Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/037 Issued: 10 October 2019 at 14:00

Prismaflex haemofiltration systems installed with software versions 8.10, 7.20 and lower – risk of unexpected machine shutdown during treatment

Summary

Manufactured by Baxter – Communication error alarms may result in unintentional delay and interruption of treatment due to system shutdown.

Action

- Identify affected devices.
- If a communication error alarm occurs, follow the manufacturer's advice in the appropriate Field Safety Notice (FSN) – see Problem/background.
- Baxter will contact users to schedule the software upgrade of your devices when the appropriate upgrade is available.
- Have systems in place to ensure this upgrade is done as soon as possible or at least by the next planned annual maintenance service.
  Note: you can continue using the Prismaflex system until the software upgrade can be performed.
- Return the Field Safety Notice acknowledgement form to Baxter. The manufacturer hasn't received enough responses.
- Report suspected or actual 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
Intensive care physicians, intensive care nurses, theatre managers, renal technicians and EBME departments.

Deadlines for actions
Actions underway: 07 November 2019
Actions complete: 06 January 2020

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

This issue is covered by two FSNs.

- For machines with software version 8.10, the software corrections will be done as part of the upgrade action addressed by an earlier FSN for the inactive syringe pump issue with Regional Citrate Anticoagulation (RCA). This FSN was published in May 2019.
  The software will be updated to version 8.20

- For all other machines with software versions up to 7.20, the software will be upgraded as part of the corrective action described in the more recent FSN published in August 2019.
  The software will be updated to version 7.21.

Manufacturer contacts

Baxter Healthcare
Tel: 01604 704 603
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
- Haemodialysis units
- Intensive care medical staff (paediatrics)
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatrics)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Medical libraries
- Nursing executive directors
- Paediatric intensive care units
- Renal medicine departments
- Risk managers

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/2019/037 or 2019/008/013/487/036.

Technical aspects

Roopa Prabhakar or Eliz Mustafa

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 (Northern Ireland)

Tel: 028 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 255278 and 03000 255510

Email: Haz-Aic@gov.wales

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).