HeartSine® samaritan® PAD 450P AED

HeartSine®

Automated External Defibrillator with Integrated CPR Rate Advisor™

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. Typically, only about five percent of SCA victims survive. However, survival rates can increase up to 74%[1] 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.[2]

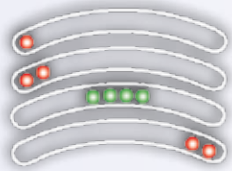
More than a simple AED, the HeartSine samaritan PAD 450P (SAM 450P) Automated External Defibrillator (AED) with integrated CPR Rate Advisor meets the needs of two key links in the chain of survival. Not only can the semi-automatic SAM 450P deliver a lifesaving shock, it provides real-time visual and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

Real-Time CPR Rate Feedback

ICG-based feedback. With its revolutionary technology, HeartSine's proprietary CPR Rate Advisor detects the rate of CPR being applied via the defibrillator electrodes, without the addition of accelerometers (or pucks) commonly used in other AED solutions.

Easy-to-follow visual and verbal guides. Designed for ease of use, the HeartSine samaritan PAD 450P uses easy-to-understand visual and voice prompts to guide the rescuer through the entire CPR process, providing specific feedback on the rate of compressions.

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



No CPR being performed/"Begin CPR"

"Push Faster"

"Good Speed"

"Push Slower"

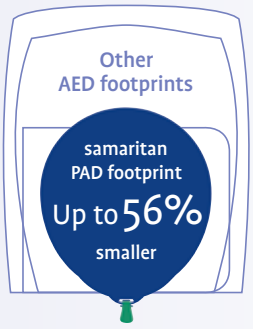
Visual indicators and verbal feedback tell the rescuer if the rate of CPR is in line with the AHA guidelines.

Ready to Shock

Highest level of protection from dust and water. With its IP56 rating, the HeartSine samaritan PAD 450P defibrillator offers unmatched ruggedness.

Clinically validated technology.[3] The HeartSine samaritan PAD 450P utilizes proprietary electrode technology and SCOPE™ biphasic technology, an escalating, low-energy waveform that automatically adjusts for differences in patient impedance.

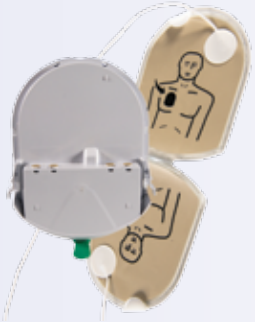
Most compact design. At 2.4 lbs and with a compact footprint, the HeartSine samaritan PAD is the most portable AED on the market.



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. With a shelf life of four years from date of manufacture, the Pad-Pak offers significant savings over other defibrillators that require separate battery and electrode replacements.



Pad-Pak and Pediatric-Pak™

with pre-attached electrodes.

The HeartSine samaritan PAD's built-in intelligence and unique Pediatric-Pak ensure the appropriate energy level is delivered for children, between 1 and 8 years of age or up to 55 lbs (25 kg).

CPR Rate Advisor is deactivated when the Pediatric-Pak is in use.

Technical Overview

Physical	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 lbs (1.1 kg)
Defibrillator	
Waveform:	Self-Compensating Output Pulse Envelope (SCOPE) optimized biphasic escalating waveform compensates energy, slope and duration for patient impedance
Warranty:	8-year limited warranty
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 IEC/EN 60601-2-4
Impedance Range:	20 - 230 ohms
Environmental	
Operating/Standby Temperature:	32°F to 122°F (0°C to 50°C)
Transportation Temperature:	14°F to 122°F (–10°C to 50°C) for up to two days. If the device has been stored 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)
Enclosure:	IEC/EN 60529 IP56
Altitude:	0 to 15,000 feet (0 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
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)

SAM 450P

Energy Selection	
Pad-Pak:	Shock 1: 150J; Shock 2: 150J; Shock 3: 200J
Pediatric-Pak:	Shock 1: 50J; Shock 2: 50J; Shock 3: 50J

Charging Time	
New Battery:	Typically 150J in < 8 seconds, 200J in < 12 seconds

Event Recording	
Type:	Internal Memory
Memory:	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	
Housing:	ABS, Santoprene
Electrodes:	Hydrogel, Silver, Aluminum and Polyester

Pad-Pak — Electrode and Battery Cartridge Adult Pad-Pak (Pad-Pak-01) and Pediatric Pad-Pak (Pad-Pak-02) **TSO/ETSO-certified aviation Pad-Pak also available*	
Shelf Life/Standby Life:	See the expiration date on the Pad-Pak/Pediatric-Pak (4 years from manufacture date)
Weight:	0.44 lbs (0.2 kg)
Size:	3.93 in x 5.24 in x .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 200J or 6 hours of continuous monitoring
Electrodes:	HeartSine samaritan 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)

Brief summary of indications and important safety information on back.

HeartSine®

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.

1. 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.
2. 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.
3. Walsh SJ, McClelland A, Owens CG, Allen J, McCanderson J, Turner C, Adgey J. Efficacy of distinct energy delivery protocols comparing two biphasic defibrillators for cardiac arrest. *Am J Cardiol.* 2004;94:378–380.

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CE 0120 The HeartSine products described in this brochure meet the European Medical Directive requirement.

UL Classified. See complete marking on product.

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www.heartsine.com

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