

HeartSine samaritan® PAD Family



ACCESSORIES

Pad-Pak™



Adult Pad-Pak
for patients > 8 years or
55 lbs (25 kg)
PAD-PAK-01



Pediatric-Pak™
for patients 1 to 8 years or
up to 55 lbs (25 kg)
PAD-PAK-02



**Adult Pad-Pak
with TSO-C142a**
for use on aircraft
PAD-PAK-07

HeartSine has taken an innovative approach to maintenance items by incorporating the AED batteries and electrodes into one single-use cartridge called the Pad-Pak. The advantage to the Pad-Pak is that there is only one date to monitor and only one item to replace on expiration or after use.

Each Pad-Pak has an industry-first four-year life, and provides 60 shocks or six hours of continuous monitoring. When battery power is down to less than 10 shocks, the samaritan PAD status indicator changes from green to red and emits an audible prompt to indicate the Pad-Pak should be replaced.

When used with the Pediatric-Pak, the samaritan PAD ensures the appropriate energy level (50 J) is delivered for children ages 1-8 years old and weighing < 55 lbs (25 kg).

For use on aircraft, HeartSine offers the TSO-C142a certified Pad-Pak.

Software



USB Data Cable
The custom USB Data Cable is for use with the Saver EVO™ data management software to download event data and to perform software upgrades to the samaritan PAD devices.
PAD-ACC-02



Saver EVO Data Management Software
Saver EVO is free icon-based, data management software for downloading, reviewing and printing ECG waveforms and event history data recorded in a samaritan PAD.

Features include:

- Comprehensive event documentation to facilitate physician oversight
- Utstein style reporting and report export capabilities
- User configuration setup and time synchronization
- Simple point and click operation

Saver EVO requires the optional HeartSine USB Data Cable to interface with the samaritan PAD. The Saver EVO software can be downloaded free of charge on the HeartSine website.

Storage and Signs



Carrying Case
(Replacement)
PAD-BAG-01

Every HeartSine samaritan PAD is supplied with a custom-designed case with two zippered compartments. Each case has storage space to carry:

- HeartSine samaritan PAD AED
- CPR Prep Kit
- Additional Adult Pad-Pak or Pediatric-Pak
- Data Cable
- User Manual



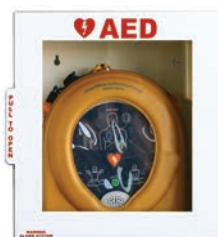
**Mobile AED
Rescue Backpack**
PAD-BAG-02

AED and first aid kit not included.

The HeartSine Mobile AED Rescue Backpack, custom made for the HeartSine samaritan Public Access Defibrillator (PAD), lets you create and transport a heart safe solution to virtually any location.

The HeartSine Mobile AED Rescue Backpack has room for everything you will need to keep members of your group heart safe. This customized backpack can readily carry a samaritan PAD AED with Pad-Pak, a Pediatric-Pak or extra Pad-Pak, CPR prep kit and first aid kit.

Storage and Signs continued

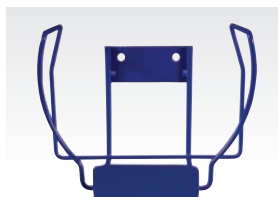


Wall Cabinet with Alarm, Custom Made

Custom made for the samaritan PAD, this small profile wall cabinet sounds an alarm when opened.

Dimensions: 12"H x 11"W x 5"D
Weight: 5 lbs (2.27 kg)

PAD-CAB-04



Wall Bracket

Made of metal, this premium wire wall bracket provides convenient storage for the samaritan PAD in a room.

PAD-CAB-02



AED Wall Sign, Triangular

This three-dimensional wall sign is placed above the wall cabinet or wall bracket to call attention to the mounted samaritan PAD.

PAD-ACC-05

TRAINING

samaritan PAD Trainer



TRN-350-US (SAM 350P)



TRN-360-US (SAM 360P)



TRN-450-US (SAM 450P)

The samaritan PAD Trainer with remote control guides users through simulated analysis, energy delivery and prompted CPR with the look and feel of a live samaritan Public Access Defibrillator (PAD) without the actual charge and discharge of an electrical shock.

Includes Trainer-Pak with three pairs of training electrodes, battery charger and carrying case.

NOTE: The samaritan PAD Trainers have no capability to diagnose or treat an arrhythmia. They are intended to simulate the use of an AED for instructional purposes only.

Trainer Accessories



Trainer-Pak

(Replacement Electrode Cartridge)
With an easy-to-use rewind system, the Trainer-Pak Electrode Cartridge stores the electrode pads and cables. The handy rewind feature reduces time spent resetting the system.

TRAINER-PAK-04



Training Electrodes

Reusable, replaceable training electrode pads, for use on training manikins, are easy to place back on the pad liner.

10/pak TRN-ACC-02

25/pak TRN-ACC-03



Remote

(Replacement)

TRN-ACC-16 (SAM 350P)

TRN-ACC-18 (SAM 360P)

TRN-ACC-19 (SAM 450P)

Multi-function remote control enables selection of among six AHA/ERC scenarios for live demonstrations or training. One remote control can even operate multiple trainer units at a time (within a range of 10-15 feet (3-5 meters)).

The SAM 450P Trainer remote provides the training instructor with the flexibility to choose the appropriate CPR Rate Advisor prompts based on the student's compression rate.



Battery Charger

(Replacement)

The Battery Charger charges the internal battery of the samaritan PAD Trainer in just four hours, which enables the Trainer to operate up to seven hours—a full day of training—on a single charge.

TRN-ACC-14

HeartSine® samaritan® PAD Automated External Defibrillators (AEDs)

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE

The HeartSine samaritan PAD SAM 350P (SAM 350P), HeartSine samaritan PAD SAM 360P (SAM 360P) and HeartSine samaritan PAD SAM 450P (SAM 450P) are indicated for use on victims of cardiac arrest who are exhibiting the following signs: unconscious, not breathing, without circulation (without a pulse). The devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program. The devices are indicated for use on patients greater than 8 years old or over 55 lbs (25 kg) when used with the adult Pad-Pak™ (Pad-Pak-01 or Pad-Pak-07). They are indicated for use on children between 1 and 8 years of age or up to 55 lbs (25 kg) when used with the Pediatric-Pak™ (Pad-Pak-02).

CONTRAINDICATION


If the patient is responsive or conscious, do not use the HeartSine samaritan PAD to provide treatment.

WARNINGS

AEDs:

- The HeartSine samaritan PAD delivers therapeutic electrical shocks that can cause serious harm to either users or bystanders. Take care to ensure that no one touches the patient when a shock is to be delivered.
- Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process. Avoid contact with the patient while the HeartSine samaritan PAD is analyzing the patient. The device will instruct you when it is safe to touch the patient.
- Do not delay treatment trying to find out the patient's exact age and weight. If a Pediatric-Pak or an alternative suitable defibrillator is not available, you may use an adult Pad-Pak.
- The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention.
- The SAM 450P CPR Rate Advisor is currently only intended to provide feedback on adult patients. If you treat a pediatric patient with the SAM 450P and an adult Pad-Pak, ignore any voice prompts regarding the rate of CPR.
- Do NOT use the HeartSine samaritan PAD in the vicinity of explosive gases, including flammable anesthetics or concentrated oxygen.
- Do NOT open or repair the device under any circumstances as there could be danger of electric shock. If damage is suspected, immediately replace the HeartSine samaritan PAD.

Pad-Paks:

- Do not use if the gel is dry.
- The Pediatric Pad-Pak is not for use on patients under 1 year old. For use with children up to the age of 8 years or up to 55 lbs (25 kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT.
- Only HeartSine samaritan PADs with the  label are suitable for use with the Pediatric-Pak. If the HeartSine samaritan PAD you are using does not have this label, use the adult Pad-Pak if no alternatives are available.
- The use of the Pediatric-Pak will enable delivery of 50J shocks to the pediatric patient.
- The Pediatric-Pak contains a magnetic component (surface strength 6500 gauss). Avoid storage next to magnetically sensitive storage media. It is advised that Pediatric-Paks are stored separately when not in use.
- Never charge, short circuit, puncture, deform, incinerate, heat above 85°C or expose contents of TSO (Aviation) Pad-Pak to water. Remove when discharged.

PRECAUTIONS

AEDs:

- Proper placement of the HeartSine samaritan PAD electrode pads is critical. Electrode pads must be at least 1 in (2.5 cm) apart and should never touch one another.
- Do not use electrode pads if pouch is not sealed.
- Check the device periodically in accordance with the service and maintenance instructions provided in the User Manual.
- Operate the HeartSine samaritan PAD at least 6 feet (2 meters) away from all radio frequency devices or switch off any equipment causing interference.
- Use of the device outside the operating and storage ranges specified in the User Manual may cause the device to malfunction or reduce the shelf life of the Pad-Pak.
- Do not immerse any part of the HeartSine samaritan PAD in water or any type of fluid.
- Do not turn on the device unnecessarily as this may reduce the standby life of the device.
- Do not use any unauthorized accessories with the device as the HeartSine samaritan PAD may malfunction if non-approved accessories are used.
- Dispose of the device in accordance with national or local regulations.
- Check with the relevant local government health department for information about any requirements associated with ownership and use of a defibrillator in the region where it is to be used.

Pad-Paks:

- Check expiration date.

Saver EVO™ Software:

- Download the complete HeartSine samaritan PAD memory prior to erasing it. This information should be stored safely for future reference. Ensure that only the events you want to delete have been selected prior to deleting. Once deleted from your computer's memory, events cannot be regenerated and all information will be lost.

POTENTIAL ADVERSE EFFECTS

The potential adverse effects (e.g., complications) associated with the use of an automated external defibrillator include, but are not limited to, the following:

- Failure to identify shockable arrhythmia.
- Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury.
- Inappropriate energy which could cause failed defibrillation or post-shock dysfunction.
- Myocardial damage.
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents.
- Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest.
- Bystander shock from patient contact during defibrillation shock.
- Interaction with pacemakers.
- Skin burns around the electrode placement area.
- Allergic dermatitis due to sensitivity to materials used in electrode construction.
- Minor skin rash.

CAUTION

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

Please consult the User Manual at www.heartsine.com for the complete list of indications, contraindications, warnings, precautions, potential adverse events, safety and effectiveness data, instructions for use and other important information.

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The HeartSine products described in this brochure meet the European Medical Directive requirement.



UL Classified.
See complete marking on product.
H009-032-223-3 US

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner.
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