

HeartSine Connected AED / HeartSine Gateway™

Implementation Checklist

This document is intended to provide you with guidance on the recommended steps to prepare for the deployment of your AED program with a HeartSine® Connected AED.

As an integrated addition to the HeartSine samaritan® PAD, the HeartSine Gateway™ enables communication via Wi-Fi® to LIFELINKcentral™ AED Program Manager or LIFENET® System, enabling program managers to readily manage AEDs across multiple locations. The HeartSine Gateway is a self-powered communication device for HeartSine samaritan PAD **devices manufactured during or after 2013**. You may have purchased the HeartSine Gateway with your AED, or as an accessory for each of your existing AEDs.

Instructions on setting up your HeartSine Gateway and connecting it to a wireless network will be provided with the user manual. The following additional information is being provided to help you prepare for the installation.

1. Choose a logical and visible location for each of your AEDs.

Like fire extinguishers, your AED devices must be placed in visible, accessible locations so one can be reached quickly in an emergency.

In developing your plan, review the floor plan of your facility. It is a good idea to get input from employees to understand where they would like an AED. These are the people most likely to use the device, so it is helpful to get their input as to its location. You'll want good coverage of areas where large numbers of people visit, work or assemble, such as cafeterias, auditoriums, meeting spaces, gyms, outdoor sports areas, manufacturing floors and offices. Other locations of concern are high-traffic areas such as hallways near restrooms, reception areas and main entrances.

Also consider places:

- That are harder for emergency medical system teams to reach (such as deep inside a facility, high in a tall building, inside secured/restricted areas or remote locations)
- Where people may be subject to strenuous activity, including exercise
- Near hazards such as high voltage electricity
- Near emergency exits, first aid kits or fire extinguishers

Consider locating AEDs so they are:

- Highly visible, such as in wall mount brackets or glass cabinets on building walls in general view—similar to fire extinguishers
 - Near expected responders, such as in security vehicles or at a security or first aid station
 - Close to where the largest number of people spend their time
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2. Ensure the Wi-Fi signal at that location is strong.

Before you determine the ideal location for your HeartSine Connected AED, confirm that the intended location has a strong connection to the Wi-Fi network. Test the signal strength of the Wi-Fi network at the intended AED location using a different wireless device such as a smartphone.

3. Confirm with your IT department the following basic network requirements before installing the HeartSine Gateway.

- A computer with Windows® 7 or above operating system and Internet Explorer or Chrome browser is available to configure the HeartSine Gateway.
 - A 2.4 GHz wireless network is available to which the HeartSine Gateway can connect. Note that 5 GHz wireless networks are not supported.
 - Understand any restrictions for connections to your Wi-Fi network such as proxy server, MAC address filtering (Access Control List or ACL), or port restrictions.
 - If you intend to connect the HeartSine Gateway to an open Wi-Fi network, Terms & Conditions on that network should be disabled. The HeartSine Gateway cannot connect to networks which require a user agreement page.
 - In order to connect your HeartSine Gateway, you must know the SSID and password of your current router/access point. The password, which can include special characters, must be limited to 33 characters.
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Technical requirements and specifications

The following information is intended for your IT department. It is being provided to help you configure your network in preparation for the installation of the HeartSine Gateway.

Connectivity

The HeartSine Gateway connects to LIFELINKcentral AED Program Manager by making outbound requests using TCP and TLS protocols on remote port 443.

Network Configuration

Internet access is required for the HeartSine Gateway's wireless data transmission to work.

Network security systems may need to be configured to properly allow communications to the LIFELINKcentral website. There are many methods to secure a network that is connected to the Internet. In order to help you successfully implement the HeartSine Gateway on your network, the following information should be considered.

For all solutions, it may be necessary to know details about where the LIFELINKcentral system is located on the Internet.

- The URL for LIFELINKcentral is <https://lifelink.lifenetsystems.com>.
- The IP subnet for LIFELINKcentral is 209.67.69.186, or a 28 bit submask.
- Please ensure the following IP address is also reachable (pool server):
74.200.9.47.<https://pool.lifenetsystems.com>

LIFELINKcentral System Properties

- Protocol - HyperText Transfer Protocol with Privacy (HTTPS)
- Connection - TLS 1.0, 1.1, 1.2; 128 bit or higher encryption; RSA 2048 bit exchange.

Email Filters

Email filters may need to be set to allow emails originating from LIFELINKcentral. Notifications are received from no-reply@lifelink.lifenetsystems.com.

Supported Security Protocols

- Open
- WPA-Personal
- WPA2-Personal

Non-Supported Security Protocols

- WPA-Enterprise
- WPA2-Enterprise
- WEP

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.

For further information contact us at heartsinesupport@stryker.com or visit our website at www.heartsine.com.

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

H009-043-008-0 US

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

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