HeartSine®

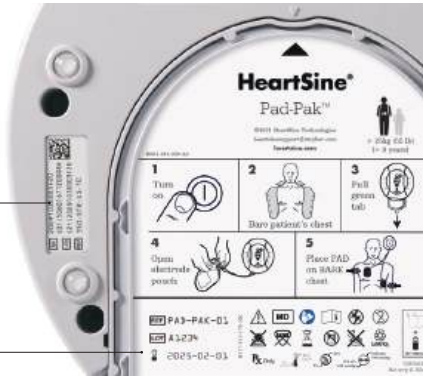
EN-US

HeartSine® samaritan® PAD
user manual

SAM 360P
Fully automatic defibrillator

SAM 450P
Semi-automatic defibrillator with CPR Rate Advisor

About **your AED**



Serial number (SN)

Pad-Pak expiration date (YYYY-MM-DD)

Put information about your AED here:

Model ☐ HeartSine SAM 360P
☐ HeartSine SAM 450P

Serial number _____

Pad-Pak expiration date _____

Date of purchase _____

Purchased from _____

Registration date _____

Customer support number

For questions about your AED and its use, please contact our customer support team: **800 442 1142**

Table of contents

Appendices

Use of this manual

It is important that you read this manual carefully before using your HeartSine samaritan PAD. This manual is presented in support of any training you may have received. If you have any questions, contact your Authorized Distributor or HeartSine Technologies directly.

Caution

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

Indications for use

The HeartSine samaritan PAD 360P (SAM 360P) and HeartSine samaritan PAD 450P (SAM 450P) have the identical indications for use. Each is indicated for use on victims of cardiac arrest who are exhibiting 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 lb (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 lb (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 HeartSine samaritan PAD to provide treatment.

Caution

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

Warnings

Patients suitable for treatment

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

HeartSine samaritan PAD uses an interchangeable battery and electrode pack called Pad-Pak. HeartSine samaritan PAD in combination with an adult Pad-Pak is suitable for use on patients of over 55 lb (25 kg) in weight or equivalent to a child of approximately 8 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 the CPR Rate Advisor feedback prompts provided. 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

HeartSine 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

HeartSine 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 your HeartSine samaritan PAD.

Avoid explosive or flammable gases

HeartSine 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 HeartSine 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 HeartSine samaritan PAD is analyzing the patient. The device will instruct you when it is safe to touch the patient.

Fully automatic defibrillator (SAM 360P)

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.

Susceptibility to electromagnetic interference

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 12 in (30 cm) to any part of HeartSine samaritan PAD including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Use of competitor or third-party products

Do not use HeartSine samaritan PAD, Pad-Pak or Pediatric-Pak with any competitor or third-party products. Use of electrical accessories, transducers and cables other than those specified or provided by HeartSine Technologies could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Use of the device

Use of HeartSine samaritan PAD adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, HeartSine samaritan PAD and the other equipment should be observed to verify that they are operating normally.

Use with other medical equipment

Disconnect non-defibrillation protected electronic devices or medical equipment from the patient before using HeartSine samaritan PAD.

Use with pacemakers

The presence of a pacemaker should not affect the functioning of the AED. However, to avoid damage to the pacemaker, it is recommended that the pads are placed at least 3.1 in (8 cm) away from a pacemaker. A noticeable lump with a surgical scar should indicate the location of an implanted device.[1]

⚠ Cautions

Correct placement of electrode pads

Proper placement of electrode pads is critical. You must strictly observe the instructions shown on pages 20-27 and on the device. Wrong placement or the presence of air, hair, fabric, surgical dressings or medicine patches between the pads and the skin could reduce defibrillation effectiveness or potentially cause skin burns. Slightly red skin after shock therapy is normal.

Do not use electrode pads if pouch is not sealed

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.

Temperature range for operation

HeartSine 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
HeartSine 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 HeartSine 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
HeartSine samaritan PAD 360P and 450P 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.

Regular maintenance
Check the device periodically. See Maintain HeartSine samaritan PAD on page 31.

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 you use your HeartSine samaritan PAD on page 28.

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.

Symbols
The following symbols are used in this manual:

⚠ **WARNING:** WARNING STATEMENTS DESCRIBE CONDITIONS OR ACTIONS THAT CAN RESULT IN DEATH OR SERIOUS INJURY

⚠ **CAUTION:** Caution statements describe conditions or actions that can result in minor injury or damage to the AED

Note: Notes contain important additional information about using the AED

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.

HeartSine 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, HeartSine samaritan PAD will charge and advise the user to press the shock button (SAM 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 HeartSine samaritan PAD, will not administer a shock unless a lifesaving shock is required.

Introduction

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

HeartSine samaritan PAD 360P (SAM 360P)
HeartSine samaritan PAD 450P (SAM 450P)

About HeartSine samaritan PAD

HeartSine samaritan PAD family of AEDs is designed to quickly deliver a defibrillation shock to victims of sudden cardiac arrest (SCA). Each HeartSine 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 HeartSine samaritan PAD models are very similar in use, there are distinct differences between the models as shown in Table 1 below.

SAM 360P is a fully automatic defibrillator and SAM 450P is a semi-automatic defibrillator with integrated CPR Rate Advisor.

⚠ **WARNING:** SAM 360P IS A FULLY AUTOMATIC DEFIBRILLATOR. WHEN REQUIRED, IT WILL DELIVER A SHOCK TO THE PATIENT WITHOUT USER INTERVENTION

CPR metronome

When HeartSine 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 to the latest 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.

Table 1. HeartSine samaritan PAD AEDs

Feature	SAM 360P	SAM 450P
Shock delivery	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)	✔	✔*

* If a Pediatric-Pak is used, the CPR Rate Advisor function is disabled.

CPR Rate Advisor

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

SAM 450P with CPR Rate Advisor provides feedback to the rescuers on the rate of the CPR they are providing to the victim. SAM 450P uses impedance cardiogram measurements to analyze the speed of compressions and provide the user with instruction to push faster or push slower or to continue to provide compressions at a good speed according to the AHA resuscitation guidelines. 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-10.

WARNING: 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

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.

HeartSine samaritan PAD 360P and 450P 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. 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 HeartSine 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 360P and SAM 450P safety and effectiveness data.

Getting to know your HeartSine SAM 450P AED

Data port
Remove blue cover and plug in the custom USB data cable to download event data from the AED.

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

Adult and pediatric symbols
Indicates that 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.

Speaker
Listen for the metronome and verbal prompts.

Green tab
Pull this tab to release the electrodes.

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

Shock button
Press this button to deliver a therapeutic shock.

Do not touch icon/ action arrows
Do not touch the patient when the action arrows above this icon are flashing. 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.

Unpack

Verify that the contents include the HeartSine samaritan PAD, carry case, Pad-Pak, user manual and warranty registration card.

Pad-Pak

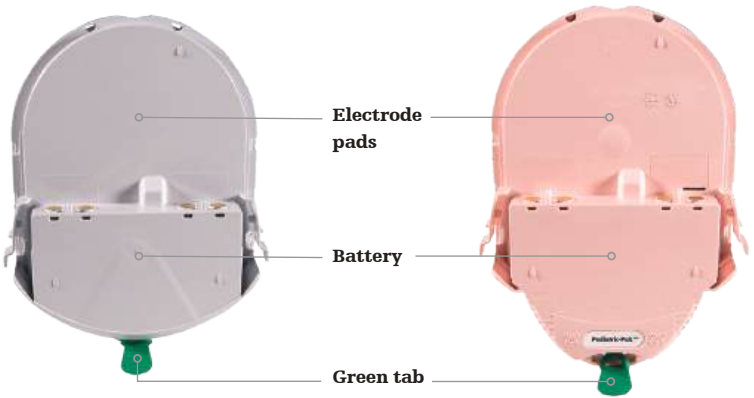
A Pad-Pak is a single-use removable cartridge that includes the battery and electrode pads in a single unit. The Pad-Pak is available in two versions[1]:

1. Pad-Pak (gray color shown in Figure 1) for use on patients weighing over 55 lb (25 kg), or equivalent to a child of approximately 8 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 lb (25 kg)).

⚠ **WARNING:** DO NOT DELAY TREATMENT TRYING TO DETERMINE THE PATIENT'S EXACT AGE AND WEIGHT

Figure 1. Adult Pad-Pak

Figure 2. Pediatric-Pak



[1] Pad-Pak also is available in a TSO/ETSO-certified version for use on commercial fixed-wing aircraft.

Put HeartSine samaritan PAD into service

Follow these steps to place your HeartSine samaritan PAD into service:

1. Check the expiration date (YYYY-MM-DD) 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.

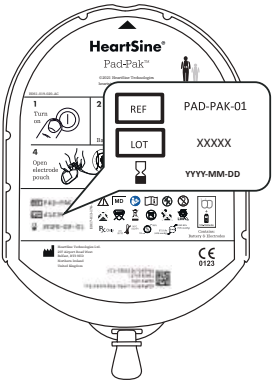


Figure 3. Expiration date

2. Unpack the Pad-Pak and retain the packaging in case you need to return the Pad-Pak to HeartSine Technologies.

3. Place HeartSine samaritan PAD face up on a flat surface and slide the Pad-Pak into HeartSine 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.

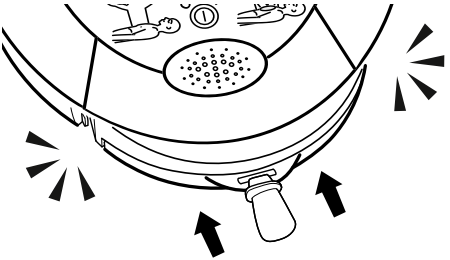


Figure 4. Inserting a Pad-Pak

4. Record the serial number for the AED, the expiration date for the Pad-Pak and other information about your AED in the space provided on the inside front cover of this manual.

5. Verify that the green Status indicator (see the layout for your model on pages 11-12) is blinking to indicate the initial self-test routine has been performed and the device is ready for use.

6. Press the On/Off button to turn on HeartSine samaritan PAD. Listen for, but do not follow, the voice prompts to ensure that no warning messages are played and that the device prompts are in the expected language.

CAUTION: 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

CAUTION: Only turn on HeartSine 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

7. Press the On/Off button to turn off HeartSine 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.

8. Place HeartSine samaritan PAD in its supplied soft carry case. Store HeartSine samaritan PAD where it will be seen and heard in an unobstructed, secure location in a **clean, dry environment**. Store HeartSine samaritan PAD out of reach of small children and pets. Be sure to store the device according to the environmental specifications (see Technical data in Appendix C on page C-1).

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

9. Register online, or complete the warranty registration card and return it to your Authorized Distributor or HeartSine Technologies directly (see Tracking requirements on page 30).

10. Create a service schedule (see Maintain HeartSine samaritan PAD on page 31).

Preparation checklist

Following is a checklist of the steps required to set up your HeartSine 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.** Record information about your AED on the inside front cover of this user manual
- ☐ **Step 4.** Turn on HeartSine samaritan PAD to check operation.
- ☐ **Step 5.** Turn off HeartSine samaritan PAD.
- ☐ **Step 6.** Store HeartSine samaritan PAD in a clean, dry environment at 32°F to 122°F (0°C to 50°C).
- ☐ **Step 7.** Register your HeartSine samaritan PAD.
- ☐ **Step 8.** Create a service schedule. (See Maintain HeartSine samaritan PAD on page 31.)

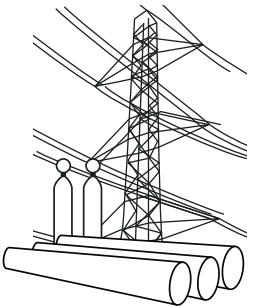
Using HeartSine samaritan PAD

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 devices see Voice prompts in Appendix D.

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

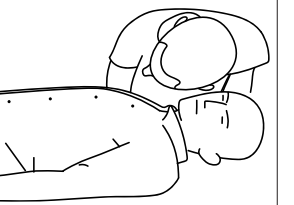
1. Remove danger

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



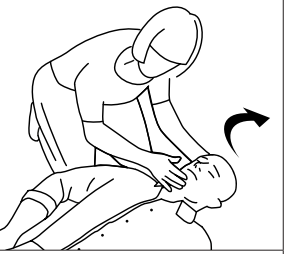
2. Check for a response

- 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

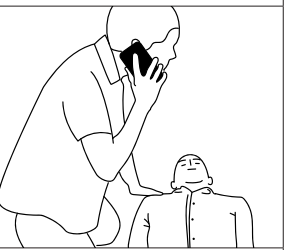


3. Check for airway

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



4. Call for medical assistance

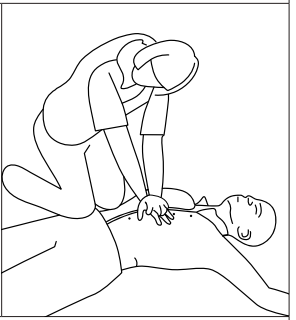


5. Retrieve the AED

- Ask others nearby to do so

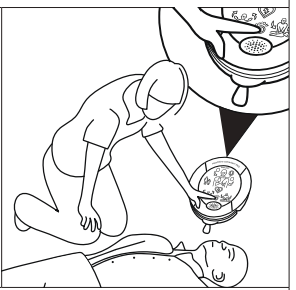
6. Perform CPR

- 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 2 to 2.4 in (5 to 6 cm)
- If you feel able to give rescue breaths perform 30 compressions followed by two rescue breaths



7. Turn on the AED

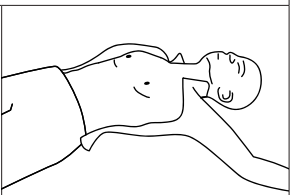
- Press the On/Off button to turn on the AED



8. Defibrillation therapy

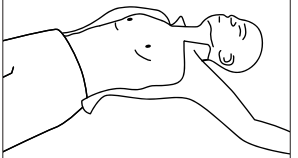
Defibrillation therapy is tailored depending on whether a Pad-Pak or Pediatric-Pak is installed

- If the patient is under 55 lb (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 24)
- If a Pediatric-Pak is not available, you may use the Pad-Pak



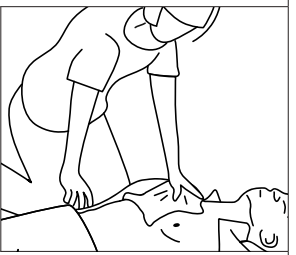
9. Bare the chest area

- Remove clothing from patient's chest to expose BARE skin
- Remove any metal (bras or jewelry) where possible from the pad placement area



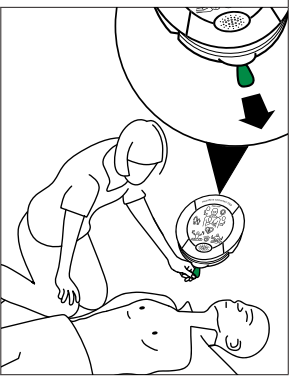
10. Dry the patient's chest

- Dry the patient's chest if wet or clammy
- If a lot of chest hair is present, shave the patient's chest where the electrodes will be placed



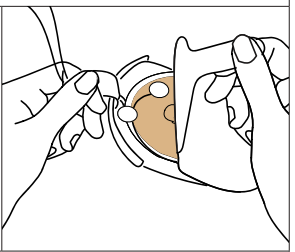
11. Pull the green tab

- Pull the green tab to remove the electrode pad pouch from the AED



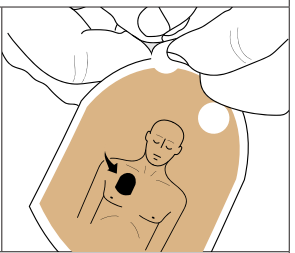
12. Open the electrode pouch

- Tear open the pouch to remove the electrode pads



13. Peel first pad from liner

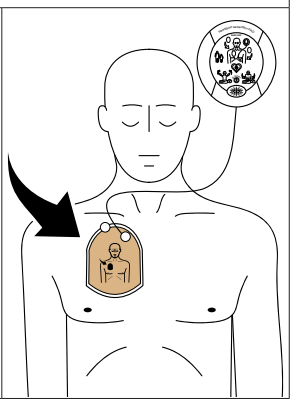
- With both thumbs on the white and clear round tabs, peel the first pad from the plastic liner



14. Place first pad

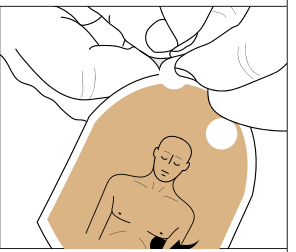
- For a patient over 8 years of age or weighing over 55 lb (25 kg), apply the first electrode pad firmly to the patient's bare chest, vertically as shown in picture
- For use on a young child (from 1 to 8 years of age or weighing 55 lb or less), see Electrode placement on page 27.

Note: If you are placing pads on a patient with a pacemaker, do not place pads on top of the implant, which you will see as a lump in the skin or a scar. Make sure the pads are placed at least 3.1 inches (8 cm) away from the pacemaker



15. Peel second pad from liner

- With both thumbs on the white and clear round tabs, peel the second pad from the plastic liner



16. Place second pad

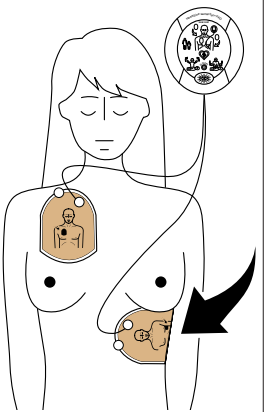
- For a patient over 8 years of age or weighing over 55 lb (25 kg), apply the second electrode pad firmly to the patient's bare chest, horizontally as shown in picture
- For use on a young child (from 1 to 8 years of age or weighing 55 lb or less), see Electrode placement on page 27.

⚠ **WARNING:** PADS SHOULD BE AT LEAST 1 INCH APART AND NEVER TOUCHING ONE ANOTHER

Note: On a large-breasted patient, place the pad on the patient's left to the side of or underneath the left breast, avoiding breast tissue

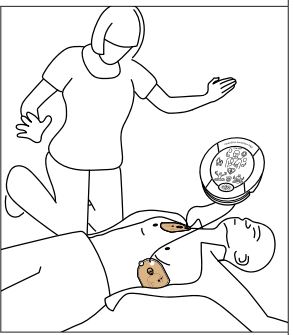
After you have placed pads on the patient's chest, if you continue to hear "Check pads. Press pads firmly to patient's bare chest," check that:

- Pads are placed correctly as shown in the pictures
- Pads are not touching and at least 1 inch (2.5 cm) apart
- Entire surface of each pad is stuck 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
- If the message continues, seek an alternative defibrillator and continue CPR



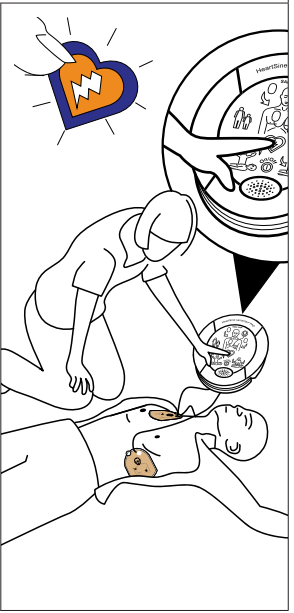
17. Do not touch the patient

- When prompted, ensure that you are not touching the patient



18. Stand clear when advised

- 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 450P) to deliver a shock
- If using SAM 360P, the AED will automatically deliver the shock after a verbal 3, 2, 1 countdown



19. Begin CPR when advised

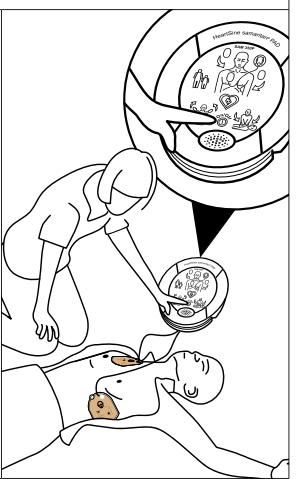
- When advised that a shockable rhythm is not detected, begin CPR. To do so, place overlapping hands in the middle of the patient's chest and, with straight arms, press firmly and quickly in time with the metronome
- Continue to perform CPR until the AED begins to analyze the patient's heart rhythm again
- When using SAM 450P, follow the CPR Rate Advisor voice prompts. Refer to CPR Rate Advisor on page C-10 for more information

20. Repeat the process from step 17

- Repeat the process from step 17 until emergency services arrive

21. When emergency services arrive

- If emergency services advise, press the On/Off button to turn off the AED and remove the electrode pads.



Pad-Pak and Pediatric-Pak

Pad-Pak and Pediatric-Pak are the single use battery and electrode cartridges used with HeartSine samaritan PAD. Defibrillation therapy is tailored depending on whether a Pad-Pak or Pediatric-Pak is inserted.

Each Pad-Pak and Pediatric-Pak contain one set of disposable defibrillation pads and a $LiMnO_2$ (18V – 1500mAh) non-rechargeable battery. Pad-Pak and Pediatric-Pak options are listed in Table 2 below.

It is recommended that HeartSine samaritan PAD be stored with an adult Pad-Pak inserted and that a spare Pad-Pak and Pediatric-Pak be stored in the carry case or nearby. The stored Pad-Pak or Pediatric-Pak should remain in the protective plastic pouch until use.

Note: When you switch on your HeartSine samaritan PAD with a Pediatric-Pak inserted you should hear the voice prompt "Child patient"

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

WARNING: DO NOT USE IF PAD-PAK OR PEDIATRIC-PAK IS OPENED OR DAMAGED. THIS MAY RESULT IN THE ELECTRODE GEL BEING DRY. THE ELECTRODES ARE SEALED IN A PROTECTIVE FOIL AND SHOULD ONLY BE OPENED DURING USE. IF DAMAGED, REPLACE IMMEDIATELY

Table 2. Comparing Pad-Pak, Pediatric-Pak and Aviation Pad-Pak

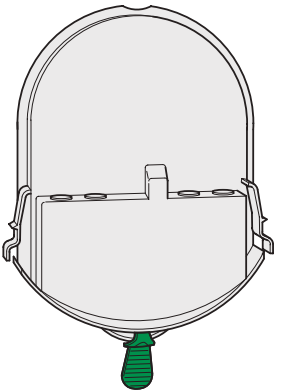
Feature	Pad-Pak	Pediatric-Pak	Aviation Pad-Pak (TSO/ETSO-certified)
Color	Gray	Pink	Gray (with aircraft symbol)
Intended patient age and weight	Adult and children > 8 years or > 55 lb (25 kg)	Children 1 – 8 years or < 55 lb (25 kg)	Adult and children > 8 years or > 55 lb (25 kg)
Energy	Shock 1: 150 J Shock 2: 150 J Shock 3: 200 J	Shock 1: 50 J Shock 2: 50 J Shock 3: 50 J	Shock 1: 150 J Shock 2: 150 J Shock 3: 200 J
Use on aircraft	No	No	Yes: commercial fixed wing

WARNING: NOT FOR USE ON PATIENTS UNDER 1 YEAR OLD

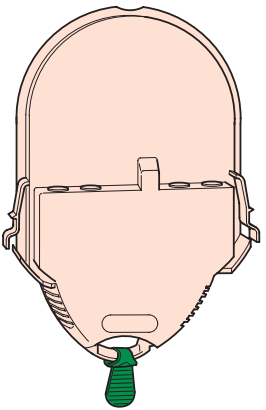
WARNING: **DO NOT** DELAY THERAPY IF YOU ARE UNSURE OF THE EXACT AGE OR WEIGHT. IF THE PEDIATRIC-PAK IS UNAVAILABLE, YOU MAY USE THE PAD-PAK

CAUTION: Pad-Pak and Pediatric-Pak are single use only. Reuse may cause device to be unable to deliver therapy leading to a failure to resuscitate. It may also lead to cross-infection between patients

Adult Pad-Pak



Pediatric Pad-Pak

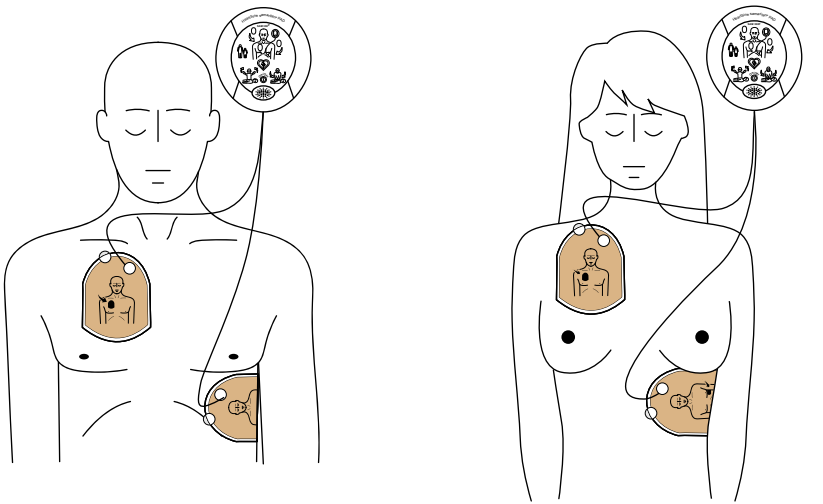


Adult placement

For a patient over 8 years of age or weighing over 55 lb (25 kg), place the electrodes on the patient's BARE chest as shown in Figure 5.

In large-breasted individuals, place the left electrode pad lateral to or underneath the left breast, avoiding breast tissue.

Figure 5.



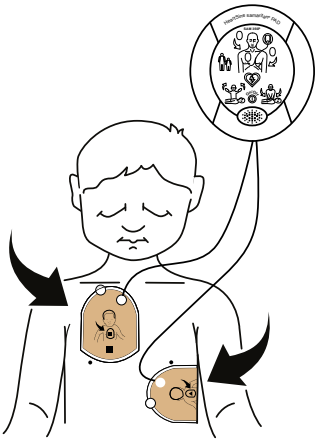
Pediatric placement

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

Pad placement for children

If a child's chest is large enough to permit at least 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 electrode pads on patient's BARE chest as shown in Figure 6.

Figure 6. Anterior-Lateral

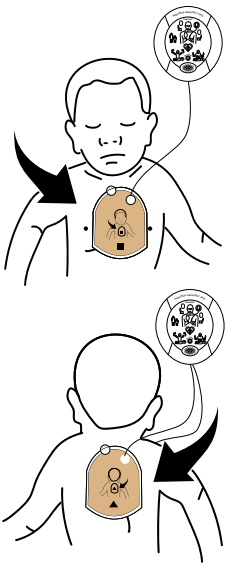


⚠ **WARNING:** ELECTRODE PADS MUST BE AT LEAST 1 IN (2.5 CM) APART AND SHOULD NEVER TOUCH ONE ANOTHER

Pad placement for smaller children

If a child's chest is small, it may be necessary to place one electrode pad in the center of the child's BARE chest, and the other electrode pad in the center of the ribcage on the child's BARE back as shown in Figure 7.

Figure 7. Anterior-Posterior



Cleaning HeartSine 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. Pad-Pak is a single-use item that contains lithium batteries. Replace the Pad-Pak after each use. With HeartSine 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 HeartSine samaritan PAD. The Pad-Pak will slide forward (see Figure 8).

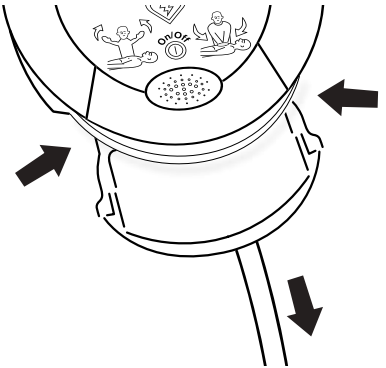


Figure 8. Removing the Pad-Pak

3. Check HeartSine 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)

CAUTION: Do not immerse any part of HeartSine 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

CAUTION: Do not clean HeartSine samaritan PAD with abrasive materials, cleaners or solvents

4. Check HeartSine samaritan PAD for damage. If the AED is damaged, replace it immediately.

5. Install a new Pad-Pak. Before installing the Pad-Pak, check the expiration date (see Set up your HeartSine samaritan PAD on page 14). After installation, confirm that the status indicator is blinking green.

6. Report use of HeartSine samaritan PAD to HeartSine Technologies or your Authorized Distributor. (See back cover for contact details.)

Download and submit event information

HeartSine Saver EVO software lets you manage the event data after your HeartSine samaritan PAD is used. You can provide this data, if requested, to a patient's doctor, and/or use it to obtain a free Pad-Pak if you have an eligible event.

This software can be downloaded from our website at no extra cost:

heartsine.com/downloads

In addition to Saver EVO, the optional USB data cable (PAD-ACC-02) is required to download event data. Contact your Authorized Distributor or Stryker representative 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 HeartSine samaritan PAD (see Figure 9).
2. Connect the USB connector on the data cable to a PC running Microsoft Windows.

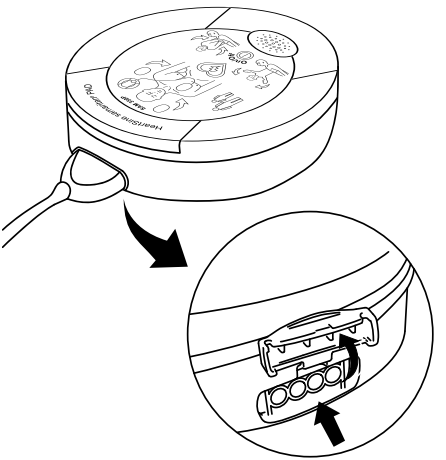
   Note: HeartSine samaritan PAD should be connected to an IEC60950-1 certified PC
3. Install and launch HeartSine Saver EVO software.
4. Follow the instructions provided in the Saver EVO manual to save or erase the event data on your HeartSine samaritan PAD.
5. Upload the Saver EVO file on the HeartSine Technologies website.

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

Disposal

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.

Figure 9. USB data port



Tracking requirements

Medical device regulations require HeartSine Technologies to track the location of each HeartSine samaritan PAD AED, Pad-Pak, and Pediatric-Pak sold. Therefore, it is important that you register your device, either using our on-line registration tool at:

heartsine.com/register

Or by completing the HeartSine samaritan PAD warranty registration card and returning it to your Authorized Distributor or HeartSine Technologies directly. As an alternative to the card and on-line registration tool, you may send an email to:

heartsinesupport@stryker.com

The email should contain the following information:

- Name
- Address
- Device serial number

If there is a change in the information you have provided to us, such as a change of address or ownership of your HeartSine samaritan PAD, provide the updated information to us via email or the online registration tool.

When you register your AED, we will contact you with any important notifications about HeartSine samaritan PAD, such as software updates or field safety corrective actions.

Maintain HeartSine samaritan PAD

HeartSine AEDs do not require any servicing or testing as the devices are designed to perform a weekly self-test. However, HeartSine Technologies recommends users perform regular maintenance checks, which include the following:

Weekly

- ☐ Check the status indicator. HeartSine 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 10-12, 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 your HeartSine samaritan PAD 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 HeartSine samaritan PAD or if, for any reason, you suspect that your HeartSine samaritan PAD is not working properly, consult Troubleshooting in Appendix B.

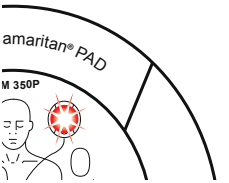


Figure 10. Flashing red light and/or beeping; See Troubleshooting in Appendix B.

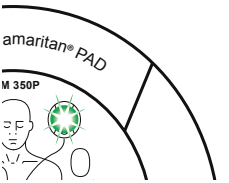


Figure 11. Flashing green LED; no action required.

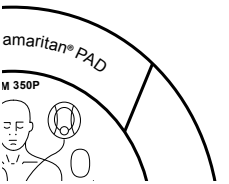


Figure 12. No status indicator light; See Troubleshooting in Appendix B.

Testing with simulators and manikins

HeartSine AEDs cannot be tested using industry-standard simulators and manikins.

Appendices

Appendix A Symbols

	On/Off
	Consult operating instructions
	Single use item; do not re-use
	A-Recyclable
	Non-rechargeable battery
	Do not short circuit battery
	Do not crush battery
	Refer to instruction manual
	Caution
	Insert Pad-Pak this way
	Manufacturer
	Non-sterile
	Lot number

	Medical device
	Pressure limitations
	Humidity limitations
	Catalog number
	Unique device identification
	Battery and electrodes
	Ingress protection classified as IP56 according to EN 60529
	Automated external defibrillator
	Defibrillation protected, Type BF connection
	Do not incinerate or expose to high heat or open flame
	Not made with natural rubber latex
	Authorized Representative in the European community
	Date of manufacture; YYYY-MM-DD

	Temperature limitation as indicated
	Expiration date for Pad-Pak; YYYY-MM-DD
	Dispose of in accordance with country requirements
	Do not use if package is damaged and consult instructions for use
	Rx only **Caution:** US Federal law restricts this device to sale by or on the order of a physician.
	Serial number; 14 digit, for example, "22D90000001AYY" where the last three characters denote month (single letter) and year of manufacture (2-digit number), A = January, B = February...and 22 = year
	Automated external defibrillator: with respect to electrical shock, fire and mechanical hazards only in accordance with: • AAMI ES60601-1:2005/(R)2012 • CAN/CSA-C22.2 No. 60601-1:14/(R)2018 • IEC 60601-1 Ed 3.1 (2012) • IEC 60601-2-4:2010/AMD1:2018

Appendix B Troubleshooting

Indication	Solution
Flashing red status indicator/ continual beeping, or no status indicator light is lit	Check the expiration date on your Pad-Pak (see Set up your HeartSine samaritan PAD 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 HeartSine 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.
"Low battery" warning	While this message does not indicate a fault, you should replace the battery as soon as possible. The first time you hear the message "Warning low battery," the AED 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.
"Memory full" prompt	This message does not indicate a fault. The memory is full and can no longer record ECG data or events. However, the AED can still analyze and deliver a shock if required. Contact HeartSine Technologies Technical Support for guidance on how to clear the memory.
Three rapid beeps when device is turned off or after weekly self-test has been performed	Your AED 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 AED, with its battery and electrodes is designed to operate, and verify that the beeping has stopped.

Indication	Solution
Red status indicator and beeping while device is on	**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
"Device service required" warning	**WARNING:** IF YOU HEAR THIS MESSAGE DURING USE, SEEK AN ALTERNATIVE DEFIBRILLATOR IMMEDIATELY DO NOT ATTEMPT TO SERVICE THE DEVICE AS NO MODIFICATION OF THIS EQUIPMENT IS POSSIBLE. CONTACT HEARTSINE TECHNOLOGIES OR YOUR AUTHORIZED DISTRIBUTOR IMMEDIATELY
"Warning off button pressed" prompt	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.
"Disarming" prompt	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.
"Check pads" prompt	If you hear the voice prompt "Check pads", confirm that the pads have fully adhered to the patient as directed on the electrode placement diagram and that the skin is free from hair, moisture and debris. Adjust pads if needed. If message continues, remove the Pad-Pak and reinsert. If the message still continues, seek an alternative defibrillator and continue CPR.

Appendix B Troubleshooting

Obtaining support

If you have completed the troubleshooting steps and find the AED is still not working correctly, contact your Authorized Distributor or HeartSine Technologies Technical Support at:

heartsinesupport@stryker.com

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:

- AED has been opened
- Unauthorized modifications have been made
- AED 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
- AED has been used or stored outside its indicated temperature range
- Pad-Pak or Pediatric-Pak is not returned in its original packaging
- AED has been tested using unapproved methods or inappropriate equipment (see Warnings and cautions on pages 5-7)

Appendix C Technical data

Table 3. Specifications

Service life	
Expected service life:	Service life is defined as the length of the warranty period. Please refer to the HeartSine limited warranty statement for details (Appendix F)
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 lb (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:	32°F to 122°F (0°C to 50°C) **Note:** If the device with Pad-Pak or Pediatric-Pak has been transported while temperatures are 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:	-1,250 to 15,000 feet (-381 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
Atmospheric pressure:	572 hPa to 1060hPa (429 mmHg to 795 mmHg)

Appendix C Technical data

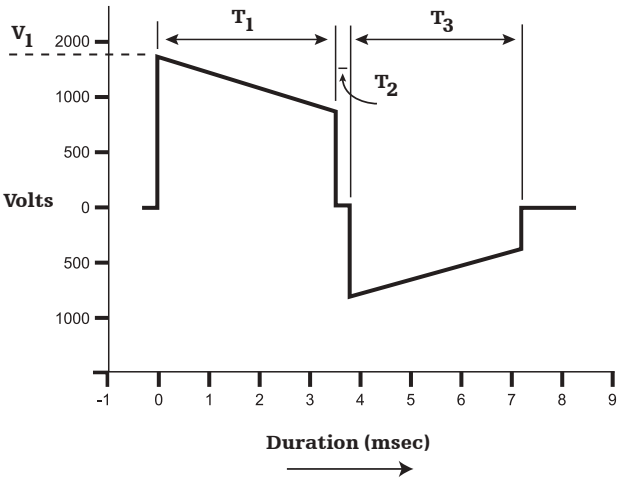
Pad-Pak and Pediatric-Pak specifications	
Weight:	0.44 lb (0.2 kg)
Battery type:	Disposable single-use combined battery and defibrillation electrode cartridge (lithium manganese dioxide ($LiMnO_2$) 18V)
Battery capacity (new):	>60 shocks at 200 J or 6 hours of battery use
Battery capacity (4 years):	>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 or Pediatric-Pak
Aircraft safety test (TSO/ ETSO-certified Pad-Pak):	RTCA DO-227 (TSO/ETSO-C142a)/EASA.21O.10042190
Patient analysis system	
Method:	Evaluates the patient's ECG, electrode contact integrity and patient impedance to determine if defibrillation is required
Sensitivity/specificity:	Meets IEC/EN 60601-2-4 (Refer to page C-9 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 Voice prompts in Appendix D)
Languages:	HeartSine samaritan PAD is available in English or Spanish. Contact your HeartSine Authorized Distributor.

Controls:	On/Off button (both models), shock button (SAM 450P only) and green tab
Defibrillator performance	
Charging time:	Typically 150 J in < 8 seconds, 200 J in < 12 seconds
Time to shock delivery following CPR:	SAM 360P: Typically 19 seconds SAM 450P: Typically 12 seconds
Impedance range:	Adult: 20 Ω to 230 Ω Pediatric: 0 Ω to 176 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: 150 J; Shock 2: 150 J; Shock 3: 200 J Pediatric-Pak: Shock 1: 50 J; Shock 2: 50 J; Shock 3: 50 J
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 (see pages C-12 to C-15 for full details)
Aircraft:	RTCA/DO-160G, Section 21 (Category M) RTCA DO-227 (TSO/ETSO C142a1/EASA.21O.10042190)

SCOPE Biphasic Waveform

HeartSine samaritan PAD delivers a Self-Compensating Output Pulse Envelope (SCOPE) biphasic waveform (see Figure 13) 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.

Figure 13. SCOPE Biphasic Waveform



The specific SCOPE waveform characteristics for a 200 Joules pulse are shown in Table 4. An example of waveform parameters for the Pediatric-Pak are shown in Table 5.

Table 4. Pad-Pak waveform specification

Resistance (Ohms)	Waveform voltages (Volts)	Waveform duration (ms)	
	V_1	T_1	T_3
25	1880	3.5	3.5
50	1880	5.5	5.5
75	1880	8	8
100	1880	10	10
125	1880	13	13
150	1880	14.5	14.5
175	1880	17.5	17.5
200	1880	19	19
225	1880	20.5	20.5

Table 5. Pediatric-Pak waveform specification

Resistance (Ohms)	Waveform voltages (Volts)	Waveform duration (ms)	
	V_1	T_1	T_3
25	514	7.8	5.4
50	671	8.8	6
75	751	10	6.6
100	813	10.8	6.8
125	858	11.5	7.3

Note: All values are nominal

Appendix C Technical data

Table 6. Adult energy delivery range

Patient resistance (Ohms)	Rated delivered energy (Joules)	Actual delivered energy (Joules) Min-max (150/200 J ± 10%)
25	150	135 - 165
50	150	135 - 165
75	150	135 - 165
100	150	135 - 165
125	150	135 - 165
150	150	135 - 165
175	150	135 - 165
200	150	135 - 165
225	150	135 - 165
25	200	180 - 220
50	200	180 - 220
75	200	180 - 220
100	200	180 - 220
125	200	180 - 220
150	200	180 - 220
175	200	180 - 220
200	200	180 - 220
225	200	180 - 220

Note: All values are nominal

Table 7. Pediatric energy delivery range

Patient resistance (Ohms)	Rated delivered energy (Joules)	Actual delivered energy (Joules) Min-max (50 J ± 15%)
25	50	42.5 - 57.5
50	50	42.5 - 57.5
75	50	42.5 - 57.5
100	50	42.5 - 57.5
125	50	42.5 - 57.5
150	50	42.5 - 57.5
175	50	42.5 - 57.5

Table 8. Sample pediatric nominal energy

Age (Years)	50th percentile weight* (kg)	50 J energy dose (Joules per kg)
1	10.3	4.9
2	12.7	4.0
3	14.3	3.5
4	16.0	3.2
5	18.0	2.8
6	21.0	2.4
7	23.0	2.2
8	25.0	2.0

*Doses provided in Table 8 are based on CDC growth charts for the 50th percentile body weight of boys. National Center for Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).

Note: All values are nominal

Appendix C Technical data

Motion detection algorithm (SAM 360P only)

SAM 360P uses the HeartSine 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, 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

Arrhythmia analysis algorithm

HeartSine 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, HeartSine samaritan PAD will charge and advise the user to stand clear and to press the shock button (SAM 450P) or automatically shock the patient after a verbal 3, 2, 1 countdown (SAM 360P). If no shock is advised, the AED will pause to allow the user to deliver CPR.

The HeartSine 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 HeartSine samaritan PAD ECG arrhythmia analysis algorithm's sensitivity and specificity meet the requirements of IEC/EN 60601-2-4.

The HeartSine samaritan PAD ECG arrhythmia analysis algorithm performance is summarized in Table 9.

Table 9. Performance of the HeartSine 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[1] DF39)	✔ Met
Non-shockable rhythm: NSR[2]	100	165	Specificity >99% (exceeds AAMI DF39)	✔ Met
Non-shockable rhythm: AF, SB, SVT, Heart Block, Idioventricular, PVCs[2]	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

[2] 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

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, 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).

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 10 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 10. 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"	

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 8 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 8 years old weighing more than 55 lb (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 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

Appendix C Technical data

Electromagnetic conformity - guidance and manufacturer's declaration

HeartSine samaritan PAD is suitable for use in all professional and domestic establishments. It is not intended for use near intentional transmitters of radio energy such as high frequency surgical equipment, radar installations or radio transmitters, nor in the vicinity of magnetic resonance imaging (MRI) equipment.

HeartSine samaritan PAD is intended for use in the electromagnetic environments specified in Table 11 on next page and Table 12 on pages C-14 and C-15. The user of HeartSine samaritan PAD should assure that it is used in such an environment

The essential performance of HeartSine samaritan PAD is the ability to provide defibrillation therapy following correct analysis of a shockable/non-shockable rhythm, together with the provision of appropriate operator instruction. Operation outside of the environment specified in Table 12 could result in the misinterpretation of the ECG rhythms, interference to the audio or visual prompts, or the inability to deliver therapy.

There are no special maintenance procedures required to ensure that the essential performance and basic safety of HeartSine samaritan PAD are maintained with regard to electromagnetic disturbances over the service life of the device.

Table 11. Electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment – guidance
RF CISPR 11	Group 1 Class B	HeartSine samaritan PAD 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. HeartSine samaritan PAD is 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 emission IEC/EN 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emission IEC/EN 61000-3-3	Not applicable	

Appendix C Technical data

Table 12. Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 8kV Contact ± 15kV Air	± 8kV Contact ± 15kV Air
Electrical fast transients/bursts IEC/EN 61000-4-4	Not applicable	Not applicable
Surges, line to line IEC/EN 61000-4-5	Not applicable	Not applicable
Surges, line to ground IEC/EN 61000-4-5	Not applicable	Not applicable
Voltage dips, interruptions and variations on power supply input lines IEC/EN 61000-4-11	Not applicable	Not applicable
Power frequency (50/60Hz) Magnetic Field IEC/EN 61000-4-8	30A/m	30A/m
Radiated RF IEC/EN 61000-4-3	10 V/m 80MHz – 2.7GHz	10V/m[a] 80MHz – 2.7GHz 80% AM 5Hz modulation 20V/m[b] 80MHz – 2.7GHz 80% AM 5Hz modulation
Conducted RF IEC/EN 61000-4-6	3V rms outside ISM and amateur radio bands[d] 6V rms inside ISM and amateur radio bands[d]	6V rms 1.8MHz to 80MHz 80% AM, 5Hz modulation

Table 12. (continued)

Immunity test	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	There are no special requirements with respect to electrostatic discharge
Electrical fast transients/bursts IEC/EN 61000-4-4	
Surges, line to line IEC/EN 61000-4-5	
Surges, line to ground IEC/EN 61000-4-5	
Voltage dips, interruptions and variations on power supply input lines IEC/EN 61000-4-11	
Power frequency (50/60Hz) Magnetic Field IEC/EN 61000-4-8	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. There are no special requirements for non-commercial/non-hospital environments
Radiated RF IEC/EN 61000-4-3	Portable and mobile RF communications equipment should be used no closer to any part of HeartSine samaritan PAD, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter, or 12 in (30 cm), whichever is greater.[c] Interference may occur in the vicinity of equipment marked with this symbol 
Conducted RF IEC/EN 61000-4-6	

Appendix C Technical data

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

[a] Test level to show compliance with the criteria identified as providing basic safety and essential performance.

[b] Test level to show compliance with the additional requirements of the particular standard IEC60601-2-4 relating to no inadvertent shock delivery.

[c] Field strengths from fixed transmitters, such as base stations for cellular telephones, amateur radio, FM and AM radio broadcast and television broadcast cannot be predicted theoretically with a great deal of accuracy. In such cases, an electromagnetic site survey should be considered to properly assess the electromagnetic environment. If the measured field strength in the location in which HeartSine samaritan PAD is intended to be used exceeds the applicable RF compliance levels noted above, the device should be observed to verify normal operation. If abnormal performance is observed, consideration should be given to relocating HeartSine samaritan PAD if possible.

[d] The ISM (industrial, scientific and medical) bands between 0.15 MHz 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. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Appendix D Voice prompts

Following are the voice prompts used by HeartSine samaritan PAD. 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 360P	SAM 450P
Before and during analysis		
"Adult patient" (heard when Pad-Pak installed)	✔	✔
"Child patient" (heard when Pediatric-Pak installed)	✔	✔
"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"	✔	
"Check pads"	✔	✔
CPR Rate Advisor		
"Push faster"*		✔
"Push slower"*		✔
"Good speed"*		✔

Appendix D Voice prompts

For all patients

Prompt	SAM 360P	SAM 450P
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"*	✔	✔

* 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[2,3,4].

The results from the preclinical laboratory testing performed on HeartSine 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 SAM 360P and SAM 450P of 99%.

Two animal studies were conducted to determine whether the SCOPE waveform induces refibrillation 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 refibrillation 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 refibrillation 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 SAM 360P and SAM 450P devices.

Published clinical data

The study by Walsh et al. evaluated the SCOPE defibrillation waveform used in 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 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 = 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 = 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 patients (32%) received amiodarone, whereas 29 of 40 HSXL patients (73%) and 34 of 38 SAM patients (89%) received epinephrine (p = 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 = 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 13). 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 waveforms[5]. These data were not powered to demonstrate differences in return of spontaneous circulation or survival.

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

Appendix E Safety and effectiveness data

Table 13. Summary of successful defibrillation episodes with both devices

	HeartSine samaritan (100-150-200 J)		Philips HeartstreamXL (150-150-150 J)				
Success by	Frequency	Proportion	Frequency	Proportion	Mean difference	SD	Probability that samaritan better than Heartstream
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%) 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.[5]

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 14 summarizes the relationship between event location and user training, response time, and percentage survival to hospital admission.

Table 14. 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 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 15 summarizes shock success and survival by defibrillator model.

Appendix E Safety and effectiveness data

Table 15. 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

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 literature[5]. Finally, algorithm performance for combined VF/VT had a sensitivity of 98.8% in this analysis.

Appendix F Limited warranty statement

What is covered?

Stryker provides to the original end user a limited warranty that all HeartSine products that are purchased in the United States from a distributor, sub-distributor, person or entity authorized by Stryker ("Authorized Agents") are substantially free from defects in material and workmanship. This limited warranty applies only to the original end user and may not be assigned or transferred. An original end user is one who is able to provide proof of purchase from Stryker or an Authorized Agent. Persons who are not original end users take the products "as is" and with all faults. Please be prepared to provide proof of purchase demonstrating that you are the original end user and eligible to make a valid claim under this warranty. If you are not sure if the distributor, sub-distributor, person or entity from whom you purchased any HeartSine samaritan products is authorized by Stryker please contact Customer Support at 800 442 1142 or heartsinesupport@stryker.com.

For how long?

HeartSine warrants, from the date of the sale to the original end user, the HeartSine samaritan PAD for the full eight (8) year service life. Products with a stated expiration date are warranted until such expiration date.

Limited warranty does not cover:

This limited warranty does not cover defects or damages of any sort resulting from, but not limited to, accidents, damage while in transit to our service location, alterations, unauthorized service, unauthorized product case opening, failure to follow instructions, improper use, improper or inadequate maintenance, abuse, neglect, fire, flood, war or acts of God. We do not warrant your HeartSine products to be compatible with any other medical devices.

This limited warranty is void if:

You purchased any HeartSine products from anyone other than an Authorized Agent; your HeartSine product is serviced or repaired by anyone other than Stryker; your HeartSine product is opened by unauthorized personnel or if a product is not used in accordance with the "Instructions for Use" and the "Indications for Use" provided with your product; your HeartSine product is used in conjunction with incompatible parts or accessories, including, but not limited to batteries. Parts and accessories are not compatible if they are not HeartSine products.

What you should do:

As the original end user you should return the completed postage-paid warranty registration card within 30 days of original purchase to HeartSine Technologies at the address provided on the card. If you wish to mail the warranty card in a stamped envelope, please use the following address:

HeartSine Technologies
PO Box 1297
Newtown, PA 18940-0874

Appendix F Limited warranty statement

Or register online using the Warranty Registration link on our website heartsine.com. To obtain warranty service for your HeartSine product, contact your local Stryker Authorized Agent or call Customer Support at 800 442 1142. Our technical representative will try to resolve your issue over the phone. If necessary, and at our sole discretion, we will arrange for service or a replacement of your HeartSine product. You must not send back any product without our authorization.

What we will do:

If your HeartSine product contains defects in material or workmanship and it is returned, at the direction of a technical service representative, within the warranty period, we, at our sole discretion, will repair your product or replace it with a new or reconditioned product of the same or similar design. The repaired or reconditioned product will be warranted subject to the terms and conditions of this limited warranty for either (a) 90 days or (b) the remainder of the original warranty period, whichever is longer, provided the warranty applies and the warranty period has not expired.

If our inspection does not detect any defects in material or workmanship of your HeartSine product, regular service charges will apply.

Obligations and limitation of liability:

THE FOREGOING LIMITED WARRANTY IS IN LIEU OF AND SPECIFICALLY EXCLUDES AND REPLACES ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, TITLE, AND NON-INFRINGEMENT. Some states do not allow limitations on how long an implied warranty lasts, so this limitation may not apply to you.

NO PERSON (INCLUDING ANY AGENT, DEALER, OR REPRESENTATIVE OF Stryker) IS AUTHORIZED TO MAKE ANY REPRESENTATION OR WARRANTY CONCERNING HEARTSINE PRODUCTS, EXCEPT TO REFER TO THIS LIMITED WARRANTY.

YOUR EXCLUSIVE REMEDY WITH RESPECT TO ANY AND ALL LOSSES OR DAMAGES RESULTING FROM ANY CAUSE WHATSOEVER SHALL BE AS SPECIFIED ABOVE. Stryker SHALL IN NO EVENT BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND, INCLUDING, BUT NOT LIMITED TO, EXEMPLARY DAMAGES, PUNITIVE DAMAGES, COMMERCIAL LOSS FROM ANY CAUSE, BUSINESS INTERRUPTION OF ANY NATURE, LOSS OF PROFITS OR PERSONAL INJURY OR DEATH EVEN IF WE HAVE BEEN ADVISED OF THE POSSIBILITIES OF SUCH DAMAGES, HOWEVER OCCASIONED, WHETHER BY NEGLIGENCE OR OTHERWISE. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

References

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heartsine.com

HeartSine samaritan PAD user manuals in all available languages can be found on our website at **heartsine.com/product-manuals**

To view information regarding environmental regulatory requirements, please refer to **heartsine.com/environmental-regulations**

For further information contact us at heartsinesupport@stryker.com or visit our website at heartsine.com

Packaging and labeling for your HeartSine AED, and/or Pad-Pak are for illustration purposes and may be different in your region than those shown in this publication.

Please report any serious incident that occurs with this device to HeartSine Technologies, Ltd. and to the US Food and Drug Administration as per local regulations.

CE 0123 Pad-Pak; Pediatric-Pak

HeartSine samaritan PAD: UL Classified. See complete marking on product.

Date of Issue: 03/2022
Made in U.K.
M0000007216-AA EN-US
HeartSine SAM 450P is not available for sale outside of the U.S. or Japan.

!USA | Rx Only

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