



URGENT FIELD SAFETY NOTICE

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

20 November 2019

GEHC Ref# 36141

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

RE: **Failure of an O₂ 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:

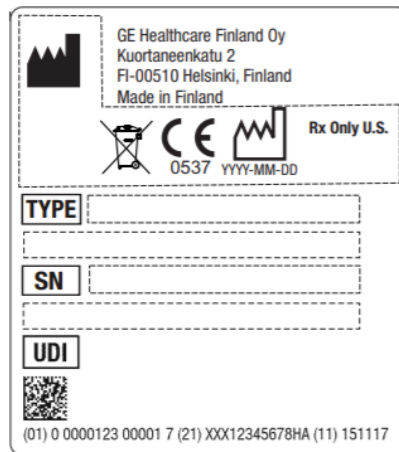
- 1) Connect the module to the host device;
- 2) Ensure the module is fully warmed up by having it powered on for minimum 20 minutes;
- 3) Configure the O₂ reading and waveform to the host device screen as defined in the host device instructions;
- 4) Feed 100% O₂ gas flow from the ventilator to the module and observe the O₂ reading and waveform; and
- 5) Ensure the O₂ reading is within specifications 100% \pm 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 CS² and Aisys CS² 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 or your local Service Representative.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

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,

Laila Gurney
Senior Executive, Quality & Regulatory
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare



**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form (this page) and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice and required actions to be taken GEHC Ref# 36141.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

email Address: _____

Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form scanning or taking a photo of the completed form e-mailing to:

Recall.36141@ge.com

You may obtain this e-mail address through the QR code below:

Scan QR code, attach photo to email, click Send



APPENDIX A

Serial Number Lists of affected CARESCAPE Respiratory Modules E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE; Airway Gas Option N-CAiO and their respective service exchange units and field replaceable units

CARESCAPE Respiratory Module E-sCO, E-sCOV, E-sCOVX, E-sCAiO, E-sCAiOV, E-sCAiOVX, E-sCAiOE, E-sCAiOVE Serial Numbers						
SGV19240060HA	SGV19240365HA	SGV19251002HA	SGV19261013HA	SGV19264036HA	SGV19274044HA	SGV19285005HA
SGV19240073HA	SGV19240366HA	SGV19251007HA	SGV19261015HA	SGV19264037HA	SGV19274045HA	SGV19285007HA
SGV19240076HA	SGV19240371HA	SGV19251019HA	SGV19261016HA	SGV19264038HA	SGV19276001HA	SGV19285013HA
SGV19240082HA	SGV19240373HA	SGV19251020HA	SGV19261017HA	SGV19264040HA	SGV19276013HA	SGV19285015HA
SGV19240084HA	SGV19240376HA	SGV19251023HA	SGV19261019HA	SGV19264041HA	SGV19276023HA	SGV19285017HA
SGV19240085HA	SGV19240377HA	SGV19251024HA	SGV19261021HA	SGV19264043HA	SGV19276028HA	SGV19285019HA
SGV19240090HA	SGV19240381HA	SGV19251028HA	SGV19261023HA	SGV19264045HA	SGV19276029HA	SGV19290003HA
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SGV19240094HA	SGV19240392HA	SGV19251034HA	SGV19261025HA	SGV19264047HA	SGV19276042HA	SGV19290025HA
SGV19240095HA	SGV19240395HA	SGV19251037HA	SGV19261027HA	SGV19264048HA	SGV19280005HA	SGV19290027HA
SGV19240098HA	SGV19240398HA	SGV19251044HA	SGV19261028HA	SGV19264049HA	SGV19280006HA	SGV19290029HA
SGV19240100HA	SGV19240401HA	SGV19251045HA	SGV19261030HA	SGV19264050HA	SGV19280010HA	SGV19290030HA
SGV19240101HA	SGV19240406HA	SGV19251049HA	SGV19261031HA	SGV19264051HA	SGV19280017HA	SGV19290035HA
SGV19240103HA	SGV19240413HA	SGV19251051HA	SGV19261032HA	SGV19264056HA	SGV19280029HA	SGV19290037HA
SGV19240104HA	SGV19240416HA	SGV19251052HA	SGV19261033HA	SGV19264059HA	SGV19280074HA	SGV19290054HA
SGV19240105HA	SGV19241001HA	SGV19251055HA	SGV19261034HA	SGV19264060HA	SGV19280083HA	SGV19290060HA
SGV19240106HA	SGV19241002HA	SGV19251057HA	SGV19261077HA	SGV19266005HA	SGV19280087HA	SGV19290061HA
SGV19240108HA	SGV19241003HA	SGV19251058HA	SGV19261084HA	SGV19266006HA	SGV19280088HA	SGV19290063HA
SGV19240109HA	SGV19241005HA	SGV19251059HA	SGV19261086HA	SGV19266011HA	SGV19280094HA	SGV19290079HA
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SGV19240156HA	SGV19241055HA	SGV19251117HA	SGV19261139HA	SGV19270084HA	SGV19281066HA	SGV19291077HA
SGV19240157HA	SGV19241056HA	SGV19254025HA	SGV19261141HA	SGV19270085HA	SGV19281077HA	SGV19293004HA
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SGV19240179HA	SGV19250005HA	SGV19254033HA	SGV19261149HA	SGV19271021HA	SGV19283004HA	SGV19294008HA
SGV19240180HA	SGV19250006HA	SGV19254034HA	SGV19261151HA	SGV19271022HA	SGV19283006HA	SGV19294012HA
SGV19240181HA	SGV19250007HA	SGV19254036HA	SGV19261152HA	SGV19271028HA	SGV19283007HA	SGV19294016HA
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SGV19240242HA	SGV19250053HA	SGV19255009HA	SGV19261196HA	SGV19271064HA	SGV19283017HA	SGV19294040HA
SGV19240243HA	SGV19250056HA	SGV19255010HA	SGV19261197HA	SGV19271099HA	SGV19283019HA	SGV19295006HA
SGV19240247HA	SGV19250061HA	SGV19255017HA	SGV19261199HA	SGV19271112HA	SGV19283024HA	SGV19295013HA
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SGV19240266HA	SGV19250067HA	SGV19260049HA	SGV19264003HA	SGV19271150HA	SGV19283032HA	SGV19300040HA
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SGV19240275HA	SGV19250080HA	SGV19260064HA	SGV19264009HA	SGV19271170HA	SGV19283037HA	SGV19300062HA
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SGV19240278HA	SGV19250089HA	SGV19260071HA	SGV19264014HA	SGV19274007HA	SGV19283043HA	SGV19300090HA
SGV19240279HA	SGV19250093HA	SGV19260074HA	SGV19264018HA	SGV19274008HA	SGV19283044HA	SGV19300091HA
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SGV19240286HA	SGV19250107HA	SGV19260088HA	SGV19264025HA	SGV19274028HA	SGV19283057HA	SGV19300106HA
SGV19240287HA	SGV19250110HA	SGV19260089HA	SGV19264026HA	SGV19274030HA	SGV19283058HA	SGV19304010HA
SGV19240288HA	SGV19250114HA	SGV19260091HA	SGV19264027HA	SGV19274032HA	SGV19283059HA	SGV19304026HA
SGV19240290HA	SGV19250120HA	SGV19260093HA	SGV19264028HA	SGV19274033HA	SGV19283060HA	SGV19304032HA
SGV19240291HA	SGV19250125HA	SGV19261005HA	SGV19264029HA	SGV19274035HA	SGV19283061HA	SGV19304037HA
SGV19240292HA	SGV19250131HA	SGV19261006HA	SGV19264030HA	SGV19274037HA	SGV19283063HA	SGV19315034HA
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SGV19240362HA	SGV19250157HA	SGV19261012HA	SGV19264035HA	SGV19274043HA	SGV19285002HA	SGV18150053HA

Airway Gas Option N-CAiO Serial Numbers

SGV19248001HA	SGV19258002HA	SGV19258006HA	SGV19258009HA	SGV19258030HA	SGV19268004HA	SGV19268011HA
SGV19248004HA	SGV19258003HA	SGV19258007HA	SGV19258012HA	SGV19258040HA	SGV19268005HA	SGV19268019HA
SGV19248013HA	SGV19258005HA	SGV19258008HA	SGV19258020HA	SGV19268003HA	SGV19268009HA	SGV19318013HA

Service Exchange Unit and Field Replaceable Unit Serial Numbers

SGV19229311HA	SGV19269313HA	SGV19329312HA	SGV14437642HA	SGV15393013HA	SGV17060096HA	SGV18031029HA
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SGV19259302HA	SGV19269323HA	SGV19329316HA	SGV14450567HA	SGV15451005HA	SGV17140055HA	SGV18050091HA
SGV19259303HA	SGV19269326HA	SGV19329318HA	SGV14473815HA	SGV15451020HA	SGV17143008HA	SGV18051011HA
SGV19259305HA	SGV19269402HA	SGV19329410HA	SGV14495993HA	SGV15451204HA	SGV17153075HA	SGV18071004HA
SGV19259306HA	SGV19269601HA	SGV12336914HA	SGV15010212HA	SGV15451210HA	SGV17171017HA	SGV18161013HA
SGV19259309HA	SGV19269605HA	SGV13275929HA	SGV15020952HA	SGV15463045HA	SGV17173072HA	SGV18179620HA
SGV19259310HA	SGV19269606HA	SGV13486917HA	SGV15031909HA	SGV16040081HA	SGV17194016HA	SGV18183007HA
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SGV19269301HA	SGV19269803HA	SGV14302171HA	SGV15124090HA	SGV16401072HA	SGV17331016HA	SGV18310028HA
SGV19269302HA	SGV19299201HA	SGV14313468HA	SGV15145406HA	SGV16434022HA	SGV17333012HA	SGV18310031HA
SGV19269303HA	SGV19319407HA	SGV14357513HA	SGV15166562HA	SGV16440093HA	SGV17350070HA	SGV18340117HA
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