Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/015 Issued: 16 May 2018 at 14:00 Valid until: May /2019

Gambro Ultrafilter U9000 microbial water filter for haemodialysis – risk of hypovolemia due to filter leaks during use

Summary

Manufactured by Baxter Healthcare – Updated instructions for use regarding filter lifespan as cracks may develop after repeated disinfection cycles

Action

For all healthcare staff

- When using the Ultrafilter U9000, be aware of the potential for fluid leakage to occur around the cap of the Ultrafilter, particularly when patients vulnerable to fluid change effects are being treated.
- Be vigilant when using the AK96 and AK98 v1 as they do not alarm when there is an Ultrafilter leak
- Be aware of the updated advice on maximum lifetime usage in the manufacturer's Field Safety Notice
- Ensure home patients are aware of the risk that fluid leakage may occur and they are informed on how to safely manage any leaks.

For all technical staff

- Check dialysis machines using the Ultrafilter to see whether the filter requires replacing as per the manufacturer's Field Safety Notice
- Update processes for replacing Ultrafilters in line with manufacturer's updated guidance
- Ensure counter maximum is corrected at next manufacturer service

Action by
Renal nurses, renal technicians and staff supporting patients receiving haemodialysis at home

Deadlines for actions
Actions underway: 13 June 2018
Actions complete: 08 August 2018

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Problem / background

Baxter Healthcare has updated the maximum usage lifetime of the Ultrafilter U9000 to reduce the occurrence of leaks. This applies when the Ultrafilter is used with the AK96 and AK98 v1 machines. The lifespan remains unchanged if the Ultrafilter is used with AK98 v2 and Artis machines as they have a leak detector sensor. The updated advice is listed in the manufacturer's Field Safety Notice.

Manufacturer contacts

Baxter Healthcare
Tel: 0160 470 4603
Email: uk_shs_fca@baxter.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

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

- Adult intensive care units
- Biomedical engineering staff
- Equipment stores
- Equipment libraries and stores
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Nursing executive directors
- Paediatric intensive care units
- Paediatric wards
- Renal medicine departments
- Renal medicine, directors of
- Risk managers
- Special care baby units
- Staff supporting patients receiving haemodialysis at home

Independent distribution

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

- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies

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@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/015** or **2018/003/013/478/002**.

Technical aspects
Roopa Prabhakar or Emma Rooke, MHRA

Tel: 020 3080 7293/6609

Email: Roopa.Prabhakar@mhra.gov.uk or emma.rooke@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NICAS system.

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

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

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

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales
Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government
Tel: 02920 823 624 / 02920 825 510
Email: Haz-Aic@wales.gsi.gov.uk

Reporting adverse incidents in Wales
Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).