stryker

HeartSine Gateway™

with **LIFELINKcentral™** AED Program Manager

Data sheet

Features

- Wireless connectivity
- Self-monitoring
- Backward compatible
- Low cost of ownership

HeartSine Gateway enables AED (Automated External Defibrillator) program managers to readily manage a fleet of HeartSine AEDs across a single or multiple locations by providing remote readiness information about each AED.

When integrated into a HeartSine samaritan PAD 350P, 360P or 450P, HeartSine Gateway communicates, via a Wi-Fi connection to LIFELINKcentral AED Program Manager or LIFENET System, the results of the weekly AED self-test including if the AED battery is low.

Readiness made easy

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

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

Self-monitoring
Independently monitors its own readiness, sending email alerts when it reaches low battery power or is out of operational temperature range.

Made for you

Backward compatible
Compatible with many installed HeartSine SAM 350P, SAM 360P and SAM 500P AEDs, or provided as part of the HeartSine Connected AED solution.

Easy set up
Straightforward and hassle-free set-up with the HeartSine Gateway configuration tool.

Simple to own

Self-powered
Preserves the AED battery life as it is self-powered using off-the-shelf batteries.

Protection in challenging environments
Offers the same high level of protection against dust and water as the AED.

HeartSine Gateway

Specifications

Controls

Power Button: When off and pressed, turns on the HeartSine Gateway; when held for six seconds, places HeartSine Gateway into set-up mode; and when on and pressed, initiates a manual check-in.

Connections

Data port connector: Connects HeartSine Gateway to the HeartSine AED.

Micro USB port: Enables connection to Saver EVO™ software via a Micro USB cable.

User interface

Status indicator: Provides information on the status of HeartSine Gateway.

Removal tool: Disconnects HeartSine Gateway from a HeartSine AED.

Physical characteristics

With batteries installed

Size:
6.69 in x 2.76 in x 1.97 in
(17 cm x 7 cm x 5 cm)

Weight: .41 lb (.185 kg)

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

Enclosure: IEC 60529 IP56

Altitude: -1,250 to 15,000 feet (-381 to 4,575 meters)

Shock: MIL-STD 810F: 2000 Method 516.5 Procedure 1

Vibration: MIL-STD 810F: 2000 Method 514.5 Procedure 1 categories 4 & 7

EMC: IEC 60601-1-2

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, 1550 mAh down to 2V

Volume: 0.43 in^3 (7 ccm)

Communications

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

Compatibility

Compatible with all HeartSine samaritan PAD models manufactured during or after 2013 (with serial number beginning with “13” or above).

Warranty

2-year limited warranty

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 85ºC 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.

AED BRANDS®
We're in it for life®

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.
H009-043-006-3 US

UL Classified. See complete marking on product.

!USA | Rx Only

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