July 2008

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE CORRECTION

LIFEPAK CR® Plus defibrillator / LIFEPAK EXPRESS® defibrillator

Medtronic Reference: FA394

Dear Customer:

Physio-Control, Inc., a division of Medtronic, Inc. is notifying customers who own a LIFEPAK CR Plus and/or a LIFEPAK EXPRESS automated external defibrillator (AED) manufactured between November 2006 and March 2008. These AEDs may contain a specific internal flex cable that may be susceptible to failure and could potentially short, preventing the AED from powering on. Failure to power on will prevent delivery of therapy to a patient. There have been no reports of adverse events for this issue.

We have investigated three confirmed events of this shorting issue occurring during AED testing in the field. In these reports, the AED would not power on although the OK indicator was visible on the Readiness Display. Physio-Control recommends customers immediately inspect their AED for this issue by pressing the On / Off button to verify the device will power on and that voice prompts begin. See full recommendations below. An enclosed list identifies your potentially affected AEDs by serial number.

Recommendations:

- Immediately verify your AED powers on ***and*** voice prompts begin.
  After verification, press and hold the On / Off button for approximately two seconds to turn the AED off.

- Keep your AED in use and perform monthly inspections ***that include the additional AED power on test***. A monthly inspection is consistent with the LIFEPAK CR Plus/LIFEPAK EXPRESS AED Operating Instructions.

- If "OK" is visible on the Readiness Display and the AED powers on, it is ready for use.

- If, at any time, the AED does not power on or if any other indicator displays (i.e.,  ,  , or ), please immediately call <insert local contact #>

A Physio-Control representative will contact you within 60 days to make arrangements to correct all your potentially affected defibrillator(s) at no charge.

Please ensure this notification is appropriately forwarded to all your sites. If you no longer have the defibrillator(s) on the attached list, please notify us as soon as possible.

Medtronic is communicating this information to the appropriate regulatory agencies in your country.

If you have additional questions about whether your defibrillator is included in this notification, you can visit our website at www.physio-control-notices.com/flex.

If you have any questions or would like additional information, please call <insert local contact #>.

Sincerely,

Attachment: List of affected devices.