BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

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: Distributors

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

Dear Distributor,

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.

As a distributor of these pumps, you have the responsibility for informing your customers of this issue via a Field Safety Notice and ensuring the devices are remediated.

Full instructions on performing the software upgrade will be provided with the upgrade kit when you place your order.

Actions Required of You:

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

1. Immediately quarantine all impacted devices in your possession until the software upgrade has been completed.

2. Inform all your customers who have received the Alaris™ VP pumps from your organisation via a Field Safety Notice

    a. A template customer Field Safety Notice has been provided for your use which you may adapt and translate as appropriate (Appendix II). BD strongly recommend only adapting the highlighted yellow areas and the italicized blue font to meet your local needs.

    b. Please note, your customers are to communicate directly with you and not with BD.

3. Complete and return the attached Distributor Confirmation Form to BD (Appendix I) using the instructions provided as early as possible and no later than the **22nd March 2019**.

4. Place an order for the upgrade kit part number **1000SP02153** (*note: BD must have received your Distributor Confirmation Form before you place your order).* A BD representative will contact you to arrange deliveries of the upgrade kit after you have placed your order.

5. On receipt of your upgrade kit, perform the software upgrade for all impacted devices in your and your customer's possession using the instructions provided with the upgrade kit.

6. Maintain all records associated with this Field Safety Corrective Action.

7. Where applicable and if required, please inform your regulatory agency. BD has informed the European Competent Authorities of this action.

8. 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.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize 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, EMEA Quality Compliance

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

Appendix I - Distributor Confirmation 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 as soon as possible and **no later than the 22 March 2019**.

Name of Distributor	
Distributor Address	
Email Address	
Telephone Number	
Name	
Signature	
Date	

Please confirm the following by checking the box:

☐ I have read and understood the contents of the Field Safety Notice

☐ I will execute the actions outlined in the Field Safety Notice for affected pumps in my inventory and/or for affected pumps that I have distributed to my customers.

Please return your completed Acknowledgement Form to: ***<<insert BD contact details>>***.

Appendix II

Instructions to the Distributor : INSERT COMPANY LETTER HEAD

<<Insert Date>>

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 latest software version V1.4.9 as 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.

Advice on action to be taken:

1) For all Alaris™ VP pumps, the software needs to be upgraded.

Return the customer acknowledgement form to <<insert distributor contact details here>> as soon as possible and no later than the <<insert date>>. On receipt of the acknowledgement form, we will contact you to arrange remediation.

2) Please distribute this notice to all those who need to be aware of this action within your organisation. If you are no longer in possession of the Alaris™ VP pumps, please pass this notice and all the related documentation on to the current user(s).

Appendix II

Instructions to the Distributor : INSERT COMPANY LETTER HEAD

3) 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 *<<insert distributor contact details here>>*.

Yours sincerely,

<< Insert Distributor details>>

Appendix II

Instructions to the Distributor : INSERT COMPANY LETTER HEAD

Appendix I- Customer Confirmation 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 and **<<insert date>>**

Customer Name	
Customer Address	
Email Address	
Telephone Number	
Name	
Signature	
Date	

Please confirm the following by checking the box:

☐ I have read and understood the contents of the Field Safety Notice

If you have affected pumps in your inventory, please confirm the following by checking the box:

☐ I wish <<insert distributor name>> to perform the software upgrade.

OR

If you do not have any of the affected pumps in your inventory, please confirm the following by checking the box:

☐ I confirm that I do not have any of the affected pumps in my inventory

Please return your completed Acknowledgement Form to: *<< insert distributor contact details>>*.