CareFusion

Medical Device Recall Notification

AFFECTED DEVICE: Alaris® EtCO₂ Module (Model 8300)

December 7, 2015

Dear Valued Alaris® System Customer:

Director of Biomedical Engineering
Director of Nursing
Director of Risk Management
Director of Materials Management

CareFusion has identified an issue with the Alaris EtCO₂ module model 8300 that is detected during device check-in. This notification is intended to provide important information about the importance of testing and recommended steps for users to take.

Affected Units: Alaris EtCO₂ modules model 8300 that were repaired in the CareFusion Service Department from March 3, 2015, to April 28, 2015. See Attachment A for a list of affected serial numbers.

Issue: EtCO₂ modules that were repaired in the CareFusion Service Department from March 3, 2015, to April 28, 2015 were calibrated using 7% CO₂ instead of 5% CO₂.

Potential Risk: The effect to the EtCO₂ module tested with a higher concentration of CO₂ will lead to an incorrect measurement of CO₂. The condition is detected during the check-in and the preventive maintenance procedures specified in the Alaris System Maintenance Manual and the Alaris EtCO₂ Manual. All complaints received were detected by the customer during this check-in procedure, and there have been no reports of serious injury or death.

Required Action for Users:

1. Customer with the affected serial numbers shall call the CareFusion Support Center (CSC) at 888-562-6018.
2. CSC will receive a list of the affected serial numbers from the customers for return.
3. CSC will create a Return Good Authorization for each serial number.
4. CSC will send boxes and CareFusion paid shipping labels.
5. Customer will pack and label the devices with the boxes and labels provided by CareFusion and send to a CareFusion facility.
6. CareFusion will perform remediation activities.
7. CareFusion will send the devices back to the customer with updated documentation.
If you have any questions regarding this product, please contact:

<table>
<thead>
<tr>
<th>CareFusion Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>CareFusion 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>Recall Related Questions</td>
</tr>
<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>
</tr>
<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-TechSupport@carefusion.com">DL-US-INF-TechSupport@carefusion.com</a></td>
<td>Technical Questions Regarding the Alaris EtCO₂ Module</td>
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The US Food and Drug Administration has been notified of this situation. 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

CareFusion is committed to serving your infusion product needs and our primary objectives are patient safety, exceptional product reliability, and the highest level of customer satisfaction. Thank you for your prompt support on this important matter.

Please promptly complete and return the enclosed Customer Response Card to expedite the corrective action process.

Sincerely,

Chuck Donlon
Vice President, Quality and Regulatory Affairs
Infusion Systems

Enclosures:
- Affected Serial Numbers
- Customer Response Card
- External FAQs