POWER TO SAVE A LIFE

HEARTSTART®
DEFIBRILLATORS

HEARTSTART
AUTOMATED EXTERNAL DEFIBRILLATORS

TECHNICAL REFERENCE MANUAL

Edition 3

PHILIPS

Introductory Note

In 1992, Heartstream, Inc. was founded with the mission to develop a small, low-cost, rugged, reliable, safe, easy-to-use, and maintenance-free automated external defibrillator (AED) that could be successfully used by a layperson responding to sudden cardiac arrest. 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 the 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.

Heartstream became part of Philips Medical Systems in 2001 when Philips purchased the entire Medical Group from Agilent Technologies. In 2002, Philips re-branded all of their defibrillators as HeartStart Defibrillators. In the same year, Philips introduced a new family of defibrillators, including the HeartStart Home and HeartStart OnSite AEDs.

This manual is intended to provide technical and product information that generally applies to the following AEDs:

ForeRunner and FR AEDs:

Heartstream ForeRunner	Laerdal Heartstart FR

FR2 series AEDs:

Agilent Technologies FR2	Laerdal Heartstart FR2
Philips HeartStart FR2+	Laerdal Heartstart FR2+

HS1 family of AEDs:

Philips HeartStart OnSite	Laerdal HeartStart
Philips HeartStart Home	

To help simplify the information presented, the HeartStart FR2 is used as an example in many parts of this manual. Where the discussion involves features related to a specific product, it is so noted.

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1 HeartStart Automated External Defibrillators

Each year in the United States alone, approximately 250,000 people suffer sudden cardiac arrest (SCA). 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, the chances of survival decrease by about 10%.

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 a defibrillator to be used by the first people (typically lay persons) responding to an emergency. 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 HeartStart AEDs

The HeartStart AEDs are designed specifically to be used by the first people responding to an emergency. It is reliable, easy to use, and virtually maintenance free. The design allows HeartStart AEDs to be used by people with no medical training in places where defibrillators have not traditionally been used. In order to accomplish this, consideration was given to the fact that an AED might not be used very often, may be subjected to harsh environments, and probably would not have personnel available to perform regular maintenance.

The HeartStart AED was not designed to replace the manual defibrillators used by more highly trained individuals. Instead, it was intended to complement the efforts of medical personnel by allowing the initial shock to be delivered by the first person to arrive at the scene. Some models of HeartStart 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 lay rescuer to more highly trained medical personnel.

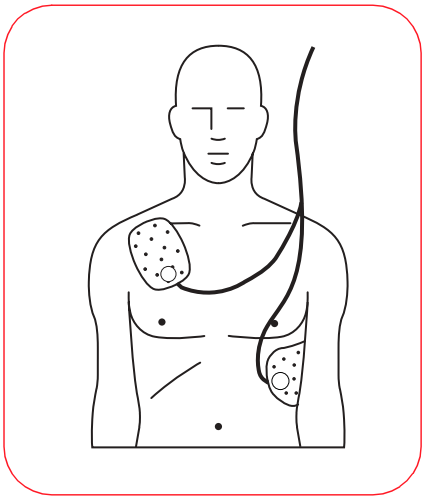
Design Features of HeartStart AEDs

Reliability and Safety

- **Fail-Safe Design** - The HeartStart AED is intended to detect a shockable rhythm and deliver a shock if needed. It will not allow a shock if one is not required.
- **Rugged Mechanical Design** - The HeartStart AED is built with high-impact plastics, has few openings, and incorporates 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 HeartStart AED performs a daily self-test to help ensure it is ready to use when needed. An active status indicator demonstrates at a glance that the unit is working and ready to use.
- **Environmental Parameters** - Extensive environmental tests were conducted to prove the HeartStart AED's reliability and ability to operate in conditions relevant to expected use.
- **Non-Rechargeable Lithium Battery** - The HeartStart AED battery pack was designed for use in an emergency environment and is therefore 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 HeartStart AED 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 and may be disposed of with normal waste.

Ease of Use

- **Small and Light** - The biphasic waveform technology used in the HeartStart AEDs have allowed them to be small and light. They can easily be carried and operated by one person.
- **Self-Contained** - The carry case has room for extra defibrillation pads and an extra battery. When stored in the carrying case, the AED has everything necessary for a person to respond to an event of SCA.
- **Voice Prompts** - The HeartStart AED provides audible prompts that guide the user through the process of using the device. The prompts reinforce the messages that appear on the AED screen (FR2 series models) 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 indicator light next to the pads connector port on the FR2 series AED draws the user's attention to where the pads connector should be plugged in. The HS1 family of AEDs uses a pads cartridge that is connected as soon as it is installed in the AED. The illuminated Shock button identifies the button to be pushed to deliver a shock; the Shock button only flashes when the unit has charged for a shock and directs the user to press the orange shock button.
- **Clear Labeling and Graphics** - The HeartStart AED is 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. The Quick Reference Card mounted inside the carrying case reinforces these instructions. The pad placement icon on the FR2 series AED 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 HeartStart 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** (on the FR2+) - The text screen displays message prompts to remind the user what steps to follow during an incident. On some HeartStart AED models, the screen also displays the victim's ECG signal. The ECG helps ALS providers when they arrive on the scene, by

enabling them to rapidly assess the patient's heart rhythm to prioritize their initial care of the patient.

- **Proven Analysis System** - The rhythm analysis system is the decision-maker inside the AED that 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 only advise a shock when it is appropriate treatment for the patient.
- **Artifact Detection System** - The AED's artifact detection system indicates if the ECG has been corrupted by some forms 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 the AED from making a shock decision, the AED compensates by filtering 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 HeartStart AED's pads detection system helps ensure good defibrillation pad contact by providing a voice prompt to the user if the pads are not making proper contact with the patient's skin.

No Maintenance

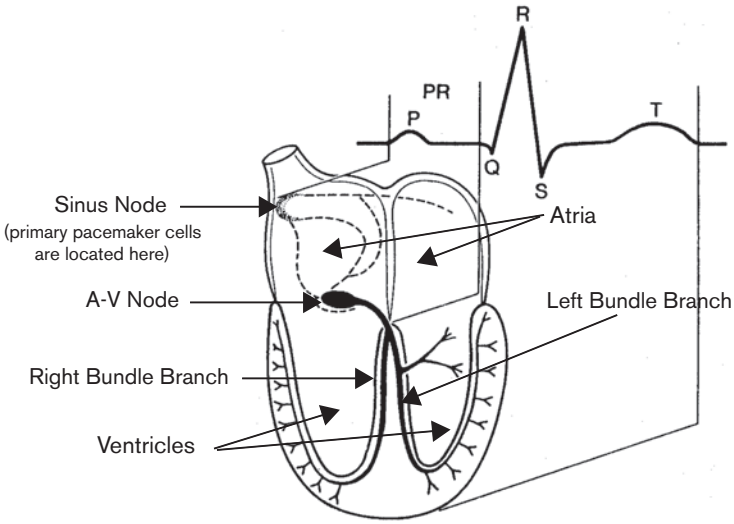
Unlike manual defibrillators (used in a hospital or by ALS providers) automated external defibrillators may be used infrequently, possibly less than once a year. However, they must be ready to use when needed.

- **Automatic Daily/Weekly/Monthly Self-tests** - There is no need for calibration, energy verification, or manual testing with the HeartStart AED. Calibration and energy verification are automatically performed once a month as part of the AED's self-test routine.
- **Active Status Indicator** - The HeartStart AED's status indicator shows whether or not the AED has passed its last self-test. The FR2+ is ready to use when the indicator is a flashing black hourglass. If the status indicator displays a flashing red X accompanied by an audible beep, this means the AED needs attention. A solid red X means that the AED cannot be used. For the HS1, a flashing green light indicates that it is ready to use.
- **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 battery needs to be replaced.

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.



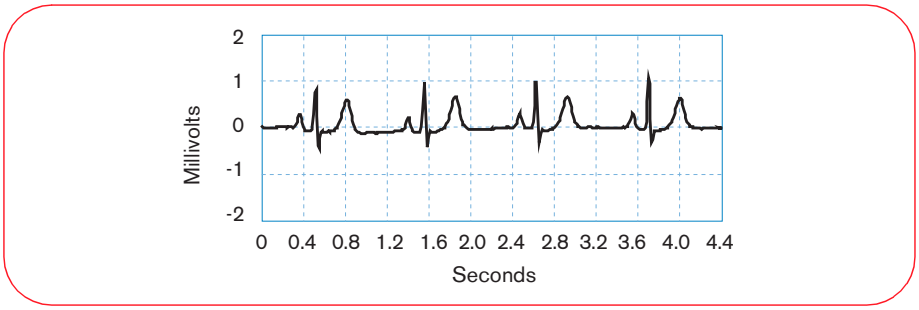
Relation of an ECG to the
Anatomy of the Cardiac Conduction System

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



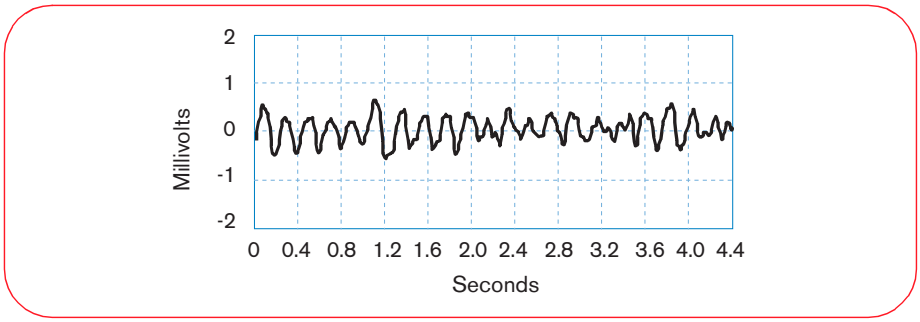
Sudden cardiac arrest (SCA) occurs when the heart stops beating in an organized manner and is unable to pump blood throughout the body. A person stricken with SCA will lose consciousness and stop breathing within a matter of seconds. SCA is a disorder of the heart's electrical conduction pathway that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

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.

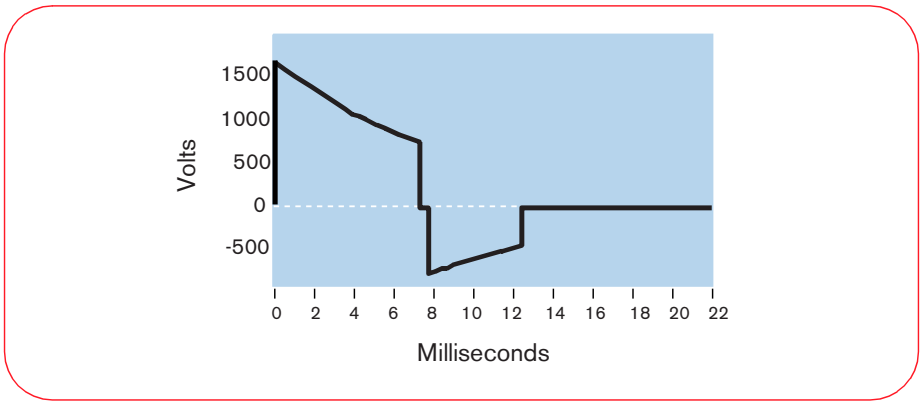
In the case of the biphasic waveforms shown in the following pages, energy (**E**) is the power (**P**) delivered over a specified time (**t**), or **E = P x t**.

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 $E = I^2R \times t$

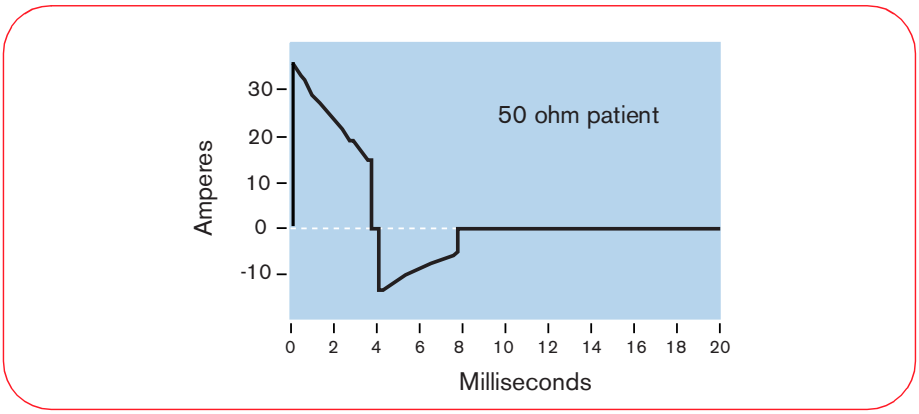
* Voltage is measured in volts, current is measured in amperes (amps), and impedance is measured in ohms. Large amounts of electrical energy are measured in kilowatt-hours, as seen on your electric bill. Small amounts can be measured in joules (J), which are watt-seconds.

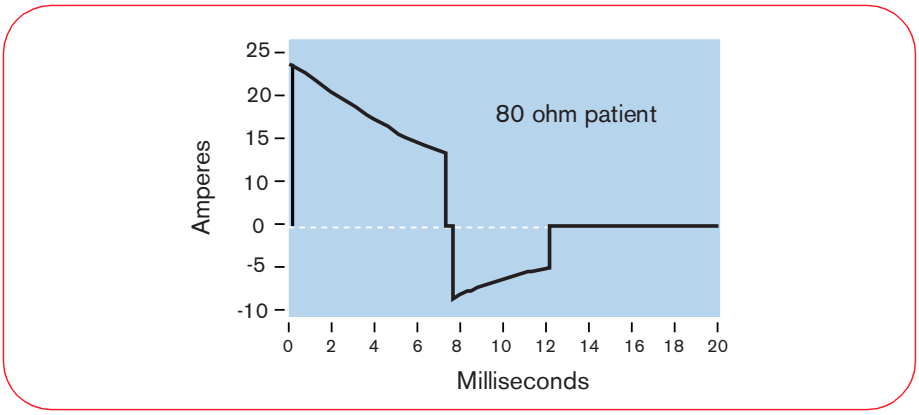
In determining how effective the energy is at converting a heart in fibrillation, how the energy is delivered -- or the shape of the waveform (the value of the voltage over time) -- is actually more important than the amount of energy delivered.

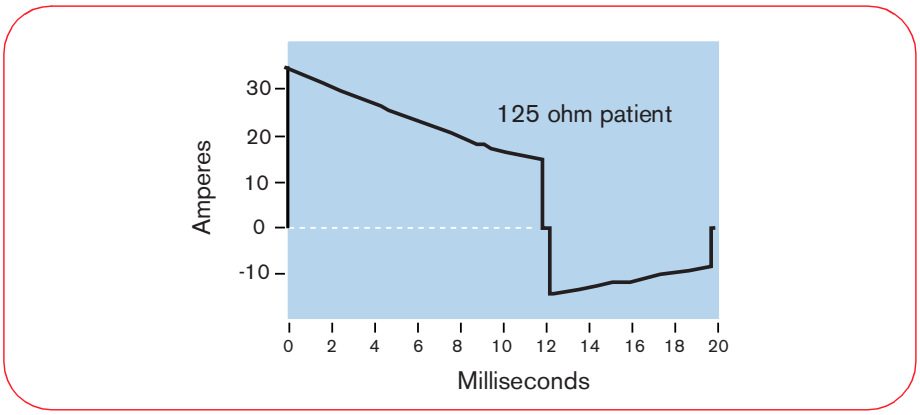
For the SMART Biphasic waveform, the design strategy involved starting with a set peak voltage stored on the capacitor that will decay exponentially as current is delivered to the patient. The SMART Biphasic waveform shown here is displayed with the voltage plotted versus time, for a patient with an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



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 three graphs shown here 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 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.

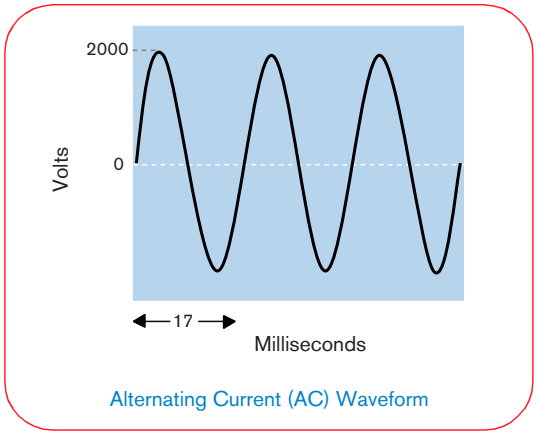
Notes

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.

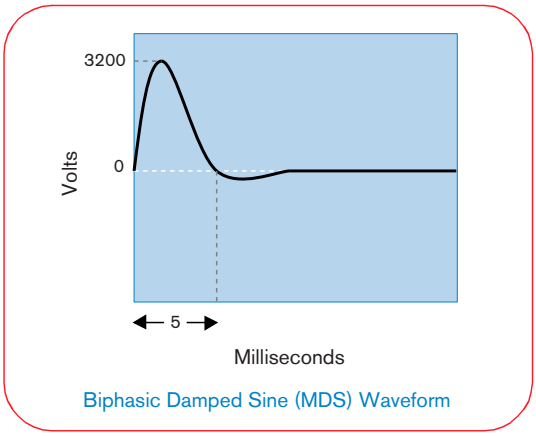


Alternating Current (AC) Waveform

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.

During the last 30 years, 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.

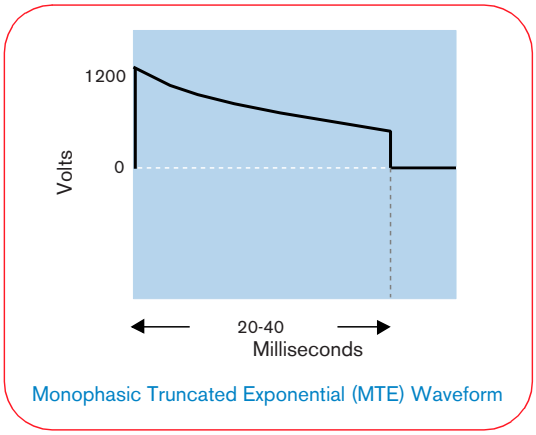


Biphasic Damped Sine (MDS) Waveform

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]

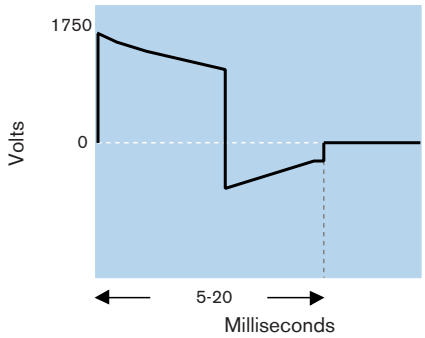


Monophasic Truncated Exponential (MTE) Waveform

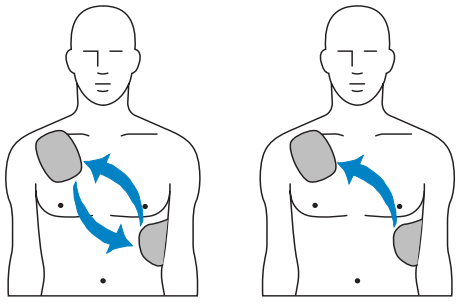
Despite the phenomenal advances in the medical and electronics fields during the last half of the 20th century, the waveform technology used for external defibrillation remained the same until just recently. In 1992, research scientists and engineers at Heartstream (now part of Philips Medical Systems) 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.

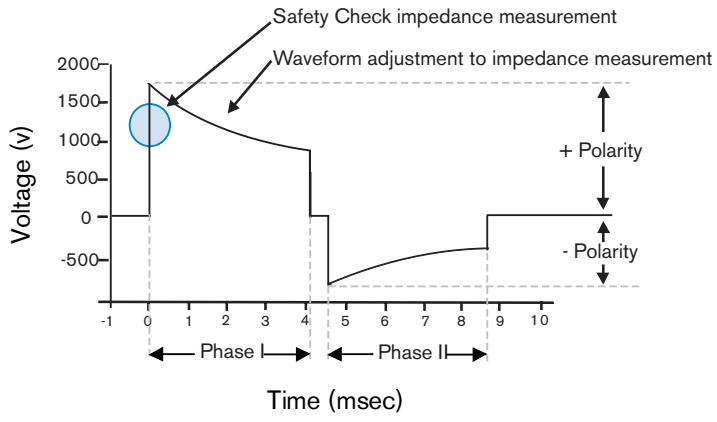
3. Lower energy is better for the patient because it reduces post-shock dysfunction. While this is not a new idea, it has become increasingly clear as more studies have been published.

The characteristics for the monophasic damped sine and monophasic truncated exponential waveforms are specified in the AAMI standard DF2-1989; 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. HeartStart was the first company to develop a biphasic waveform for use in AEDs.



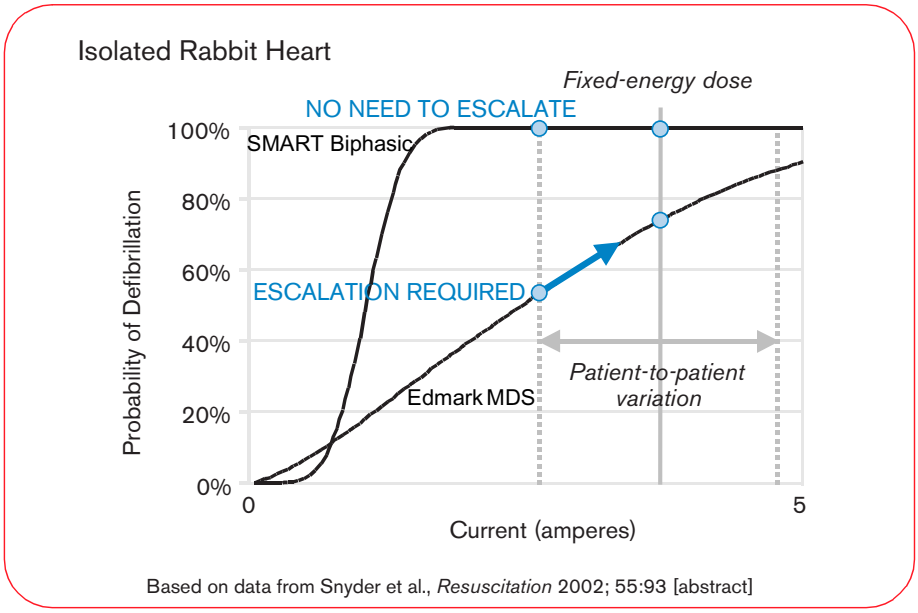
SMART Biphasic Waveform

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,[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 HeartStart 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 five years, 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 18 peer-reviewed manuscripts to prove the efficacy and safety of the SMART Biphasic waveform. Ten 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] 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

	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 139 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]
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]
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. SMART Biphasic defibrillated at higher rates than MTE and MDS, 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]

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. Consequently, 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] 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 just to satisfy the current AHA recommendation.

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

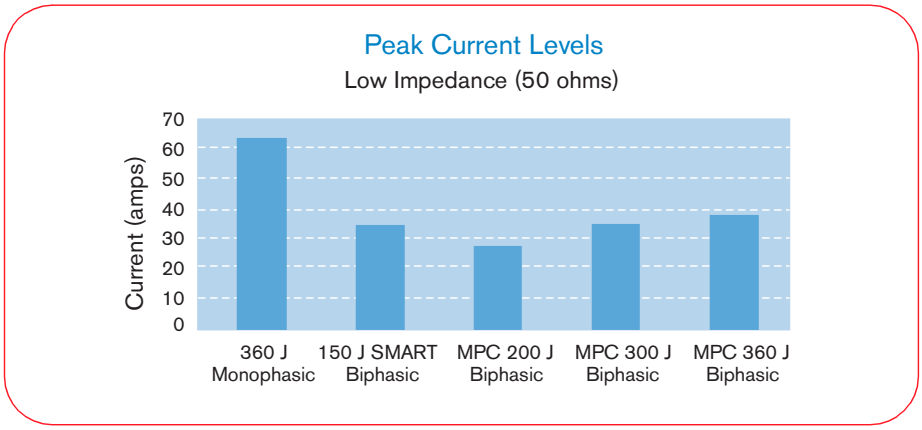
The way the energy is delivered makes a significant difference in the efficacy of the waveform. Electric current has been demonstrated to be the variable most highly correlated with defibrillation efficacy. The SMART Biphasic waveform uses a 100 μF capacitor to store the energy inside the

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:

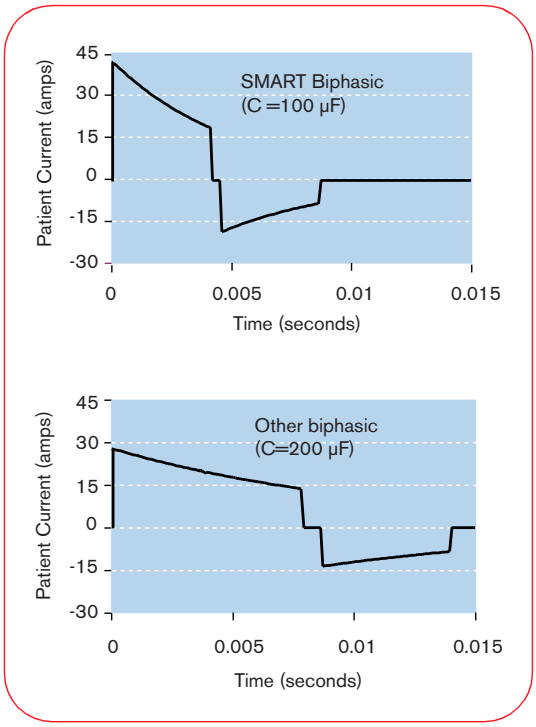
$$E = \frac{1}{2} C V^2$$

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

$$V = I R$$



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 2000,"[5] the AHA states, "Energy levels vary with the type of device and type of waveform used." (I-90) The SMART Biphasic waveform has been optimized for ventricular defibrillation efficacy at 150 J. Referring to studies involving the SMART Biphasic waveform, it states, "This research indicates that repetitive lower-energy biphasic waveform shocks (repeated shocks at < 200 J) have equivalent or higher success for eventual termination of VF than defibrillators that increase the current (200, 300, 360 J) with successive shocks (escalating)." (I-90)

All HeartStart AEDs use the 150 J SMART Biphasic waveform. Two products, the HeartStart XL and XLT, provide an AED mode as well as manual defibrillation, synchronized cardioversion, electrocardiogram monitoring,

SpO_2 monitoring, and non-invasive pacing. Selectable energy settings (from 5 to 200 J for the XLT or 2 to 200 J for the XL) are available in the XL and XLT 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 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.

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.

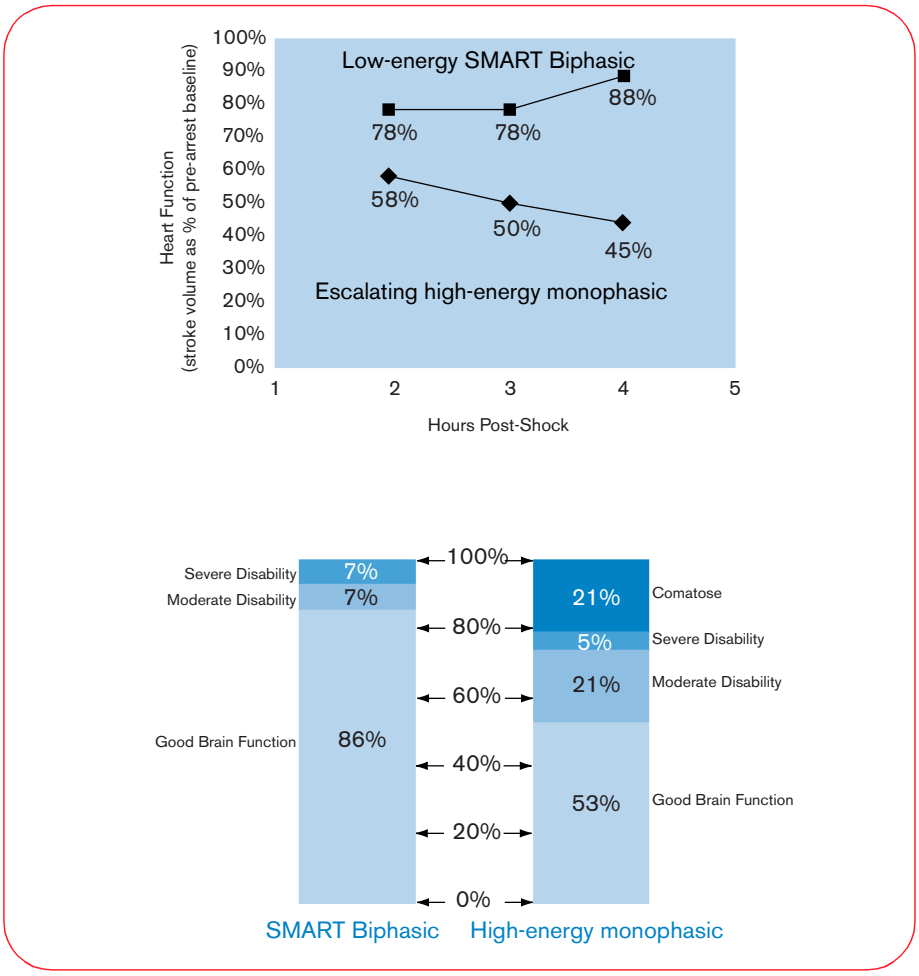
Inaccurate Electrode Pad Placement

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 XLT 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 intended to direct the user's attention to the pads with statements like “Apply Pads,” “Press Pads Firmly,” or “Poor Pads Contact” to correct the situation.

Artifact Detection

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.

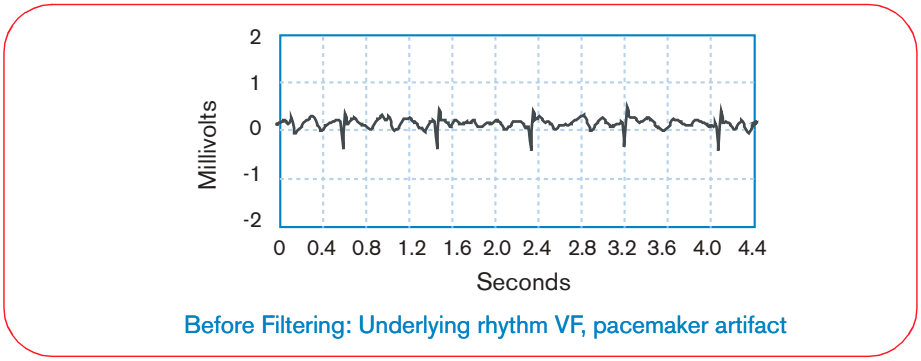
Artifact can be caused in a variety of ways, including CPR, agonal breathing, transportation, patient handling, and the presence of a pacemaker in the patient. The action taken depends on how the artifact looks in relation to the ECG signal.

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.

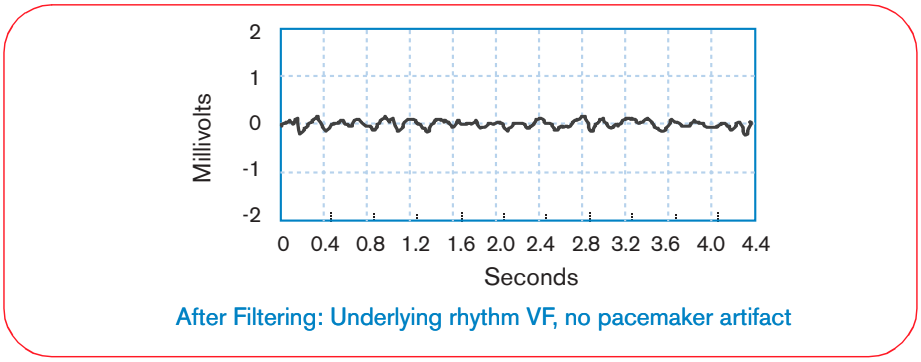
If the amplitude of the underlying ECG signal is small compared to an artifact signal, then the HeartStart AED will respond by giving voice prompts that tell the user “Do not touch the patient,” “Analyzing interrupted,” or “Patient and device must remain still.” In this situation, the defibrillator can 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.

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.

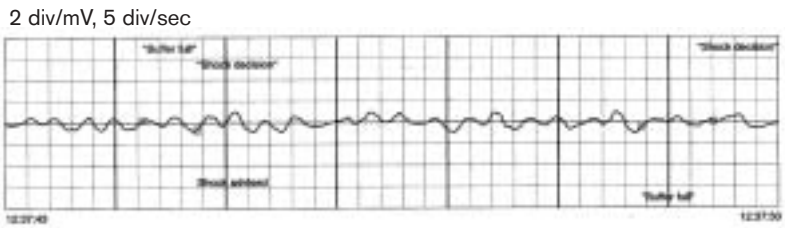


Before Filtering: Underlying rhythm VF, pacemaker artifact



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. On the following page 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

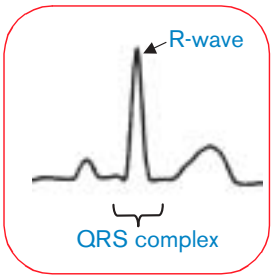
Delivering a shock to a patient in asystole will not return the heart to a normal rhythm and may actually prevent more appropriate therapies from being successful.

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 SMART Analysis system algorithm simultaneously looks at four key indicators to determine whether a rhythm is shockable or non-shockable. These four indicators are rate, conduction, stability and amplitude.

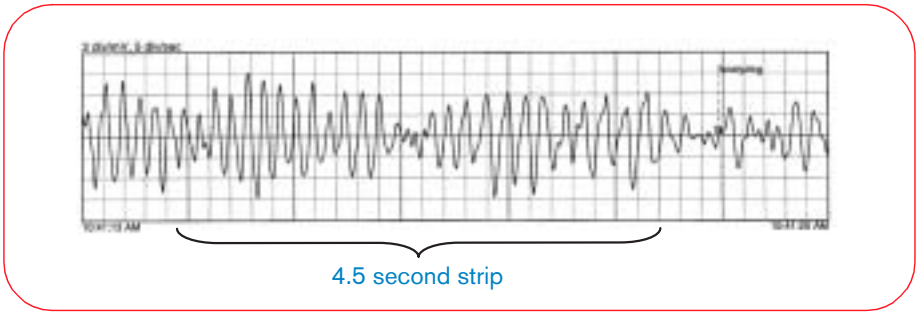
- Rate is determined by how many times the heart beats per minute (bpm). A healthy heart beats 60-100 bpm. Some normal rhythms can be very fast. Therefore, it is important to have additional indicators in the analysis system of an AED.
- Conduction is determined by examining the “R” wave of the QRS complex. A healthy “R” wave appears as a narrow spike and indicates that



electrical waves are flowing through the heart properly. A wide, rounded "R" wave is indicative of an unhealthy heart.

- Stability is the repeatability of the QRS complexes. A healthy heart will have repeatable, stable QRS complexes. An unhealthy heart will have chaotic, unstable complexes.
- 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.



The AED must identify multiple ECG strips as shockable before it will allow the device to charge. 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.

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. AEDs are designed to be used by lay rescuers, whereas manual defibrillators are designed to be used by trained medical personnel. The main difference is that the algorithm in an AED should try to differentiate between ventricular tachycardia that has a pulse and one without. The consequence of this is that the HeartStart AEDs are more conservative in shocking intermediate rhythms such as fine VF and VT that don't meet all criteria for inclusion in the shockable VT rhythm category.

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.[2] 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.

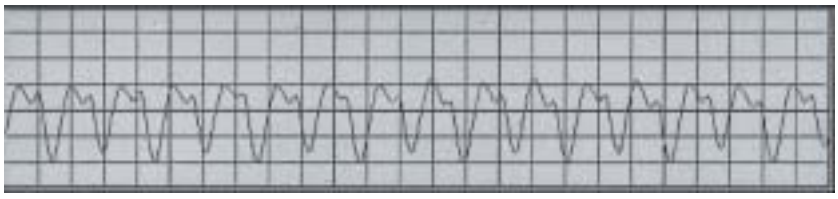
For rhythms that have poorer morphological stability such as polymorphic VT and VF, the rate threshold varies in a similar manner described above. As morphological stability degrades, the rate threshold will be progressively reduced, approaching a minimum rate threshold of about 135 bpm.

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

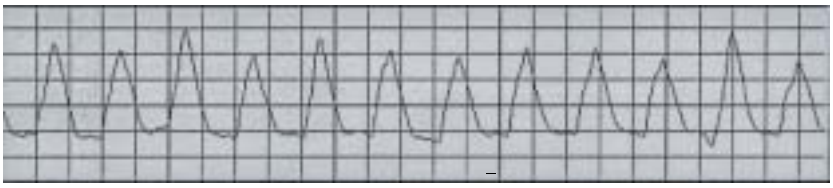
2 Kerber et al, *Circulation*, 1997;95:1677-1682

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.

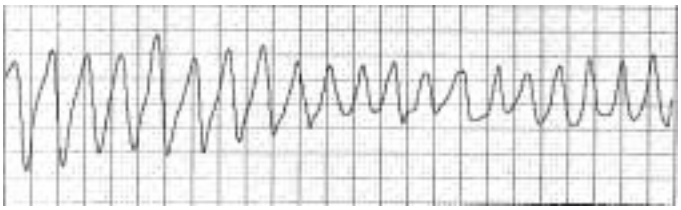


Rate ~ 192 bpm No Shock Advised

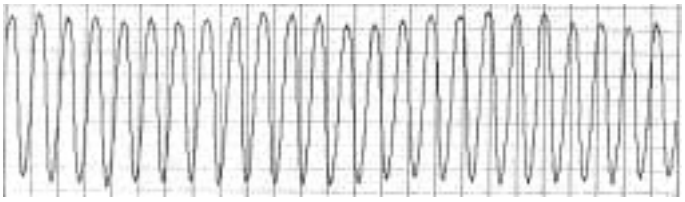


Rate ~ 144 bpm No Shock Advised

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



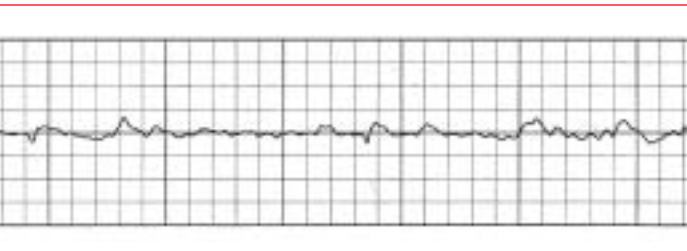
Rate ~ 240 bpm Shock Advised



Rate ~ 288 bpm Shock Advised

In the back of the HeartStart AED *Instructions for Use* manual, the statement is made, “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/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. CPR tends to oxygenate the myocardium and increase the electrical activity of the heart, making it more susceptible to defibrillation.



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.

ECG Analysis Performance

rhythm class	HeartStart AED validation results[a] meets AHA recommendations[b] for adult defibrillation				
	AAMI DEF39 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 ForeRunner AED 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 by an engineer 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 FR2 Patient 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]

References

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.

5 Self-Tests

HeartStart 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 ready to use.

Battery Insertion Test

When a user installs a battery in a HeartStart AED, the AED runs a complete self-test, called a Battery Insertion Test (BIT), which ensures that the AED is ready for use. The BIT verifies that the defibrillator circuitry is fully operational, the device is properly calibrated, and that the AED is operating within its performance specifications.

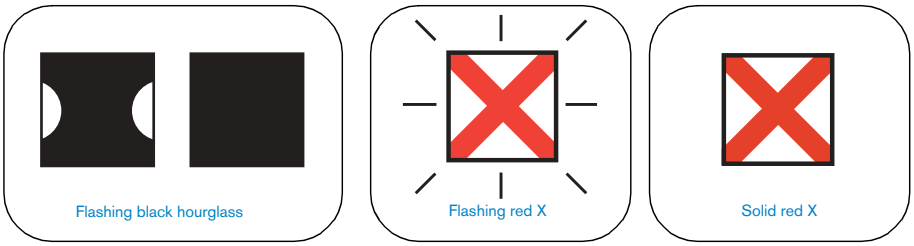
It is recommended that the full BIT (including the interactive portion at the end) be run only under the following conditions:

- When the HeartStart AED is first put into service and following each 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.

The BIT should not be performed on a regular basis since this is unnecessary and shortens the life of the battery. The HeartStart AED will automatically perform periodic self-tests every 24 hours to ensure the device remains ready for use. Therefore, the BIT only needs to be run when the battery is first inserted in the AED or after the AED has been used.

ForeRunner and FR2 Series AEDs

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



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)

HeartStart HS1 Family of AEDs

The HS1 family has a green Ready light that serves as its status indicator.

BEHAVIOR	MEANING
green Ready light blinks	The AED passed the battery insertion self-test and the last periodic self-test and is therefore ready for use.
green Ready light is solid	The AED is being used or a self-test is being run.
green Ready light is off ...HeartStart chirps, ...i-button flashes	A self-test error has occurred, there is a problem with the pads cartridge, or the battery power is low. Press the blue i-button for more information.
green Ready light is off ...HeartStart does not chirp ...i-button does not flash	There is no battery inserted, the battery is depleted, or the AED needs repair.

Periodic Self-Tests

When a battery is installed in the HeartStart AED, the unit will automatically perform a self-test at least once every 24 hours. An exception to this is when an AED is stored outside of its operating temperature range, which is indicated on the ForeRunner and FR2 series units by a blinking red X on the status indicator and on HS1 AEDs by a warning chirp and flashing blue i-button. An AED should not be stored outside of its specified temperature range. In the event that it is, the AED will wait for a time that its temperature is within specified limits before resuming self-testing. This lets the AED automatically reschedule its 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 that is 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 or blinking green Ready light means that the HeartStart AED has passed a self-test within the last 24 hours and is ready for use. If a written record of the periodic check is required, the visual check can be noted in an Operator's Checklist as suggested in the Maintenance chapter of the HeartStart AED *Instructions for Use*. Event Review Software has the capability of printing a self-test report for both the HeartStart FR2+ and the HS1 AEDs.

Table 1: Standby Self-Tests

HeartStart 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 Measurement 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.	
User Interface				User Interactive Tests - FR2/FR2+: 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 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 insure 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 Table 2, below.

Table 2: Power On and In-Use Self-Tests

HeartStart AED 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 Measurement Standards	Time Base Reference Check - Cross checks two independent system clocks. These time references are traceable to NIST when the instrument is manufactured, and they are checked against each other each day over the life of the instrument.	System Power Supply Voltage Check - Checks internal power supply voltages used to operate the instrument.
ECG Rhythm Analysis System		Voltage Reference Check - Cross checks two independent voltage reference standards. These references are traceable to NIST when the instrument is manufactured, and they are checked against each other each day over the life of the instrument. Patient ECG Front End Functional Check - Verifies the integrity of the 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 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

Background

Technical Professionals occasionally request supplemental information about maintaining the ForeRunner and FR2. This document is intended to supplement the User information for ForeRunner or FR2 use and maintenance provided by the ForeRunner *User's Guide*, part number 07-10001 or the FR2 *Instructions for Use*, part number M3860-91900.

This Supplemental Technical Information is intended for use by Technical Professionals and addresses calibration requirements and intervals, maintenance testing, verification of energy discharge, and service/maintenance and repair manual.

Calibration requirements and intervals

Users frequently ask about the requirement to calibrate and/or verify energy delivery. This document shall serve as evidence that the ForeRunner and FR2 do not require user calibration or verification of energy delivery prior to placing it in service. Further, the ForeRunner and FR2 do not require user calibration at regular intervals, including annual intervals.

Maintenance testing

Maintenance testing is unnecessary as the ForeRunner and FR2 automatically perform daily self-tests and correct operation is verified during battery insertion tests.

This document shall serve as evidence that when the Status Indicator displays a flashing hourglass 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

This document shall serve as evidence that the ForeRunner and FR2 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 ForeRunner or FR2 energy delivery, using instructions available from Philips. Improper testing can seriously damage the AED and render it unusable.

Service/Maintenance and Repair Manual

The ForeRunner and FR2 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. Customer Service contact: 800-263-3342, 206-664-7745.

Notes

6 Theory of Operation

IMPORTANT NOTE: The internal construction of 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 an automated external defibrillator (AED) works.

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

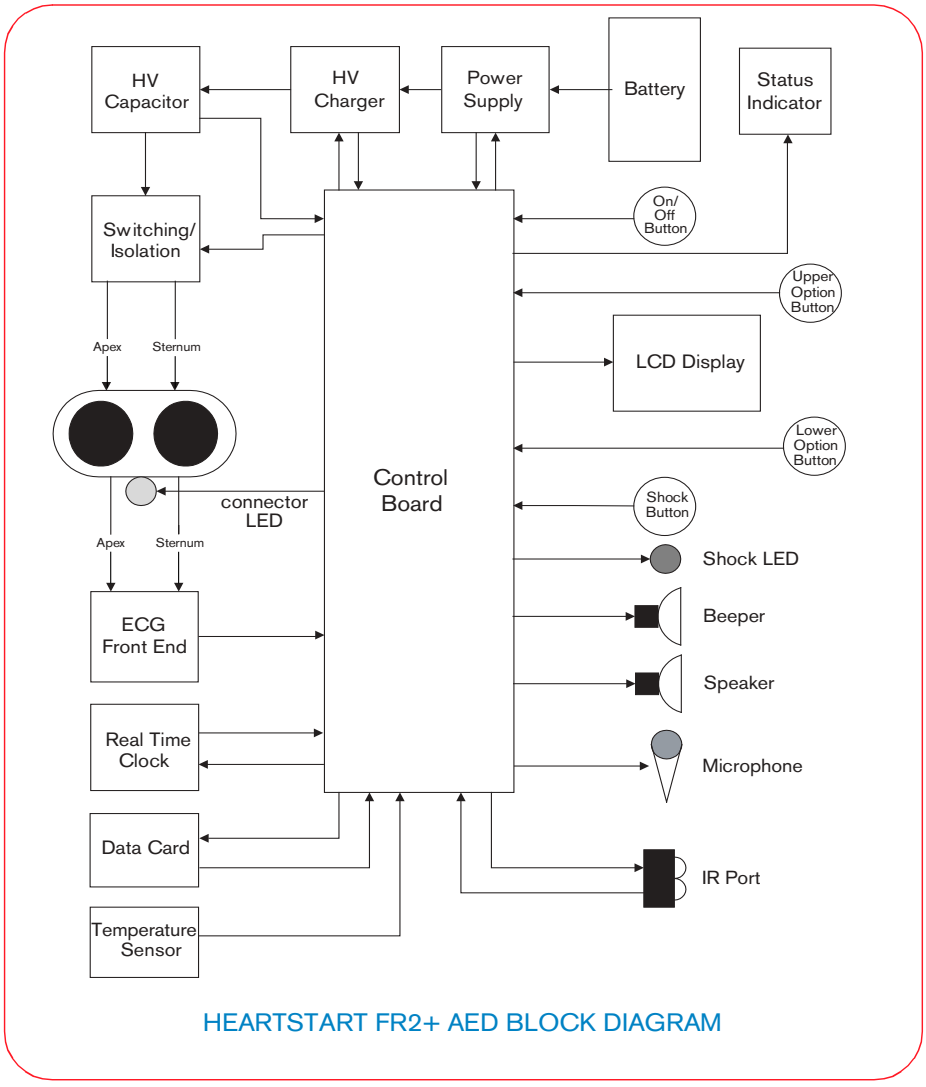
- Input the ECG signal and convert it into a digital format that the microprocessor can analyze.
- Analyze the ECG and determine if the device should charge and allow a shock to be delivered.
- Charge the internal capacitor to a voltage high enough to effectively defibrillate the patient.
- Instruct 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

Automated external defibrillators were designed to be used by rescuers who aren't trained to read ECGs and to distinguish between shockable and non-shockable rhythms, so the AEDs 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. 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+ AED BLOCK DIAGRAM

User interface

The following discussion uses the FR2+ device as the user interface example.

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

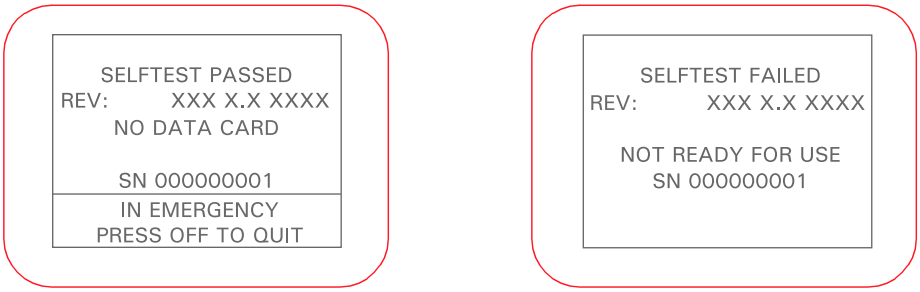
In normal operation, text prompts are displayed on the main LCD, and voice prompts are provided through the speaker. These prompts guide the rescuer in the use of the device and give warnings (such as low battery) to call the user's attention to certain parts of the device that may need attention. The 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 AED. If the AED 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 AED 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 HeartStart AEDs primarily consists of the user checking the status indicator regularly to verify that the unit is working and ready to be used. The AED 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 daily or monthly self-tests, it will display a flashing or solid red X on the status indicator, which may be accompanied by beeping. (For additional information, please refer to the Self-tests chapter.)

Troubleshooting

The LCD display, beeper, and status indicator are also used for troubleshooting the device. The main troubleshooting tool is the battery insertion test, or BIT. To execute a BIT, the battery is removed and then reinserted. The AED then executes a full functional test automatically 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," along with other information about the revision of the hardware and software and status of the AED.



Configuration

The LCD display and option buttons are used in configuration mode to set the clock or customize the configuration of the AED. 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 AED. 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 power source for the FR2+ is a 12 V, 4.2 Ah battery pack. The battery pack contains 12 $LiMnO_2$ battery cells, similar to those used in cameras. The battery packs are non-rechargeable and can be disposed of with regular waste when depleted. (The battery packs for the ForeRunner and HS1 AEDs are smaller, but also contain the same $LiMnO_2$ battery cells.)

Power Supply

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

ECG Front End

The front end 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 to deliver the defibrillation waveform to the patient. A large amount of energy is stored in the battery: enough for over 100 shocks in the ForeRunner battery and for over 300 shocks in the FR2 battery. However, this energy is stored in the battery at a low voltage (18 V in ForeRunner, 12 V in FR2) that is not effective for a defibrillation shock. In order for a patient to be defibrillated, enough energy for one shock must be transferred to the high-voltage (HV) capacitor at a voltage high enough to make the defibrillation waveform effective (about 1800 VDC for the SMART Biphasic waveform).

When a decision to shock is made by the AED, the high-voltage (HV) charger circuit transfers energy stored in the battery at a voltage of 12-18 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.

Recording

When the AED 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 AED can also record all the audio information from the event through its microphone. The ECG and audio information can later be reviewed using Event Review data management software.

Temperature Sensor

All HeartStart AEDs incorporate a temperature sensor that allows the control board to determine the ambient temperature of the device. This enables the AED to determine if it is exposed to temperatures outside the recommended storage range that could damage or reduce the life of the defibrillation electrode pads or the batteries. If the temperature of the AED falls outside the recommended range, it will generate an error that 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 occurs. 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+ AED 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+ AED incorporates an infrared (IR) port that can be used to communicate with other FR2+ AEDs or an IR port on a PC. The IR port can be used to send or receive time and date information or configuration data from a PC or other FR2+ devices.

7 Literature Summary for HeartStart AEDs

The following pages list references for numerous studies completed to demonstrate the validity and effectiveness of the HeartStart AED technology. 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 a dozen peer reviewed manuscripts that have been published to support the SMART Biphasic waveform and at this time is the only biphasic waveform to have published data from out-of-hospital cardiac arrests to demonstrate its safety and effectiveness.

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 shape that the waveform must take 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 model 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.

References

Animal Studies (peer-reviewed manuscripts)	Conclusions
Gliner BE, Lyster TE, Dillion SM, Bardy GH. Transthoracic defibrillation of swine with monophasic and biphasic waveforms. *Circulation* 1995; 92:1634-1643.	"This study demonstrates the superiority of truncated biphasic waveforms over truncated monophasic waveforms for transthoracic defibrillation of swine."
Xie J, Weil MH, Sun S, Tang W, Sato Y, Jin X, Bisera J. High-energy defibrillation increases the severity of postresuscitation myocardial dysfunction. *Circulation* 1997 Jul 15; 96(2):683-8.	"…we observed global myocardial dysfunction after cardiac resuscitation from VF, reminiscent of that observed after regional ischemia. The severity of postresuscitation myocardial dysfunction and the duration of survival corresponded to the magnitude of electrical energy that was delivered for the purposes of defibrillation."

Animal Studies (peer-reviewed manuscripts)	Conclusions
Tang W, Weil MH, Sun S, Yamaguchi H, Povoas HP, Pernat AM, Bisera J. The effects of biphasic and monophasic waveform defibrillation on postresuscitation myocardial function. *JACC* 1999;34:815-822.	"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."

Electrophysiology Laboratory and other studies (peer-reviewed manuscripts)	Conclusions
Bardy GH, Gliner BE, Kudenchuk PJ, Poole JE, Dolack GL, Jones GK, Anderson J, Troutman C, Johnson G. Truncated biphasic pulses for transthoracic defibrillation. *Circulation* 1995; 91: 1768-74.	"The results of this study suggest that biphasic truncated transthoracic shocks of low energy (115 and 130J) are as effective as 200-J damped sine wave shocks used in standard transthoracic defibrillators."
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 Dampled Sine Wave Monophasic Shocks for Transthoracic Ventricular Defibrillation. *Circulation* 1996; 94:2507-14.	"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."
Ricard P, Lévy S, Boccara G, Lakhal E, Bardy G External cardioversion of atrial fibrillation: comparison of biphasic vs monophasic waveform shocks. *Europace* 2001; 3: 96-99.	"This study suggests that at the same energy level of 150J, biphasic impedance compensating waveform shocks are superior to monophasic damped sine waveform shocks cardioversion of atrial fibrillation."
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."
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 Eexternal 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."

Sudden Cardiac Arrest (peer-reviewed manuscripts)	Conclusions
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."
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 OHCA. The observed defibrillation rate exceeds that of published studies on higher energy monophasic waveforms. Higher energy is not clinically warranted with this BTE 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. ….we recommend that defibrillation should uniformly be defined as termination of VF for a minimum of 5-s after shock delivery. Rhythms should be reported at 5-s after shock delivery to assess early effects of the defibrillation shock and at 60-s after shock delivery to assess the interaction of the defibrillation therapy and factors, such as post-shock myocardial dysfunction and the patient's underlying cardiac disease."
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 and better neurological status at the time of hospital discharge."
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. *NEJM* 2000; 343:1210-1216.	"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."

Sudden Cardiac Arrest (peer-reviewed manuscripts)	Conclusions
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 and MDS design. The biphasic devices were also quicker to first shock and to first successful shock."
White RD, Hankins DE, Atkinson EJ. Patient Outcomes Following Defibrillation With a Low Energy Biphasic Truncated Exponential Waveform in Out-of-Hospital Cardiac Arrest. *Resuscitation* 2001; 49:9-14.	"Low-energy (150J) 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."

Animal Studies (abstracts)	Conclusions
Tang W, Weil MH, Sun Shijie, et.al. Defibrillation with low-energy biphasic waveform reduces the severity of post-resuscitation myocardial dysfunction after prolonged cardiac arrest. *J Crit Care Med* 1999;27:A43	"Low-energy biphasic waveform was as effective as monophasic waveform for successful defibrillation after 7 minutes of untreated VF but produced significantly less post-resuscitation myocardial dysfunction."
Tang W, Weil MH, Klouche K, et.al. Effects of low- and higher-energy biphasic waveform defibrillation on success of resuscitation and post-resuscitation myocardial function. *Circulation* (suppl)1999;100(18):I-662(Abstract #3491).	"We conclude that low energy biphasic shocks increase the likelihood of successful defibrillation and minimize post resuscitation myocardial dysfunction after prolonged cardiac arrest."
Tang W, Weil MH, Klouche K, et.al. Low capacitance biphasic waveform shocks improve immediate resuscitation after prolonged cardiac arrest. *Circulation* (suppl)1999;100(18):I-663(Abstract #3493).	"Low-capacitance biphasic defibrillation therefore significantly improved the success of initial resuscitation but not post resuscitation myocardial function after prolonged cardiac arrest."

Out-of-Hospital Study (abstract)	Conclusions
Snyder D, Lyster T. Performance of an Automatic External Defibrillator in the Presence of Implanted Pacemaker Artifact. *Circulation* (suppl)1998; 98(17):I-411 (Abstract #2163)	"A new AED shock advisory algorithm achieves excellent rhythm detection specificity and VF/VT sensitivity in the presence of pacemaker artifact."

Related Papers and Publications	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."

Related Papers and Publications	Conclusions
Cecchin F, et al. 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."
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.	Summary: "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."
American Heart Association. *Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*. August, 2000	In reference to SMART Biphasic waveform: "The growing body of evidence is now considered sufficient to support a Class IIa recommendation for this low energy, BTE waveform." (I-63) Class IIa defined as: "Good to very good evidence", a "standard of care", "intervention of choice" (I-5) "At this time no studies have reported experience with other biphasic waveforms in long-duration VF…"(I-63) "When such data becomes available it will need to be assessed by the same evidence-evaluation process..." (I-63) "The safety and efficacy data related to specific biphasic waveforms must be evaluated on an individual basis in both in-hospital (electrophysiology studies, ICD testing) and out-of-hospital settings." (I-63)
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.

Study Summaries

HeartStart Defibrillation Therapy Testing in Adult Victims of Out-of-Hospital Cardiac Arrest

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 150 J SMART Biphasic waveform defibrillated 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 </= 2 shocks </= 3 shocks	 52/54 (96%) 52/54 (96%) 53/54 (98%)	 36/61 (59%) 39/61 (64%) 42/61 (69%)	 <0.0001 <0.0001 <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

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[1]	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%

1 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

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

8 Condensed Application Notes

- Defibrillation on Wet or Metal Surfaces
- Defibrillating in the Presence of Oxygen
- Value of an ECG Display on HeartStart AEDs
- Defibrillation Pad Placement with HeartStart AEDs
- SMART Analysis - Classification of Rhythms
- Artifact Detection
- Use of Automated External Defibrillators in Hospitals
- HeartStart AED Battery Safety

Defibrillation on Wet or Metal Surfaces

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 that no one is touching the patient when the shock button is pressed.

As long as there is no direct contact between the user and the patient when the shock is delivered, there is no current path that would cause the user to experience a shock. In unpublished studies conducted at Philips, it was demonstrated that no appreciable charge will build up on a wet or metal surface when a patient is defibrillated.

The current that travels between the pads will always seek the path of least resistance; if the user does not touch the patient during the discharge, there is no danger of the user receiving a shock. Conversely, if the user is touching the patient when the AED is discharged, he or she will probably receive a noticeable shock.

HeartStart AEDs were designed to be easy to use and have clear voice prompts that reinforce the proper use of the product. When the HeartStart AED is analyzing the ECG, it will say, “Do not touch the patient.” When it decides to shock and begins to charge, it will tell the user to “Stay clear of patient.” It will also inform the user “It is safe to touch the patient” when that is the case following a shock or analysis period. All of these messages are intended to make the unit safe and easy to use.

Defibrillating in the Presence of Oxygen

The *Instructions for Use* manual for the HeartStart AEDs contains a warning, “Danger: There is a possibility of explosion if the ... ForeRunner (FR2) 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 will typically 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.

Value of an ECG Display on HeartStart AEDs

The ECG display on the ForeRunner and FR2+ 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.

Defibrillation Pad Placement with HeartStart AEDs

The pad placement for ForeRunner and FR2 series AEDs is specified with a diagram in the *User's Guide*, with icons on the pads package, and on the pads themselves. The *User's Guide* tells the user to place the pads on the patient in the position shown on the pad itself. The diagrams on the pads themselves indicate a specific location for each individual pad.

Use studies with the Forerunner demonstrated that 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 will not reduce the performance of the AED’s algorithm or the efficacy of the delivered energy in any way.

HeartStart AEDs are intended for use by people with minimal training and are therefore 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.

SMART Analysis - Classification of Rhythms

SMART Analysis simultaneously measures four key parameters in a 4.5 second segment of ECG, and then classifies the ECG as a shockable or non-shockable rhythm. The first three measures are rate, wave conduction, and morphological stability. In addition, an amplitude threshold of 100 microvolts must be satisfied to enable a shock.

In order for the device to charge and allow a shock to be delivered, multiple 4.5 second strips must be considered shockable. If the device detects three consecutive strips as 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 transition into “monitor” mode. The device then continues to monitor the ECG, but it will only give more voice prompts if it identifies a strip as shockable, at which point it will transition back into analyze mode where it can make a decision to allow a shock.

SMART Analysis is 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 (essentially infinite) for rhythms with healthy normal conduction. Thus, rhythms with normal conduction will not be shocked regardless of the rate. However, if the wave conduction degrades to a point which makes the rhythm indistinguishable from hemodynamically unstable VT, then classifying SVT as a shockable rhythm is possible but highly unlikely.

The AHA issued a Scientific Statement (Kerber et al, Circulation, 1997;95:1677-1682) clearly identifying SVT as a non-shockable rhythm, and requiring a minimum defibrillator algorithm specificity of 95% to this rhythm. This high specificity requirement presupposes 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 having poorer morphological stability (such as polymorphic VT and VF), the rate threshold will vary in a similar manner described above. But 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.

In addition, if significant artifact is detected in the ECG, based on high correlation with static charge, the analysis system suspends further analysis until reliable data quality is available. This artifact detection method provides an additional margin of safety when adverse conditions are present. If a patient has a pacemaker, the “pacemaker artifact” is actively removed from the ECG, which allows high sensitivity to VF for pacemaker patients.

Artifact Detection in HeartStart AEDs

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 in some way. 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 that can cause incorrect or delayed treatment of the patient.

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 the artifact signal mimics the ECG signal, then artifact is detected and appropriate action is taken; if it doesn't mimic the ECG, then analysis proceeds and the defibrillator is free to make shock/no-shock decisions.

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

If the underlying ECG signal has a small amplitude compared to an artifact signal with a large amplitude, the HeartStart AED will respond by giving voice prompts that tell the user “Do not touch the patient,” “Analyzing interrupted,” or “Patient and device must remain still.” In this situation, the defibrillator can not accurately analyze the underlying ECG due to the amount of noise present, so the AED will give messages with the hope of stopping or minimizing the artifact in the environment.

If the amplitude of the ECG signal is sufficiently high compared to the artifact signal and the shape of the artifact differs from 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 can continue to make shock decisions and deliver a shock if appropriate.

In the event that the patient has an implanted pacemaker, the HeartStart AEDs have special filters that remove the pacemaker artifact and allow the defibrillator to shock the patient if appropriate. The performance of the HeartStart AED in the presence of pacemaker artifact was presented at the 1998 AHA Scientific Sessions (Snyder et al, Circulation 98(17) (Supplement), I-411) which reported “excellent rhythm detection specificity and VF/VT sensitivity in the presence of pacemaker artifact.”

Use of Automated External Defibrillators (AEDs) in Hospitals

HeartStart AEDs are designed primarily to be used by lay rescuers, but they are also well suited for the hospital environment provided the proper training takes place. Many hospitals deploy AEDs in non-monitored wards of the facility to be used by BLS trained personnel; this use model is very similar to use by lay rescuers. Extra training is necessary, however, if the implementation plan includes the use of AEDs by more highly trained medical professionals in a manual mode of operation. If certain personnel expect to use the device in the advanced mode, they need to be trained how to enter the advanced mode and what features are available to them in that state.

Manual Mode of Operation with HeartStart AEDs

HeartStart AEDs will always power up in the AED mode of operation, even if they are capable of being used in a manual mode of operation. In AED mode, the device is continuously analyzing the patient's ECG and will only charge and deliver a shock when a shockable rhythm has been detected. However, both the ForeRunner model EM and the FR2/FR2+ model M3860A can also be used in a manual mode of operation.

The ForeRunner model EM has a special manual override button on the front that is used for this purpose. This button is pressed once to enter manual mode; pressing the button a second time within 5 seconds causes the unit to charge and to allow a shock to be delivered by the user regardless of the rhythm that is present. After the shock is delivered the unit returns to semi-automatic mode and will analyze the patient's heart rhythm.

The FR2/FR2+ model M3860A must be configured beforehand for the advanced mode feature using the M3864A Training and Administration Pack. If the device is configured for Advanced Mode with the Charge setting selected, then the manual mode may be entered after pads have been attached to the patient by pressing both blue option buttons at the same time. Once manual mode has been entered, the user may manually analyze the rhythm by pressing the “Analyze” button (bottom option key). The user may also enter the manual charge mode by pressing the “Manual” button (top option key). This allows the user to manually charge the AED by pressing the “Manual Charge” button (top option key again). Once the manual mode is entered, the FR2 remains in manual mode until the device is turned off.

It is very important that personnel be trained on how the manual mode works, especially with the FR2. Since the FR2 requires special button pushes to enter the manual mode of operation, medical personnel need to be trained ahead of time on how to enter manual mode if that is how they intend to use the device. Manual mode is not the default mode of operation for HeartStart AEDs.

Analysis System in HeartStart AEDs

HeartStart AEDs have a built-in analysis system that is designed to analyze the patient's heart rhythm and determine if a shock is appropriate. In order for the analysis system to work properly, the patient should remain still and no one should be touching the patient during the analysis period. This means that activity immediately around the patient should also be minimized during analysis to prevent vibration or static electricity from adding electrical noise to the ECG.

The AED will give a voice prompt instructing the user, “Analyzing heart rhythm. Do not touch the patient,” when analysis is taking place. It is very important for the user to follow this instruction so that the device has the opportunity to make an accurate shock/no-shock decision on the rhythm. If the AED detects artifact from patient handling or other sources, it will inform the user that analysis was interrupted and remind them that they should not touch the patient.

Once a no-shock decision has been advised, the AED will inform the user that it is safe to touch the patient. When CPR is initiated, it is important to remember to pause for patient assessment after each minute. This pause also allows the defibrillator to analyze the heart rhythm with no CPR artifact.

As long as the defibrillator remains in AED mode, it is essential that the user follow the instructions given by the AED with the voice prompts. If the user chooses to put the unit into the advanced mode, the voice prompts are greatly reduced and the user assumes responsibility for both the protocol and the shock decisions.

Shockable/Non-Shockable Rhythms

As stated in Appendix B of the FR2 User's Guide, “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.” The analysis system in HeartStart AEDs is different from that found in the AED modes of the manual defibrillators and is tailored to users who are not highly trained medical personnel. Specifically, it will only advise a shock when there is a high degree of certainty, from the ECG rhythm alone, that the patient is in cardiac arrest.

This fact should be made clear to hospital users who may be trained to recognize various arrhythmias since they may occasionally see rhythms that they would want to shock when the AED has advised no-shock. In these situations, it may be appropriate for those users to switch to the manual mode of operation and deliver a shock.

The ventricular fibrillation (VF) rhythms that fall into this no-shock category are fine VF that show either a very low amplitude or low frequency ECG and may be indistinguishable from coarse asystole. The analysis system has classified these rhythms with a no-shock decision either because there is a possibility that the rhythm is actually caused by artifact or because it considers other therapy, such as CPR, more appropriate at this point.

The analysis system was designed to be conservative with ventricular tachycardia (VT), and will only advise a shock when there is a very high probability that there is no pulse associated with the VT. This means that monomorphic VT requires a much higher rate to be considered shockable than polymorphic VT and ventricular flutter. Also, the analysis system was not designed to shock supraventricular tachycardia (SVT), per recommendations of the American Heart Association (AHA).

Defibrillation Pads for HeartStart AEDs

The FR2 now has pediatric pads (M3870A) available for treating children under the age of 8 years old. These pads contain special circuitry to reduce the amount of energy delivered so that the child only receives 50 J instead of the adult dose of 150 J. These pads will only connect to the FR2 AED and cannot be used on the ForeRunner AED or other HeartStart AEDs.

Conversely, the pediatric pads available for the HeartStart manual defibrillators will not work on HeartStart AEDs. The FR2 AEDs do not have the ability to select the delivered energy, so it was necessary to attenuate the delivered energy in the pads themselves insuring that a pediatric patient will receive the appropriate dose. A different connector was used on the FR2 pads so that they could not be used in the manual defibrillators.

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

Each HeartStart 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 ForeRunner and FR2 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.

CPR Performed at High Rates of Compression

As stated in chapter 3 of the FR2 *Instructions for Use*, “WARNING: CPR rates significantly above 100 compressions per minute can cause incorrect or delayed analysis by the HeartStart FR2.”

CPR performed with chest compressions of rates over 135 can sometimes mimic a shockable rhythm. These high CPR rates can cause the AED to interrupt the rescuer doing CPR and instruct them 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.

If a medical director wishes to enable higher rates of CPR, the HeartStart AEDs can be configured to pause for a period between 30 seconds and 3 minutes after a no-shock advised decision (NSA Pause). During this pause period, the defibrillator will not analyze the rhythm at all, which allows the user to perform uninterrupted CPR.

HeartStart AED Battery Safety

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

The standard non-rechargeable batteries used in the HeartStart AED contain consumer grade lithium manganese dioxide ($LiMnO_2$) cells. A total of six “2/3A” size standard camera batteries are built into the custom battery pack used by the ForeRunner (12 in the FR2 series, 9 in the HS1); 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 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. Philips evaluated both chemistries and found $LiSO_2$ to be 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 AED’s 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.

Additional Advantages of the HeartStart AEDs Battery: Disposable vs. Rechargeable

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 normally 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.

The HeartStart $LiMnO_2$ battery packs meet the U.S. EPA's Toxicity Characteristic Leaching Procedure and therefore may be disposed of with normal waste without a complicated recycling process. $LiSO_2$ batteries require the user to manually disable them prior to disposal.

For those organizations that use the AED more frequently and have a battery maintenance program, Philips Medical Systems offers a rechargeable LiION battery (M3848A) that uses the same battery technology as used in most laptop computers. These should only be used by organizations that are committed to providing the extra resources required to operate a battery maintenance program.

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

9 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 HS1 AEDs, the ForeRunner AEDs (Models S, E, and EM), and the HeartStart FR2 AEDs (Models M3860A and M3861A). The Laerdal Heartstart FR AEDs are equivalent to the ForeRunner while the Laerdal Heartstart FR2 is equivalent to the HeartStart FR2. 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

- IEC 60601-1:1988 / EN 60601-1:1990
- IEC 601-2-4:1983
- IEC 60101-1-2:1993 / EN 60601-1-2:1993
- CAN/CSA-C22.2 No 601.1-M90 and Supplement 1:1994
- AAMI DF 39:1993
- EN 61000-4-3 (HeartStart FR2 only)
- CISPR 11:1990 / EN 55011:1991
- RTCA/DO-160C: 1989 (ForeRunner only)
- RTCA/DO-160D: 1997 (HeartStart FR2 only)

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.

ForeRunner and FR2 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

AED Specifications

Physical

category	HeartStart ForeRunner	HeartStart FR2	HeartStart HS1
size	2.53” high x 8.75” wide x 8.0” deep (6.4 cm x 22.3 cm x 20.3 cm).	2.6” high x 8.6” wide x 8.6” deep (6.6 cm x 21.8 cm x 21.8 cm).	2.80” high x 8.30” wide x 7.40” deep (7.1 cm x 21 cm x 19 cm).
weight	Approximately 4.4 lbs (2 kg) with battery installed.	Approximately 4.7 lbs (2.1 kg) with standard battery installed. Approximately 4.5 lbs (2 kg) with optional rechargeable battery installed.	Approximately 3.3 lbs (1.5 kg) with battery and pads cartridge installed.

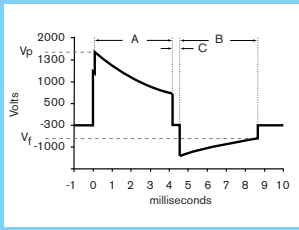
Environmental

category	ForeRunner and FR2	HeartStart HS1
operating temperature and humidity	32° to 122° F (0° to 50° C). 0% to 95% relative humidity (non-condensing).	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.	50° to 109° F (10° to 43° C). 10% to 75% relative humidity (non-condensing).
altitude	Meets MIL-810E 500.3, Procedure II (-500 feet to 15,000 feet).	Operates at 0 to 15,000 feet; can be stored at up to 8,500 feet in standby mode.
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).	Withstands 1 meter drop to any edge, corner, or surface.
vibration	Meets MIL-STD-810E 514.4-17.	Operating: meets EN1789 random, road ambulance. Standby: meets EN1789 swept sine, road ambulance.
sealing	With data card tray and battery installed, meets IEC 529 class IP54.	Drip proof per EN60529 class Ipx1. Solid Objects per EN60529 class IP2x.
ESD	Meets EN 61000-4-2:1998 Severity Level 4.	Meets EN 60601-1-2 limits (1993), method EN61000-4-2 Severity Level 4.
EMI (radiated)	Meets EN 60601-1-2 limits (1993), method EN 55011:1998 Group 1 Level B.	Meets EN 60601-1-2, EN55011.
EMI (immunity)	Meets EN 60601-1-2 limits (1993), method EN 61000-4-3:1998 Level 2.	Meets EN 60601-1-2, method EN61000 Level 2 (normal operation; 10V/m, 26MHz - 2.5 GHz) and Level 3 (impaired but safe; 10 V/m, 26MHz-2.5 GHz.
aircraft: method	Meets RTCA/DO-160D:1997 Section 21 (Category M - Charging).	Not tested.

AED (HeartStart HS1 Family)

See the *Instructions for Use* for the FR2+ and *User's Guide* for the ForeRunner AEDs for corresponding information.

category	HeartStart HS1 AEDs
waveform parameters	Biphasic truncated exponential. Waveform parameters are automatically adjusted as a function of patient defibrillation impedance. In the diagrams at left, A is the duration of phase 1 and B is the duration of phase 2 of the waveform, C is the interphase delay, V_p is the peak voltage, and V_f the final voltage. The HeartStart HS1 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:

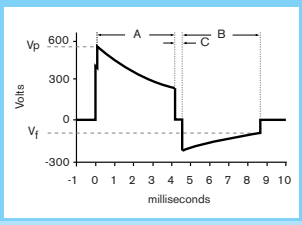


adult defibrillation

load resistance (ohms)	phase 1 duration (ms)	phase 2 duration (ms)	delivered energy (J)
25	2.8	2.8	128
50	4.5	4.5	150
75	6.25	5.0	155
100	8.0	5.3	157
125	9.65	6.4	159
150	11.5	7.7	160
175	12.0	8.0	158

pediatric defibrillation
(using M5070A Infant/Child SMART Pads)

load resistance (ohms)	phase 1 duration (ms)	phase 2 duration (ms)	delivered energy (J)
25	4.1	2.8	35
50	5.1	3.4	46
75	6.2	4.1	52
100	7.2	4.8	54
125	8.3	5.5	56
150	9.0	6.0	57
175	9.0	6.0	55



energy

Using HeartStart Adult SMART Pads: 150 J nominal into a 50 ohm load.

Using HeartStart Infant/Child SMART Pads: 50 J nominal 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.

category	HeartStart HS1 AEDs
charge control	Controlled by Patient Analysis System.
charge time from “shock advised”	< 10 s typical, including confirming analysis. Charge time increases near end of battery service life.
shock-to-shock cycle time	< 20 s typical, including analysis.
“charge complete” indicator	Shock button flashes, audio tone sounds.
disarm (AED mode)	Once charged, the HS1 AED will disarm if: • patient’s heart rhythm changes to non-shockable rhythm. • a shock is not delivered within 30 s after the HS1 is armed. • the On/Off button is pressed to turn off the HS1. • the defibrillation pads are removed from the patient or the SMART Pads cartridge is removed from the AED.
shock delivery vector	Via defibrillation pads placed in the anterior-anterior (Lead II) position if Adult SMART Pads cartridge is used or via HS1 pediatric defibrillation pads placed in the anterior-posterior position if the Infant/Child SMART Pads cartridge is used.

ECG Analysis System*

category	ForeRunner	HeartStart FR2	HeartStart HS1
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.		Default settings can only be changed using Event Review software.
shockable rhythms	Ventricular fibrillation (VF) and certain ventricular tachycardias, including ventricular flutter and polymorphic ventricular tachycardia (VT). The HEARTSTREAM 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	Gives voice prompts only if ECG changes to a shockable rhythm.	On detection of asystole, provides CPR prompt at programmed interval.	On detection of asystole, provides CPR prompt at programmed interval.

* See Chapter 4 for information about ECG Analysis Performance.

category	ForeRunner	HeartStart FR2	HeartStart HS1
pacemaker detection	Pacemaker artifact is removed from the signal for rhythm analysis.	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.	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

NOTE: The HeartStart HS1 AEDs do not have a display screen.

category	ForeRunner	HeartStart FR2
monitored ECG lead	ECG information is received from defibrillation pads in anterior-anterior (Lead II) position. (Displayed on Models E and EM 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. (Displayed on M3860A only.)
display range (M3860A only)	Differential: +/-2 mV full scale, nominal. (Models E and EM only)	Differential: ±2 mV full scale, nominal. (M3860A only; (brighter and higher contract than FORERUNNER model))
screen type	High resolution LCD with backlight.	High-resolution liquid crystal display (LCD) with backlight.
screen dimensions	2.8” wide x 2.3” high (70 mm x 58 mm).	
sweep speed	23 mm/s nominal. (Models E and EM only)	23 mm/s nominal. (M3860A only)
ECG display	3 second-segments displayed. (Models E and EM only)	3 second-segments displayed (M3860A only).
frequency response (bandwidth)	Nondiagnostic rhythm monitor 1 Hz to 20 Hz (-3 dB), nominal.	
sensitivity	1.16 cm/mV, nominal.	

category	ForeRunner	HeartStart FR2
heart rate displayed (normal sinus rhythm)	30 to 300 bpm, updated each analysis period. Displayed (Models E and EM only) during monitoring and advanced modes.	30 to 300 bpm, updated each analysis period. Displayed (M3860A only) during monitoring and advanced modes.

Controls and Indicators

category	ForeRunner	HeartStart FR2	HeartStart HS1
LCD screen	A high resolution, backlit LCD screen displays ECG (Models E and EM) and informational/instructional text messages on all models.	High-resolution, backlighted LCD screen displays ECG (M3860A only) and text messages.	N/A
controls	• On/Off button • Shock button • Manual override button (Model EM only) • Contrast up button • Contrast down button	• On/Off button • Shock button • Option buttons	• Green SMART Pads cartridge handle • Green On/Off button • Orange Shock button • Blue Information Button (“i-button“)
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.		• Ready light: green; blinks when the AED is in standby mode (ready for use); solid when the AED is being used, off indicates unit needs attention. • i-button: blue, flashes when information is available, on solid during patient care pause. • Caution light: flashes when the AED is analyzing, comes on solid when the AED is ready to deliver a shock • Shock button: orange, flashes when the AED is charged and ready to deliver a shock.
audio speaker	Provides voice prompts. Volume of voice prompts is adjustable using Setup card.	Provides voice prompts. Volume is adjustable via Setup screen.	Provides voice prompts and warning tones during normal use.
beeper	Chirps when a selftest has failed. Provides various warning beeps during normal use.		

category	ForeRunner	HeartStart FR2	HeartStart HS1
status indicator	Status indicator LCD displays device readiness for use.		Ready light 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.		AED chirps, the green Ready light stops blinking, and the blue i-button starts flashing.

Data Management Specifications

category	ForeRunner	HeartStart FR2	HeartStart HS1
capacity	ER1 data card: 15 minutes of event and ECG data. EC1 data card: 30 minutes of event and ECG data. VC1 data card: 30 minutes of event and ECG data.; 28 minutes of audio recording.	M3854A data card: 4 hours of event and ECG data, or 30 minutes with voice recording.	15 minutes of ECG and event data is stored in internal memory in the AED. *NOTE: The last-use ECG recordings will be retained for at least 30 days after a use so they can be downloaded to a computer. (If the battery is removed during this period, the AED retains the files. When the battery is reinstalled, the last-use ECG recordings will be kept in defibrillator memory for an additional 30 days.) After this time, the last-use ECG recordings will automatically be erased to prepare for a future use. You can also erase the last-use ECG recordings prior to this time by using HeartStart Event Review data management software.*
data transfer	PCMCIA data card reader	Compact flash data card reader	Infrared (IR) communication port to PC running Event Summary Software

Accessories Specifications

Battery Packs

category	ForeRunner	HeartStart FR2	HeartStart HS1
battery type	18 VDC, 1.3 Ah, lithium manganese dioxide. Disposable, recyclable, long-life primary cells.	12 VDC, 4.2 Ah, lithium manganese dioxide. Disposable, recyclable, long-life primary cell.	9 VDC, 4.2 Ah, lithium manganese dioxide. Disposable, long-life primary cells.
capacity	When new, a minimum of 100 shocks or 5 hours' operating time or 10 hours of training time at 77° F (25° C).	When new, a minimum of 300 shocks or 12 hours' operating time at 77° F (25° C).	When new, a minimum of 90 shocks or 3 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 more than one year when stored under standby environmental conditions (1 battery insert test and no uses or training)	Typically, 5 years when stored under standby environmental conditions (battery installed, FR2 unused).	Typically 4 years when stored under standby environmental conditions.
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.		Good battery: flashing green Ready light. Low battery: AED chirps, the green Ready light stops blinking, and the blue i-button starts flashing. Dead battery: green Ready light is off.
storage temperature	32° to 109° F (0° to 43° C).		

HeartStart Defibrillation Pads

category	ForeRunner	HeartStart FR2	HeartStart HS1
adult pads, cable, and connector	DP2/DP6: disposable, adhesive defibrillator pads with a nominal active surface area of 100 cm^2 each with an integrated 22 cm (48 inch), typical, cable and connector, provided in a sealed package.		M5071A: disposable, adhesive defibrillation pads with a nominal active surface area of 85 cm2 each, provided in a snap-in cartridge with an integrated 54 inch (137.1 cm), typical, cable

category	ForeRunner	HeartStart FR2	HeartStart HS1
infant/child pads, cable, and connector	Not available.	M3870A: disposable, self-adhesive, provided in a sealed package. Active surface area: 44 cm^2 each Integrated cable and connector (incorporated attenuating electronics): 122 cm (48 inch), typical.	M5072A: disposable, adhesive defibrillation pads with a nominal active surface area of 85 cm2 each, provided in a snap-in cartridge with an integrated 40 inch (101.6 cm), typical, cable. Cartridge incorporates teddy bear icon on cover of seal for ready identification.
defibrillation pad requirements	Use only HeartStart defibrillator pads with the ForeRunner or FR2 series AEDs. Place the pads on the patient as illustrated on each pad.		Use only HeartStart SMART Pads cartridges with HS1 AEDs. Place the pads on the patient as illustrated on each pad.

10 Features of the ForeRunner, FR2, and HS1 AEDs

Overview

There are currently three families of HeartStart AED products that are in service throughout the world, each with different features and targeted for different use environments.

The ForeRunner was the first generation of AED, released in 1996 and manufactured until the year 2000. The ForeRunner was mainly intended to be used by lay rescuers and Basic Life Support (BLS) providers, but some models display the ECG, and one of these models also incorporates a manual override button.

The FR2 is the second generation of HeartStart AED and incorporates improved features like a brighter display, a longer battery life, an off-the-shelf data card, and an optional Training/Administration pack with an integrated rechargeable battery and a separate charger. The FR2 was also intended mainly for lay rescuers and BLS providers, but it contains improved advanced mode features for use by ALS trained personnel. 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.

The Philips HeartStart HS1 family of AEDs has been designed for simplified use by non-medical personnel. As a result, the HS1 AED feature set has been deliberately limited in comparison to those of the ForeRunner and FR2 devices, and has not been tested to the more stringent environmental specifications used for the FR2. The HeartStart HS1 is smaller and lighter in weight; has no display screen, data card, or voice recording capability; and incorporates pre-connected pads through a replaceable cartridge. It does record up to 15 minutes worth of ECG data internally during use. It does not have manual override capability, as it is not intended to be used in situations where a medically trained user would be likely to override the analysis system.

Feature Comparison

FORERUNNER		FR2		HS1	
THREE MODELS		TWO MODELS		THREE MODELS	
EM	ECG display with optional manual mode (manual charge and discharge).	M3860A	ECG display, programmable advanced mode options (analysis on demand, or both analysis and charge/disarm on demand).	M5066A	HeartStart OnSite
E	ECG display, no manual mode.			M5067A	HeartStart
S	No ECG display, no manual mode.			M5068A	HeartStart Home
		M3861A	No ECG display, programmable advanced mode option (analysis on demand only).		No ECG display, no display screen, no advanced mode, no manual override capability.
PRIMARY BATTERY		PRIMARY BATTERY		PRIMARY BATTERY	
capacity	Typically 100 shocks or 5 hours of operating time.	capacity	Typically 300 shocks or 12 hours of operating time.	capacity	Typically 90 shocks or 3 hours of operating time at 77° F.
standby life	Typically 1 year.	standby life	Typically 5 years.	standby life	Typically 4 years.
RECHARGEABLE BATTERY		RECHARGEABLE BATTERY		RECHARGEABLE BATTERY	
not available		capacity	Typically 100 shocks or 5 hours of ECG display time.	not available	
TRAINING/ADMINISTRATION		TRAINING/ADMINISTRATION		TRAINING/ADMINISTRATION	
training	Requires Training Card; uses standard battery; provides 8 training scripts.	training	Requires Training & Administration Pack; uses integrated rechargeable battery;* provides 10 training scripts.	training	Training cartridge uses standard battery; provides 8 training scripts.
administration	Requires Setup Card; uses standard battery.	administration	Requires Training & Administration Pack; uses integrated rechargeable battery.*	administration	IR port connection to PC running Event Review software.
			* *Battery Charger available separately*		
data transfer	No data transfer.	data transfer	Wireless (infrared) data transfer.	data transfer	Wireless (infrared) data transfer.
DEFIBRILLATION PADS		DEFIBRILLATION PADS		DEFIBRILLATION PADS	
dimensions	adult: 100 cm^2 infant/child: not available.	dimensions	adult: 100 cm^2 infant/child: 44 cm^2	dimensions	adult: 85cm^2 infant/child: 85 cm^2
deployment	Untethered, user plugs in pads.	deployment	Untethered, user plugs in pads.	deployment	Pre-connected cartridge system.

FORERUNNER	FR2	HS1
PANEL LAYOUT AND CONTROLS display — LCD display with back-lighting. contrast buttons — Small, close together. manual mode entry — Separate Manual Override button on front panel (EM only); returns to AED mode after shock delivery or manual timeout.	PANEL LAYOUT AND CONTROLS display — Brighter, higher-contrast LCD display. option buttons — Larger, spaced further apart. “advanced” mode entry — Uses Option buttons for fast patient hand-off to ALS responders; remains in advanced mode until turned off.	PANEL LAYOUT AND CONTROLS i-button — Accesses CPR instructions and other information. no advanced mode
DATA REVIEW AND MANAGEMENT PC cards — Three cards of limited capacity (ER1, typically 15 min. EC1, typically 30 min. VC1, typically 26 min.), using clock on card. data display — No on-screen review of presenting ECG.	DATA REVIEW AND MANAGEMENT data card — One cost-effective card, with significantly increased capacity (minimum 4 hrs. of event and ECG data, or 30 min. with voice), using FR2’s internal clock. data display — On-screen review of presenting ECG.	DATA REVIEW AND MANAGEMENT internal memory — Internal memory recording of approximately 15 min. of event and ECG data, no voice recording. no data card no data display

Voice Prompt Comparison

FORERUNNER	FR2	HS1
Standard Operation		
“Apply pads to patient's bare chest.“	“Apply pads to patient's bare chest.“	“Place pad exactly as shown in the picture.“
“Plug in pads connector next to flashing light.“	“Plug in pads connector next to flashing light.“	
“Apply pads.“	“Apply pads.“	
“Plug in connector.“	“Plug in connector.“ “Insert connector FIRMLY.“	
“Analyzing heart rhythm.“	“Analyzing heart rhythm.“	“Analyzing.“
“Do not touch the patient.“	“Do not touch the patient.“	“Do not touch the patient.“
“Shock advised.“	“Shock advised.“	“Shock advised.“

FORERUNNER	FR2	HS1
“Charging.“	Charging.“	
“Stay clear of patient.“	“Stay clear of patient.“	“Stay clear of patient.“
“Stand by.“	“Stand by.“	
“Deliver shock now.“	“Deliver shock now.“	“Deliver shock now.“
“Press the orange button now.“	“Press the orange button now.“	“Press the flashing orange button now.“
“Shock delivered.”	“Shock delivered.“	“Shock delivered.”
“No shock advised.“	“No shock advised.“	“Shock not advised.”
“It is safe to touch the patient.“	“It is safe to touch the patient.“	“It is safe to touch the patient.“
“Check airway, check breathing, check pulse. If needed, begin CPR.“	“Check airway, check breathing, check pulse. If needed, begin CPR.“	“Check airway, check breathing, check circulation. If needed, begin CPR.“
Troubleshooting		
“Press pads firmly to patient's bare chest“	“Press pads firmly to patient's bare chest.“	Press pads firmly to patient's bare skin.“
	“Poor pads contact.“	
“Replace pads.“	“Replace pads.“	“Pads not usable, insert new pads cartridge.“
“Analyzing interrupted.“	“Analyzing interrupted.“	“No one should touch the patient.“
“Patient and device must remain still.“	“Stop all motion.“	“Stop all motion.“
	“Cannot analyze.“	
“No shock delivered.“	“No shock delivered.“	“Shock not delivered.”
	“Shock button not pressed.”	“Shock button not pressed.”
	“Shock canceled.”	
	“If needed, press pause and begin CPR.“	
“Paused.”	“Paused.”	
“Low battery!“	“Low battery!“	“Low battery, insert fresh battery.”
“Replace battery now!“	“Replace battery now!“	“Replace battery immediately.”
“Manual Override selected.“	“Manual Override selected.“	
	“Press analyze.“	
	“Attach leads.“	
	“If needed, attach defibrillation pads.“	

Additional HS1 Voice Instructions

Topic	Instruction
Numbers	“1,” “2,”…”20,” “30,” “40,” or” “more than 40”
CPR Guidance	“b-r-e-a-t-h-e.” “Continue with compressions.” “For help with CPR, press the flashing blue button.” “For patients less than one year old, use two fingers instead of the heel of your hand.” “Keep time with the beat.” “Pinch nose, tilt head and give one small breath.” “Pinch nose, tilt head and give two full breaths.” “Place the heel of one hand in the center of the chest between the nipples.” “Place your other hand on top of the first.” “Push the chest down firmly 1 inch.” “Push the chest down firmly 2 inches.” “Stop CPR.”
Preparation	“Be sure Emergency Medical Services have been called.” “Begin by removing all clothing from the patient's chest.” “Cut clothing if needed.” “Look carefully at the pictures on the white adhesive pads.” “Make sure that the yellow plastic liner is completely removed from both pads.” “Pads must not be touching clothing or each other.” “Peel one pad from the yellow plastic liner.” “Peel the second pad from the yellow plastic liner.” “Remove all clothing from the patient's ches.t” “When the patient's chest is bare, remove protective cover and take out white adhesive pads.” “When the first pad is in place, look carefully at the picture on the second pad.”
Pads maintenance	“Adult pads.” “Adult training pads.” “Cartridge type not recognized.” “Infant/child pads.” “Infant/child training pads.” “Insert new pads cartridge.” “Insert pads cartridge.” “Install pads cartridge cover.” “No cartridge installed, insert pads cartridge.”

Topic	Instruction
Self-test	“Error.” “If the orange button is flashing, press it.” “Remove and reinsert battery to test.” “Self-test.” “Self-test incomplete, not stored in recommended temperature range.” “Testing.” “Verified.” “Shock button not verified, remove and reinsert battery to test button.” “Not ready for use.” “Ready for use.”
Status	“… until analysis will resume.” “15 seconds until analysis will resume.” “30 seconds until analysis will resume.” “45 seconds until analysis will resume.” “one minute until analysis will resume.” “two minutes until analysis will resume.” “Ending pause early.” “In case of emergency, press the green on/off button.” “No shocks.” “xxx shocks.” “yyy minutes.”
Administration	“Administration.” “Ending administration.” “Mode one.” “Mode two.” “Sending.”
Training	“Training.” “In case of emergency, remove the training cartridge and insert pads cartridge.” “Press the flashing blue button to choose the training scenario.” “Scenario XXX.”

AED Trainers

Training for the ForeRunner AED can be conducted with the defibrillator itself by installing a red Training Card (product # 04-10400), or by using the ForeRunner Trainer (product # 07-10801). Using the ForeRunner with the training card allows the user to gain experience with the real unit by going through training scenarios using training pads, but the disadvantage is that it drains the primary lithium battery. The ForeRunner Trainer does not have an active display, but it operates on 6 C-cell batteries, so it conserves the primary battery in the ForeRunner AED.

The HeartStart FR2 AED can be used for training purposes by using the Training/Administration Pack (product # M3864A). With the Training & Administration Pack inserted in the FR2, the user can go through the FR2 training scenarios listed below, using training pads, with the added advantage that the Training & Administration Pack contains rechargeable batteries, so that the defibrillator's primary battery is not drained during training. (A battery charger is available separately.) An FR2 Trainer is available for users who do not wish to dedicate a real unit for training purposes. Similar to the FORERUNNER Trainer, it does not have an active display and it operates on 6 C-cell batteries. The FR2 Trainer has the added advantages of an optional remote control and the ability to program three additional custom training scenarios using software available on the internet.

Both the ForeRunner and FR2 Trainer are less expensive than the AEDs and may be more economical for organizations conducting a lot of training.

Training for the HeartStart HS1 is conducted using a HeartStart Adult or Child/Infant training pads cartridge with the HS1 AED, which provides access to eight training scenarios.

Training scenarios for the each of the AEDs are listed in the following table.

Training Scenarios

Scenario	ForeRunner and HS1	FR2+
1	Shockable rhythm 1 shock Non-shockable rhythm	Shockable rhythm 1 shock Non-shockable rhythm
2	Shockable rhythm 3 shocks 1 minute CPR time-out 4th shock Non-shockable rhythm	Shockable rhythm Programmed shock series Programmed CPR timeout Additional shock Non-shockable rhythm
3	Poor pad connection Shockable rhythm 1 shock Non-shockable rhythm	Poor pad connection Shockable rhythm 1 shock Non-shockable rhythm
4	Shockable rhythm 1 shock Non-shockable rhythm Refibrillation - shockable rhythm 2nd shock Non-shockable rhythm	Shockable rhythm 1 shock Non-shockable rhythm Refibrillation - shockable rhythm 2nd shock Non-shockable rhythm
5	Non-shockable rhythm throughout	Non-shockable rhythm throughout

Scenario	ForeRunner and HS1	FR2+
6	Shockable rhythm 2 shocks Non-shockable rhythm	Shockable rhythm 2 shocks Non-shockable rhythm
7	Shockable rhythm 2 shocks Non-shockable rhythm Refibrillation - shockable rhythm 3rd shock Non-shockable rhythm	Shockable rhythm 2 shocks Non-shockable rhythm Refibrillation - shockable rhythm 3rd shock Non-shockable rhythm
8	Poor pad connection Shockable rhythm 2 shocks Non-shockable rhythm	Poor pad connection Shockable rhythm 2 shocks Non-shockable rhythm
9	N/A	(externally driven; responds realistically to ECG rhythm produced by a simulator or specially equipped manikin)
10	N/A	ECG rhythm with artifact Shockable rhythm 3 aborted shocks shockable rhythm battery depletion 1 shock non-shockable rhythm

Pediatric Pads

While the ForeRunner AED is recommended for use with patients over 8 years old, the HeartStart FR2 AED now has reduced-energy Infant/Child defibrillator pads available (product # M3870A) that allow the FR2 AED to be used on children under 8 years of age. These pads were designed with components built into the connector that reduce the actual energy delivered to the child. When these pads are used, the child will only receive 50 joules of energy instead of the normal adult dose of 150 joules.

The HeartStart HS1 AEDs have an Infant/Child SMART Pads cartridge available, (product # M5072A). When this cartridge is installed, the HS1 will only deliver 50 joules of energy.

11 HeartStart Data Management Software

HeartStart data management software allows the data from an 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

There are three different applications, depending on the needs of the organization. Event Review Pro 2.3 allows multiple users on a shared network to use the software and share the files. With this application, the software loads and the data resides on the user's server; the data is stored in a Microsoft Access or an SQL 7 database.

Event Review 3.0 is tailored for a single user. With this application, the software and data reside on the user's PC and no network or internet access is required. The event data is saved to the Event Review software or can be exported as a file on the user's PC that can be sent to other users as an e-mail attachment.

Event Review Express is a reduced-feature version of this software that can be downloaded from the Philips website free of charge. This version allows the user to read in the data from an incident and print out the ECG, but it does not allow the data to be saved or reports to be generated.

The table on the next page summarizes the differences between Event Review Pro 2.3 and Event Review 3.0 software.

Comparison of Event Review Pro 2.3 and Event Review 3.0

	Event Review Pro 2.3 system-wide event review	Event Review 3.0 individual code review for stand-alone PCs
access	For data sharing computer networks Software loads and data resides on user's server, network, or stand-alone PC	For single-user PC-based computer workstations Software loads and data resides on single-user PCs
features	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	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
reports	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	Provides standard pre-defined report for each patient
data storage	Stores ECG data within user's networked system on a Microsoft Access 2000 or SQL 7 database	Stores ECG data on user's PC for direct review and reporting
defibrillators supported	Heartstream or Heartstart: FR, ForeRunner, FR2/FR2+, XL, XLT, 4000	Heartstream or HeartStart: FR. ForeRunner. FR2/FR2+, HS1, XL, XLT, 4000
defibrillator configuration	Enables quick configuration of multiple 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	English
investment	$1,295 system-wide (#M3831A)	$395 (#M3834A)

System Requirements

In order for a PC to run the Event Review software, it must have the following hardware:

- Processor: Pentium III class processor or higher
- Monitor: Super VGA 256-color recommended. Resolution 800 x 600 minimum.
- Memory: 64 MB RAM minimum, 128 MB RAM recommended
- CD-ROM: 4x speed or higher

Operating Systems

Listed below are the operating systems and browsers that are supported with the Event Review software.

	Event Review Pro 2.3	Event Review 3.0
Operating System		
Windows 95	✓	
Windows 98 SE	✓	✓
Windows NT 4.0 SP4	✓	✓
Windows ME		✓
Windows 2000		✓
Windows XE		✓
Browser		
Internet Explorer 5.0	✓	
Internet Explorer 5.5	✓	
Internet Explorer 6.0	✓	

Data Card Readers

The card reader required for your system depends on three factors:

- Will the software be installed on a desktop PC or a laptop PC?
- Which operating system does the PC run?
- Which defibrillator(s) will be used?

Using the answers to these three questions, the appropriate card reader can be determined from the matrix below.

Operating System	HeartStart Defibrillator	External		Internal - PCMCIA	
		ATA Flash Kingston	Compact Flash Kingston	Linksys or SCM Micro-systems	Built in to laptop
Desktop Card Readers					
Windows 95, 98, 2000	ForeRunner, FR	N/A	N/A	✓	N/A
	FR2, FR2+	✓	✓	✓	N/A
	XL, XLT	✓	N/A	N/A	N/A
Windows NT 4.0	ForeRunner, FR	N/A	N/A	✓**	N/A
	FR2, FR2+	✓*	✓	N/A	N/A
	XL, XLT	✓	N/A	N/A	N/A
Laptop Card Readers					
Windows 95, 98, 2000	ForeRunner, FR	N/A	N/A	N/A	✓
	FR2, FR2+	✓*	✓	N/A	✓*
	XL, XLT	✓	N/A	N/A	✓
Windows NT 4.0	ForeRunner, FR	✓	N/A	N/A	✓**
	FR2, FR2+	✓*	✓	N/A	N/A
	XL, XLT	✓	N/A	N/A	N/A

* *with adapter*
** *reboot between card install*

An infrared (IR) adapter is required to communicate with the HeartStart HS1 AEDs, since they do not use a data card. Event Review 3.0 was tested with IR adapters from ACTISYS. An approved ACTISYS adapter is available from Philips Medical Systems.

Previous Data Management Software Versions

Event Review 3.0, introduced in early 2003, is intended to replace the stand-alone CodeRunner Web Express software. When Event Review 3.0 was introduced, the CodeRunner Web software was renamed Event Review Pro 2.3. Event Review 3.0 and Event Review Pro 2.3 are the current data management software packages available for purchase.

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

SOFTWARE PACKAGE	SUPPORTED DEFIBRILLATORS
CodeRunner 1.3	Heartstream ForeRunner, Laerdal FR
CodeRunner Web Express	Philips/Agilent/Hewlett-Packard Defibrillators: Heartstream ForeRunner, Heartstream FR2, HeartStart FR2+, HeartStart XL, HeartStart XLT Laerdal Defibrillators: Heartstart FR, Heartstart FR2, Heartstart 911, Heartstart 3000, Heartstart 4000, HeartStart
CodeRunner Web	Philips/Agilent/Hewlett-Packard Defibrillators: Heartstream ForeRunner, Heartstream FR2, HeartStart FR2+, HeartStart XL, HeartStart XLT Laerdal Defibrillators: Heartstart FR, Heartstart FR2, Heartstart 911, Heartstart 3000, Heartstart 4000, HeartStart
Event Review Pro 2.3	Philips/Agilent/Hewlett-Packard Defibrillators: Heartstream ForeRunner, Heartstream FR2, HeartStart FR2+, HeartStart XL, HeartStart XLT Laerdal Defibrillators: Heartstart FR, Heartstart FR2, Heartstart 911, Heartstart 3000, Heartstart 4000, HeartStart
Event Review 3.0	Philips/Agilent/Hewlett-Packard Defibrillators: Heartstream ForeRunner, Heartstream FR2, HeartStart FR2+, HeartStart XL, HeartStart XLT, HeartStart Home, HeartStart OnSite, HeartStart Laerdal Defibrillators: Heartstart FR, Heartstart FR2, Heartstart 911, Heartstart 3000, Heartstart 4000, HeartStart

System Annotations

A variety of different event annotations appear on the ECG when the 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” and “disarmed,” are less obvious and relate to the internal state of the defibrillator. Annotations that can appear on the ECG printout 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.

DISARMED - Energy has been removed from the internal capacitor. If the defibrillator is fully armed or is charging the capacitor after a shock has been advised, and a change in the patient's rhythm causes the unit to cancel the “shock advised” and return to analyzing, “disarmed” will be annotated on the ECG to indicate that some energy has been drained from the capacitor. Also, if the device gives a “no-shock advised” prompt, the “disarmed” annotation indicates that the partial charge present on the capacitor when the unit is in analyze mode has been removed.

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 transitioning back into analyze mode after completing a pause period.

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 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

Online

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.

Via Telephone

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

Appendix Troubleshooting the ForeRunner and FR2 Series AEDs

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 while the second involves user interaction. The automatic part takes about 1 minute and 20 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, “Self Test 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, “Self Test Failed,” and an error code will be displayed two lines below that consists of a single letter followed by 8 numbers; e.g., C0004 0000.

The user interaction portion of the self-test is intended to test features that cannot be tested automatically. This portion of the test takes about 1 minute, during which time 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.

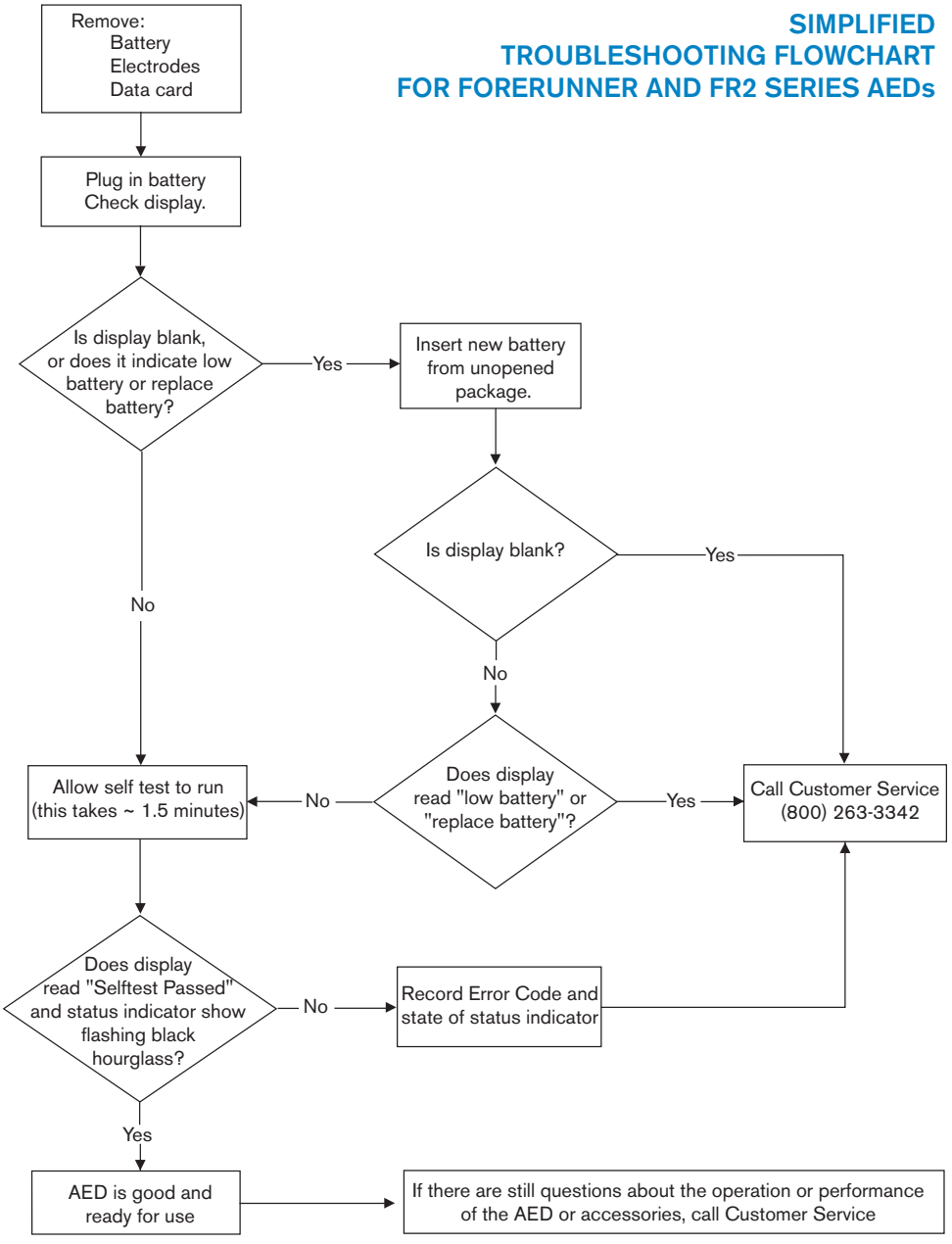
The troubleshooting flowchart on the following page is intended to verify whether the AED is in working order or if it needs to be replaced. If, after completing the battery insertion test, the unit displays a “Self Test Passed” and there is a flashing black hourglass, you can be confident that the AED meets its specifications and is ready to be used on a patient. If the AED does not display a flashing hourglass, then call Philips Customer Service at (800) 263-3342 in order 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 FORERUNNER AND FR2 SERIES AEDs



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