URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>

GEHC Ref # 34122

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

RE: Carestation 750/750c Anesthesia Delivery Systems - After a specific sequence of actions, audible tone of "O_2 supply pressure low" alarm will remain silenced until system reboot.

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

Carestation 750/750c anesthesia delivery systems have a software defect related to the "O_2 supply pressure low" high priority alarm. After a loss of O_2 supply pressure, the user can choose to temporarily silence the audible tone of that high priority alarm by placing the device in "Air Only" use mode. If the O_2 pressure is reestablished while still in "Air Only" mode, the software defect causes the system to not reactivate the audible tone for this particular alarm. Thereafter, at each subsequent occurrence of an "O_2 supply pressure low" condition, the resulting alarm will not sound the audible tone until the system is rebooted. The visible on-screen alarm message of "O_2 supply pressure low" and the popup message of "O2 pressure low" continue to function properly, as do all other alarms and all the other functions of the system.

If the clinician does not notice the loss of oxygen supply pressure and take appropriate action because the audible tone is silenced, the patient could receive a gas mixture with an O_2 content lower than clinically desired.

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.

- Always use some form of O_2 monitoring to monitor the inhaled O_2 concentration and ensure the measured values match the intended O_2 delivery.
- Set appropriate alarm limits for the fraction of inspired oxygen (FiO_2).
- Use SpO_2 monitoring to monitor the level of blood oxygenation.
- Reboot the system after the current patient case ends to reset the alarm to its proper function if an "O_2 supply pressure low" alarm is triggered, and the sequence of events described above causes the audible tone to be silenced.

Affected Product Details

All Carestation 750/750c Anesthesia Delivery Systems (GTIN: 00840682145596, 00840682146425, 00840682146470, 00840682146463) and all software media (USB key) containing Carestation 750 or Carestation 750c software version 02 SP02 (part number: M7002070)

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 software update.

After the Carestation 750/750c anesthesia delivery system has been updated with software version 02 SP04, please destroy any software media containing previous versions of Carestation 750/750c software.

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

GE Healthcare

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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 Medical Device Correction Notice Ref # 34122.

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 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 has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: FMI34122.Alarmissue@ge.com

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