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

May 17, 2021

URGENT: FIELD SAFETY NOTICE – MMS-21-3999

T34 ™ Ambulatory Syringe Pumps
3rd Edition
Serial numbers: S00402878 and onwards

Type of Action: Field Work

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 a software upgrade for certain serial numbers of **3rd Edition T34™ Ambulatory Syringe Pumps** to enhance the battery life of the pumps. Our distribution records indicate that your organisation may have received impacted pumps.

Description of the Problem

Through customer feedback, BD has identified that the battery life of the **3rd Edition T34™ Ambulatory Syringe Pumps** may not meet customer expectations and clinical workflow. As a result, BD has taken the decision to upgrade the **3rd Edition T34™ Ambulatory Syringe Pumps** on the market to align with the battery life of the newly released **BD Bodyguard T™ pump** (refer to Table 1)**.**

	T34 3rd Edition – DFU999-103EN	**BD BodyGuard™ T – DFU999-103BDEN**
Rate	Approximate battery life	Operating Time
1ml / hr	25 hrs	> 50 hrs
5 ml / hr	20 hrs	> 35 hrs

Table 1: Operating time of T34 3rd Edition and BD Bodyguard T™

Clinical Risk

The battery life of the 3rd Edition T34™ Ambulatory Syringe Pumps is functioning as designed and as intended. The Directions for Use for the 3rd Edition pumps also describes the correct functioning. A potential risk exists if the User expects the device to function as a 2nd Edition T34™ Ambulatory Syringe Pump which has a longer battery life. This risk is expected to be low as in a hospital environment the Clinical User will be present and, in a homecare setting the infusions are mostly set up for 24 hours or less. The risk will be further mitigated through the software upgrade as the battery life of the pump will be increased (approx. 2x).

Corrective Actions By BD

Serial numbers within the range S00402878 and onwards are in scope of this software upgrade and will be issued a new version of the Directions for Use (DFU) once upgraded. Please refer to Appendix 1 for guidance on identifying the serial number on your 3rd Edition T34™ Ambulatory Syringe Pump.

Note: The serial numbers within the range S00402877 and previous are not in scope of the software upgrade. Per the customer letter dated November 16th, 2020, these pumps are being swapped out as part of remediation activities of the previous FSN MMS-19-1572. Please refer to Appendix 2 for an overall summary of remediation activities on the 3rd Edition T34™ Ambulatory Syringe Pumps. If you require a copy of the forementioned customer letter, contact BDT34replacement@bd.com.

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Advice on actions to be taken by the user

1. Ensure the contents of this Field Safety Notice 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. Please complete the Customer Reply Form (Page 3) indicating whether you wish the software upgrade of the pumps to be performed by BD (**Option 1**) or by your organisation/service provider (**Option 2**) and return the completed form to BD at T34FieldAction@bd.com no later than **15th June 2021**.

    - If selecting **Option 1**, a BD representative will contact you upon receipt of your completed Customer Reply Form to discuss BD scheduling the software upgrade.
    - If selecting **Option 2,** a BD representative will contact you upon receipt of your completed Customer Reply Form to discuss providing the instructions to conduct the software upgrade activity.

3. All sites that receive the software upgrade will also receive new Directions for Use (**DFU999-103BDEN**) for the pumps
    - Once your pump receives the software upgrade, BD recommends destroying all previous version of the T34 3rd Edition DFU (**DFU999-103EN**) in your possession
    - Users can identify on the pump that the software has been upgraded as the display on the pump will display the new software version (per Figure 1 below)

Figure 1: Display of pump with updated software

Contact Reference Person

Should you have any questions about this please contact your local BD representative. Clinical training will be provided as part of the software roll-out to provide information on other pump changes implemented as part of the upgrade. If you experience any issues with the software following the pump upgrade, please contact bd-blackpool-customersupport@bd.com.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD 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 to resolve this matter as quickly and effectively as possible.

Thank you for your attention and cooperation.

Yours sincerely,

Lorna Darrock
Senior Manager, Post Market Quality, BDX EMEA

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Customer Reply Form – MMS-21-3999

T34™ Ambulatory Syringe Pumps

Please read in conjunction with Field Safety Notice MMS-21-3999 and return the completed and signed form as soon as possible or **no later than 15th June 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 or Organisation			
Your Facility / Hospital address			
Postcode		**Type of establishment** *(please select)*	☐ Hospital / Acute ☐ Homecare / Care / Hospice ☐ Other ……
Telephone number		**E-mail address**	

	Facility / Hospital Name	**Postcode**
Please list all Facilities / Hospitals covered by this response *(e.g. other sites within your Trust or Organisation)*		
Continue onto another page if required.		

Please check (✓) one of the following options:

Option 1: We require BD to perform the software upgrade, please contact us **using the details below** *(if different from above)* ☐	**Option 2:** We/Our service provider will perform the software upgrade, please contact us **using the details below** *(if different from above)* ☐

*For both of the above options, attach a list of the serial numbers in your possession within the range **S00402878 – onwards**. This is required in order for BD to process your request.*

OR - I confirm that our facility **does not have any** of the pumps in scope of this Field Safety Notice. ☐

Contact Name	**Job Title**	**Telephone**	**Email**
Address			**Submit Form**

Please return your completed Customer Reply Form to: T34FieldAction@bd.com
This form must be returned to BD before this action can be considered closed for your account.

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Appendix 1: Identification of the serial number on the reverse of T34™ Ambulatory Syringe Pumps

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Appendix 2: Remediation Guide for 3rd Edition T34™ Ambulatory Syringe Pumps

Serial Numbers	Manufacture Dates	Remediation Summary
S00402877 and previous	September 2018 to May 2020	Under scope of the previous FSN **MMS-19-1572** GB: https://mhra-gov.filecamp.com/s/flZdLhcA50zFqbpA/d Pumps will be swapped for BD BodyGuard T™
S00402878 and onwards	May 2020 onwards	Under scope of the current FSN **MMS-21-3999** Pumps will receive a software upgrade and a new Directions for Use (DFU)