ROCKFORD HEALTHCARE

Unit 3,
The Westway Centre,
Ballymount Avenue,
Dublin,
D12 X237

23rd August 2021

URGENT: FIELD SAFETY NOTICE – MMS-21-4135

CME/BD BodyGuard™ Infusion Pump Systems
(Large Volume Infusion Pump Systems)
REF: See Appendix 1 and 2

Type of Action: Field Work

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

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

Dear Customer,

BD is issuing an advisory Field Safety Notice for the large volume CME/BD BodyGuard™ Infusion Pump systems and according to our distribution records your organisation may have received the impacted product.

Description of the Problem

Based on customer feedback, BD has identified potential flow rate issues when using the CME/BD BodyGuard™ MicroSets/Bodysets Infusion sets, as listed in Appendix 1, with the associated CME/BD BodyGuard™ Infusion Pump, as listed in Appendix 2. The investigation showed an increased risk of under-infusion when using the pump system at high flow rate settings in both continuous and an intermittent infusion like PCA mode. Deviations of nominal accuracy (5-7%) were detected above 500 mL/h and were most prevalent and significant (>-20%) when running infusions at flow rates ≥ 800 mL/h in continuous mode. Similarly, when PCA bolus (intermittent) are delivered at rates ≥ 500 mL/h in combination with low basal rates.

Note: The scope of this Field Safety Notice is limited to the BodyGuard™ large volume infusion pump portfolios as listed in Appendix 2. ***BD BodyGuard T and CME T34 syringe pumps are NOT impacted.***

Clinical Impact

Infusions running slower than expected (under-infusions) can lead to remaining fluid at the end of infusion or a reduced clinical effect.

BD has not identified any reports of serious adverse events to date that could be associated with this Field Safety Corrective Action.

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Corrective Actions by BD

An investigation has been launched to identify root cause and in the short-term, BD instructs restricting the maximum infusion rate and Bolus rate of the BodyGuard™ Infusion Pump System as defined in this FSN below. BD is issuing a Technical Service Bulletin (SB09248) to all approved service organizations providing instructions to limit infusion rates in the settings of the pump. BD will inform you in the future about product corrective actions resolving the issue once identified and implemented.

BD BodyGuard™ Microsets/Bodysets Infusion sets (per Appendix 1) are dedicated to the Bodyguard™ Pump portfolio and to maintain continuity of care, BD will continue to ship the products to the market. Future shipments of the pumps will have the settings limited as described in this Field Safety Notice.

Advice for EBME/Biomedical/Service Organisations

BD is issuing a Technical Service Bulletin (SB09248) to all service organisations to provide instructions to limit these infusion rates in the settings of the pump. These limitations in the settings are only accessible with an access code provided to approved service organisations. By limiting the settings in the software this will ensure that the Clinical User of the pump would not be able to use the higher flow rates without the access code and instructions.

Advice for Clinical Users

Until the settings are limited on your pump by your service organisation, please follow these instructions.

- **Do not use** the Bodyguard Infusion pump **if** an alternative infusion pump is available.
- Healthcare professionals should evaluate medications, prescribed therapies and patient populations prior to utilizing the infusion pump.
- As the device can infuse at rates slower than expected at high flow rates, clinicians administering infusions should assess the fluid container for volumes infused, volumes remaining in the container at the end of the infusion and ensure the total volume of prescribed medication is delivered. The volume to be infused may need to be re-programmed on the device to complete the infusion.
- If you chose to use the pump, please ensure you do the following:
  1. Limit the maximum rate to 800mL/hr when using Continuous Mode on the CME BodyGuard 323, CME BodyGuard 323 Color Vision, CME BodyGuard 121 Twins, CME BodyGuard Quadro, BD BodyGuard™ DUO and BD BodyGuard™ Infusion Systems
  2. Limit the maximum rate to 300mL/hr when using an Intermittent Infusion (Bolus) like PCA Mode on all BD BodyGuard infusion Systems listed in Appendix 2.

Note: If your site is using existing protocols, macros, or the drug library program, you must ensure the rate changes listed in this Field Safety Notice are factored into them.

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Actions for Customers to take:

1. Circulate this Field Safety Notice to all those within your organisation that may use the CME/BD BodyGuard™ Infusion Pump system.

2. If you have further distributed the product, please identify those users and notify them at once of this Field Safety Notice.

3. Please contact your service organization to implement the limitations on the infusion rates per Technical Service Bulletin (SB09248).

4. Complete the customer response form on page 4 indicating whether you wish the limiting of Maximum Infusion Rate and Bolus rate to be performed by BD (**Option 1**) or by your service organization (**Option 2**) and return it to fieldsafetyaction@rockford.ie **as soon as possible or no later than 03 September 2021.**

5. If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office on +353 1 450 9050 or e-mail fieldsafetyaction@rockford.ie

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
Senior Manager, Post Market Quality
BD EMEA

C/O
Denise Coleman
Field Safety / Complaints Coordinator
Phone: 01-4509050

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Customer Response Form – MMS-21-4135

CME/BD BodyGuard™ Infusion Pump System (Large Volume infusion Pump Systems)

REF: See Appendix 1 and 2

Please read in conjunction with Field Safety Notice MMS-21-4135 and return the completed and signed form as soon as possible or **no later than 03 September 2021** to Fax +353 1 450 9060/ fieldsafetyaction@rockford.ie

By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Name of Trust	
Name of Hospital/s covered by this response:	
Email Address	
Telephone Number	
Name	
Signature	
Date	

Please tick **ONE** of the following boxes:

☐ **Option 1**: BD to perform the changes to settings

Please provide a contact name of a representative from your organisation who will be the point of contact for BD:

Name:	Tel No.:	E-mail:	Please attach a list of the product codes/serial numbers in scope

OR

☐ **Option 2**: The customer facility's service organisation to perform the settings changes

Please attach a list of the product codes/serial numbers in scope

OR

☐ I confirm that our facility **does not have any** of the affected products listed in this Field Safety Notice.

Please return your completed and signed Customer Response Form to: Fax 01 450 9060/ fieldsafetyaction@rockford.ie

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

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BD

Appendix 1 – CME/BD BodyGuard™ MicroSets/Bodysets Infusion sets

Item Number	Description	Item Number	Description
100-163X2YNKS	MICROSET,MRI,NON-DEHP,PR	ONC00008	MICROSET,ONCOLOGY,LOW- S
100-163XN2YNKS	IV SET,MICROSET,SR, PRIMA	ONC00010	MICROSET,ONCOLOGY,LOW SO
100-163XNKS	IV SET,CONTINUUM,STREIGH	ONC00011	MICROSET,ONCOLOGY,LOW SO
120-000DBLSE	MICROSET,NON-DEHP,BLOOD,	ONC00012	MICROSET,ONCOLOGY,LOW SO
120-000DBLSK	MICROSET,NON DEHP,BLOOD	TPN00001	MICROSET,TPN,NON-DEHP, 1
120-000TF	IV SET,TWINS,FILTER 1.2,	TPN00003	MICROSET,TPN,NON-DEHP, 1
120-000TS	IV SET,TWINS DUAL DRIP C	TPN00004	MICROSET,TPN,NON-DEHP, L
120-000XY	IV SET,BODYSET, Y CONNEC	TPN00005	MICROSET,TPN,NON-DEHP,1.
120-000XYLNK	MICROSET,LIGHT SENSITIVE	100-160XE	MICROSET,EPIDURAL,NON -DEHP
120-000XYNK	IV SET,BODYSET, Y CONNEC	100-160XSM	MICROSET,PCA,LARGE SPIKE
120-003TS	MICROSET,NON DEHP,TWINS,	100-160XSMG90EK	MICROSET,PCA,LARGE SPIKE
120-003XS2YV	MICROSET,NON DEHP, 2 NEE	100-163XE90SK	MICROSET,EPIDURAL, NON D
120-112XPEFKY	MICROSET,LOW SORBING, 1.	100-163XESK	MICROSET,EPIDURAL,NDEHP,
120-112XSFK	IV SET,MICROSET, NDEHP,1	100-163XESVK	MICROSET,EPIDURAL,NDEHP,
120-112XSFV	IV SET,MICROSET, NDEHP,1	100-184XSK	MICROSET,PCA, ALL BLUE,
120-112XSFVK	MICROSET,NON DEHP,1.2m F	100-184XSYK	MICROSET,PCA, ALL BLUE S
120-124XSFK	MICROSET,NON DEHP, 1.2µ	101-163XE90SK	MICROSET,EPIDURAL,ALL YE
120-124XSK	IV SET,BODYSET, ONC,NDEH	101-163XESK	MICROSET,EPIDURAL,ALL
120-160XSV	IV SET,MICROSET, NDEHP,S	110-163XE90SK	MICROSET,EPIDURAL,SURETY
120-160XSVK	MICROSET,NON DEHP, PRIMI	120-160X90SK	MICROSET,BLUE ST,NDEHP,
120-160XYSK	MICROSET,Y CONN,SPIKE. D	120-160XCS	IV SET,MICROSET, Y CONN,
120-163XBSK	MICROSET,NON DEHP, BURET	120-160XCSEK	IV SET,MICROSET, Y CONN,
7290012271014	IV SET,STANDARD, AFF VAL	120-160XCSK	MICROSET,PCA,NON DEHP, Y
7290012271021	IV SET,LIGHT SENSITIVE D	120-160XPS	IV SET,MICROSET, BLUE ST
7290012271045	BLOOD & IV INFUSION PUMP	120-160XSFM	IV SET,MICROSET, NDEHP,0
7290012271069	IV SET,PCA, O.2M FILTER,	120-160XSFMK	IV SET,MICROSET,NDEHP 0.
A120-003XS2YV	IV SET,510(k) 042696, LI	121-160XCSEK	MICROSET,PCA,ALL BLUE, Y
GEN00001	MICROSET,NONDEHP,STRAIGH	130-163XE90SK	MICROSET,REGIONAL,CLEAR
GEN00002	MICROSET,NON DEHP,DRIP C	130-163XESK	MICROSET,REGIONAL CLEAR
GEN00003	MICROSET,NON DEHP,15µ FI	7290012271069	IV SET,PCA, O.2M FILTER,
GEN00004	MICROSET,NON-DEHP,LIGHT	EPI00001	MICROSET,EPIDURAL, NON-D
GEN00005	MICROSET,NON-DEHP,LIGHT-	EPI00003	MICROSET,EPIDURAL, NON-D
GEN00007	MICROSET, N-DEHP, LIGHT-	EPI00011-NRF	MICROSET,EPIDURAL, NON D
GEN00014	MICROSET, N-DEHP, STRAIG	EPI00012-NRF	MICROSET,EPIDURAL,ALL YE
HBO00002	MICROSET,NON DEHP,DRIP	PCA00001	MICROSET,PCA,NON-DEHP, A
HK120-000XYS	IV SET,BODYSET Y CONNECT	PCA00002	MICROSET,PCA,LOW SORBING
ONC00001	MICROSET,ONCOLOGY,	PCA00003	MICROSET,PCA,LOW SORBING
ONC00002	MICROSET,ONCOLOGY,NON DE	PCA00004	MICROSET,PCA,NON-DEHP
ONC00004	MICROSET,ONCOLOGY, LOW S	PCA00005	MICROSET,NON DEHP,PCA, E
ONC00004UV	MICROSET,ONCOLOGY, LOW S	PCA00009	MICROSET,PCA,NON-DEHP, D
ONC00005	MICROSET,LOW SORBING, DR	PCA00010	MICROSET,PCA,ALL BLUE
ONC00006	MICROSET, LOW SORBING,DR	PCA00013	MICROSET,PCA,NON DEHP,Y

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Appendix 2 – BodyGuard™ Infusion Pump System Portfolio

	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

Your local service provider is:

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Fax +353 1 4509060
E-mail fieldsafetyaction@rockford.ie