October 30, 2020

PRODUCT DISCONTINUATION NOTICE

Dear Valued Stryker Customer,

The purpose of this letter is to notify you of updated guidance from FDA regarding support of accessories for non-PMA AED devices. Due to the COVID-19 pandemic, the FDA has extended the deadline to cease the distribution of supporting accessories for affected non-PMA devices for another year, shifting from February 3, 2021 to now February 3, 2022. *"Manufacturers of legacy AEDs are expected to communicate the extension date with customers and continue to facilitate customer transition from any legacy AED to an FDA-approved AED as appropriate."* After this date the Pad-Pak™ will not be available for use with the HeartSine® samaritan PAD 300 (SAM 300) or 300P (SAM 300P) and the Pediatric-Pak™ will not be available for use with the HeartSine SAM 300P.

Stryker has discontinued support for the HeartSine samaritan® AED, HeartSine SAM 300 and 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 HeartSine samaritan AED was discontinued in 2006 and accessories have not been marketed since 2013. The Pad-Pak and Pediatric-Pak are not PMA-approved for use with the legacy SAM 300 and SAM 300P devices; however, will continue to be available for use with the HeartSine PMA-approved SAM 350P, SAM 360P, and SAM 450P devices.

The FDA requires AED manufacturers to ensure customers who previously purchased the HeartSine 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. 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 **LIFEPAK® CR2 AED**.

- **HeartSine 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.
- **HeartSine SAM 360P:** In addition to the features available on the HeartSine SAM 350P, the HeartSine 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.
- **HeartSine SAM 450P:** In addition to the features available on the HeartSine SAM 350P, the HeartSine 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.

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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