Urgent Field Safety Notice

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

Date of Letter Deployment

GEHC Ref. # 34125

To: Chief of Anesthesia
Director of Biomedical / Clinical Engineering
Health Care Administrator / Risk Manager

RE: **Carestation 750/750c anesthesia delivery systems used with optional auxiliary outlets – Mixer failure state can be triggered.**

This document contains important information for your product. Please ensure 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

Carestation 750/750c anesthesia delivery systems used with one of the optional auxiliary outlets [ACGO (Auxiliary Common Gas Outlet) or Auxiliary O2+AIR] could trigger a mixer failure under certain conditions. At specific O2 and total flow settings (described below) when using the auxiliary outlets, if there is an occlusion in the nasal cannula or linear circuit (e.g. due to clamping, kinking, blocked circuit, or high resistance), this can cause a mixer failure state. This will persist until the next reboot of the device.

If this mixer failure occurs, the system activates Alternate O2 gas delivery (100% O2) to continue ventilation, with audible and visual alarms. Prolonged use of 100% O2 with patients that have a higher sensitivity to oxygen, such as neonates and pediatric patients, when not strictly necessary, exposes these patients to the potential risk of hyperoxia and oxygen toxicity.

There have been no injuries reported as a result of this issue.

Actions to be taken by Customer/ User

You can continue to use the anesthesia system in accordance with the instructions in the User Manual and the actions described below:

1. Always use some form of O2 monitoring to monitor the inhaled O2 concentration and blood oxygen saturation.
2. **If the failure state occurs** [i.e., Alternate O2 is triggered following an occlusion on the auxiliary ports (ACGO or AUX O2+AIR)]:
   a. When Alternate O2 is activated, use low flow techniques to dilute the 100% O2 fresh gas flow, when it's clinically appropriate.
   b. Reboot the system after the current patient case ends to reset the electronic mixer to its proper function.
3. **To avoid this failure state**:
   a. Prevent kinking or clamping of nasal cannula tubing or linear circuits to avoid creating occlusions.
   b. Avoid using very high fresh gas flow settings (higher than 12 l/min), unless clinically indicated, if you are using low (21-35%) or high (90-100%) O2 settings or if you are using small bore tubes or circuits with high flow resistance.
   c. Avoid using fresh gas flow settings of 21% O2 with Total flow values in the format x.25/x.75 (e.g. 3.25 l/min), and use instead values in the format x.00 or x.50 (e.g. 3.0 or 3.5 l/min).
4. Complete the attached Medical Device Notification Acknowledgement Response form and send to **FMI34125.MixerError@ge.com**

Affected Product Details

All Carestation 750/750c Anesthesia Delivery Systems (GTIN: 00840682145596, 00840682146425, 00840682146470, 00840682146463) with software version 02SP04 or earlier that have the following options:

- Auxiliary Common Gas Outlet, identified by the label ACGO on the cover of the auxiliary port.

or

- Auxiliary O2+Air, identified by the label Aux O2+Air on the cover of the auxiliary.

Field Upgrade Kits:
ACGO ASSY + AUXILIARY O2 P/N M7009412 and M7009412-G
AUXILIARY O2+AIR – P/N M7009415

Intended Use
The Carestation 750/750c anesthesia delivery systems are intended to provide monitored anesthesia care, general inhalation anesthesia and/ or ventilatory support to a wide range of patients (neonatal, pediatric, and adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general 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.

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
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form 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 Urgent Field Safety Notice.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

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

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

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: FMI34125.MixerError@ge.com

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