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HeartSine® samaritan® PAD family

	HeartSine samaritan PAD SAM 350P	HeartSine samaritan PAD SAM 360P	HeartSine samaritan PAD SAM 450P with CPR Rate Advisor
ICG-based real-time feedback on CPR rate ("Push faster," "Push slower," "Good speed")			X
CPR coaching with metronome	X	X	X
Fully automatic shock delivery		X	
Semi-automatic shock delivery	X		X
High level of protection from dust and water ingress (IP56)	X	X	X
Integrated battery and electrode for one-change maintenance	X	X	X
4-year electrode and battery life	X	X	X
Low energy escalating protocol (utilizing the SCOPE waveform)	X	X	X
Operating impedance range of 20 – 230 ohms	X	X	X
Audible and visual metronome for CPR rate guidance	X	X	X
Compact, portable, and lightweight	X 2.4 lb (1.1 kg)	X 2.4 lb (1.1 kg)	X 2.4 lb (1.1 kg)
Pediatric compatible	X	X	X*
90-minute ECG recording time	X	X	X
Automatic self test	X	X	X
Field upgradeable software	X	X	X
Carry case included	X	X	X
Prescription not required	X**		

*CPR Rate Advisor is disabled when used with Pediatric-Pak.

**With its simplified instructions and self-training videos, HeartSine samaritan PAD 350P is available over-the-counter without a prescription, unlike most other AEDs.

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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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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