URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188
USA

< Date of Letter Deployment >

GEHC Ref# 36141

To: Hospital Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering
Chairman Medical Board
Relevant Head of Departments for hospital

RE: **Failure of an O_2 sensor in the CARESCAPE Respiratory Modules (E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE), the Airway Gas Option (N-CAiO) and their respective service exchange units or field replaceable units with specific serial numbers installed or repaired beginning in June 2019.**

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

Displayed End Tidal Oxygen (EtO2) and Fraction of Inspired Oxygen (FiO2) values may be incorrect which could cause up to 50% measurement error in the EtO2/FiO2 values. This issue can occur in the O2 sensor of the CARESCAPE Respiratory Modules and Airway Gas Options. An incorrect EtO2/FiO2 value could lead to a potential hypoxic or hyperoxic situation or delayed and/or impaired clinical decision making. There have been no injuries reported as a result of this issue.

Note: Measured value does not change any setting for oxygen fraction or flow chosen by the clinician.

Safety Instructions

Replace the affected respiratory module with another module that is not affected by this issue. If you do not have a replacement module, ensure that your respiratory module O2 reading is within specifications by following the below instructions (a) before any new patient case is started and (b) for prolonged patient cases, at a minimum of once a day:

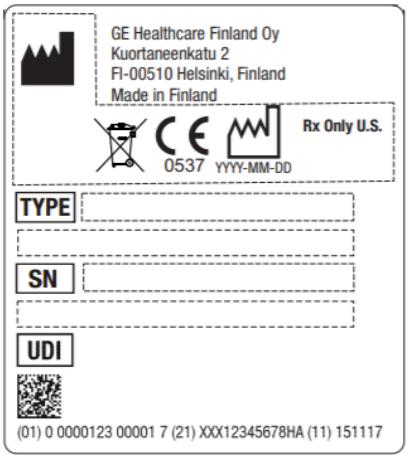
1) Connect the module to the host device;
2) Ensure the module is fully warmed up by having it powered on for minimum 20 minutes;
3) Configure the O2 reading and waveform to the host device screen as defined in the host device instructions;
4) Feed 100% O2 gas flow from the ventilator to the module and observe the O2 reading and waveform; and
5) Ensure the O2 reading is within specifications 100% ±3% and there is no erratic behavior in the waveform.
6) If you are unable to complete the above steps successfully, remove the respiratory module from clinical use and quarantine. Contact GE Healthcare Service or your local Service Representative.

Affected Product Details

CARESCAPE Respiratory Modules, the Airway Gas Option, and their respective service exchange and field replaceable units, installed or repaired beginning in June 2019.

Product	GTIN
CARESCAPE Respiratory Module E-sCO	00840682104173
CARESCAPE Respiratory Module E-sCOV	00840682104258
CARESCAPE Respiratory Module E-sCOVX	00840682104289
CARESCAPE Respiratory Module E-sCAiO	00840682104180
CARESCAPE Respiratory Module E-sCAiOV	00840682104142
CARESCAPE Respiratory Module E-sCAiOVX	00840682104067
CARESCAPE Respiratory Module E-sCAiOE	00840682104135
CARESCAPE Respiratory Module E-sCAiOVE	00840682104302
Airway Gas Option N-CAiO	00840682104074

See attached Appendix A for a list of affected serial numbers. The serial number (SN) of the module can be found on the device plate of the module as indicated in the picture below. The device plate is located on the side of the module.



The affected exchange units and field replaceable units may have been used beginning June 2019 to repair CARESCAPE Respiratory Modules (E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE) or Airway Gas Option (N-CAiO).

The affected modules could be in use with any of the following GE Healthcare host devices:

- CARESCAPE Respiratory Modules (E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE) can be used with:
  - CARESCAPE B850, B650 and B450 Patient Monitors
  - B40(i), B105, B125 Patient Monitors
  - Avance CS^2 and Aisys CS^2 Anesthesia Carestation
  - Carestation 620, 650, 650c for Anesthesia
  - CARESCAPE R860 Ventilator for Critical Care
  - S/5 modular monitors

- Airway Gas Option (N-CAiO) can be used with:
  - B40(i), B105, B125 Patient Monitors
  - Carestation 620, 650, 650c for Anesthesia

Product Correction	GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,

[redacted]

Laila Gurney
Senior Executive, Quality & Regulatory
GE Healthcare

[redacted]

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare