas with such fields present. Working personnel and emergency medical services staff should be informed about potential risks and the possible need for patient evacuation before AEDs are attached and shock recommendations are followed."

PEDIATRIC DEFIBRILLATION	EXCERPTS/CONCLUSIONS
Gurnett CA, Atkins DL. Successful use of a biphasic waveform automated external defibrillator in a high-risk child. *Am J Cardiol* 2000 Nov 1;86(9):1051-3.	"This case report suggests that in young children, defibrillation can be accomplished and risk of myocardial damage using currently available truncated biphasic waveform defibrillation may be small."
Cecchin F, Jorgenson DB, Berul CI, Perry JC, Zimmerman AA, Duncan BW, Lupinetti FM, Snyder D, Lyster TD, Rosenthal GL, Cross B, Atkins DL. Is arrhythmia detection by automatic external defibrillator accurate for children? *Circulation* 2001; 103:2483-2488.	"There was excellent AED rhythm analysis sensitivity and specificity in all age groups for ventricular fibrillation and nonshockable rhythms. The high specificity and sensitivity indicate that there is a very low risk of an inappropriate shock and that the AED correctly identifies shockable rhythms, making the algorithm both safe and effective for children."
Atkins DL and Jorgenson DB. Attenuated pediatric electrode pads for automated external defibrillator use in children. *Resuscitation* 2005 Jul; 66(1):31-7.	"Voluntary reports of the use of attenuated pediatric defibrillation pads indicate the devices performed appropriately. All eight VF patients had termination of VF and five survived to hospital discharge. These data support the rapid deployment of AEDs for young children as well as adolescents and adults. Since the pediatric pads are available and deliver an appropriate dose for children, their use should be strongly encouraged."

DEFIBRILLATION AND CPR	CONCLUSIONS
Young C, Bisera J, Gehman S, Snyder D, Tang W, Weil MH. Amplitude spectrum area: measuring the probability of successful defibrillation as applied to human data. *Crit Care Med* 2004 Sep; 32(9 Suppl):S356-8.	Based on the spectral characteristics of ventricular fibrillation potentials, we examined the probability of successful conversion to an organized viable rhythm, including the return of spontaneous circulation. The incentive was to predict the likelihood of successful defibrillation and thereby improve outcomes by minimizing interruptions in chest compression and minimizing electrically induced myocardial injury due to repetitive high-current shocks… AMSA [amplitude spectral area] predicts the success of electrical defibrillation with high specificity. AMSA therefore serves to minimize interruptions of precordial compression and the myocardial damage caused by delivery of repetitive and ineffective electrical shocks

DEFIBRILLATION AND CPR	CONCLUSIONS
Snyder D and Morgan C. Wide variation in cardiopulmonary resuscitation interruption intervals among commercially available automated external defibrillators may affect survival despite high defibrillation efficacy. *Crit Care Med* 2004 Sep; 32(9 Suppl):S421-4.	In addition to defibrillation waveform and dose, researchers should consider the hands-off cardiopulmonary resuscitation interruption interval between cardiopulmonary resuscitation and subsequent defibrillation shock to be an important covariate of outcome in resuscitation studies. Defibrillator design should minimize this interval to avoid potential adverse consequences on patient survival. See Selected Clinical Studies at the end of this chapter for a more detailed discussion of this publication.
Snyder DE, White RD, Jorgenson DB. Outcome prediction for guidance of initial resuscitation protocol: Shock first or CPR first. *Resuscitation* 2007; 72:45-51.	Both call-to-shock interval and a real-time ECG analysis are predictive of patient outcome. The ECG analysis is more predictive of neurologically intact survival. Moreover, the ECG analysis is dependent only upon the patient's condition at the time of treatment, with no need for knowledge of the response interval, which may be difficult to estimate at the time of treatment.

AED USE AND RESCUER SAFETY	EXCERPTS/CONCLUSIONS
Lyster T, Jorgenson D, and Morgan C. The safe use of automated external defibrillators in a wet environment. *Prehosp Emerg Care* 2003 Jul-2003 Sep 30; 7(3)307-11	"ABSTRACT There has been concern regarding potential shock hazards for rescuers or bystanders when a defibrillator is used in a wet environment and the recommended safety procedure, moving the patient to a dry area, is not followed. OBJECTIVE To measure the electrical potentials associated with the use of an automated external defibrillator (AED) in a realistically modeled wet environment. METHODS A raw processed turkey was used as a patient surrogate. The turkey was placed on a cement floor while pool water was applied to the surrounding area. To simulate a rescuer or bystander in the vicinity of a patient, a custom sense probe was constructed. Defibrillation shocks were delivered to the turkey and the probe was used to measure the voltage an operator/bystander would receive at different points surrounding the surrogate. The test was repeated with salt water. RESULTS The maximum voltage occurred approximately 15 cm from the simulated patient and measured 14 V peak (current 14 mA peak) in the case of pool water, and 30 V peak (current 30 mA peak) in the case of salt water. CONCLUSIONS Thirty volts may result in some minor sensation by the operator or bystander, but is considered unlikely to be hazardous under these circumstances. The maximum currents were lower than allowed by safety standards. Although defibrillation in a wet environment is not recommended practice, our simulation of a patient and a rescuer/bystander in a wet environment did not show significant risk should circumstances demand it."

AED USE BY LAY RESCUERS	EXCERPTS/CONCLUSIONS
Gundry JW, Comess KA, DeRook FA, Jorgenson D, Bardy GH. Comparison of naïve sixth-grade children with trained professionals in the use of an automated external defibrillator. *Circulation* 1999; 100:1703-1707.	"During mock cardiac arrest, the speed of AED use by untrained children is only modestly slower than that of professionals. The difference between the groups is surprisingly small, considering the naivete of the children as untutored first-time users."

AED USE BY LAY RESCUERS	EXCERPTS/CONCLUSIONS
Page RL, Joglar JA, Kowal RC, Zagrodzky JD, Nelson LL, Ramaswamy K, Barbera SJ, Hamdan MH, McKenas DK. Use of automated external defibrillators by a U.S. airline. *N Engl J Med* 2000 Oct 26; 343(17):1210-6.	"The use of the automated external defibrillator aboard commercial aircraft is effective, with an excellent rate of survival to discharge from the hospital after conversion of ventricular fibrillation. There are not likely to be complications when the device is used as a monitor in the absence of ventricular fibrillation."
Capucci A, Aschieri D, Piepoli MF, Bardy GH, Iconomu E, Arvedi M. Tripling survival from sudden cardiac arrest via early defibrillation without traditional education in cardiopulmonary resuscitation. *Circulation* 2002 Aug 27; 106(9):1065-70.	"Broad dissemination of AEDs for use by nonmedical volunteers enabled early defibrillation and tripled the survival rate for out-of-hospital SCA."
Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. *N Engl J Med* 2002 Oct 17; 347(16):1242-7.	"Automated external defibrillators deployed in readily accessible, well-marked public areas in Chicago airports were used effectively to assist patients with cardiac arrest. In the cases of survivors, most of the users had no duty to act and no prior training in the use of these devices"
Jorgenson DB, Skarr T, Russell JK, Snyder DE, Uhrbrock K. AED use in businesses, public facilities and homes by minimally trained first responders. *Resuscitation* 2003 Nov; 59(2):225-33.	"This survey demonstrates that AEDs purchased by businesses and homes were frequently taken to suspected cardiac arrests. Lay responders were able to successfully use the AEDs in emergency situations. Further, there were no reports of harm or injury to the operators, bystanders or patients from lay responder use of the AEDs."
Capucci A and Aschieri D. [Early defibrillation in the treatment of sudden cardiac arrest]. *Recenti Prog Med* 2003 Jun; 94(6):241-6.	"Improvement in in-hospital survival rates from cardiac arrest is not as evident as in the emergency medical service community. Medical centers need to assess response times to cardiac arrest and implement AED programs. All the nurses should learn to use an AED as part of basic life support training."
Andre AD, Jorgenson DB, Froman JA, Snyder DE, Poole JE. Automated external defibrillator use by untrained bystanders: Can the public-use model work? *Prehospital Emergency Care* 2004; 8:284-291.	"This study demonstrated that the AED user interface significantly influences the ability of untrained caregivers to appropriately place pads and quickly deliver a shock. Avoiding grossly inappropriate pad placement and failure to place AED pads directly on skin may be correctable with improvements in the AED instruction user interface."

EASE OF USE AND USER-INTERFACE STUDIES	EXCERPTS/CONCLUSIONS
Eames P, Larson PD, Galletly DC. Comparison of ease of use of three automated external defibrillators by untrained lay people. *Resuscitation* 2003 Jul; 58(1):25-30.	"Zoll AEDPlus, Medtronic Physio-Control LifePak CR Plus and Philips/Laerdal HeartStart OnSite Defibrillator. Subjects' performance were videotaped and reviewed for time to defibrillate, pad positioning and safety. Subjects were asked to rate the three units in terms of ease-of-use. Average times to first shock were 74.8 s for the Physio-Control, 83.0 s for the Laerdal and 153.4 s for the Zoll defibrillator. Pad positioning was scored as correct in 23/24 Laerdal trials, 19/24 Physio-Control trials and 14/24 Zoll trials. 23 out of the 24 subjects rated the Zoll most difficult to use. All subjects safely stayed clear of the unit when required. The majority of subjects safely and effectively delivered defibrillating shocks without any prior training and within quite acceptable times. Untrained subjects find the Physio-Control and Laerdal Defibrillator easier to use than the Zoll device."
Nurmi J, Rosenberg P, Castren M. Adherence to guidelines when positioning the defibrillation electrodes. *Resuscitation* 2004 May; 61(2):143-7.	"Professionals were recruited from emergency medical services, university hospitals and primary care. Not revealing the purpose of the test, participants were asked to place self-adhesive electrodes on a manikin as they would do in the resuscitation situation and to answer a questionnaire about resuscitation training and familiarity with the guidelines… The publication of the national evidence based resuscitation guidelines did not seem to have influenced the practice of placement of the defibrillation electrodes to any major extent. The correct placement of the electrodes needs be emphasized more in the resuscitation training."

EASE OF USE AND USER-INTERFACE STUDIES	EXCERPTS/CONCLUSIONS
Fleischhackl R, Losert H, Haugk M, Eisenburger P, Sterz F, Laggner A N, Herkner H. Differing operational outcomes with six commercially available automated external defibrillators. *Resuscitation* 2004 Aug; 62(2):167-74.	"Electrodes were not attached correctly in nine cases (4 Power Heart, 2 AED+, 2 Access, 1 CR+). Volunteers stated that they were confused about the electrode positioning in 12 cases (5 Power Heart, 3 Access, 2 Fred easy®, 2 CR+ 1 AED+) but placed the pads correctly. In two cases the lay rescuers did not remove the plastic liner from the pads (1 Power Heart, 1 AED+). Two volunteers in the AED+ group did not remove clothing from the manikin's chest before attaching the electrodes. The information button provided by the HS1 was pressed by all users (15 out of 15) to be guided through BLS… "HS1 (Philips Medical Systems, Andover, Seattle, USA) This device guides the user with slow and clear prompts. Users stated that the different signed electrodes of this device were useful. It also provides an information button to get further instruction as to how to start and provide BLS. All users pressed this button and did exactly what the device prompted. The recommended heart compression rate given by a metronome was appreciated by the volunteers. Mouth to mouth ventilation was explained precisely as well as chest compression… …there are significant differences between AEDs, concerning important operational outcomes like time to first shock and the start of BLS [basic life support]. Further research and development is urgently required to optimise user-friendliness and operational outcomes."
Callejas S, Barry A, Demertsidis E, Jorgenson D, Becker LB. Human factors impact successful lay person automated external defibrillator use during simulated cardiac arrest. *Crit Care Med* 2004 Sep;32 (9 Suppl): S406-13.	"Both devices [Philips FR2 or HS1] are safe with either video-trained or naive users. The successful use of each device is high when participants view the training videotape designed for the device. Collectively, these data support the notion that human factors associated with ease of use may play a critical factor in survival rates achieved by specific devices.

EASE OF USE AND USER-INTERFACE STUDIES	EXCERPTS/CONCLUSIONS
Nurmi J and Castren M. Layperson positioning of defibrillation electrodes guided by pictorial instructions. *Resuscitation* 2005 Feb; 64(2):177-80.	"Defibrillation electrodes from five manufacturers (Access Cardio Systems, Schiller, Medtronic, Cardiac Science and Philips) were included in the study and compared with electrodes with a lateral view picture, designed for the study, showing the placement of the apical electrode… The current practice in designing pictures on the electrodes does not seem to be optimal in showing the recommended position of the apical electrode as recommended by Guidelines 2000. It is suggested that by showing a lateral view in the instructions, success in placing the apical electrodes correctly can be improved." [NOTE: All Philips AED pads use a lateral view for the apical pad.]
Cappato R, Curnis A, Marzollo P, Mascioli G, Bordonali T, Beretti S, Scalfi F, Bontempi L, Carolei A, Bardy G, De Ambroggi L, Dei Cas L. Prospective assessment of integrating the existing emergency medical system with automated external defibrillators fully operated by volunteers and laypersons for out-of-hospital cardiac arrest: the Brescia Early Defibrillation Study (BEDS). *Eur Heart J* 2006 Mar; 27(5):553-61.	"Diffuse implementation of AEDs fully operated by trained volunteers and laypersons within a broad and unselected environment proved safe and was associated with a significantly higher long-term survival of CA [cardiac arrest] victims."

SELECTED STUDY SUMMARIES

The following summaries of published study results are provided to demonstrate the scientific basis for certain features of the Philips HeartStart automated external defibrillators.

HEARTSTART LOW-ENERGY, HIGH-CURRENT DESIGN

SUMMARY OF: Wanchun Tang, MD; Max Harry Weil, MD, PHD; Shijie Sun, MD; Dawn Jorgenson, PHD; Carl Morgan, MSEE; Kada Klouche, MD; David Snyder, MSEE. The effects of biphasic waveform design on post-resuscitation myocardial function. *JACC* 2004 Apr 7; 43, (7) 1228-35.

INTRODUCTION

This study, supported in part by grants from NIH National Heart, Blood and Lung Institute, the American Heart Association, and Philips Medical Systems, examined the effects of biphasic truncated exponential waveform design on survival and post-resuscitation myocardial function after prolonged ventricular fibrillation (VF).

BACKGROUND

It has been established that biphasic waveforms are more effective than monophasic waveforms for successful defibrillation, but optimization of energy and current levels to minimize post-resuscitation myocardial dysfunction has been largely unexplored. A biphasic truncated exponential (BTE) waveform may be designed to minimize the defibrillation threshold in terms of either energy or peak current but these two notions of optimization result in different waveform shapes.

Using two biphasic waveforms commonly available in commercial products — a low-capacitance waveform typical of low-energy application (low-energy biphasic truncated exponential [BTEL]; 100 µF, 100-200 J) and a high-capacitance waveform typical of high-energy application (high-energy biphasic truncated exponential [BTEH]; 200 µF, 200-360 J) — this study examined resuscitation outcomes after seven minutes of untreated ventricular fibrillation.

METHODS

Four groups of anesthetized 40- to 45-kg pigs were investigated. After 7 minutes of electrically induced ventricular fibrillation, a 15-minute resuscitation attempt was made using sequences of up to 3 defibrillation shocks followed by 1 minute of cardiopulmonary resuscitation. Animals were randomized to BTEL at 150 J or 200 J or to BTEH at 200 J or 360 J.

RESULTS AND DISCUSSION

A significant overall effect was detected for survival as a function of waveform. All animals were successfully resuscitated after delivery of BTEL 150-J or 200-J shocks as well as with BTEH 360-J shocks. However, only two of five animals were successfully resuscitated after BTEH 200-J shocks. All resuscitated animals survived for more than 72 h, with no differences in neurological alertness score among the four groups. Animals treated with BTEL shocks required fewer shocks, less CPR, and less total energy to resuscitate than animals treated with BTEH.

Myocardial function, as judged by hemodynamic performance, was reduced in all animals after successful resuscitation. Although post-resuscitation hemodynamics continuously improved over time, substantial deficits were still apparent in animals treated with higher-energy shocks at the conclusion of the 4-hour observation period.

The study confirmed that biphasic waveform defibrillation with a BTEL waveform at 150 J is as effective as the same waveform at 200 J and as effective as BTEH shocks at 360 J for successful return of spontaneous circulation, with the additional benefit of minimizing post-resuscitation myocardial dysfunction. Less than half the subjects treated with BTEH shocks at 200 J were resuscitated.

These effects are attributable to specific characteristics of waveform design. In particular, higher peak current is positively associated with improved survival, whereas higher energy and higher average current are associated with increased post-resuscitation myocardial dysfunction. Post-resuscitation myocardial dysfunction has been associated with early death after initial successful resuscitation. Earlier studies have shown that the severity of post-resuscitation myocardial dysfunction is closely related to the duration of cardiac arrest, treatment with betaadrenergic agents, and the severity of hypercarbic myocardial acidosis. Further, the total electrical energy delivered during defibrillation attempts has been shown to be related to the severity of post-resuscitation myocardial dysfunction and survival in both rat and pig models.

CONCLUSIONS

This study demonstrated that for biphasic truncated exponential waveforms representative of commercial implementations, peak electrical current is the primary factor in survival. Maximum survival and minimum myocardial dysfunction were observed with the low capacitance 150-J waveform, which delivered higher peak current while minimizing energy and average current. These findings suggest that peak current is a more appropriate measure of defibrillation dose than either energy or average current. Furthermore, these conclusions suggest that post-resuscitation myocardial dysfunction is related to a cumulative, as opposed to an instantaneous, electrical exposure mechanism.

HEARTSTART QUICK SHOCK FEATURE

SUMMARY OF: Wanchun Tang, MD; David Snyder, MSEE; Jinglan Wang, MD, PhD; Lei Huang, MD; Yun-Te Chang, MD; Shijie Sun, MD; Max Harry Weil, MD, PhD. One-shock versus three-shock defibrillation protocol significantly improves outcome in a porcine model of prolonged ventricular fibrillation cardiac arrest. *Circulation*. 2006 June 13; 113(23)2683-9.

INTRODUCTION

This study, funded by Philips Medical Systems and the American Heart Association, was undertaken in response to suggestions by previous clinical studies that AED-imposed interruptions of cardiopulmonary resuscitation (CPR) occurring after initial defibrillation shocks may adversely affect patient outcomes.

These concerns had been corroborated in laboratory experiments, especially with respect to the interval required for automated rhythm analysis and defibrillator charging between CPR and defibrillation shock.

BACKGROUND

This study examined the hypothesis that wide variations in AED design, especially with respect to CPR interruption intervals, have a significant impact on resuscitation success. It also tested the hypothesis that a new one-shock defibrillation protocol designed to increase the percentage of time devoted to ventilation and circulatory support would improve resuscitation outcomes and minimize the impact of AED design variations.

METHODS

Of seven commercially available automated AEDs whose CPR interruption intervals were measured in a separate study, the energy delivery regimen of the fastest and slowest two devices were selected for use in configuring the manual defibrillators for this study. The manual defibrillators were manufactured by the same companies and delivered the same waveforms as the corresponding AEDs. Both waveforms are impedance compensating but differ significantly in other aspects, with AED1 a low-energy (150 J) device using a 100 µF capacitor, and AED2 an escalating energy (200-300-360 J) device using a 200 µF capacitor.

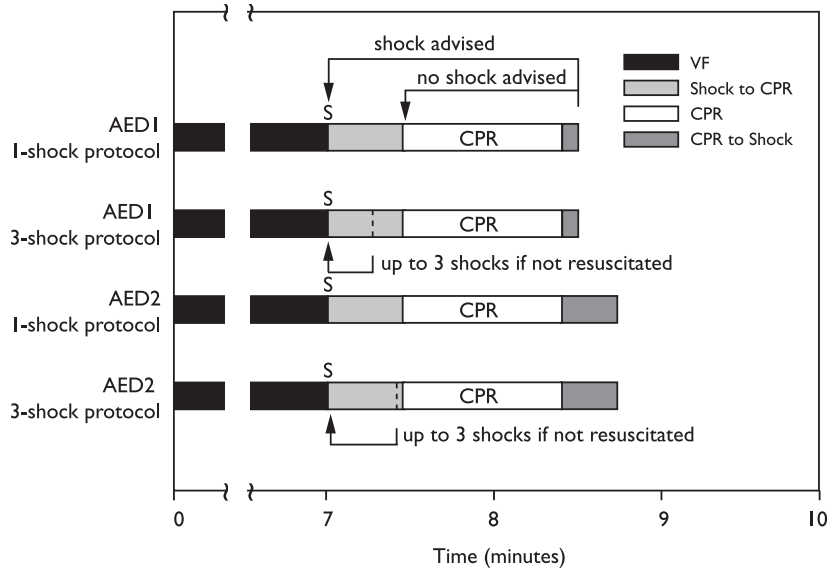
Cardiac arrest was induced in adult male pigs randomized to each of four groups by AED regimen and defibrillation protocol: low-energy, single-shock; low-energy, up to three shocks; high energy, single shock; and high energy, up to three shocks. After seven minutes of untreated ventricular fibrillation (VF), resuscitation was attempted using an initial sequence of one or up to three sequential shocks. If resuscitation using defibrillation was unsuccessful,

compressions were performed for 60 seconds and mechanical ventilation was provided.

Primary observations included success of initial resuscitation, 72-hour post-resuscitation survival, and post-resuscitation myocardial function characterized by left ventricular ejection fraction and stroke volume.

RESULTS

The study found that adoption of a one-shock defibrillation protocol successfully increased the percentage of time during which subjects received CPR during a resuscitation attempt compared with a three-shock protocol, thereby reducing post-resuscitation myocardial dysfunction and increasing survival. It also demonstrated that with a three-shock protocol, design variations among currently available AEDs have a significant impact on resuscitation success, despite similar defibrillation efficacy. Importantly, the one-shock protocol was also found to minimize the impact of AED-imposed treatment variations.



OUTCOME

With long downtime cases of cardiac arrest, providing continuous, quality CPR, especially chest compressions, is an extremely important factor in successful resuscitation. Experimental and clinical studies have shown that interruption of chest compressions for as little as 10 seconds between each interval of CPR for rhythm analysis, ventilation, or patient assessment significantly reduces the number of chest compressions delivered to a patient. This results in a reduction of coronary perfusion pressure and myocardial blood flow and decreases the likelihood of successful resuscitation. In addition, fewer chest compressions increases the severity of

post-resuscitation myocardial and cerebral dysfunction in subjects who survive.

This finding is especially important with regard to AEDs, because most currently available AEDs require significantly longer than 10 seconds for rhythm analysis and charging. CPR interruptions are prolonged even further when the three-shock protocol is used. It is clear that the performance of a defibrillator must be viewed in a much larger context than its efficacy at terminating VF. In addition to such efficacy, an optimal defibrillator must minimize interruptions of CPR for voice prompts, rhythm analysis, and capacitor charging.

Of additional significance, myocardial function was reduced in all animals after successful resuscitation, with the degree of impairment significantly dependent on choice of AED but not shock protocol. For the same shock protocol, AED1 always produced significantly less myocardial dysfunction than did AED2.

Both left ventricular ejection fraction and stroke volume were better after treatment with AED1 compared with AED2, but neither was significantly affected by shock protocol. Stroke volume continuously improved over time, but at the end of the four-hour observation period, substantial deficits were still apparent in animals treated with AED2 combined with a three-shock protocol and not in the other treatment groups. Ejection fraction did not show much improvement over the four-hour observation period for both AED2 and a three-shock protocol.

Mean aortic pressure and cardiac output did not differ significantly between groups, being compensated for by higher observed heart rates in the groups with decreased left ventricular volumes (Table 4). Myocardial function for all surviving animals returned to baseline by the end of the 72-hour observation period

CONCLUSIONS

In conclusion, the present study demonstrated that when a conventional three-shock defibrillation protocol was used, design variations among commercially available AEDs had a significant impact on the initial success of resuscitation, post-resuscitation myocardial dysfunction, and 72-hour survival after prolonged VF. Adoption of a one-shock protocol, however, improved initial resuscitation and survival. Post-resuscitation myocardial dysfunction was less pronounced with the low-energy waveform, independent of shock protocol.

HEARTSTART DEFIBRILLATION THERAPY TESTING IN ADULT VICTIMS OF OUT-OF-HOSPITAL CARDIAC ARREST

SUMMARY OF: Schneider T, Martens PR, Paschen H, Kuisma M, Wolcke B, Gliner BE, Russell JK, Weaver WD, Bossaert L, Chamberlain D. Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 360-J monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. Circulation 2000 Oct 10; 102(15): 1780-7.

INTRODUCTION

The HeartStart FR3 utilizes the patented SMART Biphasic waveform. This waveform has been extensively tested in pre-clinical and both electrophysiology laboratory and out-of-hospital clinical studies. The following information summarizes the results of a large study comparing the use of SMART Biphasic AEDs to conventional monophasic in out-of-hospital emergency resuscitation situations.

BACKGROUND

Heartstream conducted an international, multicenter, prospective, randomized clinical study to assess the effectiveness of the SMART Biphasic waveform in out-of-hospital sudden cardiac arrests (SCAs) as compared to monophasic waveforms. The primary objective of the study was to compare the percent of patients with ventricular fibrillation (VF) as the initial monitored rhythm that were defibrillated in the first series of three shocks or fewer.

METHODS

Victims of out-of-hospital SCA were prospectively enrolled in four emergency medical service (EMS) systems. Responders used either 150 J SMART Biphasic AEDs or 200-360 J monophasic waveform AEDs. A sequence of up to three defibrillation shocks was delivered. For the biphasic AEDs there was a single energy output of 150 J for all shocks. For monophasic AEDs, the shock sequence was 200-200-360 J. Defibrillation was defined as termination of VF for at least five seconds, without regard to hemodynamic factors.

RESULTS

Randomization to the use of monophasic or SMART Biphasic AEDs was done in 338 SCAs from four emergency medical service systems. VF was observed as the first monitored rhythm in 115 patients. The biphasic and monophasic groups for these 115 patients were similar in terms of age, sex, weight, primary structural heart disease, cause and location of arrest, and bystanders witnessing the arrest or performing CPR. The average time from call to first shock was 8.9 ± 3 minutes.

The 150 J SMART Biphasic waveform defibrillated 96% of VF patients in the first shock and 98% of VF patients in the first series of three shocks or fewer compared with 69% of patients treated with monophasic waveform shocks. Outcomes are summarized as follows:

	SMART BIPHASIC PATIENTS NUMBER (%)	MONOPHASIC PATIENTS NUMBER (%)	P VALUE (CHI SQUARE)
Defibrillation Efficacy:			
single shock only	52/54 (96%)	36/61 (59%)	<0.0001
</= 2 shocks	52/54 (96%)	39/61 (64%)	<0.0001
</= 3 shocks	53/54 (98%)	42/61 (69%)	<0.0001
Patients Defibrillated	54/54 (100%)	49/58 (84%)	0.003
ROSC	41/54 (76%)	33/61 (54%)	0.01
Survival to Hospital Admission	33/54 (61%)	31/61 (51%)	0.27
Survival to Hospital Discharge	15/54 (28%)	19/61 (31%)	0.69
CPC = 1 (good)	13/15 (87%)	10/19 (53%)	0.04

CONCLUSIONS

The 150 J SMART Biphasic waveform defibrillated at higher rates than the 200-360 J monophasic waveforms, resulting in more patients achieving return of spontaneous circulation (ROSC) (p=0.01). EMS system outcomes of survival discharge were not significantly different statistically. However, patients resuscitated with the lower-energy SMART Biphasic waveform were more likely to have good cerebral performance (CPC, cerebral performance category) (p=0.04).

HEARTSTART PATIENT ANALYSIS SYSTEM TESTING WITH PEDIATRIC RHYTHMS

SUMMARY OF: Cecchin F, Jorgenson DB, Berul CI, Perry JC, Zimmerman AA, Duncan BW, Lupinetti FM, Snyder D, Lyster TD, Rosenthal GL, Cross B, Atkins DL. Is arrhythmia detection by automatic external defibrillator accurate for children? *Circulation*. 2001; 103:2483-2488.

BACKGROUND

Heartstream sponsored a multicenter study to develop an ECG database of shockable and non-shockable rhythms from a broad range of pediatric patients and then test the accuracy of the HeartStart Patient Analysis System (PAS) for sensitivity and specificity with those rhythms.

METHODS

Two sources were used for the database: (1) RECORDED DATA, a clinical study where rhythms were recorded from pediatric patients via a modified ForeRunner AED and (2) DIGITIZED DATA, a collection of infrequently observed shockable pediatric rhythms, solicited from pediatric electrophysiologists worldwide, that had been captured on paper and were subsequently digitized. The study resulted in a database of 697 rhythm segments from 191 patients, collected from four investigational sites. The children were divided into three groups according to age: up to 1 year, greater than 1 year and less than 8 years and 8 years through 12 years. The demographic characteristics for the three groups are displayed in Tables 1 and 2 for the recorded and digitized groups, respectively. Patient enrollment was initiated on October 2, 1998, and patient enrollment concluded on August 28, 1999.

Table 1. Recorded Rhythms

AGE GROUP (N)	MEDIAN AGE (RANGE)	MEDIAN WEIGHT (RANGE)	GENDER (M/F)
≤1 year (59)	90 days (1 day–1 yr)	4.7 kg (2.1-10.1 kg)	40/19
>1 <8 years (40)	3 yrs (1.1-7 yrs)	15.5 kg (7.6-38.0 kg)	20/20
≥8 ≤12 years (35)	9 yrs (8-12 yrs)	34.2 kg (22.0-70.7 kg)	21/14
Total (134)	1.8 yrs	10.0 kg	81/53

Table 2. Digitized Rhythms

AGE GROUP (N)	MEDIAN AGE (RANGE)	MEDIAN WEIGHT (RANGE)	GENDER (M/F)
≤1 year (15)	0.5 yr (16 days – 1 yr)	6.8 kg (3.0-9.1 kg)	7/8
>1 <8 years (22)	5.0 yrs (1.2-7.7 yrs)	16.8 kg (10-31 kg)	10/12
≥8 ≤12 years (20)	10.9 yrs (8-12 yrs)	43 kg (24-61.4 kg)	12/8
Total (57)	6.0 yrs	18.0 kg	29/28

RESULTS

The results of this study are provided in Table 3. The "AHA goal" columns refer to the American Heart Association's performance goals for AED algorithms, which were established for adults. Although the scope of these performance goals does not apply to pediatric patients, the values are provided here for reference.

Table 3. Pooled Rhythms Sensitivity and Specificity n(%) and Lower Confidence Limits

RHYTHM	SENSI-TIVITY	SPECI-FICITY	AHA GOAL	90% ONE-SIDED LCL*	AHA LCL GOAL
VF	73 (95.9%)	NA	>90%	91.1%	87%
VT, rapid	58 (70.7%)	NA	>75%	61.7%	67%
SR	NA	173 (100%)	>99%	98.7%	97%
SVA	NA	116 (100%)	>95%	98.0%	88%
VEB	NA	95 (100%)	>95%	97.6%	88%
idio	NA	40 (100%)	>95%	94.4%	88%
asystole	NA	39 (100%)	>95%	94.3%	92%

* Armitage P and Berry G, *Statistical Methods in Medical Research*, Blackwell Scientific Publications, 2nd edition, 1987.

This study demonstrated that the HeartStart PAS has excellent sensitivity to pediatric VF rhythms (95.9%), and excellent specificity for all non-shockable rhythms (100%). The AHA sensitivity and specificity performance goals as stated for adult patients were met in all pediatric rhythm categories except for rapid VT, where sensitivity is slightly lower (70.7% vs. 75%). Although the adult performance goal was missed for this group, a conservative approach in this rhythm category for pediatric patients is appropriate due to both the higher uncertainty of association of pediatric tachycardias with cardiac arrest, and the low rate of presenting VT occurrence in the out-of-hospital setting. Further, non-perfusing tachycardias are likely to rapidly degenerate into VF. With regard to the intermediate rhythm group in which the benefits of defibrillation are limited or uncertain, the PAS was appropriately conservative, tending not to advise shocks. Importantly, these data show that the PAS is highly unlikely to inappropriately shock a pediatric rhythm. This is important in light of safety concerns for the use of an automated external defibrillator with children. This study indicates that the HeartStart Patient Analysis System can be used safely and effectively for both adults and children.

HEARTSTART DEFIBRILLATION THERAPY TESTING IN A PEDIATRIC ANIMAL MODEL

SUMMARY OF: Tang, W.; Weil, M. H.; Jorgenson, D.; Klouche, K.; Morgan, C.; Yu, T.; Sun, S., and Snyder, D. Fixed-energy biphasic waveform defibrillation in a pediatric model of cardiac arrest and resuscitation. *Crit Care Med.* 2002 Dec; 30(12):2736-41

BACKGROUND

The FR3 AED with attenuated defibrillation pads delivers at least a 2 J/kg dose in the intended patient population, based on United States Center for Disease Control growth charts. Two animal studies were conducted to demonstrate the safety and effectiveness of the Heartstream biphasic waveform at 50 J in a pediatric animal model across the weight range of the intended patient population.

METHODS

The first study utilized a research AED capable of delivering the Heartstream impedance-compensating biphasic waveform at a 50 J energy setting in 20 pigs in four weight categories ranging from 3.5 to 25 kg and corresponding to weights of human newborn, six month, three year and eight year old patients. The pigs in the smallest group were just over two weeks old. The second study utilized prototype attenuated electrodes with an FR2 AED in nine additional animals in three of the weight categories, including 3.5 and 25 kg weight groups. In both studies, VF was induced in the pigs, and allowed to be sustained for seven minutes prior to delivery of up to three shocks using a fixed 50 J Heartstream biphasic waveform.

A porcine model was used for these studies, because the chest configuration, anatomy and physiology of the porcine cardiovascular and pulmonary systems are similar to humans. In addition, prior studies have shown that pigs require higher energy dose per kilogram than humans and therefore they present a good "worst case" model for defibrillation effectiveness.

RESULTS

In both studies, all animals across all weight categories were successfully resuscitated with fixed, 50 J Heartstream biphasic shocks, and all survived for the duration of the follow-up period (up to 72 hours). The results showed that the delivered peak currents were close to those expected for human pediatric patients. These studies showed no difference in hemoglobin and oxyhemoglobin, blood gas measurements, arterial lactate, end-tidal CO_2, pulmonary artery pressure, right atrium pressure, calculated coronary perfusion pressure and neurological alertness among the groups prior to arrest and after successful resuscitation. There was no difference in post-resuscitation myocardial function as measured by echocardiographic ejection fraction and fractional area change among the groups. Stroke

volume, cardiac output and left ventricular volumes returned to baseline values within 120 minutes after successful resuscitation in all groups.

These studies demonstrated that fixed 50 J Heartstream biphasic waveform shocks successfully resuscitated pigs ranging from 3.5 to 25 kg regardless of weight. All animals survived and there was no evidence of compromised post-resuscitation systolic or diastolic myocardial function.

PHILIPS

Philips Medical Systems is part of Royal Philips Electronics

Philips Medical Systems

United States
Philips Medical Systems
2301 Fifth Avenue, Suite 200
Seattle, WA 98121-1825, USA
(800) 263-3342

Canada
Philips Healthcare, a Division of Philips Electronics Ltd.
281 Hillmount Road
Markham, Ontario
L6C 2S3 Canada
(800) 291-6743

Europe, Middle East, and Africa
Philips Medizin Systeme Boeblingen GmbH
Cardiac and Monitoring Systems
Hewlett-Packard Strasse 2
71034 Boeblingen, Germany
(+49) 7031 463-2254

Latin America
Philips Medical Systems Ltda.
Rua Verbo Divino - 1400 - 7o Andar
04719-002 -Sao Paulo, Brazil
0800 7017789

Asia Pacific
Philips Electronics Hong Kong Ltd.
6/F, Core Building 1
1 Science Park East Avenue
Hong Kong Science Park
Shatin. New Territories, Hong Kong
(852) 2821 5888