April 2009

URGENT FIELD SAFETY NOTICE

Biphasic LIFEPAK® 12 Defibrillator/Monitor series

Medical Device Correction

Medtronic reference: FA428

Dear Physio-Control Customer:

Physio-Control Inc., a division of Medtronic Inc., is voluntarily conducting a correction to specific Biphasic LIFEPAK® 12 defibrillator/monitors manufactured with a printed circuit board assembly (PCBA) that contain a component with excess solder which could cause an intermittent short. If this occurs, it may result in no therapy delivery or delivery of an incorrect defibrillation waveform. There have been no reported failures or complaints due to this potential issue.

Our records indicate you own at least one of the identified LIFEPAK 12 defibrillator/monitors. Refer to the enclosed list for specific serial numbers manufactured with the suspect PCBA. If you no longer have a defibrillator indicated on the attached list, please notify us so our records can be updated.

A Physio-Control representative will contact you within 30 days to make arrangements to update all affected devices. In the meantime, please follow the appropriate interim recommendations indicated below. In the meantime, please continue to test your device in accordance with the Operating Instructions Section 8 - Maintaining the Equipment, specifically the User Test.

Recommendation
Keep your device(s) in use and continue to perform the user test daily. This test can detect a short caused by excess solder.

Instructions to perform the User Test:

1. Press ON to turn on the LIFEPAK 12 defibrillator/monitor. If disconnecting the defibrillator/monitor from AC or DC line power, **wait at least 2 seconds** between disconnecting and powering on regardless of the order of these actions. This allows the defibrillator/monitor time to switch to battery power.
2. Press OPTIONS to access User Test. When selected, the User Test automatically performs the following tasks:
   - Performs self-tests
   - Charges to 10J and discharges internally (this energy is not accessible at the therapy connector)
   - Prints a Pass/Fail report

If the LIFEPAK 12 defibrillator/monitor detects a failure during the User Test, the Service LED lights and the printed report indicates that the test failed. If this occurs or if you have any questions regarding this notification, please call {insert contact information} or visit our website at www.physio-control-notices.com/LP12pcba. Physio-Control is committed to meet the highest quality standards for our products and in fully supporting our customers.

Please ensure this notification is forwarded to all your sites. If you no longer have a LIFEPAK 12 defibrillator, which is on the attached list, please notify us as soon as possible.

We have informed the <insert name of country regulatory agency> about this Field Safety Notice.

Sincerely,