Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

# Medical Device Alert

MDA/2017/020 Issued: 11 July 2017 at 14:30 Valid until: July 2018

## Haemofiltration machine: all Prismaflex systems installed with software version 6.10 – risk of under-infusion of anticoagulant

## Summary

Manufactured by Baxter – the software fails to save the syringe type and size in service and custom modes, and so reverts to default settings.

## Action

- Identify affected devices.
- Ensure that:
  - > users understand the problem detailed in the Field Safety Notice and follow the manufacturer's advice
  - > verify correct syringe settings prior to treatment commencement
- Have systems in place to ensure the upgrade is undertaken as soon as possible or at least by the next planned annual maintenance service. Baxter will contact users to schedule the software upgrade of your devices to rectify the issue.
- Return the Field Safety Notice acknowledgement form to Baxter as currently the manufacturer hasn't received enough responses.

**Action by**
Haemodialysis nurses, haemodialysis physicians, intensive care physicians, intensive care nurses, theatre managers, renal technicians and EBME departments.

**Deadlines for actions**
Actions underway: 18/07/2017
Actions complete: 01/08/2017

Note: These deadlines are for users to be aware of the issue and not for completion of the upgrade.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

## Manufacturer contacts

Pranil Patil
Team Lead CQA
Baxter Healthcare Ltd.
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
- Anaesthetists
- Biomedical engineering staff
- Haemodialysis nurses
- Haemodialysis units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Nursing executive directors
- Paediatricians
- Renal medicine departments
- Renal medicine, directors of
- Risk managers
- Staff supporting patients receiving haemodialysis at home
- Theatre 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 Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

## Enquiries

**England**
Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/020** or **2015/007/008/401/501**.

**Technical aspects**
Helen Stidwill or Enitan Taiwo, MHRA
Tel: 020 3080 7047 / 0203 080 7122
Email: helen.stidwill@mhra.gov.uk / enitan.taiwo@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
Fax: 0131 314 0722

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).