URGENT MEDICAL DEVICE CORRECTION – ACTION REQUIRED
LIFEPAK® 20e Defibrillator/Monitor

PHYSIO CONTROL

Physio-Control, Inc. | Lifesaving starts here.™

ADDRESS
11811 Willows Road NE
Redmond, WA 98052

PHONE
GENERAL
425 867 4000
TOLL-FREE
800 442 1142

www.physio-control.com

Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your LIFEPAK® 20e Defibrillator/Monitors.

December 2017

Dear Valued Customer,

Physio-Control is conducting a voluntary Field Correction for specific units of the LIFEPAK 20e Defibrillator/Monitor built between September 2016 and June 2017. This communication is intended to provide critical information regarding the readiness of your device.

The attached Confirmation Sheet includes a list of device serial numbers that our records show are in your possession and are impacted by this Field Correction.

Description of Issue

Physio-Control is aware that some devices have had power-related failures as customers prepared their device for initial deployment or during use within the first year of distribution. The symptoms of these failures may include unexpected power on and power off, device lock-up, or a failure to power on or off, any of which has the potential to result in a failure to deliver therapy to the patient and serious injury or death.

These failures are the result of manufacturing process residue located beneath a component mounted on the Power printed circuit board assembly (PCBA).

Physio-Control has received 37 complaints which affects 3,814 devices. There have been no adverse events reported as a result of this issue.

Physio-Control's Planned Actions

Physio-Control will contact customers with LIFEPAK 20e devices who are potentially affected to arrange for a device correction. This correction will include the replacement of the Power PCBA.

Required Customer Actions

1. Please forward this letter to all of your sites, trainers, and users that have an affected LIFEPAK 20e device(s) as identified on the attached Confirmation Sheet.
2. Promptly return the completed Confirmation Sheet to Physio-Control.
3. Follow the recommended daily Operator's Checklist steps in accordance with LIFEPAK 20e defibrillator/monitor Operating Instructions – Section 7 – Maintaining the Equipment. The checklist can be found in Appendix D of the Operating Instructions.
4. You may continue to use your defibrillator/monitor as long as it passes steps 1 and 8 of the Operator's Checklist.
5. If you experience any of the symptoms described above, or the defibrillator/monitor fails steps 1 and/or 8 of the Operator's Checklist, contact Physio-Control immediately to arrange servicing of your device.

If your LIFEPAK 20e defibrillator/monitor exhibits any power issues that cannot be resolved, contact Physio-Control immediately. Contact Physio-Control if you have any questions about this matter at 1-866-231-1220, 6:00 A.M. to 4:00 P.M. (PST), Monday – Friday.

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

Sincerely,

Kathryn Janecke
Senior Director, Quality
Physio-Control, now part of Stryker