URGENT MEDICAL DEVICE CORRECTION

27 November 2025

GE HealthCare Ref. # 34143

To: Chief of Anesthesia
Director of Clinical/Biomedical Engineering
Chief of Nursing
Risk Manager/Healthcare Administrator

RE: **Unexpected shutdown of Carestation 600 and 700 Series Anesthesia Systems, containing certain power management boards, when AC mains power is disconnected or AC mains power is lost**

Safety Issue

GE HealthCare has become aware of the potential unexpected shutdown of Carestation 600 and 700 Series Anesthesia Systems containing certain power management boards (see Affected Product Details below), if the AC mains power is unplugged or in the event of an AC mains power failure.

Anesthesia systems only operate on battery power in a rare event that AC mains power is lost and there is no continuous backup emergency power. If AC power is interrupted, the system will not automatically switch over to the battery supply mode and will reboot. If this issue occurs, a temporary disruption of mechanical ventilation, manual ventilation, and volatile agent delivery may occur. Following the reboot, the system will not return to the previous ventilation settings.

If this situation is not identified and addressed by the user, the loss of ventilation may be life threatening.

There have been no injuries reported to GE HealthCare as a result of this issue.

Actions to be taken by Customer /User

Pending correction by GE HealthCare, you can continue to use the Anesthesia machine with affected power management boards by following the instructions below:

1. **Always ensure the device has a secure connection to an AC mains power source.**
2. If there is a loss of AC mains power to the system leading to an unexpected system shutdown:

    - Promptly initiate ventilation using a self-inflating bag connected to an oxygen source.
    - Assess oxygenation via pulse oximetry.
    - Because volatile anesthetic agent delivery may transiently be disrupted, supplement with or transition to intravenous anesthetics as needed.
    - Following system reboot, the system will enter pre-use check. Press "Start Anesthesia" or “Start Case” and then select the "Bypass" button to bypass the checkout. Proceed to selecting the ventilation parameters and volatile agent concentration appropriate for the patient.

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

Please retain this document for your records.

Please complete and return the attached acknowledgement form to RECALL.FMI34143@gehealthcare.com or submit the acknowledgment using survey.

Affected Product Details

Carestation 600 and 700 Series Anesthesia systems manufactured with the affected Power Management Board and Power Management Board (PMB) Field Replaceable Unit (FRU), 2076139-001-S, distributed between June 2, 2025 and October 21, 2025.

Manufacturing Date Range (YYYY-MM-DD date format, located underneath date of manufacture symbol)
June 02, 2025 (2025-06-02) – October 21, 2025 (2025-10-21)

Affected (PMB) have been shipped or used with the following products:

Table 1: Products shipped with potentially affected PMB:

Product	Ref#	GTIN Number
Carestation 610 A1	1012-9620-222	00195278626301
Carestation 620 A1	1012-9620-000	00840682103985
Carestation 620 A1	1012-9620-200	00195278439536
Carestation 620 A1	1012-9620-202	00195278626158
Carestation 620 SE A1	1012-9620-212	00195278626561
Carestation 630 A1	1012-9650-222	00195278626592
Carestation 650 A1	1012-9650-000	00840682103947
Carestation 650 A1	1012-9650-200	00195278439529
Carestation 650 A1	1012-9650-202	00195278626585
Carestation 650 SE A1	1012-9650-212	00195278625687
Carestation 650c A1	1012-9655-202	00195278625953
Carestation 750 A1	1012-9750-000	00840682145596
Carestation 750 A2	1012-9750-002	00840682146470
Carestation 750c A1	1012-9755-000	00840682146425

In addition to the products listed in table 1 above, the affected PMB could also be installed as spare part with the following products:

Table 2. In addition to Table 1, Products for which affected PMB can be used as a spare part

Product	Ref#	GTIN Number
Carestation 620 A2	1012-9620-002	00840682124546
Carestation 620 SE A2	1012-9620-012	00195278569677
Carestation 650 A2	1012-9650-002	00840682124560
Carestation 650 SE A2	1012-9650-012	00195278569684
Carestation 650c A1	1012-9655-000	00840682103954
Carestation 650c A2	1012-9655-002	00840682124539
Carestation 650c A1	1012-9655-200	00195278439543
Carestation 750c A2	1012-9755-002	00840682146463

Carestation 620/650/650c(Software Revision 01) Intended Use:
The Carestation 620/650/650c anesthesia systems are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonates, pediatric and adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

Carestation 620/650/650c(Software Revision 01) (United States) Intended Use:
The Carestation 620/650/650c anesthesia systems are intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (pediatric, and adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

Carestation 620/650/650c (Software Revision 02) Intended Use:
The Carestation 620/650/650c anesthesia systems are intended to provide monitored anesthesia care, general inhalation anesthesia and/ or ventilatory support to a wide range of patients (neonatal, pediatric, and adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general anesthesia.

Carestation 750/750c Intended Use:
The Carestation750/750c anesthesia systems are intended to provide monitored anesthesia care, general inhalation anesthesia and/ or ventilatory support to a wide range of patients (neonatal, pediatric, and adult). The anesthesia systems are suitable for use in a patient environment, such as hospitals, surgical centers, or clinics. The systems are intended to be operated by a clinician qualified in the administration of general anesthesia

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 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 as per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

Please complete this form and return it to GE Healthcare promptly upon receipt of this letter and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

There are two options for your convenience:

1) Electronic response form (this page)

   OR

2) Manual filled and scanned response form (next page)

Please scan the QR code or follow the link below to complete the workflow

https://buildsmart.capgemini.com/esurveys/takesurvey/18446744073712302388

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Manual filled and scanned response form

Alternatively, if the workflow on the previous page is not possible, please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

By signing this form, we acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed all potential users and have taken and will take appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: RECALL.FMI34143@gehealthcare.com You can obtain this email address through the QR code below: