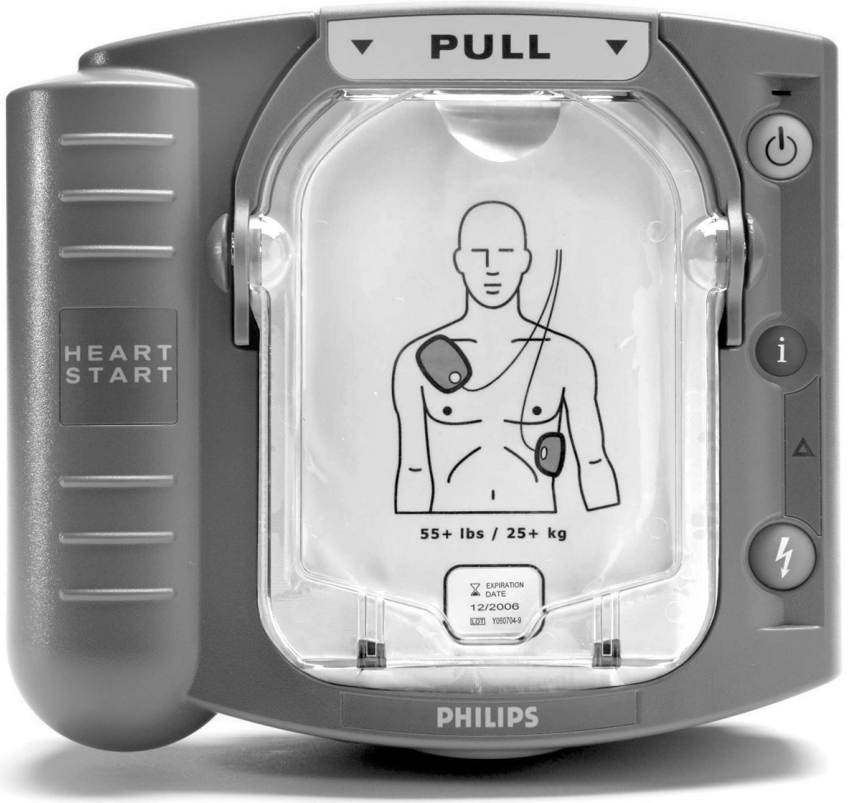
OnSite Defibrillator

OWNER'S MANUAL

Guide to Set Up, Operation, Maintenance, and Accessories



M5066A

Edition 15

PHILIPS

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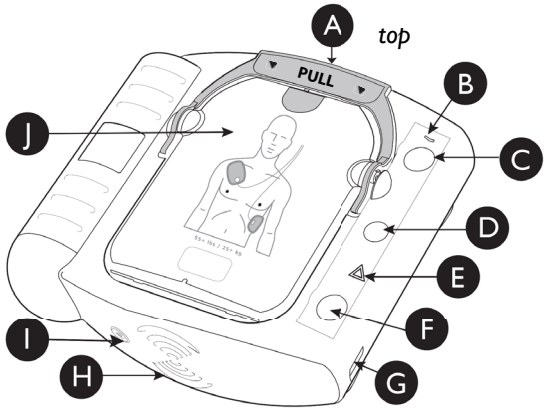
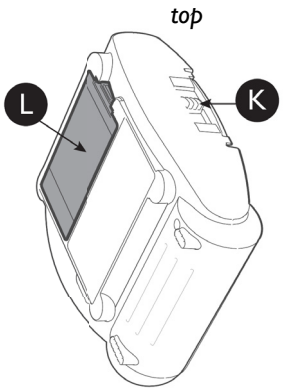


front view



back view

The OnSite Defibrillator M5066A

PHILIPS MEDICAL SYSTEMS

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

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

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

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

D Information Button. This "i-button" flashes blue when it has information you can access by pressing it. It also flashes at the beginning of a patient care pause when CPR guidance 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 OnSite to deliver a shock, press this flashing orange button.

G Infrared (IR) Communications Port. This special lens, or "eye," is used to transfer OnSite 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 OnSite "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. Shown with adult OnSite pads cartridge.

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

L Battery. The non-rechargeable battery is inserted in a recess on the back of the OnSite.

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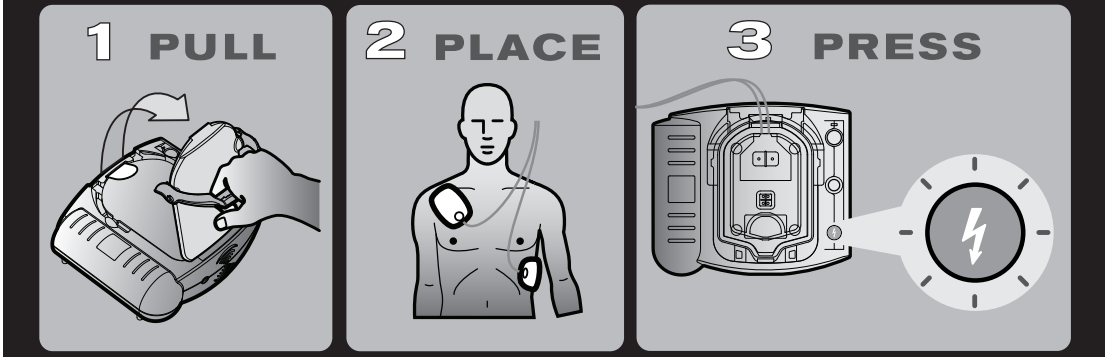
OnSite Defibrillator

QUICK REFERENCE

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



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HeartStart OnSite
M5066A
Automated External Defibrillator

OWNER'S MANUAL
Edition 15

IMPORTANT NOTE:

It is important to understand that survival rates for sudden cardiac arrest are directly related to how soon victims receive treatment. For every minute of delay, the chance of survival declines by 7% to 10%.

Treatment cannot assure survival. In some victims, the underlying problem causing the cardiac arrest is simply not survivable despite any available care.

PHILIPS MEDICAL SYSTEMS

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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, including the HeartStart, the HeartStart OnSite, and the HeartStart Home defibrillator. This information is subject to change. Please contact Philips at www.philips.com/AEDsupport or your local Philips representative for information on revisions.

Edition History

Edition 15
Publication Date: June 2019
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Notices

Specifications are subject to change without notice.

Caution

The Philips OnSite Defibrillator is designed to be used only with Philips-approved accessories. The OnSite 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 OnSite has been sold, donated, lost, stolen, exported, or destroyed, notify Philips Medical Systems or your distributor.

Device manufacturer

Philips Medical Systems
22100 Bothell Everett Highway
Bothell, WA 98021-8431, USA

Patents

Patents listing at www.ip.philips.com/patentmarking.

For Technical Support

If you need technical support, please contact your local Philips representative by calling the regional number on the back cover of this manual, or go to www.philips.com/AEDsupport.

To download additional copies of this manual, go to www.philips.com/AEDsupport.

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CONTENTS

APPENDICES

1 INTRODUCTION TO THE HEARTSTART ONSITE

DEVICE DESCRIPTION

The HeartStart OnSite (M5066A) Defibrillator is a light-weight, easy-to-use Automated External Defibrillator (AED), indicated to treat victims of sudden cardiac arrest (SCA).

The OnSite with the adult SMART pads cartridges (M5071A) is designated for over-the-counter sale; the infant/child SMART pads cartridge (M5072A) is prescription-use only. The HeartStart OnSite defibrillator is designed for use by a lay-person and is indicated for public access defibrillation.

The OnSite prompts the user to take specific actions if a potentially shockable rhythm is detected. The OnSite uses defibrillation pads placed on the victim's skin to deliver a shock. Once the defibrillation pads are placed on the patient, it analyzes the heart rhythm, determines whether or not a shock is required, charges the capacitor, and indicates to deliver a shock. The OnSite is able to provide verbal instructions to the user, detect where the user is in the event response, and provide general CPR guidance.

The HeartStart OnSite, which includes the necessary accessories of a battery and SMART pads cartridge (adult and infant/child), uses a proprietary shock advisory algorithm (Patient Analysis System [PAS]) and a truncated exponential biphasic shock waveform (impedance compensating SMART Biphasic waveform) to deliver a 150 J nominal shock to adults and 50 J nominal shock to pediatric patients to achieve its intended use.

SUDDEN CARDIAC ARREST

The OnSite is used to treat ventricular fibrillation (VF), a common cause of sudden cardiac arrest (SCA), and pulseless ventricular tachycardias (VTs). SCA is a condition that occurs when the heart unexpectedly stops pumping. SCA can occur to anyone – infant, child, adult, male or female – anywhere, at any time. Many victims of SCA do not have warning signs or symptoms.

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.

Note: Rx Only. Federal law (USA) restricts the Infant/Child SMART Pads Cartridge (M5072A) for sale by or on the order of a physician.

ESSENTIAL PERFORMANCE

The Onsite defibrillator maintains safe and effective performance of the defibrillation therapy and patient monitoring functions when operated in the electromagnetic environment specified in the Appendix G tables.

INDICATIONS FOR USE

The HeartStart OnSite (Model M5066A) is indicated for use on potential victims of cardiac arrest with the following symptoms:

- Unconsciousness; and
- Absence of normal breathing

The HeartStart OnSite (Model M5066A) is indicated for adults over 55 pounds (25 kg). The OnSite is also indicated for infants/children under 55 pounds (25 kg) or 8 years old when used with the optional Infant/Child SMART Pads (Model M5072A). If Infant/Child SMART pads are not available, or you are uncertain of the child's age or weight, proceed with treatment using adult SMART Pads (Model M5071A).

CONTRAINDICATIONS

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

DANGERS, WARNINGS, AND CAUTIONS

It is important to understand how to use your HeartStart OnSite Defibrillator safely. Not following or considering this information could lead to a delay of

therapy for the patient or cause harm to yourself and others around you. Please read these carefully.

- DANGER — Immediate hazards that will result in serious personal injury or death to the user and/or the victim.
- WARNING — Conditions, hazards, or unsafe practices that can result in serious personal injury or death.
- CAUTION — Conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the OnSite, or loss of data stored in the device.

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

DANGERS

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

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

WARNINGS

battery — Removing the battery may reset the OnSite, delaying patient defibrillation. Removing and reinserting the battery one or more times when the OnSite emits a series of triple chirps may reset the device and cause it to report it is ready for use, though it may be unable to deliver therapy during a rescue. Removing and reinserting the battery when your OnSite is emitting a pattern of triple chirps should only be done during an emergency. If your device is emitting a series of triple chirps in stand-by mode, or after an emergency, please remove the OnSite from service and contact Philips immediately.

fluids — Do not let fluids get into the OnSite. Avoid spilling any fluids on the OnSite or its accessories. Spilling fluids into the OnSite may damage it or cause a fire or shock hazard. Do not sterilize the OnSite or its accessories.

accessories — Using damaged or expired equipment or accessories may cause the OnSite to perform improperly, and/or injure the patient or the user.

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

cell phones — The OnSite can work correctly when it is fairly close to equipment like emergency two-way radios and cell phones. Normally, using a cell phone near the patient should not cause a problem for the OnSite. However, it is best to keep such equipment only as close as necessary to the patient and the OnSite.

pads — Do not allow the pads to contact other electrodes or metal parts that are in contact with the patient.

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

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

- Provide infant/child CPR while a bystander calls EMS and retrieves the OnSite.
- If no bystander is available, provide 1-2 minutes of CPR before calling EMS and retrieving the OnSite.
- If you witnessed the child's collapse, call EMS immediately and then get the OnSite.

Alternatively, follow your local protocol.

CAUTIONS

device handling — The OnSite was designed to be sturdy and reliable for many different use conditions. However, handling the OnSite too roughly can damage it or its accessories and will invalidate the warranty. Check the OnSite and accessories regularly for damage, according to directions.

maintenance	Improper maintenance may damage the OnSite or cause it to function improperly. Maintain the OnSite according to directions. Check supplies, accessories, packaging, and spares for damage and expiration dating.
skin burns	Do not let the pads touch each other or other electrodes, lead wires, dressings, medicine patches, etc. Such contact can cause electrical arcing and skin burns during a shock and may also divert the electrical current away from the patient's heart. During a shock, air pockets between the skin and pads can cause skin burns. To help prevent air pockets, make sure pads stick well to the skin. Do not use dried out pads because they will not provide good contact with the skin.
shock hazard	The OnSite is not protected from electrical shock hazard if it is opened. The OnSite is protected from electrical shock hazard while it is intact. Do not open the OnSite, remove its covers, or attempt to repair it. There are no user-serviceable components in the OnSite. If repair is required, return the OnSite to an authorized service center.
patient	If the patient's chest is not clean, the defibrillation pads may not make adequate contact with the patient. Remove any medicine patches and residual adhesive from the patient's chest before applying the pads.
radiated emissions	While the OnSite complies with radiated emission standards, some medical equipment may still be impacted by emissions from the OnSite. If this occurs, move the impacted equipment away from the OnSite until the OnSite is no longer needed for the patient, or EMS arrives and takes over the scene.
environmental conditions	Environmental conditions may cause improper operation. Using the OnSite outside of the specified environmental range (temperature, humidity, atmospheric pressure) may result in incorrect or intermittent operation. Make sure the OnSite is stored in an environment according to the owner's manual.
configuration	An incorrectly configured language may prevent the OnSite from being applied properly. The OnSite uses lighted buttons and voice instructions to guide a user through a rescue. If a user is not familiar with the language that the OnSite is set to, the OnSite may not be used effectively to treat a patient in need, reducing the likelihood of survival for that patient. Make sure that the language of the OnSite is set to a language that the majority of the users of that OnSite may be familiar with.

pacemakers

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

pads

If the pads do not stick well to the skin, check that the pads adhesive has not dried out. Each pad has a layer of adhesive gel. If the gel is not sticky to the touch, replace the pads with a new set. (For ease of handling, the pad is designed with a non-gel area around the connector cable.)

device operation

The OnSite will only deliver a shock if the flashing orange Shock button is pressed when the instruction is given. If the Shock button is not pressed within 30 seconds after the instruction, the OnSite will disarm itself, and (for the first CPR interval) give a reminder to make sure emergency medical services have been called. The OnSite will then begin a CPR interval. This is designed to minimize interruption of CPR and help ensure ongoing patient support.

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

accessories

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

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

cpr

CPR causes injury to the patient. Even when CPR is applied correctly, the patient's chest may become bruised or ribs may be fractured. Performing CPR incorrectly could cause additional injuries to a patient, or may not provide needed benefit to the patient. Be sure to follow the CPR guidance instructions provided by the OnSite. Be sure to turn on CPR guidance if you are unsure of your CPR skills.

patient handling

Keep the patient still and keep any movement around the patient to a minimum during rhythm analysis. Do not touch the patient or the pads while the Caution light is on solid or flashing. If the OnSite is unable to analyze due to electrical "noise" (artifact), it will tell you to stop all movement and remind you not to touch the patient. If the artifact continues for more than 30 seconds, the OnSite

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

PROBABLE ADVERSE EFFECTS OF THE DEVICE ON HEALTH

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

- Failure to identify shockable arrhythmia
- Failure to deliver a defibrillation shock in the presence of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT), which may result in death or permanent injury
- Inappropriate energy, which could cause failed defibrillation or postshock dysfunction
- Myocardial damage
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents
- Incorrectly shocking a pulse sustaining rhythm and inducing VF or cardiac arrest
- Bystander shock from patient contact during defibrillation shock;
- Interaction with pacemakers
- Skin burns around the defibrillation pads placement area
- Allergic dermatitis due to sensitivity to the materials used in the defibrillation pads construction
- Minor skin rash.

CLINICAL SUMMARY OF SAFETY & PERFORMANCE DATA

Philips, or its predecessor Heartstream, was directly responsible for the conduct of clinical trials related to the safety and effectiveness of the Philips family of AEDs.

A. Adult Defibrillation Waveform

The pivotal clinical trial supporting the Philips SMART biphasic waveform was comprised of 3 studies. The first was a single center feasibility trial (Gemini I);

followed by a prospective randomized clinical trial (Gemini II), and finally a safety sub-study (Gemini Safety). These studies supported the safety and effectiveness of the SMART Biphasic defibrillation waveform.

1. *Gemini I Feasibility Study*[1]

Objective: Gemini I was a clinical evaluation of the transthoracic defibrillation effectiveness of two different biphasic truncated exponential waveforms (115 J and 130 J), with that of a then standard 200 J monophasic damped sine waveform.

Study Design: The study was a single site, prospective, randomized and blinded study involving patients undergoing transvenous ICD surgery. Transthoracic ventricular defibrillation rescue shocks were tested after a failed transvenous defibrillation shock was delivered in the course of ICD testing. Each of the three different rescue shocks was tested in random order in each patient. The shock was considered a success if it defibrillated a patient. The biphasic waveforms were generated using a custom, experimental defibrillation (Heartstream) system. The damped sine wave was from the Physio-Control LifePak 6s defibrillator.

Results: Thirty-three patients were enrolled and 30 completed the protocol. Of the 30 patients, 22 were men. All were undergoing a planned procedure for ICD implantation and consented to inclusion in the clinical study. All 3 waveforms were equally effective at 97%, with 1 patient failing to be defibrillated with each waveform. The defibrillation energy for the two biphasic waveforms was significantly lower as compared to the damped sine wave ($p < 0.001$), as was the peak current and voltage.

Conclusion: The results showed that biphasic truncated transthoracic shocks of low energy (115 J and 130 J) were as effective in the tested group as 200 J damped sine wave shocks used in standard transthoracic defibrillators.

[1] Bardy GH, Gliner BE, Kudenchuk PJ, Poole JE, Dolack GL, Jones GK, Anderson J, Troutman C, Johnson G: Truncated biphasic pulses for transthoracic defibrillation. *Circulation* 1995, 91(6):1768-1774

2. *Gemini II Pivotal Study*[2]

Objective: The objective of this randomized, controlled, multi-center trial was to evaluate the safety and effectiveness of the investigational biphasic truncated exponential waveform vs. the control monophasic damped sinusoidal waveform from standard commercially marketed external defibrillators.

Study Design: The study was a prospective, randomized, double-blinded investigation conducted at 14 sites in the United States and Canada. The study population consisted of 318 patients undergoing testing for insertion of an implantable defibrillator or follow-up electrophysiological evaluation post-implantation. In this study rescue shocks of investigational biphasic waveforms of 115 and 130 J were compared to monophasic waveforms of 200 J and 360 J.

Results: A total of 318 patients were enrolled in the study, and after exclusion criteria were applied there were 294 patients included in the study analyses, for a total of 513 shocks delivered during the study.

[2] Bardy GH, Marchlinski FE, Sharma AD, Worley SJ, Luceri RM, Yee R, Halperin BD, Fellows CL, Ahern TS, Chilson DA *et al*: Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. Transthoracic Investigators. *Circulation* 1996, 94(10):2507-2514

Overall, for the 294 included patients analyzed, 513 transthoracic defibrillation attempts (shocks) were performed. The overall breakdown by waveform and success rates is as follows in the table below.

Successful Defibrillations by Waveform Type

Waveform	Successful Defibrillation N (%)	95% Confidence Interval (%)
115 J Biphasic	86 (89)	82-95
130 J Biphasic	144 (86)	81-92
200 J Damped Sine	143 (86)	81-91
360 J Damped Sine	80 (96)	92-100

Conclusion: For the primary hypothesis, the effectiveness of the 130 J truncated biphasic waveform and the 200 J monophasic waveform was not significantly different using the Pearson chi-square test (p = 0.97). The 115 J and 130 J biphasic waveforms both demonstrate transthoracic defibrillation effectiveness equivalent to either the 200 J or 360 J monophasic waveforms.

The energy dose increased to 150 J in later clinical studies (ORCA study by Schneider[3]), and 150 J is the energy dose in the SMART biphasic waveform used in the OnSite AED.

[3] Schneider T, Martens PR, Paschen H, Kuisma M, Wolcke B, Gliner BE, Russell JK, Weaver WD, Bossaert L, Chamberlain D: Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 360-J monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. Optimized Response to Cardiac Arrest (ORCA) Investigators. *Circulation* 2000, 102(15):1780-1787

3. *Gemini II Safety Sub-Study*[4]

A single center, prospective analysis was conducted to look at potential differences in ECG ST-segment changes when comparing the waveforms from the pivotal trial. In this study the ST-segment changes were used as a surrogate for myocardial injury. Each patient received two low-energy biphasic waveform shocks at 115 J and 130 J and a 200 J monophasic shock. ECGs were reviewed by two blinded, independent reviewers. This 30 patient sub-study showed that ST-segment elevation was significantly greater for the 200 J damped sine wave ($p<0.001$), indicating a potential safety advantage associated with the biphasic waveform.

4. *ORCA (Out of Hospital Response to Cardiac Arrest) Trial*[5]

This postmarket study supports the safe and effective use of the Philips HeartStart HS1 (Home and OnSite) in out-of-hospital defibrillation. The ForeRunner device used in this study, and the HeartStart HS1 (Home and OnSite) device subject to PMA, both use SMART biphasic waveforms and PAS shock advisory algorithm technology.

Study Design: Patients were prospectively enrolled in four European EMS systems and included a total of 338 patients. First responders used either impedance-compensated biphasic waveform AEDs (Philips ForeRunner 150 J) or standard monophasic damped sine (MDS) and monophasic truncated exponential (MTE) AEDs with an escalating energy protocol on victims of sudden collapse when defibrillator application was indicated. A sequence of up to three defibrillation shocks was delivered (150 J for each of the three biphasic shock; for monophasic AEDs, 200 J, 200 J, then 360 J).

[4] Reddy RK, Gleva MJ, Gliner BE, Dolack GL, Kudenchuk PJ, Poole JE, Bardy GH: Biphasic transthoracic defibrillation causes fewer ECG ST-segment changes after shock. *Annals of emergency medicine* 1997, 30(2):127-134

[5] Schneider T, Martens PR, Paschen H, Kuisma M, Wolcke B, Gliner BE, Russell JK, Weaver WD, Bossaert L, Chamberlain D: Multicenter, randomized, controlled trial of 150-J biphasic shocks compared with 200- to 360-J monophasic shocks in the resuscitation of out-of-hospital cardiac arrest victims. Optimized Response to Cardiac Arrest (ORCA) Investigators. *Circulation* 2000, 102(15):1780-1787

Results: A total of 338 patients were enrolled. After exclusion criteria were applied, 115 patients were included in the principal analyses, 54 treated with biphasic and 61 with monophasic AED shocks. 53 of 54 (98%) VF patients were defibrillated using 150 J biphasic shocks compared with 42 of 61 (69%) with 200-360 J monophasic shocks ($p < 0.0001$). The impedance-corrected biphasic truncated exponential (ICBTE) waveform was more effective than the MDS waveform (98% vs. 77%, $p = 0.02$).

A higher percentage of patients (76%) achieved ROSC following 150 J biphasic waveform defibrillation compared with higher energy monophasic waveform defibrillation (54%) ($p = 0.01$).

Conclusion: The study demonstrated that an appropriately dosed low-energy impedance-compensating biphasic waveform strategy results in superior defibrillation performance when compared with escalating, high-energy monophasic shocks in out-of-hospital cardiac arrest. Although survival rates to hospital admission and discharge did not differ, discharged patients who had been resuscitated with biphasic shocks were more likely to have good cerebral performance.

B. Pediatric Defibrillation Waveform

Pediatric defibrillation effectiveness is supported with an animal study[6] for the biphasic waveform energy of 50 J and a postmarket surveillance study for Pediatric AED use[7].

1. *Animal Study*[6]

Tang et al.[6] conducted an evaluation of a 50 J biphasic waveform in a porcine model to determine if 50 J was an appropriate energy level (Phase 1), and then to evaluate the implementation of reducing the adult dose to the pediatric dose by means of attenuated pediatric pads (Phase 2).

[6] Tang W, Weil MH, Jorgenson D, Klouche K, Morgan C, Yu T, Sun S, Snyder D: Fixed-energy biphasic waveform defibrillation in a pediatric model of cardiac arrest and resuscitation. *Critical care medicine* 2002, 30(12):2736-2741

[7] Atkins DL, Jorgenson DB: Attenuated pediatric electrode pads for automated external defibrillator use in children. *Resuscitation* 2005, 66(1):31-37

In Phase 1 of the Tang et al.[6] study, 4 groups of 5 anesthetized mechanically ventilated piglets weighing 3.8, 7.5, 15, and 25 kg were evaluated for a total of 20 animals. Ventricular fibrillation was induced after 7 minutes of untreated VF, defibrillations were attempted with an impedance-compensated biphasic waveform defibrillator modified to deliver shocks with a nominal energy level of 50 J.

In Phase 2 of the study, shocks were delivered through special pediatric pads in conjunction with a conventional adult AED (FR2; Philips Medical Systems). The same VF induction and resuscitation protocol as Phase 1 was exercised on three (3) piglets in three (3) weight groups (3.7, 13.5, and 24.2 kg). The SMART biphasic waveform as implemented in the FR2 used in this study supports the SMART biphasic waveform as implemented on the OnSite and Home AED.

In both phases, all animals were successfully resuscitated. The average total number of shocks and total delivered energy was not weight dependent ($p < 0.05$). Post-resuscitation hemodynamic and myocardial function quickly returned to baseline values in both experimental groups; 100% of the animals survived. Animals were monitored for survival at 24, 48 and 72 hours in Phase 1 and in Phase 2 for four hours; all animals survived through the last time-point.

2. *Postmarket Surveillance Study of Pediatric AED Use*[7]

The objective of the post-market surveillance study was to confirm that certain adult AEDs with shock intensity attenuation could be used safely and effectively in the pediatric population. The study population was infants and children less than 8 years of age or under 55 pounds. The HeartStart FR2 Defibrillator is a predecessor to the HeartStart OnSite defibrillator. Data from this defibrillator is applicable to the safety and effectiveness of the HeartStart OnSite defibrillator.

[6] Tang W, Weil MH, Jorgenson D, Klouche K, Morgan C, Yu T, Sun S, Snyder D: Fixed-energy biphasic waveform defibrillation in a pediatric model of cardiac arrest and resuscitation. *Critical care medicine* 2002, 30(12):2736-2741

[7] Atkins DL, Jorgenson DB: Attenuated pediatric electrode pads for automated external defibrillator use in children. *Resuscitation* 2005, 66(1):31-37

Study Design: This prospective, observational, post-market surveillance study included the Philips FR2 AED and Pediatric Attenuated Electrodes, and the HeartStart OnSite AED with the infant/child SMART pads cartridge.

Results: Through September 2004, there were 26 confirmed pediatric-use cases: 25 of 26 reported use of the FR2 and one reported use of the OnSite. The median age was 2 years. The users were predominately EMS personnel or health care professionals (n=24). Most arrests occurred at home (n=16). Most patients to whom the device was applied had non-shockable rhythms (16, of which 13 were confirmed with AED data). Of 7 patients who had ventricular fibrillation and received attenuated shocks, all had termination of ventricular fibrillation and 5 survived to hospital discharge. The median age of the 7 patients was 3 years (range 18 months to 10 years). These patients received on average 2 shocks (range 1-4).

Conclusion: Based on the post market surveillance data, the FR2 AED used with the FR2 infant/child attenuated pads and the HeartStart OnSite AED used with the infant/child pads cartridge performed safely and effectively in the pediatric population.

C. OTC Home Use

1. Home Use AED Post Market Study[8]

The Philips HeartStart Home OTC defibrillator was cleared in 2004. After clearance, FDA issued a 522 Mandatory Post Market Study order for the Philips HeartStart Home Over-the-Counter study to discuss removal of the prescription requirement for the AED.

[8] Jorgenson DB, Yount TB, White RD, Liu PY, Eisenberg MS, Becker LB: Impacting sudden cardiac arrest in the home: a safety and effectiveness study of privately-owned AEDs. Resuscitation 2013, 84(2):149-153

Objective: This observational, post-market study was to monitor and learn more about the use of defibrillators in the home, with no hypothesis testing or calculated sample size criteria. This study collected information from owners of HeartStart Home AED who purchased between November 2002 and December 2009.

Study Design: The methods used for obtaining information on home AED uses included surveying AED owners, identifying and contacting care providers, and subsequently completing detailed interviews of the care providers. The interviews sought to obtain information on any safety issues that arose during a use including harm to the patient, caregiver, or bystanders. The interviews allowed the user to describe the use in his/her own words as well as asked some specific questions regarding device use.

Data Collection: This study collected cumulative information from HeartStart Home AED owners who purchased their device after November 2002 through December 31, 2009. Survey data were solicited from all owners, with a total of 23,480 surveys distributed and 13,328 responses obtained. Only users who purchased OTC devices (no prescription needed) were included in the dataset for analysis.

Results: A total of 23,480 surveys were distributed and 13,328 responses were received. 18 OTC uses were reported that resulted in pads being applied to an adult patient in SCA (median age 66 years). There were additionally 3 pediatric uses, despite the fact that the pediatric pad cartridge requires a prescription; these were excluded in this analysis.

In 12/18 (67%) uses, the arrest was witnessed. In 10/18 (56%) of the uses the patient presented in VF/shockable rhythm and at least one shock was delivered, median 1.5 shocks per patient (range 1-5). Shock effectiveness was 100% (10/10) for termination of VF. Of those shocked, 8/10 (80%) had a witnessed arrest and 2/10 (20%) were unwitnessed.

The patients with unwitnessed arrest who were shocked survived to hospital admission but later died in hospital 2/2 (100%). Of the patients with a witnessed arrest who were shocked, 5/8 (63%) survived to hospital discharge. No relevant trend was observed comparing responders to non-responders.

Conclusion: No new safety or effectiveness issues were identified upon completion of the study. The ability of home users, some with minimal training or experience, to use an AED was demonstrated. In this report of OTC use of AEDs in the home, 5 of 8 (63%) patients with a witnessed VF arrest survived to hospital discharge. The survival rate observed in this post market study, with an acknowledged limited number of patients, validates the ability of lay responders to successfully and safely use an AED to help those in sudden cardiac arrest. This study on the HeartStart Home OTC AED and its conclusions are relevant to a finding of safety and effectiveness for the OnSite AED since the devices are identical in their design.

PRINCIPLES OF OPERATION

The HeartStart OnSite defibrillator is designed to provide external defibrillation therapy to someone experiencing sudden cardiac arrest caused by ventricular fibrillation (VF), the most common cause of SCA, and pulseless ventricular tachycardias (VTs). The only effective treatment for these non-perfusing arrhythmias is defibrillation. The OnSite treats them by sending a shock across the heart, so it can start beating regularly again. The OnSite is designed to be easy to use. In its default AED mode, when connected to defibrillator pads that are properly applied to the patient's bare chest, the OnSite prompts you to take specific actions; automatically analyzes the patient's heart rhythm and advises you whether or not the rhythm is shockable; and, if advised by its rhythm analysis algorithm, arms the Shock button and instructs you to press it to deliver a biphasic electric pulse designed to defibrillate the heart. For detailed instructions for use, see Chapter 3, "Using the Heartstart Onsite."

IMPLEMENTATION CONSIDERATIONS

Check with your local health department to see if there are any national or local requirements about owning and using a defibrillator. The OnSite is one part of a

well-designed emergency response plan. Recognized resuscitation councils recommend that emergency response plans include physician oversight and training in cardiopulmonary resuscitation (CPR).

Several national and local organizations offer combined CPR/AED training. Philips recommends that you train on the device you will be using. Contact your Philips representative for information, or visit us online at www.philips.com/AED.

NOTE: Training accessories are available for practicing use of the HeartStart OnSite Defibrillator. See Appendix A for information.

FOR MORE INFORMATION

Contact your local Philips representative 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.*

* Clinical summaries also include ForeRunner and FR2 Defibrillators.

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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 battery M5070A, pre-installed
- 1 Adult SMART Pads Cartridge M5071A, containing one set of adhesive defibrillation pads, pre-installed
- 1 Quick Reference Guide
- 1 Owner's Manual
- 1 HeartStart Quick Setup Guide
- 1 inspection log/maintenance booklet with plastic storage sleeve and maintenance tags*

If you have purchased the OnSite Ready-Pack configuration, the OnSite is installed in a carry case, which also contains a spare adult SMART Pads Cartridge.

Training materials and optional accessories for the OnSite are also available from Philips. See Appendix A for information.

SETTING UP THE HEARTSTART ONSITE

Setting up the OnSite is simple and quick. The OnSite Quick Setup Guide provides illustrated instructions for setup, which is described in detail below.

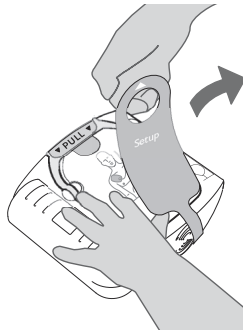
1. Remove the OnSite from its packaging. Check that the battery and pads cartridge are installed.†

* In Japan, the OnSite comes with a different style of maintenance tag and inspection log/maintenance booklet.

† If the battery and pads are not installed, or if you wish to install an infant/child SMART Pads Cartridge, follow the directions in Chapter 4, "After Using the OnSite" to install the pads and battery.

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.

2. Pull out and discard the green Setup tab.



3. The OnSite will automatically run a self-test. Press the Shock button when instructed. Be sure to let the self-test run all the way to completion. 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.

4. Install the OnSite in its carry case, if it is not pre-installed. Ensure that the Quick Reference Guide† is face up in the clear plastic window on the inside of the carry case. Philips recommends that you store a spare pads cartridge and spare battery with your OnSite. If you are using a standard carry case, there is an area in the upper lid of the case, under the flap, to store a spare adult SMART Pads Cartridge or an infant/child SMART Pads Cartridge and a spare battery.‡

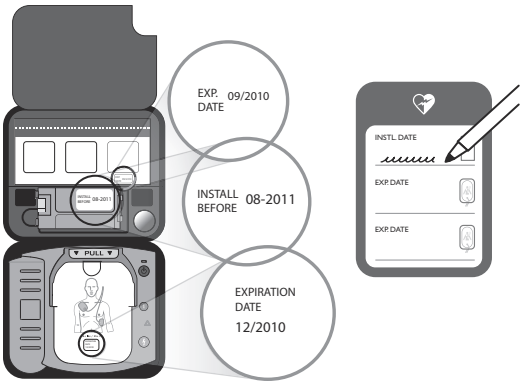
NOTE: Do not store anything in the OnSite carry case that it is not designed to accommodate. Store all objects in their intended location in the case.

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

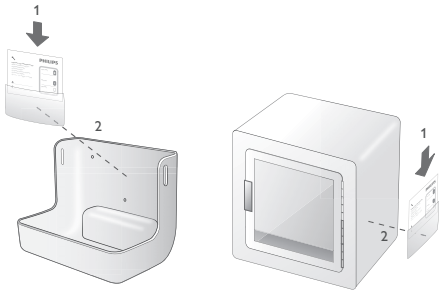
† The illustration on the cover of the Quick Reference Guide is a 3-step guide to using the OnSite. Detailed illustrated directions are inside, for reference in an emergency, or if you are hearing impaired or using the OnSite where it is hard to hear the voice instructions.

‡ See Chapter 4, "After Using the HeartStart OnSite," for directions on how to replace the battery in the OnSite.

5. Use the maintenance tag* provided to record the expiration date of the installed SMART pads cartridge. If you have a spare SMART pads cartridge and spare battery, record the pads expiration date and battery install-by date on the maintenance tag.



6. The maintenance tag and inspection log/ maintenance booklet should be kept with your OnSite. Adhere the plastic storage sleeve* for the booklet to the AED wall mount or cabinet and store the booklet in it for ready reference.



7. Store the OnSite in its carry case 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 location will be near a telephone, so the Emergency Response Team or Emergency Medical Services can be alerted as fast as possible in the event of a possible SCA.

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 D for details. As long as a battery and a SMART pads cartridge are installed, the green Ready light should be blinking to show that the OnSite has passed its most recent self-test and is therefore ready to use.

* In Japan, the OnSite comes with a different style of maintenance tag and inspection log/maintenance booklet.

NOTE: Always store the OnSite with a pads cartridge and a battery installed, so it will be ready to use and can perform daily self-tests. Training pads should be stored separately from the OnSite to avoid confusion during a use.

RECOMMENDED ACCESSORIES

It is always a good idea to have a spare battery and a spare Smart 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 information.

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. 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 guidance is selected, the OnSite provides guidance appropriate for infants and children. Directions for using the infant/child SMART Pads cartridge are provided in Chapter 3, "Using the HeartStart OnSite."

3 USING THE HEARTSTART ONSITE

IMPORTANT NOTE: Be sure to read the WARNINGS and CAUTIONS throughout this manual as well as in Section 1.

WARNING: Do not use or stack the OnSite unit with other equipment. If the unit is used or stacked with other equipment, verify proper operation prior to use.

OVERVIEW

If you think someone is in SCA, act quickly and calmly.

- If the patient is an infant or child, first perform CPR, then call for emergency medical services (EMS) before you apply the OnSite. See the special section on treating infants and children.
- Call your emergency services provider. *If someone else is available*, ask him or her to call for emergency medical assistance while you get the OnSite.
- Quickly get the OnSite and bring it to the victim's side. If there is any delay in getting the defibrillator, check the patient and perform cardiopulmonary resuscitation (CPR) if needed until the OnSite is available.
- It is safe to use the HeartStart OnSite Defibrillator on a patient lying on a wet surface. Before doing so, remove the patient from standing water, such as a pool or bathtub. It is also safe to use the HeartStart OnSite Defibrillator on a patient lying on a conductive surface, such as a metal surface. It is important to dry the patient's chest completely, so that the pads stick well to the dry, bare skin.
- 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.

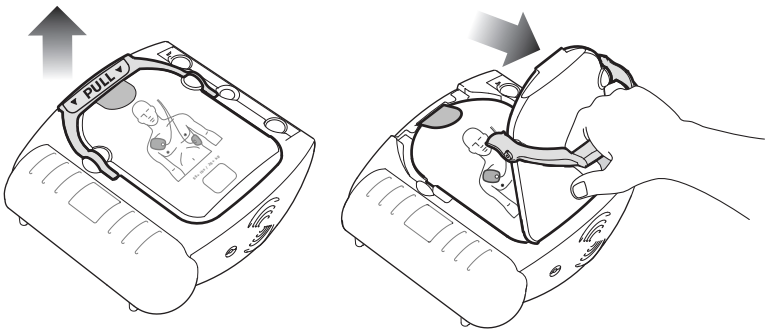
There are three basic steps to using the OnSite to treat someone who may be in sudden cardiac arrest:

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.

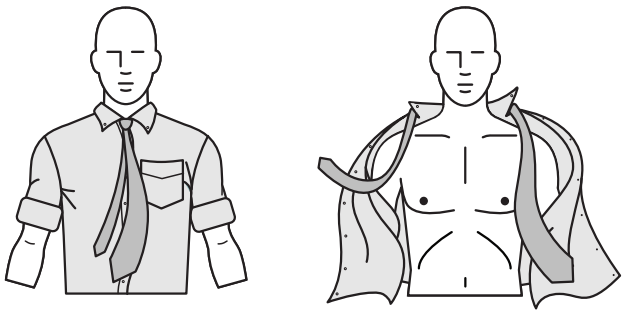
The following pages provide details about each step.

STEP 1: PULL THE GREEN HANDLE

Turn on the OnSite 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 OnSite's instructions.



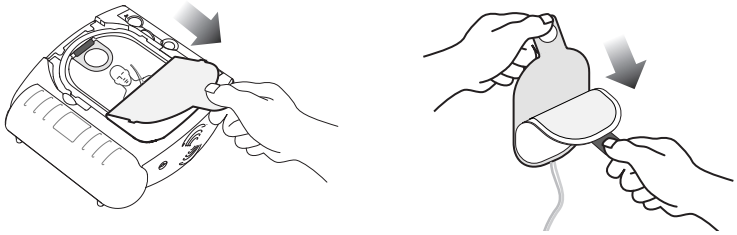
The OnSite starts by directing you to remove all clothes from the patient's chest. If necessary, rip or cut off the clothing to bare the person's chest



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

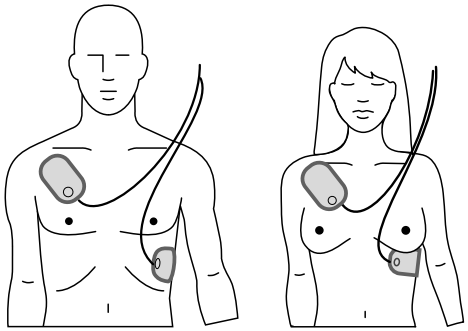
STEP 2: PLACE THE PADS

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.

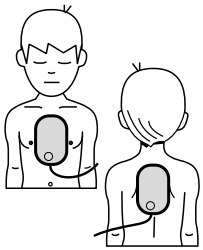


Peel one pad off the liner. Place the pad on the patient's bare skin, *exactly as shown in the picture on the pad*. Press the pad down firmly. Then repeat this with the other pad. Be sure the pads have been removed from the liner before placing them.

Where to place pads on adults (anterior-anterior).

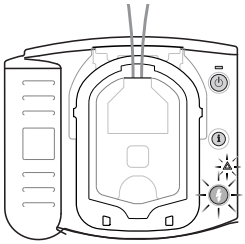


Where to place pads on infants or children under 55 pounds/25 kg or 8 years old (anterior-posterior).



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.

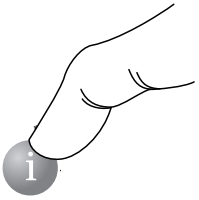


If a shock is needed:

The Caution light goes from flashing to solid, the orange Shock button starts flashing, and the OnSite tells you to press the flashing orange button. Before you press the button, make sure no one is touching the patient. When you press the Shock button, the OnSite tells you that the shock has been delivered. Then the OnSite tells you it is safe to touch the patient, instructs you to begin CPR, and invites you to press the flashing blue i-button for CPR guidance if desired.

If a shock is not needed:

The OnSite tells you it is safe to touch the patient and instructs you to perform CPR if needed. (If CPR is not needed – for example, if the patient is moving or regaining consciousness – follow your local protocol until emergency medical personnel arrive.) Then the OnSite invites you to press the flashing blue i-button for CPR guidance, if desired.



For CPR guidance:

Press the flashing blue i-button during the first 30 seconds of the patient care pause to activate CPR guidance.* (If the Infant/Child SMART Pads Cartridge is inserted, CPR guidance will provide guidance 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.

* The default configuration for the OnSite provides CPR guidance 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. See Appendix E for more information.

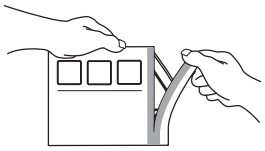
TREATING INFANTS AND CHILDREN

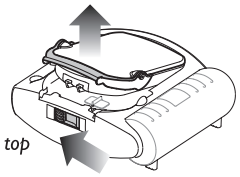
WARNING: Most cardiac arrests in children are not caused by heart problems. When responding to cardiac arrest in an infant or child:

- Provide infant/child CPR while a bystander calls EMS and brings the OnSite.
- If no bystander is available, provide 1-2 minutes of CPR before calling EMS and retrieving the OnSite.
- If you witnessed the child's collapse, call EMS *immediately* and *then* get the OnSite.

Alternatively, follow your local protocol.

If the patient is under 55 pounds (25 kg) or 8 years old, and you have an infant/child SMART Pads Cartridge:





- Remove the Infant/Child SMART Pads Cartridge from its package.*
- Locate the latch at the top edge of the defibrillator, and slide it to the side. Any installed SMART pads cartridge will be released. Remove the old cartridge.
- Install the new infant/child SMART Pads 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 OnSite 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 SMART 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 guidance. Place the pads exactly as shown on the illustration on the pads.

* Philips recommends that the OnSite be stored with an adult pads cartridge installed, as pediatric cardiac arrest is not common.

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

If the patient is under 55 pounds (25 kg) or 8 years old, but you do NOT have an infant/child SMART 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 SMART 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 the patient is over 55 pounds (25 kg) or 8 years old, or if you are not sure of the exact weight or age:

- DO NOT DELAY TREATMENT.
- Remove all clothing from the chest.
- Apply the OnSite using the adult SMART pads cartridge, and place the pads as illustrated on the pads (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 SMART pads cartridge, and insert a new SMART pads cartridge before returning the OnSite to service, to be sure it is ready for use.

* See Chapter 4,"After Using the HeartStart 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.
- Avoid placing the pads directly over an implanted pacemaker or defibrillator. A noticeable lump with a surgical scar should indicate the position of an implanted device.
- 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 movement 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 deal with 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, and (for the first CPR interval) give a reminder to make sure emergency medical services have been called, then begin a CPR interval. This is designed to minimize interruption of CPR and help ensure ongoing patient support.
- 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 defibrillator will disarm and tell you a shock is not advised.
- If for any reason you want to turn off the defibrillator during a use, you can press the On/Off button – holding it down for at least one second – to return the device to standby mode.

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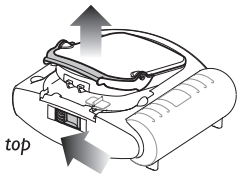
4 AFTER USING THE HEARTSTART ONSITE

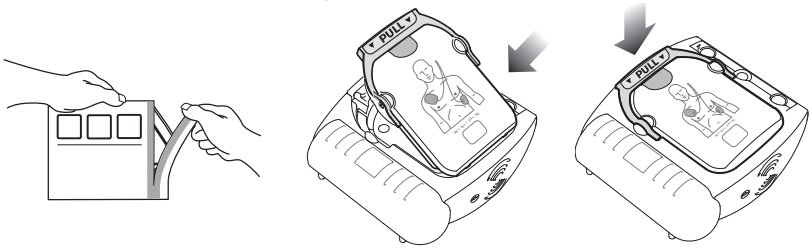
AFTER EACH USE

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. The single-use SMART pads must be replaced after being used. Locate the latch at the top edge of the OnSite and slide it to the side. The SMART pads cartridge will be released. Lift out the used SMART pads cartridge.



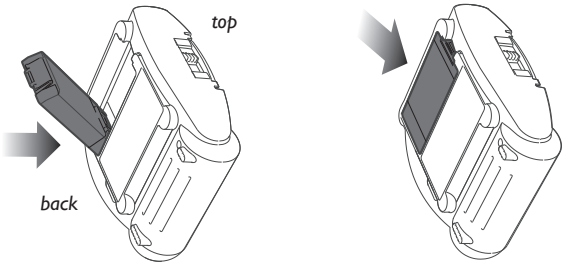
3. Remove a new SMART Pads Cartridge from its package and insert the cartridge into the cartridge well on the front of the OnSite. It should click into place when properly seated. The green PULL handle should be all the way down.



NOTE: To prevent the SMART 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. Check supplies and accessories for damage and expiration dates. Replace any used, damaged or expired items. Use a new maintenance tag to record the SMART pads expiration date for the new installed SMART pads cartridge. If you replace the spare pads and/or battery be sure to record the dates for them on the maintenance tag as described in Chapter 2. Then sign and date the inspection log/maintenance booklet.

5. 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.



Battery installation.

6. The OnSite will automatically run a self-test when the battery is inserted. Press the Shock button when instructed. Be sure to let the self-test run all the way to completion. 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.†

NOTE: Always store the OnSite with a SMART pads cartridge and a battery installed, so it will be ready to use and can perform daily self-tests. Philips recommends storing your OnSite with an adult SMART pads cartridge installed.

7. Return the OnSite to its storage location so it will be ready for use when needed. Place the updated inspection log/maintenance booklet on the defibrillator wall mount or cabinet.

* If you leave the battery in the OnSite after using the defibrillator, then transfer the last-use data to a computer running HeartStart Event Review software, the software will calculate the local date and time of the device use. However, if you remove the battery prior to transferring the data, the software will only show elapsed time.

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

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 at www.philips.com/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.

The information automatically stored by the OnSite includes a summary of last-use data and detailed data about its last clinical use. You can get a voice summary of information about the last use of the OnSite by holding the i-button down until it beeps once. The OnSite will tell you how many shocks were delivered and how long it has been since it was turned on. Summary data are available anytime the OnSite is ready for use (the battery and OnSite 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.

Last-use data stored in internal memory include:

- ECG recordings (a maximum of 15 minutes following SMART 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)

* 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 appropriate Event Review software. (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 OnSite memory for an additional 30 days.) After this time, the last-use ECG recordings will automatically be erased to prepare for a future use.

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

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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. The OnSite has no user-serviceable parts.

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, return the OnSite to Philips for service.

REMINDERS:

- Do not leave the OnSite without a SMART pads cartridge installed; the OnSite will start chirping and the i-button will start flashing. For directions on changing the pads cartridge, see Chapter 4, "After Using 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.

Record each periodic check in your inspection log/maintenance booklet.

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 your 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.

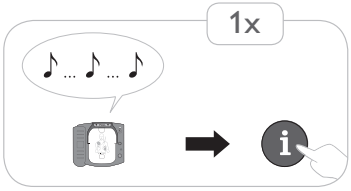
READY LIGHT TROUBLESHOOTING TIPS

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

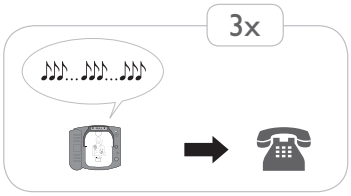
- If the Ready light is blinking: The OnSite has passed the battery insertion self-test and the last periodic self-test and is therefore ready for use.
- If the Ready light is solid: The OnSite is in use or running a self-test.
- If the Ready light is off, the OnSite is emitting a series of single chirps, 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, and the OnSite is emitting a series of triple chirps, please call Philips for technical support. See "Troubleshooting a chirping OnSite" on page 5-3 for more information.
- 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.

TROUBLESHOOTING A CHIRPING ONSITE

Your OnSite tests itself at regular intervals to ensure it is ready for use. If your OnSite emits a series of single chirps (♪... ♪... ♪...), press the blue i-button for information.



A triple-chirp alert (♪♪♪... ♪♪♪... ♪♪♪...) could mean that a potentially serious problem was detected during self-test that could prevent your OnSite from delivering therapy in an emergency. If you ever hear your OnSite emit a series of triple chirps:



- in stand-by mode — please call Philips immediately for technical support at the regional number listed on the back cover of this manual.
- in an emergency rescue — press the flashing blue i-button and follow the voice prompts. Removing and reinserting the battery can clear some errors and equip the device to deliver therapy in a rescue. The battery removal and reinsertion procedure should only be done in an emergency situation. Once the emergency is over, please call Philips immediately for technical support.

WARNING: Removing and reinserting the battery one or more times when an OnSite emits a series of triple chirps may reset the device and cause it to report it is ready for use, though it may be unable to deliver therapy during a rescue. Removing and reinserting the battery when your OnSite is emitting a pattern of triple chirps should only be done during an emergency. *If your device is emitting a series of triple chirps in stand-by mode, or after an emergency, please remove the* OnSite *from service and contact Philips immediately.*

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

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A ACCESSORIES FOR THE HEARTSTART ONSITE

Accessories* for the HeartStart OnSite Defibrillator available separately from your Philips representative or on-line at www.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]
  - Plastic waterproof hardshell carry case [REF: YC]
- Fast Response Kit (pouch containing a pocket mask, a disposable razor, two pairs of gloves, a pair of paramedic's scissors, and an absorbent wipe) [REF: 68-PCHAT]
- Cabinets and Wall Mounts
  - AED wall mount bracket [REF: 989803170891]
  - Basic surface-mounted cabinet [REF: 989803136531]
  - Premium surface-mounted cabinet [REF: PFE7024D]
  - Premium semi-recessed cabinet [REF: PFE7023D]
- AED Signage
  - AED awareness placard, red [REF: 989803170901]
  - AED awareness placard, green [REF: 989803170911]
  - AED Wall Sign, red [REF: 989803170921]
  - AED Wall Sign, green [REF: 989803170931]

* Certain accessories require a prescription in the United States.

- Data Management Software
  - HeartStart Configure version 3.1 or higher [REF: 861487]
  - HeartStart Event Review version 4.2.1
    - single PC license [REF: 861489 option A01]
    - organization-wide license [REF: 861489 option A02]
  - HeartStart Event Review Pro (version 5.0 most current release)
    - single PC license [REF: 861431 option A01]
    - organization-wide license [REF: 861431 option A03]
  - HeartStart Event Review Pro upgrade
    - single PC license [REF: 861436 option A01]
    - organization-wide license [REF: 861436 option A03]
  - HeartStart Data Messenger version 4.3 or higher
- Infrared cable for use with HeartStart Event Review software [REF: ACT-IR]
- Training
  - Adult Training Pads Cartridge [REF: M5073A]
  - Adult Training Replacement Pads [REF: M5093A]
  - Infant/Child Training Pads Cartridge [REF: M5074A]
  - Infant/Child Training Replacement Pads [REF: M5094A]

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 OnSite. 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 defibrillator.
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.
CPR	Cardiopulmonary resuscitation. A technique for providing artificial respiration and heart compressions.
CPR guidance	Basic verbal instructions for performing cardiopulmonary resuscitation, including hand placement, rescue breathing, compression depth and timing, provided by the OnSite when the flashing blue i-button is pressed during the first 30 seconds of a patient care pause.
defibrillation	Termination of cardiac fibrillation by applying electrical energy.
ECG	Electrocardiogram, a record of the electrical rhythm of the heart as detected through defibrillation pads.
fibrillation	A disturbance of the normal heart rhythm that results in chaotic, disorganized activity that cannot effectively pump blood. Ventricular fibrillation (fibrillation in the lower chambers of the heart) is associated with sudden cardiac arrest.

HeartStart Event Review	A suite of data management software applications for use by trained personnel to review and analyze OnSite patient use and by authorized personnel to alter OnSite configuration. Information is available from Philips Healthcare on the internet at www.philips.com/eventreview.
i-button	An "information" button on the front of the OnSite. If the i-button is pressed during the 30 seconds it flashes during a patient care pause, the OnSite provides CPR guidance;* if the i-button is pressed when it is flashing and the OnSite is chirping, the OnSite provides troubleshooting guidance. At other times, if the i-button is 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.
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.
NSA	"No Shock Advised," a decision made by the OnSite that a shock is not needed, based on analysis of the patient's heart rhythm.
NSA pause	A pause provided by the OnSite 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 monitoring of patient rhythm. During a SMART NSA pause, the defibrillator conducts background monitoring and, if it detects an artifact-free shockable rhythm, will exit the pause and begin rhythm analysis. If the OnSite detects artifact such as that created by CPR, or if the user presses the i-button for CPR guidance during a SMART NSA pause, the defibrillator will not exit the pause for rhythm analysis in order to allow CPR to be completed uninterrupted.
non-shockable rhythm	A heart rhythm that the OnSite determines is not appropriate for defibrillation.
On/Off button	A green button located on the front of the OnSite. Pressing the On/Off button when the defibrillator is in standby mode turns the defibrillator on; pressing and holding the On/Off button for one second when the OnSite is on turns the defibrillator off and disarms it. In addition, pressing the On/Off button stops the battery insertion self-test that automatically runs when a battery is inserted.
pads	See "SMART pads."
patient care pause	A defined pause to allow patient assessment, treatment, and/or CPR. See "NSA pause" and "protocol pause."

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

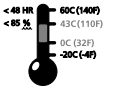
periodic self-tests	Daily, weekly, and monthly tests automatically conducted by the OnSite when it is in its standby mode. The tests monitor many key functions and parameters of the OnSite, including battery capacity, pads cartridge readiness, and the state of its internal circuitry.
protocol	A sequence of operations performed by the OnSite to direct patient care in the AED mode.
protocol pause	A pause provided by the OnSite after a shock series, during which the responder can administer CPR. 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 OnSite. A blinking Ready light means the OnSite is ready for use; a solid Ready light means the OnSite is being used.
rhythm analysis	See "SMART analysis."
Shock button	An orange button with a lightning bolt symbol on it, located on the front of the OnSite. The Shock button flashes when a shock is advised. You must press the button for the shock to be delivered.
shockable rhythm	A heart rhythm that the OnSite 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 OnSite to decide if the shocks are part of the same shock series.
SMART analysis	The proprietary algorithm used by the OnSite to analyze the patient's heart rhythm and determine whether the rhythm is shockable.
SMART biphasic waveform	The patented, low-energy defibrillation shock waveform used by the OnSite. 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 OnSite. 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 OnSite.
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)	Sudden cardiac arrest is the abrupt cessation of the heart's normal pumping of blood, frequently caused by an electrical malfunction in the heart. SCA results in a stoppage of blood flow, absent or abnormal breathing, and unconsciousness.
waveform	See "SMART biphasic waveform."

C GLOSSARY OF SYMBOLS/CONTROLS

symbol	description
	Pads cartridge handle. Green. Pulling the handle turns on the OnSite and opens pads cartridge for use.
	Refer to operating instructions.
	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). 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.

symbol	description
	Meets the requirements of the applicable European Directives, including RoHS Directive 2011/65/EU, The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment.
	Meets the requirements of the European Medical Device Directive 93/42/EEC. The four numerical digits indicate the identification number of the Notified Body involved in assessing the product's conformity with the directive.
	Device manufacturer.
	Indicates the AHA/ERC/ILCOR resuscitation Guidelines version for which the device is optimized (expressed as a year).
	Certified by the Canadian Standards Association.
	Reference order number.
	Authorized EU representative.
	Expiration date.
	Lithium manganese dioxide battery.
	One battery in package.
	Do not crush the battery.
	Do not expose the battery to high heat or open flames. Do not incinerate the battery.
	Do not mutilate the battery or open the battery case.

symbol	description
	Class 9 miscellaneous dangerous goods. (Symbol required on outer packaging by freight carrier regulations to identify shipments containing lithium batteries.)
	Install the battery in the defibrillator before the date (MM-YYYY) shown on the associated label.
	Needs to be protected from moisture.
	Handle with care.
	This side up.
	Transportation requirements (refer to associated thermometer symbol).
	Storage requirements (refer to associated thermometer symbol).
	Environmental requirements for transportation (black text) and storage (gray text).
	Environmental requirements.
	Relative humidity requirements.
	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 32° and 122° F (0° and 50° C).
	This product is not sterile.
	This product is not made with natural rubber latex.
	Pads indicated for use on infant or child under 8 years or 55 pounds (25 kg).
	Expiration (see associated date code).
	Serial number.
	Lot number.
Rx only	Federal law (USA) restricts this device to sale by or on the order of a physician.
	Do not use the HeartStart in a magnetic resonance environment.
	Wastes must be discarded in an environmentally sound manner in compliance with local regulations.
	Printed on recycled paper.
	Example of the Unique Device Identification (UDI) bar-code

D TECHNICAL INFORMATION

HEARTSTART ONSITE DEFIBRILLATOR SPECIFICATIONS

The specifications provided in the following tables are nominal values.

PHYSICAL

category	specifications
size	2.85 in H x 7.40 in D x 8.30 in W (7.2cm H x 19cm D x 21cm W).
weight	Approximately 3.3 pounds (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 (between uses with 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 (4,572 m); can be stored at up to 8,500 feet (2,591 m), in standby mode.
atmospheric pressure	Operates at 1013 hPa to 590 hPa; can be stored at up to 750 hPa, in standby mode.
shock/drop abuse tolerance	Withstands 3.3 foot (1 meter) drop to any edge, corner, or surface.
vibration	Operating: meets EN1789 random, road ambulance. Standby: meets EN1789 swept sine, road ambulance.

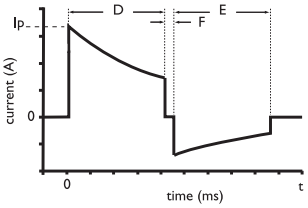
category	specifications
sealing	Meets IEC 60529 class IP21. Protected against access to hazardous parts with a finger and protected against ingress of solid foreign objects of 0.5 in (1.25 cm) diameter and greater per IEC 60529 class IP2x. Protected against a uniform flow of water drops over the defibrillator per IEC 60529 class IPxI.
ESD/EMI (radiated and immunity)	See Electromagnetic Conformity tables.

CONTROLS AND INDICATORS

category	specifications
controls	Green SMART Pads Cartridge handle Green On/Off button i-button (flashes blue) 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: flashes blue 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, D is the duration of phase 1 and E is the duration of phase 2 of the waveform, F is the interphase delay (500 µs), and Ip is the peak current.



The 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 (Ω)	phase 1 duration (ms)	phase 2 duration (ms)	peak current (A)	delivered energy (J)
25	2.8	2.8	55	128
50	4.5	4.5	32	150
75	6.3	5.0	23	155
100	8.0	5.3	18	157
125	9.7	6.4	14	159
150	11.5	7.7	12	160
175	12.0	8.0	11	158

pediatric defibrillation
(using M5072A infant/child SMART defibrillator pads)

load resistance (Ω	phase 1 duration (ms)	phase 2 duration (ms)	peak current (A)	delivered energy (J)
25	4.1	2.8	24	35
50	5.1	3.4	16	46
75	6.2	4.1	12	52
100	7.2	4.8	10	54
125	8.3	5.5	8	56
150	9.0	6.0	7	57
175	9.0	6.0	6	55

category	specifications
energy* (pediatric doses indicated are based on CDC growth charts for the 50th percentile weights.)	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, modified* November 21, 2000. Atlanta, GA: Centers for Disease Control and Prevention © 2000.
charge control	Controlled by Patient Analysis System for automated operation.
"charge complete" indicator	Shock button flashes, audio tone sounds.
shock-to-shock cycle time	<20 seconds, typical, including analysis.
patient care pause-to-shock time	Quick Shock. 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 SMART pads cartridge is disconnected from the OnSite, • the battery is removed or is completely depleted or • the impedance between pads is out of range.
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 the patient's 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 HeartStart 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 E, "Configuration."

ECG ANALYSIS PERFORMANCE

		meets AHA recommendations[b] for adult defibrillation	
rhythm class	ECG test sample[a] size	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%)
non-shockable rhythm — all other non-shockable rhythms[c]	450	specificity >95% (meets AAMI DF80 requirement)	(88%)

a. From Philips Medical Systems 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 in (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 in (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.

ENVIRONMENTAL CONSIDERATIONS

By complying with your national regulations regarding disposal of electric, electronic, and battery waste, you can make a positive contribution to our shared environment. Such waste can introduce harmful elements into the environment as a whole and may also endanger human health.

product	information
defibrillator	The OnSite contains electronic components. Do not dispose of it as unsorted municipal waste. Collect such electronic waste separately and dispose of it at an appropriate recycling facility according to your country's regulations.
battery	The battery cells contain chemicals. The chemistry used in each battery is identified by a symbol on the label; symbols are defined in the OnSite's User's Guide/Instructions for Use/Owner's Manual. Recycle the battery at an appropriate recycling facility.
pads	The used SMART pads may be contaminated with body tissue, fluid, or blood. Cut them off and dispose of them as infectious waste. Recycle the remaining cartridge components at an appropriate recycling facility in accordance with local regulations.

The Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), a European Union regulation, requires Philips Healthcare to provide chemical content information for Substances of Very High Concern (SVHC) if they are present above 0.1% of the article weight. The SVHC list is updated on a regular basis. Therefore, refer to the following Philips REACH website for the most up-to-date list of products containing SVHC above the threshold: http://www.philips.com/about/sustainability/REACH.page

E 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 software. This software is for use by trained personnel. Information about HeartStart data management products is available online at www.philips.com/eventreview.

DEVICE OPTIONS

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

parameter	settings	default	default description
speaker volume	1, 2, 3, 4, 5, 6, 7, 8	8	The volume of the OnSite's speaker is set to 8, highest.
auto send periodic self-test (PST) data	On, Off	On	Enables the periodic self-test data to be broadcast through the device's infrared data port.
ECG out data	On, Off	On	Enables the ECG data to be broadcast through the device's infrared data port.

PATIENT TREATMENT PROTOCOL OPTIONS

parameter	settings	default	default description
"call EMS" voice reminder timing	• At power on (when the user turns on the OnSite) • At power on and at the start of the first patient care pause • At the start of the first patient care pause • No reminder	At the start of the first patient care pause	Provides a voice reminder to make sure emergency medical services have been called, at the start of the first patient care pause.
shock series	1, 2, 3, 4	1	The automatic protocol pause for CPR is activated each time a shock is delivered.* During the protocol pause, the OnSite does not perform rhythm analysis. The length of the protocol pause after a shock series is completed is determined by the protocol pause timer 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. *NOTE: This parameter is only applicable when the shock series is not configured to the default 1 shock.*

* A shock series begins when a shock is delivered after the OnSite is turned on. A new shock series begins after a protocol pause. If shock series is configured for 2 or more, a new shock series also begins if the time since the previous shock exceeds the shock series interval setting.

parameter	settings	default	default description
protocol pause timer (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	2.0	A 2-minute protocol pause for CPR automatically starts after voice instruction is given when a shock series is completed. After the protocol pause, the OnSite returns to rhythm analysis. If the user presses the i-button for optional CPR guidance, the OnSite provides guidance for 5 cycles of CPR, starting and ending with compressions, when the CPR guidance parameters are also set to their default values. The number of CPR cycles varies for other protocol pause timer and CPR guidance parameter settings. *NOTE: Because the protocol pause ends upon completion of a CPR cycle in order to maximize the benefits of CPR, the actual duration of the pause may differ slightly from the timer setting.*
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. 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 OnSite detects CPR in progress or if the responder has pressed the i-button for CPR guidance, the SMART NSA pause will be converted to a standard NSA pause. During the standard NSA pause, the* OnSite *does not perform rhythm analysis.*

parameter	settings	default	default description
NSA pause timer (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	2.0	A 2-minute NSA pause for CPR automatically starts after voice instruction is given when no shock is advised (NSA).* If the user presses the i-button for optional CPR guidance, the OnSite provides guidance for 5 cycles of CPR, starting and ending with compressions, when the CPR guidance parameters are also set to their default values. The number of CPR cycles varies for other NSA pause timer and CPR guidance parameter settings. *NOTE: Because the NSA pause ends upon completion of a CPR cycle in order to maximize the benefits of CPR, the actual duration of the pause may differ slightly from the timer setting.*
CPR prompt	• CPR1: Instructs the user to begin CPR. • CPR2: Instructs the user that it is safe to touch the patient and to begin CPR. • CPR3: Instructs the user to begin CPR and to press the i-button for CPR guidance. • CPR4: Instructs the user that it is safe to touch the patient, to begin CPR, and to press the i-button for CPR guidance.	CPR4: Instructs the user that it is safe to touch the patient, to begin CPR, and to press the i-button for CPR guidance.	The CPR reminder voice instructions provided at the beginning of a pause interval assures the user that it is safe to touch the patient, instructs the user to begin CPR, and invites the user to press the i-button for guidance in the basic steps of CPR. *NOTE: CPR guidance is available only with the CPR3 and CPR4 settings.*

* If the shock series is configured to 2 or more, and a shock has been delivered as part of a series, the length of the first NSA pause within that shock series is determined by the protocol pause timer setting. Otherwise, the length of an NSA pause is determined by the NSA pause timer setting.

parameter	settings	default	default description
CPR guidance adult ventilation instruction	Yes, No	Yes	Optional CPR guidance includes rescue breaths at the rate determined by the CPR guidance compression:ventilation ratio for adults when an adult SMART pads cartridge is installed. *NOTE: if this parameter is configured to NO, CPR guidance will always be compressions-only when an adult* SMART *pads cartridge is installed.*
CPR guidance infant/child ventilation instruction	Yes, No	Yes	Optional CPR guidance includes rescue breaths at the rate determined by the CPR guidance compression:ventilation ratio for infants and children when an infant/child SMART pads cartridge is installed. *NOTE: if this parameter is configured to NO, CPR guidance will always be compressions-only when an infant/child pads* SMART *cartridge is installed.*
CPR guidance compression:ventilation ratio	• 30:2 adult and 30:2 infant/child • 30:2 adult and 15:2 infant/child • 15:2 adult and 15:2 infant/child	30:2 adult and 30:2 infant/child	If the user presses the i-button for optional CPR guidance during a protocol pause or NSA pause, the OnSite provides guidance in basic CPR for cycles of 30 compressions and 2 ventilations for adults, children, and infants. Pauses begin and end with compressions.

Intentionally blank.

F TESTING AND TROUBLESHOOTING

TESTING

As long as a battery is installed, the HeartStart OnSite Defibrillator automatically tests itself every day and alerts you if it finds a problem. The self-test includes pads readiness testing. In addition, it runs a pads self-test each time a SMART pads cartridge is inserted. It alerts you if it finds a problem.

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 OnSite 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 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 SMART pads cartridge has been removed. • The pads cartridge has been damaged.	Insert a new SMART 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 SMART 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 SMART 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 SMART pads cartridge.	Replace the damaged SMART 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 SMART 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)

NOTE: In the event of a triple-chirp alert, even if the failure is cleared by a battery insertion test, please contact Philips for service. In the event of repeated instances of a self-test failure resulting in single-chirp alerts, even if such failures are cleared by a battery insertion test, please contact Philips for service.

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 SMART pads cartridge installed, or the installed SMART pads cartridge may not have its hard cover in place. • The SMART 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 flashing blue i-button. Replace the battery or SMART pads cartridge if instructed. • Make sure the SMART pads cartridge is properly installed with the hard cover in place. (See Chapter 5, "Maintaining the HeartStart," for directions on installing the SMART pads cartridge.) • Remove the training pads cartridge and replace it with an adult or infant/child SMART 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.
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 defibrillator. Contact Philips for service.

G ADDITIONAL TECHNICAL INFORMATION REQUIRED FOR EUROPEAN CONFORMITY

ELECTROMAGNETIC CONFORMITY

Guidance and manufacturer's declaration: The HeartStart OnSite Defibrillator is intended for use in the electromagnetic environment specified in the tables below. The customer or user of the 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 industrial establishments, domestic establishments, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

ELECTROMAGNETIC IMMUNITY

The OnSite Defibrillator is intended for use in the electromagnetic environment specified below. The customer or user of the OnSite should assure that it is used in such an environment.

immunity test	IEC 60601 test level	compliance level	electromagnetic environment - guidance
electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 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	30 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.
conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[b]	3 Vrms	Recommended separation distance: $d = 1.20\ \sqrt{P}$ [c]
	10 Vrms 150 kHz to 80 MHz in ISM bands[b]	10 Vrms	$d = 1.20\ \sqrt{P}$ [c]

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 medical) bands between 150 kHz and 80 MHz are 6.77 MHz to 6.80 MHz; 13.55 MHz to 13.57 MHz; 26.96 MHz to 27.28 MHz; and 40.66 MHz to 40.70 MHz.

c. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

immunity test	IEC 60601 test level	compliance level	electromagnetic environment - guidance
radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	20 V/m	$d = 0.60\sqrt{P}$ 80 MHz to 800 MHz $d = 1.20\sqrt{P}$ 80 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[a] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[b] should be less than the compliance level in each frequency range.[c] 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. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

b. 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 HeartStart is used exceeds the applicable RF compliance level above, the HeartStart should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HeartStart.

c. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE ONSITE

The OnSite is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OnSite can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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)			
	150 kHz to 80 MHz outside ISM bands $d = 1.20\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.20\sqrt{P}$	80 MHz to 800 MHz $d = 0.60\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.15\sqrt{P}$
0.01	0.12	0.12	0.06	0.12
0.1	0.38	0.38	0.19	0.36
1	1.20	1.20	0.60	1.15
10	3.79	3.79	1.90	3.64
100	12.00	12.00	6.00	11.50

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 medical) bands between 150 kHz and 80 MHz are 6.77 MHz to 6.80 MHz; 13.55 MHz to 13.57 MHz; 26.96 MHz to 27.28 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.

IMPORTANT WARNINGS AND REMINDERS

- Do not allow the pads to contact other electrodes or metal parts that are in contact with the patient.
- Before delivering a shock, it is important to disconnect the patient from other medical electrical equipment, such as blood-flow meters, that may not incorporate defibrillation protections. In addition, make sure the pads are not in contact with metal objects such as a bedframe or stretcher.
- Check supplies, accessories, packaging, and spares for damage and expiration dating.

ENVIRONMENTAL CONSIDERATIONS

- The OnSite contains electronic components. Dispose of it at an appropriate recycling facility.
- The battery cells contain chemicals. Recycle the battery at an appropriate recycling facility.
- The used SMART pads may be contaminated. Cut them off and dispose of them properly. Recycle the remaining cartridge components at an appropriate recycling facility.

SHOCK CYCLE TIMING

The OnSite's Quick Shock feature allows it to deliver a shock within 8 seconds, typical, following the prompt ending a CPR Interval. From shock to shock, the OnSite takes <20 seconds, typical, including analysis. After 15 shocks, the OnSite takes <30 seconds from analyzing to ready-to-shock. After 200 shocks, the OnSite takes <40 seconds from initial power-on to ready-to-shock.

AIRCRAFT

The HeartStart OnSite has not been tested for use in an aircraft environment.

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