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6th February 2025

URGENT: FIELD SAFETY NOTICE – MMS-25-5222
Product Name: Alaris™ GP Guardrails™ Volumetric Pump with Plus software and Alaris™ VP Plus with Guardrails™
REF / Serial Numbers: See Table 1
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 issuing a Field Safety Corrective Action for specific serial numbers of Alaris™ GP Guardrails™ Volumetric Pump with Plus software and Alaris™ VP Plus with Guardrails™. According to our distribution records your organisation may have received the impacted product listed in Table 1.

Manufacturer's SRN: CH-MF-000026539

Product Code (REF)	Description	Serial Number	UDI-DI
9002TIG03-G	Alaris™ GP Guardrails™ Volumetric Pump with Plus software	470072000	10885403462290
9003TIG03-G	Alaris™ VP Plus with Guardrails™	570033530	10885403460906
		570033162	10885403460906

Table 1: Impacted product

This Field Safety Notice is limited to the product codes and serial numbers listed in Table 1. No other product codes or serial numbers are affected.

Description of the problem

Based on customer feedback, BD has identified that the specific Alaris™ GP Guardrails™ Volumetric Pump with Plus software and Alaris™ VP Plus with Guardrails™ pumps listed in Table 1 may potentially have been manufactured without a required component, specifically a bearing in the camshaft assembly. The absence of this component may result in the pump not being operational.

BD does not have confirmation that the component is missing and will verify its presence by inspecting the impacted pumps.

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Clinical risk

If the identified component is missing, it could cause an issue with the motor of the pump and would result in the generation of a “DO NOT USE” error as shown in Fig.1 below.

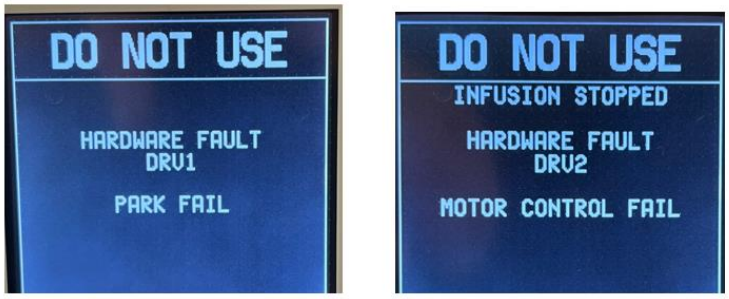

Fig.1

The outcome of the error is the pump will stop infusing (if an infusion is in progress), or the user may not be able to commence a new infusion, if the issue is detected at power on. This would result in an interruption of infusion, or a delay in the start of an infusion. A high priority alarm would accompany the display of the issue. The risks associated with such an issue would depend on the medication being delivered, and the clinical area in which the device is being used. The likely harm associated with such an event would be haemodynamic instability, if a short half-life vasoactive medication is being instigated at the time of the event. No additional follow-up activities are required for patients already successfully treated with the product.

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

BD Actions

As a result of this investigation, BD or an approved Distributor is inspecting all units that have potentially been affected by the error. This will require inspection of the pumps listed in Table 1 to be performed by a BD representative or an approved Distributor.

Future shipments will not be considered in scope of this notice.

Clinical User Actions

Identify, cease use and quarantine any of the specific affected Alaris™ GP Guardrails™ Volumetric Pumps with Plus software and any Alaris™ VP Plus with Guardrails™ Pumps listed in Table 1.

Biomedical Actions

- Locate the serial numbers listed in Table 1, remove from service and await additional instructions from BD.
    - On the Customer Response Form, please provide a contact name of a representative from your organisation who will be the point of contact to organise product remediation.
- Continue to perform all other service activities on the Alaris™ GP Guardrails™ Volumetric Pump with Plus software and Alaris™ VP Plus with Guardrails™ per the current Technical Service Manuals and instructions provided on My BD Learning (BD Technical Service Portal).

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Customer Actions:

- Review the information in Table 1 to determine if any Alaris™ GP Guardrails™ Volumetric Pumps with Plus software or any Alaris™ VP Plus with Guardrails™ Pumps in your possession are impacted.
- Cease use of any impacted pumps.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 3rd March 2025.**
- 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 Table 1 to determine if the Alaris™ GP Guardrails™ Volumetric Pumps with Plus software and/or Alaris™ VP Plus with Guardrails™ Pumps in your possession are impacted.
- Cease distribution of any of the above-mentioned pumps.
- Identify the facilities where you have distributed affected 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 **3rd March 2025.**
- 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	BDFieldActions@bd.com
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 or require assistance relating to this Field Safety Notice, please contact your local BD representative or the local BD office.

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,

Kinga Stolinska
Director, Post Market Quality
EMEA Quality

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Customer Response Form - MMS-25-5222

Product Name: Alaris™ GP Guardrails™ Volumetric Pump with Plus software and Alaris™ VP Plus with Guardrails™.

REF / Serial Numbers: See Table 1 of FSN

Return to BDFieldActions@bd.com as soon as possible or **no later than the 3rd March 2025**.

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:

☐ I have one or more affected product(s) within my organisation.

Please provide a contact name of a representative from your organisation who will be the point of contact to organise product remediation, if different from above:

Name:	*Telephone No:*	*Email:*	*Serial Number of Impacted product:*

OR

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

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