IRISH MEDICINES BOARD
SAFETY NOTICE

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LIFEPAK® CR Plus Automatic External Defibrillator

IMB Safety Notice: SN2010(08)
Circulation Date: 19 July 2010

MANUFACTURER/SUPPLIER
Physio-Control/Medtronic

TARGET GROUPS
General Practitioners
General Public
Community First Responder schemes
Risk Managers
Hospitals
Nursing Homes
Schools
Sports clubs
Hospitality

ISSUE
The potential for the LIFEPAK® CR Plus to not deliver therapy still exists due to a device upgrade that has not been completed on all of the affected devices on the Irish market.

BACKGROUND
LIFEPAK® CR Plus AEDs manufactured between November 2006 and March 2008 may contain a faulty internal cable that may prevent the AED from powering on. Failure to power on will prevent delivery of therapy to a patient. Please see Attachment 1 for affected serial numbers of this device.

The manufacturer issued a Field Safety Notice (FSN) to all affected Irish customers in August 2008 advising of the issue and initiated a field corrective action to correct the fault (Please see the attached FSN). However, despite their best effort, they have experienced problems locating all of the affected devices.

In the view of the above, the IMB is issuing this safety notice to advise the users of LIFEPAK® CR Plus to locate their devices and check whether they have been upgraded in relation to this issue.

ACTION OR RECOMMENDATIONS
1. Ensure the appropriate personnel are made aware of this notice.
2. Identify affected LIFEPAK® CR Plus defibrillators (Please see Attachment 1 for affected serial numbers)

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3. Confirm if defibrillators have been upgraded by Oxygen Care (repair and servicing company for Physio-Control products in Ireland) in relation to this issue.
4. If any of the affected defibrillators has not been upgraded, immediately contact Medtronic or Oxygen Care (see contact details below) to arrange the correction of the defibrillator, and follow the recommendations listed in the FSN.
5. Perform regular monthly inspection as per LIFEPAK® CR Plus operating instructions **AND verify that the voice prompt is heard at power on.**
6. If, at any time, the voice prompt is not heard or any other indicator displays bar "OK", immediately contact Medtronic.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie

Enquiries should be addressed to:

Manufacturer:

Medtronic Ltd
Building 9
Croxley Green Business Park
Hatters Lane
Watford
WD18 8WW

Contact Person: David Dunham

Telephone: +44 1923 212213
E-mail: david.dunham@medtronic.com

Repair and Servicing:

Oxygen Care Ltd
2 Holfeld Business Park
Kilmacanogue
Co. Wicklow

Telephone: +353 1 276 9700