Caesarea Medical Electronics

To whom it may concern

FSN2018-001_Updated – Foam Pad remediation on T34 ™ Ambulatory Syringe Pump

Please take into consideration which information is applicable to your organization. Difference exist for NHS Trust vs. Non-NHS Trust organizations

➔ For NHS Trust customers: FSN pages **2 to 5** are applicable.
➔ For Non-NHS customers: FSN pages **6 to 11** are applicable.

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Caesarea Medical Electronics

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

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

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 users 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 that the battery rests securely against the battery 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.

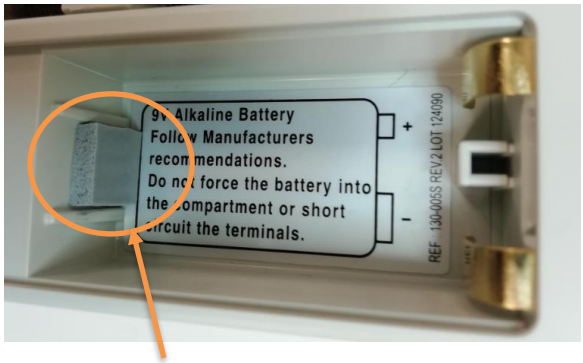

Figure 1 : new foam pad added to the battery compartment

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.

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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.

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 T34™ 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.

2) Complete and return the attached Acknowledgement Form (Appendix I) to CME using the instructions provided.

3) You should order one of the following kits once you have completed and returned the Acknowledgement form to CME:

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

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

A CME representative will contact you to arrange deliveries of the kits after you have placed your order. Upon your receipt of the new kit, follow the T34 Technical Bulletin for installing the foam pad in the battery compartment.

Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organization.

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).

Your competent authority has already been notified of this Field Safety Corrective Action by a CME representative.

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

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

Sincerely,

Sharon Bukay

Sr. QA Manager

CME/BD

Caesarea Medical Electronics

Appendix I: NHS Trust Acknowledgement 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 Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	
Date	

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.

If your facility has any of the affected syringe pumps listed in this Field Safety Notice, please confirm the following by checking the box:

☐ The customer facility will carry out the Foam pad remediation to the battery compartment. I confirm to bear the responsibility of correcting all the pumps in my possession as described in this Field Safety Notice. I will follow the T34 Battery Foam Pad and Battery Cover Instructions Label Procedure in the Technical Service Bulletin.

Please return your completed Acknowledgement Form to:

Local CME representative : cmefsn0119@cmemedical.co.uk

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

Ref: FSN2018-001_Updated

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

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Batch Numbers:	All T34 ™ Syringe Drivers
Date:	January 2019

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Dear valued customer,

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CME is undertaking a corrective action to inform users 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 battery 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.

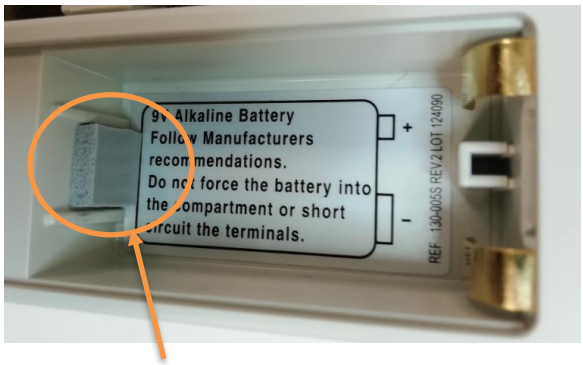

Figure 1 : new foam pad added to the battery compartment

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.

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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.

Update to T34™ Operator Manual

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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 T34™ 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. There are two options available to add the foam pad:

    a) **Option 1**: CME to remediate – 1a. either pump is sent to depot or 1b. Field Service Engineer to visit

    b) **Option 2**: For the customer to order the foam pad kits and remediate themselves

    Consider what option is best for your facility/devices.

2) Complete and return the attached Acknowledgement Form (Appendix I) to CME using the instructions provided. On the Acknowledgement Form you will be required to select either **Option 1** or **Option 2**.

b) For **Option 1**, a CME representative will contact you upon receipt of your completed Acknowledgement Form to schedule an appointment or the device return pending your preferred option (1a or 1b)

c) For **Option 2**, upon CME's receipt of your completed Acknowledgement Form, you may order one of the following 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)

A CME representative will contact you to arrange deliveries of the kits after you have placed your order. Upon your receipt of the new kit, follow the T34 Technical Bulletin for installing the foam pad in the battery compartment.

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Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organisation.

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).

Your competent authority has already been notified of this Field Safety Corrective Action by a CME representative.

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

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

Sharon Bukay

Sr. QA Manager

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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 Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	
Date	

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.

If your facility has any of the affected syringe pumps listed in this Field Safety Notice, please confirm **one** of the following options;

☐ **Option 1**: CME to carry out the remediation work for the Foam Pad to the battery compartment.
Preferred option: 1a. pump is sent to Depot ☐
1b. Field Service Engineer to visit ☐

☐ **Option 2**: The customer facility will carry out the Foam pad remediation to the battery compartment.

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I confirm to bear the responsibility of correcting all the pumps in my possession as described in this Field Safety Notice. I will follow the T34 Battery Foam Pad and Battery Cover Instructions Label Procedure in the Technical Service Bulletin.

Please return your completed Acknowledgement Form to:

Local CME representative : cmefsn0119@cmemedical.co.uk