Urgent Medical Device Correction

LIFEPAK® 1000 Defibrillator

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

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Urgent– Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your LIFEPAK® 1000 defibrillators.

January 2017

Dear Valued Customer,

Physio-Control is conducting a voluntary **Field Correction** of the LIFEPAK® 1000 defibrillator. This communication is intended to provide you with critical information regarding the readiness of your device.

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

Description of Issue

Physio-Control has received 34 reports of incidents where customers have attempted to use their LIFEPAK 1000 defibrillator and the device has shut down unexpectedly during patient treatment. This unexpected shut down is due to an intermittent connection between the battery and device contacts. A defibrillator in this scenario may not be able to deliver therapy during a resuscitation attempt, which may expose patients to the risk of serious harm or death. We are aware of 8 adverse events related to this issue.

We have determined that this intermittent connection is a result of wear and subsequent oxidation formation between the battery and device electrical contacts. This has been observed to occur in devices that are exposed to vibration and have a battery installed for extended time without being removed from the LIFEPAK 1000 for inspection and then reinstalled. The LIFEPAK 1000 Defibrillator Operating Instructions instruct users to inspect the battery well and battery contacts routinely as part of the maintenance and testing schedule.

You must immediately follow the Required Customer Actions set forth below. If these steps are followed, your device may be kept in service.

If your device powers off unexpectedly, either during inspection or during patient treatment, immediately remove and reinstall your existing battery to restore power to the device. If power is not restored, replace the battery with a spare battery and call Physio-Control immediately to arrange for servicing of your device.

Physio-Control's Planned Actions

Physio-Control is contacting customers with affected devices to inform them to immediately perform the **Required Customer Actions** set forth below.

Physio-Control will begin contacting customers to schedule a device correction for your LIFEPAK 1000 devices at no charge upon availability of the hardware device correction.

Required Customer Actions

For the Device:

1. Immediately remove and reinstall the battery from your LIFEPAK 1000 defibrillator. The removal and reinstallation of the battery will clean the contacts of oxidation and will restore power to the device.

2. It is critically important that you implement a weekly schedule of battery removal and reinstallation for all LIFEPAK 1000 devices. Removing and reinstalling the battery on a weekly basis will help ensure your device is ready for use. It is also important to always carry a spare, fully charged battery.

We have included a Battery Inspection Checklist for your use. This weekly schedule of battery removal must be performed until your device correction has been completed.

For the Notification:

1. Please forward this information to all of your sites, trainers and users who have LIFEPAK 1000 device(s).

2. Follow the instructions on the Confirmation Sheet for each device in your possession as indicated by serial number listed. Promptly return the completed Confirmation Sheet to Physio-Control.

If you experience an unexpected shut down after powering on the device or during device operation, please contact Physio-Control immediately to arrange for servicing for your device.

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.

Should you have any questions about this subject, please contact us at 1-866-231-1220, 6:00 A.M. to 4:00 P.M. (Pacific), Monday – Friday.

Sincerely,
PHYSIO-CONTROL, INC.

Rod J. Rylands
Vice President, Quality Assurance

Enclosures:
1. Confirmation Sheet
2. Check List