CareFusion

July 20, 2015

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 July 20, 2015

1. What devices are affected?

   Alaris Syringe Module model 8110 (Syringe module) manufactured between March 2014 and September 2014.

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 this recall?

CareFusion will perform assessment of the affected Syringe modules, and if adjustment is required – Syringe modules will be sent to CareFusion San Diego Repair Center (SDRC) for repair.

14. What is the turnaround time if affected devices are sent to the CareFusion 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.

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

No.

16. 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 correction action.

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

No. CareFusion must perform the corrective action.

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

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

19. How do I return affected device(s) 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.**

20. Who pays the shipping for affected devices sent to the CareFusion San Diego Repair Center?

CareFusion pays all of the shipping costs.

21. Will CareFusion provide loaner devices?

No. CareFusion will not be offering additional devices.

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

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

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

No.

24. 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:

CareFusion Contact	Contact Information	Areas of Support
CareFusion Support Center	Phone: 888-562-6018 Phone hours: 7:00am to 4:00pm PT, Monday - Friday Email: SupportCenter@carefusion.com	Recall Related Questions
Customer Advocacy	Phone: 888-812-3266 Phone hours: 24 hours a day, 7 days a week Email: customerfeedback@carefusion.com	Adverse Event Reports
Technical Support	Phone: 888-812-3229 Phone hours: 6:00am to 5:00pm PT, Monday – Friday Email: DL-US-INF-Tech-Support@carefusion.com	Technical Questions for Alaris System