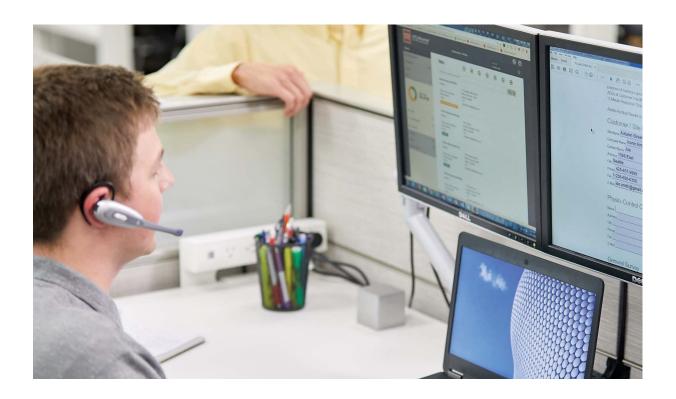


# Readiness matters.

SAM 450P

LIFELINKcentral™ AED Program Manager and HeartSine® Connected AEDs





# But only if they're ready.

Sudden cardiac arrest (SCA) can happen to anyone, anywhere. That's why public access defibrillators are so important. They put lifesaving technology where it can do the most good. Ongoing system maintenance, however, has been time-consuming and at risk for human errors.

# Readiness made easy.

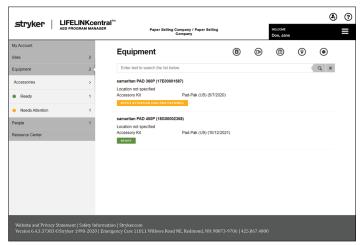
With LIFELINKcentral AED Program Manager, managing your AEDs is easier and more accurate. LIFELINKcentral Program Manager facilitates remote management with a Wi-Fi connection to each HeartSine Connected AED. Readiness information, automatically collected by the software, and Pad-Pak expirations are tracked for easy management — whether you have one AED or 100, in a single office or across thousands of miles. LIFELINKcentral AED Program Manager even sends you alerts of conditions affecting readiness.

For each HeartSine Connected AED, you can:

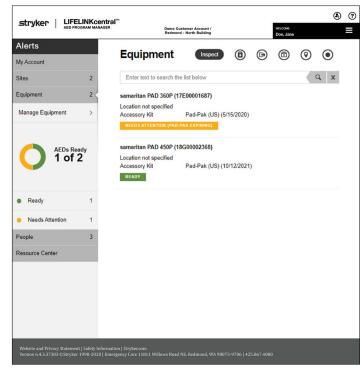
- Remotely monitor readiness information
- Receive alerts of conditions affecting readiness
- View the status of all connected AEDs
- Get notifications if a Pad-Pak is expiring or has expired
- View manually-entered location on a map

# Complete management system.\*

You can manage all your AEDs with LIFELINKcentral AED Program Manager, even those that aren't connected. Once the device information is entered manually for you, you can update inspection data on a regular schedule. With LIFELINKcentral, you will have complete snapshot of your site readiness. You can even pinpoint them on a map and create alerts for scheduled battery or electrode replacement.



Basic license



PRO license or Premium package



# Choose the package or license that fits your needs

LIFELINKcentral AED Program Manager Basic license is included with each Stryker connected AED, but there are numerous reasons to invest in the PRO license or Premium package.

reasons to invest in the PRO license or Premium package.  LIFELINKcentral options	Licenses		Service Package
	Basic	PRO	Premium
	Included with Stryker connected AED	Account fee applies <sup>1</sup>	Per AED fee applies <sup>1</sup>
Equipment management			
Supported devices/equipment			
HeartSine connected AED with HeartSine Gateway, Pad-Pak and/or Pediatric-Pak	X	X	X
LIFEPAK CR2 connected AED with battery and QUIK-STEP electrodes	X <sup>2</sup>	X	X
Stryker non-connected AEDs (manually uploaded by Stryker support team)		$X^3$	X
All other AEDs (manually uploaded by Stryker support team)		$X^3$	X
All other accessories and custom equipment		X	X
Tracking equipment readiness			
Edit and view equipment details	X	Х	Х
View device readiness and test logs (connected AEDs)	X	X	Х
View equipment map	X	Х	Х
View equipment status via readiness wheel		Х	Х
Record manual inspections		Х	Х
Site management			
Tracking site readiness			
Add, edit and view site information	Х	Х	х
Manage software and setup options	X	X	X
View site map	X	X	X
View site status via readiness wheel		X	X
View program status summary report		X	X
Set custom inspection schedules		X	X
People management		A	A
User profiles and roles			
Add, edit, and view user profiles	X	Х	х
Assign program coordinator and site coordinator roles	X	X	X
Responder readiness	Α	Λ	Λ
View training status via readiness wheel		Х	х
		X	X
Assign AED inspector and trained responder roles			
Track trained responder certifications/readiness		Х	Х
Training events			
Manage training events and rosters		Х	X
Email notifications			
Readiness notifications for HeartSine and LIFEPAK CR2 connected AEDs	X	X	X
Readiness notifications for all other AEDs (for equipment manually uploaded by Stryker support team)		<b>X</b> <sup>3</sup>	X
Readiness notifications for custom equipment		X	X
In use notifications for LIFEPAK CR2 connected AEDs	X	X	X
AED Program Administrator follow-up to email notifications			X
Implementation Support			
Ongoing medical direction and registration			X
Site assessment for AED implementation			X
Account Support			
Access to online Resource Center	X	X	X
Customer service	X	X	X
Dedicated AED Program Administrator			X
AED Program Administrator proactive oversight/calls, follow-up to LLC email notifications, monthly status updates, and quarterly program and site compliance audits			Х
Post event services for Stryker AEDs			
Onsite post-event summary report download and counseling, plus clinical review			X
Post-event supply replenishment			X
A la carte options (Available only with PRO license or Premium package)			
The out to options (it valuable only with 1 to not not of 11 children package)		X	Incl
		X	X
Site assessment for AED implementation (included with Premium package)		X X	X
Site assessment for AED implementation (included with Premium package)  Onsite AED/CPR training options  Blended (e-learning and onsite) AED/CPR training options			
Site assessment for AED implementation (included with Premium package)  Onsite AED/CPR training options  Blended (e-learning and onsite) AED/CPR training options  Onsite device inspection (annual per device option; four devices minimum)		X	Х
Site assessment for AED implementation (included with Premium package)  Onsite AED/CPR training options  Blended (e-learning and onsite) AED/CPR training options		X X	X X

- 1. LIFELINKcentral PRO license offers the services listed, and is charged as an annual fee per account. Premium package is charged as an annual fee per AED.
- 2. The battery and OUIK-STEP electrodes delivered in the LIFEPAK CR AED box will be managed with the Basic license. PRO license is require to manage spare batteries and/or additional OUIK-STEP electrode trays.
- 3. Upload fee applies.

#### BRIEF SUMMARY OF INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS FOR USE: The HeartSine samaritan PAD SAM 350P (SAM 350P), HeartSine samaritan PAD SAM 360P (SAM 360P) and HeartSine samaritan PAD SAM 450P (SAM 450P) are indicated for use on victims of cardiac arrest who are exhibiting the following signs: unconscious, not breathing, without circulation (without a pulse). The devices are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program. The devices are indicated for use on patients greater than 8 years old or over 55 lbs (25 kg) when used with the adult Pad-Pak-" (Pad-Pak-01 or Pad-Pak-07). They are indicated for use on children between 1 and 8 years of age or up to 55 lbs (25 kg) when used with the Pediatric-Pak-" (Pad-Pak-02).

CONTRAINDICATION: If the patient is responsive or conscious, do not use the HeartSine samaritan PAD to provide treatment.

WARNINGS: AEDs: • The HeartSine samaritan PAD delivers therapeutic electrical shocks that can cause serious harm to either users or bystanders. Take care to ensure that no one touches the patient when a shock is to be delivered. • Touching the patient during the analysis phase of treatment can cause interference with the diagnostic process. Avoid contact with the patient while the HeartSine samaritan PAD is analyzing the patient. The device will instruct you when it is safe to touch the patient. • Do not delay treatment trying to find out the patient's exact age and weight. If a Pediatric-Pak or an alternative suitable defibrillator is not available, you may use an adult Pad-Pak. • The SAM 360P is a fully automatic defibrillator. When required, it will deliver a shock to the patient WITHOUT user intervention. • The SAM 450P CPR Rate Advisor is currently only intended to provide feedback on adult patients. If you treat a pediatric patient with the SAM 450P and an adult Pad-Pak, ignore any voice prompts regarding the rate of CPR. • Do NOT use the HeartSine samaritan PAD in the vicinity of explosive gases, including flammable anesthetics or concentrated oxygen. • Do NOT open or repair the device under any circumstances as there could be danger of electric shock. If damage is suspected, immediately replace the HeartSine samaritan PAD. Pad-Paks: • Do not use if the gel is dry. • The Pediatric Pad-Pak is not for use on patients under 1 year old. For use with children up to the age of 8 years or up to 55 lbs (25 kg). DO NOT DELAY THERAPY IF YOU ARE NOT SURE OF EXACT AGE OR WEIGHT. • Only HeartSine samaritan PADs with the label are suitable for use with the Pediatric-Pak will enable delivery of 50J shocks to the pediatric patient. • The Pediatric-Pak contains a magnetic component (surface strength 6500 gauss). Avoid storage next to magnetically sensitive storage media. It is advised that Pediatric-Pak as are stored separately when not in use. • Never charge, short circuit, puncture, deform, incinerate, heat above 85°C

PRECAUTIONS: AEDs: • Proper placement of the HeartSine samaritan PAD electrode pads is critical. Electrode pads must be at least 1 in (2.5 cm) apart and should never touch one another. • Do not use electrode pads if pouch is not sealed. • Check the device periodically in accordance with the service and maintenance instructions provided in the User Manual. • Operate the HeartSine samaritan PAD at least 6 feet (2 meters) away from all radio frequency devices or switch off any equipment causing interference. • Use of the device outside the operating and storage ranges specified in the User Manual may cause the device to malfunction or reduce the shelf life of the Pad-Pak. • Do not immerse any part of the HeartSine samaritan PAD in water or any type of fluid. • Do not turn on the device unnecessarily as this may reduce the standby life of the device. • Do not use any unauthorized accessories with the device as the HeartSine samaritan PAD may malfunction if non-approved accessories are used. • Dispose of the device in accordance with national or local regulations. • Check with the relevant local government health department for information about any requirements associated with ownership and use of a defibrillator in the region where it is to be used. Pad-Paks: • Check expiration date. Saver EVO" Software: • Download the complete HeartSine samaritan PAD memory prior to erasing it. This information should be stored safely for future reference. Ensure that only the events you want to delete have been selected prior to deleting. Once deleted from your computer's memory, events cannot be regenerated and all information will be lost.

POTENTIAL ADVERSE EFFECTS: The potential adverse effects (e.g., complications) associated with the use of an automated external defibrillator include, but are not limited to, the following: • Failure to identify shockable arrhythmia. • Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury. • Inappropriate energy which could cause failed defibrillation or post-shock dysfunction. • Myocardial damage. • Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents. • Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest. • Bystander shock from patient contact during defibrillation shock. • Interaction with pacemakers. • Skin burns around the electrode placement area. • Allergic dermatitis due to sensitivity to materials used in electrode construction. • Minor skin rash.

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

Please consult the User Manual at www.heartsine.com for the complete list of indications, contraindications, warnings, precautions, potential adverse events, safety and effectiveness data, instructions for use and other important information.

If you purchased your HeartSine Connected AED from an authorized Stryker distributor or reseller, this distributor or reseller will have access to your LIFELINKcentral AED Program Manager account and may receive notifications prompted by the HeartSine Connected AED. Please note that this setting to notify your distributor or reseller can be disabled at ANY time: if you wish to disable this setting, please send a request to Stryker Customer Support to self-manage your site without notifications to your distributor or reseller.

All claims valid as of June 2020.

For further information, please contact Stryker at 800 442 1142 (U.S.) or visit our web site at strykeremergencycare.com

# **Emergency Care Public Access**

Stryker's AEDs require a prescription in the U.S. Please consult your physician. AED users should be trained in CPR and in the use of the AED.

Although not everyone can be saved, studies show that early defibrillation can dramatically improve survival rates. AEDs are indicated for use on adults and children. AEDs may be used on children weighing less than 55 lb (25 kg) but some models require separate defibrillation electrodes.

The information presented is intended to demonstrate Stryker's product offerings. Refer to operating instructions for complete directions for use indications, contraindications, warnings, cautions, and potential adverse events, before using any of Stryker's products. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your representative if you have questions about the availability of Stryker's products in your area. Specifications subject to change without notice.

Stryker or its affiliated entities own, use, or have applied for the following trademarks or service marks: CPR Rate Advisor, HeartSine, HeartSine Gateway, LIFELINKcentral, LIFEPAK, Pad-Pak, Pediatric-Pak, QUIK-STEP, samaritan, Saver EVO, Stryker. All other trademarks are trademarks of their respective owners or holders.

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.

06/2020

HeartSine SAM 450P is not available for sale outside of the U.S. or Japan. HeartSine Gateway is not available in all countries. Made in U.K. Date of Issue: 2020/06

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