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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 20, 2020

Dear Valued 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

- **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.**

Emergency Care
11811 Willows Road NE, Redmond, WA 98052 USA | P +1 425 867 4000 | Toll-free +1 800 442 1142 | stryker.com

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LIFEPAK® 500 AED

Addendum to Operating Instructions

CAUTION!

- **Possible Equipment Damage.** This device may be damaged by mechanical or physical abuse such as immersion in water or dropping the device. If the device has been abused, remove it from use and contact a qualified service technician.
- **Possible Therapy Connector Damage.** The LIFEPAK 500 AED has an eight (8) year expected life. Using this 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.

Troubleshooting During Patient Care

Observation	Possible Cause	Corrective Action
CONNECT ELECTRODES message appears.	Inadequate connection to AED.	• Check for complete insertion of connector to AED. • Remove and reinstall electrode connector to AED.
	Electrode does not adhere properly to the patient.	• Press electrodes firmly on patient's skin. • Clean, shave, and dry the patient's skin as recommended.
	Electrodes are dry, damaged, or out-of-date.	• Replace the electrodes.

Stryker
Emergency Care
11811 Willows Road NE
P.O. Box 97006
Redmond, WA 98073-9706
Tel 425 867 4000
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01/2020 PN 3343289

LIFEPAK® 500 AED CONFIRMATION SHEET

Sign, date and send completed sheet(s) to the contact below

Account #: 1495343

SUFFOLK COUNTY EMS DIVISION
Consignee Name

SC DEPT OF HEALTH SERVICES
Address Line 1

BUILDING 13 YAPHANK AVENUE KEN HILL
Address Line 2

YAPHANK NY 11980
City, State, Zip code

Completed By: _____
Please Print

Sign and date: _____ _____
Signature Date

Phone Number: _____

Email: _____

Please return completed form:

- **By fax to: 1-866-448-9567**
- **By email to:** rsrecall@stryker.com
- **Or by mail to: Physio-Control, Inc.**
  PO Box 970006, Dept. 15N
  Redmond, WA 98073-9706

INSTRUCTIONS

1. **Verify the status of your devices using one of the selections provided in the table below.**
   - **Check that the serial number(s) listed matches the serial number on the label located on the back of your device.**
   - **If any serial number listed below does not belong at the account information above, please provide the new address and contact information, if you have it.**
   - **Please list any additional LIFEPAK® 500 devices not listed below. You may use the back of the form if necessary.**
2. **If you have any additional questions, contact Stryker Customer Support at 1-800-787-9537, option 2, 8:00 A.M. to 6:00 P.M. (EST), Monday – Friday.**

Serial Number	Confirmed possession	Never possessed the device	Device scrapped	Device permanently retired	Device lost or stolen	Device transferred to another location*	*Please provide the new address and new contact information
11069497	☐	☐	☐	☐	☐	☐	