stryker

HeartSine® samaritan® PAD 350P/360P

Connected AEDs

Semi-Automatic/Fully Automatic Public Access Defibrillators with Integrated Wi-Fi® Connectivity

Data sheet

Readiness matters.

When sudden cardiac arrest occurs, immediate treatment is vital. A victim's chance of survival dramatically decreases for every minute without treatment.[1] This means not only must an Automated External Defibrillator (AED) be close at hand and easy to use, it must be ready to shock.

Connected for extra protection, HeartSine samaritan PAD 350P and 360P Connected AEDs offer key features that help ensure readiness:

- Simplified readiness monitoring
- Integrated Wi-Fi connectivity
- AED program management
- Low cost of ownership

Readiness made easy

LIFELINKcentral AED Program Manager
Monitors AED programs by tracking AED readiness status, Pad-Pak expirations, CPR/AED training certificates and more.

Integrated connectivity
Communicates via Wi-Fi with LIFELINKcentral AED Program Manager to enable AEDs to be managed across a single or multiple locations.

Made for you

Real-time CPR coaching
Easy-to-understand visual and voice prompts guide the rescuer through the entire resuscitation process, including CPR.

Unique Pediatric-Pak
Ensures the appropriate energy level is delivered for children, between 1 and 8 years of age or up to 55 lb (25 kg).

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

Automatic shock delivery / Motion detection
Fully automatic SAM 360P detects motion, such as performing CPR or moving the patient, to reduce the likelihood that the user is touching the patient prior to shock delivery.

Highly portable
With the lightest weight and most compact footprint among leading AEDs, is easily transported and fit into constrained spaces.

Clinically validated technology[2]
Proprietary electrode technology and SCOPE biphasic technology, a low energy escalating waveform, that automatically adjusts for differences in patient impedance.

High level of protection from dust and water
Offers IP56 rating, one of the highest ratings in the industry.

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
Shelf life of four years means that the Pad-Pak offers savings over other defibrillators that require separate battery and electrode replacements.

8-year warranty
AED is backed by an 8-year limited warranty.

Specifications

Defibrillator

Waveform: Self-Compensating Output Pulse Envelope (SCOPE) optimized biphasic escalating waveform compensates energy, slope and duration for patient impedance

Patient analysis system

Method: Evaluates patient's ECG, 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

Energy selection

Pad-Pak shock:
Shock 1: 150J
Shock 2: 150J
Shock 3: 200J

Pediatric-Pak:
Shock 1: 50J
Shock 2: 50J
Shock 3: 50J

Charge time (typical):
150J in < 8 seconds,
200J in < 12 seconds

Environmental

Operating/Standby temperature:
32°F to 122°F (0°C to 50°C)

Transport temperature:
32°F to 122°F (0°C to 50°C)

NOTE: It is recommended that the device should be placed in an ambient temperature of between 32°F to 122°F (0°C to 50°C) for at least 24 hours upon first receipt.

Relative humidity: 5% to 95% non-condensing

Water resistance:
IEC 60529/ EN60529 IPX6 with electrodes connected and battery installed

Dust resistance: IEC 60529/ EN60529 IP5X with electrodes connected and battery installed

Enclosure: IEC/EN 60529 IP56

Altitude: -1,250 to 15,000 feet (-381 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

Atmospheric pressure: 572 hPa to 1060hPa (429 mmHg to 795 mmHg)

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 80MHz-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)

Falling height: 3.3 feet (1 meter)

Physical characteristics

With Pad-Pak inserted and HeartSine Gateway, with batteries, attached:

Size: 9.21 in x 7.25 in x 1.9 in (23.4 cm x 18.4 cm x 4.8 cm)

Weight: 2.83 lb (1.285 kg)

Accessories

Pad-Pak Electrode and Battery Cartridge

Shelf life/Standby life: See the expiration date on the Pad-Pak/Pediatric-Pak (4 years from manufacture date)

Weight: 0.44 lb (0.2 kg)

Size: 3.93 in x 5.24 in x 0.94 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 battery use

Electrodes: 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 (ETSO-C142a)

HeartSine Gateway Battery

Type: CR123A 3V, Non-rechargeable

Type number: 6205

Designation IEC: CR 17345

Weight (per battery): 17g

Quantity: Four

System: Lithium Manganese Dioxide / Organic Electrolyte

UL recognition: MH 13654 (N)

Nominal voltage (per battery): 3V

Typical capacity load:
100 Ohm, at 68°F (20°C), 1550 mAh down to 2V

Volume: 0.43 in^3 (7 ccm)

Data storage

Memory type: Internal memory

Memory storage: 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

Defibrillator housing / HeartSine Gateway: ABS, Santoprene

Electrodes: Hydrogel, Silver, Aluminium and Polyester

Warranty

AED: 8-year limited warranty

HeartSine Gateway: 2-year limited warranty

Communications

- Wireless 802.11 b/g/n data transfer to LIFELINKcentral AED Program Manager
- USB connection to Saver EVO software through Micro USB port

Brief summary of indications and important safety information on back.

References

1. Graham R, McCoy M, Schultz A. Strategies to Improve Cardiac Arrest Survival, A Time to Act. Institute of Medicine Report, 2015.

2. Walsh SJ, McClelland A, Owens CG, Allen J, McC Anderson 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.

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.

If you purchased your HeartSine Connected AED from an authorized Stryker distributor or reseller, this distributor or reseller will have access to your LIFELINKcentral AED Program Manager account and may receive notifications prompted by the HeartSine Connected AED. Please note that this setting to notify your distributor or reseller can be disabled at ANY time: if you wish to disable this setting, please send a request to Stryker Customer Support to self-manage your site without notifications to your distributor or reseller.

All claims valid as April 2020.

For further information, please contact Stryker at 800 442 1142 (U.S.) or visit our web site at strykeremergencycare.com

Emergency Care Public Access

Stryker's AEDs require a prescription in the U.S. Please consult your physician. AED users should be trained in CPR and in the use of the AED.

Although not everyone can be saved, studies show that early defibrillation can dramatically improve survival rates. AEDs are indicated for use on adults and children. AEDs may be used on children weighing less than 55 lb (25 kg) but some models require separate defibrillation electrodes.

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.

04/2020
HeartSine Gateway is not available in all countries. Made in U.K.

UL Classified. See complete marking on product.

!USA | Rx Only

Manufactured by:

HeartSine Technologies Ltd.
203 Airport Road West
Belfast, BT3 9ED
United Kingdom
Tel +44 28 9093 9400
Fax +44 28 9093 9401
heartsinesupport@stryker.com
heartsine.com

Distributed in U.S. by:

Stryker Emergency Care
11811 Willows Road NE
Redmond, WA, 98052 U.S.A.
Toll free 800 442 1142
strykeremergencycare.com