1030 Eskdale Road
Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

February 5, 2021

URGENT: FIELD SAFETY NOTICE – MMS-21-3992

T34™ Ambulatory Syringe Pumps
3rd Editions
Serial numbers: All Serial Numbers

Type of Action: Advisory

Attention: Clinical Engineering Managers, Clinical Personnel, Risk Managers

This letter contains important information which requires your attention.

Dear Customer,

BD is issuing this field safety notice to advise of an update being made to the Directions for Use (DFU) for the **3rd Edition T34™ Ambulatory Syringe Pumps**. Our distribution records indicate that your organisation may have received impacted pumps.

Description of the Problem

BD has become aware through customer feedback that if the T34™ 3rd Edition Ambulatory Syringe Pump is stored without the main 9V battery for several days or weeks, it may result in partial or full depletion of the 3V internal battery. The 3V battery powers the internal real-time clock. The 3V depletion may trigger two different issues: "Timer's battery fail" alarm and real-time clock time lag/delay.

To address the issue, BD is communicating an update to information in the Directions for Use for the 3rd Edition T34™ Ambulatory Syringe Pumps (DFU999-103EN Rev. 04). The following 2 statements are to be used in addition to the current DFU contents.

Section 1.7 - Syringe Pump and Unpacking

> ***Verify that the date and time are accurate before starting the infusion by checking the last entry in the event log. If the date and time are not correct, adjust the date and time per Section 5.6 of the DFU (Practice Scenarios for Changing Pump Configuration).***

Section 8.3 - Pump Storage

> ***If the pump is stored without a 9V battery verify the date and time are accurate before starting the infusion by checking the last entry in the event log. In the case, date and time is not correct, please adjust date and time accordingly.***

Programming and running an infusion isn´t dependent on a properly set internal Real Time Clock and it will not cause any safety risks for patients if the internal Real Time Clock is not properly set. The clock is not visible from the main screen of the pump, the time lag will be noticed in the Event log only (directly in Events Log option in the pump menu or via BodyComm™). Although the time and date would be incorrect, the sequence and the time between events would be correct.

The event log can be impacted by an incorrect internal Real Time Clock. This may have an impact on clinical investigations and audit trails, requiring event log timings, if the Real Time Clock is not correctly set, however, the investigator would still be able to obtain data to assist any investigation. BD has issued the following Technical Service Bulletin (TB08675 Rev. 00) on how to resolve any time lag issues associated with the event described above.

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Advice on actions to be taken by the user

1. Ensure the contents of this Field Safety Notice including the contraindications are read and understood by those within your organisation who may use or service the 3rd Edition T34™ Ambulatory Syringe Pumps.
    - If you have further distributed the pumps to other organisations, please identify those organisations and notify them at once of this Field Safety Notice.

2. Append Attachment 1 of this Field Safety Notice to your current Directions for Use (DFU999-103EN Rev. 04) for the 3rd Edition T34™ Ambulatory Syringe Pumps in your possession.

3. Please complete the Customer Acknowledgement Form (Page 3) and return the completed form to BD at T34FieldAction@bd.com no later than **5th March 2021**.

4. If you are no longer in possession of or no longer use the 3rd Edition T34™ Ambulatory Syringe Pumps, please indicate this on the response form and return to BD so we may update our records.

Should you have any questions or experience any issues associated with the product or issue described in this Field Safety Notice, please contact T34FieldAction@bd.com. We confirm that the appropriate regulatory agencies have been informed of these actions.

BD 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.

Yours sincerely,

Lorna Darrock
Senior Manager, Post Market Quality EMEA

Attachment 1: Updated Information for 3rd Edition T34™ Ambulatory Syringe Pumps DFU
Attachment 2: Technical Bulletin - T34™ 3V Battery Depletion Effects on Real-Time Clock (TB08675 Rev. 00)

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Customer Acknowledgement Form – MMS-21-3992

T34™ Ambulatory Syringe Pumps

Please read in conjunction with Field Safety Notice MMS-21-3992 and return the completed and signed form as soon as possible or **no later than 5th March 2021** to T34FieldAction@bd.com.

By completing the information below you confirm you have read, understood and distributed the contents of this Field Safety Notice accordingly.

Name of Trust / Organisation			
Your Facility Address			
Postcode		**Type of establishment** *(please select)*	☐ Hospital / Acute ☐ Homecare / Hospice ☐ Other
Telephone number		**E-mail address**	

	Facility / Hospital Name	**Postcode**
Please list all Facilities / Hospitals covered by this response *(e.g. other hospitals within your Trust)* Please continue on another sheet if required.		

Number of T34™ 3rd Edition Pumps covered by your response (approx.)	
We have no T34™ 3rd Edition Pumps in our possession. Please remove the above establishment from BD/CME records (*please tick box*)	☐

Your Name			
Signature		**Date**	

Please return your completed and signed Acknowledgement Form to: T34FieldAction@bd.com

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Attachment 1: Updated Information for 3rd Edition T34™ Ambulatory Syringe Pumps DFU

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