



HeartSine®

Inventor. Innovator. Lifesaver.

samaritan® PAD 450P SAM 450P



User Manual

Contents

Contents	2	Pediatric-Pak	20
Indications for Use	4	Service and Maintenance	22
Indications for use	4	Tracking Requirements	23
Contraindications for use	4	Data Management	24
Intended users	4	Troubleshooting	25
Warnings and Cautions	5	Status indicator flashing red	25
Introduction	10	Low battery warning	25
The SAM 450P	10	Memory full warning	25
Sudden cardiac arrest (SCA)	10	Audible warnings	25
Ventricular fibrillation	10	Device service required	26
CPR Rate Advisor™	11	Sources of support	26
Impedance cardiogram	11	Warranty exclusion	26
Recommended training	12	Technical Data	27
CPR metronome	12	List of Voice Prompts	41
SAM 450P Overview	13	Adult patient/child patient	41
Preparation	14	CPR Rate Advisor	41
Unpacking	14	If a shock is not required...	41
Checks before putting into service	14	If a shock is required...	41
Preparation checklist	16		
Using the SAM 450P	17		
When to use	17		
Using the SAM 450P	17		
After use	18		

Symbols used in this manual



Warning: Risk of death or serious injury



Caution: Risk of injury



Notice: Risk of damage to data or material



Further information

Symbols used on this device



On/Off

IP56

Ingress protection classified as IP56 according to IEC 60529



Consult operating instructions



Single use item. Do not re-use



Defibrillation protected,
Type BF connection



Do not expose to high heat or open flame. Do not incinerate



Does not contain natural rubber latex



Non-sterile



Recyclable



Non-rechargeable battery



Do not short circuit battery



Do not crush battery



Temperature limitation as indicated



Use by yyyy-mm-dd



Dispose of in accordance with country requirements



Automated External Defibrillator

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

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



Follow instructions for use



Serial number, e.g. yyG01234567
where yy = year of manufacture

Indications for Use

Indications for use

The HeartSine® samaritan® PAD 450P is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not breathing
- Without circulation

The samaritan PAD 450P is indicated for use on patients greater than 8 years old or over 55 lbs (25 kg) when used with the adult samaritan Pad-Pak™ (Pad-Pak-01 or Pad-Pak-07). The SAM 450P is indicated for use on children between 1 and 8 years of age or up to 55 lbs (25 kg) when used with the samaritan Pediatric-Pak™ (Pad-Pak-02).

Contraindications for use

If the patient is responsive or conscious, do not use the SAM 450P to provide treatment.

Intended users

The SAM 450P is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support / AED, advanced life support or a physician-authorized emergency medical response training program.

Caution

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

Warnings and Cautions



Warning

Patients suitable for treatment

The SAM 450P has been designed to work on unconscious, unresponsive patients. If the patient is responsive or conscious, do not use the SAM 450P to provide treatment.

The SAM 450P uses an interchangeable battery and electrode pack called Pad-Pak. The SAM 450P in combination with an adult Pad-Pak is suitable for use on patients of over 55 lbs (25 kg) in weight or equivalent to a child of approximately eight years old or over.

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

If you treat a pediatric patient with an adult Pad-Pak, ignore any voice prompts regarding the rate of the cardiopulmonary resuscitation (CPR). The

CPR Rate Advisor is currently only intended to provide feedback on adult patients.

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

Risk of electric shock

The SAM 450P delivers therapeutic electrical shocks that can cause serious harm to either operators or bystanders. Take care to ensure that nobody touches the patient when a shock is to be delivered.

Avoid opening or repairing

The SAM 450P 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, replace the SAM 450P immediately.

Warnings and Cautions

Avoid explosive or flammable gases

It has been determined that the SAM 450P 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 SAM 450P in the vicinity of explosive gases, including flammable anesthetics or concentrated oxygen.



Caution

Correct placement of the electrode pads

Proper placement of the SAM 450P electrode pads is critical. You must strictly observe the instructions shown in the Emergency User Guide and on the device. Wrong placement, or the presence of air, hair, surgical dressings or medicine patches between the pads and the skin, could reduce defibrillation effectiveness. Slightly red skin after shock therapy is normal.

Do not 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 analysis is being carried out. The device will instruct you when it is safe to touch the patient.

Do not use if the pouch containing the electrodes is not sealed

The Pad-Pak is a single-use item and you must replace it after each use or if the pouch that seals defibrillation pads has been broken or compromised in any way. If you suspect that the Pad-Pak is damaged, you must replace it immediately.



Notice

Susceptibility to electromagnetic interference

To safeguard against interference, you must operate the SAM 450P at least 6 feet (2 m) away from all radio frequency devices. Alternatively, switch off the equipment causing the electromagnetic interference.

Temperature range for operation

The SAM 450P, with its battery, pads 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 this range may cause malfunction.

Ingress protection

The IP56 rating does not cover the immersion of any part of the SAM 450P in water or any type of fluid. Contact with fluids may seriously damage the device or cause fire or a shock hazard.

Warnings and Cautions

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.

Do not test on simulators and manikins

Our devices cannot be tested using industry-standard simulators and manikins.

Our algorithm uses heart rate variability as one of its criteria for measuring ventricular fibrillation (VF). Consequently we do not recommend the use of normal simulators to test our device.



Further Information

Use of this manual

It is important that you read this manual carefully before using the SAM 450P. 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 (support@heartsine.com) for advice or explanation.

The information in this manual is subject to change without notice and does not represent a commitment on behalf of HeartSine Technologies. No part of this manual may be reproduced or transmitted in any form or by any means, electrical or mechanical, including photocopying and recording, for any purpose without the express written permission of HeartSine Technologies.

Operator training

The SAM 450P is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support / AED, advanced life support or a physician-authorized emergency medical response training program.

Use of accessories

The SAM 450P is a self-contained device. Do not use any unauthorized accessories with it. The SAM 450P may malfunction if non-approved accessories are used.

Regular maintenance

Check the device periodically. See 'Service and Maintenance' on page 22.

Correct disposal of the device

Dispose of the device in accordance with your national or local regulations, or contact your HeartSine authorized distributor. Please follow the 'After use' on page 18.

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.

Introduction

The SAM 450P

The SAM 450P is a semi-automatic external defibrillator designed to quickly deliver a defibrillation shock to victims of sudden cardiac arrest (SCA).

The SAM 450P is designed to operate in accordance with the joint American Heart Association (AHA) and European Resuscitation Council (ERC) 2010 guidelines on Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC).

Sudden cardiac arrest (SCA)

Sudden cardiac arrest is a condition in which the heart suddenly stops pumping effectively due to a malfunction of the heart's electrical system. Often victims of SCA have no prior warning signs or symptoms. SCA can also 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 collapse can greatly improve patient's chances of survival. Heart attack and SCA are not the same, though sometimes a heart attack can lead to an SCA. If the patient is experiencing symptoms of a heart attack (chest pain, pressure, shortness of breath, tight feeling in the chest or elsewhere in the body), seek emergency medical attention immediately.

Ventricular fibrillation

The normal electrical rhythm by which the heart muscle contracts to create blood flow around the body is known as normal sinus rhythm (NSR). Ventricular fibrillation (VF), caused by chaotic electrical signals in the heart, is often the cause of SCA. 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.

Introduction

CPR Rate Advisor

When providing cardiopulmonary resuscitation (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. As a response to this problem, HeartSine has developed the SAM 450P with CPR Rate Advisor.

The SAM 450P with CPR Rate Advisor provides feedback to the rescuers on the rate of the cardiopulmonary resuscitation (CPR) they are providing to the victim. The SAM 450P uses impedance cardiogram measurements to analyze the speed of compressions and provide the user with instructions to push faster or push slower or to continue to provide compressions at an optimal speed according to the AHA resuscitation

guidelines. The SAM 450P uses both audible and visual feedback to give the responder instruction on CPR rate.



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

Impedance cardiogram (ICG)

The impedance cardiogram is a method of measuring changes in the patient's impedance due to motion, blood flow and changes to the shape of the heart. The SAM 450P uses these measurements to estimate the impedance changes in the chest as a way to determine the effectiveness of compression rate given during CPR.

Introduction

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.

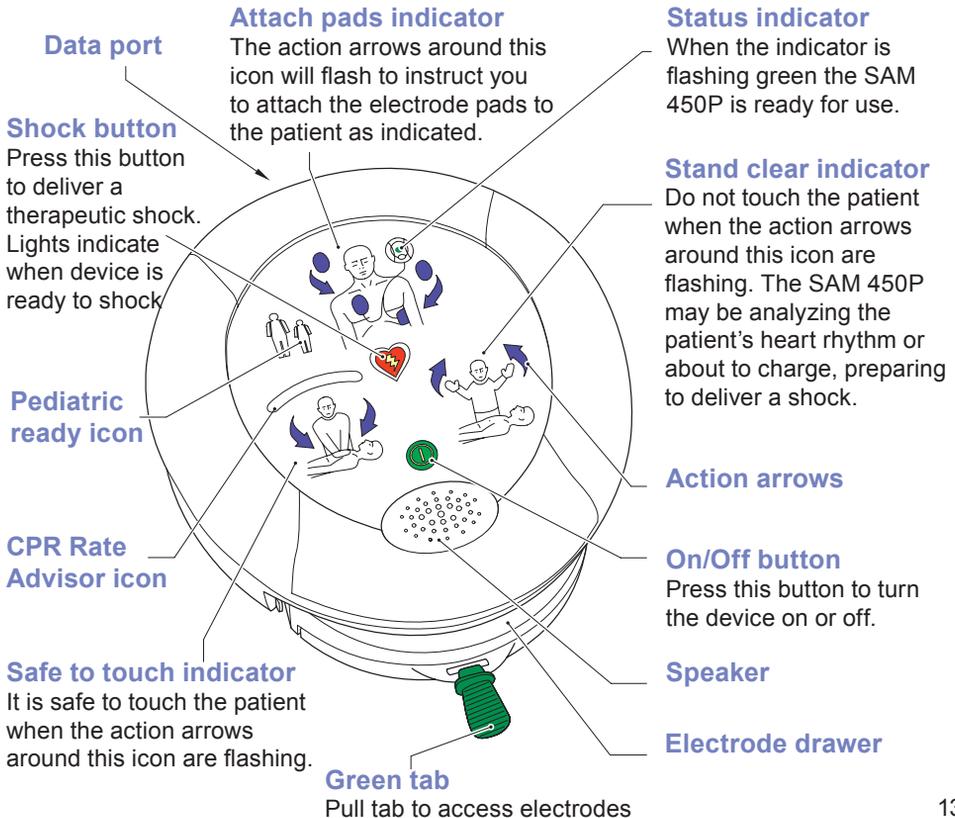
To properly diagnose this condition, HeartSine recommends that all potential users of the SAM 450P are fully trained in cardiopulmonary resuscitation (CPR), basic life support (BLS) and, in particular, the use of an automated external defibrillator. HeartSine also recommends that this training be kept up to date by regular refresher courses as and when recommended by your training provider.

If potential users of the SAM 450P are not trained in these techniques, contact your authorized or HeartSine Technologies directly. Either can arrange for training to be provided. Alternatively contact your local government health department for information on certified training organizations in your region.

CPR metronome

During CPR the SAM 450P will play an audible beep and flash the 'Safe To Touch' indicator at a rate compliant with 2010 AHA/ERC guidelines. This feature is referred to as the CPR metronome. Use the metronome as a guide on how frequently to compress a patient's chest if you need to apply CPR.

SAM 450P Overview

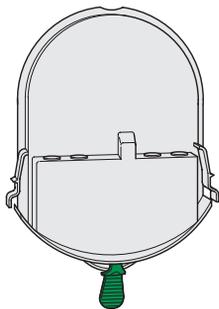


Preparation

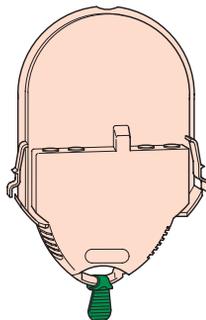
Unpacking

Check that the contents include the User Manual, soft case, Pad-Pak, Registration and Warranty Card and Emergency User Guide.

A Pad-Pak is a single-use removable battery and electrode pack in one unit. It is available in two versions¹: gray colored Pad-Pak for use with adults and a pink colored Pediatric-Pak for use with children (see the illustration below).



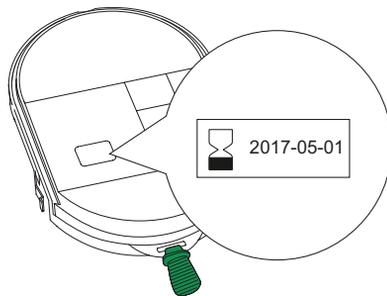
Adult Pad-Pak



Pediatric-Pak

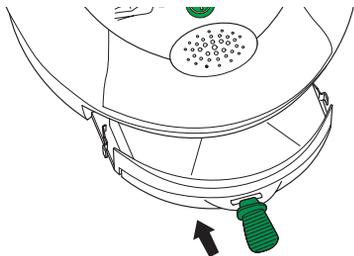
Checks before putting into service

1. Check the expiration date (year-month-day) on the rear of the Pad-Pak (see the illustration below). If the expiration date has passed, you must replace the Pad-Pak.



¹ A third version is also available specifically for airlines

2. Unpack the Pad-Pak. Retain the packaging in case you need to return the Pad-Pak to HeartSine. Place the SAM 450P on a flat surface. Insert the Pad-Pak into the SAM 450P (see the illustration below). Listen for the “click” sound and ensure both tabs are fully engaged.



3. If required, the SAM 450P will run a self test routine. The action arrows will flash during this process. On successful completion of the self-test routine, the green status indicator (see ‘SAM 450P Overview’ on page 13) will blink. If so, your SAM 450P is ready for use.

4. Turn on the SAM 450P by pressing  on the front panel to check that the device is operating correctly. Listen for the voice prompts but do **NOT** follow them. Make sure that no warning messages are played.



Notice: Do NOT pull the green tab on the Pad-Pak. If you have opened the electrode drawer, you may have to replace your Pad-Pak.

Turn the SAM 450P on only ONCE. If you turn it on and off repeatedly, you will exhaust the batteries prematurely and you may need to replace the Pad-Pak.

5. Turn off the SAM 450P by pressing  on the front panel. Check the status indicator (see ‘SAM 450P Overview’ on page 13) is flashing green. If you have heard no warning messages and the status indicator is flashing green, the device is ready for use.

Preparation

6. Place the SAM 450P in its supplied soft carry case. Store the SAM 450P in an unobstructed, secure location in a **clean, dry environment** specifically where it will be seen and heard. Be sure to store according to specifications (see 'Technical Data' on page 27).

Standby temperature: 32 °F to 122 °F
(0 °C to 50 °C)

Relative humidity: 5% to 95%
(non-condensing)



Notice: HeartSine recommends that you keep a spare Pad-Pak with your SAM 450P. You can store it in the rear section of the soft carry case.

7. Complete the Registration and Warranty Card and return it to your authorized or HeartSine Technologies directly (see 'Tracking Requirements' on page 23).

Preparation checklist

- Step 1. Check the Pad-Pak expiration date.
- Step 2. Install the Pad-Pak.
- Step 3. Check for a successful completion of the self-test routine.
- Step 4. Turn on to check operation.
- Step 5. Turn off.
- Step 6. Store the SAM 450P correctly.
- Step 7. Register your SAM 450P.
- Step 8. Create a service schedule (see 'Service and Maintenance' on page 22).

Using the SAM 450P

When to use

The SAM 450P is indicated for use on victims of sudden cardiac arrest who are exhibiting the following signs:

Unconscious

Not breathing

Without circulation

The SAM 450P has been designed to work on unconscious, unresponsive patients. If the patient is responsive or conscious, do not use the SAM 450P to provide treatment.

When used with an adult Pad-Pak, the SAM 450P is suitable for use on patients of over 55 lbs (25 kg) in weight or equivalent to a child of approximately eight years old or over.

For use on smaller children (from 1 to 8 years old), remove the adult Pad-Pak and install a Pediatric-Pak.

If a Pediatric-Pak or an alternative suitable defibrillator is not available, you may use an adult Pad-Pak.

Using the SAM 450P

Refer to the separate Emergency User Guide. During use the SAM 450P will give extensive voice prompts and LED indications to guide a user. See 'List of Voice Prompts' on page 41 and the LED sequence shown in the table on page 34.

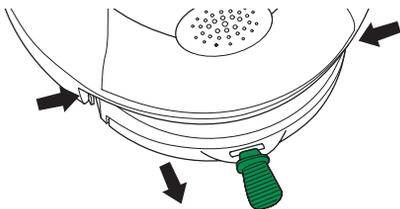


Notice: The SAM 450P aborts a ready to shock condition once a non-shockable rhythm is detected.

Using the SAM 450P

After use

1. Turn off the SAM 450P by pressing  on the front panel.
2. Remove the electrode pads from the patient and stick them together 'face to face'. The electrodes may be contaminated with human bodily tissue, fluid or blood. Dispose of the electrodes separately as an infectious waste material.
3. The Pad-Pak contains Lithium batteries. It is a single-use item and must be replaced after each use. Remove the Pad-Pak by pressing the two tabs on either side of the Pad-Pak. The Pad-Pak will slide forward (see the illustration below).



Do not dispose of the SAM 450P or Pad-Pak in the normal waste. Dispose of it at an appropriate recycling facility according to local requirements. Alternatively return it to your authorized distributor for disposal or replacement.

4. Check the SAM 450P for dirt or contamination. If necessary, clean it using a soft cloth dampened by one of the following:

Soapy water

Isopropyl alcohol (70% solution).



Caution: Do not immerse any part of the SAM 450P in water or any type of fluid. Contact with fluids may seriously damage the device or cause a fire or a shock hazard.



Notice: Do not clean the SAM 450P with abrasive materials, cleaners or solvents.

5. Check the SAM 450P for damage. If the SAM 450P is damaged, replace it immediately.
6. Install a new Pad-Pak. Before installing, check the Pad-Pak expiration date (see 'Preparation' on page 14). After installation check the status indicator is blinking green.

Pediatric-Pak

Using the Pediatric-Pak

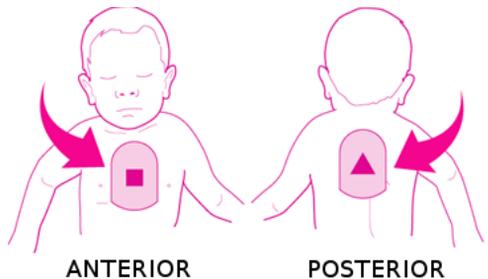
The Pediatric-Pak is intended to provide therapy for pediatric (child) victims of SCA between the ages of 1 and 8 years old who are:

- Unconscious
- Not breathing
- Without circulation

Electrode Placement:

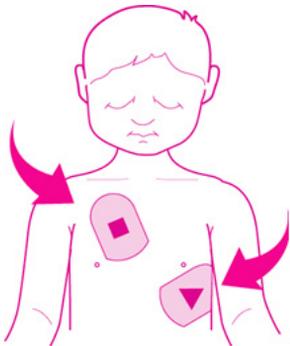
For pediatric patients there are two options for electrode placement:

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



Method a)

b. If a child's chest is large enough to permit a 1 inch (2.5cm) gap between the pads, pad placement can be used similar to adult placement. Place one pad on child's BARE upper right chest above nipple and one pad on child's BARE lower left ribcage below nipple as shown in Method b).



Method b)

Electrodes can be placed on the child's chest if their chest is large enough OR if trauma does not allow for the placement as shown in Method a).



Warning: Defibrillation electrodes must be at least 1 inch (approx 2.5 cm) apart and should never be touching one another.



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



Warning: Not for use on patients under 1 year old. For use with children up to the age of 8 years or up to 55lbs (25kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.

Service and Maintenance

HeartSine recommends users perform regular maintenance checks. The recommended maintenance checks are:

Weekly

- Check the status indicator. If the green status indicator is not flashing every 5 to 10 seconds or if the red status indicator is flashing or if you hear beeping, a problem has been detected. See 'Troubleshooting' on page 25. The SAM 450P performs a self-test routine at midnight GMT every Sunday. During this self-test the status light blinks red but returns to green on successful completion of the self-test routine. The self-test takes no more than 10 seconds to complete. If the status indicator continues to flash red the SAM 450P has a fault (see 'Troubleshooting' on page 25).

Monthly

- If the device shows any signs of physical damage, contact your authorized distributor or HeartSine Technologies directly.

- Check the expiration date of the SAM 450P Pad-Pak (see 'Preparation' on page 14 for the location of the date). If the date has expired, or is near expiration, replace with a new Pad-Pak or contact your local HeartSine authorized distributor for a replacement.

If you hear a warning message when you turn on your SAM 450P or if, for any reason, you have suspicions that your SAM 450P is not working correctly, read the section 'Troubleshooting' on page 25.

Tracking Requirements

Medical Devices Regulations require us to track the location of all medical devices sold.

It is important that you complete the Registration and Warranty Card with your details and return it to your authorized distributor or HeartSine Technologies directly.

Alternatively send an email, to support@heartsine.com, containing:

Name

Address

Device serial number

or use our on-line registration tool at <https://secure.heartsine.com/UserRegistration.html>

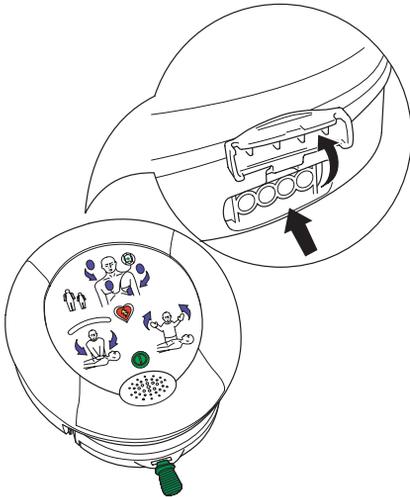
Your participation will allow us to contact you with any important notifications about the SAM 450P, such as any future software updates or field safety corrective actions.

If there is a change in the information you have provided to us, such as a change of address or a change in ownership of your SAM 450P, contact us with the updated information.

Data Management

The HeartSine Saver EVO® software is an optional accessory. Contact your authorized distributor or HeartSine Technologies directly about the after-use data management service.

1. Connect the custom USB cable (supplied separately) to the SAM 450P (see illustration below).



2. Connect the USB cable to a PC.
3. Launch the HeartSine Saver EVO utility.



Notice: The SAM 450P should only be connected to an IEC60950 PC.



Caution: You cannot defibrillate while the SAM 450P is connected to a PC.

For further information on this optional accessory, contact your authorized distributor or HeartSine Technologies directly.

Troubleshooting

Status indicator flashing red

If the status indicator is flashing red or if the device is emitting a 'beep', check the expiration date on your Pad-Pak (see 'Preparation' on page 14). If the expiration date has not been passed, turn on the SAM 450P by pressing  on the front panel and listen for the voice prompt 'call for medical assistance'. Then turn off by pressing  on the front panel. If this action does not correct the problem, contact your authorized distributor or HeartSine Technologies immediately.

Low battery warning



This message does not indicate a fault.

The first time the device plays the message 'warning low battery', it will still continue to function properly. However, it may have fewer than 10 shocks left. If you hear this message, 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 warning

If the device plays the message 'memory full', then the memory can record no further ECG data or events. However, the device can still analyze and deliver a shock if required. If you hear this message, contact HeartSine Technologies technical support. Alternatively, use the HeartSine Saver EVO software to clear the memory (refer to the Saver EVO user manual).

Audible warnings

If the device emits 3 beeps rapidly when turned off, it has sensed that the ambient temperature is outside of the specified operating range. This beeping could also occur during the weekly self-test. If you hear this beeping, please ensure the device is returned to the specified operating conditions.

During use, if the status indicator changes from green to red and the device starts to 'beep', there is insufficient battery capacity to deliver a shock. The device will continue to analyze the patient's heart rhythm and advise when CPR is needed.

Troubleshooting

Device service required

If the device plays the message 'device service required', then it has detected a fault. Contact your authorized distributor or HeartSine directly for further instruction.



Warning: If you hear this message during use, seek an alternative defibrillator immediately.

No modification of this equipment is allowed.

Sources of support

If you have completed the troubleshooting steps above and you find the device is still not working correctly, contact your authorized distributor or HeartSine Technologies Technical Support at support@HeartSine.com.

Warranty exclusion

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

The device has been opened.

Unauthorized modifications have been made.

The device has not been used in accordance with the instructions provided in this manual.

The serial number has been removed, defaced, altered or, by any other means, made unreadable.

The device has been used or stored outside its indicated temperature range.

The Pad-Pak packaging is not returned.

The device has been tested using unapproved methods or inappropriate equipment, (see 'Warnings and Cautions' on page 5).

Technical Data

Physical parameters (with Pad-Pak installed)

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

Environmental

Operating temperature: 32 °F to 122 °F (0 °C to 50 °C)
Standby temperature: 32 °F to 122 °F (0 °C to 50 °C)
Transport temperature: 14 °F to 122 °F (-10 °C to 50 °C) for up to two days. If the device has been stored below 32 °F (0 °C), it should be returned to an ambient temperature of between 32 °F to 122 °F (0 °C to 50 °C) for at least 24 hours before use.
Relative humidity: 5% to 95% (non-condensing)
Enclosure: IEC 60529/EN 60529 IP56
Altitude: 0 feet to 15 000 feet (0 meters to 4575 meters)
Shock: MIL STD 810F Method 516.5, Procedure 1 (40G's)
Vibration: MIL STD 810F Method 514.5 Procedure 1 Category 4
MIL STD 810F Method 514.5 Procedure 1 Category 7

Technical Data

Pad-Pak and Pediatric-Pak

Weight:	0.44 lbs (0.2 kg)
Battery type:	Disposable single-use combined battery and defibrillation electrode cartridge (lithium manganese dioxide (LiMnO ₂) 18V)
Battery capacity (new):	>60 shocks at 200 J or 6 hours of continuous monitoring
Battery capacity (4 years):	>10 shocks at 200 J
Standby life:	See the expiration date on the Pad-Pak.
Electrode type:	Single-use pre-attached combined ECG sensor/defibrillation pad
Electrode placement:	Adult: anterior-lateral Pediatric: electrodes anterior-posterior or anterior-lateral
Electrode active area:	15.5 inch ² (100 cm ²)
Electrode cable length:	3.25 ft (1 m)
Electrode shelf life:	See the expiration date on the Pad-Pak.

Patient analysis system

Method:	Evaluates the patient's ECG, signal quality, electrode contact integrity and patient impedance to determine if defibrillation is required
Sensitivity/Specificity:	Meets IEC 60601-2-4

User Interface

Visual prompts:	Attach pads, stand clear, perform CPR, shock now, status indicator, CPR Rate Advisor indicator
Audible prompts:	Extensive voice prompts guide the user through the operation sequence (see 'List of Voice Prompts' on page 41)
Languages:	Contact your HeartSine authorized distributor
Controls:	Two buttons: 'On/Off' and 'Shock'

Defibrillator performance

Times to shock delivery (fresh battery or after 6 shocks):	
Charging time:	Typically 150J in < 8 sec, 200 J in < 12 sec
Following CPR:	Typically 8 seconds
Impedance range:	20 Ω to 230 Ω

Therapeutic shock

Waveform:	SCOPE™ (Self Compensating Output Pulse Envelope) biphasic escalating waveform. Optimized biphasic waveform compensates energy, slope and envelope for patient impedance
Energy:	Pre-configured factory settings for escalating energy are Version AHA/ERC 2010 Adult: Shock 1: 150J; Shock 2: 150J; Shock 3: 200J Pediatric: Shock 1: 50J; Shock 2: 50J; Shock 3: 50J

Technical Data

Event recording

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

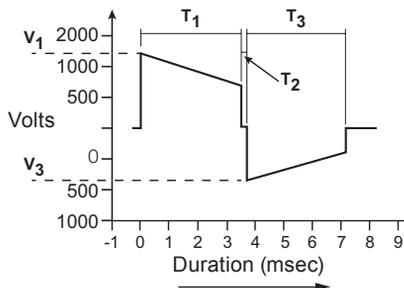
Electromagnetic compatibility

EMC:	IEC60601-1-2
Radiated emissions:	IEC55011
Electrostatic discharge:	IEC61000-4-2 (8 kV)
RF immunity:	IEC61000-4-3 80 MHz – 2.5 GHz, (10 V/m)
Magnetic field immunity:	IEC61000-4-8 (3 A/m)
Aircraft:	RTCA/DO-160F, Section 21 (Category M) RTCA DO-227 (ETSO-C142a)

SCOPE Biphasic Waveform

The SAM 450P delivers a Self Compensating Output Pulse Envelope (SCOPE) biphasic waveform. This waveform 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 (T1) duration is always equivalent to the second phase (T3) duration. The interphase pause (T2) is always a constant 0.4 ms for all patient impedances.

The specific SCOPE waveform characteristics for a 150 joules pulse are listed opposite.



Resistance (ohms)	Waveform Voltages (volts)		Waveform Duration (ms)	
	V ₁	Tilt %	T ₁	T ₃
25	1640	63.1	3	3
50	1650	52.7	4.5	4.5
75	1660	51.4	6.5	6.5
100	1670	48.7	8	8
125	1670	50.4	10.5	10.5
150	1670	48.7	12	12
175	1670	48.7	14	14
200	1670	47.6	15.5	15.5
225	1680	46.7	17	17

Adult Pad-Pak waveform specification

All values are nominal

Technical Data

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

Example Pediatric-Pak waveform parameters

Arrhythmia analysis algorithm

The SAM 450P 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 SAM 450P 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.

The SAM 450P ECG arrhythmia analysis algorithm performance has been extensively evaluated by using several databases of real-life ECG traces. Included in this are the American Heart Association's (AHA) database and the Massachusetts Institute of Technology MIT – NST database. The SAM 450P ECG arrhythmia analysis algorithm's sensitivity and specificity meet the requirements of IEC60601-2-4.

The SAM 450P ECG arrhythmia analysis algorithm performance is summarized in the table below:

Rhythm Class	Total Blocks (seconds)	Required Performance	Results (%)	90% Lower Confidence Limit
Shockable Rhythm: Ventricular Fibrillation (VF)	14538	Sensitivity > 90%	97.03	95.31
Shockable Rhythm: Ventricular Tachycardia (VT)	2321	Sensitivity > 75%	92.55	80.52
Non-Shockable Rhythm: Combined Non-Shockable Rhythms	301177	Specificity > 95%	98.30	95.02

Technical Data

CPR Rate Advisor

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

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

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

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

Pediatric restriction

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

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

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



Notice: 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, you must ignore the CPR Rate Advisor feedback prompts provided. CPR Rate Advisor is currently only intended to provide feedback on adult patients.

Technical Data

Guidance and manufacturer's declaration – electromagnetic emissions

The SAM 450P is intended for use in the electromagnetic environment specified below. The customer or user of the SAM 450P must assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SAM 450P 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.
RF emissions CISPR 11	Class B	The device 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 emissions IEC/EN 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC/EN 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The SAM 450P is intended for use in the electromagnetic environment specified below. The customer or user of the SAM 450P must assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2kV for power supply lines ±1 kV for input/output lines	Not Applicable	Not Applicable
Surge IEC/EN 61000-4-5	±1kV differential mode ±2 kV common mode	Not Applicable	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5 % Ut (>95 % dip in Ut) for 0.5 cycle 40 % Ut (60% dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) for 5 sec	Not Applicable	Not Applicable
Power-frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: Ut is the a.c.mains voltage prior to application of the test level

Technical Data

Guidance and manufacturer's declaration – electromagnetic immunity

The SAM 450P is intended for use in the electromagnetic environment specified below. The customer or user of the SAM 450P must assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands ^a	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the SAM 450P, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance Not applicable
	10 Vrms 150 kHz to 80 MHz in ISM bands ^a	Not applicable	Not applicable
Radiated RF IEC/EN 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) ^b . Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^c , should be less than the ... [next page]

Guidance and manufacturer's declaration – electromagnetic immunity

... compliance level in each frequency range.
Interference may occur in the vicinity of equipment marked with the following symbol:



Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a The ISM (industrial, scientific and medical) bands between 150kHz 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; 40,66 MHz to 40,70 MHz.
- b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.
- c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the SAM 450P is used exceeds the applicable RF compliance level (see above), the SAM 450P should be observed to verify that it is operating normally. If abnormal operation is observed, additional measures may be necessary, such as re-orienting or relocating the SAM 450P.

Technical Data

Recommended separation distances between portable and mobile RF communication equipment and the SAM 450P

The SAM 450P is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SAM 450P can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SAM 450P as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	Not Applicable	Not applicable	0.12	0.23
0.1	Not Applicable	Not applicable	0.38	0.73
1	Not Applicable	Not Applicable	1.2	2.3
10	Not Applicable	Not Applicable	3.8	7.3
100	Not Applicable	Not Applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

List of Voice Prompts

Some of the voice prompts used by the SAM 450P are listed below. Read the voice prompts before you use the SAM 450P so you are familiar with the types of instructions given.

Note This is not a complete list of voice prompts - just the ones you will encounter most often.

Adult patient/child patient

- “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”

CPR Rate Advisor

- “Push faster” *
- “Push slower” *
- “Good speed” *

If a shock is not required...

- “No shock advised”
- “Begin CPR”
- “It is safe to touch the patient”
- “Place overlapping hands in middle of chest” *
- “Press directly down on the chest in time with the 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 the metronome” *
- “Remain calm” *

** Voice messages not provided when pediatric Pad-Pak is installed*

Notes



Authorized Distributor

www.heartsine.com

info@heartsine.com



EMEA/APAC

HeartSine Technologies, Ltd.
203 Airport Road West
Belfast, Northern Ireland BT3 9ED

Tel: +44 28 9093 9400

Fax: +44 28 9093 9401

US/Americas

HeartSine Technologies, Inc.
121 Friends Lane, Suite 400
Newtown, PA 18940

Tel: +1 215 860 8100

Toll Free: +1 866 478 7463

Fax: +1 215 860 8192

H041-019-100-2
English (US)