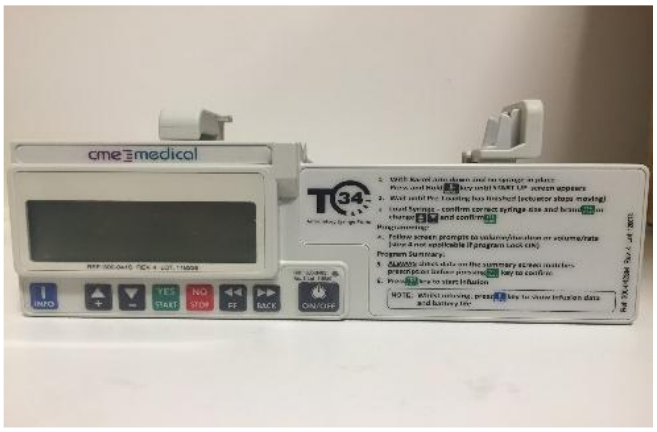
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

T34 Ambulatory Syringe Pumps -Update

Priority 2 – Warning



HPRA Safety Notice: SN2018(34) **Issue Date: 16th October 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 HPRA published an updated Safety Notice SN2018(31) on 24th September 2018 after the manufacturer issued a follow-up field safety notice (FSN) providing additional advice to customers regarding this issue. The follow-up FSN included a recommendation to use the Duracell® brand 9-volt (6LR61) battery in T34 syringe pumps.

Following receipt of a number of queries from Irish users, the manufacturer has provided the HPRA with a higher level of detail regarding the recommended battery. Specifically, the manufacturer has advised that it recommends any battery type that has the code MN1604 and the IEC designation 6LR61, with a minimum battery length (from base to terminal tip) of 47.2mm and an impedance (resistance) of 1,700 m-ohm @1kHz. The manufacturer has also advised that 9 V batteries with an IEC designation of 6LP3146 (formerly 6LF22) are not recommended for use in the T34 syringe pump as these are higher resistance batteries that can decrease battery longevity under load (i.e. while pumping).

The manufacturer has also advised the HPRA that it is in the process of validating the use of a foam pad designed to be affixed to the inside end of the T34 battery compartment to prevent any gap between the battery and the battery contacts. The manufacturer plans to issue an updated FSN for this corrective action in November 2018. The HPRA understands that this action will not impact the manufacturer's battery recommendation.

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.

The follow-up FSN recommends the use of the Duracell® brand 9-volt (6LR61) battery in T34 syringe pumps, however the manufacturer has since clarified that it recommends any battery type that has the code MN1604 and the IEC designation 6LR61, with a minimum battery length (from base to terminal tip) of 47.2mm and an impedance (resistance) of 1,700 m-ohm @1kHz.

The manufacturer clarified that the Duracell brand was initially recommended as this is the battery that was originally tested for use in T34 syringe pumps.

The manufacturer has advised the HPRA that it continues to evaluate various 9 V batteries, from various manufacturers, to better understand what specific battery types are available to customers in Ireland.

CME has confirmed to the HPRA that information relating to pump maintenance is available in the updated Technical Services Manual, which was 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.

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	Telephone:	+ 44-1253-206-700
Unit 1 Kincraig Business Park	Fax:	+ 44-1253-896-648
Kincraig Road	E-mail:	QA@cmemedical.co.uk
Blackpool		
FY2 0PJ		
United Kingdom		

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

Rockford Healthcare Limited	Telephone:	+353-1-4509050
3 The Westway Centre	Fax:	+353-1-4509060
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		