URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
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Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 34082

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 has Potential for Elevated FiCO2 and Unexpected System Malfunction

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

Safety Issue

Issue #1:
An incomplete seal can exist between the disposable absorber and the breathing circuit lower assembly of the Carestation 600 Series systems. This incomplete seal can allow rebreathing of patient gases that have bypassed the Carbon Dioxide (CO2) Absorbent material and could result in unintended elevated inspired levels of CO2 (FiCO2), which could lead to hypercarbia.

Issue #2:
An unexpected transition to a system malfunction state can occur on the Carestation 600 Series systems. When this does occur, you will see this message displayed on the screen: “System Malfunction Internal problem prevents normal operation. Use Backup Ventilation. To restart, turn power Off and On.”

The system will continue to perform in the following manner:

- Continue Oxygen flow,
- Provide an indication of Oxygen flow rate using the total flow tube,
- Stop the flow of any balance gas (Air or N2O),
- Provide high priority audible and visible alarms,
- Provide on display instructions to manually ventilate the patient,
- Continue to deliver anesthetic agent at the existing vaporizer setting.

If the System Malfunction is left unresolved, it could result in loss of mechanical patient ventilation, which could lead to hypoxia.

There have been no injuries reported as a result of these issues.

Safety Instructions

Issue #1 Instructions:
If elevated FiCO2 is observed, increasing the flow of fresh gas can reduce the volume of patient gas that could be rebreathed, consistent with standard clinical practices. If the FiCO2 cannot be adequately reduced with this action, consider switching to another anesthesia device.

GE Healthcare recommends the use of a CO2 monitor whenever anesthesia is delivered, per the advisory in our User Reference Manuals:

"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."

Issue #2 Instructions:
If this unexpected transition to a System Malfunction state occurs:

- Manually ventilate the patient (move bag-to-vent switch to bag position, adjust APL, increase Oxygen (O2) flow as needed to fill the manual bag),
- Monitor the patient,
- Cycle the system power off then on by pressing the power switch twice 5 seconds apart to run the power up self-tests and restore normal operation.

Ensure that existing pre-use instructions are followed. These are included both in the User Reference Manual of the device and in the Integrated System Checkout of the device, and instruct the user to verify that a method of back-up ventilation, independent of the anesthesia machine, is available and functional prior to use.

Affected Product Details

Carestation 620 A1, Carestation 650 A1, and Carestation 650c A1 Anesthesia devices shipped from the GE Healthcare manufacturing centers.

GTIN number of affected products:
Carestation 620 A1 (GTIN: 00840682103985)
Carestation 650 A1 (GTIN: 00840682103947)
Carestation 650c A1 (GTIN: 00840682103954)

This Recall Safety Notice DOES NOT affect the refillable reusable CO2 absorber canister (P/N 2071165-001).

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 correction.

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,

[redacted]

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

[redacted]

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