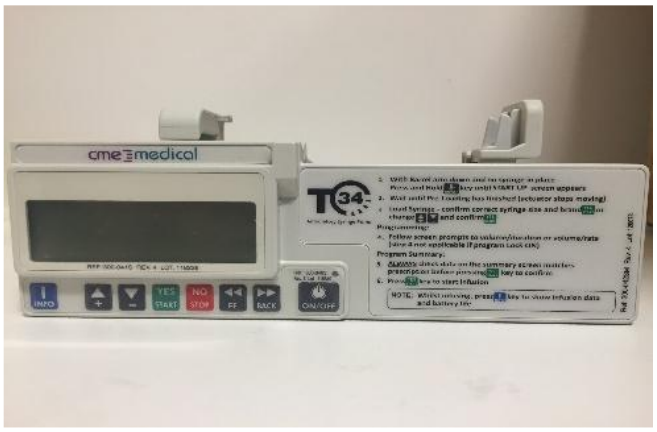
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

T34 Ambulatory Syringe Pumps -Update

Priority 2 – Warning



HPRA Safety Notice: SN2018(31) **Issue Date: 24 September 2018**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Caesarea Medical Electronics Ltd.	V35346

ISSUE

The Health Products Regulatory Authority (HPRA) published a Safety Notice SN2018(09) on 3rd April 2018 in relation to T34 Ambulatory Syringe Pumps whereby Caesarea Medical Electronics Ltd (CME) had identified that a variation in battery size can cause connection problems in the battery housing, which could result in the pump powering down.

The manufacturer has now issued a follow-up field safety notice (FSN) providing additional advice to customers regarding this issue. The follow-up FSN also includes a recommendation to use the Duracell® brand 9-volt (6LR61) battery in T34 syringe pumps.

Please refer to the accompanying FSN for further details.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying follow-up FSN and follow the instructions provided by the manufacturer.

2. Acknowledge receipt of the follow-up FSN if you have not already done so.

3. Forward a copy of this safety notice and the follow-up FSN to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.

4. Report any concerns/incidents regarding these devices and this issue to the manufacturer and the HPRA.

TARGET GROUPS

Hospital Managers / CEOs	All wards
Risk Managers	Palliative Care Staff
Clinical Directors	Purchasing Managers
Nursing Managers	Supplies Managers
Oncology Nurse Specialists	Nursing Homes
Nursing staff	Hospices
Community care managers	Carers
Community nurses	

BACKGROUND

A 2mm +/- overall length difference has been identified between 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 powering down of the device. This could result in under-infusion of pain medication.

The follow-up FSN contains additional information for users and service providers, please see accompanying FSN for details.

CME has advised the HPRA that information relating to pump maintenance will be available in the updated Technical Services Manual due to be released in September 2018. The HPRA also understands that the Operator's manual will be updated in due course to include information on the recommended battery for use with these pumps [Duracell® brand 9-volt (6LR61)].

The HPRA is issuing this safety notice to raise awareness of this issue. Please refer to the accompanying follow-up FSN for further details.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

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

CME Medical UK Limited
Unit 1 Kincraig Business Park
Kincraig Road
Blackpool
FY2 0PJ

Telephone: + 44-1253-206-700
Fax: + 44-1253-896-648
E-mail: QA@cmemedical.co.uk

United Kingdom

Enquiries to the **Irish distributor** should be addressed to:

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

HPRA CONTACT INFORMATION

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

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