IRISH MEDICINES BOARD

Notice Information: - Advisory
19 July 2010

Part 1. Product Information

a)	Title:	LIFEPAK® CR Plus Automatic External Defibrillator
b)	Product Name/Type:	LIFEPAK® CR Plus Automatic External Defibrillator
c)	Reference:	SN2010(08)
d)	Manufacturer/Supplier:	Physio-Control/Medtronic

Part 2. Target Audience

a) Target Audience:

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

Part 3. Problem/Issue

a) Problem/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.

Part 4. Background Information

a)	Background Information:	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.

Part 5. Action to be taken

a) Action to be taken:	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) 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.

Part 6. Enquiries

a)	All enquiries should be made to:	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.dun

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 (0)1 276 9700

Please Click Here to download a PDF version of the Saftey Notice

Please Click Here to download a PDF version of the Field Safety Notice

Please Click Here to Download a PDF attachment of Serial Numbers