PHILIPS

HeartStart FR2 Series Defibrillators

TECHNICAL REFERENCE MANUAL

HEARTSTART
DEFIBRILLATORS

Introductory Note

Heartstream, Inc., was founded in 1992. Its mission was to design and produce an automated external defibrillator (AED) that could be successfully used by a layperson responding to sudden cardiac arrest and that was:

- small
- light-weight
- low-cost
- rugged
- reliable
- safe
- easy-to-use, and
- maintenance-free.

Heartstream introduced its first AED, the ForeRunner, in 1996. The Heartstream ForeRunner AED marked the first widespread commercial use of a biphasic waveform in an external defibrillator.

Hewlett-Packard (HP) purchased Heartstream in 1997. Heartstream then added a relabeled version of the ForeRunner for Laerdal Medical Corporation called the Heartstart FR.

In 1999, Hewlett-Packard spun off its Medical Products Group, including the Heartstream Operation, into **Agilent Technologies**. While part of Agilent, Heartstream introduced a new AED, the Agilent Heartstream FR2. Laerdal Medical marketed this device as the Laerdal Heartstart FR2. The FR2 evolved into the FR2+, with the addition of an enhanced feature set, in 2001.

Heartstream became part of **Philips Medical Systems** in 2001, when Philips purchased the entire Medical Group from Agilent Technologies. The following year, all Philips defibrillators were rebranded as HeartStart Defibrillators, and Philips introduced the HeartStart HS1 family of AEDs, including the Philips and Laerdal HeartStart, and Philips HeartStart Home, and Philips HeartStart OnSite defibrillators. The Philips HeartStart FRx AED was brought onto the market in 2005, along with a Laerdal version.

This manual is intended to provide technical and product information that generally applies to the HeartStart FR2 series Defibrillators models M3860A, M3861A, M3840A, and M3841A.

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APPENDICES

1 The HeartStart FR2 Series Defibrillators

Sudden cardiac arrest and the automated external defibrillator

Each year in the United States alone, approximately 340,000 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 of VF in the absence of cardiopulmonary resuscitation (CPR), the chances of survival decrease by 7% to 10%.[2]

Traditionally, only trained medical personnel were allowed to use a defibrillator because of the high level of knowledge and training involved. Initially, this meant that the victim of SCA would have to be transported to a medical facility in order to be defibrillated. In 1969, paramedic programs were developed in several communities in the U.S. to act as an extension of the hospital emergency room. Paramedics went through extensive training to learn how to deliver emergency medical care outside the hospital, including training in defibrillation. In the early 1980s, some Emergency Medical Technicians (EMTs) were also being trained to use defibrillators to treat victims of SCA. However, even with these advances, in 1990 fewer than half of the ambulances in the United States carried a defibrillator, so the chances of surviving SCA outside the hospital or in communities without highly developed Emergency Medical Systems were still very small.

The development of the automated external defibrillator (AED) made it possible for the first responders (typically lay persons) at the scene to treat SCA with defibrillation. People trained to perform CPR can now use a defibrillator to defibrillate a victim of SCA. The result: victims of sudden cardiac arrest can be defibrillated more rapidly than ever before, and they have a better chance of surviving until more highly trained medical personnel arrive who can treat the underlying causes.

Design philosophy for the FR2 series defibrillators

The Philips HeartStart FR2 series automated external defibrillators (AEDs) include the FR2 and the FR2+. Each is available in two models, one with an ECG and text display screen and one with a text display screen only. The FR2+ units incorporate new hardware and software that allow the device to use a rechargeable battery and a 3-wire ECG assessment module.

1 American Heart Association. *Heart Disease and Stroke Statistics - 2005 Update*. Dallas, TX.:American Heart Association;2005.
2 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2005;112 Supplement IV

The FR2 series AEDs are designed specifically for use by first responders. They allow these AEDs to be used by people with little medical training in places where defibrillators have not traditionally been used. Factors that had to be considered in their design included the fact that an AED might not be used very often, might be subjected to harsh environments, and probably would not have personnel available to perform regular maintenance.

The FR2 series defibrillators were not designed to replace the manual defibrillators used by more highly trained individuals. Instead, they are intended to complement the efforts of medical personnel skilled in advanced life support, by allowing the initial shock to be delivered by a first responder. Some models of these AEDs can be configured for advanced mode use, to allow the device to be used as a manual defibrillator. This can be beneficial for transitioning the patient care from a first responder to more highly trained medical personnel.

Design features of the FR2 series AEDs

Reliability and Safety

- FAIL-SAFE DESIGN — The FR2 series AEDs are intended to detect a shockable rhythm and instruct the user to deliver a shock if needed. They will not allow a shock if the rhythm is not shockable.
- RUGGED MECHANICAL DESIGN — The FR2 series AEDs are built with high-impact plastics, have few openings, and incorporate a rugged defibrillation pads connector and battery interface. Using the carry case provides additional protection as well as storage for extra sets of pads and a spare battery.
- DAILY AUTOMATIC SELF-TEST — The FR2 series AEDs perform daily as well as weekly and monthly self-tests to help ensure they are ready to use when needed. An active status indicator demonstrates 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 FR2 series AEDs' reliability and ability to operate in conditions relevant to expected use.
- NON-RECHARGEABLE LITHIUM BATTERY — The FR2 standard long-life battery pack M3863A was designed for use in an emergency environment and is small, lightweight, and safe to use. Each battery pack contains multiple 2/3A size, standard lithium camera batteries. These same batteries can be purchased at local drug stores for use in other consumer products. These batteries have been proven to be reliable and safe over many years of operation. The FR2 battery pack uses lithium manganese dioxide (Li/MnO_2) technology and does not contain pressurized sulfur dioxide. 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.

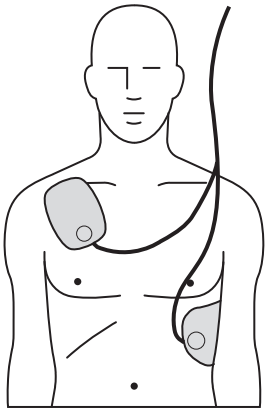
- OPTIONAL RECHARGEABLE LITHIUM BATTERY — The HeartStart FR2+ can be used with an optional M3848A FR2+ lithium ion rechargeable battery, designed for environments in which the defibrillator is expected to see frequent use. This battery is not designed for use in aircraft. It is recommended that this battery not be used as a spare or backup battery and, due to its shorter standby life, that it not be used as the primary or spare battery in applications where the FR2+ is infrequently used. The M3849A charger is designed for use with the M3948A rechargeable battery only.
- TSO-CERTIFIED NON-RECHARGEABLE LITHIUM BATTERY — In certain markets, a TSO-certified 989803136291 lithium manganese dioxide battery is available for use in aircraft. It has the same form and function was the M3863A battery.
- QUICK SHOCK — FR2+ AEDs can provide a patient care pause-to-shock time of less than 10 seconds, typical, from end of a patient care pause to shock delivery. Minimizing the time from the end of CPR chest compressions to shock delivery can potentially improve the return of circulation.
- ADULT AND INFANT/CHILD PADS — FR2 AEDs are designed for use with standard adult DP2/DP6 defibrillator pads on most patients. To defibrillate infants or child under 55 pounds (25 kg) or 8 years of age, optional FR2 Infant/Child Reduced-Energy Defibrillator Pads M3870A are available. Special attenuation circuitry in the M3870A pads reduces the defibrillation energy delivered to a level more appropriate for smaller patients.

Ease of Use

- SMALL AND LIGHT — The biphasic waveform technology used in the FR2 series AEDs has allowed them to be small and light. They can easily be carried and operated by one person.
- SELF-CONTAINED — Several available carry cases for the AEDs have room for extra defibrillation pads and an extra battery.
- VOICE PROMPTS — The FR2 series AEDs provide audible prompts that guide the user through the process of using the device. The voice prompts reinforce the messages that appear on the text screen and allow the user to attend to the patient while receiving detailed instructions for each step of the rescue.
- PADS CONNECTOR LIGHT AND FLASHING SHOCK BUTTON — The flashing indicator light next to the pads connector port on the FR2 series AEDs draws the user's attention to where the pads connector

should be plugged in. The orange Shock button bears a lightning bolt symbol to identify it and flashes when the unit has charged for a shock and directs the user to press the button to deliver a shock.

- CLEAR LABELING AND GRAPHICS — The FR2 series AEDs are designed to enable fast response by the user. The 1-2-3 operation guides the user to: 1) turn the unit on, 2) follow the prompts, and 3) deliver a shock if instructed. A Quick Reference Card mounted inside the carrying case reinforces these instructions. The pads placement icon on the FR2+ indicates clearly where pads should be placed, and 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.



- LCD SCREEN — The FR2 series AEDs have a text screen that displays message prompts to remind the user of each step to follow during an incident. On some models, the screen can also be configured to display the victim's ECG signal. When ALS providers arrive on scene, the displayed ECG helps them to rapidly assess the patient's heart rhythm and prioritize initial patient care accordingly.
- PROVEN ANALYSIS SYSTEM — The SMART rhythm analysis system used in the FR2 series AEDs analyzes the patient's ECG rhythm and determines whether or not a shock should be administered. The algorithm's decision criteria allow the user to be confident that the AED will advise a shock only when it is appropriate treatment for the patient.
- ARTIFACT DETECTION SYSTEM — An artifact detection system in the FR2 series AEDs senses if the ECG is being corrupted by some form of artifact from electrical "noise" in the surrounding environment, patient handling, or the activity of an implanted pacemaker. Because such artifact might inhibit or delay a shock decision, the AED filters out the noise from the ECG, prompting the user to stop patient handling, or determining that the level of artifact does not pose a problem for the algorithm.
- PADS DETECTION SYSTEM — The FR2 series AEDs' pads detection system provides a voice prompt to alert the user if the pads are not making proper contact with the patient's skin.

No Maintenance

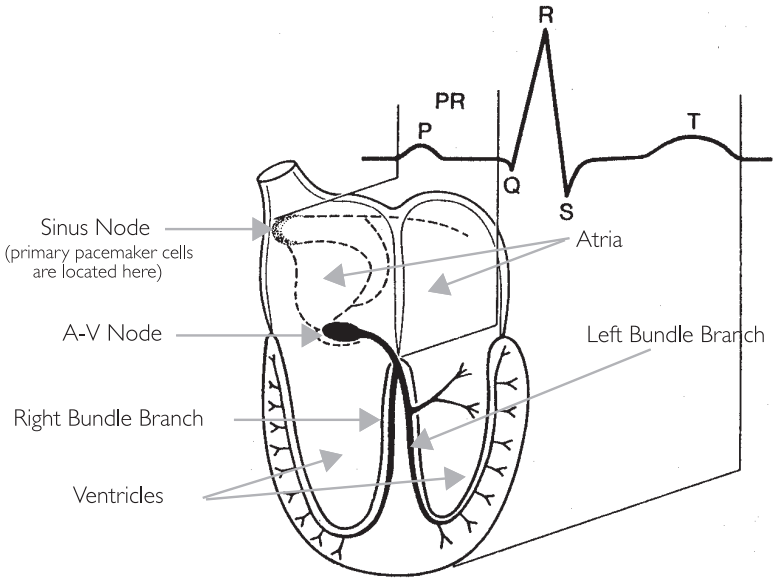
- AUTOMATIC DAILY/WEEKLY/MONTHLY SELF-TESTS — There is no need for calibration, energy verification, or manual testing with the FR2 series AEDs. Calibration and energy verification are automatically performed once a month as part of the AED self-test routine.
- ACTIVE STATUS INDICATOR — The status indicator in the upper right-hand corner of the FR2 series AEDs shows whether or not the device has passed its last self-test. A flashing black hourglass means the AED is ready for use. If the status indicator displays a flashing red X and the unit is beeping, this means the AED needs attention. A solid red X means that the device should not be used.
- BATTERY LEVEL INDICATOR — The FR2 series AEDs prompt the user via the Status Indicator and an audible alarm when the battery needs to be replaced.
- NON-RECHARGEABLE LITHIUM BATTERY — Non-rechargeable batteries store more energy in the same size package, have a longer shelf life than rechargeable batteries, and eliminate the need to manage and maintain a recharging process. The HeartStart AED prompts the user via the Status Indicator and an audible alarm when the standard battery needs to be replaced.

Notes

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.

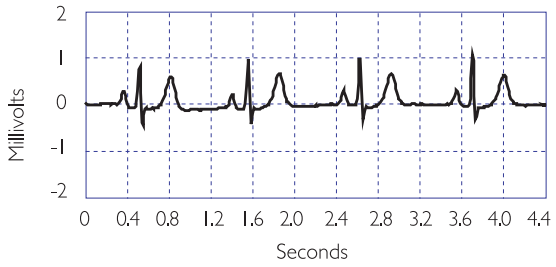


Relation of an ECG to the anatomy of the cardiac conduction system

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.

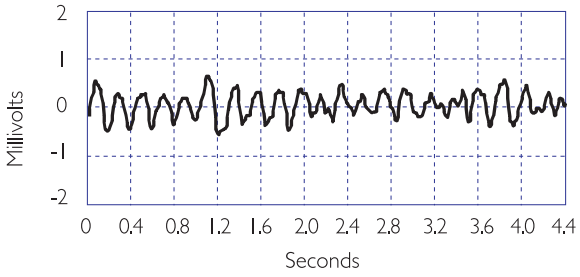


Normal sinus rhythm

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 where blood flow is restricted to 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 a person'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.

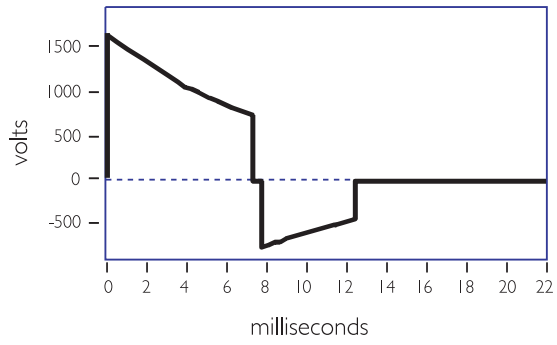
In the case of the biphasic waveforms shown in the following pages, energy (E) is the power (P) delivered over a specified time (t), or $E = P \times t$.

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.

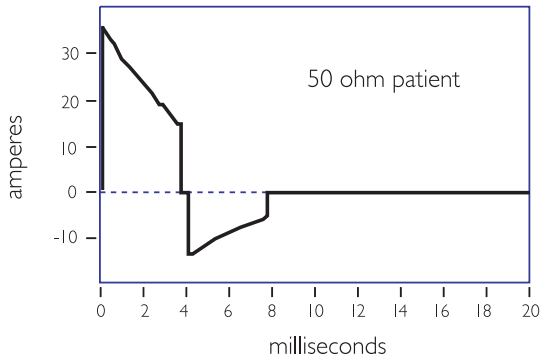
For the SMART Biphasic waveform, the design strategy involved starting with a set peak voltage stored on the capacitor that will decay exponentially as current is delivered to the patient. The SMART Biphasic waveform shown here is displayed with the voltage plotted versus time, for a patient with an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

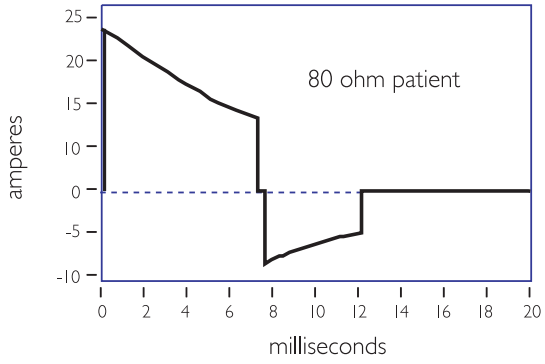


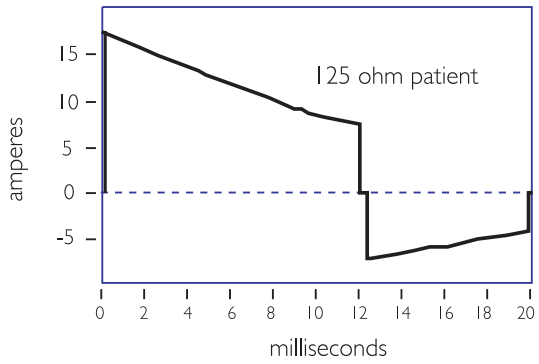
SMART Biphasic waveform

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 conventional defibrillators. Moreover, the lower energy delivered results in less post-shock dysfunction of the heart, resulting in better outcomes for survivors.

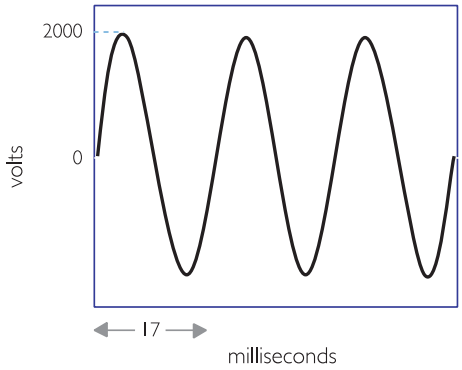
Notes

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.

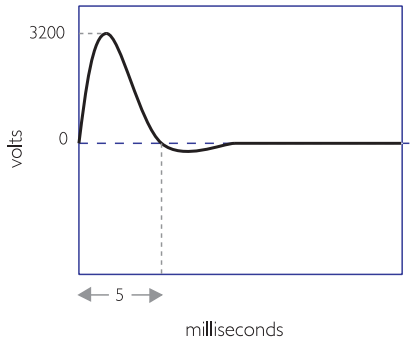


alternating current (AC) waveform

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.

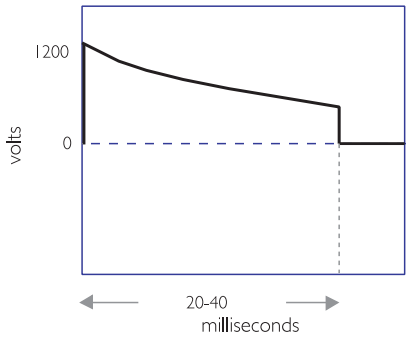


biphasic damped sine (MDS) waveform

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.

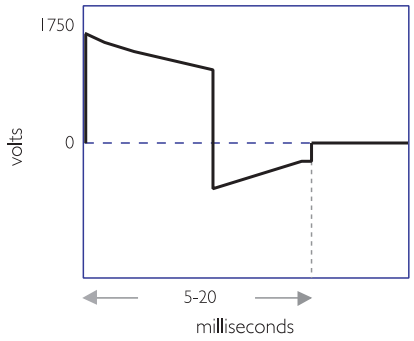
The monophasic truncated exponential (MTE) waveform also uses energy settings of up to 360 J. Because it uses a lower voltage than the MDS waveform, the MTE waveform requires a longer duration to deliver the full energy to patients with higher impedances. This form of impedance compensation does not 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]



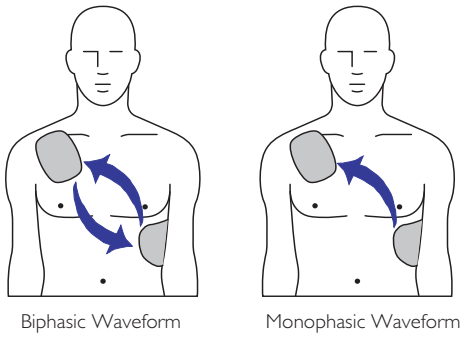
monophasic truncated exponential (MTE) waveform

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 for similar reasons; 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

The basic difference 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:

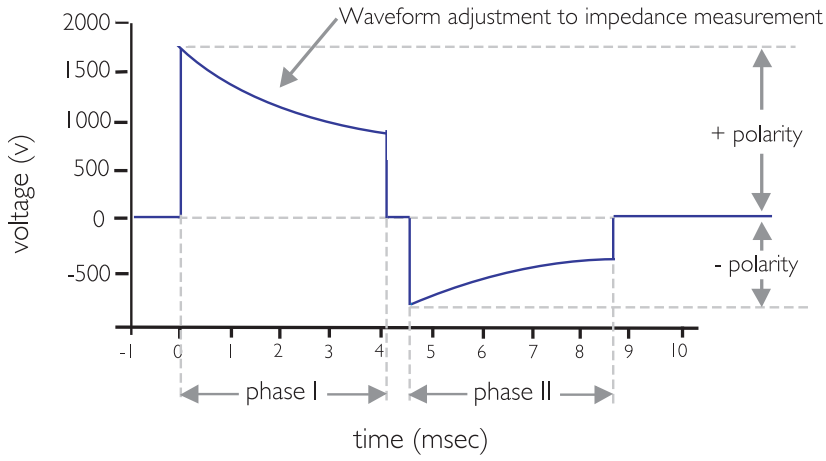
1. Not all waveforms are equally effective. How the energy is delivered (the waveform used) is actually more important than how much energy is delivered.
2. Compensation is needed in the waveform to adjust for differing patient impedances because the effectiveness of the waveform may be affected by patient 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.



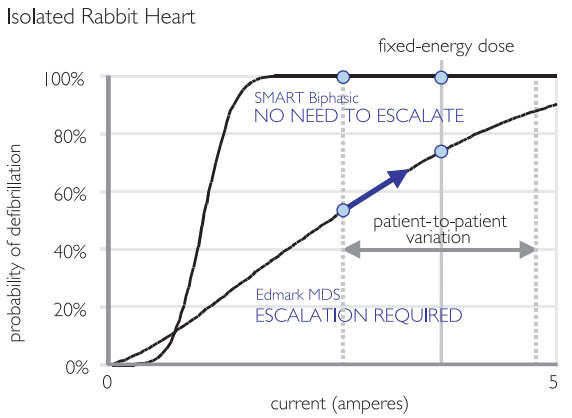
SMART Biphasic waveform

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 Heartstream AED, post-market studies were used to prove the efficacy of the SMART Biphasic 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.[9,10,11,29] 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] A more recent 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 a decade, 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,[27] the data from the ORCA study[15,34] 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.[34]
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.[35]
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.[36]

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.

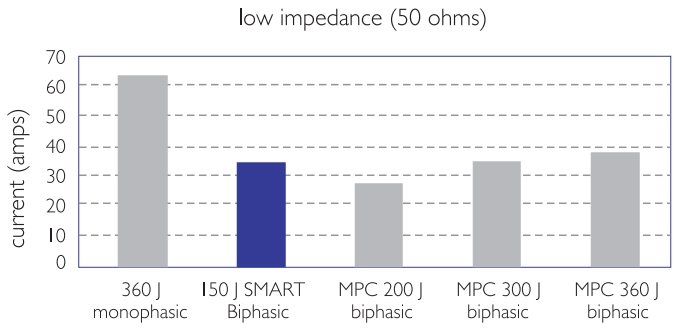
How can the SMART Biphasic waveform be more effective at lower energy?

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:

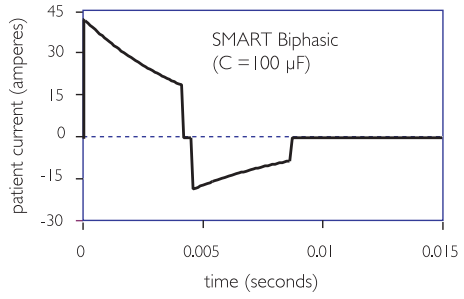
$$V = I R$$

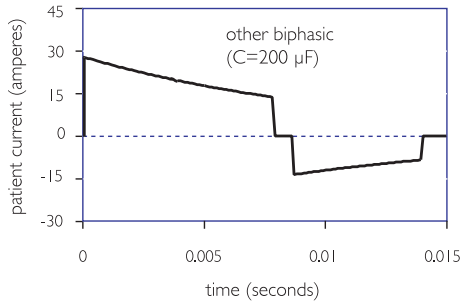


Peak Current Levels

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 at right 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?

Not with SMART Biphasic technology. In the "Guidelines 2005,"[5] the AHA states, "Energy levels vary by type of device." (IV-37) The SMART Biphasic waveform has been optimized for ventricular defibrillation efficacy at 150 J. Referring to studies involving the SMART Biphasic waveform, it states, "Overall this research indicates that lower-energy biphasic waveform shocks have equivalent or higher success for termination of VF than either damped sinusoidal or truncated exponential monophasic waveform shocks delivering escalating energy (200 J, 300 J, 360 J) with successive shocks." (IV-37)

All HeartStart AEDs use the 150 J SMART Biphasic waveform. Two ALS defibrillator products, the HeartStart XL and MRx, provide an AED mode as well as ALS features such as manual defibrillation, synchronized cardio-

version, etc. Selectable energy settings (from 2 to 200 J for the XL or 1 to 200 J for the MRx) are available in the XL and MRx only in the manual mode. A wider range of energy settings is appropriate in a device designed for use by advanced life support (ALS) responders who may perform manual pediatric defibrillation or synchronized cardioversion, as energy requirements may vary depending on the type of cardioversion rhythm.[25,26] For treating VF in patients over eight years of age in the AED mode, however, the energy is preset to 150 J.

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 indicates that other BTE waveforms may require more than 150 J for defibrillating patients in VF.

Heart Attacks

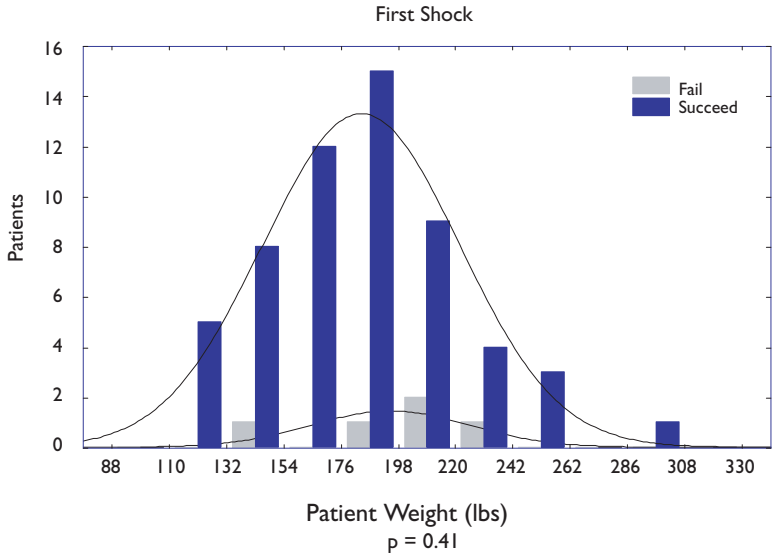
One manufacturer references only animal studies using their waveform to support their claim that a patient may require more than 200 J for cardiac arrests caused by heart attacks (myocardial infarction) when using their waveform. The SMART Biphasic waveform has been tested in the real world with real 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

The SMART Biphasic waveform is the only biphasic waveform to have extensive, peer-reviewed and published emergency resuscitation data for long-duration VF. 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.

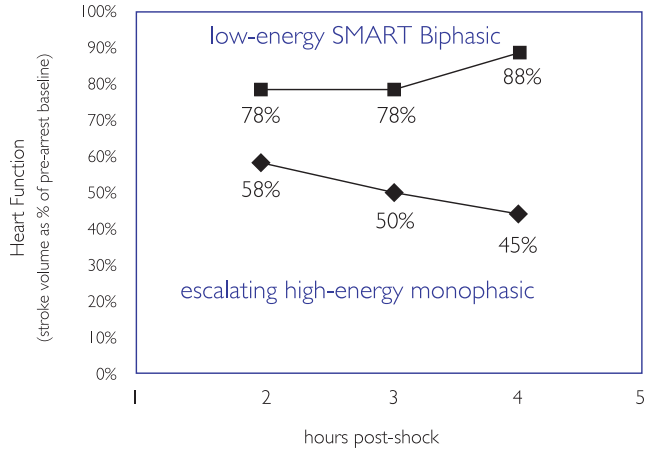
Inaccurate Electrode Pad Placement

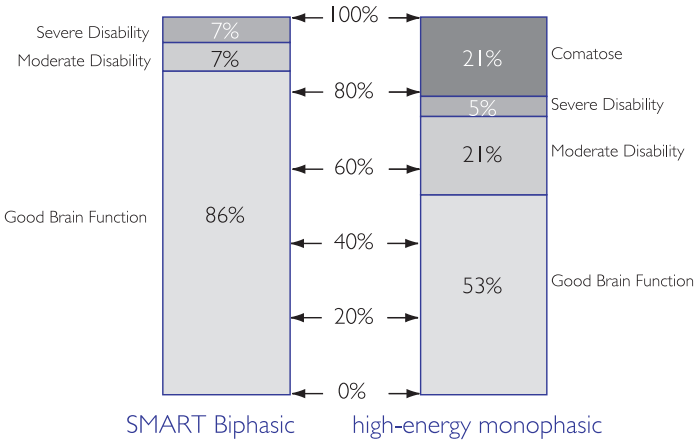
The claim that more energy is possibly required if the pads are not placed properly is a purely speculative argument with no basis in scientific evidence. However, common sense would suggest that if a given biphasic waveform needs more energy when pads are located properly, why would it perform any better 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.

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.[8,28] 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."[29] Several other studies also provide data to support this conclusion for biphasic as well as monophasic waveforms.[21,30,31]

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."[32]

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."

Commitment to SMART Biphasic

All HeartStart defibrillator products use the 150 J SMART Biphasic waveform. The HeartStart XL and MRx are manual defibrillators designed to be used by advanced cardiac life support personnel, but they also include an AED mode. These products provide selectable energy settings from 2 to 200 J in the manual mode but utilize a constant 150 J in the AED mode.

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.[7,8,29,30,33]

Since the SMART Biphasic waveform has been proven effective for defibrillation at 150 J, there is no need to deliver more energy.

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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.

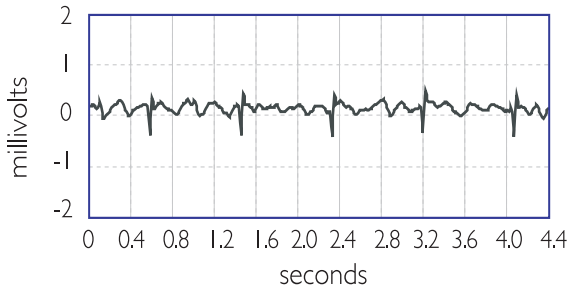
If the amplitude of the ECG signal is sufficiently high compared to the artifact signal or if the artifact does not correlate with the ECG signal, the artifact will not interfere with the normal operation of the AED. In these cases, the defibrillator recognizes that artifact is present, but the defibrillator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

CPR at High Rates of Compression

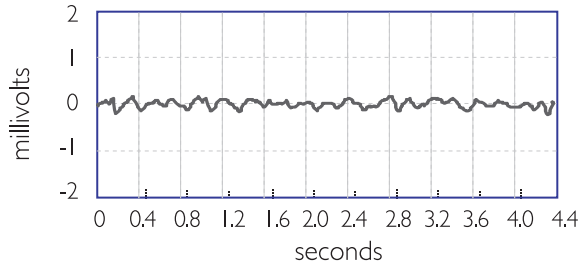
CPR rates significantly above 100 compressions per minute can cause incorrect or delayed analysis by the HeartStart AED. CPR performed with chest compressions of rates over 135/minute can sometimes mimic a shockable rhythm. In the presence of detected high CPR rates, the AED will interrupt the rescuer 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 have the spikes removed. The two strips in the following figure represent the ECG before and after the pacemaker artifact is filtered out.

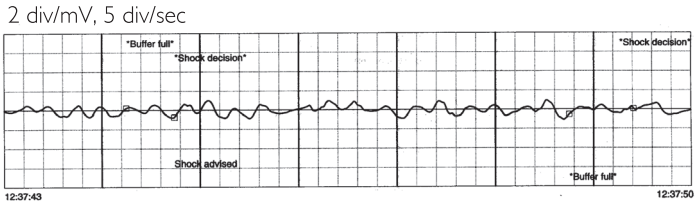


Before filtering: Underlying rhythm VF, pacemaker artifact

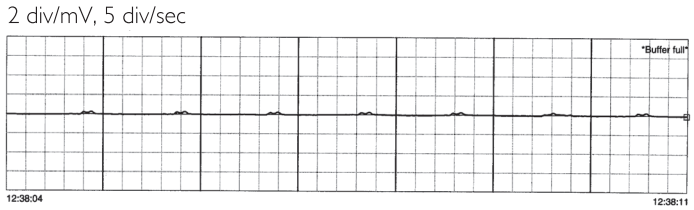


After filtering: Underlying rhythm VF, no pacemaker artifact

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.



CPR artifact: underlying rhythm asystole



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.

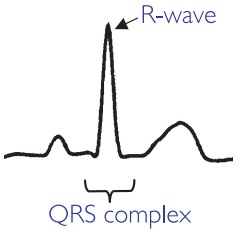
Arrhythmia Detection

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.

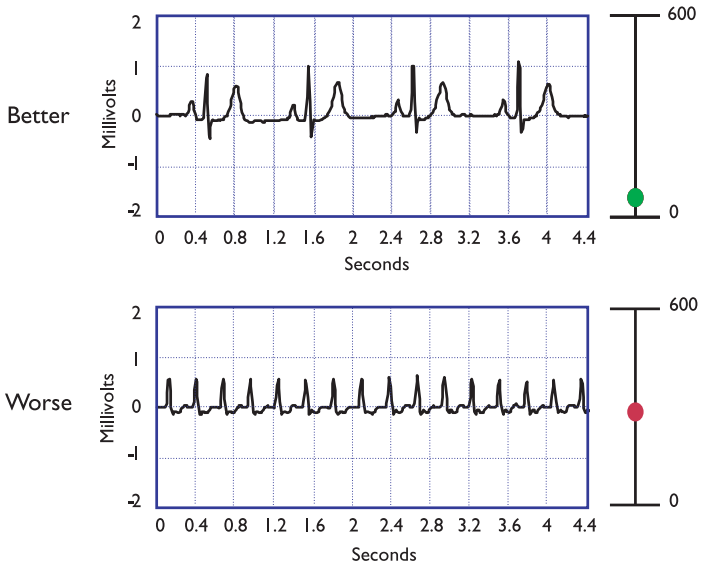
The HeartStart analysis system (SMART Analysis) was developed and tested to ensure that its sensitivity (ability to detect shockable rhythms) and the specificity (ability to detect non-shockable rhythms) exceeded the AHA and AAMI DF80 recommendations. The ECG strips contained in the development database 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



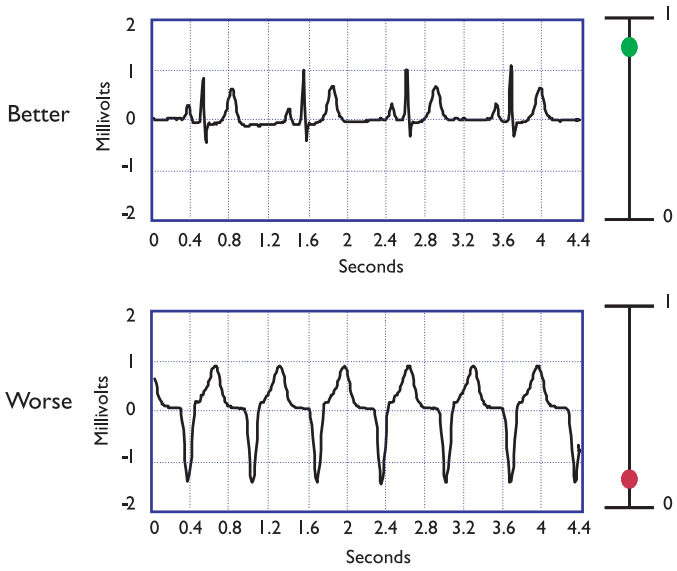
Rate is determined by how many times the heart beats per minute (bpm). A healthy heart beats 60-100 bpm. Some normal rhythms can be very fast. Therefore, it is important to have additional indicators in the analysis system of an AED. Rate is used along with the other parameters to help determine whether 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

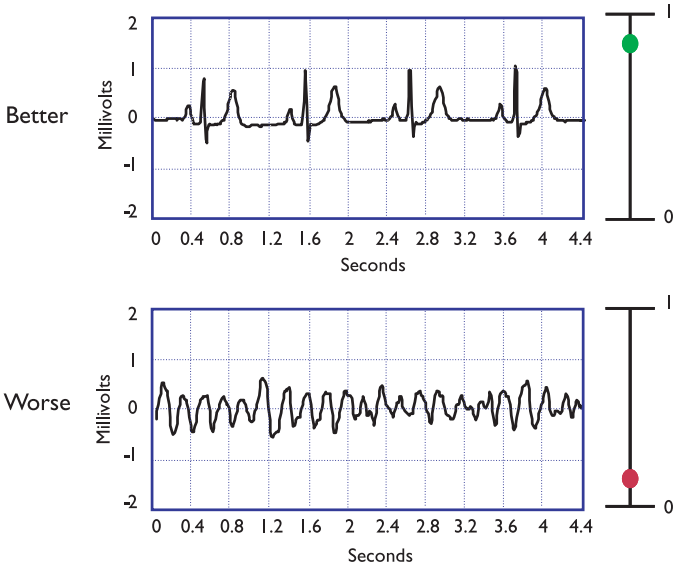
Conduction is determined by examining the R-wave of the QRS complex. conduction is related to the propagation of electrical impulses through the ventricles. In a healthy heart, the ventricles contract in unison, which is reflected in the ECG by narrow QRS complexes with sharp transitions. Non-perfusing 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 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. An unhealthy heart will have chaotic, unstable complexes.

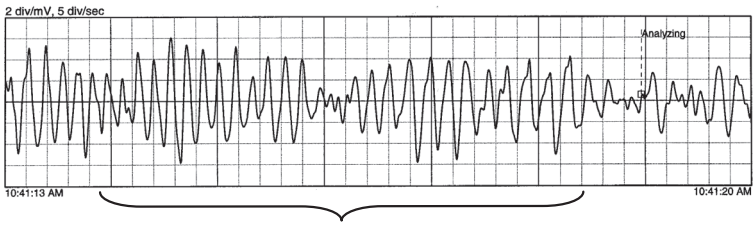


Stability parameter

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

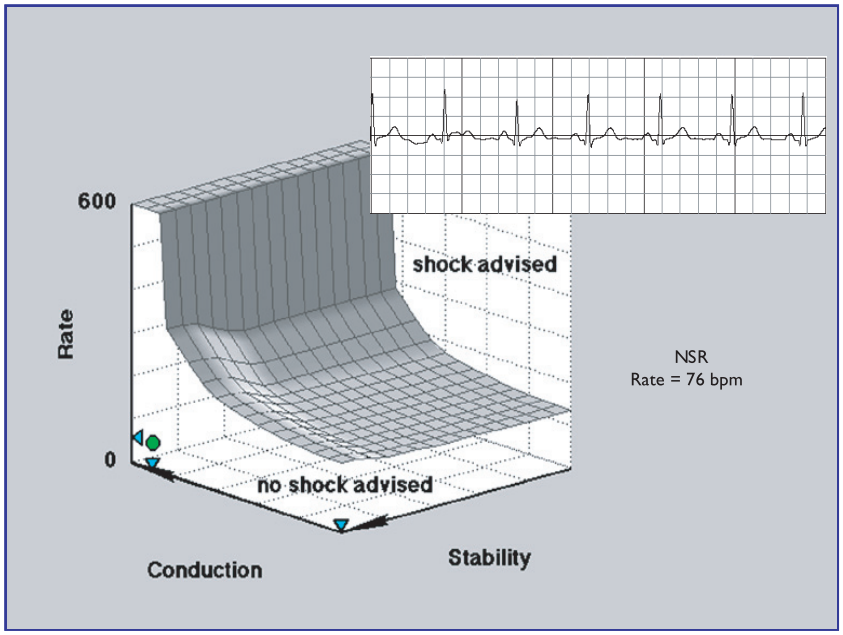
The AED must identify multiple ECG strips as shockable before it will allow the device to arm. The device must then continue to see shockable strips in order to allow a shock to be delivered. HeartStart AEDs differ from other AEDs in that they continue to monitor the ECG even after a shock decision has 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. 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.

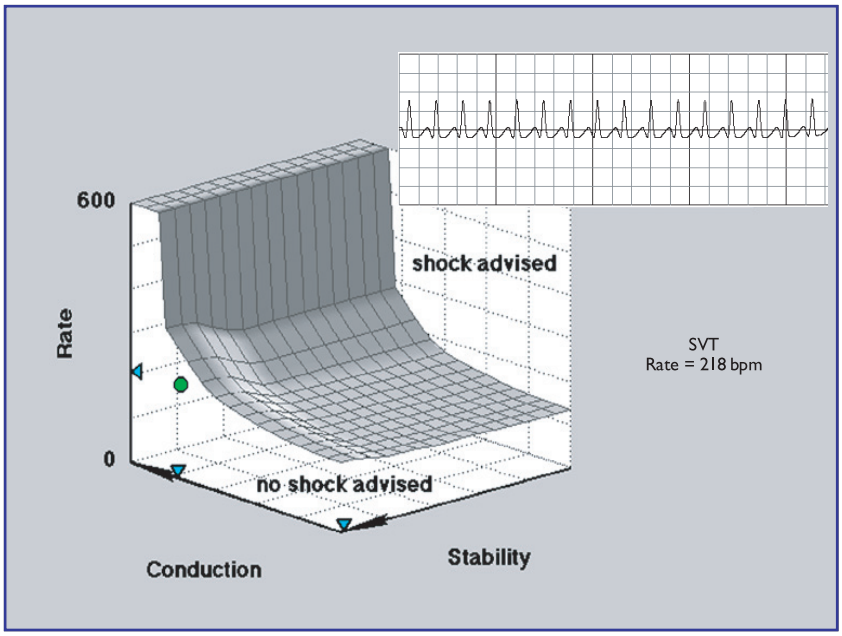
Specific Analysis Examples

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

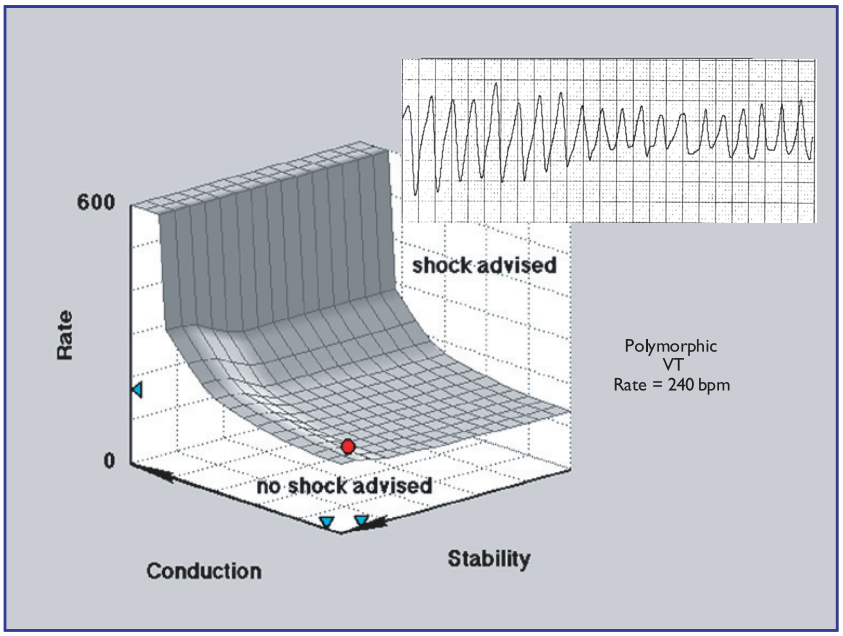
rhythms, and red dots indicate a shock advised for the polymorphic VT and VF rhythms.



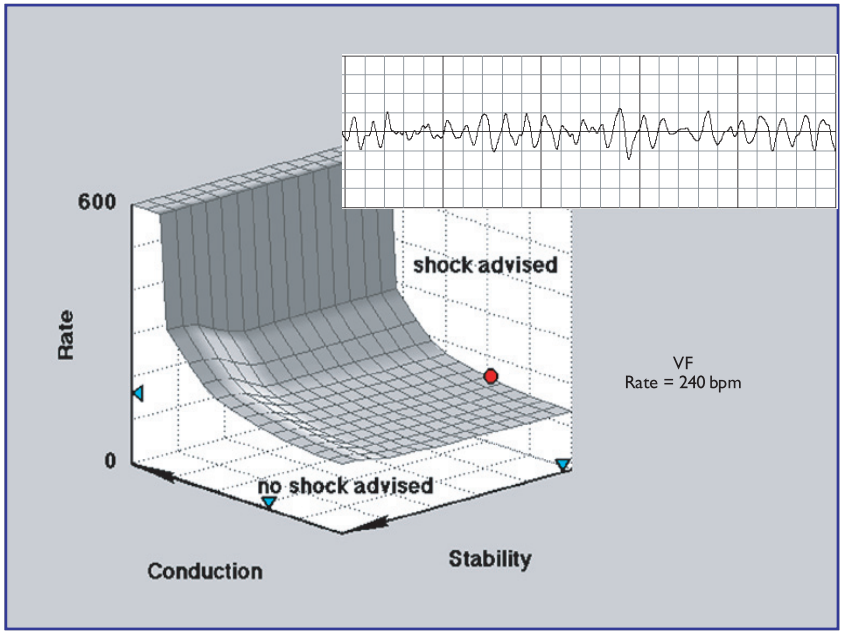
Normal Sinus Rhythm: No-shock advised - excellent stability, conduction, and rate



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



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



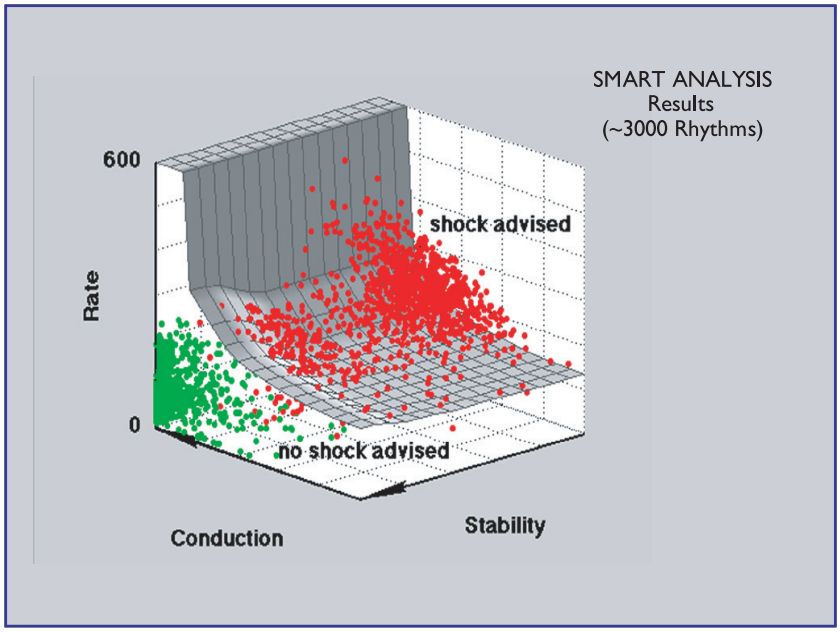
Ventricular fibrillation: Shock advised - very poor stability and conduction, high rate

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

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.

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

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.

rhythms such as fine VF and VT that don't meet all criteria for inclusion in the shockable VT rhythm category.

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.

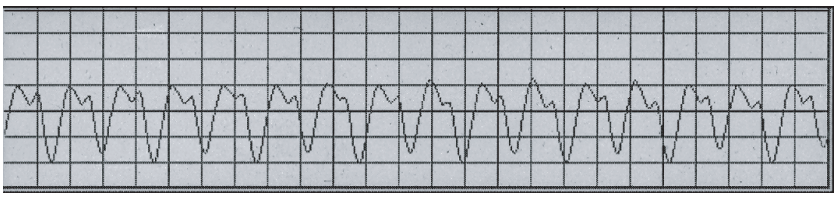
The AHA has issued a Scientific Statement clearly identifying SVT as a non-shockable rhythm, and requiring a minimum defibrillator algorithm specificity of 95% for this rhythm.[1] This high-specificity requirement assumes that a high-quality assessment of perfusion status has been made, thereby eliminating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

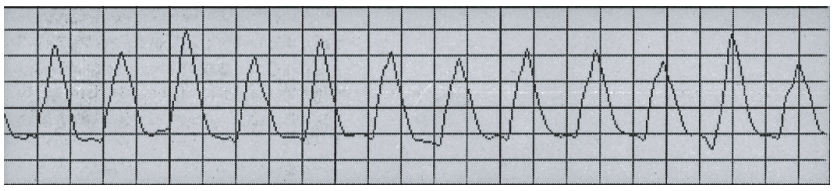
This adaptive design allows the rate threshold to be varied from a minimum level for the most lethal VF rhythms, providing very high sensitivity, to increasingly higher rate thresholds as the stability or conduction characteristics approach normal, providing very high specificity. Borderline rhythms, 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 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: a statement for health professionals from the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy. *Circulation*. 95(6):1677-1682, March 18, 1997.

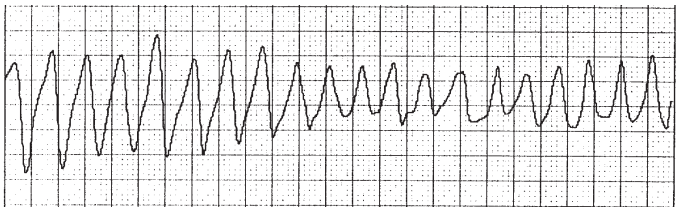


Rate ~ 192 bpm No Shock Advised

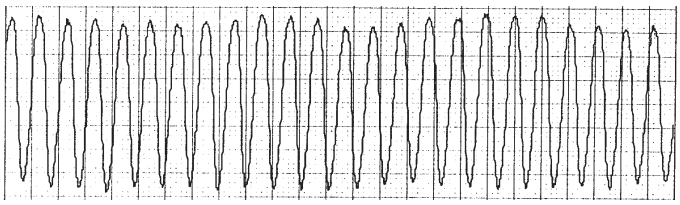


Rate ~ 144 bpm No Shock Advised

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.



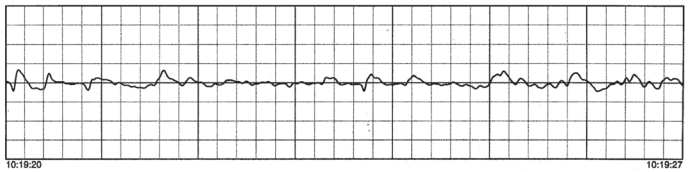
Rate ~ 240 bpm Shock Advised



Rate ~ 288 bpm Shock Advised

The FR2 series AED *Instructions for Use* 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, low-amplitude or low-frequency VF may sometimes be the result of 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 FR2+ 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. We 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.

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 ventricular 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.

Manual Override

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 FR2+ AED (models M3840A and M3860A) can be configured for advanced mode. In advanced mode, the user can manually override the analysis system.

It is important that qualified users be trained in how to use the manual override feature of properly configured instruments. The FR2+ was designed to minimize access of this feature for the lay user. A Training & Administration Pack (M3864A) is required to configure the units for access to advanced mode use. The FR2+ should only be configured for advanced mode if authorized by the Medical Director of the AED program, and configuration should be done under the supervision of the AED Coordinator. Instructions for configuring the devices, manually charging, and delivering the shock can be found in the FR2+ *Instructions For Use* in the "Using Advanced Mode Features" section.

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 FR2+ 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.

Notes

5 Other Features of the HeartStart FR2 Series Defibrillators

Overview

FR2 series defibrillators are in service throughout the world. The FR2 is intended mainly for lay rescuers and BLS providers, but it contains advanced mode features for use by ALS trained personnel. Compared to the FR2, the HeartStart FR2+ AED incorporates new hardware and software that allows the device to use a rechargeable battery and a 3-lead ECG assessment module.

Self-Tests

HeartStart FR2 series AEDs are 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 before the AED is put into service or at regular intervals. Maintenance testing is not required because the AED automatically runs a self-test at least once per day. By visually checking the status indicator daily, the user can verify that the AED has passed a self-test within the last 24 hours and is therefore ready for use.

Battery Insertion Test

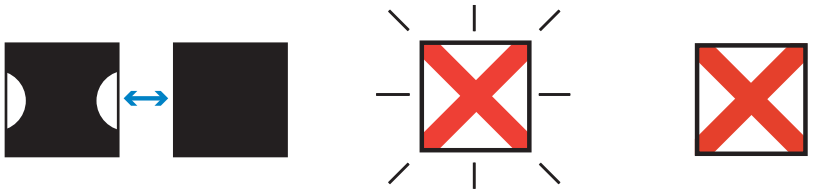
When a user installs a battery in an FR2 series AED, the device runs a comprehensive self-test, called a Battery Insertion Test (BIT). The BIT verifies that the AED circuitry is fully operational, the device is properly calibrated, and that the device is operating within its performance specifications.

The BIT should not be performed on a regular basis since this is unnecessary and shortens the life of the battery. It is recommended that the full BIT (including the interactive portion at the end) be run only under the following conditions:

- When the FR2 series AED is first put into service and following each emergency use.
- Whenever the battery is replaced (except when the AED is in use on a patient).
- Whenever expired pads are replaced during periodic maintenance.
- Whenever the AED may have sustained physical damage.

Status Indicators

The status indicator, located on the upper right face corner of the FR2 series unit, indicates the readiness of the AED.



flashing black hourglass *flashing red X* *solid red X*

A flashing black hourglass shape signifies that the AED has passed its most recent self-test and is ready to use.

A flashing red X on the status indicator signifies that the AED requires attention. It may still be usable, but the device must be checked as soon as possible. The most common reason for the flashing red-X is that the AED has a low battery, but it may also indicate that the unit has been outside the recommended temperature range or that some other clearable error has occurred. If this is the case, a BIT should be run to clear the error.

A solid red X indicates that the battery is missing or completely depleted or that a critical error has occurred and the unit is not usable. If this occurs, contact Philips Medical Systems Customer Service for assistance. (800 263-3342).

Periodic Self-Tests

As long as a battery is installed in the FR2 series 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 BIT, 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 will be noticeable.

A blinking hourglass status symbol means that the HeartStart FR2 series has passed a self-test within the last 24 hours 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. In addition, HeartStart Event Review Software, available from Philips, can be used to print a self-test report.

FR2 series AED Subsystem	Daily Self-Tests	Weekly Self-Test	Monthly Self-Test	Battery Insertion Self-Test
Battery	Battery Capacity Check - Measures remaining battery capacity to warn user when the battery becomes low or the instrument is stored outside of 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.			
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.	

FR2 series AED Subsystem	Daily Self-Tests	Weekly Self-Test	Monthly Self-Test	Battery Insertion Self-Test
User Interface				User Interactive Tests - FR2 series: Prompts the user to verify the buttons, LCD display, LED indicators, and speaker. HS1: Prompts user to push Shock button.

"Power On" and "In Use" Self-Tests

When the FR2 series 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 incident. 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.

FR2 Series 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.

FR2 Series Subsystem	Power On Self-Test	In-Use Self-Test
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 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.
User Interface		Shock Button Safety Test -Tests the shock button through two independent signal paths. If the two paths are inconsistent or if the shock button is stuck, the instrument will not deliver a shock.

Cumulative Device Record

The Cumulative Device Record (CDR) contains a list of the events that the FR2 series 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. Although the CDR does not contain any ECG or voice information, it stores information from each use of the device such as the elapsed time of the use, number of shocks delivered, pads condition, and the number of shock and no-shock decisions made during each use.

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

Users frequently ask about the requirement to calibrate and/or verify energy delivery. The FR2 series AEDs do not require user calibration or verification of energy delivery prior to placing it in service. Further, the FR2 series units do not require user calibration at regular intervals, including annual intervals.

Maintenance testing

Maintenance testing is unnecessary as the FR2 series automatically perform daily self-tests and correct operation is verified during battery insertion tests. When the Status Indicator displays a flashing hourglass, 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 FR2 series do not require manual verification of energy delivery because monthly automatic self-tests verify the waveform delivery system. However, a qualified technical professional can test FR2 series AED energy delivery, using instructions available from Philips. Improper testing can seriously damage the AED and render it unusable.

Service/Maintenance and Repair Manual

The FR2 series AEDs have 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.

Configurability

The FR2 series defibrillators come 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 FR2+. All of them require use of products or accessories available separately from Philips

- Use the M3864A Training & Administration Pack to enable software within the FR2+ to modify its setup. (Instructions are provided with the Pack.)
- Read a revised setup from a data card containing the setup. (Instructions are provided in the FR2 series *Instructions for Use*.)
- Use the infrared communications feature of the FR2+ to receive the revised setup from another FR2+. (Instructions are provided in the FR2 series *Instructions for Use*.)

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 FR2 software version 1.7. Certain functions of this software are new or differ from previous software versions. Contact Philips for information on how to upgrade your FR2 or FR2+ to the latest software version. In addition, the configuration settings information provided in Edition 5 or earlier of the Training & Administration Pack Instructions for Use is superseded by the information presented here. Other directions for use of the Training & Administration Pack provided in its Instructions for Use remain unchanged.

Non-protocol parameters

The following table presents parameters that do not affect the treatment protocol.

parameter	settings	default	description
speaker volume	1, 2, 3, 4, 5, 6, 7, 8	8	Sets volume of the FR2+'s speaker. 1 is lowest; 8 highest. The speaker is used for voice prompts and the armed-for-shock tone.
record voice	yes, no	no	Enables or disables the audio recording during incident. Voice recording requires use of a data card.
ECG display	on, off	on	Enables (ON) or disables (OFF) ECG display on the screen of the M3860A only. FR2+ rhythm analysis does not require ECG display to be on. (ECG display cannot be changed from the default, OFF, for M3861A.)
ECG Out	on, off	off	Enables (ON) or disables (OFF) ECG data transmission from the infrared communications port of the FR2+. ECG data can be sent even if ECG display is disabled or (M3861A) unavailable. *NOTE: If ECG out is set to ON,* ***autosend PST*** *is automatically set to OFF.*
autosend PST	N/A	on	No longer configurable. Transmission of the results of the FR2+'s periodic selftests (PST) from its infrared communications port is always on.

Automatic protocol parameters

The HeartStart FR2+ is designed to follow an automatic patient care protocol defined by the parameters in the following table. Many of these parameters interact with each other, so it is very important to understand how each parameter affects the protocol. The description of each parameter identifies any interacting parameters in **boldface type**.

parameter	settings	default	description
shock series	1, 2, 3, 4	1	Sets the number of shocks that must be delivered to activate an automatic CPR interval. A new Shock Series begins when a shock is delivered: • after the FR2+ is turned on • after the automatic CPR interval, or • after the **Pause Key** (if enabled) has been pressed, or • (with shock series set to a non-default value) if the time since the previous shock exceeds the **protocol timeout** setting.
protocol timeout (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, ∞ (infinite)	1.0	Sets the time interval used to determine if a delivered shock should be counted as part of the current shock series. This parameter is relevant only when the **shock series** is set to a non-default value.
CPR timer (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	2.0	Sets the length of the CPR Interval as well as **CPR First** and manually initiated pauses. After the CPR Interval, the FR2+ returns to automatic rhythm analysis. *NOTE: The actual CPR Interval may be up to 10 seconds longer than the selected setting, to allow time for initial voice prompting.*

parameter	settings	default	description
NSA action (No Shock Advised action) (minutes)	monitor, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0	2.0	Sets how the FR2+ behaves during ongoing care of patients not in a shockable rhythm. MONITOR — provides continuous background analysis of the non-shockable rhythm. However, if the ECG changes, the FR2+ automatically leaves monitoring mode and begins rhythm analysis to determine if a shock is needed. When the ECG display is enabled or the user puts the device into the advanced mode, the patient's heart rate is displayed during background monitoring. *NOTE: CPR may interfere with background heart rhythm monitoring by the FR2+ in monitoring mode. during CPR, periodically pause for 15 seconds to reassess the patient and allow the FR2+ to analyze the patient's heart rhythm without possible interference from CPR artifact.* TIME SETTING — provides patient care pause intervals of the selected duration, alternating with rhythm analysis. *NOTE: If a shock series is set to a non-default value and an NSA decision occurs within a partially complete shock series, the CPR timer setting overrides the NSA Action.*

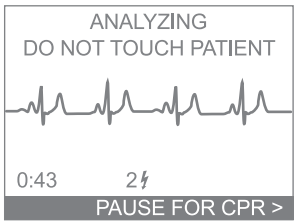
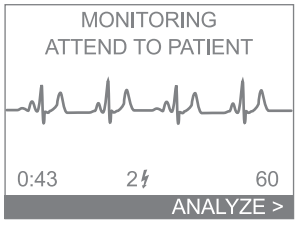
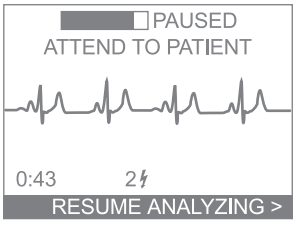
parameter	settings	default	description
CPR First	no, auto1, auto2, user	no	Enables a Medical Director to configure the FR2+ to provide the opportunity for an interval of uninterrupted CPR prior to defibrillation. The SMART CPR AUTO1 and AUTO2 settings automate the decision of whether to provide CPR first or deliver a shock first, based on characteristics of the presenting arrhythmia. NO (default) — CPR First option is disabled; FR2+ will not provide an initial CPR interval. SMART CPR AUTO1 — Provides immediate defibrillation for more than 90% 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 (User-initiated CPR Interval) — This setting provides a protocol under which responders decide whether to perform CPR first. If so, the responder presses the CPR Pause key to initiate a CPR interval. The FR2+ will continue with rhythm analysis unless the CPR Pause key is pressed. The duration of the CPR First interval for AUTO1 and AUTO2 and USER is determined by the **CPR Timer** parameter.

parameter	settings	default	description
CPR prompt	long, short	short	Sets the level of detail provided in the CPR reminder voice prompts provided at the start of a CPR interval or **CPR First** interval (User setting). LONG — prompts the user to assess the patient before beginning CPR. SHORT — simply directs user to begin CPR.
monitor prompt interval (minutes)	1.0, 1.5, 2.0, 2.5, 3.0, ∞ (infinite)	1.0	Sets the interval for patient care prompts provided during FR2+ monitoring of the patient's ECG following an NSA decision. Selection of ∞ (infinite) means that no repeat prompting will be provided during ECG monitoring. This parameter only applies when the **NSA action** is set to monitor.

Manual override parameters

The parameters in the following table are used to enable different kinds of manual override.

parameter	settings	default	description
advanced	off, analyze, charge	off	Enables or disables advanced mode entry for ALS or tiered-response systems. OFF — disables advanced mode features. ANALYZE — enables user-initiated rhythm analysis and disarm, and (M3860A only) automatically turns on ECG display when advanced mode is entered. CHARGE (M3860A only) — in addition to enabling the analyze feature, enables user-initiated charging and disarming.

parameter	settings	default	description
pause key	on, off	off	Enables (ON) or disables (OFF) a user-initiated CPR interval in the automatic protocol. The interval length is defined by the **CPR timer** setting. The pause key is disabled when an advanced mode feature (analyze or charge) is enabled and accessed, and during Monitoring. If either the **CPR timer** or the **NSA action** setting is programmed to 2.5 minutes or longer, the Resume Key setting is automatically enabled (on). The Resume Key is always automatically enabled for any **CPR First** interval. OFF — disables availability of user-initiated pause. ON — enables user-initiated pause by pressing the lower Option button indicated by an arrow on the FR2+ display, at any time except when the device is monitoring or is already paused. If enabled, the pause is initiated by pressing the lower Option button indicated by an arrow on the FR2+ display, as shown in the sample screen. 
resume key	on, off	off	Enables (ON) or disables (OFF) user-initiated interruption of CPR and patient care intervals and return to analyzing, by pressing the lower Option button indicated by an arrow on the FR2+ display. If either the **CPR timer** or the **NSA action** setting is programmed to 2.5 minutes or longer, the Resume Key setting is automatically enabled (ON). The Resume Key is always automatically enabled for any CPR First interval. If enabled, analysis is initiated by pressing the lower Option button indicated by an arrow on the FR2+ display, as shown in the sample screen:  

parameter	settings	default	description
advanced use prompt interval (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	0.5	Sets the interval for patient care prompts provided during advanced mode operation.

Quick Shock

The HeartStart FR2+ is able to deliver a shock in less than 10 seconds, typical, following the end of the prompt at the end of a CPR Interval.

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.

SMART CPR

Philips has augmented the HeartStart FR2+'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. Note that previous versions of the FR2+ could be attached for data collection during initial CPR, via an enabled Pause key.

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.

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] 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 FR2+, 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 FR2+ advises an immediate shock. Otherwise, the FR2+ advises CPR prior to a shock. SMART CPR is designed to help responders make better-informed, more refined treatment decisions. It supports an emerging response protocol that current scientific literature, and 2005 American Heart Association Guidelines,[1] suggest 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, 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.

1 American Heart Association. Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. December, 2005;IV:37.

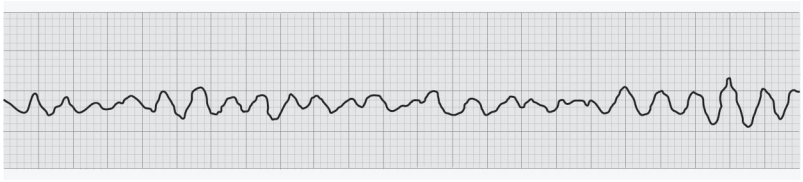


Figure 1a: Short-term VF rhythm with high frequency and amplitude, characteristic of a heart receptive to a defibrillation shock

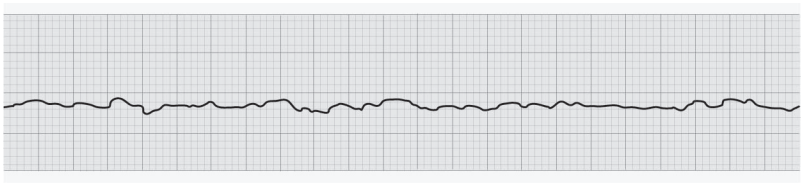


Figure 1b: Long-term VF rhythm with low frequency and amplitude, characteristic of a heart that is unlikely to return to circulation with a shock. CPR prior to a shock may improve the outcome.

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 survival is higher for patients with rhythms typical of long-duration VF (> 5 minutes) 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. The other group received an interval of CPR followed by shocks. 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. Figure 2 shows the survival curve over time for that group of patients. Of particular interest is that the figure also shows that, among patients with longer-duration VF, those in the group receiving an interval of CPR prior to a shock had significantly better survival.

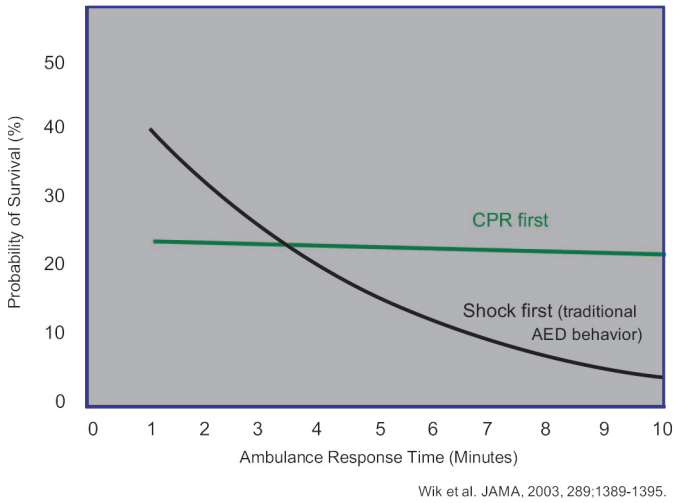


Figure 2: Patients with short-duration VF had good survival rates when they received immediate shocks. However, those with long-duration VF had higher survival rates when receiving CPR prior to a shock.

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 prior to shocks 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.

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

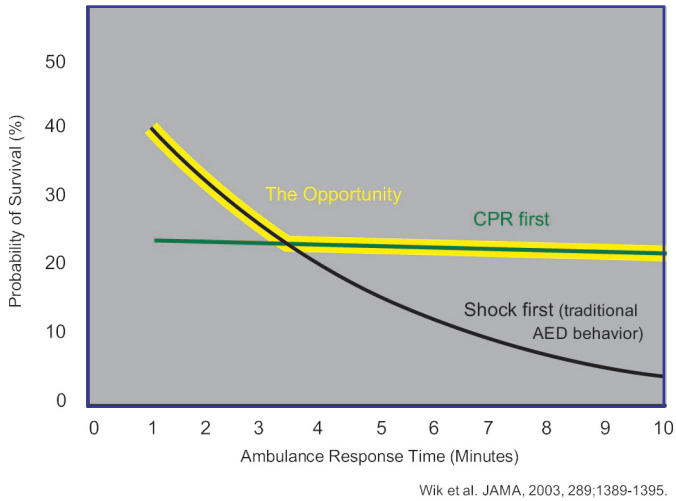


Figure 3: The opportunity to improve survival of SCA with a change in response protocol.

However, 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 FR2+ 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 FR2+ 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 FR2+ adjusts its voice instructions accordingly.

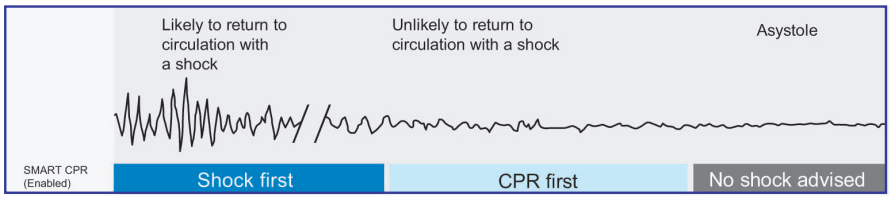


Figure 4: A conceptual representation of the progression of VF over time, showing SMART CPR's response.

In deciding whether to enable SMART CPR in the FR2+, the Medical Director should consider the overall impact the selected setting would have on the SCA emergency response system, and train responders accordingly. If a system-wide change is desirable, software upgrades for existing FR2/FR2+ defibrillators predating SMART CPR are available from Philips. 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 FR2+ to any of four CPR First settings: NO, SMART CPR AUTO1, SMART CPR AUTO2, and USER. These are defined in greater detail below.

NO setting

The NO setting means the FR2+ will not provide an initial CPR interval prior to defibrillation of a shockable rhythm. Thus, once the FR2+ 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 FR2+ 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 FR2+ 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).

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.

SMART CPR AUTO1. Provides immediate defibrillation for more than 90%†[1] 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 FR2+ 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 FR2+ will continue with rhythm analysis unless the CPR Pause key is pressed.

With the FR2+ CPR First setting set to USER, the FR2+ provides an opportunity for the responder to initiate a CPR interval for all patients — even those who may benefit from immediate defibrillation.

Information on how to upgrade an FR2 series defibrillator to permit configuration for the SMART CPR feature is provided in Appendix E.

Pediatric Defibrillation

The HeartStart FR2 series defibrillators can be used with reduced-energy Infant/Child defibrillator pads (REF: M3870A) to treat children under 8 years of age or 55 pounds (25 kg). These pads are designed with components built into the connector that reduce the actual energy delivered from the adult dose of 150 joules to 50 joules.

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 FR2+.
- If no bystander is available, provide 1-2 minutes of CPR before calling EMS and retrieving the FR2+.
- If you witnessed the child's collapse, call EMS *immediately* and *then* get the FR2+.

Alternatively, follow your local protocol.

1 Based on observed performance. ROSC was determined by several parameters, including patient assessment, ECG analysis, and/or patient impedance cardiography.

If the victim is under 55 pounds or 8 years old, but you do not have Infant/Child pads, do not delay treatment. Use standard adult pads but 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. Use standard adult pads but place the pads as illustrated on each pad (anterior-anterior). Make sure the pads do not overlap or touch each other.

Trainer Options

Training & Administration Pack

The HeartStart FR2 series AEDs can be used for training purposes with the Training & Administration Pack (REF: M3864A) and HeartStart adult (07-10900) and pediatric (M3871A) training pads. Use of the Training & Administration Pack allows the user to select among a total of ten training scenarios. The Training & Administration Pack contains rechargeable batteries, so that the defibrillator's primary battery is not drained during training. (The battery charger M3855A for the Training & Administration Pack is available separately.)

Trainer 2

The M3752A Trainer 2 is available for FR2 series AED users who do not wish to dedicate a therapeutic unit for training purposes. The Trainer 2 resembles the FR2 series defibrillators but does not have an active display and operates on six replaceable C-cell batteries

The Trainer 2 is pre-configured with 10 training scenarios that simulate realistic sudden cardiac arrest episodes. These scenarios are compatible with training programs developed by nationally and internationally recognized responder programs. In addition, three custom scenarios can be created using the optional M3754A programming kit PC software. The software is available at no charge via the internet at http://www.medical.philips.com/goto/Trainer2, or you can order it on CD from Philips. The CD is shipped with a cable for connecting the Trainer 2 to your PC. Note that this software also enables change of trainer language and configuration settings.

The AED Trainer 2 can be used with an optional M3753A infrared remote control. The remote control gives the instructor the ability to alter training scenarios while in progress, to test student response.

The Trainer 2 provides simulated shock delivery. It has no high-voltage capabilities, ensuring safety during training. The Trainer 2 is designed for use with HeartStart adult (07-10900) and pediatric (M3871A) training pads. 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 2 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.

Training Scenarios

The following ten training scenarios are available when using HeartStart training pads with the HeartStart FR2 series AED and a Training & Administration Pack. The training behavior of the Trainer 2 may differ slightly from the descriptions below. See the Trainer 2 *Instructions for Use* for a description of the Trainer 2 scenarios.

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.

no.	scenario overview	scenario details
1	Shockable rhythm, single-shock conversion	• shockable rhythm; one shock • non-shockable rhythm
2	Shockable rhythm, multiple shocks needed for conversion	• shockable rhythm; one shock • repeats until four shocks are delivered • non-shockable rhythm
3	Troubleshooting: poor pads contact, one shock needed for conversion	• poor pads contact *(press firmly* or *remove and reapply a pad)* • shockable rhythm; one shock • non-shockable rhythm
4	Refibrillation: Shockable rhythm, conversion followed by refibrillation	• shockable rhythm; one shock • non-shockable rhythm; no shock advised • refibrillation – shockable rhythm; one shock • non-shockable rhythm
5	Non-shockable rhythm	• non-shockable rhythm throughout
6	Shockable rhythm, two shocks needed for conversion	• shockable rhythm; one shock • shockable rhythm; one shock • non-shockable rhythm

no.	scenario overview	scenario details
7	Shockable rhythm, conversion followed by refibrillation during initial CPR interval*	• shockable rhythm; one shock • non-shockable rhythm followed by refibrillation during first CPR interval; one shock • non-shockable rhythm
8	Troubleshooting: poor pads contact, two shocks needed for conversion	• poor pads contact *(press firmly or remove and reapply a pad)* • shockable rhythm; one shock • shockable rhythm; one shock • non-shockable rhythm
9	Shockable rhythm (using Trainer2) *OR* Live input ECG training (using defibrillator)	• shockable rhythm throughout *OR* • externally driven; responds realistically to ECG rhythm produced by a simulator or specially equipped manikin
10	Troubleshooting: excessive motion, poor pads connection, low battery, one shock required for conversion	• motion artifacts, analysis interrupted *(press Resume Analyze key)* • shockable rhythm; shock abort • poor pads connection; replace pads *(remove and re-insert pads connector)* • shockable rhythm; one shock • non-shockable rhythm • battery low

* This scenario is useful when training on an FR2+ with ECG. It is intended to train users on the importance of performing CPR for the entire interval, no matter what rhythm changes appear on the ECG display.

6 Theory of Operation

IMPORTANT NOTE: The internal construction of all HeartStart AEDs is extremely sophisticated. They 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 FR2 series AEDs monitor the patient's electrocardiogram (ECG) and advise the user to deliver a shock when appropriate. In order to do this, the AED has to perform a number of functions, including:

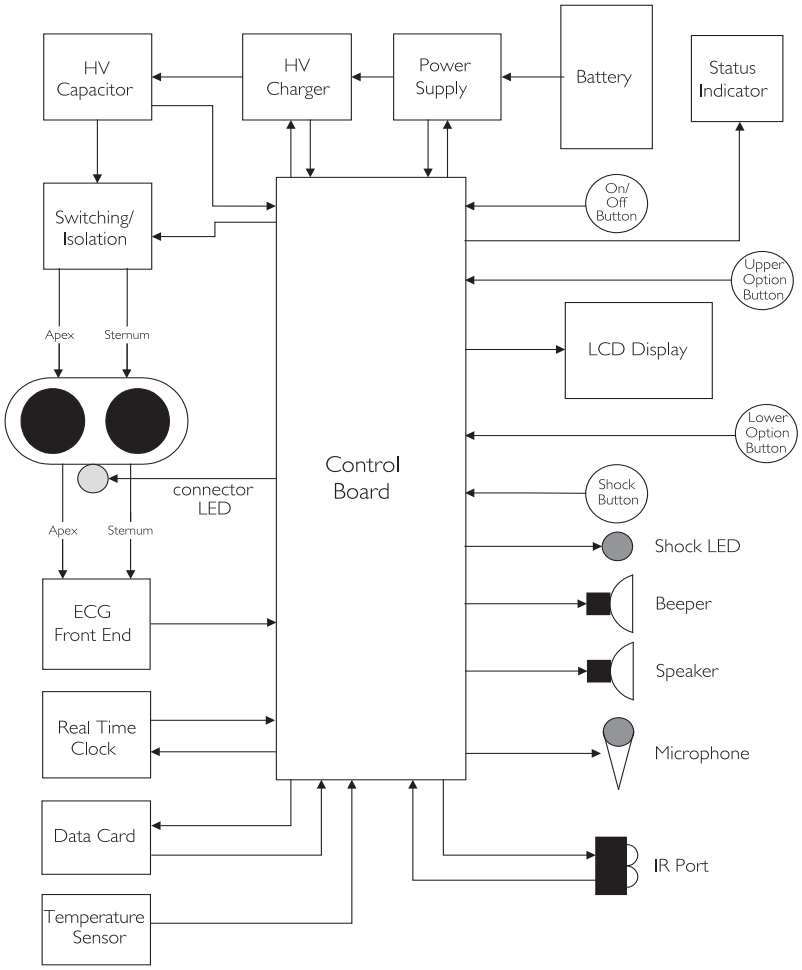
- Input the ECG signal and convert it into a digital format that the microprocessor can analyze.
- Analyze the ECG and determine if the device should charge and allow a shock to be delivered.
- Charge the internal capacitor to a voltage high enough to effectively defibrillate the patient.
- Instruct 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 FR2 series AEDs are 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 them in the process of assisting the patient.
- Provide audio and visual indicators to call attention to various parts of the device at appropriate times (connector or shock button light, status indicator, 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 FR2+ AED as an example. These include:

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



HeartStart FR2+ block diagram

User Interface

The following discussion uses the HeartStart FR2+ device as the user interface example. The principles discussed apply to the FR2 devices as well. The user interface consists of the main LCD display, the on/off button, the shock button, the two option buttons, the connector light and shock button light, the beeper, the speaker, and the status indicator.

Operation

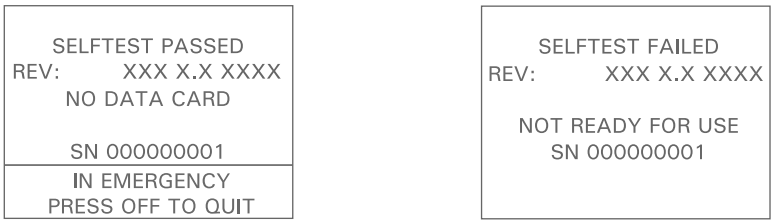
In normal operation, text prompts are displayed on the HeartStart FR2+ main LCD, and voice prompts are provided through the speaker. These prompts guide the rescuer in the use of the device and give warnings (such as low battery) to call the user's attention to certain parts of the device that may need 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 FR2+. If the FR2+ 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 FR2+ 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

Maintenance for the HeartStart FR2+ Defibrillator primarily consists of the user checking the status indicator regularly to verify that the unit is working and ready to be used. The FR2+ 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, it will display a flashing or solid red X on the status indicator, which may be accompanied by beeping.

Troubleshooting

The LCD display, beeper, and status indicator are also used for trouble-shooting the HeartStart FR2+. The main troubleshooting tool is the battery insertion test, or BIT. To initiate a BIT, the battery is removed and then reinserted. The FR2+ then executes an automatic comprehensive functional test, followed by an interactive test that allows the user to verify that all the buttons, the beeper, and the displays are working. The automatic part of the BIT takes about 1.5 minutes to run and ends with a screen that displays either "SELFTEST PASSED" or "SELFTEST FAILED" (see sample screens, below), along with other information about the revision of the hardware and software and status of the FR2+.



Sample FR2+ selftest results screens

Configuration

The LCD display and option buttons are used in configuration mode to set the clock or customize the configuration of the HeartStart FR2+. 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.

Control Board

The control board holds the main processor and all of the circuitry required to control the real time functions of the HeartStart FR2+. The real time control provides the signals 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 control board runs all of the data processing for the analysis system.

Battery

The HeartStart FR2+ has three power source options. The M3864A is a 12 V, 4.2 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. In certain markets, A TSO-certified battery for aviation applications is available. The 989803136291 battery has the same chemistry, capacity, and specifications as the M3864A. In addition, the FR2+ can be used with a rechargeable battery. The M3848A is a rechargeable, 12 V, 2.2 Ah lithium ion battery used with the dedicated M3849A charger. The rechargeable battery option is not recommended for units that do not see frequent use.

Power Supply

The power supply is used to convert the battery voltage to the various voltages needed to supply the electronics within the HeartStart FR2+.

ECG Front End

The front end of the HeartStart FR2+ amplifies and filters the ECG signal input from the electrodes and feeds this signal into the A/D converter. The sampling rate for the A/D converter is 200 Hz, and this digital data is fed into the control board 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 FR2+ to deliver the defibrillation waveform to the patient. A large amount of energy is stored in the battery: enough for over 300 shocks in the FR2 battery. However, this energy is stored in the battery at a low voltage (12 V in FR2) 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 FR2+, 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 FR2+ 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 FR2+ 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 your FR2/FR2+ *Instructions for Use* for a complete description of the data available from the FR2 series AED.

Temperature Sensor

The HeartStart FR2+ incorporates a temperature sensor that allows the control board to determine the ambient temperature of the device. This 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. If the self-test is postponed three times in a row for this reason, an error is generated, which causes the status indicator to display a flashing red X and the unit to begin beeping. 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 FR2+ contains a real-time clock that is the reference time for any event that occurs. Any use of the AED will have this time and date information annotated on the data recorded on the data card. The time and date can be set with the AED itself or it can be synchronized with another AED by using the IR port to read in the time from another device.

IR Port

The HeartStart FR2+ incorporates an infrared (IR) port that can be used to communicate with other FR2+ AEDs. The IR port can be used to send or receive time and date information or configuration data from other FR2+ devices.

1 HeartStart Data Management Software

Overview

HeartStart data management software allows the data from an FR2 series 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. Software version numbers are current as of June 2007.

HeartStart Event Review 3.5[1] 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, you can integrate ECGs from multiple defibrillators 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. Event Review can also be used to configure the HeartStart FRx and HS1 family of AEDs. Available in English, French, German, Spanish, Italian, and Japanese.

Event Review Pro 3.5 is a comprehensive application for electronically managing the case data recorded by your 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 them collect and review more comprehensive response and patient data than Event Review, including detailed BLS and ALS responder observations and interventions. You can

1 Event Review, introduced in early 2003, replaced the stand-alone CodeRunner Web Express software. When Event Review was introduced, the CodeRunner Web software was renamed Event Review Pro.

integrate ECGs from multiple defibrillators into one case for a complete event history. With Event Review Pro, you can produce case reports, 12-lead reports, Utstein reports and overall system response time summaries. With Event Review Pro, 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. Available in English, French, German, Spanish, Italian, and Japanese.

HeartStart Review Express Connect 3.5 is designed to be an easy-to-use wizard that guides you through the steps of downloading an ECG from a Philips or Laerdal defibrillator, allowing you to view and print the ECG, save it to a file, e-mail it to a central data manager or medical director, and erase patient data from the defibrillator's data card or internal memory. Review Express Connect is particularly helpful when you simply want to download a case from a defibrillator and e-mail it to a central data manager or medical director for analysis using the more comprehensive HeartStart Event Review or Event Review Pro data management program. Available in English, French, German, Spanish, Italian, and Japanese.

Review Express Software is available for download at no charge from medical.philips.com/heartstart. Using this software, you can download ECG data from your AED's data card or infrared (IR) port, view it on your PC screen, print it, and erase your data card or defibrillator's internal memory.

Event Review was tested with IR adapters from ACTISYS. An approved ACTISYS adapter is available from Philips Medical Systems.

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 the Event Review or Event Review Pro revision 3.5 or higher software for managing data from FR2 series AEDs, it must be equipped as follows:

PC Element	Requirement
operating system	Windows 2000 Professional (with SP4) or Windows XP Pro (with SP1 or higher)
processor	Pentium® processor, 500 MHz or higher
display	Minimum: Super VGA 800x600 16-bit color Recommended: 1024x768 screen resolution with 16-bit color
memory	256 MB recommended
CD-ROM	4x speed or higher
hard disk space	For installation: 300 MB For event storage: 100 MB minimum
file transfer	Data card reader or IR reader
sound card	100% Sound Blaster® compatible sound card

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
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

	Event Review	Event Review Pro
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

Data Management Software Versions

Event Review, introduced in early 2003, replaced the stand-alone CodeRunner Web Express software. When Event Review was introduced, the CodeRunner Web software was renamed Event Review Pro. 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
CodeRunner	Heartstream ForeRunner, Laerdal FR
CodeRunner Web Express	Philips/Agilent/Hewlett-Packard: Heartstream ForeRunner, Heartstream FR2, HeartStart FR2+ Laerdal: Heartstart FR, Heartstart FR2, HeartStart FR2+
CodeRunner Web	Philips/Agilent/Hewlett-Packard: Heartstream ForeRunner, Heartstream FR2, HeartStart FR2+ Laerdal: Heartstart FR, Heartstart FR2, HeartStart FR2+
Event Review Pro	Philips/Agilent/Hewlett-Packard: Heartstream ForeRunner, Heartstream FR2, HeartStart FR2, HeartStart FR2+, HeartStart Home, HeartStart OnSite, HeartStart HS1, HeartStart FRx 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 Laerdal: Heartstart FR, Heartstart FR2, HeartStart FR2+, HeartStart, HeartStart FRx
HeartStart Review Express Connect	Philips/Agilent/Hewlett-Packard: Heartstream ForeRunner, Heartstream FR2, HeartStart FR2+ Laerdal: Heartstart FR, Heartstart FR2, HeartStart FR2+
HeartStart CaseCapture	Philips: HeartStart Home, HeartStart OnSite, HeartStart HS1, HeartStart FRx Laerdal: HeartStart, HeartStart FRx
HeartStart Configure	Philips: HeartStart Home, HeartStart OnSite, HeartStart HS1, HeartStart FRx Laerdal: HeartStart, HeartStart FRx

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.

CONTINUED USE — The defibrillator has been turned back on within five minutes of the previous use. It is assumed that the defibrillator is being used on the same patient, so this ECG is appended to the previous ECG.

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 three shocks) 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 "officially" 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 is available by calling (800) 263-3342.

Notes

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 and results in a product that performs well in the many new environments that an AED may be used in. To date, HeartStart AEDs have accumulated over a billion hours of powered service.

Except as otherwise noted, the information below applies to the HeartStart and Laerdal FR2 series AEDs (models M3860A, M3861A, M3840A, M3841A). 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, Heartstream.

Standards Applied

- AAMI DF39:1993
- AAMI DF80
- IEC 60601-1:1988 / EN 60601-1:1990
- EN 60601-1-2:1993 / IEC 60601-1-2:1993
- EN 55011:1991 (Class B) / CISPR 11:1990
- EN 61000-4-3:1995
- CAN/CSA-C22.2 No 601.1-M90 and Supplement 1:1994
- CISPR 11:1990 / EN 55011:1991
- RTCA/DO-160D:1997

In addition to the standard testing done on medical devices, HeartStart AEDs have been tested in numerous field environments where devices have been deployed. These field environments may subject the devices to environmental conditions well past the specifications listed below and may involve much higher electric or magnetic field strengths. When there is concern about using an AED in extreme conditions, it is possible to test on site to insure that the performance of the HeartStart AED will not be adversely affected by the environment or will not affect the performance of surrounding equipment if used in that environment.

FR2 series AEDs have been tested in the following special 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

FR2 Series AED Specifications

Physical

category	nominal specification
size	2.6" high x 8.6" wide x 8.6" deep (6.6 cm x 21.8 cm x 21.8 cm).
weight	Approximately 4.7 lbs (2.1 kg) with standard battery installed. Approximately 4.5 lbs (2 kg) with optional rechargeable battery installed.

Environmental

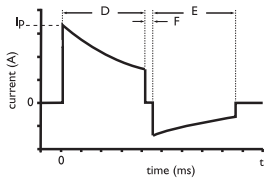
category	nominal specification
operating temperature and humidity	32° to 122° F (0° to 50° C).0% to 95% relative humidity (non-condensing).
standby temperature and humidity	32° to 109° F (0° to 43° C). 0% to 75% relative humidity (non-condensing), with battery installed and stored with defibrillation pads.
altitude	Meets MIL-810E 500.3, Procedure II (-500 feet to 15,000 feet).
shock/drop abuse tolerance	Meets MIL-STD-810E 516.4, Procedure IV (after a 1 meter drop to any edge, corner, or surface, in standby mode).
vibration	Meets MIL-STD-810E 514.4-17 and 514.4-17.
sealing	With data card tray and battery installed, meets IEC 529 class IP54.
electrostatic discharge (ESD)	Meets IEC 61000-4-2
EMI (radiated)	Meets RF CISPR 11 Group 1 Class B
EMI (immunity)	Meets IEC 61000-4-3
aircraft: method	Meets RTCA/DO-160D:1997 Section 21 (Category M - Charging).

Controls and Indicators

category	FR2 series
LCD screen	High-resolution, backlighted LCD screen displays ECG (M3860A only) and text messages.
controls	• On/Off button • Shock button • Option buttons
LED indicators	• Connector socket LED, flashes to indicate socket location. • LED is covered when defibrillation pad connector is properly inserted. • Shock button LED flashes when AED is armed.
audio speaker	Provides voice prompts. Volume is adjustable via Setup screen.
beeper	Chirps when a selftest has failed. Provides various warning beeps during normal use.
status indicator	Status indicator LCD displays device readiness for use.
low battery detection	Automatic during daily periodic selftesting.
low battery indicator	Solid or flashing red **X** Status Indicator on front panel; screen display LOW BATTERY or REPLACE BATTERY warning, as appropriate.

Defibrillation

category	nominal specifications
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 (400 µs), and Ip is the peak current.



The HeartStart FR2 series 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	60	140
50	4.1	4.1	33	150
75	5.8 or 7.2	3.8 or 4.8	23	153
100	9.0	6.0	17	157
125	12.0	8.0	14	161
150	12.0	8.0	12	157
175	12.0	8.0	10	151

pediatric defibrillation
(using M3870A FR2 infant/child reduced-energy defibrillator pads)

load resistance (Ω)	phase 1 duration (ms)	phase 2 duration (ms)	peak current (A)	delivered energy (J)
25	4.1	4.1	22	35
50	5.8	3.8	17	48
75	5.8	3.8	14	53
100	7.2	4.8	11	55
125	7.2	4.8	10	54
150	9.0	6.0	9	54
175	9.0	6.0	8	53

NOTE: The values given are nominal. The actual phase durations for a given load resistance on the pediatric table above could be those of an adjacent row.

category	nominal specifications
energy	Using adult defibrillator pads: 150 J nominal (±15%) into a 50 ohm load. Using infant/child reduced-energy defibrillator pads: 50 J nominal (±15%) into a 50 ohm load. Sample pediatric energy doses: age — energy dose newborn — 14 J/kg 1 year — 5 J/kg 2 - 3 years — 4 J/kg 4 - 5 years — 3 J/kg 6 - 8 years — 2 J/kg Doses indicated are based on CDC growth charts for the 50th percentile weights for boys.* * National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion. *CDC growth charts: weight-for-age percentiles, revised and corrected* November 28, 2000. Atlanta, GA: Centers for Disease Control and Prevention © 2000.
charge control	Controlled by Patient Analysis System for automated operation. Can be programmed for manual initiation using advanced mode of the M3860A.
shock cycle timing	End of "Stop CPR" prompt to armed time: Quick Shock. < 10 seconds typical, including analysis. After 15 shocks, the FR2+ takes <30 seconds from analyzing to ready-to-shock. After 200 shocks, the FR2+ takes <40 seconds from initial power-on to ready-to-shock.
manual mode charge time	< 5 seconds.
"charge complete" indicator	Shock button flashes, audio tone sounds.
disarm (AED mode)	Once charged, the HeartStart FR2+ will disarm if: • patient's heart rhythm changes to non-shockable rhythm, • a shock is not delivered within 30 seconds after the FR2+ is armed, • the Pause button (if enabled) is pressed, • the On/Off button is pressed to turn off the FR2+, or • the defibrillator pads are removed from the patient or the pads connector is disconnected from the FR2+.

category	nominal specifications
disarm (advanced mode)	Once charged, the HeartStart FR2+ will disarm if: in advanced mode ANALYZE • the manual disarm button is pressed, • a patient's heart rhythm changes to non-shockable rhythm, • a shock is not delivered within 30 seconds after the FR2+ is armed, • the On/Off button is pressed to turn off the FR2+, • the defibrillator pads are removed from the patient, or • the pads connector is disconnected from the FR2+. in advanced mode CHARGE (M3860A only) • the manual disarm button is pressed, • a shock is not delivered within 30 s after charging, • the On/Off button is pressed to turn off the FR2+, • the defibrillator pads are removed from the patient, or • the pads connector is disconnected from the FR2+.
shock delivery vector	Via adult defibrillator pads placed in the anterior-anterior (Lead II) position or via FR2 infant/child reduced-energy defibrillator pads placed in the anterior-posterior position.

ECG Analysis System

category	FR2 series
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.*
asystole	On detection of asystole, provides CPR prompt at programmed interval.

category	FR2 series
pacemaker detection	On detection of a pacemaker (in advanced mode or with M3848A ECG display cable), provides screen display of PACEMAKER DETECTED alert, and M3860A includes pacemaker artifact in ECG display. In both models, pacemaker artifact is removed from the signal for rhythm analysis.
artifact detection	If electrical "noise" (artifact) is detected which interferes with accurate rhythm analysis, analysis will be delayed until the ECG signal is clean.
analysis protocol	Depending on results of analysis, either prepares for shock delivery or provides a pause.

Display

category	FR2 series
monitored ECG lead	(M3860A only) ECG information is received from adult defibrillation pads in anterior-anterior (Lead II) position or from FR2 reduced-energy infant/child defibrillator pads in anterior-posterior position.
display range	(M3860A only) Differential: ±2 mV full scale, nominal.
screen type	High-resolution liquid crystal display (LCD) with backlight.
screen dimensions	2.8" wide x 2.3" high (70 mm x 58 mm).
sweep speed	(M3860A only) 23 mm/s nominal.
ECG display	(M3860A only) 3 second-segments displayed.
frequency response (bandwidth)	Nondiagnostic rhythm monitor 1 Hz to 20 Hz (-3 dB), nominal.
sensitivity	1.16 cm/mV, nominal.
heart rate displayed during normal sinus rhythm	(M3860A only) 30 to 300 bpm, updated each analysis period. Displayed during monitoring and advanced modes.

Data Management

category	FR2 series
capacity	M3854A data card: 88 hours of event and ECG data, or 1 hour with voice recording.
data transfer	Compact flash data card reader

Electromagnetic Conformity

Guidance and manufacturer's declaration: The HeartStart FR2+ is intended for use in the electromagnetic environment specified in the tables below. The customer or user of the HeartStart FR2+ 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 FR2 series AED uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The FR2 series 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	[E1] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the HeartStart FR2 series 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 FR2 series AED is used exceeds the applicable RF compliance level above, the HeartStart FR2 series 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 FR2 series AED is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FR2 series AED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FR2 series 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

M3863A FR2 Battery and 989803136291 TSO Certified Battery[1]

category	FR2 series
battery type	12 VDC, 4.2 Ah, lithium manganese dioxide. Disposable, recyclable, long-life primary cell.
capacity	When new, a minimum of 300 shocks or 12 hours' operating time at 77° F (25° C).
shelf life (prior to installation)	Typically, 5 years from date of manufacture when stored under standby environmental conditions in original packaging.
standby life (after installation)	Typically, 5 years when stored under standby environmental conditions (battery installed, FR2 unused).
status indicators	Good battery: flashing back hourglass on status indicator. Low battery: flashing red X on status indicator. Dead battery: solid red X on status indicator.
storage temperature	32° to 109° F (0° to 43° C).

M3848A FR2+ Rechargeable Battery

category	nominal specifications
battery type	12 VDC, 2.2 Ah, lithium ion. Rechargeable cell using the M3849A charger.
capacity	When freshly charged and used at 77° F (25° C), provides a minimum of 80 shocks (typically 100 shocks), or 3.5 hours (typically 5 hours) of ECG display time only, before recharging is indicated.
standby life (after installation)	6 months when installed fully charged in a defibrillator labeled FR2+.
status indicators	Good battery: bar graph on display screen indicating remaining power level. Low battery: flashing red **X** on the front panel of the FR2+ (When low battery indicator appears, there is still enough energy to deliver 9 shocks plus 15 minutes of ECG display time). Dead battery: solid red **X** on the front panel of the FR2+.
storage/transport temperature	32° to 109° F (0° to 43° C).

1 The conditions and tests required for TSO approval of this battery are minimum performance standards. It is the responsibility of those desiring to install this battery in a specific class of aircraft to determine that the aircraft installation conditions are within the TSO standards. Lithium battery safety concerns include the possibility of fire, venting violently, and venting of toxic gases.

M3849A Charger for M3848A FR2+ rechargeable battery

category	nominal specifications
application	For use with M3848A FR2+ rechargeable battery only.
power requirements	100 to 240 VAC, 47 to 63 Hz, 30 Watts
storage/transport temperature	32° to 122° F (0° to 50° C).
conformance testing	International: EN60335-1:1994 Class 1. North America: UL 1310 Class 2.

M3870A and DP2/DP6 HeartStart Defibrillator Pads

category	FR2 series
adult pads, cable, and connector	DP2/DP6: disposable, adhesive defibrillator pads with a nominal active surface area of 85 cm^2 each with an integrated 22 cm (48 inch), typical, cable and connector, provided in a sealed package.
infant/child pads, cable, and connector	M3870A: disposable, self-adhesive, provided in a sealed package. Active surface area: 85 cm^2 each Integrated cable and connector (incorporated attenuating electronics): 122 cm (48 inch), typical.
defibrillation pad requirements	Use only HeartStart defibrillator pads with the FR2 series AEDs. Place the pads on the patient as illustrated on each pad.

M3854A Data Card

category	nominal specifications
capacity	8 hours of event and ECG data, or 60 minutes with voice recording.

M3864A Training & Administration Pack

category	nominal specifications
battery type	12 V, 1.1 Ah, nickel metal hydride. Disposable, rechargeable cell using the M3855A charger.
capacity	Provides 4 hours of operating time at 77 °F (25 °C).
status indicators	Low battery: flashing red **X** on the front panel of the FR2+. Dead battery: solid red **X** on the front panel of the FR2+.
storage/transport temperature	50° to 104° F (10° to 40° C).

M3855A Charger for Training & Administration Pack

category	nominal specifications
application	For use with M3864A Training & Administration Pack only.
power requirements	With appropriate power cord, any AC mains power input or inverter-type power sources.
storage/transport temperature	32° to 113° F (0° to 45° C).
conformance testing	International: EN60335-1:1994 Class I North America: UL 1310 Class 2

M3873A/M3874A FR2+ ECG Module

category	nominal specifications
application	For use with the FR2+ M3860A with ECG display enabled and running version 1.5 software or higher (denoted by *FR2+* on the front panel or rear label).
length and weight	100 inches (182 cm); 1 lb. (2.2 kg).
operating temperature	32° to 122° F (0° to 50° C).
storage/transport temperature	32° to 109° F (0° to 43° C).
patient lead wire designation	M3873A (AAMI): positive lead — red negative lead — white reference lead — black M3874A (IEC): positive lead — green negative lead — red reference lead — yellow
typical (lead II) connection	Lead II vectors: positive — left leg negative — right arm reference — left arm Other limb vectors can be obtained by different electrode positions.
battery type	3 V, 1 Ah, poly-carbonmonofluoride lithium (LiCFx). Non-replaceable disposable primary cell.
service life	Typically, 5 years.
performance with FR2+ defibrillator	Meets environmental specifications cited for FR2+ Defibrillator on page B-1 through B-2.

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.

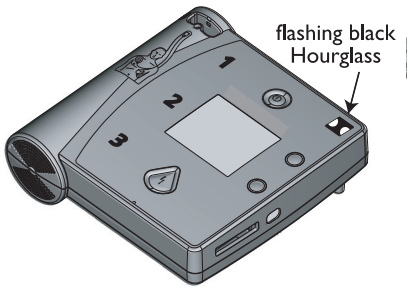
product	information
defibrillator	The defibrillator contains electronic components. Do not dispose of it as unsorted municipal waste. Collect such electronic waste separately and dispose of it at an appropriate recycling facility according to your country's or local regulations.
battery	The battery cells contain chemicals. The chemistry used in each battery is identified by a symbol on the label; symbols are defined in the defibrillator Owner's Manual. 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

Troubleshooting the Heartstart FR2+ Defibrillator

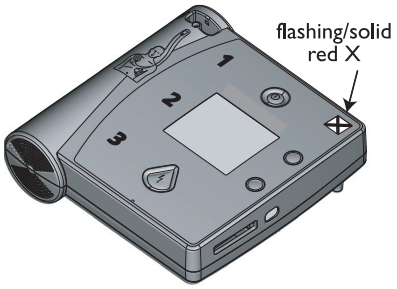
Flashing Hourglass

A flashing black hourglass in the status indicator window on the upper right of the HeartStart FR2+ Defibrillator means that it has passed its last self-test and is ready for use.



Flashing or Solid Red X

If the defibrillator detects an issue, the status indictor will display either a flashing red X or a solid red X, and the defibrillator will start chirping. (Note, however, that if the unit stops functioning or the battery is completely depleted, it may not be able to chirp.)



Possible Causes

- The battery needs to be replaced.
- The FR2+ may have been turned off with the pads left plugged into the device.
- The FR2+ has detected an error during a selftest and cannot successfully complete the test.
- The Training & Administration Pack has been left in the FR2+ for more than one hour.
- The FR2+ has been stored outside the recommended temperature range of 32° F to 122° F (0° C to 50° C).
- The FR2+ may have been physically damaged.

Troubleshooting Steps

Perform a battery insertion test: remove the battery for at least five seconds, then reinstall it to automatically run a comprehensive selftest of the defibrillator.

Make sure to follow the prompts during the interactive part of the test (button presses), in order to verify button operation and screen functionality. If the test fails, perform the test again with a new battery. If the defibrillator

continues to fail the test, do not use the defibrillator. Contact Philips Medical Systems for technical support.

The Battery Insertion Test (BIT) is the main troubleshooting tool used with HeartStart AEDs. If the device passes the BIT and displays a flashing black hourglass on the status indicator, the device is within its specifications and is ready for use.

The BIT consists of two parts; the first runs automatically and the second involves user interaction. The automatic part takes about 80 seconds to complete, during which time the internal circuits are being tested, various sounds are made, and the display and lights are turned on and off. Also during this time, various messages can appear on the display. At the end of this portion of the test, if the unit passed, the display will read "SELFTEST PASSED" prior to the interactive portion of the BIT, and the status indicator will show a flashing black hourglass. If the unit does not pass the test, the display will read, "SELFTEST FAILED," and an error code will be displayed consisting of a single letter followed by 8 numbers; e.g., C0004 0000.

The interactive portion of the self-test is intended to test features that cannot be tested automatically. This portion of the test takes about 60 seconds, during which the user is asked to push various buttons, verify that the certain sounds are generated, and that the display and the lights are working properly.

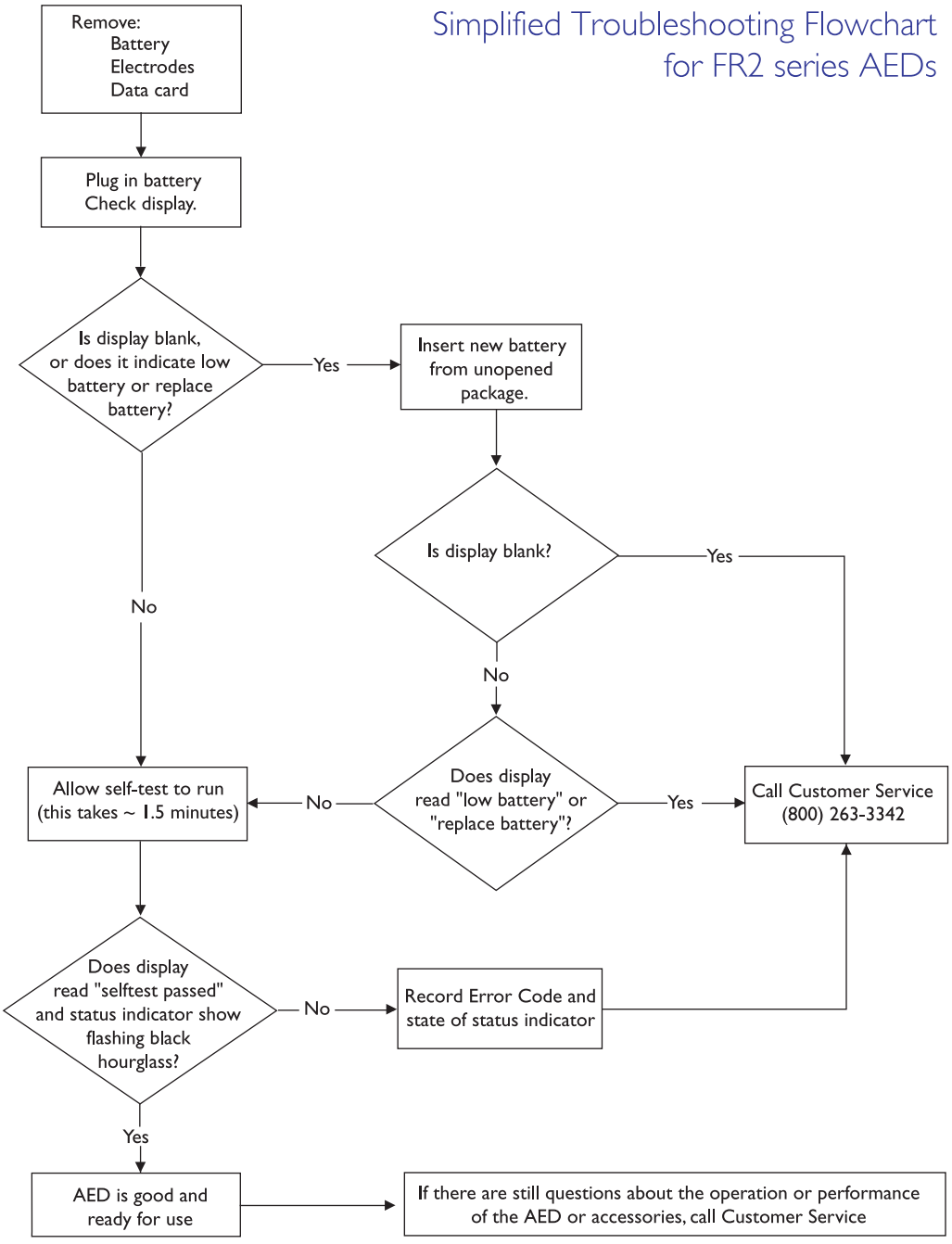
The troubleshooting flowchart on the following page is intended to verify whether the AED is in working order or if it needs to be replaced. If, after completing the battery insertion test, the unit displays "SELFTEST PASSED" and there is a flashing black hourglass, you can be confident that the AED meets its specifications and is ready to be used on a patient. If the AED does not display a flashing hourglass, call Philips Customer Service at 800-263-3342 to arrange for a replacement unit. If the AED passes the BIT and you still have questions about the AED or the accessories, you may still call Philips Customer Service.

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: HeartStart_data@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.

Simplified Troubleshooting Flowchart for FR2 series AEDs



Verification of Energy Delivery

The FR2 series defibrillators do 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:
   a. Set RANGE to Hi
   b. Set POWER to On
   c. Press ENERGY (F1)
   d. Press VFIB (F3)
5. Press the AED On/Off button.
6. Wait for the AED to recommend a shock and when prompted, press the orange button.
7. Verify that the Impulse 3000 indicates 130-170 Joules.
8. 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:
   a. Set POWER to On
   b. Press DEFIB (F1)
   c. Press NO (F1)
   d. Press ENERGY (F1)
   e. Press HIGH (F2)
   f. 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 Medical Systems Customer Service at 1-800-263-3342 for assistance.

Notes

C Pads, Batteries, and Display

The supplemental information in this appendix is drawn from Application and Technical Notes relating to the FR2 series defibrillators.

Defibrillator Pads for the HeartStart FR2 Series AEDs

Each FR2 series AED is shipped with two sets of adult pads. These pads have an expiration date of two years from the date of manufacture and they should be checked and replaced as needed. The recommended adult defibrillator pads for the FR2 series AEDs are DP2 (2-packs) or DP6 (6-packs). These pads are labeled with instructions for lay rescuers, which makes the AED easier to use by people who are not highly trained medical personnel.

The FR2 series AED uses special pediatric pads (M3870A) for treating children under 55 pounds (25 kg) or less than 8 years old. These pads contain special circuitry to reduce the amount of energy delivered, so that the patient receives 50 J instead of the adult dose of 150 J. These pads only connect to the FR2 series devices.

Conversely, the pediatric pads available for the HeartStart manual defibrillators do not work on HeartStart AEDs. Because the FR2 series AEDs do not allow user-selected delivered energy levels, energy attenuation takes place in the pads themselves in order to ensure that a pediatric patient receives the appropriate dose. A different connector is used on the FR2 series infant/child pads to prevent their use with the manual defibrillators.

Users cannot standardize on any one pediatric defibrillator pad. Manual defibrillators must use the HeartStart manual pediatric pads (M3717A). The HeartStart FR2 series devices must use the FR2 reduced-energy infant/child pads (M3870A). There are no pediatric pads available for the ForeRunner AED.

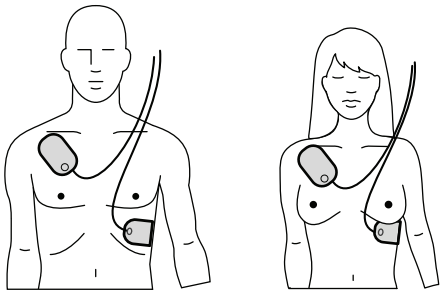
Defibrillator Pads Placement with FR2 Series AEDs

Proper pads placement for adult defibrillation with the HeartStart FR2 series defibrillator is specified with an illustration on the left side of the front of the FR2,[1] on the pads themselves, and with a diagram in the *Instructions for Use*. The diagrams on the back of each pad indicate a specific location for the pad.

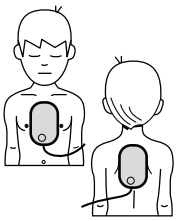
1 The icons on the front panel of the FR2 series AED show pads placement for patients over 55 pounds or 8 years old; the illustrations on the Infant/Child pads show pads placement on infants and children under 55 pounds or 8 years old.

The FR2 Infant/Child reduced-energy defibrillator pads have icons on the pads illustrating 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 unit is much easier to use 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 FR2 series AED s are 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. We believe the pad labeling reassures the user during an episode and speeds up pad application, which allows them to deliver the first shock as quickly as possible when needed.

Problems Associated with Pre-Attaching Pads to the FR2 Series AEDs

Background

The FR2 series AEDs have been designed to be used with defibrillator pads that must be attached to the defibrillator by a responder during an incident. This configuration allows for sealing of the pads packaging during storage and easier placement of the pads during an incident. However, in an attempt to save seconds during an incident, some users have inquired about opening the

packages and inserting the pads connector into the defibrillator for storage. These pads are not designed for pre-connection and shold not be pre-installed for two reasons: pad dry out and self-test failures. Pads used with the FR2 series AEDs should always be left in their sealed package until needed for use on a patient.

Batteries for FR2 Series AEDs

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 FR2 series AEDs contain consumer grade lithium manganese dioxide ($LiMnO_2$) cells. The M3863A battery used by the FR2 series AEDs contains twelve "2/3A" size standard camera batteries built into a custom battery pack. These same battery cells can be purchased individually at local camera stores or drugstores for use in consumer electronic devices. These batteries are designed specifically for high-volume consumer applications, where safety is of the utmost importance.

The batteries chosen for HeartStart AEDs meet Philips's 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 called PTCs 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.

Since automated external defibrillators are typically used infrequently, they need to be as maintenance free as possible. HeartStart AEDs are designed to monitor the battery and prompt the user by way of the status indicator and audio signal if it needs to be replaced.

While $LiSO_2$ batteries must be manually disabled prior to disposal, HeartStart $LiMnO_2$ batteries meet the U.S. EPA's Toxicity Characteristic Leaching Procedure and therefore may be disposed of with normal waste without a complicated recycling process. However, out of environmental considerations, Philips recommends that all batteries be recycled at an appropriate recycling center.

For those organizations that use the FR2/FR2+ more frequently and have a battery maintenance program, Philips offers a rechargeable LiION battery (M3848A) that uses the same battery technology as used in most laptop computers. The M3848A rechargeable battery is not recommended for use as a spare battery and should only be used by organizations committed to providing the resources required to operate a battery maintenance program.

Battery Usage

The M3863A battery is designed to provide a minimum of 300 shocks or 12 hours of operating life, or to last 5 years, typical, in standby mode,.

There are other activities that use small amounts of energy in the battery, and if these activities are performed frequently, they can lead to a reduction in the performance life of the FR, FR2 or HS1 series battery. A summary of these activities is outlined below:

Training

A separate, rechargeable Training/Administration Pack (battery) is used for training with the FR2 series AEDs. Note, however, that the AEDs will experience a higher number of Battery Insertion Tests with training usage.

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

Battery Insertion Tests (BIT)

Upon installation of the battery into the defibrillator, the unit will perform a BIT which will completely test the unit. A significant amount of energy is used during this test, including capacitor charges and discharges at 150 Joules. As a result, frequent removal and replacement of the battery will result in a noticeable reduction in battery life. Further, turning the unit off during a BIT will cause the unit to perform a monthly self-test in two hours (see below), which also expends battery power.

Frequent Power-ons

During the first few seconds after turning the defibrillator on, several tests are performed to ensure the AED is ready to perform properly. As a result, frequent power-ons will significantly affect battery life. Turning the unit on periodically in an effort to ensure that the defibrillator is operating properly is unnecessary as the defibrillator will test itself periodically during stand-by mode to help verify the unit is ready for operation at all times. If servicing is required, the FR2 series AEDs will notify the user through a flashing or solid 'X' in the status window and a loud chirping sound.

Troubleshooting

Anytime that a battery is suspected of being low or having problems, the first troubleshooting step should be to perform a BIT using the suspect battery, which is initiated by removing then re-inserting the battery into the unit. If the unit passes a BIT with no indications of battery problems, the unit and battery are both ready for service. Other conditions, such as keeping the unit outside the recommended storage temperature can cause failure messages similar to a low battery message. These messages will be cleared out with a successful BIT. If the unit does not pass the BIT, the BIT should be reattempted with a known good battery in order to determine if the battery is the cause of the failed BIT. If the unit again does not pass, contact Philips Customer Service. In the United States, contact Philips Medical Systems at 1-800-263-3342 for assistance.

FR2 Advanced Battery Troubleshooting

The FR2 series has several advanced features to help the user determine battery health. Each FR2 series standard battery (M3863A) contains electronics that records how much it has been used. This can be checked by inserting the battery into an FR2 series defibrillator and paging through the screens using the upper and lower blue option buttons to get to the Battery History screen (see Section 4 of the *Instructions for Use/User's Guide*). This will show the USE MINUTES and the CHARGES delivered by the battery. A charge is how many times it has been used to charge the capacitor to 150 Joules, regardless of whether the energy is used for a patient or for internal testing.

Another troubleshooting feature of the FR2 series is the Device History screen of the defibrillator. This screen can be accessed similarly to the Battery History screen. It can be used to obtain the number of USES, SHOCKS, and TESTS that have been performed by the unit. Four figures are shown for TESTS; daily, weekly, and monthly periodic self-tests, and BITs. Note that to the FR2 series, shocks and charges are not equivalent. SHOCKS references how many shocks have been delivered by the defibrillator. It is not uncommon for the number of monthly self-tests to be greater than the number of weekly self-tests. This is due to the monthly self-tests occurring during additional situations (see above).

Value of an ECG Display on FR2 Series AEDs

The ECG display on the FR2 series AEDs was not designed to meet the AAMI Standard for Cardiac Monitors, but was instead designed to provide a simple display of the ECG through Lead II. There are a number of differences, but some of the more significant ones are that the HeartStart AED:

- Displays Lead II only - cardiac monitors typically display multiple leads (Lead I, II, and III)
- Has a smaller bandwidth - AAMI standard is 0.5 Hz - 40 Hz, the HeartStart AED is 1 Hz - 20 Hz (typical of transport defibrillators)
- Has a shorter trace length - Monitors typically display greater than 4 seconds of ECG, the HeartStart AED displays 3 seconds of ECG

As stated in the manual, the LCD screen does not provide the resolution required for diagnostic and ST segment interpretation. This requires the use of a 12 lead ECG.

While HeartStart AEDs were not designed to be monitors, the displayed ECG 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 an ALS provider who is familiar with the HeartStart AED sees an organized rhythm on the screen, they may choose to leave the AED on the patient and immediately assess the ABCs (airway, breathing, circulation), provide an airway with intubation and establish an intravenous line for administering medication. During this entire 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.

Notes

D Use Environment

Defibrillation in the Presence of Oxygen

The *Instructions for Use* provided with the FR2 series AED contains a warning that there is a possibility of explosion if the device is used in the presence of flammable anesthetics or concentrated oxygen. This 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 FR2 series defibrillators are 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

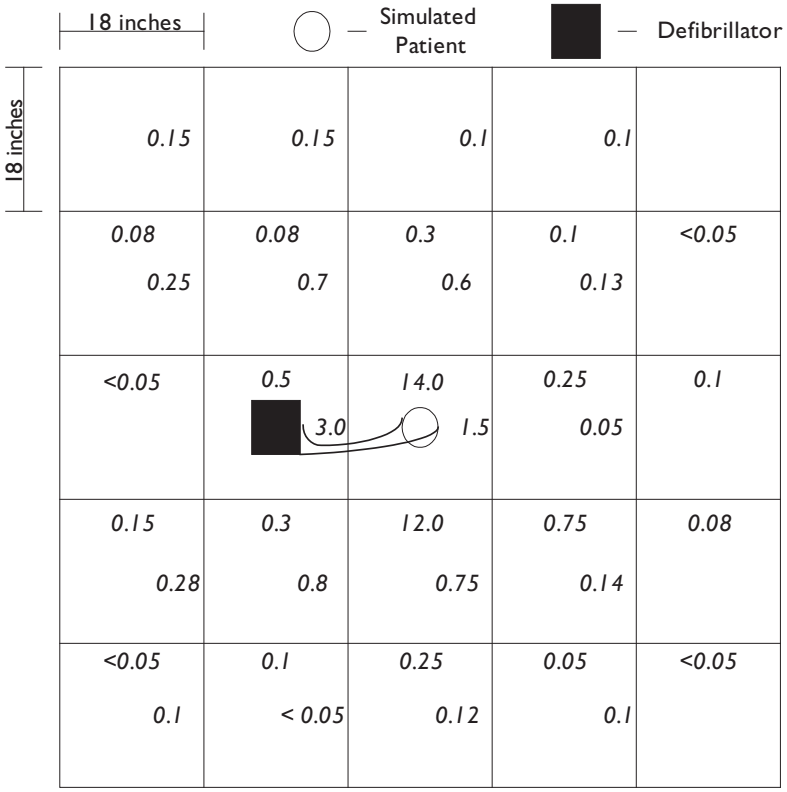
When a patient is externally defibrillated, the current that travels between the pads will always seek the path of least resistance. Some of this current will pass over the surface of the patient's skin, and if the patient is resting on an electrically insulating surface, all defibrillation energy is kept within the patient. If the user does not touch the patient during the discharge, there is no danger of them 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

Our 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

First Number	Degree of Protection	
	User Protection from Hazards	Solid Object Protection
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 FR2 series AEDs meet the specifications for IP54. The tests performed by Philips to meet this standard are outlined below.

IPX4 Testing

The defibrillator was placed in an enclosed chamber where water was sprayed on all sides of the defibrillator for 5 or 10 minutes, depending on the test methodology employed. After the designated time for the test methodology, the defibrillator was removed, inspected, and tested to ensure that the water had not accumulated enough to affect the performance or safety of the defibrillator.

IPX5 Testing

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 FR2 series defibrillators have a recommended environmental range of:

Environment	Range
Operating Temperature	32° F to 122 °F (0° C to 50° C)
Operating Humidity	0% to 95% RH (Relative Humidity)
Standby Temperature	32° F to 109° F (0° C to 43° C) - FR2 series
Standby Humidity	0% to 75% RH

These ranges are specified in the I*nstructions 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.

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 defibrillators will not perform the daily self-tests if the temperature is below 32° F (0° C) or above 122° F (50° C) for the FR, FR2, and FRx series; or below 32° F (0° C) or above 109° F (43° C) for the HS1 series. 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 and produce a flashing red 'X' in the status display to warn the user that the tests are not being performed and the unit may not be ready for use. A Battery Insertion Test (initiated by removing and re-inserting the battery) will test the unit 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 devices 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 produce 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) FR2 series 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

FR2 series AEDs 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 FR2 series will display a text message on the screen announcing that the defibrillator has been stored outside the acceptable temperature limits.

What To Do

If 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) — as noted in the *Instructions for Use*.

E Guidelines 2005

Reconfiguring the FR2/FR2+ to Meet the AHA 2005 Guidelines

Background

Currently shipping HeartStart FR2+ defibrillators have a factory default configuration that meets the American Heart Association Guidelines 2005. FR2 series defibrillators (M3840A, M3841A, M3860A, and M3861A) shipped before this change can be reconfigured by the user to adapt to the major elements of the American Heart Association Guidelines 2005. FR2 defibrillators running software version 1.5 or lower can be reconfigured to meet the pertinent new recommendations; FR2 defibrillators running software version 1.6 or later can be optimized for the Guidelines. The 1.7 software upgrade (REF: M3876A FR2 1.7) ships with default configuration settings that comply with the Guidelines 2005.

NOTE: To check which software version is used by your FR2, remove and reinstall the battery to perform the battery insertion test. The software revision (e.g., v1.3, v1.4, v1.5, v1.6, v1.7) is displayed on the screen at the end of the test.

Medical directors should consider their programs and – if the decision is made to reconfigure the defibrillator – train users to the new protocol before revising the defibrillator settings.

The following changes need to be made to the FR2 default configuration in order to comply with the Guidelines. These changes will override any previous changes.

Parameter	New Setting	Change
Shock Series	1	Changes the 3-shock sequence to a 1-shock sequence.
Resume Key	ON	Activates the Resume key to allow the user to initiate an analysis. *NOTE: The Resume key is automatically set to ON (and cannot be turned off) if the selected CPR Timer setting is > 1.0 minute.*
CPR Timer	2.0	Changes the CPR pause following a shock to 2 minutes.
NSA Action	2.0	Changes the CPR pause following a No Shock Advised decision to 2 minutes.

Parameter	New Setting	Change
CPR Prompt	SHORT	Shortens the voice prompts after a shock by eliminating the instructions to check for circulation and breathing. The longer prompts will still be given after a No Shock Advised decision, and include a circulation check. *NOTE: Short prompts are available after both Shock and No Shock Advised decisions with the M3876A FR2 1.6 software upgrade, which also includes SMART CPR and Quick Shock.*

Methods

There are two methods that you can use to reconfigure your FR2 Defibrillator.

To Reconfigure a Single FR2/FR2+ Defibrillator

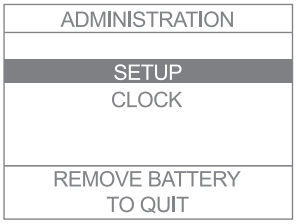
Requirements

- M3864A Training and Administration battery pack
- M3855A Training and Administration battery pack charger (needed to recharge the M3864A)

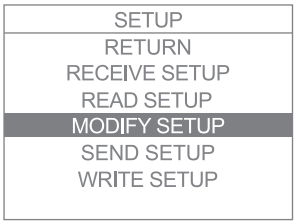
Procedure

Modify parameter settings. *In the following instructions, use the lower option button to move the highlight bar, and use the upper option button to make your selection.*

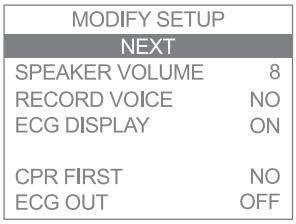
1. Remove the gray (M3863A) standard battery or blue (M3848A) rechargeable battery.
2. Insert the yellow M3864A Training & Administration Pack into the defibrillator while pressing both blue option buttons at the same time.
3. Select SETUP to bring up the SETUP screen.



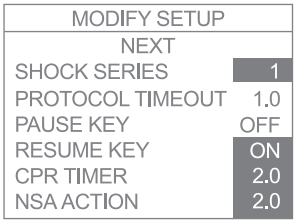
4. Select MODIFY SETUP to bring up the first MODIFY SETUP screen.



5. Select NEXT to bring up the second MODIFY SETUP screen.

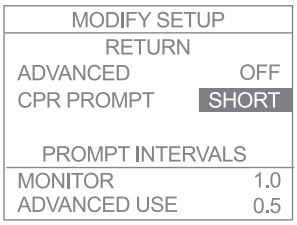


6. Make the following setting selections (highlighted in illustration):
   SHOCK SERIES — set to 1
   RESUME KEY — set to ON
   CPR TIMER — set to 2.0
   NSA ACTION — set to 2.0



7. Select NEXT to bring up the third MODIFY SETUP screen.

8. Make the following setting selection (highlighted in illustration):
   CPR PROMPT — set to SHORT



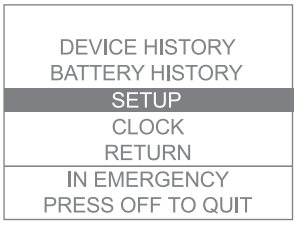
Verification

Verify the new setup selections as follows:

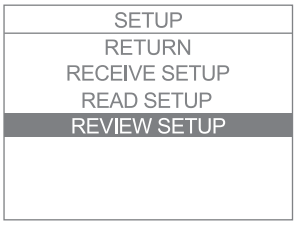
1. Remove the yellow Training & Administration battery pack.

2. Insert the gray M3863A or blue M3848A battery and select NEXT from the main menu within 10 seconds. (If the defibrillator begins a battery insertion selftest before the new setup is reviewed, remove and reinsert the battery.)

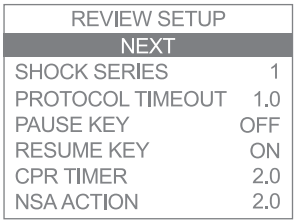
3. Select SETUP to bring up the SETUP screen.



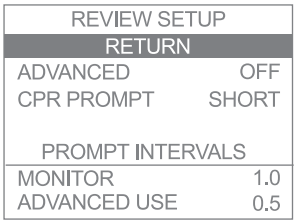
4. Select REVIEW SETUP to bring up the first REVIEW SETUP screen.



5. Select NEXT to bring up the second REVIEW SETUP screen. The screen should display the new SHOCK SERIES, RESUME KEY, CPR TIMER, and NSA ACTION setting selections.



6. Select NEXT to bring up the third REVIEW SETUP screen. The screen should display the new CPR PROMPT setting selection.
7. Remove and reinsert the battery to run a battery insertion self-test.



The defibrillator has now been reconfigured.

To Reconfigure Multiple FR2/FR2+ Defibrillators

To reconfigure multiple units, each defibrillator can be reconfigured individually, as described above, or the revised configuration information file can be transferred to a data card and then transferred to additional devices, as described in the following steps.

NOTE: Configuration file data cards created on FR2s with the new version 1.6 software will not transfer to devices with older software, or vice versa. The 1.6 software has added configuration options (e.g., SMART CPR) that are not compatible with older software revisions. The FR2's software version is displayed on the screen at the end of the battery insertion test, which is performed by removing and reinserting the battery.

Requirements

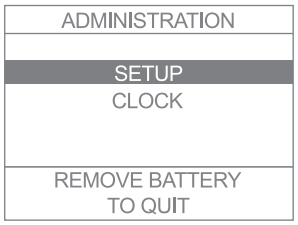
- M3854A data card
- M3864A Training and Administration battery pack
- M3855A Training and Administration battery pack charger (needed to recharge the M3864A)
- FR2 Defibrillator set to the revised parameter settings as described above for a single defibrillator.

Procedure

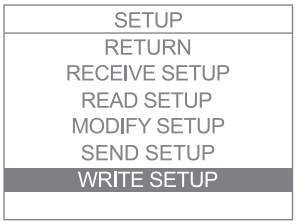
Write the parameter settings to the data card. *In the following instructions, use the lower option button to move the highlight bar, and use the upper option button to make your selection.*

1. Remove the gray (M3863A) standard battery or blue (M3848A) rechargeable battery.
2. Insert an unused data card in the defibrillator.

3. Insert the M3864A Training & Administration Pack in the defibrillator while pressing both blue option buttons at the same time.
4. Select SETUP to bring up the first SETUP screen.



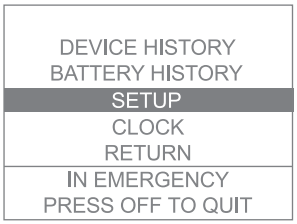
5. Select WRITE SETUP to write the SETUP setting selections to the data card.
6. Remove the data card.
7. Remove the yellow Training & Administration battery pack.
8. Insert the gray M3863A or blue M3848A battery to run a battery insertion self-test and return the unit to service.



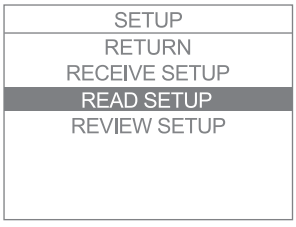
Write the parameter settings from the data card to another defibrillator.

1. Insert the data card in the next defibrillator.
2. Remove and reinsert the gray (M3863A) standard battery or blue (M3848A) rechargeable battery and select NEXT from the main menu within 10 seconds. (If the defibrillator begins a battery insertion selftest before you select NEXT, remove and reinsert the battery.)

3. Select SETUP to bring up the first SETUP screen.



4. Select READ SETUP to read the SETUP setting selections from the data card.



The defibrillator has now been reconfigured.

Verification

Verify the new setup selections as described for a single defibrillator, above. Remove the data card and repeat the procedure for reading setup to all defibrillators to be updated.

If you require additional assistance, please contact Philips Medical Systems at 1-800-263-3342 or your local Philips representative.

Reconfiguring the Trainer 2 to Meet the AHA 2005 Guidelines

Background

The HeartStart AED Trainer 2 uses scenarios simulating use of the HeartStart FR2/FR2+ defibrillator to train medical professionals and lay responders in the use of the HeartStart FR2/FR2+ defibrillator. Where FR2/FR2+ defibrillators have been reconfigured to adapt to the major elements of the American Heart Association Guidelines 2005, the Medical Director may also want to reconfigure the HeartStart Trainer 2 accordingly.

The following changes need to be made to the AED Trainer 2 default configuration in order to comply with the Guidelines. These changes will override any previous changes.

Parameter	New Setting	Change
Shock Series	1	Changes the 3-shock sequence to a 1-shock sequence.
CPR Timer	2.0	Changes the CPR pause following a shock to 2 minutes.
CPR Prompt	SHORT	Shortens the voice prompts after a shock by eliminating the instructions to check for circulation and breathing.
NSA Action	2.0	Changes the CPR pause following a No Shock Advised decision to 2 minutes.

Method

The procedure described below will override any previous changes to the parameter settings of the AED Trainer 2.

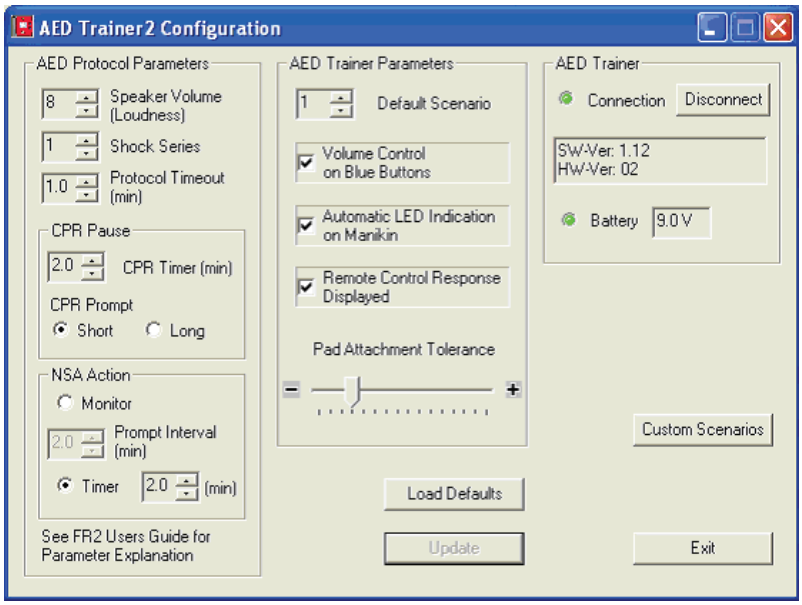
Requirements

- M3754A Programming Kit for AED Trainer 2 (includes PC cable and CD with software)
- Personal computer or laptop with a COM port.

Procedure

1. Turn on your PC and install the AED Trainer 2 Programming CD into the CD-ROM drive. The CONFIGURATION program from the CD will be automatically installed on your PC.
2. Plug one end of the PC cable provided into the COM port on your PC or laptop.
   NOTE: If you are using a laptop, it is recommended that you remove the laptop from its docking station. Often, the COM port on the docking station will not work correctly for this process.
3. Turn on your AED Trainer 2.

4. Plug the other end of the PC cable provided into the COM port on the back of your AED Trainer 2.
5. On your PC, go to the Start menu and launch the CONFIGURATION program.
6. Click CONNECT. The PC will display the current settings of your Trainer 2.



Configuration screen showing parameter settings updated for Guidelines 2005

7. Select the following parameter settings using the menus in the AED Trainer 2 Configuration window:
   - SHOCK SERIES — 1
   - CPR TIMER — 2.0
   - CPR PROMPT — SHORT
   - NSA ACTION — 2.0
8. Click UPDATE.
9. An AED Trainer Updated window will be displayed to verify successful reconfiguration of the AED Trainer 2.
10. Click OK. The AED Trainer 2 has now been reconfigured for Guidelines 2005.

Verification screen

Notes

F 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 other manufacturers may 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, defibrillation models developed for animal studies must be proven in out-of-hospital cardiac arrest 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."
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.

Defibrillation Waveform -- Clinical Studies	Excerpts/Conclusions
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."
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."

Defibrillation Waveform -- Clinical Studies	Excerpts/Conclusions
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.
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."
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. *Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*. December, 2005;IV:37.	In reference to Biphasic Waveform Defibrillators: "Researchers have collected data from both out-of-hospital and in-hospital studies (electrophsyiologic studies and implantable cardioverter-defibrillator [ICD] testing and evaluation). Overall this research indicates that lower-energy biphasic waveform shocks have equivalent or higher success for termination of VF than either damped sinusoidal or truncated exponential monophasic waveform shocks delivering escalating energy (200 J, 300 J, 360 J) with successive shocks."
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 electromagnetic 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
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.

Defibrillation and CPR	Conclusions
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.
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.]

Ease of Use and User-Interface Studies	Excerpts/Conclusions
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.

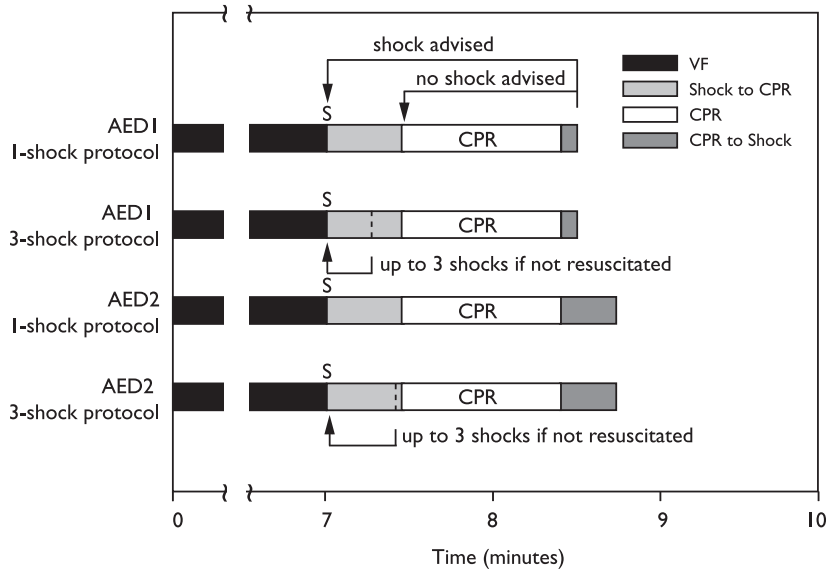
Cardiac arrest was induced in adult male pigs randomized to each of four groups by AED regimen and defibrillation protocol: low-energy, single-shock; low-energy, up to three shocks; high energy, single shock; and high energy, up to three shocks. After seven minutes of untreated ventricular fibrillation (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 FR2 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	sensitivity	specificity	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 FR2 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.

Notes

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