1030 Eskdale Road
Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

3rd March, 2021

URGENT: FIELD SAFETY NOTICE – MMS-20-3893

BD BodyGuard™ Duo Infusion Pump

Product Codes: 999-903EN; 999-903ES; 999-903IT

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 initiating this Field Safety Notice for the BD BodyGuard™ Duo infusion pump to advise of a required software upgrade.

Description of the Problem

During an internal product review, BD has identified 2 potential situations for the BD BodyGuard™ Duo infusion pump for which a software remediation is required:

Situation 1 – In Intermittent program only, pausing a dose delivery before the programmed volume has been delivered, could administer two consecutive intermittent doses right after another, leading to an over infusion.

Situation 2 – The EOI (End of Infusion) with KVO (Keep Vein Open) triggers a medium priority alarm instead of high priority alarm, as specified in the Directions for Use (DFU). The current EOI medium priority alarm may also cause confusion with NEOI (Near End of Infusion) which is a low priority alarm; both have the same auditory signal.

It is important to note that BD has not received any reported events to date relating to either of these two situations. Please refer to the Attachments of this Field Safety Notice for detailed information on each situation.

A software upgrade has been developed for the BD BodyGuard™ Duo infusion pump that will be released during 2021, following approval by the Notified Body. The software upgrade will be a mandatory upgrade for all pumps in the market. This software and the updated pump DFU will eliminate the two situations listed above.

Advice on actions to be taken by the Customer:

1. Ensure the contents of this Field Safety Notice, including the attached information on the 2 situations, are read and understood by those within your organisation who may use the BD BodyGuard™ Duo infusion pump.
    - If you have further distributed the product to other organisations, please identify those organisations and notify them at once of this Field Action.

2. Please complete the Customer Acknowledgement Form (Page 3) indicating whether you wish the software upgrade on the pumps to be performed by BD (**Option 1**) or by your organisation (**Option 2**) and return the completed form to BD at BDUKFieldAction@bd.com o later than March 31st, 2021.

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- If selecting **Option 1**, a BD representative will contact you upon receipt of your completed Customer Acknowledgement Form to discuss BD scheduling the software upgrade.

- If selecting **Option 2**, a BD representative will contact you upon receipt of your completed Customer Acknowledgement Form to discuss the equipment and training for the software upgrade.

NOTE: For options 1 and 2, all equipment and remediation activities for this software upgrade will be provided free of charge by BD.

3. If you are no longer in possession of or no longer use the BD BodyGuard™ Duo infusion pump, please indicate this on the Customer Acknowledgement Form and return it to BD so we may update our records.

Should you have any questions or require assistance relating to this Field Safety Corrective Action, please contact BDUKFieldAction@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 and user safety and providing you with quality products. We apologise for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours sincerely,

Lorna Darrock
Senior Manager Post Market Quality, EMEA

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Customer Acknowledgement Form – MMS-20-3893

BD BodyGuard™ Duo Infusion Pump – Software Upgrade

Please read in conjunction with Field Safety Notice MMS-20-3893 and return the completed and signed form as soon as possible or **no later than March 31st, 2021,** to BDUKFieldAction@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 / Organisation			
Your Facility Address			
Postcode			
Telephone number		**E-mail address**	
Name of your supplier for this product *(if not direct from BD)*			

Number of BodyGuard™ Duo Infusion Pumps in your possession (approx.):	
OR* - *Our facility does NOT have any of the pumps listed in this Field Safety Notice (check):	☐

Please check (✓) one of the following options:

Option 1:	BD to perform the software upgrade, **please provide contact details below** *(if different from above)* ☐	**Option 2:**	Your organisation/service provider will perform the software upgrade, **please provide contact details below** *(if different from above)* ☐

Name:	**Job Title:**	**Telephone:**	**E-mail:**
Address:			

Your Name		**Job Title**	
Signature		**Date**	

Please return your completed and signed Customer Response Form to: BDUKFieldAction@bd.com.

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

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Situation 1: Issue if a dose is paused in Intermittent program

Issue: In Intermittent program only, pausing a dose delivery before the programmed volume has been delivered, could administer two consecutive intermittent bolus doses right after another, leading to an over infusion.

Overview of situation
Per Section 5.6.4 of the current Directions for Use, the Intermittent program delivers a dose at set intervals. Each dose is given at a set time. The pump will run in KVO mode between the doses. The program continues until the total volume to be infused is delivered.

If the pump is turned off during intermittent program, the internal clock continues to monitor the timing of the infusion. Refer to Figure 1 below for an outline of the intermittent program. Basically, the pump will try to keep the interval time (T1) consistent across the infusion program. A software upgrade will be rolled out by BD to ensure that any pause of the dose duration (T2) is added to the interval duration (T1). Until then BD advises Users of the following, if using the Intermittent Program:

- If the pump is stopped during a dose (T2), the operator will be able to resume the remaining time. The pump will keep the interval time (T1) fixed. In the case of a short interval time, the KVO time (T3) will be reduced by the time of the interruption (Figure 2).
- If the pump is stopped during a dose (T2) and restarted after the next scheduled dose time has passed, the pump will start the next dose immediately from the beginning followed by a complete interval as set by the operator. It will not administer the remaining previous dose.
- If the pump is stopped during the Intermittent KVO (T3), the user can restart the pump any time before the next scheduled dose without impacting the infusion program. If the pump is restarted after the next scheduled dose, the pump will start with the next dose immediately followed by a complete interval (T3).

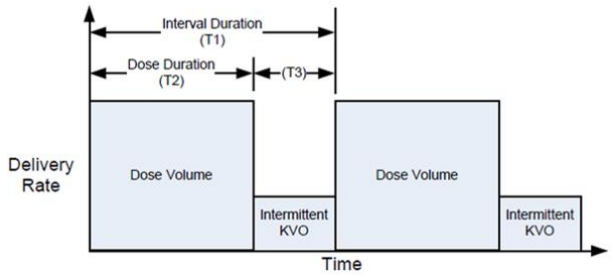

Figure 1: Outline of Intermittent program – without pausing dose delivery

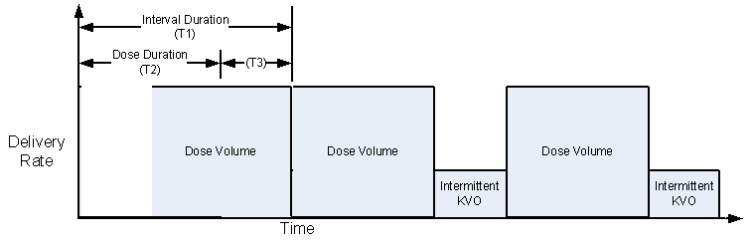

Figure 2: Outline of Intermittent program – pausing and restarting a dose delivery

Immediate Action for Clinical Users:

- Ensure the contents of this FSN and the information listed above regarding use of the pump in Intermittent Program are understood by Users of the BodyGuard™ Duo pumps.

Clinical Risk:

- If the User is not aware of the points above relating to the Intermittent program, there is the potential to administer two consecutive doses without a pause between the two doses. This could lead to an over-infusion and result in patient harm depending on the drug being administered.
- BD has not received any reported events associated with this issue.

Corrective Action by BD:

- BD will roll out a software upgrade and revised DFU for the BodyGuard™ Duo Infusion pump
  - This software will update the Intermittent program to ensure that if the Dose Duration (T2) is paused the overall interval duration (T1) will be increased by the amount of time of this pause.

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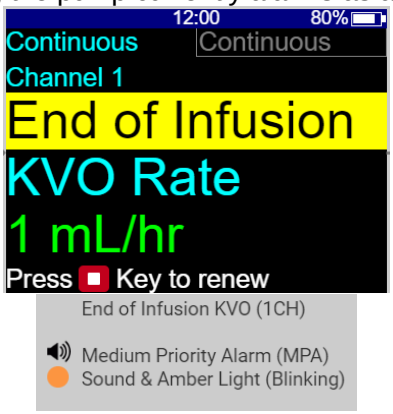
Situation 2: Incorrect alarm priority for EOI (End of Infusion) with KVO (Keep Vein Open)

Issue: In BodyGuard™ Duo pumps, the EOI (End of Infusion) with KVO (Keep Vein Open) triggers a medium priority alarm instead of high priority alarm, as specified in DFU. The current medium priority alarm may also cause confusion with NEOI (Near End of Infusion) which is a low priority alarm; both have the same auditory signal as per 60601-1-8.

Overview of Situation:
In the case of End of Infusion with KVO, the pump currently alarms as a medium priority alarm:



Once the KVO has been completed, a high priority End of Infusion alarm is activated:

Immediate Action for clinical users:

- Ensure the contents of this FSN and the following information regarding the pump alarms are understood by Users of the BodyGuard™ Duo pumps.

Clinical Risk:

- Clinicians may not be able to differentiate between the NEOI (low priority) and EOI (medium priority) alarms and may react incorrectly.
- A potential drop of the flow rate may cause an under-infusion resulting in patient harm depending on the drug being administered.
- BD has not received any reported events associated with this issue.

Corrective Actions by BD:

- BD will roll out a software upgrade and revised DFU for the BodyGuard™ Duo infusion pump
    - This software will update the alarm priority as high for the EOI (End of Infusion) with KVO (Keep Vein Open)