



Physio-Control, Inc.  
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[www.physio-control.com](http://www.physio-control.com)

October 2010

**URGENT** · MEDICAL DEVICE INFORMATION

Dear Physio Customer,

It is important to us the LIFEPAK<sup>®</sup> 12 Defibrillator/Monitor meets your standards for durability and dependability. We want to take this opportunity to review and reinforce some specific information in the LIFEPAK 12 Monitor/Defibrillator Operating Instructions.

**What is the reason for this notification?**

We have received reports from customers that suggest LIFEPAK 12 Operating Instructions that describe the process for disconnecting the device from AC (wall) power are not always being followed. When the instructions are not followed and the Power ON button is pushed within 2 seconds after disconnecting the device from AC power, the service indicator will illuminate and the device may fail to charge the defibrillator and/or initiate pacing. If this occurs, the device will not deliver a shock until the Operator instructions are followed and the power is cycled off, then on again.

There are no product related, corrective or preventative actions in place for this device behavior and this notification is strictly to ensure users are aware of this device behavior and operate their devices according to current Operating Instructions.

**What should I do?**

Follow current Operating Instructions indicated below and wait at least 2 seconds to push the Power ON button after disconnecting the device from AC power. If the instructions are not followed and the Power ON button is pushed within 2 seconds after disconnecting the device from AC power and the service indicator illuminates, it's important to be aware that turning the device off, then back on again, will reset the device and restore full functionality.

***LIFEPAK 12 Operating Instructions – Section 7.5 - AC Power Adapter Operation***

**Note:** The SERVICE indicator on the LIFEPAK 12 defibrillator/monitor may illuminate if you turn on the defibrillator/monitor and disconnect the AC Power Adapter from the defibrillator/monitor or power source at the same time. Wait at least 2 seconds between disconnecting the power adapter and turning on the defibrillator/monitor regardless of the order of the actions. If the service indicator comes on, continue to use the defibrillator if needed. The service condition may be cleared by turning the defibrillator off and then back on. If the service LED remains lit, remove the defibrillator from active use and contact your service representative.

A complete copy of our current LIFEPAK 12 Operating Instructions is available from our website at [www.physio-control.com/products/defibrillators](http://www.physio-control.com/products/defibrillators). Select LIFEPAK 12 - Select Documents.

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Physio-Control is committed to making sure customers are fully supported. If you have any questions regarding this product update, please call our Technical Support Team at 1.800.442.1142 – option 5, 6:00 A.M. to 4:00 P.M. (Pacific), Monday – Friday.

Sincerely,

A handwritten signature in blue ink that reads "James R. Dabbs". The signature is fluid and cursive, with a long horizontal line extending to the right.

James R. Dabbs  
VP Quality Assurance  
Physio-Control, Inc. (a division of Medtronic, Inc.)