URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. # 34142

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

RE: **Carestation 620/650/650c and 750/750c Anesthesia Systems– mechanical ventilation not effective in Volume Control Ventilation (VCV) mode**

Safety Issue

GE HealthCare has become aware that certain Carestation 620/650/650c and 750/750c Anesthesia Delivery Systems (see Affected Products List in this letter) will not provide effective ventilation in Volume Control Ventilation (VCV) mode. In these systems, effective ventilation can be achieved in Pressure Control Ventilation (PCV) or Pressure Control Ventilation Volume Guarantee (PCV-VG) modes or with Manual ventilation.

If this issue occurs, it will be obvious to the user via observation and multiple alarms. The inflated bellows, visible through transparent glass, will stop moving and an audible alarm and visual 'Unable to Drive Bellows' message will alert the user. Additional alarms including 'Apnea', 'EtCO2 low', 'MVexp low', 'RR low', and 'TVexp low' will also alert the user to inadequate ventilation.

In the unlikely event this issue occurs and it is not noticed, it can result in hypoxia.

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

Actions to be taken by Customer/ User

You can continue to use your Anesthesia system by following the instructions below:

Perform the Ventilation Screening Test specified in **Appendix 1** for each affected Carestation system.

If the Carestation system passes the Ventilation Screening Test, you can continue to use the device in accordance with the instructions in the User Reference Manual (URM).

If the Carestation system fails the Ventilation Screening Test and must be used prior to the system being corrected by GE HealthCare, follow the instructions below:

1. Use the device in accordance with the instructions in the User Reference Manual (URM) with these changes:
    i. Use only Pressure Control Ventilation (PCV) or Pressure Control Ventilation Volume Guarantee (PCV-VG) mode to mechanically ventilate a patient.
    ii. Do not use Volume Control Ventilation (VCV) mode to mechanically ventilate a patient.

    NOTE: Manual mode of the anesthesia system can be used to provide manual ventilation or allow spontaneous ventilation of the patient.
2. Ensure users are made aware not to use Volume Control Ventilation (VCV) mode on the device until the device has been corrected by GE HealthCare.

Please ensure all potential staff 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 Medical Device Notification Acknowledgement Response Form to RECALL.FMI34142@gehealthcare.com

Affected Product Details

- CARESTATION 620/650/650c/750/750c Anesthesia Systems manufactured between January 01, 2023, to February 14, 2025.

Product	Ref #	GTIN Number
Carestation 620 A1	1012-9620-200	00195278439536
Carestation 650C A1	1012-9655-200	00195278439543
Carestation 650 A1	1012-9650-200	00195278439529
Carestation 620 A1	1012-9620-000	00840682103985
Carestation 650 A1	1012-9650-000	00840682103947
Carestation 650c A1	1012-9655-000	00840682103954
Carestation 620 A2	1012-9620-002	00840682124546
Carestation 650 A2	1012-9650-002	00840682124560
Carestation 650c A2	1012-9655-002	00840682124539
Carestation 650 SE A2	1012-9650-012	00195278569684
Carestation 620 SE A2	1012-9620-012	00195278569677
Carestation 750 A1	1012-9750-000	00840682145596
Carestation 750c A1	1012-9755-000	00840682146425
Carestation 750 A2	1012-9750-002	00840682146470
Carestation 750c A2	1012-9755-002	00840682146463

- VENTILATOR ENGINE SERVICE ASSY Field Replaceable (FRU), 2071117-001-S, distributed between January 01, 2023, to February 14, 2025.

Carestation 620/650/650c Intended Use:
The Carestation 620/650/650canesthesia 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 (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 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 devices that fail the Ventilation Screening Test 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.

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 per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

Appendix 1: Ventilation Screening Test

1. Connect the gas supply if not already connected.
2. Plug in the AC power cord if not already connected.
3. Turn on the system. Do not perform a **Full Test**.
4. Attach an adult anesthesia patient circuit to the inspiratory and expiratory ports on the system.
5. Attach a 2 Liter reservoir bag to the wye connector of the anesthesia circuit.
6. Set the Bag/Vent switch to Bag.
7. Select **Start Case** and then select **Bypass** to bypass the Full Test and Checkout.
8. Adjust the Fresh Gas and Ventilation parameter settings to the following values:

O2	Total Flow
100 %	3.00 l/min

Mode	TV	RR	I:E	Tpause	PEEP	Pmax
VCV	50 ml	29 /min	1:2	OFF %	OFF cmH2O	40 cmH2O

9. Move the Bag/Vent switch to Vent to start mechanical ventilation.
10. Press the O2 flush button to inflate the bellows.
11. Wait for the system to deliver 6 breaths to the test circuit.
    a. If “Unable to Drive Bellows” alarm message occurs, the device failed the test.
    b. Record the Serial Number of the device on the Medical Device Notification Acknowledgement Response Form.
    c. If “Unable to Drive Bellows” alarm message does not occur, proceed to next step.
12. Move the Bag/Vent switch to Bag.
13. Select **End Case.**
14. Select **Start Case** and then select **Bypass** to bypass the Full Test and Checkout.
15. Adjust the Fresh Gas and Ventilation parameter settings to the following values:

O2	Total Flow
100 %	0.20 l/min

Mode	TV	RR	I:E	Tpause	PEEP	Pmax
VCV	85 ml	4 /min	1:2	OFF %	OFF cmH2O	40 cmH2O

16. Move the Bag/Vent switch to Vent to start mechanical ventilation
17. Press the O2 flush button to inflate the bellows.
18. Wait for the system to deliver 6 breaths to the test circuit.
    a. If “Unable to Drive Bellows” alarm message occurs, the device failed the test.
    b. Record the Serial Number of the device on the Medical Device Notification Acknowledgement Response Form.
19. If “Unable to Drive Bellows” alarm message does not occur, the device passed the test.
20. Move Bag/Vent switch to Bag.
21. Select **End Case.**

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MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED

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 Urgent Field Safety 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.

We've checked all the affected devices within scope of this action, those with serial numbers (SN) listed below failed the ventilation screening test. All other devices passed.

List of Device Serial Numbers that Failed Ventilation Screening Test			

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

Signature: _____

Printed Name: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of the completed form and email to: RECALL.FMI34142@gehealthcare.com