HeartSine® samaritan® PAD 350P/360P AEDs

Semi-Automatic/Fully Automatic Public Access Defibrillators

Compact, Easy-to-Use, Lifesaving Technology for Public Access

Sudden cardiac arrest strikes 7 million people a year worldwide with no warning and no pattern. There's little time to react and even less time to think. 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 industry-leading value and environmental protection, all in an easy-to-operate system in the smallest and lightest package available.

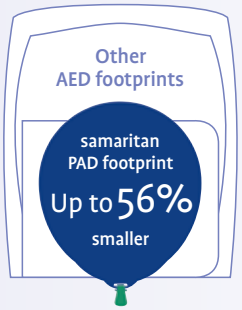
The fully automatic SAM 360P detects motion or other significant interference to reduce the likelihood that the user is touching the patient prior to shock delivery.

Ready to Shock

Portable and lightweight. The HeartSine samaritan PAD is much lighter (2.4 lbs) and smaller than other defibrillators.

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

Clinically Validated Technology.[1] The HeartSine samaritan PAD utilizes proprietary electrode technology and SCOPE™ biphasic technology, an escalating, low-energy waveform that automatically adjusts for differences in patient impedance.



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—a key link in the chain of survival.

One- and two-button operation. With just an ON/OFF button (and the SHOCK button on the SAM 350P), the samaritan PAD offers a simple, straightforward operation.

Automatic Shock Delivery. After analyzing heart rhythm, the SAM 360P[2] will automatically deliver a shock (if needed), eliminating the need for the rescuer to push a shock button.

Always ready. A System Status Ready Indicator flashes to show that the complete system is operational and ready for use. The device automatically runs a self-check each week.

"Apply pads to patient's bare chest as shown in picture"

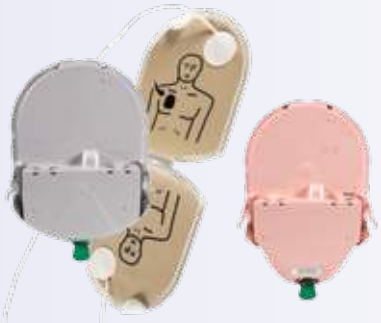
"Stand clear of the patient"

"Safe to touch the patient"

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 (50 J) is delivered for children, between 1 and 8 years of age or up to 55 lbs (25 kg).

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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 350P/360P

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.

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BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

Indications for Use: The HeartSine samaritan PAD SAM 350P (SAM 350P) and HeartSine samaritan PAD SAM 360P (SAM 360P) 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 samaritan PAD to provide treatment.

Warnings:

- The 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 samaritan PAD is analyzing the patient. The device will instruct you when it is safe to touch the patient.
- 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.
- 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.
- Do NOT use the 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 samaritan PAD.
- 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.
- Only samaritan PADs with the label are suitable for use with the Pediatric-Pak. If the 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 50 J shocks to the pediatric patient.
- Do not use if the gel is dry.

Precautions:

- Proper placement of the 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 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 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 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.
- Check expiration date.

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. 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.

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

1. 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.
2. Warning: The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention.

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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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