Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/030 Issued: 18 September at 14:00

All models of T34 ambulatory syringe pumps – updated cleaning advice and maintenance requirements due to the risk of fluid ingress.

Summary

Manufactured by CME (a BD company) – function may be affected by fluid getting into the pump and building up over time because of specific cleaning and disinfection practices.

Action

Have systems in place to ensure:

- healthcare staff are made aware of the updated cleaning advice (Appendix 1 of the manufacturer's Field Safety Notice) and that this is added to the instructions for use for this product
- healthcare staff know that they need to check regularly that an infusion is running as expected and to follow troubleshooting advice in the instructions for use. If you can't resolve a problem, contact the technical staff in your organisation or the manufacturer for help
- technical staff are made aware of the updated technical bulletin (Appendix 2 of the FSN) and that this is added to the technical service manual
- reporting of any incidents or complaints involving this product to BD/CME, to your local incident reporting system and/or the national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.

Action by
All technical staff responsible for servicing these devices and healthcare staff who use these pumps.

Deadlines for actions
Actions underway: 31 October 2019
Actions complete: 11 December 2019

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

BD/CME has published a field safety notice (FSN), which includes revised ‘manufacturer recommended cleaning’ instructions and an updated technical bulletin.

The manufacturer has also produced guidance steps to identify whether additional action is required for the pump in Appendix 3 of the FSN. MHRA is seeking further clarification regarding these actions.

Manufacturer contacts

Becton Dickinson UK Ltd.

Customer service line: 0800 917 8776 (press option 2, then option 4)

BDUKFieldAction@bd.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
- Anaesthetic medical staff
- Biomedical engineering staff
- Community children’s nurses
- Community hospitals
- Community nurses
- District nurses
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Hospital at home units
- In-house maintenance staff
- IV nurse specialists
- Maintenance staff
- Medical directors
- Medical libraries
- Medical oncologists
- Medical oncology, directors of
- Medical physics departments
- Oncology nurse specialists
- Paediatric nurse specialists
- Paediatric oncologists
- Palliative care teams
- Purchasing managers
- Radiation & medical oncology departments
- Supplies managers

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- General practitioners (for information only)
- General practice managers
- General practice nurses

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Equipment stores
- Equipment supplies managers
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers

Independent distribution

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

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED

- Children's services
- Educational establishments with beds for children
- Residential special schools

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/2019/030** or 2019/008/019/487/023.

Technical aspects

Roopa Prabhakar or Emma Rooke, 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 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).