T34 3RD EDITION DEVICES
MEDICAL DEVICE ALERT
FAQ UK

November, 2019
1. **Is the hold imposed by any Authority?**
   The hold was voluntarily initiated by BD after MHRA (UK Competent Authority) raised concerns related to CME 3rd Edition. T34™ syringe pump DFU language and companion software (BodyComm™ V3.0) compatibility. The hold remains in place until the relevant DFU has been updated and the BodyComm™ training released.

2. **Are T34™ 3rd Edition pumps safe to operate?**
   T34™ 3rd Edition Syringe pumps can be used when it is determined to be clinically appropriate. In the UK, further direction about device operation has been provided by MHRA in the published MDA and FAQ.

3. **Does the action affect only new product shipments, or does it also include devices already placed on the market?**
   The MHRA MDA impacts all T34™ 3rd Edition devices placed on the UK market and prevents new devices to be installed in the UK until the issues highlighted in the MDA have been resolved.

4. **What about products already in distributors’ warehouse or otherwise available in the distribution chain?**
   T34™ 3rd Edition pumps in the BD distribution chain are also impacted by this action and therefore are prevented to be used in the UK.

5. **Are T34™ 2nd Edition pumps affected as well?**
   No, only T34™ 3rd Edition pumps are affected.
6. How do we differentiate a 2nd Edition T34™ versus a 3rd Edition T34™?

One key visual differentiator is the keypad (icons vs. text)

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7. What has changed in 3rd Edition vs. 2nd Edition pump?

The key changes are:

- Hardware and software updates to ensure standard compliance with IEC 60601-1 Edition 3.1 (priority alarms, redundancy etc.)
- New BodyComm™ V3.0 technical utility software
- IP22 rating
- Intended use to include immunoglobulins and biosimilars
- Intended use to exclude epidural indication
- Bolus function
- Flow rate increments and KVO rate range updates
- Battery life claim update to 25h @ 1ml/h and 20h @ 5ml/h
- New battery connectors design
- Rechargeable back-up battery
- Additional tests (sound, alarm, LED0 available in boot-up and Technician Mode)
- New DFU and Quick Reference Guide

Please refer to the following document containing a detailed overview of the implemented changes:
8. What is the issue with BodyComm™ compatibility?

BodyComm™ V3.0 Software should be used with T34™ 3rd Edition devices:

- This optional technical utility software has been upgraded for optimal use with T34™ 3rd Edition pumps. The BodyComm™ V3.0 Software is not compatible with 2nd Edition T34™ pumps and therefore must not be used in this configuration.

- Previous versions of BodyComm™ (V88 to V102) are not compatible with T34™ 3rd Edition pumps and therefore must not be used in this configuration.

9. Is the updated version of BodyComm™ available?

Yes, BodyComm™ V3.0 is available. Please contact T34™ Hotline, Telephone 01253 20 66 22 or email BDUKGCSAction@bd.com to obtain and get training and certification.

10. Is there a BodyComm™ training available?

Yes, our Global Customer Service can assist you upon request.
11. Is there a 3rd Edition T34™ device training available?

We have designed a new Quick Reference Guides to help user operate the device. In addition, our local representatives will be happy to assist you with any questions and will work with you to schedule the training, if needed.

Furthermore, the following aids will be available in the next coming weeks:
- “Differences between 2nd & 3rd Edition”: A new video available on website from 27th November 2019

12. Will the battery life/performance improve?

BD is investigating how the battery life for 3rd Edition devices could be optimized. BD will communicate if a solution becomes available.

13. What are the changes that need to be implemented in the Directions for Use [DFU]

The instructions for use for this product are referred to as the Directions for Use [DFU]. Primary requested changes relate to the battery life performance claims, but there could be other potential changes based on MHRA’s feedback and BD’s internal review.

14. When will the updated DFU become available?

The DFU is being reviewed by BD and MHRA. This is being given the highest priority. We currently aim to get the revised electronic version approved and released by the end of November. Printed version should become available mid-December.

15. When can we resume the use of T34™ 3rd Edition?

To resume the use of 3rd Edition device in the UK customers need to be trained and certified on the BodyComm™ V3.0 and have access to the updated DFU

ANY ADDITIONAL QUESTIONS ON SHOULD BE REFERRED TO YOUR LOCAL BD REPRESENTATIVE