



## 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  
Chairman Medical Board and relevant Head of Departments

RE: **Carestation 620, 650 and 650c - Potential for Elevated FiCO<sub>2</sub>**

**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 CO<sub>2</sub> absorber and the breathing circuit CO<sub>2</sub> bypass port assembly of the Carestation 600 Series systems. An incomplete seal can allow rebreathing of patient gases that have bypassed the CO<sub>2</sub> absorbent material and could result in unintended elevated levels of inspired CO<sub>2</sub> (FiCO<sub>2</sub>), which could lead to hypercarbia. There have been no injuries reported as a result of this issue.

### **Safety Instructions**

If you observe elevated FiCO<sub>2</sub>, increase the flow of fresh gas to reduce the volume of patient gas that is rebreathed. If the FiCO<sub>2</sub> cannot be adequately reduced with this action, consider switching to another anesthesia delivery device.

GE Healthcare recommends the use of a CO<sub>2</sub> 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.
- O<sub>2</sub> monitoring.
- CO<sub>2</sub> 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**

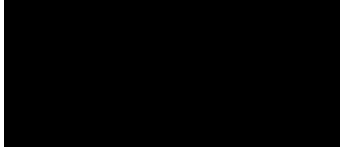
GE Healthcare is releasing revised parts that minimize the likelihood of incomplete gas flow through the CO<sub>2</sub> absorbent canister. GEHC will correct all affected products by installing updated parts at no cost to you. A GE Healthcare representative will contact you to arrange for this correction. 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 at 1-800-437-1171 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,



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



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