HeartSine®

Product Comparison

HeartSine® samaritan® PAD Family

	SAM 350P Semi-Automatic	SAM 360P Fully Automatic	SAM 450P with CPR Rate Advisor™
CPR Rate Advisor, ICG-based real-time audible and visual feedback on CPR rate ("Push faster", "Push slower")			✔
Fully automatic shock delivery		✔	
Semi-automatic shock delivery	✔		✔
Highest level of protection from dust and water ingress in the industry (IP56)	✔	✔	✔
Integrated battery and electrode for one-change maintenance	✔	✔	✔
4-year electrode and battery life	✔	✔	✔
Low escalating energy protocol (SCOPE™)	✔	✔	✔
Operating impedance range of 20 – 230 ohms	✔	✔	✔
Audible and visual metronome for CPR rate guidance	✔	✔	✔
Compact, portable, and lightweight 2.4 lbs (1.1 kg)	✔	✔	✔
Pediatric compatible *(When used with Pediatric-Pak™, CPR Rate Advisor is disabled)*	✔	✔	✔
90-minute ECG recording time	✔	✔	✔
Automatic self test	✔	✔	✔
Field upgradeable software	✔	✔	✔
Carry case included	✔	✔	✔

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-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.
- 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 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.
- Do not use if the gel is dry.
- 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 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
- 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.

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.

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.

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

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

UL Classified. See complete marking on product.

H009-032-336-2

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner.

www.heartsine.com

HeartSine®