



Medical Device Alert

MDA/2019/024

Issued: 26 June 2019 at 15:30

Dialog+ haemodialysis machines with software versions 9.xx (excluding versions 9.18, 9.1A, 9.1B) – software and hardware upgrade required

Summary

Manufactured by B. Braun Avitum AG – Malfunction of the temperature sensor can result in temperature of the dialysis fluid to be more than $\pm 1^{\circ}\text{C}$ outside the programmed values, which can lead to inadequate treatment.

Action

- Identify affected machines
- Contact the manufacturer to obtain service kit SW 9.1B or to schedule machines for a service upgrade.
- Ensure this upgrade is scheduled at the next planned service, prioritising patients who use this machine at home.
- Whilst waiting for the scheduled upgrade:
 - > be aware of the potential for incorrect dialysis fluid temperatures whilst patients are undergoing treatment. **The machine will alarm and stop treatment if the temperature goes outside the range 33 to 41 °C.**
 - > consider adding a check for dialysis fluid temperature if a patient complains about unexpectedly feeling warmer or cooler than usual during treatment.
- 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

All staff responsible for using and maintaining haemodialysis equipment.

Deadlines for actions

Actions underway: 18 September 2019

Actions complete: 26 June 2020

Problem

It has been identified that if the temperature sensor at the dialyser inlet (TDSE) experiences a malfunction, the Dialog+ machine may try to incorrectly heat or cool the dialysis fluid anywhere between 33 and 41°C. The machine will continue to operate but will not alarm to indicate that the temperature of the dialysis fluid is $\pm 1^\circ\text{C}$ outside its prescribed value. Implementing the service kit SW9.1B will resolve this issue.

If the temperature of the dialysis fluid falls below 33°C or exceeds 41°C at the temperature sensor in the machine, treatment will stop and the machine will alarm.

Device details

This issue affects all Dialog+ machines with software versions 9.xx (excluding software 9.18, 9.1A, 9.1B). The current software version of your machines can be identified from the start screen in the lower right corner, after you switch on the machine.

The dialysis fluid temperature can be accessed via a service screen for comprehensive review by a trained service technician.

Manufacturer contacts

Product Complaints – B. Braun Medical UK
Tel: 0114 2259155
Email: catherine.clulow@bbraun.com

Business Manager – B. Braun Avitum UK
Tel: 0114 2259000
Email: christine.mccabe@bbraun.com

B. Braun Avitum UK will contact customers directly to provide additional information.

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
- Risk managers
- 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/2019/024** or **2019/003/004/401/005**.

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, Social Services and Public Safety

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.irc@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 \(Wales\)](#).

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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