Heartsine AED Manual

Get an original copy of the Heartsine AED Manual for manufacturer information about service, available accessories and how to use and maintain your device.

HEARTSINE™
TECHNOLOGIES

samaritan® AED User Manual

Table of Contents

1. Introduction

This manual explains how to use the Samaritan AED. The Samaritan AED is a semi-automatic device used for the delivery of external defibrillation therapy to resuscitate victims of sudden cardiac arrest (SCA) who are: unresponsive to stimulus, are not breathing or have no signs of circulation. The Samaritan AED can also be used in conjunction with the Saver™ system. The Saver™ system is software and hardware that is used to configure and to analyze the use of the Samaritan AED. Information about Saver™ is provided in the Saver™ User Manual for that product.

Note: United States Federal Law restricts this device to use by or on the order of a physician.

1.1 Regulatory Requirements

Defibrillator Tracking Requirements:

The U.S. Federal Regulations (21 CFR 821) requires that manufacturers of defibrillators track the location of each defibrillator it manufactures. This regulation further requires that each purchaser or owner of a defibrillator notify the manufacturer if the product is lost, stolen, or destroyed. If the defibrillator changes ownership (either by donation, reselling, or distribution) the manufacturer must be notified of the new location.

Notification of Adverse Events Requirements:

Medical Device Reporting (US), Incident reporting (EU) and Mandatory Problem Reporting (Canada) regulations require that HeartSine Technologies is notified of any specific adverse events involving a HeartSine Technologies product. These events relate to serious reports; involving death, serious injury, or illness of a patient, and near incidents. Further information can be found in U.S. Federal Regulations, 21 CFR 803, the EU Medical Devices Directive (93/42/EEC) and Canadian Medical Devices Regulations. If you are unsure of what to do, always

report any Samaritan AED malfunctions or failures to HeartSine Technologies.

2. Overview of this Manual

This manual describes how to use the Samaritan AED. It helps you understand the basic operation of the device and takes you through it using task-driven exercises.

To draw your attention to certain items of importance in the manual and to help you understand instructions, this guide presents particularly important items in a stylized way.

- Conventions are used for the following:
- Notes and Hints
- Warnings
- References to Other Sources of Information
- Lists of instructions
- Buttons

2.1 Notes and Hints

Points worthy of note or those that provide you with a hint are shown in italic lettering with a pencil symbol to bring them to your attention, for example:

The Samaritan AED is designed to be stored with a Samaritan Data-Pak battery installed.

2.2 Warnings

Warnings are shown in bold lettering with a symbol of a red triangle and exclamation mark to bring them to your attention, for example:

If the Status Indicator displays a flashing or solid red exclamation mark, a problem has been detected.

2.3 References to Other Sources of Information

References to other sources of information are shown in sans serif lettering with a book symbol to bring them to your attention, for example:

Refer to the Saver™ User Manual for further information on reviewing details of therapy stored in the Samaritan Data-Pak Battery.

2.4 Lists of Instructions

Instructions that you must follow in a sequential order are shown in a numbered list, for example:

1. Press the **On/Off** button once to switch on Samaritan AED.
2. Insert the connector into the socket beside the flashing light at the top of Samaritan AED.

2.5 Buttons

Device buttons are shown in bold sans serif lettering with initial capital letters, for example:

Press the **On/Off** button once to switch on Samaritan AED.

3. Warnings & Cautions

3.1 Electromagnetic Interference Precaution

The Samaritan AED has successfully passed stringent irradiated interference tests however, devices such as cellular phones and two-way radios may cause the Samaritan AED to operate erroneously due to radio frequency interference (RFI). Operation of a Samaritan AED may also adversely affect other susceptible equipment.

To safeguard against interference, you must operate Samaritan AED at least 2 meters (6 feet) away from all RF devices and other susceptible equipment. Alternatively, switch off the equipment affected by or causing the Electromagnetic Interference.

3.2 Temperature and Humidity Constraints

Successful operation and storage of the Samaritan AED is restricted by important environmental factors.

Operating – during operation of the AED, temperature must be between 0˚C to 50˚C, with relative humidity (non-condensing) between 5% to 95%.

Storage & Transport – during storage of the AED, temperature must be between -10˚C to 60˚C, with relative humidity (including condensation) between 10% to 100%.

4. Quick Overview

This chapter provides you with essential information about your Samaritan AED and various key features. Before using the Samaritan AED familiarize yourself with the device by reading through this chapter.

4.1 Understanding the 3 Different Samaritan AED Models

The Samaritan AED is available in 3 different configurations. Each configuration differs in the type of optional capabilities that are enabled. To determine which model Samaritan AED you have, turn over your Samaritan AED and look for the Model number (SAM 001, SAM 002 or SAM 003) on the Model Number label.

Samaritan Type	Model Number	Text/Icon Display	ECG Display	Manual Override
Advanced	SAM 001	Yes	Yes	Yes
Standard	SAM 002	Yes	Yes	No
Basic	SAM 003	Yes	No	No

4.2 Indications for Use

The HeartSine Samaritan AED is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not Breathing
- Without Circulation (no pulse)

The Samaritan AED is intended for use by personnel who have been trained in its operation. Users should have received training in basic life support / AED, advanced life support, or a physician-authorized emergency medical response training program. The Samaritan AED is not currently indicated for use on children less than 8 years old.

4.3 The Samaritan AED Controls

The Samaritan AED has 5 Control buttons. These controls have specific operational aspects that can be helpful when using the Samaritan AED.

1. **Backlight:** Turns on and off the backlight of the display.
2. **Contrast:** Controls the contrast of the display.
3. **On/Off:** Used to turn on and off the Samaritan AED.
4. **Shock:** Used to deliver a defibrillation shock to a patient.
5. **Manual Override:** Optional function to manually operate the Samaritan AED.

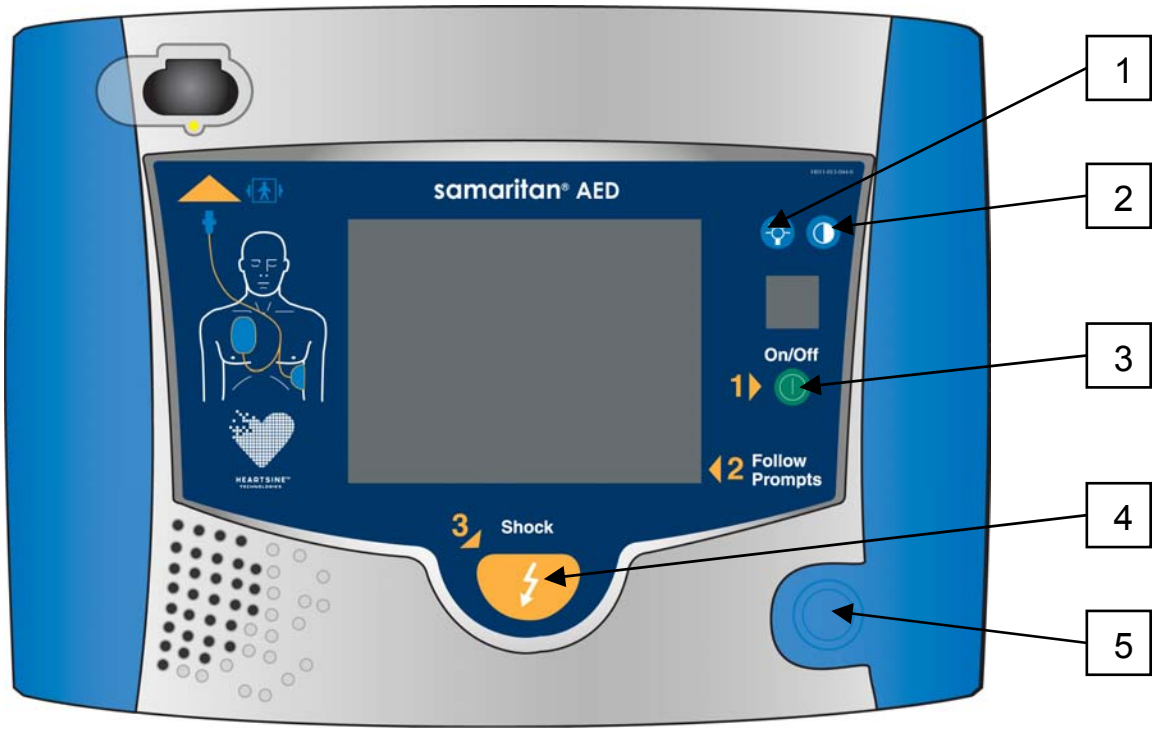
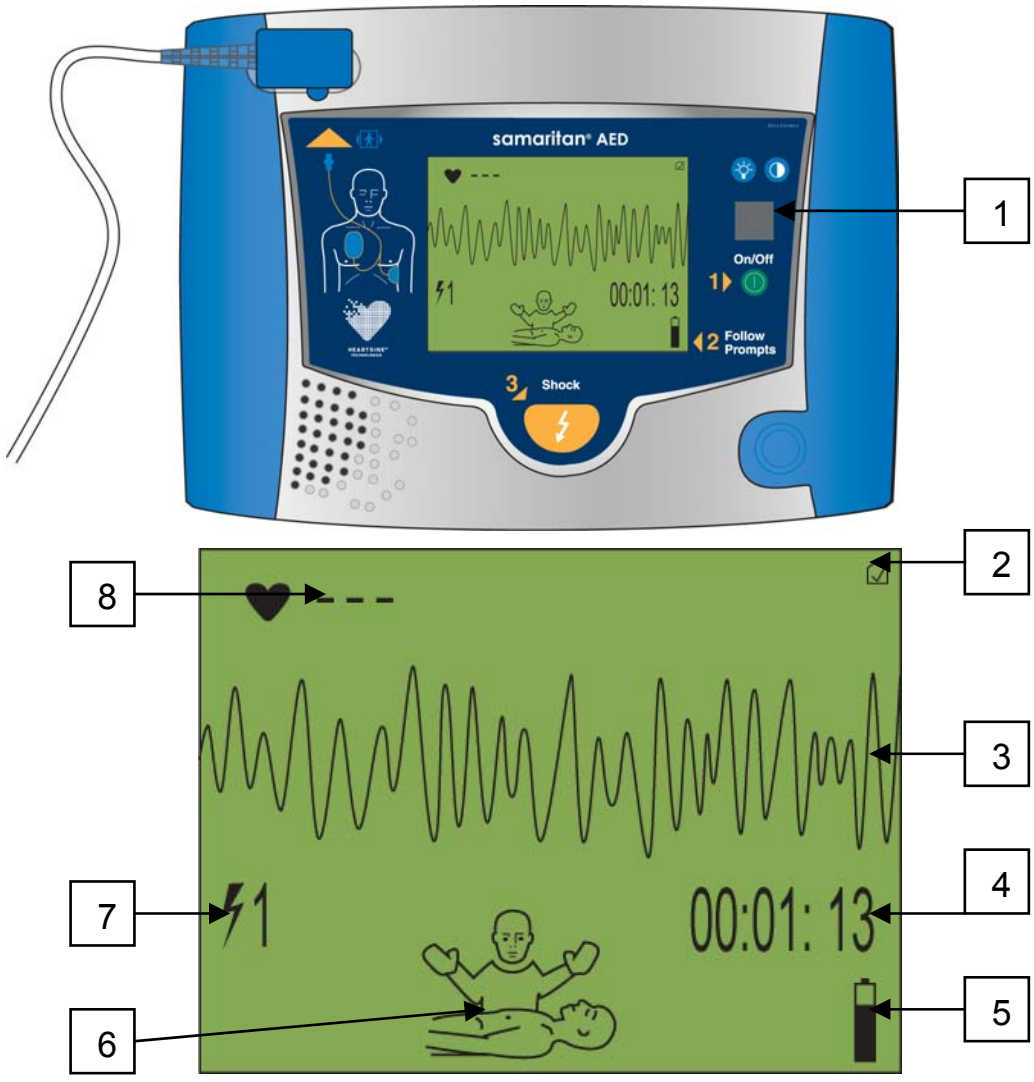


Figure 4.1 – Samaritan AED Controls

4.4 The Samaritan AED Display and Status Indicator

The Samaritan AED has a large LCD display and a status indicator. The screen will display important information while using the Samaritan AED to help guide the rescuer. Unique to the Samaritan AED are text or visual prompts that appear in the lower center of the screen. A variety of universal key images coincide with audible prompts to instruct the rescuer each step of the way.



1. Satus indicator
2. Data
3. ECG
4. Elapsed Time
5. Battery Level
6. Visual Prompts
7. Shocks Delivered
8. Heart Rate

Figure 4.2 – Samaritan AED display

4.5 The Samaritan AED Data-Pak Battery

The Data-Pak is a combination battery and data recorder for the Samaritan AED. Once inserted into the Samaritan AED, it prompts the AED to perform self-tests on a regular basis to assure that the Samaritan AED is ready for use. The integrated data recorder in the battery gives you data recording reliability.

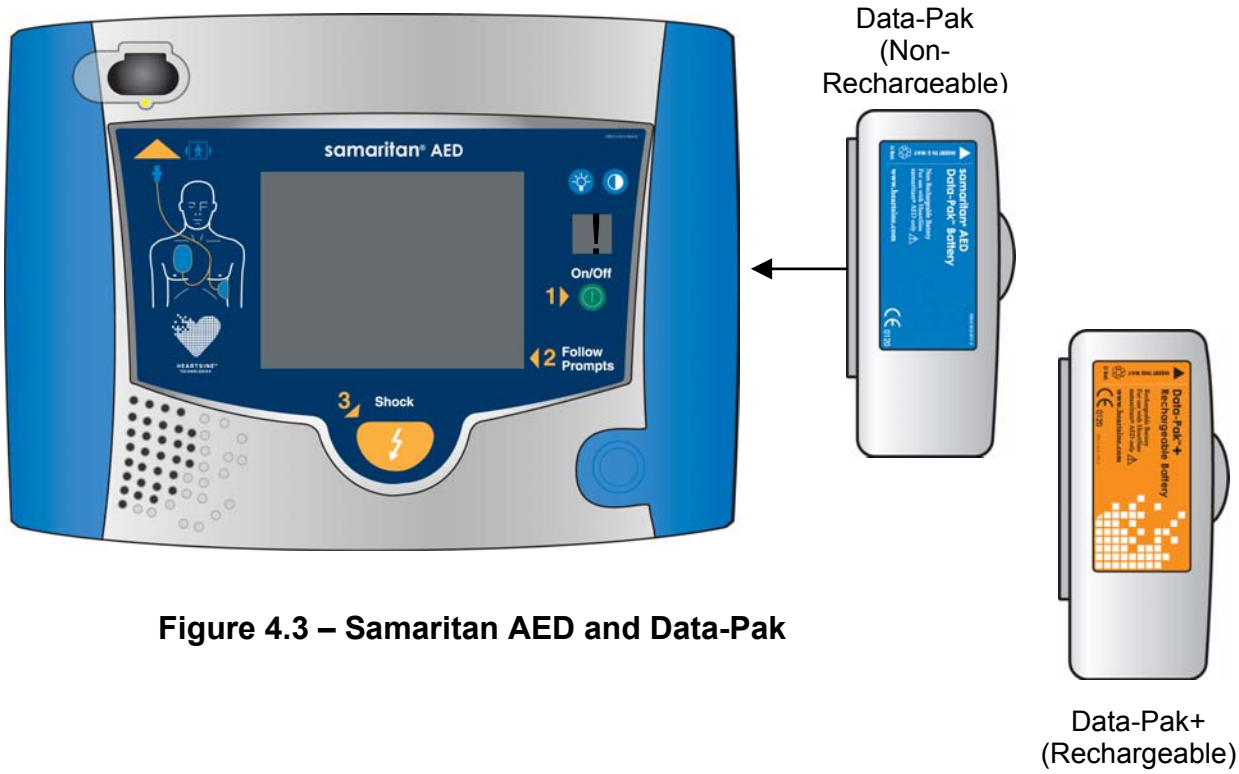


Figure 4.3 – Samaritan AED and Data-Pak

The Samaritan Data-Pak Battery must be installed into Samaritan AED by the "install before" date printed on the pack. Once installed the Samaritan Data-Pak has a 2-year standby life (See Appendix A for Data-Pak capacity). The Data-Pak is a non-rechargeable battery and must be disposed of carefully when depleted. HeartSine also produces a Data-Pak+ battery that is rechargeable (see chapter 6).

4.6 Samaritan AED Carry Case

The Samaritan AED carrying case is available to carry your Samaritan AED plus other items you may need in a rescue. Below is an example of what the carry case holds.

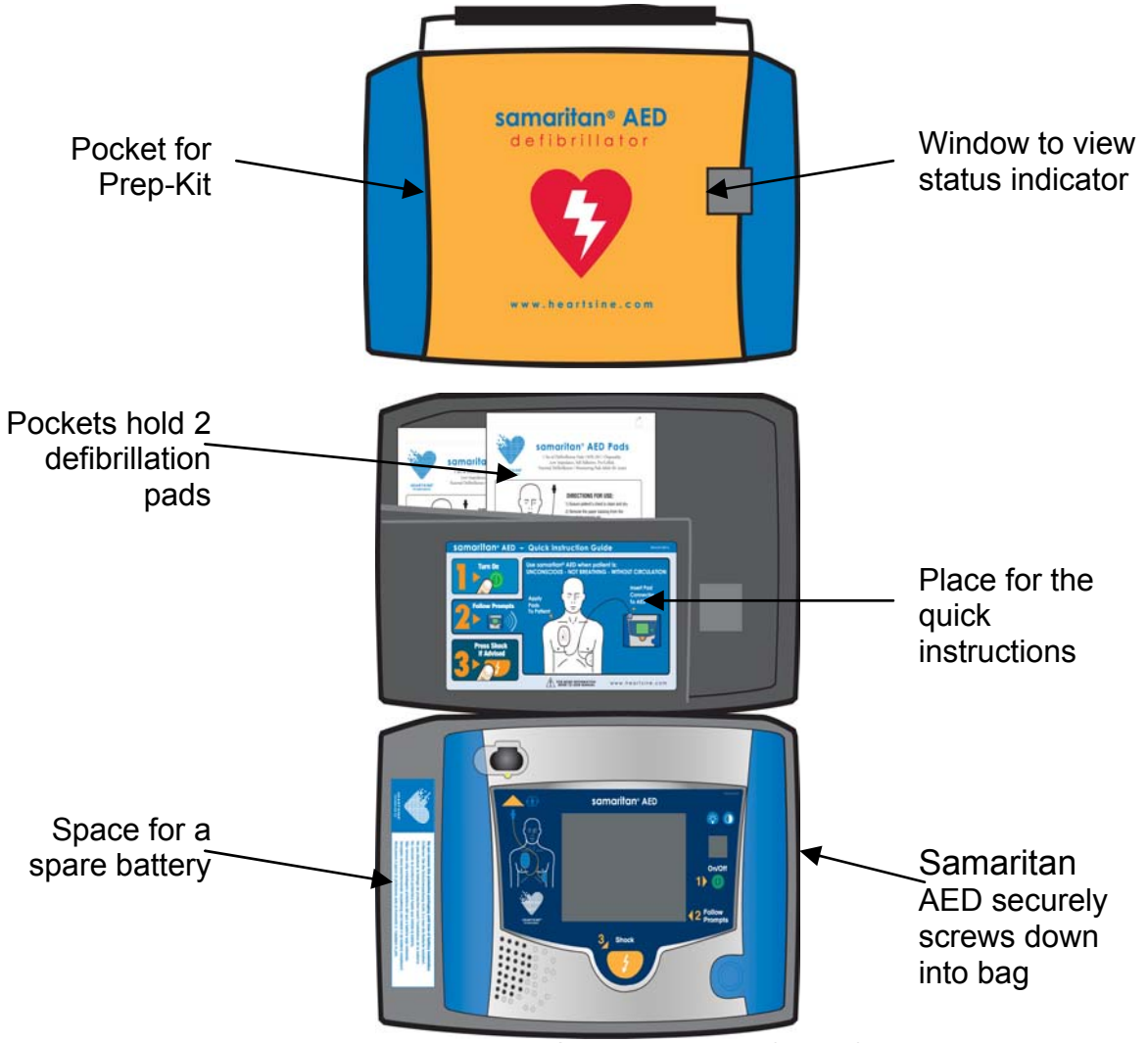


Figure 4.4 – Samaritan AED Carry Case

4.7 International Considerations

The Samaritan AED is available for use worldwide. With this in mind, there may be subtle differences in the appearance of Samaritan AEDs sold in different territories to accommodate for language variations. These differences relate to the top label of the Samaritan AED and the spoken voice prompts.

5 Preparing the Samaritan AED for Use

This chapter contains the following sub-sections:

It is imperative that the AED is always prepared for operational use, since it is designed for use in emergency situations. This section provides you with information that will help you ensure that the device is always ready for emergency use.

5.1 Quick List

Ensure that you follow this quick list to make certain that the Samaritan AED is ready for use:

- Ensure that Samaritan AED is clean and dry
- Insert the Samaritan Data-Pak Battery into Samaritan AED
- Switch on the Samaritan AED
- Ensure the Status Indicator is blank, indicating ready for use
- Switch off the Samaritan AED
- Position the Samaritan AED in a suitable and pre-arranged location

5.2 The Samaritan AED Data-Pak Battery

The Samaritan Data-Pak Battery is the power source for the Samaritan AED and is also used to store configuration information for your Samaritan AED. This configuration information can be changed using Saver™.

Saver ™ is software that is used to configure the Samaritan AED and to view information that has been saved to the Samaritan Data-Pak Battery during the use of Samaritan AED.

5.3 Installing the Samaritan AED Data-Pak Battery

Before you begin to use the Samaritan AED, the Samaritan Data-Pak Battery must be fitted correctly. This is easily achieved as the battery can only be inserted in one direction.

To insert the Samaritan Data-Pak Battery:

Slide the Samaritan Data-Pak Battery firmly into the slot on the right-hand side of Samaritan AED until it clicks, as illustrated in Figure 5.1 below.

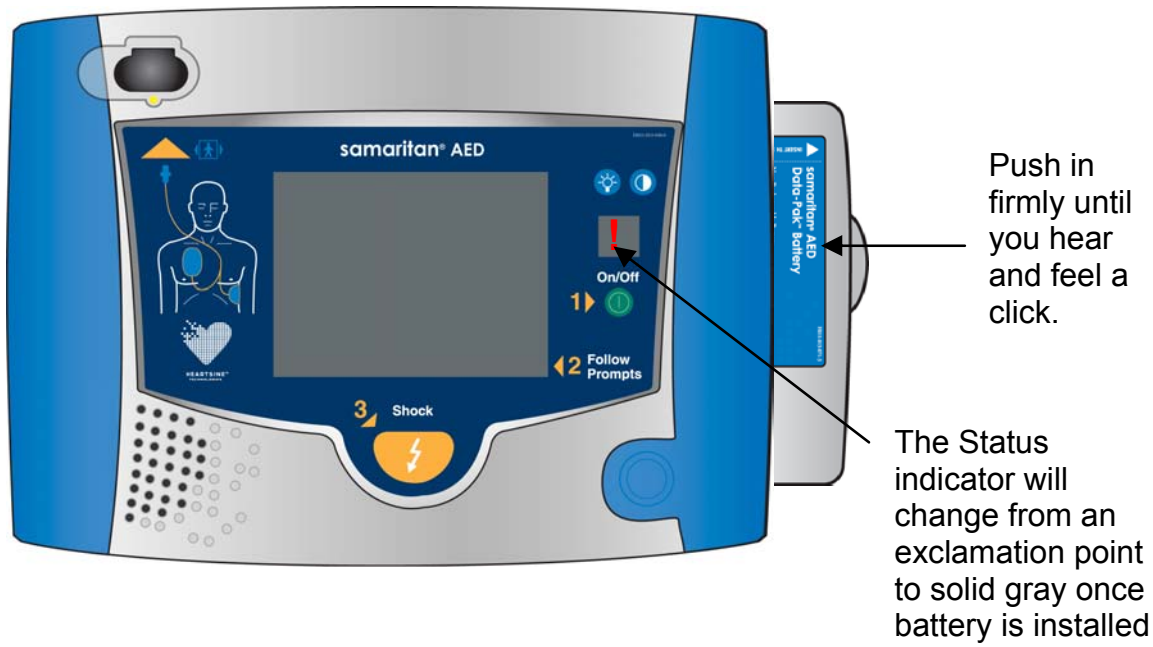


Figure 5.1 – Inserting the Samaritan Data-Pak Battery

Once the battery pack has been successfully inserted, the red exclamation mark on the Status Indicator on the front panel of the Samaritan AED will disappear.

5.4 Ensuring the Samaritan AED is Working Correctly

After insertion of the Samaritan Data-Pak battery the Samaritan AED should be switched on to ensure that the system is functioning correctly. This is indicated by the voice prompt “Apply Pads” in the absence of defibrillation pads being connected.

Check that there is sufficient battery power shown by the battery indicator on the LCD screen and that no low battery warning voice prompts have been given.

An automatic self-test occurs weekly and each time the Samaritan AED is switched on. For this test, the AED performs basic checks and configures itself with the default settings in the Samaritan Data-Pak Battery.

If the STATUS INDCATOR is solid gray, the Samaritan AED is ready for use. If the STATUS INDICTOR box displays a static or flashing Exclamation Mark, check your battery install before date and capacity or contact HeartSine Technologies for support.

5.5 Where to Place the Samaritan AED

The Samaritan AED should be placed in an easily accessible location when not in use. The **Status Indicator** must be clearly visible. The AED performs periodic self-checks with a Data-Pak installed to ensure that it remains ready for use.

It is recommended that Samaritan AED is stored with a Samaritan Data-Pak Battery installed.

6 Using the Samaritan AED

This chapter contains the following sub-sections:

- **Useful Hints**
- **Quick Instructions**
- **Step-by-Step Instructions**
- **Post Use Procedures**
- **Manual Override Instructions**
- **ECG Monitoring Cable Instructions**
- **Data-Pak+ Rechargeable Battery Instructions**

This chapter provides you with all of the instructions that you need to use the Samaritan AED in an emergency. The Quick Instructions section has been designed for immediate reference in times of emergency, but users should also read this section whenever they receive the equipment.

It is imperative that the patient is fully prepared prior to use of a Samaritan AED. This chapter also provides you with instructions that you should follow to ensure that they are ready to receive therapy.

6.1 Useful Hints

Don't worry! The Samaritan AED will provide audio and visual/text prompts to guide the rescuer through the resuscitation process.

The Samaritan AED will automatically pause for CPR to allow the rescuer to administer Cardiopulmonary Resuscitation (CPR) after each set of 3 shocks.

Good contact between the electrodes and the patient is essential.

Delivering a shock to a patient that is not adequately prepared, can have fatal consequences or may cause the therapy to be unsuccessful.

6.2 Quick Instructions

Every Samaritan AED in a carry case comes with a Quick Instruction guide that should be placed with the device at all times. This is an easy-to-follow quick reference card to help rescuers during an emergency.

The HeartSine Samaritan AED is indicated for use on victims of cardiac arrest who are exhibiting the following signs:

- Unconscious
- Not Breathing
- Without Circulation (no pulse)

1 Turn on AED -
Press and release the **On/Off** button to switch on the AED.

2 Follow Prompts -
Voice and visual instructions will instruct you to:

"Apply pads to patients bare chest"

"Plug in connector next to flashing light"

3 If directed, administer therapy by pressing the **Shock** key.

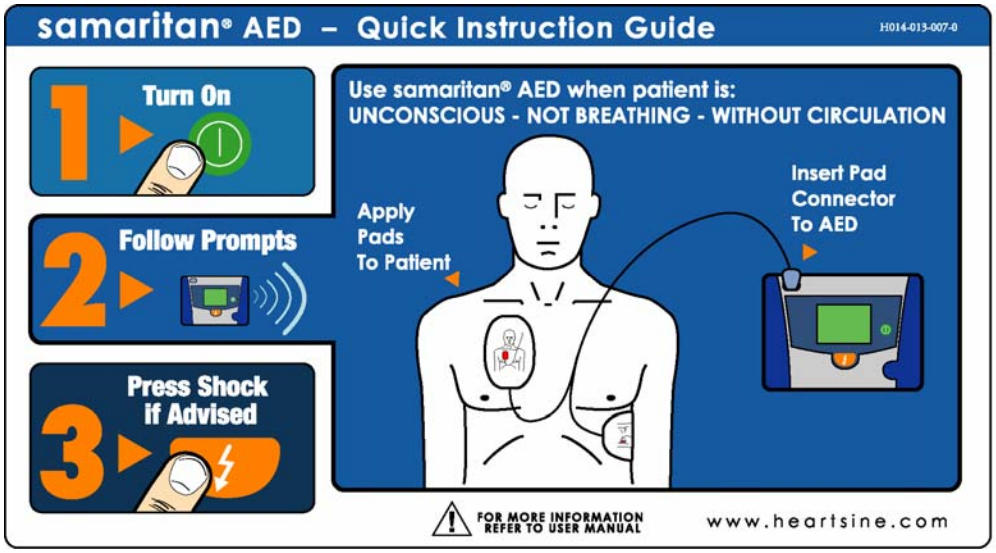


Figure 6.1 – Samaritan AED Quick Instruction Card

6.3 Step-by-Step Instructions

Preparing patient

It is essential that the Samaritan AED Disposable Defibrillation Electrodes be connected correctly to the patient. It is these electrodes that monitor the heart and deliver the therapeutic shock treatment.

When preparing the patient for their therapy, you should use the following checklist to ensure that patient is correctly prepared:

Dry the patient's chest and remove excessive hair.

Ensure the disposable defibrillation electrodes are properly attached to the patient's skin.

Ensure the patient is not in contact with metal objects.

To connect the electrodes to the patient:

1. Press the **On/Off** button once to switch on the Samaritan AED.
2. Open the defibrillation electrode pads package.
3. Remove the protective liner from the pads. Pads should not be damaged and conductive gel should not be dried out.
4. Firmly place the pads sticky side down on the patient's bare chest as indicated on the electrode label.
5. Place one pad just below the right collarbone and place the other pad over the patient's ribs in line with the armpit and below the left breast. See Figure 6.2 Proper Pad Placement.
6. Ensure pads are completely adhered to skin.

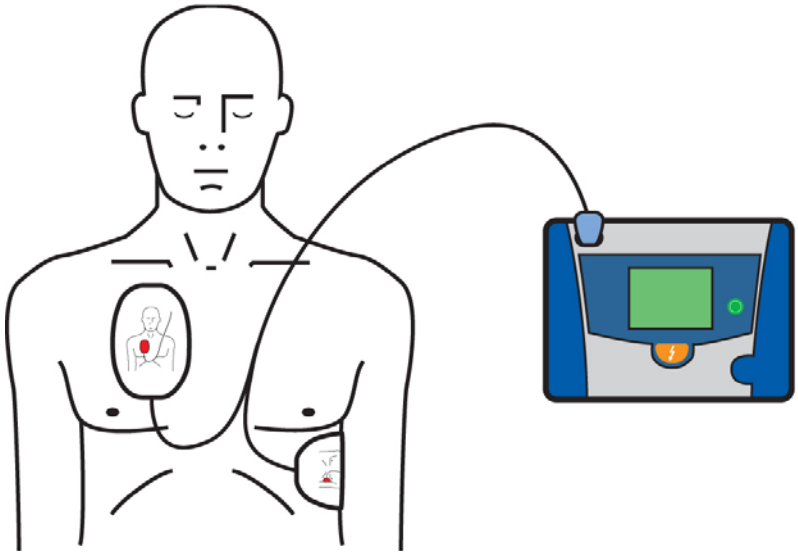


Figure 6.2 – Proper Pad Placement

The defibrillation pads must not touch each other. This can cause electrical arcing and possible skin burns, and may divert defibrillating energy away from the heart.

Insert the connector into the socket beside the flashing light at the top of Samaritan AED as in Figure 6.3:

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A flashing light indicates the socket location

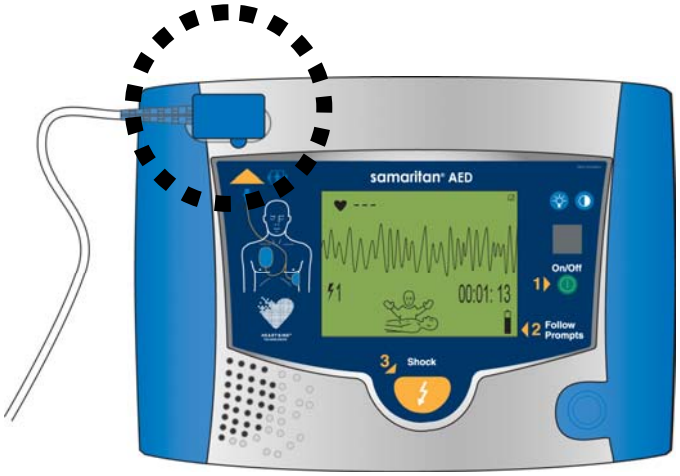


Figure 6.3 – Plugged in Pad Connector

Once the connector is firmly seated, the Samaritan AED will automatically begin to analyze the patient. You will hear the audio prompt:

"Analyzing, Do not touch the patient."

If the pads are not correctly attached to the patient, you will hear the audio prompts:

"Check pads and pads' connector."
"Apply pads to patient's bare chest."
"Plug in pads' connector next to flashing light."

If the pads are correctly connected, you will see the following LCD display:

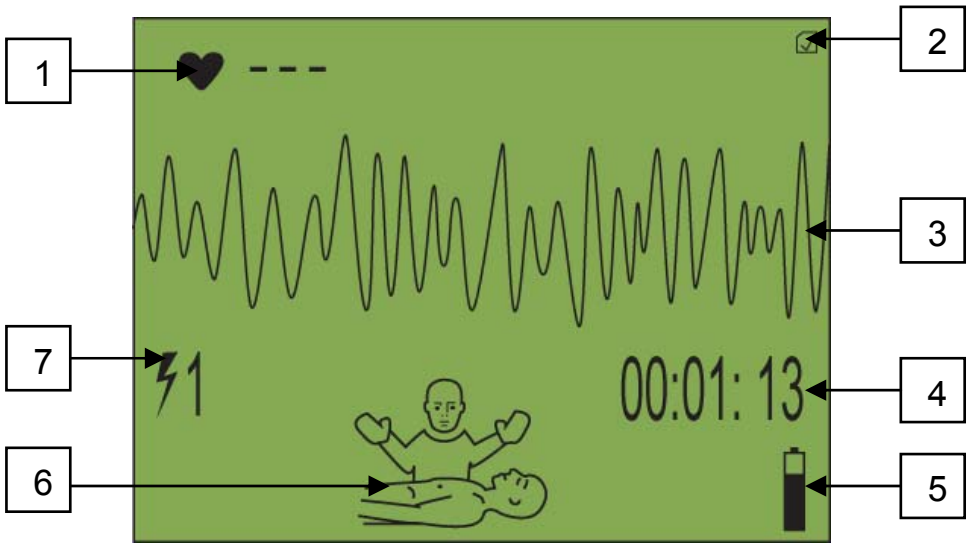


Figure 6.4 – Samaritan AED in "Stand Clear" mode

This display provides the following details of the patient's condition and about the therapy:

1. Heartrate (BPM) in the top left of the LCD display.
2. ☒ or ☑ symbol in the top right of the LCD display indicating whether the communication between the AED and the Samaritan Data-Pak Battery is working correctly.
3. ECG trace along the upper portion of the LCD display.
4. Time elapsed since Samaritan AED was switched on in the lower right of the LCD display.
5. The battery life remaining in the Samaritan AED Battery Pack in the bottom right of the LCD display.
6. A message confirming the current status of the therapy at the bottom of the LCD display. This will either be text or Icons.
7. The number of shocks that have been delivered during the therapy so far is displayed in the bottom left of the LCD display.

Keep the patient still during ECG analysis. You will be prompted as to how to proceed by audio and visual prompts.

You must ensure the patient is kept still and that no one is in contact with the patient during analysis and therapy. Moving the patient can lead to incorrect or delayed diagnosis.

The Samaritan AED display is intended only for basic ECG rhythm identification. The frequency response is not intended for diagnostic and ST segment interpretation.

If a defibrillation shock is required on the first application to the patient, Samaritan AED will prepare for shock delivery by automatically charging the energy delivery system.

You will hear the audio prompt:

"Analyzing, do not touch the patient."

After a 3 second delay, you will hear a rising tone and the "Stand Clear" visual prompt will be displayed on the LCD.

You will then hear the audio prompt:

"Do not touch the patient."

Once the Samaritan AED unit is charged, you will see the **Shock** button illuminate, hear a constant tone, and the audio prompt:

"Shock advised, press the **Shock** button now."

Press the **Shock** button to deliver the therapy.

Do not touch the patient while defibrillation therapy is in process. Defibrillation energy can cause injury.

The patient's heart rhythm will automatically be analyzed to determine if the shock was successful.

If the **Shock** button is not pressed within 30 seconds after recommendation, the device will disarm and resume analyzing the patient's heart rhythm.

Follow the audio and visual instructions to repeat therapy if the initial shock was unsuccessful.

- The Samaritan AED initially uses the base energy level to provide the shock. You can specify the base energy level using Saver™ whenever you configure the device. If the initial shock is unsuccessful, the device will use the next highest energy level that has been specified in the configuration of the AED to deliver another shock.

After three shocks or after a successful shock, you will be prompted to check patient and if needed, to perform CPR for 60 seconds. After this time has elapsed, automated patient analysis will resume.

- If no shock has been advised during any of the three automated shock delivery sequence, Samaritan AED will alert you that it is safe to touch the patient. It will monitor, analyze, and display the patient's ECG until the unit is detached from the patient or switched off.

6.4 Post Use Procedure

Once therapy is completed, check the Data-Pak energy level to determine how much battery capacity remains. If your protocols call for it, power off the device and replace Data-Pak.

- Press **On/off** button to turn the Samaritan AED off.
- If the Samaritan AED is displaying 10 shocks or less completely remove the Data-Pak from the Samaritan AED and dispose of it safely.
- Insert a new Data-Pak in the Samaritan AED if required.
- Clean the Samaritan AED properly as described in the Cleaning and Maintenance section of this manual.
- Check the Status Indicator.
- Position the Samaritan AED in a suitable and pre-arranged location.
- Discard used defibrillation electrodes and check that new electrodes are available.

6.5 Aborting a Shock

(SAM 001, SAM 002 and SAM 003 Models)

Samaritan AED allows you to abort a shock using the Manual Override button. You may disarm the Samaritan AED when the Samaritan AED is charging or has reached the full charge state (when the Samaritan AED advises to press the Shock button). After a shock has been aborted, the Samaritan AED will return to automatic mode and begin assessing the patient's rhythm.

To abort a shock during defibrillator charging or after the Samaritan AED advises that it is READY TO SHOCK:

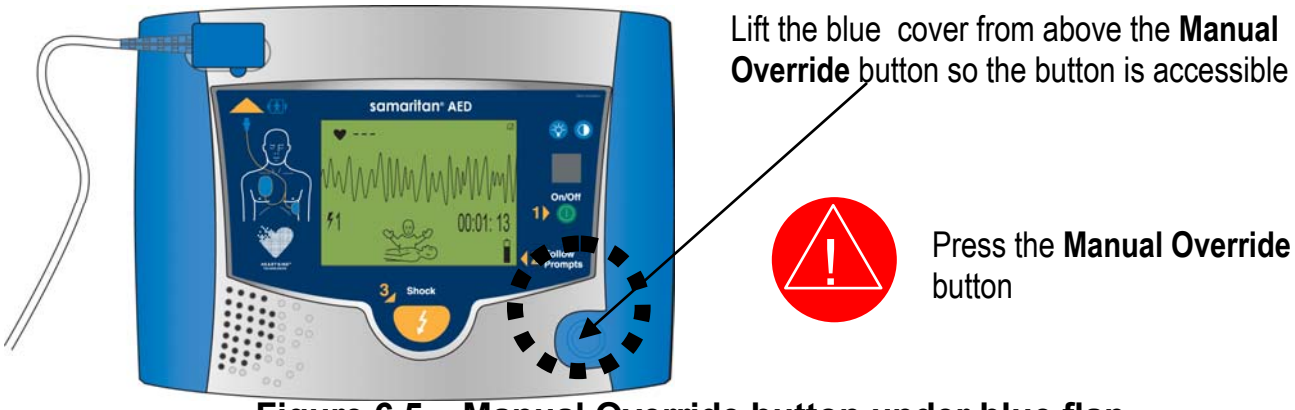


Figure 6.5 – Manual Override button under blue flap.

You will hear the following audio prompt:

"Disarming."

The device returns to patient monitoring mode.

You can abort a shock whenever the AED is charging or is charged.

If you wait for 30 seconds after Samaritan AED has first instructed you to press the **Shock** button, the charge will be aborted.

6.6 Manual Override Instructions

Only Available in the Samaritan AED Advanced Model (SAM 001)

Manual Override

The Manual Override feature is an option that is set by the manufacturer. Only the Samaritan AED Advanced Model (SAM 001) has the Manual Override option enabled. This feature is disabled in the Samaritan AED Basic (SAM 003) and Standard (SAM 002).

Performing a Manual Shock

With the Samaritan AED Advanced (SAM 001) model, you can perform a manual shock if you believe that the patient requires a shock immediately without waiting for the Samaritan AED to fully analyze the patient

.

Figure 6.6 – Manual Override button under blue flap.

After you press the Manual Override button you will hear the following audio prompt:

"Manual Override Selected."

The display will indicate manual mode selected.

Press the **Manual Override** button again (within 5 seconds) to select an energy delivery level.

You can select an energy delivery level by pressing the **Manual Override** button 1, 2, 3 or 4 times in quick successions, depending on the energy level required. Pressing the **Manual Override** button a fifth time will resume automated operation.

In the Manual Override mode, you may select one of four energy delivery levels. These energy levels are:

1	100 Joules
2	150 Joules
3	200 Joules
4	230 Joules

With each press of the manual override button, the text or Icon display will indicate the selected energy.

For Text Displays	For Icons Displays
CHARGE TO 100 J	
CHARGE TO 150 J	
CHARGE TO 200 J	
CHARGE TO 230 J	

200J is not selectable for a patient with an impedance of < 25Ω. 230J is not selectable for patients with an impedance of < 30Ω

After selecting an energy level, the Samaritan AED will charge and you will hear a rising tone along with the following audio prompt:

"Do not touch the patient!"

The **Shock** button illuminates when the charging cycle is complete and you will hear the following audio prompt:

"Deliver shock now."

The display will provide a prompt indicating ready to shock.

Press the **Shock** button to deliver the selected energy. After the shock is administered, you will hear the following audio prompt:

"Shock delivered."

The Samaritan AED will revert back to the automatic mode after delivery of the shock. If required, the process can be repeated either under the automatic or manual mode.

After any sequence of three automated or manually delivered shocks, the Samaritan AED will pause for 60 seconds to allow for CPR to be performed.

Performing Cardiopulmonary Resuscitation (CPR) on a patient connected to Samaritan AED may interfere with ECG monitoring. The Samaritan AED will automatically pause for 60 seconds after each set of 3 shocks to allow for CPR to be performed, without affecting the ECG analysis. After the pause for CPR, the Samaritan AED will resume ECG rhythm analysis. The Samaritan AED will provide an audio prompt to "Stop CPR" at the completion of the pause for CPR.

The manual override is an optional feature and should only be used under the authorization and direction of a medical director.

If you are an advanced user and have been authorized by your medical director to use the Manual Override feature, the Manual Override feature will allow you to select the energy and charge the defibrillator – without having to wait for the ECG rhythm analysis system to render a shock decision. This chapter provides you with the information that you will require to operate the Manual Override function of Samaritan AED Advanced Model.

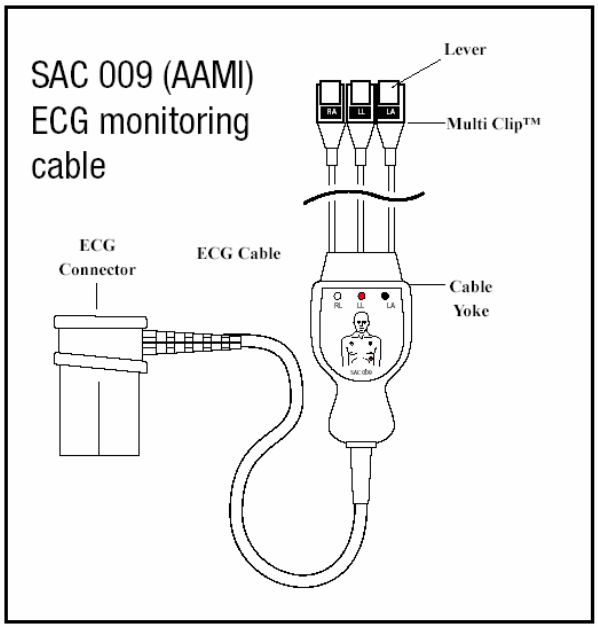
Only authorized advanced users trained in cardiac rhythm recognition and the use of manual charge and shock defibrillation therapy should use the Manual Override feature. These advanced users should be certified in Advanced Life Support (ALS).

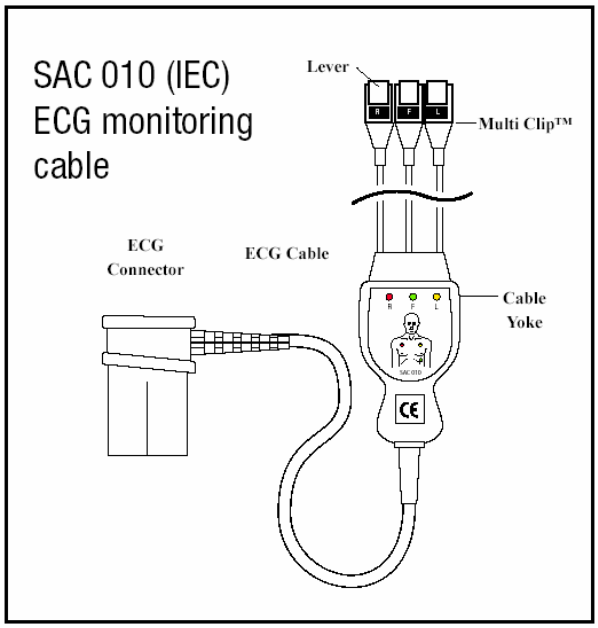
6.7 ECG Monitoring Cable User Instructions

The samaritan AED ECG monitoring Cable can be used on any samaritan AED with 1.0.19 software or higher.

Only SAM 001 and SAM 002 will display an ECG trace and Heart Rate. SAM 003 devices will only have voice prompts in relation to the patient reading.

CAUTION: As with other ECG monitoring devices, the use of monitoring only electrodes are susceptible to excessive ECG signal artifact. This artifact can cause inaccurate AED rhythm analysis decisions. It is imperative that the user performs proper skin preparations, placement and use of fresh, high quality monitoring (wet gel) electrodes to minimize artifact. Should the AED advise to “Apply Pads”, while using the ECG cable adaptor, attach the defibrillation electrodes to the patient and follow the AED voice prompts.





The ECG Monitoring Cable uses AMC Multi-Clip™ electrode connector that “locks” on to both resting snap and diagnostic tab electrodes. They can be applied easily with one hand, without applying excessive pressure on the electrode site, and is more comfortable for the patient and more ergonomic for the health professional.

How to Use the Samaritan AED ECG Monitoring Cable:

1. Locate the “yoke” of the ECG cable. This “yoke” illustrates the proper placement of the ECG electrodes on the patient.
2. Make sure the patient’s chest is clean and dry.
3. Apply ECG electrodes to the patient’s chest as illustrated on the cable “yoke”.
4. Locate the Multi-Clip™ on the ECG Cable. Notice that each Multi-Clip™ has a small lever. This lever is used to clamp onto. Or release from the round ECG electrodes.
5. Open the Multi-Clip™ levers,
6. Match the appropriate color coded Multi-Clip™ with its appropriately positioned electrode (as shown on cable “yoke” diagram) and attach by lowering lever.
7. Once Multi-Clip™s are attached to the patient, switch on the samaritan AED unit using the On/Off key.
8. The samaritan AED will begin to analyze the patient’s heart rhythm.

If Shock Advised:

If an irregular heart rhythm is analyzed that requires defibrillation (such as ventricular fibrillation), the samaritan AED will instruct the operator to attach the defibrillation pads through audible prompts.

“Apply Pads”

Once defibrillation pads are attached to the patient, the samaritan AED will operate in it’s normal AED mode.

Defibrillation can only occur when defibrillation pads are connected to the samaritan AED.

Troubleshooting:

If the following audio prompts occur while using the ECG Monitoring Cable:

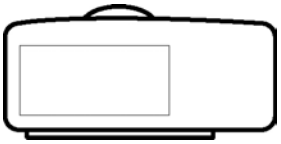
"Check Pads and Pads Connector"

1. Check ECG electrodes. Make sure they are attached to the patient correctly.
2. Assure that ECG cable connector is plugged into samaritan AED firmly.
3. If no ECG trace is displayed on the screen of the samaritan AED:
    - Turn over the samaritan AED, and check that model number is SAM 001 or SAM 002.
    - If SAM 003, ECG will not be displayed.

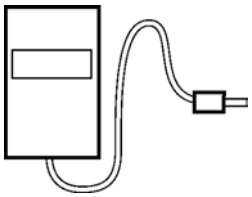
It should be noted that the ECG cable has an expiration date. Verify that this has not been exceded before use. The date can be checked on the "Use Until" label attached to the ECG cable.

6.8 Data-Pak+ Rechargeable Battery and Charger Instructions

SBP 002



SBP 010



Read these instructions before charging and using the SBP 002 Data-Pak+ battery or SBP 010 Charger.

Note:

The SBP 002 Data-Pak+ battery is only compatible with Samaritan AED revision 1.0.24 software or higher.

The SBP 010 charger is intended only for charging HeartSine Technologies SBP 002 Data-Pak+ rechargeable batteries.

Instructions for Use

1. Review the SBP 002 Data-Pak+ Instructions for Charging and Use and the SBP 010 Charger's User Manual before charging or using the SBP 002 Data-Pak+.
2. Prior to using the SBP 002 Data-Pak+ battery, charge completely.
3. Recharge the SBP 002 Data-Pak+ battery in accordance with the Instructions for Charging and Use provided with the battery.

Caution

Use only the SBP 010 charger supplied by HeartSine Technologies to charge Data-Pak+ (SBP 002) battery. Use of any other charger may cause battery damage or malfunction of the Samaritan AED, and will nullify the warranty.

Ensure that the nine (9) contact terminals on the SBP 002 battery are clean, shiny, and free from corrosion or deep scratches. Do not attempt to use or charge the Data-Pak+ (SBP 002) battery if charger or battery appears damaged or if battery's charger jack or any charger connections appear loose.

Only charge the Data-Pak+ (SBP 002) battery in a dry environment.

Do not use the Data-Pak+ (SBP 002) battery if it exhibits an unexpectedly short life after a full charge.

Do not attempt to disassemble or service the Data-Pak+ (SBP 002) battery.

Additional Cautions and Warnings are listed in the Data-Pak+ (SBP 002) Instructions for Charging and Use (provided with the Data-Pak+ battery).

Warranty

HeartSine Technologies warrants the Data-Pak+ (SBP 002) battery to be free from defects in material and workmanship until the expiration date shown on battery.

Do not use the Data-Pak+ (SBP 002) battery after its expiration date.

HeartSine Technologies warrants the SBP 010 charger for one (1) year from date of purchase.

Insertion of the SBP 002 into a Samaritan AED unit configured with software versions below 1.0.24 may result in corruption of the SBP 002. Corruption will render the SBP 002 unusable.

7 Understanding the Samaritan AED Interface

This chapter contains the following sub-sections:

- **Altering the Contrast**
- **Turning Off the Backlight**
- **Understanding Visual Indicators**
- **Understanding Display Information**
- **Icon Messages**
- **Audible Instructions**

Figure 7.1: The Samaritan AED uses a large, high resolution Liquid Crystal Display (LCD) screen. The screen displays information as text, icons and numerically. Audible prompts are also given from the AED speaker.

The visual display can be altered:

- Directly by Samaritan AED operator
- Indirectly by PC programmed configuration

Refer to the Saver™ User Manual for further information on configuring the LCD display using Saver™.

This chapter provides you with the information that you require to successfully understand and interpret the Samaritan AED interface.

7.1 Altering the Contrast

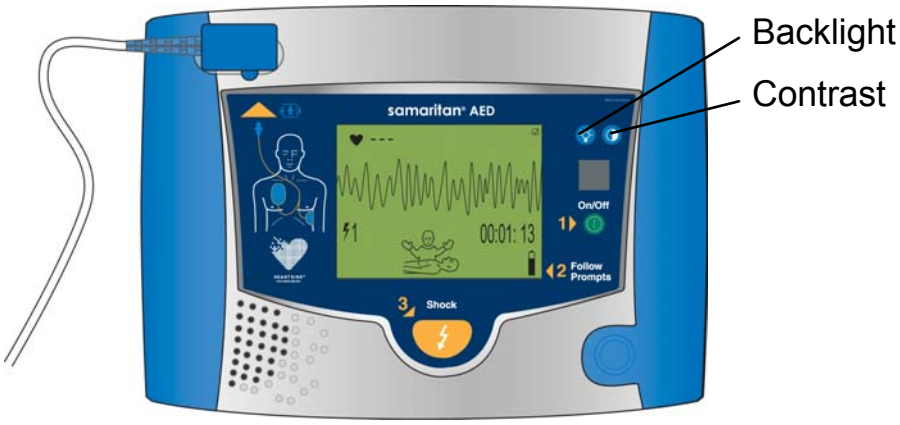


Figure 7.2

You may wish to alter the contrast of the LCD screen if you cannot see the screen properly.

To alter the contrast of the LCD screen:

- Press the **Contrast** button to increase the contrast to the maximum; each press will intensify the contrast of the LCD display.

When the maximum contrast has been reached, the next time you press the Contrast button, the display will return to the minimum contrast.

The Contrast and Backlight buttons will not operate during the actual delivery of the therapy.

7.2 Turning off the Backlight

You may wish to turn off the backlight of the LCD screen if you cannot see the screen properly or if you want to ensure that the battery lasts longer.

By default the backlight is turned on.

To alter the backlight of the LCD screen:

Press the **Backlight** button once to turn the backlight off.

Press the **Backlight** button again to turn the backlight on.

You can configure a timer for the backlight using Saver™. This feature allows you to specify the length of time the backlight should remain on while the device is powered on.

Refer to the Saver™ User Manual for information on how to set the backlight timer using Saver™.

7.3 Understanding Visual Indicators

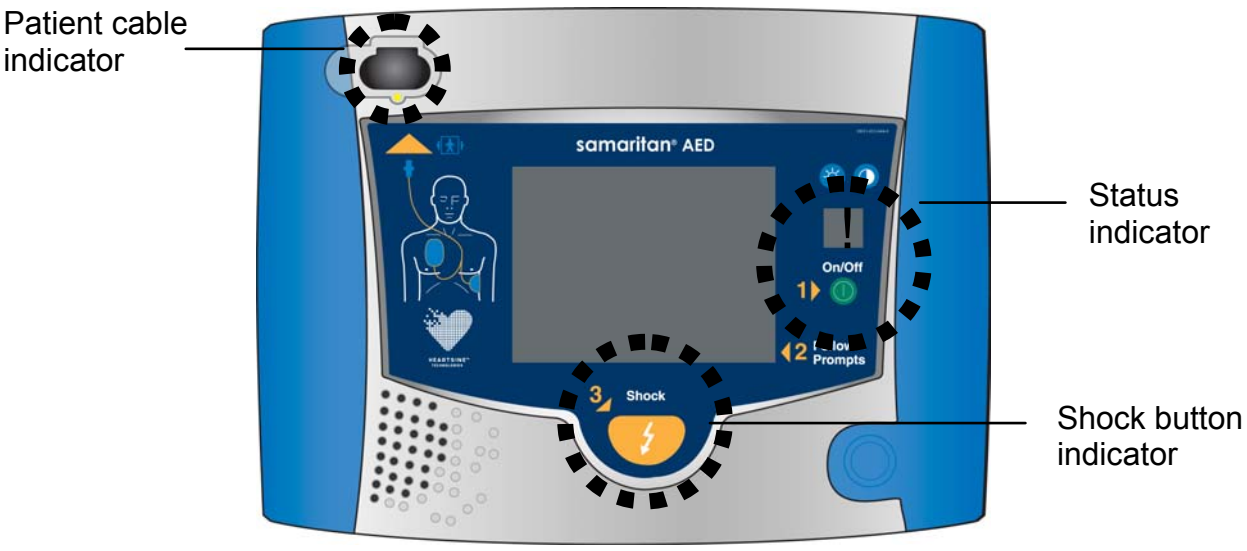


Figure 7.3

Samaritan AED employs three different indicators in order to signal that something is wrong or to tell you the status of the device. These are:

- Status indicator
- Patient cable indicator
- Shock button indicator

The following sections provide you with information on understanding the messages conveyed by each of these indicators.

Status Indicator

The **Status indicator** is located above the **On/Off** button on Samaritan AED. The **Status indicator** verifies that the Samaritan AED Data-Pak is inserted and that the self-test has been successful.

The Status indicator can be interpreted by the following:

- If the Status indicator is blank, Samaritan AED is powered and the self-test has been successful
- If the red exclamation mark is displayed in the Status indicator and is steady, Samaritan AED is not powered
- If the red exclamation mark is flashing in the Status indicator, the Samaritan AED has detected one or more errors

Do not use Samaritan AED if a flashing red exclamation point is displayed in the Status indicator.

Patient Cable Indicator

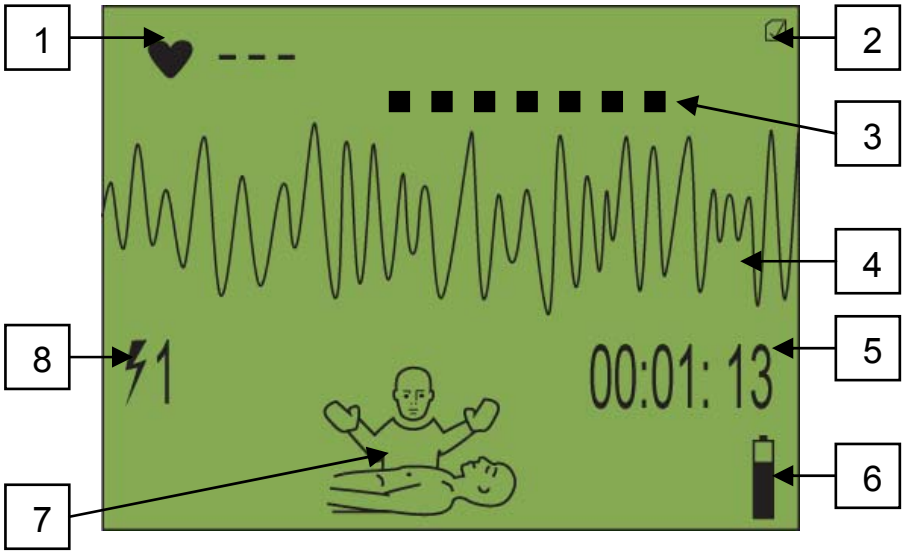
The **patient cable** indicator is a flashing amber indicator located next to the patient cable connector. The indicator will flash only if the **patient cable** is not inserted in Samaritan AED correctly.

If the amber indicator is flashing, the patient cable is either not connected or not correctly connected.

Shock Button Indicator

The shock button indicator illuminates the **Shock** button. If the shock button indicator is illuminated then the Samaritan AED is fully charged and ready to deliver therapy once the **Shock** button is pressed.

7.4 Understanding Display Information



1. Heart Rate
2. Data
3. CPR Timer
4. ECG
5. Elapsed Time
6. Battery Level
7. Visual Prompts
8. Shocks Delivered

Figure7.4 – Samaritan AED Display

Information is shown on the LCD screen using several different means:

- The ECG trace
- Information relating to the patient and the AED, such as heart rate, elapsed time, the number of shocks delivered, or charging status
- Text / icon messages telling you the status of the therapy or providing instructions.

ECG Display

The Samaritan AED displays the Electrical Activity of the Heart (ECG) in scrolling mode and exhibits the actual activity under analysis by the embedded software.

The Samaritan AED display is intended only for basic ECG rhythm identification. The frequency response is not intended for diagnostic and ST segment interpretation.

The Samaritan AED is able to minimize the effects of:

- Electrical noise
- Respiration
- Transience due to shock therapy

As a consequence of the suppression of these interferences, the ECG waveform can be quickly re-established after therapy to resume ECG analysis immediately.

Patient / Therapy Information

The LCD displays information relating to both the patient and the AED. The four types of information displayed are:

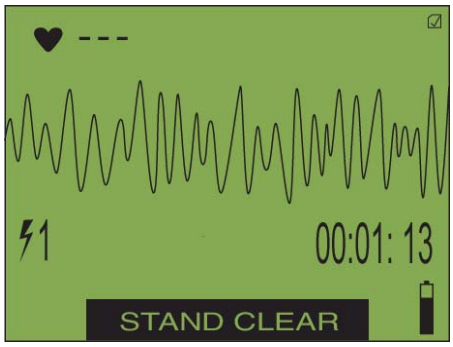
- Heart rate – this can display up to 240 beats/minute (BPM)
- Elapsed time – this can display up to 99hrs, 59mins, 59secs
- Charging status – this graphic displays current therapy energy
- Patient timer – this one-minute countdown timer indicates when Samaritan AED is disabled and CPR may be safely applied
- Shock counter – this displays the number of shocks delivered since the device was switched on
- Status icon – this displays either a ☒ or ☑ symbol that tells you if data recording is active between the Samaritan Data-Pak Battery and the Samaritan AED.

The Samaritan AED can be used to administer therapy while ☒ is displayed, but data will not be recorded.

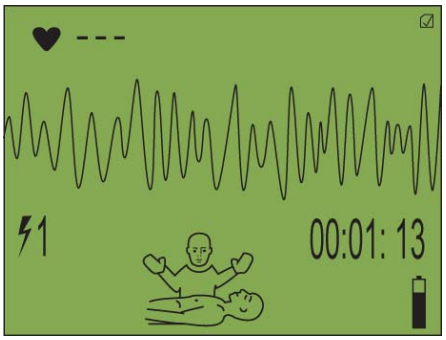
- Shocks Remaining Indicator – This is only displayed when the Data-Pak battery capacity drops to a level where 10 or less shocks may be delivered. It indicates the appropriate number of shocks that may be delivered before the battery is depleted.

7.5 Text vs. Icon Messages

Depending on the version of software operating your Samaritan AED, you will see either text or icons instructions in the lower portion of the display. See the below example for “Stand Clear.”



TEXT MESSAGES

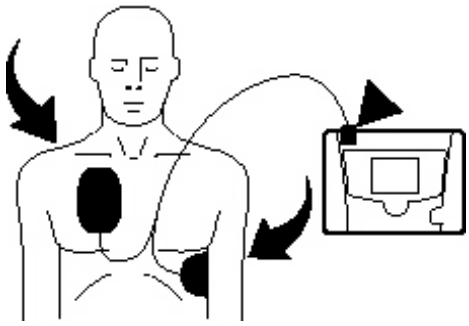


ICON MESSAGES

7.6 Icon Messages

Icon messages can be displayed on the LCD to signal information to the user visually. Icons are used to provide a universally accepted means of communicating with an operator, making the Samaritan AED virtually language independent. The Icon Messages are accompanied by audible prompts in most cases. The following is a list of icons that may appear during operation.

Display Icon



Apply Pads to Patient PLUG IN PAD CONNECTOR

MONITORING or Analyzing

SHOCK ADVISED

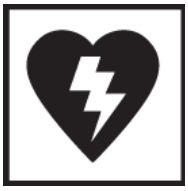
DON'T TOUCH PATIENT

ON-OFF BUTTON PRESSED

STAND CLEAR

BPM:

CHARGE TO 100J



READY TO SHOCK

CHARGE TO 150J

PRESS ANY KEY If YOU CAN HEAR A BEEP

CHARGE TO 200J

PRESS ON OFF KEY ONCE

CHARGE TO 230J

PRESS MANUAL KEY ONCE

CHECK PADS

CHECK PATIENT

XX SHOCKS LEFT

PRESS ANY KEY If YOU CAN READ THIS MESSAGE

Self Test Failed

Self Test Passed

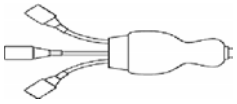
PRESS SHOCK KEY ONCE

PRESS CONTRAST KEY ONCE

PRESS BACKLIGHT KEY ONCE

XXXXXXX Serial number

XXXXXXXX DEMO VERSION



3 Lead cable attached

No Data Recording

7.7 Audible Instructions

The Samaritan AED employs two types of audible prompts:

- Audible indications, such as a rising tone, which lets you know that the device is charging
- Voice prompting, such as instructions or warnings

Audible Indications

An audible indication is used to alert you to the occurrence of two critical events:

Start-up – when the **On/Off** button is pressed, the Samaritan AED emits a short audible tone to indicate that power has been applied

Charging – when the Samaritan AED is charging, a continuous audible tone is emitted. The pitch of the tone will rise according to the increasing voltage. A fixed high pitch will indicate that the required charge level has been achieved

The audible tone emitted during charging will continue until therapy has been applied or aborted.

Voice Prompts

The Samaritan AED features a voice prompt facility. They are accompanied by text or icon prompts in most cases. Voice messages are used to provide the following types of information:

- Incorrect use
- Progress
- Instructions
- Warnings

A number of languages are available for the Samaritan AED. Languages are programmed into the Samaritan AED, by the manufacturer, prior to delivery. For complete list of languages contact your Authorized Heartsine Distributor.

8. Recording Samaritan AED's Usage

This section contains the following sub-sections:

- **Recorded ECG Information**
- **Events Log**
- **Audio Recording**
- **Other Information Recorded**

A sophisticated event-recording system is automatically started each time the Samaritan AED is powered on. The battery pack can hold all the information gathered during a battery lifetime, without the need for retrieval.

A battery lifetime can be up to 12 hours monitoring with the backlight on or 16 hours monitoring with the backlight off.

Each time the Samaritan AED is powered on, a new session is begun and the data recorded during this session is retrievable as a block via Saver™.

Refer to the Saver™ User Manual for information on retrieving information saved by the Samaritan Data-Pak Battery.

The four types of information the Event-Recording System records are, ECG information, events that occur during the therapy, sounds recorded within five feet (1.5 metres) of the device, and other information, such as date, time, and serial number. This chapter provides information on each of these different types of information.

8.1 Recorded ECG Information

The Samaritan AED is able to record the electrical activity of the heart (ECG) before, during, and after therapy.

A clear indication of the heart's activity is given. Transience and other adverse effects are suppressed.

8.2 Events Log

The Samaritan AED recording system can record events that take place during the therapy session. The time and date is stored with each event. The types of events that can be recorded are:

- Buttons or keys pressed
- Mode changes
- Power up
- Monitoring
- Charging
- Therapy delivery
- Charge disarm
- Manual Override
- Self-test
- Shut down
- Error codes – the error code associated with any visual or audio error messages

8.3 Audio Recording

The Samaritan AED can record all audio activity that takes place within 5 feet (1.5 metres) of the unit. This includes the messages emitted by the Samaritan AED, as well as, speech from anyone in attendance.

The Samaritan AED has the capacity to record 60 minutes of audio. Once this limit is reached, the Samaritan AED will stop recording audio.

8.4 Other Information Recorded

Other information specific to the particular Samaritan AED and Samaritan Data-Pak battery is recorded for reference. The types of specific information stored are:

- Time
- Date
- AED serial number
- Operating software revision number
- Battery consumption

9 Understanding How the Samaritan AED Works

This chapter contains the following sub-sections:

9.1 What is the Samaritan AED?

The Samaritan AED is a semi-automatic device used for the delivery of external defibrillation therapy to resuscitate victims of sudden cardiac arrest (SCA), who are unresponsive to stimulus, are not breathing, or have no detectable pulse.

In accordance with the regulations of the American Heart Association and the European Resuscitation Council, the Samaritan AED should not be used on children under 8 years of age.

9.2 What does a Samaritan AED do?

A Samaritan AED provides the rapid application of defibrillation therapy, the only definitive treatment for potentially fatal heart arrhythmias. When the disposable defibrillation electrodes are properly applied to the patient's chest and a Samaritan AED is used, the device:

- Monitors heart rhythm.
- Advises whether or not therapy should be applied by providing audio and visual instructions.
- Delivers therapy using a carefully defined electrical shock, designed to stop the chaotic electrical activity experienced within the heart muscle during SCA, and return the heart to a normal rhythm.

9.3 What is Heart Rhythm?

The normal electrical rhythm by which the heart muscle contracts and expands to create blood flow around the body is known as **Sinus Rhythm**. When an individual suffers a sudden cardiac arrest (SCA), the heart may lose this rhythm and cease pumping. This results in a life-threatening, but "shockable" rhythm - Ventricular Fibrillation (VF). An electrical shock can be administered to re-establish normal sinus rhythm.

Shock therapy should be used only when appropriate. Therapy can result in injury or death to the patient if delivered when it is not required.

The Samaritan AED embeds cardiac rhythm software. This software has been developed through many years of research into the accurate detection and identification of Ventricular Fibrillation. The device is, therefore, highly reliable in advising you when to deliver a shock.

9.4 How Does the Samaritan AED Work?

HeartSine and Academia have spent several years researching the analysis of heart rhythms to identify the optimal technique of applying the lowest possible amount of electrical energy in order to resuscitate a victim of SCA.

The Samaritan AED incorporates an advanced cardiac rhythm detection algorithm and the patented SCOPE™ biphasic energy delivery system. This ensures a high degree of defibrillation efficacy and patient safety.

The Samaritan AED works as follows:

- The electrical rhythm of the heart is monitored via disposable defibrillation electrodes and displayed on a large LCD screen.
- The AED automatically analyzes the heart rhythm.
- If the AED decides the heart rhythm is one of a number of potentially fatal heart arrhythmias; the AED delivery system is charged and the operator will be advised to shock the patient by pressing the illuminated **Shock** button.

The Samaritan AED provides the operator with audio and visual prompts. These prompts:

- Instruct the operator on the next step when using the device
- Signals to the operator the current activity of the AED
- Warns of any problems that have occurred
- Advises on safety requirements

All events during the monitoring and delivery of the defibrillation therapy are recorded and stored by the AED in the Samaritan Data-Pak Battery and can be reviewed later using a PC.

Refer to the Saver™ User's Manual for further information on reviewing details of therapy stored in the Samaritan Data-Pak Battery.

What is Biphasic?

A biphasic shock involves an electrical current being passed through the heart, initially in one direction, then in another, in order to restart the heart. Therapy must not only deliver energy, but also discharge it in a controlled and clinically effective manner.

Extensive research and clinical trials have led to the recognition of the biphasic shock as the best definitive therapy for treating victims of cardiac arrest. A biphasic shock has been found to be as effective as higher energy monophasic shocks.

HeartSine has developed the Samaritan SCOPE™ biphasic technology. The **Self-Compensating Output Pulse Envelope Waveform** is incorporated in the Samaritan AED, and delivers maximum effective therapy while minimizing any damage that could be caused by excess current. SCOPE™ is able to do this by adjusting the biphasic energy waveform in terms of:

- Slope
- Amplitude
- Width

The above manipulation is based on a patient's impedance and provides the most effective defibrillation for the specific patient.

Performing Cardiopulmonary Resuscitation (CPR) on a patient connected to a Samaritan AED may interfere with ECG monitoring. The Samaritan AED will automatically pause for 60 seconds after each set of 3 shocks to allow for CPR to be performed, without affecting the ECG analysis. After the pause for CPR, the Samaritan AED will resume ECG rhythm analysis. The Samaritan AED will provide an audio prompt to "Stop CPR" at the completion of the pause for CPR.

Escalating Energy Protocol

The Samaritan AED incorporates an escalating energy protocol. This is utilized by:

- An initial shock delivered at 100 Joules.
- Heart rhythm analysis indicates if further therapy is advised.
- A subsequent two shocks may be delivered at 150 and 200 Joules, respectively.
- CPR will be advised if three unsuccessful shocks have been delivered.
- Heart rhythm analysis indicates if further therapy is advised.
- If further therapy is required, the AED will continue at 200 Joules (following the set CPR protocol) until NSR (Normal Sinus Rhythm) is restored.
- 200J only available for patients with impedance greater than or equal to 25Ω. In the case of < 25Ω, further therapy will continue at 150J.

The escalating energy protocol can be configured using Saver™.

Refer to the Saver™ User Manual for details on configuring the escalating energy protocol.

Samaritan AED will automatically disable energy charging and delivery for one minute at the end of any sequence of three automated or manual deliveries to allow for CPR.

Biphasic Waveform Description

The Samaritan AED generates therapy in the form of a Biphasic truncated exponential wave. The patient's impedance is measured and this forms the basis of the Waveform parameters, which are adjusted by Samaritan AED before therapy.

Samaritan AED charges the internal storage capacitors to a selected level. The output pulse phase is adjusted to ensure delivery of the selected level of energy.

Phase A and Phase B of the output pulse envelope are always of the same duration

9.5 Why is Impedance Measured?

An impedance measurement is performed when a Samaritan AED is switched on.

This measurement is important for the following reasons:

- It checks the integrity of the pad-patient contact and of the pad leads. If the impedance is too high, patient-pad contact is poor. If the impedance is too low, the pads are touching each other.
- It is used to adjust the Biphasic Waveform parameters to ensure optimum efficacy of the therapy.

When Samaritan AED is switched on:

The patient-pad impedance is measured and Samaritan AED determines if the pads are correctly connected to the patient.

If a problem is found, Samaritan AED will alert the operator and further use of the defibrillator will be disabled until the problem is corrected.

✍ *Measurement of the impedance level is continuous. Therapy cannot be delivered if proper connection between the pads and patient is lost at any stage.*

The impedance value is used to determine some of the primary parameters of the waveform of the energy that is delivered in order to customize the delivery pattern to the requirements of the individual patient.

10 Maintaining the Samaritan AED

This chapter contains the following sub-sections:

- **Checking after each use**
- **Daily checks to perform**
- **Monthly checks to perform**
- **Cleaning the device**
- **Storing the device**
- **Configuring Samaritan AED**

It is imperative that you maintain the Samaritan AED correctly to ensure that you can rely on the device in times of an emergency. The Samaritan AED automatically performs self-checks weekly to verify the readiness of the unit.

Improper maintenance may damage the Samaritan AED or cause malfunction. The device must be maintained and cleaned as advised.

To properly maintain the Samaritan AED, you must carry out regular checks:

- After each use
- Daily
- Monthly

The following sections include information on what is required for these checks, as well as, cleaning and storage information.

10.1 Checking After Each Use

The following procedure should be followed each time the AED is used:

1. Remove the Samaritan Data-Pak Battery from Samaritan and use Saver™ to download any stored information.
2. Re-install the Samaritan Data-Pak Battery in Samaritan**.**
3. Check the Status Indicator.

   If the **Status Indicator** is blank Samaritan AED is ready to use.

   If the **Status Indicator** displays a static or flashing **Exclamation mark**:
4. Remove the battery pack and configure it for full self-test via Saver™.

Refer to Saver™ User Manual for information on configuring Samaritan AED for a full self-test.

5. Re-install the battery and press the **On/Off** button on the samartian AED to run the self-test.
6. If the Status Indicator is blank after the self-test, the Samaritan AED is ready to use. If the self-test fails, repeat step 2. If the new self-test fails, contact HeartSine Technologies for technical support.
7. Check supplies, accessories, and spares for damage or expiration; replace immediately if any damage or expiration is found.
8. Check the exterior of the Samaritan AED and the connector sockets for cracks or other signs of damage; contact HeartSine Technologies if any damage is found.
9. Check the exterior of the Samaritan AED and the connector sockets for dirt or contamination; clean Samaritan if dirt or contamination is found.
10. Ensure that the defibrillation pads are disconnected when not in use.

10.2 Daily Checks to Perform

The following checks should be performed daily:

Check the Status Indicator.

If the Status Indicator is blank, Samaritan AED is ready to use.

If the Status Indicator box displays a static or flashing Exclamation mark:

1. Remove the battery pack and configure it for full self-test via Saver™.
2. Reinstall the battery to run the self-test.

If the Status Indicator is blank after the self-test, Samaritan AED is ready to use.

If the self-test fails, repeat step 2. If the new self-test fails, contact HeartSine Technologies for technical support.

10.3 Monthly Checks to Perform

The following checks should be performed monthly:

- Check supplies, accessories and spares for damage or expiration; replace immediately if any damage or expiration is found.
- Check the exterior of the Samaritan AED and the connector sockets for cracks, dirt or other signs of damage. Clean the Samaritan AED if dirty or contaminated. Contact HeartSine Technologies if any damage is found.

10.4 Cleaning the Device

To clean the Samaritan AED wipe the Samaritan AED with a soft cloth that has been dampened in one of the following:

- Soapy water
- Isopropyl alcohol (70% solution)

Do not immerse any part of the Samaritan AED 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 AED with abrasive materials, cleaners, or solvents.

10.5 Storing the Device

This section provides you with the information on how to store Samaritan AED correctly. Important points to remember when storing Samaritan AED are:

- Store the Samaritan AED in a suitable location for easy access
- Store the Samaritan AED in a clean and dry environment
- Ensure that the defibrillation pads are disconnected when not in use

10.6 Configuring the Samaritan AED

There are some features of the Samaritan AED that you can configure using Saver™. This is the same tool that is used to retrieve information saved on the Samaritan Data-Pak Battery. The features that are configurable using Saver™ include:

- The clock
- The backlight timer
- Therapy sequence
- Audio recording (on or off)
- Speaker volume

Refer to the Saver™ User Manual for further information on using Saver™ to configure the Samaritan AED.

11. Accessories for the Samaritan AED

Part Number	Unit
	Samaritan AED Defibrillators
SAM 001	Samaritan AED Advanced - Text/IconECG Display and Manual Override
SAM 002	Samaritan AED Basic+ - Text/Icon & ECG Display Capability
SAM 003	Samaritan AED Basic – Text/Icon Only
	Samaritan Data-Pak Battery
SBP-001	Samaritan Data-Pak Battery (non-rechargeable)
SBP-002	Samaritan Data-Pak+ Battery (rechargeable)
SBP-010	Samaritan Data-Pak+ Charger
	Samaritan AED Defibrillation Electrodes
SDE-201	1 set of defibrillation electrodes
SDE-210	10 sets of defibrillation electrodes
	Samaritan AED Data Storage and Recall
SDU-001	Samaritan AED Data Recovery Unit (SDRU) & SAVER™ Software System
SDU-002	Additional SAVER™ Data Management & Review Software Licenses
SDU-003	Additional Samaritan AED Data Recovery Units (SDRU)

Samaritan AED Carrying Cases and Storage Systems

SSS-001	Soft Carrying Case - Samaritan AED
SSS-002	Hard Carrying Case - Samaritan AED
SSS-011	Rescue Cabinet with Alarm - Deluxe (Designed to fit AED & O2 tank)
SSS-012	Rescue Cabinet with Alarm - Basic (Designed to fit AED)
SSS-013	Wall Bracket - Samaritan AED
SSS-014	Vehicle Bracket - Samaritan AED
SSS-021	AED Wall Sign - includes triangular wall mount

Samaritan AED Accessories

SAC 009	3 Lead Monitoring Cable (AAMI)
SAC 010	3 Lead Monitoring Cable (IEC)
SAC 011	AED Prep Kit

Samaritan AED Training System

STU-001	Samaritan AED Trainer
STU-002	Samaritan AED Trainer Replacement Battery Charger
STU-003	Samaritan AED Trainer Defibrillation Pad (1 set)
STU-004	Samaritan AED Trainer Nylon Carry Case
STU-005	Samaritan AED ECG / Defibrillation Simulator

12. Troubleshooting

This chapter provides some useful troubleshooting information for the Samaritan AED:

- If the Samaritan AED indicator is not grey or is flashing:
- Check that a Data-Pak™ is inserted into the Samaritan AED.
- Check that the Data-Pak™ is correctly inserted. When inserting the Data-Pak™ you will hear a “click” once it is properly seated.
- If the unit is properly powered, the Status Indicator will remain solid grey.

Contact support@HeartSine.com if you find that the device is still not working correctly.

13 Warranty and Repair

HeartSine Technologies will provide the following services under warranty:

- All faulty components which fail due to defective manufacturing will be replaced free of charge for the following periods from the original date of purchase:
- Samaritan AED – 5 years
- Data-Pak™ – 2 years
- HeartSine is responsible for extensions of the warranty period only when specifically agreed between HeartSine Technologies and the distributor.

Please Note: HeartSine Technologies or the distributor are not obliged to carry out service under warranty if:

- Unauthorized modifications have been made to the device.
- Non-standard components are used.
- The user has not used the device in accordance with the instructions provided in this manual.
- The serial number of the apparatus is removed, defaced, misused, or altered.
- The device, pads, or batteries are stored or used operationally outside of environmentally specified conditions listed within this manual.
- Defibrillation pad packaging is not returned.

Any claims made under warranty must be directed via the distributor from whom the device was originally purchased. The distributor, before carrying out service under warranty, may require evidence of purchase.

The product must be used in accordance with the user manual and for the purpose that it was intended.

If you have a query, please contact support@HeartSine.com for assistance.

14 Appendix

This chapter contains the following sub-sections:

- **A - Samaritan AED technical specifications**
- **B - SCOPE™ Biphasic™ waveform specifications**
- **C - ECG analysis detection system description**
- **D - ECG arrhythmia analysis algorithm performance**
- **E - SCOPE™ Biphasic™ waveform clinical summary**

A - Samaritan AED Technical Specifications

PHYSICAL

Size: 20.5cm H x 25.8cm W x 6cm D (8.1in H x 10.2in W x 2.4in D)

Weight: 1.9kg (4.2lbs) including battery and 2 sets of electrodes

DEFIBRILLATOR

Waveform: SCOPE® (Self-Compensating Output Pulse Envelope) Biphasic Escalating waveform. Optimized biphasic waveform compensates energy, slope, and envelope for patient impedance

Energy Selection: Pre-configured automated protocol (escalating from 100J, 150J, to 200J - user configurable). Manual override: 100J, 150J, 200J, and 230J

Charge Time: 100J in less than 6 seconds and 200J in less than 10 seconds with new non-rechargeable battery pack (typical)

Shock Cycle Time: <60 seconds for three analysis/shock cycles (typical)

Controls: On/Off, shock, manual override, display, contrast, and backlight LCD

PATIENT ANALYSIS SYSTEM

Method: Evaluates patient's ECG, signal quality, electrode contact integrity, and patient impedance to determine if defibrillation is required.

Sensitivity / Specificity: Meets AAMI DF 39 requirements.

DISPLAY

Display Type: High Resolution, LCD switchable backlight.

Display Size: 100 mm x 75.5 mm (4 in W x 3 in H)

Frequency Response: 1 to 20 Hz

Heart Rate: 30 to 280 BPM

ECG View Time: 3.8 seconds

Sweep Speed: 25 mm / sec.

Leakage Current: < 100 μA

Display Information: ECG waveform & heart rate (optional), shock counter, elapsed time, battery capacity gauge, CPR duration graph, energy select charge graph, test message prompts, data recording status icon.

Indicators: Low battery, (at least 10 discharges remaining), audible tone (alerts user of electrode disconnect), electrode connector LED, service icon shows ! if self-tests fail, no battery, or when service required

Voice and Text/Icon prompts: Extensive voice and text/icon prompts guide the user through the operation sequence

Languages: English and other languages (contact your local distributor or HeartSine Technologies for information)

ENVIRONMENTAL

Operating Temperature: 0° to 50° C (+32° to +122°F)

Storage Temperature: -10° to 60° C

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

Water Resistance: IEC 60529/EN 60529 IP44

Altitude: 0 - 4,575 meters (0 to 15,000 feet)

Shock: MIL STD 810F Method 516.5, Procedure I (40G's)

Vibration: MIL STD 810F Method 514.5

Category 4 Truck Transportation - US Highways

Category 7 Aircraft - Jet (737 & General Aviation Exposure)

EMC: EN 60601-1-2: 2001 Second Edition

Radiated Emissions: EN55011:1991, Class B

Electrostatic Discharge Immunity: EN61000-4-2:1995 (8KV)

RF Immunity: EN61000-4-3:1996, 80 MHz - 2.5 GHz (10V/m)

Magnetic Field Immunity: EN61000-4-8:1994 (3 A/m)

Aircraft: RTCA / DO - 160D: 1997, Section 21 (Category M)

EVENT DOCUMENTATION

Type: Samaritan Data-Pak Battery with memory

Memory Capacity: 12 hours of ECG (full disclosure) and event/incident recording. Up to 60 minutes audio recording.

Playback Capabilities: Samaritan AED Data Recovery Unit and SAVER® windows-based data review software

DATA-PAK™ BATTERY PACK

Type: Lithium Manganese Dioxide (LiMnO2) 21V, 1.4 Amp Hrs

Capacity: 120 shocks at 200J or 12 hours of continuous monitoring with backlight on (typical)

Shelf Life: 5 years, 2 years standby life

Weight: 0.2kg (0.44 lbs)

SAMARITAN AED DEFIBRILLATION ELECTRODES

Electrodes: Samaritan AED disposable defibrillation electrodes are supplied as standard with each device. Standard placement (anterior-lateral).

Active Gel Area: 120 cm^2

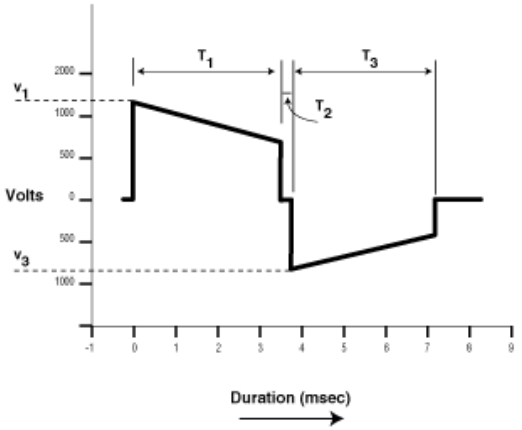
Cable Length: 100.7 cm (3.5 ft)

Shelf Life: 2 years

Specifications and performance may be subject to change without notice.

B - SCOPE™ Biphasic Waveform Specifications

The HeartSine Samaritan AED 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 25 ohms to 190 ohms. The delivered waveform to the patient is an optimized impedance compensated biphasic truncated exponential waveform, which incorporates an escalating energy protocol of 100 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 msec for all patient impedances. The specific SCOPE waveform characteristics for a 100 J pulse are listed below.



Resistance (Ohms)	Waveform Voltages (Volts)		Waveform Duration (msec)	
	V_1	Tilt %	T_1	T_3
25	1230	57.4	3	3
50	1320	39.3	3.5	3.5
75	1330	34.8	4.5	4.5
100	1420	40.1	6	6
125	1420	38.1	7	7
150	1420	40.1	9	9
175	1420	38.7	10	10
190	1420	37.7	10.5	10.5
205	1420	38.2	11.5	11.5

C - ECG Analysis Detection System Description

The HeartSine Samaritan AED ECG Analysis Detection System has been designed to provide a Shock Advised decision for the following ECG Arrhythmias:

- Ventricular Fibrillation – consisting of peak-to-peak amplitude of 150 μV.
- Ventricular Tachycardia – consisting of a heart rate 180 BPM, and a QRS duration equivalent to > 0.16 seconds.

The HeartSine Samaritan AED ECG Analysis Detection System has been designed to provide a No-Shock Advised decision for ECG Arrhythmias consisting of, but not limited to:

- Normal Sinus Rhythm (NSR)
- Supraventricular Tachycardia (SVT)
- Bradycardia
- Pulse-less Electrical Activity (PEA)

The HeartSine Samaritan AED ECG Analysis Detection System analyzes 5 seconds segments of the patient's ECG. Should 2 of 3 five-seconds contiguous segments of the patient's ECG meet the shockable rhythm criteria, then the HeartSine Samaritan AED shall provide a "SHOCK ADVISED" audible and visual prompts.

Should 2 of 3 five-seconds contiguous segments of the patient's ECG meet the non-shockable rhythm criteria, then the HeartSine Samaritan AED shall provide a "NO-SHOCK ADVISED" audible and visual prompts.

Even after a "SHOCK ADVISED" decision is rendered, the Samaritan AED ECG Analysis Detection System continuously assesses the patient's ECG; if the patient's heart rhythm spontaneously returns to a non-shockable rhythm, the Samaritan AED will automatically disarm the defibrillator and advise the operator.

D - ECG Arrhythmia Analysis Algorithm Performance

The HeartSine Samaritan **AED** ECG Arrhythmia Analysis Algorithm Performance has been extensively evaluated by using the American Heart Association's (AHA) Database and the Massachusetts Institute of Technology MIT – NST database. The HeartSine Samaritan AED ECG Arrhythmia Analysis Algorithm Sensitivity and Specificity meets the AAMI DF39a requirements and AHAb recommendations. The HeartSine Samaritan **AED** 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)	696	Sensitivity > 90% (VF) Sensitivity > 75% (VT)	94.75% 100%	93.66% 100* %
Non-Shockable Rhythm: Normal Sinus Rhythm (NSR)	15,541	Specificity > 99% (NSR)	99.48%	99.41%
Non-Shockable Rhythm: Asystole	480	Specificity > 95% (NSR)	100%	100* %
Non-Shockable Rhythm: All other Rhythms	5,706	Specificity > 95% (NSR)	99.47%	99.35%

* No error to measure

A. Association for the Advancement of Medical Instrumentation. DF-39 – 1993 Standard for Automatic External Defibrillators and Remote-Control Defibrillators. Arlington VA: AAMI; 1993.

B. Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety and Efficacy. AHA Task Force on Automatic

External Defibrillation, Subcommittee on AED Safety and Efficacy. Circulation, 1997, Vol. 95, 1677-1682.

C. AHA and MIT-NST databases

E - SCOPE Biphasic Clinical Summary

The HeartSine SCOPE Biphasic waveform has been clinically tested in a three-phase validation program. Numerous animal studies have been conducted to compare the efficacy of the SCOPE biphasic to other defibrillation waveforms. Results of these studies have been published.

> "Optimization of transthoracic ventricular defibrillation-biphasic and triphasic shocks, waveform rounding and synchronized shock delivery." Kidwai BJ, McIntyre A, Anderson J, Adgey AAJ. Journal of Electrocardiology, Vol. 35, No. 3, 2002.

In addition, a Human Clinical Trial has been conducted comparing the SCOPE biphasic waveform to a currently marketed, constant energy, biphasic defibrillator (Biphasic "X"). Results from this study are submitted below.

PURPOSE:

To establish the efficacy of conversion of VF/VT at low energies with a new biphasic waveform by demonstrating that the HeartSine Samaritan SCOPE is at least equivalent to another clinically marketed, constant energy, biphasic system (Biphasic "X").

METHODS:

Standard disposable defibrillator pads were used by both devices. The shock protocol used by the arrest team followed the hospital standard of care - 150J shocks for the 1st, 2nd, and 3rd shocks on each VF/VT episode. The Samaritan AED was used to deliver the 1st shock energy of 100J followed by 150J, and then 200J for the 2nd and 3rd shocks, respectively. Any shocks delivered after these first three shocks were at the discretion of the attending physician for either device. CPR proceeded as per UK Resuscitation Council Guidelines.

DATA COLLECTION:

The two devices to be compared were utilized on alternate days. The responding team arrived at each arrest with the defibrillator appropriate to the day of attendance.

Inclusions:

- Known or suspected cardiac arrest patients:

Exclusions:

- Any patient who had already received a thoracic shock therapy prior to the resuscitation team.
- Patients < 36kg.
- Patients with do-not-resuscitate (DNR) instructions.
- Patients whose cardiac arrest had obviously resulted from a non-cardiac cause (trauma, drowning etc.)

ANALYSIS:

Each record was interpreted by a qualified cardiologist and annotated to detail each VF/VT episode and determine the success or failure of a device to terminate the arrhythmia. Successful defibrillation was defined as termination of VF for > 5 seconds, or termination of other "shockable" Ventricular Tachyarrhythmia for > 5 seconds. Any subsequent recurrence was defined as a new episode.

RESULTS:

Total number of patients: HeartSine Samaritan AED = 8

Biphasic "X" = 23

VF Summary	**HeartSine Samaritan AED**		**Biphasic "X"**	
Parameter		%		%
Total number of episodes	28.0	100.0	62.0	100.0
Total number of successful shocks	28.0	66.7	61.0	39.4
Total number of unsuccessful shocks	14.0	33.3	94.0	60.6
Success within 1 shock	18.0	64.3	36.0	58.1
Success within 2 shocks	24.0	85.7	43.0	69.4
Success within 3 shocks	28.0	100.0	48.0	77.4
Average number of shocks required	1.5		2.5	
Average energy required (J)	125.0		150.0	
Average energy reduction (J)	25.0	16.6		

SUMMARY

The initial results from the Human Clinical trial suggests that the HeartSine SCOPE biphasic waveform is at least as effective as the other marketed, constant energy biphasic waveform system.

Glossary

Battery Pack

The Samaritan Data-Pak Battery is a special battery that supplies power to Samaritan AED and is also able to save information about the use of the device.

Biphasic Shock

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

Defibrillation Electrodes

Defibrillation Electrodes are pads 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 Samaritan AED.

Impedance Measurement

Impedance measurement is a check that is performed to verify the integrity of pad-patient contact.

Manual Override

The Manual Override is a feature of Samaritan AED that allows the operator to abort a shock or manually administer a shock.

Samaritan AED

Samaritan AED is a semi-automatic device used for the delivery of external defibrillation therapy to resuscitate victims of sudden cardiac arrest (SCA), who are unresponsive to stimulus, are not breathing, or do not exhibit signs of circulation.

Saver™

Saver™ is software that can be used in conjunction with Samaritan AED to retrieve and view information about therapy delivered using Samaritan AED and to configure Samaritan AED so that you can tailor the device to suit your requirements.

SCOPE™

SCOPE™ stands for Self-Compensating Output Pulse Envelope waveform. This is the biphasic technology developed by HeartSine that is incorporated into Samaritan AED.

Sinus Rhythm

Sinus Rhythm is the normal electrical rhythm by which the heart muscle contracts and expands to create blood flow around the body.

Self-test

A Self-test is a semi-automatic test that is used to check that Samaritan AED is working correctly.

Ventricular Fibrillation

Ventricular Fibrillation is a life-threatening heart rhythm that is treatable with the therapy using Samaritan AED.

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