URGENT FIELD SAFETY NOTICE

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
USA

<Date of Letter Deployment>

GEHC Ref# 34074

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

RE: **BTV (Bag to Ventilation) Switch Issue on Carestation 600 Series Anesthesia Systems**

GE Healthcare has recently become aware of a potential safety issue with the BTV switch of certain Carestation 600 Series Anesthesia systems. **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue

The BTV switch could become difficult to move between mechanical ventilation and manual bag modes or remain in a position where it is not possible to ventilate the patient using the anesthesia system. This issue could result in loss of patient ventilation potentially resulting in hypoxia. There have been no customer complaints or injuries reported as a result of this issue.

Safety Instructions

In the event the issue described above does occur, where both mechanical and manual modes of ventilation are lost, a backup method is required to ventilate the patient. If problems with patient ventilation occur, consider the immediate use of a self-inflating bag.

The pre-use instructions included both in the User Reference Manual of the device and also in the integrated System Checkout of the device provide user instructions for verifying prior to use that back-up ventilation, independent of the anesthesia machine, is available and functional.

Your anesthesia device provides alarms to help ensure patient safety, including the following relevant alarms:

- “Apnea” along with “Breathing System Loose”
- “Apnea > 120 seconds” along with “Breathing System Loose”
- “Breathing System Loose”
- Low Minute volume “MVexp low” along with “Breathing System Loose”
- Low Tidal volume “TVexp low” along with “Breathing System Loose”

You can continue to use your anesthesia device.

Affected Product Details

Carestation 620 A1, Carestation 650 A1, and Carestation 650c A1 Anesthesia devices shipped from the GE Healthcare manufacturing center before January 11, 2016. Serial number range of affected products:
Carestation 620 A1 (GTIN: 00840682103985): SM615020004WA to SM616010008WA.
Carestation 650 A1 (GTIN: 00840682103947): SM715020005WA to SM716010008WA.
Carestation 650c A1 (GTIN: 00840682103954): SM815020001WA to SM815500001WA.

Service kits containing the BTV switch assembly shipped from June 01, 2015 through

January 11, 2016 are also affected and could have been installed on Carestation 620 A1, Carestation 650 A1, or Carestation 650c A1 systems. Part numbers and descriptions of service kits:
2071003-001-S , BTV SWITCH ASSEMBLY
2081000-001-S , ASSY BOTTOM BC
2082466-001-S, ASSY BOTTOM BC AUS FEMALE 22

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 your local Service Representative:

UKI Technical Support Representative.
01707 263570 or askuktechnicalsupport@ge.com

UKI Regulatory Affairs
Paul Mardle
01707 263570 or paul.mardle@ge.com

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 per the contact information above.

Sincerely,

[redacted]

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