



# Medical Device Alert

MDA/2018/035

Issued: 14 November 2018 at 14:00

Valid until: 14 November 2019

## All T34 ambulatory syringe pumps – update concerning battery information

### Summary

Manufactured by Caesarea Medical Electronics (CME) Ltd, a BD company – additional suitable battery identified for use in the T34 pump

### Action

The manufacturer has confirmed the **Enix NX 6LR61** as an additional brand of 9V battery suitable for use in the T34 pump.

#### For all healthcare staff who use the pump:

- **Ensure checks on whether infusion is running ‘as expected’ is included as part of regular checks**
- if you experience problems with the battery connections (e.g. battery movement within the battery compartment), 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
- continue to ensure that the checks on battery connectors are included as part of the regular maintenance regime, as advised in the manufacturer’s [field safety notice](#) and updated technical service manual which became available in April 2018

#### If you are a home patient

- You have received this Alert for information only. Your healthcare provider should be aware of this issue. However, if you experience concerns, contact your healthcare provider for further advice.

This MDA supersedes MDA/2018/010

#### Action by

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

#### Deadlines for actions

Actions underway: 11 December 2018

Actions complete: 08 January 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.

## Device details

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

## 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 have undertaken additional battery testing on the Enix NX 6LR61 battery. CME has stated that whichever battery is recommended, it only goes part way to solve the problem of the battery not fitting securely against the contacts in the battery compartment.

As a result, CME is planning to fit a sponge pad to the battery compartment to compensate for the +/- 2mm tolerance in size of the batteries. CME plans to have this in place in November and to inform customers via a new field safety notice.

## Manufacturer contacts

CME Medical UK (UK Distributor), a Becton Dickinson acquired company  
 Mr Michael Garfitt  
 Tel: 01253 206700  
 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

### **Public Health England**

Directors for onward distribution to:

- Regional directors
- Regional leads
- Risk manager
- Safety officers

### **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
- 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/2018/035** or **2018/002/026/291/004**.

### Technical aspects

Roopa Prabhakar or Enitan Taiwo, MHRA

Tel: 020 3080 7293/7122

Email: [roopa.prabhakar@mhra.gov.uk](mailto:roopa.prabhakar@mhra.gov.uk) or [enitan.taiwo@mhra.gov.uk](mailto:enitan.taiwo@mhra.gov.uk)

### Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: [dct@mhra.gov.uk](mailto: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](mailto: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](mailto: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](mailto: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 and Social Care.

© Crown Copyright 2018

Addressees may take copies for distribution within their own organisations