March 2007

Urgent Field Safety Corrective Action

LIFEPAK CR® Plus defibrillator / LIFEPAK EXPRESS® defibrillator

Dear Customer:

Physio-Control, Inc., a division of Medtronic Inc., is alerting customers who own a LIFEPAK CR Plus and/or a LIFEPAK EXPRESS defibrillator manufactured between December 2005 and August 2006. Defibrillators manufactured during this period include an electrical component that may fail and cause a short that will prematurely deplete the battery. A defibrillator will not function if the battery is fully depleted. Our investigation indicates that these electrical components came from a single lot. A small percentage of the defibrillators that use this component have failed early in product life. Our analysis indicates that the potential for future failures is remote.

The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are programmed to conduct weekly self-tests that check, among other things, the defibrillator's battery capacity. The test results appear on an easy-to-read readiness display located on the top of each defibrillator.

When you receive this letter, please immediately inspect your defibrillator to ensure the battery is functional. Use the enclosed Inspection Sheet and refer to the instructions to confirm inspection. If "OK" is visible on the readiness display, this indicates that the defibrillator is ready for use. If any other indicator is present (i.e., ▭, ⚠, or 🔧), please immediately contact your authorized Physio-Control service personnel at Oxygen Care on Dublin 295 3421

In addition to performing this initial defibrillator check, we strongly recommend that you inspect your defibrillator at least monthly. This is consistent with the LIFEPAK CR Plus/EXPRESS defibrillator Operating Instructions.

We also recommend that you do the following with respect to your LIFEPAK CR Plus and/or LIFEPAK EXPRESS defibrillator:

- Immediately inspect your defibrillator to ensure the battery is functional.
  - If "OK" is visible on the readiness display, your defibrillator is ready for use. Please indicate that you have conducted this check on the attached form and return it to Physio-Control as directed.
  - If any other indicator is present (i.e., ▭, ⚠, or 🔧), please immediately contact your authorized Physio-Control service personnel at Oxygen Care on Dublin 295 3421

- Inspect your defibrillator monthly as per the Operating Instructions to ensure the battery is functional.
  - If "OK" is visible on the readiness display, your defibrillator is ready for use.
  - If any other indicator is present (i.e., ▭, ⚠, or 🔧), please immediately contact your authorized Physio-Control service personnel at Oxygen Care on Dublin 295 3421

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If you have additional questions about whether your defibrillator is included in this field safety corrective action, you can visit our website at www.medtronic-ers.com/notices/CRSafety.

The Irish Medicines Board (IMB) have been informed of this notification.

Physio-Control is committed to ensuring that our products meet the highest quality standards and to fully supporting our customers. If you have any questions or would like additional information, please call Andie Healy at Oxygen Care on Dublin 295 3421 or visit our website referenced above.

Yours sincerely

D. G. Dunham.

David G. Dunham BSc. PhD
Regulatory Affairs Manager – UK & Ireland

Attachment: - Inspection Sheet