



Caesarea Medical Electronics

## IMPORTANT UPDATE TO URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

**Important Update to Field Safety Notice issued 07 March 2018**

**Ref: FSN2018-001\_Updated UK**

**Product Name:** T34 Ambulatory Syringe Pump  
**Product Code:** Pumps - 100-100PSM, 100-100SM, 100-100PSMLTR, X100-100SM  
**Batch Numbers:** All T34 Syringe Drivers  
**Date:** 4<sup>th</sup> September 2018

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### **Description of the Issue:**

The T34™ Ambulatory Syringe Pump, powered by a disposable 9-volt battery, is intended for patients who require maintenance medications, analgesics, chemotherapeutic agents and general fluids therapy in hospital and homecare environments.

It has been identified that there can be a 2mm +/- overall length difference between various manufacturers' batteries that can be used in CME's T34™ Ambulatory Syringe Pumps. If the battery does not fit securely against the contacts in the battery compartment, there could be movement of the battery within the compartment leading to a possible loss of battery connection, resulting in the pump powering down. If the pump unexpectedly powers down, the patient is at risk of not receiving therapy.

To date CME Medical UK Ltd. has received a total of 13 reports in the UK of the battery losing connection, resulting in under infusion of therapy. This equates to a reported incident rate of 0.04%.

### **Actions for Users:**

As per the T34™ Operator Manual recommendation, ensure that procedures are established for regular checks of the pump, accessories and progress of the infusion. Specifically,

- **Ensure you use the appropriate batteries for the T34™ Ambulatory Syringe Pump**  
Batteries from different manufacturers can vary by 2mm in length, and shorter batteries may be at risk of losing connection. Therefore, to minimize the risk of losing battery connection, CME Medical recommends using the Duracell® brand 9-volt (6LR61) battery in your T34™ pump, as this was the battery validated for use with the pump.
- **Use caution when inserting a new battery into the T34™ Ambulatory Syringe Pump**  
Check that the battery fits securely into the battery housing. Never try to force a battery into the T34™ pump as this may damage the contacts. If you feel the battery is loose, you should not use the pump. If you have concerns about battery fit, arrange for the syringe pump to have a maintenance check by your own maintenance team, your third-party provider or by calling CME Medical on 01253 206700.

- **Perform checks during the infusion**

Once you have started an infusion, it is important you check that the infusion is running as expected. Hospitals usually have a policy of checking every hour and at least after four hours. This level of checking can be a challenge in care homes, the home environment and where district or home care nurses visit for a short time. If possible, involve the patient and/or carer in knowing that the infusion is running so that they can notify a healthcare professional without delay in the rare occurrence that the infusion does stop.

- **Regularly maintain your T34™ Ambulatory Syringe Pump**

- It is recommended that you service your T34™ pump every 12 months.
- As part of a regular maintenance regime, ensure that the T34™ pump battery connectors are checked for signs of wear or loss of connection. Information relating to pump maintenance is available in the updated Technical Services Manual.
- For further information regarding maintenance of the T34™ pump, please contact CME Medical UK Ltd. on 01253 206700.

- **Immediately report any failures you experience with your T34™ Ambulatory Syringe Pump**

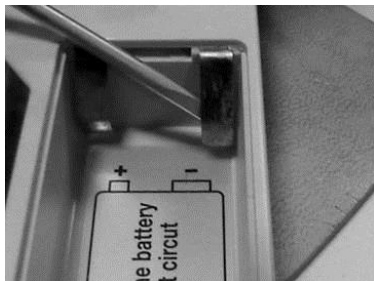
If you experience any failures or problems with your T34™ pump, including battery connection issues, please contact CME Medical UK Ltd. immediately to report the incident.

E-mail: [QA@cmemmedical.co.uk](mailto:QA@cmemmedical.co.uk)  
Customer Support: 01253 206700

### **Actions for Service Engineers:**

If a battery within the T34™ pump housing appears loose, careful adjustment of the battery connections (adjustment to move outward into the compartment) may be required as shown in Figure 1.0 below. Never try to force a battery into the T34™ pump as this could damage the battery contacts.

It is recommended that as part of a regular maintenance regime the T34™ battery connectors are checked for signs of wear or loss of connection. Information relating to pump maintenance is available in the updated Technical Services Manual.



**Figure 1:** Adjustment of battery contacts



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**Action for Users and Service Engineers:**

**As soon as possible, complete and return the attached Acknowledgement Form (Appendix I) to CME Medical UK Ltd. using the instructions provided.**

**Transmission of this Field Safety Notice:**

This notice must be passed on to all those who are responsible for use, maintenance and servicing within your organisation or to any organisation where pumps have been transferred.

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

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

**Customer Support: 01253 206700**

**Email:** [customersupport@cmemedical.co.uk](mailto:customersupport@cmemedical.co.uk)

**Contact reference person:**

**Michael Garfitt: Product Quality Officer CME Medical UK Ltd**

**E-mail:** [QA@cmemedical.co.uk](mailto:QA@cmemedical.co.uk)

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

Signed:

A blue ink signature of Colin Edmondson, consisting of several overlapping loops and a horizontal stroke at the end.

Colin Edmondson  
Country Business Leader  
MMS Infusion, BD UK

A blue ink signature of Sharon Bukay, featuring a stylized, cursive 'S' followed by a few loops.

Sharon Bukay  
Head of Site QA  
CME Israel



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### Appendix I: Acknowledgement Form

**Important Update to Field Safety Notice issued 07 March 2018**

**Ref: FSN2018-001\_Updated UK**

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Please complete the following information:

<b>Name of Hospital / Facility</b>	
<b>Hospital / Facility Address</b>	
<b>Telephone Number</b>	
<b>Name</b>	
<b>Signature</b>	
<b>Date</b>	

Please confirm the following by checking the boxes:

- I have read and understood the contents of this Field Safety Notice
- I will distribute this Field Safety Notice to all those who need to be made aware.

If your facility does not have any affected syringe pumps listed in this Field Safety Notice, please confirm the following by checking the box:

- I confirm that our facility **does not have any** of the affected syringe pumps listed in this Field Safety Notice.

Please pass this Field Safety Notice on to the current user if applicable.

Scan/photograph and return your completed Acknowledgement Form to the following email address:

[CMEFSN0918@cmemedical.co.uk](mailto:CMEFSN0918@cmemedical.co.uk)

Alternatively, post to:

Amy McWilliams  
 CME Medical UK Limited  
 Unit 1 Kincaig Business park  
 Kincaig Road  
 Blackpool  
 FY2 0PJ