BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 00
Fax: +41 21 556 30 99
www.BD.com

29th November 2023

URGENT: FIELD SAFETY NOTICE – MMS-23-4881

CME/BD BodyGuard™ Infusion Pump Systems

(Large Volume Infusion Pump Systems)

REF: See Appendix 1
Type of Action: Advisory

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel, Purchasing Managers

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

Dear customer,

In August 2021, BD issued a Field Safety Notice (REF: MMS-21-4135) for the large volume **CME/BD BodyGuard™ Infusion Pump systems** regarding potential flow rate issues and BD is now issuing an update to that Field Safety Notice.

Description of the problem

Previously, per Field Action, reference MMS-21-4135, BD updated the following default settings and applied a label to the **CME/BD BodyGuard™ Infusion Pumps**, listed in Appendix 1, as a temporary measure:

- The maximum flow rate was limited to 800 mL/hr when using continuous mode
- The maximum bolus administration rate was limited to 300 mL/hr

BD has now decided to make these permanent features of the CME/BD BodyGuard™ Infusion Pumps. This is because a technical design change has not proven feasible.

Clinical risk

The previous limiting of the flow rates was to remove the risk for a gross under infusion when used at higher flow rates. By making these changes permanent, it is highly unlikely to cause direct patient harm. However, BD recognizes that this change may cause customer inconvenience.

To date, BD has not identified any reports of serious adverse events that could be associated with this issue.

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 00
Fax: +41 21 556 30 99
www.BD.com

There is no requirement for customers to return any CME/BD BodyGuard™ Infusion Pump Systems to BD. These products can continue to be used in accordance with the guidance in this safety notice.

BD Actions:

BD has updated the Directions for Use for the **CME/BD BodyGuard™ Infusion Pumps** to include the Additional Warnings, per Appendix 2.

BD has updated the service instructions for the **CME/BD BodyGuard™ Infusion Pumps** and approved service organisations have been informed via *My BD Learning* (BD Technical Service Portal).

All future shipments will contain the updated Directions for Use.

Actions for Clinical Users:

Append the Additional Warnings, per Appendix 2, to your existing Directions for Use for the **CME/BD BodyGuard™ Infusion Pumps** and circulate within your organisation as required.

Continue to use your **CME/BD BodyGuard™ Infusion Pumps** per the implemented flow rate limitations.

Actions for EBME/Biomedical/Service Organisations

BD approved service organisations should continue to perform all activities on the **CME/BD BodyGuard™ Infusion Pumps** per the current Technical Service Manuals and instructions provided on *My BD Learning* (BD Technical Service Portal).

Customer Actions:

- Review the information in **Appendix 1** to determine if the **CME/BD BodyGuard™ Infusion Pumps**, in your possession are impacted.
    - Ensure the Additional Warnings, per Appendix 2, are appended to your existing Directions for Use for the **CME/BD BodyGuard™ Infusion Pumps** and circulate within your organisation as required.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 4th January 2024**.
- Circulate this notice to all those who need to be aware within your organisation or to any organisation where the potentially affected product has been transferred.
- If you experience any issues please report as a complaint as per your normal process.

Distributor Actions:

- Review the information in Appendix 1 to determine if the **CME/BD BodyGuard™ Infusion Pumps**, in your possession are impacted.

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 00
Fax: +41 21 556 30 99
www.BD.com

- Ensure the Additional Warnings, per Appendix 2, are appended to the existing Directions for Use for the **CME/BD BodyGuard™ Infusion Pumps**.

- Identify the facilities where you have distributed affected product and notify them immediately of this notice.
  - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **4th January 2024**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- If you experience any issues please report as a complaint as per your normal process.

	End User with Inventory	End User with ZERO inventory	Where to send completed form
Purchased **directly** from BD	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	<<insert contact email address here>>
Purchased from a **distributor/3rd party**	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	Return the form to your distributor/3rd party

Contact reference person

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

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.

Sincerely,

Lorna Darrock
Associate Director, Post Market Quality
EMEA Quality

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 00
Fax: +41 21 556 30 99
www.BD.com

Customer Response Form – MMS-23-4881

CME/BD BodyGuard™ Infusion Pump Systems

(Large Volume Infusion Pump Systems)

REF: See Appendix 1

Return to **<< insert email address>>** as soon as possible or **no later than the 4th January 2024**.

By signing below, you confirm this Field Safety 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:**
Name of your supplier for this product *(if not direct from BD)**	
Signature:	**Date:**

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

**If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 00
Fax: +41 21 556 30 99
www.BD.com

Appendix 1 – BodyGuard™ Infusion Pump System Portfolio

Manufacturer's SRN: IL-MF-000030321

	Single channel	Multi-channel
CME brand *(Only 2nd Edition exist)*	BodyGuard™ 323 BodyGuard™ 575 BodyGuard™ 545 BodyGuard™ 595 BodyGuard™ 575 Color Vision	BodyGuard™ 121 Twins BodyGuard™ Quadro
CME brand *(2nd and 3rd Edition)*	BodyGuard™ 323 Color Vision BodyGuard™ 545 Color Vision BodyGuard™ 595 Color Vision	
BD brand	BD BodyGuard™ BD BodyGuard™ Pain BD BodyGuard™ Epidural	BD BodyGuard™ Duo

For a full list of product codes (REF) please contact <<insert contact email address here>>

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 00
Fax: +41 21 556 30 99
www.BD.com

Appendix 2 - BD/CME BodyGuard™ Infusion Pumps Directions for Use Additional Warnings.

Warning: Use of the Infusion Pump at high infusion rates has an increased risk of under-infusion above the reported accuracy. It is recommended not to use the infusion pump above 800 mL/hr.

Warning: The infusion rate for bolus administrations is set to a maximum bolus rate of 300 mL/hr as there is an increased risk of severe under-infusion. The use above 300 mL/hr is not recommended.