Medtronic News

Physio-Control Field Correction to LIFEPAK(R) 20/20e Defibrillator/ Monitors

MINNEAPOLIS, Jul 02, 2010 (BUSINESS WIRE) --

Physio-Control, Inc., a wholly owned subsidiary of Medtronic, Inc., (NYSE: MDT), announced the company's recent initiation of a field correction on certain LIFEPAK 20/20e defibrillator/monitors manufactured prior to January 9, 2009. Analysis conducted by Physio-Control verified a possible battery (DC) power malfunction on the affected devices. In the malfunction scenario, a loss of battery power may occur while the unit is in operation. The LIFEPAK 20/20e defibrillator/monitor was designed with a dual power supply system. The primary source of power is wall (AC) power, which remains available in the event of the loss of battery power. If a malfunction of battery power occurs, customers can plug the device into wall (AC) power to relieve the reliability issue. A loss of DC power during patient use is highly unlikely, but if it occurs and AC power is not readily available, it could delay the delivery of defibrillation therapy, which could potentially result in serious injury or death. While there have been reports of failures during patient use, over the eight year product life, there has been one unconfirmed adverse patient event.

Physio-Control is in the process of notifying all affected U.S and global customers by Certified Mail. The plan is to update all affected power supplies at no charge, during one field service update at the customer site (in most geographies). All customers may also visit the website at www.physio-control-notices.com/LP20Power for more information and to determine if a device is defective.

"Physio-Control is committed to providing the highest quality devices, ensuring patient safety, and minimizing the impact to our customers' operations," said Brian Webster, president of Physio-Control. "The LIFEPAK 20/20e monitor is one of our most reliable hospital products and this product correction will make these devices even more reliable."

In the meantime, Physio-Control recommends customers follow the interim recommendations below.

Recommendations:

Customers are advised to keep units in service and to continue testing their devices frequently and regularly, in accordance with the Operating Instructions (Section 7 - Maintaining the Equipment). A copy of the daily operator's checklist can also be downloaded from the Physio-Control website at www.physio-control-notices.com/LP20Power.

Keep normally functioning LIFEPAK 20/20e devices in service connected to AC Power and continually charging DC power whenever possible. Physio-Control service representatives are scheduling service visits to update all affected devices. If your monitor/defibrillator exhibits any power issues that cannot be resolved, in the United States immediately call Physio-Control's Technical Support at 1-800-442-1142 - option 5, 6 a.m. to 4 p.m. (Pacific), Monday - Friday. Outside the United States, customers should contact their local Physio-Control representative.

If customers no longer have a LIFEPAK 20/20e defibrillator/monitor, they are instructed to call Physio-Control as soon as possible.

Physio-Control is committed to ensuring customers are fully supported. In the United States, customers may email Technical Support at rs.sealifepaksupport-usa@medtronic.com or call Physio-Control Technical Support at 1-800-442-1142, option 5, between 6 a.m. and 4 p.m. (Pacific) with any questions related to this action. Outside the United States, customers should contact their local Physio-Control representative for additional information. All customers may also visit the website at www.physio-control-notices.com/LP20Power for more information.

U.S. Food and Drug Administration (FDA)

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Safety Information and Adverse Event Reporting Program online [at www.fda.gov/MedWatch/report.htm, by phone 1-800-332-1088 [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from the MedWatch "Download Forms" page], by mail [to address on the pre-addressed form] or fax [1-800-FDA-0178].

About Physio-Control

Physio-Control, a wholly-owned subsidiary of Medtronic, Inc., is located in Redmond, Wash. Physio-Control pioneered defibrillation technology more than 55 years ago. The company is the world's leading provider of external defibrillation and monitoring technology for the treatment of sudden cardiac arrest and other cardiorespiratory emergencies. To find out more about Physio-Control, go to www.physio-control.com or call 1-800-442-1142.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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