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Bid specifications

Automated External Defibrillator (AED)
HeartSine® samaritan® PAD 500P
HeartSine Connected AED SAM 500P with LIFELINKcentral™ AED program manager

This document provides the features of the HeartSine samaritan PAD 500P. Additional features of the connected version of the AED are identified separately.

Defibrillator	
In package	• Each HeartSine samaritan PAD is supplied with an adult Pad-Pak (combination electrodes and battery), operating instructions and carry case, as standard. • Each HeartSine Connected AED also includes a HeartSine Gateway, multilingual HeartSine Gateway Set-up guide, batteries, removal tool and LIFELINKcentral AED program manager, Basic license. NOTE: The complete user manual for HeartSine Gateway is available online at heartsine.com.
Waveform	• Optimised, impedance-based, biphasic truncated exponential, escalating waveform, called Self-Compensating Output Pulse Envelope (SCOPE), which compensates voltage, slope (tilt) and duration for patient impedance.
Patient impedance range	• 20 – 230 ohms.
Patient analysis system	• Evaluates patient's ECG, electrode contact integrity and patient impedance to determine if defibrillation is required.
Energy protocol	• Adult: 150 J, 150 J, 200 J. • Pediatric: 50 J, 50 J, 50 J.
Time to shock delivery following CPR (150J)	• Typically, 12 seconds.
Charge time	• Typically, 150J in < 8 seconds, 200J in < 12 seconds.
CPR Advisor feedback technology	• HeartSine samaritan PAD 500P (SAM 500P) with CPR Advisor provides real-time feedback to the rescuer on the force and rate of the CPR they are providing to the victim during a sudden cardiac arrest (SCA) resuscitation. – Uses ICG measurements to analyse the force and rate of compressions given, and then based on this analysis, advises the rescuer to push harder, faster or slower as appropriate. – Uses both audible and visual prompts to provide instructions to the rescuer.
Warranty	• HeartSine AED is backed by an 8-year limited warranty.

Guideline recommendations	• HeartSine AED follows the recommendations in the latest AED guidelinesfor the European Resuscitation Council (ERC), American Heart Association (AHA) and International Liaison Committee on Resuscitation (ILCOR). • HeartSine AED is consistent with current guidelines for CPR (energy protocols, CPR protocols, quality assurance).
Operation	
Semi-auto vs. Fully auto	• Upon delivery, the HeartSine samaritan PAD 500P is configured for semi-automatic operation (shock button press needed to deliver a shock).
On/Off	• HeartSine AED powers on when the ON/OFF button is pressed.
Manual override	• Manual override is not available on the HeartSine AED.
Intended use	• The devices are intended for use by personnel who have been trained in their operation. Training on CPR and in the use of an AED is strongly recommended for users. However, in an emergency situation HeartSine samaritan PAD may be used by an untrained lay rescuer.
Voice prompts	• HeartSine AED guides the operator through operating procedures with acombination of voice prompts, flashing LEDs and visual prompts.
Metronome	• HeartSine AED provides an audible metronome that sounds at a rate of between 100 to 120 beats per minute, as per the current guidelines.
Electrode placement	• HeartSine AED provides visual prompts (pictures) for placement of the electrodes: Anterior-lateral (Adult); Anterior-posterior or Anterior-lateral (Pediatric).
CPR prompts	• HeartSine AED prompts the operator to perform CPR for 120 seconds. • NOTE: In Norway, HeartSine AED prompts the operator to perform CPR for 180 seconds.
CPR feedback	• HeartSine SAM 500P provides real-time visual and verbal feedback to the rescuer on the force and rate of CPR compressions during an SCA resuscitation, without the use of an accelerometer.
Child mode	• Upon power on when an adult Pad-Pak is inserted, the HeartSine AED defaults to the energy delivery and CPR guidance set for an adult patient. • Upon power on when a Pediatric-Pak is inserted, the HeartSine AED defaults to the energy delivery and CPR guidance set for a pediatric patient.
Electrodes	• HeartSine AED uses an interchangeable battery and electrode cartridge called Pad-Pak. When used in combination with an adult Pad-Pak, HeartSine AED is suitable for use on patients of over 25 kg (55 lb) in weight or equivalent to a child of approximately eight years old or over. • For use on smaller children (from 1 to 8 years old), a Pediatric-Pak is used. If a Pediatric-Pak or an alternative suitable defibrillator is not available, an adult Pad-Pak may be used.

Real-time clock	• HeartSine AED has a real-time clock that uses Coordinated Universal Time (UTC).
Readiness indicator	• The Readiness indicator is a bright green LED that flashes every five to ten seconds to indicate the HeartSine AED is ready for use. If the HeartSine AED has detected an issue affecting readiness, the readiness indicator light on the HeartSine AED will flash red (approximately every 5-10 seconds) and emit an audible beep. • For the HeartSine Connected AED, if the HeartSine AED has detected an issue affecting readiness, after the device performs the weekly check-in, a Not Ready condition also will be reported to LIFELINKcentral AED program manager via a Wi-Fi connection, and an email is sent to the AED program manager(s), if set up in LIFELINKcentral.
Low battery indication	• When the battery needs to be replaced, the indicator light on the HeartSine AED will flash red (approximately every 5-10 seconds) and the device will emit an audible beep.
Accidental switch-off	• If the HeartSine AED is switched off during shock advisory, a warning prompt is heard, and a confirmation button press is required.
Self-test (self-check)	• HeartSine AED performs an automatic self-test on a weekly basis. If an automatic self-test detects a condition that requires attention, this negative result of the self-test is indicated by visible and audible indicators on the device. In addition, HeartSine AED runs a self-test each time the device is turned on. • For the HeartSine Connected AED, this negative result is reported in LIFELINKcentral AED program manager with an alert sent to the pre-defined AED program administrator(s). • If automatic self-tests indicate the device is ready, the HeartSine Connected AED checks in to LIFELINKcentral AED program manager once each month and reports that it is READY.
Use on aircraft	• HeartSine AED is suitable for use and storage on airplanes when used in conjunction with the EASA/ETSO/TSO-approved battery and electrodes (Pad-Pak- 07), made specifically for use on aircraft. • The manufacture and use of SAM 500P comply with these aviation standards for use on aircraft: – RTCA/DO-160G Environmental Conditions and Test Procedures for Airborne Equipment, Section 21: Emission of Radio Frequency Energy (Category M) • PAD-PAK-07 conforms to regulation (EU) No. 748/2012, Part 21, Section A, Subpart O and ETSO C142a.

Physical specifications	
Handle/case	• Each HeartSine AED is shipped with a carrying case.
Dimensions	• HeartSine AED with Pad-Pak: 20 cm x 18.4 cm x 4.8 cm (8.0 in x 7.25 in x 1.9 in). • HeartSine Connected AED with Pad-Pak and HeartSine Gateway: 23.4 cm x 18.4 cm x 4.8 cm (9.21in x 7.25 in x 1.9 in).
Weight	• HeartSine AED with Pad-Pak: 1.1 kg (2.4 lb). • HeartSine Connected AED with Pad-Pak, HeartSine Gateway and batteries: 1.285 kg (2.83 lb).
Display	• Designed for user confidence, the HeartSine AED uses simple bold graphics, audible instructions, and automated features to help users remainfocused.
Port	• HeartSine AED: Proprietary USB data port. • HeartSine Connected AED: Micro USB data port.
Communications	• HeartSine AED: Connection to Saver EVO software through a data port that uses a custom USB data cable. • HeartSine Connected AED: Communication is via Wi-Fi 802.11 b/g/n data transfer to LIFELINKcentral AED program manager or through a USB connection to Saver EVO software through a micro USB port.
Patient Analysis System	
ECG analysis	• HeartSine AED evaluates patient's ECG, electrode contact integrity and patient impedance to determine if defibrillation is required. • Analysis is performed on both adult and pediatric patients.
Motion detection	• HeartSine samaritan PAD 500P does not provide motion detection.
Overall sensitivity	• For shockable VF in excess of 95%. • For shockable VT in excess of 90%.
Overall specificity	• For all non-shockable rhythms in excess of 95%.
Patient impedance	• HeartSine AED can deliver a therapeutic shock over a patient impedance range of 20 ohms to 230 ohms, without a significant reduction in delivered shock energy.

Environmental	
Operating temperature range	• 0°C to 50°C (32°F to 122°F).
Transport temperature range	• 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.
Long term storage temperature range	• 0 to 50°C (32°F to 122°F).
Relative humidity	• 5 to 95% (non-condensing).
Atmospheric pressure (altitude)	• 0 to 4,575 metres (-0 to 15,000 feet).
Water resistance	• Meets IEC 60529/EN 60529 IPX6 with electrodes connected and battery installed.
Dust resistance	• Meets IEC 60529/EN 60529 IP5X with electrodes connected, and battery installed.
Shock	• Meets MIL-STD-810F Method 516.5, Procedure 1 (40 G's).
Vibration	• Meets MIL-STD-810F Method 514.5, Procedure 1. • Category 4 Truck Transportation – US Highways. • Category 7 Aircraft – Jet 737 & General Aviation.
Drop test	• 1 metre (3.3 feet).
Event documentation	
Memory type	• Internal digital memory (flash RAM).
ECG storage	• HeartSine AED can store 90 minutes of ECG (full disclosure) and event/incident recording.
Data retrieval	• Event data is transferred using a custom USB data cable (non-connected devices) or a micro USB cable (connected devices) to a PC with Saver EVO Windows-based data review software.
Report software	• Saver EVO Windows-based data review software.

Batteries	
Type	• HeartSine AED uses non-rechargeable, single-use combined defibrillation electrode and battery cartridge (Pad-Pak or Pediatric-Pak). The battery is lithium manganese dioxide (Li/MnO_2) 18V. • HeartSine Gateway (on the HeartSine Connected AED) uses four CR123A 3V, non-rechargeable batteries.
Amp-hours – AED battery	• 1.5.
Capacity – New AED battery	• Fully charged battery typically provides > 60 shocks at 200J or 6 hours of battery use.
Standby life (assuming only weekly tests)	• HeartSine AED Battery: 4 years from manufacture date. (See the expiration date on the Pad-Pak/Pediatric-Pak.)
Weight	• HeartSine AED Battery: 0.44 lb / 0.2 kg. • HeartSine Gateway Battery: 17 g (per battery).
Replacement cycle	• All batteries should be replaced every four years if the device has not been used. • Upon immediate expiration of the HeartSine AED battery contained in the Pad-Pak, there are at least 10 shocks at 200J (under normal device use).
Electrodes	
Adult / pediatric	• HeartSine AED uses an interchangeable battery and electrode cartridge called Pad-Pak. Used in combination with an adult Pad-Pak, HeartSine AED is suitable for use on patients of over 25 kg (55 lb) in weight or equivalent to a child of approximately eight years old or over. • For use on smaller children (from 1 to 8 years old), a Pediatric-Pak is used. If a Pediatric-Pak or an alternative suitable defibrillator is not available, an adult Pad-Pak may be used.
Operation	• Electrodes are stored in a sealed protective package within the Pad-Pak or Pediatric-Pak. The user simply pulls the green handle to reveal the electrodes package and opens the package to reveal the electrodes. The user then easily peels the electrodes from the tray and follows the image on each which indicates where it should be placed on the patient's chest.
Replacement cycle	• Electrodes (Pad-Pak, Pediatric-Pak) must be replaced every 4 years if not used.
Electrode cable length	• 1 metre (3.3 feet).

Accessories	
Defibrillator accessories	• Several accessories are available, including the following: – Pad-Pak battery and electrode cartridge – Pad-Pak battery and electrode cartridge with ETSO/TSO-C142a certification for use on aircraft – Pediatric-Pak battery and electrode cartridge – HeartSine Gateway – Custom USB data cable – Mobile AED rescue backpack – Wall bracket – Rotaid Plus wall cabinet with alarm – Rotaid Solid Plus wall cabinet with alarm – Rotaid Solid Plus Heat wall cabinet with heat and alarm – Wall cabinet with alarm (rectangular) – HeartSine samaritan PAD carry case (replacement)
Trainer/ Trainer accessories	• HeartSine samaritan PAD Trainer (available for each HeartSine AED model) • Trainer-Pak (replacement electrode cartridge) • Replacement Trainer electrodes (for use with Trainer-Pak) • Remote (replacement) • Battery charger (replacement)
On-line training	• On-line AED training is available to provide instructions on operating the device.
Trainer	
Description	• The HeartSine samaritan PAD Trainer provides realistic training in the use of the HeartSine AED without the actual charge and discharge of electrical energy. Designed to simulate the appearance of the HeartSine AED, HeartSine Trainer simulates its actual operation using the same simple user interface. • HeartSine Trainer is compatible with any CPR manikin system.
Labeling	• Includes clear labeling to identify it as a training unit, including a gold face.
Dimensions (with handle)	• 20 cm x 18.4 cm x 4.8 cm (8.0 in x 7.25 in x 1.9 in).
Weight (with batteries)	• 0.6 kg (1.3 lb).
Buttons	• On/Off, Shock.

Simulation	• All of the functions of the HeartSine Trainer are programmable to simulate the full range of scenarios users might encounter during “real life” use of the HeartSine AED. • HeartSine Trainer provides six pre-set ERC/AHA scenarios.
Training electrodes	• The training electrodes are reusable and are quick and easy to replace back into the electrode tray.
Battery	• HeartSine Trainer uses a rechargeable battery which will provide approximately seven hours of usage before needing to be recharged. • A low battery message will be played approximately one hour prior to the battery becoming depleted.
AED program management	
LIFELINKcentral AED program manager	• LIFELINKcentral AED program manager enables managing readiness of a HeartSine Connected AED readiness and HeartSine Gateway via Wi-Fi connectivity to the attached HeartSine Gateway. The program also enables manual management of AED location and of Pad-Pak and Pediatric-Pak expirations, as well as of non-connected AEDs.
Licenses and service packages	• Basic license, included at no extra charge with every HeartSine Connected AED and HeartSine Gateway, enables remote management to monitor equipment and site readiness and to manually track expirations of Pad-Pak and Pediatric-Pak, providing immediate alerts if the device needs attention. Email support and access to the online Resource Center are also provided. • The PRO license, available per account for a nominal fee with a HeartSine AED (connected or non-connected) and HeartSine Gateway, offers full portal access with expanded view and functionality: – Remote monitoring of equipment and site readiness – Manual tracking of non-connected Stryker AEDs – Manual tracking of Pad-Pak and Pediatric-Pak expirations – Immediate alerts if the device needs attention – Manual tracking/readiness notifications for non-Stryker devices, including other AEDs, accessories and disposables, and other safety devices – Manual management of training events and rosters, plus manual tracking of responder readiness (CPR/AED certifications) – Viewing of equipment, site and training readiness wheels – Setting site customer inspection schedules and recording of manual inspections – Email support and access to the online Resource Center • Service packages are available in some countries. See the LIFELINKcentral AED program manager brochure for details on services provided.