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

On April 23, 2014 CareFusion issued a recall notification informing affected customers about a potential risk associated with the Alaris® Pump module (model 8100) for the “Delay Until” option and “Multidose” feature with software version 9.1.18.

CareFusion has identified the root cause of this issue and is recommending installation of the previous Alaris Pump module software version 9.1.17 to address this recall. 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. If you experience an improper delay of an infusion contact CareFusion Customer Advocacy at 888-812-3266. As a part of the recall notification, CareFusion is notifying each affected customer and authorized distributors of this issue.

General Questions

1. What is the issue?

CareFusion has identified a software issue with the Alaris Pump that results in a situation where the Alaris Pump module will not properly delay an infusion when the “Delay Until” option or “Multidose” feature is used. “Delay Until” can be accessed through Delay Options and requires the user to enter a specific time of day to start the delayed infusion. Multidose is accessed by selecting Basic infusion and then pressing Options on the Alaris PC Unit.

This issue does not impact the “Delay For” option which is a delay for a specific number of minutes. This issue does not impact the Alaris Syringe Module “Delay Until” option. This issue only impacts the Alaris Pump module software version 9.1.18.

2. What is the potential risk?

If the Infusion starts earlier or later than intended and is not immediately detected and stopped by the clinician this could result in serious injury or death.

3. What devices are affected by this recall notification?

Alaris Pump module (model 8100 v9.1.18). A list of serial numbers of the affected Alaris Pump modules will be posted at http://www.carefusion.com/customer-support/alerts-notices/.

The list of serial numbers includes devices that may have been updated by your hospital with a recent software kit order (reference Service Bulletin 567 for Point-of-Care software kit numbers).

4. Who issued the recall notification?

CareFusion voluntarily issued this recall notification.
5. **Why is CareFusion issuing this recall notification?**

CareFusion issued this recall notification to inform affected customers about the potential risk associated with the Alaris Pump module when the "Delayed Until" option or "Multidose" feature is used.

6. **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.

7. **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, Tip Sheet, Summary of Affected Units and Response Card by overnight courier service delivered upon signed receipt. Recall notifications will be sent to the Director of Pharmacy, 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).

8. **What is the corrective action for this recall?**

CareFusion has identified the root cause of this issue and is recommending installing the previous Alaris Pump module software version 9.1.17 to address this recall. CareFusion will contact all affected customers within 60 days to initiate the scheduling process for the remediation.

Alaris Pump module software version 9.1.17 is clinically equivalent to version 9.1.18 and represents no clinical workflow changes for end users.

9. **Is there a software update in the corrective action?**

Yes. CareFusion will install the previous Alaris Pump module software version 9.1.17.

10. **Is there a hardware update in the corrective action?**

No.

11. **Has the FDA been notified?**

Yes.

12. **Have there been any reports of the issue?**

Yes. CareFusion has received a report of the issue for "Delayed Until" option.

13. **Has there been any death or serious injury related to this potential risk?**

No.
14. How long will it take to perform the software update on each Alaris Pump module?

It will take about 5-10 minutes to update the software on each Alaris Pump module. We will be able to update 120 Alaris Pump modules per day at a facility.

15. Is it necessary for CareFusion to perform this corrective action on all of my Alaris Pump module?

No. Only affected Alaris Pump modules v9.1.18 must be updated by CareFusion personnel at user facilities or affected Alaris Pump modules can be sent to the CareFusion San Diego Repair Center for remediation.

16. What is the process for remediating affected Alaris Pump modules that are not remediaded on site?

Affected Alaris Pump modules that are not remediaded during the onsite visit will be remediaded at the CareFusion San Diego Repair Center. The steps for this process are covered in question 20.

17. Can I perform the software update myself for the recalled devices?

No. Affected Alaris Pump modules must be updated by CareFusion personnel at user facilities or affected devices can be sent to the CareFusion San Diego Repair Center for remediation.

18. 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 remediaded devices.

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 recalled Alaris Pump modules to the CareFusion San Diego Repair Center (SDRC) for remediation?

a. Customer calls the CareFusion Recall Support Center (RSC) at 888-562-6018.
b. RSC gets a copy of the serial numbers of the devices to be sent in.
c. RSC will create a Return Good Authorization for each serial number.
d. RSC will send boxes and CareFusion paid shipping labels.
e. 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).
f. SDRC will perform remediation activities.
g. SDRC will send the devices back to the customer with updated documentation.

21. Who pays the shipping for affected Alaris Pump modules sent to the CareFusion San Diego Repair Center?

CareFusion pays all of the shipping costs.

22. What is the turnaround time if affected Alaris Pump modules 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.
23. What interim guidance is CareFusion providing for continued use of affected Alaris Pump modules?

Although no issues have been reported there is a potential for this risk, you should not use the "Delay Until" option or "Multidose" feature for the Pump module.

You may also update your dataset to disable both Delay Options and/or Multidose across all Profiles to prevent the use of "Delay Until" option and/or "Multidose" feature. These are shared configurations with the Alaris Syringe module and if Disabled would prevent use of these features with the Alaris Syringe module as well.

If you experience an improper delay of an infusion on the Alaris Pump module contact CareFusion Customer Advocacy at 888-812-3266.

24. Can I continue to use only the Alaris Pump module?

Yes you may continue to use the Pump module with the exception of the “Delay Until” option and “Multidose” feature.

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

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

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

No

27. 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:

<table>
<thead>
<tr>
<th>CareFusion Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
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| CareFusion Recall 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 |