

HeartSine® samaritan® PAD 350P/360P AEDs

Semi-automatic/fully automatic public access defibrillators

Data sheet

Compact, easy-to-use, lifesaving technology for public access

Sudden cardiac arrest strikes millions of people a year worldwide with no warning and no pattern.¹ Immediate treatment is vital. A victim's chance of survival dramatically decreases for every minute without treatment.² This means an automated external defibrillator (AED) must be close at hand, easy to use and ready to shock.

The semi-automatic HeartSine samaritan PAD 350P (SAM 350P) and fully automatic HeartSine samaritan PAD 360P (SAM 360P) offer a high level of environmental protection, in an easy-to-operate system in one of the smallest and lightest packages available.

With its simplified instructions and self-training videos, HeartSine samaritan PAD 350P is available without a prescription for adult and pediatric use, unlike most other AEDs.



Ready to shock



Unique Pediatric-Pak

Ensures the guidelines-recommended energy level is delivered for children, between 1 and 8 years of age or up to 55 lb (25 kg). Pediatric-Pak, for use with the SAM 350P AED, is the only FDA-approved pediatric electrode pad cartridge approved for use on children without a prescription.



High level of protection from dust and water

Offers IP56 rating, one of the highest ratings in the industry.



Clinically validated technology³

Advanced electrode technology and SCOPE (Self-Compensating Output Pulse Envelope) biphasic technology, a low energy escalating waveform that automatically adjusts for differences in patient impedance.



Highly portable

At just 2.4 lb and with one of the most compact footprints, the HeartSine AED is easily transported and fit into constrained spaces.

Easy-to-follow visual and verbal guides



User-friendly

Easy-to-understand visual and voice prompts guide the rescuer through the entire resuscitation process, including CPR.



One- or two-button operation

With just an On/Off button (and the Shock button on the SAM 350P), offers a simple, straightforward operation.



Automatic shock delivery / Motion detection

Fully automatic SAM 360P* detects motion, such as performing CPR or moving the patient, to reduce the likelihood that the user is touching the patient prior to shock delivery.



Ready for use

The status indicator flashes to show the system has passed the automatic weekly self test and is ready for use.

Simple to own



Two parts, one expiration date

The innovative Pad-Pak, an integrated battery and electrode single-use cartridge with one expiration date, offers one simple maintenance change every four years.



Low cost of ownership

Shelf life of four years means that the Pad-Pak may offer savings over other defibrillators that require separate battery and electrode replacements.



8-year warranty

Backed by an 8-year limited warranty.



No prescription needed

HeartSine samaritan PAD 350P is available without a prescription for adult and pediatric use.

* WARNING: The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient without user intervention.

Specifications

Defibrillator

Waveform: Self-Compensating Output Pulse Envelope (SCOPE) optimized biphasic escalating waveform compensates energy, slope and duration for patient impedance

Patient analysis system

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

Sensitivity/Specificity: Meets IEC/EN 60601-2-4

Impedance range: 20-230 ohms

Energy selection

Pad-Pak:

Shock 1: 150 J

Shock 2: 150 J

Shock 3: 200 J

Pediatric-Pak:

Shock 1: 50 J

Shock 2: 50 J

Shock 3: 50 J

Charge time (typical):

150 J in < 8 seconds

200 J in < 12 seconds

Environmental

Operating/Standby temperature:

32°F to 122°F (0°C to 50°C)

Note: The temperature of the electrodes could be up to 50°C if your device has been exposed to these conditions

Transport temperature:

32°F to 122°F (0°C to 50°C)

Note: If the device with Pad-Pak or Pediatric-Pak has been transported while temperatures are below 32°F (0°C), it should be returned to an ambient temperature of between 32°F to 122°F (0°C to 50°C) for at least 24 hours before use

Relative humidity:

5% to 95% non-condensing

Water resistance:

IEC 60529/ EN60529 IPX6 with electrodes connected and battery installed

Dust resistance:

IEC 60529/ EN60529 IP5X with electrodes connected and battery installed

Enclosure:

IEC/EN 60529 IP56

Altitude: -1,250 to 15,000 feet (-381 to 4,575 meters)

Shock: MIL STD 810F Method 516.5+, Procedure 1 (40 G's)

Vibration: MIL STD 810F Method 514.5, Procedure 1

Category 4 Truck Transportation – US Highways

Category 7 Aircraft – Jet 737 & General Aviation

Atmospheric pressure: 572 hPa to 1060 hPa (429 mmHg to 795 mmHg)

EMC: IEC/EN 60601-1-2

Radiated emissions: IEC/EN 55011

Electrostatic discharge:

IEC/EN 61000-4-2 (8 kV)

RF immunity:

IEC/EN 61000-4-3 80MHz-2.5 GHz, (10 V/m)

Magnetic field immunity:

IEC/EN 61000-4-8 (3 A/m)

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

RTCA/DO-227 (TSO/ETSO-C142a / EASA.210.10042190)

Falling height: 3.3 feet (1 meter)

Physical characteristics

With Pad-Pak inserted:

Size:

8.0 in x 7.25 in x 1.9 in
(20 cm x 18.4 cm x 4.8 cm)

Weight: 2.4 lb (1.1 kg)

Accessories

Pad-Pak Electrode and Battery Cartridge

Shelf life/Standby life: See the expiration date on the Pad-Pak/Pediatric-Pak

Weight: 0.44 lb (0.2 kg)

Size:

3.93 in x 5.24 in x 0.94 in
(10 cm x 13.3 cm x 2.4 cm)

Battery type: Disposable single-use combined battery and defibrillation electrode cartridge (lithium manganese dioxide (LiMnO₂) 18V)

Battery capacity (new):

> 60 shocks at 200 J or 6 hours of battery use

Electrodes: Disposable defibrillation pads are supplied as standard with each device

Electrode placement: Anterior-lateral (Adult)

Anterior-posterior or Anterior-lateral (Pediatric)

Electrode active area: 15 in² (100 cm²)

Electrode cable length: 3.3 feet (1 meter)

Aircraft safety test (TSO/ETSO-certified Pad-Pak): RTCA/DO-227 (TSO/ETSO C142a1/ EASA.210.10042190)

Data storage

Memory type: Internal memory

Memory storage: 90 minutes of ECG (full disclosure) and event/incident recording

Review: Custom USB data cable (optional) directly connected to PC with Saver EVO Windows-based data review software

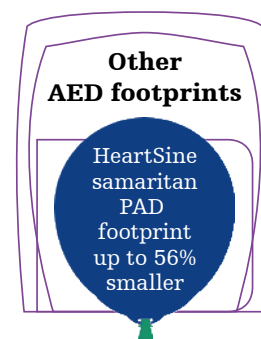
Materials used

Defibrillator housing: ABS, Santoprene

Electrodes: Hydrogel, Silver, Aluminium and Polyester

Warranty

AED: 8-year limited warranty



HeartSine samaritan PAD 360P and 450P Automated External Defibrillators (AEDs) with a prescription requirement

BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE: The HeartSine samaritan PAD 360P (SAM 360P) and HeartSine samaritan PAD 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 AEDs 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 AEDs are indicated for use on patients greater than 8 years old or over 55 lb (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 lb (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 (AED) 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 AED is analyzing the patient. The AED 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. • Disconnect non-defibrillation protected electronic devices or medical equipment from the patient before using the AED. • Do not use the AED in the vicinity of explosive gases, including flammable anesthetics or concentrated oxygen. • Do not use portable RF communications equipment closer than 12 in (30 cm) to any part of the AED. • Place pads at least 3.1 in (8 cm) away from a pacemaker. • 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 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 open or repair the AED under any circumstances as there could be danger of electric shock. If damage is suspected, immediately replace the AED. • Do not use any accessories other than those specified or provided by HeartSine Technologies as the AED may malfunction. **Pad-Pak and Pediatric-Pak:** • Do not use if the gel is dry. • Not for use on patients under 1 year old. • Pediatric-Pak is for use with children up to the age of 8 years or up to 55 lb (25 kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT. • Pediatric-Pak is suitable for use only with HeartSine samaritan PADs with the adult/child symbol*. If the AED 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 50 J shocks to the pediatric patient. • It is advised that the Pediatric-Pak is 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: • Check the AED periodically in accordance with the service and maintenance instructions provided in the user manual. • If you hear a warning message when you turn on your AED, consult Troubleshooting in the user manual. • Proper placement of the 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. • Do not pull green tab on Pad-Pak during set-up. • If a non-shockable rhythm is detected, the AED will end its ready to shock condition if it previously decided to shock. • Use of the AED outside the operating and storage ranges specified in the user manual may cause the AED to malfunction or reduce the shelf life of the Pad-Pak. • Do not immerse any part of the AED in water or any type of fluid. • Do not clean the AED with abrasive materials, cleaners or solvents. • Do not turn on the AED unnecessarily as this may reduce the standby life. • Do not use any unauthorized accessories with the AED as it may malfunction if non-approved accessories are used. • Dispose of the AED 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-Pak and Pediatric-Pak:** • Single use only. Reuse may cause AED to be unable to deliver therapy leading to a failure to resuscitate or lead to cross-infection between patients. • Do not use if open or damaged. • Check expiration date. • It is advised that a spare Pad-Pak be stored with AED in rear section of carry case. **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 the SAM 360P and SAM 450P AEDs to sale by or on the order of a physician.

Please consult the user manuals at 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.



References

1. Mehra R. Global public health problem of sudden cardiac death. *Journal of Electrocardiology*. 2007;40 (6):S118-S122.
2. Graham R, McCoy M, Schultz A. Strategies to improve cardiac arrest survival, a time to act. *Institute of Medicine Report*. 2015.
3. Walsh SJ, McClelland A, Owens CG, et al. Efficacy of distinct energy delivery protocols comparing two biphasic defibrillators for cardiac arrest. *Am J Cardiol*. 2004;94:378-380.

All claims valid as 03/2023.

For further information, please contact your Stryker representative or visit our website at strykeremergencycare.com

Emergency Care Public Access

AED users should be trained in CPR and in the use of the AED. Although not everyone can be saved, studies show that early defibrillation can dramatically improve survival rates. AEDs are indicated for use on adults and children. AEDs may be used on children weighing less than 25 kg (55 lb) but some models require separate defibrillation electrodes.

The information presented is intended to demonstrate Stryker's product offerings. Refer to operating instructions for complete directions for use indications, contraindications, warnings, cautions, and potential adverse events, before using any of Stryker's products. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your representative if you have questions about the availability of Stryker's products in your area. Specifications subject to change without notice.

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Pad-Pak; Pediatric-Pak



HeartSine samaritan PAD: UL Classified. See complete marking on product.

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