



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
Healthcare Systems
9900 Innovation Drive
Wauwatosa, WI 53226
USA

June 2014

GEHC Ref# 36100

To: Healthcare Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering

RE: **Potential loss of airway gas measurement in Compact Airway Gas Modules, E-C(Ai)O(V)(X)**

GE Healthcare has recently become aware of a potential safety issue due to gas sampling pump failure associated with the Compact Airway Gas Modules. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

Loosening of the gas sampling pump hex screw in the module pump unit may lead to pump failure that may cause loss of respiratory airway gas parameter monitoring. If this issue occurs, the monitor will show an alarm note on monitor screen of either "Low gas sample flow" or "Check sample gas out".

Safety Instructions

If the monitor is showing an alarm of "Low gas sample flow" or "Check sample gas out", check the following before continued use:

1. Check the water trap is not full or occluded. If full or occluded, empty/change the water trap.
2. Check gas sampling adapter at patient airway is not occluded.
3. Check sample line is not occluded. If occluded, change new gas sampling line.
4. Check gas exhaust outlet is not occluded. Ensure there is no blockage preventing the sample gas out flow to scavenging.

If the above actions do not remove the alarm message(s), it may be due to the issue described above. Remove the equipment from use. Contact technical support or your local service representative.

Affected Product Details

Compact Airway Modules E-CO, E-COV, E-COVX, E-CAiO, E-CAiOV and E-CAiOVX within the serial number range of 6704120 – 6778756. These affected modules were manufactured during 2011.

The above affected modules may be in use with any of the following host devices: CARESCAPE Monitors B850 and B650, Avance and Aisys Anesthesia Carestations, Engstrom Respiratory Carestation, or S/5 Anesthesia and Critical Care Monitors.

Product Correction

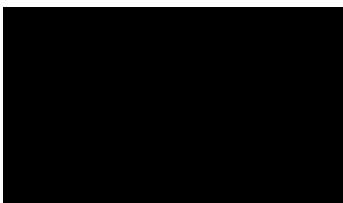
GE Healthcare will provide a correction at no charge. We will contact you to arrange for this correction.

Contact Information

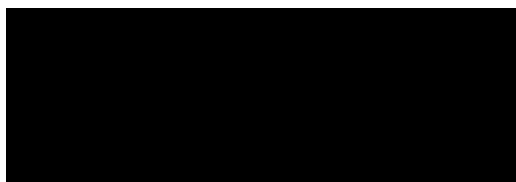
If you have any questions regarding this notice, please contact Technical Support.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,



Vice President QARA
GE Healthcare Systems



Chief Medical Officer
GE Healthcare