HeartSine®

samaritan® PAD

SAM300P USERS MANUAL

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ABOUT THIS EDITION

The information in this manual applies to the HeartSine® Technologies samaritan® PAD sam300P automatic external defibrillator. Information in this document is subject to change without notice and does not represent a commitment on behalf of HeartSine® Technologies

THE samaritan® PAD sam300P
The HeartSine samaritan® PAD 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 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 for an SCA victim depends on immediate cardiopulmonary resuscitation (CPR). The use of an external defibrillator within the first few minutes of collapse can greatly improve the patients' chances of survival. Heart attack and SCA are not the same, though sometimes a heart attack can lead to a 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 normal sinus rhythm. This treatment is called defibrillation. The samaritan® PAD is a device designed to automatically detect Ventricular Fibrillation (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 and the resulting reading is called an Electrocardiogram (ECG). The samaritan® PAD has been designed to analyze a patients ECG in order to detect Ventricular Fibrillation (VF) in the heart. If Ventricular Fibrillation (VF) is detected the samaritan® PAD 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 normal sinus rhythm.

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 all potential users of the samaritan® PAD as a minimum, are fully trained in cardiopulmonary resuscitation (CPR), basic life support (BLS) and in particular the use of an Automated External Defibrillator, specifically the samaritan® PAD. 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 samaritan® PAD are not trained in these techniques contact your 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.

INTENDED USERS
The samaritan® PAD is intended for use by those who have been trained in its operation. It is highly recommended that any potential user receives training in cardiopulmonary resuscitation (CPR), emergency cardiovascular care (ECC) and/or the use of an AED (specifically the use of the samaritan® PAD). Many training organizations offer a course that combines CPR and defibrillator (CPR-D) use. Course lengths and detail covered vary but most basic courses can be completed in one day. For information on how to get training contact your local authorised distributor or HeartSine Technologies directly.

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.

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

Within the United States of America only:

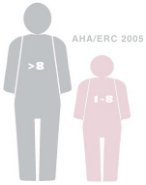
Within the United States of America, federal (U.S.) law restricts this device to sale by or on the order of a licensed practitioner.

WARRANTY REGISTRATION

Under the 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 with your details and return to your authorised distributor or HeartSine Technologies directly .

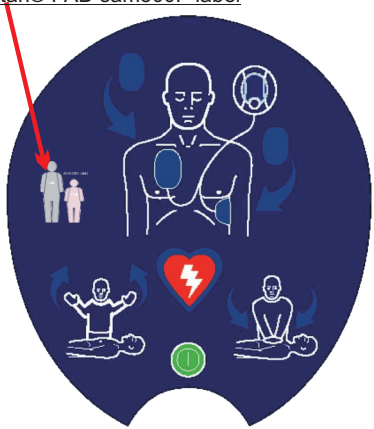
Your participation will allow us to contact you in the event of important notifications about the HeartSine samaritan® PAD such as any future software updates or field safety corrective actions. Please complete the Warranty/Registration card included with the samaritan® PAD. Registration is required to validate the product warranty. The information provided will be kept strictly confidential and will not be shared with other companies.

samaritan® sam300P label



The samaritan® PAD SAM300P can be identifed as it will have the label to the left attached. It will be located on the front of the device as shown above.

samaritan® PAD sam300P label



AHA/ERC 2005 guidelines

HeartSine Technologies provides you with a fully configured samaritan® PAD system to allow you to comply with your chosen SCA treatment protocol. Our current device is configured to be compliant with the 2005 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 HeartSine or your authorised HeartSine distributor for further information.

CPR GUIDELINES 2005 VERSUS 2000

In December 2005 both the American Heart Association (AHA) and the European Resuscitation Council (ERC) in collaboration with the International Liaison Committee on Resuscitation (ILCOR) released new guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC). These 2005 guidelines superseded the previous guidelines released in 2000 and contained several changes to the recommended procedures for both CPR and automated external defibrillation. While the AHA/ERC 2005 guidelines are based on the latest research and represent what is believed to be best practice by both the AHA and ERC both organisations state that the 2000 guidelines continue to offer safe therapy for patients suffering from Sudden Cardiac Arrest (SCA).

MAIN CHANGES IN DEFIBRILLATION THERAPY BETWEEN AHA/ERC 2000 TO 2005:

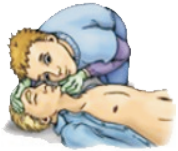
Treat Ventricular Fibrillation (VF) or Pulseless Ventricular Tachycardia (VT) with a single shock, followed by immediate resumption of CPR (2 ventilations and 30 compressions). Do not reassess the rhythm or feel for a pulse. After 2 min of CPR (= 5 cycles of 30:2), check the rhythm and give another shock (if indicated). The recommended initial energy for biphasic defibrillators is 150J-200J. Give second and subsequent shocks at 150J or greater. The 2000 guidelines recommended up to 3 shocks followed by 1 minute of CPR (15 compressions to 1 ventilation). Further details can be found on the AHA and ERC websites.

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 2005 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 samaritan® PAD are trained, by a competent training organisation in both CPR and samaritan® PAD use, prior to placing of a samaritan® PAD into service.

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

PERSON NOT RESPONSIVE?
Address person & shake on shoulder!

Watch, feel, listen



OPEN THE AIRWAY ...
CHECK FOR BREATHING!
2 breaths, if necessary

2 Breaths **30** Compressions

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

If available use an AED

If AED AVAILABLE switch ON & follow instructions

ANALYSIS
SHOCK DECISION

YES — **DELIVER SHOCK**

NO

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

CONTINUE CPR FOR 2 MINUTES/ 5 CYCLES

UN-PACKING YOUR SAMARITAN® PAD

a) Open the outer box, remove the samaritan® PAD and all accessories.

b) Fill out the Warranty/Registration card and send to HeartSine Technologies.

c) Read this User Manual.

d) Ensure all potential users are suitably trained.

e) Place the HeartSine samaritan® PAD into service

WARRANTY

The samaritan® PAD is supplied with a seven year warranty from the date of manufacture.

The year of manufacture of the samaritan® PAD is indicated by the first two digits of the serial number.

The Pad-Pak™ and Pediatric-Pak™ are single use devices with a stated expiry date. The expiry date is stated on the Pad-Pak™ and Pediatric-Pak™. The expiry date is given beside the symbol shown below.

The Pad-Pak™ and Pediatric-Pak™ has a warranty for use up until the date stated. The Pad-Pak™ and Pediatric-Pak™ should not be used beyond the stated expiry date.

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

PLEASE NOTE

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

1. Unauthorized modifications have been made to the device.
2. Non-standard components are used.
3. The user has not used the device in accordance with the indications for use or the instructions provided in this manual.
4. The serial number of the apparatus is removed, defaced, misused or altered.
5. The device, electrodes or batteries are stored or used operationally outside of environmental specifications.
6. Pad-Pak™ packaging is not returned.
7. The device has been tested using unapproved methods or inappropriate equipment (see maintenance section).

Any claims made under warranty must be directed via your distributor from whom the device was originally purchased. Before carrying out service under warranty, HeartSine Technologies require evidence of purchase.

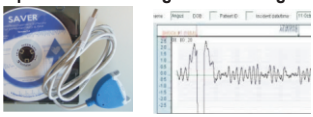
The product must be used in accordance with the user manual and for the purpose for which it was intended. If you have a query please contact *support@HeartSine.com* for assistance.

OPTIONAL DATA MANAGEMENT PACKAGE

As an accessory HeartSine offer a Data Management package for the samaritan® PAD. The package contains both the software and cable which allows users to download and manage recorded incidents from the memory of the samaritan® PAD. For further information on this optional accessory please contact your HeartSine authorised distributor.

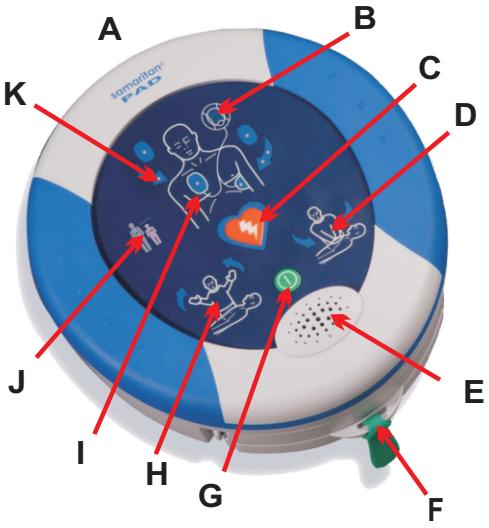
Data Port

Optional Data Management Package



Saver™ EVO Software & USB Cable

samaritan® PAD FEATURES



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) sam300P label
K) Action arrows

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 samaritan® PAD is ready for use.

Attach PADs indicator
The action arrows around this icon will flash to instruct the user that the sam300P 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 samaritan® may be analysing the patients heart rhythm or preparing to deliver a shock.

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

PAD-PAK™ INSTALLATION

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

INSTALL 1

Remove Pad-Pak™ from its packaging.

Place the samaritan® PAD 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 the time of emergency use when they are applied to a patient.

INSTALL 2

CHECK DEVICE is working optimally.

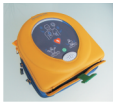
PUSH the **ON** Button. Ensure you can hear the voice prompts:

Adult patient or Child patient

CALL for medical assistance

Switch **OFF** by pressing the Button

INSTALL 3



Place the samaritan® PAD into its Soft Carry Case. For alternative transport cases ask HeartSine or your distributor.

INSTALL 4

Put into a wall case or safe visible location.

Wall cases differ in some countries. Ask HeartSine or your authorised distributor.

The samaritan® PAD should be kept in a convenient central area. Place it near a telephone so that the rescuer can call emergency medical services and retrieve the samaritan® PAD without wasting time.

Some important points to remember when selecting a storage location for the samaritan® PAD.

- Ensure the samaritan® PAD can be retrieved easily at any time. HeartSine recommend that the location selected should not be locked as finding key holders may delay the provision of therapy.
- The location selected should be clean and dry.
- The location should be maintained at a temperature between 10˚C and 50˚C (50˚F to 122˚F).
- Where possible the samaritan® PAD should be stored along with other appropriate CPR accessories such as; CPR mask, razor, scissors etc.
- Ensure that the samaritan® PAD status indicator can be seen.

Make all necessary arrangements to ensure that the device is accessible at all times. Inform any possible users of the location of the samaritan® PAD.

HeartSine recommend that an additional spare Pad-Pak™ is kept with your samaritan® PAD.

A spare Pad-Pak™ can be stored in the back section of the samaritan® PAD Soft Carry Case.
Contact HeartSine or an authorised distributor to order spare or replacement Pad-Pak™s.

MAINTENANCE

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

1. Check the Status Indicator. If the Status Indicator is not flashing a problem has been detected. Refer to the troubleshooting section of this manual.
2. 

Check the expiration date of the Pad-Pak™ currently inserted into the samaritan® PAD. If the Pad-Pak™ has exceeded its use by date, remove it from the samaritan® PAD and replace with a new Pad-Pak™. Contact your local authorised HeartSine distributor for replacements.
3. Check supplies, accessories and spares for damage or expiration. Replace any accessories found to be damaged or that have exceeded their expiration date.
4. Check the exterior of the samaritan® PAD for cracks or other signs of damage. Contact your authorised HeartSine distributor if any damage is found.
5. Check that trained responders are aware of the samaritan® PADs location and that it is easily accessible for those responders at all times.
6. 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 samaritan® PAD includes an automatic self test which is performed on a weekly basis. The self test program will run automatically and requires *no* user interaction.

Upon completion of self test the samaritan® PAD will emit a “beep”. The self test program will test your samaritan® PAD and ascertain if its functions are running. If the self test should fail then the LED will stop flashing.

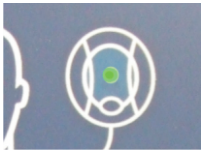
Self test is not able to determine if the battery and defibrillation pads currently inserted in samaritan® PAD are within their use by date.

You must remember to check the expiration date on the Pad-Pak™ regularly.

STATUS INDICATOR

The samaritan® PAD sam300P 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 samaritan® PAD is ready for use.

If this indicator is not flashing there is a problem with your samaritan® PAD. 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 once every five seconds. When it is flashing green it is an indication that the samaritan® PAD is ready for use.

Check that the samaritan® PAD 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 samaritan® PAD to check the status.**

REGULARLY TURNING ON THE DEVICE

HeartSine recommend that users do not activate the samaritan® PAD on a regular basis to check its functionality. Regularly turning on the samaritan® PAD is not necessary as the status indicator informs the user if there is a problem with the samaritan® PAD.

Please note:.

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

When the samaritan® PAD 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 samaritan® PAD using Saver™ EVO software.

WHEN TO REPLACE THE PAD-PAK™

The battery lifetime in use can be up to 6 hours monitoring or 30 shocks or a combination of both. A Pad-Pak™ in the stand by mode (inserted into the samaritan® PAD) has a shelf-life indicated by the expiration date (typically 3.5 years from manufacture). Replacement of the battery and defibrillation pack must be carried out if:

- the expiry date of the Pad-Pak™ has been exceeded
- When the Pad-Pak™ has been used (it is a single use item) it must be replaced with a new Pad-Pak™ cartridge.

If the status indicator on the samaritan® PAD is not flashing you may need to replace the Pad-Pak™.

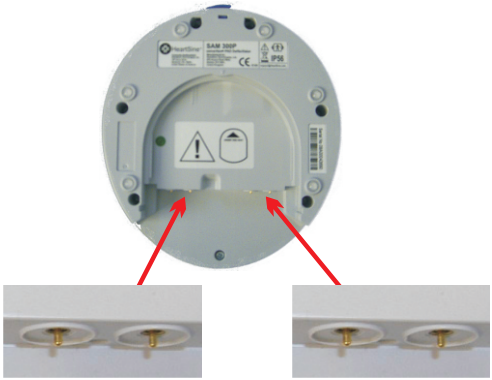
For diagnosis of the reason for the status indicator not flashing please refer to the troubleshooting section of this manual.

HOW TO REPLACE A PAD-PAK™

1. Take the replacement Pad-Pak™ from its protective bag.
2. Remove the old Pad-Pak™ which is to be replaced.
3. Follow the instruction for Pad-Pak™ installation which can be found on the page titled “Preparing your samaritan® PAD for use”.
4. Push the Pad-Pak™ firmly to ensure it is fully inserted.
5. Check status indicator. If the Pad-Pak™ has been inserted correctly, status indicator flashes green approximately every 5 seconds.
6. 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 once every five seconds.
7. If necessary inform relevant safety officer or person responsible for maintenance of the samaritan® PAD.
8. Update the relevant records to show the date that the replacement Pad-Pak™ was placed into service.
9. Dispose of the old Pad-Pak™.

CHECK THE samaritan® PAD CONTACT PINS

When changing the Pad-Pak HeartSine recommend that users check the contact pins on the samaritan® PAD. 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 samaritan® PAD look when the Pad-Pak™ has been removed.



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

TESTING THE samaritan® PAD

The Self Test function of the samaritan® PAD will determine if the device is ready for use. It is strongly recommended that the samaritan® PAD should not be tested using standard ECG simulators which have not been approved by HeartSine®.

Testing the samaritan® PAD with unapproved testing equipment may damage the device. Contact HeartSine for details on approved testing equipment and procedure.

If end users wish to test their samaritan® PAD with an ECG simulator or a defibrillator tester only HeartSine approved ECG simulators and/or defibrillator testers should be used. Contact your authorised distributor or HeartSine directly for details of HeartSine approved simulators.

STORAGE TEMPERATURE

The samaritan® PAD is intended to be stored at a temperature of between 10 to 50˚C (50 to 122˚F). The samaritan® PAD can be temporarily stored in the range -10 to 10˚C (14 to 50˚F) for up to two days.

If you believe that the samaritan® PAD has been stored below 10˚C (50˚F) it should be returned to an ambient temperature of between 10 to 50˚C (50 to122˚F) for a period of at least 24 hours before the device is considered ready for use.

Ensure that the location where the samaritan® PAD is stored is maintained at a temperature in the range of 10 to 50˚C (50 to 122˚F). Long term storage outside of this temperature range may adversely affect the performance of the device.

LOW TEMPERATURE USAGE

If the samaritan® PAD has been kept in accordance with the storage conditions indicated in this manual, between 10 to 50˚C (50 to 122˚F), for a period of at least twenty four hours, it may be used in responses where the ambient temperature is between 0 to 10˚C (32 to 50˚F). In this situation the device can be safely used in the lower temperature range for a period of up to 1 hour after it has been exposed to the lower temperature.

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

The samaritan® PAD is not intended to be used in ambient temperatures below 0˚C (32˚F) or above 50˚C (122˚F).

samaritan® PAD SOFT CARRY CASE

The samaritan® PAD and samaritan® PAD soft carry case have been designed to allow the rescuer to use the samaritan® PAD without having to open the carry case.

FRONT

BACK

Clear window for quick start card.

A clear plastic cover protects the samaritan® PAD while allowing the rescuer to operate the unit. If your samaritan® PAD 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 YOUR samaritan® PAD

To clean the samaritan® PAD 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 samaritan® PAD in water or any type of fluid. Contact with fluids may seriously damage the device or cause fire or shock hazard.

Do not clean the samaritan® PAD with abrasive materials, cleaners or solvents.

WHEN TO USE THE samaritan® PAD

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 samaritan® PAD has been designed to work on unconscious, non-responding patients. If the patient is responsive or conscious do not use the samaritan® PAD to provide treatment.

PRE DEFIBRILLATION ACTIONS

Prior to using a samaritan® PAD it is advised to perform the following checks and actions in order to prepare the patient:

- Determine if the person may have suffered a sudden cardiac arrest.
- Remove clothing to expose bare chest. All clothing must be removed including undergarments.
- If excessively hairy, shave hair from the areas to which the defibrillation pads are to be applied.
- Ensure that the patients chest is dry. If necessary dry the chest area.
- Ensure no rescuers or bystanders are in contact with the patient while the samaritan® PAD is assessing the patients heart rhythm or while defibrillation shock is being applied.

ADULT OR PEDIATRIC (CHILD) PATIENT.

The samaritan® PAD SAM300P is capable of providing therapy to either adult or pediatric (child) victims of sudden cardiac arrest. Patients who are less than eight years old and weight 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 samaritan® PAD. Full pediatric user instructions are provided with the Pediatric-Pak™.

HeartSine Technologies recommend a Pediatric-Pak™ is kept with the samaritan® PAD when the device is deployed in locations where children under the age of eight may frequent.

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

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 can not readily be found the American Heart Association and European resuscitation guidelines suggest to continue to defibrillate using an adult system.

HeartSine recommend that the samaritan® PAD is kept with a Pad-Pak™ (adult) inserted in preparation for use on adult patients.

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 over one year old and 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 the samaritan® PAD SAM300P the Pediatric-Pak™ will protrude from the bottom of the samaritan® PAD as shown above.

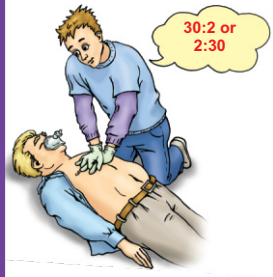
1 GENERAL

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

2 PERSON NOT RESPONSIVE? NO SIGNS OF LIFE?
Check breathing, open the airway.

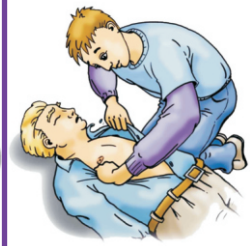
Engage other people to help you, get PAD

3 Perform CPR until a PAD is available.



4 Switch on and follow instructions.

5 Remove clothes.



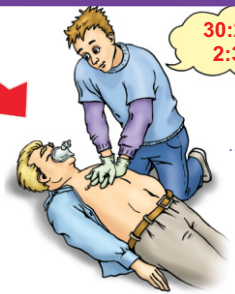
6 Open PAD, remove electrodes, peel electrodes from liner. Apply electrodes to bare chest as shown in the picture.

If necessary, shave part of chest where electrodes are placed.

Dry wet skin.

7 Follow the instructions.

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 samaritan® PAD on a flat surface.

To safeguard against interference you must operate the PAD at least 2 m (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

The samaritan® PAD is activated and you hear 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.

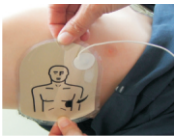
STEP 5

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

Peel the electrodes from the liner ...

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



... and apply them to the bare chest as illustrated on the electrodes.

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 (left) on the samaritan® PAD will be illuminated.

Follow audio guidance. Do not touch patient or allow any others to touch the patient while the PAD is analyzing. After completion of analysis the PAD will advise you of treatment recommended. Care must be taken to keep the 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. 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 PAD will start to charge. In such a scenario you will hear the following prompts.

Shock advised

Stand clear of patient

The samaritan® PAD 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 PAD has charged to the required level you will hear the audio prompt:

Press Shock button now

The shock button will be flashing.

Ensure no-one is touching the patient. When you are certain that no-one is touching the patient press the shock button to deliver the therapy.

The samaritan® PAD 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 audio prompts

It is safe to touch the patient

Begin CPR

Begin CPR immediately.

Use the metronome sound from the PAD for compression rate – the unit emits a tone corresponding to 100 beats per minute (to current AHA/ERC guidelines). Note too that the "OK TO TOUCH" Icon flashes at the same rate for additional guidance.

When performing CPR watch and listen to the PAD. The "OK to touch indicator" will flash. The PAD will emit ***100*** beeps per minute as a guide to CPR.
100 is the recommended rate to perform compressions under AHA/ERC 2005 guidelines.

STEP 10

The PAD will remain in CPR mode for **2** minutes. After 2 minutes of CPR you will hear the following audible prompt**:**

Stop CPR

The PAD 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 PAD.

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 samaritan® PAD cannot deliver a shock unless the electrodes are applied to someone who exhibits the signs of suffering from cardiac arrest and whose heart is in need of a shock.

Do not touch the patient while the PAD is analysing or defibrillation therapy is in process. 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.

It has been determined that the samaritan® PAD is safe to use in conjunction with oxygen mask delivery systems. However, due to the danger of explosion it is strongly advised that the samaritan® PAD 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 automated external defibrillator it is essential that you inform HeartSine Technologies of any incident where your samaritan® PAD 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 authorised distributor.

POST USE CHECKLIST

After using your samaritan® PAD HeartSine Technologies recommend you perform the following actions:

1. Use Saver™ **EVO** software to download information about the therapy performed and store appropriately. (If you do not have Saver™ EVO software please contact your dealer who can arrange for the incident to be downloaded). After downloading the defibrillation event data erase the memory of your samaritan® PAD.

2. Remove the used Pad-Pak™ from your samaritan® PAD and dispose of in a suitable manner. (For recommended disposal methods please refer to disposal instructions section)

3. Check the exterior of the samaritan® PAD for cracks or other signs of damage. Contact your distributor or HeartSine Technologies immediately if any damage is found.

4. Check the exterior of the samaritan® PAD for dirt or contamination. If needed clean device with approved cleaning products.

5. Check supplies, accessories and spares for damage or expiration. Replace immediately if any damage or expiration is found. Contact your local HeartSine approved dealer.

6. 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.

7. 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 HeartSine Technologies or your local approved distributor for technical support.

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

9. Contacting 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 sudden cardiac arrest.

DISPOSAL INSTRUCTIONS

samaritan® PAD

The samaritan® PAD is a re-useable device. If maintained in accordance with the instruction in this manual it has a warranty period of seven years from the date of manufacture. The year of manufacture of the device is indicated by the first two digits of the serial number.

Disposal

If you wish to dispose the samaritan® PAD 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 dealer or HeartSine Technologies for disposal.

Within the European Union

Do not dispose of the PAD unit as unsorted municipal waste. Collect the PAD 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 dealer or HeartSine Technologies for disposal.

Pad-Pak™

The Pad-Pak™ is a single use accessory and must be replaced after use or when its expiry date has been exceeded. The Pad-Pak™ may be disposed of in accordance with the instructions for the PAD unit however special consideration must be given to the battery and defibrillation electrodes contained within the device.

Battery

The Pad-Pak™ battery must be recycled separately in accordance with your national, state and local regulations, or return to your local dealer or HeartSine for disposal.

Electrodes

When disposing of a used Pad-Pak™ the defibrillation electrodes may be contaminated with human bodily tissue, fluid or blood. Cut the electrode wires. The electrodes should be controlled and disposed of as 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 IDENITIFICATION

If the samaritan® PAD detects a problem it will indicate to the user that there may be a problem by two ways.

Status indicator. *(see maintenance section for details)*

This should flash GREEN once every five seconds. If it is not flashing there may be a problem. Refer to troubleshooting section for further advice.

Warning message.

While turned on the samaritan® PAD 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 samaritan® PAD is full. The therapeutic capabilities of the device will be in 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 samaritan® PAD 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 samaritan® PAD 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 samaritan® PAD has detected a fault. Contact your authorised distributor or HeartSine Technologies directly for further instruction.

If you hear this message during an emergency response seek an alternative defibrillator immediately.

TROUBLE SHOOTING

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

1) 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-Pak™s contact your authorised distributor.

2) 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 samaritan® PAD plays no warning messages and the status indicator is flashing green then the samaritan® PAD can be returned to service.

3) Turn the samaritan® PAD on. Listen for the appropriate voice prompts. Turn the samaritan® PAD 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 samaritan® PAD to service.

4) Check for any signs of physical damage such as cracks in plastic. If any are found remove the samaritan® PAD from service and contact HeartSine Technologies or your authorised distributor for further advice.

5) 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 samaritan® PAD to service. Leave the working Pad-Pak™ in the samaritan® PAD. Contact your authorised distributor or HeartSine Technologies directly with details of the fault.

If this fails, or if for any reason, you have suspicions that your PAD is not working correctly contact your authorised distributor or HeartSine Technologies directly for support.

The samaritan® PAD 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.

Within the United States of America federal (U.S.) law restricts this device to sale by or on the order of a licensed practitioner.

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

The samaritan® PAD 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 samaritan® PAD 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. 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 samaritan® PAD is safe to use in conjunction with oxygen mask delivery systems. However, due to the danger of explosion it is strongly advised that the samaritan® PAD should not be used in the vicinity of explosive gases. This includes flammable anaesthetics or concentrated oxygen.

Proper placement of the samaritan® PAD 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 samaritan® PAD 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.

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 samaritan® PAD.

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

Ensure that the location where the samaritan® PAD is stored is maintained at a temperature in the range of 10 to 50˚C (50 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 samaritan® PAD is not damaged in any way.

The samaritan® PAD must only be tested using approved methods and appropriate equipment. For details contact HeartSine®.

Do not clean the samaritan® PAD with abrasive materials, cleaners or solvents.

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

The samaritan® PAD 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.

Physical	With Pad-Pak™ Battery inserted
Size:	8.0x7.25x1.9in (20x18.4x4.8cm)
Weight:	1.1kg (2.4 lbs)
Defibrillator	
Waveform:	SCOPE (**S**elf **C**ompensating **O**utput **P**ulse **E**nvelope) 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	Maximum time from first analysis period to readiness for discharge
New battery:	200J in < 20 sec.
After 6 discharges:	200J in < 20 sec.
Control	"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.
Sensitivity/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.
Indicators:	Low battery voice prompt (at least 10 discharges remain), audible prompt (alerts the user of electrode disconnect), status indicator flashes Green if device ready for use.
Event documentation	
Type:	Internal memory
Memory capacity:	45 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 HeartSine Technologies authorised dealer.

Environmental operating limits

Operating temperature:	0 to 50˚C (32 to 122˚F
Standby temperature:	10 to 50˚C (50 to 122˚F)
Temporary transportation temperature:	-10 to 50˚C (14 to 122˚F) for up to two days.
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) TSO-C142/RTCA DO-227

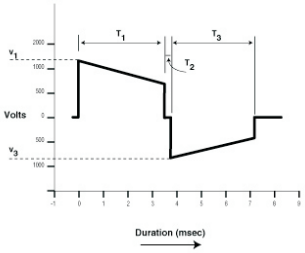
Pad-Pak™and Pediatric-Pak™	Disposable single use combined battery and defibrillation electrode cartridge.
Shelf Life:	Check expiration date (typically 3½ years from manufacture)
Weight:	0.44 lbs (0.2kg)
Size:	3.93in x 5.24in x 0.94in (10cm x 13.3cm x 2.4cm)
Battery type:	Lithium Manganese Dioxide (LiMnO2) 18V, 0.8 Amp Hrs
Capacity:	>30 shocks at 200J or 6 hours of continuous monitoring
Shelf Life:	Check expiration date (typically 3½ years from manufacture)

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:	100cm^2
Cable Length:	1m (3.5 ft)
Shelf Life:	Check expiration date (typically 3½ years from manufacture)

Pediatric-Pak™	For use on patients over one year old and 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:	100cm^2
Cable Length:	1m (3.5 ft)
Shelf Life:	Check expiration date (typically 3½ years from manufacture)

The HeartSine samaritan® PAD 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 150 J pulse are listed below.

Pad-Pak™ adult waveform specification



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	46.7	17	17

Pediatric-Pak™ child waveform specification

Resistance (Ohms)	Energy (Joules)	Waveform Voltages (Volts)		Waveform Duration (ms)	
		V1	Tilt %	T1	T3
25	47.4	514	55.6	7.8	5.4
50	51.3	671	50.4	8.8	6.0
75	52.1	751	47.1	10.0	6.6
100	51.8	813	44.3	10.8	6.8
125	52.4	858	41.4	11.5	7.3

The samaritan® PAD 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 samaritan® 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 samaritan® ECG Arrhythmia Analysis Algorithm Sensitivity and Specificity meets the AAMI DF80[a] 2003 requirements and AHA recommendations. The HeartSine samaritan® 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 defibillators).

The samaritan PAD is intended for use in the electromagnetic environment specified below. The customer or the user of the samaritan PAD should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The samaritan PAD uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
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 samaritan PAD is intended for use in the electromagnetic environment specified below. The customer or the user of the samaritan PAD 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 samaritan PAD is intended for use in the electromagnetic environment specified below. The customer or the user of the samaritan PAD 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	$d \quad 1.2\sqrt{P}$ 80MHz to 800 MHz $d \quad 2.3\sqrt{P}$ 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). [a] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[b] should be less than the compliance level in each frequency range.[c] 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 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.

b 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 samaritan PAD is used exceeds the applicable RF compliance level above, the samaritan PAD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the samaritan PAD.

c Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [*V*1] V/m.

Pad-Pak™/Pediatric-Pak™
The Pad-Pak™/Pediatric-Pak™ is a tray 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.

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 SAM300P
The 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 Software
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 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 online at **www.heartsine.com** or can be requested on CD (USA).

If you have had any occasion to use your samaritan® PAD or if you require any further information on the samaritan® PAD, its accessories or any other products please contact us.

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

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