Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/013 Issued: 10 April 2020 at 13:00

Covid-19: All haemofiltration systems including machines and accessories – serious risks if users don't follow manufacturer instructions for set-up

Summary

All manufacturers – there have been reports of off-label modifications to haemofiltration systems when treating Covid-19 patients leading to serious injury and death.

Action

Patients are at risk of serious injury or death if the manufacturer's instructions on set-up are not followed.

Healthcare professionals must be aware of the following manufacturer advice:

- **Do not** connect additional extension lines between the machine and patient as the machine will not be able to monitor pressure or blood loss accurately. Haemofiltration machines must be set up in line with the manufacturer's instructions.
- All filters used for haemofiltration treatments must be **checked prior to use** to ensure the function is appropriate for planned treatment.
- Haemo filters must be stored separately from plasma filters. The storage location should be clearly labelled and include a WARNING to check the right device is being selected.
- See Background section for more information.

Action by
Intensive care physicians, intensive care nurses, theatre managers, renal departments.

Deadlines for actions
Actions underway: As soon as possible
Actions complete: As soon as possible

Note: We won't be collecting responses.

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

Background

Haemofiltration machines
Baxter Healthcare has published safety advice (FSN 1 & FSN 2) after identifying that off-label modifications (such as the use of extension sets and connectors) were being made to their machines in order to minimise cross-contamination of SARS-CoV-2.
However, this introduces a number of new risks to the patient such as undetected blood loss, air embolism, infection and hypothermia.

This advice applies to all manufacturers' haemofiltration machines.

Filters used during haemofiltration therapy
We are also aware of reports where incorrect filters have been selected for use during haemofiltration treatment e.g. a plasma filter incorrectly used instead of a haemofilter.

The filters look similar but serve different specialised functions, which are clearly labelled.

Using the wrong filter can lead to patient death if it's not identified prior to use.

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
- Health and safety managers
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Medical directors
- Medical libraries
- Nursing executive directors
- Paediatric intensive care units
- Renal medicine departments
- Renal medicine, directors of
- Risk managers

Independent distribution

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

- 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 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/2020/013 or 2020/004/002/291/009.

Technical aspects

Roopa Prabhakar or Eliz Mustafa, 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 (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 or 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).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.
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