

Medical Device Alert

Action update

Ref: MDA/2009/076 Issued: 24 November 2009 at 14:30

Device

Aquarius haemofiltration machine.

Software versions 3.52, 4.01.11, 4.01.12 and 6.01.

Manufactured by Edwards Lifesciences Ltd.

Problem

This Alert provides an update on actions taken by Edwards Lifesciences, as advised in MDA/2009/012.

Software versions 3.52, 4.01.11 and 4.01.12

These machines will not have their software upgraded as previously intended. An ongoing training package, a warning sticker and laminated instruction sheet will be provided for each machine.

Software version 6.01. These machines are due to have their software upgraded as previously advised. Edwards Lifesciences is unable to confirm when the updated software will be available for implementation. In the meantime, Edwards Lifesciences will provide an interim training package as described for the above software versions.

Action by

Renal physicians, intensive care physicians, intensive care nurses, theatre managers and EBME departments.

CAS deadlines

Action underway: 29 December 2009
Action complete: 01 March 2010

Action

All users should ensure that:

- the warning sticker and laminated instruction sheet are placed on all of these machines
- users are reminded to check causes for balance alarms before overriding them
- end users are familiarised with the information in the previously issued errata sheet, which should be added to the Operating Manual.

Software version 3.52, 4.01.11 and 4.01.12 users should ensure that:

- Edwards Lifesciences has made contact and agreed a date for training

Software version 6.01 users should ensure that whilst waiting for upgraded software to be implemented:

- Edwards Lifesciences has made contact to arrange and agree a date for interim training

Contact

Supplier

Kieron O'Neil
Baxter Healthcare
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Device

Aquarius haemofiltration machines were manufactured by Edwards Lifesciences, but are now supported by Baxter Healthcare, which owns the Aquarius machines business.

The software version is displayed on screen when the machine is turned on to start the system safety test.

Problem

MDA/2009/012 was issued in February 2009 supporting the Field Safety Notice (dated Nov 2008) issued by Edwards Lifesciences that provided advice on two problems (problems 1 and 2 listed below). A further Field Safety Notice covering another problem (problem 3 below) was published in March 2009.

Following on from these Field Safety Notices and the Medical Device Alert, Edwards Lifesciences updated its corrective actions for the problems as detailed below.

Problem 1

The operating manual incorrectly describes how the filtrate line should be connected for haemoperfusion. In addition, for Aquarius software versions 4.01.11 and 4.01.12, these incorrect connection instructions are displayed on the 'Help Screen'.

Inadequate therapy will occur if these inaccurate instructions are followed.

Solution

An errata sheet, with the correct set-up instructions, has been provided by Edwards Lifesciences for insertion into the operating manual.

Problem 2

If users repeatedly override fluid balance alarms without resolving the cause of the alarm it is possible to remove too little or too much fluid from the patient.

Solution

Warning stickers and laminated instruction sheets have been issued by Edwards Lifesciences for placing on all machines.

For software versions 3.52, 4.01.11 and 4.01.12, a training programme will be provided to address this issue.

For software version 6.01 a training programme will also be implemented as an interim measure. A 'Total Fluid Loss Management' software upgrade, which will automatically correct fluid discrepancies following a balance alarm, will be installed in due course.

Problem 3

Following a complaint, Edwards Lifesciences has identified specific programming settings that can result in excess filtrate being removed from the patient. This can occur if the following pump flow rates are set:

- **within the range 0 ml/h to 110 ml/h for the dialysate/pre-dilution substitution pump** (pump designation will depend on the treatment modality selected).
- **0 ml/h for the post dilution pump.**

The excess filtrate removal can occur for any blood flow rate and any treatment modality.

This information supersedes the advice contained in the Field Safety Notice issued by Edwards Lifesciences ('Substitution Fluid Non-conformance', dated 30 March 2009), which previously stated not to use the parameters '100 ml/h or 110 ml/h dialysate/pre-dilution substitution pump'.

Solution

Warning stickers and laminated instruction sheets have been issued by Edwards Lifesciences for placing on all machines with software versions 3.52, 4.01.11 and 4.01.12. Software version 6.01 will be upgraded to address this issue. In the interim period, warning stickers and laminated instructions will also be placed on machines with version 6.01 of the software. Training will be provided for all software versions.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

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

- Anaesthetists
- Biomedical engineering staff
- Health and safety managers
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care physicians
- Intensive care units (adult and paediatric)
- Intensive care, directors of
- Medical directors
- Nursing executive directors
- Renal medicine departments
- Renal medicine, directors of
- Renal physicians
- Renal nursing staff
- Risk managers
- Theatre managers

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospitals in the independent sector

Contacts

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2009/076** or **2008/011/024/291/007**

Technical aspects

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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

Enquiries in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US
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

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:

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