

URGENT: FIELD SAFETY NOTICE – RA-2019-01-01

Alaris™ VP Plus Guardrails™ Volumetric Pump
Catalogue Number: 9003MED01-G, 9003TIG01-G, and 9003TIG03-G
All serial numbers

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

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

Dear valued Customer,

BD is undertaking a corrective action on the Alaris™ VP Plus Guardrails™ volumetric pumps to upgrade all existing pump software to the new software version V1.4.9. This action is a result of an investigation of a previously communicated Field Safety Notice (RA-2016-10-02) in December 2016. The device software version can be identified on the display upon starting the pump.

Description of the Problem

BD had previously identified and communicated via a Field Safety Notice in December 2016 the following issue with the Alaris™ VP pump:

1. The Upstream Occlusion (USO) alarm does not generate within the prescribed time period. This may lead to patient receiving no medication or less medication than prescribed.

During the investigation of the above issue, BD also identified a corrective fix for an additional issue:

2. The user faces an USO alarm; however, there is no blockage in the infusion path (nuisance USO alarm). This may lead to delayed infusion or interrupted infusion. This issue can be identified as there will be an alarm without any blockage in the line.

As a result of this investigation, BD has developed a new software to mitigate these two issues and all Alaris™ VP pumps require a software update to be performed either by a BD representative or by your organisation.

Advice on action to be taken:

- 1) Complete the customer Acknowledgement Form on page 3 indicating whether the software upgrade is to be performed either by a BD engineer (**Option 1**) or by your organisation (**Option 2**) and return it to BD using the instructions provided no later than the **21st March 2019**.
 - If selecting **Option 1**, a BD representative will contact you upon receipt of your completed Acknowledgement Form to schedule the software upgrade for your pumps.



- If selecting **Option 2**, return your completed Acknowledgement Form along with a zero-cost purchase order for the upgrade kit part number **1000SP02153** to BDUKFieldaction@bd.com
 - Upon your receipt of the upgrade kit at your facility, follow the software upgrade instructions included in the upgrade kit.
- 2) Distribute this notice to all those who need to be aware of this action within your organisation.
 - 3) If you are no longer in possession of the Alaris™ VP pumps, please pass this notice and all the related documentation to the current user(s).
 - 4) Until the recommended software upgrade implementation is completed, BD would like to remind the user to follow the recommendations provided in the Direction For Use (DFU) with regards to:
 - The use of a flow sensor when infusing critical drugs to identify “no flow “conditions
 - Troubleshooting upstream occlusion alarms

Should you have any questions or require assistance relating to this Field Safety Corrective Action, please contact your local BD representative at BDUKFieldAction@bd.com.

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 and user safety and providing you with quality products. We apologise for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours sincerely,

William David
Senior Director, Quality Compliance EMEA

Field Safety Notice Acknowledgement Form

Alaris™ VP Plus Guardrails™ Volumetric Pump
Catalogue Number: 9003MED01-G, 9003TIG01-G and 9003TIG03-G
All serial numbers

Please read in conjunction with Field Safety Notice RA-2019-01-01 and return completed form to as soon as possible or **no later than the 21st March 2019** to BDUKFieldAction@bd.com

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

Please confirm the following by checking the box:

- I have read and understood the contents of this Field Safety Notice
- I will distribute this Field Safety Notice to all those who need to be made aware.

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

- Option 1:** BD representative to upgrade the pump software.

Please provide a contact name of a representative from your organisation who will be the point of contact to organise site visits for BD representatives, if different from above:

Name:	Telephone No:	Email:
-------	---------------	--------

- Option 2:** The customer facility to upgrade the pump software.

I confirm to bear the responsibility of correcting all the pumps in my possession as described in this Field Safety Notice. I will follow the software upgrade instructions included in the upgrade kit 1000SP02153.

OR

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

Please return your completed Acknowledgement Form to: BDUKFieldAction@bd.com