



## PRODUCT SAFETY NOTICE

GE Healthcare

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

<Date of Letter Deployment>

GEHC Ref# 34080

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

RE: Potential Battery Function Failures on 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**

Battery function failures can occur on certain Carestation 600 series anesthesia systems after repeated exposure to corrosive aerosol room fumigation agents. The Carestation 600 User Reference Manual cautions against cleaning the system with halogenated or other harsh cleaning agents; this contraindication encompasses corrosive aerosol room fumigation agents. This issue could result in loss of patient ventilation potentially resulting in hypoxia. There have been no injuries reported as a result of this issue.

### **Safety Instructions**

If you do not use corrosive aerosolized agents to fumigate rooms in which the Carestation 600 is used or stored, and no alarm messages have been seen, you can continue using the device.

If you use corrosive aerosolized agents to fumigate rooms in which the Carestation 600 is used or stored, you can continue to use the device and provided you monitor for alarm messages: "Internal failure. System can shut down." or "No battery Backup". If any of these alarm messages occur, complete the current case then discontinue use of the systems and contact your GE Healthcare Service representative to perform corrective repairs

In the event that primary electrical power is lost while battery backup is not available and mechanical modes of ventilation are lost, the Carestation 600:

- 1) Continues to deliver a flow of 100% oxygen to the fresh gas supply, and
- 2) Manual ventilation remains immediately available through the integrated bag.

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

**Affected  
Product  
Details**

Carestation 620 A1, Carestation 650 A1, and Carestation 650c A1 Anesthesia devices shipped from the GE Healthcare manufacturing center to India before November 08, 2016.

GTIN number of affected products:

Carestation 620 A1 (GTIN: 00840682103985)

Carestation 650 A1 (GTIN: 00840682103947)

Carestation 650c A1 (GTIN: 00840682103954)

See the appendix for serial numbers of affected Carestation 600 series anesthesia devices.

**Product  
Correction**

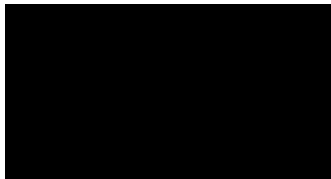
GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

**Contact  
Information**

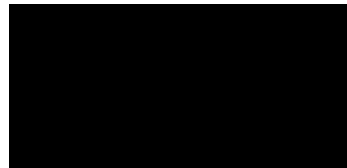
If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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  
GE Healthcare

**Appendix**  
**Serial Number List of affected Carestation 600 series Anesthesia Devices:**

SM614430001WA	SM615440001WA	SM616150005WA	SM616330010WA	SM715510004WA
SM615260034WA	SM615440002WA	SM616150006WA	SM616330018WA	SM715510005WA
SM615330048WA	SM615440003WA	SM616150008WA	SM616340044WA	SM715510006WA
SM615340070WA	SM615440004WA	SM616160009WA	SM616340045WA	SM716010006WA
SM615340071WA	SM615440005WA	SM616160010WA	SM616360005WA	SM716020001WA
SM615350072WA	SM615440006WA	SM616190013WA	SM616360022WA	SM716020002WA
SM615350075WA	SM615440007WA	SM616190014WA	SM616370001WA	SM716020003WA
SM615350077WA	SM615480006WA	SM616190015WA	SM616420009WA	SM716020005WA
SM615350078WA	SM615480007WA	SM616190016WA	SM616430042WA	SM716020006WA
SM615350082WA	SM615480008WA	SM616200002WA	SM616430043WA	SM716020007WA
SM615350083WA	SM615480009WA	SM616210001WA	SM616430044WA	SM716100048WA
SM615350084WA	SM615480010WA	SM616210002WA	SM616440011WA	SM716100049WA
SM615350085WA	SM615490010WA	SM616210003WA	SM616440012WA	SM716100051WA
SM615350088WA	SM615500001WA	SM616220001WA	SM616440013WA	SM716100052WA
SM615350089WA	SM615500004WA	SM616220007WA	SM715260033WA	SM716150011WA
SM615360005WA	SM615500009WA	SM616220008WA	SM715330049WA	SM716220002WA
SM615370001WA	SM615500011WA	SM616220012WA	SM715340064WA	SM716230009WA
SM615370002WA	SM615500012WA	SM616220013WA	SM715350076WA	SM716230010WA
SM615370003WA	SM615500012WA	SM616220019WA	SM715420001WA	SM716240003WA
SM615370004WA	SM615500013WA	SM616220020WA	SM715420002WA	SM716240018WA
SM615370005WA	SM615500014WA	SM616220021WA	SM715420003WA	SM716240019WA
SM615370006WA	SM615500015WA	SM616220022WA	SM715450003WA	SM716240026WA
SM615370007WA	SM615500016WA	SM616220023WA	SM715450003WA	SM716240027WA
SM615370008WA	SM615510001WA	SM616220024WA	SM715480008WA	SM716240028WA
SM615370009WA	SM615510002WA	SM616220025WA	SM715490002WA	SM716240029WA
SM615370010WA	SM615510003WA	SM616240003WA	SM715490003WA	SM716240043WA
SM615370011WA	SM615510004WA	SM616240004WA	SM715490004WA	SM716300006WA
SM615370012WA	SM615510005WA	SM616240005WA	SM715500009WA	SM716300019WA
SM615370013WA	SM615510006WA	SM616240006WA	SM715500010WA	SM716320008WA
SM615370014WA	SM616080004WA	SM616240009WA	SM715500011WA	SM716330010WA
SM615370015WA	SM616080005WA	SM616300003WA	SM715500012WA	SM716330017WA
SM615370016WA	SM616080006WA	SM616300004WA	SM715500013WA	SM716360006WA
SM615370017WA	SM616100031WA	SM616320022WA	SM715500018WA	SM716360008WA
SM615370018WA	SM616100032WA	SM616320023WA	SM715500019WA	SM716360012WA
SM615370019WA	SM616100033WA	SM616320025WA	SM715500020WA	SM716370009WA
SM615370020WA	SM616100034WA	SM616330001WA	SM715500021WA	SM716420017WA
SM615370021WA	SM616100036WA	SM616330006WA	SM715500022WA	SM716440005WA
SM615370022WA	SM616100037WA	SM616330007WA	SM715510001WA	SM716440020WA
SM615430001WA	SM616100038WA	SM616330008WA	SM715510002WA	SM815460001WA
SM615430005WA	SM616150004WA	SM616330009WA	SM715510003WA	SM815460002WA