POWER TO SAVE A LIFE

HEARTSTART
ONSITE DEFIBRILLATOR

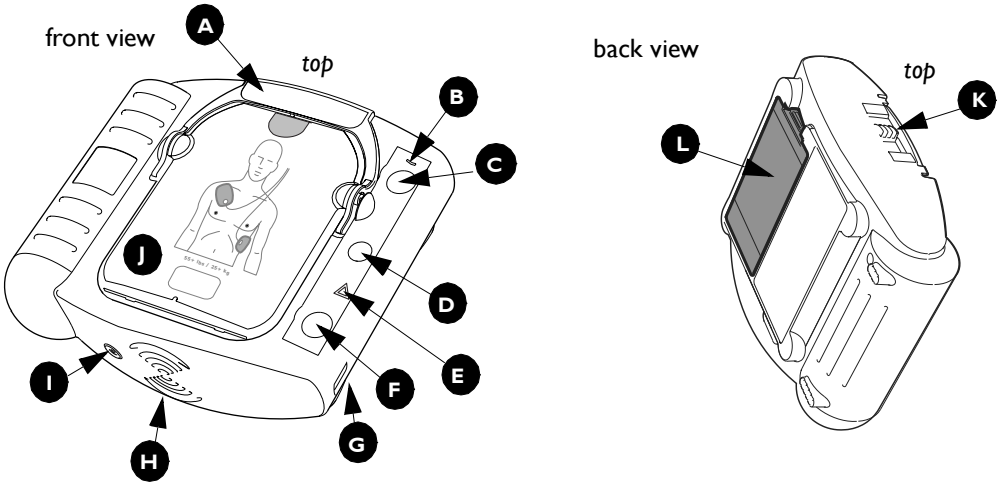
HeartStart OnSite Defibrillator

OWNER'S MANUAL

Guide to Set-Up, Operation, Maintenance, and Accessories

PHILIPS

M5066A
Edition 5



The HeartStart OnSite Defibrillator

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

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

Blinking:	standby mode (ready for use)
Solid:	in use
Off:	needs attention (HeartStart "chirps" and i-button flashes)

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

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

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

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

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

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

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

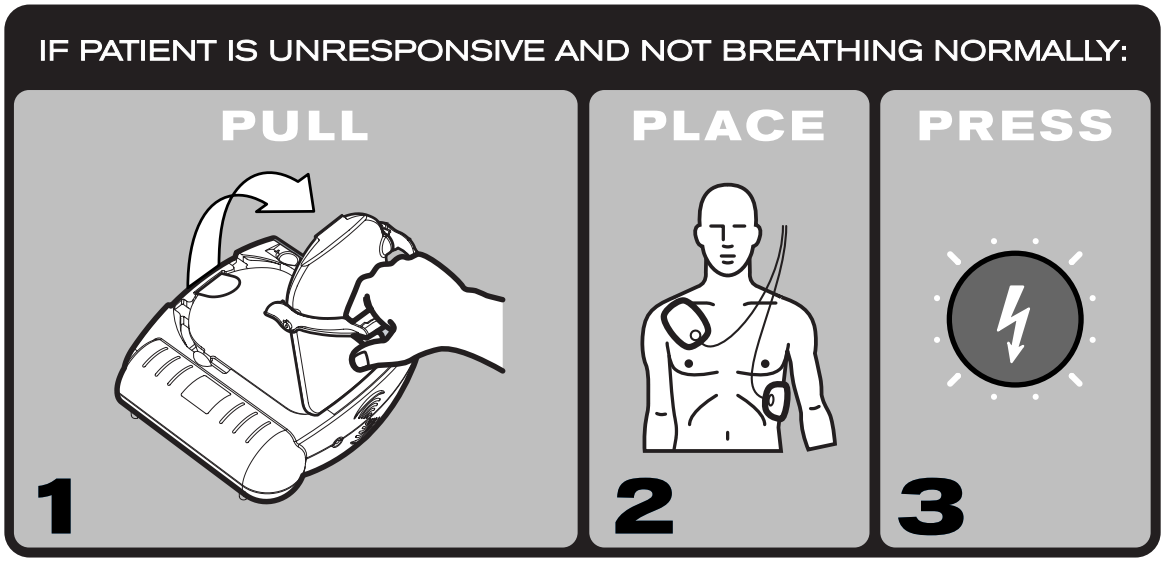
J SMART Pads Cartridge. This disposable cartridge contains self-adhesive pads with attached cable.

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

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

HeartStart OnSite Defibrillator

QUICK REFERENCE



Philips Medical Systems

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HeartStart OnSite
M5066A
Automated External Defibrillator

OWNER'S MANUAL
Edition 5

IMPORTANT NOTE:

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

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

Philips Medical Systems

PHILIPS

About this edition

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

Edition history

Edition 5
Publication date: January 2005
Publication #: M5066A-91900
Assembly #: 011666-0005
Printed in the U.S.A.

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Caution

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

Device tracking

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

Device manufacturer

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

Patents

This product is manufactured and sold under one or more of the following United States patents: US6047212, US6317635, US5892046, US5891049, US6356785, US5650750, US6553257, US5902249, US6287328, US6662056, US5617853, US5951598, US6272385, US6234816, US6346014, US6230054, US6299574, US5607454, US5803927, US5735879, US5749905, US5601612, US6441582, US5889388, US5773961, US6016059, US6075369, US5904707, US5868792, US5899926, US5879374, US5632280, US5800460, US6185458, US5611815, US6556864, and other patents pending.

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APPENDICES

1 Introduction to the HeartStart OnSite

Description

The Philips HeartStart OnSite Defibrillator M5066A ("OnSite") is part of the Philips HeartStart HS1 family of defibrillators. Small, lightweight, and battery powered, it is designed for simple and reliable operation.

Sudden Cardiac Arrest

The OnSite is used to treat ventricular fibrillation (VF), the most common cause of sudden cardiac arrest (SCA). SCA is 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 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.

VF is a chaotic quivering of the heart muscle that prevents it from pumping blood. The only effective treatment for VF is defibrillation.The OnSite treats 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. For every minute after collapse, the chances for successful defibrillation drop by about 10%.*

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

Indications for Use

The OnSite should 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. Follow the voice instructions for each step in using the OnSite.

Training and practice

The OnSite is one part of a well-designed emergency response plan. Any emergency response plan should be under the oversight of a physician and include training in cardiopulmonary resuscitation (CPR).

Several national and local organizations offer combined CPR/ defibrillator training. Contact your Philips representative, or visit us on-line at www.medical.philips.com, for information about training programs in your area.

NOTE: Training accessories are available from Philips for practicing use of the OnSite. See Appendix A for information on ordering accessories.

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.

For more information

Contact your local Philips distributor for additional information about the OnSite. We will be happy to answer any questions you may have and to provide you with copies of the clinical summaries of several key studies using Philips automated external defibrillators.*

You can also find the clinical summaries online at www.medical.philips.com. Technical information about all Philips HeartStart automated external defibrillators is also available online, in the *Technical Reference Guide* for HeartStart Defibrillators.

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

Notes

2 Setting up the HeartStart OnSite

Package contents

Check the contents of the HeartStart OnSite Defibrillator M5066A box to be sure it contains:

- 1 HeartStart OnSite Defibrillator
- 1 carry case, as selected at time of order (packaged separately)
- 1 four-year battery M5070A
- 1 Adult SMART Pads cartridge M5071A, containing one set of adhesive defibrillation pads
- 1 Owner's Manual
- 1 Quick Reference Guide
- 1 Quick Start poster

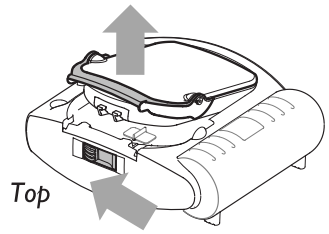
Training materials and optional accessories for the HeartStart OnSite are also available from Philips. See Appendix A for a description of these items.

Setting up the OnSite

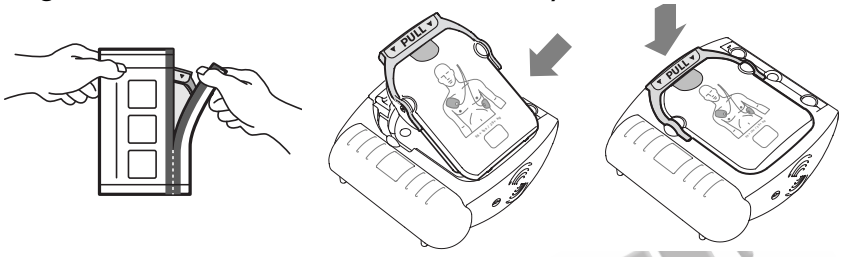
Setting-up the OnSite is simple and quick.

1. Remove the OnSite from its packaging.
2. Remove a new SMART Pads cartridge from its package.*

* To replace a used cartridge or insert a different cartridge, first locate the latch at the top edge of the OnSite, and slide it to the side. The pads cartridge will be released. Lift out the cartridge and replace as described in steps 2 and 3.

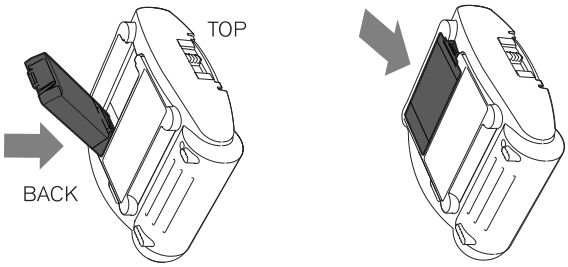


3. Insert the cartridge into the cartridge well on the front of the OnSite. It should click into place when properly seated. The green PULL handle should be all the way down.



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

4. Remove the battery from its packaging. Install it in the battery compartment on the back of the OnSite.



5. The OnSite will automatically run a self-test when the battery is inserted. Press the Shock button when instructed. When the self-test is over, the OnSite will report the result, 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.*) Then the OnSite will turn off and go to standby mode. The green Ready light will be blinking to show the OnSite is ready for use.*

* As long as a battery is installed, turning the OnSite "off" puts it into standby mode, which means that it is ready for use.

6. Place the OnSite in the carry case, pressing it firmly into place. Insert the Quick Reference Guide*, face up, in the clear plastic window on the inside of the case. If you purchased a spare SMART Pads Cartridge or an Infant/Child Pads Cartridge, place it in the storage area in the case.

NOTE: Do not store anything in the defibrillator carry case that it is not designed to accommodate. Store all objects in their intended location in the case.

7. Store the OnSite in accordance with your site's emergency response protocol. Typically, this will be in a high-traffic area that is easy to access, convenient for checking the Ready light periodically, and easy to hear the alarm chirp if the battery power gets low or the OnSite needs attention. Ideally, the OnSite should be stored near a telephone, so the Emergency Response Team or Emergency Medical Services can be alerted quickly in the event of a possible SCA. If possible, keep the spare SMART Pads cartridge and other accessories with the OnSite in the carry case, for quick access when needed. In general, treat the OnSite as you would any piece of electronic equipment, such as a computer. Be sure to store the OnSite according to its specifications. See Appendix E for details.

NOTE: If you have a training pads cartridge, it is recommended that you store it separately from the OnSite, to help prevent confusion with the regular pads in an emergency.

* The illustration on the cover of the Quick Reference Guide is a 3-step guide to using the HeartStart. Detailed illustrated directions are inside, for reference in an emergency, or if you are hearing impaired or using the HeartStart where it is hard to hear the voice instructions.

Recommended accessories

It is always a good idea to have a spare battery and a spare pads set. Other things that are useful to keep with the OnSite include:

- scissors — for cutting the victim's clothes if needed
- 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. See Appendix A for details.

If you may need to defibrillate an infant or a child under 55 pounds (25 kg) or 8 years old, it is recommended that you order the Infant/Child SMART Pads Cartridge, available separately by prescription. When the Infant/Child Pads Cartridge is installed in the OnSite, the OnSite automatically reduces the defibrillation energy to an energy level more appropriate for infants and children. In addition, if optional CPR coaching is selected, the OnSite provides coaching appropriate for infants and children when the Infant/Child SMART Pads Cartridge is installed. Directions for treating infants and children are provided in Chapter 3, "Using the HeartStart OnSite."

3 Using the HeartStart OnSite

IMPORTANT NOTE: Be sure to read the Reminders section at the end of this chapter as well as the warnings and precautions in Appendix D.

Overview

If you think someone is in SCA, act quickly and calmly. *If someone else is available*, ask him or her to call for emergency medical assistance while you get the OnSite. *If you are alone*, follow these steps:

- Call your emergency services provider.
- Quickly get the OnSite and bring it to the victim's side. If there is any delay in getting the OnSite, check the patient and perform cardiopulmonary resuscitation (CPR) if needed until the OnSite is available.
- If the victim is an infant or child, first perform CPR, then call for emergency medical services (EMS) before you apply the OnSite. *See special section on treating infants and children on page 3-5.*
- Check the immediate environment for flammable gases. Do not use the OnSite in the presence of flammable gases, such as an oxygen tent. However, it is safe to use the OnSite on someone wearing an oxygen mask.

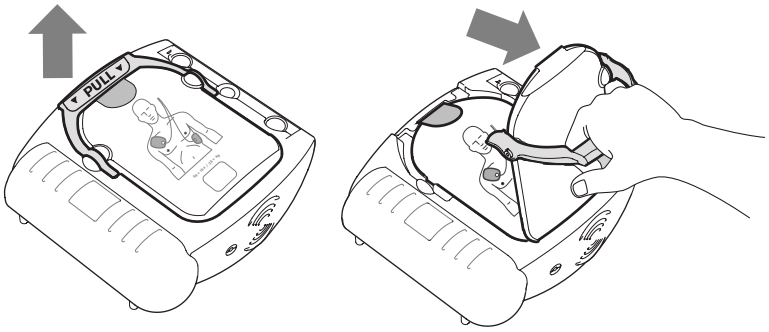
There are three basic steps to using the OnSite to treat someone who may be in sudden cardiac arrest:

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.

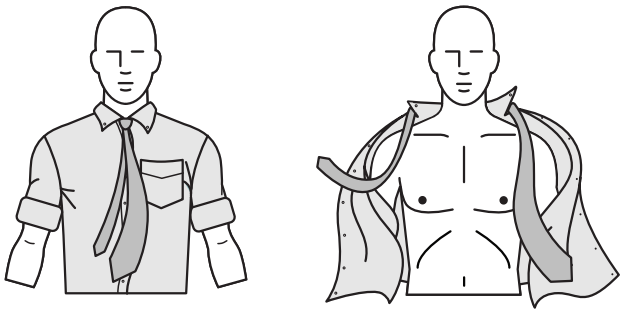
The following pages provide details about each step.

STEP 1: PULL the green handle

Turn on the HeartStart 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 HeartStart's instructions.



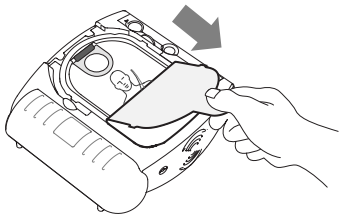
The OnSite starts by directing you to remove all clothes from the patient's chest. If necessary, rip or cut off the clothing to bare the person's chest.

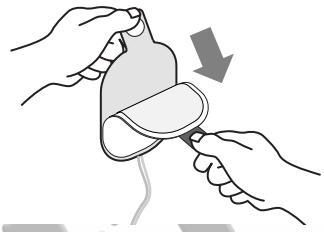


* You can also turn on the OnSite by pressing the green On/Off button.

STEP 2: PLACE the pads

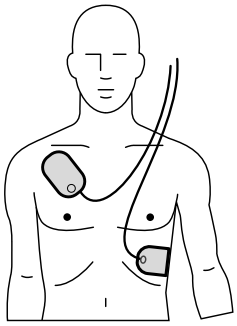
Pull the tab at the top of the pads cartridge to peel off the film seal. Inside are two adhesive pads on a plastic liner. Remove the pads from the cartridge.

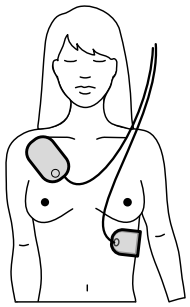




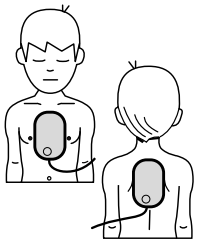
Peel one pad off the liner. Place the pad on the patient's bare skin, *exactly as shown in the picture on the pad*. Press the pad down firmly. Then repeat this with the other pad. Be sure the pads have been removed from the liner before placing them.

Where to place pads on adults and children over 55 pounds or 8 years old (anterior-anterior).

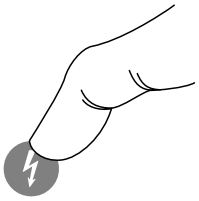




Where to place pads on infants or children under 55 pounds or 8 years old (anterior-posterior).

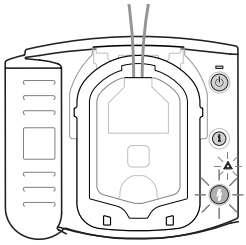


STEP 3: PRESS the Shock button

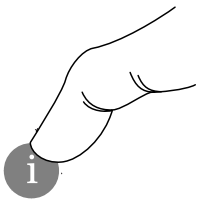


As soon as the OnSite detects that the pads are attached to the patient, it begins analyzing the patient's heart rhythm. It tells you that no one should be touching the patient, and the Caution light ⚠ begins flashing as a reminder.

If a shock is not needed:
The OnSite 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 ⚠ goes from flashing to solid, the orange Shock button ϟ starts flashing, and the OnSite tells you to press the flashing orange button. When you press the Shock button, the OnSite tells you that the shock has been delivered. Then it automatically analyzes the heart rhythm again to see if another shock is needed.



For CPR coaching:
Press the flashing blue i-button ⓘ during the first 30 seconds of the patient care pause to activate HeartStart CPR Coach.* (If the Infant/Child SMART Pads cartridge is inserted, the HeartStart CPR Coach will provide coaching for infant/child CPR.) When the pause is over, the OnSite tells 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.

If CPR is not needed, follow your local protocol until emergency medical personnel arrive.

* The default configuration for the OnSite provides CPR coaching when you press the i-button in this situation; however, the default setting can be revised by your Medical Director using Philips software available separately by prescription. See Appendix F for more information.

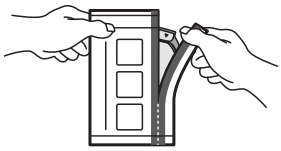
Treating infants and children

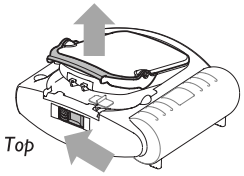
WARNING: Infants and children more often become unresponsive due to breathing or other issues than to heart problems. For infants and children:

- Give one minute of infant/child CPR while a bystander calls EMS.
- If no bystander is available, call EMS after giving CPR for 1 minute.
- Apply the OnSite using the Infant/Child Pads, if available.

Alternatively, follow your local protocol.

If the victim is under 55 pounds or 8 years old and you have an Infant/ Child Pads Cartridge:





- Remove the Infant/Child Pads Cartridge from its package.
- Locate the latch at the top edge of the OnSite, and slide it to the side. The pads cartridge will be released. Remove the old cartridge.
- 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 that Infant/Child Pads have been inserted, then it will turn off to be ready for use.
- Pull the green handle to start the rescue.
- Remove all clothing from the upper body, to bare both the chest and the back. Place one pad in the center of the chest between the nipples, and the other in the center of the back (anterior-posterior).

With the Infant/Child Pads Cartridge inserted, the OnSite automatically reduces the defibrillation energy from the adult dose of 150 joules to 50 Joules* and provides optional infant/child CPR coaching. Place the pads exactly as shown on the illustration on the pads.

* This lower energy level may not be effective for treating an adult.

If the victim is under 55 pounds or 8 years old, but you do NOT have an Infant/Child Pads Cartridge:

- DO NOT DELAY TREATMENT.
- Remove all clothing from the torso, to bare both the chest and the back.
- Apply the OnSite using the adult pads cartridge, but place one pad in the center of the chest between the nipples, and the other in the center of the back (anterior-posterior).

If you are not sure the victim is under 55 pounds or 8 years old:

- DO NOT DELAY TREATMENT.
- Remove all clothing from the chest.
- Apply the OnSite using the adult pads cartridge, and place the pads as illustrated on each pad (anterior-anterior). Make sure the pads do not overlap or touch each other.

When emergency medical services arrive

When Emergency Medical Services (EMS) personnel arrive to care for the patient, they may decide to apply another defibrillator to allow monitoring of the patient. The SMART Pads should be removed from the patient prior to using another defibrillator. EMS personnel may want a summary of the last-use data* stored in the OnSite. To hear the summary data, hold down the i-button until the OnSite beeps.

NOTE: After the EMS team removes the SMART Pads from the patient, remove the used pads cartridge, and insert a new pads cartridge before returning the OnSite to service, to be sure it is ready for use. See detailed directions in Chapter 4.

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

Reminders

- Remove any medicine patches and residual adhesive from the patient's chest before applying the pads.
- Do not allow the pads to contact other electrodes or metal parts that are in contact with the patient.
- If the pads do not stick well, 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.
- 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 OnSite is unable to analyze due to electrical "noise" (artifact), it will tell you to stop all motion and remind you not to touch the patient. If the artifact continues for more than 30 seconds, the OnSite will pause briefly to allow you to address the source of the noise, then resume analysis.
- The OnSite 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 OnSite tells you to, it 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 OnSite 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 OnSite will disarm and tell you a shock is not advised.
- If for any reason you want to turn off the OnSite 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.

Notes

4 After using the HeartStart OnSite

After each use

1. Check the outside of the OnSite for signs of damage, dirt, or contamination. If you see signs of damage, contact Philips for technical support. If the OnSite is dirty or contaminated, clean it according to the guidelines in Chapter 5, "Maintaining the HeartStart OnSite."
2. Insert a new SMART Pads cartridge into the OnSite. Check supplies and accessories for damage and expiration dates. Replace any used, damaged or expired items. For directions on changing the pads and replacing the battery, please see Chapter 2, "Setting Up the HeartStart OnSite." The single-use pads must be replaced after being used.
3. Unless your protocol requires that the battery remain installed,* remove the battery for five seconds, then reinstall it to run the battery insertion self-test to check the operation of the OnSite. When the test is complete, check that the green Ready light is blinking.
4. Return the OnSite to its storage location so it will be ready for use when needed.

* If it is important to know the actual local time of each stored event rather than the elapsed time between events, do not remove the battery until after defibrillator data has been transferred.

OnSite data storage

The OnSite automatically stores data about its last clinical use in its internal memory. The stored data can be conveniently transferred to a personal computer or a handheld computer running the appropriate application in the Philips HeartStart Event Review data management software suite. Event Review software is for use by trained personnel only. Information about HeartStart Event Review is available online www.medical.philips.com/goto/eventreview.

Follow your local protocol with regard to prompt data transfer for medical review after using the OnSite.* Details about data transfer and timing are provided in Event Review documentation.

To get a voice s*ummary of last-use data*, hold the i-button ⓘ down until it beeps once. The summary data include:

- How many shocks were delivered
- How long it has been since the OnSite was turned on.

Summary data are available anytime the OnSite is ready for use (the battery and pads are installed, and the OnSite is not turned on) or while it is actually in use. Removing the battery erases the summary data for the last use.

* The OnSite automatically stores information about its last clinical use in its internal memory for at least 30 days, so the data can be downloaded to a computer running an Event Review software product. (If the battery is removed during this period, the OnSite retains the files. When the battery is reinstalled, the last-use ECG recording will be kept in defibrillator memory for an additional 30 days.) After this time, the last-use ECG recordings will automatically be erased to prepare for a future use.

Detailed last-use data stored in internal memory include:

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

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

† If you leave the battery in the OnSite after using the defibrillator, then transfer the data to a computer running HeartStart Event Review software, the software will calculate the local time of each stored event. If you remove the battery prior to data transfer, only elapsed time between events will be recorded.

Notes

5 Maintaining the HeartStart OnSite

Routine Maintenance

The OnSite is very simple to maintain. The OnSite performs a self-test every day. In addition, a battery insertion self-test is run whenever a battery is installed in the device. The OnSite's extensive automatic self-test features eliminate the need for any manual calibration.

WARNING: *Electrical shock hazard.* Do not open the OnSite, remove its covers, or attempt repair. There are no user-serviceable components in the OnSite. If repair is required, contact Philips.

Reminders:

- Do not leave the OnSite without a pads cartridge installed; the OnSite will start chirping and the i-button will start flashing. For directions on changing the pads cartridge, see Chapter 2, "Setting up the HeartStart OnSite."
- The OnSite runs daily self-tests. As long as the green Ready light is blinking, it is NOT necessary to test the OnSite by initiating a battery insertion self-test. This uses battery power and risks draining the battery prematurely.

Periodic checks

Other than the checks recommended after each use of the OnSite, maintenance is limited to periodically checking the following:

- Check the green Ready light. If the green Ready light is not blinking, see Troubleshooting Tips, below.
- Replace any used, damaged or expired supplies and accessories.
- Check the outside of the OnSite. If you see cracks or other signs of damage, contact Philips for technical support.

Cleaning the OnSite

The outside of the OnSite and its carry case can be cleaned with a soft cloth dampened in soapy water, chlorine bleach (2 tablespoons per quart or liter of water), or 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 the OnSite.
- Do not immerse the OnSite in fluids or allow fluids to spill onto it. Do not sterilize the OnSite or its accessories.

Disposing of the OnSite

The OnSite and its accessories should be disposed of in accordance with local regulations.

Troubleshooting tips

The OnSite's green Ready light is your guide to knowing if the defibrillator is ready for use.

- If the Ready light is blinking: The OnSite has passed the battery insertion self-test and the last periodic self-test and is therefore ready for use.
- If the Ready light is solid: The OnSite is in use or running a self-test.

- If the Ready light is off, the OnSite is chirping, and the i-button is flashing: A self-test error has occurred, there is a problem with the pads or the battery power is low. Press the i-button for instructions.
- If the Ready light is off but the OnSite is not chirping and the i-button is not flashing: there is no battery inserted, the battery is depleted, or the OnSite needs repair. Insert/replace battery and run the self-test. As long as the OnSite passes the self-test, you can be assured it is ready for use.

More detailed testing and troubleshooting information is available in Appendix G.

Notes

A Accessories for the HeartStart OnSite

Accessories for the HeartStart OnSite Defibrillator available separately from your Philips representative or visit us on-line at www.medical.philips.com/heartstart include:

- Battery (spare recommended) [REF: M5070A]
- Pads
  - Adult SMART Pads Cartridge (spare recommended) [REF: M5071A]
  - Infant/Child SMART Pads Cartridge* [REF: M5072A]
- Carry Cases
  - Standard carry case, with paramedic's scissors and room for spare pad cartridge and battery [REF: M5075A]
  - Slim carry case, with paramedic's scissors [REF: M5076A]
- Fast Response Kit (pouch containing a pocket mask, a disposable razor, 2 pairs of gloves, a pair of paramedic's scissors, and an absorbent wipe) [REF: 68-PCHAT]
- Data Management Software
  - HeartStart Configure PDA software* [REF: 989803142041]
  - HeartStart CaseCapture PDA software [REF: 989803143051]
  - HeartStart Event Review,* single PC license [REF: M3848A]
  - HeartStart Event Review,* organization-wide license [REF: 989803141811]
  - HeartStart Event Review Pro* [REF: 861276 option A01]
- Infrared cable for use with HeartStart Event Review software [REF: ACT-IR]
- HeartStart OnSite Defibrillator Quick Reference Guide [REF: M5066-97800]
- Training
  - Adult Training Pads Cartridge [REF: M5073A]
  - Adult Training Replacement Pads [REF: M5093A]
  - Adults Pads Placement Guide [REF: M5090A]
  - Infant/Child Training Pads Cartridge [REF: M5074A]
  - Infant/Child Training Replacement Pads [REF: M5094A]

* Available by prescription only.

- Infant/Child Pads Placement Guide [REF: 989803139281]
- HeartStart Defibrillator Instructor's Training Toolkit [REF: M5066-89100]
- HeartStart Trainer [REF: M5085A]
- Internal Manikin Adapter [REF: M5088A]
- External Manikin Adapter, 10 pack [REF: M5089A]

B Glossary of terms

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

AED — Automated external defibrillator (a semi-automatic defibrillator).

AED mode — The standard treatment mode for the HeartStart OnSite Defibrillator. It provides voice instructions guiding the rescuer through applying the adhesive pads, waiting for rhythm analysis, and delivering a shock if needed.

analysis — See "SMART analysis."

arrhythmia — An unhealthy, often irregular, beating of the heart.

artifact — Electrical "noise" caused by sources such as muscle movements, CPR, patient transport, or static electricity that may interfere with rhythm analysis.

battery — The sealed lithium manganese dioxide battery used to power the HeartStart OnSite Defibrillator. It is provided in a pack that fits into a compartment on the back of the OnSite.

Caution light — A triangular light on the front of the HeartStart OnSite Defibrillator that flashes during rhythm analysis and is on solid when a shock is advised, as a reminder not to touch the patient.

configuration — The settings for all operating options of the HeartStart OnSite Defibrillator, including treatment protocol. The factory default configuration can be modified by authorized personnel using HeartStart Event Review software, available by prescription.

CPR — Cardiopulmonary resuscitation. A technique for providing artificial respiration and heart compressions to maintain life in a victim of SCA until defibrillation can be performed.

defibrillation — Termination of cardiac fibrillation by applying electrical energy.

defibrillation charge — Electrical energy stored in the capacitor of the HeartStart as it arms for shock delivery.

defibrillation shock — See "SMART biphasic waveform."

disarm — The OnSite safely discharges its defibrillation energy internally.

ECG — Electrocardiogram, a record of the electrical rhythm of the heart as detected through defibrillation pads.

event	An action recognized or performed by the HeartStart OnSite Defibrillator as a step in the sequence of using it in an incident. Examples include: applying the pads, analyzing heart rhythm, delivering a shock, etc.
fibrillation	A disturbance of the normal heart rhythm that results in chaotic, disorganized activity that cannot effectively pump blood. Ventricular fibrillation (fibrillation in the lower chambers of the heart) is most often associated with sudden cardiac arrest.
heart rhythm (ECG) analysis	See "SMART analysis."
HeartStart Event Review	A dedicated data management software system for use by trained personnel with the HeartStart OnSite Defibrillator. Information is available from Philips Medical Systems on the internet at http://www.medical.philips.com/goto/eventreview.
i-button	A blue "information" button on the front of the HeartStart OnSite Defibrillator that, if pressed during the 30 seconds it flashes during a patient care pause, provides CPR guidance;* if pressed when it flashes and the OnSite chirps, provides troubleshooting guidance. At other times, if the i-button pressed and held until it beeps once, the OnSite provides summary information about its last clinical use and device status. When the i-button is on solid (not flashing), it indicates the user may safely touch the patient.
impedance	Electrically, this is the resistance of the body to the flow of the electrical shock waveform delivered by the HeartStart OnSite Defibrillator. The OnSite automatically monitors the electrical impedance between the adhesive pads placed on the patient's bare chest, and adjusts the shock waveform appropriately.
incident	The series of events involved in treating a patient with the HeartStart OnSite Defibrillator.
infrared communications	A method of sending information using a special part of the light spectrum. It is used to transmit information between the HeartStart OnSite Defibrillator and a computer running HeartStart Event Review software.
monitoring	A mode of background analysis conducted on a motionless patient (i.e., no CPR is being performed) to determine if the patient rhythm has changed to a shockable rhythm.
NSA	"No Shock Advised," a decision made by the HeartStart OnSite Defibrillator that a shock is not needed, based on analysis of the patient's heart rhythm.
NSA pause	A pause provided by the HeartStart OnSite Defibrillator following an NSA decision. The pause can be configured to a "standard" NSA pause or a "SMART" NSA pause. During a standard NSA pause the OnSite performs no background

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

	monitoring of patient rhythm. During a SMART NSA pause, the OnSite conducts background monitoring and, if it detects an artifact-free shockable rhythm, will exit the pause and begin rhythm analysis. If the user presses the i-button for CPR guidance during a SMART NSA pause, that pause will become a standard NSA pause.
non-shockable rhythm	A heart rhythm that the HeartStart OnSite Defibrillator determines is not appropriate for defibrillation.
On/Off button	A green button located on the front of the HeartStart OnSite Defibrillator. Pressing the On/Off button when the OnSite is in standby mode turns the OnSite on; pressing and holding the On/Off button for one second when the OnSite is on turns the OnSite off and disarms the defibrillator. In addition, pressing the On/Off button stops the battery insertion self-test that automatically runs when a battery is inserted.
pacemaker	External or implanted cardiac pulse generator that stimulates the heart electronically.
pads	See "SMART pads."
patient care pause	A defined period to allow patient assessment, treatment, and/or CPR. See "NSA pause" and "protocol pause."
periodic self-tests	Daily, weekly, and monthly tests automatically conducted by the HeartStart OnSite Defibrillator when it is in its standby mode. The tests monitor many key functions and parameters of the OnSite, including battery capacity, pads cartridge readiness, and the state of its internal circuitry.
protocol	A sequence of operations performed by the HeartStart OnSite Defibrillator to direct patient care in the AED mode.
protocol pause	A period provided by the HeartStart OnSite Defibrillator after a shock series, during which the responder can administer CPR if needed. The OnSite does not conduct background monitoring of the patient's heart rhythm during this pause.
Ready light	A green LED showing the readiness for use of the HeartStart OnSite Defibrillator. A blinking Ready light means the OnSite is ready for use; a solid Ready light means the OnSite is being used.
relative timing	The elapsed time between the events in a clinical use of the HeartStart OnSite Defibrillator, stored in the OnSite's memory for data review.
rhythm analysis	See "SMART analysis."
sensitivity	A measure of the ability of the HeartStart OnSite Defibrillator to reliably detect and identify shockable heart rhythms.

Shock button	An orange button with a lightning bolt symbol on it, located on the front of the HeartStart OnSite Defibrillator. The Shock button flashes when a shock is advised. You must press the button for the shock to be delivered.
shock series	A configurable number of shocks, each separated by no more than a preset interval. After completion of a shock series, the HeartStart OnSite Defibrillator automatically pauses for CPR. See "protocol pause."
shockable rhythm	A heart rhythm that the HeartStart OnSite Defibrillator determines is appropriate for defibrillation, such as ventricular fibrillation and some ventricular tachycardias associated with sudden cardiac arrest.
shock series interval	A configurable interval between shocks, used by the HeartStart OnSite Defibrillator to decide if the shocks are part of the same shock series.
shock waveform	See "SMART biphasic waveform."
SMART analysis	The proprietary algorithm used by the HeartStart OnSite Defibrillator to analyze the patient's heart rhythm and determine whether the patient's heart rhythm is shockable.
SMART biphasic waveform	The patented, low-energy defibrillation shock waveform used by the HeartStart OnSite Defibrillator. It is an impedance-compensated biphasic waveform. Used with the Adult SMART Pads, it delivers 150 Joules, nominal, into a 50 ohm load; used with the Infant/Child SMART Pads, it delivers 50 Joules, nominal, into a 50 ohm load.
SMART NSA pause	See "NSA pause."
SMART Pads	The adhesive pads, supplied in a cartridge, used with the HeartStart OnSite Defibrillator. Pulling the handle on the cartridge turns on the OnSite and opens the cartridge. The pads are applied to the patient's bare skin and used to detect the patient's heart rhythm and to transfer the defibrillation shock. Only HeartStart SMART Pads can be used with the HeartStart OnSite Defibrillator.
specificity	A measure of the ability of the HeartStart OnSite Defibrillator to reliably detect and identify non-shockable heart rhythms.
standby mode	The operating mode of the HeartStart OnSite Defibrillator when a battery has been installed, and the unit is turned off and ready for use when needed. Shown by blinking green READY light.
standard NSA pause	See "NSA pause."
sudden cardiac arrest (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."

C Glossary of symbols/controls

HeartStart OnSite Defibrillator

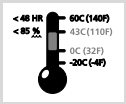
Symbol	Description
	Pads cartridge handle. Green. Pulling the handle turns on the OnSite and opens pads cartridge for use.
	On/Off button. Green. Pressing the On/Off button when the OnSite is in standby mode turns the OnSite on; pressing and holding the On/Off button for one second when the OnSite is on turns the OnSite 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 OnSite is chirping provides troubleshooting guidance. Pressing it until it beeps at other times provides summary information about the OnSite'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 OnSite is charged. If a shock is needed, the OnSite directs the user to press the Shock button to deliver a shock to the patient.
	Defibrillation protection. Defibrillation protected, type BF patient connection.
	Refer to operating instructions.
	Certified by the Canadian Standards Association.

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

Accessories

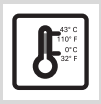
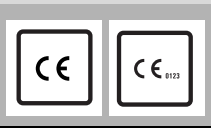
HeartStart battery M5070A and packaging

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

Symbol	Description
	Handle with care.
	Transportation and storage requirements (refer to associated thermometer symbol).
	Environmental (temperature and relative humidity) requirements.
	Install the battery in the OnSite 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 M5071A
HeartStart Infant/Child SMART Pads M5072A
HeartStart Adult Training Pads M5073A
HeartStart Infant/Child Training Pads M5074A

Symbol	Description
	These pads are disposable and are for single patient use only.
	Cartridge contents: one set of two defibrillation pads.

Symbol	Description
	Store the pads at temperatures between 0° and 43° C (32° and 110° F).
	Refer to operating instructions.
	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 Warnings and precautions

You should be aware of the safety concerns listed here when you use the HeartStart OnSite Defibrillator. Read them carefully. You will also see some of these messages in other parts of this Owner's Manual. 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 OnSite 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 OnSite is used in the presence of flammable anesthetics or concentrated oxygen. However, it is safe to use the HeartStart OnSite Defibrillator on someone who has an oxygen mask in place.
WARNING	The OnSite 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 OnSite is not to be used in the presence of flammable substance/air mixtures.
WARNING	Use the OnSite only as described in this *Owner's Manual*. Improper use of the OnSite 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 OnSite in water or other fluids. Do not allow fluids to enter the OnSite. Avoid spilling any fluids on the OnSite or its accessories. Spilling fluids into the OnSite 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 OnSite to perform improperly, and/or injure the patient or the user.
PRECAUTION	CPR during rhythm analysis can cause incorrect or delayed analysis by the OnSite.
PRECAUTION	Follow all instructions supplied with the HeartStart adhesive pads. Use the pads before the expiration date shown on the package and on the film seal. Do not reuse the pads. Discard them after use.
PRECAUTION	Aggressive handling of the adhesive pads prior to use can damage the pads. Discard the pads if they become damaged.
PRECAUTION	The HeartStart OnSite Defibrillator was designed to be sturdy and reliable for many different field use conditions. However, excessively rough handling can result in damage to the OnSite or its accessories and will invalidate the warranty. Inspect the OnSite and accessories periodically according to instructions.
PRECAUTION	Alteration of the factory default setup of the OnSite can affect its performance and must be performed by an authorized person. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.

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

Defibrillation warnings and precautions

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

safety levels	possible limitations of ECG interpretation
WARNING	Handling or transporting the patient during heart rhythm analysis can cause an incorrect or delayed diagnosis. If the OnSite 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 OnSite 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 OnSite, remove its covers, or attempt repair. There are no user-serviceable components in the OnSite. If repair is needed, contact Philips.

E Technical information

HeartStart OnSite Defibrillator specifications

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

Physical

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

Environmental

category	specifications
temperature and relative humidity	Operating (battery and pads cartridge installed): 32° to 122° F (0° to 50° C); 0% to 95% RH (non-condensing). Standby (battery and pads cartridge installed): 50° to 109° F (10° to 43° C); 10% to 75% RH (non-condensing). Storage/shipping (with battery and pads cartridge): -4° to 140° F (-20° to 60° C) for up to 2 days; 0% to 85% RH (non-condensing)
altitude	Operates at 0 to 15,000 feet; can be stored at up to 8,500 feet, in standby mode.
shock/drop abuse tolerance	Withstands 1 meter drop to any edge, corner, or surface.
vibration	Operating: meets EN1789 random, road ambulance. Standby: meets EN1789 swept sine, road ambulance.

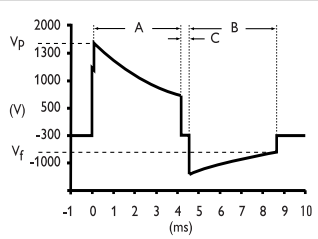
category	specifications
sealing	Drip proof per EN60529 class IPx1. Solid Objects per EN60529 class IP2x.
ESD/EMI (radiated and immunity)	See Electromagnetic Conformity tables.

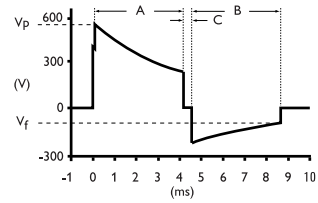
Controls and indicators

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 OnSite is in standby mode (ready for use); solid when the OnSite is being used. i-button: blue, flashes when information is available, on solid during patient care pause. Caution light: flashes when the OnSite is analyzing, comes on solid when the OnSite is ready to deliver a shock. Shock button: orange, flashes when the OnSite 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.

Defibrillation Waveform

category	specifications
waveform parameters	Biphasic truncated exponential. Waveform parameters are automatically adjusted as a function of patient defibrillation impedance. In the diagram at left, A is the duration of phase 1 and B is the duration of phase 2 of the waveform, C is the interphase delay, V_p is the peak voltage, and V_f the final voltage. The HeartStart OnSite delivers shocks to load impedances from 25 to 180 ohms. The duration of each phase of the waveform is dynamically adjusted based on delivered charge, in order to compensate for patient impedance variations, as shown below:





adult defibrillation

load resistance (ohms)	phase 1 duration (ms)	phase 2 duration (ms)	delivered energy (J)
25	2.8	2.8	128
50	4.5	4.5	150
75	6.3	5.0	155
100	8.0	5.3	157
125	9.7	6.4	159
150	11.5	7.7	160
175	12.0	8.0	158

pediatric defibrillation
(using M5072A infant/child reduced-energy defibrillator pads)

load resistance (ohms)	phase 1 duration (ms)	phase 2 duration (ms)	delivered energy (J)
25	4.1	2.8	35
50	5.1	3.0	46
75	6.2	4.1	52
100	7.2	4.8	54
125	8.3	5.5	56
150	9.0	6.0	57
175	9.0	6.0	55

category	specifications
energy* * Pediatric doses indicated are based on CDC growth charts for the 50th percentile weights for boys.	Using HeartStart Adult SMART Pads: 150 J nominal (±15%) into a 50 ohm load. Using HeartStart Infant/Child SMART Pads: 50 J nominal (±15%) into a 50 ohm load. Sample pediatric energy doses: age — energy dose newborn — 14 J/kg 1 year — 5 J/kg 2 – 3 years — 4 J/kg 4 – 5 years — 3 J/kg 6 – 8 years — 2 J/kg * National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion. *CDC growth charts: weight-for-age percentiles, revised and corrected* November 28, 2000. Atlanta, GA: Centers for Disease Control and Prevention © 2000.
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.
CPR pause-to-shock time	QuickShock. 8 seconds, typical, from end of patient care pause to shock delivery.
disarm (AED mode)	Once charged, the OnSite will disarm if: • the patient's heart rhythm changes to non-shockable rhythm, • a shock is not delivered within 30 seconds after the OnSite has charged for shock delivery, • the On/Off button is pressed and held down for at least one (1) second to turn off the OnSite, • the adhesive pads are removed from the patient or the pads cartridge is disconnected from the OnSite, 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.

ECG analysis system

category	specifications
function	Evaluates impedance of adhesive pads for proper contact with patient skin, and evaluates the ECG rhythm and signal quality to determine if a shock is appropriate.
shockable rhythms	Ventricular fibrillation (VF) and some ventricular tachycardias associated with a lack of circulation, including ventricular flutter and polymorphic ventricular tachycardia (VT). The HeartStart uses multiple parameters to determine if a rhythm is shockable. *NOTE: For patient safety reasons, some very low-amplitude or low-frequency rhythms may not be interpreted as shockable VF rhythms. Also, some VT rhythms usually associated with circulation will not be interpreted as shockable rhythms.*
non-shockable rhythms	SMART Analysis is designed to detect non-shockable rhythms as defined by AHA/AAMI DF-80. See following table. On detection of any non-shockable rhythm, the OnSite prompts user to perform CPR if needed.
pacemaker detection	Pacemaker artifact is removed from the signal for rhythm analysis.
artifact detection	If electrical "noise" (artifact) is detected which interferes with accurate rhythm analysis, analysis will be delayed until the ECG signal is clean.
analysis protocol	Depending on results of analysis, either prepares for shock delivery or provides a pause. For details of protocol, see Appendix F, "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 DF80 requirement)	(87%)
shockable rhythm — ventricular tachycardia	100	sensitivity >75% (meets AAMI DF80 requirement)	(67%)
non-shockable rhythm — normal sinus rhythm	300	specificity >99% (meets AAMI DF80 requirement)	(97%)
non-shockable rhythm — asystole	100	specificity >95% (meets AAMI DF80 requirement)	(92%)

rhythm class	ECG test sample[a] size	meets AHA recommendations[b] for adult defibrillation	
		observed performance	90% one-sided lower confidence limit
non-shockable rhythm — all other non-shockable rhythms[c]	450	specificity >95% (meets AAMI DF80 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.
c. Supraventricular tachycardia (SVT) is specifically included in the non-shockable rhythm class, in accordance with AHA recommendations[b] and the AAMI standard DF80.

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 200 shocks or 4 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 this *Owner's Manual*.
standby life (after insertion)	Typically, 4 years when stored and maintained according to directions provided in this *Owner's Manual*.
training life	Supports 10 hours of use in training mode.

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

category	specifications
adult pads	Disposable, adhesive defibrillation pads with a nominal active surface area of 85 cm^2 each, provided in a snap-in cartridge with an integrated 54 inch (137.1 cm), typical, cable.
infant/child pads	Disposable, adhesive defibrillation pads with a nominal active surface area of 85 cm^2 each, provided in a snap-in cartridge with an integrated 40 inch (101.6 cm), typical, cable. Cartridge incorporates teddy bear icon on cover of seal for ready identification.
defibrillation pad requirements	Use only HeartStart Adult SMART Pads M5071A or Infant/Child SMART Pads M5072A with the HeartStart OnSite Defibrillator.

Notes

F Configuration

Overview

The Philips HeartStart OnSite Defibrillator comes with a factory default configuration designed to meet the needs of most users. This configuration can only be changed by an authorized person using HeartStart Configure, Event Review, or Event Review Pro software. This software is for use by trained personnel and is available from Philips by prescription only. Information about HeartStart data management products is available online http://www.medical.philips.com/goto/eventreview.

Device options

The following table includes the features of HeartStart OnSite 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 of the HeartStart's speaker is set to 8, highest. The speaker is used for voice instructions and the charge-done tone.
Auto send periodic self test (PST) data	On, Off	On	Enables the periodic self-test data broadcast through the device's infrared data port.
ECG out data	On, Off	On	Enables the ECG data broadcast through the device's infrared data port.

Patient treatment protocol options

parameter	settings	default	description
"call EMS" voice reminder	• At power on (when the user turns on the OnSite) • 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	Three shocks must be delivered in a series to activate the automatic protocol pause for patient assessment and CPR. During the protocol pause, the OnSite does not perform rhythm analysis. The length of the protocol pause after a shock series is completed is defined by the protocol pause timer setting. A new shock series begins: • when a shock is delivered after the OnSite 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	A delivered shock must occur within 1 minute of the previous shock to be counted as part of the current shock series.
protocol pause timer (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	1.0	A protocol pause interval of 1 minute automatically starts after voice instruction is given when a shock series is completed. After the protocol pause, the OnSite returns to rhythm analysis.

parameter	settings	default	description
NSA pause type	• Standard NSA pause: OnSite does not perform rhythm analysis during the NSA pause. • SMART NSA pause: OnSite conducts background monitoring during the SMART NSA pause. If a potentially shockable rhythm is detected, OnSite terminates the SMART NSA pause and resumes rhythm analysis.	SMART NSA pause	During a SMART NSA pause, the OnSite conducts background monitoring during the pause. If a potentially shockable rhythm is detected in a motionless patient, the OnSite terminates the SMART NSA pause and resumes rhythm analysis. *NOTE: If the Shock button is not pressed for 30 seconds after the HeartStart is armed, or continuous artifact is encountered for 30 seconds during rhythm analysis, a 30 second SMART pause is automatically initiated.* *NOTE: Use of the optional i-button CPR coaching will convert the SMART NSA pause to a standard NSA pause. During the standard NSA pause, the OnSite does not perform rhythm analysis for the pause time determined by the selected protocol pause timer and NSA pause timer settings.*
NSA pause timer (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	1.0	An NSA pause interval of 1 minute automatically starts after a no shock advised (NSA) decision: • If a shock has been delivered within the shock series interval, the length of the pause is defined by the protocol pause timer setting. • Otherwise, the length of the NSA pause is defined by the NSA pause timer setting.

parameter	settings	default	description
CPR prompt	• 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.	The CPR reminder voice instructions provided at the beginning of a pause interval directs the user to check the patient's airway, breathing, and circulation and to begin CPR if needed, then invites the user to press the i-button for guidance in the basic steps of CPR.
CPR prompt rate (compressions per minute)	80, 100	100	Signals for CPR compressions are given at a rate of 100 per minute when the user presses the i-button for optional CPR coaching.

G Testing and troubleshooting

Testing

The HeartStart OnSite Defibrillator automatically tests itself every day and alerts you if it finds a problem. In addition, it runs a pads self-test each time a pads cartridge is inserted. It alerts you if it finds a problem. See the *Technical Reference Guide,* available online at www.medical.philips.com, for a detailed discussion of the self-tests.

You can also test the OnSite at any time by removing the battery for five seconds then reinstalling it. This test takes about one minute. 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 OnSite is first put into service.
- after each time the OnSite is used to treat a patient.
- when the battery is replaced.
- when the OnSite may have been damaged.

If you need to use the OnSite in an emergency while you are running a battery self-test, pull the SMART Pads cartridge handle to stop the test and to turn on the HeartStart for use.

Troubleshooting

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

Recommended action during an emergency

If for any reason the OnSite does not turn on when you pull the SMART Pads cartridge handle, Press the On/Off button (⏻).

If that does not turn on the OnSite, remove the battery and replace it with a new battery if available and press the On/Off button to turn on the OnSite. If no spare

battery is available, remove the installed battery for five seconds, then reinsert it and run a battery insertion self-test.

If the problem continues, do not use the OnSite. Attend to the patient, providing CPR if needed, until Emergency Medical Services Personnel arrive.

Troubleshooting while the OnSite is in use

(green Ready light is solid)

OnSite Tells You:	Possible Cause	Recommended Action
... to replace the battery immediately	The battery is nearly depleted. The OnSite 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	• The pads cartridge has been removed. • The pads cartridge has been damaged.	Insert a new pads cartridge.
... to press the pads firmly to the skin ... to make sure the pads have been removed from the liner ... the pads should not be touching the patient's clothing.	• The pads are not properly applied to the patient. • The pads are not making good contact with the patient's bare chest because of moisture or excessive hair. • The pads are touching each other. • The pads may not have been removed from the liner or may be on the patient's clothing.	• Make sure that the pads are sticking completely to the patient's skin. • If the pads are not sticking, dry the patient's chest and shave or clip any excessive chest hair. • Reposition the pads. • Make sure the pads are not on the liner or the patient's clothing. If the voice instruction continues after you do these things, insert another pads cartridge.
... 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 pads cartridge. Pull up the handle on the cartridge cover, and replace pads on patient with new pads to continue with the rescue.

OnSite Tells You:	Possible Cause	Recommended Action
... to stop all motion	• The patient is being moved or jostled. • The environment is dry and movement around the patient is causing static electricity to interfere with ECG analysis. • Radio or electrical sources are interfering with ECG analysis.	• Stop CPR; do not touch the patient. Minimize patient motion. If the patient is being transported, stop the vehicle. • Responders and bystanders should minimize motion, particularly in dry environments that can generate static electricity. • Check for possible causes of radio and electrical interference and turn them off or remove them from the area.
... the shock was not delivered	• The pads may not be making good contact with the patient's skin. • The pads may be touching each other. • The pads may be damaged.	• Press the pads firmly to the patient's chest. • Make sure the adhesive pads are correctly positioned on the patient. • Replace the pads if necessary.
... the shock button was not pressed	Shock has been advised but the shock button has not been pressed within 30 seconds.	When next prompted, press the Shock button to deliver shock.

Troubleshooting while the OnSite is not in use

(green Ready light is *not* on)

Behavior	Possible Cause	Recommended Action
chirps or i-button flashes	• The battery power is low or the SMART Pads cartridge needs to be replaced. • The OnSite may have been turned off without a pads cartridge installed, or the installed pads cartridge may not have its hard cover in place. • The training pads cartridge has been left in the OnSite. • The OnSite has been stored outside the recommended temperature range. • The OnSite has detected an error during a self-test or cannot perform a self-test, or the Shock button is damaged.	• Press the blue i-button. Replace the battery or pads cartridge if instructed. • Make sure the pads cartridge is properly installed with the hard cover in place. (See Chapter 5, "Maintaining the HeartStart OnSite," for directions on installing the pads cartridge.) • Remove the training pads cartridge and replace it with an Adult or Infant/Child Pads Cartridge. • Remove the battery for five seconds then reinstall it to start the battery insertion self-test. If it fails, insert a new battery to repeat the test. If it fails again, do not use the OnSite. If it passes, store the OnSite within the recommended temperature range. • Contact Philips for service if needed.
no chirping and/or i-button does not flash	• The battery is missing or completely depleted. • The OnSite 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 OnSite. Contact Philips for service.

H Additional technical information required for European conformity

Electromagnetic conformity

Guidance and manufacturer's declaration: The HeartStart OnSite is intended for use in the electromagnetic environment specified in the tables below. The customer or user of the HeartStart OnSite should assure that it is used in such an environment

Electromagnetic emissions

emissions test	compliance	electromagnetic environment – guidance
RF CISPR 11	Group 1 Class B	The OnSite uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The OnSite is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic immunity

immunity test	IEC 60601 test level	compliance level	electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	There are no special requirements with respect to electrostatic discharge.[a]
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial/hospital environment. There are no special requirements for non-commercial/non-hospital environments.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	20 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the OnSite, including cables, than is absolutely necessary.[b,c] The recommended separation distances for various transmitters and the AED are shown in the following table. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a. Generally, AEDs are sometimes susceptible to interference generated by patient and/or responder motion in environments in which a high static electric field is present (e.g., low humidity, synthetic carpets, etc.). As a safety measure, Philips AEDs incorporate a patented method to sense possible corruption of the ECG signal by such interference and to respond by directing the user to stop all motion. In these cases, it is important to minimize movement in the vicinity of the patient during rhythm analysis in order to ensure that the signal being analyzed accurately reflects the patient's underlying heart rhythm.

b. The ISM (industrial, scientific and medial) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13, 567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OnSite is used exceeds the applicable RF compliance level above, the OnSite should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the OnSite.

Recommended separation distances between portable and mobile RF communications equipment and the HeartStart OnSite

The HeartStart OnSite is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HeartStart OnSite can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HeartStart OnSite as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz $d = 0.6\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.15\sqrt{P}$
0.01	0.06	0.115
0.1	0.19	0.36
1	0.6	1.15
10	1.9	3.64
100	6.0	11.5

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medial) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13, 567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Shock cycle timing

The OnSite takes <20 seconds typical, including analysis, from shock to shock in AED mode. From analyzing to ready to shock after 15 shocks, the OnSite takes a maximum of 30 seconds; from initial power on to ready to shock after 200 shocks, a maximum of 40 seconds.

Intentionally blank.

POWER TO SAVE A LIFE

HEARTSTART

ONSITE DEFIBRILLATOR

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