

Name
Address

URGENT FIELD SAFETY NOTICE

Product Name: **Alaris™ PK Plus Syringe Pump**
Product codes: **8005TIG01 (manufactured between April 2016 & August 2016)**
Product Manufacturing: **from 13 Apr 2016 to 24 Aug 2016.**
Serial Numbers: **from 50000001 to 500001014.**
FSCA Identifier: **RA-2016-10-01**
Date: **01 February 2017**
Type of Action: **Field Safety Notice**

ATTENTION: Clinical Personnel, Risk Managers, Biomedical Personnel

Description of the Problem

CareFusion has identified a risk with the Alaris PK Plus Syringe Pump that resulted in a situation where the Near End of Infusion (NEOI) audible alarm on the 8005TIG01 PK syringe pumps was not heard and/or not recognised by the clinician.

The issue is isolated to the product code 8005TIG01 only.

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

- An interruption of infusion, resulting in sub-therapeutic levels of medication administered.
- If the user does not hear the alarm and does not see the visual beacon, the anaesthesiologist may not have the next syringe prepared which may result in anaesthetic awareness.

Action Required

CareFusion intends to inform the customers who received these new 3rd Edition (IEC60601-2-24: 2012) compliant PK pumps about the changes to alarm tones. This new standard specifies that the Near End Of Infusion (NEOI) alarm should be changed from a medium priority to a low priority. The previous versions of the PK pumps had two levels of alarm priority: medium and high. The new pumps have three levels of alarm priority; low, medium and high. The new low setting has a lower audible volume with a longer period between the beeps. The NEOI alarm now fits into this low priority alarm specification.

If requested, the local CareFusion representative will provide training to the clinicians using the new pumps, to demonstrate the variance in the NEOI alarm behaviour between the new pumps and previous versions.

Your competent authority has already been notified of this Field Safety Notice 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 Notice, 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,

Ralph HILBERATH

VP Regulatory Affairs & Compliance, WWID

Appendix 1 – To be completed and returned by End User

URGENT FIELD SAFETY NOTICE – Acknowledgement Form

Product Name: **Alaris™ PK Plus Syringe Pump**
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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.
- We are asking to schedule for a training to the anaesthesiologists using the new pumps, to demonstrate the variance in the NEOI alarm behaviour between the new pumps and previous versions.

Please return to:

Local CareFusion Representative

Address:

Via Fax:

Via Email: