Medical Device Alert

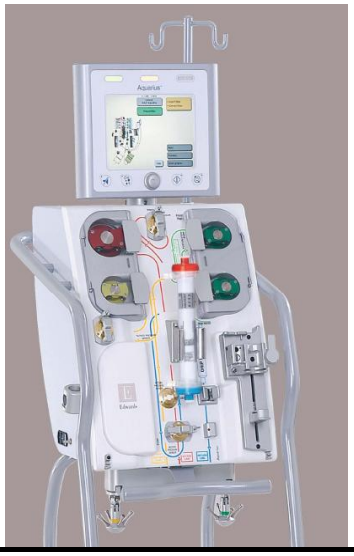
Action

Ref: MDA/2010/039 Issued: 12 May 2010 at 15:00

Device

All Aquarius haemofiltration machines.

Manufactured by Edwards Lifesciences Ltd and supplied by Baxter Healthcare.



Problem

Reports have been received of the wheels breaking due to wear or improper use. There is a risk of the machine toppling or falling over, which can cause injury and therapy interruption.

Action by

Intensive care physicians, intensive care nurses, theatre managers, renal technicians and EBME departments.

Action

Users should ensure that machines are transported in accordance with the instructions in the operating manual.

Maintenance staff should ensure that:

- they are aware of the recent technical bulletin (see appendix), which describes specific wheel inspections
- all wheels are inspected for wear and/or damage and appropriate action is taken, as required.

CAS deadlines

Action underway: 09 June 2010
Action complete: 04 August 2010

Contact

Supplier
Surecall
Baxter Healthcare
Tel: 01635 206 345
Email: surecall@baxter.com

Device

Aquarius haemofiltration machines used to be manufactured and badged by Edwards Lifesciences. However, Baxter Healthcare took over responsibility for the supply and servicing of Aquarius Haemofiltration Devices in September 2009, following their acquisition of the Edwards Haemofiltration business.

Problem

Damage to the wheels (which are referred to in the attached technical bulletin as 'rollers') may not have been detected during routine servicing, so it is essential to check them regularly. If the wheels are damaged, the machine should be taken out of service and repaired.

Action

Users should refer to the instructions in the operating manual in order to minimise damage to the machine's wheels, which is most likely to be caused by movement of the machine over steps, stairs or other uneven surfaces. The instructions state:
'To move or transport the Aquarius it is necessary to release the locking tabs on the wheels. The Aquarius can then be rotated and freely moved about. To move the Aquarius over steps or stairs the locking tabs must be released. The system should be tilted, lifted, and carried by at least three people. The Aquarius must not be pushed over uneven floors'.

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 technicians
- 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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RG20 7QW

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/039 or 2010/003/011/291/021**

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

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.iric@nhs.net
http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

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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Appendix

Edwards	Edwards Lifesciences ABP Business Unit Technical Service	Bulletin Nr. 134 Rev.A

TOOLS REQUIRED

NW-H008-00

Expected time: 5 minutes

CAUTIONS

1. Only trained and qualified personnel should service this instrument. Refer to a copy of the Aquarius Service Manual as instructed.
2. Disconnect the power cord from the unit before removing the rear cover.
3. Disconnect the internal battery when working in the display or power distribution module areas to avoid potential damage to the instrument or exposure to high voltage.
4. Take the standard precautions to protect the instrument from ESD (electrostatic discharge) when handling any of the printed circuit board assemblies or programmed devices.
5. Retrieve all loose hardware from the unit.

CHECKING AND FIXING THE ROLLER

Make sure that the rollers are securely attached to the frame of the Aquarius. Use the NW-H008-00 tool to tighten the roller bolt to the frame. The roller needs to be securely attached to prevent tipping of the machine.

Image I

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