30 Tuas Avenue 2
Singapore 639461
Registration No. 201114149N

bd.com

Medical Device Safety Notification

AFFECTED DEVICE: Alaris™ Pump Module 8100

21st March 2017

Dear Customer,

Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

Copy: Chairman Medical Board and Head of Departments

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 information details the issue and recommended steps for the users to take.

Affected Product: 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.

Issue:
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. In some cases, these false AIL alarms may be attributed to a faulty AIL sensor.

Potential Risk:
During an infusion, a false 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 would be a delay in putting the device into service.

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Required 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 in 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 air has been removed from the line and 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.
4. Review the attached tip sheet that provides instruction on troubleshooting nuisance Air-In-Line alarms. Access to our video on troubleshooting nuisance air-in-line alarms is located at http://bd.com/air-in-line.

Additional Actions for Biomedical Engineering:
If a pump has been identified as having recurring AIL alarms without evidence of air in the line, then replace the AIL sensor with a new AIL sensor provided by BD.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Please fill in the attached form whether or not you have any inventory remaining so that we may acknowledge your receipt of this notification. Simply complete the attached form, sign and fax the completed form to your local BD contact.

2. We also request that you forward this notice to any other person or groups within your organization for whom this information may be relevant.

For all other inquiries please contact your local BD representative and they will ensure that you are put in contact with the most appropriate individual to address your concerns.

BD sincerely regrets the inconvenience this may cause you. BD is committed to serving your infusion product needs and our primary objectives are patient safety, exceptional product reliability, and the highest level of customer support. Thank you for your continued support while we address these challenges.

Sincerely,

[redacted]

Rose Kwong
Senior Regulatory Affairs & Compliance Executive

Enclosures:
- **FAQs**
- **Troubleshooting Nuisance Air-in-Line Tip Sheet**

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(CUSTOMER ACKNOWLEDGEMENT)

AFFECTED DEVICE: Alaris™ Pump Module 8100

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to your local BD contact.

- ❑ I confirmed that I have read and understood the Medical Device Safety Notification dated 21st March 2017, regarding the above BD products.
- ❑ Other comments:

_____

_____

_____

_____

Completed by:

Name: _____ **Signature / Date:** _____

Facility: _____

Please use full, current facility name. Do not use initials.

Street Address: _____

Telephone No.: _____ **Fax No.**: _____

Company stamp:

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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.

4. Review the attached tip sheet that provides instruction on troubleshooting nuisance Air-In-Line alarms. Access to our video on troubleshooting nuisance air-in-line alarms is located at http://bd.com/air-in-line.

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 Test IV Segment into the pump and run an infusion. If the AIL sensor is faulty, the AIL alarm will occur. The Test IV Segment (P/N 2220-07) can be ordered through Customer Order Management at 1-800-482-4822. This part is available in boxes of 20 and is a no charge item until further notice. Customers will be limited to one case of 20 at this time. Test IV Segments can, and should, be used multiple times until they no longer function as intended.

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/ or use the chart provided below for questions and support:

BD Contact	Contact Information	Areas of Support
BD Support Center	Phone: 888-562-6018 Phone hours: 7:00am to 4:00pm PT, Monday - Friday Email: SupportCenter@carefusion.com	Safety Notification Related Questions
Customer Advocacy	Phone: 888-812-3266 Phone hours: 24 hours a day, 7 days a week Email: customerfeedback@carefusion.com	Clinical Inquiries Product Complaints Clinical Troubleshooting
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
Customer Order Management	Phone: 1-800-482-4822 Phone hours: 8:00 AM-5:00 PM Central Time Email: GMB-CTS-CustCareInfusion@carefusion.com	Order of AIL Assembly

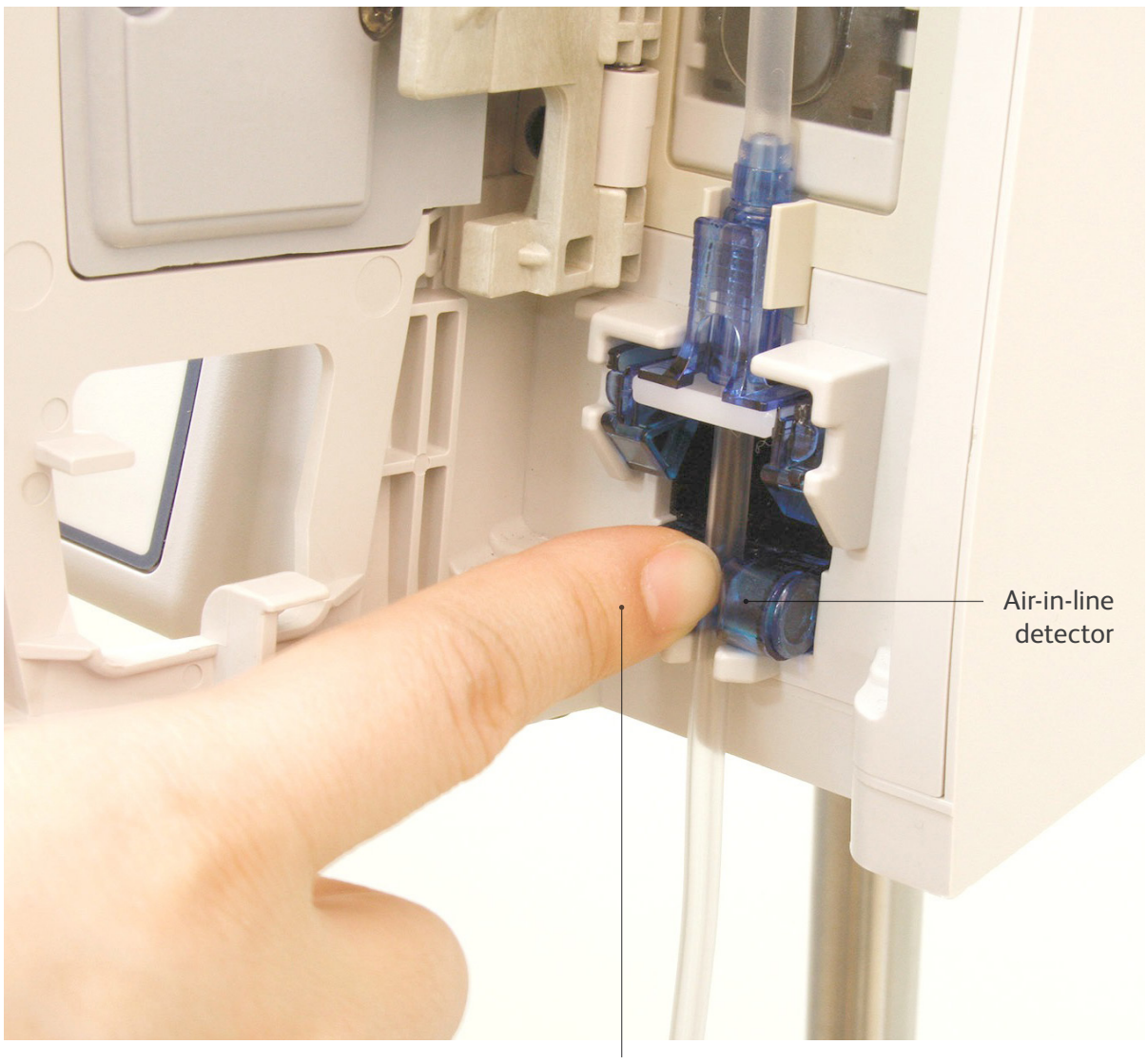
Troubleshooting nuisance air-in-line alarms

Alaris™ Pump module

A user may experience nuisance air-in-line alarms *(when no air is visible in the tubing near the air-in-line detector)* when a set is loaded improperly or when a sensor needs to be replaced.

When loading the administration set into the Alaris™ Pump module, the tubing needs to be **pushed back into the air-in-line detector**. If it is not pushed back far enough, the air-in-line detector will sense air behind the tubing and alarm.

If you have confirmed that the tubing is properly pushed back into the air-in-line detector and the pump continues to alarm, take the device out of service and send it to your hospital biomedical engineering department.



Use a fingertip to firmly push the tubing toward the back of the air-in-line detector.

For product support, contact Customer Advocacy at **888.812.3266** or email **customerfeedback@bd.com.**
For technical support, contact Instrument Technical Support at **888.812.3648**.
For product orders, contact Customer Order Management at **800.482.4822**.

BD, San Diego, CA, 92130, U.S.

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