

DEVICE SAFETY INFORMATION (DSI)

BD BodyComm[™] version 3.3 software used for BodyGuard infusion pumps, BodyGuard-T and T34 syringe drivers: Important steps to manage transition to Windows 11 DSI/2025/006

Specialisms: Electro-biomedical engineering personnel (EBME departments), medical physics, care home staff, critical care, general practice, haematology & oncology, obstetrics & gynaecology, paediatrics, pharmacy, anaesthesia, Community Nursing, palliative care and specialist palliative care; medical device and equipment managers

DEVICE DETAILS

BD BodyComm™ software Software version 3.3

AFFECTED LOT SERIAL NUMBERS

Affects all BodyGuard infusion pumps, BodyGuard-T and CME T-34 syringe drivers which can be configured and serviced with the BodyComm software, and utilise the USB to Serial cable, code 197-100X

MANUFACTURED BY

Manufactured by Caesarea Medical Electronics Ltd (CME), a Becton Dickinson (BD) company.

Summary

The BodyComm software is used for the servicing and set up of the Bodyguard pumps, Bodyguard-T and T34 syringe drivers. These pumps are used for pain management and other infusion therapies.

Windows 10 will no longer be supported by Microsoft from 14th October 2025. An updated cable is therefore required to connect the pumps to BodyComm software, due to the upcoming transition to Windows 11. However, the cables may not be available until after the Windows transition date. This will need effective management to mitigate potential impact to patient treatment.

Advice for Clinical Engineers, EBME staff, Medical Device Managers and MDSOs:

BD have issued a customer letter advising that all impacted customers should take effective action to allow for continuous use of the BD BodyComm 3.3 software.

- Identify whether your site uses the BodyComm software for configuration or servicing of BodyGuard pumps, or for BodyGuard-T and T34 syringe drivers (see device details section).
- 2. If you do have the BodyComm software, ensure the following is in place:
 - A plan to manage service and maintenance of pumps and syringe drivers, which are due for servicing during October 2025 and November 2025 to allow sufficient time to receive the new USB-to-serial cable (OKT00037) for use with Windows 11.
 - Consider updating the service schedule of BodyGuard pumps and BodyGuard-T/T34 syringe drivers to complete servicing prior to Windows 11 updates in your department or;
 - as an alternative, in collaboration with your IT department, consider retaining access to a Windows 10 PC to ensure continued servicing and setup of BodyGuard pumps, BodyGuard-T and T34 syringe drivers. This PC will not need a live internet connection for BodyComm to be used, but will require the old USBto-serial 197-100X cable for connection
 - Should either of the above options not be possible, manual servicing and operation of pumps and syringe drivers remains possible, but is more time consuming.
- 3. In the event of usage disruption consider if alternative pump options can be used for patients treated in hospital to ease the pressure on the usage of BodyGuard pumps and BodyGuard-T and T34 syringe drivers.
- 4. BD will contact you once their new USB to Serial communication cable (product code: OKT00037) for use with Windows 11 and associated instructions for use are ready for release. Once received, ensure the new cable is used as per BD guidance and replace the old communication cable.
- 5. Ensure that the correct cable is used at all times, as the old and new cable are not interchangeable.

Please note, **no** update is required to the infusion pumps themselves (BodyGuard infusion pumps, BodyGuard-T and T34 syringe drivers)

Advice for Healthcare Professionals to Provide to Patients:

The advice in this DSI is aimed at clinical engineering/EBME/medical physics departments, who are responsible for managing the equipment. If you have any concerns about this advice, contact your healthcare professional for assistance.

Patients or caregivers using this device should follow the advice of the patient's healthcare professional.

Advice for Distributors:

N/A

Explanation of identified safety issue

The BodyComm is a configuration software, used to service and set up BodyGuard pumps and BodyGuard-T and T34 syringe drivers efficiently. These pumps can be serviced manually; but this will be more time consuming and may lead to delays in patient treatment.

The MHRA has been made aware of the potential disruption to the servicing and operation of BodyGuard pumps and BodyGuard-T and T34 syringe drivers. This is due to Microsoft ceasing support for Windows 10 from 14th October 2025, and NHS organisations transitioning to implementing Windows 11.

The relevant BD pumps and syringe drivers require a 'USB to Serial' cable provided with the BodyComm version 3.3 software for routine servicing as well as pump setup. The current 197-100X cable is only compatible with Windows 10. BD are working to develop a new 'USB to Serial' communication cable, to allow continued usage of BodyComm 3.3 software with Windows 11.

Operating System	Correct USB to Serial Cable Code
Windows 10	197-100X
Windows 11	OKT00037

The new 'USB to Serial' cable and associated instructions for use are expected to become available at short notice after NHS organisations begin to transition to Windows 11. This DSI is designed to ensure that measures are put in place to avoid any delays to patient treatment.

Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to <u>Incident Reporting & Investigation Centre (IRIC)</u> and their local incident recording system
- in Northern Ireland to the Yellow Card website in accordance with your organisations medical device policies and procedures.

Additional information:

You can <u>sign up</u> to receive email updates on alerts and device safety information from the MHRA.

You can sign up to receive our monthly roundup of safety communications.

For any enquiries, please contact <u>info@mhra.gov.uk</u> or BD <u>Bodyguard-</u>CustomerService@bd.com

Stakeholder engagement:

- NHS England National Patient Safety team
- NHS National Services Scotland
- Welsh Government
- Northern Ireland Department of Health
- NHS England Palliative & End of Life Care Team and Nursing Directorate
- MDSOs