Alaris® Syringe Module (Model 8110)

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

The following FAQs are for external use regarding the customer letter delivered on October 15, 2015

1. What devices are affected?

   Alaris Syringe Module model 8110 (shipped before July 13, 2015)

   Alaris Syringe Module replacement kits:
   - BOM Housing Assembly Service (Part Number 10010997)
   - Kit Lower Housing / Carriage Block Assembly ROHS (Part Number 49000226)
   - Kit Lower Housing / Carriage Block Assembly (Part Number 148188-100)

2. How can a customer identify which devices need corrective action?

   Each affected customer will receive a summary of serial numbers requiring corrective action.

3. What is the issue?

   The affected Syringe modules may exhibit error code 351.6740. When error code 351.6740 occurs, a visual notification appears on the Alaris® PC unit (PC unit), a channel error is displayed on the Syringe module, and an audio alarm sounds.

   Although the error code may be cleared, the Syringe module is unresponsive to key presses until the next power cycle or until the module is detached and reattached to the PC unit.

4. What interim guidance is CareFusion providing for continued use of affected devices?

   If system error code 351.6740 occurs:
   - Clinician can utilize another Syringe module.
   - Clinician can utilize IV syringe push in certain clinical applications.
   - Clearly mark and sequester (e.g. Biomed department) the device that exhibited the error code.
   - Notify CareFusion Support Center at 888-562-6018 or SupportCenter@carefusion.com

5. Is this a recall?

   Yes.

6. Has the FDA been notified?

   Yes.

7. Has there been any death or serious injury related to this risk?

   There have been no reports of serious injury or death, but there have been reports of medical intervention due to an interruption in infusion.
8. What is the potential risk?

The error code can occur during an infusion and may result in an interruption of infusion. An interruption of infusion could result in serious injury or death.

9. Who issued this recall?

CareFusion voluntarily issued this recall notification.

10. Why is CareFusion issuing this recall notification?

CareFusion has identified an issue with the affected Syringe modules.

11. 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.

12. How will 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, FAQ, Summary of Affected Serial Numbers 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

13. What is the corrective action for the Alaris Syringe Pump module model 8110 for this recall?

CareFusion will perform an assessment of the affected Syringe modules. Most syringe modules will not require any adjustments and can be put back in service. CareFusion will perform the adjustments either on site at the customer’s facility or at a CareFusion facility. If the adjustment is not successful, these units will be sent to a CareFusion facility for remediation.

14. What is the corrective action for the Alaris Syringe Pump replacement kits (BOM Housing Assembly Service (Part Number 10010997), Kit Lower Housing / Carriage Block Assembly ROHS (Part Number 49000226), and Kit Lower Housing / Carriage Block Assembly (Part Number 148188-100)) for this recall?

Contact CareFusion Support Center at 888-562-6018 or SupportCenter@carefusion.com to return the kit and receive a replacement. If the kit is currently in use, the CareFusion technician will perform the remediated process.

15. What is the turnaround time if affected devices are sent to a CareFusion facility?

The turnaround time is 7 working days from the date the CareFusion facility receives the device to the date the customer receives the device.

16. Is there a software update in the corrective action?

No.
17. Is it necessary for CareFusion to perform this corrective action on all Syringe modules?

No. Only affected Syringe modules as defined in Question 1 are impacted by this corrective action.

18. Can a customer perform the corrective action for the affected Syringe modules?

No. CareFusion must perform the corrective action.

19. Will CareFusion offer any compensation to customers for the corrective action?

CareFusion will not be offering any customer compensation for this corrective action.

20. How do I return affected device(s) to a CareFusion facility 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 a CareFusion facility.
− CareFusion will perform remediation activities.
− CareFusion will send the devices back to the customer with updated documentation.

21. Who pays the shipping for affected devices sent to the CareFusion facility?

CareFusion pays all of the shipping costs.

22. Will CareFusion provide loaner devices?

No. CareFusion will not be offering additional devices.

23. Who should I contact if I have additional questions about this recall?

Please contact the CareFusion Recall Support Center directly at 888-562-6018.

24. Does this recall result in inability to ship any Alaris System products?

No.

25. 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</td>
<td>Phone: 888-562-6018 Phone hours: 7:00am to 4:00pm PT, Monday - Friday Email:</td>
<td>Recall Related Questions</td>
</tr>
<tr>
<td>Center</td>
<td><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 Phone hours: 24 hours a day, 7 days a week Email:</td>
<td>Adverse Event Reports</td>
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<td></td>
<td><a href="mailto:customerfeedback@carefusion.com">customerfeedback@carefusion.com</a></td>
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<tr>
<td>Technical Support</td>
<td>Phone: 888-812-3229 Phone hours: 6:00am to 5:00pm PT, Monday – Friday Email:</td>
<td>Technical Questions for Alaris System</td>
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<td><a href="mailto:DL-US-INF-Tech-Support@carefusion.com">DL-US-INF-Tech-Support@carefusion.com</a></td>
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