



Urgent Field Safety Notice

GE Healthcare

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

GE Healthcare Ref: 34117

June 3, 2021

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

RE: Carestation 750/750c A1 Anesthesia Delivery Systems - Specific devices could exhibit an excessive or insufficient inhaled anesthetic agent delivery when using Alternative O2 as the source of fresh gas flow.

***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 Specific Carestation 750/750c anesthesia delivery systems have a potential assembly error related to the pressure regulator connection. When using Alternative O2 (ALT O2) as the source of medical gas, if the pressure regulator is not assembled correctly, this could cause inaccurate inhaled anesthetic agent delivery (either excessive or insufficient). If not detected using gas monitoring, inaccurate inhaled anesthetic agent delivery could potentially lead to hypotension or contribute to intraoperative awareness.

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

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

- Always use anesthetic agent monitoring to monitor the inhaled and exhaled anesthetic agent concentrations and ensure the measured values match the intended agent delivery and level of sedation.
- Set appropriate alarm limits for inhaled and exhaled anesthetic agent concentrations.
- If inhaled anesthetic agent monitoring is not available, or if the desired inhaled anesthetic agent delivery cannot be achieved from the vaporizer, switch to intravenous anesthesia.

Affected Product Details Carestation 750/750c A1 Anesthesia Delivery Systems (GTIN: 00840682145596, 00840682146425) See attached appendix for a list of affected serial numbers.

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 inspection and correct your system if required.

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.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Laila', followed by a long horizontal flourish.

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

A handwritten signature in blue ink, appearing to read 'JH', with a stylized, overlapping structure.

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 Medical Device Correction Notice Ref# 34117.**

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

FMI34117.RegulatorTube@ge.com

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



APPENDIX

Carestation 750/750c Anesthesia System Affected Serial Numbers		
SQT19520002WA	SQS21020001WA	SQS21080018WA
SQS19520004WA	SQS21020002WA	SQS21080019WA
SQS19520007WA	SQS21030001WA	SQS21080020WA
SQS19520008WA	SQS21040001WA	SQS21080021WA
SQS19520009WA	SQS21040002WA	SQS21100001WA
SQS19520011WA	SQS21040003WA	SQS21100002WA
SQS19520013WA	SQS21040004WA	SQS21100003WA
SQS19520014WA	SQS21040005WA	SQS21100004WA
SQS19520015WA	SQS21040006WA	SQS21100005WA
SQS19520019WA	SQS21040007WA	SQS21100006WA
SQS19520020WA	SQS21040008WA	SQS21100007WA
SQS19520021WA	SQS21040009WA	SQS21100008WA
SQS19520022WA	SQS21040010WA	SQS21100009WA
SQS19520023WA	SQS21050001WA	SQS21100010WA
SQS20490004WA	SQS21050002WA	SQS21100011WA
SQS20490005WA	SQS21050004WA	SQS21120001WA
SQS20490006WA	SQS21050011WA	SQS21120002WA
SQS20490007WA	SQS21050012WA	SQS21130001WA
SQS20490008WA	SQS21050013WA	SQS21140002WA
SQS20490009WA	SQS21070001WA	SQS21140003WA
SQS20490010WA	SQS21070002WA	SQS21140004WA
SQS20490011WA	SQS21080001WA	SQS21140005WA
SQS20490012WA	SQS21080002WA	SQS21140006WA
SQS20490013WA	SQS21080003WA	SQS21140007WA
SQS20500001WA	SQS21080004WA	SQS21140008WA
SQS20500002WA	SQS21080005WA	SQS21140009WA
SQS20500003WA	SQS21080006WA	SQS21140010WA
SQS20500004WA	SQS21080007WA	SQS21140019WA
SQS20520001WA	SQS21080008WA	SQS21140020WA
SQS20520002WA	SQS21080009WA	SQS21140021WA
SQS20520003WA	SQS21080010WA	SQS21140022WA
SQS20520004WA	SQS21080011WA	SQS21140023WA
SQS21010001WA	SQS21080012WA	SQS21150001WA
SQS21010002WA	SQS21080013WA	SQS21150002WA
SQS21010003WA	SQS21080014WA	SQS21150024WA
SQS21010004WA	SQS21080015WA	SQS21150025WA
SQS21010005WA	SQS21080016WA	SQS21150026WA
SQS21010006WA	SQS21080017WA	