

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Safety Information **Field Safety Notice**

Ref: FSN2018-001

Product Details:

Product name: T34 Ambulatory Syringe Pump

Product Code: Pumps - 100-100PSM, 100-100SM, 100-100PSMLTR, X100-100SM

Batch Numbers: All T34 Syringe Drivers

Date: 07th March 2018

Type of Action: Safety Information

Description of the Issue:

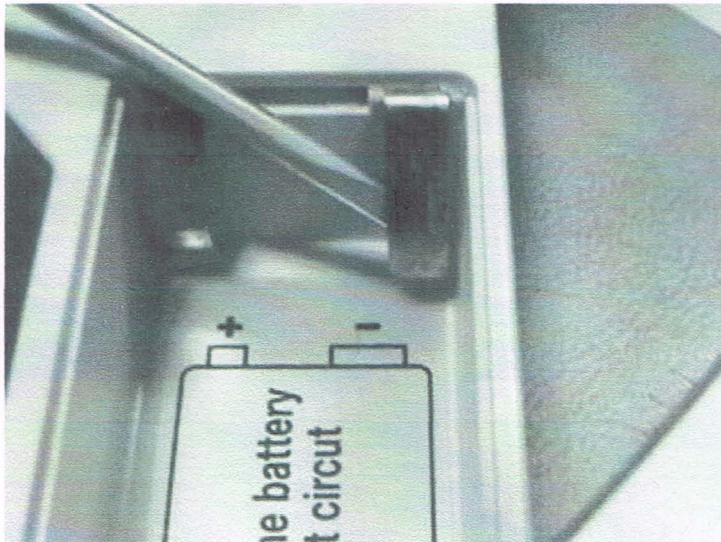
It has been identified that there can be a 2mm +/- overall length difference between various manufacturers PP3 batteries that could be used in CME's T34™ Ambulatory Syringe Pumps.

This could result in movement within the battery housing leading to a possible loss of connection, resulting in the pump powering down and a possible under infusion of pain medication occurring.

Advice to service engineers.

If a battery within the T34™ housing appears loose, careful adjustment of the battery connections (adjustment to move outward into the compartment) may be required as identified in figure 1.0.

Alternatively, never try to force a battery into the T34™ as this may damage the contacts.



We advise that as part of a regular maintenance regime the T34™ battery connectors are checked for signs of wear or loss of connection. This information will be available in the updated Technical Service Manual we will be issuing in April 2018.



Caesarea Medical Electronics

Transmission of this Field Safety Notice:

This notice must be passed on to all those who are responsible for maintenance and servicing within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

For Technical queries relating to this FSN please contact our Customer Support Team:

Customer Support – (+44) 01253 206700

Email: customersupport@cmemedical.co.uk

Contact reference person:

Brendan McGee – Product Quality Officer CME Medical UK Ltd

E-mail: QA@cmemedical.co.uk

The opening of this Field Safety Notice, from the link in the attached email, will be used as acknowledgement of receipt. If you have any questions, please contact the email above.

The undersigned confirms that the relevant competent authorities have been advised of this safety notice.

Signed:

A handwritten signature in blue ink, appearing to read 'Alon Stiassny', is written over a horizontal line.

Alon Stiassny
Sr. QA Manager
CME Ltd.