



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 34086

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

RE: **Carestation 620, 650 and 650c - Potential for Elevated FiCO₂**

Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.

Safety Issue

GE Healthcare has recently become aware that an incomplete seal can exist between the CO₂ absorber and the breathing circuit CO₂ bypass port assembly of the Carestation 600 Series systems. An incomplete seal can allow rebreathing of patient gases that have bypassed the CO₂ absorbent material and could result in unintended elevated levels of inspired CO₂ (FiCO₂), which could lead to hypercarbia. There have been no injuries reported as a result of this issue.

Safety Instructions

If you observe elevated FiCO₂, increase the flow of fresh gas to reduce the volume of patient gas that is rebreathed. If the FiCO₂ cannot be adequately reduced with this action, consider switching to another anesthesia delivery device.

GE Healthcare recommends the use of a CO₂ monitor whenever anesthesia is delivered. Per the advisory in the User Reference Manual, "European, international, and national standards require the following monitoring be used with this system:

- Exhaled volume monitoring.
- O₂ monitoring.
- CO₂ monitoring.
- Anesthetic agent monitoring be used when anesthetic vaporizers are in use."

Affected Product Details

All Carestation 620, Carestation 650, and Carestation 650c Anesthesia systems

Product Correction

GE Healthcare is releasing revised parts that minimize the likelihood of incomplete gas flow through the CO₂ absorbent canister. GEHC will correct all affected products by installing updated parts at no cost to you. A GE Healthcare representative will contact you to arrange for this correction. Going forward, the updated parts will be included in the 12-month preventative maintenance replacement schedule for the Carestation 600 Series system.

**Contact
Information**

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

Toll Free number: 8004292222

SaudiArabiaServiceCenter@ge.com

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,



James W. Dennison
Vice President - Quality & Regulatory
GE Healthcare



Jeff Hersh, PhD MD
Chief Medical Officer – Medical Safety
GE Healthcare