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Philips Medical Systems

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**Philips Medical Systems is part
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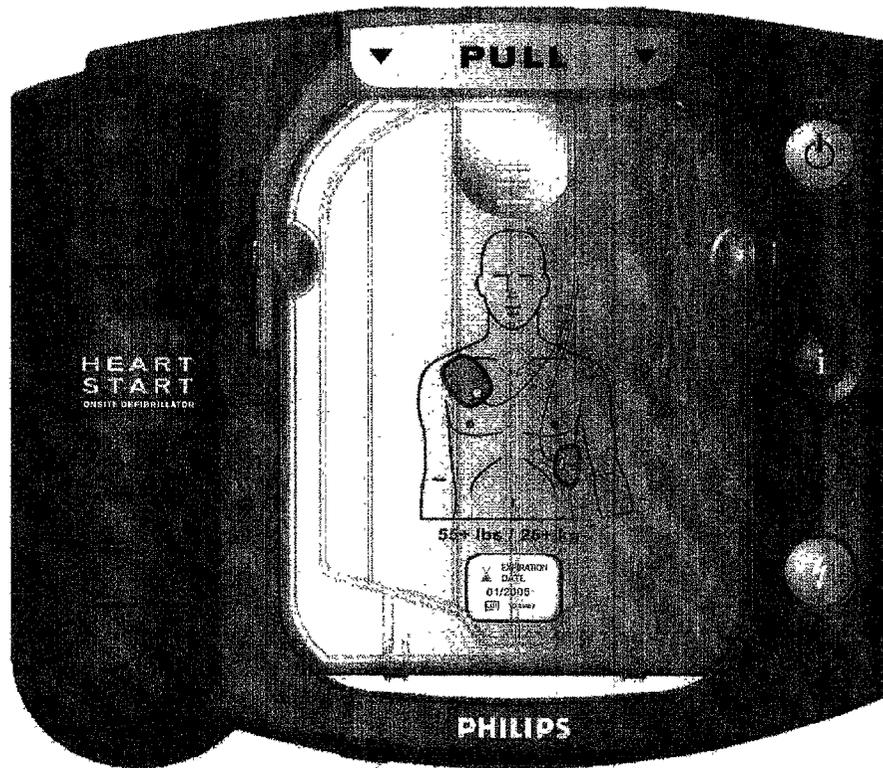
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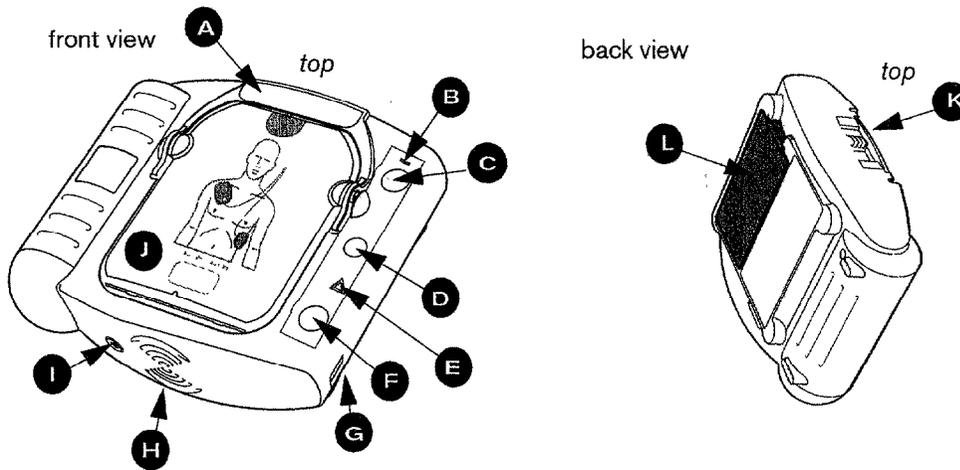
HEARTSTART
ON-SITE DEFIBRILLATOR



HEARTSTART ON-SITE DEFIBRILLATOR
INSTRUCTIONS FOR USE

PHILIPS

M5066A
Edition 4



The HeartStart OnSite Defibrillator

A PADS CARTRIDGE HANDLE. Pull the handle to turn on the HeartStart and remove the cartridge's hard cover.

B READY LIGHT. This green light tells you the readiness of the HeartStart.
 Blinking: standby mode (ready for use)
 Solid: in use
 Off: needs attention (HeartStart "chirps" and i-button flashes)

C ON/OFF BUTTON. Press this green button to turn on the HeartStart. To turn off the HeartStart, press the green button again and hold it down for one (1) second.

D INFORMATION-BUTTON. This blue "i-button" flashes when it has

information you can access by pressing it. It also flashes at the beginning of a patient care pause when CPR coaching is enabled.

E CAUTION LIGHT. This triangular light flashes during rhythm analysis and is on when a shock is advised, as a reminder that no one should be touching the patient.

F SHOCK BUTTON. When instructed by the HeartStart to deliver a shock, press this flashing orange button.

G INFRARED (IR) COMMUNICATIONS PORT. This special lens, or "eye," is used to transfer HeartStart data directly to or from a computer.

H SPEAKER. When the device is being used, its voice instructions come from this speaker.

I BEEPER. The HeartStart "chirps" through this beeper to alert you when it needs attention.

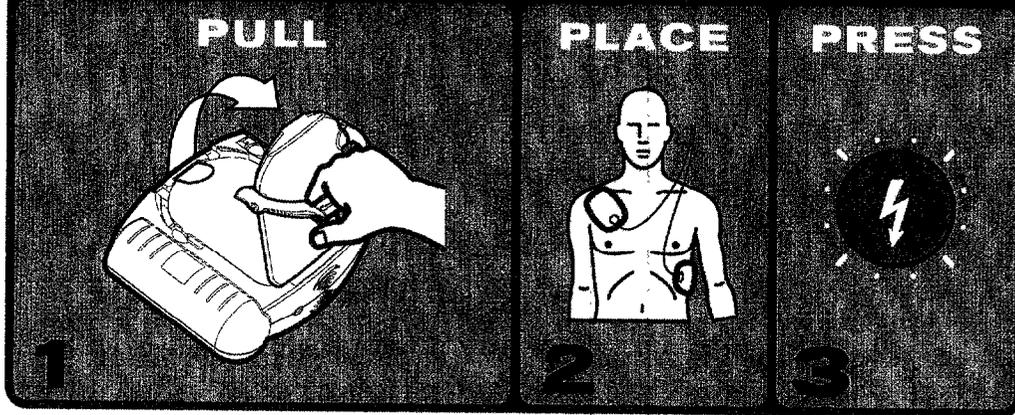
J SMART PADS CARTRIDGE. This disposable cartridge contains self-adhesive pads with attached cable.

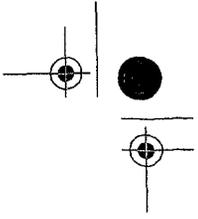
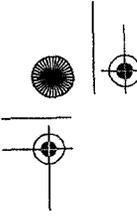
K SMART PADS CARTRIDGE LATCH. Slide the latch to the right to release the pads cartridge for replacement.

L BATTERY. The disposable battery is inserted in a recess on the back of the HeartStart.

HeartStart OnSite Defibrillator QUICK REFERENCE

IF PATIENT IS UNRESPONSIVE AND NOT BREATHING NORMALLY:

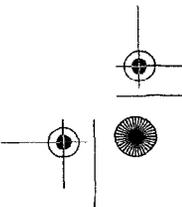
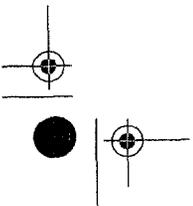




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Philips Medical Systems



HEARTSTART ONSITE M5066A Automated External Defibrillator

INSTRUCTIONS FOR USE

Edition 4

Philips Medical Systems

PHILIPS

About This Edition

The information in this guide applies to the model M5066A HeartStart OnSite Defibrillator. Its technical contents apply to all models in the HeartStart HS1 family of defibrillators. This information is subject to change. Please contact Philips at www.medical.philips.com/cms or 1.800.263.3342 for information on revisions.

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CAUTION

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

The Philips HeartStart is designed to be used only with Philips-approved accessories. The HeartStart may perform improperly if non-approved accessories are used.

Device Tracking

In the U.S.A., this device is subject to tracking requirements by the manufacturer and distributors. If the defibrillator has been sold, donated, lost, stolen, exported, or destroyed, notify Philips Medical Systems or your distributor.

Device Manufacturer

The HeartStart OnSite Defibrillator is manufactured by Philips Medical Systems, Seattle, Washington, USA.

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1 Introduction to the HeartStart OnSite Defibrillator

What is it?

The HeartStart OnSite Defibrillator is part of the HeartStart HS1 family of defibrillators by Philips. It is a small, light, easy-to-use automated external defibrillator (AED) designed for use by minimally trained individuals. It is a battery-powered first-aid device for the heart that may help you save the life of someone experiencing sudden cardiac arrest.

When is it used?

The HeartStart OnSite Defibrillator is used to treat sudden cardiac arrest (SCA), a condition that occurs when the heart unexpectedly stops pumping. SCA can occur to anyone – young or old, male or female – anywhere, at any time. Many victims have no warning signs or symptoms.

SCA is usually caused by fibrillation, a chaotic quivering of the heart muscle that prevents it from pumping blood. The only effective treatment for fibrillation is defibrillation. Using the HeartStart Defibrillator, you can deliver an electric shock to defibrillate the SCA victim's heart.

Unless effective treatment is available within minutes, the person will die. For every minute after collapse, the chances for successful defibrillation drop by about 10%.*

How do I know if I should use it?

The HeartStart OnSite Defibrillator is designed to be used on a person in sudden cardiac arrest, who is:

- unresponsive when shaken, and
- not breathing normally.

If in doubt, apply the pads.

* *AHA Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, I-61.*

What do I do if I need to use it?

Stay calm and act quickly. If someone else is available, ask them to call Emergency Medical Services while you get the HeartStart OnSite Defibrillator. If you are alone, follow these steps:

1. **Call Emergency Medical Services** (dial 911 or the local equivalent).
2. Tell the emergency operator:
"This is [GIVE YOUR NAME].
I am at [GIVE THE ADDRESS OF YOUR LOCATION].
There is someone here in sudden cardiac arrest.
I have a defibrillator. Please send help."
3. Get the defibrillator and pull the SMART Pads cartridge handle to turn it on. Follow the defibrillator's voice instructions to treat the patient.

Instructions for using the defibrillator are provided in Chapter 3, "Using the HeartStart Defibrillator."

How does it work?

As soon as you turn on the HeartStart OnSite Defibrillator, it starts talking to you, to guide you through each step. It tells you to attach the adhesive pads to the person's bare skin according to the pictures on the pads. The defibrillator uses HeartStart SMART Pads, which are placed on the person's bare skin. Each pad has a picture on it showing exactly how it should be placed. When the pads are attached, the defibrillator immediately begins to analyze the person's heart rhythm using a sophisticated computer algorithm called SMART Analysis.

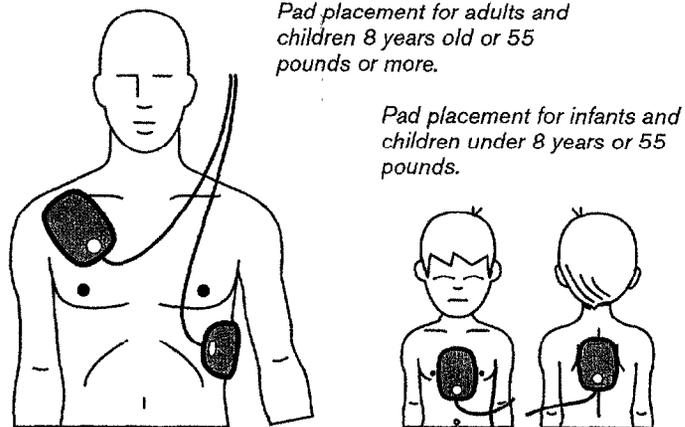
If a shock is needed, the defibrillator instructs you to push the flashing orange button . If a shock is *not* needed, it tells you so and instructs you to attend to the patient and begin cardiopulmonary resuscitation (CPR) if needed. The blue i-button  flashes, to let you know that more information is available. Push the i-button if you want step-by-step instructions in how to perform CPR.

Can I use it on a young child?

Yes. If the victim is an infant or a child younger than eight years old or weighs less than 55 pounds (25 Kg), you should use the special HeartStart Infant/Child SMART Pads. If the child appears older/larger, use the HeartStart Adult SMART Pads. **DO NOT DELAY TREATMENT TO DETERMINE THE CHILD'S EXACT AGE/WEIGHT.**

Instructions for changing the SMART Pads cartridge are provided in Chapter 5, "Maintaining the HeartStart OnSite Defibrillator."

NOTE: Pads placement for infants and young children is different than for adults and older children. Correct pad placement is shown in the illustrations below.



Who can use it?

The HeartStart OnSite Defibrillator is intended for use by people who have been specifically trained in its operation. A HeartStart OnSite Defibrillator user should also have training in cardiopulmonary resuscitation (CPR) or another physician-authorized emergency response program in accordance with local and state requirements.

More information about clinical use of the HeartStart OnSite

Contact Philips Medical Systems at 1.800.263.3342. We will be happy to answer any questions you may have and to provide you with copies of the clinical summaries of several key studies using Philips automated external defibrillators.*

IMPORTANT NOTE:

It is important to understand that survival rates for sudden cardiac arrest are directly related to how soon victims are defibrillated. For every minute of delay, the chance of survival declines by about 10%.

Defibrillation cannot assure survival, no matter how rapid the treatment. In some patients, the underlying problem causing the cardiac arrest is simply not survivable despite any available care.

* Clinical studies also included defibrillators sold as Heartstream ForeRunner and FR2.

2 Getting started with the HeartStart OnSite Defibrillator

2

HeartStart Defibrillator package contents

The HeartStart OnSite Defibrillator M5066A box contains the following items:

- 1 HeartStart OnSite Defibrillator
- 1 battery M5070A
- 2 Adult SMART Pads cartridges M5071A, each containing one set of adhesive defibrillation pads
- 1 Instructions for Use
- 1 Quick Reference

Training materials and optional accessories for the HeartStart HS1 family of defibrillators are also available from Philips. See Appendix A for a description of these items.

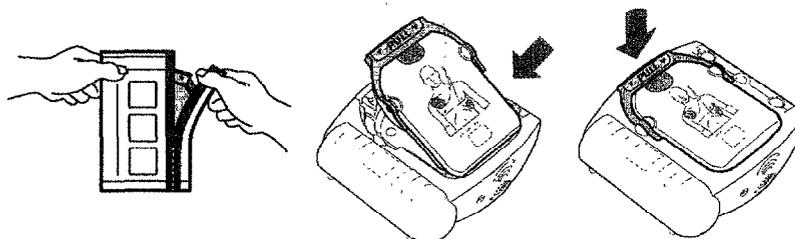
Setting up the HeartStart Defibrillator

Setting-up the HeartStart OnSite Defibrillator is simple and quick.

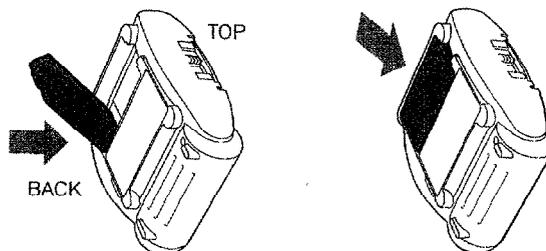
1. Remove the defibrillator from its packaging.
2. Take a moment to study the front of the device. Check the drawing and descriptions on the inside front cover of this book. Locate the controls and features of the defibrillator.

3. Remove a SMART Pads cartridge from its package and insert the cartridge firmly into the defibrillator. Be sure the green handle is pressed all the way down.

NOTE: To prevent adhesive gel from drying out, do not open the hard cover or film seal of the cartridge until ready to use the pads.



4. Remove the battery from its packaging and install it in the battery compartment on the back of the defibrillator, as shown in the drawing below.



5. The defibrillator will automatically run a self-test when the battery is inserted. Be sure to press the Shock button when instructed, to ensure that the defibrillator will be ready for use. When the self-test is over, the defibrillator will report the results, then turn off and go to standby mode. The green Ready light will be blinking to show the defibrillator is ready for use. (As long as the defibrillator has a battery and pads cartridge installed, turning it "off" puts it into standby mode, which means that it is ready for use.)
6. Be sure the Quick Reference* is placed near the defibrillator.

* The cover of the Quick Reference provides an illustrated 3-step guide to using the HeartStart. Inside are more detailed illustrated directions for reference if you are hearing impaired or operating the HeartStart where it is difficult to hear the voice instructions.

7. If you have a carrying case, place the defibrillator in the case, pressing it firmly into place. Insert the Quick Reference, face up, in the clear plastic window on the inside of the case. Place the spare SMART Pads cartridge in the storage area in the case.

2

Readiness check

If the HeartStart OnSite Defibrillator is correctly set up, it will now be in "standby mode" and the green Ready light will be blinking. This means the defibrillator has passed its most recent self-test and is therefore ready to use. To test this:

1. Press the blue i-button  on the front of the device.

The defibrillator will report the status of the unit and tell you to push the green On/Off button in case of an emergency. Do not push the green button *unless this is an actual emergency*.

2. Check the green Ready light in the upper right-hand corner of the device.

The green Ready light will be blinking. (If the green Ready light is not blinking or if the defibrillator is chirping and the blue i-button is flashing, you can press the i-button  and the defibrillator will tell you what is wrong and what to do about it. See Chapter 6, "Testing and Troubleshooting the HeartStart OnSite Defibrillator," for troubleshooting guidelines.)

Training and practice

A HeartStart OnSite Defibrillator user should complete cardiopulmonary resuscitation (CPR) and defibrillator use training or another program authorized by the Medical Director. Several national and local organizations offer combined CPR/defibrillator training. Contact your Philips Medical Systems representative, or visit us on-line at www.medical.philips.com/cms, for information about training programs in your area.

NOTE: Training accessories are available from Philips Medical Systems for practicing use of the HeartStart OnSite Defibrillator. See Appendix A for information on ordering the training pads cartridges.

Storing the HeartStart Defibrillator

Store the HeartStart OnSite Defibrillator in a high-traffic area that is easy to get to. It should be a place that is convenient for you to check the Ready light periodically, and where you can hear the alarm chirp if the battery power gets low or the defibrillator needs attention.

Ideally, the defibrillator should be stored near a telephone, so you can contact Emergency Medical Services as fast as possible. It is recommended that you keep the spare SMART Pads cartridge and other accessories with the defibrillator, in the carry case if one is used, for quick access when needed.

In general, treat the HeartStart as you would any piece of sophisticated electronic equipment, such as a computer. Store the defibrillator where the temperatures stay between 50° and 109° F (10° and 43° C). *Do not keep the HeartStart in the trunk of a car for long periods if you live in a very hot or cold climate.*

NOTE: If you have a training pads cartridge, it is recommended that you store it separately from the HeartStart, so the training pads cannot be confused with the regular pads in an emergency.

3 Using the HeartStart OnSite Defibrillator

Steps for using the HeartStart Defibrillator

First, try to relax and stay calm. The HeartStart OnSite Defibrillator automatically talks you through each step of its use. Time is very important in treating SCA, so you must act swiftly but stay calm so you can follow the HeartStart's instructions carefully.

If there is any delay in getting the defibrillator to the patient's side, check the patient and perform cardiopulmonary resuscitation (CPR) if needed.

Remember, the first thing to do if someone collapses is to call Emergency Medical Services (usually 911). Then quickly get the HeartStart OnSite Defibrillator and bring it to the victim's side.

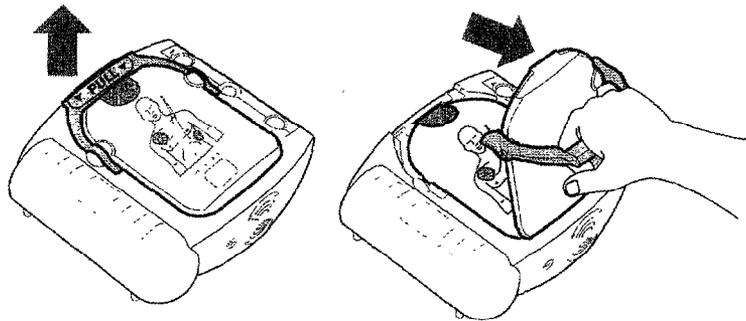
There are three basic steps to using the defibrillator to treat someone who may be in sudden cardiac arrest:

1. PULL up the handle on the SMART Pads cartridge.
2. PLACE the pads on the patient's bare skin.
3. PRESS the flashing Shock button  if instructed.

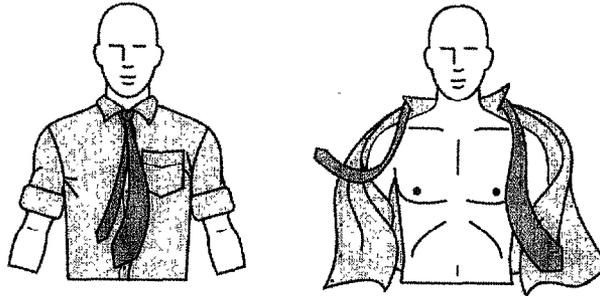
The following pages provide details about each step. At the end of this chapter are some important warnings and precautions.

STEP 1: PULL the green handle

Turn on the defibrillator by pulling the SMART Pads cartridge's green handle.* Remove the hard cover from the pads cartridge and set it aside. Remain calm and follow the defibrillator's instructions.



The defibrillator will direct you to remove all clothes from the person's chest.

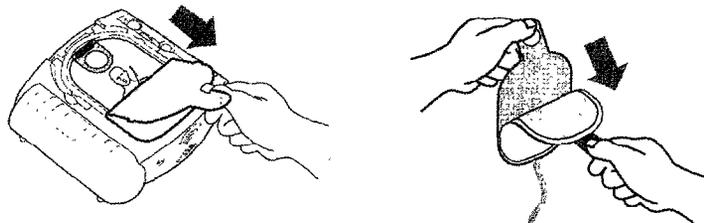


- Reminders:**
- *Time is very important in treating SCA. Don't waste time trying to remove clothing neatly. If necessary, rip or cut off the clothing to bare the person's chest. If you are treating a young child, remove all clothing from the torso to permit placing one pad in the center of the child's back.*
 - *Be sure to move any flammable gases from the area near the patient before applying the defibrillator. However, it is safe to use the HeartStart OnSite Defibrillator on someone who has an oxygen mask in place.*

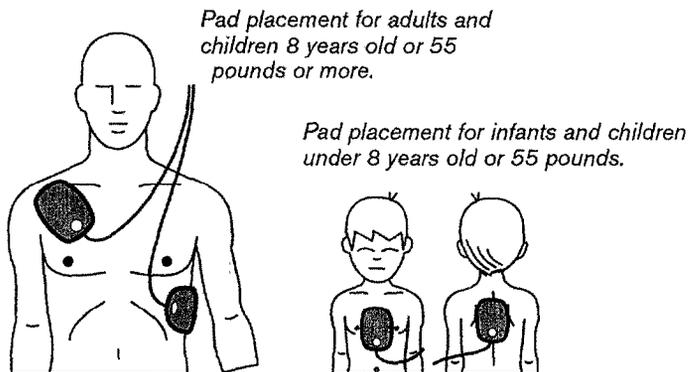
* You can also turn on the HeartStart OnSite Defibrillator by pressing the green On/Off button.

STEP 2: PLACE the pads

Pull the tab at the top of the pads cartridge to peel off the film seal. Inside are two adhesive pads on a plastic liner. Remove the pads from the cartridge.



Peel one pad off the liner. Place the pad on the person's bare skin, exactly as shown in the picture on the pad. Press the pad down firmly. Then repeat this with the other pad. Be sure the pads have been removed from the liner before placing them.



Pad placement for adults and children 8 years old or 55 pounds or more.

Pad placement for infants and children under 8 years old or 55 pounds.

Reminders:

- *It may be necessary to dry the patient's skin, or to clip or shave excessive chest hair, in order to provide good contact between the pads and the skin.*
- *Remove any medicine patches and any residual adhesive before applying the pads.*
- *If needed, dry the skin where the pads will be placed.*
- *If the pads do not stick well, check that the pads adhesive has not dried out. The pads must have good contact with the patient's skin. The pads have a layer of adhesive gel under the plastic liner. If the gel is not sticky to the touch, insert a new pads cartridge.*

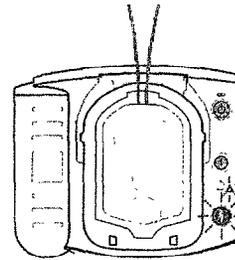
STEP 3: PRESS the Shock button

As soon as the HeartStart OnSite Defibrillator detects that the adhesive pads are attached to the patient, it begins analyzing the patient's heart rhythm. It tells you that no one should be touching the patient, and the Caution light  begins flashing as a reminder.



If a shock is not needed, the defibrillator tells you it is safe to touch the patient and instructs you to assess the patient and perform CPR if needed. The blue i-button  will come on during this patient care pause.

If a shock is needed, the Caution light  turns on, the orange Shock button  will start flashing, and the defibrillator will tell you to press the flashing orange button. When you press the Shock button, the defibrillator will tell you that the shock has been delivered. Then it automatically analyzes the heart rhythm again to see if another shock is needed.



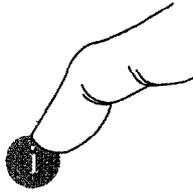
Reminders:

- *It is important to keep the patient still and to keep any movement around the patient to a minimum during rhythm analysis. Do not touch the patient or the pads while the Caution light  is on solid or flashing. If the device is unable to analyze due to electrical "noise," it will instruct you to stop all movement and remind you not to touch the patient. Should the artifact continue for over 30 seconds, the defibrillator will wait 30 seconds to allow you to deal with the source of the noise, then resume analysis.*
- *The HeartStart OnSite Defibrillator will not deliver a shock unless you press the flashing orange Shock button . If you do not press the Shock button within 30 seconds after the it tells you to, the defibrillator will disarm itself. After a short pause, it will reanalyze the patient's heart rhythm.*
- *While waiting for you to press the Shock button, the defibrillator will continue to analyze the heart rhythm. If the patient's rhythm changes before you press the Shock button, and a shock is no longer needed, the defibrillator will disarm and tell you a shock is not advised.*

- If for any reason you want to turn off the defibrillator, you can press the On/Off button  — holding it down for at least one second — to return the device to standby mode.

Performing CPR

When instructed by the HeartStart OnSite Defibrillator, assess the patient and perform CPR if needed. The defibrillator will tell you to press the blue i-button if you want coaching on how to perform CPR. You must press the i-button within 30 seconds for CPR coaching.



NOTE: If you press the i-button for CPR coaching, the defibrillator will not perform background monitoring during the CPR pause, even if configured for the SMART NSA pause. See Appendix F for information on the NSA pause.

When the pause is over, the defibrillator will tell you to stop CPR, so it can analyze the patient's heart rhythm. The motion caused by CPR can interfere with analysis, so be sure to stop all motion when instructed.

When emergency medical services arrive

When Emergency Medical Services personnel arrive to care for the patient, they may decide to apply another defibrillator to allow monitoring of the patient. *The HeartStart OnSite Defibrillator's pads should be removed from the patient prior to using another defibrillator.*

Emergency Services personnel may want a summary of the last-use data* stored in the HeartStart OnSite Defibrillator. It gives a spoken summary of the data if the i-button  is held down until the device beeps.

* See Chapter 4, "After Using the HeartStart OnSite Defibrillator," for details about data storage.

WARNINGS AND PRECAUTIONS

WARNING: There is a possibility of explosion if the defibrillator is used in the presence of flammable anesthetics or concentrated oxygen. However, it is safe to use the HeartStart OnSite Defibrillator on someone who has an oxygen mask in place.

WARNING: The electrical energy used to shock the heart can cause operator or bystander injury. Do not touch the patient during the shock.

WARNING: Handling or transporting the patient during heart rhythm analysis can cause an incorrect or delayed diagnosis. If the defibrillator gives a **SHOCK ADVISED** prompt during such handling or transport, stop the vehicle and keep the patient as still as possible for at least 15 seconds before pressing the Shock button, to allow the defibrillator to reconfirm the rhythm analysis.

WARNING: Do not allow the defibrillation pads to touch each other or ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may also divert the defibrillation current away from the heart.

PRECAUTION: During defibrillation, air pockets between the skin and adhesive pads can cause patient skin burns. To help prevent air pockets, make sure adhesive pads completely adhere to the skin.

PRECAUTION: CPR during rhythm analysis can cause incorrect or delayed analysis by the HeartStart.

PRECAUTION: Aggressive handling of the pads prior to or during use can damage the pads. Discard the adhesive pads if they become damaged and insert another pads cartridge in the defibrillator.

4 After using the HeartStart OnSite defibrillator

Overview

The HeartStart OnSite Defibrillator automatically stores data about its last clinical use in its internal memory. Your Emergency Medical Services provider or physician may want to check this information after each use.

As described later in this chapter, the stored data can be conveniently transferred to a personal computer running HeartStart Event Review data management software (version 3.0 or higher).

The HeartStart OnSite Defibrillator's internal clock measures the elapsed time since the last battery insertion. It does not record local time. HeartStart Event Review software can calculate the local time *if the defibrillator's battery is not removed prior to data transfer*. Therefore, if **absolute timing** (based on the local time) is required, do not remove the battery until after data transfer has been done. In most cases, the **relative timing** (elapsed time between last battery installation and each of the stored events of the subsequent use) is adequate for data review. If relative timing is adequate and you do not have another cartridge available, or if you want to send the defibrillator to a data administrator for a data download, then remove the battery to preserve the data.

HeartStart data storage

The information automatically stored by the HeartStart OnSite Defibrillator includes detailed data about its last clinical use and a summary of last-use data.

Summary data

You can get a voice summary of information about the last use of the defibrillator by holding the blue i-button  down until it beeps once. The device will tell you how many shocks were delivered and how long it has

been since the defibrillator was turned on. This information is also included in the data transferred using HeartStart Event Review software.

The summary is available when the defibrillator is ready for use (the battery and pads cartridge are in place, and the defibrillator is not turned on) or while it is actually in use. Removing the battery erases the summary data for the last use.

Last-use data

Data about the incident when the defibrillator was last used are stored in its internal memory. This information includes:

- ECG recordings (a maximum of 15 minutes following pads application*)
- the HeartStart's status (entire incident)
- the HeartStart's rhythm analysis decisions (entire incident)
- the elapsed time associated with stored events[†] (entire incident)

NOTE: Your HeartStart OnSite Defibrillator will retain status and rhythm analysis data in defibrillator memory for at least seven years of typical use. 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 defibrillator 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.

After each use

1. Check the outside of the defibrillator for signs of damage, dirt, or contamination. If you see signs of damage, contact Philips Medical

* If ECG recordings from a previous use have not been erased, the maximum time for new ECG recordings may be less.

† As described earlier in this chapter, if you leave the battery in the HeartStart OnSite Defibrillator after using the defibrillator, then transfer the data to a computer running HeartStart Event Review software, the software will calculate the local time.

- Systems for technical support. If the defibrillator is dirty or contaminated, clean it according to the guidelines in Chapter 5, "Maintaining the HeartStart OnSite Defibrillator."
2. Install a new SMART Pads cartridge in the defibrillator. Check supplies and accessories for damage and expiration dating. Replace any used, damaged or expired items.
 3. Remove the battery for five seconds, then reinstall it to run the battery insertion self-test to check the operation of the defibrillator. (Do not remove the battery if absolute timing is required for the event review report.) When the test is complete, check that the green Ready light is blinking.
 4. Transfer the data to a computer running HeartStart Event Review software, according to the directions provided later in this chapter. This software will then allow you to erase the last-use ECG recordings so that your HeartStart OnSite Defibrillator can record the next-use ECG for the maximum 15 minutes.
 5. Reinstall the unused SMART Pads cartridge when data transfer is complete. If the battery has been left in place to provide absolute timing, remove the battery for five seconds, then reinstall it to run the battery insertion self-test. Be sure the green Ready light is blinking to show that the defibrillator is ready for use.
 6. Return the defibrillator to its normal location so it will be ready for use when needed.

Data transfer

The HeartStart OnSite Defibrillator is designed to make it easy for physicians and emergency medical personnel to manage incident data. There is an infrared (IR) communications port located on the lower right side of the device. The port is used to transfer data to a personal computer running HeartStart Event Review software, version 3.0 or higher. This software allows storage and review of the recorded information, as well as transfer of any revised configuration settings to the defibrillator.*

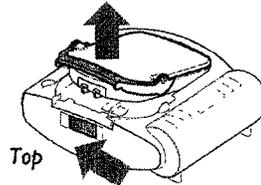
* For detailed directions, see the *Instructions for Use* for HeartStart Event Review.

To review the recorded data, your medical provider will need:

- A computer loaded with HeartStart Event Review software version 3.0 or higher from Philips Medical Systems. (This software is for use by trained personnel only. Information about HeartStart Event Review software is available on the internet at [http://www.medical.philips.com/goto/eventreview.](http://www.medical.philips.com/goto/eventreview))
- An infrared data cable, available from Philips Medical Systems.

To transfer the data, start the HeartStart Event Review program, select the option to load data from defibrillator, and follow these steps:

1. Be sure the infrared cable is connected to the computer and the cable's eye is aligned with (in the line-of-sight of) the infrared (IR) communications port on the right side of the defibrillator.
2. Slide the latch at the top of the defibrillator to release the pads cartridge, and remove the cartridge.
3. Press the blue i-button  and hold it down until the defibrillator chirps a total of three times. It will tell you that it is in the Administration mode.
4. Press the blue i-button  again briefly, and the defibrillator will announce that it is in Mode One, which means it is ready to transfer the stored data to the computer. Make sure the cable's IR eye and the IR communications port are still aligned.
5. Follow the directions in HeartStart Event Review to transfer the data.
6. When data transfer is complete, reinstall the pads cartridge. This will turn off the defibrillator and return it to its standby mode, ready for use.



5 Maintaining your HeartStart OnSite Defibrillator

HeartStart maintenance

Your HeartStart OnSite Defibrillator is very simple to maintain. As described in Chapter 6, "Testing and Troubleshooting Your HeartStart OnSite Defibrillator," the defibrillator performs a self-test every day. In addition, a battery insertion self-test is run whenever you install a battery in the device.

The defibrillator's extensive automatic self-test features eliminate the need for any manual calibration. It has no user-serviceable parts.

WARNINGS AND PRECAUTIONS

PRECAUTION: *Improper maintenance may damage the defibrillator or cause it to function incorrectly. Maintain the defibrillator only as described in this manual. Testing the device with equipment not authorized by Philips Medical Systems may damage the defibrillator and will invalidate the product warranty. If your organization requires manual testing of this device, contact Philips Medical Systems for instructions.*

PRECAUTION: *Electrical shock hazard. Dangerous high voltages and currents are present. Do not open the defibrillator housing or attempt repair.*

PRECAUTION: *Do not attempt to charge the HeartStart battery M5070A. It is not a rechargeable battery.*

Periodic checks

Other than the checks described in Chapter 4, "After Using Your HeartStart OnSite Defibrillator," user maintenance is limited to periodic performance of the following tasks:

- Check the green Ready light. If the green Ready light is not blinking, consult Chapter 6, "Testing and Troubleshooting Your HeartStart OnSite Defibrillator," for recommended action.
- Check supplies and accessories for damage and expiration dating. Replace any used, damaged or expired items.

- Check the outside of the defibrillator for cracks or other signs of damage. If you see signs of damage, contact Philips Medical Systems for technical support.

Changing the pads cartridge

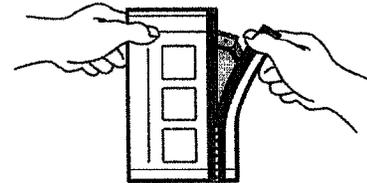
There are four kinds of HeartStart pads cartridges designed for use with your defibrillator: HeartStart Adult SMART Pads, HeartStart Infant/Child SMART Pads, reusable HeartStart Adult Training Pads, and reusable HeartStart Infant/Child Training Pads.

Adult adhesive SMART Pads are intended for any patient eight years or older, or weighing 55 pounds (25 kilograms) or more. Infants and younger or smaller children should be treated using the HeartStart Infant/Child adhesive SMART Pads.

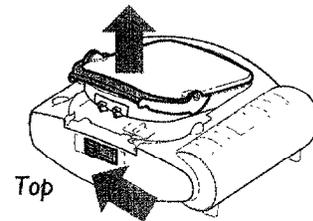
The HeartStart training pads are for practicing how to use your HeartStart OnSite Defibrillator. **They cannot be used to treat sudden cardiac arrest. Do not store the training pads with your HeartStart OnSite Defibrillator.**

To change the pads cartridge, or to replace an expired pads cartridge, follow these steps:

1. Remove the new cartridge from its package.

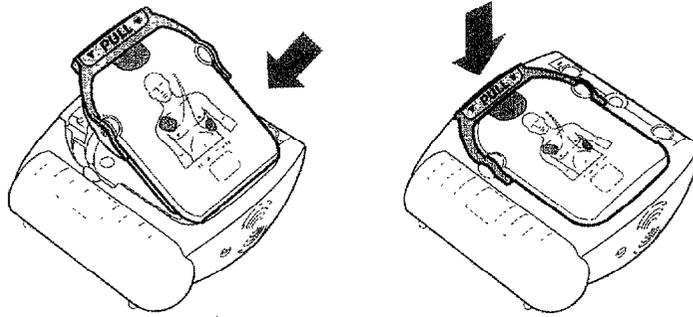


2. Locate the latch at the top edge of the defibrillator, and slide it to the side. The pads cartridge will be released. Remove the old cartridge.



3. Install the new cartridge: slide the bottom end of the cartridge into the recess, then press in the cartridge until the latch clicks into place. Be

sure the green handle is pressed down firmly. The defibrillator will tell you what kind of pads (Adult, Infant/Child, Adult Training, Infant/Child Training) have been inserted, then it will turn off to be ready for use.



4. Remove the battery for at least 5 seconds, then reinsert it to run a self-test. (If for any reason the self-test does not pass, press the blue i-button for information and refer to the Troubleshooting information in Chapter 6.)
5. Check the green Ready light to make sure it is blinking. Your HeartStart OnSite Defibrillator is ready for use.

Reminders:

- Do not remove the hard cover or film seal from the pads cartridge until you need to use the pads.
- Do not leave your defibrillator without a HeartStart Adult or Infant/Child adhesive pads cartridge inserted. After about one minute without a pads cartridge installed, the defibrillator will start chirping and the i-button will start flashing.

5

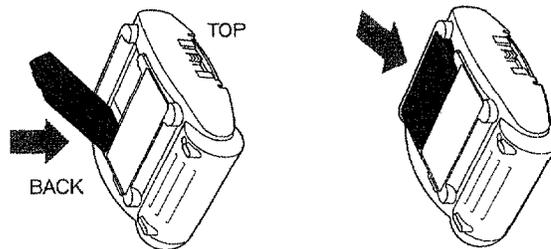
Replacing the battery

Your HeartStart OnSite Defibrillator is equipped with a disposable, long-life battery that will typically last for four years in the standby mode. It is recommended that you keep a spare battery available at all times. *Keep the spare battery in its protective plastic bag until it is needed for use.*

When the battery power gets low, the defibrillator will alert you in several ways: it will begin chirping, the green Ready light will stop blinking, and the blue i-button  will start flashing.

To replace the battery:

1. Make sure you have a pads cartridge installed in the defibrillator.
2. Locate the battery compartment on the back of the defibrillator.
3. Press the tab attached to the top of the battery to release the catch. Remove the battery.
4. Slide a new battery into place. Check to see that its latch is holding it in place.



5. A battery insertion self-test will automatically run. It is important to press the Shock button when instructed, to ensure that the defibrillator will be ready for use. When it is done, make sure the green Ready light is blinking. Your HeartStart OnSite Defibrillator is ready for use.

- Reminder:**
- *As long as the green Ready light is blinking, it is NOT necessary to test the defibrillator. The self-test uses battery power, and running the battery insertion self-test more often than necessary will drain the battery prematurely.*

Cleaning your HeartStart OnSite Defibrillator

The outside of your HeartStart OnSite Defibrillator and its case can be cleaned with a soft cloth dampened in one of the cleaning agents below:

- Soapy water
- Chlorine bleach (2 tablespoons per quart or liter of water)
- Ammonia-based cleaners

- Reminders:**
- *Do not use isopropyl (rubbing) alcohol, strong solvents such as acetone or acetone-based cleaners, abrasive materials, or enzymatic cleaners to clean your HeartStart.*
 - *Do not immerse the defibrillator in fluids or allow fluids to spill onto it. Do not sterilize the defibrillator or its accessories.*

6 Testing and troubleshooting the HeartStart OnSite defibrillator

Testing

The HeartStart OnSite Defibrillator automatically tests itself every day and alerts you if it finds a problem. In addition, it runs a pads self-test each time a pads cartridge is inserted. You can also test the defibrillator at any time by removing the battery for five seconds then reinstalling it. (As explained later in this chapter, the battery insertion self-test is not recommended except under certain circumstances.)

Periodic self-tests

The HeartStart OnSite Defibrillator automatically performs various daily, weekly, and monthly self-tests. These periodic self-tests check many important functions of the defibrillator, including battery capacity, internal circuitry, and the pads readiness for use. As long as the self-test is passed, the green Ready light continues to blink as usual. If any part of a test fails, the defibrillator chirps, the green Ready light goes off, and the blue i-button  flashes. Press the i-button for information.

NOTE: The HeartStart OnSite Defibrillator self-tests are designed to check that it is ready for use. However, in the event that the defibrillator has been dropped or mishandled, it is recommended that you run a battery insertion self-test by removing the battery for five seconds then reinserting it. If the defibrillator has visible signs of damage, contact Philips Medical Systems for technical support.

Pads identification self-test

The defibrillator automatically runs a pads self-test when you insert a new pads cartridge. This test verifies the cartridge's identity and that the cartridge is correctly installed. (See Chapter 5, "Maintaining the HeartStart OnSite Defibrillator," for directions on installing the pads cartridge correctly.)

If the defibrillator identifies the pads as Adult, Infant/Child, Adult Training, or Infant/Child Training pads, it then automatically turns off and goes into standby mode to be ready for use. If the pads identification self-test fails, the defibrillator chirps, the green Ready light does not blink, and the device tells you that the pads are unusable and a new cartridge should be inserted.

Battery insertion self-test

When you insert the battery in the defibrillator, a self-test will automatically run. This test takes about one minute. If you need to use the defibrillator in an emergency, pull the SMART Pads cartridge handle to stop the test and turn on the HeartStart for use.

NOTE: Under certain circumstances, the behavior of the defibrillator will be different. For example, the self-test will not run when a battery is inserted if:

- *the adhesive pads cartridge is not installed properly (with the hard cover in place), or*
- *the battery power is low or totally depleted.*

Because the battery insertion self-test is very detailed and uses battery power, running it more often than necessary will drain the battery prematurely. It is recommended that you run the battery insertion self-test only:

- when the defibrillator is first put into service.
- after each time the defibrillator is used to treat a patient.*
- when the battery is replaced.
- when the SMART Pads cartridge is replaced.
- when the defibrillator may have been damaged.

NOTE: If you open the pads cartridge during the battery insertion self-test, the test will stop but the defibrillator will not turn off, so you can use it immediately.

* See Chapter 4, "After Using the HeartStart OnSite Defibrillator," for directions on transferring data after using the device.

If the self-test passes, the defibrillator tells you the test has passed, the green Ready light begins blinking, and the defibrillator turns off and is ready for use. If the self-test does not pass, the defibrillator gives you a status message and instructions. It then starts chirping, the green Ready light does not blink, and the blue i-button  starts flashing. Press the i-button for information. If following the defibrillator's instructions does not clear the problem, refer to the Troubleshooting information, below.

NOTE: If the defibrillator tells you to remove and reinsert the battery, be sure to remove it for at least five seconds before reinserting it.

NOTE: If the voice prompts cannot be clearly heard or the Shock button is not verified when pressed during the battery insertion test, contact Philips Medical Systems for technical support.

Troubleshooting

The HeartStart OnSite Defibrillator's green Ready light is the signal that tells you if the defibrillator is ready for use. The defibrillator also uses chirps and the i-button  flashes to alert you to a problem.

NOTE: Perform CPR (if needed) any time there is a delay before the defibrillator can be used.

Readiness summary

| BEHAVIOR | MEANING |
|--|--|
| green Ready light blinks | The defibrillator passed the battery insertion self-test and the last periodic self-test and is therefore ready for use. |
| green Ready light is on | The defibrillator 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. |
| red light blinks HeartStart flashes I-button flashes I-button does not flash | There is no battery inserted, the battery is depleted, or the defibrillator needs repair. |

Recommended action during an emergency

If for any reason the defibrillator does not turn on when you pull the SMART Pads cartridge handle:

1. Press the On/Off button . If that does not turn on the defibrillator, then
2. remove the battery for five seconds, then reinsert it or replace it with a new battery if available. After installing the battery, press the On/Off button again to turn on the defibrillator.

If the problem continues, do not use the defibrillator. Attend to the patient, providing CPR if needed, until emergency medical personnel arrive.

Troubleshooting while the defibrillator is being used

(green Ready light is solid)

| DEFIBRILLATOR TELLS YOU: | POSSIBLE CAUSE | RECOMMENDED ACTION |
|---|---|---|
| ... to replace the battery immediately | The battery is nearly depleted. The defibrillator will turn off if a new battery is not inserted. | Replace the battery with a new battery immediately. |
| ... to insert a new pads cartridge | <ul style="list-style-type: none"> The pads cartridge has been removed. The pads cartridge has been damaged. | Insert a new pads cartridge. |
| ... to press the pads firmly to the skin ... to make sure the pads have been removed from the liner ... the pads should not be touching the patient's clothing. | <ul style="list-style-type: none"> The pads are not properly applied to the patient. The pads are not making good contact with the patient's bare chest because of moisture or excessive hair. The pads are touching each other. The pads may not have been removed from the liner. The pads may be on the patient's clothing. | <ul style="list-style-type: none"> Make sure that the pads are sticking completely to the patient's skin. If the pads are not sticking, dry the patient's chest and shave or clip any excessive chest hair. Reposition the pads. If the voice instruction continues after you do these things, insert another pads cartridge. |
| ... to insert a new pads cartridge | The pads cartridge has been opened and the pads peeled off the liner, but the pads have not been successfully attached to the patient. There may be a problem with the pads cartridge. | Replace the damaged or defective pads cartridge. Pull up the handle on the cartridge cover and replace pads on patient with new pads to continue with the rescue. |

| DEFIBRILLATOR TELLS YOU: | POSSIBLE CAUSE | RECOMMENDED ACTION |
|---|--|---|
| <p>to stop all motion</p> | <ul style="list-style-type: none"> • The patient is being moved or jostled. • The environment is dry and movement around the patient is causing static electricity to interfere with ECG analysis. • Radio or electrical sources are interfering with ECG analysis. | <ul style="list-style-type: none"> • Stop CPR; do not touch the patient. Minimize patient motion. If the patient is being transported, stop the vehicle. • Responders and bystanders should minimize motion, particularly in dry environments that can generate static electricity. • Check for possible causes of radio and electrical interference and turn them off or remove them from the area. |
| <p>the shock was not delivered</p> | <ul style="list-style-type: none"> • The pads may not be making good contact with the patient's skin. • The pads may be touching each other. • The pads may be defective. | <ul style="list-style-type: none"> • Press the pads firmly to the patient's chest. • Make sure the adhesive pads are correctly positioned on the patient. • Replace the pads if necessary. |
| <p>the shock button was not pressed</p> | <p>Shock has been advised but the shock button has not been pressed within 30 seconds.</p> | <p>When next prompted, press the Shock button to deliver shock.</p> |

Troubleshooting while the defibrillator is not being used

(green Ready light is *not* on)

| BEHAVIOR | POSSIBLE CAUSE | RECOMMENDED ACTION |
|--|--|---|
| <p>chirps or i-button flashes</p> | <ul style="list-style-type: none"> • The battery power is low or the SMART Pads cartridge needs to be replaced. • The defibrillator may have been turned off without a pads cartridge installed, or the installed pads cartridge may not have its hard cover in place. • The training pads cartridge has been left in the defibrillator. • The defibrillator has been stored outside the recommended temperature range. • The defibrillator has detected an error during a self-test or cannot perform a self-test. • Shock button is defective. | <ul style="list-style-type: none"> • Press the blue i-button. Replace the battery or pads cartridge if instructed. • Make sure the pads cartridge is properly installed with the hard cover in place. (See Chapter 5, "Maintaining the HeartStart OnSite Defibrillator," for directions on installing the pads cartridge.) • Remove the training pads cartridge and replace it with an Adult or Infant/Child Pads Cartridge. • Remove the battery for five seconds then reinstall it to start the battery insertion self-test. If it fails, insert a new battery to repeat the test. If it fails again, do not use the defibrillator. If it passes, store the defibrillator within the recommended temperature range. • Contact Philips Medical Systems for service if needed. |
| <p>no charging and i-button does not flash</p> | <ul style="list-style-type: none"> • The battery is missing or completely depleted. • The defibrillator may have been physically damaged. | <p>Remove the battery for five seconds then reinstall it to start the battery insertion self-test. If it fails, insert a new battery and repeat the test. If it fails again, do not use the defibrillator. Contact Philips Medical Systems for service.</p> |



Notes



A Accessories for the HeartStart OnSite Defibrillator

Standard accessories

Accessories for the HeartStart OnSite Defibrillator available separately from Philips Medical Systems include:

- Spare battery M5070A (recommended)
- Spare Adult SMART Pads Cartridge M5071A (recommended)
- Infant/Child SMART Pads Cartridge M5072A
- Adult Training Pads Cartridge M5073A
- Infant/Child Training Pads Cartridge M5074A
- Standard carry case M5075A, with paramedics scissors and room for spare pad cartridge and battery
- Slim carry case M5076A, with paramedics scissors
- Infrared cable ACT-IR for use with HeartStart Event Review software
- Fast Response Kit 68-PCHAT (pouch containing a pocket mask, a disposable razor, 2 pairs of gloves, a pair of paramedics scissors, and an absorbent wipe)
- HeartStart Event Review M3834A data management software
- HeartStart Defibrillator Quick Reference M5066-97800
- HeartStart Defibrillator Instructor's Training Toolkit M5066-89100

To order any of these and other accessories, call the your Philips Medical Systems representative or visit us on-line at www.medical.philips.com/cms.

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Suggested additional items

It may be useful to keep some additional items with your HeartStart OnSite Defibrillator for possible use when an incident occurs. In addition to the following suggested supplies, your physician may have other requirements.

- a pair of paramedic's shears or scissors*
- a disposable razor designed for removing chest hair*
- a pocket mask or face shield*
- disposable gloves*
- a towel or antiseptic wipes*
- a source of oxygen

* Contained in the Fast Response Kit from Philips Medical Systems.

B Technical information

Clinical studies synopsis

The HeartStart OnSite uses the SMART Biphasic and SMART Analysis technologies used in the HeartStart FR2 and ForeRunner AEDs, as demonstrated in multiple clinical studies. The following summarizes these clinical studies.* For more detailed information, refer to the *Technical Reference Manual* for HeartStart Automated External Defibrillators, located online at www.medical.philips.com.

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

In an international, multicenter, prospective, randomized clinical study, the effectiveness of the SMART Biphasic waveform in out-of-hospital sudden cardiac arrests (SCAs) as compared to monophasic waveforms was assessed. 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) ($p=0.01$). Survival to hospital discharge was 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

In a multicenter study, an ECG database of shockable and non-shockable rhythms from a broad range of pediatric patients was developed and then used to test the accuracy of the HeartStart Patient Analysis System (PAS) for sensitivity and specificity with those rhythms. 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 (71% vs. 75%). This study indicates that the HeartStart Patient

* Clinical studies also included defibrillators sold as Heartstream ForeRunner and FR2.

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B-2

Analysis System can be used safely and effectively for both adults and children.

HeartStart Defibrillation Therapy Testing in a Pediatric Animal Model

The HeartStart OnSite defibrillator used with infant/child SMART 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 (2) animal studies were conducted to demonstrate the safety and effectiveness of the HeartStart biphasic waveform at 50 J in a pediatric animal model across the weight range of the intended patient population. These studies demonstrated that fixed 50 J HeartStart 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.

HeartStart OnSite Defibrillator specifications

The specifications provided in the following tables are nominal values. Additional information can be found in the *Technical Reference Manual* for HeartStart Automated External Defibrillators, located online at www.medical.philips.com.

Physical

| CATEGORY | SPECIFICATIONS |
|----------|---|
| size | 2.80" H x 7.40" D x 8.30" W (7.1cm H x 19cm D x 21cm W). |
| weight | Approximately 3.3 lbs (1.5 kg) with battery and pads cartridge installed. |

Philips Medical Systems

HEARTSTART ONSITE M5066A

Environmental

| CATEGORY | SPECIFICATIONS |
|--|---|
| temperature and relative humidity (HeartStart with battery and pads cartridge installed) | <p>Operating: 32° to 122° F (0° to 50° C); 0% to 95% RH (non-condensing).</p> <p>Standby: 50° to 109° F (10° to 43° C); 10% to 75% RH (non-condensing).</p> |
| altitude | Operates at 0 to 15,000 feet; can be stored at up to 6,500 feet, in standby mode. |
| shock/drop abuse tolerance | Withstands 1 meter drop to any edge, corner, or surface. |
| vibration | <p>Operating: meets EN1789 random, road ambulance.</p> <p>Standby: meets EN1789 swept sine, road ambulance.</p> |
| sealing | Drip proof per EN60529 class IPx1. Solid Objects per EN60529 class IP2x. |
| ESD | Meets EN60601-1-2 limits (1999), method EN61000-4-2 Severity Level 4. |
| EMI (radiated) | Meets EN60601-1-2, EN55011. |
| EMI (immunity) | Meets EN60601-1-2, method EN61000 Level 2 (normal operation: 10 V/m, 26 MHz - 2.5 GHz) and Level 3 (impaired but safe: 10 V/m, 26 MHz - 2.5 GHz). |

B

ECG analysis system

| CATEGORY | SPECIFICATIONS |
|------------------|---|
| function | Evaluates impedance of adhesive pads for proper contact with patient skin, and evaluates the ECG rhythm and signal quality to determine if a shock is appropriate. |
| shockable rhythm | <p>Ventricular fibrillation (VF) and some ventricular tachycardias, including ventricular flutter and polymorphic ventricular tachycardia (VT). The HeartStart OnSite Defibrillator uses multiple parameters to determine if a rhythm is shockable.</p> <p><i>NOTE: 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.</i></p> |

B-4

| CATEGORY | SPECIFICATIONS |
|-----------------------|---|
| non-shockable rhythms | On detection of any non-shockable rhythm, provides prompt to user to perform CPR if needed. |
| pacemaker detection | 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. For details of protocols see Appendix F, HeartStart OnSite Default Configuration. |

ECG analysis performance

| rhythm class | ECG test sample ^a size | meets AHA recommendations ^b for adult defibrillation | |
|--|-----------------------------------|---|--------------------------------------|
| | | observed performance | 90% one-sided lower confidence limit |
| shockable rhythm – ventricular fibrillation | 300 | sensitivity >90% (meets AAMI DF39 requirement) | (87%) |
| shockable rhythm – ventricular tachycardia | 100 | sensitivity >75% (meets AAMI DF39 requirement) | (67%) |
| non-shockable rhythm – normal sinus rhythm | 300 | specificity >99% (meets AAMI DF39 requirement) | (97%) |
| non-shockable rhythm – asystole | 100 | specificity >95% (meets AAMI DF39 requirement) | (92%) |
| non-shockable rhythm – all other non-shockable rhythms | 450 | specificity >95% (meets AAMI DF39 requirement) | (88%) |

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

Philips Medical Systems

Defibrillator

| CATEGORY | SPECIFICATIONS |
|------------------------------------|--|
| waveform | <p>Biphasic truncated exponential.</p> <p>The SMART Biphasic waveform parameters are automatically adjusted as a function of patient defibrillation impedance.</p> <p>The HeartStart OnSite Defibrillator 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.</p> |
| energy | <p>Using HeartStart Adult SMART Pads: 150 J nominal into a 50 ohm load.</p> <p>Using HeartStart Infant/Child SMART Pads: 50 J nominal into a 50 ohm load.</p> |
| charge control | Controlled by Patient Analysis System for automated operation. |
| shock-to-shock cycling | < 20 seconds typical, including analysis. |
| "charge complete" indicator | Shock button flashes, audio tone sounds. |
| disarm | <p>Once charged, the defibrillator will disarm if:</p> <ul style="list-style-type: none"> the patient's heart rhythm changes to non-shockable rhythm, a shock is not delivered within 30 seconds after the defibrillator has charged for shock delivery, the On/Off button is pressed and held down for at least one (1) second to turn off the defibrillator, the adhesive pads are removed from the patient or the pad cartridge is disconnected from the defibrillator, or the battery is removed or is completely depleted. |
| adult shock delivery vector | Via adhesive pads placed in the anterior-anterior (Lead II) position. |
| infant/child shock delivery vector | Via adhesive pads typically placed in the anterior-posterior position. |

B

B-6

Controls and indicators

| CATEGORY | SPECIFICATIONS |
|---------------|--|
| controls | <ul style="list-style-type: none"> Green SMART Pads cartridge handle Green On/Off button Blue i-button Orange Shock button |
| indicators | <ul style="list-style-type: none"> Ready light: green, blinks when the defibrillator is in standby mode (ready for use), solid when the defibrillator is being used. i-button: blue, flashes when information is available, on solid during patient care pause. Caution light: flashes when the defibrillator is analyzing, comes on solid when the defibrillator is ready to deliver a shock. Shock button: orange, flashes when the defibrillator is charged and ready to deliver a shock. |
| audio speaker | Provides voice prompts and warning tones during normal use. |
| beep | Provides chirps when troubleshooting is needed. |

Accessories specifications

Battery M5070A

| CATEGORY | SPECIFICATIONS |
|---------------------------------|--|
| battery type | 9 VDC, 4.2 Ah, lithium manganese dioxide. Disposable, long-life primary cell. |
| capacity | When new, a minimum of 90 shocks or 3 hours of operating time at 77° F (25° C). |
| shelf life (prior to insertion) | A minimum of 5 years from date of manufacture when stored and maintained according to directions provided in these <i>Instructions for Use</i> . |
| standby life (after insertion) | Typically 4 years when stored and maintained according to directions provided in these <i>Instructions for Use</i> . |
| training life | Supports 10 hours of use in training mode. |

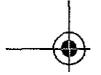
Philips Medical Systems

HEARTSTART ONSITE M5066A

HeartStart Adult SMART Pads M5071A and Infant/Child SMART Pads M5072A

| CATEGORY | SPECIFICATIONS |
|---------------------------------|--|
| adult pads | Disposable, adhesive defibrillation pads with a nominal active surface area of 85 cm ² each, provided in a snap-in cartridge with an integrated 54 inch (137.1 cm), typical, cable. |
| infant/child pads | Disposable, adhesive defibrillation pads with a nominal active surface area of 85 cm ² 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 Adult SMART Pads M5071A or Infant/Child SMART Pads M5072A with the HeartStart OnSite Defibrillator. |

B



Notes

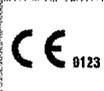


C Glossary of symbols/controls

HeartStart OnSite Defibrillator

| SYMBOL | DESCRIPTION |
|---|--|
|  | Pads cartridge handle. Green. Pulling the handle turns on the defibrillator and opens pads cartridge for use. |
|  | On/Off button. Green. Pressing the On/Off button when the defibrillator is in standby mode turns the defibrillator on; pressing and holding the On/Off button for one second when the defibrillator is on turns the defibrillator off and disarms the defibrillator. In addition, pressing the On/Off button stops the battery insertion self-test that automatically runs when a battery is inserted. |
|  | Information button (i-button). Blue. Pressing the i-button while it is flashing during a patient care pause provides CPR guidance; pressing it while it is flashing and the defibrillator is chirping provides troubleshooting guidance. Pressing it until it beeps at other times provides summary information about the defibrillator's last clinical use and device status. |
|  | Caution light. Flashes during rhythm analysis, and is on but not flashing when a shock is advised, as a reminder not to touch the patient. |
|  | Shock button. Orange. Flashes when the defibrillator is charged. If a shock is needed, the defibrillator directs the user to press the Shock button to deliver a shock to the patient. |
|  | Defibrillation protection. Defibrillation protected, type B/F patient connection. |
|  | Refer to operating instructions. |
|  | Certified by the Canadian Standards Association. |

C-2

| SYMBOL | DESCRIPTION |
|---|---|
|  | Meets the requirements of the European medical device directives. |
|  | Reference order number. |
|  | Serial number. |

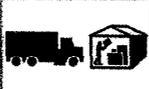
Accessories

HeartStart battery M5070A and packaging

| SYMBOL | DESCRIPTION |
|---|---|
|  | Lithium manganese dioxide battery. |
|  | One battery in package. |
|  | Do not crush the battery. |
|  | Do not expose the battery to high heat or open flames. Do not incinerate the battery. |
|  | Do not mutilate the battery or open the battery case. |
|  | Do not expose to moisture. |

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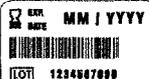
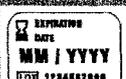
HEARTSTART ONSITE M5066A

| SYMBOL | DESCRIPTION |
|---|--|
|  | Handle with care. |
|  | Transportation and storage requirements (refer to associated thermometer symbol). |
|  | Environmental (temperature and relative humidity) requirements. |
|  | Install the battery in the defibrillator before the date (MM/YY/YY) shown on the associated label. |
|  | Meets the requirements of the European medical device directives. |
|  | Lot number. |
|  | Refer to operating instructions. |

**HeartStart Adult SMART Pads M5071A,
HeartStart Infant/Child SMART Pads M5072A,
HeartStart Adult Training Pads M5073A, and
HeartStart Infant/Child Training Pads M5074A**

| SYMBOL | DESCRIPTION |
|---|--|
|  | These pads are disposable and are for single patient use only. |
|  | Cartridge contents: one set of two defibrillation pads. |

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| SYMBOL | DESCRIPTION |
|---|---|
|  | <p>Store the pads at temperatures between 0° and 43° C (32° and 110° F).</p> |
|  | <p>Refer to operating instructions.</p> |
|  | <p>This product does not contain natural rubber latex.</p> |
|  | <p>This product is not sterile.</p> |
|  | <p>(On package) Expiration date; discard the pads after the date shown. Lot number.</p> |
|  | <p>(On foil seal) Expiration date; discard the pads after the date shown. Lot number.</p> |
|  | <p>Pads intended for use on infant or child under 8 years or 55 pounds (25 Kg).</p> |
|  | <p>Meets the requirements of the European medical device directives.</p> |

Philips Medical Systems

HEARTSTART ONSITE M5066A

D Glossary of terms

The terms listed in this Glossary are defined in the context of the Philips HeartStart OnSite Defibrillator and its use.

- absolute timing** The local time calculated by HeartStart Event Review software from the elapsed time between events and the last battery installation, stored in the HeartStart OnSite Defibrillator's memory for data review.
- adhesive pads** See "SMART Pads."
- AED** Automated external defibrillator (a semi-automatic defibrillator).
- AED mode** The standard treatment mode for the HeartStart OnSite Defibrillator. It provides voice instructions guiding the rescuer through applying the adhesive pads, waiting for rhythm analysis, and delivering a shock if needed.
- ALS** Advanced Life Support.
- analysis** See "SMART analysis."
- arrhythmia** An unhealthy, often irregular, beating of the heart.
- artifact** Electrical "noise" caused by sources such as muscle movements, CPR, patient transport, or static electricity that may interfere with rhythm analysis.
- battery** The sealed lithium manganese dioxide battery used to power the HeartStart OnSite Defibrillator. It is provided in a pack that fits into a compartment on the back of the defibrillator.
- BLS** Basic Life Support.
- caution light** A triangular light on the front of the HeartStart OnSite Defibrillator that flashes during rhythm analysis and is on solid when a shock is advised, as a reminder not to touch the patient
- configuration** The settings for all operating options of the HeartStart OnSite Defibrillator, including treatment protocol. The factory default configuration can be modified by authorized personnel using HeartStart Event Review software.

D-2

| | |
|------------------------------------|--|
| CPR | Cardiopulmonary resuscitation. A technique for providing artificial respiration and heart compressions to maintain life in a victim of SCA until defibrillation can be performed. |
| defibrillation | Termination of cardiac fibrillation by applying electrical energy. |
| defibrillation charge | Electrical energy stored in the capacitor of the HeartStart as it arms for shock delivery. |
| defibrillation shock | See "SMART biphasic waveform." |
| disarm | The defibrillator safely discharges its defibrillation energy internally. |
| ECG | Electrocardiogram, a record of the electrical rhythm of the heart as detected through defibrillation pads. |
| event | An action recognized or performed by the HeartStart OnSite Defibrillator as a step in the sequence of using it in an incident. Examples include: applying the pads, analyzing heart rhythm, delivering a shock, etc. |
| fibrillation | A disturbance of the normal heart rhythm that results in chaotic, disorganized activity that cannot effectively pump blood. Ventricular fibrillation (fibrillation in the lower chambers of the heart) is associated with sudden cardiac arrest. |
| heart rhythm (ECG) analysis | A system used by the HeartStart OnSite Defibrillator to determine if the patient's heart rhythm is shockable – ventricular fibrillation (VF) or certain ventricular tachycardias (VTs). See "SMART analysis." |
| HeartStart Event Review | A dedicated data management software system for use by trained personnel with the HeartStart OnSite Defibrillator. Information is available from Philips Medical Systems on the internet at http://www.medical.philips.com/goto/eventreview . |
| i-button | A blue button on the front of the HeartStart OnSite Defibrillator that, if pressed during the 30 seconds it flashes during a patient care pause, provides CPR guidance;* if pressed when it flashes and the defibrillator chirps, provides troubleshooting guidance. At other times, if the i-button pressed and held until it beeps once, the defibrillator provides summary information about its last clinical use and device status. |

* Pressing the i-button during a SMART NSA pause turns off background monitoring.

| | |
|--------------------------------|--|
| impedance | Electrically, this is the resistance of the body to the flow of the electrical shock waveform delivered by the HeartStart OnSite Defibrillator. The defibrillator automatically monitors the electrical impedance between the adhesive pads placed on the patient's bare chest, and adjusts the shock waveform appropriately. |
| incident | The series of events involved in treating a patient with the HeartStart OnSite Defibrillator. |
| infrared communications | A method of sending information using a special part of the light spectrum. It is used to transmit information between the HeartStart OnSite Defibrillator and a computer running HeartStart Event Review software. |
| monitoring | A mode of background analysis conducted on a motionless patient (i.e., no CPR is being performed) to determine if the patient rhythm has changed to a shockable rhythm. |
| NSA | "No Shock Advised," a decision made by the HeartStart OnSite Defibrillator that a shock is not needed, based on analysis of the patient's heart rhythm. |
| NSA pause | A pause provided by the HeartStart OnSite Defibrillator following an NSA decision. The pause can be configured to a "standard" NSA pause or a "SMART" NSA pause. During a standard NSA pause the defibrillator performs no background monitoring of patient rhythm. During a SMART NSA pause, the defibrillator conducts background monitoring and, if it detects an artifact-free shockable rhythm, will exit the pause and begin rhythm analysis. If the user presses the i-button for CPR guidance during a SMART NSA pause, that pause will become a standard NSA pause. |
| non-shockable rhythm | A heart rhythm that the HeartStart OnSite Defibrillator determines is not appropriate for defibrillation. |
| on/off button | A green button located on the front of the HeartStart OnSite Defibrillator. Pressing the On/Off button when the defibrillator is in standby mode turns the defibrillator on; pressing and holding the On/Off button for one second when the defibrillator is on turns the defibrillator off and disarms the defibrillator. In addition, pressing the On/Off button stops the battery insertion self-test that automatically runs when a battery is inserted. |
| pacemaker | External or implanted cardiac pulse generator that stimulates the heart electronically. |
| pads | See "SMART pads." |



D-4

| | |
|----------------------------|--|
| patient care pause | A defined period to allow patient assessment, treatment, and/or CPR. See "NSA pause" and "protocol pause." |
| periodic self-tests | Daily, weekly, and monthly tests automatically conducted by the HeartStart OnSite Defibrillator when it is in its standby mode. The tests monitor many key functions and parameters of the defibrillator, including battery capacity, pads cartridge readiness, and the state of its internal circuitry. |
| prompts | The voice instructions used to guide the rescuer through use of the HeartStart OnSite Defibrillator to treat the patient. |
| protocol | A sequence of operations performed by the HeartStart OnSite Defibrillator to direct patient care in the AED mode. |
| protocol pause | A period provided by the HeartStart OnSite Defibrillator after a shock series, during which the responder can administer CPR if needed. The defibrillator does not conduct background monitoring of the patient's heart rhythm during this pause. |
| ready light | A green LED showing the readiness for use of the HeartStart OnSite Defibrillator. A blinking Ready light means the defibrillator is ready for use; a solid Ready light means the defibrillator is being used. |
| relative timing | The elapsed time between events and the previous battery installation, stored in the HeartStart OnSite Defibrillator's memory for data review. |
| rhythm analysis | See "SMART analysis." |
| sensitivity | A measure of the ability of the HeartStart OnSite Defibrillator to reliably detect and identify shockable heart rhythms. |
| shock button | An orange button with a lightning bolt symbol on it, located on the front of the HeartStart OnSite Defibrillator. The Shock button flashes when a shock is advised. You must press the button for the shock to be delivered. |
| shock series | A configurable number of shocks, each separated by no more than a preset interval. After completion of a shock series, the HeartStart OnSite Defibrillator automatically pauses for CPR. See "protocol pause." |
| shockable rhythm | A heart rhythm that the HeartStart OnSite Defibrillator determines is appropriate for defibrillation, such as ventricular fibrillation and some ventricular tachycardias associated with sudden cardiac arrest. |

| | |
|--------------------------------|---|
| shock series interval | A configurable interval between shocks, used by the HeartStart OnSite Defibrillator to decide if the shocks are part of the same shock series. |
| shock waveform | See "SMART biphasic waveform." |
| SMART analysis | The proprietary algorithm used by the HeartStart OnSite Defibrillator to analyze the patient's heart rhythm and determine whether a shock is advised. |
| SMART biphasic waveform | The patented, low-energy defibrillation shock waveform used by the HeartStart OnSite Defibrillator. It is an impedance-compensated biphasic waveform. Used with the Adult SMART Pads, it delivers 150 Joules, nominal, into a 50 ohm load; used with the Infant/Child SMART Pads, it delivers 50 Joules, nominal, into a 50 ohm load. |
| SMART NSA pause | See "NSA pause." |
| SMART Pads | The adhesive pads, supplied in a cartridge, used with the HeartStart OnSite Defibrillator. Pulling the handle on the cartridge turns on the defibrillator and opens the cartridge. The pads are applied to the patient's bare skin and used to detect the patient's heart rhythm and to transfer the defibrillation shock. Only HeartStart SMART Pads can be used with the HeartStart OnSite Defibrillator. |
| specificity | A measure of the ability of the HeartStart OnSite Defibrillator to reliably detect and identify non-shockable heart rhythms. |
| standby mode | The operating mode of the HeartStart OnSite Defibrillator when a battery has been installed, and the unit is turned off and ready for use when needed. Shown by blinking green READY light. |
| standard NSA pause | See "NSA pause." |
| sudden cardiac arrest | The sudden stopping of the heart's pumping rhythm, accompanied by loss of consciousness, absence of respiration, and lack of a pulse. |
| waveform | See "SMART biphasic waveform." |



Notes

E Safety considerations

You should be aware of the safety concerns listed here when you use the HeartStart OnSite Defibrillator. Read them carefully. You will also see some of these messages in other parts of these Instructions for Use. The messages are labeled Warning or Precaution.

- **WARNING:** Condition, hazard, or unsafe practice that can result in serious personal injury or death.
- **PRECAUTION:** Condition, hazard, or unsafe practice that can result in minor personal injury, damage to the HeartStart, loss of data stored in the device, or less than optimal defibrillation effectiveness.

These safety considerations are divided into four groups: safety concerns about the defibrillator in general use, defibrillation, monitoring, and maintenance activities.

General warnings and precautions

| SAFETY LEVEL | POSSIBLE SHOCK OR FIRE HAZARD, OR EXPLOSION |
|--------------|---|
| WARNING | There is a possibility of explosion if the defibrillator is used in the presence of flammable anesthetics or concentrated oxygen. However, it is safe to use the HeartStart OnSite Defibrillator on someone who has an oxygen mask in place. |
| WARNING | The defibrillator has not been evaluated or approved for use in hazardous locations as defined in the National Electrical Code (Articles 500-505). In accordance with the IEC Classifications (Section 6.3), the defibrillator is not to be used in the presence of flammable substance/air mixtures. |
| WARNING | Use the defibrillator only as described in these <i>Instructions for Use</i> . Improper use of the defibrillator can cause death or injury. Do not press the Shock button if the defibrillator pads are touching each other or are open and exposed. |
| PRECAUTION | Hazardous electrical output. |

| SAFETY LEVEL | POSSIBLE SHOCK OR FIRE HAZARD, OR EXPLOSION |
|--------------|---|
|--------------|---|

| | |
|------------|--|
| PRECAUTION | Do not immerse any portion of the defibrillator in water or other fluids. Do not allow fluids to enter the defibrillator. Avoid spilling any fluids on the defibrillator or its accessories. Spilling fluids into the defibrillator may damage it or present a fire or shock hazard. |
|------------|--|

| SAFETY LEVEL | POSSIBLE IMPROPER DEVICE PERFORMANCE |
|--------------|--------------------------------------|
|--------------|--------------------------------------|

| | |
|---------|---|
| WARNING | Prolonged or aggressive CPR to a patient with defibrillator pads attached can damage the pads. Replace the defibrillator pads if they are damaged during use or handling. |
|---------|---|

| | |
|---------|---|
| WARNING | Using damaged or expired equipment or accessories may cause the defibrillator to perform improperly, and/or injure the patient or the user. |
|---------|---|

| | |
|------------|--|
| PRECAUTION | CPR during rhythm analysis can cause incorrect or delayed analysis by the defibrillator. |
|------------|--|

| | |
|------------|---|
| PRECAUTION | Follow all instructions supplied with the HeartStart adhesive pads. Use the pads before the expiration date shown on the package and on the film seal. Do not reuse the pads. Discard them after use. |
|------------|---|

| | |
|------------|---|
| PRECAUTION | Aggressive handling of the adhesive pads prior to use can damage the pads. Discard the pads if they become damaged. |
|------------|---|

| | |
|------------|--|
| PRECAUTION | The HeartStart OnSite Defibrillator was designed to be sturdy and reliable for many different field use conditions. However, excessively rough handling can result in damage to the defibrillator or its accessories and will invalidate the warranty. Inspect the defibrillator and accessories periodically according to instructions. |
|------------|--|

| | |
|------------|--|
| PRECAUTION | Alteration of the factory default setup of the defibrillator can affect its performance and must be performed by an authorized person. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training. |
|------------|--|

SAFETY LEVEL

POSSIBLE ELECTRICAL INTERFERENCE WITH RHYTHM ANALYSIS

WARNING

The HeartStart OnSite Defibrillator has demonstrated operational immunity to modulated RF (radio-frequency) EM (electro-magnetic) fields in accordance with the requirements of EN60601-1-2. These test methods simulate a broad EM environment for the purpose of evaluating how the product functions in the presence of emergency 2-way radios, cellular phones, and other equipment designated as an intentional emitter of radio-frequency energy. The HeartStart OnSite Defibrillator has proved its ability to operate correctly in relatively close proximity to radio-frequency generating equipment. However, as a precaution, it is best to keep RF devices only as close to the patient/defibrillator area as is necessary. A likely scenario might involve a responder using a cellular phone while handling the patient. Under normal circumstances, this should not represent a problem for the HeartStart OnSite Defibrillator.

Defibrillation warnings and precautions

SAFETY LEVEL

POSSIBLE SHOCK HAZARD

WARNING

The electrical energy used to shock the heart can cause operator or bystander injury. Do not touch the patient during the shock.

SAFETY LEVELS

POSSIBLE LIMITATIONS OF ECG INTERPRETATION

WARNING

Handling or transporting the patient during heart rhythm analysis can cause an incorrect or delayed diagnosis. If the defibrillator gives a SHOCK ADVISED prompt during such handling or transport, stop the vehicle and keep the patient as still as possible for at least 10 seconds before pressing the Shock button, to allow the defibrillator to reconfirm the rhythm analysis.

SAFETY LEVELS

POSSIBLE BURNS AND INEFFECTIVE ENERGY

WARNING

Do not allow the defibrillator pads to touch each other or ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may also divert the defibrillation current away from the heart.



E-4

SAFETY LEVELS

POSSIBLE BURNS AND INEFFECTIVE ENERGY

PREVENTION

During defibrillation, air pockets between the skin and defibrillator pads can cause patient skin burns. To help prevent air pockets, make sure defibrillator pads completely adhere to the skin. Do not use dried out defibrillator pads.

Maintenance warning

SAFETY LEVEL

POSSIBLE FIRE OR SHOCK HAZARD

WARNING

Electrical shock hazard. Dangerous high voltages and currents are present. Do not open the defibrillator, remove its covers, or attempt repair. There are no user-serviceable components in the defibrillator. The defibrillator should be returned to an authorized service center for repair.

F HeartStart OnSite default configuration

Overview

The Philips HeartStart OnSite Defibrillator comes with a factory default configuration designed to meet the needs of most users. This configuration can only be changed by an authorized person using HeartStart Event Review software. The software provides password-protected directions for how to alter the configuration, confirms changes to the configuration, and provides a printout of the summary of the new configuration settings, along with current status information including the results of the latest defibrillator self-test, the defibrillator's device history, the battery history (since the last insertion), and the defibrillator serial number. The *Instructions for Use* provided with HeartStart Event Review provides information all the various settings available for each parameter. The default configuration settings are described below.

Device options

The following table includes the features of HeartStart OnSite Defibrillator operation that are not related to patient treatment.

| PARAMETER | DEFAULT | DESCRIPTION |
|---|---------|---|
| speaker volume | 8 | The volume of the HeartStart's speaker is set to 8, highest. The speaker is used for voice instructions and the charge-done tone. |
| Auto send periodic self test (PST) data | On | Enables the periodic self-test data broadcast through the device's infrared data port |
| ECG out data | On | Enables the ECG data broadcast through the device's infrared data port |



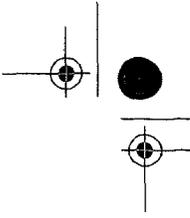
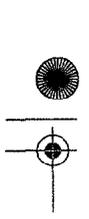
Patient treatment protocol options

| PARAMETER | DEFAULT | DESCRIPTION |
|---------------------------------|--------------|--|
| "call EMS" voice reminder | as described | The voice reminder to call emergency medical services occurs at the start of the first pause interval. |
| shock series | 3 | <p>Three shocks must be delivered in a series to activate the automatic protocol pause for patient assessment and CPR.</p> <p>During the protocol pause, the HeartStart does not perform rhythm analysis.</p> <p>The length of the protocol pause after a shock series is completed is defined by the protocol pause timer setting. A new shock series begins:</p> <ul style="list-style-type: none"> • when a shock is delivered after the HeartStart is turned on, • after a protocol pause, or • if the time since the previous shock exceeds the shock series interval setting. |
| shock series interval (minutes) | 1.0 | A delivered shock must occur within 1 minute of the previous shock to be counted as part of the current shock series. |
| protocol pause timer (minutes) | 1.0 | A protocol pause interval of 1 minute automatically starts after voice instruction is given when a shock series is completed. After the protocol pause, the defibrillator returns to rhythm analysis. |

| PARAMETER | DEFAULT | DESCRIPTION |
|--------------------------------|-----------------|--|
| NSA pause type | SMART NSA pause | <p>During a SMART NSA pause, the defibrillator conducts background monitoring during the pause. If a potentially shockable rhythm is detected in a motionless patient, the defibrillator terminates the SMART NSA pause and resumes rhythm analysis.</p> <p><i>NOTE: If the Shock button is not pressed for 30 seconds after the HeartStart is armed, or continuous artifact is encountered for 30 seconds during rhythm analysis, a 30 second SMART pause is automatically initiated.</i></p> <p><i>NOTE: Use of the optional i-button CPR coaching will convert the SMART NSA pause to a standard NSA pause. During the standard NSA pause, the defibrillator does not perform rhythm analysis for the pause time determined by the selected protocol pause timer and NSA pause timer settings.</i></p> |
| NSA pause timer | 1:0 | <p>An NSA pause interval of 1 minute automatically starts after a no shock advised (NSA) decision.</p> <ul style="list-style-type: none"> • If a shock has been delivered within the shock series interval, the length of the pause is defined by the protocol pause timer setting. • Otherwise, the length of the NSA pause is defined by the NSA pause timer setting. |
| CPR prompt | as described | <p>The CPR reminder voice instructions provided at the beginning of a pause interval directs the user to check the patient's airway, breathing, and circulation and to begin CPR if needed, then invites the user to press the i-button for guidance in the basic steps of CPR.</p> <p><i>NOTE: In U.K. English HeartStart defibrillators, the CPR reminder directs the user to check for signs of circulation and, if there are none, to start CPR. Optional CPR guidance is available by pressing the i-button.</i></p> |
| CPR prompt rate (beeps/minute) | 100 | <p>Signals for CPR compressions are given at a rate of 100 per minute when the user presses the i-button for optional CPR coaching.</p> |



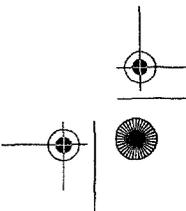
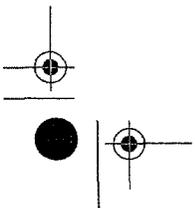
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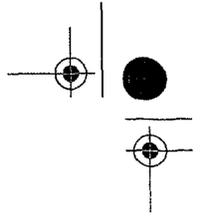
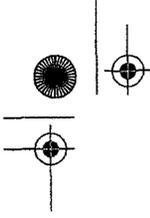


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Philips Medical Systems

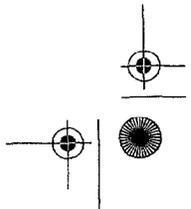
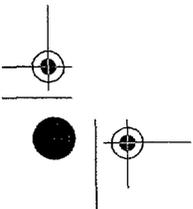




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POWER TO SAVE A LIFE

HEARTSTART

ONSITE DEFIBRILLATOR

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PHILIPS

Attachment 3

K955628
Sept. 10, 1996

Appendix 25
510(k) Summary of Safety and Effectiveness

Heartstream, Inc. ForeRunner External Defibrillator and Accessories

General Information

| | |
|----------------|---|
| Classification | Class II |
| Trade Name | ForeRunner External Defibrillator and Accessories |
| Submitter | Heartstream, Inc. 2401 Fourth Avenue Suite 300 Seattle, Washington, USA 98121 |
| Contact | Lori Glastetter Director, Regulatory Affairs |

Substantially Equivalent and Preamendment Devices

| <u>Manufacturer</u> | <u>Product</u> |
|--|--|
| Zoll Medical Corporation | Semi-Automatic External Defibrillator |
| SurVivaLink Corporation | VivaLink Semi-Automatic External Defibrillator |
| Laerdal Medical Corporation | Heartstart Semi-automatic External Defibrillator |
| Hewlett Packard Corporation | Codemaster XL Defibrillator/Monitor |
| PhysioControl Corporation | LifePak 100 External Defibrillator |
| W. Kouwenhoven, M.D. (Johns Hopkins Hospital) | Biphasic External Defibrillator |
| Mine Safety Appliance Company | Biphasic External Defibrillator |
| Katecho, Inc. | External Pacing and Defibrillation electrodes |
| Zoll Medical Corporation | Multi-function electrodes |
| SurVivaLink Corporation | Defibrillation electrodes |

Intended use

The ForeRunner external defibrillator, is indicated for use on victims of sudden cardiac arrest on whom an apparent lack of circulation is indicated by unconsciousness, absence of breathing and absence of detectable pulse.

Device Description

The ForeRunner external defibrillator is a semi-automatic external defibrillator incorporating voice prompts to advise the operator of the need to deliver a defibrillating shock. The device is designed to be used by emergency responders in the treatment of cardiac arrest. The device is portable, weighing approximately 4 pounds and measuring approximately 2.5"(H) x 8"(W) x 8.8"(D). The ForeRunner product line consists of the defibrillator, a disposable battery, a pack of disposable single use electrodes, carrying cases and other optional accessories, such as event recording data cards and event review software.

Testing

Extensive environmental and performance tests are conducted on the ForeRunner external defibrillator. These tests included performance tests in accordance to established industry standards. The electrocardiogram (ECG) recognition algorithm is evaluated using recordings of actual cardiac signals in accordance to established industry standards. Further, the software for the product is validated per recognized validation techniques.

Biocompatibility testing is performed on patient contact materials of defibrillation electrodes in accordance to international standards.

All testing of the products yielded acceptable results prior to commercial distribution.

Summary of Substantial Equivalence

The ForeRunner external defibrillator is intended for emergency treatment of cardiac arrest. The ForeRunner external defibrillator is a portable, battery powered semi-automatic low energy DC defibrillator.

Portable low power DC defibrillators are commonly used by emergency personnel to defibrillate unconscious patients. The ForeRunner functions in the same manner as the predicate devices in that it is a portable, low power, battery operated defibrillator. The ForeRunner external defibrillator is semi-automatic and has visual and voice prompts for ease of operations.

The design features and materials used in the manufacture of the ForeRunner external defibrillator are substantially equivalent to the predicate products. Additionally, the ForeRunner external defibrillator is of similar shape and functionality to predicate devices. The defibrillation waveform has been shown to be substantially equivalent to predicate product waveform with respect to defibrillation effectiveness and safety in an extensive clinical trial.

Therefore, due to the similarity of design features, materials, test results, clinical results and the similarity of the indicated use to other predicate devices, Heartstream, Inc. believes this product does not raise any new safety or effectiveness issues.

Indications for Use

510(k) Number (if known): To be assigned **K003565**

Device Name: Agilent Technologies Heartstream FR2 Semi-Automatic External Defibrillator (AED)

Indications For Use: The Heartstream FR2 is indicated for use on victims of sudden cardiac arrest exhibiting the following signs:

- Unresponsiveness
- Absence of breathing

The Heartstream FR2 is intended for use by personnel who have been trained in its operation. The user should be qualified by training in basic life support, advanced life support, or other physician-authorized emergency medical response.

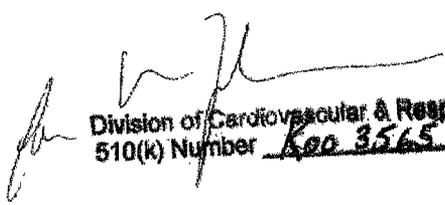
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Concurrence of CDRH, Office of Device Evaluation (ODE)

REC'D DEC 26 2000

Prescription Use or Over-The-Counter Use

(Per 21 CFR 801.109)


 Division of Cardiovascular & Respiratory Devices
 510(k) Number **K00 3565**

12. Indications for Use

Indications for Use

510(k) Number (if known): K014157

Device Name: Philips Medical Systems, Heartstream FR2 Automated External Defibrillator (AED)

Indications for Use: The Heartstream FR2 is indicated for use on persons experiencing the symptoms of sudden cardiac arrest:

- Lack of responsiveness
- Lack of breathing

When the patient is under 8 years or weighs less than 55 pounds (25 kg), the FR2 should be used with attenuated pediatric defibrillation pads. **DO NOT DELAY TREATMENT TO DETERMINE THE CHILD'S EXACT AGE/WEIGHT.**

The Heartstream FR2 is intended for use by personnel who have been trained in its operation. The user should be qualified by training in basic life support, advanced life support, or other physician-authorized emergency medical response.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Denk T. W.
 Division of Cardiovascular & Respiratory Devices
 510(k) Number K014157

Prescription Use or Over-The-Counter Use

12. Indications for Use

November 1, 2002

510(k) Number (if known): #K020715

Device Name: Philips M5066A/M5068A

Indications for Use: The M5066A is designed to be used on a person in sudden cardiac arrest, who is:

- unresponsive when shaken, and
- not breathing normally.

If in doubt, apply the pads.

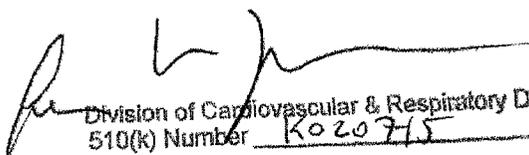
If the victim is an infant or child younger than eight years old or weighs less than 55 lbs (25 kg), you should use the special infant/child pads. If the child appears older/larger, use the adult pads. Do not delay treatment to determine the child's exact age or weight.

The M5066A is intended for use by people who have been specifically trained in its operation. A M5066A user should also have training in cardiopulmonary resuscitation (CPR) or another physician-authorized emergency medical response program in accordance with local and state requirements.

Caution: Federal Law (USA) restricts this device to the sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)


 Division of Cardiovascular & Respiratory Devices
 510(k) Number K020715

Prescription Use _____ or Over-The-Counter Use _____

Indications for Use (continued)

November 1, 2002

510(k) Number (if known): #K020715

Device Name: Philips M5066A/M5068A

Indications for Use: The M5068A is designed to be used on a person who is in sudden cardiac arrest and who is:

- unresponsive when shaken, and
- not breathing normally.

The defibrillator should not be used on a person who is:

- responsive when shaken, or
- breathing normally.

If you are not certain if the person is in sudden cardiac arrest, apply the defibrillator and follow its instructions.

For children 8 years or older, or who weigh 55 pounds or more, use the M5068A with the adult pads that come with it. For younger children to those who weigh less than 55 pounds, the special infant/child pads should be used. When used with these pads, the M5068A delivers a lower energy appropriate for infants and small children.

The M5068A is intended for use by people who have been specifically trained in its operation. The user should also have training in cardiopulmonary resuscitation (CPR) or another physician-authorized emergency response program in accordance with local and state requirements.

Caution: Federal Law (USA) restricts this device to the sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)


 Division of Cardiovascular & Respiratory Devices
 510(k) Number K020715

Prescription Use

or

Over-The-Counter Use