



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 34093

Chief of Anesthesia
Director of Biomedical / Clinical Engineering
Health Care Administrator / Risk Manager
Chairman Medical Board” and “Relevant Head of Departments for hospital

RE: Potential Loss of Fresh Gas Flow - Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 and 9100c NXT Anesthesia Systems

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

Safety Issue

On systems equipped with the Auxiliary Common Gas Outlet (ACGO), there is a potential for the auxiliary gas switch to unexpectedly switch from the ACGO position back to the circle position. On systems equipped with the Aux O2 + Air function the switch could unexpectedly switch from the Aux O2 + Air position back to the circle position. These situations could lead to hypoxia. It would still be possible to ventilate the patient using the circle breathing system in the manual bag or mechanical ventilation modes. There have been no injuries reported as a result of this issue.

Safety Instructions

You can continue to use the anesthesia systems listed in the affected product details below. If you observe the switch change from the ACGO/Aux to circle positions while using ACGO or Aux O2+Air, use the circle breathing system to ventilate the patient. When the ACGO or Aux O2+Air is active there is an indication on the display. Should the switch change to circle position, it can be observed that the indication on the display disappears, the switch rotates to the circle position, and that the gas flow from the ACGO or Aux O2+Air port stops flowing. If you observe any of these signs, please use the circle breathing system to ventilate the patient. At any time, the clinician may use a self-inflating bag to ventilate the patient and/or switch to another anesthesia device.

Affected Product Details

Carestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 and 9100c NXT Anesthesia systems, see attached Appendix for list of affected serial numbers:

Carestation 620 A1 (GTIN: 00840682103985)
Carestation 650 A1 (GTIN: 00840682103947)
Carestation 650c A1 (GTIN: 00840682103954)

Product Correction

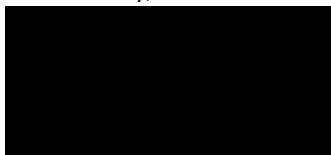
GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information

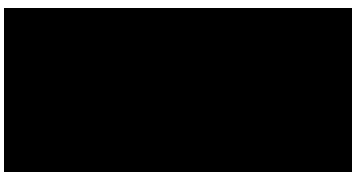
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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,



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



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