

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

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[Link to full Medical Device Alert](http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON062962)

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