

URGENT MEDICAL DEVICE SAFETY NOTICE & CORRECTION

ACTION REQUIRED

LIFEPAK® 15 Monitor/Defibrillator

Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your LIFEPAK 15 Monitor/Defibrillators.

December 20, 2019

Dear Valued Customer,

Stryker is conducting a Voluntary Correction for specific LIFEPAK 15 Monitor/Defibrillator devices (Part Number V15-2-XXXXXX) that may not deliver a shock after the “Shock” button on the keypad is pressed. The affected population includes devices which were either manufactured with or received an upgrade kit that contained an affected keypad. Please forward this notice to all your sites, trainers and users.

Description of issue

The company has become aware that certain LIFEPAK 15 Monitor/Defibrillators may not deliver a defibrillation shock when the device “Shock” button is pressed as a result of oxidation that has formed over time within the button. The hard paddle shock button is not affected by this issue. There have been two Adverse Event Reports submitted for this failure mode where the shock button did not deliver one shock out of a series of defibrillation shocks, however the patients ultimately expired.

Identification of Impacted Product

The 29,952 impacted LIFEPAK 15 Monitor/ Defibrillators have part numbers beginning with V15-2. The part number of the device is located on the serial label as shown in the figure below.

The Part Number (PN) can be found in battery well 1.



LIFEPAK 15 devices with Part Numbers beginning with V15-5 or V15-7 are not impacted by this issue. For more information, or to verify if your LIFEPAK 15 device is affected by this Voluntary Correction, please go to the following website: <http://www.strykeremergencycare.com/productnotices>.

Required customer actions

- Review your attached affected device list. Go to www.strykeremergencycare.com/fa282response to provide Stryker with confirmation of the location or disposition status of the devices listed.
- Upon confirmation of your device status, a member of our field service personnel will contact you to arrange for the correction of your device. The devices subject to this correction are planned to be serviced by June 30, 2021.
- 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.

You may continue to use your LIFEPAK 15 Monitor/Defibrillator according to the Operating Instructions until the correction can be completed. The other functions of the device are not affected by this issue.

The majority of complaints associated with this issue were detected prior to patient use. Routine testing of your device may detect this fault condition. You should continue to perform the daily check as described in the Operator's Checklist, specifically, the QUIK-COMBO therapy cable check as described in the General Maintenance and Testing Section (pages 10-4 and the LIFEPAK 15 Monitor/Defibrillator Operator's Checklist, number 7). If the device fails the test, a "disarming" message will be displayed, and the service light will be illuminated. Contact Stryker Technical Support immediately to report the incident at 1-800-787-9537, option 2, 8:00 A.M. to 6:00 P.M. (EST), Monday - Friday.

If the issue occurs during patient use, a "disarming" message will be displayed, and the service light will illuminate. Immediately repeat your charge and shock cycle according to the Operating Instructions. If you receive the "disarming" message again, utilize hard paddles or a backup device. Remove the LIFEPAK 15 from service and contact Stryker Technical Support immediately to report the incident at 1-800-787-9537, option 2, 8:00 A.M. to 6:00 P.M. (EST), Monday - Friday.

Stryker's planned actions

The Company is contacting customers with affected LIFEPAK 15 Monitor / Defibrillators to schedule the correction of their device(s), which will include a replacement of the affected keypad. Stryker anticipates that all devices subject to this field action will be serviced by June 30, 2021.

Contact Stryker if you have any questions about this matter at 1-800-787-9537, option 2, 8:00 A.M. to 6:00 P.M. (EST), 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/>, by phone 1 800 332 1088 or fax 1 800 FDA 0178.

Sincerely,



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

Attachments:

- Impacted device list