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16th December 2019

URGENT: FIELD SAFETY NOTICE – MMS-20-1907

T34™ Syringe Pump, 3rd Edition

All Serial Numbers

Type of Action: Advisory - Updated Directions for Use

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your **immediate** attention.

Dear valued Customer,

BD/CME is issuing an advisory Field Safety Notice for the T34™ Syringe Pump, 3rd edition (Figure 1). According to our distribution records your organisation may have received the impacted product which BD/CME distributed ***between February 2019 to December 11, 2019***.

Figure 1: T34™ Syringe Pump, 3rd edition

Description of the Problem

Based on feedback relating to the T34™ Syringe Pump, 3rd edition, BD/CME has undertaken an extensive internal review of the Directions for Use (DFU). As a result, the DFU has been updated and a summary of these changes are provided in Appendix 1.

An electronic version of the updated Directions for Use is available at:

https://www.bd.com/en-uk/products/infusion/infusion-devices/cme-ambulatory-infusion-systems/t-series-syringe-pumps/t34-ambulatory-syringe-pump-3rd-edition

BD will send hard copies of the Directions for Use on receipt of the Customer Response Form (page 3).

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Actions for Customers to take:

1. Circulate this Field Safety Notice to all those within your organisation that may use the 3rd Edition, T34™ Syringe Pump.

2. If you have further distributed the product, please identify those users and notify them at once of this Field Safety Notice.

3. Complete the Customer Response Form on page 3 and return it to <<insert contact details here>> **as soon as possible or no later than the 10th January 2020.** If you do not have the product in your possession, it is still important that you return the Customer Response Form for our reconciliation purposes.

4. On receipt of the updated DFU, replace all previous 3rd edition, T34™ syringe pump DFUs in your possession and provide copies of the DFU to your end customers.

5. As per your organisation's processes, please continue to monitor use of the 3rd edition, T34™ Syringe Pump and report any issues to BD/CME.

There is no requirement for customers to return any T34™ Syringe Pump, 3rd edition to BD. These products can continue to be used in accordance with the updated Directions for Use.

Contact Reference Person

If you have any questions about this, please contact your local BD/CME representative or the local BD/CME office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

BD/CME is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD/CME to resolve this matter as quickly and effectively as possible.

Sincerely,

Sharon Burkay
Sr. Quality Manager,
BD/CME Israel

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Customer Response Form – MMS-20-1907

T34™ Syringe Pump, 3rd Edition

Please read in conjunction with Field Safety Notice MMS-20-1907and return the completed and signed form as soon as possible or **no later than the 10th January 2020** to <*<insert fax/email address here>>*.

By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Account/Organisation Name:	
Department *(if applicable)*:	
Address:	
Postcode:	**City:**
Contact Name:	
Job Title:	
Contact Telephone Number:	**Contact E-mail Address:**
Signature:	**Date:**

If different to above, please provide below the best contact name, address and telephone number for BD/CME to send hard copies of the updated Directions for Use (DFU) for the T34™ Syringe Pump, 3rd edition. This information is required to courier the updated DFUs to the relevant locations.

Number of DFUs required: ……

Name	**Job Title**	**Telephone**	**Email**
Address			

This form must be returned to BD/CME before this action can be considered closed for your account.

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Appendix 1 – Summary of Changes to Directions for Use

Type of change	Description of the change	Pages in the DFU
Revisions-Inconsistencies Related	Information on battery life was revised	10, 17
Revisions-Inconsistencies Related	The bolus parameters were revised to include accurate flow rates increments	10, 29
Revisions-Inconsistencies Related	The warning referring to BodyGuard™ was removed	5
Revisions-Inconsistencies Related	The reference to “maintenance and service in accordance with this manual” was removed	6
Revisions-Inconsistencies Related	The reference to colour coded sets was removed	14
Revisions-Inconsistencies Related	The section 3.1 ”overview” was reworded to separate “features” and “safety features”	19
Revisions-Inconsistencies Related	The section 8.2 “cleaning” was revised to ensure clear instructions are provided to caregiver and address disinfection	54
Revisions-Inconsistencies Related	T34™ Syringe Pump dimensions were corrected	10
Revisions-Inconsistencies Related	T34 2nd ed. images were replaced with 3rd ed. images	across document
Revisions-Inconsistencies Related	The default syringe brands table was revised to remove Monoject 50	13
Revisions-Inconsistencies Related	“Indication to change a battery” note was revised to include reference to flow rate	16
Revisions-Inconsistencies Related	Information with regards to Max. KVO volume were added	31
Clarification	3rd ed. reference was added to avoid confusion	1-pages header
Clarification	Symbols description were clarified	7-9
Clarification	Battery type warning was revised to include battery types not to use	16
Clarification	“Time to Alarm” on “Occlusion and Response” section were reworded to eliminate ambiguous terms and reference to the time to alarm specification table was added	23
Clarification	Step # 1 & 2 were added to the purge sequence for clarification	31
Clarification	The wording was revised on “Operating Precautions and Warnings”, “Infusion Precautions and Warnings” and “General Precautions and Warnings” sections	6,7
Clarification	A note with regards to “Load and Prime” was added to ensure full data is provided	25, 42
Naming convention	“DFU” or “Manual” were replaced with “Directions For Use”	across document
Naming convention	“Pump” or “Pump System” “Infusion Pump” were replaced with “T34™ Syringe Pump”	across document
Naming convention	"IV line” or “Set” or “Administration Set” or “Delivery Tubing” or “Extension Line” were replaced with “Syringe Extension Sets”	across document