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XX November 2020

URGENT: FIELD SAFETY NOTICE – MMS-20-3862

BD Alaris™ GP Plus; BD Alaris™ GP Plus Guardrails; BD Alaris™ neXus GP

REF / Serial Number: Refer to Table 1

Type of Action: Field Work

Attention: EBME / Clinical Engineering Managers, Clinical Personnel, Risk Managers

This letter contains important information which requires your attention.

Dear Customer,

BD is issuing this Field Safety Notice in relation to a hardware issue identified on the specific serial numbers of **Alaris™ GP Volumetric Pump with Plus software (REF: 9002TIG03)**, **Alaris™ GP Guardrails™ Volumetric Pump with Plus software (REF: 9002TIG03-G)** and **BD Alaris™ neXus GP (REF: GPNEXUS1)** listed in Table 1 below. Our distribution records indicate that your organisation may have received impacted instruments which were manufactured between July 2019 to June 2020.

Table 1: List of impacted instruments

REF	Product Description	Impacted Serial Number Range	Manufacturing Dates
9002TIG03	Alaris™ GP Volumetric Pump with Plus software	400008724 to 400009451	Jul-19 to May-20
9002TIG03-G	Alaris™ GP Guardrails™ Volumetric Pump with Plus software	470034144 to 470044446	Sept-19 to June-20
GPNEXUS1	BD Alaris™ neXus GP	410000002 to 410004377	Prior to June-20

Description of the Problem

BD has become aware through customer feedback that the specific Alaris pumps listed in Table 1 above manufactured with consolidated Printed Circuit Board Assemblies (PCBA) have the potential to exhibit spurious counting of Flow Sensor pulses. This is resulting in the reporting of false flow error alarms or failure to detect No Flow which in clinical practice may result in an interruption to infusion or cause a delay in infusion.

Based on customer feedback provided, this issue has been primarily detected when the EBME/Engineering department is performing the installation Product Verification Performance per the Technical Service Manual testing with the flow sensor present on the device.

Corrective Actions by BD

As a result of this issue, BD is remediating the Printed Circuit Board Assemblies (PCBA) of all pump serial numbers listed in Table 1.

Advice for Clinical Users

If the device enters clinical use and results in a false Flow Error Alarm, the user should follow the current Directions for Use (DFU) to try to clear the error. If the alarm persists the User should remove the device from service and contact Qualified Service Personnel, in line with current DFU, for any device behaving abnormally.

In line with current clinical practice, the infusion can be re-commenced on an alternate device. For infusions which can be delivered under gravity, consult the relevant DFU for instructions on activating the Alaris Safety Clamp.

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Advice on actions to be taken by the user

1. Ensure the contents of this Field Safety Notice are read and understood by those within your organisation who may use or service the Alaris™ GP Volumetric Pump with Plus software (REF: 9002TIG03), Alaris™ GP Guardrails™ Volumetric Pump with Plus software (REF: 9002TIG03-G) and BD Alaris™ neXus GP (REF: GPNEXUS1).
    - 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 Response form (Page 3) indicating whether you wish the remediation of the instruments to be performed by BD (**Option 1**) or by your organisation (**Option 2**) and return the completed form to BD at <<insert email address>> no later than <<insert date>> 2020.

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

    - If selecting **Option 2,** a BD representative will contact you upon receipt of your completed Customer Response Form to discuss providing the spare parts and instructions to conduct the remediation activity.

    NOTE: For Options 1 and 2, all spare parts for remediation activities will be provided free of charge by BD.

3. If you are no longer in possession of or no longer use the instruments listed in Table 1, please indicate this on the response form and return to BD so we may update our records.

Should you have any questions or experience any issues associated with the product or issue described in this Field Safety Notice, please contact your local BD representative. We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to ensuring that safe and effective product is available to customers and this Field Safety Notice is taken with due consideration of this commitment.

Thank you for your attention and cooperation.

Yours sincerely,

William David
Senior Director Quality Compliance EMEA

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Customer Acknowledgement Form – MMS-20-3862

BD Alaris GP Plus; BD Alaris GP Plus Guardrails; BD Alaris neXus GP

REF / Serial Number: Refer to Table 1

Please read in conjunction with Field Safety Notice MMS-20-3862 and return the completed and signed form as soon as possible or **no later than November 30th, 2020** to <<email>>.

By completing the information below you confirm you have read, understood and distributed the contents of this Field Safety Notice accordingly.

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

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

☐ **Option 1**: BD to perform the remediation of the PCBA's

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 (approx.) 9002TIG03: _____ 9002TIG03-G: _____ GPNEXUS1: _____

OR

☐ **Option 2**: The distributor/customer facility 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 (approx.) 9002TIG03: _____ 9002TIG03-G: _____ GPNEXUS1: _____

OR

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

Please return your completed and signed Customer Response Form to: *<<insert fax/email address here>>*

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