Alaris® Point of Care Unit  
(Model 8015 with 5.7” screen only)

Medical Device Recall Notification  
“System Error message”

Frequently Asked Questions (FAQ’s) – For External Use

On March 12, 2015 CareFusion issued a recall notification informing affected customers about a potential risk associated with the Alaris® PC unit model 8015 with 5.7” screen only (PC Unit) for Error code 110.6021, which may appear on the PC Unit during the “Power-On Self Test”.

CareFusion has identified the root cause of this issue and will replace the affected front keypad assembly on the PC Unit. CareFusion will contact all affected customers within 60 days to initiate the scheduling process for the remediation.

CareFusion does not require that customers return their devices. As a part of the recall notification, CareFusion is notifying each affected customer and authorized distributors of this issue.

Please review the following list of FAQ’s which will provide further detail about this notification.
General Questions

1. What units are affected?
Alaris PC units model 8015 with 5.7” screen and manufactured between September 1, 2012 through October 22, 2013. See Attachment A for a list of the serial numbers of the affected PC Units. See Figure 1 for visual differences between multiple models of Alaris PC units.

2. How do I locate the serial number and manufacturing date of Alaris PC Unit?
Alaris PC Unit serial number and manufacturing date are located on a sticker on the back of the device. See Figure 2 for an image of the sticker located on the back of the PC Unit.
3. **What is the issue?**
Error code 110.6021 may appear on the PC unit during the “Power-On Self Test” (Figure 3) due to a keypad issue. This error code will be accompanied by an audio and visual alarm. The Power-On Self Test is designed to occur during power on in order to detect issues prior to initiation of an infusion.

![Figure 3. Power-On Self Test](image)

4. **What is the 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.

5. **What devices are affected by this recall notification?**
Alaris PC Unit(model 8015) with 5.7” screen. A list of serial numbers of the affected Alaris PC Units will be posted at [http://www.carefusion.com/customer-support/alerts-notices/](http://www.carefusion.com/customer-support/alerts-notices/).

6. **Who issued the recall notification?**
CareFusion voluntarily issued this recall notification.
7. **Why is CareFusion issuing this recall notification?**
CareFusion issued this recall notification to inform affected customers about the potential delay of infusion that may occur when Error code 110.6021 appears.

8. **What actions is CareFusion taking?**
CareFusion will contact all affected facilities by mail to notify them of this recall. CareFusion will also contact all affected facilities within 60 days to initiate the scheduling process for the corrective action.

9. **How will the affected customers and distributors be notified of this issue and to whom will the notification be addressed?**
Each affected customer and distributor will receive a Letter, FAQs, Summary of Affected Units and Response Card by overnight courier service delivered upon signed receipt. Recall notifications will be sent to the Director of Nursing, Director of Risk Management and Director of Biomedical Engineering of each facility. Only affected customers will receive the notification. Copies of this information can be found on our website at [http://www.carefusion.com/customer-support/alerts-notices](http://www.carefusion.com/customer-support/alerts-notices)

10. **What is the corrective action for this recall?**
CareFusion has identified the root cause of this issue and will replace the affected front keypad assembly on the PC Unit. CareFusion will contact all affected customers within 60 days to initiate the scheduling process for the remediation.

11. **Is there a software update in the corrective action?**
No.

12. **Is there a hardware update in the corrective action?**
Yes, CareFusion will replace the affected front keypad assembly on the PC Unit. An upgraded plastic case and keypad will replace the current assembly.

13. **Has the FDA been notified?**
Yes.

14. **Have there been any reports of the issue?**
Yes. CareFusion has received minimal reports of the issue.

15. **Has there been any death or serious injury related to this potential risk?**
No.
16. **How long will it take to perform the hardware update on each Alaris PC Unit?**
   It will take about 10-15 minutes to update the hardware on each PC Unit. CareFusion will be able to update approximately 40 Alaris PC units per day at a facility.

17. **Is it necessary for CareFusion to perform this corrective action on all of my Alaris PC Units?**
   No. Only affected Alaris PC Units as defined in Question 1 must be updated by CareFusion personnel at user facilities or affected Alaris PC Units can be sent to the CareFusion San Diego Repair Center for remediation.

18. **What is the process for remediating affected Alaris PC Units that are not remediated on site?**
   Affected PC Units that are not remediated during the onsite visit will be remediated at the CareFusion San Diego Repair Center.

19. **Can I perform the hardware update myself for the recalled devices?**
   No. PC Units must be updated by CareFusion personnel at user facilities or affected devices can be sent to the CareFusion San Diego Repair Center for remediation.

20. **How will I be able to tell which devices have had the corrective action performed?**
   The CareFusion field team will provide a list of serial numbers for remediated devices.

21. **Will CareFusion offer any compensation to customers for the corrective action?**
   CareFusion will not be offering any customer compensation for this corrective action.
22. How do I return affected PC Units to the CareFusion San Diego Repair Center (SDRC) for remediation?
- Customer calls the CareFusion Support Center (CSC) at 888-562-6018.
- CSC gets a copy of the serial numbers of the devices to be sent in.
- CSC will create a Return Good Authorization for each serial number.
- CSC will send boxes and CareFusion paid shipping labels.
- Customer will pack and label the devices with the boxes and labels provided by CareFusion and send to the CareFusion San Diego Repair Center (SDRC).
- SDRC will perform remediation activities.
- SDRC will send the devices back to the customer with updated documentation.

23. Who pays the shipping for affected Alaris Pump modules sent to the CareFusion San Diego Repair Center?
CareFusion pays all of the shipping costs.

24. What is the turnaround time if affected PC Units are sent to the San Diego Repair Center (SDRC)?
The turnaround time is 5 working days from the date the SDRC receives the device to the date the customer receives the device.

25. What interim guidance is CareFusion providing for continued use of affected Alaris Pump modules?
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 sequester (e.g. Biomed department) the PC Unit that exhibited the error code.
4. Notify CareFusion Support Center at 888-562-6018 or SupportCenter@carefusion.com

26. Will CareFusion provide loaner PC Units?
No, CareFusion will not be offering additional PC Units.
27. Who should I contact if I have additional questions about this recall?
   Please contact the CareFusion Recall Support Center directly at 888-562-6018.

28. Does this recall result in inability to ship any Alaris System products?
   No.

29. Where can I find more details about this recall?
   More details of this recall can be found on our website at http://www.carefusion.com/customer-support/alerts-notices/ or use the chart provided below for questions and support:

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<tr>
<th>CareFusion Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
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<tr>
<td>CareFusion Support Center</td>
<td>Phone: 888-562-6018</td>
<td>Recall Related Questions</td>
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<tr>
<td></td>
<td>Phone hours: 7:00am to 4:00pm PT, Monday - Friday</td>
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<td>Email: <a href="mailto:SupportCenter@carefusion.com">SupportCenter@carefusion.com</a></td>
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<tr>
<td>Customer Advocacy</td>
<td>Phone: 888-812-3266</td>
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<tr>
<td></td>
<td>Phone hours: 24 hours a day, 7 days a week</td>
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<tr>
<td>Technical Support</td>
<td>Phone: 888-812-3229</td>
<td>Technical Questions for Alaris System</td>
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<td>Phone hours: 6:00am to 5:00pm PT, Monday – Friday</td>
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