1030 Eskdale Road
Winnersh Triangle
Wokingham
RG41 5TS
Tel : 0800 090 2460 (GB)
www.BD.com

7th September 2020

URGENT: FIELD SAFETY NOTICE – MMS-20-3887

T34 ™ Ambulatory Syringe Pumps
2nd and 3rd Editions
Serial numbers: All Serial Numbers

Type of Action: Advisory

Attention: EBME / Clinical Engineering Managers, Clinical Personnel, Community Nursing Teams, Risk Managers, Care Home Managers, End of Life Care Providers (e.g. Hospices)

This letter contains important information which requires your attention.

Dear Customer,

BD/CME is issuing this advisory Field Safety Notice to inform users of the T34™ Ambulatory Syringe Pumps of important updates related to the use of different brands of 9V/ 6LR61 batteries commonly used in the T34™ device.

Description:

Customers have reported to BD/CME occurrences of early/premature 9V/6LR61 battery voltage drops when using T34™ 2nd and 3rd edition devices causing the following during infusion:

- Premature “low battery” alarms
- Premature “end battery” alarms
- Unexpected pump shut down with or without alarm

These occurrences of early/premature 9V/6LR61 battery voltage drops have the potential to cause interruption to infusions.

BD/CME has determined the root cause of early/premature 9V/6LR61 battery voltage drop is related to brand-to-brand variation in the internal resistance in 9V/6LR61 batteries.

Actions Required of T34™ Pump Users:

1. ***For devices currently in clinical use***, BD/CME recommends that customers use the battery brand:
   - Duracell Plus

   NOTE: If the recommended battery brand is not available, other battery brands 9V/6LR61 may still continue to be used with the device but with increased infusion monitoring to detect and react to potential early/premature alarms during infusion. BD has identified the probability of early/premature alarms may be higher for some non-recommended batteries.

2. ***For devices that have NOT YET been commissioned/put into clinical use***, these devices shall NOT be put into service until BD/CME has performed in-field monitoring of battery performance. BD/CME will notify customers once non-commissioned devices may be put into clinical use.

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3. Read and distribute this FSN and ensure that all the contents are understood by those within your organisation who need to be aware.
    - If you have further distributed this device/s, please identify those users and notify them at once of this advisory Field Safety Notice.

4. Return the signed and completed Customer Acknowledgement Form to T34FieldAction@bd.com no later than the **September 30, 2020.**
    - BD/CME will contact your facility regarding non-commissioned pumps with further information when available.

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

Should you have any questions or require assistance relating to this Field Safety Notice, please contact your local BD/CME representative or phone **0800 090 2460 (GB)**. We confirm that the appropriate regulatory agencies have been informed of these actions.

BD/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.

Yours sincerely,

William David
Senior Director Quality Compliance EMEA

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Customer Acknowledgement Form – MMS-20-3887

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Please read in conjunction with Field Safety Notice MMS-20-3887 and return the completed and signed form as soon as possible or **no later than the September 30th, 2020** 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 *(if applicable)*			
Name of all Facilities / Hospitals covered by this response *(e.g. other hospitals within your Trust)*			
Facility / Hospital address			
Postcode		**Type of establishment** *(please select)*	☐ Hospital / Acute ☐ Homecare / Hospice ☐ Other
Telephone number		**E-mail address**	
Name			
Signature		**Date**	

Please complete the following for BD/CME to process your response as quickly as possible:

Number of T34™ Pumps in your possession that are in or available for Clinical Use (approx.)	
Number of T34™ Pumps in your possession that are NOT yet commissioned for / in Clinical Use (approx.)	
I have no T34 pumps in our possession / no longer in Clinical use and these have been disposed of. Please remove the above establishment from BD/CME records (*please tick box*)	☐

For future communications from BD/CME on non-commissioned T34™ devices, please provide contact details below if different from above:

Name	Telephone	E-mail

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