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 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 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