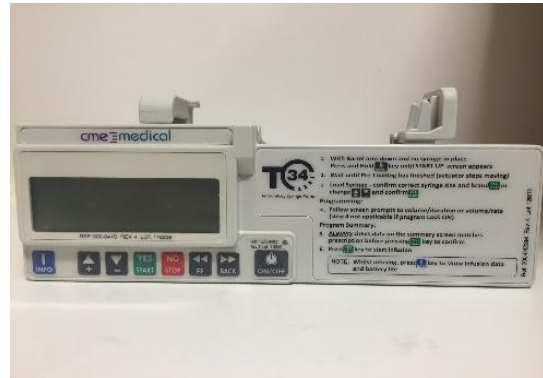


Safety Notice

Medical Devices

CME T34 Ambulatory Syringe Pumps

Priority 3 – Advisory



HPRA Safety Notice: SN2016(41)

Issue Date: 09 December 2016

| MANUFACTURER / SUPPLIER | HPRA CASE REFERENCE |
|--------------------------------------------|---------------------|
| Caesarea Medical Electronics (CME), Israel | V26596 |

ISSUE

The Health Products Regulatory Authority (HPRA) is issuing this safety notice as a follow-up to HPRA Safety Notice SN2016(05): CME Syringe Extension Sets and T34 Ambulatory Syringe Pumps, which was circulated to the Irish market in February 2016. This safety notice relates to T34 Ambulatory Syringe Pumps only.

CME is advising customers to use all CME syringe pumps in a pouch if used in direct sunlight. Pouches are available from CME. CME have now included this warning in the operating manual.

The HPRA advises users to familiarise themselves with the information contained in the attached field safety notice (FSN) and to address any concerns to the manufacturer.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- (1) Be aware of the information in the attached FSN.

- (2) Forward a copy of this HPRA safety notice and the attached FSN to all those who need to be aware of this issue within your organisation and to any organisation / person to whom these devices have been transferred.
- (3) Ensure that relevant personnel receive a copy of the attached FSN.
- (4) Acknowledge receipt of the FSN, informing CME of the number of labels required.
- (5) Adhere the label identifying the warning to the syringe pumps.
- (6) Report any adverse events / incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

| | |
|----------------------------|-----------------------|
| Hospital Managers / CEOs | Palliative Care Staff |
| Risk Managers | Purchasing Managers |
| Clinical Directors | Supplies Managers |
| Nursing Managers | Hospital Pharmacists |
| Oncology Nurse Specialists | Nursing Homes |
| Nursing Staff | Hospices |
| All Wards | |

BACKGROUND

CME T34 pumps are used for pain management and symptom relief in palliative care.

CME is notifying users of a revision to the operating manuals for the T34 syringe pumps. A new warning has been included in the operating manual advising customers to use all CME syringe pumps in a pouch if used in direct sunlight. If the pump is exposed to direct sunlight, it may affect functionality.

CME will provide labels identifying this new warning. Users are requested to adhere the labels to the syringe pump as a reminder.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

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

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

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

Rockford Healthcare Limited
3 The Westway Centre
Ballymount Avenue
Dublin 12

Telephone: 01-4509050
Fax: 01-4509060
E-mail: sales@rockford.ie

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