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A-One Business Centre
Zone d'activités, Vers-la-Pièce No 10
Rolle, CH-1180
Switzerland

carefusion.com

Name
Address

URGENT FIELD SAFETY NOTICE

Product Name:	**Alaris VP Plus with Guardrails**
Product codes:	**9003MED01-G and 9003TIG01-G**
FSCA Identifier:	**RA-2016-10-02**
Date:	**November 2016**
Type of Action:	**Advisory Notice**

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Description of the Problem

CareFusion has identified a potential risk with the Alaris VP LVP that results in a situation where the upstream occlusion alarm does not generate within the prescribed time period.

CareFusion is not aware of any report of injury attributed to this issue; however this situation may cause the following:

- The patient receiving less medication than prescribed, resulting in an under-infusion. Life threatening condition may require medical intervention.

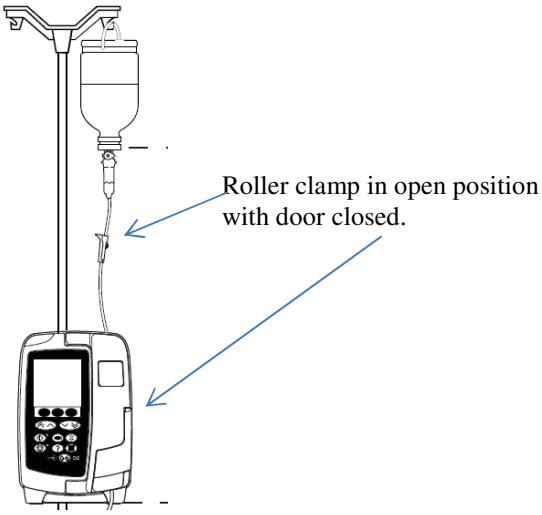
- This clinician may discover the occlusion condition (e.g. a closed roller clamp) for a non-critical infusion. This may result in an unintended delay in the start of an infusion leading to temporary impairment or damage to body structure not requiring medical / surgical intervention.

The root cause is still being investigated; CareFusion will provide a follow up notification once root cause has been identified.

Recommended Action Required

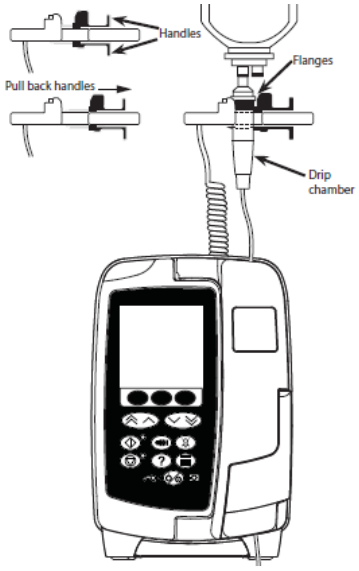
CareFusion recommends the following actions to ensure the Upstream Occlusion Alarm is detected as intended

1. The Alaris™ VP *plus* Guardrails™ Directions for Use state that upon completion of loading the tubing into the pumping chamber, the user should close the door and open the roller clamp.



Opening the roller clamp once the door is closed will eliminate the potential for an upstream occlusion.

2. Use of a Flow Sensor: The Model 180 Flow Sensor is an optional component that automatically monitors the infusion flow rate through the drip chamber. The flow sensor will cause the Pump to alarm if a significant deviation from the infusion rate occurs**. For this reason we recommend use of a flow sensor wherever possible, excluding secondary infusions**. For additional information on flow sensor placement and operation, refer to the Alaris™ VP *plus* Guardrails™ Directions for Use.



Your competent authority has already been notified of this Field Safety Corrective Action by CareFusion's Authorised EU Representative.

We sincerely apologise for any inconvenience this action may have caused you or your staff.

Should you have any questions or require assistance relating to this Field Safety Corrective Action, please contact your Local CareFusion representative.

Transmission of this Field Safety Notice

Please distribute this notice to all those who need to be aware of this action within your organisation.

Sincerely,

CareFusion Representative

Appendix 1 – To be completed and returned by End User

URGENT FIELD SAFETY NOTICE – Acknowledgement Form

Product Name: **Alaris VP Plus with Guardrails**

Product codes: **9003MED01-G and 9003TIG01-G**

FSCA Identifier: **RA-2016-10-02**

Date: **November 2016**

Type of Action: **Advisory Notice**

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	
Date	

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

Please return to:

Local CareFusion Representative

Address:

Via Fax:

Via Email: