Product Bulletin

Physio-Control Launches HeartSine® samaritan® PAD 360P Automated External Defibrillator in United States

Small, Lightweight, Automated AED Offers Innovation and Value Advantages

(Redmond, Washington) – Physio-Control announced today that the company's HeartSine® samaritan® PAD 360P (SAM 360P) fully automatic external defibrillator (AED) is now available for sale in the United States, having received U.S. Food and Drug Administration (FDA) Premarket Approval (PMA).

HeartSine, acquired by Physio-Control in 2015, is the first to receive approval for a new AED product under the FDA PMA regulatory process, which is the most stringent for medical devices in the United States and is a new FDA regulatory requirement for the AED industry.

"As part of our diverse portfolio of AED offerings, the SAM 360P is an intuitive, compact and cost-effective device that assists caregivers – whether at a business, care facility, or a public place – in delivering potentially lifesaving defibrillation in cases of sudden cardiac arrest," said Ryan Landon, Physio-Control VP/GM, Workplace and Community.

The SAM 360P will complement the SAM 350P and SAM 450P, which also have FDA PMA and are offered in the United States, by providing users with a choice of a fully automatic device, a semi-automatic device, and a device with integrated real-time cardiopulmonary resuscitation (CPR) rate feedback.

The Physio-Control HeartSine samaritan PAD 360P analyzes the cardiac rhythm and automatically delivers an electrical shock to a victim of sudden cardiac arrest in order to restore the heart to normal rhythm. This user-friendly AED provides easy-to-follow visual and audio prompts, including CPR coaching which verbally guides the rescuer through the CPR process. Shock delivery, if required, is fully automatic which means there is no shock button to press.

With a durability rating of IP56, Physio-Control HeartSine AEDs provide the highest level of dust and water ingress protection in the industry, making the device well suited to a variety of usage locations – including places where exposure to the elements presents a challenge.

All Physio-Control HeartSine AED models use the company's interchangeable Pad-Pak™ cartridge, which has also received PMA approval. With a single expiration date for both battery and electrodes, the expense of tracking and maintaining accessories with different expiration dates is eliminated. In addition, the Pad-Pak features a rapid replacement mechanism that enables the battery and pads to be replaced easily in seconds.

Along with the SAM 360P, Physio-Control will offer a new HeartSine samaritan PAD Trainer that simplifies CPR and AED training. The new samaritan PAD 360P Trainer guides users through simulated analyses, simulated energy delivery and prompted CPR intervals with a training device which looks like a SAM 360P, is cost effective, and does not deliver defibrillation shocks.

About Physio-Control

Physio-Control, now part of Stryker, is the world's leading provider of professional emergency medical response solutions that predict or intervene in life-threatening emergencies. The company's products include LIFEPAK® monitor/defibrillators and automated external defibrillators, LUCAS® chest compression systems, the LIFENET® System, HeartSine® AEDs and more. Learn more about HeartSine AEDs at www.heartsine.com.

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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 samaritan PAD to provide treatment.

Warnings: The 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 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 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 samaritan PAD. • The Pediatric-Pak contains a magnetic component (surface strength 6500 gauss). Avoid storage next to magnetically sensitive storage media. • Do not use if the gel is dry.

Precautions: Proper placement of the 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 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 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 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. • Check expiration date.

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, warnings, precautions, potential adverse events, safety and effectiveness data, instructions for use and other important information.

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Product Images (2)
(Caption) -- The HeartSine® samaritan® PAD 360P fully automated external defibrillator (AED) from Physio-Control is now available for sale in the United States, having received U.S. Food and Drug Administration (FDA) Premarket Approval. The SAM 360P will complement the SAM 350P and SAM 450P, which are currently offered in the United States, by providing users with a choice of a fully-automatic device, a semi-automatic device, and a device with integrated real-time CPR rate feedback.