URGENT: FIELD SAFETY NOTICE - FSN-CC-202511-001-01

BD neXus V700 Infusion Pump
and
BD neXus S700 Syringe Pump

Type of Action: Field Work

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

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

Dear customer,

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD., as Legal Manufacturer, is issuing Field Safety Corrective Action for **BD neXus V700 Infusion Pumps and BD neXus S700 Syringe Pumps**. According to distribution records your organization may have received the impacted product in Table 1.

Manufacturer's SRN: CN-MF-000005925
Legal Manufacturer: MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.

Catalog Number (REF)	Trade Name	UDI-DI	Intended Purpose	Software version
V700-00	BD neXus V700 Infusion Pump	06926802608784	This product is intended to be used in conjunction with an IV set to control the dose of liquid infused into the patient's body in clinical departments or used in conjunction with a transfusion set for blood transfusion.	UI Program (neXus V700 V2.7.0.0110)
S700-00	BD neXus S700 Syringe Pump	06926802608753	This product is intended to be used in conjunction with the syringe to control the dose of fluid infused into the patient's body in clinical departments.	UI Program (neXus S700) V1.10.0.0099

Table 1: Impacted product

This Field Safety Notice is limited to the product codes (including all pump serial numbers) and software versions listed in Table 1. No other product codes are affected.

Description of the problem

Based on customer feedback, Medcaptain has identified that the BD neXus Infusion and Syringe Pumps when infusing in Guardrails mode, may shut down or restart unexpectedly without generating a high priority alarm. The investigation indicates this issue could occur randomly and is being caused by a software bug. Clinically, this issue could result in treatment interruption and delays in patient therapy.

Clinical risk

If an unexpected restart or shutdown occurs during infusion, it will lead to interruption of therapy. If healthcare providers fail to detect and intervene in this situation promptly while high-risk medications (such as life-sustaining drugs or anaesthetics) are being administered, it may in the worst-case scenario result in patient death.

To date, there have been no reported serious adverse events worldwide related to this issue.

Clinical User Actions

1. Cease using the Guardrails mode on BD neXus Infusion and Syringe Pumps.
2. The pumps can continue to be used in ml/h mode, Handover mode, TPN mode, Multi-Step Mode and Loading Dose mode as normal. When infusing in ml/h, check the programmed rate against the written prescription, as per local hospital guidelines.
3. When infusing critical medications, as per good clinical practice, ensure spare equipment is readily available.
4. Ensure the BD neXus Infusion and Syringe Pumps are made available for remediation when contacted by your service organisations.

Corrective Actions

Medcaptain, as the Legal Manufacturer, is releasing a software update to fix the issue and BD, as distributor, will roll this out to all sites once available and in conjunction with the listed point of contact for the clinical site in the Customer Response Form.

Until the updated software is made available, follow the above listed clinical user actions. Medcaptain does not plan to initiate any further advice or information in a follow-up FSN.

Actions for Biomedical Engineers / Service organisations

BD will be in contact with qualified Biomedical Engineers and affected Service Organisations on how to upgrade the Software once it is released by MedCaptain, the Legal Manufacturer.

Customer Actions:

- Review the information in Table 1 to confirm if the BD neXus Infusion and/or Syringe Pump(s) are in your possession.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by <insert date>,** clearly indicating the applicable contact person at your facility to support the software upgrade, when available.
- 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.

- Transfer this notice to other organisations on which this action has an impact.
- Maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Distributor Actions

- Review the information in Table 1 and determine if the BD neXus Infusion and/or Syringe Pump(s) are in your possession.
- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where these BD neXus Pumps have been transferred. (As appropriate)
- Identify the facilities where you have distributed BD neXus Pumps and notify them immediately of this notice.
  - Have your customers complete and return the Customer Response Form to your organisation for reconciliation purposes by **<<insert Date>>**.
  - There is no requirement to return your Customer Response Forms to BD, you should maintain these on file at your facility. Return only your final consolidated response form.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- Maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Report all device-related incidents to the manufacturer, or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

	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/third party

Contact reference person

If you have any questions or require assistance relating to this Field Safety Notice, please contact at e-mail **<< insert email address>>**.

The Regulatory Authority of your country has been informed about this communication to customers.

Sincerely,

Name
Title

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Customer Response Form - FSN-CC-202511-001-01

BD neXus V700 Infusion Pump and BD neXus S700 Syringe Pump

Return to **<insert email address>** as soon as possible or **no later than** the <insert date>.

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.*

Please confirm **ONE** of the following options:

☐ **Option 1**: **BD to perform the remediation activity**.
Please provide a contact name of a representative from your organisation who will be the point of contact for BD, if different from above:

Name:	Tel No.:	E-mail:	No. of devices impacted:

OR

☐ **Option 2**: **The qualified Biomedical Engineers/Service Organisations to perform the remediation activity**
Please provide a contact name of a representative from your organisation who will be the point of contact for BD, if different from above:

Name:	Tel No.:	E-mail:	No. of devices impacted:

OR

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

All product that is not available for remediation will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified.