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% 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.

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.

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. 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

<table>
<thead>
<tr>
<th><strong>Physical</strong></th>
<th>With Pad-Pak Inserted</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size:</strong></td>
<td>8.0 in x 7.25 in x 1.9 in (20 cm x 18.4 cm x 4.8 cm)</td>
</tr>
<tr>
<td><strong>Weight:</strong></td>
<td>2.4 lbs (1.1 kg)</td>
</tr>
</tbody>
</table>

### 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) |
### Energy Selection

<table>
<thead>
<tr>
<th>Pad-Pak:</th>
<th>Shock 1: 150J; Shock 2: 150J; Shock 3: 200J</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric-Pak:</td>
<td>Shock 1: 50J; Shock 2: 50J; Shock 3: 50J</td>
</tr>
</tbody>
</table>

### 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 in² (100 cm²) |
| 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.
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 Pad-Pak™ (Pad-Pak-02).

CONTRAINDICATIONS
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.
• Do not use any unauthorized accessories with the device as the HeartSine samaritan PAD may not function properly.
• 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 50 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.

CONTRAINDICATIONS
Do not use if the gel is dry.

Pad-Paks:
• Do not use the Pediatric Pad-Pak 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 50 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.

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.


EMEA/APAC
HeartSine Technologies, Ltd.
203 Airport Road West
Belfast, Northern Ireland
BT3 9ED
Tel: +44 28 9093 9400
Fax: +44 28 9093 9401
info@heartsine.com

U.S./Americas
HeartSine Technologies LLC
121 Friends Lane, Suite 400
Newtown, PA 18940
Toll Free: (866) 478 7463
Tel: +1 215 860 8100
Fax: +1 215 860 8192
info@heartsine.com

The HeartSine products described in this brochure meet the European Medical Directive requirement.
UL Classified. See complete marking on product.
CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner. © 2017 HeartSine Technologies LLC. All rights reserved.
www.heartsine.com