

HeartSine® samaritan® PAD

SAM 350P Semi-Automatic Defibrillator

SAM 360P Fully Automatic Defibrillator

SAM 450P Semi-Automatic Defibrillator



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Indications for Use

The HeartSine samaritan PAD SAM 350P (SAM 350P), HeartSine samaritan PAD SAM 360P (SAM 360P) and HeartSine samaritan PAD SAM 450P (SAM 450P) all have the identical indications for use. Each is indicated for use on victims of cardiac arrest who are exhibiting the the following signs:

- **Unconscious**
- **Not breathing**
- **Without circulation (without a pulse)**

The devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program.

The devices are indicated for use on patients greater than 8 years old or over 55 lbs/25 kg when used with the adult Pad-Pak™ (Pad-Pak-01 or Pad-Pak-07). They are indicated for use on children between 1 and 8 years of age or up to 55 lbs/25 kg when used with the Pediatric-Pak™ (Pad-Pak-02).

Contraindications for Use

If the patient is responsive or conscious, do not use the samaritan PAD to provide treatment.

Caution

U.S. Federal law restricts this device to sale by or on the order of a physician.

Warnings and Precautions

WARNINGS

Patients Suitable for Treatment

The samaritan PAD has been designed to work on unconscious, nonresponsive patients. If the patient is responsive or conscious, do not use the samaritan PAD to provide treatment.

The samaritan PAD uses an interchangeable battery and electrode pack called Pad-Pak. The samaritan PAD in combination with an adult Pad-Pak is suitable for use on patients of over 55 lbs (25 kg) in weight or equivalent to a child of approximately eight years old or over.

For use on smaller children (from 1 to 8 years old), remove the adult Pad-Pak and install a Pediatric-Pak. If a Pediatric-Pak or an alternative suitable defibrillator is not available, you may use an adult Pad-Pak.

If you treat a pediatric patient with an adult Pad-Pak, ignore any voice prompts regarding the rate of CPR. The SAM 450P CPR Rate Advisor is currently only intended to provide feedback on adult patients.

Do Not Delay Treatment

Do not delay treatment trying to find out the patient's exact age and weight.

Risk of Electric Shock

The samaritan PAD delivers therapeutic electrical shocks that can cause serious harm to either users or bystanders. Take care to ensure that no one touches the patient when a shock is to be delivered.

Do Not Open or Repair

The samaritan PAD has no serviceable parts. Do NOT open or repair the device under any circumstances as there could be danger of electric shock. If damage is suspected, immediately replace the samaritan PAD.

Avoid Explosive or Flammable Gases

The samaritan PAD is safe to use with oxygen mask delivery systems. However, to avoid the risk of an explosion, it is strongly advised that you do NOT use the samaritan PAD in the vicinity of explosive gases, including flammable anesthetics or concentrated oxygen.

Do Not Touch the Patient during Analysis

Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process. Avoid contact with the patient while the samaritan PAD is analyzing the patient. The device will instruct you when it is safe to touch the patient.

Warnings and Precautions *continued*

WARNINGS

Fully Automatic Defibrillator (SAM 360P)

The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention.

CPR Rate Advisor Function (SAM 450P)

The CPR Rate Advisor function is intended for use on adult patients only. If a Pediatric-Pak is used, the CPR Rate Advisor function is disabled. In this case, the rescuer is prompted to begin CPR in time with the metronome but receives no CPR Rate Advisor feedback.

PRECAUTIONS

Correct Placement of Electrode Pads

Proper placement of the samaritan PAD electrode pads is critical. You must strictly observe the instructions shown on pages 19-22 and on the device. Wrong placement or the presence of air, hair, surgical dressings or medicine patches between the pads and the skin could reduce defibrillation effectiveness. Slightly red skin after shock therapy is normal.

Do Not Use Electrode Pads if Pouch is Not Sealed

The Pad-Pak and Pediatric-Pak are single-use items which must be replaced after each use or if the pouch that seals the electrode pads has been broken or compromised in any way. If you suspect that the Pad-Pak or Pediatric-Pak is damaged, replace it immediately.

Susceptibility to Electromagnetic Interference

To safeguard against interference, operate the samaritan PAD at least 6 feet/2 meters away from all radio frequency devices. Alternatively, switch off the equipment causing the electromagnetic interference.

Temperature Range for Operation

The samaritan PAD, with its battery and electrodes, is designed to operate in the temperature range of 32°F to 122°F/0°C to 50°C. Use of the device outside of this range may cause the device to malfunction.

Ingress Protection

The samaritan PAD has an IP56 rating against dust and sprays of water. However, the IP56 rating does not cover the immersion of any part of the samaritan PAD in water or any type of fluid. Contact with fluids may seriously damage the device or cause fire or a shock hazard.

Prolonging Battery Life

Do not turn on the device unnecessarily as this may reduce the standby life of the device.

Standby storage outside the range of 32°F to 122°F/0°C to 50°C may decrease the shelf-life of the Pad-Pak.

Operator Training

The samaritan PAD is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support/AED, advanced life support, or a physician-authorized emergency medical response training program.

Use of Accessories

The samaritan PAD is a self-contained device. Do not use any unauthorized accessories with the device as the samaritan PAD may malfunction if non-approved accessories are used.

Regular Maintenance

Check the device periodically. See *Service and Maintenance* on page 27.

Correct Disposal of the Device

Dispose of the device in accordance with your national or local regulations, or contact your Authorized Distributor for assistance. Please follow the steps provided in *After Using the samaritan PAD* on page 25.

Compliance with Local Regulations

Check with the relevant local government health department for information about any requirements associated with ownership and use of a defibrillator in the region where it is to be used.

Overview

Sudden Cardiac Arrest

Sudden cardiac arrest (SCA) is a condition in which the heart suddenly stops pumping blood effectively due to a malfunction of the heart's electrical system. Often victims of SCA have no prior warning signs or symptoms. SCA also can occur in people with previously diagnosed heart conditions. Survival from SCA depends on immediate and effective cardiopulmonary resuscitation (CPR).

The use of an external defibrillator within the first few minutes of a collapse can greatly improve a patient's chance of survival. Heart attack and SCA are not the same, though sometimes a heart attack can lead to an SCA. If you are experiencing symptoms of a heart attack (chest pain, pressure, shortness of breath, tight feeling in the chest or elsewhere in the body), immediately seek medical attention.

Sinus Rhythm and Ventricular Fibrillation

The normal heart rhythm, known as sinus rhythm, creates electrical activity resulting in coordinated contraction of the heart muscle. This generates normal blood flow around the body.

Ventricular fibrillation (V-fib or VF) is a condition in which there is uncoordinated contraction of the heart muscle, making it quiver rather than contract properly. Ventricular fibrillation is the most commonly identified arrhythmia in SCA patients. In victims of SCA it is possible to re-establish normal

sinus rhythm by means of an electric shock across the heart. This treatment is called defibrillation.

Ventricular Tachycardia

Ventricular tachycardia (VT) is a type of tachycardia (rapid heartbeat) that arises from improper electrical activity of the heart. VT starts in the bottom chambers of the heart, called the ventricles. Although there are many different types of VT, this arrhythmia can be potentially life-threatening if the patient presents with no pulse and is unresponsive. If not treated with immediate defibrillation VT may lead to other arrhythmias.

Treatment by AED

It is a common misconception that CPR alone and calling emergency services is enough. CPR is a temporary measure that maintains blood flow and oxygen to the brain. CPR alone will not return a heart to a normal rhythm during VF or VT. The key to survival is defibrillation – and the sooner the better.

Defibrillation is a common treatment for life-threatening arrhythmias, mainly ventricular fibrillation. Defibrillation consists of delivering an electrical shock to the heart with a device called a defibrillator. This restores normal heart muscle contractions and allows normal sinus rhythm to be restored by the body's natural pacemaker in the heart.

The samaritan PAD uses the HeartSine samaritan ECG arrhythmia analysis algorithm. This algorithm will evaluate the patient's ECG to ascertain if a therapeutic shock is appropriate. If a shock is required, the samaritan PAD will charge and advise the user to press the shock button (SAM 350P/450P) or will automatically deliver a shock (SAM 360P). If no shock is advised, the device will pause to allow the user to deliver CPR.

It is important to note that cardiac defibrillators, like the HeartSine samaritan PAD, will not administer a shock unless a lifesaving shock is required.



Introduction

This manual provides instructions for the following models of the HeartSine samaritan PAD:

samaritan PAD 350P (SAM 350P)

samaritan PAD 360P (SAM 360P)

samaritan PAD 450P (SAM 450P)

About the samaritan PAD

The samaritan PAD family of AEDs is designed to quickly deliver a defibrillation shock to victims of sudden cardiac arrest (SCA). Each samaritan PAD is designed to operate in accordance with the current joint American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines on Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC).

While all of the samaritan PAD models are very similar in use, there are distinct differences between the models as shown in Table 1 below.

The SAM 350P is a semi-automatic defibrillator, the SAM 360P is a fully automatic defibrillator, and the SAM 450P is a semi-automatic defibrillator with integrated CPR Rate Advisor™.



WARNING: The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention.

CPR Metronome

When the samaritan PAD instructs you to perform CPR, you will hear an audible beep and see the Safe to Touch indicator flash at a rate compliant with 2015 AHA/ERC guidelines. This feature, referred to as the CPR metronome, will guide you to the rate at which to compress a patient's chest during CPR.

CPR Rate Advisor

When providing CPR treatment to a victim of sudden cardiac arrest, it is vital the chest compressions are


Table 1. samaritan PAD AEDs

	SAM 350P	SAM 360P	SAM 450P
Shock delivery	Semi-Automatic	Fully Automatic	Semi-Automatic
Four-year electrode and battery life	✓	✓	✓
Audible and visual indicators	✓	✓	✓
CPR coaching with metronome	✓	✓	✓
CPR Rate Advisor			✓
Pediatric use-compatible (with Pediatric Pad-Pak)	✓	✓	✓

of a good quality. If the quality of the CPR provided is good, the chances of successfully resuscitating a patient are greatly increased.

Research has demonstrated that non-professional responders regularly provide ineffective CPR due to inexperience.

The SAM 450P with CPR Rate Advisor provides feedback to the rescuers on the rate of the CPR they are providing to the victim. The SAM 450P uses impedance cardiogram measurements to analyze the speed of compressions and provide the user with instructions to push faster or push slower or to continue to provide compressions at a good speed according to the AHA resuscitation guidelines. The SAM 450P uses both audible and visual feedback to give the responder instruction on CPR rate. Refer to *Technical Data* in Appendix C on page C-7.

 **WARNING: The CPR Rate Advisor function is intended for use on adult patients only. If a Pediatric-Pak is used, the CPR function is disabled. In this case, the rescuer is prompted to begin CPR in time with the metronome but receives no CPR Rate Advisor feedback.**

Recommended Training

SCA is a condition requiring immediate emergency medical intervention. Due to the nature of the condition, this intervention can be performed before seeking the advice of a physician.

The samaritan PAD is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support/AED, advanced life support, or a physician-authorized emergency medical response training program. HeartSine Technologies also recommends that this training be kept up to date by regular refresher courses as and when recommended by your training provider.

If potential users of the samaritan PAD are not trained in these techniques, contact your Authorized Distributor or HeartSine Technologies directly. Either can arrange for training to be provided. Alternatively contact your local government health department for information on certified training organizations in your area.

Safety and Effectiveness Data

Please refer to Appendix E for the potential risks associated with the use of an AED and a summary of SAM 350P, SAM 360P and SAM 450P safety and effectiveness data.

Introduction *continued*

SAM 350P Layout

Data Port

Plug the custom USB cable into this port to download event data from the AED. (See Figure 8, page 24.)

Shock Button

Press this button to deliver a therapeutic shock.

Adult and Pediatric Symbols

Indicates that the SAM 350P is compatible with both the Pad-Pak and Pediatric-Pak.

Do Not Touch Icon/Action Arrows

Do not touch the patient when the action arrows above this icon are flashing. The SAM 350P may be analyzing the patient's heart rhythm or about to charge, in preparation to deliver a shock.

Attach Pads Icon/Action Arrows

Attach the electrode pads to the patient's bare chest as indicated when the action arrows are flashing.

Status Indicator

The SAM 350P is ready for use when this indicator is flashing green.

Safe to Touch Icon/Action Arrows

You may touch the patient when the action arrows around this icon are flashing.

On/Off button

Press this button to turn on or turn off the device.

Speaker

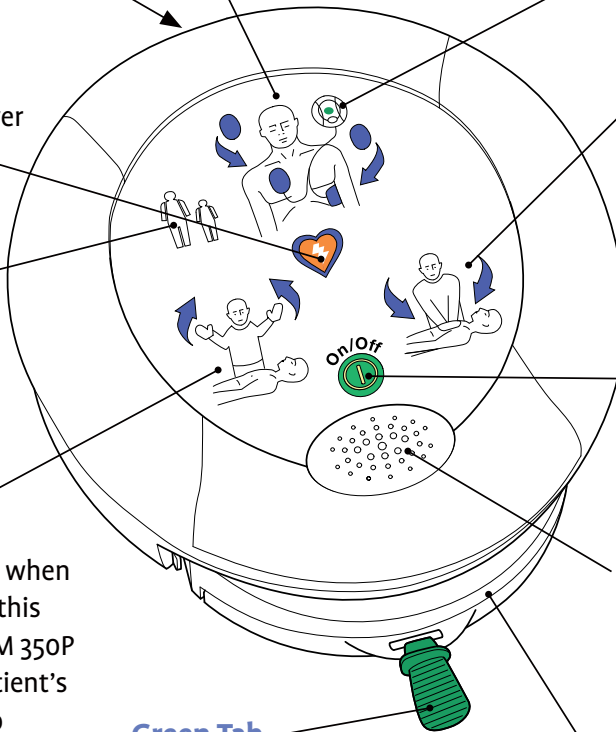
Listen for the metronome and verbal prompts.

Green Tab

Pull this tab to release the electrodes.

Pad-Pak

Contains the battery and electrode pads.



SAM 360P Layout

Data Port

Plug the custom USB cable into this port to download event data from the AED. (See Figure 8, page 24.)

Shock Icon

Flashes to indicate a shock will be delivered.

Adult and Pediatric Symbols

Indicates that the SAM 360P is compatible with both the Pad-Pak and Pediatric-Pak.

Do Not Touch Icon/Action Arrows

Do not touch the patient when the action arrows above this icon are flashing. The SAM 360P may be analyzing the patient's heart rhythm or about to charge, in preparation to deliver a shock.

Attach Pads Icon/Action Arrows

Attach the electrode pads to the patient's bare chest as indicated when the action arrows are flashing.

Status Indicator

The SAM 360P is ready for use when this indicator is flashing green.

Safe to Touch Icon/Action Arrows

You may touch the patient when the action arrows around this icon are flashing.

On/Off button

Press this button to turn on or turn off the device.

Speaker

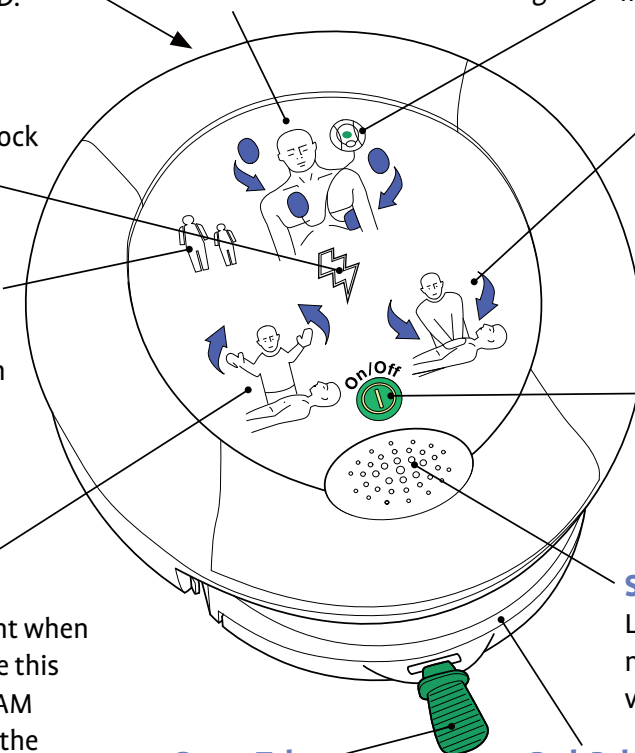
Listen for the metronome and verbal prompts.

Green Tab

Pull this tab to release the electrodes.

Pad-Pak

Contains the battery and electrode pads.



Introduction *continued*

SAM 450P Layout

Data Port

Plug the custom USB cable into this port to download event data from the AED. (See Figure 8, page 24.)

Shock Button

Press this button to deliver a therapeutic shock.

Adult and Pediatric Symbols

Indicates that the SAM 450P is compatible with both the Pad-Pak and Pediatric-Pak.

CPR Rate Advisor Icon

Provides visual feedback about the rate of chest compressions during CPR.

Safe to Touch Icon/Action Arrows

You may touch the patient when the action arrows around this icon are flashing.

Attach Pads Icon/Action Arrows

Attach the electrode pads to the patient's bare chest as indicated when the action arrows are flashing.

Status Indicator

The SAM 450P is ready for use when this indicator is flashing green.

Do Not Touch Icon/Action Arrows

Do not touch the patient when the action arrows above this icon are flashing. The SAM 450P may be analyzing the patient's heart rhythm or about to charge, in preparation to deliver a shock.

On/Off button

Press this button to turn on or turn off the device.

Pad-Pak

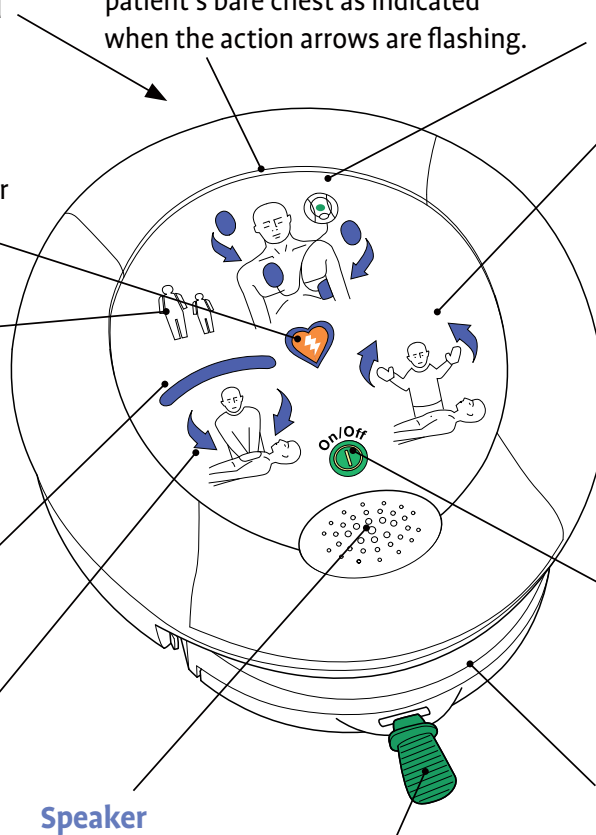
Contains the battery and electrode pads.

Speaker

Listen for the metronome and verbal prompts.

Green Tab

Pull this tab to release the electrodes.



Set-up

Unpacking

Verify that the contents include the samaritan PAD, carry case, Pad-Pak, User Manual, Warranty Statement and Warranty Card.

Pad-Pak

A Pad-Pak is a single-use removable cartridge that includes the battery and electrode pads in a single unit. The Pad-Pak is available in two versions:

1. Pad-Pak (gray color shown in Figure 1) for use on patients weighing over 55 lbs/25 kg, or equivalent to a child of approximately eight years of age or older.
2. The optional Pediatric-Pak (pink color shown in Figure 2) for use on smaller children (from 1 to 8 years old and weighing under 55 lbs/25 kg).

! WARNING: Do not delay treatment trying to determine the patient's exact age and weight.

¹The Pad-Pak also is available in a TSO-certified version for use on aircraft.

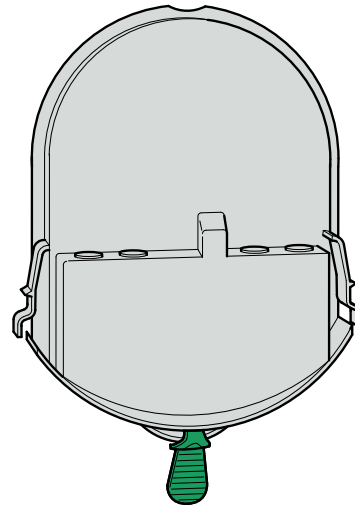


Figure 1. Adult Pad-Pak

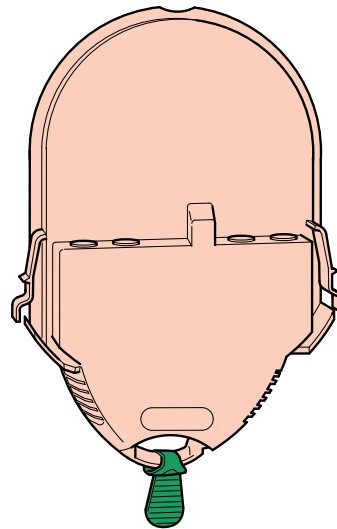


Figure 2. Pediatric-Pak

Set-up *continued*

Putting the samaritan PAD into Service

Follow these steps to place your samaritan PAD into service:

1. Check the expiration date (year-month-day) on the rear of the Pad-Pak (see Figure 3). If the expiration date has passed, do not use and immediately replace the expired Pad-Pak.

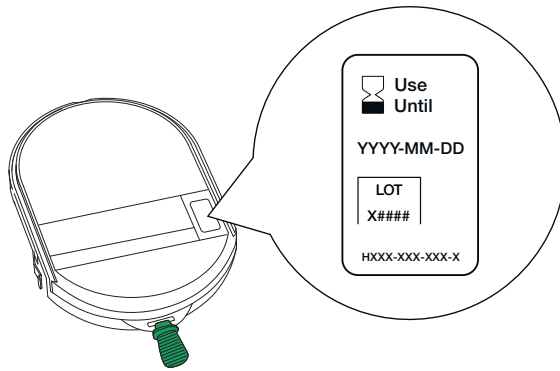


Figure 3. Expiration Date

2. Unpack the Pad-Pak and retain the packaging in case you need to return the Pad-Pak to HeartSine Technologies.
3. Place the samaritan PAD face up on a flat surface and slide the Pad-Pak into the samaritan PAD (see Figure 4) until you hear the “double click” to indicate that the tabs on the right and left sides of the Pad-Pak are fully engaged.

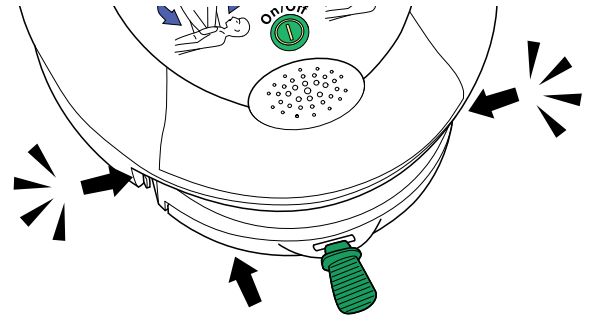





Figure 4. Inserting a Pad-Pak

4. Verify that the green Status indicator (see the layout for your model on pages 10-12) is blinking to indicate the initial self-test routine has been performed and the device is ready for use.
5. Press the On/Off Button  to turn on the samaritan PAD. Listen for, but do not follow, the voice prompts to ensure that no warning messages are played.

 **PRECAUTION:** Do NOT pull the green tab on the Pad-Pak at this time. If you have pulled the tab and opened the electrode drawer, you may need to replace your Pad-Pak.

Only turn on the samaritan PAD ONCE. If you turn it on and off repeatedly, you will deplete the batteries prematurely and may need to replace the Pad-Pak.

6. Press the On/Off Button  to turn off the samaritan PAD. Verify that the Status Indicator is flashing green. If you have not heard a warning message and the Status Indicator continues to flash green, the device is ready for use.
7. Place the samaritan PAD in its supplied soft carry case. Store the samaritan PAD where it will be seen and heard in an unobstructed, secure location in a clean, dry environment. Be sure to store the device according to the environmental specifications (see *Technical Data* in Appendix C on page C-1).



PRECAUTION: HeartSine Technologies recommends that you store a spare Pad-Pak with your samaritan PAD in the rear section of the soft carry case.

8. Register online, or complete the Warranty Card and return it to your Authorized Distributor or HeartSine Technologies directly (see *Tracking Requirements* on page 26).
9. Create a service schedule (see *Service and Maintenance* on page 27).

Preparation Checklist

Following is a checklist of the steps required to set up your samaritan PAD:

- Step 1. Check the Pad-Pak expiration date.
- Step 2. Install the Pad-Pak and check for a green status indicator.
- Step 3. Turn on the samaritan PAD to check operation.
- Step 4. Turn off the samaritan PAD.
- Step 5. Store the samaritan PAD in a clean, dry environment at 32°F to 122°F/0°C to 50°C.
- Step 6. Register your samaritan PAD.
- Step 7. Create a service schedule. (See *Service and Maintenance* on page 27.)

Using the samaritan PAD

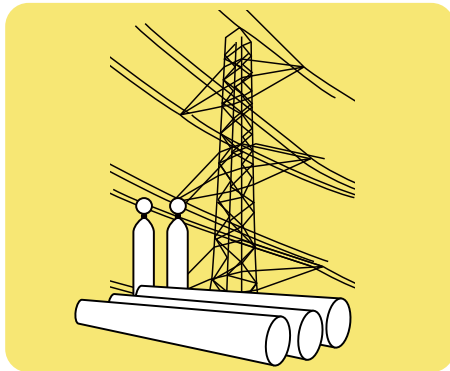
Using the samaritan PAD

Follow these steps to use your AED, which will provide you with step-by-step voice prompts. For a full list of voice prompts for your device see *Voice Prompts* in Appendix D.



PRECAUTION: Once a non-shockable rhythm is detected, the samaritan PAD will end its ready to shock condition if it had previously decided to shock.

1. If necessary, move the patient to a safe location, or remove any source of danger.



**REMOVE
DANGER**



PRECAUTION: You must use the samaritan PAD at least 6 feet/2 meters from all radio frequency devices, or switch off any equipment causing electromagnetic interference.

2. If the patient is non-responsive, shake the patient by the shoulders while speaking loudly. If the patient becomes responsive, do not use the AED.



**CHECK
FOR A
RESPONSE**

3. Check that the patient's airway is not blocked, using a head-chin tilt if necessary.



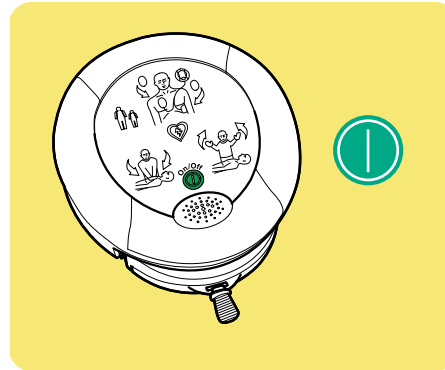
**CHECK
FOR
AIRWAY**

4. Call for medical assistance.
5. Retrieve the AED, asking others nearby to do so.
6. While waiting for the AED, begin CPR, pushing hard and fast at a rate of between 100 and 120 compressions per minute (cpm) and a depth of 5 to 6 cm. If you feel able to give rescue breaths perform 30 compressions followed by two rescue breaths.



**PERFORM
CPR**

7. Press the On/Off Button  to turn on the AED.



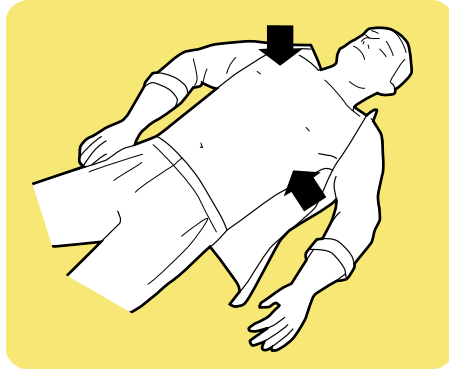
**TURN ON
THE AED**

8. Defibrillation therapy is tailored depending on whether a Pad-Pak or Pediatric-Pak is installed. If the patient is under 55 lbs/25 kg or 8 years of age, remove the Pad-Pak, insert a Pediatric-Pak and press the On/Off button again (see *Pediatric-Pak* on page 21). If a Pediatric-Pak is not available, you may use the Pad-Pak.



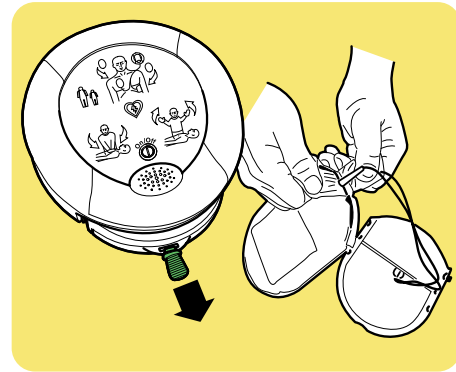
Using the samaritan PAD *continued*

9. Remove clothing from patient's chest to expose bare skin, removing any metal (bras or jewelry) where possible from the pad placement area.



**BARE THE
CHEST
AREA**

12. Tear open the pouch to remove the electrode pads.



**OPEN
THE
ELECTRODE
POUCH**

10. Dry the patient's chest if wet or clammy, and if a lot of chest hair is present, shave the patient's chest where the electrodes will be placed.
11. Pull the green tab to remove the electrode pad pouch from the AED.



13. Peel the liner from each electrode pad and apply each electrode pad firmly to the patient's bare chest. For a patient over 8 years of age or weighing over 55 lbs/25 kg, place one electrode pad horizontally on the right chest, and the other vertically on the left rib cage. For a patient under 8 years of age or weighing less than 55 lbs/25 kg, you can place one electrode pad on the center of the chest and the other on the center of the back. Refer to pages 21-22 for detailed instructions for electrode pad placement.

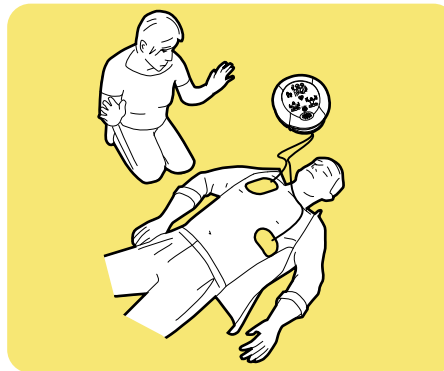


**PLACE
THE
ELECTRODE
PADS**

14. If you again hear the prompt to apply pads firmly to patient's bare chest, check that the:

- ***Pads are placed correctly as per pad placement shown.***
- ***Pads are not touching and at least 2.5 cm apart.***
- ***Entire surface of each pad is adhered to bare skin. If the chest is hairy, shave the chest; if the chest is wet, dry the chest.***
- ***Ensure the Pad-Pak has not expired, and is correctly inserted into the device.***

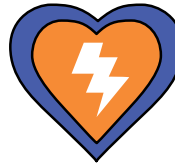
15. When prompted, ensure that you are not touching the patient.



**DO NOT
TOUCH
THE
PATIENT**

Using the samaritan PAD *continued*

16. When advised that a shockable rhythm is detected, stand clear of patient as directed. When advised to do so, press the orange shock button (SAM 350P/SAM 450P) to deliver a shock, or if using a SAM 360P, the AED will automatically deliver the shock after a verbal 3, 2, 1 countdown.



17. When advised that a shockable rhythm is not detected, begin CPR. To do so, place overlapping hands in the middle of the patient's chest and, with straight arms, press firmly and quickly in time with the metronome. Continue to perform CPR until the AED begins to analyze the patient's heart rhythm again.

When using the SAM 450P, follow the CPR Rate Advisor voice prompts. Refer to CPR Rate Advisor on page C-7 for more information.

18. Repeat the process from step 15 until emergency services arrive.
19. When emergency services arrive, press the On/Off button to turn off the AED and remove the electrode pads.



Treating Small Children and Infants

The Pediatric-Pak is intended to provide therapy for pediatric (child) victims of SCA between the ages of 1 and 8 years old or weighing less than 55 lbs/25 kg who are:

- **Unconscious**
- **Not breathing**
- **Without circulation (without a pulse)**

! WARNING: The Pediatric-Pak contains a magnetic component (surface strength 6500 gauss). Avoid storage next to magnetically-sensitive storage media.

! WARNING: Not for use on patients under one year old. For use with children up to the age of 8 years or up to 55 lbs/25 kg. **DO NOT DELAY THERAPY IF YOU ARE UNSURE OF THE EXACT AGE OR WEIGHT.**

Electrode Placement

For pediatric patients there are two options for electrode placement: anterior-posterior and anterior-lateral.

ANTERIOR-POSTERIOR PLACEMENT

If a child's chest is small it may be necessary to place one electrode pad in the centre of the child's BARE chest (anterior), and the other electrode pad in the center of the ribcage on the child's BARE back (posterior) as shown in Figure 5.

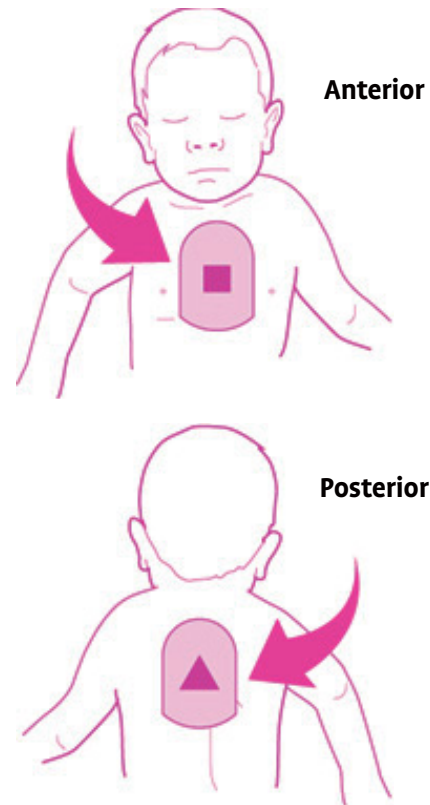


Figure 5. Anterior/Posterior Placement

Pediatric-Pak *continued*

ANTERIOR-LATERAL PLACEMENT

If a child's chest is large enough to permit a 1 in/2.5 cm gap between the electrode pads, OR if trauma does not allow for placement on the back, the pads can be placed according to the adult anterior-lateral placement. Place one electrode pad on the child's BARE upper right chest above nipple and one electrode pad on child's BARE lower left ribcage below nipple as shown in Figure 6.

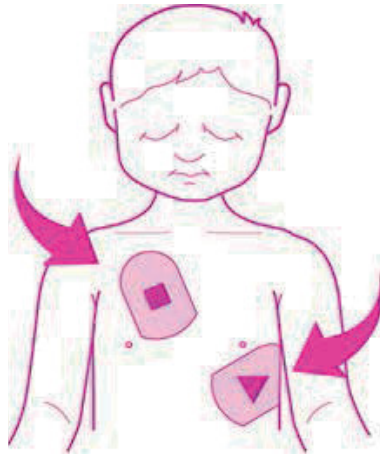


Figure 6. Anterior-Lateral Placement

! **WARNING:** Electrode pads must be at least 1 in/2.5 cm apart and should never touch one another.



After Using the samaritan PAD

Cleaning the samaritan PAD

1. Remove the electrode pads from the patient and stick the pads together face to face. The electrodes may be contaminated with human bodily tissue, fluid or blood so dispose of the electrodes separately as infectious waste material.
2. The Pad-Pak is a single-use item that contains lithium batteries. Replace the Pad-Pak after each use. With the samaritan PAD placed face up on a flat surface, squeeze the two tabs on the sides of the Pad-Pak and pull to remove it from the samaritan PAD. The Pad-Pak will slide forward (see Figure 7).

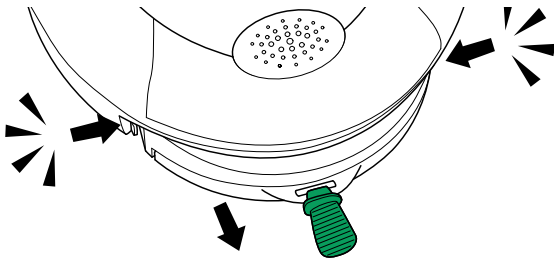


Figure 7. Removing the Pad-Pak

3. Check the samaritan PAD for dirt or contamination. If necessary, clean the device using a soft cloth dampened by one of the following:

- **Soapy water**
- **Isopropyl alcohol (70% solution)**

⚠ PRECAUTION: Do not immerse any part of the samaritan PAD in water or any type of fluid. Contact with fluids may seriously damage the device or cause a fire or a shock hazard.

⚠ PRECAUTION: Do not clean the samaritan PAD with abrasive materials, cleaners or solvents.

4. Check the samaritan PAD for damage. If the device is damaged, replace it immediately.
5. Install a new Pad-Pak. Before installing the Pad-Pak, check the expiration date (see *Set-up* on page 14). After installation, confirm that the Status Indicator is blinking green.
6. Report the use of the samaritan PAD to HeartSine Technologies or your Authorized Distributor. (See back cover for contact details.)

After using the samaritan PAD *continued*

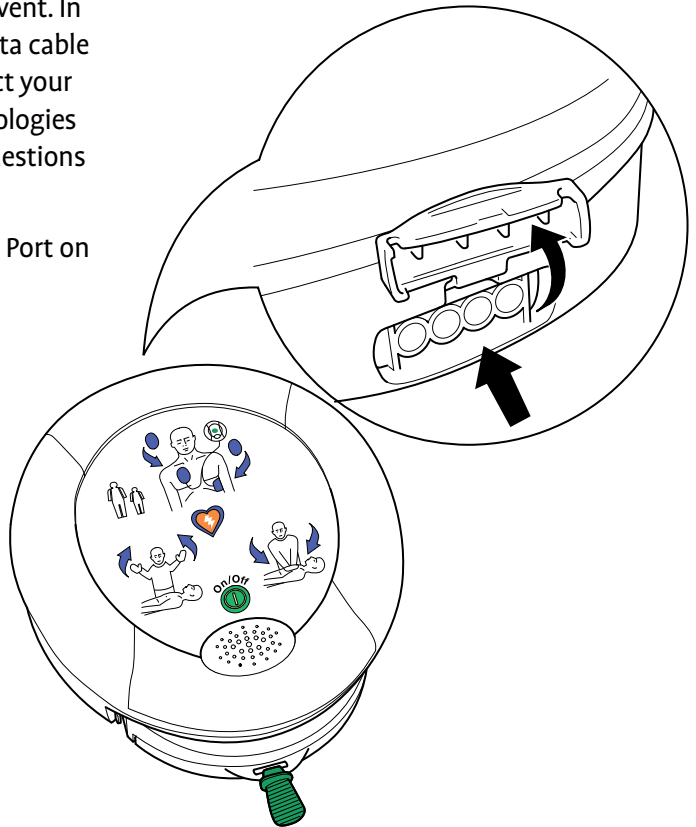
Downloading and Submitting Event Information

The optional HeartSine Saver EVO™ software can be downloaded at no charge from heartsine website.

This software lets you manage the events in which your samaritan PAD was used. You can provide this data to a patient's doctor, and/or use it to obtain a Pad-Pak if you have a qualifying event. In addition to Saver EVO, the optional USB data cable is required to download event data. Contact your Authorized Distributor or HeartSine Technologies directly to obtain the data cable or with questions about downloading and using Saver EVO.

1. Connect the USB data cable to the Data Port on the samaritan PAD (see Figure 8).

Figure 8. USB Data Port



2. Connect the USB connector on the data cable to a PC.
3. Install and launch the HeartSine Saver EVO software.
4. Follow the instructions provided in the Saver EVO manual to save or erase the event data on your samaritan PAD.
5. Upload the Saver EVO file on the HeartSine Technologies site.

For further information on managing the event data on your samaritan PAD, contact your Authorized Distributor or HeartSine Technologies directly.

Disposal

The Pad-Pak and Pediatric-Pak contain lithium batteries and cannot be disposed of in normal waste. Dispose of each at an appropriate recycling facility according to your local requirements. Alternatively return the Pad-Pak or Pediatric-Pak to your Authorized Distributor for disposal or replacement.

Tracking

Tracking Requirements

Medical device regulations require HeartSine Technologies to track the location of each samaritan PAD AED, Pad-Pak, and Pediatric-Pak sold.

Service and Maintenance

HeartSine Technologies recommends users perform regular maintenance checks, which include the following:

WEEKLY

- Check the Status Indicator. The samaritan PAD performs a self-test routine at midnight GMT every Sunday. During this self-test the status light blinks red but returns to green upon successful completion of the self-test routine. If the Status Indicator is not flashing green every 5 to 10 seconds or if the status indicator is flashing red or you hear continuous beeping, a problem has been detected. (See Figures 9-11, and *Troubleshooting* in Appendix B on page B-1.)

MONTHLY

- If the device shows any signs of physical damage, contact your Authorized Distributor or HeartSine Technologies directly.
- Check the expiration date of the Pad-Pak (see *Set-up* on page 14 for the location of the date). If the date has expired, or is near expiration, immediately replace the Pad-Pak or contact your Authorized Distributor for a replacement.
- If you hear a warning message when you turn on your samaritan PAD or if, for any reason, you suspect that your samaritan PAD is not working properly, consult *Troubleshooting* in Appendix B.

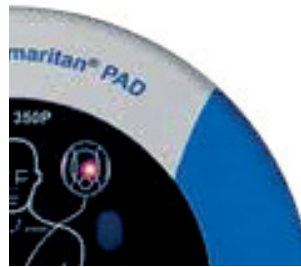


Figure 9.
Flashing red light
and/or beeping; See
Troubleshooting in
Appendix B.



Figure 10.
Flashing green LED;
no action required.



Figure 11.
No status
indicator light; See
Troubleshooting in
Appendix B.

Testing with Simulators and Manikins

HeartSine devices cannot be tested using industry-standard simulators and manikins. Therefore, to test the samaritan PAD with a simulator or manikin, contact HeartSine Technologies or your Authorized Distributor for assistance.

Appendices

APPENDIX A Symbols

Symbols Used in This Manual



WARNING: Risk of death or serious injury



PRECAUTION: Risk of injury

Symbols Used on the samaritan PAD



On/Off

IP56

Ingress protection classified as IP56 according to EN 60529



Consult operating instructions



Single use item; do not re-use



Defibrillation protected, Type BF connection



Do not incinerate or expose to high heat or open flame



Does not contain natural rubber latex



Non-sterile



A-Recyclable



Non-rechargeable battery



Do not short circuit battery



Do not crush battery



Temperature limitation as indicated



Expiration date for Pad-Pak;
yyyy-mm-dd



Dispose of in accordance with country requirements

Automated External Defibrillator

With respect to electrical shock, fire and mechanical hazards only in accordance with:



- ANSI/AAMI ES60601-1:2005
- CSA C22.2 NO. 60601-1:2008
- IEC60601-2-4:2010







Follow instructions for use



Serial number; For example
“yyB01234567”
where yy = year of manufacture

APPENDIX B Troubleshooting

<p>Flashing Red Status Indicator/ Continual Beeping, or No Status Indicator Light is Lit</p>	<p>Check the expiration date on your Pad-Pak (see <i>Set-up</i> on page 14). If the expiration date has passed, immediately replace the Pad-Pak. If the expiration date has not passed, press the On/Off Button  on the face to turn on the samaritan PAD and listen for the voice prompt “Call for medical assistance”. Then press the On/Off Button  again to turn off the device. If either of these actions do not correct the problem, contact your Authorized Distributor or HeartSine Technologies immediately.</p>
<p>“Low Battery” Warning</p>	<p>While this message does not indicate a fault, you should replace the battery as soon as possible.</p> <p>The first time you hear the message “Warning low battery,” the device will continue to function properly. However, it may have fewer than 10 shocks left so prepare the spare Pad-Pak for use and be prepared to swap it quickly. Order a new Pad-Pak as soon as possible.</p>
<p>“Memory Full” Prompt</p>	<p>This message does not indicate a fault. The memory is full and can no longer record ECG data or events. However, the device can still analyze and deliver a shock if required. Contact HeartSine Technologies Technical Support for guidance on how to clear the memory.</p>
<p>Three Rapid Beeps When Device Is Turned Off or After Weekly Self-Test Has Been Performed</p>	<p>Your device has sensed that the ambient temperature is outside the specified operating range. Return your device to the specified operating conditions of 32°F to 122°F/0°C to 50°C, in which your device, with its battery and electrodes is designed to operate, and verify that the beeping has stopped.</p>

<p>Red Status Indicator and Beeping While Device is On</p>	<p> Warning: There is insufficient battery capacity to deliver a shock. Immediately replace the Pad-Pak or seek an alternative defibrillator. If a spare Pad-Pak or alternative defibrillator is not available, the device will continue to analyze the patient’s heart rhythm and advise when CPR is needed, but it will not be able to deliver a shock.</p>
<p>“Device service required” Warning</p>	<p> Warning: If you hear this message during use, seek an alternative defibrillator immediately.</p> <p>Do not attempt to service the device as no modification of this equipment is possible. Contact HeartSine Technologies or your Authorized Distributor immediately.</p>
<p>“You have pressed the off button” Warning</p>	<p>You have pressed the On/Off button while the AED is being used to treat a patient. If you are sure you want to turn off the AED, quickly press On/Off again.</p>
<p>“Disarming” Prompt</p>	<p>This message does not indicate a fault; rather it means that the AED has converted to a decision to not shock after it has initially decided to shock. This occurs when your AED has initially determined that the patient’s rhythm is shockable (such as VF) and upon confirming the decision (before proceeding with a shock), the rhythm changed or interference (due to CPR) prevents the confirmation. Continue to follow the device prompts.</p>

APPENDIX B Troubleshooting *continued*

Warranty Exclusion

HeartSine Technologies or its Authorized Distributors are not obliged to replace or repair under warranty if one or more of the following conditions apply:

- Device has been opened.
- Unauthorized modifications have been made.
- Device has not been used in accordance with the instructions provided in this manual.
- Serial number has been removed, defaced, altered or, by any other means, made unreadable.
- Device has been used or stored outside its indicated temperature range.
- The Pad-Pak or Pediatric-Pak is not returned in its original packaging.
- Device has been tested using unapproved methods or inappropriate equipment (see *Warnings and Precautions* on pages 3-5).

APPENDIX C Technical Data

Physical Specifications (with Pad-Pak installed)

Size: 8.0 in x 7.25 in x 1.9 in/20 cm x 18.4 cm x 4.8 cm
Weight: 2.4 lbs/1.1 kg

Environmental Specifications

Operating temperature: 32°F to 122°F/0°C to 50°C
Standby temperature: 32°F to 122°F/0°C to 50°C
Transport temperature: 14°F to 122°F/-10°C to 50°C for up to two days. If the device has been stored below 32°F/0°C, it should be returned to an ambient temperature of between 32°F to 122°F/0°C to 50°C for at least 24 hours before use.
Relative humidity: 5% to 95% (non-condensing)
Enclosure: IEC/EN 60529 IP56
Altitude: 0 to 15,000 feet/0 to 4,575 meters
Shock: MIL STD 810F Method 516.5, Procedure 1 (40G's)
Vibration: MIL STD 810F Method 514.5+ Procedure 1
Category 4 Truck Transportation – US Highways
Category 7 Aircraft – Jet 737 & General Aviation

APPENDIX C Technical Data *continued*

Pad-Pak and Pediatric-Pak Specifications

Weight:	0.44 lbs/0.2 kg
Battery type:	Disposable single-use combined battery and defibrillation electrode cartridge (lithium manganese dioxide (LiMnO ₂) 18V)
Battery capacity (new):	>60 shocks at 200J or 6 hours of continuous monitoring
Battery capacity (4 years):	> 10 shocks at 200 J
Electrode type:	Single-use pre-attached combined ECG sensor/defibrillation pad
Electrode placement:	
Adult:	Anterior-lateral
Pediatric:	Anterior-posterior or anterior-lateral
Electrode active area:	15 in ² /100 cm ²
Electrode cable length:	3.3 feet/1 m
Shelf life/Standby life:	See the expiration date on the Pad-Pak/Pediatric-Pak
Aircraft Safety Test (TSO-Certified Pad-Pak):	RTCA DO-227 (ETSO-C142a)

Patient Analysis System

Method:	Evaluates the patient's ECG, signal quality, electrode contact integrity and patient impedance to determine if defibrillation is required
Sensitivity/Specificity:	Meets IEC/EN 60601-2-4 (Refer to page C-6 for sensitivity/specificity data.)

User Interface

Visual prompts:	Adult and Pediatric Symbols, Do Not Touch Icon/Action Arrows, Safe to Touch Icon/Action Arrows, Status Indicator, Attach Pads Icon/Action Arrows, CPR Rate Advisor Indicator (SAM 450P only)
Audible prompts:	Extensive voice prompts guide the user through the operation sequence (see <i>Voice Prompts</i> in Appendix D)
Languages:	samaritan PAD is available in English and Spanish. Contact your HeartSine Authorized Distributor.
Controls:	On/Off Button (all models), Shock Button (SAM 350P and 450P only) and Green Tab

Defibrillator Performance

Charging time:	Typically 150J in < 8 seconds, 200J in < 12 seconds
Time to shock delivery following CPR:	
SAM 350P:	Typically 8 seconds
SAM 360P:	Typically 19 seconds
SAM 450P:	Typically 12 seconds
Impedance range:	20 Ω to 230 Ω

Therapeutic Shock

Waveform:	SCOPE™ (Self Compensating Output Pulse Envelope) optimized biphasic escalating waveform compensates energy, slope and envelope for patient impedance
Energy:	Pre-configured factory settings for escalating energy are based on the current AHA/ERC guidelines
Pad-Pak:	Shock 1: 150J; Shock 2: 150J; Shock 3: 200J
Pediatric-Pak:	Shock 1: 50J; Shock 2: 50J; Shock 3: 50J

Event Recording

Type:	Internal memory
Memory:	90 minutes of ECG (full disclosure) and event/incident recording
Review:	Custom USB data cable (optional) directly connected to a PC with Saver EVO Windows-based data review software

Electromagnetic Compatibility/Battery Safety

EMC:	IEC/EN 60601-1-2
Radiated emissions:	IEC/EN 55011
Electrostatic discharge:	IEC/EN 61000-4-2 (8 kV)
RF immunity:	IEC/EN 61000-4-3 80 MHz – 2.5 GHz, (10 V/m)
Magnetic field immunity:	IEC/EN 61000-4-8 (3 A/m)
Aircraft:	RTCA/DO-160G, Section 21 (Category M) RTCA DO-227 (ETSO-c142a)

APPENDIX C Technical Data *continued*

SCOPE Biphasic Waveform

The samaritan PAD delivers a Self-Compensating Output Pulse Envelope (SCOPE) biphasic waveform which automatically optimizes the waveform pulse envelope (amplitude, slope, and duration) for a wide range of patient impedances, from 20 ohms to 230 ohms. The delivered waveform to the patient is an optimized, impedance-compensated, biphasic, truncated exponential waveform that incorporates an escalating energy protocol of 150 joules, 150 Joules, and 200 joules. The duration of each phase is automatically adjusted to compensate for varying patient impedances. The first phase (T_1) duration is always equivalent to the second phase (T_3) duration. The interphase pause (T_2) is always a constant 0.4 ms for all patient impedances.

The specific SCOPE waveform characteristics for a 150 joules pulse are shown in Table 2. An example of waveform parameters for the Pediatric-Pak are shown in Table 3.

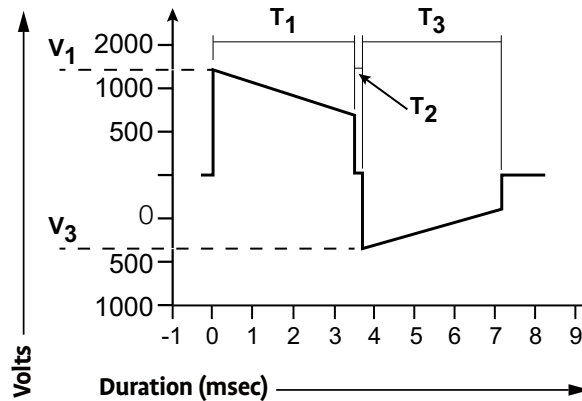


Figure 12. SCOPE Biphasic Waveform

Table 2. Pad-Pak Waveform Specification

Resistance (ohms)	Waveform Voltages (volts)		Waveform Duration (ms)	
	V_1	Tilt %	T_1	T_3
25	1640	63.1	3	3
50	1650	52.7	4.5	4.5
75	1660	51.4	6.5	6.5
100	1670	48.7	8	8
125	1670	50.4	10.5	10.5
150	1670	48.7	12	12
175	1670	48.7	14	14
200	1670	47.6	15.5	15.5
225	1680	46.7	17	17

NOTE: All values are nominal.

Table 3. Pediatric-Pak Waveform Specification

Resistance (ohms)	Energy (joules)	Waveform Voltages (volts)		Waveform Duration (ms)	
		V ₁	Tilt %	T ₁	T ₃
25	47.5	514	55.6	7.8	5.4
50	51.3	671	50.4	8.8	6
75	52.1	751	47.1	10	6.6
100	51.8	813	44.3	10.8	6.8
125	52.4	858	41.4	11.5	7.3

NOTE: Table contains example Pediatric-Pak waveform parameters.

Motion Detection Algorithm (SAM 360P only)

The SAM 360P uses the samaritan PAD ICG analysis to detect chest compression artefact and other forms of motion in order to play a verbal warning to stop CPR or other motion.

If the algorithm detects motion or other significant interference, the SAM 360P will issue the voice prompt “Motion detected, do not touch the patient.” This is intended to reduce the likelihood that the user is touching the patient prior to shock delivery.

NOTE: Motion Detection Algorithm performance may be reduced during low battery operation.

APPENDIX C Technical Data *continued*

Arrhythmia Analysis Algorithm

The samaritan PAD uses its ECG arrhythmia analysis algorithm to evaluate the patient's ECG to determine if a therapeutic shock is appropriate. If a shock is required, the samaritan PAD will charge and advise the user to stand clear and to press the shock button (SAM 350P and 450P) or automatically shock the patient after a verbal 3, 2, 1 countdown (SAM 360P). If no shock is advised, the device will pause to allow the user to deliver CPR.

The samaritan PAD ECG arrhythmia analysis algorithm performance has been extensively evaluated by using several databases of real-life ECG traces. Included in this are the AHA database and the Massachusetts Institute of Technology (MIT) NST database. The samaritan PAD ECG arrhythmia analysis algorithm's sensitivity and specificity meet the requirements of IEC/EN 60601-2-4.

The samaritan PAD ECG arrhythmia analysis algorithm performance is summarized in Table 4.

Table 4. Performance of the samaritan PAD ECG Arrhythmia Analysis Algorithm

Rhythm Class	Minimum Test Sample Size	Test Sample Size	Performance Goal	Observed Performance
Shockable Rhythm: Coarse Ventricular Fibrillation	200	350	Sensitivity > 90%	✓ Met
Shockable Rhythm: Rapid Ventricular Tachycardia	50	53	Sensitivity > 75% (AAMI' DF39)	✓ Met
Non-Shockable Rhythm: NSR ¹	100	165	Specificity > 99% (exceeds AAMI DF39)	✓ Met
Non-Shockable Rhythm: AF, SB, SVT, Heart Block, Idioventricular, PVCs ¹	30	153	Specificity > 95% (from AAMI DF39)	✓ Met
Non-Shockable Rhythm: Asystole	100	117	Specificity > 95%	✓ Met
Intermediate: Fine Ventricular Fibrillation	25	46	Report Only	>45% Sensitivity
Intermediate: Other Ventricular Tachycardia	25	29	Report Only	>65% Specificity

1. AAMI Association for Advancement of Medical Instrumentation: NSR, normal sinus rhythm; AF, atrial fibrillation/flutter; +SB, sinus bradycardia; SVT, supraventricular tachycardia; PVCs, premature ventricular contractions.







CPR Rate Advisor

The SAM 450P utilizes the ICG (Impedance Cardiogram) capability to assess the rate of chest compressions being applied during cardiopulmonary resuscitation (CPR).

Based on the measured rate, the SAM 450P provides verbal feedback to the user to “push faster”, “push slower”, or continue to provide “good speed” in accordance with the current AHA resuscitation guidelines (target CPR rate of at least 100 CPM).

The SAM 450P also uses the ICG to provide CPR Rate Advisor feedback in the form of a colored traffic light (green-amber-red) configuration LED array as shown in Table 5 below. The LED array is accompanied by text on the device’s top cover membrane to indicate when the operator’s compressions are ‘too slow’ or ‘too fast’.

Table 5. Visual guidance for CPR Rate Advisor

Description	Audio message	LED sequence
N/A	“Begin CPR”	
Compression rate is slower than 90 per minute	“Push faster”	
Compression rate is between 90 and 99 per minute	Metronome only	
Compression rate is between 100 and 120 per minute	“Good speed”	
Compression rate is between 121 and 130 per minute	Metronome only	
Compression rate is faster than 130 per minute	“Push slower”	

APPENDIX C Technical Data *continued*


Pediatric Restriction

Use of the CPR Rate Advisor function is restricted to adult patients only. Chest compression techniques differ for the different ages and sizes of pediatric patients (up to eight years old). For younger pediatric patients, rescuers should compress the lower half of the sternum but not compress over the xiphoid. For patients at the upper end of the pediatric range, adult-style compressions should be performed. CPR Rate Advisor is currently configured only to advise compressions at a rate suitable for adult patients (over eight years old weighing more than 55 lbs/25 kg).

Electrode placement also may differ in pediatric patients. Depending on the patient size, the electrodes may be placed anterior-posterior (front and back) or anterior-lateral (standard adult placement). Differing electrode positions may result in different ICG readings. Current technology does not support CPR Rate Advisor in determining which electrode placements are being used and therefore electrodes must be placed anterior-lateral for CPR Rate Advisor to function correctly.

For these reasons, CPR Rate Advisor is disabled when a Pediatric-Pak is used in the SAM 450P.

NOTE: The ECG readings used to determine if the patient requires a defibrillation shock are not affected by the electrode positions selected in pediatric patients.

 **WARNING:** If a pediatric patient is treated with an adult Pad-Pak, ignore the CPR Rate Advisor feedback prompts provided. CPR Rate Advisor is currently only intended to provide feedback on adult patients.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The samaritan PAD is intended for use in the electromagnetic environment specified in Table 6.

The customer or the user of the samaritan PAD should assure that it is used in such an environment.

Table 6. Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The SAM 350P, SAM 360P and SAM 450P use 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.
RF emissions CISPR 11	Class B	The SAM 350P, SAM 360P and SAM 450P are suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC/EN 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The samaritan PAD is intended for use in the electromagnetic environment specified in Table 7.

The customer or the user of the samaritan PAD should assure that it is used in such an environment.

APPENDIX C Technical Data *continued*

Table 7. Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air
Electrical fast transient/burst IEC/EN 61000-4-4	±2kV for power supply lines ±1 kV for input/output lines	Not Applicable
Surge IEC/EN 61000-4-5	±1kV differential mode ±2 kV common mode	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not Applicable
NOTE: U_T is the a.c. mains voltage prior to application of the test level		
Power-frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3A/m
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands ^a 10 Vrms 150 kHz to 80 MHz in ISM bands ^a	Not applicable
Radiated RF IEC/EN 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz

Electromagnetic Environment – Guidance

Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Not Applicable

Not Applicable

Not Applicable

Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Portable and mobile RF communications equipment should be used no closer to any part of the SAM 350P, SAM 360P or SAM 450P, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

Not applicable

$$d = 1.2 \sqrt{P} \dots 80 \text{ MHz to } 800 \text{ MHz}$$

$$d = 2.3 \sqrt{P} \dots 800 \text{ MHz to } 2.5 \text{ GHz}$$

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)^b.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^c, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol:



APPENDIX C Technical Data *continued*

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 ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- b. 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.
- c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the samaritan PAD is used exceeds the applicable RF compliance level above, the samaritan PAD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the samaritan PAD.

Recommended Separation Distances between Portable and Mobile RF Communication Equipment and the samaritan PAD

The samaritan PAD is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the samaritan PAD can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the samaritan PAD as recommended in Table 8, according to the maximum output power of the communications equipment.

Table 8. Separation Distances

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter m			
	150 kHz to 80 MHz Outside ISM Bands	150 kHz to 80 MHz in ISM Bands	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	Not applicable	Not applicable	0.12	0.23
0.1	Not applicable	Not applicable	0.38	0.73
1	Not applicable	Not applicable	1.2	2.3
10	Not applicable	Not applicable	3.8	7.3
100	Not applicable	Not applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated 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.

APPENDIX C Technical Data *continued*

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 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3: An additional factor of $10/3$ has been incorporated into the formulae 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.



APPENDIX D Voice Prompts

Following are the voice prompts used by the samaritan PAD devices. Models using specific voice prompts are indicated. Read the voice prompts in advance of use to be familiar with the types of instructions given.

For All Patients			
PROMPT	SAM 350P	SAM 360P	SAM 450P
“Call for medical assistance”	✓	✓	✓
“Remove clothing from patient’s chest to expose bare skin”	✓	✓	✓
“Pull green tab to remove pads”	✓	✓	✓
“Peel pads from liner”	✓	✓	✓
“Apply pads to patient’s bare chest as shown in picture”	✓	✓	✓
“Press pads firmly to patient’s bare skin”	✓	✓	✓
“Assessing heart rhythm; do not touch the patient”	✓	✓	✓
“Analyzing; do not touch the patient”	✓	✓	✓
“Motion detected”		✓	



APPENDIX D Voice Prompts *continued*

PROMPT	SAM 350P	SAM 360P	SAM 450P
CPR Rate Advisor			
“Push faster” *			✓
“Push slower” *			✓
“Good speed” *			✓
If a Shock Is Not Required			
“No shock advised”	✓	✓	✓
“Begin CPR”	✓	✓	✓
“It is safe to touch the patient”	✓	✓	✓
“Place overlapping hands in middle of chest” *	✓	✓	✓
“Press directly down on the chest in time with metronome” *	✓	✓	✓
“Remain calm” *	✓	✓	✓
If a Shock is Required			
“Stand clear of patient; shock advised”	✓	✓	✓
“Stand clear of patient; press the orange shock button now”	✓		✓
“Stand clear of patient; shock will be delivered in 3, 2, 1”		✓	
“Shock delivered”	✓	✓	✓
“Begin CPR”	✓	✓	✓
“It is safe to touch the patient”	✓	✓	✓
“Place overlapping hands in middle of chest” *	✓	✓	✓
“Press directly down on the chest in time with metronome” *	✓	✓	✓
“Remain calm” *	✓	✓	✓

D-2 * Voice prompts not provided when Pediatric-Pak is installed.

APPENDIX E

Safety and Effectiveness Data

Potential Adverse Effects

The potential adverse effects (e.g., complications) associated with the use of an automated external defibrillator include, but are not limited to, the following:

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

Overall Safety Summary

It is difficult to determine the percentage of the intended population that could expect to experience a harmful event without a prospective, randomized clinical trial. In lieu of such a trial, the risks of the device are based on nonclinical laboratory and animal studies as well as data collected in published literature^{1,2,3}.

The results from the preclinical laboratory testing performed on the HeartSine SAM 350P, SAM 360P and SAM 450P devices demonstrated appropriate electrical safety, electromagnetic compatibility, biocompatibility, mechanical integrity, and overall performance.

Six animal studies were conducted to demonstrate device safety. The first study involved 15 pigs and demonstrated first shock success of the SCOPE waveform used in the SAM 350P, SAM 360P and SAM 450P of 99%.

APPENDIX E **Safety and Effectiveness Data** *continued*

Two animal studies were conducted to determine whether the SCOPE waveform induces refrillation or increases defibrillation thresholds (DFTs) if the pulse duration exceeds 20 ms. The first of these studies included 6 pigs and the delivery of 208 shocks, including 68 shocks with pulse durations greater than or equal to 20 ms; the second pulse width study included 5 pigs and 96 delivered shocks, of which 91 shocks had pulse durations greater than or equal to 20 ms. There were no incidents of refrillation in the 5 minutes immediately following a successful first shock in either study. In addition, successful defibrillation demonstrated that the SCOPE waveform at longer pulse durations does not increase DFTs.

The fourth animal study was conducted to assess the impact of administering repeated shocks on a pig model wearing an underwire bra. In this study, the bra's underwire was intentionally exposed by removal of bra fabric and the electrode pad was placed so that the electrode gel on the electrode's lower surface was in direct contact with the bra's metal wire, to maximize the potential of arcing or other adverse events. A total of 126 shocks were administered at the device's maximum energy of 200 J, with 100% first shock success and no evidence of arcing, redirection of current away from the subject, scorching or burning to the animal or fabric, or any other skin damage to the animal observed post-resuscitation.

The fifth animal study demonstrated the accuracy of the SAM 360P audio feedback ("Motion detected", "Do not touch the patient" and "Stand clear") by determining if CPR motion/interference which was intentionally created during the ECG rhythm analysis period was detected by the SAM 360P Motion Detection Algorithm. This 12-pig study demonstrated a sensitivity for the "motion detected" audio feedback of 97.9% and a specificity of 100%.

The sixth animal study demonstrated the accuracy of the SAM 450P CPR Rate Feedback algorithm. This 12-pig study demonstrated that the proportion of correct audio and visual feedback provided by the SAM 450P was 95.2% in comparison to the actual CPR compression rate as demonstrated in video recordings.

The animal studies collectively demonstrate: the safety of the devices' energy protocol; that pulse durations greater than 20 ms do not induce refrillation or increase DFTs; that placement of the electrodes in proximity with a bra does not pose a risk; and that the SAM 360P motion/interference detection algorithm and SAM 450P CPR Rate Feedback features do not adversely affect CPR quality or shock delivery.

Overall Effectiveness Summary

In addition to the bench and animal studies described previously, bench testing demonstrates that the arrhythmia analysis algorithm meets AHA recommendations for sensitivity and specificity for detecting shockable and non-shockable arrhythmias. A published clinical study on the SCOPE waveform, postmarket clinical experience involving 805 events, and usability studies conducted on each device demonstrate the effectiveness of the SAM 350P, SAM 360P and SAM 450P devices.

Published Clinical Data

The study by Walsh et al. evaluated the SCOPE defibrillation waveform used in the SAM 350P, SAM 360P and SAM 450P and was published in the American Journal of Cardiology in 2004.³ This study compared two (2) impedance compensated biphasic waveforms:

- HeartSine's samaritan (SAM) (100-150-200 J energy protocol at the time based on the AHA guidelines then in effect) using the same SCOPE defibrillation waveform present in the SAM 350P, SAM 360P and SAM 450P; and
- Philips Medical Systems Heartstream XL (150-150-150 J protocol) (HSXL)

The primary endpoint was discontinuation of ventricular arrhythmia. Success was defined as the discontinuation of ventricular arrhythmia for greater than 5 seconds. Patients were excluded from participation if they weighed less than 36 kg, had cardiac arrest due to trauma or had current "do not resuscitate" instructions.

As reported in the publication, 78 consecutive patients were studied: 40 HSXL (19 men) and 38 SAM (28 men). Mean age was 69 ± 11 years for HSXL patients and 65 ± 14 years for SAM patients ($p = \text{NS}$). Cardiac arrest out-of-hospital occurred in 13 of 40 HSXL patients (33%) and in 26 of 38 SAM patients (68%) ($p = 0.003$). Mean response time from arrest to physician arrival was 1.4 ± 1.3 minutes for in-hospital patients and 9 ± 6 minutes for out-of-hospital patients.

The rhythm when first recorded was VF in 20 of 40 HSXL patients (50%) and 16 of 38 SAM patients (42%), VT in 3 of 40 HSXL patients (8%) and 1 of 38 SAM patients (3%), and electromechanical dissociation or asystole in 16 of 40 HSXL patients (40%) and 20 of 38 SAM patients (53%) (all rhythms, $p = \text{NS}$). One (1) patient in each group had a palpable pulse when first attended by the physician. Drugs given during cardiac arrest were similar in the two (2) groups. A total of 15 of 40 HSXL patients (38%) and 12 of 38 SAM

APPENDIX E Safety and Effectiveness Data *continued*

patients (32%) received amiodarone, whereas 29 of 40 HSXL patients (73%) and 34 of 38 SAM patients (89%) received epinephrine ($p = \text{NS}$).

VF episodes were 107 HSXL and 117 SAM. The energy selection protocol was adhered to in 95 of 107 HSXL (89%) and 79 of 117 SAM (68%) defibrillation episodes. Protocol violations for energy selection occurred when the attending physician misinterpreted a successful shock followed by early recurrence of arrhythmia (greater than 5 seconds) as unsuccessful. This resulted in a progression to the next stage of the energy selection protocol (i.e., a higher energy was therefore selected inappropriately). Less incorrect energy selection was seen with the HSXL due to the non-escalating nature of the protocol (150-150-150 J; the physician could only select 200 J at the fourth shock or beyond).

Excluding VF episodes when energy selection was not as per protocol, success after one (1) shock was seen for 64% of HSXL and 58% of SAM episodes ($p = \text{NS}$). Success occurred by shock two (2) in 78% of HSXL and 82% of SAM episodes and by shock three (3) in 83% of HSXL and 92% of SAM episodes.

An analysis of the difference of proportions in success by a certain shock was performed by the authors (see Table 9). The defibrillation success rate is acceptable because it is consistent with defibrillation success rates (greater than 85%) reported in the literature for randomized controlled clinical trials using other devices and waveforms⁴. These data were not powered to demonstrate differences in return of spontaneous circulation or survival.

This study was conducted on the HeartSine samaritan AED (cleared under 510(k) K023854) with the identical SCOPE waveform as used in the SAM 350P, SAM 360P and SAM 450P.

Table 9: Summary of Successful Defibrillation Episodes with Both Devices

Success by	HeartSine samaritan (100-150-200J)		Philips HeartstreamXL (150-150-150J)		Mean Difference	SD	Probability that samaritan Better than Heartstream
	Frequency	Proportion	Frequency	Proportion			
First Shock	46	0.582	61	0.642	-0.0598	0.0742	0.210
Second Shock	65	0.823	74	0.779	0.0438	0.0605	0.766
Third Shock	73	0.924	79	0.832	0.0925	0.0486	0.971*
Total Episodes	79		95				

*p = 0.029

Postmarket Clinical Data

In addition to the published clinical study data described above, postmarket clinical data were received and analyzed from 28 countries worldwide including USA, Singapore, Germany, Netherlands, Canada, Australia, United Kingdom, and Sweden which comprised approximately 85% of the total number of events.

Postmarket clinical reports for 805 events were received between January 2012 and December 2015. Of these, 550 (68.3%) events involved the SAM 300P device, 122 (15.2%) events involved the SAM 350P device, three (3) (0.4%) events involved the SAM 360P device, no (0%) events involved the SAM 450P device, and 130 (16.1%) events involved the SAM 500P device. The SAM 500P is not marketed in the United States but uses the identical defibrillation waveform, the identical arrhythmia detection algorithm and identical Pad-Paks. The SAM 300P is the precursor to the SAM 350P and also uses identical defibrillation waveform, arrhythmia detection algorithm and Pad-Paks.

Success was defined as discontinuation of ventricular fibrillation or ventricular tachycardia within 5 seconds of shock delivery. A total of 334 patients in the “All Cases” dataset initially presented with a shockable rhythm, of which 327 (97.9%) patients were in ventricular fibrillation and seven (7) (2.1%)

APPENDIX E Safety and Effectiveness Data *continued*

were in ventricular tachycardia. Of these 334 patients, a shock was delivered in 322 patients. Of these 322 events, 220 (68.3%) events involved the SAM 300P device, 37 (11.5%) events involved the SAM 350P device, 2 (0.6%) events involved the SAM 360P device, no (0%) events involved the SAM 450P device and 63 (19.6%) events involved the SAM 500P device.

Of the 322 first shocks delivered, 293 (91.0%) were successful, with 95% CI estimated to be (87.3%, 93.9%). This is consistent with defibrillation success rates (greater than 85%) reported in the literature for randomized controlled clinical trials using other devices and waveforms.⁴

Of the “Shock Delivered” dataset, a total of 187 (58.1%) patients were reported to have survived to hospital admission, 61 (18.9%) patients did not survive to hospital admission, and survival information was unavailable for 74 (23.0%) patients. Table 10 summarizes the relationship between event location and user training, response time, and percentage survival to hospital admission.

Table 10: Location of Events, Trained Users, Response Time and Survival

Location of Events	N	Percentage of Total Number of Shock Delivered Events	Percentage of Trained Users	Mean (SD) Response Time (minutes)	Percentage Survival to Hospital Admission
Home	44	13.7	88.6	4.87 (2.56)	34.1
Medical Facility	28	8.7	89.3	4.07 (4.85)	67.9
Office	19	5.9	68.4	3.86 (2.97)	68.4
Public	110	34.2	81.8	3.82 (3.95)	69.1
School/University	4	1.2	100.0	4.00	75.0
Sports Facility	62	18.9	79.0	4.30 (5.41)	80.6
Unknown	57	17.7	30.3	5.59 (2.00)	11.8
Total	322	100.0	73.0	4.21 (4.11)	58.1

First shock success was found to be significantly associated with survival to hospital admission, with an Odds Ratio (OR) = 3.13, 95% CI = (1.30, 7.51), and $p = 0.0107$. The analysis was repeated when adjusting for age and gender, with consistent results (OR = 3.29, $p = 0.0095$). Age was found to be significantly associated with survival to admission in this analysis (OR = 0.98 for a 1-year increase in age, $p = 0.0324$).

Shock success and survival were similar among the HeartSine public access defibrillators studied in this analysis, which was anticipated since all the devices use the same defibrillation waveform, the same arrhythmia detection algorithm, and the same Pad-Pak electrode-battery packs. Table 11 summarizes shock success and survival by defibrillator model.

Table 11: Shock Success and Survival to Hospital Admission

Device Type	Number of Patients with a Shockable Rhythm	Percentage First Shock Success (%)	Percentage Second Shock Success (%)	Percentage Third Shock Success (%)	Percentage Survival to Hospital Admission ("All Cases" Dataset) (%)	Percentage Survival to Hospital Admission of Those Who Received a Shock (%)
SAM 300P	225	91.3	89.2	79.4	26.2	55.0
SAM 350P	41	89.2	76.5	90.9	22.1	62.2
SAM 360P	2	100.0	100.0	100.0	33.3	50.0
SAM 450P	0	N/A	N/A	N/A	N/A	N/A
SAM 500P	66	92.1	82.8	76.9	37.7	66.7
Total	334	91.3	86.4	81.4	27.5	58.1

APPENDIX E Safety and Effectiveness Data *continued*

The primary adverse event was failure to deliver a shock when presented with a shockable rhythm. A total of 12 of the 334 patients initially presented with a shockable rhythm but no shock was delivered. Based on a review of the ECG records, in only 1 of the 12 cases was algorithm performance determined to be inappropriate. In addition, 12 events were associated with audio prompts indicating the user repeatedly removed the electrodes throughout the event. No other adverse events were observed in this postmarket experience.

In summary, the postmarket data collected provides information on the real-world performance of the arrhythmia detection algorithm, waveform effectiveness and the overall usability of HeartSine's public access defibrillators. First shock success and survival to admission were comparable in this study to rates reported in published literature⁴. Finally, algorithm performance for combined VF/VT had a sensitivity of 98.8% in this analysis.

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