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ABN 26 003 080215

2<sup>nd</sup> April 2015

**Generic letter**  
*Customer Name*  
*Address*  
XXXXX  
XXXXX

Dear Valued CareFusion Customer:  
Director of Biomedical Engineering  
Director of Nursing  
Director of Risk Management

## Medical Device Recall for Product Correction

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<b>Affected Device:</b>	Alaris <sup>®</sup> System PC Unit model 8015.		
<b>Material Codes:</b>	8015LSBIXEN9121; 8015LSAIXE9121; 8015LSCIXE91240; 12279909.		
<b>ARTG:</b>	146664	<b>TGA Recall Ref:</b>	RC-2015-RN-00289-1
<b>Serial Numbers:</b>	Specific to those manufactured between September 1, 2012 and October 22, 2013 having a 5.7" screen. As attached for your facility.		
<b>Issue:</b>	A system error (code 110.6021) is displayed with concurrent audio and visual alarm, however it cannot be cleared by restarting or rebooting the PC unit. When the error code occurs this can cause a delay of infusion. A delay of infusion at start up is unlikely to cause harm		
<b>Action:</b>	CareFusion will replace the affected front keypad assembly. Please return the Customer Acknowledgment Form and completed Serial Number Checklist.		
<b>Incidence:</b>	There have been no adverse events reported however several service requests lead to the finding.		

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CareFusion USA, the manufacturer of the Alaris<sup>®</sup> System infusion pump has identified an issue with the PC Unit Model 8015 following receipt of reports from customers experiencing a system error.

**Description of Issue:** CareFusion has received service reports of a system error on the Alaris PC unit 8015. The Alaris PC units were manufactured between September 1, 2012 and October 22, 2013. Error code 110.6021 is displayed on the PC unit with an audio and visual alarm.

The error code may occur upon power on during the "Power-On Self Test" (Figure 1) due to a keypad issue. The Power-On Self Test is designed to occur during power on, in order to detect issues prior to initiation of an infusion. The system cannot be cleared by restarting or rebooting the PC unit.

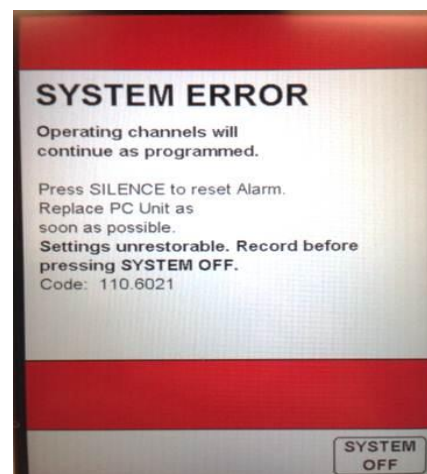
**Correction:** CareFusion has identified the root cause of this issue and will replace the affected front keypad assembly on the Alaris PC unit.

**Potential Risk:** The system error occurs upon power on during the "Power-On Self Test". The system error will cause an audible and visual alarm displaying the Error code 110.6021.

The system cannot be cleared by restarting or rebooting the PC unit. When the error code occurs this can cause a delay of infusion. A delay of infusion at start up is unlikely to cause harm.

There have been no reports of serious injury or death.

**Figure 1:** System Error message



### Clinical Action for Users who may experience this issue:

If system error code 110.6021 occurs;

1. Clinician can utilize another Alaris System PC unit.
2. Clinician can utilize gravity infusions outside the pump or IV syringe push in certain clinical applications.
3. Clearly mark and segregate (e.g. Biomed department) the PC Unit that exhibited the error code.
4. Notify CareFusion Customer Support on 1300 729 258

### Required Actions for Users:

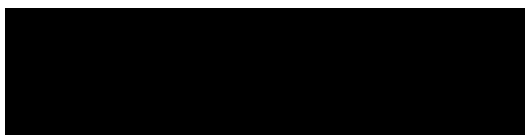
- You have received this recall as we know your facility has been distributed affected stock therefore begin to identify the serial numbers affected at your facility (list below).
- On receipt of a specifically addressed Recall Notification letter containing a list of serial numbers affected at your facility **immediately complete the Customer Acknowledgment Form**.
- As soon as possible **also return a copy of the Serial Number checklist** as this is needed in order to create and track repairs.

CareFusion will contact all affected customers following receipt of the Customer Acknowledgement Form (below attached) to initiate the scheduling process for the remediation.

This Recall has been agreed in consultation with the Therapeutic Goods Administration.

We appreciate your co-operation. Should you require further recall or quality related information, please contact Melissa Robins, Senior Regulatory Affairs Associate on 02 9624 9013.

Sincerely,



**Alex Leung**  
**Director Quality & Regulatory Affairs**  
Asia Pacific

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### Enclosures:

- Serial Number Checklist (Except where long and provided in Excel format directly)
- Customer Acknowledgement Form

## CUSTOMER ACKNOWLEDGEMENT FORM

### MEDICAL DEVICE RECALL FOR PRODUCT CORRECTION

- Affected Device:** Alaris® PC unit model 8015.  
**Material Codes:** 8015LSBIXEN9121; 8015LSAIXE9121; 8015LSCIXE91240; 12279909.  
**ARTG:** 146664 **TGA Recall Ref:** RC-2015-RN-00289-1
- Serial Numbers:** Specific to those manufactured between **September 1, 2012 and October 22, 2013**; as attached for your facility.
- Issue:** A system error (code 110.6021) is displayed with concurrent audio and visual alarm, however it cannot be cleared by restarting or rebooting the PC unit. When the error code occurs this can cause a delay of infusion. A delay of infusion at start up is unlikely to cause harm
- Action:** Identify location of the serial numbers affected in your facility using the Checklist provided and return with the Acknowledgement form or shortly thereafter.

<b>Name of Hospital :-</b>	(generic)
<b>Name of Purchasing Group :-</b>	
<b>Name of recall or biomedical coordinator</b>	
<b>Contact Phone for coordinator</b> <b>*Essential.</b>	
<b>Date:</b>	
<b>Hospital / Facility Address</b>	

- I have read and understood the contents of this Action and confirm that our inventory has been identified.  
 On return of this Acknowledgment Form you will be contacted so we can arrange correction services for the keypad to be replaced.
- We prefer to return our pumps to CareFusion approved repair centres. Serial number checklist [is] / [will be] attached.
- We prefer to discuss a time when CareFusion approved personnel can come on site and carry out repairs. Serial number checklist [is] / [will be] attached.
- I have read and understood the contents of this Action and no longer have those serial numbers affected at our site. (this will allow CareFusion to follow up any pump movement)

**Please return to:** Melissa Robins, Senior Regulatory Affairs Associate  
**FAX 02 9624 9034**  
 Email: Melissa.Robins@carefusion.com

2<sup>nd</sup> April 2015

**Serial Number Checklist – Customer specific**

**Alaris System PC Unit Recall**

**TGA Recall Reference:** RC-2015-RN-00289-1

**Model:** 8015; only the 5.7" LCD monitor

**Material Numbers:** 8015LSBIXEN9121; 8015LSAIXE9121; 8015LSCIXE91240; 12279909.



**4.7" Small Screen LCD**



**5.7" Large Screen LCD**



**NAME of Customer:** [generic example]

**List of Serial Numbers affected** – return a copy via Fax or Email to CareFusion as soon as possible.

Serial Number	Location of PCU in your facility.	Comments space