



Information Bulletin

Physio-Control Launches Voluntary Field Action for LIFEPAK 1000 Defibrillator

(Redmond, WA) – January 13, 2017 – Physio-Control announced today that the company is launching a voluntary field action for the LIFEPAK 1000 defibrillator due to reported instances where the device has shut down unexpectedly during patient treatment.

The company is notifying LIFEPAK 1000 customers of an issue that may affect the readiness of the device. The company has received 34 reports where customers have attempted to use their LIFEPAK 1000 defibrillator and the device has shut down unexpectedly due to an intermittent connection between the battery and device electrical 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. The company is aware of 8 adverse events related to this issue.

The company has determined that this intermittent connection is a result of wear and subsequent oxidation formation between the battery and device electrical contacts. This condition can occur over time in LIFEPAK 1000 devices that are exposed to vibration and have a battery installed for long periods of time. This issue can potentially affect any LIFEPAK 1000 device, however customers with non-rechargeable batteries who do not routinely remove the battery for inspection, as indicated in the LIFEPAK 1000 Defibrillator Operating Instructions, are more susceptible to this issue.

The company is contacting customers and advising them to immediately remove and reinstall the battery from their device(s). Customers are also being advised to implement a weekly schedule of battery removal and reinstallation for all LIFEPAK 1000 devices. The removal and reinstallation of the battery will clean the contacts of oxidation and will reduce the likelihood of this issue from occurring. Physio-Control will be initiating a hardware device correction for all affected LIFEPAK 1000 devices and the company will contact customers to schedule device corrections once the hardware correction is ready for implementation. The company will provide customers with updated information regarding the timing for this device correction at the website URL shown below, when it is available.

Information about this notice is available at: www.physio-control.com/lifepak1000-274. Affected customers will be notified by letter. Customers with questions regarding this notification, please contact Physio-Control by calling 1-866-231-1220, 6:00 a.m. to 4:00 p.m. (Pacific) Monday – Friday, or by email to rsrecalls@physio-control.com or fax to 1-866-448-9567.

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.

About Physio-Control

Physio-Control is the world's leading provider of professional emergency medical response solutions that predict or intervene in life-threatening emergencies. The company's products include LIFEPAK® monitor/defibrillators and automated external defibrillators (AED), LUCAS® Chest Compression Systems, the LIFENET® System, HeartSine® AEDs and more. Learn more at www.physio-control.com

CONTACT:

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