stryker

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.

February 1, 2019

Dear Valued Customer,

Stryker is conducting a voluntary Field Action for specific LIFEPAK 15 Monitor/Defibrillator devices that may lock-up after a defibrillation shock is delivered. This communication is intended to provide you with critical safety information regarding the readiness of your device. Please forward this notice to all of your sites, trainers and users.

The issue is limited to LIFEPAK 15 Monitor/Defibrillator devices with certain System Printed Circuit Board Assemblies. The attached impacted device list provides serial numbers that our records show are in your possession. For more information on this recall, or to check if other LIFEPAK 15 devices are affected by this Field Action, please go to the following website: http://www.strykeremergencycare.com/productnotices.

Description of issue

Stryker has become aware that certain LIFEPAK 15 Monitor/Defibrillators were reported to experience a lock-up condition after a defibrillation shock was delivered. This condition is defined as a blank monitor display with LED lights on, indicating power to the device, but no response in the keypad and device functions. A device in this condition has the potential to delay delivery of therapy, and this delay in therapy has the potential to result in serious injury or death.

Since the initial commercialization of LIFEPAK 15 in 2009, Stryker has become aware of 58 complaints reported globally for this issue, including 6 events in which the patient died following a delay in therapy. In all six of these cases, at least one shock was delivered prior to the device experiencing the lock-up condition. There are 13,003 devices potentially affected by this issue and within scope of this field action.

Required customer actions

- Review the attached impacted device list. Go to www.strykeremergencycare.com/fa281response to provide Stryker verification of the 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 field action are planned to be serviced by December 31, 2019.
- If you have questions regarding the continued safe use of your products, please contact our Customer Support team by calling 1 800 442 1142 and selecting option 7.

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

Continue to use your LIFEPAK 15 Monitor/Defibrillator according to the Operating Instructions until the correction can be completed.

Device Automatic Self-Tests do not identify this fault, as it occurs during defibrillation. Customers 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 a device exhibits the lockup condition during patient use, the steps from the General Troubleshooting Section (page 10-18) of the LIFEPAK 15 Monitor/Defibrillator Operating Instructions should be followed:

1. Press and hold **ON** until the LED turns off (~5 seconds). Then press **ON** to turn the device back on.
2. If the device does not turn off, remove both batteries and disconnect the device from the power adapter, if applicable. Then reinsert batteries and/or, reconnect the power adapter, and press **ON** to turn the device back on.

If you experience this issue, contact your local Field Service Representative or Stryker immediately to report the incident at 1 800 442 1142, option 7, 6:00 A.M to 4:00 P.M. (PST), Monday – Friday.

Stryker's planned actions

The Company is contacting customers with impacted devices to schedule the correction of their device(s), which will include an update to the firmware for the affected component on the System PCBA. Stryker anticipates that all devices subject to this field action will be serviced by December 31, 2019.

Contact Stryker if you have any questions about this matter at 1 800 442 1142, option 7, 6:00 A.M. to 4:00 P.M. (PST), 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

Kathryn E. Janecke
Senior Director, Quality
Stryker
Emergency Care

Attachments:

- Impacted device list