Medical Device Safety Notification

AFFECTED DEVICE: Alaris™ Pump Module 8100

December 2, 2016

Dear Valued Alaris™ System Customer:

Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

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.


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.

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 the AIL sensor. False AIL alarms may occur if tubing is not properly installed. When inserting the tubing into the AIL sensor, use a fingertip and firmly push the tubing toward the back of the AIL sensor.
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 AIL alarms. Access to our video on troubleshooting nuisance AIL 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.

Follow-up Actions by BD:
The US Food and Drug Administration has been notified of this action. Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA’s MedWatch Program by:

- Web: MedWatch website at www.fda.gov/medwatch
- Phone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178, or by
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

If you have any questions regarding the products, please contact:

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<tr>
<th>BD Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
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<tbody>
<tr>
<td>BD Support Center</td>
<td>Phone: 888-562-6018</td>
<td>Safety Notification Related Questions</td>
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<td>Phone hours: 7:00am to 4:00pm PT, Monday - Friday</td>
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<td>Email: <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</td>
<td>Adverse Event Reports</td>
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<td>Phone hours: 24 hours a day, 7 days a week</td>
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<td>Email: <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</td>
<td>Technical Questions Regarding the Alaris System</td>
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<td>Phone hours: 6:00am to 5:00pm PT, Monday – Friday</td>
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<td></td>
<td>Email: <a href="mailto:DL-US-INF-TechSupport@carefusion.com">DL-US-INF-TechSupport@carefusion.com</a></td>
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<tr>
<td>Customer Order Management</td>
<td>Phone: 1-800-482-4822</td>
<td>Order of AIL Assembly</td>
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<td>Phone hours: 8:00 AM-5:00 PM Central Time</td>
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<td>Email: <a href="mailto:GMB-CTS-CustCareInfusion@carefusion.com">GMB-CTS-CustCareInfusion@carefusion.com</a></td>
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Please promptly complete and return the enclosed Customer Response Card to acknowledge receipt of this notification.

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,

Keith McLain
Vice President, Quality and Regulatory Affairs
Infusion Solutions

Enclosures:
- FAQs
- Customer Response Card
- Troubleshooting Nuisance Air-in-Line Tip Sheet