



HeartSine Gateway[™]

with LIFELINK central[™] AED Program Manager

User Manual



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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 the HeartSine Gateway, its accessories or packaging.

	Manufacturer
Ê	HeartSine Gateway is certified to applicable Japanese wireless requirements
${}^{\bigcirc}$	Consult user manual
\triangle	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 $50^\circ C~(32^\circ$ to $122^\circ F)$
(((•)))	HeartSine Gateway includes RF transmitter
	Product complies with applicable Australian ACMA standards
CE	Mark of conformity to applicable European Directives
	DC voltage
FC	Complies with (USA) Federal Communications Commission regulations
LiMnO ₂	Lithium Manganese Dioxide battery
SN	Serial number
c 91 'us	UL Recognized Component Safety Mark
REF	Catalogue number

Section 2 Introduction to the HeartSine Gateway

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

The HeartSine Gateway will communicate via Wi-Fi with LIFELINKcentral AED Program Manager and LIFENET System, enabling AED program managers to readily manage an AED across multiple locations.

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

NOTE Your AED will continue to operate as normal with or without the HeartSine Gateway attached.

Indications for use

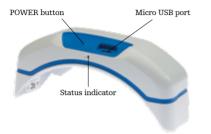
The HeartSine Gateway is indicated for use with a HeartSine samaritan PAD manufactured during or after 2013. (The first two digits in the serial number indicate the year of manufacture. The HeartSine Gateway can be used with any HeartSine AED with 13 or above for these two digits.)

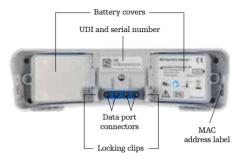
Included in the box

- 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 the 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 the HeartSine Gateway.

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



Removal tool

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 the HeartSine Gateway.

Data port connectors: Connects HeartSine Gateway to the AED.

Locking clips: Lock the HeartSine Gateway to the AED.

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

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

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 the HeartSine Gateway from the AED and follow the set-up instructions in the AED User Manual before reconnecting the HeartSine Gateway.

Unpack

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

Disconnect the HeartSine Gateway from your AED (if connected)

If the 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 the HeartSine Gateway away from the AED.



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

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



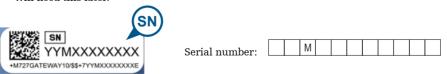
- 3. Install the four CR123A batteries provided. Ensure the batteries are inserted as indicated in the HeartSine Gateway battery compartment.
- 4. Replace the battery covers and tighten screws.

PRECAUTION

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

Record your HeartSine Gateway serial number

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



Connect the HeartSine Gateway to your AED

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



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



3. Slide the 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 the 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 and LIFENET System are online AED program management systems that can be used to manage all your AEDs. The HeartSine Gateway sends data from your AED to one of these AED program management systems (depending on which you use). LIFELINKcentral AED Program Manager, provided with each HeartSine Connected AED, is used by customers to manage AEDs and accessories, such as a Pad-Pak. LIFENET System is used by health care organizations, such as emergency medical systems and hospitals, to manage AEDs and other emergency equipment. You will need an online account for one of these websites.

Many health care organizations have existing LIFENET System accounts to manage their HeartSine Gateways. If your organization has a LIFENET System account, refer to the LIFENET website for instructions about using LIFENET System to manage your HeartSine Gateway. If your organization does not have a LIFENET System account, a LIFELINKcentral AED Program Manager account was set up for you when you ordered your HeartSine Gateway.

Log in to your account

Before you attempt to connect your HeartSine Gateway to LIFELINKcentral AED Program Manager or LIFENET System for the first time, you should confirm your account is active by logging into the applicable website.

If you are a LIFENET System user, contact your account administrator at your facility for logon credentials.

If you are not a LIFENET System user, you will have received a "Welcome to LIFELINKcentral" email.

- 1. Click the link provided in the mail to go to the LIFELINKcentral website.
- 2. Enter the username 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 2 of this user manual.

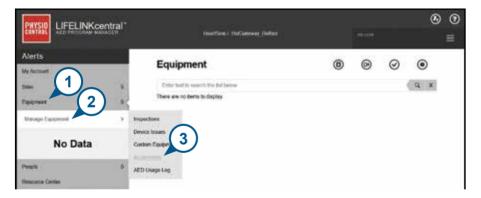


Register your HeartSine Gateway

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

To register each HeartSine Gateway:

- 1. Click Equipment on the main menu.
- 2. Point to Manage Equipment.
- 3. Click Accessories.



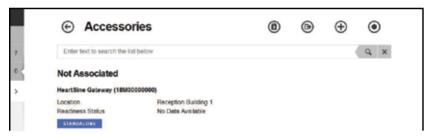
4. From the Accessories screen, click \bigoplus (Add Accessory).



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

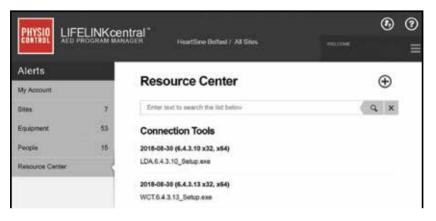
Add Accessory		х
Site* 5	HeartSine / Building 1 (US009680)	
Model*	HeartSine Gateway	
Location		
Serial Number*	18M00000000	
Associated With Device		
	Submit Cancel	

If successfully registered your HeartSine Gateway will appear in the list of Accessories.



Download and install the HeartSine Gateway Configuration Tool

After you have registered your HeartSine Gateway, you must download the HeartSine Gateway Configuration Tool, which is required to connect the HeartSine Gateway to your network. This tool is provided in the Resource Center section of LIFELINKcentral AED Program Manager and the Assets Menu of LIFENET System.



- 1. Select **RESOURCE CENTER** (in LIFELINKcentral AED Program Manager) or **ASSETS** menu (in LIFENET System).
- 2. Select the HeartSine Gateway Configuration Tool.
- 3. Click (T) to download the 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.)

PLEASE 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.
- The HeartSine Gateway Configuration Tool should launch automatically after installation. If you need to start the 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.

Section 5 Connect the HeartSine Gateway to your local network

Once you have confirmed your LIFELINKcentral AED Program Manager or LIFENET System account is active and you have registered your HeartSine Gateway, it is now time to connect your HeartSine Gateway to the local network.

The wireless set-up procedure configures the HeartSine Gateway to connect with your Wi-Fi network enabling the HeartSine Gateway to communicate directly with LIFELINKcentral AED Program Manager or LIFENET System.

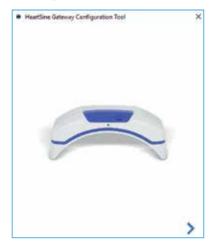
Setup checklist

Before you can connect your HeartSine Gateway to your chosen Wi-Fi network please check that you have the following:

- $\hfill\square$ Wi-Fi enabled PC or laptop with Windows 7 or above operating system and an internet connection
- □ Administrator rights for the computer
- □ Serial number for your HeartSine Gateway
- □ Location for the 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. If you do not have this information, ask your IT department for assistance.
- □ Access to your LIFELINKcentral AED Program Manager or LIFENET System account.

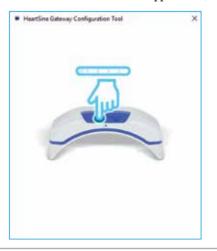
Connect the HeartSine Gateway to your network

1. Launch the HeartSine Gateway Configuration Tool.



2. Click the right arrow to proceed.

3. As shown on the screen, place the 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 3.)



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

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



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



6. When a 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 drop-down list. To connect a single HeartSine Gateway, select the relevant HeartSine Gateway serial number from this list.



7. Click the right arrow to proceed.

8. From the drop-down list, select your Wi-Fi network and enter the network password.
(To view the entered password, hover over the button.)



 Click Settings to view the network type. If you need to change the network type, select an option from the drop-down list .



10. Click the right arrow to proceed.

 The HeartSine Gateway Configuration Tool will try to connect to the HeartSine Gateway.



When the data you entered for the network has been received by the 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 the HeartSine Gateway Configuration Tool and the HeartSine Gateway will be disabled.



- 12. The 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.
- 13. For multiple HeartSine Gateway devices, repeat these steps for each HeartSine Gateway.
- 14. Click the right arrow to close the program.
- **15.** 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 the 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 the connection was successful

When you have connected your HeartSine Gateway to your chosen network, go to your LIFELINKcentral AED Program Manager or LIFENET System 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 Devices in LIFENET System. The HeartSine Gateway will appear as an accessory for the AED.

LIFELINKcentral AED Program Manager Users

- 1. Log in to your LIFELINKcentral account.
- 2. Go to the EQUIPMENT page and verify that the status of your AED says **READY**.

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Alerts		o = · ·	0	~	0	0	0	0	
My Account		Equipment	•	۲	۲	8	0	\odot	
Sites		samaritan PAD 450P (1	869000	0015)					
Equipment	15 <	READY							
Manage Equipment		This device is ready to use.							

LIFENET System Users

- 1. Log in to your LIFENET System account.
- 2. Open the MY NETWORK tab.
- 3. Select DEVICES and verify that the status of your HeartSine Gateway 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 the HeartSine Gateway.

Connecting your HeartSine Gateway to a different Wi-Fi network

To connect your HeartSine Gateway to a different Wi-Fi network, place the HeartSine Gateway into set-up mode by holding the POWER button for approximately six seconds (until the status LED on the HeartSine Gateway turns solid blue) and repeat the steps beginning on page 23.

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 the 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 the 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 that came with your HeartSine AED. This will enable LIFELINKcentral or LIFENET System to track the expiration of each Pad-Pak and provide notifications when each Pad-Pak needs to be replaced.

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



To register each Pad-Pak:

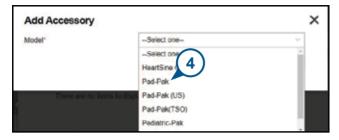
- 1. From the Equipment section, click the AED with which the Pad-Pak will be used and/or stored.
- 2. Click () to view the accessories associated with the AED.

	entral [*]	٩	0
CONTROL AED PROGRAM M	ANAGER HeartSine Belfast / Systems welcome Engineering		≡
Alerts	⊕ Equipment ⊮ ⊗ A ® Ø	Ø	
My Account		0	
Sites 1 6	samaritan PAD 450P (18G90000015)		
Equipment 15	READY		
Manage Equipment >	This device is ready to use.		

3. From the Accessories screen, click \bigoplus (Add Accessory).



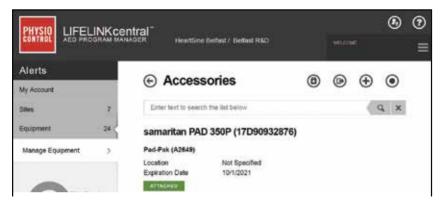
4. From the Model menu, select Pad-Pak or Pediatric-Pak.



- 5. Enter the expiration date (month/date/year) provided on the Pad-Pak label.
- 6. Enter the Lot Code (number) from the Pad-Pak label.
- 7. If the Pad-Pak is installed in the AED, click Attached To Device.
- 8. Click Submit.

Add Accessory		
Model*	Ped-Pak	1
Customer ID	HeartSine	
Serial Number	(5)	
Expiration Date	6 10/1/2021	
Lot Code	A2649	
Attached To Device	V	(8)
	5	ubmit Cancel

If successfully registered your Pad-Pak will appear in the list of Accessories.



Section 7 Monitoring your HeartSine AED

The HeartSine Gateway is designed to operate automatically. The 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 or LIFENET System account. When the 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 or LIFENET System account.

If there is no communication between HeartSine Gateway and LIFELINKcentral or LIFENET System during its scheduled monthly 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

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

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

Replace all batteries at the same time, do not mix new with old.

Dispose of depleted batteries according to local regulations.

SAFETY RISK AND POSSIBLE EQUIPMENT DAMAGE

- Rechargeable batteries **CANNOT** be used in the HeartSine Gateway. Using rechargeable batteries will damage the 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.

Cleaning your HeartSine Gateway

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

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

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

Warranty information

A detailed warranty statement is included with your HeartSine Gateway.

Appendix 1 Warnings and precautions

WARNINGS

Do not open casing

Do NOT attempt to open or repair the 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 the HeartSine Gateway and void your warranty.

Removing the HeartSine Gateway from the AED

Do NOT attempt to remove the HeartSine Gateway using anything other than the supplied removal tool. Using anything other than the supplied removal tool may damage the 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 the HeartSine Gateway, remove it from the AED and contact customer support.

EMC warnings

Use of the 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, the 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 the HeartSine

Gateway, including cables specified by the manufacturer. Otherwise, degradation of the performance of the HeartSine Gateway could result.

PRECAUTIONS

Temperature range

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

Ingress Protection

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

Prolonging Battery Life

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

Correct Disposal of the HeartSine Gateway

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

Appendix 2 Troubleshooting

Problem	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 4 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.
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 the HeartSine Gateway Configuration Tool.	 Ensure the 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. The LED turns solid blue. Ensure the HeartSine Gateway is within Wi-Fi range of the PC/laptop. Manually refresh the PC/laptop Wi-Fi list.
HeartSine Gateway is not connecting to the 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.

Problem	Solution
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.
AED is not showing in LIFELINKcentral AED Program Manager/ LIFENET System.	 Place the 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 the 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 the HeartSine Gateway. Only HeartSine samaritan devices manufactured during or after 2013 are supported.
AED is showing as NOT READY on LIFELINKcentral AED Program Manager/ LIFENET System.	• Select the AED from the Equipment section and follow the on-screen advice. If the problem persists, contact your local Authorized Distributor or Stryker representative for assistance.
I need my MAC Address.	• The MAC address label is located on the underside of the HeartSine Gateway on the side. (See Section 2 for exact location.)

Solution

Downloaded HeartSine Gateway Configuration Tool file did not appear on my computer.

If you receive an email, from LIFELINKcentral AED Program Manager, stating that your AED is NOT READY or NEEDS ATTENTION. • Check the 'Downloads' folder on your PC/laptop.

Follow these steps:

1. Click the link within the email to open LIFELINKcentral and view the equipment status details as shown.



- 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 indicator is flashing green.

Solution

(continued)

If you receive an email, from LIFELINKcentral AED Program Manager, stating that your AED is NOT READY or NEEDS ATTENTION.

- 3. When you have resolved the issue and the status indicator on the AED is flashing green, return to LIFELINKcentral and select the relevant AED.
- 4. From the Equipment menu, click Inspections (F).

Aeta		C. Redenard	
To do in a		Equipment	
the l		samariun PAD 450P (18	Castology India Alia
Augustan .	147	and better partners	
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7 of 15		Anadoric Inprint Tru-	#2112114401PM or the first lateral
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A 1949		Manual Instantion Subseque	ACC research formation
Carlos and		Baracite Theirs	All the second s
 Notherry 	1	Times Installation	Ingline
* 1. mart 1		Date Name	420074
1.1.1	-	Reference instance	484
Non-	12	Suffering and Salar Splatter Super-	(Trends)
		Public Access To Device	

5. Click Perform Inspections

the Accord	2	 Equipment samaritan PAD 450P (18 	
Minipe Texament	1	The decay to tel wath to part your accounts in LFCD, Million with	Napica iliu tading manufasing Dinko Access Disaya Patri and Ni water. Il al Salah Representati nationg an Ni Accession II. Mark in para al accession
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8 Aug		Beauty Ingential Stratus Decore Trans	dili menun Acena Artes
a milian	181	tions transferrer	Hardbeet
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(continued)

If you receive an email, from LIFELINKcentral AED Program Manager, stating that your AED is NOT READY or NEEDS ATTENTION.

Solution

6. Click the Device Present checkbox (6a) and the Flashing Green button (6b) to indicate that you found the device and resolved the issue.

Perform Inspection semattan PAD 400P (1959000		×
EQUIPMENT INFORMATION		
ACCESSORIES	\bigcirc	
INSPECTION CHECKLIST	6a	
Device Present	6b	
Visible Damage		
Readiness indicator	Flashing Green	
	C Fleiving Red	
	() of	
Readness Status	Ready	\bigcirc
NOTES		
	Subm	t Cance

7. Press Submit.

Solution

(continued)

If you receive an email, from LIFELINKcentral AED Program Manager, stating that your AED is NOT READY or NEEDS ATTENTION. 8. The AED should now show as READY in LIFELINKcentral (as shown).

Alerts			
My Account		⊕ Equipment ⊛ ⊘ ⊗ ® ⊘ ⊘	
She		samaritan PAD	450P (18G90000015)
Epopment	15	Mary	
Manage Equipment		This device is ready	10 Udel.
Oren	15	Location Readiness Reported Time Unique Device Identification (UDI)	Building 1 Reception 8/27/2018 4:30 PM via HeartSine Galmony Not Specified
Ready		Mobile Device	No
Not Ready	2	Manual Inspection Schedule	AEQ Inseedion Schedule
Editarian (12	Device State	Active

9. On the HeartSine Gateway attached to the relevant AED, press and release the POWER button.

Appendix 3 LED status indicator

The LED Status Indicator on the front of the 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 or LIFENET System.
Solid blue	Network Setup Mode	System is in Network Setup Mode.
Flashing blue	Not Connected	HeartSine Gateway is not connected to a network.
Solid red	Critical Fault	A critical fault is detected. Consult LIFELINKcentral AED Program Manager or LIFENET System 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 or LIFENET System.

Appendix 4 LIFELINKcentral AED Program Manager/ LIFENET System URL and email address

Network Configuration

Internet access is required for the HeartSine Gateway wireless data transmission to work. Network security systems may need to be configured to properly allow communications to the LIFELINKcentral or LIFENET System website. There are many methods to secure a network that is connected to the Internet. 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 is located on the Internet.

- FODNs for LIFELINKcentral are provided below.
- IP subnet for LIFELINKcentral is 62.29.175.234, 255.255.255.240 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 or LIFENET System. The email for your country is provided in the table on pages 44 and 45.

Country	URL Record Name	Email address*
Argentina	https://lifelink-ar.lifenetsystems.com	web@ar-lifenetsystems.com
Australia	https://lifelink-au.lifenetsystems.com	web@au-lifenetsystems.com
Austria	https://lifelink-at.lifenetsystems.com	web@at-lifenetsystems.com
Bahrain	https://lifelink-bh.lifenetsystems.com	web@bh-lifenetsystems.com
Belgium	https://lifelink-be.lifenetsystems.com	web@be-lifenetsystems.com
Costa Rica	https://lifelink-cr.lifenetsystems.com	web@cr-lifenetsystems.com
Canada	https://lifelink-ca.lifenetsystems.com	web@ca-lifenetsystems.com
Denmark	https://lifelink-dk.lifenetsystems.com	web@dk-lifenetsystems.com
Faroe Islands	https://lifelink-fo.lifenetsystems.com	web@fo-lifenetsystems.com
Finland	https://lifelink-fi.lifenetsystems.com	web@fi-lifenetsystems.com
France	https://lifelink-fr.lifenetsystems.com	web @ fr-lifenet systems.com
Germany	https://lifelink-de.lifenetsystems.com	web@de-lifenetsystems.com
Greenland	https://lifelink-gl.lifenetsystems.com	web@gl-lifenetsystems.com
Hungary	https://lifelink-hu.lifenetsystems.com	web@hu-lifenetsystems.com
Hong Kong	https://lifelink-hk.lifenetsystems.com	web@hk-lifenetsystems.com
Ireland	https://lifelink-ie.lifenetsystems.com	web@ie-lifenetsystems.com
Israel	https://lifelink-il.lifenetsystems.com	web@il-lifenetsystems.com
Italy	https://lifelink-it.lifenetsystems.com	web@it-lifenetsystems.com
Japan	https://lifelink-jp.lifenetsystems.com	web@jp-lifenetsystems.com

Country	URL Record Name	Email address*
Kuwait	https://lifelink-kw.lifenetsystems.com	web@kw-lifenetsystems.com
Liechtenstein	https://lifelink-li.lifenetsystems.com	web@li-lifenetsystems.com
Luxembourg	https://lifelink-lu.lifenetsystems.com	web@lu-lifenetsystems.com
Malta	https://lifelink-mt.lifenetsystems.com	web@mt-lifenetsystems.com
Netherlands	https://lifelink-nl.lifenetsystems.com	web@nl-lifenetsystems.com
New Zealand	https://lifelink-nz.lifenetsystems.com	web@nz-lifenetsystems.com
Norway	https://lifelink-no.lifenetsystems.com	web@no-lifenetsystems.com
Poland	https://lifelink-pl.lifenetsystems.com	web@pl-lifenetsystems.com
Qatar	https://lifelink-qa.lifenetsystems.com	web@qa-lifenetsystems.com
Singapore	https://lifelink-sg.lifenetsystems.com	web@sg-lifenetsystems.com
Spain	https://lifelink-es.lifenetsystems.com	web@es-lifenetsystems.com
Sweden	https://lifelink-se.lifenetsystems.com	web@se-lifenetsystems.com
Switzerland	https://lifelink-ch.lifenetsystems.com	web@ch-lifenetsystems.com
Taiwan	https://lifelink-tw.lifenetsystems.com	web@tw-lifenetsystems.com
Turkey	https://lifelink-tr.lifenetsystems.com	web@tr-lifenetsystems.com
United Arab Emirates	https://lifelink-ae.lifenetsystems.com	web@ae-lifenetsystems.com
United Kingdom	https://lifelink-uk.lifenetsystems.com	web@uk-lifenetsystems.com
United States	https://lifelink.lifenetsystems.com	${\it no-reply@lifelink.lifenetsystems.com}$

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

Appendix 5 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

0°C to 50°C (32°F to 122°F)
-10°C to 50°C (14°F to 122°F) for up to two days. If the device has been stored below 0°C (32°F), it should be returned to an ambient temperature between 0°C to 50°C (32°F to 122°F) for at least 24 hours before use.
5% to 95% non-condensing
IEC 60529 IP56
0 to 4572 meters (0 to 15,000 feet)
MIL-STD 810F: 2000 Methods 516.5 Procedure 1
MIL-STD 810F: 2000 Method 514.5 Procedure 1 categories 4 & 7
IEC 60601-1-2

Communications

Communications	Wireless 802.11 b/g/n	
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Batteries

Туре	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 (LiMnO2) / 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

The 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.

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

The essential performance of the 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 the HeartSine Gateway device.

There are no special maintenance procedures required to ensure that the essential performance and basic safety of the 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	The 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. The 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 the HeartSine Gateway is intended to be used exceeds the applicable RF compliance levels noted above, the HeartSine Gateway should be observed to verify normal operation. If abnormal performance is observed, consideration should be given to relocating the 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

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

The 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. The HeartSine Gateway may not cause harmful interference, and
- 2. The 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.

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

H052-019-100-2

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