



# Medical Device Alert

MDA/2019/013

Issued: 4 March 2019 at 11:00

All T34 ambulatory syringe pumps need a sponge pad fitted to the battery compartment to prevent battery connection issues

## Summary

Manufactured by Caesarea Medical Electronics (CME) Ltd, a BD company – instructions provided to reduce the risk of delay to therapy and loss of infusion if the battery loses connection.

## Action

BD/CME issued 2 versions of the Field Safety Notices (FSNs) with actions targeted to the type of healthcare provider.

There is a combined version on MHRA's [website](#). Make sure you read the appropriate pages of the combined version of the FSN.

In Scotland, the NDC Reference is Customer Alert Notice CAN336v5.

### NHS users: read pages 2-5 of the [combined FSN](#)

- Ensure technical/servicing staff know about the actions listed in the manufacturer's [FSN](#).
- If you need more help to carry out the corrective actions, contact the customer service line on 01253 206 700.

### Non-NHS users: read pages 6-11 of the [combined FSN](#)

- Ensure staff responsible for setting up pumps know about the actions listed in the manufacturer's [FSN](#).
- If you need more help to carry out the corrective actions, contact the customer service line on 01253 206 700.

**Note:** The manufacturer has produced a [short video](#) for customers, which shows how to apply the foam inserts into the battery compartment.

### All users:

- Remember that **it's vital to carry out regular checks 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 manufacturer for help.
- Report any incidents or complaints involving this product to BD/CME, your local incident reporting system and/or the national incident reporting authority as appropriate: [England](#), [Scotland](#), [Northern Ireland](#), [Wales](#).

This MDA replaces MDA/2018/035.

**Action by**

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

**Deadlines for actions**

Actions underway: 01 April 2019

Actions complete: 28 May 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.

## Problem / background

The battery that was originally validated for use in the T34 pump was the Duracell (MN1604) 6LR61 9v battery.

There is a +/- 2mm tolerance in size, which is allowed within IEC Standards. However, this could result in the battery moving within its housing, leading to a possible loss of connection. In some circumstances, this may result in the pump shutting down.

CME are now rolling out a corrective action to fit sponge pads within the battery compartment of the syringe pumps, in order to improve battery connectivity.

**CME have undertaken additional battery testing on the Enix NX 6LR61 battery and have confirmed that this brand of battery is still suitable for use in the T34 pump.**

National Supply Codes for the Enix NX 6LR61 battery:

NHS Supply Chain ref (England)	NDC code	BSO PaLS ref (Northern Ireland)
WPA147	N/A	PNB000459
469340	Yellow	

## Manufacturer contacts

CME Medical UK (UK Distributor), a Becton Dickinson acquired company

Mr Michael Garfitt

Customer service line: 01253 206 700

Email: [customersupport@cmemedical.co.uk](mailto: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:

- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Biomedical engineering
- Clinical governance leads
- 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
- Paediatric nurse specialists
- Paediatric oncologists
- Palliative care teams
- Purchasing managers
- 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
- 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](mailto:safetyalerts@mhra.gov.uk) and requesting this facility.

## **Enquiries**

### **England**

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/013** or **2019/001/024/487/009**.

### **Technical aspects**

Roopa Prabhakar or Jenifer Hannon, MHRA

Tel: 020 3080 6000

Email: [DSS-TM@mhra.gov.uk](mailto:DSS-TM@mhra.gov.uk)

### **Clinical aspects**

**Devices Clinical Team, MHRA**

Tel: 020 3080 7274

Email: [dct@mhra.gov.uk](mailto: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: 0208 9052 3868

Email: [niaic@health-ni.gov.uk](mailto: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](mailto: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](mailto: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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