

PHILIPS



For the ordinary person in
the extraordinary moment

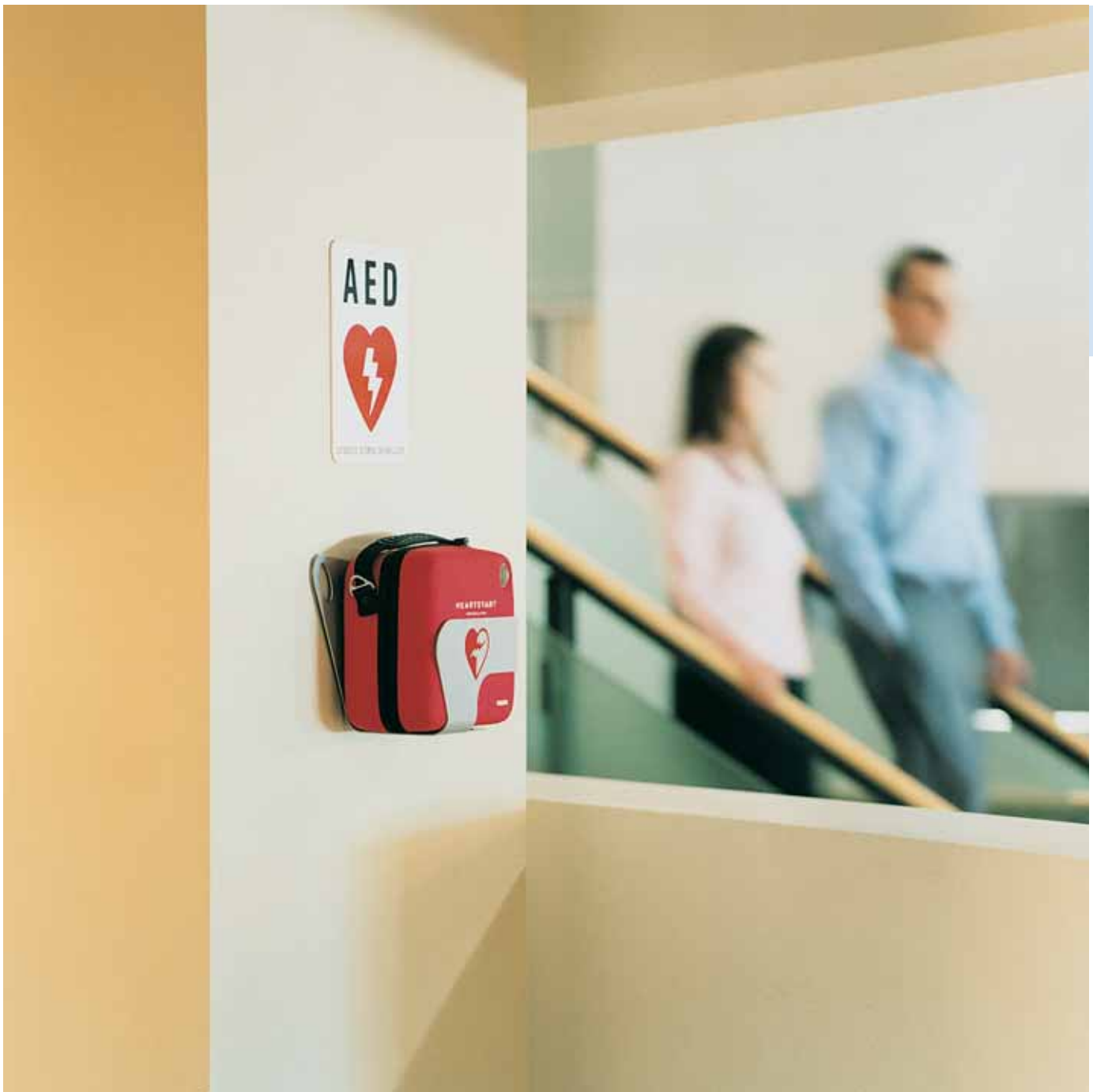


Philips HeartStart OnSite Defibrillator

Product information

HEARTSTART
DEFIBRILLATORS

Sudden cardiac arrest can anyone,



happen to anytime, anywhere.

- The current national survival rate for SCA is less than 5%.
- The likelihood of successful resuscitation decreases by about 10% with every minute that passes.
- An additional 40,000 lives could be saved each year in the U.S. alone with widespread access to defibrillators.

Power to save a life

Each year sudden cardiac arrest (SCA) strikes approximately 340,000 people in the U.S. alone. The majority of these people have no warning, since they show no prior symptoms. And sadly, fewer than 5% survive, often because emergency medical services cannot reach them in time.

SCA most often occurs when the electrical system of the heart becomes chaotic, causing it to stop beating effectively. Lacking proper blood flow, the person loses consciousness, stops breathing, and will die unless promptly treated. CPR is important, but it alone cannot restore a normal heart rhythm. A “shock” from a defibrillator is the most effective way to restore the heart’s normal pumping rhythm. The victim’s best chance of survival is to receive that shock within 5 minutes of collapse.

Just as seat belts or airbags do not save every life in a traffic accident, a defibrillator will not save every person who suffers a sudden cardiac arrest. Yet many lives could be saved if more people could be reached more quickly.

Philips HeartStart Defibrillators enable virtually anyone to treat the most common cause of SCA quickly and effectively, wherever it happens — at work, at play, in the air — providing the power to save a life.



The Philips HeartStart

OnSite Defibrillator



Philips, the leader in portable defibrillation technology,¹ designed the HeartStart OnSite Defibrillator for the ordinary person in the extraordinary moment. Available without a prescription, the OnSite is designed to be the easiest to use and most reliable defibrillator available.^{2,3} Our innovative technology, based on extensive research and user feedback, has produced a defibrillator so easy to use that you can potentially save the life of a co-worker, friend, or anyone else stricken with sudden cardiac arrest.

Weighing just 3.3 lbs., this small and lightweight defibrillator can be easily carried to the victim's side. Using clear, calm voice instructions, the OnSite Defibrillator guides you through each step of defibrillation, including CPR Coaching. Integrated SMART Pads placed on the victim's bare skin transmit information to the defibrillator, which senses and adapts to your actions every step of the way.

HeartStart OnSite includes proven Philips technologies for heart rhythm assessment (SMART Analysis) and defibrillation energy delivery (SMART Biphasic). And like all HeartStart Defibrillators, it can be used to treat adults, as well as infants and children.⁴

The first defibrillator available without a prescription to commercial users

Ready when needed

The OnSite has a long life battery:

- 5 year shelf life plus 4 year installed life
- The same battery technology used with confidence in millions of cameras

Automatic self-tests help ensure continued readiness:

- Daily self-tests check electrical components, subsystems and battery
- A self-test also verifies that the pads cartridge is installed and in working order
- A blinking green “Ready” light means the OnSite has passed its last self test, so you can be confident the defibrillator is ready for use

Easy to use

Using the HeartStart OnSite Defibrillator is simple. Pulling the green handle activates the defibrillator and voice instructions. These instructions are paced to your actions, to help guide you through the entire process — from placing each pad on the patient to delivering a defibrillation shock.



HeartStart OnSite determines if a heart rhythm is shockable.

- If a shock is indicated, the defibrillator directs you to press the flashing orange “Shock” button. Then HeartStart OnSite delivers a dose of low-energy biphasic therapy, a highly-effective defibrillation waveform that is also gentle to the heart.
- If a shock is not indicated, the OnSite Defibrillator instructs you to assess the patient and to perform CPR if necessary. While performing CPR, the defibrillator’s voice instructions can be activated to coach you on the frequency and depth of compressions.

HeartStart OnSite also reminds you to call emergency medical services (EMS). And should EMS need a summary of care, it can be retrieved from the defibrillator’s internal memory. An EMS provider simply presses the “i-button” and HeartStart OnSite verbally recounts events from its last clinical use.

Replaceable SMART Pads Cartridges

The cartridge contains two adhesive pads that are placed on the patient's bare skin as indicated by the pictures on the pads. The pads are smart because they sense when they have been removed from the cartridge and when each has been applied to the patient, adjusting the voice instructions to your pace.

The HeartStart OnSite can be used on patients of any age, including infants and children. OnSite senses when the special infant/child SMART Pads Cartridge is installed. It automatically adjusts to use a lower energy level more appropriate for infants and children, and also provides coaching for performing infant/child CPR.

To practice your skills, a special training pads cartridge (adult or infant/child) can be installed in the defibrillator. It suspends the defibrillator's ability to shock, while walking you through patient care scenarios.



Designed to help save a life in extraordinary circumstances

Lightweight

Just 3.3 lbs fully equipped.

Intuitive

Clean design and clear voice instructions, including CPR Coaching, instill the confidence that's needed when treating a person in cardiac arrest.

Versatile

Available for use on anyone of any age, including children and infants.

Effective

Patented SMART Analysis heart rhythm assessment and SMART Biphasic defibrillation therapy, clinically proven in nearly 10 years of use. No other biphasic waveform is as well documented. And with patented Quick Shock, the OnSite is fastest in class at delivering a shock after CPR. Studies show that minimizing time to shock after CPR may improve survival.^{5,6,7,8,9}

Philips HeartStart OnSite Defibrillator

Product specifications

Defibrillator

Defibrillator Model	HeartStart M5066A
Defibrillator Family	HSI
How Supplied	Defibrillator; Owner's Manual, battery, 1 adult SMART Pads cartridge, Quick Reference Guide, Quick Start poster; and your choice of carry case.
Waveform	Truncated Exponential Biphasic. Waveform parameters adjusted as a function of each patient's impedance.
Energy	Single energy output. Adult: nominal 150 Joules into a 50 ohm load. Infant/Child: nominal 50 Joules into a 50 ohm load. Automatically set based on type of SMART Pads cartridge installed.
Shock-to-Shock Cycle Time	Typically less than 20 seconds between shocks in a series.
Quick Shock	Able to deliver a shock after the CPR pause, typically in 8 seconds.
Voice Instructions	Detailed voice messages guide responder through use of the defibrillator.
CPR Coaching	Instructions for adult and infant/child CPR available at user's option.
Shock Delivery	Via adhesive pads placed on patient's bare skin as illustrated on pads.
Controls	Green SMART Pads Cartridge handle, green on/off button, blue i-button, orange shock button.
Indicators	Ready light; blue i-button; caution light.

Physical Specifications

Size	2.8 x 7.4 x 8.3 inches (7 x 19 x 21 cm) H x D x W
Weight	With battery and pads case: 3.3 lbs. (1.5 kg) Without battery or pads case: 2.4 lbs. (1 kg)

Environmental/Physical Requirements

Sealing	Solid objects per EN60529 class IP2X. Drip-proof per EN60529 class IPX1.
Temperature	Operating: 32° - 122° F (0° - 50° C) Standby: 50° - 109° F (10° - 43° C)
Humidity	Operating: 0% to 95% relative, non-condensing Standby: 0% to 75% relative, non-condensing
Altitude	Operating: 0 to 15,000 feet Standby: 0 to 8,500 feet > 48 hours and 8,500 to 15,000 feet < 48 hours
Shock/Drop Abuse	Withstands 1 meter drop to any edge, corner or surface.
Vibration	Meets EN1789 random and swept sine, road ambulance specification in operating and standby states.
EMI (Radiated/Immunity)	Meets EN55011 Group I Level B Class B and EN61000-4-3.

Patient Analysis System

Patient Analysis	Evaluates patient ECG to determine if a rhythm is shockable. Rhythms considered shockable are ventricular fibrillation (VF) and certain ventricular tachycardias (VT) associated with lack of circulation. For safety reasons, some VT rhythms associated with circulation will not be interpreted as shockable, and some very low-amplitude or low-frequency rhythms will not be interpreted as shockable VF.
Sensitivity/Specificity	Meets AAMI DF80 guidelines and AHA recommendations for adult defibrillation (Circulation 1997;95:1677-1682).
Artifact Detection	The effects of pacemaker artifact and electrical noise are minimized with artifact detection.

Battery (M5070A)

Type	9Volt DC, 4.2Ah, composed of disposable long-life lithium manganese dioxide primary cells.
Capacity	Minimum 200 shocks or 4 hours of operating time.
Install-By Date	Battery is labeled with an install-by date of at least five years from date of manufacture.
Standby Life	Four years typical when battery is installed by the install-by date. (Will power the AED in standby state within the specified standby temperature range, assuming one battery insertion test and no defibrillation uses.)

SMART Pads

Adult SMART Pads Cartridge	M5071A defibrillation pads for patients 8 years of age and older or 55 lbs. (25 kg) and over.
Infant/Child SMART Pads Cartridge	M5072A defibrillation pads for patients under 8 years of age or 55 lbs. (25 kg). Rx only.
Energy Delivered	Adult: nominal 150 Joules into a 50 ohm load. Infant/Child: nominal 50 Joules into a 50 ohm load.
How Supplied	Disposable cartridge, containing adhesive defibrillation pads, clicks into defibrillator for an integrated pads solution.
Active Surface Area	13.2 in ² (85 cm ²) each
Cable Length	Adult pads: 54 in (137.1 cm) Infant/Child pads: 40 in (101.6 cm)
Use-By Date	Cartridge is labeled with a use-by date of at least two years from date of manufacture.

Training Pads

Adult Training Pads Cartridge	M5073A
Infant/Child Training Pads Cartridge	M5074A
Function	Special pads put HeartStart OnSite into training mode and disable its energy delivery capability. Training pads feature 8 real-world training scripts. Used with training mat (included) or with adapters on manikins.

Automated and User-Activated Self-Tests

Daily Automatic Self-tests	Tests internal circuitry, waveform delivery system, pads cartridge and battery capacity.
Pads Integrity Test	Specifically tests readiness-for-use of pads (gel moisture).
Battery Insertion Test	Upon battery insertion, extensive automatic self-tests and user-interactive test check device readiness.
Status Indicator	Blinking green "Ready" light indicates ready for use. Audible "chirp" indicates need for maintenance.

Data and Recording and Transmission

Infrared	Wireless transmission of event data to personal computer using the IrDA protocol.
Data Stored	First 15 minutes of ECG and the entire incident's events and analysis decisions.

* Refer to HeartStart OnSite Defibrillator Owner's Manual for detailed product instructions. All specifications based on 25° C unless otherwise noted. The defibrillator and its accessories are made of latex-free materials.



Philips — The trusted choice

- One of the world's largest medical products companies with annual revenue of over \$6 billion
- History of innovation. Philips introduced the medical X-ray tube in 1918, the audiocassette in 1963, the first VCR and created compact disc technology
- With over 200,000 automated external defibrillators installed, Philips has more AEDs on the job, in the air, in the classroom and in your neighborhood than anyone else¹
- Over 4.5 billion HeartStart Defibrillator service hours logged, with an additional 2.7 million hours added every day
- Over 17% of Fortune 1000 companies, 8 out of 10 major airlines and 43 professional sports teams rely on Philips HeartStart Defibrillators

The HeartStart OnSite Defibrillator is the first defibrillator for commercial and institutional users without a prescription. As the leader in innovative defibrillation technology,¹ Philips is committed to making defibrillators more widely available so that more lives can be saved. Now with over-the-counter status, Philips is making it easier for companies and organizations to institute early defibrillation programs.

Defibrillators are one part of a well-planned resuscitation program. Philips recommends medical oversight of your early defibrillation program by a physician or other authorized medical practitioner. Consult your state and local requirements regarding owning and operating defibrillators, and medical oversight.

To learn more about the HeartStart OnSite Defibrillator and Philips Medical Systems, visit www.philips.com/heartstart or call 800.934.7372.

Philips Medical Systems is part of Royal Philips Electronics

On the Web

www.philips.com/heartstart

Via email

medical@philips.com

By fax

+31 40 27 64 887

By postal service

Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1085

Asia

Tel: +852 2821 5888

Europe, Middle East and Africa

Tel: +31 40 27 63005

Latin America

Tel: +55 11 2125 0764

North America

Tel: +1 800 934 7372

© Koninklijke Philips Electronics N.V. 2005 All rights reserved.
Reproduction in whole or in part is prohibited without the prior written consent of the copyright holder.

Philips Medical Systems North America Corporation reserves the right to make changes in specifications or to discontinue any product at any time without notice or obligation and will not be liable for any consequences resulting from the use of this publication.

Printed in the U.S.
452297700761 * 2005-02

References

¹ Frost & Sullivan

² Andre, et al. Automated External Defibrillator Use by Untrained Bystanders: Can the Public-use Model Work? Prehospital Emergency Care 2004;8:284-291

³ Snyder; Time to Shock vs Voice Prompt Duration: Optimization of Defibrillators for Public Access and Home Deployment. 6th Scientific Congress of the European Resuscitation Council, Oct 2002

⁴ The Infant/Child pads cartridge is sold separately, and available only under the order of a physician.

⁵ Yu et al. Adverse Outcomes of Interrupted Precordial Compression During Automated Defibrillation. Circulation 2002; 106:368-372.

⁶ Eftesol T, Sunde K, Steen PA. Effects of Interrupting Precordial Compressions in the Calculated Probability of Defibrillation Success During Out-of-Hospital Cardiac Arrest. Circulation 2002; 105:2270-2273.

⁷ Snyder et al. Biphasic Defibrillation Waveform Combined with AED-Imposed "Hands-Off" Intervals Significantly Affect Outcome Following Prolonged Cardiac Arrest. Abstract from 7th Scientific Congress of the European Council, 2004

⁸ Snyder & Morgan. CPR Interruption Interval Varies Widely Among Commercially Available AEDs. Abstract from 7th Scientific Congress of the European Council, 2004

⁹ Snyder, D.E. and Morgan, C. Wide Variations in Cardiopulmonary Resuscitation Intervals Among Commercially Available Automated External Defibrillators May Affect Survival Despite High Defibrillation Efficacy. Critical Care Medicine. 2004;32(9) Supplement:S421-S424