IRISH MEDICINES BOARD
SAFETY NOTICE

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Zoll AED Plus Defibrillator

IMB Safety Notice: SN2009(13) Updated Version
Circulation Date: 23rd May 2011

MANUFACTURER/SUPPLIER
Zoll Medical Corporation

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

ISSUE
The Zoll AED Plus Defibrillator may not deliver therapy.

BACKGROUND
Zoll received reports that following a long period without use (typically greater than four years); a ZOLL® AED Plus® may prompt "change batteries" during use and fail to deliver therapy. Turning the device off completely, waiting ten seconds for the unit to re-set and then turning it back on is necessary to resume proper operation.

Zoll's investigation of this problem has determined that some batteries may develop high internal resistance that interferes with the batteries' expected performance, lengthening charging time beyond specified and clinically acceptable limits.

In February 2009, ZOLL Medical Corporation started to inform owners of all AED Plus devices with serial numbers below **X_ _ _200000** to replace batteries that have been installed in devices for a period longer than three (3) years and at subsequent three (3) year intervals.

Units above serial number **X_ _ _200000** are not affected by this corrective action as they contain software that can detect this battery condition and identify when batteries require replacement. In lieu of adding the battery replacement label, users may obtain this new software for their AEDs at no cost at www.ZOLLAEDPlusbatteryhelp.com

Four distributors have supplied the affected product in Ireland, ***Pulse Medical Ltd, Heartbeat Safety Ltd, AED Direct and Medilink Services***. Zoll has been working with the distributors to ensure that the issue is communicated to all users of the product in Ireland. Zoll have been unable to confirm to the IMB that the recommended actions have been completed on all devices.

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ACTION OR RECOMMENDATIONS

1. Ensure that the relevant personnel in your organisation are made aware of this issue.

2. Determine if you have purchased the affected serial numbers of this product, AED Plus devices with serial numbers below **X_ _ _200000**.

3. If you have an affected device confirm that the recommended actions have been completed:

Ensure that the date when the batteries were installed in your device has been checked.

a. If batteries were installed more than three (3) years ago, replace the batteries as soon as possible and add the label provided by Zoll showing the next scheduled replacement date. Read and add the addendum incorporating this information to the administrator's guide that was provided by Zoll.

b. If batteries are not more than three (3) years old, add the label provided by Zoll completed with the next scheduled replacement date. Read and add the addendum, provided by Zoll, incorporating this information to the administrator's guide.

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 to the manufacturer should be addressed to:

Manufacturer:

Zoll Medical Corporation
269 Mill Road
Chelmsford
Massachusetts
USA

Telephone: + 31 651937017
E-mail: erozeboom@zoll.com

Distributor:

Pulse Medical Ltd
Unit 8

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Ballyboggin Business Centre
Ballyboggan Road
Glasnevin
Dublin 11
Ireland

Telephone: +353 1 8602631
Fax: +353 1 8602640

Heartbeat Safety Ltd.
Unit 3
Crookstown Business Park
Crookstown
Co Kildare
Ireland

Telephone: +353 59 8623975
Fax: +353 59 8623870

Medilink Services
Link House
81 Sydenham Road
Belfast
Northern Ireland

Telephone: +44 2890 582999
Fax: +44 2890 582900