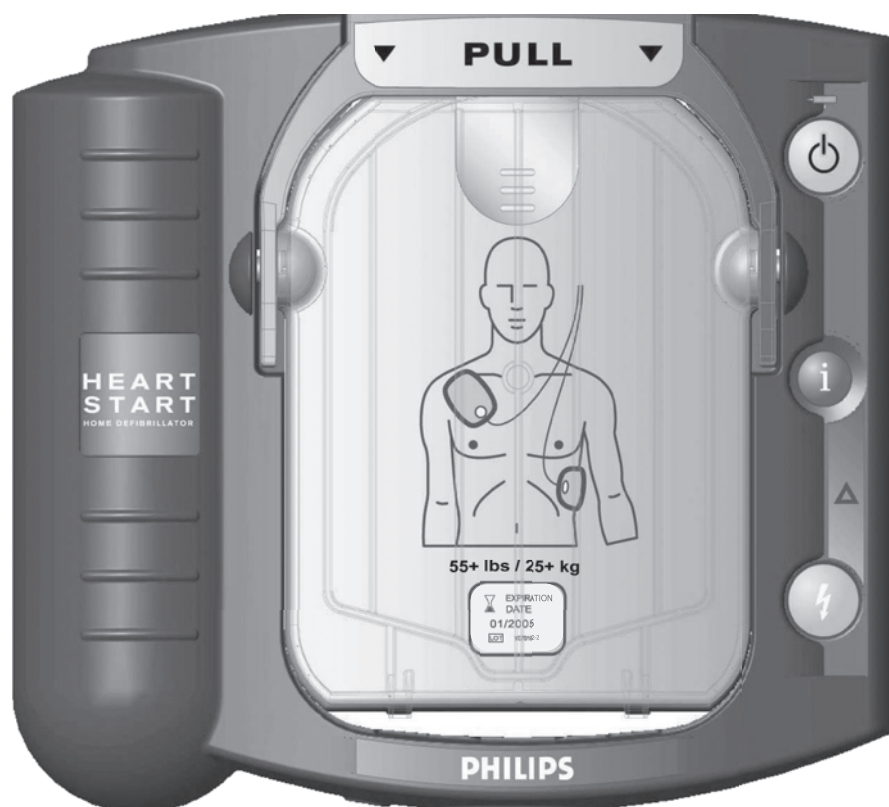


POWER TO SAVE A LIFE



**HEART
START**
HOME DEFIBRILLATOR

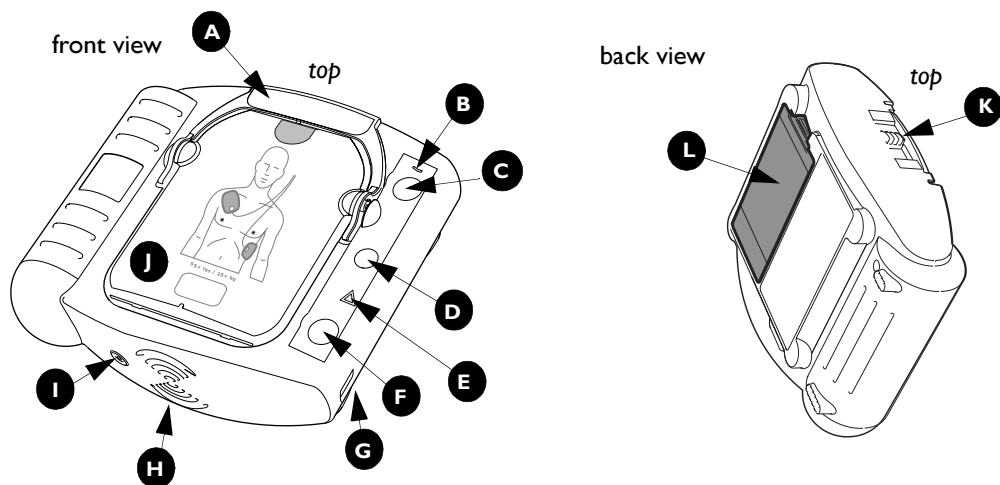


HEARTSTART HOME DEFIBRILLATOR

INSTRUCTIONS FOR USE

PHILIPS

M5068A
Edition 6



The HeartStart Home Defibrillator


A Pads Cartridge Handle. Pull the handle to turn on the HeartStart and remove the cartridge's hard cover.


B Ready Light. This green light tells you the readiness of the HeartStart.


Blinking: standby mode (ready for use)


Solid: in use

Off: needs attention (HeartStart "chirps" and i-button flashes)

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

D Information-Button. This blue "i-button"  flashes when it has information you can access by pressing it. It also flashes at the beginning of a patient care pause when CPR coaching is enabled.

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

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

G Infrared (IR) Communications Port. This special lens, or "eye," is used to transfer HeartStart data directly to or from a computer.

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

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

J SMART Pads Cartridge. This disposable cartridge contains self-adhesive pads with attached cable.

K SMART Pads Cartridge Latch. Slide the latch to the right to release the pads cartridge for replacement.

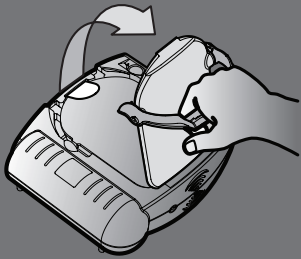
L Battery. The disposable battery is inserted in a recess on the back of the HeartStart.

HeartStart Home Defibrillator

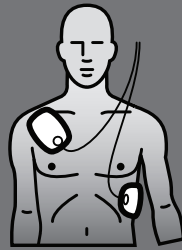
QUICK REFERENCE

Check for signs of Sudden Cardiac Arrest: ☒ Unresponsive
☒ Not Breathing Normally

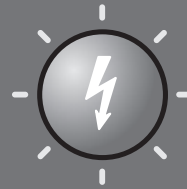
1.PULL



2.PLACE



3.PRESS



Intentionally blank.

HEARTSTART HOME
M5068A
Automated External Defibrillator

INSTRUCTIONS FOR USE

Edition 6

About This Edition

The information in this guide applies to the model M5068A HeartStart Home Defibrillator. This information is subject to change. Please contact Philips at www.HeartStartHome.com or 1.866.333.4246 for information on revisions.

Edition History

Edition 6

Publication date: September 2004

Publication #: M5068-91900

Assembly #: 012026-0006

Printed in the U.S.A.

Copyright

Copyright © 2004

Philips Electronics North America Corp.

No part of this publication may be reproduced, transmitted, transcribed, stored in a retrieval system or translated into any human or computer language in any form by any means without the consent of the copyright holder.

Unauthorized copying of this publication may not only infringe copyright but also reduce the ability of Philips to provide accurate and up-to-date information to users and operators alike.

Authorized EU Representative

Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard Strasse 2
71034 Boeblingen, Germany
(+49) 7031 463-1552

Device Manufacturer

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

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

Contents

I	Introduction to your HeartStart Home Defibrillator	
	What is it?	I-1
	When is it used?	I-1
	How do I know if I should use it?	I-1
	What do I do if I need to use it?	I-2
	How does it work?	I-2
	Can I use it on a young child?	I-3
	Who can use it?	I-4
	More information about clinical use of the HeartStart Home Defibrillator	I-4
2	Getting started with your HeartStart Home Defibrillator	
	HeartStart Home Defibrillator package contents	2-1
	Setting up your HeartStart Home Defibrillator	2-1
	Readiness check	2-4
	Training and practice	2-5
	State and Local Requirements	2-5
3	Using your HeartStart Home Defibrillator	
	Steps for using your HeartStart Home 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

4	After using your HeartStart Home Defibrillator	
	Contacting Philips after a use	4-1
	HeartStart Home Defibrillator data storage	4-1
	Summary data	4-2
	Last-use data	4-2
	After each use	4-2
5	Maintaining your HeartStart Home Defibrillator	
	Routine maintenance	5-1
	Periodic checks	5-1
	Changing the pads cartridge	5-2
	Replacing the battery	5-3
	Cleaning your HeartStart Home Defibrillator	5-4
6	Testing and troubleshooting your HeartStart Home 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	6-3
	Recommended action during an emergency	6-4
	Troubleshooting while the defibrillator is being used	6-6

APPENDICES

A	Accessories for your HeartStart Home Defibrillator	
B	Technical information	
	Clinical studies synopses	B-1
	HeartStart Home Defibrillator specifications	B-2
	Accessories specifications	B-6
C	Glossary of symbols/controls	
	HeartStart Home Defibrillator	C-1
	Accessories	C-2
D	Glossary of terms	
E	Safety considerations	
	General warnings and precautions	E-1
	Defibrillation warnings and precautions	E-3
	Maintenance warning	E-4
F	HeartStart Home configuration	
	Overview	F-1
	Device options	F-1
	Patient treatment protocol options	F-2

Notes



I Introduction to your HeartStart Home Defibrillator

What is it?

The HeartStart Home Defibrillator is part of the HeartStart HSI family of defibrillators by Philips. It is a small, lightweight, automated external defibrillator (AED). Designed to be easy to use, the HeartStart Home Defibrillator is a battery-powered first-aid device for the heart that may help you save the life of someone experiencing sudden cardiac arrest.

If you have concerns about your health or an existing medical condition, talk to your doctor. A defibrillator is not a replacement for seeking medical care.

When is it used?

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

SCA is usually caused by fibrillation, a chaotic quivering of the heart muscle that prevents it from pumping blood. The only effective treatment for fibrillation is defibrillation. Using the HeartStart Home 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 Home Defibrillator should *only* be used to treat someone you think may be a victim of SCA. A person in SCA:

- does not respond when shaken, and
- is not breathing normally.

If in doubt, apply the pads.

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

What do I do if I need to use it?



Stay calm and act quickly. If someone else is available, ask them to call Emergency Medical Services while you get the HeartStart Home 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 Home Defibrillator.”

How does it work?

As soon as you turn on the HeartStart Home Defibrillator, it starts talking to you, to guide you through each step. It tells you to attach the 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.

* The order of treatment for infants and children is different. See the following page for details.

Can I use it on a young child?

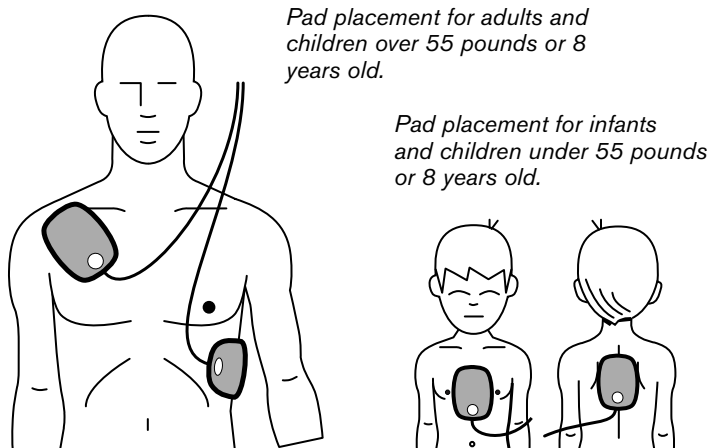
Yes. If the victim is an infant or a child younger than eight years old or weighs less than 55 pounds (25 kg), you should use the special HeartStart Infant/Child SMART Pads.*

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

If you are not sure about the child's exact age or weight or if infant/child pads are not available, **DO NOT DELAY TREATMENT.**

- Perform 1 minute of infant/child CPR
- Call 911
- Then apply the defibrillator.

Use the adult pads, but place them on the child's chest and back, as shown below. Remember that, with the adult pads on a child, the optional CPR coaching will be for an adult.



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

* Available by prescription only. Talk to your doctor.

Who can use it?

You cannot use the HeartStart to treat yourself. The HeartStart talks the user through each step of treating someone who is in SCA. However, anyone who might use the device should review the training materials that come with it, and should be trained in cardiopulmonary resuscitation (CPR). Responding to SCA may require the user to kneel.

More information about clinical use of the HeartStart Home Defibrillator

Contact Philips at 1.866.333.4246 or www.HeartStartHome.com. We will be happy to answer any questions you may have. Clinical summaries of several key studies using Philips automated external defibrillators,* as well as the *Technical Reference Manual* for HeartStart Automated External Defibrillators, are available online at www.medical.philips.com.

IMPORTANT NOTE:

Time is critical in treating sudden cardiac arrest! Survival rates are directly related to how soon victims are defibrillated. For every minute of delay, the chance of survival drops by about 10%. However, it is important to understand that defibrillation cannot always assure survival. In some cases, the cause of the cardiac arrest simply cannot be survived no matter how quickly the victim is treated.

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

2 Getting started with your HeartStart Home Defibrillator

2

HeartStart Home Defibrillator package contents

The M5068A HeartStart Home Defibrillator box contains the following items:

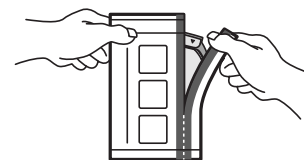
- 1 HeartStart Home Defibrillator in slim carry case M5076A, containing 1 pair scissors, Quick Reference Guide, and Call 911/EMS carry case cards
- 1 battery M5070A
- 1 Adult SMART Pads cartridge M5071A, containing a pair of pads
- 1 literature envelope containing: Owner's Manual, Quick Start poster, HeartStart Support Program enrollment card, Call 911 telephone reminder sticker
- 1 training videotape

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

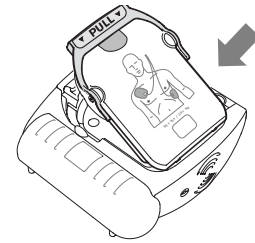
Setting up your HeartStart Home Defibrillator

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

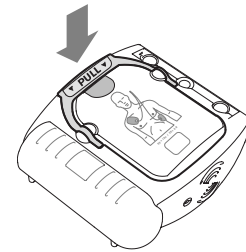
1. Take the HeartStart out of its case.
 - Take a moment to study the front of the HeartStart.
 - Check the drawing and descriptions on the inside front cover of this book. Locate the controls and features of the defibrillator.
2. Put in the SMART Pads cartridge.
 - Open the pads foil pouch and take out the cartridge.



- With the PULL handle side up, put the lower end of the cartridge into the pads compartment.



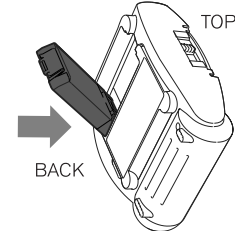
- Press down the top end until the cartridge clicks into place with the PULL handle pressed down.




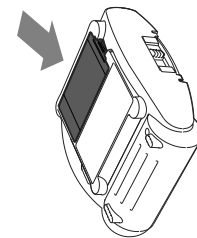
NOTE: To prevent adhesive gel from drying out, **do not open the pads cartridge until you need to use the pads in an emergency.**

3. Put in the battery.

- Take the battery out of its package.
- Put the battery, bottom end first, into the battery compartment on the back of the HeartStart.




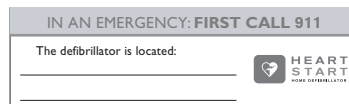
- Press the top (latch) end down until the battery clicks into place.
- The HeartStart runs a one-minute self-test.
- Press the flashing Shock button  when the voice tells you to. (No shock will be given.)
- When the HeartStart passes the self-test it turns off and the Ready light starts blinking to show that the HeartStart is in standby mode and ready for use.



4. Review training materials.

- Watch the short training video for a step-by-step demonstration.
- Read the HeartStart Owner's Manual for information on set up, operation, maintenance, and accessories. Store it in the carry case in the pocket behind the Quick Reference Guide.
- Review the Quick Reference Guide,* found inside the carry case. Return it to the clear window in the red carry case for use in an emergency if needed.

5. Decide where to keep the HeartStart.

- Write your address on the Call 911 card on the back of the carry case. (If 911 is not your Emergency Medical Services number, use the back of the card and write in your EMS number.) A smaller Call 911 card is on the front of the case. (Use the back of the card if 911 is not your EMS number.)

- Place HeartStart in a convenient, central location. It should be near a telephone and where it can be easily seen and heard.
- Locate the telephone reminder sticker. Write the HeartStart storage spot on the sticker. Place the sticker with other emergency numbers so that anyone reporting an emergency will know where to find the HeartStart.

- 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.*
- If you have a practice pads cartridge, it is recommended that you store it separately from the HeartStart, so the practice pads cannot be

* The cover of the Quick Reference Guide 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.

confused with the regular pads in an emergency. The HeartStart will chirp if the practice pads cartridge remains installed for over one hour without being used.

6. Enroll in the HeartStart Support Program.

- We urge you to take a few minutes to enroll in the Philips HeartStart Support Program. This allows Philips or the FDA to send you important notifications about the product. Your participation also allows us to contact you and learn more about home defibrillation. You can also choose to get accessory reminders and other special services.
- For these same reasons, we ask you to contact Philips if you move or if you sell, give away, or throw away your HeartStart.


Readiness check

If the HeartStart Home 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 Home Defibrillator,” for troubleshooting guidelines.)

Training and practice

The HeartStart Home Defibrillator comes with training materials, including a training video and an Owner's Manual, which should be reviewed by anyone who may use the defibrillator.

Reusable accessories are available from Philips for practicing use of the HeartStart Home Defibrillator. See Appendix A for information on ordering Practice Kits.

It is also important to have training in cardiopulmonary resuscitation (CPR). Many training organizations offer a combined course in CPR and defibrillator use. For a list of organizations offering CPR and defibrillator training in your area, contact us by phone at 1.866.DEFIBHOME (1.866.333.4246) or visit us on-line at www.HeartStartHome.com.

State and Local Requirements

Check with your state health department to see if there are any local or state requirements about owning and using a defibrillator. You can find contact information for learning about your state's requirements online, at www.HeartStartHome.com.

Notes

3 Using your HeartStart Home Defibrillator


Steps for using your HeartStart Home Defibrillator

First, try to relax and stay calm. The HeartStart Home Defibrillator automatically talks you through each step of its use. Time is very important, 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 Home Defibrillator and bring it to the victim's side.

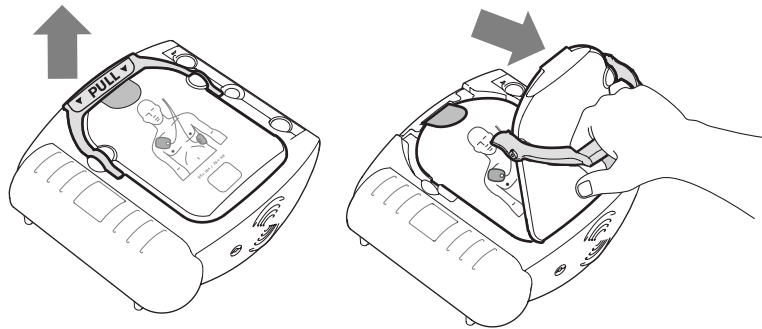
There are three basic steps to using the defibrillator to treat someone who may be in sudden cardiac arrest:

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

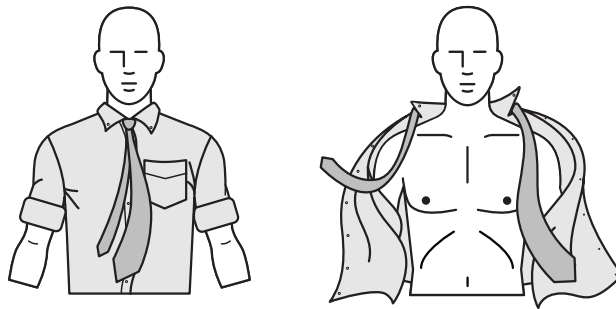
The following pages provide details about each step. At the end of this chapter are some important warnings and precautions.

STEP 1: PULL the green handle

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



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

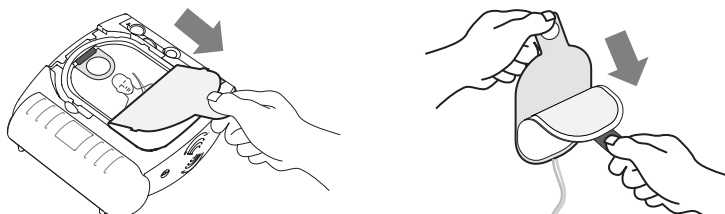
**Reminders:**

- **Time is very important.** 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 Home Defibrillator on someone who has an oxygen mask in place.

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

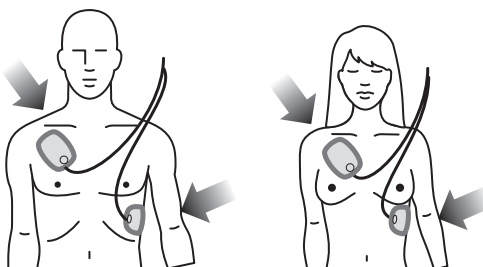
STEP 2: PLACE the pads

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

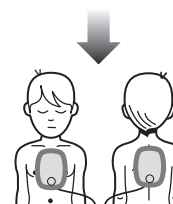


Peel one pad off the liner. Place the pad on the person's bare skin, exactly as shown in the picture on the pad. Press the pad down firmly. Then repeat this with the other pad. Be sure the pads have been removed from the liner before placing them.

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

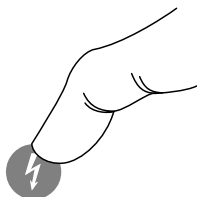



Pad placement for infants or children less than 55 pounds or 8 years old.




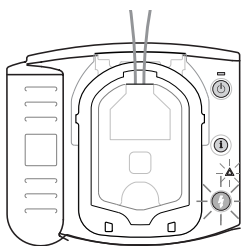
Reminders:



- It may be necessary to dry the patient's skin where the pads will be placed, 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.
- The HeartStart may be used on someone who has an implanted device such as a pacemaker or ICD, but do not place the pads directly over the implant. You can tell where an implant is located by a lump in the skin and a scar.
- 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 Home Defibrillator detects that the 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.

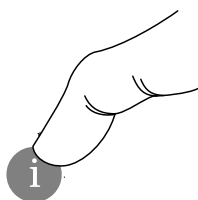
If a shock is not needed, the HeartStart tells you it is safe to touch the patient and instructs you to assess the patient and perform CPR if needed. The blue i-button  will come on during this patient care pause. Press it for CPR coaching.



If a shock is needed, the Caution light  turns on, the orange Shock button  starts flashing, and the defibrillator tells you to press the flashing orange button. When you press the Shock button, the defibrillator tells 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 Home Defibrillator will not deliver a shock unless you press the flashing orange Shock button . If you do not press the Shock button within 30 seconds after the it tells you to, the defibrillator will disarm itself. After a short pause, it will reanalyze the patient's heart rhythm.
- While waiting for you to press the Shock button, the defibrillator will continue to analyze the heart rhythm. If the patient's rhythm changes before you press the Shock button, and a shock is no longer needed, the defibrillator will disarm and tell you a shock is not advised.
- If for any reason you want to turn off the defibrillator, you can press the On/Off button  — holding it down for at least one second — to return the device to standby mode.



Performing CPR


When instructed by the HeartStart Home 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 Home 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 Home Defibrillator. It gives a spoken summary of the data if the i-button  is held down until the defibrillator beeps.

* See Chapter 4, "After using your HeartStart Home 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 Home 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 pads can cause patient skin burns. To help prevent air pockets, make sure 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 pads if they become damaged and insert another pads cartridge.

4 After using your HeartStart Home Defibrillator

Contacting Philips after a use

If you have used or seen use of the HeartStart Home Defibrillator, we urge you to contact us by phone at 1.866.DEFIBHOME (1.866.333.4246) or email at www.HeartStartHome.com. You will be helping us learn more about sudden cardiac arrest.

We are here to answer any questions you may have about the experience. We will also provide counseling services upon request.

With your permission, we will have a medical professional contact you to discuss the use. We assure you that we will maintain patient privacy, and the information you provide will not be shared with other companies.

Also, please let us know if you ever have any problems using or maintaining your HeartStart Home Defibrillator.


HeartStart Home Defibrillator data storage

The HeartStart Home 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 the HeartStart has been used.

The HeartStart is designed to make it easy for physicians and emergency medical personnel to download data. There is an infrared (IR) communications port located on the lower right side of the HeartStart. The port is used to transfer data to a personal computer running HeartStart Event Review software,*version 3.0 or higher, available from Philips. This software allows storage and review of the recorded information, as well as transfer of any revised configuration settings to the defibrillator. Information about Event Review is available from Philips on the internet at <http://www.medical.philips.com/goto/eventreview>.

* CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Summary data

You can get a voice summary of information about the last use of the defibrillator by holding the blue i-button  down until it beeps once. The device will tell you how many shocks were delivered and how long it has been since the defibrillator was turned on. This information is also included in the data transferred using HeartStart Event Review software.

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

Last-use data

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

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

NOTE: Status and rhythm analysis data are kept in the HeartStart's 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 and then erased.† After this time, the last-use ECG recordings will automatically be erased to prepare for a future use.

After each use

1. Promptly provide the HeartStart to medical professionals to download the internal data as needed and return the HeartStart to you.
2. Check the outside of the defibrillator for signs of damage, dirt, or contamination. If you see signs of damage, contact Philips for technical support. If the defibrillator is dirty or contaminated, clean it according to

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

† 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.

the guidelines in Chapter 5, “Maintaining your HeartStart Home Defibrillator.”

3. 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.
4. Remove the battery for five seconds, then reinstall it to run the battery insertion self-test to check the operation of the defibrillator. When the test is complete, check that the green Ready light is blinking.
5. Return the defibrillator to its storage location so it will be ready for use when needed.

Notes

5 Maintaining your HeartStart Home Defibrillator

Routine maintenance

Your Philips HeartStart Home Defibrillator is very simple to maintain. As described in Chapter 6, “Testing and troubleshooting your HeartStart Home 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 may damage the defibrillator and will invalidate the product warranty.

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 Home 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 Home Defibrillator,” for recommended action.
- Check supplies and accessories for damage and expiration dating. Replace any used, damaged or expired items.
- Check the outside of the defibrillator for cracks or other signs of damage. If you see signs of damage, contact Philips for technical support.

Changing the pads cartridge

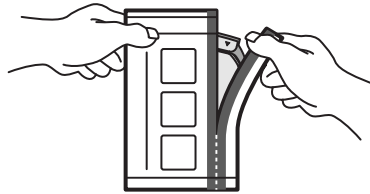
There are four kinds of HeartStart pads cartridges designed for use with your defibrillator: HeartStart Adult SMART Pads, HeartStart Infant/Child SMART Pads, reusable HeartStart Adult Practice Pads, and reusable Infant/Child Practice Pads.

Adult 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 SMART Pads, if available; otherwise, use the Adult SMART Pads placed on the chest and back.

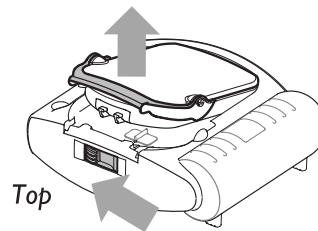
The HeartStart practice pads are for practicing how to use your HeartStart Home Defibrillator. **They cannot be used to treat sudden cardiac arrest. Store the practice pads separately from your HeartStart Home Defibrillator.**

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

1. Remove the new cartridge from its foil pouch.

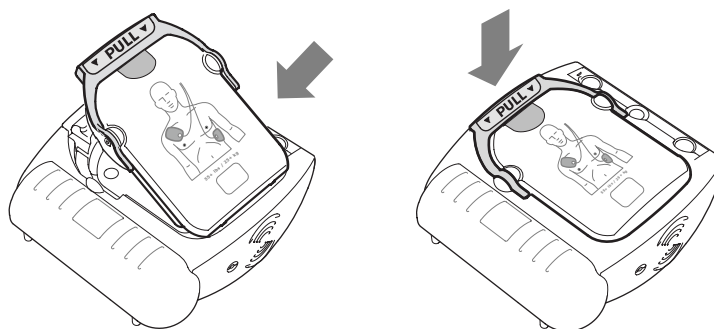


2. Locate the latch at the top edge of the defibrillator, and slide it to the side. The pads cartridge will be released. Remove the old cartridge.



3. Install the new cartridge: slide the bottom end of the cartridge into the recess, then press in the cartridge until the latch clicks into place. Be sure the green handle is pressed down firmly. The HeartStart 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.



5. 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.)
6. Check the green Ready light to make sure it is blinking. Your HeartStart Home 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 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

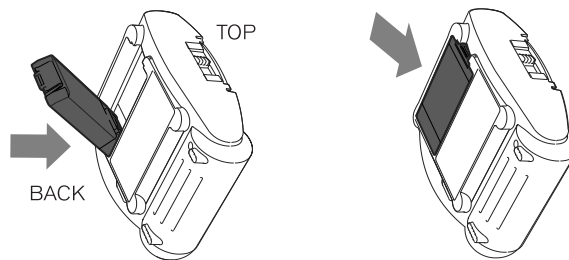
Your HeartStart Home Defibrillator is equipped with a disposable, long-life battery that will typically last for four years in the standby mode. It is recommended that you keep a spare battery available at all times. *Keep the spare battery in its protective plastic bag until it is needed for use.*


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

To replace the battery:

- I. 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 Home 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 Home Defibrillator

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

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

Reminders:

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


6 Testing and troubleshooting your HeartStart Home Defibrillator

Testing

The HeartStart Home 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. (Because it uses power, the battery insertion self-test is not recommended except under certain circumstances.)

Periodic self-tests

The HeartStart Home 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. If you have any question about what to do, call Philips for technical support at 1.866.333.4246.

NOTE: The HeartStart self-tests are designed to check that it is ready for use. However, if your HeartStart 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 HeartStart has visible signs of damage, contact Philips for technical support at 1.866.333.4246.

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 your HeartStart Home Defibrillator," for directions on installing the pads cartridge correctly.)

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

Battery insertion self-test

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


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

- the 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.

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 for technical support.

Troubleshooting

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


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

Readiness summary

behavior	meaning
green Ready light blinks	The defibrillator passed the battery insertion self-test and the last periodic self-test and is therefore ready for use.
green Ready light is 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.

Troubleshooting while the defibrillator is being used

(green Ready light is solid)

HeartStart 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.
... there is no cartridge installed, and ... to insert a pads cartridge	<ul style="list-style-type: none"> The pads cartridge has been removed. The pads cartridge has been damaged. 	Insert a new pads cartridge.
... to press the pads firmly to the skin ... to make sure the pads have been removed from the liner ... the pads should not be touching the patient's clothing.	<ul style="list-style-type: none"> The pads are not properly applied to the patient. The pads are not making good contact with the patient's bare chest because of moisture or excessive hair. The pads are touching each other. The pads may not have been removed from the liner. The pads may be on the patient's clothing. 	<ul style="list-style-type: none"> Make sure that the pads are sticking completely to the patient's skin. If the pads are not sticking, dry the patient's chest and shave or clip any excessive chest hair. Reposition the pads. If the voice instruction continues after you do these things, insert another pads cartridge.

HeartStart tells you:	possible cause	recommended action
... to insert new pads cartridge	The pads cartridge has been opened and the pads peeled off the liner, but the pads have not been successfully attached to the patient. There may be a problem with the pads cartridge.	Replace the damaged or defective pads cartridge. Pull up the handle on the cartridge cover, and replace pads on patient with new pads to continue with the rescue.
... to stop all motion	<ul style="list-style-type: none"> • The patient is being moved or jostled. • The environment is dry and movement around the patient is causing static electricity to interfere with ECG analysis. • Radio or electrical sources are interfering with ECG analysis. 	<ul style="list-style-type: none"> • Stop CPR; do not touch the patient. Minimize patient motion. If the patient is being transported, stop the vehicle. • Responders and bystanders should minimize motion, particularly in dry environments that can generate static electricity. • Check for possible causes of radio and electrical interference and turn them off or remove them from the area.
... the shock was not delivered	<ul style="list-style-type: none"> • The pads may not be making good contact with the patient's skin. • The pads may be touching each other. • The pads may be defective. 	<ul style="list-style-type: none"> • Press the pads firmly to the patient's chest. • Make sure the 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	<ul style="list-style-type: none"> • The battery power is low or the SMART Pads cartridge needs to be replaced. • The defibrillator may have been turned off without a pads cartridge installed, or the installed pads cartridge may not have its hard cover in place. • The practice pads cartridge has been left in the defibrillator. • The defibrillator has been stored outside the recommended temperature range. • The defibrillator has detected an error during a self-test or cannot perform a self-test. • Shock button is defective. 	<ul style="list-style-type: none"> • Press the blue i-button. Replace the battery or pads cartridge if instructed. • Make sure the pads cartridge is properly installed with the hard cover in place. (See Chapter 5, "Maintaining your HeartStart Home Defibrillator," for directions on installing the pads cartridge.) • Remove the practice 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 for service if needed.

behavior	possible cause	recommended action
no chirping and/or i-button does not flash	<ul style="list-style-type: none">• 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 for service.

Notes

A Accessories for your HeartStart Home Defibrillator

Accessories for the HeartStart Home Defibrillator available separately from Philips include:

- Spare battery M5070A (recommended)
- Spare Adult SMART Pads Cartridge M5071A (recommended)
- Infant/Child SMART Pads Cartridge M5072A*
- Adult Practice Kit M5073A, with practice pads cartridge and adult pads placement guide
- Infant/Child Practice Kit M5074A, with practice pads cartridge and infant/child pads placement guide
- Standard carry case M5075A, with paramedics scissors and room for spare pad cartridge and battery
- 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 Defibrillator Quick Reference Guide M5066-97800

To order any of these and other accessories, call Philips at 1.866.333.4246 or visit us on-line at www.HeartStartHome.com.

* Available by prescription only. Talk to your doctor.

Notes

B Technical information

B

Clinical studies synopses

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

* Clinical studies include defibrillators sold as Heartstream ForeRunner and FR2.

HeartStart Defibrillation Therapy Testing in a Pediatric Animal Model

The HeartStart Home 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 Home 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.

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.

category	specifications
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 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 Home Defibrillator uses multiple parameters to determine if a rhythm is shockable. <i>NOTE: Some very low-amplitude or low-frequency rhythms may not be interpreted as shockable VF rhythms. Also, some VT rhythms may not be interpreted as shockable rhythms.</i>
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.

category	specifications
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 Home Default Configuration.”

ECG analysis performance

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

a. From Philips Medical Systems Heartstream ECG rhythm databases.

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

Defibrillator

B

category	specifications
waveform	<p>Biphasic truncated exponential.</p> <p>The SMART Biphasic waveform parameters are automatically adjusted as a function of patient defibrillation impedance.</p> <p>The HeartStart Home Defibrillator delivers shocks to load impedances from 25 to 180 ohms. The duration of each phase of the waveform is dynamically adjusted based on delivered charge, in order to compensate for patient impedance variations.</p>
energy	<p>Using HeartStart Adult SMART Pads: 150 J nominal into a 50 ohm load.</p> <p>Using HeartStart Infant/Child SMART Pads: 50 J nominal into a 50 ohm load.</p>
charge control	Controlled by Patient Analysis System for automated operation.
shock-to-shock cycle time	< 20 seconds typical, including analysis.
“charge complete” indicator	Shock button flashes, audio tone sounds.
disarm	<p>Once charged, the defibrillator will disarm if:</p> <ul style="list-style-type: none"> the patient’s heart rhythm changes to non-shockable rhythm, a shock is not delivered within 30 seconds after the defibrillator has charged for shock delivery, the On/Off button is pressed and held down for at least one (1) second to turn off the defibrillator, the 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 <i>Instructions for Use</i> .
standby life (after insertion)	Typically, 4 years when stored and maintained according to directions provided in these <i>Instructions for Use</i> .
training life	Supports 10 hours of use in training mode.

HeartStart Adult SMART Pads M5071A and
HeartStart 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 M5071A Adult SMART Pads or M5072A Infant/Child SMART Pads with the HeartStart Home Defibrillator.








B





* Available by prescription only. Talk to your doctor.

Notes

C Glossary of symbols/controls






HeartStart Home Defibrillator




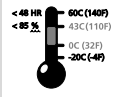




symbol	description
	Pads cartridge handle. Green. Pulling the handle turns on the defibrillator and opens pads cartridge for use.
	On/Off button. Green. Pressing the On/Off button when the defibrillator is in standby mode turns the defibrillator on; pressing and holding the On/Off button for one second 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.

symbol	description
	Certified by the Canadian Standards Association.
	Meets the requirements of the European medical device directives.
	Reference order number.
	Serial number.


Accessories










HeartStart battery M5070A and packaging

symbol	description
	Lithium manganese dioxide battery.
	One battery in package.
	Do not crush the battery.
	Do not expose the battery to high heat or open flames. Do not incinerate the battery.
	Do not mutilate the battery or open the battery case.

symbol	description
	Do not expose to moisture.
	Handle with care.
	Transportation and storage requirements (refer to associated thermometer symbol).
	Environmental (temperature and relative humidity) requirements.
	Install the battery in the defibrillator before the date (MM-YYYY) shown on the associated label.
	Meets the requirements of the European medical device directives.
	Lot number.
	Refer to operating instructions.

HeartStart Adult SMART Pads Cartridge M5071A,
HeartStart Infant/Child SMART Pads Cartridge M5072A,
HeartStart Adult Practice Pads Cartridge M5073A, and
HeartStart Infant/Child Practice Pads Cartridge M5074A

symbol	description
	These pads are disposable and are for single patient use only.

symbol	description
	Cartridge contents: one set of two defibrillation pads.
	Store the pads at temperatures between 0° and 43° C (32° and 110° F).
	Refer to operating instructions.
	This product does not contain natural rubber latex.
	This product is not sterile.
	(On package) Expiration date; discard the pads after the date shown. Lot number.
	(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).
	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 Home Defibrillator and its use.

adhesive pads	See “SMART Pads.”
AED	Automated external defibrillator (a semi-automatic defibrillator).
AED mode	The standard treatment mode for the HeartStart Home Defibrillator. It provides voice instructions guiding the rescuer through applying the 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 Home 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 Home 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 Home Defibrillator, including treatment protocol. The factory default configuration can be modified using HeartStart Event Review software.
CPR	Cardiopulmonary resuscitation. A technique for providing artificial respiration and heart compressions.
defibrillation	Termination of ventricular fibrillation by applying electrical energy.

defibrillation charge	Electrical energy stored in the capacitor of the HeartStart Home Defibrillator 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 Home 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 the most common cause of sudden cardiac arrest.
heart rhythm (ECG) analysis	A system used by the HeartStart Home 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 with the HeartStart Home Defibrillator. Information is available from Philips on the internet at http://www.medical.philips.com/goto/eventreview .
i-button	A blue button on the front of the HeartStart Home 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.
impedance	Electrically, this is the resistance of the body to the flow of the electrical shock waveform delivered by the HeartStart Home Defibrillator. The defibrillator automatically monitors the electrical impedance between the 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 Home Defibrillator.

* CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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

infrared communications	A method of sending information using a special part of the light spectrum. It is used to transmit information between the HeartStart Home 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 Home Defibrillator that a shock is not needed, based on analysis of the patient’s heart rhythm.
NSA pause	A pause provided by the HeartStart Home 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 Home Defibrillator determines is not appropriate for defibrillation.
on/off button	A green button located on the front of the HeartStart Home 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.”
pads placement guide	A fold-out guide provided with the HeartStart Adult and Infant/Child Practice Kits, showing correct pads placement.
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 Home 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.
practice kits	Kits containing a reusable adult or infant/child practice pads cartridge and a pads placement guide, designed for repeated use to practice correct placement of pads. The defibrillator will chirp if the training cartridge remains installed for over one hour without being used.
prompts	The voice instructions used to guide the rescuer through use of the HeartStart Home Defibrillator to treat the patient.
protocol	A sequence of operations performed by the HeartStart Home Defibrillator to direct patient care in the AED mode.
protocol pause	A period provided by the HeartStart Home 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 Home Defibrillator. A blinking Ready light means the defibrillator is ready for use; a solid Ready light means the defibrillator is being used.
rhythm analysis	See "SMART analysis."
sensitivity	A measure of the ability of the HeartStart Home 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 Home 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 Home Defibrillator automatically pauses for CPR. See "protocol pause."
shockable rhythm	A heart rhythm that the HeartStart Home Defibrillator determines is appropriate for defibrillation, such as ventricular fibrillation and some ventricular tachycardias associated with sudden cardiac arrest.
shock series interval	A configurable interval between shocks, used by the HeartStart Home 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 Home 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 Home 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 Home 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 Home Defibrillator.
specificity	A measure of the ability of the HeartStart Home Defibrillator to reliably detect and identify non-shockable heart rhythms.
standby mode	The operating mode of the HeartStart Home 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 (SCA)	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 Home 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 Home 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 5.5.), the defibrillator is not to be used in the presence of flammable substance/air mixtures.
WARNING	Use the defibrillator only as described in these <i>Instructions for Use</i> . Improper use of the defibrillator can cause death or injury. Do not press the Shock button if the defibrillator pads are touching each other or are open and exposed.
PRECAUTION	Hazardous electrical output.

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

safety level	possible improper device performance
WARNING	Prolonged or aggressive CPR to a patient with defibrillator pads attached can damage the pads. Replace the defibrillator pads if they are damaged during use or handling.
WARNING	Using damaged or expired equipment or accessories may cause the defibrillator to perform improperly, and/or injure the patient or the user.
PRECAUTION	CPR during rhythm analysis can cause incorrect or delayed analysis by the defibrillator.
PRECAUTION	Follow all instructions supplied with the HeartStart 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 pads prior to use can damage the pads. Discard the pads if they become damaged.
PRECAUTION	The HeartStart Home Defibrillator was designed to be sturdy and reliable for many different field use conditions. However, excessively rough handling can result in damage to the defibrillator or its accessories and will invalidate the warranty. Inspect the defibrillator and accessories periodically according to instructions.
PRECAUTION	Alteration of the factory default setup of the defibrillator can affect its performance and must be performed by an authorized person. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.

safety level	possible electrical interference with rhythm analysis
WARNING	The HeartStart Home 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 Home 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 Home 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.
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. Call Philips for technical support at 1.866.333.4246.

F HeartStart Home configuration

Overview

The Philips HeartStart Home Defibrillator comes with a factory default configuration designed to meet the needs of most users. This configuration can only be changed 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.

Device options

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

parameter	settings	default	description
speaker volume	1, 2, 3, 4, 5, 6, 7, 8	8	The volume level of the HeartStart's speaker, used for voice instructions and the charge-done tone.
Auto send periodic self-test (PST) data	On, Off	On	Enables or disables the periodic self-test data broadcast through the device's infrared data port.
ECG out data	On, Off	On	Enables or disables the ECG data broadcast through the device's infrared data port.

* CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

Patient treatment protocol options

parameter	settings	default	description
"call EMS" voice reminder	<ul style="list-style-type: none"> • At power on (when the user turns on the HeartStart) • At power on and at the start of the first pause interval • At the start of the first pause interval • No reminder 	At the start of the first pause interval	The voice reminder to call emergency medical services.
shock series	1, 2, 3, 4	3	<p>The number of shocks that must be delivered in a series to activate the automatic protocol pause for patient assessment and CPR.</p> <p>During the protocol pause, the HeartStart does not perform rhythm analysis.</p> <p>The length of the protocol pause after a shock series is completed is defined by the protocol pause timer setting.</p> <p>A new shock series begins:</p> <ul style="list-style-type: none"> • when a shock is delivered after the HeartStart is turned on, • after a protocol pause, or • if the time since the previous shock exceeds the shock series interval setting.
shock series interval (minutes)	1.0, 2.0, ∞ (infinity)	1.0	The interval within which a delivered shock must occur following the previous shock to be counted as part of the current shock series.

parameter	settings	default	description
protocol pause timer (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	1.0	An automatic protocol pause interval after voice instruction when a shock series is completed. After the protocol pause, the defibrillator returns to rhythm analysis.
NSA pause type	<ul style="list-style-type: none"> Standard NSA pause: HeartStart does not perform rhythm analysis during the NSA pause. SMART NSA pause: HeartStart conducts background monitoring during the SMART NSA pause. If a potentially shockable rhythm is detected, HeartStart terminates the SMART NSA pause and resumes rhythm analysis. 	SMART NSA pause	<p>The type of pause following a No Shock Advised decision, defined by whether or not the device performs background monitoring of a motionless during the NSA pause.</p> <p><i>NOTE: If the Shock button is not pressed for 30 seconds after the HeartStart is armed, or continuous artifact is encountered for 30 seconds during rhythm analysis, a 30 second SMART pause is automatically initiated.</i></p> <p><i>NOTE: Use of the optional i-button CPR coaching will convert the SMART NSA pause to a standard NSA pause. During the standard NSA pause, the defibrillator does not perform rhythm analysis for the pause time determined by the selected protocol pause timer and NSA pause timer settings.</i></p>
NSA pause timer (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	1.0	<p>An automatic NSA pause interval after a no shock advised (NSA) decision.</p> <ul style="list-style-type: none"> If a shock has been delivered within the shock series interval, the length of the pause is defined by the protocol pause timer setting. Otherwise, the length of the NSA pause is defined by the NSA pause timer setting.

parameter	settings	default	description
CPR prompt	<ul style="list-style-type: none"> • Check circulation and begin CPR if needed. • Check airway, breathing, and circulation and begin CPR if needed. • Check circulation and begin CPR if needed. Press the i-button for CPR coaching. • Check airway, breathing, and circulation. Begin CPR if needed. Press the i-button for CPR coaching. 	Check airway, breathing, and circulation. Begin CPR if needed. Press the i-button for CPR coaching. ^a	The CPR reminder voice instructions provided at the beginning of a pause interval.
CPR prompt rate (compressions per minute)	80, 100	100	Rate of signals given or CPR compressions when the user presses the i-button for optional CPR coaching.

- a. 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.

Intentionally blank.

POWER TO SAVE A LIFE



**HEART
START**
HOME DEFIBRILLATOR

Philips Medical Systems is part of
Royal Philips Electronics

Philips Medical Systems

United States

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

Canada

Philips Medical Systems
281 Hillmount Road
Markham, Ontario
L6C 2S3
(800) 291-6743

Europe, Middle East, and Africa

Philips Medizin Systeme Boeblingen GmbH
Cardiac and Monitoring Systems
Hewlett-Packard Strasse 2
71034 Boeblingen, Germany
(+49) 7031 463-1552

Latin America

Philips Medical Systems
1550 Sawgrass Corporate Parkway, Suite 300
Sunrise, FL 33323, USA
(954) 835-2660

Asia Pacific

Philips Electronics Hong Kong Ltd.
30th Floor, Hopewell Centre,
17, Kennedy Road, Wanchai,
Hong Kong
(852) 2821 5888

CE 0123

PHILIPS

M5068-91900



012026-0006