Alaris™ Pump module model 8100

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

BD has identified an issue with the Alaris Pump module. We have received reports of Air-In-Line (AIL) alarms that have occurred when no air is observed in the line. The following FAQs are for external use only regarding the customer letters dated on December 2, 2016.

General Questions

1. **What device is affected?**

   Alaris Pump Module model 8100 (Large Volume Pump) manufactured between October 2011 and June 2015 and AIL sensor kits (P/N 147083-102 and P/N 49000221) distributed between October 2011 and June 2015.

2. **What is the issue associated with the Alaris Pump Module?**

   While the pump is infusing, the system may indicate that an Air-In-Line (AIL) alarm has occurred when no air is in the line. This has two primary causes: 1) the tubing is not pushed back far enough into the air-in-line detector or 2) the AIL sensor may be faulty by having a lack of conductivity with the AIL circuitry.

3. **What is the potential risk?**

   During an infusion, a nuisance AIL alarm would cause the infusion to be interrupted. This would require the operator to clear the alarm. If the AIL sensor is faulty, the alarm may reoccur. Interruption of infusion could lead to injury requiring medical intervention.

   False AIL alarms due to faulty AIL sensors could also occur during service or maintenance operations. In these cases, there could be a delay in putting the device into service.

4. **What is the probability of a customer having a faulty AIL sensor?**

   Approximately 1.4% of Alaris Pump modules received a complaint from October 2011 to June 2015.

5. **What is the recommended action for users?**

   If an Air-In-Line (AIL) alarm occurs, the user should do the following:

   1. Determine if there is air visible in the tubing that has caused the alarm. If there is air visible in the line, press the RESTART key to advance the air bubble past the sensor so that the clinician can evaluate whether or not it is clinically significant and remove it according to hospital protocol, if necessary.

   2. If no air is observed, ensure that tubing is properly installed into the Air-in-Line (AIL) Detector. False AIL alarms may occur if tubing is not properly installed. When inserting the tubing into the Air-in-Line detector, use a fingertip and firmly push the tubing toward the back of the AIL detector.

   3. If AIL alarms continue to reoccur on the same pump, after tubing has been properly loaded, the AIL sensor may be faulty. Sequester the pump so that Biomedical Engineering can investigate the issue. If the AIL sensor needs to be replaced, BD will provide replacement parts at no charge.

6. **What is the recommended action for biomedical engineering?**

   If a pump has been confirmed as having recurring AIL alarms without evidence of air in the line, then replace the AIL sensor with a new AIL assembly provided by BD.

7. **If the user receives an AIL alarm, will the infusion stop?**

   Yes. If the user receives an AIL alarm, the infusion will stop and AIR-IN-LINE will be displayed on the module’s message display along with an audio and visual alarm. The PC unit will also display ALARM. If the user clears the AIL alarm by removing the air bubble and/or properly reloading the tubing, the user can press RESTART to resume the infusion.

**Customer Actions**

8. **What should the customer do if they have a faulty AIL sensor?**

   The customer should sequester the device so that Biomedical Engineering can investigate the issue. If the AIL sensor needs to be replaced, new AIL assemblies (P/N 49000355) can be ordered through Customer Order Management at 1-800-482-4822. The AIL assembly is a no charge item for customers with a faulty AIL sensor.

9. **How can Biomedical Engineering test if the AIL sensor is faulty?**

   Biomedical Engineering can load a fluid filled set into the pump and run a Basic infusion at a rate of 125 mL/hr and VTBI of 10 mL/hr for 2 minutes. If the AIL sensor is faulty, the AIL alarm will occur.

10. **How can the user visually identify a faulty AIL sensor?**

   There is no visual way to identify a faulty AIL sensor.

11. **How can Biomedical Engineering repair a faulty AIL sensor?**

   Biomedical Engineering must replace the faulty AIL sensor by replacing the AIL assembly in accordance with the Alaris Technical Service Manual.

12. **How long does it take to replace the AIL assembly?**

   30-45 minutes.

13. **If the customer has a scheduled remediation at the customer’s facility can BD personnel replace faulty AIL assemblies on Pump modules experiencing this issue?**

   Yes. If BD has a scheduled remediation, or will be scheduling a remediation, at the customer’s facility, BD can replace any faulty AIL assemblies that are experiencing this issue while onsite.
14. **Can the customer send devices that are experiencing this issue to the BD Service Depot for AIL assembly replacement?**

Yes. BD can perform the replacement of the AIL assembly for devices experiencing this issues. The BD service depot can accommodate up to 20 devices per request.

15. **What is the ordering process for a replacement AIL assembly?**

AIL assemblies (P/N 49000355) can be ordered through Customer Order Management at 1-800-482-4822. Small orders (20 or less) will be shipped within 5 business days based on availability. AIL assembly orders of more than 20 will be reviewed weekly. Customers who place AIL assembly orders of more than 20 will be called by the Service Contract team to determine a shipping schedule. AIL assemblies for these large orders will be shipped in lots of 20 assemblies per week.

16. **How can the customer return the faulty AIL assemblies?**

For customers ordering more than 20 AIL assemblies BD will require customers to return faulty AIL assemblies.

1. Customer Order Management will provide the customer with a RGA number when placing the new order with the customer.

2. Customer Order Management will submit a request for a Call Tag (prepaid shipping label) to CareLogix. CareLogix will create a Call Tag and email it to the customer.

3. Customers should package the faulty AIL assemblies and label outside of the returned box with the provided RGA number and use the call tag to ship the faulty parts to BD.

17. **Will BD pay for freight to ship the faulty AIL assemblies back to BD?**

Yes, BD will pay for freight.

18. **Should the customer order AIL assemblies to have in stock in the event that they experience this issue?**

No, the customer should order as needed and only if the AIL sensor is faulty. If the customer experiences a faulty AIL sensor at a future date, BD will provide the AIL assembly at no charge for up to the number of affected pumps and/or the number of affected AIL assembly kits.

19. **What is BD doing to increase the inventory of the AIL assembly?**

BD is actively working with our suppliers to increase our inventory of the AIL.

20. **Will BD offer any compensation to customers for this remediation?**

No, BD will not offer any customer compensation for the remediation.

21. **Will BD provide loaner devices?**

No, BD will not offer loaner Alaris Pump modules.
22. Can an IDN submit a response card on behalf of all their facilities?

Yes. The IDN can sign on behalf of the affected facilities by identifying each facility it is representing. The IDN must acknowledge that they will notify their affected facilities on the response card.

23. Where can the customer find more details about this notification?

More details of this safety notification can be found on our website at [http://www.carefusion.com/customer-support/alerts-notices/](http://www.carefusion.com/customer-support/alerts-notices/) or use the chart provided below for questions and support:

<table>
<thead>
<tr>
<th>BD Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>BD Support Center</td>
<td>Phone: 888-562-6018 Phone hours: 7:00am to 4:00pm PT, Monday - Friday Email: <a href="mailto:SupportCenter@carefusion.com">SupportCenter@carefusion.com</a></td>
<td>Safety Notification Related Questions</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: <a href="mailto:customerfeedback@carefusion.com">customerfeedback@carefusion.com</a></td>
<td>Clinical Inquiries Product Complaints Clinical Troubleshooting</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: <a href="mailto:DL-US-INF-Tech-Support@carefusion.com">DL-US-INF-Tech-Support@carefusion.com</a></td>
<td>Technical Questions for Alaris System</td>
</tr>
<tr>
<td>Customer Order Management</td>
<td>Phone: 1-800-482-4822 Phone hours: 8:00 AM-5:00 PM Central Time Email: <a href="mailto:GMB-CTS-CustCareInfusion@carefusion.com">GMB-CTS-CustCareInfusion@carefusion.com</a></td>
<td>Order of AIL Assembly</td>
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