16 June 2020

URGENT Field Safety Notice: RA2020- 2310673

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**.

FSCA identification: Product recall RA2020-2310673
Action type: Field Safety Corrective Action
Affected items: See attached list
Product description: LIFEPAK 500 AEDs

Dear Customer,

Stryker is conducting a Voluntary 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

We request that you read this notice carefully and complete the following actions:

1. **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.**
2. 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 outside of patient care. If during this test, a "CONNECT ELECTRODES" voice prompt message is received, immediately remove the device from service.
3. 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.
4. 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 to XXXX .

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/.

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. We request that you respond to this notice within 07 calendar days from the date of receipt.

The LIFEPAK 500AED has an eight (8) year expected life. Using the device beyond 8 years may result in excessive wear and damage of components within the Therapy Connector. Devices should not be in use beyond the eight (8) year expected life.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:

Position:

Email:

Phone:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours faithfully,

stryker

Acknowledgment of Field Safety Notice: RA2020- 2310673

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Affected items: See attached list
Product description: LIFEPAK 500 AEDs

I acknowledge receipt of the Field Safety Notice for RA2020-2310673 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*		
We have located the following devices:		
Product Description	Product Reference	Serial Number
We have further distributed subject devices to the following organizations:		
Facility Name		
Facility Address		

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organization		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND EMAIL TO PLEASE COMPLETE AND FAX THIS FORM
TO XXXX
OR EMAIL TO XXXX