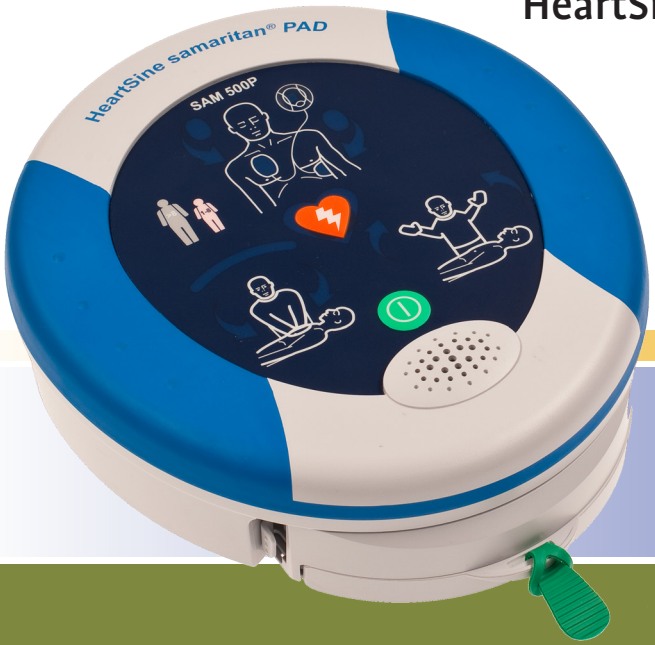
HeartSine

HeartSine samaritan® PAD SAM 500P



User Manual

Contents

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 EN 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

LATEX Does not contain natural rubber latex

NON STERILE Non-sterile

Recyclable

Non- rechargeable battery

Do not short circuit battery

Do not crush battery

Temperature limitation as indicated

Use by yyyy/mm

Dispose of in accordance with country requirements

Automated External Defibrillator

CLASSIFIED C UL US 3XN6

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

SN e.g. “yyB01234567”
yy = year of manufacture

Indications for Use

Indications for use

The HeartSine® samaritan® PAD 500P is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not breathing
- Without circulation

The samaritan PAD 500P (SAM 500P) is indicated for use on patients greater than 8 years old or over 25 kg (55 lbs) when used with the adult samaritan Pad-Pak™. The SAM 500P is indicated for use on children between 1 and 8 years of age or up to 25 kg (55 lbs) when used with the samaritan Paediatric-Pak™.

Contraindications for use

If the patient is responsive or conscious, do not use the SAM 500P to provide treatment.

Intended users

The SAM 500P 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-authorised emergency medical response training program.

Warnings and Cautions

Warning

Patients suitable for treatment

The SAM 500P has been designed to work on unconscious, nonresponsive patients. If the patient is responsive or conscious, do not use the SAM 500P to provide treatment.

The SAM 500P uses an interchangeable battery and electrode pack called Pad-Pak. The SAM 500P in combination with an adult Pad-Pak is suitable for use on patients of over 25 kilograms (55 pounds) 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 Paediatric-Pak. If a Paediatric-Pak or an alternative suitable defibrillator is not available, you may use an adult system.

If you treat a paediatric patient with an adult Pad-Pak, ignore any voice prompts regarding the quality of the cardiopulmonary resuscitation (CPR). The CPR 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 500P 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 500P 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 500P immediately.

Warnings and Cautions

Avoid explosive or flammable gases

It has been determined that the SAM 500P 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 500P in the vicinity of explosive gases, including flammable anaesthetics or concentrated oxygen.

Caution

Correct placement of the electrode pads

Proper placement of the SAM 500P 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 500P at least 2 m (6 feet) away from all radio frequency devices. Alternatively, switch off the equipment causing the electromagnetic interference.

Temperature range for operation

The SAM 500P, with its battery, pads and electrodes, is designed to operate in the temperature range of 0 ºC to 50 ºC (32 °F to 122 °F). 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 500P 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 0 ºC to 50 ºC (32 °F to 122 °F) 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 500P. 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 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 500P 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-authorised emergency medical response training program.

Use of accessories

The SAM 500P is a self-contained device. Do not use any unauthorised accessories with it. The SAM 500P 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 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 500P

The SAM 500P is a semi-automatic external defibrillator designed to quickly deliver a defibrillation shock to victims of sudden cardiac arrest (SCA).

The SAM 500P is designed to operate in accordance with the joint European Resuscitation Council (ERC) and American Heart Association (AHA) 2015 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 you are 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 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 500P with CPR Advisor.

The SAM 500P with CPR Advisor can provide feedback to rescuers on the effectiveness of the cardiopulmonary resuscitation (CPR) they are providing to the victim. The SAM 500P uses ICG measurements to analyse the effectiveness and rate of compressions given and then, based on this analysis, advises the rescuer to push harder, faster or slower as appropriate. The SAM 500P uses both audible and visual prompts to give the responder feedback on the quality of the compressions administered.

Warning: The CPR Advisor function is intended for use on adult patients only. If a Paediatric-Pak is used, the CPR function is disabled. In this case, the rescuer is prompted to begin CPR but receives no CPR 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 500P uses these measurements to estimate the impedance changes in the chest and so as a way to determine the effectiveness of compressions 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.

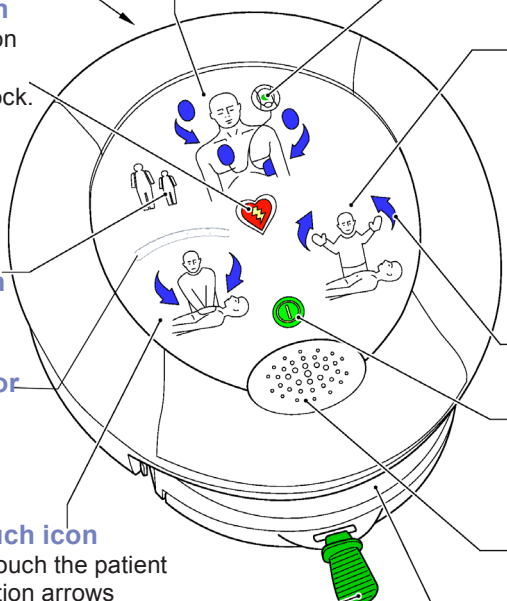
To properly diagnose this condition, HeartSine recommends that all potential users of the SAM 500P are fully trained in cardiopulmonary resuscitation (CPR), basic life support (BLS) and, in particular, the use of an automated external defibrillator. HeartSine also recommends that this training be kept up to date by regular refresher courses as and when recommended by your training provider.

If potential users of the SAM 500P 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 region.

CPR metronome

During CPR the SAM 500P will play an audible beep and flash the “Safe To Touch” indicator at a rate compliant with 2015 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 500P Overview



Data port

Attach pads icon
The action arrows around this icon will flash to instruct you to attach the electrode pads to the patient as indicated.

Status indicator
When the indicator is flashing green the SAM 500P is ready for use.

Shock button
Press this button to deliver a therapeutic shock.

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

Paediatric ready icon

Action arrows

CPR Advisor icon

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

Safe to touch icon
It is safe to touch the patient when the action arrows around this icon are flashing.

Speaker

Green tab

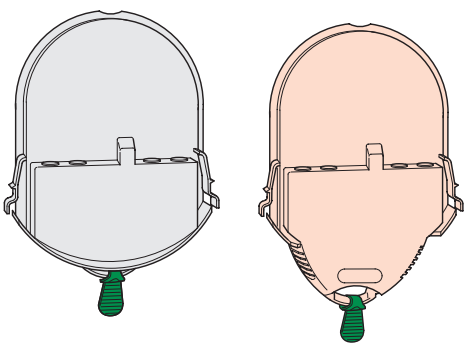
Electrode drawer

Preparation

Unpacking

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

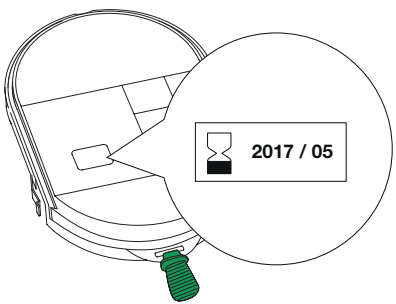
A Pad-Pak is a single-use removable battery and electrode pack in one unit. It is available in two versions[1]: grey coloured Pad-Pak for use with adults and a pink coloured Paediatric-Pak for use with children (see the illustration below).



Adult Pad-Pak Paediatric-Pak

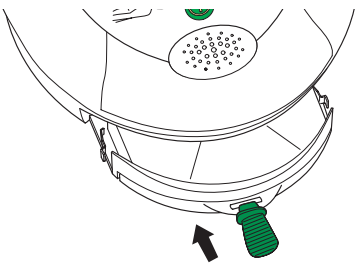
Checks before putting into service

1. Check the expiry date (year/month) on the rear of the Pad-Pak (see the illustration below). If the expiry 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 500P on a flat surface. Insert the Pad-Pak into the SAM 500P (see the illustration below). Listen for the “click” sound and ensure both tabs are fully engaged.



3. If required, the SAM 500P 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 500P Overview’ on page 13) will blink. If so, your SAM 500P is ready for use.

4. Turn on the SAM 500P 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.

Only turn the SAM 500P on 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 500P by pressing ⏻ on the front panel. Check the status indicator (see ‘SAM 500P 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 500P in its supplied soft carry case. Store the SAM 500P 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:	0 °C to 50 °C (50 °F to 122 °F)
Relative humidity:	5% to 95% (non-condensing)

Notice: HeartSine recommends that you keep a spare Pad-Pak with your SAM 500P. You can store it in the rear section of the soft carry case.

7. Complete the Warranty Card and return it to your authorised distributor or HeartSine Technologies directly (see ‘Tracking Requirements’ on page 23).

Preparation checklist

- Step 1. Check the Pad-Pak expiry 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 500P correctly.
- Step 7. Register your SAM 500P.
- Step 8. Create a service schedule (see ‘Service and Maintenance’ on page 22).

Using the SAM 500P

When to use

The SAM 500P is indicated for use on victims of sudden cardiac arrest who are exhibiting the following signs:

Unconscious

Not breathing

Without circulation

The SAM 500P has been designed to work on unconscious, nonresponsive patients. If the patient is responsive or conscious, do not use the SAM 500P to provide treatment.

The SAM 500P is suitable for use on patients of over 25 kg (55 lbs) 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 Paediatric-Pak.

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

Using the SAM 500P

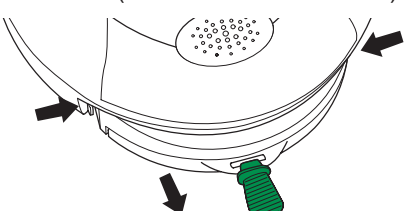
Refer to the separate Emergency User Guide. During use the SAM 500P will give extensive voice prompts to guide a user. For full list of voice prompts see ‘List of Voice Prompts’ on page 41.

Notice: The SAM 500P aborts a ready to shock condition once a non-shockable rhythm is detected.

Using the SAM 500P

After use

1. Turn off the SAM 500P 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 500P or Pad-Pak in the normal waste. Dispose of it at an appropriate recycling facility according to local requirements. Alternatively return it to your distributor for disposal or replacement.

4. Check the SAM 500P 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 500P 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 500P with abrasive materials, cleaners or solvents.

5. Check the SAM 500P for damage. If the SAM 500P is damaged, replace it immediately.
6. Install a new Pad-Pak. Before installing, check the Pad-Pak expiry date (see ‘Preparation’ on page 14). After installation check the status indicator is blinking green.

Paediatric-Pak

Using the Paediatric-Pak

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

Unconscious

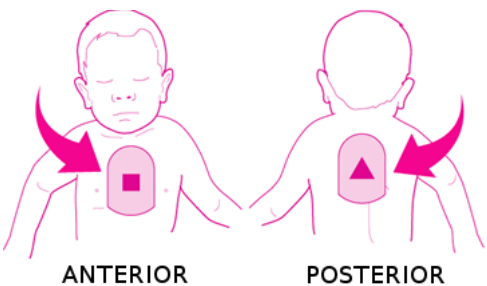
Not breathing

Without circulation

Electrode Placement:

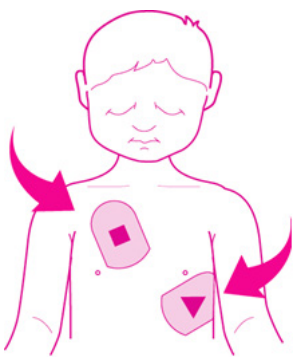
For paediatric patients there are two options for electrode placement:

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 2.5cm (1 inch) 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 approx 2.5 cm (1 inch) apart and should never be touching one another.

Warning: The Paediatric-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 25kg (55lbs). 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 500P 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 500P has a fault (see ‘Troubleshooting’ on page 25).

Monthly

- If the device shows any signs of physical damage, contact your authorised distributor or HeartSine Technologies directly.
- Check the expiry date of the SAM 500P Pad-Pak (see ‘Preparation’ on page 14 for the location of the date). If the date has expired, or is near expiry, replace with a new Pad-Pak or contact your local HeartSine distributor for a replacement.

If you hear a warning message when you turn on your SAM 500P or if, for any reason, you have suspicions that your SAM 500P 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 samaritan PAD Warranty Card with your details and return it to your authorised 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

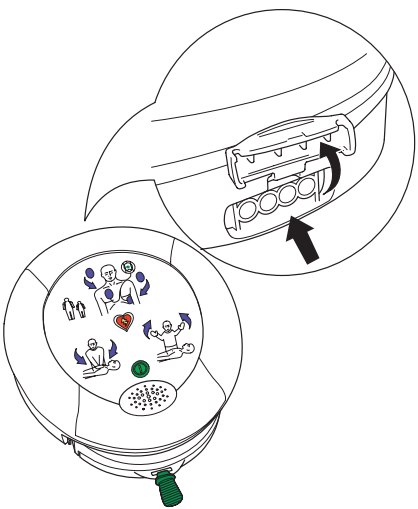
Your participation will allow us to contact you with any important notifications about the SAM 500P, such as any future software updates or field safety corrective actions.

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 500P, contact us with the updated information.

Data Management

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

1. Connect the USB cable to the SAM 500P (see illustration below).



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

Notice: The SAM 500P should only be connected to an IEC60950 PC.

Caution: You cannot defibrillate while the SAM 500P is connected to a PC.

For further information on this optional accessory, contact your authorised 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 expiry date on your Pad-Pak (see ‘Preparation’ on page 14). If the expiry date has not been passed, turn on the SAM 500P 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 authorised 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 analyse and deliver a shock if required. If you hear this message, contact HeartSine Technologies technical support.

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 analyse 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 authorised 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 authorised distributor or HeartSine Technologies Technical Support at support@HeartSine.com.

Warranty exclusion

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

- The device has been opened.
- Unauthorised 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:	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 lbs)

Environmental

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

Technical Data

Pad-Pak and Paediatric-Pak

Weight:	0.2 kg (0.44 lbs)
Battery type:	Disposable single-use combined battery and defibrillation electrode cartridge (lithium manganese dioxide ($LiMnO_2$) 18V)
Battery capacity (new):	>60 shocks or 6 hours of continuous monitoring
Battery capacity (4 years):	>10 shocks
Standby life:	See the expiry date on the Pad-Pak.
Electrode type:	Single-use pre-attached combined ECG sensor/ defibrillation pad
Electrode placement:	Adult: anterior-lateral Paediatric: electrodes anterior-posterior or anterior-lateral
Electrode active area:	100 cm^2 (40 $inch^2$)
Electrode cable length:	1 m (3.25 ft)
Electrode shelf life:	See the expiry 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, self test pass - ready state
Audible prompts:	Extensive voice prompts guide the user through the operation sequence (see ‘List of Voice Prompts’ on page 41).
Languages:	Contact your HeartSine authorised 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, 200J 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. Optimised biphasic waveform compensates energy, slope and envelope for patient impedance
Energy:	Pre-configured factory settings for escalating energy are Version AHA/ERC 2015 Adult: Shock 1: 150J; Shock 2: 150J; Shock 3: 200J Paediatric: 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
Review:	Custom USB cable directly connected to a PC and Saver EVO Windows-based data review software

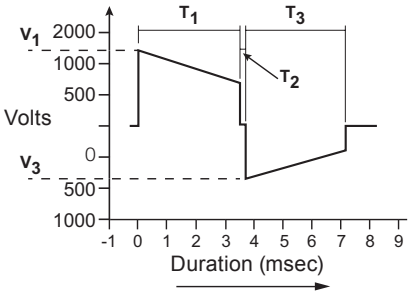
Electromagnetic compatibility

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 500P delivers a Self Compensating Output Pulse Envelope (SCOPE) biphasic waveform. This waveform 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 (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

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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

Paediatric-Pak waveform specification
All values are nominal

Arrhythmia analysis algorithm

The SAM 500P 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 500P 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 500P 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 500P ECG arrhythmia analysis algorithm's sensitivity and specificity meet the requirements of IEC60601-2-4.

The SAM 500P ECG arrhythmia analysis algorithm performance is summarised in the table below:

Rhythm Class	ECG Test Sample Size (seconds)	Required Performance Specifications	Performance Results (%)	90% One-Sided Lower Confidence Limit
Shockable Rhythm: Ventricular Fibrillation (VF)	13341	Sensitivity > 90%	96.97	96.72
Shockable Rhythm: Ventricular Tachycardia (VT)	1946	Sensitivity > 75%	91.36	90.25
Non-Shockable Rhythm: Combined Non-Shockable Rhythms	286056	Specificity > 95%	99.04	99.01

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The CPR Advisor Analysis Algorithm

The following summary shows the results produced by the CPR component of the diagnostic algorithm, when run against the clinical database.

The importance of administering effective chest compressions can mean the difference between a patient having a good quality of life following a cardiac arrest and having the misfortune of suffering neurological impairment due to inadequate cerebral oxygenation. Most modern defibrillators and mechanical resuscitation systems have a metronome facility to ensure an operator administers CPR at the correct rate. A feedback system to ensure the operator delivers compressions at the correct depth, so enabling adequate re-filling time, would optimise coronary perfusion pressures. Impedance cardiography (ICG) measures the changes of shape and movement of blood in the thorax, which can be a useful indicator of perfusion levels during external cardiac massage. The impedance cardiogram can be accurately measured using two standard defibrillator electrodes.

Combining both the force and speed CPR management tools will enhance CPR efficacy for both lay users and minimally trained bystanders.

CPR Criteria	Performance Specifications	Performance Results (%)
CPR speed: good	Sensitivity > 90% Specificity > 90%	96.05 93.01
CPR force: adequate	Sensitivity > 90% Specificity > 90%	99.91 97.95

Paediatric restriction

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

Electrode placement may also differ in paediatric 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 Paediatric-Pak is used in the SAM 500P.

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

Warning: If a paediatric patient is treated with an adult Pak-Pad, you must ignore the prompts provided. The CPR Advisor is currently only intended to provide feedback on adult patients.

Technical Data

Guidance and manufacturer's declaration – electromagnetic emissions		
The SAM 500P is intended for use in the electromagnetic environment specified below. The customer or user of the SAM 500P must assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The SAM 500P 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 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 500P is intended for use in the electromagnetic environment specified below. The customer or user of the SAM 500P 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 500P is intended for use in the electromagnetic environment specified below. The customer or user of the SAM 500P must assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the SAM 500P, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	Not applicable	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 metres (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 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;

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 500P is used exceeds the applicable RF compliance level (see above), the SAM 500P 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 500P.

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Recommended separation distances between portable and mobile RF communication equipment and the SAM 500P

The SAM 500P is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SAM 500P can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SAM 500P 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 metres (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 150kHz and 80 MHz and in the frequency range 80MHz to 2.5GHz 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

Listed below are the voice prompts used by the SAM 500P. Read the voice prompts in advance of use to be familiar with the types of instructions given.

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"

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"

"Push faster"

"Push slower"

"Push harder"

"Good compressions"

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"

"Push faster"

"Push slower"

"Push harder"

"Good compressions"

Notes

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