Medtronic News

Physio-Control Launches Voluntary Field Correction to a Limited Number of LIFEPAK(R) 15 Monitor/Defibrillators

MINNEAPOLIS, Apr 22, 2010 (BUSINESS WIRE) --Physio-Control, Inc., a wholly-owned subsidiary of Medtronic, Inc., (NYSE: MDT), announced today the U.S. Food and Drug Administration (FDA) has classified the company's decision to perform a voluntary correction of LIFEPAK 15 monitor/defibrillators manufactured prior to December 16, 2009 as a Class I recall. Analysis conducted by Physio-Control verified the affected devices were manufactured with an internal component that could cause an electrical short that leads to the device turning off/on by itself or a power loss. A loss of power could delay or prevent delivery of defibrillation therapy. There have been no adverse patient events related to this potential issue.

"Physio-Control is committed to the highest level of quality and minimizing the impact to our customers," said Brian Webster, president of Physio-Control. "This is an example of our Quality System working the way it was designed to--we were able to detect this potential issue early, it was investigated, a solution was found and is being implemented. Our goal is to minimize issues in the field and maximize patient safety and customer satisfaction."

On March 4, 2010, Physio-Control notified all affected customers by Certified Mail and has begun servicing affected devices, free of charge, at the customer site in most geographies. In the meantime, Physio-Control is providing the following interim recommendations for customers to follow:

Recommendations:
Customers are advised to keep units in service and to continue testing their devices in accordance with the Operating Instructions (Section 9--Maintaining the Equipment). Physio-Control service representatives are scheduling service visits to update all affected devices. If your monitor/defibrillator exhibits any power on or power off issues, in the U.S. immediately call our Technical Support at 1.800.442.1142 - option 5, 6:00 A.M. to 4:00 P.M. (Pacific), Monday - Friday. For customers outside the U.S., please contact your local Medtronic Physio-Control representative.

Physio-Control also recommends customers ensure the notification is forwarded to all of their sites. If customers no longer have a LIFEPAK 15 monitor/defibrillator, they are instructed to call Physio-Control as soon as possible.

Physio-Control is committed to making sure customers are fully supported. Customers may call Physio-Control Technical Support at 1-800-442-1142, option 5, between 6 a.m. and 4 p.m. (Pacific Time) with any questions related to this action, or visit the website at www.physio-control-notices.com/LP15pcba for more information.

About Physio-Control
Physio-Control, a wholly-owned subsidiary of Medtronic, Inc., is located in Redmond, Wash. Physio-Control pioneered defibrillation technology over 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.

SOURCE: Medtronic, Inc.

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