HeartSine®

EN-US

HeartSine® samaritan® PAD
user manual

SAM 350P

Semi-automatic defibrillator

Important:

Please watch online training videos

heartsine.com/videos

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.

Indications for use

The HeartSine samaritan PAD 350P (SAM 350P) is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- **Unconscious**
- **Not breathing normally**

The SAM 350P is intended for use in the public access and home environments. Anyone who might use the HeartSine SAM 350P should:

- Watch the training videos at heartsine.com/videos
- Carefully read the User Handbook and quick start guides
- Review these materials periodically

The AED is 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). It is 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

Do not use the HeartSine samaritan PAD to provide treatment if the patient is responsive or conscious.

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.

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 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.

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 24-28 for adult placement and pages 31-35 for a young child, and on the device. Wrong placement or the presence of air, hair, clothing, bandages 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

SAM 350P is intended for use in the public access and home environments. Anyone who might use HeartSine SAM 350P should:

- Watch the training videos at heartsine.com/videos
- Carefully read this User Handbook and quick start guides
- Review these materials periodically

Training on CPR and in the use of an AED is strongly recommended. You should attend a basic life support course, which will teach you to perform CPR and use an AED.

Regular maintenance

Check the device periodically. See Maintain your AED on page 41.

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 AED on page 36.

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.

Notes

Testing with simulators and manikins

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

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 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. 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.

When should I use the AED?

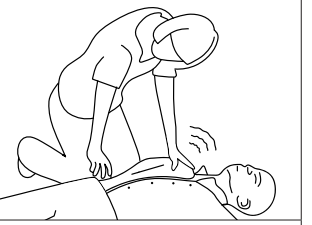
You should use your HeartSine SAM 350P on a person suffering cardiac arrest who is:

- Unconscious
- Not breathing normally

You can tell this by doing the following:

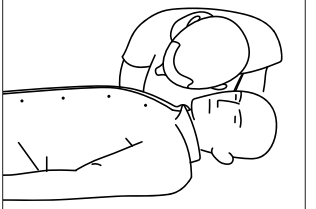
Shake the person

- Gently shake the person to see if they respond
- If the person is conscious, **do not use** HeartSine SAM 350P



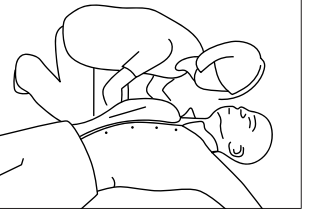
Listen to breath

- Put your ear next to the person's mouth to hear if they are breathing normally
- If the person is breathing normally, **do not use** HeartSine SAM 350P



Look for breath

- Look at person's chest to see if they are breathing normally
- If the person is breathing normally, **do not use** HeartSine SAM 350P



Introduction

About HeartSine samaritan PAD

HeartSine samaritan PAD 350P (HeartSine SAM 350P) Automated External Defibrillator (AED) is designed to automatically assess the patient's heart rhythm and to quickly provide a defibrillation shock to victims of sudden cardiac arrest (SCA). The AED provides instructions that you can hear and see to guide you through the entire resuscitation process, including CPR.

HeartSine SAM 350P is a semi-automatic defibrillator, which means that you will need to push the shock button if the AED tells you that a shock is required.

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).

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.

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 SAM 350P is intended for use in the public access and home environments. Anyone who might use HeartSine SAM 350P should:

- Watch the training videos at heartsine.com/videos
- Carefully read this User Handbook and quick start guides
- Review these materials periodically

Training on CPR and in the use of an AED is strongly recommended. You should attend a basic life support course, which will teach you to perform CPR and use an AED. The company or store where you bought your HeartSine AED may provide CPR/AED training, or you can search online to find CPR/AED training near you or contact your local government health department for information on certified training organizations in your area.

HeartSine Technologies recommends that this training is kept up to date with regular refresher courses as and when recommended by your training provider.

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 safety and effectiveness data.

Getting to know your HeartSine SAM 350P AED

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

Attach pads indicator/ 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 350P is compatible with both the Pad-Pak and Pediatric-Pak.

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

Speaker
Listen for the metronome and verbal prompts.

Green tab
Pull this tab to release the electrodes.

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

Shock button
Press this button to deliver a therapeutic shock.

Safe to touch indicator/action arrows
You may touch the patient when the action arrows around this indicator are flashing.

On/Off button
Press this button to turn on or turn off the device.

Pad-Pak
Single-use cartridge with battery and electrode pads.

About Pad-Pak and Pediatric-Pak

Each Pad-Pak and Pediatric-Pak is a single-use removable cartridge that includes the battery and electrode pads in a single unit, for use with HeartSine samaritan PAD. Each Pad-Pak and Pediatric-Pak contains one set of disposable defibrillation pads and a $LiMnO_2$ (18V – 1500mAh) non-rechargeable battery.

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

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

Pad-Pak also is available in a TSO/ETSO/EASA-certified version for use on commercial fixed-wing aircraft (called Aviation Pad-Pak).

Pad-Pak and Pediatric-Pak options are provided in Table 1.

One Pad-Pak is always provided as standard with each HeartSine samaritan PAD. Pediatric-Pak or additional Pad-Paks are available as an option.

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.

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

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

Pad-Pak

Pediatric-Pak

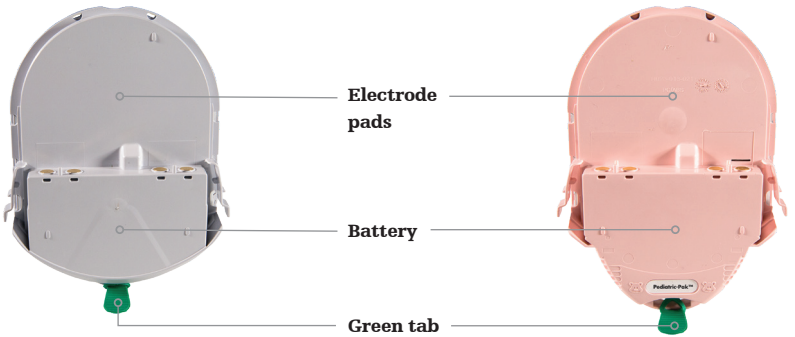


Table 1. Comparing Pad-Pak, Pediatric-Pak and Aviation Pad-Pak

Feature	Pad-Pak	Pediatric-Pak	Aviation Pad-Pak
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

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

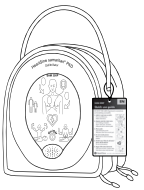
Set up your AED

1. Watch the training video

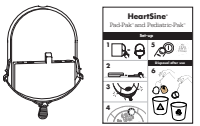
- Scan the QR code with your smartphone camera to link to training videos page
- Watch Set up Your AED at heartsine.com/videos

2. Unpack your AED and Pad-Pak

Unpack your AED, removing these items from the box:
HeartSine SAM 350P AED in carry case with attached quick use guide hangtag

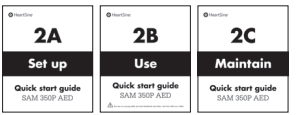


Unpack your Pad-Pak:
Pad-Pak (Battery and electrode cartridge), Set up insert (Pad-Pak is provided in a separate shipping box. It must be inserted into the AED at Set up)



Important notice plus Warranty Registration Card

Quick start guides



User Handbook

Note: Retain the Pad-Pak packaging in case you need to return the Pad-Pak to HeartSine Technologies

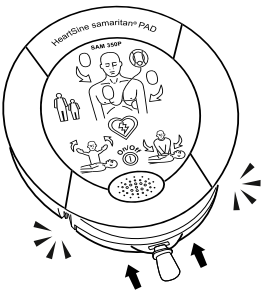
3. Remove AED from carry case and place AED and Pad-Pak on a table

- Remove AED from carry case
- Place your HeartSine SAM 350P AED and Pad-Pak face up on a table
- Check that the expiration date (YYYY-MM-DD) on the back of the Pad-Pak has not passed

⚠ **CAUTION:** If the expiration date has passed, immediately replace the expired Pad-Pak. **Do not** use the expired Pad-Pak

4. Insert the Pad-Pak

- Slide the Pad-Pak into bottom of the AED as shown until you hear the "double click"



⚠ **WARNING: Do not** USE IF THE PAD-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

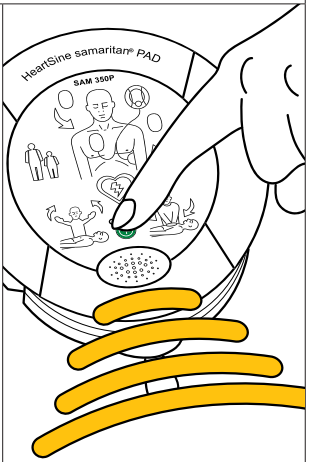
⚠ **CAUTION: Do not** pull the green tab on the Pad-Pak at this time. If you have pulled the tab or opened the foil around the pads, you may need to replace your Pad-Pak. If you are not sure if you need to replace your Pad-Pak, contact us at heartsinesupport@stryker.com

5. Check the language on the AED

- Press the On/Off button to turn on the AED
- Listen for – **but do not follow** – the voice prompts to ensure that you hear English and do not hear a warning message
- If you do not hear your expected language, email Stryker at heartsinesupport@stryker.com
- Press the On/Off button again to turn off the AED

⚠ **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.

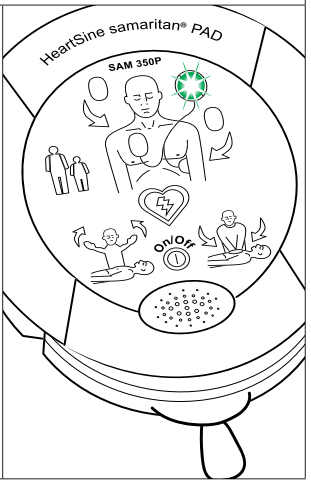
Note: Only turn on the AED once. If you turn it on and off over and over, you will drain the batteries before the expiration date and may need to replace the Pad-Pak



6. Check that the status indicator is flashing green

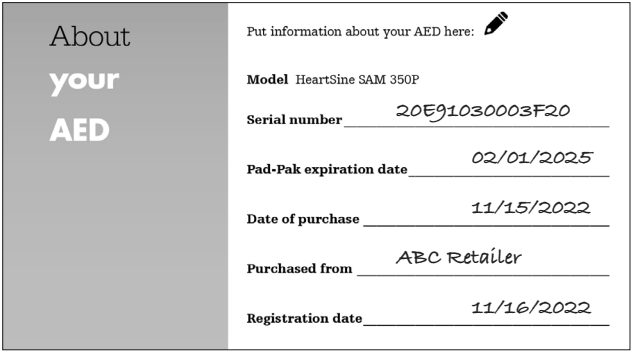
- Check that the status indicator on the AED is flashing green
- If you have not heard a warning message and the status indicator continues to flash green, the device is ready for use

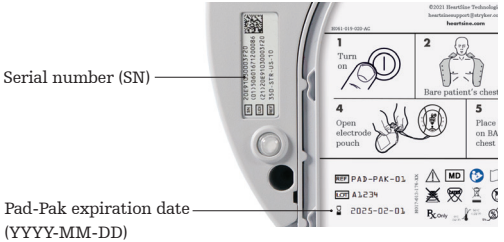
Note: Do not remove Pad-Pak from the AED as it must be stored with the Pad-Pak inserted



7. Write AED information on inside front cover of User Handbook

- Find the AED serial number on the rear of the AED and write it in the space provided on inside front cover of User Handbook provided with your AED
- Find the expiration date on the rear of the Pad-Pak (YYYY-MM-DD) and write it in the space provided
- Write the date you purchased your HeartSine AED and the name of the company or store where you bought your AED





⚠ **CAUTION:** If the expiration date has passed, immediately replace the expired Pad-Pak. **Do not** use the expired Pad-Pak

8. Register your AED

We are required to track the location of each HeartSine AED in the market. Therefore, it is very important that you register your AED. This will enable us to contact you with any important updates about your AED.

- Please register your AED at heartsine.com/register
- Or, complete the warranty registration card and return it to the HeartSine Technologies address on the card
- 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

Note: If you move the AED to another location or sell or give the AED to another person, please provide the updated information to us using the online registration page or email heartsinesupport@stryker.com

Scan the QR code with your smartphone camera to link to registration page:

heartsine.com/register

9. Review training videos, quick start guides and User Handbook

So you and anyone who might use the AED will be ready to use HeartSine samaritan PAD 350P:

- Watch the training videos at heartsine.com/videos
- Read the quick start guides
- Review the User Handbook which provides basic instructions on using the AED. For full instructions, you can review this User Manual

Scan the QR code with your smartphone camera to link to training videos:

heartsine.com/videos

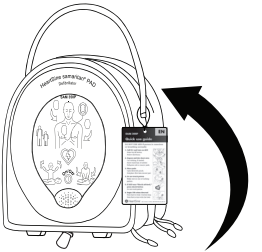
10. Place AED, instructions, scissors and razor in carry case

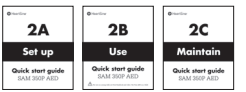
Place the following in the storage compartment on the back of the carry case:

- User Handbook
- Quick reference guides
- Scissors (Not included in AED package*)
- Razor (Not included in AED package*)
- If you ordered an extra Pad-Pak or a Pediatric-Pak, remove each from the box and place it in the storage compartment

Note: The hangtag tied to your carry case is a quick use guide that can help remind you how to use your AED in an emergency

*You may need scissors to cut a person's clothing and a razor to shave a chest with a lot of hair. You can use your own scissors or razor or you may be able to buy a kit with scissors and a razor from the AED store or company where you bought the AED.

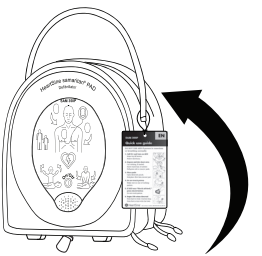




11. Store your AED to complete the set up

- Place the HeartSine AED with the Pad-Pak inserted in its supplied soft carry case
- Store your AED where it will be seen and heard, out of reach of small children and pets
- Store the AED in an unobstructed, secure location in a clean, dry environment, where the temperature is between 32°F to 122°F (see environmental specifications in 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



12. Create a service schedule

- Create a weekly and monthly service schedule
- See Maintain your AED on page 41

13. Check that you completed all of the set up steps:

- ☐ **Step 1.** Watch the Set up your AED video.
- ☐ **Step 2** Unpack.
- ☐ **Step 3.** Remove AED from carry case.
- ☐ **Step 4.** Insert the Pad-Pak.
- ☐ **Step 5.** Check the language on the AED.
- ☐ **Step 6.** Check that status indicator is flashing green.
- ☐ **Step 7.** Record AED information/Pad-Pak expiration date.
- ☐ **Step 8.** Register your AED.
- ☐ **Step 9.** Review training videos and User Manual.
- ☐ **Step 10.** Place AED, instructions, scissors and razor in carry case.
- ☐ **Step 11.** Store your AED.
- ☐ **Step 12.** Create a service schedule. (See Maintain your AED on page 41.)

Use your AED on an adult

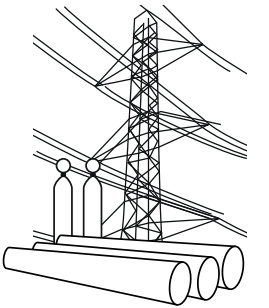
Defibrillation therapy is tailored depending on whether a Pad-Pak or Pediatric-Pak is installed. For an adult patient or a child patient over 8 years of age or weighing 55 lb or over, use the Pad-Pak. Follow these steps to use your AED, which will provide you with step-by-step voice prompts. For a full list of voice prompts for your device, see Voice prompts in Appendix D.

If the patient is under 55 lb (25 kg) or 1 to 8 years of age, refer to the Use your AED on a young child section on page 29.

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.

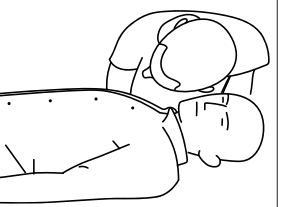
1. Remove danger

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



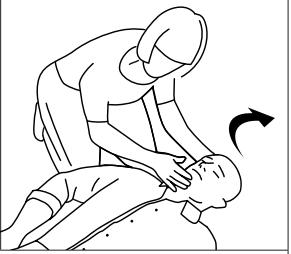
2. Check for a response

- 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

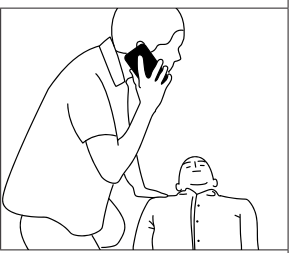


3. Check for airway

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



4. Call 911 for medical help



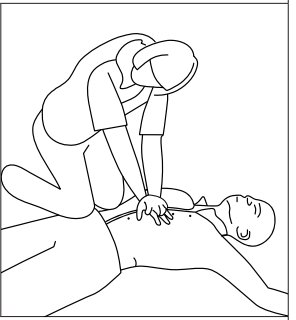
5. Get the AED

- Ask others nearby to get the AED

6. Begin CPR (until AED arrives)

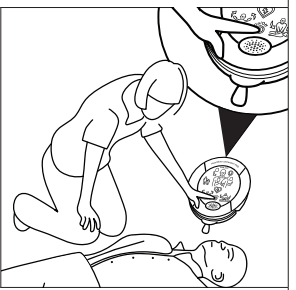
While waiting for the AED, begin CPR.

- Push hard between 2 to 2.4 inches (5 to 6 cm) deep
- Push fast at a rate of between 100 and 120 compressions per minute
- If you feel able to give rescue breaths perform 30 compressions followed by two rescue breaths



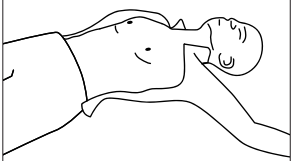
7. Press the On/Off button to turn on the AED and follow the voice directions

- Kneel next to the patient
- Place the AED on the floor next to you
- Press the On/Off button to turn on AED
- Listen for the voice prompts and follow the directions



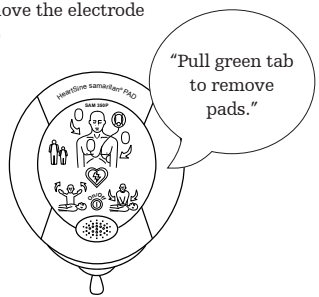
8. Expose and dry chest area

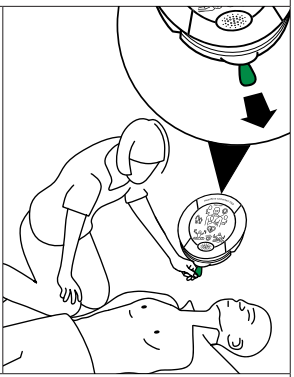
- Remove clothing to expose the patient's bare chest, removing any metal (bras or jewelry) where possible from the pad placement area
- Cut the clothing with scissors, if needed
- If patient's upper body is wet or clammy, dry the chest area
- If patient has a lot of chest hair, use a razor to quickly shave the hair where the pads will be placed



9. Pull the green tab

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

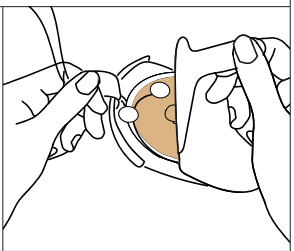




10. Open the electrode pouch

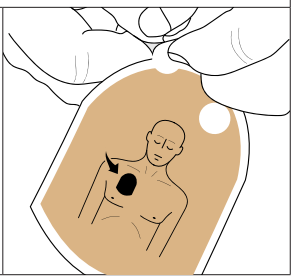
- With both thumbs on the foil tabs, open the foil to release the pads

⚠ **WARNING: DO NOT** USE THE PADS IF POUCH IS OPENED OR DAMAGED; IMMEDIATELY REPLACE THE PAD-PAK



11. Peel first pad from liner

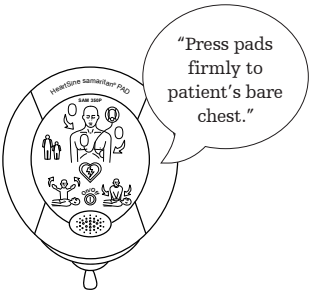
- With both thumbs on the white and clear round tabs, peel the first pad from the plastic liner

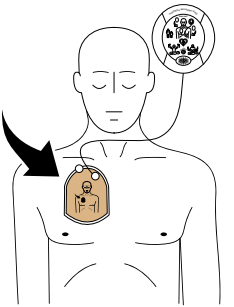


12. Place first pad

- Place the first pad as shown in picture
- For a patient over 8 years of age or weighing over 55 lb (25 kg), place the first pad vertically on the bare right chest
- For use on a young child (from 1 to 8 years of age or weighing 55 lb or less), see Use your AED on a young child on page 29.

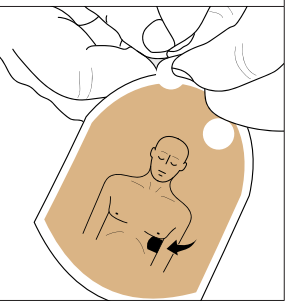
Note: If you are placing pads on a patient with a pacemaker, do not place pads on top of the implant, which you will see as a lump in the skin or a scar. Make sure the pads are placed at least 3.1 inches (8 cm) away from the pacemaker





13. Peel second pad from liner

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

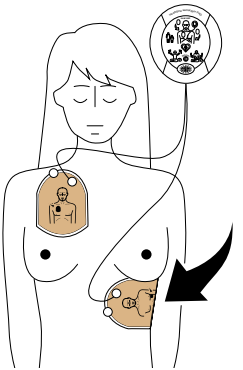


14. Place second pad

- Place the second pad as shown in picture
- For a patient over 8 years of age or weighing over 55 lb (25 kg), place the second pad horizontally on the bare left rib cage
- For use on a young child (from 1 to 8 years of age or weighing 55 lb or less), see Use your AED on a young child on page 29.

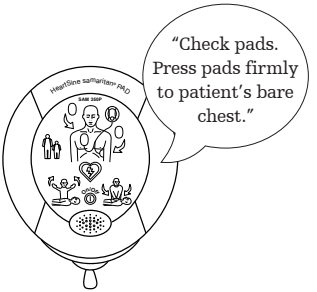
⚠ **WARNING:** PADS SHOULD BE AT LEAST 1 INCH APART AND NEVER TOUCHING ONE ANOTHER

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



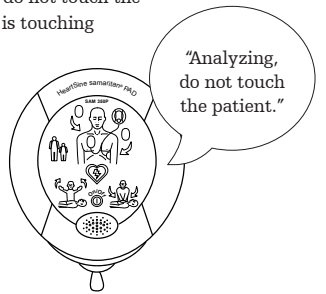
After you have placed pads on the patient's chest, if you continue to hear "Check pads. Press pads firmly to patient's bare chest," check that:

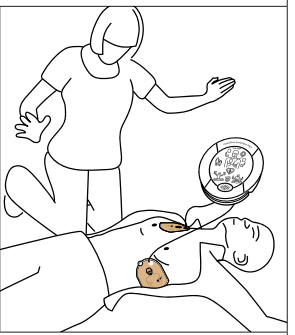
- Pads are placed correctly as shown in the pictures
- Pads are not touching and at least 1 inch (2.5 cm) apart
- Entire surface of each pad is stuck to bare skin
- If the chest is hairy, shave the chest
- If the chest is wet, dry the chest
- Ensure the Pad-Pak has not expired, and is correctly inserted into the device
- If the message continues, seek an alternative defibrillator and continue CPR



15. Do not touch the patient

- When you hear "Analyzing, do not touch the patient," make sure no one is touching the patient

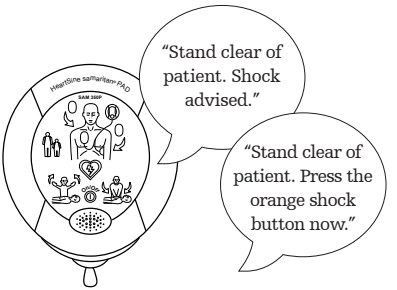


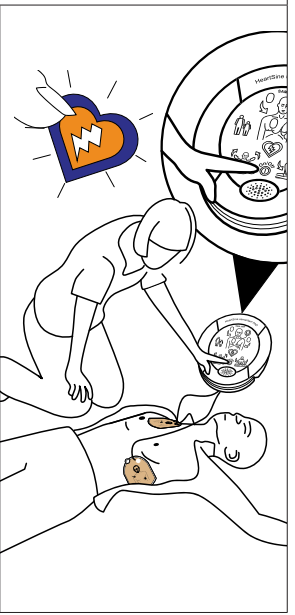


16. If a shock is needed, stand clear and press the shock button (as directed)

- When you hear "Stand clear of patient. Shock advised," lean away from the patient as directed
- When you hear "Stand clear of patient. Press the orange shock button now," press the flashing orange shock button to deliver a shock

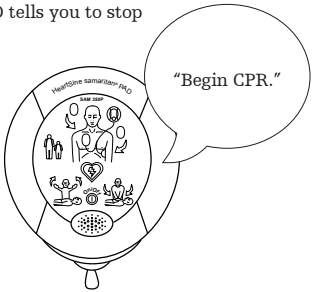
⚠ **CAUTION:** Once a non-shockable rhythm is detected, HeartSine samaritan PAD will end its ready to shock condition if it had previously decided to shock

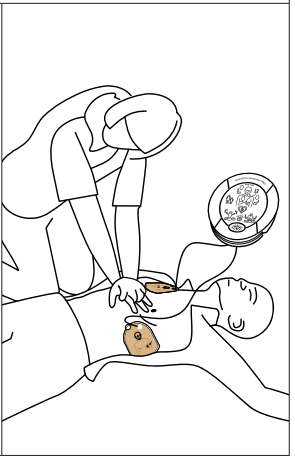




17. Begin CPR when directed

- When you hear "Begin CPR," begin CPR on the patient
- Place overlapping hands in the middle of the patient's chest
- With your arms straight, press down hard and quickly in time with the beat
- Continue CPR until the AED tells you to stop





18. Continue to follow the directions until help arrives

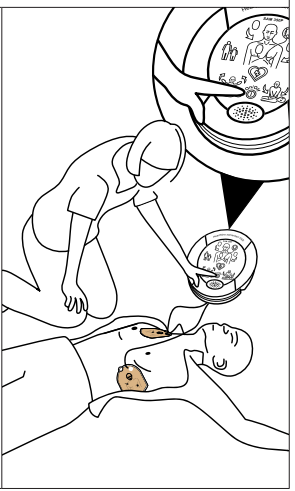
Follow the directions, which may include providing additional CPR and shocks, until:

- Patient begins breathing normally or is conscious
  or
- Medical help arrives

After emergency services has taken over care of the person:

- Press the On/Off button to turn off the AED
- Remove the pads and stick pads together, with the sticky sides stuck to one another
- For instructions on disposing of the used Pad-Pak and electrode pads, see page 36

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



Use your AED on a young child

Defibrillation therapy is tailored depending on whether a Pad-Pak or Pediatric-Pak is installed. If the person is a young child (from 1 to 8 years of age or weighing 55 lb or less), you should use a pink Pediatric-Pak in place of the gray Pad-Pak, if available. If a Pediatric-Pak is available, remove the Pad-Pak and insert the Pediatric-Pak. However, if you do not have a Pediatric-Pak, you may continue using the Pad-Pak.

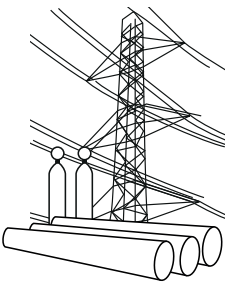
Follow these steps to use your AED on a young child, which will provide you with step-by-step voice prompts. For a full list of voice prompts for your device, see Voice prompts in Appendix D.

⚠ **WARNING: DO NOT** USE IF THE CHILD IS UNDER ONE YEAR OLD

⚠ **WARNING: DO NOT** DELAY TREATMENT TRYING TO FIND OUT THE CHILD'S EXACT AGE AND WEIGHT. IF PEDIATRIC-PAK IS UNAVAILABLE, YOU MAY USE PAD-PAK

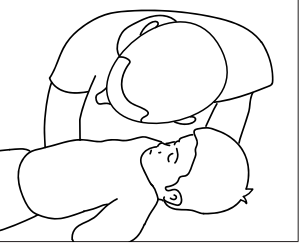
1. Remove danger

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



2. Check for a response

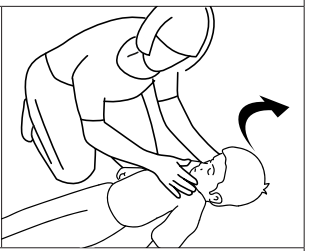
- If the patient is non-responsive, shake the patient by the shoulders while speaking loudly
- If the patient becomes responsive, do not use the AED



Use your AED on a young child

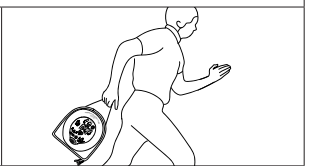
3. Check for airway

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



4. Call 911 for medical help

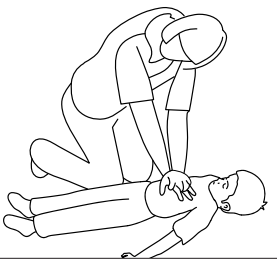
5. Get the AED



6. Begin CPR (until AED arrives)

- While waiting for the AED to arrive, begin CPR on the child
- Place overlapping hands in the middle of the child's chest*
- With your arms straight, press down hard at least two inches deep and fast (100 to 120 compressions per minute)

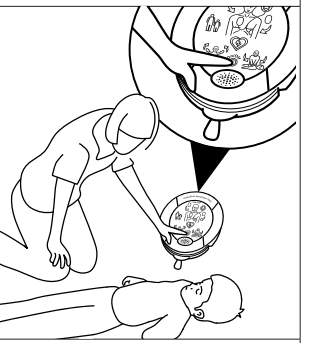
*You may use either one hand or two hands to perform CPR on children[1]



7. Press the On/Off button and follow the directions

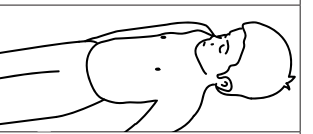
- Kneel next to the child
- Place the AED on the floor next to you
- If you have a pink Pediatric-Pak, remove the Pad-Pak and put in the Pediatric-Pak (as described in Set Up Your AED)
- If you don't have a Pediatric-Pak, continue to use the Pad-Pak
- Press the On/Off button to turn on AED
- Follow the directions

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



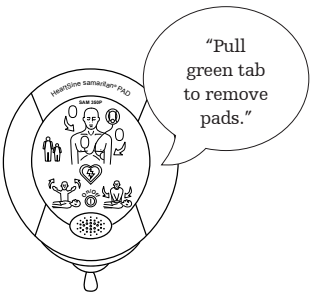
8. Expose and dry chest area

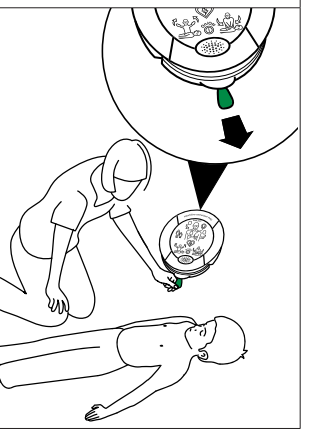
- Remove all clothing from the child's upper body
- If the child's upper body is wet, dry the chest area



9. Pull green tab to remove pads

- Pull the green tab to remove the electrode pads from the AED

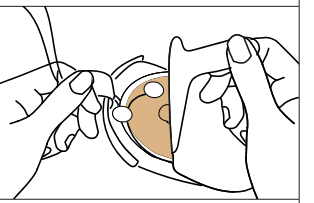




10. Open the electrode pouch

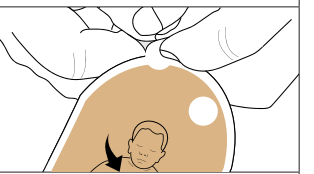
- With both thumbs on the foil tabs, open the foil to release the pads

⚠ **WARNING: DO NOT** USE THE PADS IF POUCH IS OPENED OR DAMAGED; IMMEDIATELY REPLACE THE PAD-PAK OR PEDIATRIC-PAK



11. Peel first pad from liner

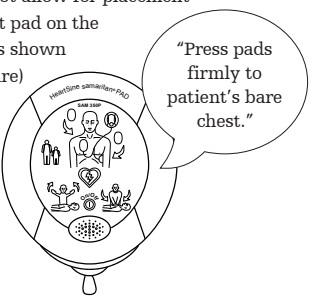
- With both thumbs on the white and clear round tabs, peel the first pad from the plastic liner

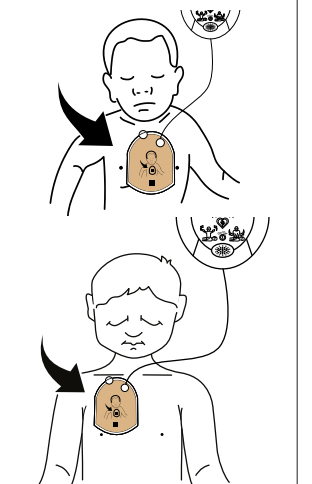


12. Place first pad

Pads should be placed at least 1 inch apart and never touching one another

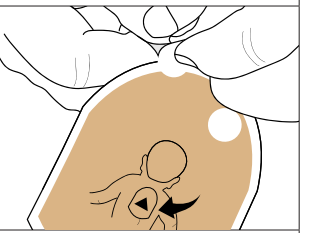
- If a child's chest is not large enough to place the pads at least 1 inch apart, place the first pad on the center of the bare chest as shown (as shown in top picture)
- If you can place the pads at least 1 inch apart on the child's chest OR if trauma does not allow for placement on the back, place the first pad on the child's bare upper chest as shown (as shown in bottom picture)





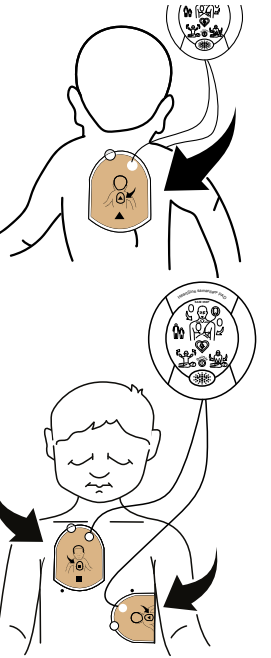
13. Peel second pad from liner

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

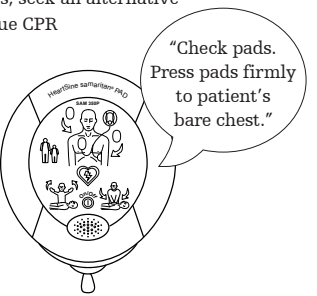


14. Place second pad

- If the child's chest is small and you cannot place the pads at least 1 inch apart, place the second pad on the center of the ribcage on the child's bare back as shown
- If you can place the pads at least 1 inch apart on the child's chest, place the second pad on the child's side of the bare chest as shown
- After you have placed pads on the child, if you continue to hear "Check pads. Press pads firmly to patient's bare chest," check that:
  - Pads are not touching and are at least 1 inch apart
  - Pads are placed correctly as shown in pictures
  - Entire surface of each pad is stuck to bare skin
  - If the chest is wet, dry the chest
  - If the message continues, seek an alternative defibrillator and continue CPR

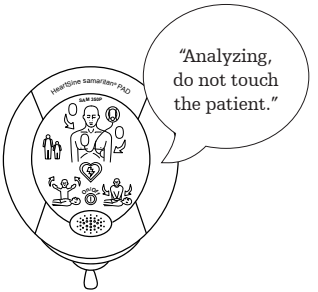


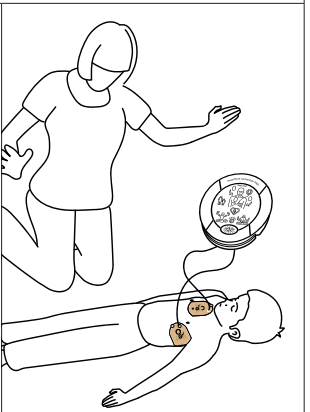
WARNING:
ELECTRODE PADS MUST BE AT LEAST 1 IN APART AND SHOULD NEVER TOUCH ONE ANOTHER



15. Do not touch the child

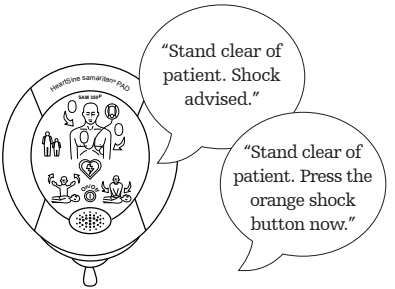
When you hear "Analyzing, do not touch the patient," make sure no one is touching the child

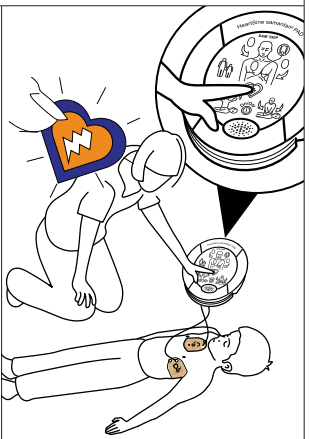




16. If a shock is needed, stand clear and press the shock button (as directed)

- When you hear "Stand clear of patient. Shock advised," lean away from the child as directed
- When you hear "Stand clear of patient. Press the orange shock button now," press the flashing shock button to deliver a shock

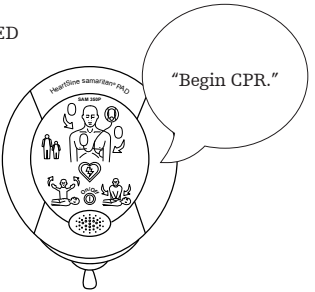


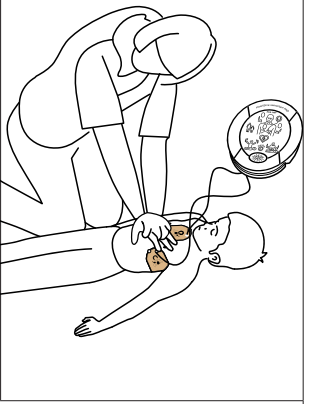


17. Begin CPR when directed

- When you hear "Begin CPR," begin CPR on the child
- Place overlapping hands in the middle of the child's chest
- With your arms straight, press down hard and fast in time with the beat
- Continue CPR until the AED tells you to stop

Note: For a small child, you may use a one-handed CPR technique





18. Continue to follow the directions

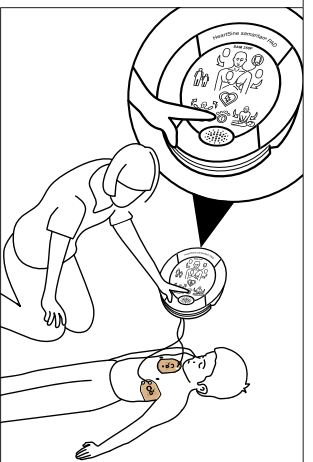
Follow the directions, which may include providing additional CPR and shocks, until:

- Child begins breathing normally or is conscious
  or
- Medical help arrives

After emergency services has taken over care of the child:

- Press the On/Off button to turn off the AED
- Remove the pads and stick pads together, with the sticky sides stuck to one another
- For instructions on disposing of the used Pad-Pak and electrode pads, see page 36

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



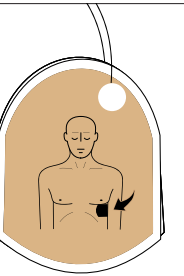
After you use your AED

Follow the steps in this section only after you have used the AED on a person. If you have not used the AED, follow the steps in the next section, Maintain your AED, to ensure that your AED is ready to use.

In the event you have used your HeartSine samaritan PAD, you must clean the AED and replace the Pad-Pak, which can be used only once.

1. Remove the electrode pads

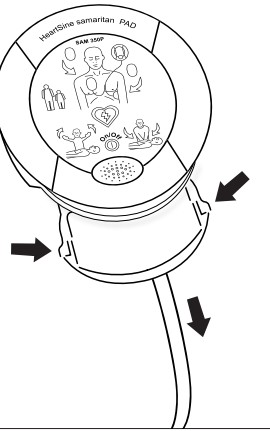
- Remove electrode pads from the person
- Stick pads together, with the sticky sides stuck to one another



2. Remove the entire Pad-Pak or Pediatric-Pak from the AED

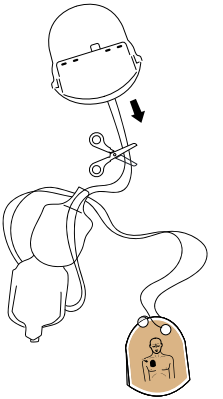
Pad-Pak or Pediatric -Pak is a single-use item, containing lithium batteries. It must be replaced after use.

- Place HeartSine samaritan PAD face up on a table or other flat surface
- Squeeze the tab on each side of the Pad-Pak
- Pull to remove Pad-Pak from the AED; it will slide forward with the electrodes attached



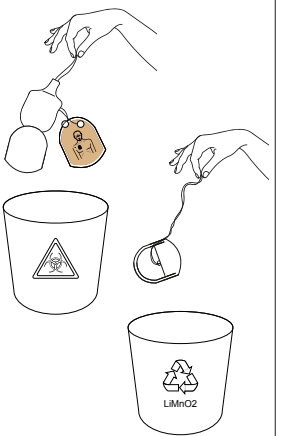
3. Separate electrode pads from battery

- Cut both cords to separate pads, tray and foil from the battery cartridge



4. Dispose of electrode pads and battery separately

- As the electrode pads may have contacted human bodily tissue, fluid or blood, they should be disposed of as infectious waste
- Alternatively, you can place the pads in a bag before putting them in your household trash
- Place the plastic tray and foil in your household trash
- As it contains lithium batteries, take the Pad-Pak battery cartridge, which should not be put into your household trash, to a place that accepts used batteries (according to your local requirements). Alternatively, you can return the Pad-Pak battery cartridge to your authorized distributor for disposal

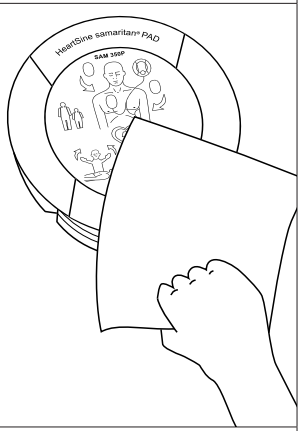


5. Clean HeartSine samaritan PAD

- Check the AED for dirt or contamination
- If necessary, use a damp cloth to clean the AED
- You may use soapy water or 70% isopropyl alcohol to remove dirt that is hard to clean

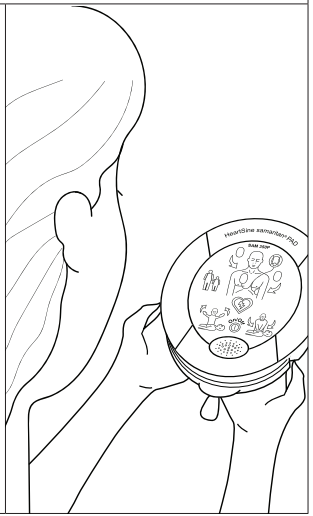
⚠ **CAUTION: Do not** clean HeartSine SAM 350P with abrasive materials, cleaners or solvents

⚠ **CAUTION: Do not** place any part of the AED in water or any type of fluid as contact with liquids may damage the AED or cause a fire or shock risk



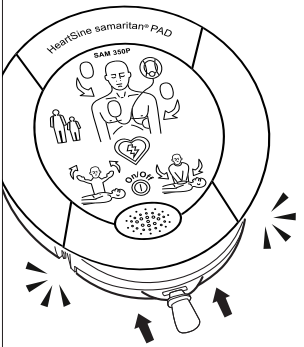
6. Check for damage

- Check HeartSine SAM 350P for damage
- If the AED is damaged, replace it immediately and email us at heartsinesupport@stryker.com



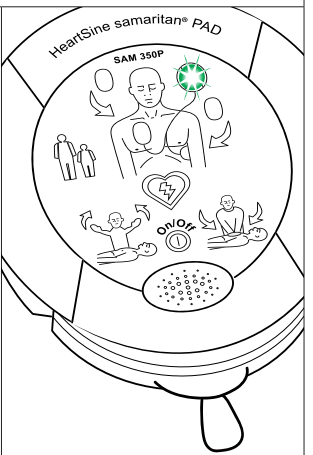
7. Insert a new Pad-Pak and note new expiration date

- Before you insert the new Pad-Pak, note the expiration date on the inside front cover of your User Handbook (see Set up your AED on page 14)



8. Check that the status indicator is flashing green

- Check that the status indicator to indicate your AED is ready for use
- Store your AED



9. Tell us when you use your AED!

Data captured when you use your AED on a patient is kept on HeartSine SAM 350P until it is erased or overwritten. You can retrieve this data using HeartSine Saver EVO software, which lets you manage the event data after your HeartSine samaritan PAD is used, and the optional USB data cable (PAD-ACC-02). Saver EVO can be downloaded from our website at no extra cost and the data cable can be purchased from an Authorized Distributor or Stryker directly.

If you send us this data, you may be eligible to receive a free replacement Pad-Pak. See heartsine.com/freepadpak for more information and instructions.

- Connect the USB data cable to the data port on the SAM 350P
- Connect the USB connector on the data cable to a PC

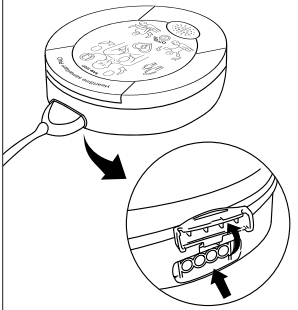
  Note: SAM 350P should be connected only to a PC running Microsoft Windows

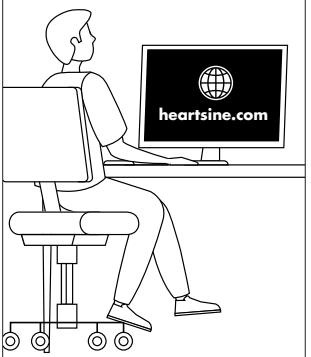
- Install and launch the HeartSine Saver EVO software
- Follow the instructions provided in the Saver EVO manual (available at heartsine.com) to save the event data from your SAM 350P
- Report use of the AED to Stryker at aedevent@stryker.com or to the AED store or company where you purchased your AED (See heartsine.com/aedevent for details)
- Once you have confirmed with Stryker that you have the correct data file, you should erase the event data from your SAM 350P

Note: Contact your Authorized Distributor or HeartSine Technologies directly for further information on managing your event data.

aedevent@stryker.com

heartsine.com





Maintain your AED

HeartSine AEDs do not require any servicing or testing as the devices are designed to perform a weekly self-test.

Your HeartSine SAM 350P AED runs a self-test each Sunday at 7 p.m. Eastern Time. If an issue is found during the self-test, the status indicator will change from flashing green to flashing red and you will hear an alert and voice instructions.

You should perform the following routine maintenance checks each week and each month:

Each week

1. Check that the status indicator is flashing green

- Check that the status indicator is flashing green every 5 to 10 seconds
- If the status indicator is not flashing green, a problem has been detected (See Troubleshooting in Appendix A)
- If the status indicator is flashing red, a problem has been detected (See Troubleshooting in Appendix A)
- If you hear a beep that does not stop, a problem has been detected (See Troubleshooting in Appendix A)
- After you have fixed the problem that caused the beep or flashing red status indicator, check that the status indicator is flashing green every 5 to 10 seconds

Note: During the self-test, the blinking status indicator changes to red. After the AED has passed the self-test, the status indicator returns to blinking green

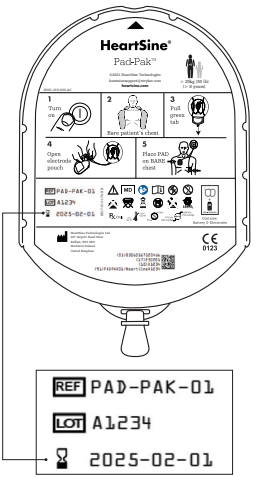
Each month

2. Check the AED for damage

- Check for damage, including:
  - Cracks or marks on the face or plastic casing
  - Pad-Pak electrode drawer (green tab) is damaged or not closing properly
- If the AED is damaged, replace it immediately or contact your Authorized Distributor or email heartsinesupport@stryker.com

3. Look at the Pad-Pak expiration date

- If the Pad-Pak expiration date (YYYY-MM-DD) has passed or is close, immediately replace the Pad-Pak



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
	14-digit, for example, “22D90000001AYY” Where the last three characters denote month (single letter) and year of manufacture (2-digit number): E.g. 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 AED 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 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.
"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 device 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 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.

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.

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 1. 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 C142a1/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 indicator/action arrows, safe to touch indicator/action arrows, status indicator, attach pads indicator/action arrows
Audible prompts:	Extensive voice prompts guide the user through the operation sequence (See Voice prompts in Appendix D)
Languages:	HeartSine samaritan PAD 350P is available in English
Controls:	On/Off button, Shock button and green tab

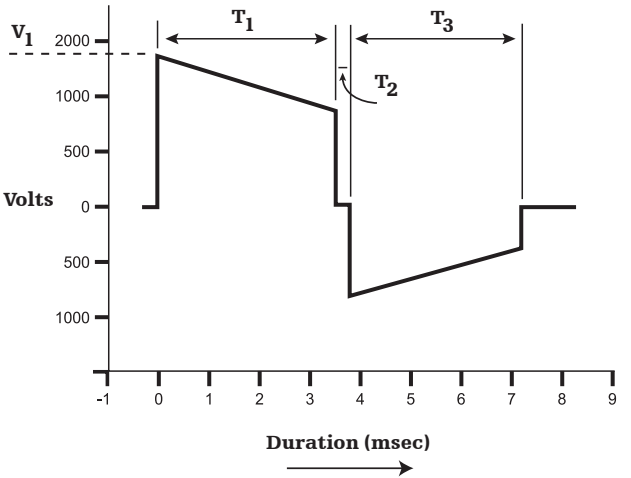
Defibrillator performance	
Charging time:	Typically 150 J in < 8 seconds, 200 J in < 12 seconds
Time to shock delivery following CPR:	Typically 8 seconds
Impedance range:	Adult: 20 Ω to 230 Ω Pediatric: 0 Ω to 176 Ω
Therapeutic shock	
Waveform:	SCOPE (Self Compensating Output Pulse Envelope) optimized 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-10 to C-13 for full details)
Aircraft:	RTCA/DO-160G, Section 21 (Category M) RTCA DO-227 (TSO/ETSO C142a1/EASA.21O.10042190)

Appendix C Technical data

SCOPE biphasic waveform

HeartSine samaritan PAD delivers a Self-Compensating Output Pulse Envelope (SCOPE) biphasic waveform (see Figure 1) 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 1. SCOPE biphasic waveform



The specific SCOPE waveform characteristics for a 200 Joules pulse are shown in Table 2. An example of waveform parameters for the Pediatric-Pak are shown in Table 3.

Table 2. 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 3. 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 4. 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 5. 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 6. 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 6 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

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. If no shock is advised, the device 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 7.

Table 7. 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.

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 8 below and Table 9 on the following page. 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 9 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 8. 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	

Table 9. 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 9 (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	

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. Read the voice prompts in advance of use to be familiar with the types of instructions given.

Prompt
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"
"Check pads"

Prompt
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"
"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 the HeartSine 350P device demonstrated appropriate electrical safety, electromagnetic compatibility, biocompatibility, mechanical integrity, and overall performance.

Four animal studies were conducted to demonstrate safety of the SAM 350P device. The first study involved 15 pigs and demonstrated first shock success of the SCOPE waveform used in the SAM 350P 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 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; and that placement of the electrodes in proximity with a bra does not pose a risk.

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 demonstrate the effectiveness of the SAM 350P device.

Published clinical data

The study by Walsh et al. evaluated the SCOPE defibrillation waveform used in the SAM 350P 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; 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.

Appendix E Safety and effectiveness data

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 10). 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 the HeartSine samaritan AED (cleared under 510(k) K023854) with the identical SCOPE waveform as used in the SAM 350P.

Table 10. 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]

Appendix E Safety and effectiveness data

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

Table 11. 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 12 summarizes shock success and survival by defibrillator model.

Table 12. 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

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.

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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.

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HeartSine SAM 450P is not available for sale outside of the U.S. or Japan.

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