IRISH MEDICINES BOARD

Notice Information: - Advisory
03 August 2012

Part 1. Product Information

a)	Title:	Cardiac Science's Powerheart and CardioVive Automated External Defibrillators
b)	Product Name/Type:	Cardiac Science's Powerheart and CardioVive Automated External Defibrillators
c)	Reference:	SN2012(11)
d)	Manufacturer/Supplier:	Cardiac Science

Part 2. Target Audience

a) Target Audience:

General Practitioners

General Public

Community First Responder schemes

Risk Managers

Hospitals

Nursing Homes

Schools

Sports clubs

Please bring this safety notice to the attention of all who need to be aware of it.

Part 3. Problem/Issue

a)	Problem/Issue:	The Cardiac Science Powerheart and CardioVive AEDs affected by two separate issues may not deliver therapy.

Part 4. Background Information

a) Background Information:

The manufacturer Cardiac Science is currently conducting two Field Safety Corrective Actions (FSCAs) on the Irish market relating to their Powerheart and CardioVive automated external defibrillators (AEDs). The issues were communicated separately in Field Safety Notices (FSN) distributed in November 2009 and January 2012 (see attached).

FSCA November 2009 - Cardiac Science Ref MDD09.070

The first issue relates to Powerheart 9300A, 9300C, 9300D, 9300E, 9300P, 9390A, 9390E, CardioVive 92531, 92532 and 92533 automated external defibrillators (AEDs) manufactured between August 2003 and August 2009. These AEDs have resistors which may fail and the failure will not be detected by the AED's periodic self-test. If the issue were to occur the AED may not be able to deliver therapy during a rescue attempt.

The manufacturer distributed a follow up FSN in June 2010 to notify users that a mandatory software update to address this issue was available for all affected models. To date, despite communications distributed by Cardiac Science and their representatives, not all customers have carried out the software update on the affected devices in Ireland.

FSCA January 2012 – Cardiac Science Ref MDD12.005

The second issue relates to Powerheart 9300A, 9300E, 9300P, 9390A, and 9390E AEDs manufactured between July 1, 2011 and December 30, 2011. In addition, certain CardioVive 92532 and 92533 model AEDs serviced during this time are also affected. The affected AEDs contain a circuit board manufactured with a component that may fail unexpectedly due to a supplier manufacturing defect. If the component were to fail during a rescue attempt, the AED may not deliver therapy.

Cardiac Science informed the IMB that they distributed the communications to all of their direct sales customers in Ireland. Please see accompanying FSNs for additional information. As some users in Ireland may have been supplied with affected devices indirectly, they may not be aware of these two issues. Cardiac Sciences advises that s

such customers should contact them directly if they identify that they have such a device.

Part 5. Action to be taken

a) Action to be taken:

1. Ensure that the relevant personnel in your organisation are made aware of the two issues.

2. Determine if you have purchased a device that is affected by either of the above issues by reviewing the attached FSNs and lists of affected AED model numbers and serial numbers.

3. If you have an affected device, please follow the instructions provided by Cardiac Science in the relevant FSN.

Part 6. Enquiries

a) All enquiries should be made to:

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Bob Odell

Cardiac Science

3303 Monte Villa Parkway Bothell

WA 98021-8969

Telephone: +1 425 402 2482

Email: aed210@cardiacscience.com

Or to Cardiac Science's European Authorised Representative:

MDSS GmbH

Schiffgraben 41

30175 Hannover, Germany

Tel.: +49 511 6262 8630

Fax: +49 511 6262 8633

Email: vigilance@mdss.com

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

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

Click here to view a PDF copy of this Safety Notice

Click here to view a copy of FSN 1

Click here to view a copy of FSN 2

Click here to view a copy of FSN 3