

**Notice Information: - Advisory
10 December 2009**

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

- a) Problem/Issue:

Part 4. Background Information

a) Background Information:

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 of this year, 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.

Part 5. Action to be taken

a) Action to be taken:

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.

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:

Zoll Medical Corporation
269 Mill Road
Chelmsford
Massachusetts
USA

Telephone: 00 31 651937017

E-mail: erozeboom@zoll.com

Distributor:

Pulse Medical Ltd

Unit 8 Ba

Distributor:

Pulse Medical Ltd

Unit 8

Ballyboggan Road

Glasnevin

Dublin 11

Ireland

Telephone: +353 1 6402615

Fax +353 1 8602640

Heartbeat Safety Ltd.

Unit 3

Crookstown Business Park

Crookstown

Co Kildare

Ireland

Telephone: +353 45895144

Fax: +353 59 8623870

AED Direct

52 Clogher Road Co Down Northern Ireland Telephone: +44 2892689604

52 Clogher Road

Co Down

Northern Ireland

Telephone: +44 2892689604

Fax:

Medilink Services

Link House

81 Sydenham Road

Belfast

Northern Ireland

Telephone: +44 7980 603670

Fax:

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