

Medical Device Alert

Ref: MDA/2011/047 Issued: 16 May 2011 at 15:00

Device

Powerheart AED G3 and CardioVive automatic external defibrillators (AEDs).

Manufactured by Cardiac Science Corporation.

Specific models and serial numbers affected.



Problem

Due to a poor response to [MDA/2010/014](#) this follow-up MDA has been issued.

There is a small risk that the AED may not deliver a shock.

A mandatory software update is available to correct this problem as advised in the manufacturer's [Field Safety Notice](#).

Action by

All those responsible for the use or maintenance of these devices.

CAS deadlines

Action underway: 23 May 2011
Action complete: 13 June 2011

Action

Check if your AED is affected on the website: www.cardiacscience.com/AED175

If you have an affected device, which has not received the software update, contact Cardiac Science Corporation (CSC) in order to receive the update or download it from the website.

When the software has been updated, provide confirmation to CSC.

Contact CSC if you are unsure of the current software status of your device.

Continue to check daily that the status indicator is green, as described in the operation and service manual.

Contact

Manufacturer/supplier
Technical Support
Cardiac Science Corporation UK
Tel: 0161 926 0011
Email: AED175@cardiacscience.com

Device

Powerheart AED G3 model numbers - 9300A, 9300C, 9300D, 9300E, 9300P, 9390A and 9390E.

CardioVive model numbers - 92531, 92532 and 92533.

Problem

The software self-test may not detect a fault with a specific internal component, so the AED may not be able to deliver a shock during a rescue attempt.

The manufacturer has advised that affected devices should remain in use, as the risk of failure is very low.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- All departments
- All wards
- Ambulance staff
- Anaesthetists
- Cardiologists
- Clinical governance leads
- EBME departments
- Intensive care units
- Medical directors
- Nursing executive directors
- Outpatient clinics
- Outpatient theatre managers
- Resuscitation officers and trainers
- Risk managers
- Theatre managers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Community defibrillation officers
- General practitioners
- Minor injury units
- NHS walk-in centres

Social services

Liaison officers for onward distribution to all relevant staff including:

- Education departments for equipment held in schools
- Equipment supplies managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Care homes providing nursing care
- Care homes providing personal care
- Clinics
- Further education colleges registered as care homes
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

Manufacturer/Supplier

Technical Support
Cardiac Science Corporation UK
The Manse, 39 Northenden Rd.
Sale, Manchester M33 2DH
Tel: 0161 926 0011
Fax: 0161 926 0002
Email: AED175@cardiacscience.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/047** or **2009/011/023/081/002**

Technical aspects

Paul Sandhu or Catriona Blake
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7266/7219
Fax: 020 8754 3965
Email: paul.sandhu@mhra.gsi.gov.uk
catriona.blake@mhra.gsi.gov.uk

Clinical aspects

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Medicines & Healthcare products Regulatory Agency
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151 Buckingham Palace Road
London SW1W 9SZ
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Fax: 020 8754 3965
Email: jonathan.plumb@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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