Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/018 Issued: 29 March 2019 at 11:00

Fresenius 5008 & 5008S haemodialysis machines – low risk of inadequate fluid removal during treatment.

Summary

Manufactured by Fresenius Medical – inadequate ultrafiltration can occur due to sudden failure of the ultrafiltration (UF) pump.

Action

Staff responsible for patient care:

- Ensure that operators of these machines have read this notice and are alerted to the potential risk of inadequate fluid removal without the machine's alarm sounding. Consider updating associated user guidance documents for these machines.
- Consider checks after each dialysis treatment to ensure that enough fluid has been removed.
- If you observe frequent episodes of inadequate fluid removal by these machines, notify your local technical/EMBE staff or the manufacturer. This will be noticeable if patient weight is frequently heavier than expected after treatment.

Staff responsible for maintenance of these machines:

- Quarantine the machine if you observe frequent unexplained episodes of inadequate fluid removal.
- Contact the manufacturer to arrange replacement of the ultrafiltration (UF) pump.
- Consider including an additional periodic UF accuracy check as part of the machine's planned maintenance checks.

If you are a home patient:

- Contact your healthcare provider for further advice if you have concerns.

Report adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
All staff responsible for using and maintenance of haemodialysis equipment.

Deadlines for actions
Actions underway: 10 May 2019
Actions complete: 21 June 2019

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Background

MHRA has been made aware of the risk of inadequate fluid removal during treatment due to the failure of the ultrafiltration (UF) pump, which cannot be identified during the manufacturer's technical safety checks. This failure can happen suddenly, without the machine alarming, and currently can only be identified by observing incomplete fluid removal from patients after dialysis treatments.

Manufacturer contacts

Fresenius Medical Care (UK) Ltd.
Tel: 01623 445 100
Email: vigilanceuk@fmc-ag.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
- EBME departments
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Hospital at home units
- In-house maintenance staff
- Medical directors
- Nursing executive directors
- Paediatric intensive care units
- Renal medicine departments
- Renal medicine, directors of
- Special care baby units
- Staff supporting patients receiving haemodialysis at home

Independent distribution

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

- Hospitals in the independent sector
- Independent treatment centres

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 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/2019/018** or **2017/009/028/401/004**.

Technical aspects

Roopa Prabhakar or Jacques Pouget MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

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

Tel: 0208 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

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

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 250986 / 03000 255510

Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).