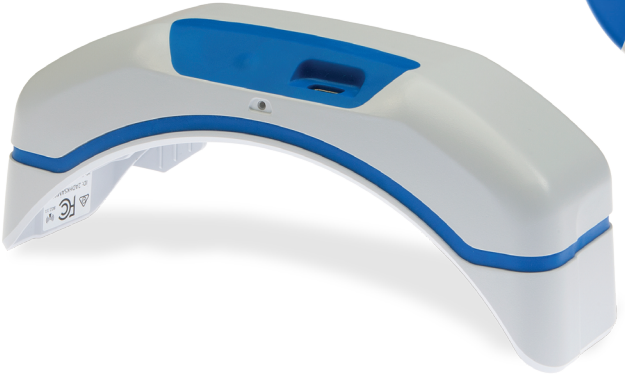
stryker

HeartSine Gateway™

with LIFELINKcentral™ AED program manager

User manual



Contents

Section 1
Before you begin 4
- Terminology 4
- Symbols 5

Section 2
Introduction to HeartSine Gateway 6
- Indications for use 6
- Included in the box 6
- Your HeartSine Gateway 7

Section 3
Assemble your HeartSine Gateway 8
- Unpack 8
- Disconnect HeartSine Gateway from your AED 9
- Insert batteries 10
- Record your HeartSine Gateway serial number 10
- Connect HeartSine Gateway to your AED 11

Section 4
Register your HeartSine Gateway 12
- Overview of Stryker AED program management systems 12
- Log in to your account 12
- Register your HeartSine Gateway 13

Section 5
Connect HeartSine Gateway to your local network 16
- Setup checklist 16
- Connect HeartSine Gateway to the network using a mobile app 17
- Connect HeartSine Gateway to your network using HeartSine Gateway Configuration Tool on your PC or laptop 18
- Confirm connection to LIFELINKcentral was successful 25
- Connecting your HeartSine Gateway to a different Wi-Fi network 26
- Connecting your HeartSine Gateway to a different HeartSine AED 26

Section 6
Set your Pad-Pak expiration date(s) 27

Section 7
Monitoring your HeartSine AED 31

Section 8
Caring for your HeartSine Gateway 32
- Maintaining the battery 32
- Cleaning your HeartSine Gateway 33
- Warranty information 33

Appendix A
Warnings and precautions **34**
Warnings 34
Precautions 35

Appendix B
Troubleshooting **36**

Appendix C
LED status indicator **43**

Appendix D
Network requirements **44**
Supported security protocols 44
Non-supported security protocols 44
Cybersecurity 44
Reporting a security incident 44
Network configuration 45
LIFELINKcentral system properties 45
MAC address filtering 45
Email filters 45

Appendix E
Technical data **48**

Appendix F
Declaration and warranty **53**
EU Declaration of Conformity 53
Warranty 54

Section 1

Before you begin

Terminology

The following terms appear in this manual:

AED	Automated External Defibrillator (your HeartSine samaritan PAD)
MAC address	Unique identifier assigned to network interfaces
PAD	Public Access Defibrillator
SAM	HeartSine samaritan PAD

Symbols

The symbols in the following table may be found on HeartSine Gateway, its accessories or packaging.

	Manufacturer
	HeartSine Gateway is certified to applicable Japanese wireless requirements
	Refer to instruction manual
	Warning, intentional radiated power from HeartSine Gateway; see Wireless Specifications and local jurisdiction requirements
	Do not dispose of this product in the unsorted municipal waste stream; dispose of this product according to local regulations
	Recommended storage and operating temperature 0° to 50°C (32° to 122°F)
	HeartSine Gateway includes RF transmitter
	Product complies with applicable Australian ACMA standards
	Mark of conformity to applicable European Directives
	DC voltage
	Complies with (USA) Federal Communications Commission regulations
	Lithium Manganese Dioxide battery
	Serial number
	Catalog number

Section 2

Introduction to HeartSine Gateway

HeartSine Gateway is a self-powered, Wi-Fi based communication module for HeartSine samaritan PAD devices manufactured during or after 2013.

HeartSine Gateway will communicate via Wi-Fi with LIFELINKcentral AED program manager enabling AED program managers to readily manage an AED across multiple locations.

This user guide provides instructions on connecting HeartSine Gateway to a compatible AED and to the internet.

Note: Your AED will continue to operate as normal with or without HeartSine Gateway attached.

Indications for use

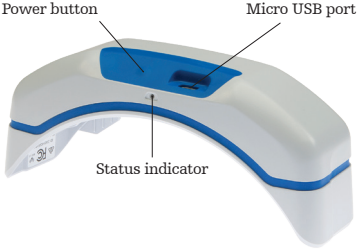
HeartSine Gateway is indicated for use with a HeartSine samaritan PAD manufactured during or after 2013. (The first two digits in the serial number indicate the year of manufacture. HeartSine Gateway can be used with any compatible HeartSine AED with 13 or above for these two digits.)

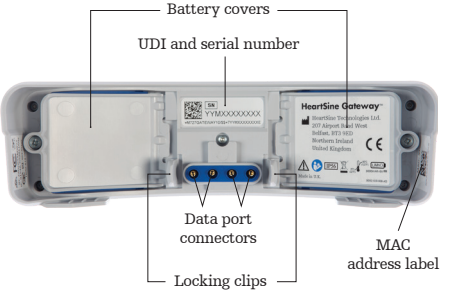
Included in the box

- HeartSine Gateway
- Four CR123A 3V batteries
- Removal tool
- Carry case

Your HeartSine Gateway

Here is the layout of your HeartSine Gateway.





Power button: Press this button to turn on HeartSine Gateway or press and hold the button for six seconds to place HeartSine Gateway into set-up mode.

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

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

Removal tool

Removal tool: Used to disconnect HeartSine Gateway from the AED.

Battery covers: Remove to insert or replace the batteries.

HeartSine Gateway UDI and serial number label: Provides the Unique Device Identifier (UDI) and Serial Number for HeartSine Gateway.

Data port connectors: Connects HeartSine Gateway to the AED.

Locking clips: Lock HeartSine Gateway to the AED.

MAC address label: Provides the MAC address for HeartSine Gateway.

Section 3

Assemble your HeartSine Gateway

This section provides the information you need to assemble your HeartSine Gateway and connect it to your AED. If your HeartSine Gateway was provided as part of a HeartSine Connected AED, after you unpack the box you will need to disconnect HeartSine Gateway from the AED and follow the set-up instructions in the AED user manual before reconnecting HeartSine Gateway.

Unpack

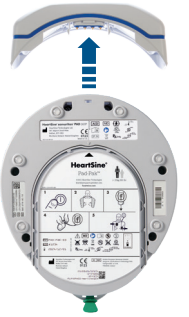
1. Unpack HeartSine Gateway, four CR123A batteries and removal tool.
2. If HeartSine Gateway is attached to an AED, you will need to remove it using the removal tool as shown on page 9.

Disconnect HeartSine Gateway from your AED (if connected)

If HeartSine Gateway is attached to the AED, and you need to change the batteries or for set-up need to view the serial number or MAC address:

1. Insert the removal tool into the back of the AED as shown.

2. Pull HeartSine Gateway away from the AED.



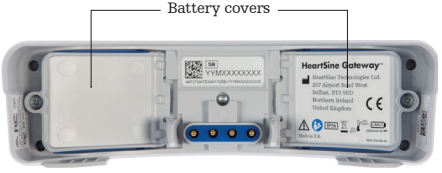
Note: If HeartSine Gateway will be stored separately from the AED, insert the blue cover on the AED data port.

⚠ WARNING

- Use only HeartSine Gateway removal tool provided as using other instruments may damage both HeartSine Gateway and the AED
- Place the AED on a flat surface when removing HeartSine Gateway to avoid dropping HeartSine Gateway

Insert batteries

1. Use an appropriate screwdriver to remove the screw on each of the two battery covers.
2. Carefully remove each battery cover.



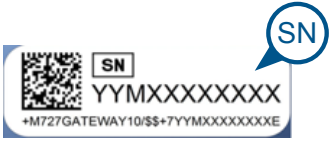
3. Install the four CR123A batteries provided. Ensure the batteries are inserted as indicated in the HeartSine Gateway battery compartment.
4. Replace the battery covers and tighten screws.

⚠ PRECAUTION

If the batteries are not inserted correctly, HeartSine Gateway will not power on.

Record your HeartSine Gateway serial number

1. Find the HeartSine Gateway 11-digit serial number (where YY = year of manufacture and XXXXXXXX = the unique sequential number) as shown in Section 2 and record it here. You will need this later.



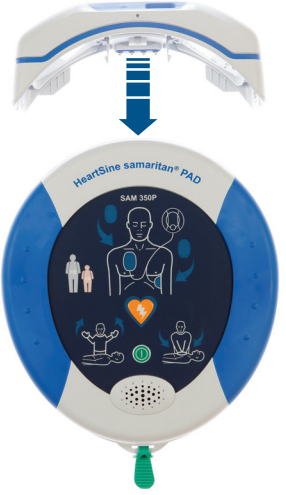
Serial number:

		M								

Connect HeartSine Gateway to your AED

1. Remove the blue cover on the data port, located at the top of the AED.

2. Carefully line up HeartSine Gateway with the LED status indicator pointing to the front of the AED.



3. Slide HeartSine Gateway onto the top of the AED allowing the four pins to connect with the contacts on the data port of the AED. When HeartSine Gateway is fully connected, an audible click should be heard as the locking clips snap into place.

4. If a Pad-Pak is not already installed in your AED, be sure and install one before you proceed. Instructions can be found in the AED user manual.

Section 4

Register your HeartSine Gateway

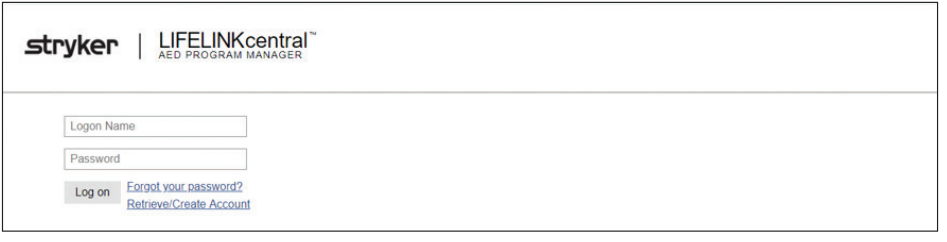
Overview of Stryker AED program management systems

LIFELINKcentral AED program manager, an online AED program management system, enables you to manage all your AEDs and accessories, such as a Pad-Pak or Pediatric-Pak. HeartSine Gateway sends data from each AED to LIFELINKcentral AED program manager, for which a Basic license is provided with each HeartSine Connected AED/HeartSine Gateway.

Log in to your account

You should have received a "Welcome to LIFELINKcentral" email with a link to LIFELINKcentral and log on information. Before you attempt to connect your HeartSine Gateway to LIFELINKcentral AED program manager for the first time, you should confirm your account is active by logging into LIFELINKcentral.

1. Click the link provided in the email to go to the LIFELINKcentral website.
2. Enter the logon name and password provided in the email.



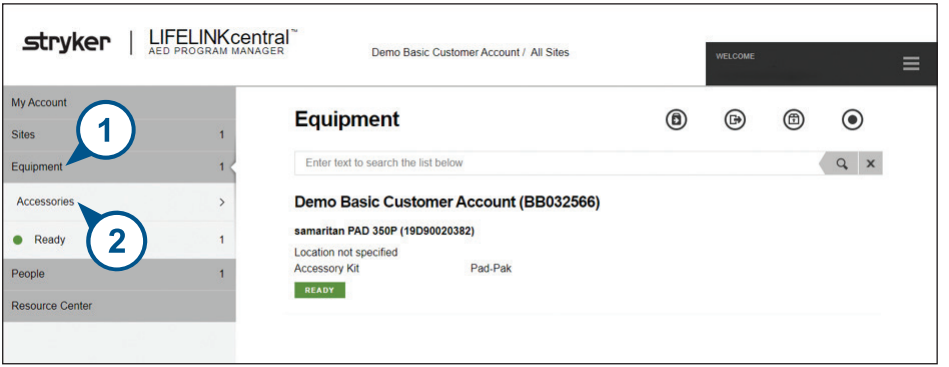
Note: If you cannot locate this email, check your junk mail folder. If needed refer to Troubleshooting in Appendix B of this user manual.

Register your HeartSine Gateway

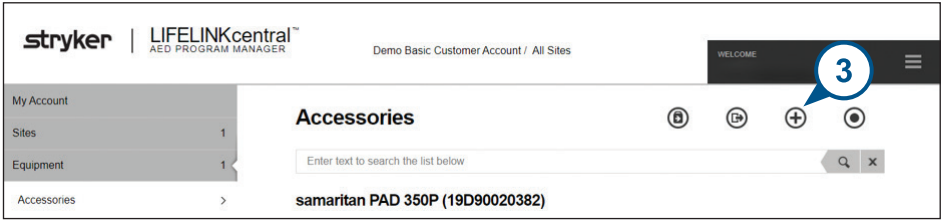
When you log into LIFELINKcentral AED program manager you must register each HeartSine Gateway using its serial number (located on the underside of HeartSine Gateway as shown in Section 2).

To register each HeartSine Gateway:

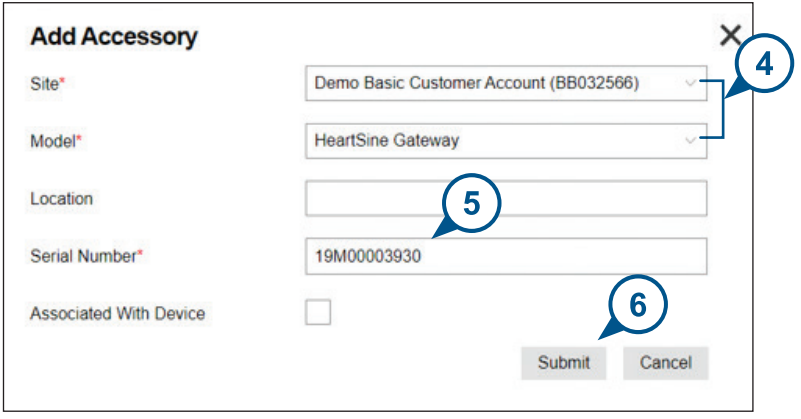
1. Click “Equipment” on the main menu.
2. Click “Accessories”.



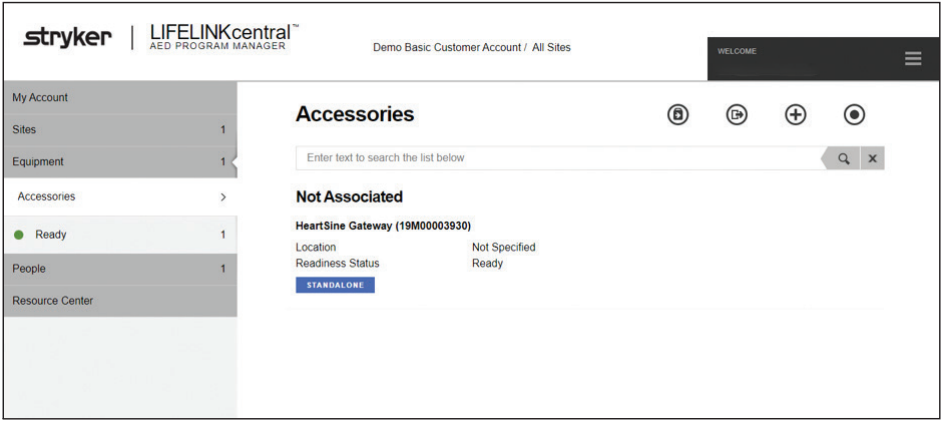
3. From "Accessories" screen, click ⊕ (Add Accessory).



4. From the pull-down menus, select the site in which HeartSine Gateway will be located and select "HeartSine Gateway" as the "Model".
5. Enter the serial number.
6. Click "Submit".



If successfully registered your HeartSine Gateway will appear in “Accessories”.



Section 5

Connect HeartSine Gateway to your local network

Once you have confirmed your LIFELINKcentral AED program manager account is active and you have registered your HeartSine Gateway, it is time to connect HeartSine Gateway to the local network.

To connect HeartSine Gateway to your local network, you can use either the HeartSine Gateway app available in the App Store or Google Play, or HeartSine Gateway Configuration Tool from your Wi-Fi enabled computer. This document outlines the steps for using HeartSine Gateway Configuration Tool. You may experience slightly different steps with the HeartSine Gateway apps.

Download on the App Store

GET IT ON Google Play

Setup checklist

Before you begin, be sure and review the network requirements provided in Appendix D. Before you can connect your HeartSine Gateway to your chosen Wi-Fi network please check that you have the following:

- ☐ Wi-Fi enabled PC or laptop with Windows 7 or above operating system and Internet Explorer or Google Chrome browser to configure HeartSine Gateway.
- ☐ A 2.4 GHz wireless network, for connection to HeartSine Gateway. Note that HeartSine Gateway cannot connect to 5 GHz wireless networks.
- ☐ Administrator rights for the computer.
- ☐ Serial number for your HeartSine Gateway.

- ☐ Location for HeartSine Gateway with a stable and adequate connection to the Wi-Fi network. (Test the signal strength of the Wi-Fi network at the intended location using a different device such as a smartphone.)
- ☐ Wi-Fi network name (SSID) and password. The password, which can include special characters, must be limited to 33 characters. If you do not have this information, ask your IT department for assistance.
- ☐ Access to your LIFELINKcentral AED program manager account.

Connect HeartSine Gateway to your network using a mobile app

Download on the App Store

GET IT ON Google Play

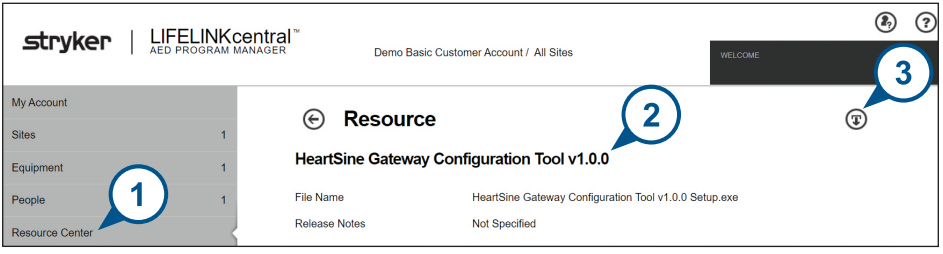
1. Download and run "HeartSine Gateway Configuration Tool" app from the App Store or Google Play.
2. Follow the instructions provided to:
   - Enter the network ID and password
   - Press and hold the power button until the solid blue light appears to put HeartSine Gateway into set-up mode
   - Scan HeartSine Gateway serial number (available on some versions of HeartSine Gateway apps)

When the data you entered for the network has been received by HeartSine Gateway, a green checkmark will appear on the screen and the HeartSine Gateway status indicator will turn solid green. The connection between the app and HeartSine Gateway will be disabled.

3. HeartSine Gateway will attempt to connect the Wi-Fi network. If the connection is successful, the HeartSine Gateway status indicator will be solid green before turning off. If the connection is not successful, the indicator will begin flashing blue. In this case, it is likely the information you entered for the network was not correct and must be re-entered. Confirm that the data you have is correct and repeat each of these steps.
4. For multiple HeartSine Gateway devices, repeat these steps for each HeartSine Gateway.

Connect HeartSine Gateway to your network using HeartSine Gateway Configuration Tool on your PC or laptop

You will need to download HeartSine Gateway Configuration Tool from the “Resource Center” section of LIFELINKcentral AED program manager.



1. Click “Resource Center” (in LIFELINKcentral AED program manager).
2. Click “HeartSine Gateway Configuration Tool”.
3. Click ⓣ to download HeartSine Gateway Configuration Tool.
4. Once the file is downloaded, double-click it to install. (If you don’t see the file, look in your Downloads folder.)

   Note: If a security warning appears, select the option to allow the file.
5. When the set-up wizard appears, follow the onscreen prompts to complete installation.

Notes:

- Depending on your network security settings you may need administration rights to download and install HeartSine Gateway Configuration Tool
- HeartSine Gateway Configuration Tool should launch automatically after installation. If you need to start HeartSine Gateway Configuration Tool manually, open the “Start” menu on your computer, open the HeartSine Gateway application folder, and click “HeartSine Gateway”
- Your computer may reboot during the installation process. If this happens, the installation will continue automatically

6. If needed, click "HeartSine Gateway Configuration Tool" to launch the application.

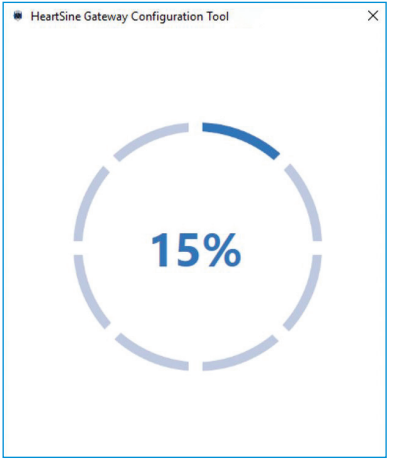
7. Click the right arrow to proceed.

8. As shown on the screen, place HeartSine Gateway into set-up mode by pressing and holding the power button for approximately six seconds until the status indicator turns solid blue. You can only connect one HeartSine Gateway at a time. (Further information on the LED status indicator can be found in Appendix C.)

Note: Your PC / laptop will disconnect from the Wi-Fi network to connect to HeartSine Gateway. When HeartSine Gateway has been configured, you may need to reconnect your PC/laptop to your Wi-Fi network.

9. When the status indicator turns solid blue, click the right arrow to proceed.

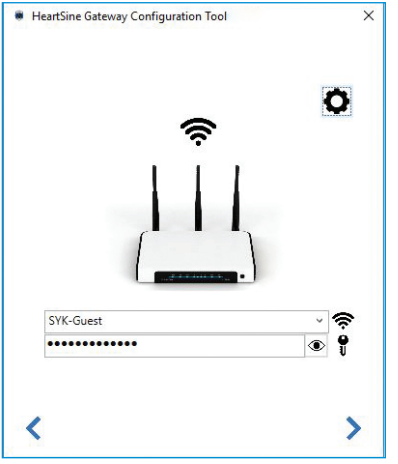
10. HeartSine Gateway Configuration Tool will search for all HeartSine Gateways in set-up mode.



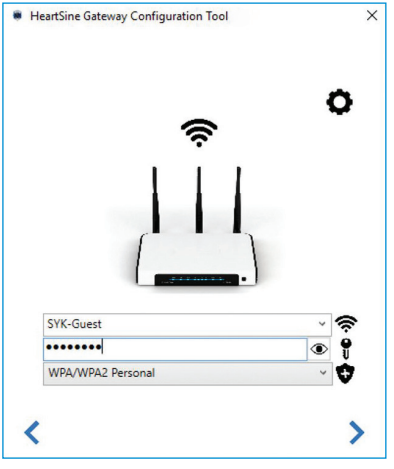
11. When HeartSine Gateway is powered on, in set-up mode and in range of your PC/ laptop, its MAC address and serial number will appear in the pull-down menu. To connect a single HeartSine Gateway, select the relevant HeartSine Gateway serial number from this list.

12. Click the right arrow to proceed.

13. From the pull-down menu, select your Wi-Fi network and enter the network password. (To view the entered password, hover over the button.)

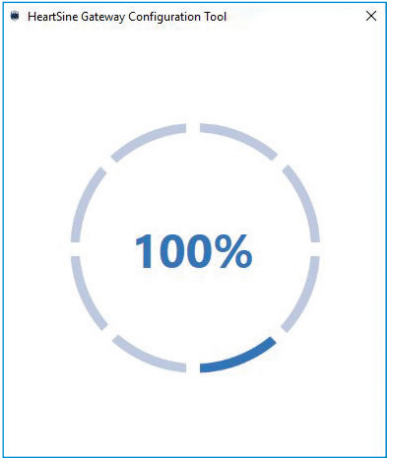


14. Click “Settings” to view the network type. If you need to change the network type, select an option from the pull-down menu.



15. Click the right arrow to proceed.

16. HeartSine Gateway Configuration Tool will try to connect to HeartSine Gateway. A progress screen will appear.



When the data you entered for the network has been received by HeartSine Gateway, a green checkmark will appear on the screen (as shown) and the HeartSine Gateway status indicator will turn solid green. The connection between HeartSine Gateway Configuration Tool and HeartSine Gateway will be disabled.

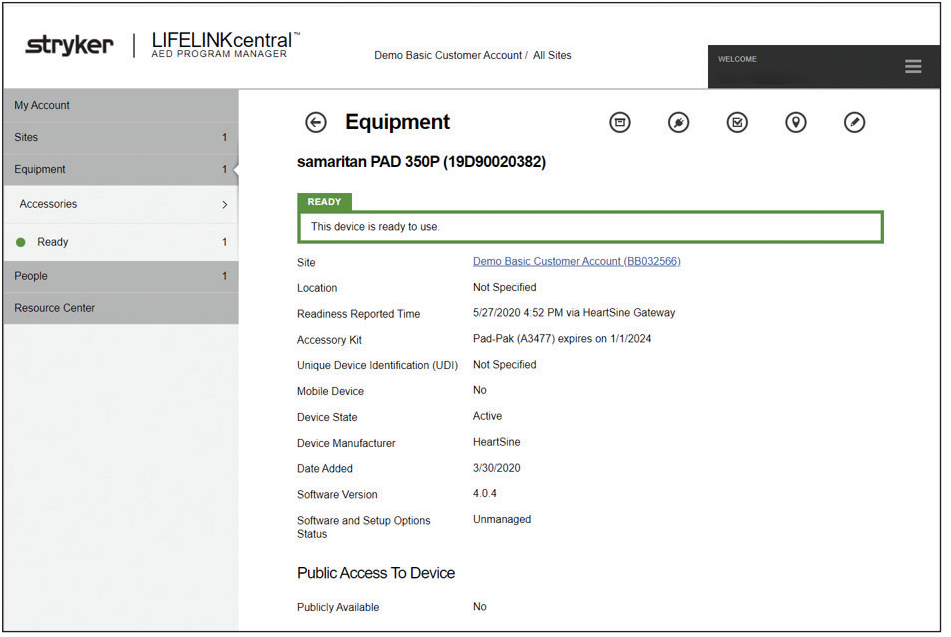
17. HeartSine Gateway will attempt to connect to the Wi-Fi network. If the connection is successful, the HeartSine Gateway status indicator will be solid green before turning off. If the connection is not successful, the indicator will begin flashing blue. In this case, it is likely the information you entered for the network was not correct and must be re-entered. Confirm that the data you have is correct and repeat each of these steps.
18. For multiple HeartSine Gateway devices, repeat these steps for each HeartSine Gateway.
19. Click the right arrow to close the program.
20. If you need to repeat any steps, relaunch the program and repeat the steps.

Note: In some instances, it may be necessary to provide your IT department with the MAC address of HeartSine Gateway so that it can gain access to your network. The MAC address is provided on the MAC address label as shown in Section 2.

Confirm connection to LIFELINKcentral was successful

When you have connected your HeartSine Gateway to your network, go to your LIFELINKcentral AED program manager account to confirm your HeartSine Gateway is registered and working. If the connection was successful, the connected HeartSine AED will appear under “Equipment” in LIFELINKcentral or HeartSine Gateway will appear as an accessory for the AED.

1. Log in to your LIFELINKcentral account.
2. Go to “Equipment” and verify that the status of your AED says “READY”.



Notes:

- If the status is “NOT READY”, refer to the Troubleshooting section of this manual
- If the AED is not shown in the equipment list, check the HeartSine Gateway readiness status in the accessories list view. If the readiness status indicates “NEEDS ATTENTION” (AED not connected), the AED is not properly connected or the AED device model is not supported by HeartSine Gateway

Connecting your HeartSine Gateway to a different Wi-Fi network

To connect your HeartSine Gateway to a different Wi-Fi network, place HeartSine Gateway into set-up mode by holding the power button for approximately six seconds (until the status LED on HeartSine Gateway turns solid blue) and repeat the steps to connect to your network.

Connecting your HeartSine Gateway to a different HeartSine AED

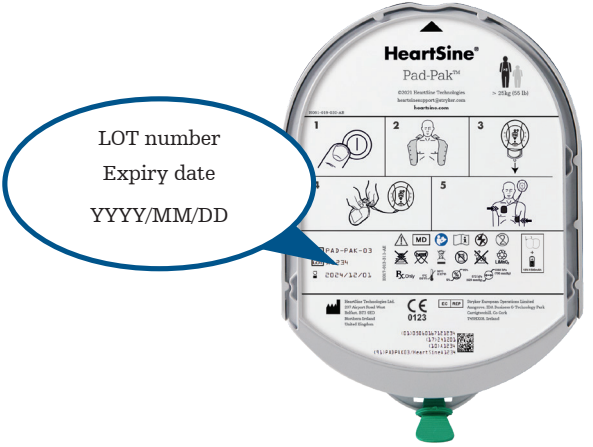
To connect your HeartSine Gateway to a different HeartSine AED, use the removal tool to detach HeartSine Gateway from the current AED and attach it to the new AED as described earlier. Press and release the HeartSine Gateway power button to automatically connect HeartSine Gateway to its preconfigured Wi-Fi network.

Section 6

Set your Pad-Pak expiration date(s)

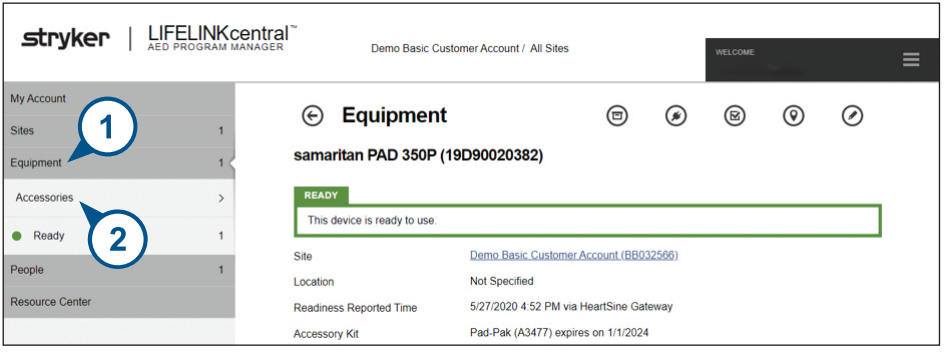
In addition to registering your HeartSine Gateway, you must set the expiration date for each Pad-Pak or Pediatric-Pak that came with your HeartSine AED. This will enable LIFELINKcentral to track the expiration of each Pad-Pak or Pediatric-Pak and provide notifications when each Pad-Pak or Pediatric-Pak needs to be replaced.

To do this, you will need the serial number and expiration date for each Pad-Pak or Pediatric-Pak. These are found on the label on the rear of the Pad-Pak or Pediatric-Pak as shown.

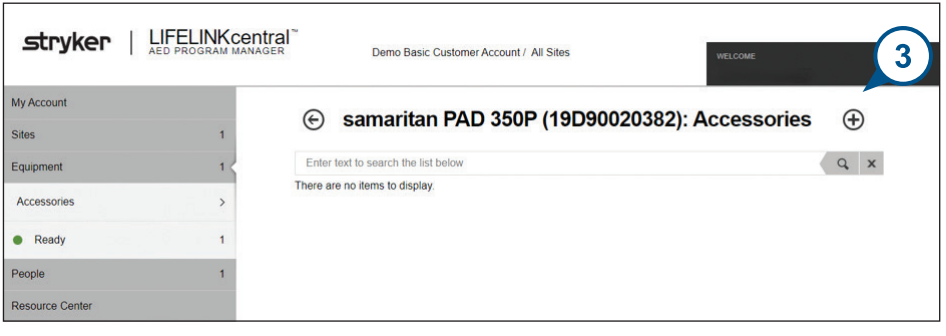


To register each Pad-Pak or Pediatric-Pak:

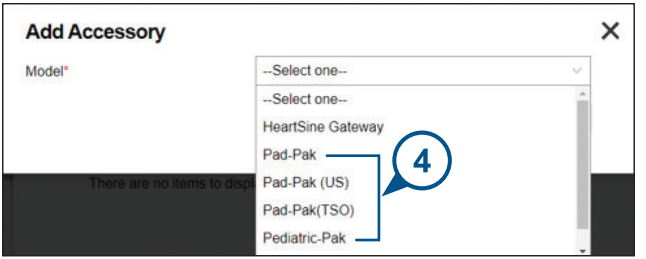
1. From the "Equipment" section, click the AED with which the Pad-Pak or Pediatric-Pak will be used and/or stored.
2. Click "Accessories".



3. From the "Accessories" screen, click ⊕ (Add Accessory).



4. From the Model menu, select “Pad-Pak” or “Pediatric-Pak”.



5. Enter the “Expiration Date” (MM/DD/YYYY) provided on the Pad-Pak or Pediatric-Pak label.

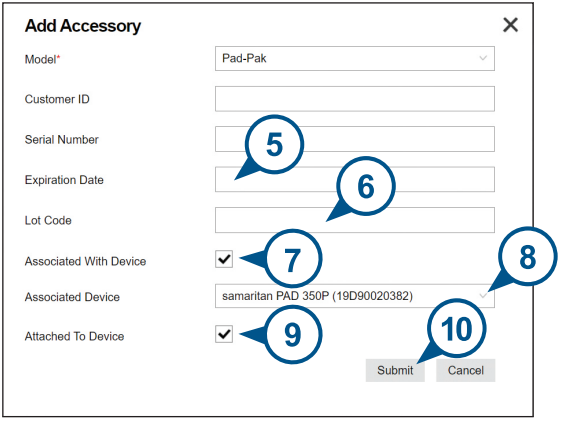
6. Enter the “Lot Code” (number) from the label.

7. To associate a Pad-Pak with a device, click “Associated With Device”.

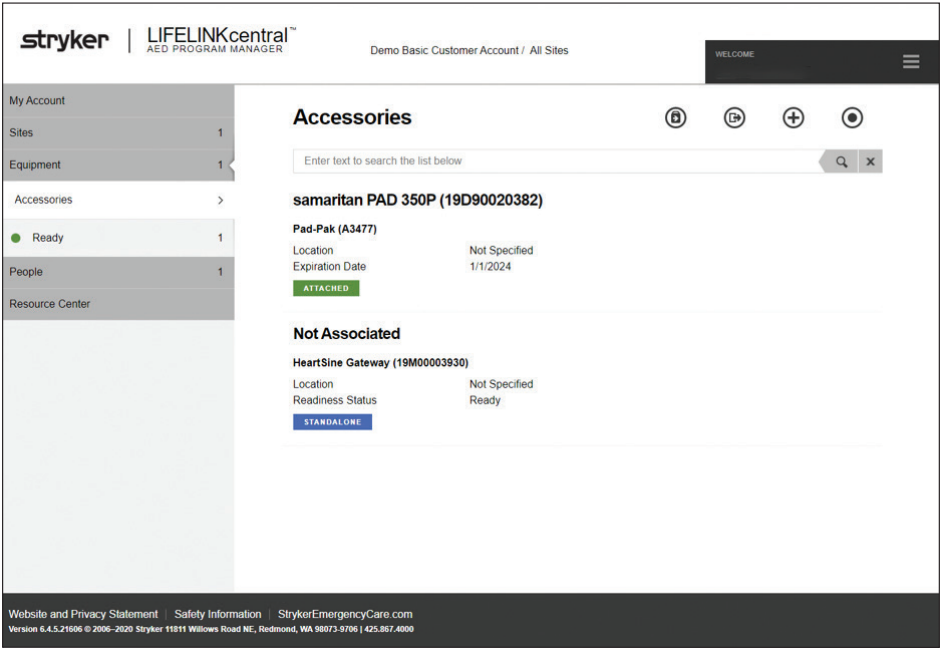
8. From the pull-down menu, select the device to which the Pad-Pak is associated.

9. If the Pad-Pak or Pediatric-Pak is installed in the AED, click “Attached To Device”.

10. Click “Submit”.



If successfully registered your Pad-Pak or Pediatric-Pak will appear in the list of accessories.



Section 7

Monitoring your HeartSine AED

HeartSine Gateway is designed to operate automatically. HeartSine Gateway will activate and connect to its AED daily, extracting self-test data stored within the AED and will upload the data on a weekly basis to your LIFELINKcentral AED program manager account. When HeartSine Gateway has completed the data package upload it will enter a “sleep” mode.

To run an additional “check-in”, press and release the HeartSine Gateway power button. This will upload the data from the last AED self-test to your LIFELINKcentral AED program manager account.

If there is no communication between HeartSine Gateway and LIFELINKcentral during its scheduled check-in, it is recommended that you visually inspect the AED and connected HeartSine Gateway.

⚠ **PRECAUTION** HeartSine Gateway battery life is based on normal operations. Running additional check-ins will deplete the battery life more quickly.

Section 8

Caring for your HeartSine Gateway

Maintaining the battery

HeartSine Gateway is powered by four CR123A 3V batteries. If HeartSine Gateway LED indicator turns red, the batteries may be low. An email notification will be sent to the pre-set user email account for notification of low battery power on HeartSine Gateway.

Batteries can be replaced by removing HeartSine Gateway from the AED and unscrewing the battery covers (see Section 3).

Replace all batteries at the same time, ensuring the batteries are inserted as indicated in the HeartSine Gateway battery compartment. Do not mix new with old.

Dispose of depleted batteries according to local regulations.

⚠ **WARNING**

SAFETY RISK AND POSSIBLE EQUIPMENT DAMAGE

- Rechargeable batteries **cannot** be used in HeartSine Gateway. Using rechargeable batteries will damage HeartSine Gateway and void your warranty
- Damaged batteries may leak and cause personal injury or equipment damage. Handle damaged or leaking batteries with extreme care

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Cleaning your HeartSine Gateway

It is recommended that you visually inspect your HeartSine Gateway at least once a year. If necessary, clean HeartSine Gateway using a soft cloth dampened by one of the following:

- Nonabrasive soap and water
- Isopropyl alcohol (70% solution)

⚠ **PRECAUTION**

- **Do not** immerse any part of HeartSine Gateway in water or any type of fluid. Immersion in fluids may seriously damage HeartSine Gateway or cause a shock hazard
- **Do not** clean any part of HeartSine Gateway or its accessories with abrasive materials or cleaners (for example bleach or bleach dilutions)
- **Do not** attempt to sterilize HeartSine Gateway

Warranty information

See Appendix F for the HeartSine detailed warranty statement.

Appendix A
Warnings and precautions ⚠

WARNINGS

Do not open casing
Do not attempt to open or repair HeartSine Gateway under any circumstances. If damage is suspected, contact your local Authorized Distributor or Stryker representative.

Do not use rechargeable batteries
Do not use rechargeable batteries. These batteries will damage HeartSine Gateway and void your warranty.

Removing HeartSine Gateway from the AED
Do not attempt to remove HeartSine Gateway using anything other than the supplied removal tool. Using anything other than the supplied removal tool may damage HeartSine Gateway and the AED.

Micro USB port
Use only for connection to Saver EVO program. **Do not** attempt to use micro USB port for any other purpose.

Faulty HeartSine Gateway
If you suspect a fault with HeartSine Gateway, remove it from the AED and contact customer support.

EMC warnings
Use of HeartSine Gateway adjacent to or stacked with other electronic equipment should be avoided because it could result in improper operation. If such use is necessary, HeartSine Gateway and the other equipment should be observed to verify they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of HeartSine Gateway, including cables specified by the manufacturer. Otherwise, degradation of the performance of HeartSine Gateway could result.

PRECAUTIONS

Temperature range
HeartSine Gateway is designed to operate in the temperature range of 0°C to 50°C (32°F to 122°F). Use of HeartSine Gateway outside of this range may cause it to malfunction.

Ingress protection
HeartSine Gateway has an IP56 rating against dust and sprays of water. Note that the IP56 rating does not cover immersion of HeartSine Gateway in water or any type of fluid. Immersion in fluids may seriously damage HeartSine Gateway or cause fire or a shock hazard.

Prolonging battery life
Do not turn on HeartSine Gateway unnecessarily as this may reduce the standby life.

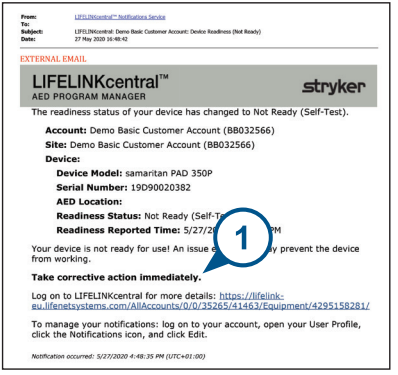
Correct disposal of HeartSine Gateway
Dispose of HeartSine Gateway in accordance with your national or local regulations or contact your local Authorized Distributor or Stryker representative for assistance.

Appendix B
Troubleshooting

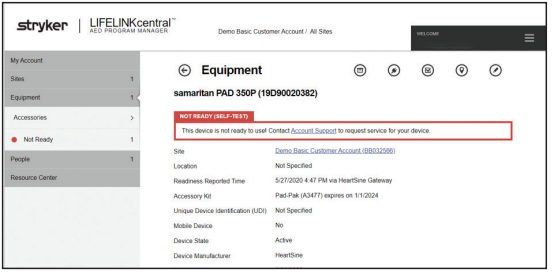
Issue	Solution
HeartSine Gateway will not power on	• Ensure batteries have been inserted correctly. • Batteries may be depleted; replace the batteries with four new **non-rechargeable** CR123A 3V batteries.
I did not receive an email with my logon name and password	• Check your junk mail/ spam folder. You may need to set email filters to allow emails originating from LIFELINKcentral email address in your country. (See Appendix D for the list for the correct email address.) • Check to see if the email was sent to another person in your organization. If you cannot find the email, contact your local Authorized Distributor or Stryker representative.
Downloaded HeartSine Gateway Configuration Tool file did not appear on my computer	• Check the "Downloads" folder on your PC/laptop.
HeartSine Gateway will not go into set up mode.	• Ensure the LED is off then press and hold the power button for at least six seconds. The LED turns solid blue. If the LED does not change color, contact your local Authorized Distributor or Stryker representative.
HeartSine Gateway serial number does not appear in HeartSine Gateway Configuration Tool	• Ensure HeartSine Gateway is in set-up mode (the LED should be solid blue). If not press and hold the power button for at least six seconds until the LED turns solid blue. • Ensure HeartSine Gateway is within Wi-Fi range of the PC/laptop. • Manually refresh the PC/laptop Wi-Fi list.

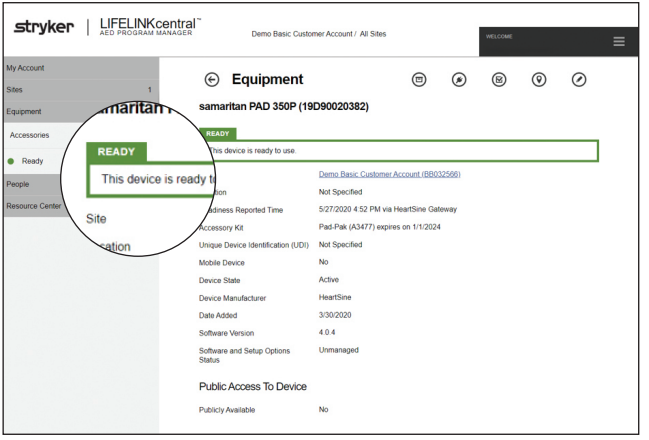
Issue	Solution
HeartSine Gateway is not connecting to HeartSine Gateway Configuration Tool	• Ensure the serial number and MAC address are correct. • Press and hold the power button for six seconds to put HeartSine Gateway into set-up mode (the LED should turn solid blue) and repeat the set-up process.
HeartSine Gateway will not connect to the network	• This may mean the Wi-Fi signal strength is not strong enough or available to connect the AED to the Wi-Fi network. - Confirm the Wi-Fi is working and has sufficient signal strength. - Move the AED closer to your Wi-Fi access point and try again. If you need assistance, contact your local Authorized Distributor or Stryker representative. • Ensure the SSID and password have been entered correctly. • If your network is using MAC address filtering, ensure you have added the HeartSine Gateway MAC address to the approved list.
I need my MAC address	• The MAC address label is located on the underside of HeartSine Gateway on the side. (See Section 2 for exact location.) If HeartSine Gateway is attached to an AED, see Section 3 for instructions for safe removal.
AED is not showing in LIFELINKcentral AED program manager	• Place HeartSine Gateway into set-up mode by holding the power button for six seconds (the LED will turn solid blue) and repeat the steps to connect your HeartSine Gateway. If the problem persists, contact your local Authorized Distributor or Stryker representative for assistance. • Check the readiness status of HeartSine Gateway in LIFELINKcentral. If the HeartSine Gateway status indicates “NEEDS ATTENTION” (AED not connected), the AED is not properly connected or the AED device is not supported by HeartSine Gateway. Only HeartSine samaritan devices manufactured during or after 2013 are supported.

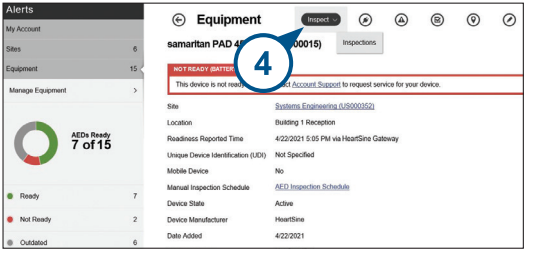
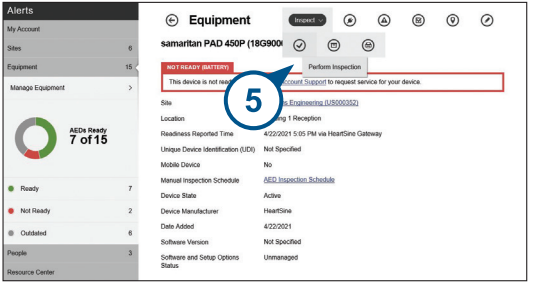
Issue	Solution
I received an email from LIFELINKcentral AED program manager stating that my AED is "NOT READY" or "NEEDS ATTENTION" **OR** **AED is showing as "NOT READY" or "NEEDS ATTENTION" in LIFELINKcentral AED program manager**	**1.** If you received an email, click the link within the email to open LIFELINKcentral and view the equipment status details as shown in the screen at the bottom of this page.

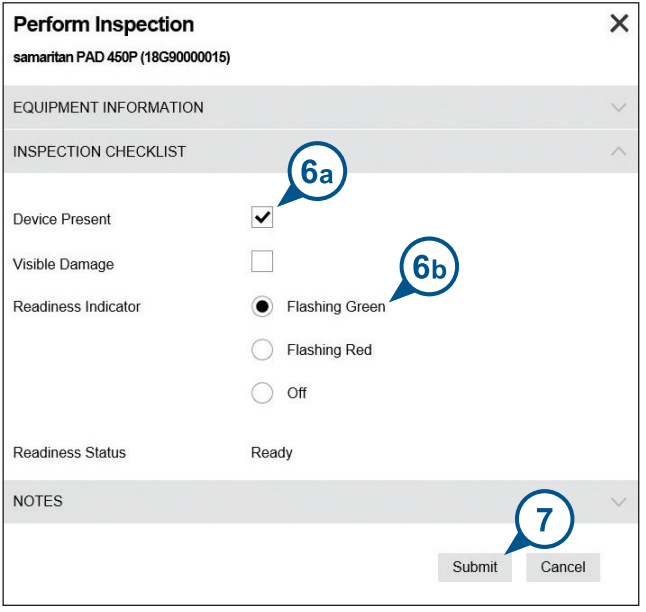


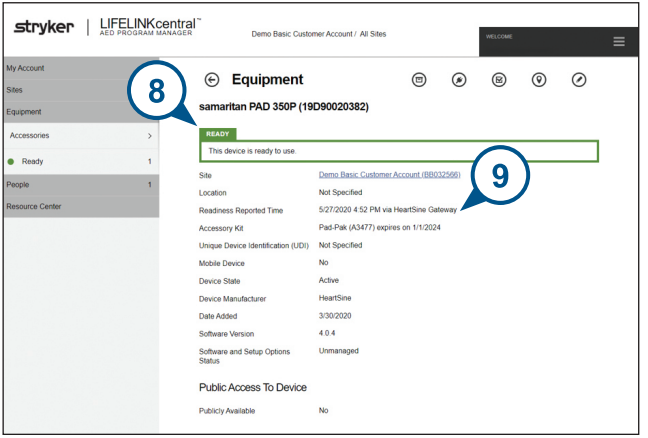
If you have seen a "NOT READY" status in LIFELINKcentral AED program manager, select the AED from the "Equipment" section and view the equipment status details as shown below.



Issue	Solution
(continued) **I received an email from LIFELINKcentral AED program manager stating that my AED is "NOT READY" or "NEEDS ATTENTION"** **OR** **AED is showing as "NOT READY" or "NEEDS ATTENTION" in LIFELINKcentral AED program manager**	**2.** Inspect the HeartSine AED and HeartSine Gateway to resolve issue causing the "NOT READY" or "NEEDS ATTENTION" status: • Check each for visible damage or wear and tear. • Press the AED power button to turn it on, then press the power button again to turn it off. Listen for any error prompts and ensure the AED status indicator is flashing green. **3.** Once you have resolved the issue, press and release the HeartSine Gateway power button. This will upload the data from the latest AED self-test to your LIFELINKcentral AED program manager account. The AED status should change to "READY" as shown. 

Issue	Solution
(continued) **I received an email from LIFELINKcentral AED program manager stating that my AED is "NOT READY" or "NEEDS ATTENTION"** **OR** **AED is showing as "NOT READY" or "NEEDS ATTENTION" in LIFELINKcentral AED program manager**	**4.** If you received a message "NOT READY (BATTERY)" and you have resolved the issue (AED status indicator is flashing green), or if you resolved another issue but the status remains as "NOT READY", you will need to do a manual inspection in LIFELINKcentral AED program manager to reset the AED to "READY". From the "Equipment" menu, click "Inspect".*  **5.** Click "Perform Inspection" ✓.  * If the "Inspect" button is not available in your version of LIFELINKcentral, contact heartsinesupport@stryker.com.

Issue	Solution
(continued) **I received an email from LIFELINKcentral AED program manager stating that my AED is "NOT READY" or "NEEDS ATTENTION"** **OR** **AED is showing as "NOT READY" or "NEEDS ATTENTION" in LIFELINKcentral AED program manager**	**6.** Click "Device Present" checkbox (6a) and "Flashing Green" button (6b) to indicate that you found the device and resolved the issue. **7.** Click "Submit". 

Issue	Solution
(continued) **I received an email from LIFELINKcentral AED program manager stating that my AED is "NOT READY" or "NEEDS ATTENTION"** **OR** **AED is showing as "NOT READY" or "NEEDS ATTENTION" in LIFELINKcentral AED program manager**	**8.** The AED should now show as "READY" in LIFELINKcentral (as shown).  **9.** To confirm that HeartSine Gateway is communicating with LIFELINKcentral, press and release the HeartSine Gateway power button. Then check the "Readiness Reported Time" to confirm the time has been updated.

Appendix C
LED status indicator

The LED status indicator on the front of HeartSine Gateway will indicate its status.

LED status	Condition	Indication
Solid green	HeartSine Gateway Active	HeartSine Gateway is active and downloading data from the AED or transmitting data to LIFELINKcentral AED program manager.
Solid blue	Network Setup Mode	System is in Network Setup mode.
Flashing blue	Not Connected	HeartSine Gateway cannot communicate with LIFELINKcentral due to no connection to the network, being blocked by network rules or the connection to the Internet from the site is unavailable.
Solid red	Critical Fault	A critical fault is detected. Consult LIFELINKcentral AED program manager for details.
Solid black	Power Off	HeartSine Gateway is powered off.
Solid white	Not Registered	HeartSine Gateway is not registered in LIFELINKcentral AED program manager.

Appendix D
Network requirements

HeartSine Gateway should be used on a secure network, with the appropriate password controls. Following are the list of security protocols supported or not supported (as indicated) by HeartSine Gateway.

Supported security protocols

- Open
- WPA-Personal
- WPA2-Personal

Non-supported security protocols

- WPA-Enterprise
- WPA2-Enterprise
- WEP

Cybersecurity

If HeartSine Gateway Configuration Tool is installed on your PC/laptop:

- Use a strong password to log on to your computer. Password should be in upper and lower case and include numbers and symbols.
- Ensure all Microsoft security patches are applied for your computer.
- It is recommended that anti-virus/anti-malware software is installed on your computer, is active and is kept up-to-date.

Reporting a security incident

In the event of a security incident involving HeartSine Gateway, please immediately contact HeartSine customer support at heartsinesupport@stryker.com

*Open networks without a user agreement page are supported.

Network configuration

Internet access is required for HeartSine Gateway 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. To help you successfully implement HeartSine Gateway on your network, the following information should be considered.

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

- FQDNs for LIFELINKcentral are provided on pages 46 and 47
- IP subnet for LIFELINKcentral:
  Canada, Ireland and UK: 74.200.9.46, 255.255.255.240 or a 28 bit submask
  All other locations: 62.29.175.224, 255.255.255.240 or a 28 bit submask
- Please ensure the following public endpoint is also reachable: 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 and ECDSA 256 bits key exchange

MAC address filtering

If your network uses MAC address filtering, please ensure access is permitted for network traffic for the HeartSine Gateway MAC address. For details locating your HeartSine Gateway MAC address please refer to section 2.

Email filters

Email filters may need to be set to allow emails originating from LIFELINKcentral. The email for your country is provided in the table on pages 46 and 47.

Country	URL record name	Email address*
Argentina	https://lifelink-ar.lifenetsystems.com	web@lifelink-ar.lifenetsystems.com
Australia	https://lifelink-au.lifenetsystems.com	web@lifelink-au.lifenetsystems.com
Austria	https://lifelink-at.lifenetsystems.com	web@lifelink-at.lifenetsystems.com
Bahrain	https://lifelink-bh.lifenetsystems.com	web@lifelink-bh.lifenetsystems.com
Belgium	https://lifelink-be.lifenetsystems.com	web@lifelink-be.lifenetsystems.com
Canada	https://lifelink-ca.lifenetsystems.com	web@lifelink-ca.lifenetsystems.com
Chile	https://lifelink-cl.lifenetsystems.com	web@lifelink-cl.lifenetsystems.com
Colombia	https://lifelink-co.lifenetsystems.com	web@lifelink-co.lifenetsystems.com
Costa Rica	https://lifelink-cr.lifenetsystems.com	web@lifelink-cr.lifenetsystems.com
Denmark	https://lifelink-dk.lifenetsystems.com	web@lifelink-dk.lifenetsystems.com
Faroe Islands	https://lifelink-fo.lifenetsystems.com	web@lifelink-fo.lifenetsystems.com
Finland	https://lifelink-fi.lifenetsystems.com	web@lifelink-fi.lifenetsystems.com
France	https://lifelink-fr.lifenetsystems.com	web@lifelink-fr.lifenetsystems.com
Germany	https://lifelink-de.lifenetsystems.com	web@lifelink-de.lifenetsystems.com
Greenland	https://lifelink-gl.lifenetsystems.com	web@lifelink-gl.lifenetsystems.com
Hong Kong	https://lifelink-hk.lifenetsystems.com	web@lifelink-hk.lifenetsystems.com
India	https://lifelink-in.lifenetsystems.com	web@lifelink-in.lifenetsystems.com
Ireland	https://lifelink-ie.lifenetsystems.com	web@lifelink-ie.lifenetsystems.com
Israel	https://lifelink-il.lifenetsystems.com	web@lifelink-il.lifenetsystems.com
Italy	https://lifelink-it.lifenetsystems.com	web@lifelink-it.lifenetsystems.com
Japan	https://lifelink-jp.lifenetsystems.com	web@lifelink-jp.lifenetsystems.com
Jordan	https://lifelink-jo.lifenetsystems.com	web@lifelink-jo.lifenetsystems.com
Kuwait	https://lifelink-kw.lifenetsystems.com	web@ lifelink-kw.lifenetsystems.com
Liechtenstein	https://lifelink-li.lifenetsystems.com	web@lifelink-li.lifenetsystems.com

Country	URL record name	Email address*
Luxembourg	https://lifelink-lu.lifenetsystems.com	web@lifelink-lu.lifenetsystems.com
Malta	https://lifelink-mt.lifenetsystems.com	web@lifelink-mt.lifenetsystems.com
Netherlands	https://lifelink-nl.lifenetsystems.com	web@lifelink-nl.lifenetsystems.com
New Zealand	https://lifelink-nz.lifenetsystems.com	web@lifelink-nz.lifenetsystems.com
Norway	https://lifelink-no.lifenetsystems.com	web@lifelink-no.lifenetsystems.com
Oman	https://lifelink-om.lifenetsystems.com	web@lifelink-om.lifenetsystems.com
Peru	https://lifelink-pe.lifenetsystems.com	web@lifelink-pe.lifenetsystems.com
Poland	https://lifelink-pl.lifenetsystems.com	web@lifelink-pl.lifenetsystems.com
Puerto Rico	https://lifelink.lifenetsystems.com	no-reply@lifelink.lifenetsystems.com
Qatar	https://lifelink-qa.lifenetsystems.com	web@lifelink-qa.lifenetsystems.com
Saudi Arabia	https://lifelink-sa.lifenetsystems.com	web@lifelink-sa.lifenetsystems.com
Singapore	https://lifelink-sg.lifenetsystems.com	web@lifelink-sg.lifenetsystems.com
South Africa	https://lifelink-za.lifenetsystems.com	web@lifelink-za.lifenetsystems.com
Spain	https://lifelink-es.lifenetsystems.com	web@lifelink-es.lifenetsystems.com
Sweden	https://lifelink-se.lifenetsystems.com	web@lifelink-se.lifenetsystems.com
Switzerland	https://lifelink-ch.lifenetsystems.com	web@lifelink-ch.lifenetsystems.com
United Arab Emirates	https://lifelink-ae.lifenetsystems.com	web@lifelink-ae.lifenetsystems.com
United Kingdom	https://lifelink-uk.lifenetsystems.com	web@lifelink-uk.lifenetsystems.com
United States	https://lifelink.lifenetsystems.com	no-reply@lifelink.lifenetsystems.com
Uruguay	https://lifelink-uy.lifenetsystems.com	web@lifelink-uy.lifenetsystems.com
U.S. Virgin Islands	https://lifelink.lifenetsystems.com	no-reply@lifelink.lifenetsystems.com

* These email addresses are unmonitored and will not accept incoming emails.

Appendix E
Technical data

Physical specifications

Size	17 x 7 x 5 cm (6.69 x 2.76 x 1.97 in)
Weight	115g (0.25 lb)
Weight (with batteries installed)	185g (0.41 lb)

Environmental specifications

Operating/Standby Temperature	0°C to 50°C (32°F to 122°F)
Transport Temperature	0°C to 50°C (32°F to 122°F) Note: It is recommended that the device should be placed in an ambient temperature of between 0°C to 50°C (32°F to 122°F) for at least 24 hours upon first receipt.
Relative Humidity	5% to 95% non-condensing
Enclosure	IEC 60529 IP56
Altitude	0 to 4572 meters (0 to 15,000 feet)
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

Communications

Communications	Wireless 802.11 b/g/n transfer to LIFELINKcentral AED program manager
Frequency Bands	2412-2472 Mhz
Maximum Frequency Power Transmitted	18dBm

Batteries

Type	CR123A 3V, Non-rechargeable
Type Number	6205
Designation IEC	CR 17345
Size	34.5 x 17 mm (1.35 x 0.67 in)
Weight	17g (0.04 lb) (1 x Battery) 68g (0.15 lb) (4 x Batteries)
System	Lithium-Manganese Dioxide ($LiMnO_2$) / Organic Electrolyte
UL Recognition	MH 13654 (N)
Nominal Voltage	3 V
Typical Capacity C Load 100 Ohm, at 20°C	1550 mAh down to 2 V
Volume	7 ccm (0.43 in^3)
Coding	Date of Manufacturing Month / Year

Electromagnetic conformity

HeartSine Gateway is suitable for use in all professional and domestic establishments. It is not intended for use near intentional transmitters of radio energy such as high frequency surgical equipment, radar installations or radio transmitters, nor in the vicinity of magnetic resonance imaging (MRI) equipment.

HeartSine Gateway is intended for use in the electromagnetic environments specified in the tables below. The user of HeartSine Gateway should assure that it is used in such an environment.

The essential performance of HeartSine Gateway is the ability to periodically request and receive data via the existing USB interface of the host defibrillator, and to wirelessly transmit this data over an established Wi-Fi connection. Operation outside of the environments specified below may result in improper operation of HeartSine Gateway device.

There are no special maintenance procedures required to ensure that the essential performance and basic safety of HeartSine Gateway are maintained with regard to electromagnetic disturbances over the service life of the device.

Emissions test	Compliance	Electromagnetic environment – guidance
RF CISPR 11	Group 1 Class B	HeartSine Gateway uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. HeartSine Gateway is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission IEC/EN 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emission IEC/EN 61000-3-3	Not Applicable	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic Discharge (ESD) IEC/EN 61000-4-2	± 8kV Contact ± 15kV Air	± 8kV Contact ± 15kV Air	There are no special requirements with respect to electrostatic discharge.
Electrical fast transients/bursts IEC/EN 61000-4-4	Not Applicable	Not Applicable	
Surges, line to line IEC/EN 61000-4-5	Not Applicable	Not Applicable	
Surges, line to ground IEC/EN 61000-4-5	Not Applicable	Not Applicable	
Voltage dips, interruptions and variations on power supply input lines IEC/EN 61000-4-11	Not Applicable	Not Applicable	
Power Frequency (50/60Hz) Magnetic Field IEC/EN 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. There are no special requirements for non-commercial/non-hospital environments.
Radiated RF IEC/EN 61000-4-3	10 V/m 80MHz – 2.7GHz	10V/m 80MHz – 2.7GHz	Portable and mobile RF communications equipment should be used no closer to any part of the HeartSine samaritan PAD, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter, or 30cm, whichever is greater.[a] Interference may occur in the vicinity of equipment marked with this symbol.
Conducted RF IEC/EN 61000-4-6	Not Applicable	Not Applicable	

[a] Field strengths from fixed transmitters, such as base stations for cellular telephones, amateur radio, FM and AM radio broadcast and television broadcast cannot be predicted theoretically with a great deal of accuracy. In such cases, an electromagnetic site survey should be considered to properly assess the electromagnetic environment. If the measured field strength in the location in which HeartSine Gateway is intended to be used exceeds the applicable RF compliance levels noted above, HeartSine Gateway should be observed to verify normal operation. If abnormal performance is observed, consideration should be given to relocating HeartSine Gateway if possible.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Federal Communications Commission (FCC) declaration

HeartSine Gateway is capable of transferring data records by wired or wireless connection.

HeartSine Gateway complies with Part 15 of the FCC rules and with Licence exempt RSS standards of Industry Canada.

Operation is subject to the following two conditions:

1. HeartSine Gateway may not cause harmful interference, and
2. HeartSine Gateway must accept any interference received, including interference that may cause undesired operation.

⚠ **PRECAUTION** Changes or modifications not expressly approved by HeartSine could void the user's authority to operate the equipment. The term "IC:" before the radio certification number only signifies that Industry Canada technical specifications were met.

Appendix F
Declaration and warranty

EC Declaration of Conformity

Manufacturer: **HeartSine Technologies Limited**
207 Airport Road West
Belfast, BT3 9ED
Northern Ireland
United Kingdom

Radio Equipment:
Device: **HeartSine Gateway**
Model: **Gateway**
Catalog:

ACC-GTW-XX-01	350-STR-XX-GW	360-STR-XX-GW
450-STR-XX-GW	500-STR-XX-GW	

(where XX denotes language)

This declaration of conformity is issued under the sole responsibility of HeartSine Technologies Ltd. who declares that the above named HeartSine Gateway is in conformity with the following regulations:

Radio Equipment Directive (RED)	2014/53/EU
ROHS2 Directive 2 (Article 4)	2011/65 EU with exceptions Annex III (6c – lead in copper alloy), incorporating ROHS3 amendments (EU 2015/863)

Conformity to the essential requirements of the legislation(s) have been demonstrated by using the following standards:

Health and Safety Article 3.1a:	IEC 60601-1:2012Edtion 3.1
EMC Article 3.1b:	Directive 2014/30/EU, EN55011:2009+A1:2010, EN60601-1-2:2014, EN 301 489-1 V2.1.1, EN 301 489-17 V3.1.1, EN61000-4-2:2009, EN61000-4-3:2006, EN61000-4-8:2010
Spectrum Article 3.2:	EN 300 328 v2.1.1

Signed for and on behalf of: HeartSine Technologies Ltd
Place and Date of Issue: Belfast, United Kingdom, 04-May-2021

Signature *Electronically signed by: Rebecca Funston Reason: I approve Date: May 4, 2021 08:46 GMT+1*

Date 04-May-2021

Rebecca Funston

Director, Global Regulatory & Clinical Affairs
HeartSine Technologies Ltd.

Warranty

What is covered? Stryker provides to the original end user a limited warranty that all HeartSine products that are purchased from a distributor, sub-distributor, person or entity authorised by Stryker ("Authorised Agents") are substantially free from defects in material and workmanship. This limited warranty applies only to the original end user and may not be assigned or transferred. An original end user is one who is able to provide proof of purchase from Stryker or an Authorised Agent. Persons who are not original end users take the products "as is" and with all faults. Please be prepared to provide proof of purchase demonstrating that you are the original end user and eligible to make a valid claim under this warranty. If you are not sure if the distributor, sub-distributor, person or entity from whom you purchased any HeartSine samaritan products is authorised by Stryker please contact Customer Support on +44 28 9093 9400 or heartsinesupport@stryker.com.

For how long? HeartSine warrants, from the date of the sale to the original end user, the HeartSine samaritan PAD for the full eight (8) year service life and the HeartSine samaritan PAD Trainer and HeartSine Gateway for a period of two (2) years. Products with a stated expiration date are warranted until such expiration date.

Limited warranty does not cover: This limited warranty does not cover defects or damages of any sort resulting from, but not limited to, accidents, damage while in transit to our service location, alterations, unauthorised service, unauthorised product case opening, failure to follow instructions, improper use, improper or inadequate maintenance, abuse, neglect, fire, flood, war or acts of God. We do not warrant your HeartSine products to be compatible with any other medical devices.

This limited warranty is void if: You purchased any HeartSine products from anyone other than an Authorised Agent; your HeartSine product is serviced or repaired by anyone other than Stryker; your HeartSine product is opened by unauthorised personnel or if a product is not used in accordance with the "Instructions for Use" and the "Indications for Use" provided with your product; your HeartSine product is used in conjunction with incompatible parts or accessories, including, but not limited to batteries. Parts and accessories are not compatible if they are not HeartSine products.

What you should do: As the original end user you should send the completed warranty registration card within 30 days of original purchase to:

HeartSine Technologies, Ltd.
207 Airport Road West
Belfast, BT3 9ED
Northern Ireland
United Kingdom

Or register online using the Warranty Registration link on our website heartsine.com. To obtain warranty service for your HeartSine product, contact your local Stryker Authorised Agent or call Customer Support on +44 28 9093 9400. Our technical representative will try to resolve your issue over the phone. If necessary, and at our sole discretion, we will arrange for service or a replacement of your HeartSine product. You must not send back any product without our authorisation.

What we will do: If your HeartSine product contains defects in material or workmanship and it is returned, at the direction of a technical service representative, within the warranty period, we, at our sole discretion, will repair your product or replace it with a new or reconditioned product of the same or similar design. The repaired or reconditioned product will be warranted subject to the terms and conditions of this limited

warranty for either (a) 90 days or (b) the remainder of the original warranty period, whichever is longer, provided the warranty applies and the warranty period has not expired.

If our inspection does not detect any defects in material or workmanship of your HeartSine product, regular service charges will apply.

Obligations and limitation of liability:
THE FOREGOING LIMITED WARRANTY IS IN LIEU OF AND SPECIFICALLY EXCLUDES AND REPLACES ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, TITLE, AND NON-INFRINGEMENT. Some states do not allow limitations on how long an implied warranty lasts, so this limitation may not apply to you.

NO PERSON (INCLUDING ANY AGENT, DEALER, OR REPRESENTATIVE OF Stryker) IS AUTHORISED TO MAKE ANY REPRESENTATION OR WARRANTY CONCERNING HEARTSINE PRODUCTS, EXCEPT TO REFER TO THIS LIMITED WARRANTY.

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HeartSine Gateway user manual can be found on our website at
https://heartsine.com/support/product-manuals/

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

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The absence of a product, feature, or service name, or logo from this list does not constitute a waiver of Stryker's trademark or other intellectual property rights concerning that name or logo.

Date of Issue: 06/2021
Made in U.K.
H052-019-300-AC EN-UK
HeartSine Gateway is not available in all countries.

Labeling for your HeartSine AED, HeartSine Gateway and/or Pad-Pak may be different in your region than labels shown in this document.

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HeartSine samaritan PAD; Pad-Pak; Pediatric-Pak CE 0123

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

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