URGENT MEDICAL DEVICE SAFETY NOTICE & CORRECTION

ACTION REQUIRED

LIFEPAK® 500 Automated External Defibrillator (AED)

Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your **LIFEPAK® 500 AED**.

March 2, 2020

Dear Valued Customer,

Stryker is conducting a Correction for all **LIFEPAK 500 AEDs** that may still be in use and, as a result, may experience a component wear out issue that can prevent the device from detecting a patient connection. We previously announced the discontinuation of repair, parts, and support on multiple occasions. Our most recent notification, in July 2019, noted that LIFEPAK 500 devices will no longer be supported, the LIFEPAK 500 AED batteries and other accessories were discontinued as of February 3, 2020, and electrodes will be discontinued February 3, 2021.

Description of issue

Stryker has become aware that LIFEPAK 500 AEDs in high-use environments (Emergency Medical Services) may not detect a patient connection due to mechanical wear-through of the contact plating on the therapy connector. Wear-through of the connector exposes base metal on which an oxide layer may form and result in the device not recognizing a patient is connected. When this circumstance arises, the device will provide the user the "CONNECT ELECTRODES" message.

This mechanical wear-through is the result of a high volume of insertion/removal cycles for the therapy electrodes and has only been observed at a single customer with a high-use environment. It has also been observed that removing and reinstalling the electrodes or replacing the electrodes may reestablish the patient connection and allow treatment to continue. There have been five Adverse Event Reports where the device failed to initially recognize a patient connection which resulted in a delay to treatment.

Identification of Impacted Product

All LIFEPAK 500 AEDs that remain in use are impacted.

Stryker's Planned Actions

The Company is notifying all customers with LIFEPAK 500 devices, regardless of age and use frequency, to make them aware of this potential safety issue, the need for device replacement and to provide additional warnings and cautions to include as supplemental labeling for any devices that are within their expected life.

Required Customer Actions

- **If you experience a "CONNECT ELECTRODES" voice prompt with the LIFEPAK 500, immediately remove and reinstall the electrodes to the device or replace the electrodes with your spare electrodes and check patient connection. If "CONNECT ELECTRODES" voice prompt continues, immediately obtain a backup device and remove the LIFEPAK 500 from use.**
- Continue to perform the External Test Load Test per Maintenance section of the LIFEPAK 500 Operating Instructions and your local protocols as this test may identify this issue prior to being used on a patient. If during this test, a "CONNECT ELECTRODES" voice prompt message is received, immediately remove the device from service.
- For any devices that are still within their expected life (meaning it has not been more than eight years since the original purchase of the new device from Physio-Control/Stryker or its authorized distributors), include the attached additional warnings and cautions as supplemental labeling for your device.
- Review your attached affected device list and confirm if your device is still in service, transferred to a new location or is no longer in service. Please return the confirmation sheet by fax at 1-866-448-9567.

We strongly recommend the replacement of any LIFEPAK 500 device as all support for the product has been discontinued. The previously referenced July 2019 notice regarding discontinuation of the LIFEPAK 500 device, support and accessories can be accessed at: https://www.strykeremergencycare.com/service--support-overview/end-of-life-notice/.

If you have questions regarding the continued safe use of your products, please contact our Technical Support team at Stryker at 1 800 787 9537 and select option 2, 8:00 A.M. to 6:00 P.M. (Eastern time), Monday – Friday.

More information from FDA regarding 'Legacy AED Systems' can be accessed at https://www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds.

As stated above, we understand the effects this situation may have on your organization and would like to assist you in replacing your LIFEPAK 500 device with the FDA-approved LIFEPAK CR2 AED, LIFEPAK 1000 defibrillator or the HeartSine defibrillators based on your needs. Contact your local Stryker sales representative or authorized distributor to discuss trade-up or flexible financing options.

If you have any questions about this matter contact Stryker at 1 800 787 9537, option 2, 8:00 A.M. to 6:00 P.M. (Eastern time), Monday – Friday.

In addition to contacting Stryker, any potential quality problems or adverse reactions or events associated with the use of a product from Stryker may be reported to the U.S. Food and Drug Administration's MedWatch Safety Information and Adverse Event Reporting Program online at https://www.fda.gov/safety/medwatch/ or by phone 1 800 332 1088 or fax 1 800 FDA 0178.

Sincerely,

Kathryn E. Janecke
Senior Director, Quality, Regulatory and Clinical Affairs
Stryker
Emergency Care

Attachments:

- Affected device list
- LP500 Supplemental labeling