Alaris® EtCO₂ Module (Model 8300)

Frequently Asked Questions (FAQ’s) – For External Use
The following FAQs are for external use regarding the customer letter delivered on December 7, 2015

1. What device is affected?

Alaris EtCO₂ Module Model 8300 that were repaired in CareFusion’s Service Department from March 3, 2015 through April 28, 2015.

2. What is the issue?

CareFusion has identified a short time period where EtCO₂ modules were tested during service using a higher than specified concentration of CO₂. An incorrect blood gas mixture with a CO₂ concentration of 7% was used to calibrate and verify EtCO₂ Modules in the Repair Center. The correct blood gas mixture should have had a CO₂ concentration of 5%. If undetected during check-in, the Point of Care Unit connected to the EtCO₂ module will display a waveform of lower amplitude than normal.

3. What actions is CareFusion taking?

CareFusion will contact all affected facilities by mail to notify them of this recall.

4. How do I return affected device(s) to a CareFusion facility for remediation?

− Customer with the affected serial numbers shall call the CareFusion Support Center (CSC) at 888-562-6018.
− CSC will receive a list of the affected serial numbers from the customers for return.
− CSC will create a Return Good Authorization for each serial number.
− CSC will send boxes and CareFusion paid shipping labels.
− Customer will pack and label the devices with the boxes and labels provided by CareFusion and send to a CareFusion facility.
− CareFusion will perform remediation activities.
− CareFusion will send the devices back to the customer with updated documentation.

5. Who pays the shipping for affected devices sent to the CareFusion facility?

CareFusion pays all of the shipping costs.

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

Please contact the CareFusion Recall Support Center directly at 888-562-6018.
7. What is the potential risk during use if a patient is using an affected EtCO\textsubscript{2} module?

   The effect on an EtCO\textsubscript{2} module calibrated with a higher concentration of CO\textsubscript{2} is an under-measurement of patient EtCO\textsubscript{2} concentration. The condition is detected during the check-in and the preventive maintenance procedures specified in the Alaris System Maintenance Manual and the Alaris EtCO\textsubscript{2} 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.

8. We use the Alaris PCA module with EtCO\textsubscript{2}. Will the PCA Pause functionality work as expected?

   Yes, PCA Pause will work as expected because the measurement of the respiratory rate is not affected.

9. Is this a recall?

   Yes.

10. Has the FDA been notified?

    Yes.

11. Has there been any death or serious injury related to this risk?

    No.

12. Who issued this recall?

    CareFusion voluntarily issued this recall notification.

13. What is the corrective action for the Alaris EtCO\textsubscript{2} module model 8300 for this recall?

    Customer shall call the CareFusion Support Center (CSC) at 888-562-6018 to receive a Return Good Authorization (RGA) for each affected serial number. Customer will send the affected devices to the CareFusion Service Depot. Once the remediation activities are complete, CareFusion will send the devices back to the customer.

14. What is the turnaround time if affected devices are sent to a CareFusion facility?

    The turnaround time is 5-7 working days from the date the CareFusion facility receives the device to the date the customer receives the device.

15. Is there a software update in the corrective action?

    No.

16. Can I perform the corrective action for the affected EtCO\textsubscript{2} modules?

    No. CareFusion must perform the corrective action.

17. Will CareFusion provide loaner devices?

    No. CareFusion will not be offering additional EtCO\textsubscript{2} devices.

18. Does this recall result in inability to ship any Alaris System products?
19. 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/](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 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 | 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  
EtCO₂ Module                  |