



Medtronic

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March 04, 2010.

To:
DIRECTOR OF MEDICAL DEVICE BUREAU
MINISTRY OF HEALTH MALAYSIA
Level 5, No. 26, Boulevard Plot 3C4,
Precinct 3,
Federal Government Administration Centre,
62675 Putrajaya,
Malaysia

Dear Sir,

MEDICAL DEVICE CORRECTION: LIFEPAK[®] 15 Monitor/Defibrillator.

This letter is to inform you that Physio-Control, Inc. a division of Medtronic, Inc., is conducting a voluntary correction for a limited number of LIFEPAK[®] 15 Monitor/Defibrillators.

The scope of this field action does not impact Malaysia market as the limited numbers of the affected LIFEPAK[®] 15 Monitor/Defibrillators were not distributed locally.

The communication letter is as attached, to provide further insights into this field action.

Do consult us should you require additional information.

Yours Sincerely,

Debra Anne Anthony Peter
REGULATORY AFFAIRS SPECIALIST
MEDTRONIC INTERNATIONAL, LTD.

Attachment: Customer Communication Letter

March 2010

URGENT

MEDICAL DEVICE CORRECTION

LIFEPAK® 15 Monitor/Defibrillator

What is the issue?

Physio-Control, Inc. a division of Medtronic, Inc. is conducting a voluntary correction for a limited number of LIFEPAK 15 monitor/defibrillators. Our internal analysis has verified that for those monitor/defibrillators an internal component could inadvertently contact the power printed circuit board assembly (PCBA). Should this occur, we have verified that the monitor/defibrillator may:

- cycle power Off then On by itself, or
- power Off by itself requiring the operator to turn it back On, or
- stay powered On and not allow itself to be turned Off.

No adverse patient events have been received related to this issue.

Am I affected by this issue?

Our records show that specific LIFEPAK 15 device serial numbers that are identified on the enclosed sheet, and that we track to your facility, are affected by this issue. To check other serial numbers, visit our website at www.physio-control-notice.com/LP15pcba.

What should I do?

We recommend keeping the monitor/defibrillator in service and to continue testing them in accordance with the Operating Instructions Section 9 – *Maintaining the Equipment*. Your local service representative will be calling you to schedule a service visit within 60 days. If your monitor/defibrillator exhibits any power on or power off issues, immediately call our Technical Support at 1.800.442.1142 – option 5, 6:00 A.M. to 4:00 P.M. (Pacific), Monday – Friday.

What if I don't have the affected device any longer or the device location has changed?

We recommend customers ensure the notification is forwarded to all of your sites. If you no longer own the identified monitor/defibrillators on the enclosed sheet, please contact Physio-Control Technical Support as soon as possible to ensure accurate updating of your account.

If you have any questions regarding this action, please visit our website at www.physio-control-notice.com/LP15pcba or call our Technical Support at 1.800.442.1142 – option 5, 6:00 A.M. to 4:00 P.M. (Pacific), Monday – Friday.

Thank you for your cooperation.



Jonathan Lee
VP Quality Assurance
Physio-Control, Inc. (a division of Medtronic, Inc.)