HeartSine samaritan® PAD
with CPR-Advisor™
model SAM 500P
User Manual

HeartSine®

Contents

About This Edition

The information in this manual applies to the HeartSine Technologies samaritan® PAD *with* CPR Advisor model SAM 500P automated external defibrillators.

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Information in this document is subject to change without notice and does not represent a commitment on behalf of HeartSine Technologies.

Symbol Definitions

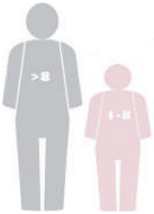
Note

Warning

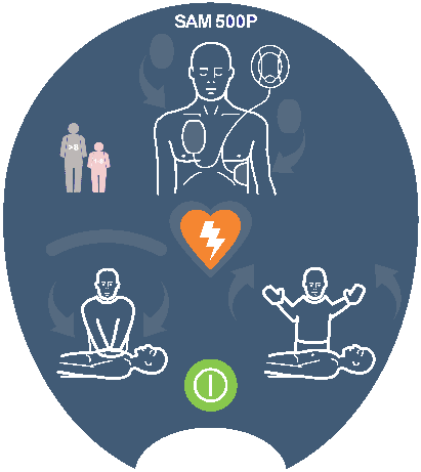
Voice Prompt

To Do

The Pediatric ready label



The SAM 500P can be identified by the “SAM 500P” and the image above marked on the front of the device



AHA/ERC 2010 Guidelines
HeartSine Technologies provides you with a fully configured system to allow you to comply with your chosen SCA treatment protocol. Our current device is configured to be compliant with the 2010 version of the American Heart Association (AHA)/European Resuscitation Council (ERC) guidelines on Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC). You should have been trained in the appropriate version of the AHA/ERC guidelines and the use of your device configuration. Contact your authorized HeartSine distributor or HeartSine directly for further Information.

The SAM 500P
The SAM 500P is an Automated External Defibrillator (AED) used for the fast delivery of defibrillation electric shock therapy to resuscitate victims of Sudden Cardiac Arrest (SCA).

Sudden Cardiac Arrest (SCA)
Sudden cardiac arrest is a condition in which the heart suddenly stops pumping effectively due to a malfunction of it'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 for SCA victims depends on immediate cardiopulmonary resuscitation (CPR). The use of an external defibrillator within the first few minutes of collapse can greatly improve the survival chances of a patient. 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 (pain, pressure, shortness of breath, squeezing feeling in chest or elsewhere in the body), seek emergency medical attention immediately.

Heart Rhythm
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, but an electrical shock can be administered to re-establish NSR. This treatment is called defibrillation. The samaritan® PAD is a device designed to automatically detect VF and perform defibrillation on victims of sudden cardiac arrest.

Detecting Fibrillation
The electrical rhythm by which the heart muscle contracts can be detected and used for medical diagnosis. The resulting reading is called an Electrocardiogram (ECG). The SAM 500P has been designed to analyze a patients ECG in order to detect VF in the heart. If VF is detected the SAM 500P will deliver a carefully engineered electrical shock designed to stop the chaotic electrical activity experienced within the heart muscle during SCA. This may allow the victim's heart to return to a NSR.

CPR Quality
When providing cardiopulmonary resuscitation (CPR) treatment to a victim of sudden cardiac arrest it is vital the heart compressions are of a good quality. If the quality of the CPR provided is good the effectiveness of defibrillation shocks is greatly improved.

Research has revealed that non-professional responders and even some professionals regularly provide ineffective CPR due to inexperience. As a response to this HeartSine have developed the HeartSine samaritan® PAD with CPR Advisor model 500P.

The HeartSine samaritan® PAD with CPR Advisor model 500P offers responders real time feedback on the quality of the CPR being administered. There is no necessity to apply extra sensors or accessories as all measurements are taken through the two defibrillation electrodes thus minimizing time to deploy the device.

CPR Advisor
The HeartSine samaritan® PAD with CPR Advisor model 500P is capable of providing feedback to rescuers on the effectiveness of the cardiopulmonary resuscitation (CPR) they are providing to the victim. The SAM 500P will use both ECG and ICG measurements to analyse the effectiveness and rate of compressions given and based on this will advise the rescuer to push harder, faster or slower as appropriate. Feedback on the quality of the compressions being given is provided to the responder by means of both audible and visual prompts.

The CPR Advisor function is intended for use on adult patients only. If a pediatric Pad-Pak is being used in a rescue the CPR Advisor function will be disabled. In this case the rescuer will be prompted to begin CPR but no CPR Advisor feedback will be provided.

Impedance Cardiogram (ICG)
The impedance cardiogram is a method of measuring changes in the patients impedance to determine the haemodynamic parameters of the heart. In the HeartSine samaritan® PAD with CPR Advisor model 500P these measurements are used to indicate blood flow from the heart which in turn is used to determine the effectiveness of compression being given during CPR.

CPR Metronome
The SAM 500P will play an audible click and flash the Safe To Touch indicator at a rate of 100 beats per minute. Responders should use this as a guide to the rate at which they are performing compressions. This feature is referred to as the CPR metronome.

CPR Guidelines
The SAM 500P is configured to operate to the joint American Heart Association and European Resuscitation Council guidelines for Cardiopulmonary Resuscitation issued in 2010. Based on these guidelines the SAM 500P will try to ensure that responders provide CPR at a rate of 100 beats per minute and to a depth of between 4 and 5 cm (one third to a half of the chest depth for a paediatric victim).

Training
SCA is a condition requiring immediate emergency medical intervention. This intervention, due to the nature of the condition, can be performed prior to seeking the advice of a physician. In order to properly diagnose this condition, HeartSine recommends that potential users of the SAM 500P are trained in cardiopulmonary resuscitation (CPR) and the use of an Automated External Defibrillator, specifically the SAM 500P. It is also recommended that this training be kept up to date by means of 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 authorized HeartSine distributor or HeartSine directly either of whom can arrange for training to be provided. Alternatively contact your local government health department for information on certified training organisations in your region.

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

Standard simulators have a constant r-r spacing and do not produce the variability displayed in the normal human heart. Our algorithm uses heart rate variability as one of its criteria for measuring VF. Consequently we do not recommend the use of normal simulators to test our device.

Store this manual with the SAM 500P (it will fit into the back section of the soft carry case). Ensure all potential users of the SAM 500P have read this manual and are familiar with its operation.

Warranty Registration
Under internationally agreed Medical Devices Regulations we are required to track the location of all medical devices sold. It is important that you complete the Warranty/Registration card and return it to your authorized distributor or HeartSine Technologies directly.
Your participation will allow us to contact you in the event of important notifications about the SAM 500P such as any future software updates or field safety corrective actions. Please complete the Warranty/Registration card included with the SAM 500P or go to www.HeartSine.com and click on ‘warranty registration’. Registration is required to validate the product warranty. The information provided will be kept strictly confidential and will not be shared with other organisations.

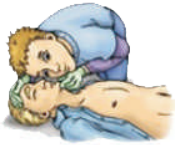
HeartSine Technologies recommend that users are trained in Cardiopulmonary Resuscitation and the use of a Defibrillator (CPR-D)

Check with 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.

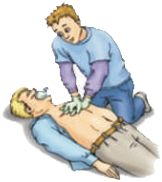
The following is a brief overview of the fundamentals of CPR for lay rescuers as advised by both the American Heart Association (AHA) and the European Resuscitation Council (ERC) in their 2010 published Guidelines for CPR and ECC. This is intended only as a quick reference for trained CPR providers. HeartSine recommend that all potential users of the SAM 500P are trained by a competent training organisation in both the use of CPR and SAM 500P, prior to placing a SAM 500P into service. Should the Guidelines change software will be available to upgrade the SAM 500P to comply, please contact your authorized HeartSine distributor or HeartSine directly.

CALL Emergency Services
(999/911/112 etc) Send for an AED

Watch, feel, listen



30 compressions 2 Breaths



If available use an AED

Continue CPR until Emergency Services arrive.
Alternate with second person after one cycle or 2 minutes

Person not responsive?
Address person and shake on shoulder

Open the airway, check for breathing

Perform CPR until an AED is available
OR arrival of emergency physician
Engage other people to help you and alternate CPR

If AED is available switch on and follow instructions

Analysis shock decision

YES — **DELIVER SHOCK**

NO

Continue CPR for 2 minutes/ 5 cycles

Unpacking Your SAM 500P

a. Open the outer box, remove the SAM 500P and all the accessories.

b. Fill out the warranty/ registration card and return to Heartsine Technologies.

c. Read this User Manual.

d. Ensure all potential users are suitably trained.

e. Place the SAM 500P into service.

Warranty
The SAM 500P is supplied with a fixed term warranty from the date of manufacture. Please check the enclosed warranty statement for details

The year of manufacture of the device is indicated by the first two digits of the serial number.

The Pad-Pak and Pediatric-Pak warranty extends to the expiry date stated on the pack. The Pad-Pak and Pediatric-Pak should not be used beyond the stated expiry date. The expiry date is given beside the symbol shown below.

The Pad-Pak and Pediatric-Pak are both single use items. If a Pad-Pak or a Pediatric-Pak are used on a patient they must not be used again.

Warranty Exclusion
HeartSine Technologies or the authorized distributor are not obliged to carry out service/repairs under warranty if:

a. Unauthorized modifications have been made to the device.

b. Non-standard components are used.

c. The user has not used the device in accordance with the indications for use or the instructions provided in this manual.

d. The serial number of the device is removed, defaced, misused or altered.

e. The device, electrodes or batteries are stored or used operationally outside of environmental specifications.

f. Pad-Pak or Pediatric-Pak packaging is not returned.

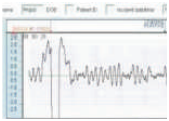
g. The device has been tested using unapproved methods or inappropriate equipment (see maintenance section).

Any claims made under warranty must be directed via the distributor from whom the device was originally purchased. Before carrying out service under warranty, HeartSine Technologies require evidence of purchase. The product must be used in accordance with the user manual and for the purpose for which it was intended. If you have a query please contact **support@heartsine.com** for assistance.

Optional Data Management Package
As an accessory HeartSine offers a Data Management cable for the SAM 500P. The cable, combined with SaverEVO software, allows users to download and manage recorded incidents from the memory of the SAM 500P. For further information on this optional accessory please contact your authorized HeartSine distributor or HeartSine directly.

USB Port

Data cable

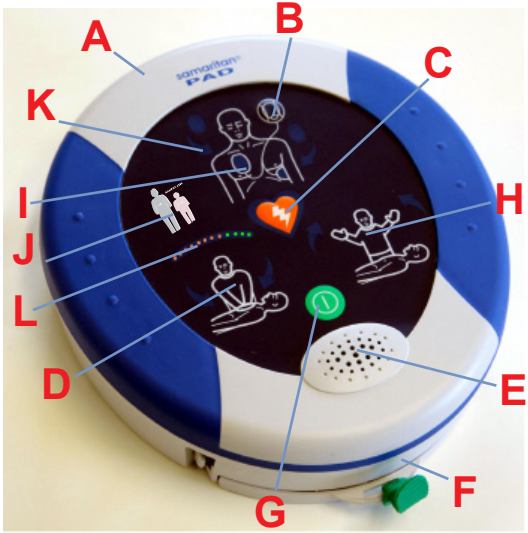


Saver™ EVO

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

Do not defibrillate while SAM 500P is connected to the PC

Software updates
The software on the SAM 500P can be upgraded using the data management package. Software updates are available on our website (www.heartsine.com).



A Data Port
B Status Indicator
C Shock Button
D Safe To Touch Indicator
E Speaker
F Pad-Pak Cartridge
G On/Off Button
H Do Not Touch Indicator
I Pads Placement Indicator
J Pediatric ready label
K Action Arrows
L CPR Indicator

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

Shock button
Press this button to deliver a therapeutic shock.

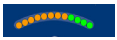
Status indicator
When the indicator is flashing green the SAM 500P is ready for use.

Attach PADs indicator
The action arrows around this icon will flash to instruct the user that the SAM 500P pads should be attached to the patient as indicated.

Safe To Touch indicator
It is safe to touch the patient when the action arrows around this icon are flashing. You may perform CPR or check the patient.

Do Not Touch indicator
Do not touch the patient when the action arrows around this icon are flashing. The SAM 500P may be analysing the patients heart rhythm or preparing to deliver a shock.

Action arrows
The action arrows around an icon will flash to indicate the actions that the user should be performing.



CPR Indicator.
This is an array of lights which provide a graduated indication of the force being applied during CPR compressions. When Green lights illuminate the compressions are considered to be of adequate force.

Pad-Pak™ Installation
The Pad-Pak includes the battery and defibrillation electrodes in one cartridge. See expiry date on label.

Installation 1

Remove the Pad-Pak from its packaging and place the SAM 500P and the Pad-Pak on a flat surface.

Push Pad-Pak into the opening and listen for the “click” sound to ensure it is properly inserted. Once the Pad-Pak is installed properly the PAD Status Indicator will begin to blink green every 5 seconds.

Do not open Pad-Pak tray or open defibrillation pads protective packaging until they are required in an emergency.

Installation 2 - Test SAM 500P

Push the ON Button. Ensure you can hear the voice prompts:

Adult patient / Child patient

Call for medical assistance

Switch Off by pressing OFF Button

Installation 3

Place the SAM 500P into its Soft Carry Case. For alternative transport cases contact your authorized HeartSine distributor or HeartSine directly.

Installation 4 - Storage of SAM 500P

Put into a wall case or other safe visible location. Wall cases differ in some countries. Contact your authorized HeartSine distributor or HeartSine directly for more information. The SAM 500P should be kept in a convenient central location. Ideally keep it alongside other emergency equipment such as first-aid, CPR preparation kits or fire extinguishers etc. If possible these should be located close to a telephone so that the rescuer can call emergency services and retrieve the SAM 500P without wasting time.
Some important points to remember when selecting a storage location for the SAM 500P:

a. Ensure the SAM 500P can be retrieved easily at any time. HeartSine recommends that the location selected should not be locked as finding key holders may delay the provision of therapy.

b. The location selected should be clean and dry. Avoid using locations which may be damp or dusty.

c. The location should be maintained at a temperature between 0°C and 50°C(32°F to 122°F). Do not select locations which may expose the defibrillator to extreme temperatures even if this is for small amounts of time.

d. Where possible the SAM 500P should be stored along with other appropriate CPR accessories such as; CPR mask, razor, scissors etc.

e. Ensure that the SAM 500P status indicator can be seen.

f. Make all necessary arrangements to ensure that the device is accessible at all times. Inform any possible users of the location of the SAM 500P.

HeartSine recommends that a spare Pad-Pak is kept with your SAM 500P.

A spare Pad-Pak can be stored in the back section of the SAM 500P Soft Carry Case. Contact your authorized HeartSine distributor or HeartSine directly to order spare or replacement Pad-Paks.

HeartSine recommends users perform regular maintenance checks. A suggested maintenance check would be:

a. Check the Status Indicator. If the Status Indicator is not flashing or is flashing red a problem has been detected. Refer to the troubleshooting section of this manual.

b. Check the expiration date of the Pad-Pak currently inserted. If the Pad-Pak has exceeded its use by date, remove it and replace with a new Pad-Pak. Contact your authorized HeartSine distributor or HeartSine directly for replacements.

c. Check supplies, accessories and spares for damage or expiration. Replace any accessories found to be damaged or that have exceeded their expiration date.

d. Check the exterior of the SAM 500P for cracks or other signs of damage. Contact your authorized HeartSine distributor or HeartSine directly if any damage is found.

e. Check that trained responders are aware of the SAM 500P's location and that it is easily accessible for those responders at all times.

f. Ensure all trained responders have up to date training for both CPR and AED use. For recommended retraining intervals please consult the organisation or body used to provide the training.

Self Test

The SAM 500P includes an automatic self test which is performed on a weekly basis. The self test program will run automatically and requires no user interaction. The SAM 500P performs a self-test routine at midnight GMT on Sunday. During this self test period, the status light will blink red. The status light shall return to green on successful completion of the self-test routine. The self-test will take no more than 10 seconds to complete. The flashing green LED indicates that the device is ready to use. Upon completion of self test the SAM 500P will emit a "beep". The self test program will test your SAM 500P and ascertain if its functions are running. If the self test should fail then the LED will flash red and the device will emit a "beep" approximately once every 5 seconds.

Self test is not able to determine if the battery and defibrillation pads currently inserted in SAM 500P are within their use by date. Remember to check the expiry date on the Pad-Pak.

The SAM 500P contains no user serviceable parts, therefore an annual service is not required.

Status Indicator

The SAM 500P includes a status indicator. This is an indicator which will flash green approximately once every five seconds. When it is flashing green it is an indication that the SAM 500P is ready for use. If this indicator is flashing red or not flashing there is a problem with your SAM 500P. If this is the case please refer to the troubleshooting section for further guidance and fault finding advice.

This is an indicator which will flash green approximately once every five seconds.
When it is flashing green it is an indication that the SAM 500P is ready for use.

Check that the SAM 500P status indicator can be seen easily. Ensure that it is flashing green approximately once every 5 seconds. It is not necessary to power up your SAM 500P to check the status.

The SAM 500P performs a self test routine at midnight GMT on Sunday. During this self test period the status light will blink red. The status light shall return to green on successful completion of the self test routine

Regularly Turning On Device

HeartSine recommends that users do not activate the SAM 500P on a regular basis to check its functionality. Regularly turning it on is not necessary as the status indicator informs the user if there is a problem with the SAM 500P.

Please note:

Every time the SAM 500P is turned on it uses power from the battery contained in the Pad-Pak. Continued regular periodic activation of the device to check functionality may reduce the standby life of your Pad-Pak resulting in the need for premature replacement.

When the SAM 500P is switched on the event recording facility is activated. Switching on repeatedly will deplete the memory and could lead to insufficient memory to record a defibrillation event. The memory can be erased from the SAM 500P using Saver™ EVO software.

Replacing The Pad-Pak™
The battery lifetime in use can be up to 6 hours monitoring, 60 shocks or a combination of both. A Pad-Pak in stand by mode (inserted into the SAM 500P) has a shelf-life indicated by the expiry date (4 years from manufacture date)*. The Pad-Pak must be replaced if:

- The expiry date of the Pad-Pak has been exceeded
- The Pad-Pak has been used (it is a single use item)

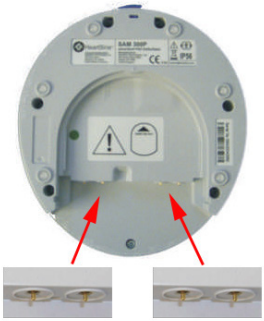
If the status indicator on the SAM 500P is flashing red or not flashing you may need to replace the Pad-Pak. For diagnosis of the reason for the status indicator flashing red or not flashing please refer to the troubleshooting section of this manual.

How To Replace A Pad-Pak™

a. Take the replacement Pad-Pak from its protective bag.
b. Remove the old Pad-Pak which is to be replaced.
c. Follow the instruction for Pad-Pak installation which can be found on page 6.
d. Push the Pad-Pak firmly to ensure it is fully inserted.
e. Check status indicator. If the Pad-Pak has been inserted correctly, status indicator flashes green approximately every 5 seconds.
f. Press the On/Off button to turn the device on. Listen for the appropriate messages to start. Press the On/Off button again to turn the device off. Ensure no warning messages are issued by the device and that the status indicator continues to flash green approximately once every five seconds.
g. If necessary inform the person responsible for maintenance of the SAM 500P.
h. Update the relevant records to show the date that the replacement Pad-Pak was placed into service.
i. Dispose of the old Pad-Pak.

* One installation test and no additional activation

Check The SAM 500P Contact Pins
When changing the Pad-Pak, HeartSine recommends that users check the contact pins on the SAM 500P. These pins are spring loaded and will retract when the Pad-Pak is inserted. The picture shown below shows how the contact pins on the SAM 500P look when the Pad-Pak has been removed.



To ensure proper operation, using your finger press lightly on each of the four pins in turn. Each pin will push back into the SAM 500P. Check that each pin springs back after it has been released.

Testing The SAM 500P
The Self Test function of the SAM 500P will determine if the device is ready for use. The SAM 500P should not be tested using standard ECG simulators.

Testing the SAM 500P with unapproved testing equipment may damage the device and will invalidate your warranty. Contact your authorized HeartSine distributor or HeartSine directly for details on how to get your SAM 500P tested.

Operating/ Standby Conditions
The SAM 500P is intended to be stored at a temperature of between 0°C to 50°C (32°F to 122°F). HeartSine recommends that if possible the device is stored at room temperature as this will ensure the peak performance for both the SAM 500P and the Pad-Pak.

Ensure that the storage location is maintained at a temperature in the range of 0°C to 50°C, (32°F to 122°F). Long term storage outside of this temperature range may adversely affect the performance of the device.

When using the samaritan® PAD in low temperature conditions HeartSine recommends that it is not exposed to the lower temperatures until it is about to be used.

Shipping And Transportation Temperature
The SAM 500P may be temporarily stored in the range -10°C to 50°C (14°F to 122°F) for up to two days. If you believe that the SAM 500P 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 a period of at least 24 hours before the device is considered ready for use.

The SAM 500P is not intended to be used in ambient temperatures below 0°C (32°F) or above 50°C (122°F).

On Board Temperature Sensor
The SAM 500P incorporates a temperature sensor. When the SAM 500P is turned on it will check the ambient temperature of the device. The SAM 500P will detect if it is outside of its intended storage temperature range of 0°C to 50°C (32°F to 122°F) by emitting three beeps when turned off.

samaritan® PAD Soft Carry Case
The SAM 500P and Soft Carry Case have been designed to allow the rescuer to use the device without having to open the SAM 500P carry case.

Front view

Back view - With clear window for quick start card

A clear plastic cover protects the SAM 500P while allowing the rescuer to operate the unit. If your SAM 500P is stored in the soft carry case it is not necessary to remove it from the case to operate it.

Pull green tab to expose electrodes package.

Cleaning The samaritan® PAD
To clean the SAM 500P wipe the device with a soft cloth that has been dampened by one of the following:

- Soapy water.
- Isopropyl alcohol (70% solution).

Do not immerse any part of the SAM 500P in water or any type of fluid. Contact with fluids may seriously damage the device, cause fire or shock hazard.

Do not clean the SAM 500P with abrasive materials, cleaners or solvents.

When To Use The SAM 500P
The HeartSine samaritan® PAD is designed for the treatment of sudden cardiac arrest (SCA). It should only be used to treat someone who may be a victim of a SCA and is:

- Unresponsive to stimulus
- Not breathing normally.
- No apparent circulation.

If the person is unresponsive but you are unsure that they have suffered from a SCA begin CPR. When appropriate apply the defibrillator and follow the audible instructions.

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

Pre Defibrillation Actions
Prior to using a SAM 500P it is advised to perform the following checks and actions in order to prepare the patient:

- Remove clothing to expose bare chest. All clothing must be removed including ALL undergarments.
- If excessively hairy, shave hair from the areas to which the defibrillation pads are to be applied.
- Ensure that the patient's chest is dry. If necessary dry the chest area.
- Ensure no rescuers or bystanders are in contact with the patient while the SAM 500P is assessing the patient's heart rhythm or while defibrillation shock is being applied.

Adult Or Pediatric (Child) Patient
The SAM 500P is capable of providing therapy to either adult or pediatric (child) victims of SCA. Patients who are less than eight years old and weigh less than 25 kilograms (55 pounds) should be treated as a pediatric patients.
For use on pediatric patients remove the Adult Pad-Pak and insert a Pediatric-Pak into the SAM 500P. Full pediatric user instructions are provided with the Pediatric-Pak.

HeartSine Technologies recommend a Pediatric-Pak is kept with the SAM 500P when the device is deployed in locations where children under the age of eight may frequent.

If the patient is more than 25 kilograms (55pounds) in weight they should be treated as an adult patient. For adult patients the adult Pad-Pak should be used in the SAM 500P.

Do not delay treatment trying to find out the patients exact age and weight.

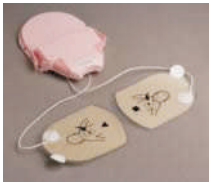
If a Pediatric-Pak is not available and an alternative defibrillator with pediatric capabilities cannot readily be found the American Heart Association and European Resuscitation Council guidelines suggest to continue to defibrillate using an adult system.

If a pediatric patient is treated with an adult Pad-Pak then the CPR prompts provided must be ignored. The CPR Advisor is currently only intended to provide feedback on adult patients.

HeartSine recommends that the SAM 500P is kept with a Pad-Pak (adult) inserted in preparation for use on adult patients.

The CPR Advisor function is intended for use on adult patients only. If a pediatric Pad-Pak is being used in a rescue the CPR Advisor function will be disabled. In this case the rescuer will be prompted to begin CPR but no CPR Advisor feedback will be provided.

Pad-Pak™ or Pediatric-Pak™
HeartSine Technologies have developed two versions of the Pad- Pak. The standard Pad-Pak is intended to be used with suspected victims of SCA who are over eight years old or weigh more than 25kg (55lb).
The Pediatric-Pak (child) is intended for use on suspected victims of SCA who are less than eight years old weighing less than 25kg (55lb). The Pediatric Pak with electrodes opened is pictured below.



The Pad-Pak (adult) and Pediatric-Pak (child) can be quickly differentiated by both colour and shape. Please familiarize yourself with the alternative battery and electrode cartridges so that you can select the appropriate version in an emergency.

Ensure you are familiar with the instructions on how to change a Pad-Pak™.

When inserted into SAM 500P the Pediatric-Pak will protrude from the bottom of the samaritan® PAD as shown above.

The CPR Advisor Function
The SAM 500P incorporates a CPR feedback function. This function provides rescuers with information on the quality of compressions being provided to adult patients during CPR.

The CPR advisor will provide the following feedback to rescuers as appropriate during the CPR pause.

- Push Harder
- Push Faster
- Push Slower

Rescuers are advised to modify the compressions being provided accordingly. If the CPR function determines that the compressions being provided are adequate the device will provide a “Good Compressions” indication.

CPR Advisor with Children
The CPR Advisor function is only available when an adult Pad-Pak is being used in the SAM 500P. The CPR advisor is intended for use only with adult patients. In the unlikely event that a pediatric patient is being treated with an adult Pad-Pak inserted the CPR advisor prompts must be ignored and responders should follow their CPR training.

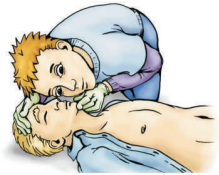
Particular care should be taken when CPR is being performed on children. HeartSine recommend that responders responsible for locations where pediatric intervention may be required should at a minimum include Basic Pediatric life support in their CPR training. Consult with your training provider to ensure that the CPR training you have received is appropriate for your purposes.

A pediatric patient is any patient who is less than eight years old weighing less than 25kg (55lb).

1. Safety

Remove patient from risk area.
Be aware of your own safety!

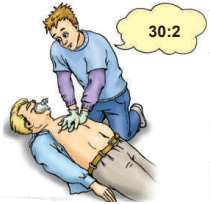
2. Not responsive? No sign of life? Check breathing, open airway



3. Contact emergency services

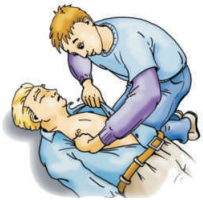
Engage other people
to help you. Get PAD

4. Perform CPR until a PAD is available

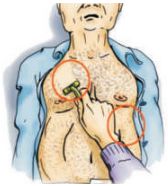


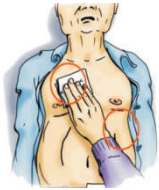
5. Switch on and follow instructions

6. Remove Clothes



7. Open Pad-Pak, remove pads, peel pads from liner. Apply pads to bare chest as shown below



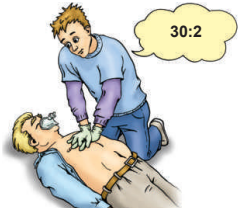


If necessary shave chest at electrodes site. Dry Skin

8. Follow Instructions

9. EITHER Press shock button

OR Perform CPR for 2 minutes or 5 cycles



Alternate with second person after one cycle
until professional rescue service arrives.

Step 1 Call for medical assistance

Step 2 Lay the SAM 500P on a flat surface

To safeguard against interference you must operate the SAM 500P at least 2m (6 feet) away from all radio frequency devices and other susceptible equipment. Alternatively switch off equipment affected by or causing the electromagnetic interference

Step 3

Press ON/OFF Button and open the green tab of the soft carry case. Listen for the audio prompts:

Adult patient or Child patient

Call for medical assistance

Remove clothing from patients chest to expose bare skin

Step 4

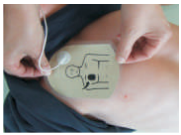
Pull green tab to remove pads

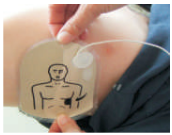
Grip the second green tab of Pad-Pak and PULL.

Step 5
Remove clothing to expose the patient's chest. If the patient has an excessively hairy chest, shave the area where the electrodes are about to be applied.

Peel pads from liner

Apply pads to patient's bare chest as shown in picture





Press pads firmly to patient's bare skin

Place the electrodes on the patients chest as indicated below. Sternum and Apex electrode pads are clearly identified on the respective electrodes.

Press the electrodes firmly to the patient's bare chest to ensure proper contact is made.

Step 6
When the electrode pads are attached correctly to the patient you will hear the audio prompts:

Assessing heart rhythm

Do not touch the patient

Stand clear of patient

The Do Not Touch indicator (above) on the samaritan® PAD will be illuminated.

Follow audio guidance. Do not touch patient or allow others to touch patient while the SAM 500P is analyzing. After completion of analysis the SAM 500P will advise you of treatment recommended. Care must be taken to keep patient still. A moving patient can lead to incorrect, delayed or less effective diagnosis and therapy.

Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process which may cause increased analysis time. Avoid contact with the patient while analysis is being carried out. The device will instruct you when it is safe to touch the patient.

Placement of the pads is critical. Strict observance of pad positioning instructions, as indicated on the labeling and in training, is essential. Failure in pad adhesion may hinder effectiveness of therapy or cause excessive skin burns to the patient if a therapeutic shock is applied.

Step 7
If the patient requires a therapeutic shock the SAM 500P will start to charge. In such a scenario you will hear the following prompts:

Shock advised

Stand clear of patient

The SAM 500P delivers electrical shocks which can cause serious harm to operators and bystanders. Caution must be taken to ensure no-one is in contact with the patient when a shock is delivered.

Step 8
When the SAM 500P has charged to the required level you will hear the audio prompt:

Press the orange Shock button now

Above left is the Do Not Touch indicator. When you are certain that no one is touching the patient press the shock button (above right) to deliver the therapy.

The SAM 500P will only administer a shock if it is needed. A voice prompt will tell you when to press the shock button to administer defibrillation therapy.

Step 9
When the shock has been delivered or ECG analysis has stopped you will hear the voice prompts:

Begin CPR

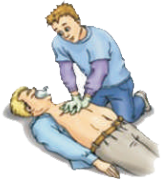
It is safe to touch the patient

Begin CPR immediately. Use the metronome sound from the SAM 500P for compression rate – the unit emits a tone corresponding to 100 beats per minute (to current AHA/ERC guidelines). Note too that the Safe To Touch indicator flashes (above) at the same rate for additional guidance.

When performing CPR watch and listen to the PAD. The Safe To Touch indicator will flash. The PAD emits 100 beeps per minute as a guide to CPR. 100 is the recommended rate to perform compressions under AHA/ERC 2010 guidelines.

As you start to provide CPR compressions the SAM 500P will continue to provide coaching on CPR with the following prompts issued.

Place overlapping hands in middle of chest



Quickly place your hands in the centre of the victims chest as shown in the illustration above.

Your hands should be placed on the lower half of the sternum (between the victims nipples).

Press directly down on the chest in time with the metronome

When providing compressions to adult victims the compressions should be to a depth of between 4 and 5 cm. Press directly down on the victims chest, listen to the metronome, or watch the flashing Safe To Touch indicator for the rate to provide compressions at.

Remain clam

Do not panic, remain calm and ensure you enlist the help of any bystanders. If there are bystanders ask if any have been trained in CPR. If there are other trained responders alternate with those responders to ensure effectiveness of CPR is maintained.

If the victim is a small child it may be more appropriate to use only one hand.
For child victims the chest should be compressed between one third to one half of the depth of the victims chest.
Ask your training provider for advise on providing CPR to child victims of sudden cardiac arrest.

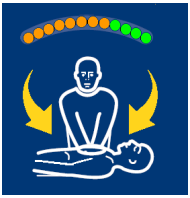
Once you have begun to provide compressions the CPR advisors function on the SAM 500P will use both ECG and ICG measurements to analyse the effectiveness of the compressions being provided. Analysis of both the force and rate of compression will be provided.

Based on this analysis the SAM 500P will provide you with advice in the form of both audible message and visual prompts.

If the SAM 500P determines the compressions are both at the correct rate and force it will play the voice prompt

Good compressions

This will be accompanied with all CPR visual indicator lights illuminating as shown below.



This is an indication that the compressions being provided are both at the correct rate and force for good CPR. Continue providing compressions at a rate of 30 compressions to two rescue breaths.

If the SAM 500P determines the compressions being provided are not hard enough it will play the voice prompt

Push harder

This will be accompanied by a graduated set of visual prompts from the CPR indicator as explained below

If, as shown above, eight orange lights illuminate this indicates that you need to push down slightly harder on the victims chest.

If, as shown above, only four orange lights illuminate this indicates that you need to push significantly harder on the victims chest.

If only one orange light illuminates this indicates that the SAM 500P has determined that either you have not begun to provide CPR compressions or they are of extremely poor quality. Check that you have placed your hands in the correct position and begin pressing down on the victims chest immediately.

A single orange light will be accompanied with the voice prompt

Begin CPR

This prompt may be given while you pause compressions to provide rescue breaths to the victim. If this is the case continue to provide rescue breaths and begin compression again after breaths have been provided. The SAM 500P will detect these compressions and analyze both rate and force with the appropriate indications provided.

The SAM 500P can determine the rate of compressions that you are providing. If it is determined that these are too slow you will hear the prompt

Push faster

If it is determined that you are pressing too fast you will hear the prompt

Push slower

If you hear either of these prompts listen to the metronome or watch the flashing Safe To Touch indicator. Ensure that the compressions you are providing are in time with the indicators provided.

Step 10
The SAM 500P will remain in CPR advisor mode for approximately 2 minutes. After 2 minutes of CPR you will hear the following voice prompt:

Stop CPR

The SAM 500P will then return to Step 6. Ensure no-one is in contact with the patient and proceed as before.

Follow the voice prompts until the emergency medical services arrive.

Your HeartSine dealer will have trained you in the particular SCA treatment protocol you have chosen. In all cases, follow the audio and visual prompts given by your SAM 500P.

User And Bystander Safety
As long as the defibrillator is used according to the directions, and no one is in contact with the patient when the Shock button is pressed, there is no risk of harm to the rescuer or bystanders.
The SAM 500P cannot deliver a shock unless electrodes are applied to someone who exhibits signs of suffering from cardiac arrest and whose heart is in need of a shock.

Do not touch the patient while the SAM 500P is in the process of delivering defibrillation therapy. Defibrillation energy can cause injury.

The Pad-Pak must be used on patients over 8 years old. The Pediatric-Pak must be used on patients less than 8 years old. Do not delay treatment through trying to find out the age and weight of the patient.

It has been determined that the SAM 500P is safe to use in conjunction with oxygen mask delivery systems. However, due to the danger of explosion it is strongly advised that the SAM 500P should not be used in the vicinity of explosive gases. This includes flammable anaesthetics or concentrated oxygen.

See **Warnings and Precautions** for complete list of warnings and precautions.

Incident Notification
As a user of an AED it is essential that you inform HeartSine Technologies of any incident where your SAM 500P is suspected to have caused a death, serious injury or illness. If you have any suspicions that this is the case you must inform HeartSine Technologies directly or through your authorized distributor.

Post Use Checklist

After using your SAM 500P HeartSine Technologies recommend you perform the following actions:

a. For data download please contact your authorized HeartSine distributor or HeartSine directly.

b. Remove the used Pad-Pak from your SAM 500P and dispose of in a suitable manner. (For recommended disposal methods please refer to disposal instructions section)

c. Check the exterior of the SAM 500P for cracks or other signs of damage. Contact your authorized HeartSine distributor or HeartSine immediately if any damage is found.

d. Check the exterior of the SAM 500P for dirt or contamination. If needed clean device with approved cleaning products.

e. Check supplies, accessories and spares for damage or expiration. Replace immediately if any damage or expiration is found. Contact your authorized HeartSine distributor or HeartSine directly.

f. Install a new Pad-Pak. Before installing the new Pad-Pak check that its expiration date has not been exceeded. Refer to the Pad-Pak installation section for full instructions.

g. After installation of the new Pad-Pak, check the status indicator. If the status indicator is not flashing green refer to the troubleshooting section of this manual. If the problem persists, contact your authorized HeartSine distributor or HeartSine directly for technical support.

h. Turn on the SAM 500P and verify that the SAM 500P operates in the correct manner i.e. audible prompt “Call for medical assistance” can be heard. Turn off the SAM 500P.

i. Contact HeartSine Technologies after use. At HeartSine we like to hear from our customers whenever they have any occasion to use any of our products, even if therapy is not delivered as part of the incident. This information is vital to the continued development and constant improvement we strive for in the treatment of SCA.

Disposal Instructions

SAM 500P
The SAM 500P is a reusable device. If maintained in accordance with the instruction in this manual it has a warranty period according to the warranty statement included with the device. The year of manufacture of the device is indicated by the first two digits of the serial number.

Disposal
If you wish to dispose of the SAM 500P unit, it should be disposed of at an appropriate recycling facility according to national, state and local requirements. Alternatively return the unit to your local distributor or HeartSine Technologies for disposal.

Within the European Union
Do not dispose of the SAM 500P unit as unsorted municipal waste. Collect the SAM 500P separately to be reused or recycled in accordance with Directive 2002/96/EEC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE), or return to your local distributor or HeartSine Technologies for disposal.

Pad-Pak™
The Pad-Pak is a single use accessory and must be replaced after use or at its expiry date. The Pad-Pak may be disposed of in accordance with the instructions for the SAM 500P unit. However special consideration must be given to the battery and defibrillation electrodes contained within the device. Alternatively, please contact your local distributor to organise the disposal of the Pad-Pak.

Battery
The Pad-Pak battery must be recycled separately in accordance with your national, state and local regulations. Please contact your authorized HeartSine distributor or HeartSine directly to organise disposal.

Electrodes
When disposing of a used Pad-Pak, the defibrillation electrodes may be contaminated with human bodily tissue, fluid or blood. Detach the electrodes from the Pad-Pak. Place the electrodes together. The electrodes must be disposed of separately as an infectious waste material. Dispose of this material in accordance with your national, state and local regulations. If the Pad-Pak electrodes have not been used they may be considered non infectious waste.

Fault Identification
If the SAM 500P detects a problem, it will indicate to the user that there may be a problem by two ways.

Status indicator
This should flash green approximately once every five seconds. If it is flashing red or not flashing at all, there may be a problem. Refer to troubleshooting section for further advice. (see maintenance section for details).

Warning message.
While turned on, the SAM 500P may play audible warning messages to indicate that there may be a problem. These messages are:

Warning - Memory Full

This message indicates that the memory for the event recording facility on the SAM 500P is full. The therapeutic capabilities of the device will be unaffected but it will no longer be able to record information for any incident it is used in. If you hear this message during an emergency response continue to use the SAM 500P until emergency services arrive.

Warning - Low Battery

This message indicates that the battery in the Pad-Pak may have less than ten defibrillation shocks left. If you hear this message during an emergency response, continue to use the SAM 500P until emergency services arrive. If available, prepare the spare Pad-Pak for use and be prepared to change it quickly.

Warning - Device Service Required

This warning indicates that the SAM 500P has detected a fault. Ccontact your authorized HeartSine distributor or HeartSine directly for further instruction. If you hear this message during an emergency response, seek an alternative defibrillator immediately.

Troubleshooting
The following is brief set of instructions of what to do if you suspect a fault on the SAM 500P or if the SAM 500P gives an indication that there may be a fault (see fault identification section).

a. Check the expiry date of the Pad-Pak battery. If the expiry date has been exceeded, change the Pad-Pak immediately. For replacement and spare Pad-Paks contact your authorized HeartSine distributor or HeartSine directly.

b. Ensure that the Pad-Pak has been correctly installed. Press the Pad-Pak firmly into place. Turn the device on and let the first audible message play. Turn the device off. If the SAM 500P plays no warning messages and the status indicator is flashing green, then the samaritan® PAD can be returned to service.

c. Turn the SAM 500P on. Listen for the appropriate voice prompts. Turn the SAM 500P off. Ensure no warning messages are played. Check that the status indicator is flashing green. If there have been no warning messages and the status indicator is flashing green, you may return the SAM 500P to service.

d. Check for any signs of physical damage such as cracks in the plastic. If any are found, remove the SAM 500P from service and contact your authorized HeartSine distributor or HeartSine directly for further advice.

e. Change the Pad-Pak. Again try turning the device on and off. If no warning messages are heard and the status indicator is flashing green, then you may return the SAM 500P to service. Leave the working Pad-Pak in the SAM 500P. Contact your authorized HeartSine distributor or HeartSine directly with details of the fault.

If this fails, or if for any reason, you have suspicions that your SAM 500P is not working correctly, contact your authorized HeartSine distributor or HeartSine directly for support.

The SAM 500P contains no user serviceable parts. It is not safe for users to attempt to open it or any of its accessories. Opening the device will nullify all warranties.

HeartSine Technologies recommend that users are trained in Cardiopulmonary resuscitation with defibrillator use (CPR-D).

Check with 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.

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

The SAM 500P has the capability to deliver therapeutic electrical shocks. The electrical shock can cause serious harm to either operators or bystanders. Caution must be taken to ensure that neither the operators nor bystanders touch the patient when a shock is to be delivered.

To safeguard against interference you must operate the SAM 500P 2 meters (6 feet) away from all radio frequency devices and other susceptible equipment. Alternatively switch off equipment affected by or causing electromagnetic interference.

Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process which may cause increased analysis time. Avoid contact with the patient while analysis is being carried out. The device will instruct you when it is safe to touch the patient.

It has been determined that the SAM 500P is safe to use in conjunction with oxygen mask delivery systems. However, due to the danger of explosion it is strongly advised that the SAM 500P should not be used in the vicinity of explosive gases. This includes flammable anaesthetics or concentrated oxygen.

Proper placement of the SAM 500P pads is critical. Strict observance of pad positioning instructions, as indicated on the labelling and in training, is essential.

Care must be taken to ensure pads are adhered to the patients' skin properly. Air pockets between the adhesive pad and skin must be eliminated. Failure in pad adhesion may hinder effectiveness of therapy or cause excessive skin burns to the patient if a therapeutic shock is applied.

The SAM 500P will only administer a shock if it is needed. A voice prompt will tell you when to press the shock button to administer defibrillation therapy.

The Pad-Pak must be used on patients over 8 years old. The Pediatric-Pak must be used on patients less than 8 years old.

The CPR Advisor function is intended for use on adult patients only. If a pediatric Pad-Pak is being used in a rescue the CPR Advisor function will be disabled. In this case the rescuer will be prompted to begin CPR but no CPR Advisor feedback will be provided.

If a pediatric patient is treated with an adult Pad-Pak then the CPR prompts provided must be ignored. The CPR Advisor is currently only intended to provide feedback on adult patients.

Do not delay treatment trying to find out the patients exact age and weight.

The Pad-Pak is a single use item and must be replaced after each use or if pouch that seals defibrillation pads has been broken/compromised in any way. If damage is suspected the Pad-Pak must be replaced immediately.

HeartSine Technologies recommend that an additional spare Pad-Pak is kept with your SAM 500P

Ensure you are familiar with the instructions on how to change a Pad-Pak.

Ensure that the location where the SAM 500P is stored is maintained at a temperature in the range of 0 to 50°C (32 to 122°F). Storage outside of this temperature range may adversely effect the performance of the device.

Periodic checks of this device must be undertaken to ensure among other things that the SAM 500P is not damaged in any way.

Testing the SAM 500P with unapproved testing equipment may damage the device and will invalidate your warranty.

Do not clean the SAM 500P with abrasive materials, cleaners or solvents.

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, cause fire or shock hazard.

The SAM 500P contains no user serviceable parts. It is not safe for users to attempt to open it or any of its accessories. Opening the device will nullify all warranties.

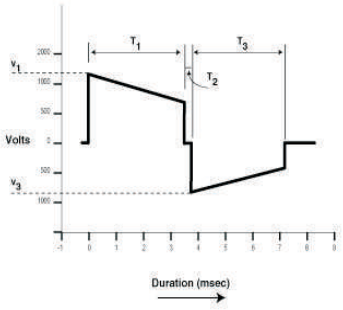
The SAM 500P performs a self test routine at midnight GMT on Sunday. During this self test period the status light will blink red. The status light shall return to green on successful completion of the self test routine. The self-test will take no longer than 10 seconds to complete.

Physical	With Pad-Pak Battery inserted
Size:	8.0x7.25x1.9in (20x18.4x4.8cm)
Weight:	1.1kg (2.4 lbs)
Defibrillator	
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 2005
Adult:	1. Shock 150J 2. Shock 150J 3. Shock 200J
Pediatric:	1. Shock 50J 2. Shock 50J 3. Shock 50J
Charging Time	
New Battery:	Typically 150J in < 8 sec., 200J in < 12 sec
After 6 discharges:	Typically 150J in < 8 sec., 200J in < 12 sec
Analysis & Discharge Time:	Time for first analysis period to readiness for discharge
New battery:	Typical: 150J in 12 secs.
After 6 discharges:	Typical: 150J in 12 secs.
Time to shock following CPR:	Typically 8 sec
Control Buttons:	“On/Off” and “Shock”
Impedance range:	20Ω - 230Ω
Patient analysis system:	(For details read clinical information section)
Method:	Evaluates patient’s ECG, signal quality, electrode contact integrity and patient impedance to determine if defibrillation is required
Specificity/Sensitivity:	Meets ISO 60601-2-4 and AAMI DF80:2003
Display:	Visual and audible prompts instructing user in steps to be taken in order to provide safe and appropriate therapeutic intervention
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
Alarms:	Low battery audible warning (typically 10 discharges remain if stored and maintained in accordance with HeartSine recommendations), check pads audible warning (alerts the user of electrode disconnect), status indicator flashes red if self-test fail or when service required, status indicator flashes green if device ready for use
Event documentation	
Type:	Internal memory
Memory capacity:	90 minutes of ECG (full disclosure) and event/incident recording.
Review capabilities:	Custom USB cable directly connected to PC and Saver EVO windows based data review software

Languages:	Contact your authorized HeartSine distributor or HeartSine directly
Environmental operating limits	
Operating/Standby temperature:	0 to 50°C (32 to 122°F)
Shipping/transportation temperature:	-10 to 50°C (14 to 122°F) for up to two days. If device has been stored below 0°C (32°F) it should be returned to an ambient temperature of between 0 to 50°C (32 to 122°F) for at least 24 hours before use.
Relative Humidity:	5 to 95% (non-condensing)
Water Resistance:	IEC 60529/EN 60529 IP56
Altitude:	0 to 15,000 feet (0 - 4,575 meters)
Shock:	MIL STD 810F Method 516.5, Procedure I (40G's)
Vibration:	MIL STD 810F Method 514.5+ Category 4 Truck Transportation - US Highways MIL STD 810F Method 514.5+ Category 7Aircraft - Jet 737& General Aviation
EMC:	EN 60601-1-2, 2002
Radiated Emissions:	EN55-11:1999 +A2:2001
Electrostatic Discharge:	EN61000-4-2:2001 (8kV)
RF Immunity:	EN61000-4-3:2001 80MHz-2.5GHz, (10V/m)
Magnetic Field Immunity:	EN61000-4-8:2001 (3 A/m)
Aircraft:	RTCA/DO-160D:1997, Section 21 (Category M) RTCA DO-227 (TSO-C142)
Pad-Pak™ and Pediatric-Pak™	Disposable single use combined battery and defibrillation electrode cartridge
Shelf Life:	Check expiration date (4 years from manufacture date)*
Size:	0.44 lbs (0.2kg)
Battery type:	Lithium Manganese Dioxide (LiMnO2) 18V
Capacity:	>60 shocks at 200J or 6 hours of continuous monitoring
Pad-Pak™	For use on patients over eight years old and 25Kg (55 lb) in weight Single Pad-Pak supplied as standard with every samaritan® PAD
Adult Electrodes type:	Single use pre-attached combined ECG sensor//Defibrillation electrodes
Placement:	Anterior-lateral
Active Area:	100cm2
Cable Length:	1m (3.5 ft)
Shelf Life:	Check expiration date (4 years from manufacture date)*
Pediatric-Pak™	For use on patients under eight years old weighing less than 25kg (55lb) Available as an optional accessory
Pediatric Electrodes type:	Single use pre-attached combined ECG sensor//Defibrillation electrodes
Placement:	Anterior - Posterior or Anterior - Lateral
Active Area:	100cm2
Cable Length:	1m (3.5 ft)
Shelf Life:	Check expiration date (4 years from manufacture date)*
Heartsine Quality Management System	ISO 9001 - GB02/54194 ISO 13485 - GB02/54195 EEC 92/43 - GB02/54193

* One installation test and no additional activation

The HeartSine SAM 500P 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 J, 150 J, & 200 J. 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 is always a constant 0.4 ms for all patient impedances. The specific SCOPE waveform characteristics for a 150J pulse are listed below.



Resistance (Ohms)	Waveform Voltages (Volts)		Waveform Duration (ms)	
	V_1	Tilt %	T_1	T_3
25	1630	63.1	3	3
50	1640	52.7	4.5	4.5
75	1650	51.4	6.5	6.5
100	1660	48.7	8	8
125	1660	50.4	10.5	10.5
150	1660	48.7	12	12
175	1660	48.7	14	14
200	1660	47.6	15.5	15.5
225	1670	467.	17	17

Pad-Pak adult waveform specification

Resistance (Ohms)	Energy (Joules)	Waveform Voltages (Volts)		Waveform Duration (ms)	
		V_1	Tilt %	T_1	T_3
25	47.4	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

Pediatric-Pak waveform specification

The SAM 500P uses the HeartSine samaritan® ECG Arrhythmia Analysis Algorithm. This Algorithm will evaluate the patients' ECG to ascertain if a therapeutic shock is appropriate. If a shock is required, the samaritan® PAD will charge and advise the user to press the shock button. If no shock is advised, the device will pause to allow the user to deliver CPR.
The HeartSine 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 HeartSine SAM 500P ECG Arrhythmia Analysis Algorithm Sensitivity and Specificity meet the AAMI DF80a 2003 requirements and AHA recommendations. The HeartSine SAM 500P ECG Arrhythmia Analysis Algorithm performance is summarized in the table below:

Rhythm Class	ECG Test Sample Size	Performance Specifications	Performance Results	90% One-Sided Lower Confidence Limit
Shockable Rhythm: Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT)	2453	Sensitivity > 90%	93.48%	90.58%
Non-Shockable Rhythm: Asystole	1902	Specificity > 95%	100%	100*%
Non-Shockable Rhythm: All other Rhythms	46711	Specificity > 95%	99.11%	95.04%

* No error to measure

a Association for the Advancement of Medical Instrumentation. DF-80 – 2003 Standard for Medical electrical equipment part 2 – 4; particular requirements for the safety of cardiac defibrillators (including automated external defibrillators).

The following is a summary of 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, enabling adequate re-filling time would optimize coronary perfusion pressures. Impedance cardiography (ICG) measures the movement of blood in the thorax which could 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 help maintain the quality of CPR administered by minimally trained bystanders by not only guiding them step-by-step through the CPR process but by continuously advising on the quality of the compressions administered.

CPR Criteria	ICG Test Sample Size(Sec)	Performance Specifications	Performance Results (%)	90% One-Sided Lower Confidence Limit (%)
CPR Speed Good	82377	Sensitivity: > 90% Specificity: > 90%	Sensitivity: 95.38 Specificity: 93.11	Sensitivity: 83.40 Specificity: 82.19
CPR Force Adequate	108728	Sensitivity: > 90% Specificity: > 90%	Sensitivity: 99.96 Specificity: 98.47	Sensitivity: 99.54 Specificity: 96.29

Pediatric restriction

Use of the CPR-Advisor function must be restricted to adult patients only. Chest compression techniques differ for the different ages/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 paediatric range adult style compressions should be performed. The force required for the pediatric 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 (patients over eight years old weighing more than 25kgs / 55 lbs).

Electrode placement may also differ in paediatric patients as dependant on the patient size the electrodes may be placed anterior – posterior (front and back) or anterior – apex (standard adult placement). The different positions that the electrodes are applied 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 – apex to allow CPR advisor to function correctly.

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

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

If a pediatric patient is treated with an adult Pad-Pak then the CPR prompts provided must be ignored. The CPR Advisor is currently only intended to provide feedback on adult patients.

The SAM 500P is intended for use in the electromagnetic environment specified below. The customer or the user of the SAM 500P should 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	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

The SAM 500P is intended for use in the electromagnetic environment specified below. The customer or the user of the SAM 500P should assure that it is used in such an environment			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 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 a least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

The SAM 500P is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10V/m	d=1.2 √P 80MHz to 800 MHz d=2.3 √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).[1] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[2] should be less than the compliance level in each frequency range.[3] 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.

[1] 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.
[2] 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 in which the SAM 500P is used exceeds the applicable RF compliance level above, the SAM 500P should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SAM 500P.
[3] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Pad-Pak™/ Pediatric-Pak™
The Pad-Pak/ Pediatric-Pak is a cartridge that fits into the samaritan® PAD. This pack contains the defibrillation electrodes and the battery that supplies power to the samaritan® PAD. Pull the green tab to access the defibrillation pads.

Biphasic Shock
A biphasic shock is an electrical current that is passed through the heart, firstly in one direction and then in another.

CPR Advisor
Function on the HeartSine samaritan® PAD with CPR Advisor model 500P which offers feedabck as to the effectiveness of compressions when performing CPR.

Defibrillation Pads
Defibrillation pads are the electrodes that are connected to the patient's chest in order to administer therapy.

Electromagnetic Interference
Electromagnetic interference is radio interference that may cause erroneous operation of electronic equipment.

Impedance Measurement
Impedance measurement is a check that is performed to check the integrity of PAD patient contact.

samaritan® PAD
The samaritan® PAD is a semi-automatic device used for the delivery of external defibrillation therapy to resuscitate victims of SCA, who are unresponsive, are not breathing, or without life signs.

Saver™ EVO
Saver is software that can be used in conjunction with the PAD and a USB cable. It can retrieve and view information about therapy delivered using the samaritan® PAD. Also, Saver software can be used to configure the PAD.

SCOPE™
SCOPE stands for Self-Compensating Output Pulse Envelope.

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Waveform
This is the biphasic technology developed by HeartSine that is incorporated into the samaritan® PAD

Sinus Rhythm
Sinus Rhythm is the normal electrical rhythm which causes the heart muscle to contract to create blood flow around the body.

Self-Test
A self-test is an automatic test that is used to check that the samaritan® PAD is working correctly.

Ventricular Fibrillation
Is a life-threatening heart rhythm that is treatable with the therapy using the samaritan® PAD.

More Information
A copy of this manual is available for download online at www.heartsine.com or can be requested on CD (USA).

Abbreviations

CPR
Cardiopulmonary Resuscitation

CPR-D
Cardiopulmonary Resuscitation-Defibrillation

SCA
Sudden Cardiac Arrest

VF
Ventricular Fibrillation

BLS
Basic Life Support

ACLS
Advanced Cardiac Life Support

NSR
Normal Sinus Rhythm

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H017-001-526-1 March 2011

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