8th October 2025

NEW

URGENT: FIELD SAFETY NOTICE – MMS-25-5342

BD Alaris™ Syringe Pumps

REF: See Table 1 and 2 **Serial Numbers:** See webpage link

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,

BD is conducting a Field Safety Corrective Action for specific serial numbers of BD Alaris™ Syringe Pumps and specific spare kits. According to our distribution records your organisation may have received the impacted product listed in Table 1 and Table 2.

Manufacturer's SRN: CH-MF-000026539

Product Name	Catalog Number	UDI-DI
BD Alaris neXus CC-Smart	CCnexus1-S	10885403485268
BD ALARIS NEXUS PK	PKnexus1	10885403484704
Alaris GH Plus Syringe Pump	8002MED01	07613203014922
Alaris GH Plus Guardrails Syringe Pump	8002MED01-G	07613203014915
Alaris GH Plus Syringe Pump	8002TIG01	07613203028080
Alaris GH Plus Guardrails Syringe Pump	8002TIG01-G	07613203028097
ALARIS CC PLUS	8003MED01	07613203014878
ALARIS CC PLUS WITH GUARDRAILS	8003MED01-G	07613203014885
Alaris CC Plus Syringe Pump	8003TIG01	07613203029162
Alaris CC Plus Guardrails Syringe Pump	8003TIG01-G	07613203029179
Alaris PK Plus MK4 2E Syringe Pump	8005PK201	10885403427893
Alaris PK Plus MK4 Syringe Pump	8005TIG03	10885403462269
Alaris Enteral Plus Syringe Pump MK4	8007ENT01	07613203032438
BD Alaris neXus CC	CCNEXUS1	10885403484711

Table 1: Impacted Pumps

Product Name	Catalog Number	UDI-DI
Alaris SP MKIV Keypad Kit GH/CC	1000SP01660	N/A
Alaris SP MKIV On/Off Keypad Kit	1000SP01661	N/A
PK MK4 All Labels Spares Kit	1000SP01908	N/A
PK MK4 On/Off Label Spares Kit	1000SP01911	N/A
Alaris Enteral Plus SP MK4 Keypad Kit	1000SP01918	N/A
Enteral Plus MK4 On/Off Keypad Kit	1000SP01921	N/A
BD Alaris neXus CC Front Case Kit	1000SP02217	N/A
BD Alaris neXus SP Keypads Kit	1000SP02220	N/A
BD Alaris neXus CC On/Off Keypad Kit	1000SP02238	N/A
FRONT CASE CE2797 SPARES KIT GH	1000SP02252	N/A
FRONT CASE CE2797 SPARES KIT GH-G	1000SP02254	N/A
FRONT CASE CE2797 SPARES KIT CC	1000SP02255	N/A
Front Case CE2797 Spares Kit CC-G	1000SP02257	N/A
ALARIS PK PLUS MK4 3E CE2797 FRONT CASE	1000SP02258	N/A
Alaris Entl+ MK4 3E CE2797 Front CaseKit	1000SP02260	N/A
BD ALARIS NEXUS PK FRONT CASE KIT	1000SP02294	N/A
BD ALARIS NEXUS PK KEYPADS KIT	1000SP02296	N/A

Table 2: Impacted Spares Kits Containing Keypad Component lot numbers: 7/24, 24/24, 13/24, 08/24 Shipped between February 2024 and 29th August 2025.

Device Type

Infusion syringe pumps.

Picture 1: BD Alaris™ Syringe Pump

Primary clinical purpose of devices

Intended to be used for the purpose of controlling rate and volume by medical staff.

Description of the product problem

Based on customer feedback, BD has identified that a potential manufacturing defect affecting certain BD Alaris™ Syringe Pumps related to keypad functionality. It has been observed that specific lots of the keypad components may exhibit unintended behaviour impacting the "On/Off", "Hold" and "Run" keys.

Specifically, the affected pumps may experience one or more of the following failure modes:

- The pump may enter "Tech Mode" autonomously during power-up.
- Keypad buttons may become unresponsive, preventing normal operation.
- A "KY1" error may be displayed, indicating a stuck key (see Picture 2 below)

Picture 2: KY1/Stuck Key Error Displayed

The specific lots of the keypad components were potentially installed by BD either during the manufacturing or the servicing of the specific BD Alaris™ Syringe Pumps listed in Table 1/ webpage link or shipped to service organisations within the spare parts kits between February 2024 and 29th August 2025 as listed in Table 2.

Note: The webpage link referenced below lists the pumps manufactured with the affected keypad components or pumps serviced directly by **BD only**. If your Service Organisation is not BD, they will contact you if any additional pumps were fitted with the impacted parts and therefore may not appear in the webpage link.

Clinical risk

A faulty keypad on the BD Alaris™ Syringe Pump may cause delays in starting or interruptions during infusion, with the severity of harm depending on the drug type, patient condition, and duration of the interruption. Potential outcomes range from no harm to critical injury, particularly when short half-life vasoactive drugs or TIVA are involved, as these are used in high-acuity patients and can lead to hemodynamic instability or reduced anesthesia within minutes.
In critical care settings (ICU, NICU, OR), spare equipment is typically available, allowing clinicians to respond before harm becomes life-threatening. The pump includes safety features such as continuous key monitoring, high-priority alarms if a key is held for over 5 minutes, and specific behavior for the "On/Off" key - especially in PK Plus mode - where infusion

continues and displays a "LOCKED" message, prompting user intervention before shutdown. Should the "On/Off" key become stuck on a BD Alaris™ GH or CC Syringe Pump, following the power off sequence, a high priority alarm would sound after approximately 15 seconds, and remain active until the key is released.

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

There is no requirement for customers to return any BD Alaris™ Syringe Pumps to BD. These products can continue to be used in accordance with the guidance in this safety notice.

Actions for Clinical Users

- Organize for the affected Alaris™ Syringe pumps serial numbers to be made available to BD, your Biomedical Engineering team or to your Service Organisation as applicable for keypad replacements.
    - Clinical users can identify impacted pumps by reviewing the list of Impacted Pumps, found on the webpage: https://bdx.my.site.com/CC360/s/impactedproducts?rn=MMS-25-5342%20GLOBAL
    - If your Service Organisation is not BD, they will contact you if any additional pumps were fitted with the impacted parts.

- Continue to use the Alaris™ Infusion pumps with their existing labeling and Directions for Use. In case you observe the pump presenting with the described issue, immediately remove it from service for inspection by Qualified Service Personnel. Use an alternative syringe pump in the meantime.
    - Reminder, as stated in the DFU for PK pumps (SKUs: PKnexus1, 8005PK201 or 8005TIG03) *"if a surgical procedure is interrupted during a TCI (Target Controlled Infusion), all current pharmacokinetic / pharmacodynamic model information will be lost. Under such circumstances, switching the pump off and on and restarting the infusion whilst the patient contains a significant residual drug dose, could result in an over-infusion and therefore the pump should not be restarted in TCI mode"*.
- If you experience any issues with the Alaris™ Infusion pumps, please report as a complaint as per your normal process.
- Per good clinical practice,
    - Ensure spare infusion pumps are available in clinical areas delivering critical or life sustaining medications.
    - If performing a patient transfer, assess if additional equipment, or alternative methods of medication administration, is required in case of system alarms.

Actions for Biomedical Engineers / Service Organisations

BD is issuing a Technical Service Bulletin (BDIN00346) to all trained Biomedical Engineers, service organisations to provide instructions on:

- Actions to take with any impacted spare part kits
- How to remediate impacted pumps

BD Actions:

BD has investigated and identified the root cause of the issue. Corrective actions have been implemented.
To date, BD does not plan to initiate any further advice or information in a follow-up FSN.

Customer Actions:

- Review the information in Table 1/ webpage link to determine if the BD Alaris™ Syringe Pumps in your possession are impacted.
- BD distributed spare part kits between February 2024 and 29th August 2025 (see Table 2) and if you serviced pumps with these parts, you may have additional impacted pumps. Review your service records and determine if pumps were serviced with impacted spare parts. Technical Service Bulletin (BDIN00346) is being issued to all Service Organisations to provide instructions on how to identify impacted spare parts and what actions to take.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 13th November 2025.**
- This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have 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/ webpage link and determine if the BD Alaris™ Syringe Pumps in your possession are impacted.
- BD distributed spare part kits between February 2024 and 29th August 2025 (see Table 2) and if you serviced pumps with these parts, you may have additional

impacted pumps. Review your service records and determine if pumps were serviced with impacted spare parts. Technical Service Bulletin (BDIN00346) is being issued to all Service Organisations to provide instructions on how to identify impacted spare parts and what actions to take. Notify these customers of this notice and replace with new, unaffected spare parts.

- 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 **13th November 2025.**
    - 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/Received **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	BDFieldActions@bd.com
Purchased/Received 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

8th October 2025

Contact reference person

If you have any questions or require assistance relating to this Field Safety Notice, please contact your local BD representative or the local BD office or e-mail BDFieldActions@bd.com

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

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,

Kinga Stolinska
Director, Post Market Quality
EMEA Quality

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.

8th October 2025

Customer Response Form - MMS-25-5342
BD Alaris™ Syringe Pumps

REF: See Table 1 and 2 **Serial Numbers:** See webpage link

Return to BDFieldActions@bd.com as soon as possible or **no later than the 13th November 2025.**

- **I 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:**

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 products.

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

This form must be returned to BD before this action can be considered closed for your account.
** If you were forwarded this Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*

Submit Button