



Medical Device Alert

MDA/2018/010

Issued: 28 March 2018 at 15:00

All T34 ambulatory syringe pumps – risk of unintended pump shutdown and delay to treatment

Summary

Manufactured by Caesarea Medical Electronics (CME) Ltd – a variation in battery size can cause problems with connections in the battery housing.

Action

For all healthcare staff who use the pump:

- identify all affected pumps
- before using the pump, check that the batteries have adequate connection within the battery housing
- you must also check the connections after **each** battery change
- if you find problems with the battery connections, contact your local or hospital servicing department, or CME UK, to arrange for them to adjust the battery housing connection.

For all technical staff responsible for servicing this pump:

- follow actions above
- ensure that the checks on battery connectors are included as part of the regular maintenance regime advised in the manufacturer's [field safety notice](#) and updated technical service manual scheduled to be available in April 2018

If you are a home patient

- Contact your healthcare provider for further advice if you have concerns

Action by

All technical staff responsible for servicing and healthcare staff who use the pump.

Deadlines for actions

Actions underway: 27 April 2018

Actions complete: 25 June 2018

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.

Problem / background

The manufacturer has identified that there can be a +/- 2mm overall size difference between battery brands used with CME's T34 ambulatory syringe pumps.

This could result in battery movement within the battery housing leading to a possible loss of connection. This may result in the pump shutting down.

Be aware that if the pump's battery connectors and/or housing are inadvertently damaged during these checks, and the pump is outside of the warranty period, the manufacturer may charge for pump repair/replacement.

Manufacturer contacts

CME Medical UK Ltd (UK Distributor)

Mr Brendan McGee

Tel: 01253 206700

Email: customersupport@cmemedical.co.uk

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:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- All departments
- All staff
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Clinical governance leads
- Community children's nurses
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units

- District nurses
- EBME departments
- Equipment libraries and stores
- General surgery
- General surgical units, directors of
- Gynaecology nurses
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Maintenance staff
- Medical directors
- Medical libraries
- Midwifery departments
- Midwifery staff
- NHS walk-in centres
- Oncology nurse specialists
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Purchasing managers
- Radiation & medical oncology departments
- Risk managers
- Supplies managers
- Theatres
- Walk-in centres

NHS England area teams

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

- General practitioners
- General practice managers
- General practice nurses

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Children's disability services

- Community care staff
- Disability equipment stores
- Equipment stores
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers

Independent distribution

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

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

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/2018/010** or 2018/002/026/291/004.

Technical aspects

Roopa Prabhakar and Ruth Lloyd-Williams MHRA

Tel: 020 3080 7293/6972

Email: roopa.prabhakar@mhra.gov.uk

ruth.lloyd-williams@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

Email: nss.irc@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 \(Wales\)](#).

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