rhythm analysis
see SMART analysis

S

safety considerations *5-1*

selftests
battery insertion *2-4*
daily *4-1*
monthly *4-1*
periodic *2-5*, *4-1*

sensitivity, definition *D-4*

setup
definition *D-4*
reading setup *6-8*
receiving setup *6-6*

shock
see SMART biphasic waveform

Shock button, description of use *C-1*

shock series
definition *6-2*, *D-4*
programmable settings *6-2*

shock waveform
see SMART biphasic waveform

shockable rhythms *D-4*

SMART analysis
definition *D-4*
during CPR *3-6*
specifications *B-4*

SMART biphasic waveform
definition *D-4*
energy delivered *B-3*
shock delivery vector *B-4*
shock waveform *B-2*
specification *B-2*

solid red **X**
see Status Indicator

speaker volume
definition *6-1*
programmable settings *6-1*

specifications
battery *B-6*
controls and indicators *B-5*
defibrillator *B-2*
defibrillator pads *B-7*
display screen *B-5*
ECG analysis performance *B-5*
ECG analysis system *B-4*
environmental *B-1*
physical *B-1*

specificity, definition *D-4*

standby mode, definition *D-4*

standby temperature *B-1*

Status Indicator
description *D-4*
flashing black hourglass *C-2*
flashing red X *4-12*, *C-2*
in standby mode *2-5*
solid red X *C-2*

sterilization *4-3*

storage conditions *B-1*

sudden cardiac arrest, definition *D-4*

symbols
on accessory packaging *C-3*
on battery *C-4*
on FR2+ control panel and back label *C-1*
on FR2+ display screen *C-2*
on FR2+ status indicator *C-2*
on Instructions for Use *C-1*

symbols and controls *C-1*

INDEX

Philips Medical Systems

FR2+IFU.book Page 6 Tuesday, August 26, 2003 9:59 AM

T

temperature
  operating *B-1*
  standby *B-1*

tiered-response features *6-9*

training & administration pack
  charger *A-1*
  description *D-5*

troubleshooting *4-11*

U

user, qualifications and training *1-2*

W

warnings, cautions, and dangers
  5-2

waveform
  see SMART biphasic waveform

X

X Status Indicator
  flashing or solid *4-11*
  solid *4-11*

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POWER TO SAVE A LIFE

HEARTSTART.
FR2+ DEFIBRILLATOR

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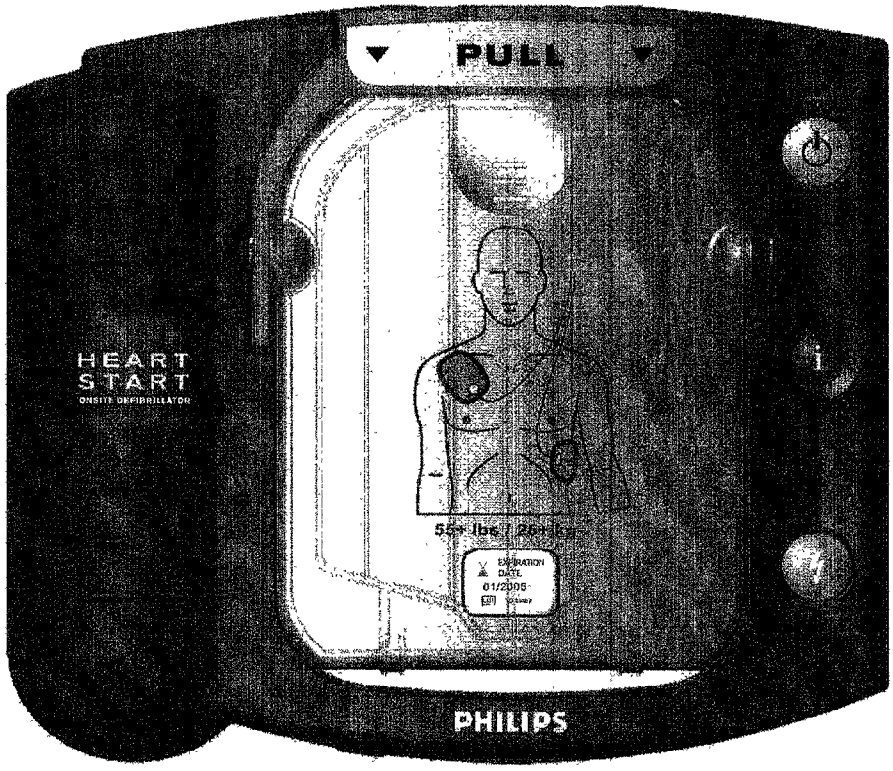
HEARTSTART
ONSITE DEFIBRILLATOR

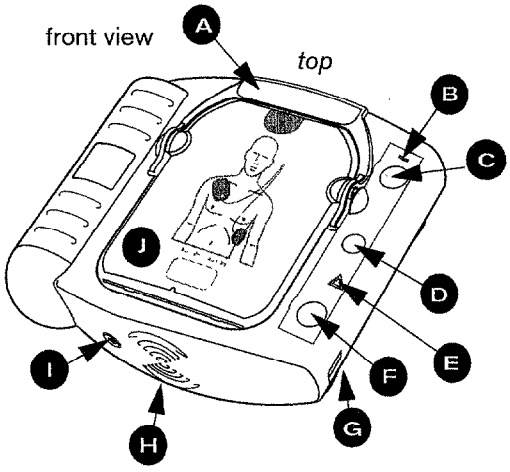


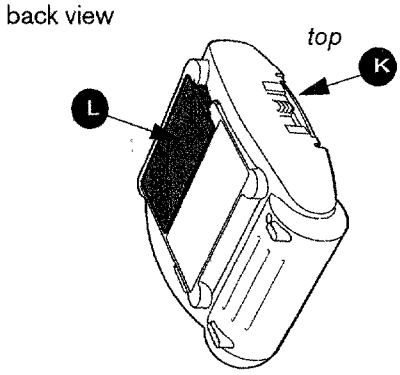
HEARTSTART ONSITE DEFIBRILLATOR

INSTRUCTIONS FOR USE

PHILIPS

M5066A
Edition 4





The HeartStart OnSite Defibrillator

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

Ⓑ 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)

Ⓒ 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.

Ⓓ 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.

Ⓔ 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.

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

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

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

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

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

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

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

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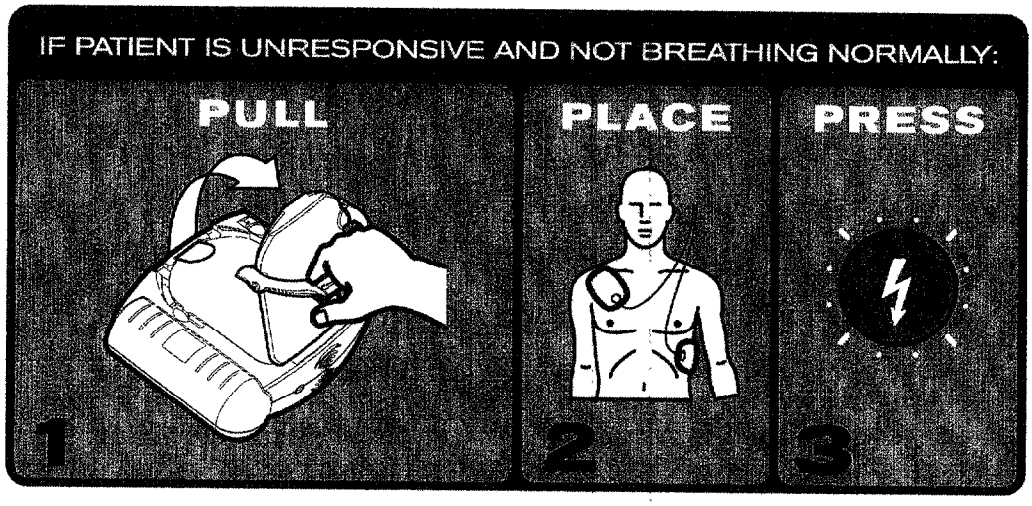
HeartStart OnSite Defibrillator
QUICK REFERENCE



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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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CONTENTS

1 Introduction to the HeartStart OnSite Defibrillator

What is it? 1-1
When is it used? 1-1
How do I know if I should use it? 1-1
What do I do if I need to use it? 1-2
How does it work? 1-2
Can I use it on a young child? 1-3
Who can use it? 1-3
More information about clinical use of the HeartStart OnSite 1-4

2 Getting started with the HeartStart OnSite Defibrillator

HeartStart Defibrillator package contents 2-1
Setting up the HeartStart Defibrillator 2-1
Readiness check 2-3
Training and practice 2-3
Storing the HeartStart Defibrillator 2-4

3 Using the HeartStart OnSite Defibrillator

Steps for using the HeartStart Defibrillator 3-1
STEP 1: PULL the green handle 3-2
STEP 2: PLACE the pads 3-3
STEP 3: PRESS the Shock button 3-4
Performing CPR 3-5
When emergency medical services arrive 3-5

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4 After using the HeartStart OnSite Defibrillator 1

Overview 4-1
HeartStart data storage 4-1
Summary data 4-1
Last-use data 4-2
After each use 4-2
Data transfer 4-3

5 Maintaining your HeartStart OnSite Defibrillator

HeartStart maintenance 5-1
Periodic checks 5-1
Changing the pads cartridge 5-2
Replacing the battery 5-3
Cleaning your HeartStart OnSite Defibrillator 5-4

6 Testing and troubleshooting the HeartStart OnSite Defibrillator

Testing 6-1
Periodic self-tests 6-1
Pads identification self-test 6-1
Battery insertion self-test 6-2
Troubleshooting 6-3
Readiness summary 6-4
Recommended action during an emergency 6-4
Troubleshooting while the defibrillator is being used 6-5
Troubleshooting while the defibrillator is not being used 6-7

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APPENDICES

A Accessories for the HeartStart OnSite Defibrillator

Standard accessories A-1
Suggested additional items A-2

B Technical information

Clinical studies synopses B-1
HeartStart OnSite Defibrillator specifications B-2
Accessories specifications B-6

C Glossary of symbols/controls 1

HeartStart OnSite Defibrillator C-1
Accessories C-2

D Glossary of terms

E Safety considerations

F HeartStart OnSite default configuration

Device options F-1
Patient treatment protocol options F-2

Notes

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 *de*fibrillation. 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.

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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.

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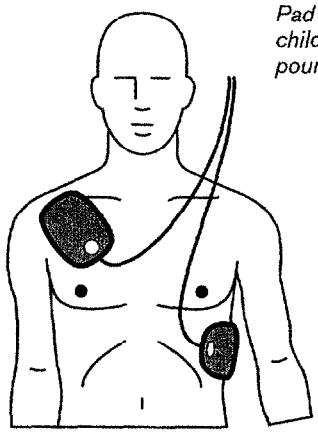
Can I use it on a young child?

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.

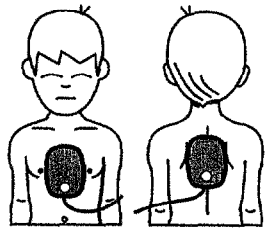
Instructions for changing the SMART Pads cartridge are provided in Chapter 5, "Maintaining the HeartStart OnSite Defibrillator."

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.



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

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



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.

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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.

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

2 Getting started with the HeartStart OnSite Defibrillator

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.

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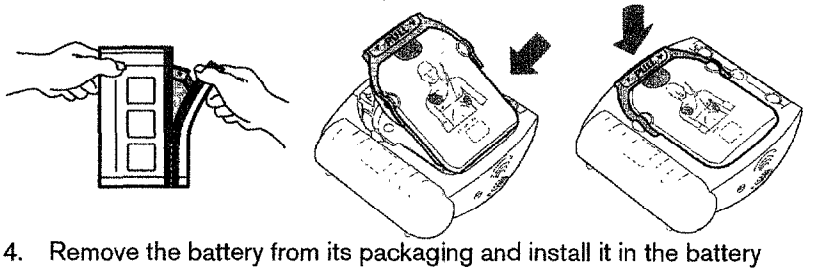
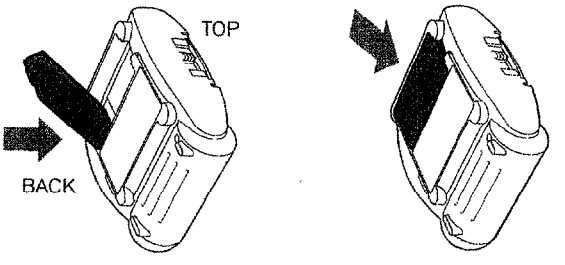
3. Remove a SMART Pads cartridge from its package and insert the cartridge firmly into the defibrillator. Be sure the green handle is pressed all the way down.

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.

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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.

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.

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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.

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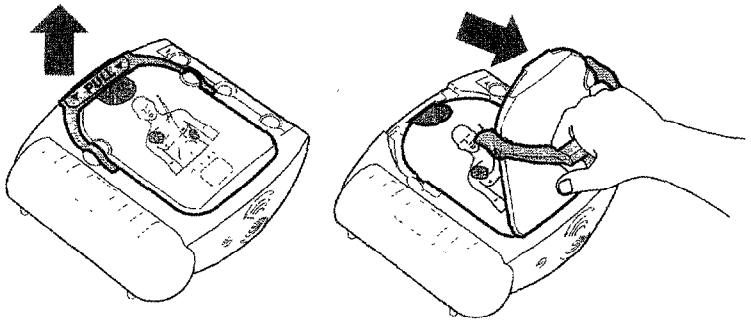
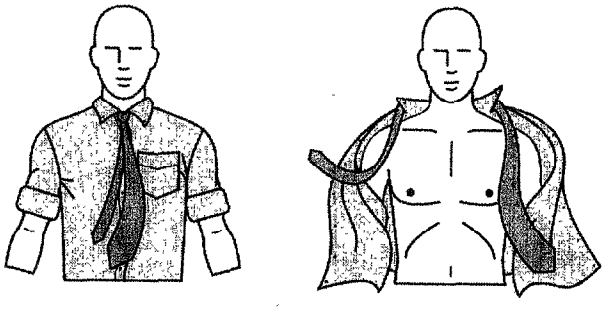
STEP 1: PULL the green handle

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.

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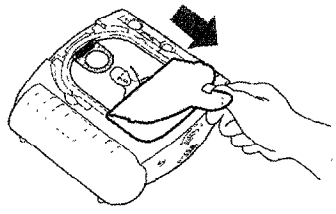
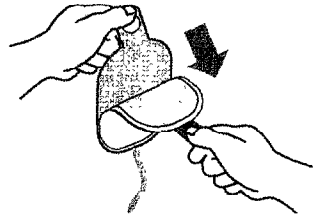
STEP 2: PLACE the pads

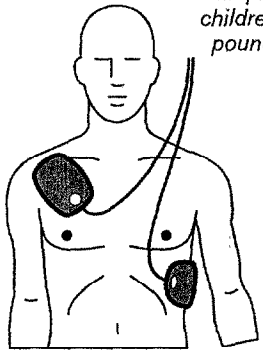
Pull the tab at the top of the pads cartridge to peel off the film seal. Inside are two adhesive pads on a plastic liner. Remove the pads from the cartridge.



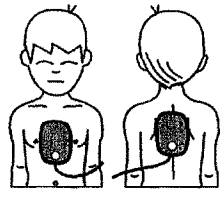


Peel one pad off the liner. Place the pad on the person's bare skin, exactly as shown in the picture on the pad. Press the pad down firmly. Then repeat this with the other pad. Be sure the pads have been removed from the liner before placing them.

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



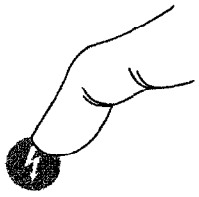
Pad placement for infants and children under 8 years old or 55 pounds.



Reminders:

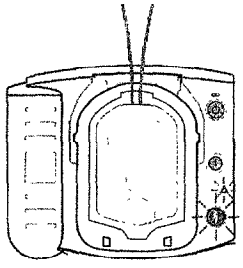
- *It may be necessary to dry the patient's skin, or to clip or shave excessive chest hair, in order to provide good contact between the pads and the skin.*
- *Remove any medicine patches and any residual adhesive before applying the pads.*
- *If needed, dry the skin where the pads will be placed.*
- *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 ❶ will come on during this patient care pause.



If a shock is needed, the Caution light ⚠ turns on, the orange Shock button ❼ 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 ❼. 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.*

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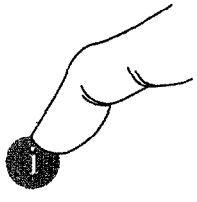
- *If for any reason you want to turn off the defibrillator, you can press the On/Off button — holding it down for at least one second — to return the device to standby mode.*

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.*

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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

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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.

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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.

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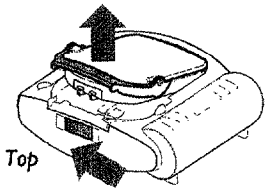
To review the recorded data, your medical provider will need:

- 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.)
- 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.

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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.

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- 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

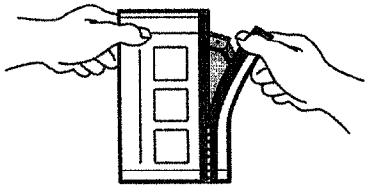
There are four kinds of HeartStart pads cartridges designed for use with your defibrillator: HeartStart Adult SMART Pads, HeartStart Infant/Child SMART Pads, reusable HeartStart Adult Training Pads, and reusable HeartStart Infant/Child Training Pads.

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.

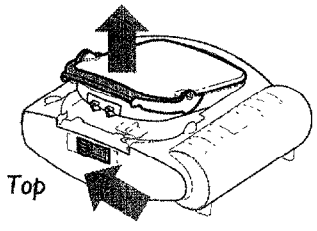
The HeartStart training pads are for practicing how to use your HeartStart OnSite Defibrillator. **They cannot be used to treat sudden cardiac arrest.** ***Do not store the training pads with your HeartStart OnSite Defibrillator.***

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

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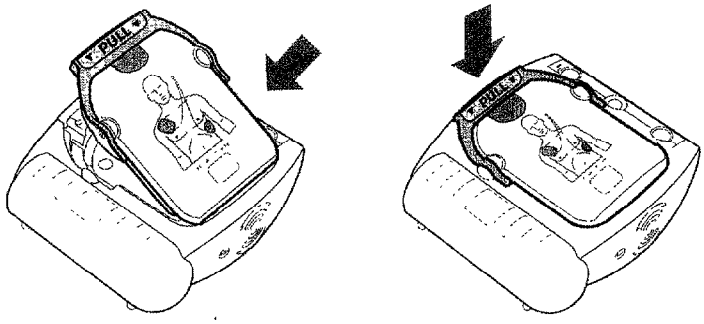
sure the green handle is pressed down firmly. The defibrillator will tell you what kind of pads (Adult, Infant/Child, Adult Training, Infant/Child Training) have been inserted, then it will turn off to be ready for use.



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.*

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.

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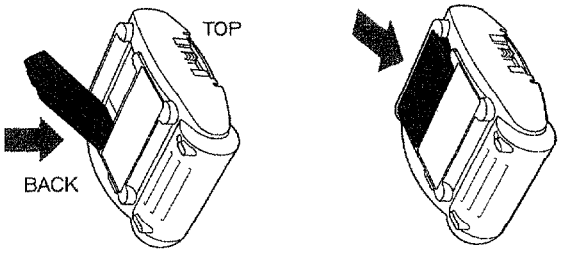
To replace the battery:

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.*

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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.)

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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.

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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.

OnSiteIFU book Page 4 Tuesday, November 12, 2002 12:27 PM

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 solid	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.
green Ready light is off HeartStart does not chirp i-button does not flash	There is no battery inserted, the battery is depleted, or the 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.

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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 pads cartridge	• 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.	• 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.	• 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 pad 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.

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DEFIBRILLATOR TELLS YOU:	POSSIBLE CAUSE	RECOMMENDED ACTION
... to stop all motion	• 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.	• 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.
... the shock was not delivered	• 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.	• 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.
... the shock button was not pressed	Shock has been advised but the shock button has not been pressed within 30 seconds.	When next prompted, press the Shock button to deliver shock.

Troubleshooting while the defibrillator is not being used

(green Ready light is *not* on)

BEHAVIOR	POSSIBLE CAUSE	RECOMMENDED ACTION
chirps or i-button flashes	• 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.	• 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.
no chirping and/or i-button does not flash	• The battery is missing or completely depleted. • The defibrillator may have been physically damaged.	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.

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

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

B Technical information

Clinical studies synopses

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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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.

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Environmental

CATEGORY	SPECIFICATIONS
temperature and relative humidity (HeartStart with battery and pads cartridge installed)	**Operating:** 32° to 122° F (0° to 50° C); 0% to 95% RH (non-condensing). **Standby:** 50° to 109° F (10° to 43° C); 10% to 75% RH (non-condensing).
altitude	Operates at 0 to 15,000 feet; can be stored at up to 8,500 feet, in standby mode.
shock/drop abuse tolerance	Withstands 1 meter drop to any edge, corner, or surface.
vibration	**Operating:** meets EN1789 random, road ambulance. **Standby:** meets EN1789 swept sine, road ambulance.
sealing	Drip proof per EN60529 class IPx1. Solid Objects per EN60529 class IP2x.
ESD	Meets EN60601-1-2 limits (1993), 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).

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 rhythms	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. *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.*

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 protocol, 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 rhythms – 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.

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Defibrillator

CATEGORY	SPECIFICATIONS
waveform	Biphasic truncated exponential. The SMART Biphasic waveform parameters are automatically adjusted as a function of patient defibrillation impedance. 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.
delivery	Using HeartStart Adult SMART Pads: 150 J nominal into a 50 ohm load. Using HeartStart Infant/Child SMART Pads: 50 J nominal into a 50 ohm load.
charge control	Controlled by Patient Analysis System for automated operation.
shock to shock cycle time	< 20 seconds typical, including analysis.
"charge complete" indicator	Shock button flashes, audio tone sounds.
disarm	Once charged, the defibrillator will disarm if: • 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 pads 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.

Controls and indicators

CATEGORY	SPECIFICATIONS
controls	Green SMART Pads cartridge handle Green On/Off button Blue i-button Orange Shock button
indicators	**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.
beeper	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 *Instructions for Use*.
standby life (after insertion)	Typically, 4 years when stored and maintained according to directions provided in these *Instructions for Use*.
training life	Supports 10 hours of use in training mode.

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OnSiteIFU.book Page 7 Tuesday, November 12, 2002 12:27 PM

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.

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 BF patient connection.
	Refer to operating instructions.
	Certified by the Canadian Standards Association.

C

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OnSiteIFU.book Page 2 Tuesday, November 12, 2002 12:27 PM

SYMBOL	DESCRIPTION
CE 0123	Meets the requirements of the European medical device directives.
REF	Reference order number.
SN	Serial number.

Accessories

HeartStart battery M5070A and packaging

SYMBOL	DESCRIPTION
	Lithium manganese dioxide battery.
QTY (1)	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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SYMBOL	DESCRIPTION
	Handle with care.
	Transportation and storage requirements (refer to associated thermometer symbol).
	Environmental (temperature and relative humidity) requirements.
INSTALL BEFORE	Install the battery in the defibrillator before the date (MM-YYYY) shown on the associated label.
CE 0123	Meets the requirements of the European medical device directives.
LOT	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.

SYMBOL	DESCRIPTION
	Store the pads at temperatures between 0° and 43° C (32° and 110° F).
	Refer to operating instructions.
LATEX	This product does not contain natural rubber latex.
NON-STERILE	This product is not sterile.
EXP DATE MM / YYYY LOT 1234567890	(On package) Expiration date; discard the pads after the date shown. Lot number.
EXPIRATION DATE MM / YYYY LOT 1234567890	(On foil seal) Expiration date; discard the pads after the date shown. Lot number.
	Pads intended for use on infant or child under 8 years or 55 pounds (25 Kg).
CE CE	Meets the requirements of the European medical device directives.

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.

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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."

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.

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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 500-503). In accordance with the IEC Classifications (Section 6.5.), the defibrillator is not to be used in the presence of flammable substance/air mixtures.
WARNING	Use the defibrillator only as described in these *Instructions for Use*. 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.

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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.

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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 15 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.

SAFETY LEVELS	POSSIBLE BURNS AND INEFFECTIVE ENERGY
PRECAUTION	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.

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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

OnSiteIFU.book Page 2 Tuesday, November 12, 2002 12:27 PM

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	Three shocks must be delivered in a series to activate the automatic **protocol pause** for patient assessment and CPR. During the **protocol pause**, the HeartStart does not perform rhythm analysis. 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: • 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.

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PARAMETER	DEFAULT	DESCRIPTION
NSA pause type	SMART NSA pause	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. *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.* *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.*
NSA pause timer (minutes)	1.0	An NSA pause interval of 1 minute automatically starts after a **no shock advised (NSA)** decision: • 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	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. *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.*
CPR prompt rate (compressions per minute)	100	Signals for CPR compressions are given at a rate of 100 per minute when the user presses the i-button for optional CPR coaching.

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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

Manufacturer	Product
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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

RECD 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.

(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 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 _____

Attachment 4

This report is considered company confidential and is not releasable to the public under 21 CFR 10.2(i) and is provided as a separate attachment in accordance with 21 CFR 10.2(ii) that addresses the handling of confidential information.

PHILIPS

Philips Automated External Defibrillator Field Performance Summary

H04044

Prepared by:	date 3/31/04 Iain Valentine, Medical Affairs
Approved by:	date 3/31/04 Teresa Skarr, Regulatory and Medical Affairs Manager
	date 3/31/2004 Dan Powers, Chief Engineer

Introduction

In the United States, sudden cardiac death claims over 1,200 lives per day.[1] The majority (nearly 80%) of these cardiac arrests happen in the home. The medical necessity of rapid defibrillation for cardiac arrest victims in ventricular fibrillation is unquestioned.

Heartstream was founded in 1992 with a commitment to preventing unnecessary deaths from sudden cardiac arrest. To achieve this goal, Heartstream, now a part of Philips Medical Systems, has worked to increase access to defibrillators by improving their ease of use and designing devices that users can rely on in an emergency. In November 2002, Philips received FDA clearance for the HeartStart Home Rx Defibrillator. This defibrillator, part of the HS1 family of products, was the culmination of 10 years of work to develop a defibrillator specifically for use in the home. The HeartStart Home OTC Defibrillator represents the next step—making these devices more readily accessible in the critical first few minutes following sudden cardiac arrest.

Beginning with the development and release of the ForeRunner defibrillator in 1996, Philips has worked to overcome obstacles to the immediate treatment of SCA by designing and producing defibrillators that provide the greatest ease of access to the largest number of potential users. Furthermore, it is known that access to a device alone is not sufficient to meet the needs of SCA victims and those who treat them. The urgency dictated by emergency use necessitates that the defibrillator be simple to use, in order to reduce the delay in the delivery of potentially life-saving therapy. Finally, because the purpose of a defibrillator is to deliver emergency therapy to a patient who otherwise will not likely survive, it is important for users to be able to rely upon it to operate without error. This design philosophy of ease of use and reliability is evident in the design of both the ForeRunner and its successor the FR2. In developing the first defibrillator of a new generation specifically for the home user, Philips worked diligently to improve upon the already excellent record of these devices in the field. The result was the HeartStart Home Rx Defibrillator.

Medical Device Reports, Product Issue Reports, and Field Incidents

The emergency use application of Automated External Defibrillators (AEDs) requires attention to several key factors in the design of each device to maximize both access to and delivery of therapy to cardiac arrest victims. Developments in the design of defibrillators over the past few decades have improved their ease of use, making the delivery of life-saving therapy more available to an increasing number and broader range of users. Philips is committed to furthering these developments, as reflected in the safety and reliability history of its more than 150,000 defibrillators in service.

In an early study of the failures associated with the use of defibrillators in a clinical setting, the Food and Drug Administration's Defibrillator Working Group concluded that the failure to deliver a defibrillatory shock is attributable to two major causes—either device malfunction or

[1] Zheng ZJ, Croft JB, Giels WH, Mensah GA. Sudden cardiac death in the United States, 1989 to 1998. Circulation 2001;104:2158-2163.

an error committed by the operator.[2] The Defibrillator Working Group's report was published during early development of the Heartstream ForeRunner and was carefully considered as design input for hazard mitigation and development of specifications as appropriate.

MDRs

As the Defibrillator Working Group observed, the urgent circumstances in which these devices are applied, and the frequently negative outcomes that occur despite their use, complicate understanding the impact of a potential device malfunction on the ability to resuscitate a patient.[3]

The Medical Device Reporting program, established in 1984, requires manufacturers to notify the FDA whenever they receive information suggesting that one of the devices that they manufacture may have caused or contributed to a death or serious injury (21 CFR part 803). In the context of defibrillators, this requirement applies even to those incidents in which the patient would not have benefited from defibrillation therapy, or in which the condition of the patient degenerated to the point at which a defibrillator could not reasonably be expected to provide benefit to the patient.[4] In addition, this regulation applies to any malfunction, such as those discovered during testing of the device, that could likely cause or contribute to a death or serious injury, if such malfunction were to recur. Some customer reports of defibrillator use are unsuccessful attempts to resuscitate, and even if no evidence indicates that the device malfunctioned or contributed to the patient's outcome, the report may require an MDR under the regulations.

For example, Philips, as of February 1, 2004, has filed 35 MDRs in which the customer reported that an AED did not produce voice prompts. Investigations of these reports found that in 32 of these cases, the problem was caused by a mechanical failure of the defibrillator's speaker; in 2 cases the reported units were not returned by customers; and in one case a faulty electrical component was responsible. In each of the 35 reports, the user reported discovering the issue during training or routine testing (e.g., a Battery Insertion Test).

The remaining MDRs filed by Philips as of February 1, 2004, concerned:

- Algorithm Sensitivity (6)
- Patient connection (11)
- Other miscellaneous (7)

Examples of the kinds of questions that are grouped in these categories are discussed in the "Emergency Use Events" section, below.

Two MDRs have been reported by customers, neither of whom were physicians. The first was a duplicate of an MDR filed by both Philips and its distributor, Laerdal Medical Corporation.

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[2] Cummins RO, Chesemore K, White RD, the Defibrillator Working Group. Defibrillator Failures: Causes of Problems and Recommendations for Improvement. *JAMA* 1990; 264:1019-2025.

[3] *Ibid.*
[4] *Ibid.*

The second was filed by one of Philips' business customers and concerned a routine self-test failure that did not occur during patient use and would not cause or contribute to death or serious injury if it were to recur.

Medical device reports for defibrillators should be considered in light of the unique application of the rules to this type of life-saving product. In all the reports Philips has received for AED failures or potential malfunctions through February 1, 2004, none has indicated that a Philips defibrillator or any of its accessories has caused a death or serious injury to a patient, user, or bystander. A complete summary of all Philips Medical Device Reports is provided in Attachment 1.

Reliability - Industry (Recalls)

In general, defibrillator manufacturers have been improving the reliability of products manufactured and distributed in the United States. A summary of class I and II recalls in the United States for defibrillators and related accessories produced by all manufacturers demonstrates an improving trend in product quality and reliability across the industry since 1989. Although minor fluctuations in the total number of industry-wide recalls occurs from year to year, the trend is clearly evident when quinquennial totals for the last 15 years are reviewed. The total number of recalls issued for the period from 1989 to 1993 is 37, for 1994-1998 is 32, and 1999-2003 is 20.

To increase access to early defibrillation sufficient to make a difference in public health requires distributing a large number of devices. This requirement demands attention to hazard mitigation to avoid recalls altogether.

When Philips Heartstream was founded in 1992, the design of existing defibrillator products relied on manufacturer-initiated product recalls to prevent potential widespread device failures following the discovery of systemic component or process-related failures. In addition to a very limited amount of automated functionality, defibrillator manufacturers of that era depended principally upon manual user testing of each device in the field to assure its readiness for use.

Philips recognized early on that the cost of failure was a huge component of the overall cost of doing business for a defibrillator manufacturer. A single field failure requires a significant investment in resources – including investigation of the issue, reporting when necessary, and implementing the appropriate corrective or preventative actions. Achieving the goal of increased access to timely defibrillation requires the deployment of hundreds of thousands, if not millions, of defibrillators worldwide. However, historic field failure and recall rates applied to these volumes of defibrillators would not permit a viable business. Consequently, Philips aligned its reliability and quality goals with its business goals. Philips recognized that it was imperative to greatly improve upon the historical norms in order to provide reliable products at a reasonable cost to the purchaser.

To date, Philips has initiated one recall of one of its AEDs. This was an FR2 AED that had been built with a component that allowed the FR2 to meet all performance specifications but might have failed one of its self-tests sooner than expected. The problem was detected by a Rework Technician who noticed parts that seemed incorrect for the FR2's circuit. He quickly identified all three FR2s in which the parts had been used, including two that had not yet been shipped. The customer was contacted the next business day after the product was shipped. The customer returned it to Philips, never having to put the device into service. The FDA determined that this was a class II recall.

Philips's product development teams use field data, manufacturing data, and significant relevant product line experience to create designs that are simple, robust, and thoroughly self-testable. Also, Philips routinely researches publicly available data related to defibrillator safety issues, such as MDRs and recalls for competitive products. The reliability improvements made with the introduction of each defibrillator model demonstrate organizational learning and a continued commitment to improving device quality.

Philips Product Reliability – Customer Product Issue Reports (PIRs)

Accounts of end-users reporting an issue encountered during use of a Philips defibrillator are an accurate reflection of our devices' reliability and readiness to provide defibrillation therapy. Philips also trends a number of different data relating to customer reports, field product quality, and field product reliability. The metrics and reports discussed below are based on field data reported to Philips from its entire customer base, including international customers for whom prescription is not required to purchase an AED.

The first metric discussed is the Product Issue Report (PIR) rate. The PIR represents all reports received from customers concerning devices. The second, the Confirmed Product Failure (CPF) rate, is a subset of the PIR and represents customer reports in which a device failure was confirmed.

A distinction is made between these metrics because the customer's perception and understanding of the device function is an important element in the successful application of the AED. The PIR rate trends all reports received prior to evaluation and analysis, in order to better understand the way in which customers perceive the operation of a defibrillator. The second metric, the CPF rate, trends all confirmed field failures. Confirmed field failures include reports unrelated to emergency use. Also, confirmed field failures include all reports in which the customer requested service for a device because the defibrillator's test feature successfully identified a potential issue or fault prior to use. When a Philips defibrillator removes itself from service, it functions as designed by alerting the customer that an issue has been detected; product labeling instructs the user to contact Philips for technical support in such situations. For a comparison of these rates, refer to the table below, titled "Product Metrics."

The defibrillators that removed themselves from service operated according to their design by successfully identifying the potential failure through self-test. However, comparing the PIR rate with these data included to the PF rates further illustrates the success of self-test in identifying potential issues prior to use.

Since the introduction of the ForeRunner in September 1996, Philips has released the FR2, a successor to the ForeRunner, and the HeartStart Home and OnSite defibrillators ("HS1"). As of December 31, 2003, Philips has shipped approximately 36,000 ForeRunners, 104,000 FR2s, and 10,000 HS1s (150,151 total as of January 15, 2004) to domestic and international customers.

The number of customer reports received for all issues concerning the entire installed base of Philips defibrillators (accessories excluded) from September 1996 through December 31, 2003 is 2,750. Of this total, fewer that 10% (226) involved questions regarding device performance during an emergency use. A chart comparing the number of use reports for each model of AED is supplied in appendix B. The defibrillators' self-test feature is designed such that self-test failures can cull out-of-specification devices before they become unusable. This is a significant improvement over the previous defibrillators produced by other manufacturers that depended upon user-conducted functional "shift checks" to determine device readiness. The ability of the Philips device to accurately measure and interpret literally hundreds of parameters created an early warning system that had no historical precedent.

When examining the failure rates of these devices, one must consider that the majority of the reported failures occurred while the defibrillator was in standby operation. Also, the PF rates of Philips AEDs should be reviewed in the context of the generation of similar devices that immediately preceded them.

The Hewlett Packard Codemaster manual defibrillator reported an annualized product failure rate at one year after its release of approximately 7.01%. When comparing the failure rates of the Codemaster defibrillator and the first generation of Philips AED (ForeRunner), it is important to consider the technical differences between the devices, the markets for which they were designed, and the impact that these differences may have on field failure rates. For example, the HP Codemaster was designed specifically for ALS and hospital use. In such an environment, it is likely that an individual Codemaster defibrillator would be used more frequently than typical AEDs and might be consistently subjected to abusive handing. However, this should not suggest that the ForeRunner is inappropriate for use in similar environments. It was designed to withstand the often harsh circumstances associated with emergency response, and has proven to be a robust and durable defibrillator for emergency use. Both ForeRunner and FR2 defibrillators are commonly used in hospitals as well as by ALS responders outside the hospital. In addition, the Codemaster was significantly more complex, including functions such patient monitoring that were excluded from the ForeRunner's design. Philips' development team recognized that product reliability tends to decrease as device complexity increases. Thus, reducing complexity in the design of the ForeRunner became an important facet of achieving the goal of maximum reliability.

At one year after its release, the annualized product failure rate for the ForeRunner was 1.3%, and the FR2 maintained the excellent reliability history of its predecessor. The newest generation defibrillator from Philips has again improved upon product reliability. The annual PF rate for the HeartStart HS1 was less than 0.04% at one year. That is, of 10,000 HeartStart HS1s in standby service, Philips would expect to have failures identified in 4 units per year. These failures, in

turn, were identified during self-testing and not during an emergency, as was also typical for the ForeRunner and FR2.

The annual Product Issue Report rate and the annual Confirmed Product Failure rate for each generation of Philips defibrillators are listed in the table below, and examples of reported questions concerning emergency use are discussed in the section that follows.

Table 1: Product Metrics

	PIRR	PIRR	PIRR
	1.68%		
	0.92%		
	0.76%		
	0.72%	0.74%	
	0.62%	0.82%	
	0.55%	0.56%	0.00%
	0.40%	0.57%	0.18%

PIRR: Product Issue Report Rate
CPFR: Confirmed Product Failure Rate

Philips Defibrillator Field Performance – Emergency Use Events

Although the rate of PIRs for Philips defibrillators is exceptionally low relative to failure rates for current manual defibrillators and previous generations of similar products still in service, the most important measure of defibrillator reliability is the rate of confirmed failures that occurred during emergency use. Although data on use failures is rarely reported as a rate, the FDA's Defibrillator Working Group summarized a discussion of defibrillator failures by researchers from the University of Washington. This group studied resuscitation attempts in King County and identified 6 device failures out of 357 cases in which the defibrillator failed to deliver a shock to a set of patients in VF when attempted, or a rate of 1.68%.[5]

Due to a broader target market, it is reasonable to assume that the use rate for Philips AEDs is lower than that of the defibrillators in the King County study. However, Philips' installed base is large enough that its ForeRunner and FR2 defibrillators have been used in approximately 600,000 cases of suspected cardiac arrest. This figure excludes an estimate of the number of events in which the HeartStart HS1 may have been used. The body of data currently available concerning the use of these devices is too small to reasonably generate such an estimate. However, it is assumed that the average rate per year that an HS1 defibrillator is used in cases of suspected cardiac arrest is lower than that of its two immediate predecessors. This assumption is based on the use model and known customer base of the three devices. The ForeRunner and the FR2 were designed for both high-use environments (e.g., hospitals, fire and EMS services) and low-use environments (e.g., public schools, local, regional and federal government offices,

[5] Cummins, et al

corporate workplaces, residences), while the HS1 was designed specifically for homes and businesses.

The rate at which HS1 defibrillators is used is likely to correlate strongly to the rates at which ForeRunner and FR2 are used in those markets for which the HS1 was designed. In 2002, Philips Medical Systems conducted a survey among its installed base of AED use in homes, businesses, and public places. Although the number of events in which an individual device was used was not studied by the survey, the results indicated that 13% of businesses (209/1581) and 5% of homes (4/73) surveyed that had owned an AED for a minimum of 12 months responded to a suspected case of cardiac arrest with an AED.[6]

Confirmed Failures

Based on device internal memory data collected from ForeRunners returned from the field for analysis, an annual use rate for Philips defibrillators was estimated. A denominator for the use failure rate was calculated based on the average annual use rate per unit and the number of service years of the installed base of Philips defibrillators. The rate at which Philips ForeRunner and FR2 defibrillators failed during use from December 1996 through December 31, 2003, is less than 0.0005%. Although the average number or uses for the HS1 per annum is presumed to be lower than ForeRunner and FR2, its confirmed use failure rate remains 0.0%.

Considering the frequency with which Philips' AEDs are used, even by lay customers, the use failure rate is very low. The total number of emergency uses in which mission success may have been compromised by a confirmed failure of a ForeRunner or an FR2 is 5, one of which was a simulated use. A summary of the report and the findings for each investigation is included as a list in Attachment 2.

- HS1: No confirmed failures
- FR2: 4 confirmed failures
- ForeRunner: 1 confirmed failure (simulated use)

Five reports involving a Philips AED were confirmed. In each case, the root cause was identified and traced to a faulty component, and in none of these incidents did the root cause occur more that once. Furthermore, in the most recent instance, the responder observed the anomalous behavior of the defibrillator during use, removed and reinserted the battery, and successfully delivered two shocks to the patient. The user stated that although it was necessary to apply another defibrillator upon the arrival of Advanced Life Support personnel, the FR2's malfunction did not have a negative impact on the outcome of the patient.

The single ForeRunner defibrillator failure was not originally reported in the context of an emergency use. During evaluation and troubleshooting of the device, Philips' Quality Engineering team recognized a potential emergency use logged in the unit's internal memory. Based on the recorded use data, it was determined that the use was most likely simulated, and it was later confirmed by the customer during the investigation that no patient was involved. The

[6] Jorgenson D, Skarr T, Russell JK, Snyder DE, Uhrbrock K. AED Use in Businesses, Public Facilities and Homes by Minimally Trained First Responders. *Resuscitation* 2003; 59:225-233.

root cause was traced to a faulty component in the ForeRunner's internal circuitry, and it remains the only reported failure of its kind Philips has received as of February 1, 2004.

Use Event Reports

As noted above, Philips received a total of 226 customer reports concerning device performance during use (use event reports) as of February 1, 2004. Use event reports are summarized below based on the customer description of the issue provided in the report. An explanation of the kind of reporting encountered in each category is also provided. The categories are summarized as follows:

- Question concerning the sensitivity of algorithm (68, 30%)
- Question concerning the connection to the patient (21, 9%)
- Reports in which the customer reported that the device interrupted analysis. (20, 9%)
- Question concerning the specificity of algorithm (19, 8%)
- Miscellaneous (98, 44%).

Sensitivity

The most commonly reported concern associated with emergency use of Philips AEDs is that a device did not recommend or deliver a shock for a rhythm that was considered shockable upon review by a medical professional. Analysis of ECG data recorded from these incidents and investigations of device performance concluded that the patients involved in these cases most typically presented asystolic or fine VF rhythms that the defibrillator algorithm identified as non-shockable according to its design and specifications. The fine VF rhythms are borderline rhythms; disagreement exists among practitioners concerning what should and should not be shockable in this region. As the AHA states in the ACLS textbook, fine VF and coarse asystole are virtually indistinguishable.[7] Also, users frequently perform CPR after the defibrillator indicates that no shock is advised. In some cases, users misinterpret artifact visible on printouts of event data as VF. However, analysis of the data by Philips personnel, including the artifact channel logged by the device, showed that the rhythms in these cases were in fact asystole, or otherwise non-shockable.

Patient Connection

Users have also occasionally reported difficulty establishing a connection between the patient and the device. The causes of the issue are dependent on the circumstances of the report and varied accordingly. In one example, the user reported attaching a total of four sets of defibrillator pads to a patient with severe psoriasis. The pads were connected to a ForeRunner defibrillator and were replaced each time the unit instructed the user that adequate contact was not established. Subsequently, the attached pads were connected to a different ForeRunner and received the same instruction to ensure the pads were firmly applied. Analysis of the ECG and event data from both units revealed that the patient's impedance did not fall below 1500 ohms

7 American Heart Association. Advanced Cardiac Life Support, 7-97, page 3-5, Fig.5.

and typically exceeded 2000 ohms throughout the incident. A delivery of a shock into impedances of this level would have been ineffective, because the current level would have been too low, and most of the energy would have been dissipated into the patient's skin. Each of the ForeRunners operated according to its design and specifications in these cases.

The majority of the remaining reports concerning patient connection issues indicated that the device instructed the user to ensure that the defibrillation pads were firmly affixed to the patient, or to use a new set of pads. It is not always possible to determine the cause of intermittent pad function after the fact. Frequently, pads have been discarded by the customer and are not available for investigation. Also, defibrillation pads are a single-use item, and circumstances of emergency use, such as CPR, can damage the pads after their application to the patient. Although Philips AEDs did not allow for a conclusive determination that the difficulties with the patient connection were not caused by the pads, due to the possibility of a problem with the pads themselves, Philips filed MDRs for some of these reports as required. The design of the HeartStart HS1 incorporates a self-diagnostic suite of tests to ensure that the defibrillation pads contained in the pre-attached pads cartridge are ready for use. The automatic self-test of the defibrillation pads provides for notification of the user of potential problems with the pads. This design is expected improve Philips' ability to investigate and determine the cause of reported patient connection issues.

Analysis Interrupted

Some users reported receiving voice prompts from the device stating that analysis was interrupted. The analysis system is designed to detect the presence of artifact that could potentially interfere with correct analysis of heart rhythm. When such artifact is detected, the device instructs the user to stop motion and to ensure that no user or bystander is in contact with the patient. Upon investigation of these reports, the most frequent cause of artifact was due to patient handling associated with CPR for patients in very low amplitude heart rhythms such as asystole.

Specificity

The smallest group of reports received by Philips concerns the specificity of the ECG analysis system used in Philips AEDs. In one such example, the user reported that the device appeared to have advised and delivered a shock to a patient presenting a PEA rhythm. An investigation of the event data revealed that the patient appeared to have a pacemaker and that the pacemaker was the source of a signal that mimicked a QRS wave, indicating a normal sinus rhythm. However, the device properly analyzed the patient's rhythm as low-frequency VF, and information provided by the user during Philips' investigation confirmed that the patient had an implanted pacemaker. The device used in this incident, and all devices used in reported events concerning the specificity of the Philips AEDs ECG analysis system, operated according to design and specification.

Miscellaneous

The specific reports included in the fifth and final group of patient involvement reports are too varied to be meaningfully organized into more discreet categories. Reports typically state that the device or, far less frequently an accessory, did not function according the user's expectations. The vast majority of the devices involved in these reports, upon investigation, were found to have functioned according to their design and specifications.

As noted in each example above, Philips defibrillators were found to function according to their design and specifications in all emergency use reports in which the sensitivity algorithm, the connection to the patient, interruption of patient analysis, or the specificity of the algorithm was questioned by the user.

Safety and Effectiveness

The data recorded and trended by Philips Heartstream, including Medical Device Reports, Product Issue Reports, Emergency Use Reports, and Product Failures demonstrates the Company's commitment to and success in designing and manufacturing the most reliable defibrillators possible. While device reliability is indispensable to providing access to early defibrillation, the safety and the effectiveness of the defibrillators are essential to successfully treatment of sudden cardiac arrest.

As noted above, Philips has received 19 reports from users concerning the specificity of the ECG analysis algorithm used in its AEDs. Subsequent investigations of each report concluded that the device involved functioned according to its design and specifications.

However, during a review of Philips Optimal Response to Cardiac Arrest (ORCA) study data, a question was raised by a member of the study's Data Safety Monitoring Board (DSMB) concerning the appropriateness of delivering the second shock of a two-shock series in one patient who survived with good cerebral performance.

The ORCA study protocol required consensus of two overreading physicians to determine shock success for each shock delivered to a patient enrolled in the study. The initial ORCA study physicians determined that the first shock was not successful in this particular case, concluding that VF was still present in the professional medical judgment of each overreading physician. During the study, Dr. Douglas Chamberlain, a member of the DSMB, questioned whether that first shock had indeed been successful. The other physician member of the DSMB disagreed with Dr. Chamberlain.

Notes of the DSMB comments were found during Philips' monitoring of the ORCA study data for compliance with the protocol. At that time, it appeared that Dr. Chamberlain's question concerning this case had not been fully resolved; as a result, Philips requested a clarification of the issue from Dr. Chamberlain. In his response, Dr. Chamberlain described the second shock as "inappropriate" because the defibrillator treated AF as VF. However, he also stated that the baseline undulation was less than 1 mm, and that "in this case the defibrillator was entitled to do so [treat AF as VF], and no harm results if there is no coordinated ventricular activity." This case was entered and investigated as a complaint according to Philips quality system requirements.

According to Dr. Douglas Chamberlain, the patient suffered no harm as a result of the second shock, and was released from the hospital with good brain function.

During the investigation of the report, Mr. David Snyder, at that time a designer of the Philips ECG analysis AED algorithm, examined the strips. Recognizing the p-waves, timing of the shock decision and the prior course VF, he agreed that Dr. Chamberlain was very likely correct about the second shock having been delivered to AF. Because the ORCA study required the consensus of two overreading physicians regarding the effectiveness of each shock delivered, two additional physicians then reviewed the patient's rhythm. They concurred that the first shock had been effective in converting the patient's VF, and that the resulting rhythm was not appropriate for an AED shock, as it was most likely AF with no ventricular activity. For reference, a copy of the first page of the ECG including the shock discussed above with annotations by one of the two final overreading physicians has been included as Attachment

Conclusions

Since 1996, Philips Medical Systems has designed and manufactured defibrillators that have proved to be highly reliable in the field. Philips' engineers recognized the importance of device reliability in the early development of the first generation of Philips' automated defibrillators and incorporated technologies that enabled individual devices to thoroughly test themselves for readiness. Implementing this approach to design mitigated the necessity for recalls involving these devices, and greatly reduced likelihood that any given unit would not be ready for use in an emergency. As a result, only four of the approximately 150,000 units distributed–and which collectively have been used an estimated 600,000 times–have failed in a use-related event in such a way as to compromise the delivery of therapy to a patient who may or may not have benefited from a defibrillatory shock. While distributing a large number of devices is an important step toward reaching Philips' goal of making early defibrillation widely accessible to victims of cardiac arrest, the devices' readiness for use and ability to deliver safe and effective treatment are also essential to success.

In addition to clinical study data, the performance of Philips defibrillators in the field has demonstrated their safety and effectiveness. To reiterate, the logged data available from internal memory of the ForeRunner and FR2 shows that these devices are estimated to:

- be used an approximate average of 2.9 times per year per device;
- have been applied to more than 1,000,000 patients in total;
- to have accumulated over 9 million minutes of use time;
- be in use mode for approximately 8 minutes 45 seconds each time they are applied to patients;
- be used more than 5 times as often without delivering a shock as they are used to deliver a shock;
- have delivered more than 600,000 shocks to patients in total.

Based on the reliability and performance history of the Philips ForeRunner and the FR2, and its own excellent reliability data, the HeartStart Home OTC Defibrillator is expected to exceed the field performance standards set by its immediate predecessors.

Appendix A
Methodology of Data Computation.

I. Product Metrics

1. Product Issue Report Rate (PIRR):

$$\frac{\text{Number of PIRs received through n year}}{\text{Installed base through the end of n year}}$$

2. Confirmed Product Failure rate (CPFR):

$$\frac{\text{Total number of confirmed device failures upon investigation of PIRs from n year}}{\text{Installed base through the end of n year}}$$

3. Failure rate at one year

$$\frac{\text{Total number of PFs from completed investigations from first 12 months of shipments}}{\text{Installed base through the end of first 12 months of shipments}}$$

II. Field Use Data

Field use data, including but not limited to:

- Number of estimated uses
- Average number of uses per unit per year
- Total estimated use minutes
- Total number of shocks delivered

These estimates are based on the recorded internal memory files of nearly 750 ForeRunner AEDs returned from the field to Philips for evaluation. The data were extracted from the records on file. A systematic review of the data then sorted events into two categories: those that were likely generated from patient use, and those that were likely generated from use with a patient simulator. Finally, with simulated use sort data excluded, the results were extrapolated to the installed base of ForeRunners and FR2s. The FR2 was the replacement product for the ForeRunner, which was sold into the same target markets.

In order to address sources of bias that may have been introduced to the data as a result of basing results on a sample limited to devices returned for service or other investigation, the use data extracted from the records on file were plotted in two histograms. The first plotted the total time in service for each unit and the frequency of selected failures that best represented potential wear-out failure modes. In general, the distribution appeared to form the left side of a Weibel distribution curve, suggesting that CPF rates for Philips AEDs have not yet begun to rise due to fatigue from extended service life. The distribution of the most common failure mode(fault with the device) for all ForeRunners was relatively normal, as expected. The second histogram plotted the frequency of the same failure modes against the number of shocks delivered by each unit. No increased frequency of the selected failure modes was evident for units with a high number of delivered shocks. In fact, the distribution suggested the contrary. As shock counts increased, the

frequency of selected failure modes as well as overall failures decreased. Most selected failure modes appear to drop into the bottom of the Weibel distribution curve with some residual failures. However, once the frequency reached the bottom of the curve, doubling or even tripling the total number of delivered shocks did not result in significant change in the frequency of failures. This evaluation of service time to failure, and frequency of failures and total delivered shocks strongly suggests that the use data available on record is representative of the total installed base of all Philips AEDs

Appendix B
Number of Patient Use Events for All ForeRunner, FR2, and HeartStart HS1 Defibrillators
December 1996 – December 2003