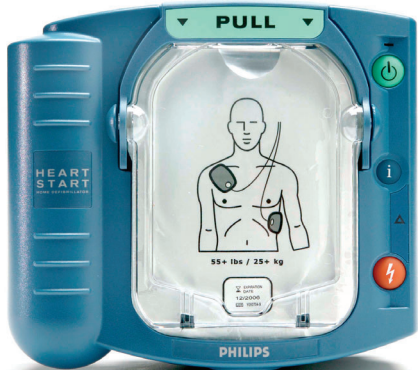


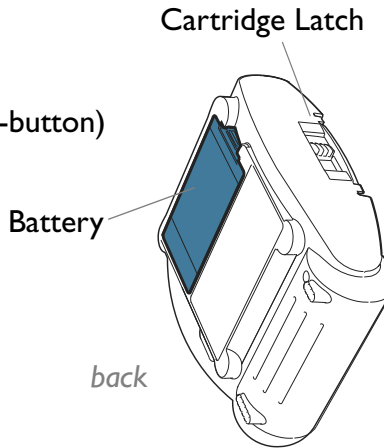
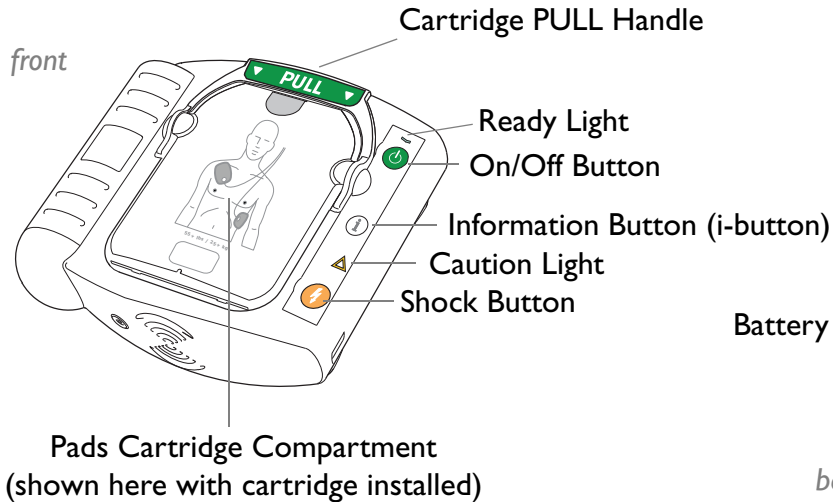
PHILIPS



HeartStart Home Owner's Manual

Your guide to set up, operation,
maintenance, and accessories

IN AN EMERGENCY, CALL EMS FIRST!



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.

HeartStart Home Owner's Manual

Edition 12

PHILIPS

ABOUT THIS EDITION

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

EDITION HISTORY

Edition 12

Publication Date: April 2023

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LANGUAGES

Please contact Philips at 1.866.333.4246 with questions about the HeartStart Defibrillator in other languages.

NOTICES

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NOTES

Use this space to record information about the HeartStart Home Defibrillator.

HeartStart Product Line: HSI

One of the Philips HSI family of defibrillators.

Model Number: M5068A

Serial Number: _____

(on back of device)

Date of Purchase: _____

Place of Purchase: _____

Date of Registration: _____

Customer Support: 1.866.333.4246

SMART Pads Cartridge

installed on: _____

expiration date: _____

installed on: _____

expiration date: _____

HeartStart Battery

installed on: _____

expiration date: _____

installed on: _____

expiration date: _____

INTRODUCTION

THE HEARTSTART DEFIBRILLATOR

The Philips HeartStart Home Defibrillator is designed to be easy to use. The HeartStart talks the user through each step of treating someone who is in 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.

SUDDEN CARDIAC ARREST

Sudden cardiac arrest (SCA) occurs when the heart unexpectedly stops pumping blood through the body. This is usually caused by a disorganized heartbeat called VF, for “ventricular fibrillation.”

Many victims of SCA do not have warning signs or symptoms. Some people may have a higher risk for SCA than others. Causes vary and may be different for infants and

children than for adults. Talk to your doctor about your risk factors.

The Philips HeartStart Home Defibrillator is used to treat VF by sending a shock across the heart, so it can start beating regularly again. Unless this is successful within the first few minutes after the heart stops beating, the victim is not likely to survive.

SCA is not the same as a heart attack, even though sometimes a heart attack can lead to SCA. If you feel the signs of a heart

attack — such as pain, pressure, or a squeezing feeling in your chest or anywhere in your upper body, shortness of breath, and stomach upset — you should call Emergency Medical Services (EMS) right away and also call your doctor.

For people with certain medical conditions who are likely to suffer SCA, an implantable cardioverter-defibrillator (ICD) may be advised. The HeartStart is not intended as a substitute for an ICD. Your doctor can tell you if an ICD might be right for you.

INDICATIONS FOR USE

The HeartStart Home (Model M5068A) is indicated for use on potential victims of cardiac arrest with the following symptoms:

- Unconsciousness; and
- Absence of normal breathing

The HeartStart Home (Model M5068A) is indicated for adults over 55 pounds (25 kg). The HeartStart Home is also indicated for infants/children under 55 pounds (25 kg) or 0-8 years old when used with the optional Infant/Child SMART pads (Model M5072A).

If Infant/Child SMART pads are not available, or you are uncertain of the child's age or weight, proceed with treatment using Adult SMART pads (Model M5071A).

CONTRAINDICATIONS

The HeartStart Home Defibrillator should not be used when a patient is conscious or breathing normally.

TRAINING AND PRACTICE

The HeartStart Home Defibrillator comes with training materials to help you become familiar with the signs of sudden cardiac

arrest and how to use the HeartStart to help a victim of SCA.

Anyone who might use the HeartStart should watch the training video that comes with it and carefully read both this Owner's Manual and the Guide. Remember, [the HeartStart cannot be used by the victim of SCA](#) — another person must use it to treat the victim.

It is important to review these materials periodically. They are intended to help make sure that, in an emergency, you will

be able to use the HeartStart quickly and confidently.

In addition, you can buy reusable supplies from Philips for practicing how to use your HeartStart. See “Ordering Accessories” for ordering information.

Anyone who might use the HeartStart should also have training in CPR (cardio-pulmonary resuscitation). Many training organizations offer a combined course in CPR and defibrillator use. For a list of organizations offering this training in your area, contact us by phone at 1.866.DEFIBHOME (1.866.333.4246) or visit www.philips.com/AEDSupport.



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.philips.com/AEDSupport.

SETTING UP THE HEARTSTART

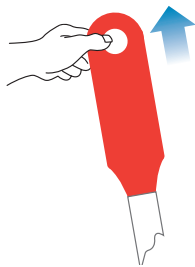
HOW TO SET IT UP THE FIRST TIME

It is easy to set up your HeartStart. Just follow these steps.

- 1 **Check the contents** of the HeartStart Home Defibrillator box.
- 2 **Take the HeartStart out** of its red case.

NOTE: Leave the pads cartridge installed. To avoid drying out the adhesive pads, do not open the cartridge until you need to use the pads in an emergency.

- 3 **Pull out the red tab** to start the automatic battery self-test.



4 Press the flashing orange Shock button when the voice tells you to. (No shock will be given.) Wait about one minute. When the HeartStart passes the self-test, it turns off and the green Ready light starts blinking.

Your HeartStart came wrapped with a set of cardboard setup instructions. Tear the cardboard along the line at the bottom and remove the wrapping. Then reinstall the defibrillator in its carry case.

If there was no voice during the self-test, if the HeartStart tells you the Shock button was not verified when you pressed it, or if the green Ready light is not blinking at the end of the test, call 1.866.DEFIBHOME (1.866.333.4246) for customer service.

NOTE: Leave the battery installed. The HeartStart runs a self-test every day to help be sure that it is ready for use.

5 Watch the short training video that comes with the HeartStart. Plan to review it at least once a year.

Review the Quick Reference Guide, found inside the carry case. It provides step-by-step illustrated emergency directions for users who are hearing impaired or who are using the HeartStart in a noisy area. Then replace the Quick Reference Guide, face up, in the clear plastic window inside the carry case. (This Owner's Manual is also designed to be stored in the case, in the

pocket behind the Quick Reference Guide window.)

Write your address on the Call 911 card on the back of the carry case. (If 911 is not your local EMS 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.)



6 Decide where to keep the HeartStart.

Some typical storage places include the family room, kitchen, or living room.

- It should be in a convenient, central area, close to a telephone, so that in an emergency the user can call Emergency Medical Services (usually 911) and get the HeartStart without wasting time.
- It should be a place where you can see and hear the HeartStart, so you can easily check that its green Ready light is blinking and hear it chirping if a self-test reveals a problem.

- Ensure storage area is free of pests and not accessible to pets or children.
- It should be somewhere the temperature stays between 50°F and 109°F. (It will work at temperatures between 32°F to 122°F.)
- Be sure everyone who may use it knows where the HeartStart is kept.

Help us stay in touch with you. Fill out the HeartStart Support Program enrollment card in the box, or call us and we will enroll you. This allows Philips or the FDA to send you important notifications about the product.

RECOMMENDED ACCESSORIES

It is always a good idea to have a spare battery and a spare pads cartridge.

There are also some other things that are useful to keep with the HeartStart:

- a pair of scissors — to cut off clothing (comes with your HeartStart)
- disposable gloves — to protect the user
- a disposable razor — to shave the chest if hair prevents good pads contact
- a pocket mask or face shield — to protect the user

- a towel or absorbent wipes — to dry the victim's skin for good pads contact

Philips has a Fast Response Kit with all these items.

You can buy special Infant/Child SMART Pads* for use on children 0-8 years old or less than 55 pounds (25 kg). Practice Kits with reusable adult or training pads and pad placement guides are also available. See “Ordering Accessories” for ordering information.

* Available by prescription only. Talk to your doctor.

USING THE HEARTSTART

WHEN TO USE IT

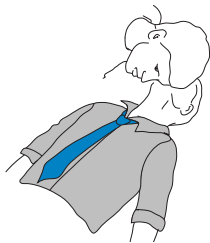
The HeartStart Home Defibrillator should *only* be used to treat someone you think may be a victim of SCA.

How can you tell if a person is in SCA? A person in SCA does not respond when shaken, and is not breathing normally.* Try to wake the person. Gently shake or tap

* Infants and children more often become unresponsive due to breathing or other issues than to heart problems. See page 27 for directions on using the HeartStart on an infant or child.

the person's shoulder and shout, "Are you OK?" Someone who is just sleeping will respond. Someone who is not responsive but not in sudden cardiac arrest will be breathing normally.

To check for breathing, put your ear near the person's mouth, and look at the chest to see if it rises and falls.



The HeartStart should not be used on a person who responds when shaken, or is breathing normally.

If you are not sure the person is in SCA, apply the HeartStart and follow its instructions. It will not let you shock someone unless a shock is needed.

HOW TO USE IT

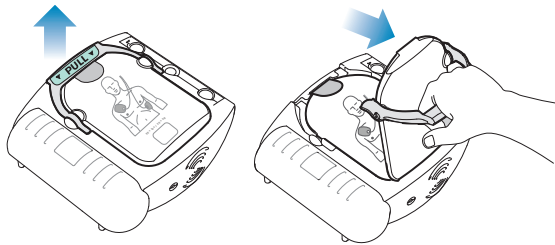
If you find someone who may be in SCA, act calmly and quickly. Time is critical!

▶ **Call Emergency Medical Services** (usually 911) immediately or, if possible, have someone else call while you use the HeartStart. Clearly tell the emergency operator:

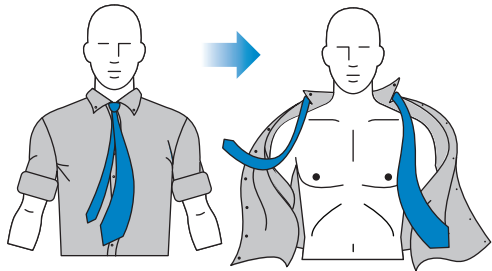
“This is (give your name and location).
Someone here has collapsed.
I have a HeartStart Home Defibrillator.
Please send help immediately.”

▶ **Quickly get the defibrillator.** Put it on the same side of the person that you are on.

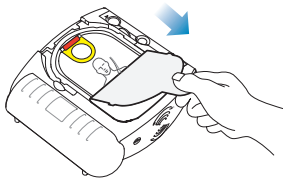
Unzip the case and open it flat. To turn on the HeartStart, **lift the cartridge PULL handle**. Set the cover aside and follow the HeartStart's voice instructions.



▶ Quickly **remove clothing from the person's chest**. If necessary, cut off the clothing with the scissors. (If the victim is an infant or young child, remove all clothing from the upper body, to bare both the chest and the back.)



► Pull the tab at the top of the pads cartridge to **peel off the film seal.**



Inside are two pads on a yellow plastic liner. Lift the pads out of the cartridge. You will notice a picture on each pad showing where to place it on the patient.

NOTES: Before applying the pads to the patient, remove any medicine patches from the person's chest, any headphones, and other electrical devices with a wire or a cable.

It is okay to use the HeartStart 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.

It is safe to use the HeartStart on someone wearing an oxygen mask.

▶ **Peel one pad off the liner.** Look at the picture on the pad. Place the pad with the sticky side down, on the person's bare skin,

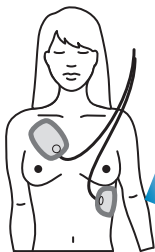
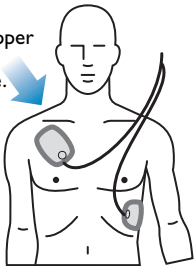


as shown in its picture.

▶ Press the pad against the skin firmly. Then **peel and place the other pad** as shown in its picture.

Where to place pads on adults and children greater than 8 years old or 55 pounds (25 kg) or more.

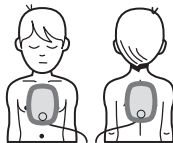
One on upper chest by collarbone.



One on ribs, wrapping around side.


Where to place pads on children 0-8 years old or less than 55 pounds (25 kg).


One on chest, one on back.



NOTE: Be sure to take each pad off the liner before applying it.


The pads have to stick well to the skin in order to work. If the person's skin is wet, dry it before applying the pads. If hair on the chest prevents the pads from sticking to the skin, clip or shave off the hair from the area where the pad will go.

As soon as both pads are in place, the HeartStart begins to analyze the patient's heart rhythm. It tells you that no one should be touching the patient and the Caution  light starts flashing.

▶ **If a shock is needed**, the HeartStart tells you to **press the flashing orange button** . When you press the Shock button, the HeartStart gives a shock. It tells you the shock has been delivered, then pauses so you can perform CPR if needed. The HeartStart then analyzes the heart rhythm again to see if another shock is needed.




NOTE: No shock is given unless you press the button when it is flashing.

▶ **If a shock is not needed**, the HeartStart tells you it is safe to touch the patient (the Caution light  turns off). It reminds you to check the patient and **perform CPR if needed**. When a shock is not needed, it may be because the person is not in cardiac arrest and may need other medical attention. Make sure EMS has been called.

HOW TO KNOW IF CPR IS NEEDED

If the person is breathing, you do not need to do CPR. If the person is not breathing,

you should perform CPR. The HeartStart tells you to press the i-button  for guidance on how to perform CPR.


NOTE: For CPR guidance, you must press the i-button while it is flashing.

WHAT TO DO NEXT


Leave the HeartStart turned on. Leave the pads on. Follow the HeartStart's instructions and tend to the patient until EMS arrives. If another shock is needed, the HeartStart will give you step-by-step instructions.

Even if you did not use the HeartStart, be sure the patient gets immediate medical care. EMS should already have been called. If possible, contact the patient's personal doctor. *Shocking the heart can save a life, but it will not cure the underlying cause of SCA.*

WHEN EMS ARRIVES

When the EMS team arrives, they will take over caring for the patient. Explain as clearly as you can what has happened. Then tell them that if they hold down the i-button  until it beeps, the HeartStart

Home Defibrillator will report how many shocks it gave and how long ago it was turned on. (More detailed information can be transferred from the HeartStart's memory to a computer running special software.)

After care is transferred to EMS, *turn off the HeartStart*: press and hold down the green On/Off button  until it turns off (about one second).

NOTE: The SMART Pads should be taken off before another defibrillator is used.

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 visit www.philips.com/AEDSupport.

You will be helping us learn more about sudden cardiac arrest.

We are here to answer any questions you may have about the experience.

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


MAINTAINING THE HEARTSTART

HOW TO CHECK THAT IT'S READY FOR USE

Check the HeartStart regularly to be sure the green Ready light is blinking. You can see the Ready light through the window in the red carry case. With the battery installed, the HeartStart tests itself every day. As long as the green Ready light is blinking, you can be confident that the defibrillator has passed its latest self-test and is ready for use.

WHAT TO DO WHEN IT CHIRPS

Your HeartStart tests itself daily, weekly, and monthly so you can be sure it is ready to use in an emergency. Any time the HeartStart chirps, it is telling you something is wrong. The green Ready light will be off, which means you need to take action so that the HeartStart will be ready to save a life.

- If you hear a pattern of single chirps (♪...♪...♪...) coming from your HeartStart, the i-button  will be flashing. Press it, and the HeartStart will tell you what to do next.

NOTE: If the HeartStart says to take out the battery then put it back in, wait for at least five seconds before putting it back in.

- If you hear a pattern of triple chirps (♪♪♪...♪♪♪...♪♪♪...) coming from your HeartStart, it could mean something serious is wrong with your AED. It may not be ready to use in an emergency, so

it's important that you call technical support.

- As long as you're not in an emergency, call Philips for technical support right away at 1.866.333.4246 if you hear triple chirps.
- If you're in an emergency and you hear triple chirps, try to use the device. You can take out the battery and put it back in, which will sometimes allow the HeartStart to work. As soon as the emergency is over, call Philips even if the device isn't chirping anymore.

WARNING: Removing and reinserting the battery one or more times when the HeartStart emits a series of triple chirps may reset the device and cause it to report it is ready for use, though it may be unable to deliver therapy during a rescue.

If you hear a pattern of triple chirps from your HeartStart, call Philips immediately, unless you are in an emergency and need to try to use your AED.

If you are in an emergency and you hear triple chirps, try to use the device. You can take out the battery and put it back in, which will sometimes allow the HeartStart to work.

WHEN TO REPLACE THE BATTERY

The lithium battery used in the HeartStart normally lasts for about four years in standby mode. (“Standby mode” means the HeartStart is ready for use, with the battery installed and the green Ready light blinking.) When the HeartStart is turned on for use, a new battery normally lasts for 4 hours, or can give up to 200 shocks.

After you put the battery in the HeartStart, the self-test checks it every day. When battery power gets low, the HeartStart will start chirping to alert you.

The battery is not rechargeable. Do not try to open, crush, or burn it. After it is used up, throw it away in household waste or according to local regulations.

NOTE: Practicing or showing how to use the HeartStart with training pads uses battery power. For example, one hour of training will use about 10% of the battery power.

See “Setting Up the HeartStart” for how to put in the battery. See “Ordering Accessories” for ordering information.

WHEN TO REPLACE THE PADS

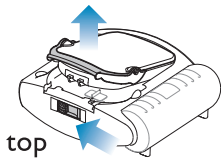
The SMART Pads are designed to last for two years in an unopened, undamaged cartridge. Each cartridge has an expiration date printed on the film seal and the package. The HeartStart checks the pads every day as part of its self-test. If for any reason the pads are no longer good, the HeartStart will start chirping and the green Ready light will turn off.

The pads are designed for only one use.

Replace the pads when they expire or are used.

To replace used pads or swap adult pads and infant/child pads cartridges, slide the latch at the top of the HeartStart over to the side. Then lift out the cartridge, and put in the new one.

If used, throw away the pads and cartridge in household waste or according to local regulations.



See “Setting Up the HeartStart” for directions on how to put in a new cartridge. See “Ordering Accessories” for ordering information.

HOW TO CLEAN IT

You can clean the outside of the HeartStart and its red carry case with a soft cloth dampened with:

- soapy water
- chlorine bleach
(2 Tbsp/quart or liter of water)
- ammonia-based cleaners

Do not put any part of the HeartStart into water or other fluids. Do not use alcohol, rough materials, cleaners, or strong solvents.

HOW TO HAVE IT REPAIRED

The HeartStart is not designed for repair by the user. Do not open the HeartStart, remove its covers, or try to repair it. You could be injured by dangerous high voltages and currents. If the HeartStart is damaged, please call 1.866.DEFIBHOME (1.866.333.4246) for service.

COMMON QUESTIONS

Some of the most common questions about using the HeartStart are answered here.

See “Dangers, Warnings, and Cautions” for more information.

Is it safe for the user and bystanders?

There is no risk of harm to the user or a bystander as long as:

- the HeartStart is used according to directions, and

- no one is touching the patient when the Shock button is pressed.

The HeartStart cannot deliver a shock unless it is used on someone whose heart needs a shock.

Even if you press the orange Shock button, the HeartStart will not deliver a shock unless the defibrillator tells you to push it.

Can I use it on an infant or a child?

Yes. For children 0-8 years old or those who weigh less than 55 pounds (25 kg), special HeartStart Infant/Child SMART Pads

are recommended. When used with these special pads, the HeartStart delivers less energy, and the optional CPR instructions are tailored for use on a child.

Infants and children more often become unresponsive due to breathing or other issues than to heart problems. Perform CPR first before calling for 911/EMS or using the HeartStart. For children greater than 8 years old, or who weigh 55 pounds (25 kg) or more, use the adult pads that come with the HeartStart.

WARNING: *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.*

Use the adult pads, but place them on the child's chest and back, as shown on page 15. (With the adult pads on a child, the optional CPR guidance will be for an adult.) **To treat an infant or child:**

- Perform infant/child CPR while a bystander calls 911/EMS and brings the HeartStart.
- If no bystander is available, perform 1-2 minutes of CPR before calling 911/EMS, then apply the HeartStart.
- If you witnessed the child's collapse, call EMS immediately and then get the HeartStart.

Can I use it on wet or metal surfaces?

Yes. It is safe to use the HeartStart on someone lying on a wet surface. It is also safe to use it on someone lying on a metal surface. As always, no one should touch the person when the Shock button is pressed. Naturally, the user should get the victim out of standing water, such as a pool or bathtub, before applying the HeartStart. It is important to dry the chest completely, so the pads will stick well to the skin.

Can I travel with it?

Yes. The HeartStart is designed to be easily

portable. Just remember that if you take it along when you travel, you should keep it where it can stay within its temperature range (see page 9). When you get back, put the HeartStart in its normal place, so everyone will know where to find it in an emergency.

There may be rules against taking a defibrillator into some countries. Before you leave, find out if there are restrictions.

Also, you may want to check with the airlines before boarding the aircraft with scissors in the case.

What if I donate the HeartStart Home to someone else?

The training materials included with this HeartStart Home defibrillator are designed to help users to use the device in a home setting, or on family outings. **If this device will be given or donated to another individual for use in the home**, be sure to provide the training materials included with the HeartStart Home and visit www.philips.com/AEDSupport to find additional training resources.

HeartStart defibrillators that are used by an organization, or in a facility that is not a home, require different considerations. These may include additional training, a review of the organization's medical emergency response policies, a site review to ensure proper placement, and medical oversight, among other things. **If this device will be given or donated to an organization where it will be used in a facility**, be sure that the recipient organization seeks medical oversight.

ORDERING ACCESSORIES

Accessories for the HeartStart Home Defibrillator include:

- M5070A battery pack
- M5071A Adult SMART Pads Cartridge
- M5072A Infant/Child SMART Pads Cartridge*
- M5073A Adult Practice Kit with training pads cartridge and pads placement guide
- M5074A Infant/Child Practice Kit with training pads cartridge and pads placement guide

* Available by prescription only. Talk to your doctor.

- M5090A adult pads placement guide
- M5075A standard carry case (for extra storage room)
- M5076A slim carry case (comes with the HeartStart Home)
- 68-PCHAT Fast Response Kit (pouch with a pair of scissors, 2 pairs of disposable gloves, a disposable razor, a pocket mask, and an absorbent wipe)

Call 1.866.DEFIBHOME (1.866.333.4246) or visit www.philips.com/AEDSupport to order.

FOR MORE INFORMATION

If you have any questions about the HeartStart Home Defibrillator after you watch the video and read this *Owner's Manual*, please contact us at 1.866.DEFIBHOME (1.866.333.4246).

We will be happy to answer your questions and to provide you with more information.

You can find detailed *Instructions for Use* for the HeartStart Home Defibrillator online at www.philips.com/IFU. Clinical summaries of research studies about the technology used in the HeartStart are also available online.

DANGERS, WARNINGS, AND CAUTIONS

It is important to understand how to use your HeartStart Home Defibrillator safely. Not following or considering this information could lead to a delay of therapy for the patient or cause harm to yourself and others around you. Please read these carefully.

DANGER — Immediate hazards that will result in serious personal injury or death to the user and/or the victim.

WARNING — Conditions, hazards, or unsafe practices that can result in serious personal injury or death.

CAUTION — Conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the HeartStart, or loss of data stored in the device.

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

DANGERS

flammable gases

If the HeartStart is used to give a shock in the presence of flammable gases such as in an oxygen tent, there is a risk of explosion. Move supplemental oxygen and oxygen delivery devices away from the defibrillation pads. (However, it is safe to use the HeartStart on someone wearing an oxygen mask.)

battery

The HeartStart M5070A battery is not rechargeable. Do not try to recharge, open, crush, or burn the battery, or it may explode or catch fire.

WARNINGS

battery

Removing and reinserting the battery one or more times when the HeartStart emits a series of triple chirps (♪♪♪... ♪♪♪... ♪♪♪...) may

reset the device and cause it to report it is ready for use, though it may be unable to deliver therapy during a rescue.

If you hear a pattern of triple chirps from your HeartStart, call Philips immediately, unless you are in an emergency and need to try to use your AED.

If you are in an emergency and you hear triple chirps, try to use the device. You can take out the battery and put it back in, which will sometimes allow the HeartStart to work.

electrical shock

There is an electrical shock hazard, or equipment damage hazard if the patient remains connected to devices other than the HeartStart. Before delivering a shock, it is important to disconnect the patient from other medical electrical equipment, such as blood-flow meters, that may not incorporate defibrillation protection.

fluids

Do not let fluids get into the HeartStart. Avoid spilling any fluids on the HeartStart

or its accessories. Spilling fluids into the HeartStart may damage it or cause a fire or shock hazard. Do not sterilize the HeartStart or its accessories.

accessories

Using damaged or expired equipment or accessories may cause the HeartStart to perform improperly, and/or injure the patient or the user. The HeartStart Defibrillator is designed to be used only with Philips-approved accessories. The

HeartStart may perform improperly if non-approved accessories are used.

patient handling

Performing CPR or otherwise handling or moving the patient while the HeartStart is analyzing heart rhythm can cause an incorrect or delayed analysis. If the HeartStart tells you a shock is advised while you are handling or moving the patient, stop the vehicle or CPR and keep the patient as still as possible for at least 15 seconds. This will give the HeartStart time

to reconfirm the analysis before telling you to press the Shock button.

The HeartStart delivers up to 150 joules of electrical energy. This electrical energy may induce ventricular fibrillation or a non-perfusing rhythm in the user or a bystander if the HeartStart is not used as described in this manual. Improper use of this device can cause serious injury or death. Ensure that the user and any bystanders are not touching the patient when the Shock button is pressed.

children

Keep the HeartStart out of reach of children to avoid the potential risk of inhalation or swallowing of small parts or strangulation by pads cables.

Most cardiac arrests in children are not caused by heart problems. When responding to cardiac arrest in an infant or child:

- Provide infant/child CPR while a bystander calls EMS and retrieves the HeartStart.

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

Alternatively, follow your local protocol.

proximity to other equipment, mobile phones and radios

The HeartStart can work correctly when it is close to other equipment, however, it is best to keep such equipment only as close

as necessary to the patient and the HeartStart, otherwise, it could result in improper operation of the HeartStart. Avoid use of the HeartStart adjacent to or stacked with other equipment. RF portable communications equipment such as emergency two-way radios and mobile phones including peripherals such as antenna cables and external antennas should be used no closer than 12 inches (30 centimeters) to any part of the HeartStart.

shock hazard

The HeartStart is not protected from electrical shock hazard if it is opened. The HeartStart is protected from electrical shock hazard while it is intact. Do not open the HeartStart, remove its covers, or attempt to repair it. There are no user-serviceable components in the HeartStart. If repair is required, return the HeartStart to an authorized service center.

CAUTIONS

device handling

The HeartStart was designed to be sturdy and reliable for many different use conditions. However, handling the HeartStart too roughly can damage it or its accessories and will invalidate the warranty. Additionally, handling a damaged HeartStart could cause injury to yourself or the patient. Check the HeartStart and accessories regularly for damage, according to directions.

infectious substances

Avoid directly handling the HeartStart or its accessories if they have been in contact with body fluids from the patient. Such substances could contain infectious material causing the spread of harmful diseases. Refer to this manual's section on cleaning the HeartStart after a use if necessary.

maintenance

Improper maintenance may damage the HeartStart or cause it to function

improperly. Maintain the HeartStart according to directions. Check supplies, accessories, packaging, and spares for damage and expiration dating.

skin burns

Do not let the pads touch each other or other electrodes, lead wires, dressings, medicine patches, etc. In addition, make sure the pads are not in contact with metal objects such as a bed frame or stretcher. Such contact can cause electrical arcing and skin burns during a shock and may also divert the

electrical current away from the patient's heart. During a shock, air pockets between the skin and pads can cause skin burns. To help prevent air pockets, make sure pads stick well to the skin. Do not use dried out pads because they will not provide good contact with the skin.

patient

The device may be unable to deliver effective defibrillation shocks if the defibrillation pads are not making good contact with the patient's skin. If the

patient's chest is not clean, the defibrillation pads may not make adequate contact with the patient. Remove any medicine patches and residual adhesive from the patient's chest before applying the pads.

radiated emissions

While the HeartStart complies with radiated emission standards, some medical equipment may still be impacted by emissions from the HeartStart. If this occurs, move the impacted equipment away from the HeartStart until the HeartStart is

no longer needed for the patient, or EMS arrives and takes over the scene.

environmental conditions

Using the HeartStart outside of the specified environmental range may result in incorrect or intermittent operation. Make sure the HeartStart is stored in an environment as described in the “Decide where to keep the HeartStart” section of this manual.

configuration

The HeartStart uses lighted buttons and voice instructions to guide a user through a rescue. If a user is not familiar with the language of the HeartStart, the HeartStart may not be used effectively to treat a patient in need, reducing the likelihood of survival for that patient. Make sure that the language of the HeartStart is a language that the majority of the users of that HeartStart may be familiar with.

pacemakers

Do not place the pads directly over an implanted pacemaker or defibrillator. A noticeable lump with a surgical scar should indicate the position of an implanted device.

pads

If the pads do not stick well to the skin, check that the pads adhesive has not dried out. Each pad has a layer of adhesive gel. If the gel is not sticky to the touch, replace the pads with a new set. (For ease of

handling, the pad is designed with a non-gel area around the connector cable.)

device operation

Defibrillation may not be provided if a user delays pressing the Shock button. The HeartStart will only deliver a shock if the flashing orange Shock button is pressed when the instruction is given. If the Shock button is not pressed within 30 seconds after the instruction, the HeartStart will disarm itself, and (for the first CPR interval) give a reminder to make sure emergency

medical services have been called. The HeartStart will then begin a CPR interval. This is designed to minimize interruption of CPR and help ensure ongoing patient support.

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

accessories

Do not leave the HeartStart without a set of pads connected; the device will start chirping and the i-button will start flashing.

The HeartStart runs daily self-tests. As long as the green Ready light is blinking, it is NOT necessary to test the defibrillator by initiating a battery insertion self-test. This uses battery power and risks draining the battery prematurely.

cpr

Even when CPR is applied correctly, the patient's chest may become bruised or ribs may be fractured. Performing CPR incorrectly could cause additional injuries to a patient, or may not provide needed benefit to the patient. Be sure to follow the CPR guidance instructions provided by the HeartStart.

Be sure to push the i-button to turn on CPR guidance if you are unsure of your CPR skills.

patient handling

Keep the patient still and 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 HeartStart is unable to analyze due to electrical "noise" (artifact), it will tell you to stop all movement and remind you not to touch the patient. If the artifact continues for more than 30 seconds, the HeartStart will

pause briefly to allow you to deal with the source of the noise, then resume analysis.

PROBABLE ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Following are the probable adverse effects of the device on health.

- Failure to identify shockable arrhythmia
- Failure to deliver a defibrillation shock in the presence of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT), which may result in death or permanent injury
- Inappropriate energy, which could cause failed defibrillation or post-shock dysfunction
- Myocardial damage
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents
- Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest
- Bystander shock from patient contact during defibrillation shock
- Interaction with pacemakers

- Skin burns around the defibrillation pads placement area
- Allergic dermatitis due to sensitivity to the materials used in the defibrillation pads construction
- Minor skin rash.

DEVICE SAFETY AND PERFORMANCE SUMMARY

Clinical summaries of several key studies using Philips automated external defibrillators is in the HeartStart Home Defibrillator *Instructions For Use* available online at www.philips.com/IFU.

GLOSSARY

AED. Automated external defibrillator. The HeartStart Home Defibrillator is an AED.

CPR. Cardiopulmonary resuscitation, a way to provide artificial breathing and heartbeats to keep a victim of SCA alive until a shock can be delivered.

i-button. An information button on the front of the HeartStart. Press the i-button while it flashes during a pause to get CPR guidance. Press the i-button if it flashes at other times to get troubleshooting information. At any time, you can press and hold the i-button (for at least

two seconds) to get summary information about the defibrillator's last use and condition.

On/Off button. A green button on the front of the HeartStart Home Defibrillator. Press the On/Off button to turn the defibrillator on or off, disarm the HeartStart, or stop the self-test that runs when a battery is put in.

Ready light. A small, bright green light that blinks to show that the HeartStart is ready for use. When the HeartStart is being used, the Ready light stays on without blinking.

Shock button. An orange button with a lightning bolt symbol, on the front of the HeartStart. The Shock button flashes when a shock is needed. You must press the button for the shock to be given.

SMART Pads. The pads, packed in a cartridge, used with the HeartStart. Lifting the cartridge PULL handle turns on the HeartStart and opens the cartridge. The pads stick to the patient's bare skin. The HeartStart uses the pads to sense the patient's heart rhythm and to transfer the shock, if needed.

Standby mode. The status of the HeartStart when the battery is in place, and the HeartStart is ready for use when needed. A blinking green Ready light means the HeartStart is in standby mode.

SCA. Sudden cardiac arrest. The sudden stopping of the heart's ability to pump blood. A person in SCA does not respond when shaken and is not breathing normally.

Ventricular fibrillation. A disturbance of the normal heart rhythm that causes a disorganized heartbeat that cannot pump blood through the body and brain. It is usually the cause of sudden cardiac arrest.

WARRANTY

HeartStart Home Defibrillator

Philips will replace or repair the HeartStart Home Defibrillator, model M5068A, within eight years of the original retail purchase, if it is found to be defective in materials or workmanship. This warranty, applicable only to residential installations, is valid for the original retail purchaser from the date of initial retail purchase. Save your receipt as proof of date of purchase. This warranty gives you specific legal rights and you may also have other rights which vary from state to state. Replacement or repair will be at Philips' sole discretion.

HeartStart HSI Defibrillator Family Accessories

Philips will replace or repair accessories for the HeartStart HSI family of defibrillators within the specified warranty period if they are found to be defective in materials or workmanship or if they do not meet the specifications published by Philips. The HSI battery is warranted for four years from the date of installation. The SMART Pads Cartridge is warranted until the expiration date listed on the cartridge. All other accessories are warranted for one year from the date of purchase. This warranty is valid for the original purchaser from the date of initial retail purchase. Save your receipt as proof of date of purchase. This warranty gives you specific legal rights and you may also have other rights which vary from state to state.

For All HeartStart Products

What is not covered under warranty: normal wear and tear; products that are modified or subjected to unusual physical or electrical stress; misuse; neglect; alteration; improper installation, repair or testing. All HeartStart products must be used in accordance with instructions and properly maintained as required in the Owner's Manual in order to be eligible for warranty protection.

How to Obtain Warranty Service

For prompt warranty service, call 1.866.DEFIBHOME (1.866.333.4246). A customer service representative will give you detailed instructions on how to fulfill your HeartStart Home Defibrillator warranty.

Implied Warranties

Any implied warranties, including implied warranties of merchantability and fitness for a particular purpose, shall be limited to the duration of the express warranties set forth in this limited warranty. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

Limitation of Remedies

In no event shall Philips be liable for any special, incidental or consequential damages based upon breach of warranty, breach of contract, negligence, tort, or any other legal theory. Such damages include, without limitation, loss of savings or revenue, loss of profit, loss of use, the claims of third parties, and cost of any substitute equipment or services. Some states do not allow the exclusion or limitations of incidental or consequential damages so the above limitation or exclusion may not apply to you.

Replacement

HeartStart Home Defibrillator replacement accessories can be purchased from Philips at 1.866.DEFIBHOME (1.866.333.4246) or www.philips.com/AEDSupport.

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HAVE YOU USED YOUR HEARTSTART?

If you have been in a situation that called for using the HeartStart Home Defibrillator, we urge you to contact us by phone at 1.866.DEFIBHOME (1.866.333.4246) or visit www.philips.com/AEDSupport to discuss the experience.

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