

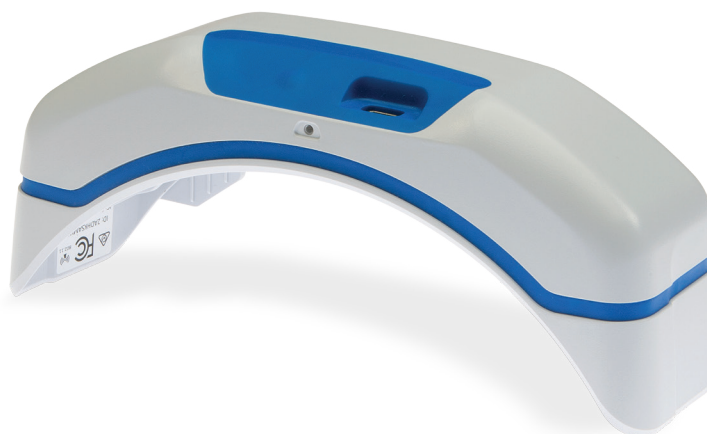
HeartSine Gateway®

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, 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 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 (see Compatibility), 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.



Specifications

Controls

Power button: When off and pressed, turns on 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 in³ (7 ccm)

Communications

- Wireless 802.11 b/g/n data transfer to LIFELINKcentral AED program manager
- 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

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.



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 of 04/2023.

For further information, please contact your Stryker representative or visit our website at strykeremergencycare.com

Emergency Care Public Access

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 25 kg (55 lb) 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.

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 0123 Pad-Pak; Pediatric-Pak

 HeartSine Gateway

 HeartSine samaritan PAD: UL Classified. See complete marking on product.

Date of Issue: 04/2023

Made in U.K.

H009-043-006-AF EN-US

HeartSine Gateway is not available in all countries.

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