HeartSine®

EN-UK

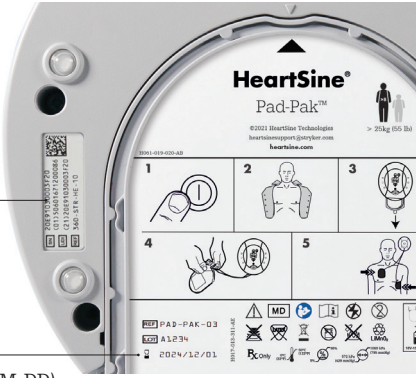
HeartSine® samaritan® PAD
user manual

SAM 350P semi-automatic defibrillator

SAM 360P fully automatic defibrillator

SAM 500P semi-automatic defibrillator with CPR Advisor

About **your AED**



Serial number (SN)

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

Write information about your automated external defibrillator (AED) in this section.

Model

☐ HeartSine SAM 350P ☐ HeartSine SAM 360P

☐ HeartSine SAM 500P

Serial number_____

Pad-Pak expiration date _____

Date of purchase _____

Purchased from _____

Registration date _____

Customer support

For questions about your AED and its use, please contact our customer support team at **heartsinesupport@stryker.com**

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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 Authorised Distributor or HeartSine Technologies directly.

Intended use

Intended purpose

The HeartSine samaritan PAD family of AEDs is designed to automatically assess the patients heart rhythm, advise and/or automatically deliver a defibrillation shock to victims of sudden cardiac arrest if required. The use of a HeartSine samaritan PAD defibrillator, to deliver the therapeutic electric shock across the heart, can stop the disruption to the heart's normal rhythm and restore blood-flow.

Indications for use

The HeartSine samaritan PAD 350P (SAM 350P), HeartSine samaritan PAD 360P (SAM 360P) and HeartSine samaritan PAD 500P (SAM 500P) each is used together with the Pad-Pak or Pediatric-Pak. Each is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

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

Intended patient population

Each device is intended for use on patients greater than 8 years old or over 25 kg (55 lb) when used with the adult Pad-Pak (PAD-PAK-01, PAD-PAK-03, PAD-PAK-07). Each is intended for use on children between 1 and 8 years of age or up to 25 kg (55 lb) when used with the Pediatric-Pak (PAD-PAK-02, PAD-PAK-04). The device also is intended for use on patients on board commercial fixed-wing aircraft when used with the adult Pad-Pak (PAD-PAK-07) which is compliant to TSO/ETSO-certified requirements.

Contraindications for use

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

Intended user

Each device is intended for use by personnel who have been trained in its operation.

Note: Each device is intended for use by lay personnel. Training on CPR and in the use of an AED is strongly recommended for users. However, in an emergency situation, the HeartSine samaritan PAD may be used by an untrained lay rescuer

Clinical benefit

The clinical benefit of the HeartSine samaritan PAD used together with the Pad-Pak or Pediatric-Pak, is the delivery of a therapeutic shock to a patient in shockable sudden cardiac arrest in order to terminate cardiac arrest rhythm and promote the return of spontaneous blood-flow.

Warnings

Patients suitable for treatment

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

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

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

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

Do not delay treatment

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

Risk of electric shock

The 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

The 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 the HeartSine samaritan PAD.

Avoid explosive or flammable gases

The 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 the HeartSine samaritan PAD in the vicinity of explosive gases, including flammable anaesthetics or concentrated oxygen.

Do not touch the patient during analysis

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

Fully automatic defibrillator (SAM 360P)

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

CPR Advisor (SAM 500P)

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

Susceptibility to electromagnetic interference

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 in) to any part of the 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 equivalent 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 this 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, this 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 the 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 8 cm (3.1 in) away from a pacemaker. A noticeable lump with a surgical scar should indicate the location of an implanted device.[1]

Incorrect use of AED

Incorrect use of AED could lead to incorrect analysis or incorrect therapy delivery resulting in failure to resuscitate, cardiac damage or injury.

Incorrect maintenance or storage of AED

Incorrect maintenance or storage of AED could lead to failure of the AED resulting in failure to resuscitate.

⚠ Cautions

Correct placement of electrode pads

Proper placement of the electrode pads is critical. You must strictly observe the instructions shown on pages 21-28 and on the device. Wrong placement or the presence of air, hair, fabric, surgical dressings or medicine patches between the pads and the skin could reduce defibrillation effectiveness or potentially cause skin burns. Slightly red skin after shock therapy is normal.

Do not use electrode pads if pouch is not sealed

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

Temperature range for operation

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

Ingress protection

The 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 the 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 0°C to 50°C (32°F to 122°F) may decrease the shelf-life of the Pad-Pak.

Operator training

The devices are intended for use by personnel who have been trained in their operation.

Note: The devices are intended for use by lay personnel. Training on CPR and in the use of an AED is strongly recommended for users. However, in an emergency situation, the HeartSine samaritan PAD may be used by an untrained lay rescuer

Regular maintenance

Check the device periodically. See Maintenance on page 32.

Correct disposal of the device

Dispose of the device in accordance with your national or local regulations, or contact your Authorised Distributor for assistance. Please follow the steps provided in After using the HeartSine samaritan PAD on page 29.

Compliance with local regulations

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

Symbols

The following symbols are used in this manual:

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

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

Note: Notes contain important additional information about using the AED

1. Panchal R, Bartos JA, Cabañas JG, et al. Part 3: Adult Basic and Advanced Life Support 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2020;142(suppl 2):S366–S468.

Overview

Sudden cardiac arrest

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

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

Sinus rhythm and ventricular fibrillation

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

Ventricular fibrillation (V-fib or VF) is a condition in which there is uncoordinated contraction of the heart muscle, making it quiver rather than contract properly. Ventricular fibrillation is the most commonly identified arrhythmia in SCA patients. In victims of SCA it is possible to re-establish normal sinus rhythm by means of an electric shock across the heart. This treatment is called defibrillation.

Ventricular tachycardia

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

Treatment by AED

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

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

The HeartSine samaritan PAD uses the HeartSine samaritan ECG arrhythmia analysis algorithm. This algorithm will evaluate the patient's ECG to ascertain if a therapeutic shock is appropriate. If a shock is required, the HeartSine samaritan PAD will charge and advise the user to press the shock button (SAM 350P/500P) or will automatically deliver a shock (SAM 360P). If no shock is advised, the device will pause to allow the user to deliver CPR.

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

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

HeartSine samaritan PAD 350P (SAM 350P)
HeartSine samaritan PAD 360P (SAM 360P)
HeartSine samaritan PAD 500P (SAM 500P)

About the HeartSine samaritan PAD

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

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

The SAM 350P is a semi-automatic defibrillator, the SAM 360P is a fully automatic defibrillator and the SAM 500P is a semi-automatic defibrillator with integrated CPR Advisor.

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

CPR metronome

When the 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 ERC/AHA guidelines. This feature, referred to as the CPR metronome, will guide you to the rate at which to compress a patient's chest during CPR.

Table 1. HeartSine samaritan PAD AEDs

Feature	SAM 350P	SAM 360P	SAM 500P
Shock delivery	Semi-automatic	Fully automatic	Semi-automatic
Four-year electrode and battery life	✔	✔	✔
Audible and visual indicators	✔	✔	✔
CPR coaching with metronome	✔	✔	✔
CPR Advisor			✔
Pediatric use-compatible (with Pediatric Pad-Pak)	✔	✔	✔*

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

CPR Advisor (SAM 500P)

When providing CPR treatment to a victim of sudden cardiac arrest, it is vital the chest compressions are of a good quality. If the quality of the CPR provided is good, the chances of successfully resuscitating a patient are greatly increased.

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

The SAM 500P with CPR Advisor provides feedback to the rescuer on the force and rate of the CPR they are providing to the victim. The SAM 500P uses impedance cardiogram measurements to analyse the force and rate of compressions and provide the user with instruction to push harder, push faster or push slower, or to continue to provide compressions according to the ERC/AHA resuscitation guidelines.

The SAM 500P uses both audible and visual feedback to give the responder instruction on CPR force and rate. Refer to Technical data in Appendix C on page C-11.

WARNING: THE CPR ADVISOR FUNCTION IS INTENDED FOR USE ON ADULT PATIENTS ONLY. IF A PEDIATRIC-PAK IS USED, THE CPR ADVISOR FUNCTION IS DISABLED. IN THIS CASE, THE RESCUER IS PROMPTED TO BEGIN CPR IN TIME WITH THE METRONOME BUT RECEIVES NO CPR ADVISOR FEEDBACK

Recommended training

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

The devices are intended for use by personnel who have been trained in their operation.

Note: The devices are intended for use by lay personnel. Training on CPR and in the use of an AED is strongly recommended for users. However, in an emergency situation, the HeartSine samaritan PAD may be used by an untrained lay rescuer

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

SAM 350P layout

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

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

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

Do not touch icon/ action arrows
Do not touch the patient when the action arrows above this icon are flashing. The SAM 350P may be analysing 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
The 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 icon/ action arrows
You may touch the patient when the action arrows around this icon are flashing.

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

Pad-Pak
Contains the battery and electrode pads.

SAM 360P layout

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

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

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

Do not touch icon/ action arrows
Do not touch the patient when the action arrows above this icon are flashing. The SAM 360P may be analysing 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
The SAM 360P is ready for use when this indicator is flashing green.

Shock icon
Flashes to indicate a shock will be delivered.

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

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

Pad-Pak
Contains the battery and electrode pads.

SAM 500P layout

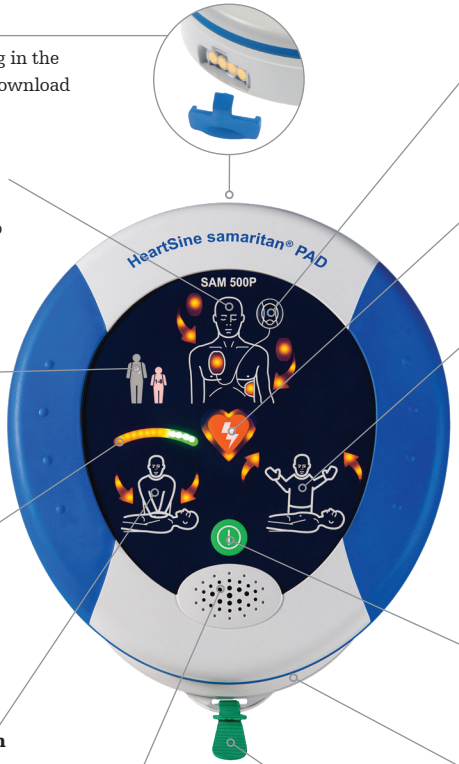
Data port
Remove blue cover and plug in the custom USB data cable to download event data from the AED.

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

Adult and pediatric symbols
Indicates that the SAM 500P is compatible with both the Pad-Pak and Pediatric-Pak.

CPR Advisor icon
Provides visual indication on the force and rate of chest compressions during CPR.

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



Speaker
Listen for the metronome and verbal prompts.

Green tab
Pull this tab to release the electrodes.

Status indicator
The SAM 500P is ready for use when this indicator is flashing green.

Shock button
Press this button to deliver a therapeutic shock.

Do not touch icon/ action arrows
Do not touch the patient when the action arrows above this icon are flashing. The SAM 500P may be analysing the patient's heart rhythm or about to charge, in preparation to deliver a shock.

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

Pad-Pak
Contains the battery and electrode pads.

Unpacking

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

Pad-Pak

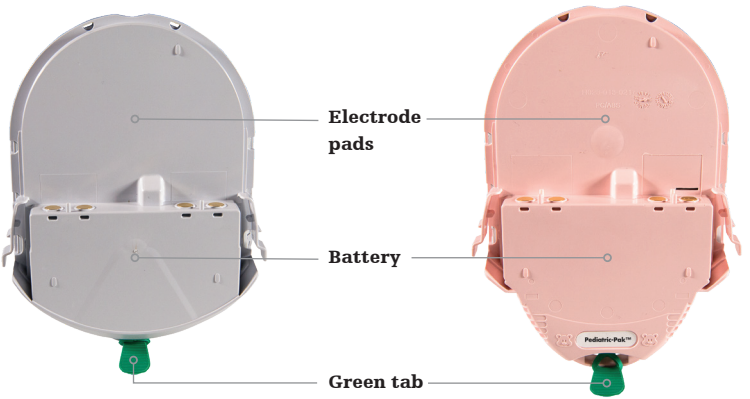
A Pad-Pak is a single-use removable cartridge that includes the battery and electrode pads in a single unit. The Pad-Pak is available in two versions[1]:

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

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

Figure 1. Adult Pad-Pak

Figure 2. Pediatric-Pak



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

Putting the HeartSine samaritan PAD into service

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

1. Check the expiration date (YYYY/MM/DD or YYYY-MM-DD) on the rear of the Pad-Pak (see Figure 3). If the expiration date has passed, do not use and immediately replace the expired Pad-Pak.

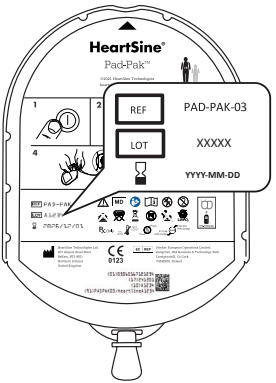


Figure 3. Expiration date

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

3. Place the HeartSine samaritan PAD face up on a flat surface and slide the Pad-Pak into the HeartSine samaritan PAD (see Figure 4) until you hear the "double click" to indicate that the tabs on the right and left sides of the Pad-Pak are fully engaged.

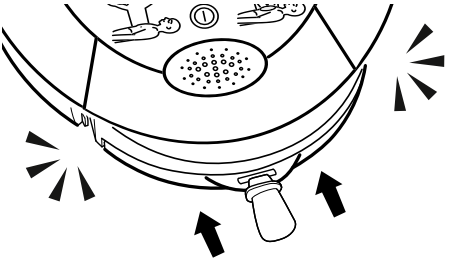


Figure 4. Inserting a Pad-Pak

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

5. Verify that the green Status indicator (see the layout for your model on pages 10-13) is blinking to indicate the initial self-test routine has been performed and the device is ready for use.

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

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

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

7. Press the On/Off button to turn off the HeartSine samaritan PAD. Verify that the status indicator is flashing green. If you have not heard a warning message and the status indicator continues to flash green, the device is ready for use.

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

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

CAUTION: By default the device should be stored with an adult Pad-Pak installed and, if needed, change to a Pediatric-Pak for a child patient

9. Register online, or complete the warranty registration card and return it to your Authorised Distributor or HeartSine Technologies directly (see Tracking requirements on page 31).

10. Create a service schedule (see Maintenance on page 32).

Preparation checklist

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

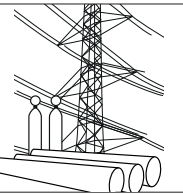
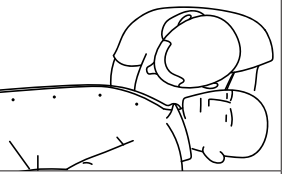
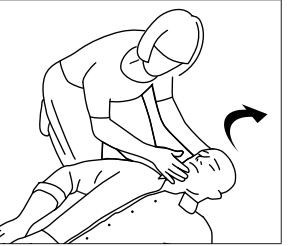
- ☐ **Step 1.** Check the Pad-Pak expiration date.
- ☐ **Step 2.** Install the Pad-Pak and check for a green status indicator.
- ☐ **Step 3.** Record information about your AED on the inside front cover of this user manual.
- ☐ **Step 4.** Turn on the HeartSine samaritan PAD to check operation.
- ☐ **Step 5.** Turn off the HeartSine samaritan PAD.
- ☐ **Step 6.** Store the HeartSine samaritan PAD in a clean, dry environment at 0°C to 50°C (32°F to 122°F).
- ☐ **Step 7.** Register your HeartSine samaritan PAD.
- ☐ **Step 8.** Create a service schedule. (See Maintenance on page 32.)

Using the HeartSine samaritan PAD

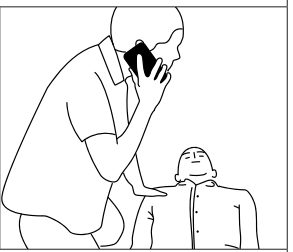
Follow these steps to use your AED, which will provide you with step-by-step voice prompts. For a full list of voice prompts for your device see Voice prompts in Appendix D.

Note: Follow the same instructions for patients who are or may be pregnant

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

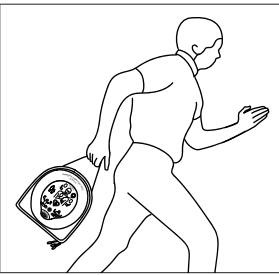
1. Remove danger	
• If necessary, move the patient to a safe location, or remove any source of danger	
2. Check for a response	
• If the patient is non-responsive, shake the patient by the shoulders while speaking loudly • If the patient becomes responsive, do not use the AED	
3. Check for airway	
• Check that the patient's airway is not blocked, using a head-chin tilt if necessary	

4. Call for medical assistance



5. Get the AED

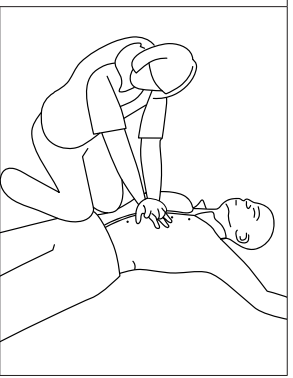
- Ask others nearby to get the AED



6. Begin CPR (until AED arrives)

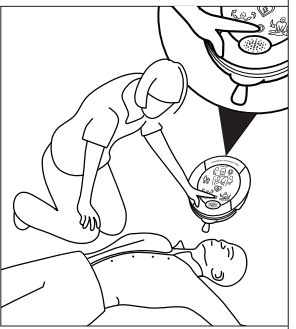
While waiting for the AED, begin CPR

- Push hard between 5 to 6 cm (2 to 2.4 inches) 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

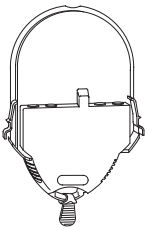
- Kneel next to the patient
- Place the AED on the floor next to you
- Press the On/Off button to turn on AED
- Listen for the voice prompts and follow the directions



8. Defibrillation therapy

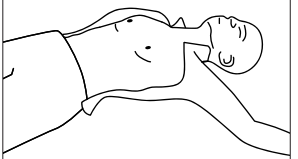
Defibrillation therapy is tailored depending on whether a Pad-Pak or Pediatric-Pak is installed

- If the patient is under 25 kg (55 lb) or 8 years of age, remove the Pad-Pak, insert a Pediatric-Pak and press the On/Off button again (see Pediatric-Pak on page 25)
- If a Pediatric-Pak is not available, you may use the Pad-Pak



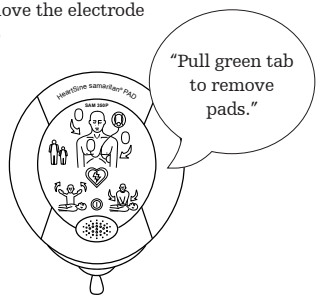
9. Expose and dry chest area

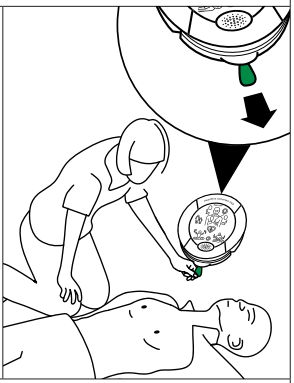
- Remove clothing to expose the patient's bare chest, removing any metal (bras or jewellery) where possible from the pad placement area
- Cut the clothing with scissors, if needed
- If patient's upper body is wet or clammy, dry the chest area
- If patient has a lot of chest hair, use a razor to quickly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



10. Pull the green tab

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

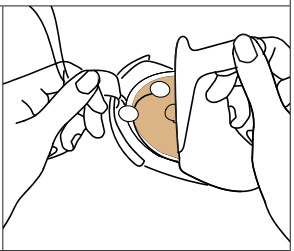




11. Open the electrode pouch

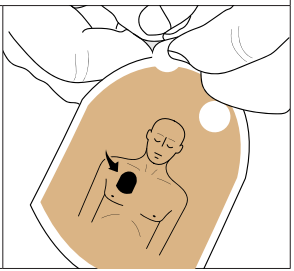
- With both thumbs on the foil tabs, open the foil to release the pads

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



12. Peel first pad from liner

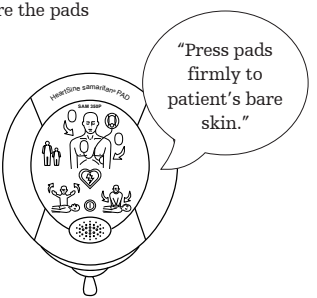
- With both thumbs on the white and clear round tabs, peel the first pad from the plastic liner

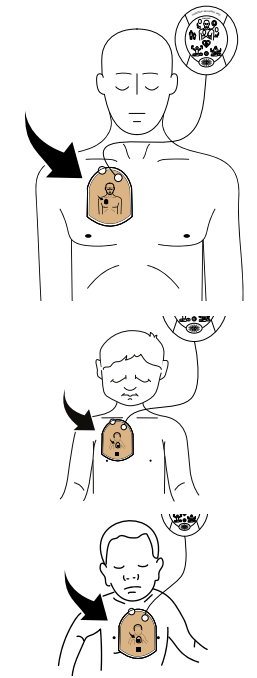


13. Place first pad

- Place the first pad as shown in picture
- For a patient over 8 years of age or weighing over 25 kg (55 lb), apply the first electrode pad firmly to the patient's bare chest, vertically as shown in picture
- For a patient under 8 years of age or weighing less than 25 kg (55 lb), you can place one electrode pad on the centre of the chest and the other on the centre of the back (Refer to pages 27-28 for detailed instructions for electrode pad placement)

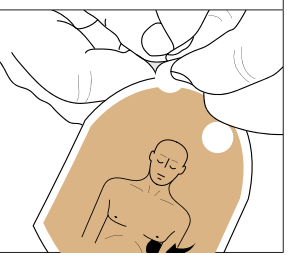
Note: If you are placing pads on a patient with a pacemaker, do not place pads on top of the implant, which you will see as a lump in the skin or a scar. Make sure the pads are placed at least 8 cm (3.1 inches) away from the pacemaker





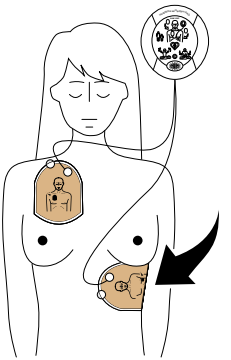
14. Peel second pad from liner

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



15. Place second pad

- For a patient over 8 years of age or weighing over 25 kg (55 lb), apply the second electrode pad firmly to the patient's bare chest, horizontally on the rib cage as shown in picture
- For a patient under 8 years of age or weighing less than 25 kg (55 lb), you can place one electrode pad on the centre of the chest and the other on the centre of the back (Refer to pages 27-28 for detailed instructions for electrode pad placement)

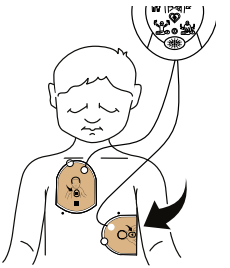


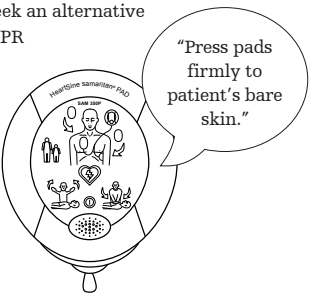
⚠ **WARNING:** PADS SHOULD BE AT LEAST 1 INCH APART AND NEVER TOUCHING ONE ANOTHER

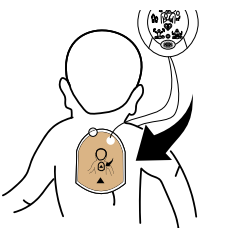
Note: On a large-breasted patient, place the pad on the patient's left to the side of or underneath the left breast, avoiding breast tissue

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

- Pads are placed correctly as shown in the pictures
- Pads are not touching and at least 2.5 cm (1 inch) 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

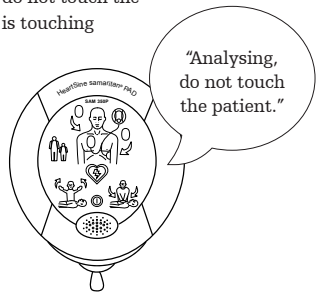


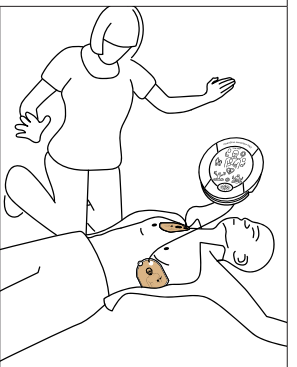




16. Do not touch the patient

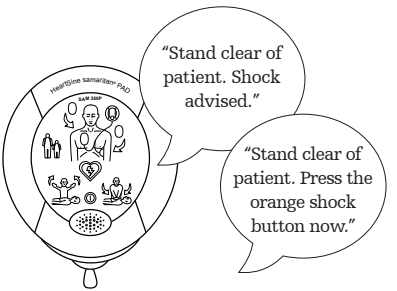
- When you hear "Analysing, do not touch the patient," make sure no one is touching the patient

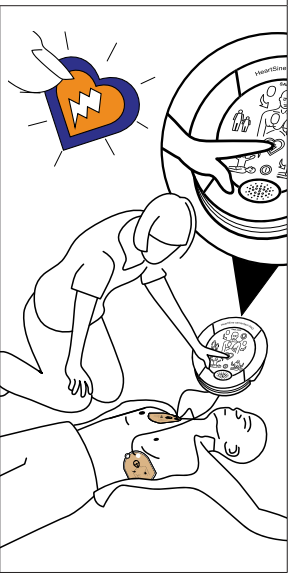




17. If a shock is needed, stand clear and press the shock button (as directed)

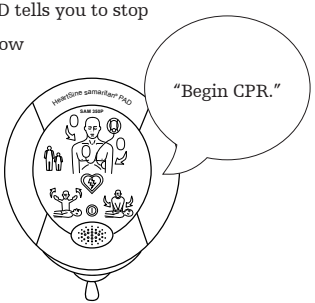
- When you hear "Stand clear of patient. Shock advised," lean away from the patient as directed
- On the SAM 350P/SAM 500P, when you hear "Stand clear of patient. Press the orange shock button now," press the flashing orange shock button to deliver a shock
- If you are using SAM 360P, the AED will automatically deliver the shock after a verbal 3, 2, 1 countdown

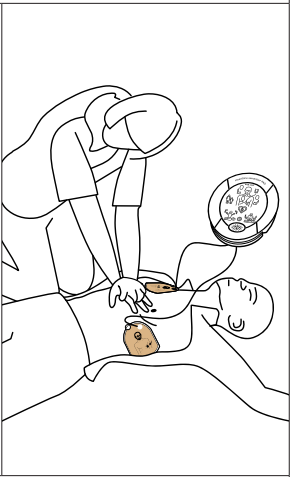




18. Begin CPR when directed

- 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
- When using SAM 500P, follow the CPR Advisor prompts (Refer to CPR Advisor)





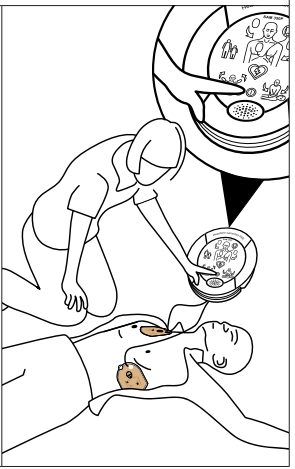
19. Continue to follow the directions until help arrives

Follow the directions, that may include providing additional shocks, until:

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

When emergency services tell you:

- 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 30



About Pad-Pak and Pediatric-Pak

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

Intended purpose

The Pad-Pak or Pediatric-Pak accessory contains the battery to power the HeartSine samaritan PAD and two electrode pads to provide the electrical connection to the patient's chest for delivery of defibrillation shock. The delivery of a defibrillation shock can stop disruption to the heart's normal rhythm and restore blood flow.

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

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

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

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

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

Table 2. Comparing Pad-Pak and Pediatric-Pak

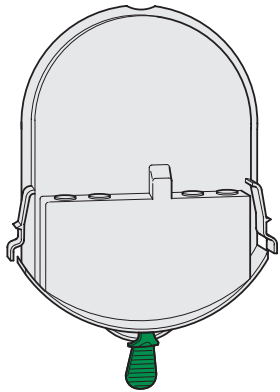
Feature	Pad-Pak	Pediatric-Pak	Aviation Pad-Pak (TSO/ETSO-certified)
Colour	Grey	Pink	Grey (with aircraft symbol)
Intended patient age and weight	Adult and children > 8 years or > 25 kg (55 lb)	Children 1 – 8 years or < 25 kg (55 lb)	Adult and children > 8 years or > 25 kg (55 lb)
Energy	Shock 1: 150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

WARNING: NOT FOR USE ON PATIENTS UNDER 1 YEAR OLD

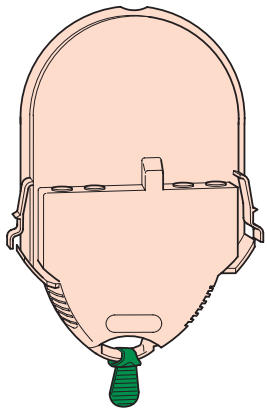
WARNING: **DO NOT** DELAY THERAPY IF YOU ARE UNSURE OF THE EXACT AGE OR WEIGHT. IF THE PEDIATRIC-PAK IS UNAVAILABLE, YOU MAY USE THE PAD-PAK

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

Adult Pad-Pak



Pediatric Pad-Pak

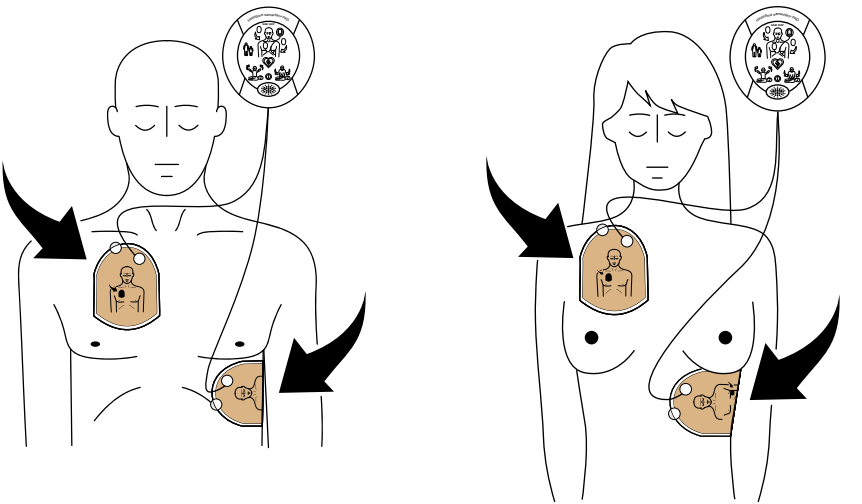


Adult placement

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

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

Figure 5.



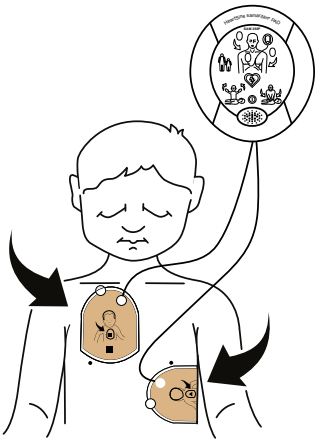
Pediatric placement

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

Pad placement for children

If a child's chest is large enough to permit at least a 2.5 cm (1 in) gap between the electrode pads, OR if trauma does not allow for placement on the back, the pads can be placed according to the adult anterior-lateral placement. Place electrode pads on patient's BARE chest as shown in Figure 6.

Figure 6. Anterior-Lateral

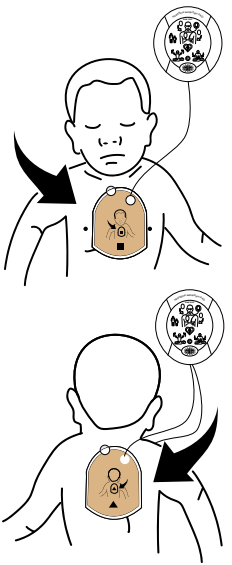


WARNING: ELECTRODE PADS MUST BE AT LEAST 2.5 CM (1 IN) APART AND SHOULD NEVER TOUCH ONE ANOTHER

Pad placement for smaller children

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

Figure 7. Anterior-Posterior



Cleaning the HeartSine samaritan PAD

1. Remove the electrode pads from the patient and stick the pads together face to face. The electrodes may be contaminated with human bodily tissue, fluid or blood so dispose of the electrodes separately as infectious waste material.

2. The Pad-Pak is a single-use item that contains lithium batteries. Replace the Pad-Pak after each use. With the HeartSine samaritan PAD placed face up on a flat surface, squeeze the two tabs on the sides of the Pad-Pak and pull to remove it from the HeartSine samaritan PAD. The Pad-Pak will slide forward (see Figure 8).

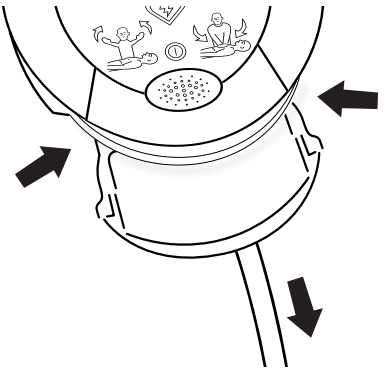


Figure 8. Removing the Pad-Pak

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

- Soapy water
- Isopropyl alcohol (70% solution)

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

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

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

5. Install a new Pad-Pak. Before installing the Pad-Pak, check the expiration date (see Set-up on page 15). After installation, confirm that the status indicator is blinking green.

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

Downloading and submitting event information

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

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

heartsine.com/saverevouk

In addition to Saver EVO, the optional USB data cable (PAD-ACC-02) is required to download event data. Contact your Authorised Distributor or Stryker representative directly to obtain the data cable or with questions about downloading and using Saver EVO.

1. Connect the USB data cable to the data port on the HeartSine samaritan PAD (see Figure 9).
2. Connect the USB connector on the data cable to a PC.

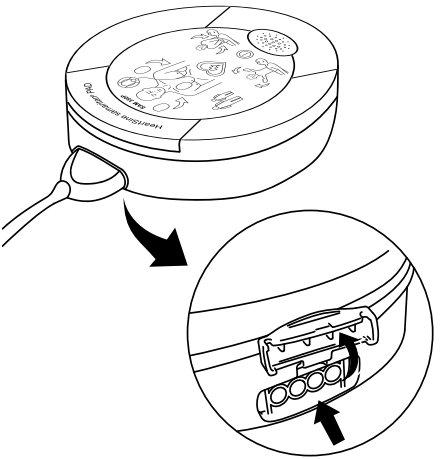
   Note: The HeartSine samaritan PAD should only be connected to an IEC 60950-1 or IEC 62368-1 certified PC
3. Install and launch the HeartSine Saver EVO software.
4. Follow the instructions provided in the Saver EVO manual to save or erase the event data on your HeartSine samaritan PAD.
5. Upload the Saver EVO file on the HeartSine Technologies website.

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

Disposal

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

Figure 9. USB data port



Tracking requirements

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

uk.heartsine.com/register

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

heartsinesupport@stryker.com

The email should contain the following information:

- Name
- Address
- Device serial number

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

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

Maintenance

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

Weekly

- ☐ Check the status indicator. The HeartSine samaritan PAD performs a self-test routine at midnight GMT every Sunday. During this self-test the status light blinks red but returns to green upon successful completion of the self-test routine. If the status indicator is not flashing green every 5 to 10 seconds or if the status indicator is flashing red or you hear continuous beeping, a problem has been detected. (See Figures 10-12, and Troubleshooting in Appendix B on page B-1.)

Monthly

- ☐ If the device shows any signs of physical damage, contact your Authorised Distributor or HeartSine Technologies directly.
- ☐ Check the expiration date of the Pad-Pak (see Set-up on page 15 for the location of the date). If the date has expired, or is near expiration, immediately replace the Pad-Pak or contact your Authorised Distributor for a replacement.
- ☐ If you hear a warning message when you turn on your HeartSine samaritan PAD or if, for any reason, you suspect that your HeartSine samaritan PAD is not working properly, consult Troubleshooting in Appendix B.

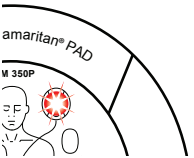


Figure 10. Flashing red light and/or beeping; See Troubleshooting in Appendix B.

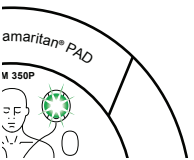


Figure 11. Flashing green LED; no action required.

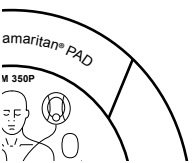


Figure 12. No status indicator light; See Troubleshooting in Appendix B.

Testing with simulators and manikins

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

	On/Off
	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

	Consult operating instructions
	Medical device
	Pressure limitations
	Humidity limitations
	Catalogue 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

	Distributor
	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
SN	Serial number; 14 digit, for example, "22D90000001AYY" where the last three characters denote month (single letter) and year of manufacture (2-digit number), A = January, B = February...and 22 = year
	Automated external defibrillator: with respect to electrical shock, fire and mechanical hazards only in accordance with: • AAMI ES60601-1:2005/ (R)2012 • CAN/CSA-C22.2 No. 60601-1:14/(R)2018 • IEC 60601-1 Ed 3.1 (2012) • IEC 60601-2-4:2010/ AMD1:2018

Appendix B Troubleshooting

Indication	Solution
Flashing red status indicator/continual beeping, or no status indicator light is lit	Check the expiration date on your Pad-Pak (see Set-up on page 15). If the expiration date has passed, immediately replace the Pad-Pak. If the expiration date has not passed, press the On/Off button on the face to turn on the 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 Authorised Distributor or HeartSine Technologies immediately
"Low battery" warning	While this message does not indicate a fault, you should replace the battery as soon as possible The first time you hear the message "Warning low battery," the AED will continue to function properly. However, it may have fewer than 10 shocks left so prepare the spare Pad-Pak for use and be prepared to swap it quickly. Order a new Pad-Pak as soon as possible
"Memory full" prompt	This message does not indicate a fault. The memory is full and can no longer record ECG data or events. However, the AED can still analyse and deliver a shock if required. Contact HeartSine Technologies Technical Support for guidance on how to clear the memory
Three rapid beeps when device is turned off or after weekly self-test has been performed	Your AED has sensed that the ambient temperature is outside the specified operating range. Return your AED to the specified operating conditions of 0°C to 50°C (32°F to 122°F), in which your AED, with its battery and electrodes is designed to operate, and verify that the beeping has stopped

Indication	Solution
Red status indicator and beeping while device is on	⚠ **WARNING:** THERE IS INSUFFICIENT BATTERY CAPACITY TO DELIVER A SHOCK. IMMEDIATELY REPLACE THE PAD-PAK OR SEEK AN ALTERNATIVE DEFIBRILLATOR. IF A SPARE PAD-PAK OR ALTERNATIVE DEFIBRILLATOR IS NOT AVAILABLE, THE DEVICE WILL CONTINUE TO ANALYSE 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 AUTHORISED DISTRIBUTOR IMMEDIATELY
"Warning off button pressed" prompt	You have pressed the On/Off button while the AED is being used to treat a patient. If you are sure you want to turn off the AED, quickly press On/Off again
"Disarming" prompt	This message does not indicate a fault; rather it means that the AED has converted to a decision to not shock after it has initially decided to shock. This occurs when your AED has initially determined that the patient's rhythm is shockable (such as VF) and upon confirming the decision (before proceeding with a shock), the rhythm changed or interference (due to CPR) prevents the confirmation. Continue to follow the device prompts
"Check pads" prompt	If you hear the voice prompt "Check pads", confirm that the pads have fully adhered to the patient as directed on the electrode placement diagram and that the skin is free from hair, moisture and debris. Adjust pads if needed. If message continues, remove the Pad-Pak and reinsert. If the message still continues, seek an alternative defibrillator and continue CPR

Appendix B Troubleshooting

Obtaining support

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

heartsinesupport@stryker.com

Warranty exclusion

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

- AED has been opened
- Unauthorised 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
- The 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)

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 E).
Physical specifications (with Pad-Pak installed)	
Size:	20 cm x 18.4 cm x 4.8 cm (8.0 in x 7.25 in x 1.9 in)
Weight:	1.1 kg (2.4 lb)
Environmental specifications	
Operating temperature:	0°C to 50°C (32°F to 122°F) **Note:** The temperature of the electrodes could be up to 50°C if your device has been exposed to these conditions
Standby temperature:	0°C to 50°C (32°F to 122°F)
Transport temperature:	0°C to 50°C (32°F to 122°F) **Note:** It is recommended that the device should be placed in an ambient temperature of between 0°C to 50°C (32°F to 122°F) for at least 24 hours upon first receipt
Relative humidity:	5% to 95% (non-condensing)
Enclosure:	IEC/EN 60529 IP56
Altitude:	-381 to 4 575 metres (-1,250 to 15,000 feet)
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:	0.2 kg (0.44 lb)
Battery type:	Disposable single-use combined battery and defibrillation electrode cartridge (lithium manganese dioxide ($LiMnO_2$) 18V)
Battery capacity (new):	>60 shocks at 200J or 6 hours of 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:	100 cm^2 (15 in^2)
Electrode cable length:	1 m (3.3 feet)
Shelf life/standby life:	See the expiration date on the Pad-Pak or Pediatric-Pak
Aircraft safety test (TSO/ETSO-certified Pad-Pak):	RTCA DO-227 (TSO/ETSO-C142a)/EASA.21O.10042190
Aircraft safety test (EASA-certified Pad-Pak):	EASA Approval number 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-10 for sensitivity/specificity data)

User interface	
Visual prompts:	Adult and pediatric symbols, do not touch icon/action arrows, safe to touch icon/action arrows, status indicator, attach pads icon/action arrows, CPR Advisor indicator (SAM 500P)
Audible prompts:	Extensive voice prompts guide the user through the operation sequence (see Voice prompts in Appendix D)
Languages:	Contact your HeartSine Authorised Distributor.
Controls:	On/Off button (all models), shock button (SAM 350P and 500P) and green tab
Defibrillator performance	
Charging time:	Typically 150 J in < 8 seconds, 200 J in < 12 seconds
Time to shock delivery following CPR:	SAM 350P: Typically 8 seconds SAM 360P: Typically 19 seconds SAM 500P: Typically 12 seconds
Impedance range:	Adult: 20 Ω to 230 Ω Pediatric: 0 Ω to 176 Ω
Therapeutic shock	
Waveform:	SCOPE (Self Compensating Output Pulse Envelope) optimised biphasic escalating waveform compensates energy, slope and envelope for patient impedance
Energy:	Pre-configured factory settings for escalating energy are based on the current ERC/AHA 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

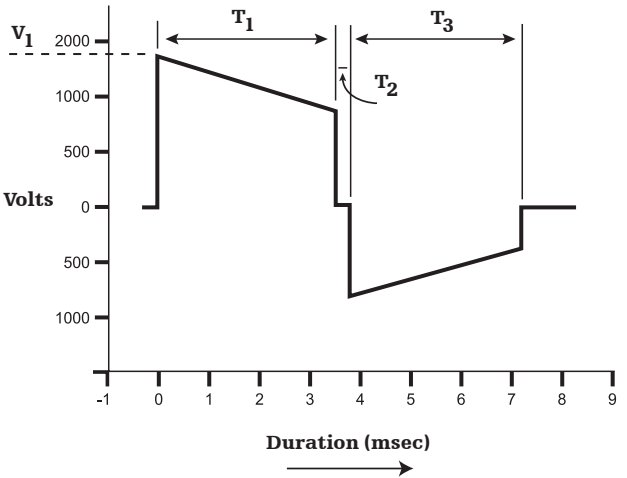
Appendix C Technical data

Event recording	
Type:	Internal memory
Memory:	90 minutes of ECG (full disclosure) and event/incident recording
Review:	Custom USB data cable (optional) directly connected to a PC with Saver EVO Windows-based data review software
Electromagnetic compatibility/battery safety	
EMC:	IEC/EN 60601-1-2 (see pages C-12 to C-14 for full details)
Aircraft:	RTCA/DO-160G, Section 21 (Category M) RTCA DO-227 (TSO/ETSO C142a/EASA.21O.10042190)

SCOPE biphasic waveform

The HeartSine samaritan PAD delivers a Self-Compensating Output Pulse Envelope (SCOPE) biphasic waveform (see Figure 13) which automatically optimises 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 optimised, impedance-compensated, biphasic, truncated exponential waveform that incorporates an escalating energy protocol of 150 Joules, 150 Joules, and 200 Joules. The duration of each phase is automatically adjusted to compensate for varying patient impedances. The first phase (T_1) duration is always equivalent to the second phase (T_3) duration. The interphase pause (T_2) is always a constant 0.4 ms for all patient impedances.

Figure 13. SCOPE biphasic waveform



The specific SCOPE waveform characteristics for a 200 Joules pulse are shown in Table 3. An example of waveform parameters for the Pediatric-Pak are shown in Table 4.

Appendix C Technical data

Table 3. 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 4. 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
150	904	11.5	7.5
175*	940	12.0	7.5

*Output not guaranteed at upper resistance limit due to component tolerances.

Note: All values are nominal

Table 5. 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

Appendix C Technical data

Table 6. 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

*Output not guaranteed at upper resistance limit due to component tolerances.

Table 7. 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 7 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

Motion detection algorithm (SAM 360P only)

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

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

Arrhythmia analysis algorithm

The 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, the HeartSine samaritan PAD will charge and advise the user to stand clear and to press the shock button (SAM 350P and SAM 500P) or automatically shock the patient after a verbal 3, 2, 1 countdown (SAM 360P). If no shock is advised, the AED will pause to allow the user to deliver CPR.

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

The HeartSine samaritan PAD ECG arrhythmia analysis algorithm performance is summarised in Table 8.

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Table 8. Performance of the HeartSine samaritan PAD ECG arrhythmia analysis algorithm

Rhythm class	Minimum test sample size	Test sample size	Performance goal	Observed performance
Shockable rhythm: Coarse ventricular fibrillation	200	350	Sensitivity >90%	✔ Met
Shockable rhythm: Rapid ventricular tachycardia	50	53	Sensitivity >75% (AAMI[1] DF39)	✔ Met
Non-shockable rhythm: NSR[2]	100	165	Specificity >99% (exceeds AAMI DF39)	✔ Met
Non-shockable rhythm: AF, SB, SVT, Heart Block, Idioventricular, PVCs[2]	30	153	Specificity >95% (from AAMI DF39)	✔ Met
Non-shockable rhythm: Asystole	100	117	Specificity >95%	✔ Met
Intermediate: Fine ventricular fibrillation	25	46	Report only	>45% Sensitivity
Intermediate: Other ventricular tachycardia	25	29	Report only	>65% Specificity

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

CPR Advisor analysis algorithm

SAM 500P utilises the ICG (Impedance Cardiogram) capability to assess the force and rate of chest compressions being applied during cardiopulmonary resuscitation (CPR).

Based on the measured rate, SAM 500P provides verbal feedback to the user to "Push faster" or "Push slower" in accordance with the current ERC/AHA resuscitation guidelines (target CPR rate of at least 100-120 CPM).

Based on the measured force, SAM 500P provides verbal feedback of "Push harder" or "Good compressions." SAM 500P also uses the ICG measurement to provide CPR Advisor feedback in the form of a coloured traffic light (green-amber-red) LED array for force feedback. The LED array indicates the force of chest compressions applied to the patient.

Pediatric restriction

Use of the CPR Advisor function is restricted to adult patients only. Chest compression techniques differ for the different ages and sizes of pediatric patients (up to 8 years old). For younger pediatric patients, rescuers should compress the lower half of the sternum but not compress over the xiphoid. For patients at the upper end of the pediatric range, adult-style compressions should be performed. CPR Advisor is currently configured only to advise compressions at a rate suitable for adult patients (over 8 years old weighing more than 25 kg (55 lb)).

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

For these reasons, CPR Advisor is disabled when a Pediatric-Pak is used in SAM 500P.

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

⚠ **WARNING:** IF A PEDIATRIC PATIENT IS TREATED WITH AN ADULT PAD-PAK, IGNORE THE CPR ADVISOR FEEDBACK PROMPTS PROVIDED. CPR ADVISOR IS CURRENTLY ONLY INTENDED TO PROVIDE FEEDBACK ON ADULT PATIENTS

Appendix C Technical data

Electromagnetic conformity - guidance and manufacturer's declaration

The 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.

⚠ **WARNING:** SAFETY RISK AND POSSIBLE EQUIPMENT DAMAGE. THIS DEFIBRILLATOR IS MR UNSAFE. KEEP AWAY FROM MAGNETIC RESONANCE IMAGING (MRI) EQUIPMENT

The HeartSine samaritan PAD is intended for use in the electromagnetic environments specified in Table 9 below and Table 10 on the following page. The user of the HeartSine samaritan PAD should assure that it is used in such an environment.

The essential performance of the 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 10 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 the HeartSine samaritan PAD are maintained with regard to electromagnetic disturbances over the service life of the device.

Table 9. Electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment – guidance
RF CISPR 11	Group 1 Class B	The 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. The 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 10. 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 10. (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 the HeartSine samaritan PAD, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter, or 30 cm (12 in), 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 the 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 the 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

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

For all patients

Prompt	SAM 350P	SAM 360P	SAM 500P
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"	✔	✔	✔
"Analysing; do not touch the patient"	✔	✔	✔
"Motion detected"		✔	
"Check pads"	✔	✔	✔
CPR Advisor			
"Push faster"*			✔
"Push slower"*			✔
"Push harder"*			✔
"Good compressions"*			✔

For all patients

Prompt	SAM 350P	SAM 360P	SAM 500P
If a shock is not required			
"No shock advised"	✔	✔	✔
"Begin CPR"	✔	✔	✔
"It is safe to touch the patient"	✔	✔	✔
"Place overlapping hands in middle of chest"*	✔	✔	✔
"Press directly down on the chest in time with metronome"*	✔	✔	✔
"Remain calm"*	✔	✔	✔
If a shock is required			
"Stand clear of patient; shock advised"	✔	✔	✔
"Stand clear of patient; press the orange shock button now"	✔		✔
"Stand clear of patient; shock will be delivered in 3, 2, 1"		✔	
"Shock delivered"	✔	✔	✔
"Begin CPR"	✔	✔	✔
"It is safe to touch the patient"	✔	✔	✔
"Place overlapping hands in middle of chest"*	✔	✔	✔
"Press directly down on the chest in time with metronome"*	✔	✔	✔
"Remain calm"*	✔	✔	✔

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

Appendix E Limited warranty statement

What is covered?

Stryker provides to the original end user a limited warranty that all HeartSine products that are purchased from a distributor, sub-distributor, person or entity authorised by Stryker ("Authorised 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 Authorised 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 authorised by Stryker please contact Customer Support on +44 28 9093 9400 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, unauthorised service, unauthorised 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 Authorised Agent; your HeartSine product is serviced or repaired by anyone other than Stryker; your HeartSine product is opened by unauthorised 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 send the completed warranty registration card within 30 days of original purchase to:

HeartSine Technologies, Ltd.
207 Airport Road West
Belfast
Northern Ireland
BT3 9ED
United Kingdom

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 Authorised Agent or call Customer Support on +44 28 9093 9400. 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 authorisation.

What we will do:

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

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

Obligations and limitation of liability:

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

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

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

The HeartSine samaritan PAD (SAM 350P, SAM 360P and SAM 500P) Summary of Safety and Clinical Performance (SSCP) will be available via EUDAMED when fully implemented by the European Commission.

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

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Please report any serious incident that occurs with this device to HeartSine Technologies, Ltd. and to your national competent authority or other local regulatory authority as per local regulations.

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

Date of Issue: 07/2022
Made in U.K.
H032-019-500-AF EN-UK

CE 0123

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