

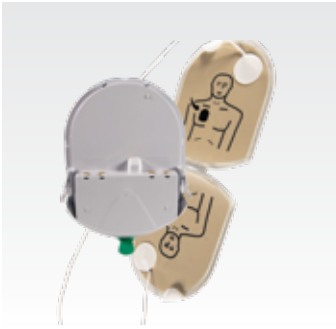
HeartSine[®]
samaritan[®] PAD
Family

Accessories

stryker

Pad-Pak™

Data Download



Adult Pad-Pak
For patients > 8 years or
55 lb (25 kg).

Pad-Pak-01
11516-000003



Pediatric-Pak™
For patients 1 to 8 years or
up to 55 lb (25 kg).

Pad-Pak-02
11516-000004



Adult Pad-Pak
With TSO-C142a certification
for use on aircraft.

Pad-Pak-07
11516-000027



USB Data Cable
For use with the Saver EVO™
data management software
to download event data and to
perform software upgrades to
the HeartSine samaritan PAD
non-connected devices.

PAD-ACC-02
11516-000018

Cabinets and Mounting Options



**Rotaid Plus Wall Cabinet
with Alarm**
For indoor use.

11996-000441 (White)
11996-000443 (Red)



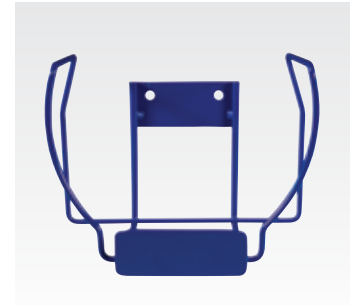
**Rotaid Solid Plus Wall
Cabinet with Alarm**
For indoor or outdoor use.

11996-000445 (White)
11996-000447 (Red)



**Rotaid Solid Plus Heat
Wall Cabinet with Heat
and Alarm**
For outdoor use.

11996-000449 (White)
11996-000451 (Red)



AED Wall Bracket
(Metal)

Dimensions:
6.14 H x 6.88 W x 4.48 D in
(15.6 H x 17.5 W x 11.4 D cm)

PAD-CAB-02
11516-000023

Training Tools



**HeartSine samaritan PAD
Trainer SAM 350P**

TRN-350-US 11516-000059
TRN-350-AS 11516-000029



**HeartSine samaritan PAD
Trainer SAM 360P**

TRN-360-US 11516-000091
TRN-360-AS 11516-000061



**HeartSine samaritan PAD
Trainer SAM 450P**

TRN-450-US 11516-000092
TRN-450-AS 11516-000093



Trainer-Pak
(Replacement Electrode
Cartridge)

TRN-PAK-04
11516-000017

HeartSine Gateway™



HeartSine Gateway
Includes removal tool, batteries
and HeartSine Connected AED
carrying case.

ACC-GTW-US-01



HeartSine Gateway
Removal Tool

ACC-REM-GW



HeartSine Gateway
Batteries

ACC-BAT-GW

Storage Options



Wall Cabinet with Alarm,
Custom Made

Dimensions:
12 H x 11 W x 5 D in
(30.48 H x 27.94 W x 12.7 D cm)

Weight: 5 lb (2.27 kg)

PAD-CAB-04
11516-000024



HeartSine AED Carrying
Case

PAD-BAG-01
11516-000022



Mobile AED
Rescue Backpack

PAD-BAG-02
11516-000114



Replacement electrodes
(for use with Trainer-Pak)

TRN-ACC-02 (10/pak)
11516-000009

TRN-ACC-03 (25/pak)
11516-000011



HeartSine samaritan PAD
Trainer Remote

TRN-ACC-16 (SAM 350P)
11516-000014

TRN-ACC-18 (SAM 360P)
11516-000016



TRN-ACC-19 (SAM 450P)
11516-000001



Battery Charger
(Replacement)

TRN-ACC-14
11516-000012

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.

For further information contact us at heartsinesupport@stryker.com or visit our website at heartsine.com.



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UL Classified. See complete marking on product.

The HeartSine SAM 450P is not available for sale outside of the U.S. or Japan.

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

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