



HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

T34 Ambulatory Syringe Pumps

Priority 2 – Warning



HPRA Safety Notice: SN2018(09)

Issue Date: 03 April 2018

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Caesarea Medical Electronics (CME)	V35346

ISSUE

The Health Products Regulatory Authority (HPRA) has been informed of an issue in relation to T34 Ambulatory Syringe Pumps.

The manufacturer has identified that a variation in battery size can cause connection problems in the battery housing, which could result in the pump powering down.

A Field Safety Notice (FSN) has been issued advising customers of the appropriate actions to take. Please refer to accompanying FSN.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying FSN and follow the instructions provided by the manufacturer.
2. Forward a copy of this Safety Notice and the accompanying FSN to all relevant personnel within your organisation and to any organisation/persons to which/whom these devices have been transferred.
3. Report any concerns/adverse incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Hospital Managers / CEOs Risk Managers Clinical Directors Nursing Managers Oncology Nurse Specialists Nursing staff	All wards Palliative Care Staff Purchasing Managers Supplies Managers Nursing Homes Hospices
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BACKGROUND

A 2mm +/- overall length difference has been identified between PP3 batteries from various manufacturers. This difference in length could result in movement of the battery within the battery housing, which can lead to a possible loss of connection and subsequent pump powering down of the device. This could result in under-infusion of pain medication.

The HPRa is issuing this safety notice to raise awareness of this issue.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION (amend as required)

Enquiries to the **manufacturer** should be addressed to:

CME Medical UK Limited Unit 1 Kincaig Business Park Kincaig Road Blackpool FY2 0PJ United Kingdom	Telephone: + 44-1253-206-700 Fax: + 44-1253-896-648 E-mail: QA@cmemedical.co.uk
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Enquiries to the **Irish distributor** should be addressed to:

Rockford Healthcare Limited 3 The Westway Centre Ballymount Avenue Dublin 12	Telephone: 01-450-9050 Fax: 01-450-9060 E-mail: sales@rockford.ie
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HPRa CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2	Telephone: +353-1-6764971 Fax: +353-1-6344033 E-mail: devicesafety@hpra.ie Website: www.hpra.ie
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