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HeartSine® samaritan® PAD 450P

Automated external defibrillator with integrated CPR Rate Advisor™

Data sheet



Key link in the chain of survival

Cardiopulmonary resuscitation (CPR) and automated external defibrillators (AEDs) are key links in the chain of survival of sudden cardiac arrest (SCA). Some cardiac events are treatable with effective CPR alone. Others require a combination of effective CPR and the delivery a lifesaving shock by an AED. Either way, every minute counts.[1]

Only about ten percent of SCA victims survive.[2] However, survival rates can increase up to 74%[3] if CPR and a shock from an AED are provided within three minutes of collapse. Reducing response time by even one or two minutes from collapse to shock can mean the difference between death and survival.[1]

Offering real-time CPR rate feedback, the HeartSine samaritan PAD 450P AED with integrated CPR Rate Advisor meets the needs of two key links in the chain of survival. Not only can the semi-automatic SAM 450P deliver a lifesaving shock, it provides real-time visual and verbal feedback to the rescuer on the rate of CPR compressions during a resuscitation — effectively assisting the rescuer to perform CPR.

Real-time CPR rate feedback



Integrated real-time CPR rate feedback

Easy-to-understand visual and voice prompts guide the rescuer through the entire resuscitation process, providing specific feedback on the rate of compressions (“Push faster,” “Push slower,” “Good speed”).



Reminders to perform CPR

To encourage more hands-on time for CPR delivery, the HeartSine samaritan PAD 450P continues to remind the rescuer to perform CPR when no CPR is detected.

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).



High level of protection from dust and water

IP56 rating, one of the highest ratings in the industry, enables both indoor and outdoor use.



Clinically validated technology[4]

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.



Compact and lightweight

At just 2.4 lb and with one of the most compact footprints, the SAM 450P is easily transported and fits into constrained spaces.

Simple to own



Two parts, one expiration date

Each HeartSine AED comes with the innovative Pad-Pak, an integrated battery and electrode single-use cartridge with one expiration date, which offers one simple change every four years.



Low total cost of ownership

A shelf life of four years from the date of manufacture, means that the Pad-Pak may offer savings over other defibrillators that require separate battery and electrode replacements.



8-year warranty

AED is backed by an 8-year limited warranty.

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 122°F (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/ EN 60529 IPX6 with electrodes connected and battery installed

Dust resistance: IEC 60529/ EN 60529 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 80 MHz-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.21O.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)

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

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 ($LiMnO_2$) 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 in^2 (100 cm^2)

Electrode cable length: 3.3 feet (1 meter)

Aircraft safety test (TSO/ETSO-certified Pad-Pak): RTCA/DO-227 (TSO/ETSO C142a/ EASA.21O.10042190)

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.

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References: 1. Mosesso Jr VN, et al. 2002. Proceedings of the National Center for Early Defibrillation Police AED Issues Forum. Prehospital Emergency Care. 6(3):273–82. **2.** Kiguchi T, Okubo M, Nishiyama C, et al. Out-of-hospital cardiac arrest across the world: first report from the International Liaison Committee on Resuscitation (ILCOR). Resuscitation. 2020; doi: https://doi.org/10.1016/j.resuscitation.2020.02.044. **3.** Valenzuela TD, et al. 2000. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. New England Journal of Medicine. 343:1206-09. **4.** 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.

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

Emergency Care Public Access

AED users should be trained in CPR and in the use of the AED. AEDs which are for public use/trained users can also be used by professional users.

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. Stryker Corporation or its divisions or other corporate affiliated entities own, use, or have applied for the following trademarks or service marks: CPR Rate Advisor, HeartSine, Pad-Pak, Pediatric-Pak, samaritan, Saver EVO, SCOPE, Stryker. All other trademarks are trademarks of their respective owners or holders.

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