Caesarea Medical Electronics

IMPORTANT ***UPDATE*** TO URGENT MEDICAL DEVICE FIELD SAFETY NOTICE FOR **DISTRIBUTOR**

Ref: FSN2018-001_Updated

Important Update to Field Safety Notice FSN2018-001 issued 07 March 2018 and 4 September 2018

Product Name:	T34™ Ambulatory Syringe Pump
Product Code:	Pumps - 100-100PSM, 100-100SM, 100-100PSMLTR, X100-100SM
Batch Numbers:	All T34™ Syringe Drivers
Date:	January 2019

Dear Distributor

Please find the attached Field Safety Notice (FSN2018-001_Updated) concerning CME's T34™ Ambulatory Syringe Pumps.

We request that you take the following actions as described in the '**Actions Required of You'** section (page 2) in response to this Notice. We apologize for any inconvenience that this issue causes you.

CME is committed to ensuring that safe and effective product is available to customers and this Field Safety Notice is taken with due consideration of this commitment.

Thank you for your attention and cooperation.

Sincerely

Sharon Bukay

Sr. Quality Manager

CME/BD

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Actions Required of You:

1. Carefully read the attached **URGENT FIELD SAFETY NOTICE** FSN2018-001_Updated, see pages 3-5

2. Identify your customers impacted by this FSN.

3. Complete and return the attached Distributor Confirmation Form (Appendix I) to CME using the instructions provided.

4. Upon CME's receipt of your completed Distributor Confirmation Form, you may order one of the two kits described in the section action required below. A CME representative will contact you to arrange deliveries of the new kits after you have placed your order.

5. Provide your customers with the information from the FSN. You may need to adapt the text and provide translations for your customers, however please ensure that you do not change the intent of the content. Your customers are to communicate directly with you and not with CME.

6. As a distributor, you are required to ensure that the Foam pad remediation to the battery compartment for all impacted devices in your possession and for all impacted devices at your customers' facilities are executed. Upon receipt of the foam pad kit follow the T34 Technical Bulletin for installing the foam Pad in the battery compartment.

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ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Dear valued customer,

CME continuously strives to improve its products performance and quality, with safety at the forefront of product development.

CME is undertaking a corrective action to inform user that a foam pad needs to be added to the battery compartment of all T34™ Ambulatory syringe pump as shown in (figure 1). The foam pad is intended to ensure the battery rests securely against the contacts in the battery compartment. This corrective action is an update to the previous Field Safety Notice issued 07 March 2018 and 4 September 2018.

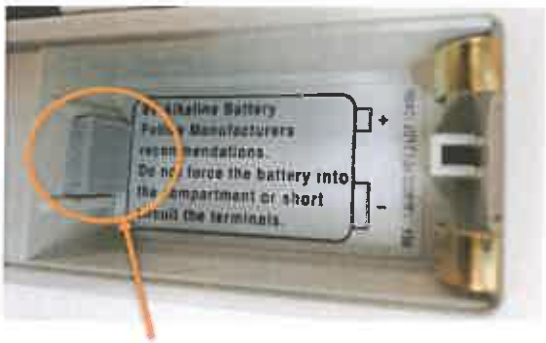

Figure 1 : new foam pad added to the battery compartment

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.

CME has identified a risk with the T34™ Ambulatory syringe pump that could result in a potential scenario for loss of battery connection resulting in the pump powering down without any warnings. 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.

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Update to T34™ Operator Manual

The **"Battery Fitting and removal"** section of the T34™ operator manual has been updated to provide further clarifications on the new foam pad in the pump battery compartment and specific instructions regarding insertion and removal of the battery into the pump.

Battery Usage

CME recommends using the Duracell® brand 9-volt (6LR61) battery, if available, in the T34™ pump, as this was the battery validated for use with the pump.

In case the Duracell® brand 9-volt (6LR61) battery is not available, and to ensure appropriate battery connection regardless of the type of battery, the foam pad solution should be implemented.

The foam pad eliminates the potential scenario for loss of battery connection, resulting in the T34TM pump powering down without any warnings, due to the 2mm +/- variation in various manufacturers' batteries. Therefore, with the foam pad added to the T34™ battery compartment (see Figure 1 above), any 9-volt disposable battery with the international marking code 6LR61 may be used in the T34™ pump, as described in the T34™ Operator Manual.

Any 9-volt battery with the marking code 6LP3 is not recommended for use in the T34™ pump, as this type of battery has a higher internal resistance which could negatively impact the operation of the pump. Please refer to the T34™ Operator Manual for more information.

Actions Required :

1) All CME's T34™ Ambulatory Syringe Pumps, need a foam pad added to the battery compartment. Please order the necessary kits:

    a. **Kit no. OKT00009,** (containing 1 battery insertion label, 4 pre-cut foam pads and the Technical Bulletin SB05309)

    b. **Kit no OKT00010**, (containing 10 battery insertion labels, 20 pre-cut foam pads and the Technical Bulletin SB05309)

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2) If you are no longer in possession of the CME's T34™ Ambulatory Syringe Pumps affected by this Field Safety Notice, please pass this notice and all the related documentation on to the current user(s).

Should you have any questions or require assistance relating to this Field Safety Corrective Action, please contact your Local CME Distributor.

We sincerely apologise for any inconvenience this action may have caused you or your staff.

Sincerely,

Sharon Bukay

Sr. Quality Manager

CME/BD

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Appendix I: Distributor Confirmation Form

Important Update to Field Safety Notice FSN2018-001 issued 07 March 2018 and 4 September 2018

Ref: FSN2018-001_Updated

Product Name:	T34 Ambulatory Syringe Pump
Product Code:	Pumps - 100-100PSM, 100-100SM, 100-100PSMLTR, X100-100SM
Batch Numbers:	All T34 Syringe Drivers
Date:	January 2019

Please complete the following information:

Name of Distributor	
Distributor Address	
Telephone Number	
Name	
Signature	
Date	

If you have affected syringe pumps in your possession and/or if you have distributed any affected syringe pumps listed in this Field Safety Notice to your customers, please confirm the following by checking the boxes:

☐ I have read and understood the contents of this Field Safety Notice

☐ I confirm I will take the required action for all affected syringe pumps in my possession and for all affected syringe pumps that I have distributed to my customers

If you have no affected syringe pumps in your possession and/or if you have not distributed any affected syringe pumps listed in this Field Safety Notice to your customers, please confirm the following by checking the boxes:

☐ I have read and understood the contents of this Field Safety Notice

☐ I confirm that our facility/customers **do 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.
Please return your completed Acknowledgement Form to:
Local CME representative: eva.partas@bd.com