

September 30, 2019

PRODUCT DISCONTINUATION NOTICE

Dear Valued Stryker Customer,

We are pleased to have FDA Premarket Approval (PMA) for the **HeartSine® samaritan® PAD family of automated external defibrillators, including the SAM 350P, SAM 360P, and SAM 450P**, as well as the **LIFEPAK® CR2**, and **LIFEPAK CR Plus AEDs**. The purpose of this communication is to follow up on previous customer communications to remind you that Stryker has discontinued support for the HeartSine samaritan AED, HeartSine samaritan PAD 300 and 300P (SAM 300, SAM 300P) “legacy” public access defibrillators in the United States. Discontinuation notices have been sent for the last few years for these older devices, as maintaining parts and service on aging products becomes increasingly complex and challenging.

The samaritan AED was discontinued in 2006 and accessories have not been marketed since 2013. While the Pad-Pak™ and Pediatric-Pak™ will continue to be available for use with the SAM 350P, SAM 360P, and SAM 450P devices, the Pad-Pak and Pediatric-Pak are not PMA approved for use with the SAM 300 or SAM 300P; therefore the Pad-Pak will not be available for use with the SAM 300 or SAM 300P and the Pediatric-Pak will not be available for use with SAM 300P after **February 3, 2021**.

The FDA requires AED manufacturers to ensure customers who previously purchased the samaritan AED, SAM 300, or SAM 300P are aware of the PMA requirement and the need to transition to a PMA-approved AED in a timely manner. More information about the transition to PMA-approved devices is available on the FDA website at:

<https://www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds>

Stryker offers a range of public access AEDs for your needs that are PMA-approved and available in the U.S.:

- **SAM 350P:** Designed for simplicity, the compact and lightweight HeartSine samaritan PAD 350P provides real-time CPR coaching, one-button operation, proprietary electrode technology, SCOPE biphasic technology, and IP56 protection against dust and water.
- **SAM 360P:** In addition to the features available on the SAM 350P, the SAM 360P eliminates the need for the rescuer to push a shock button by automatically delivering a shock, if needed, after analyzing the heart rhythm.
- **SAM 450P:** In addition to the features available on the SAM 350P, the SAM 450P provides real-time visual and verbal feedback on the rate of CPR compressions—assisting the rescuer to perform more effective CPR.
- The **LIFEPAK CR2** defibrillator, which was launched in the U.S. in February 2019, is the next generation LIFEPAK AED, featuring Wi-Fi® connectivity, cprINSIGHT™ analysis technology (which enables the defibrillator to analyze the patient’s heart rhythm while CPR is being performed), a Child Mode button and optional Language button.
- The **LIFEPAK CR Plus** is the legacy LIFEPAK AED offering easy operation and compatibility with the rest of the LIFEPAK family of devices.

We thank you for your business and continued partnership. We are committed to providing high-quality, clinically relevant products so that you can be confident in the care you are providing to your communities. Please contact your local Stryker sales representative or authorized distributor to discuss trade-up and flexible financing options to support you during this transition. You may also contact Customer Service at (800) 442-1142, option 2.

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