URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>

GEHC Ref# 34104

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

RE: Carestation 620/650/650c A1, Carestation 620/650/650c A2 Anesthesia Systems - Subset of manufactured devices could exhibit a Loss of Mechanical Ventilation

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

GE Healthcare has become aware that there is a potential for a loose cable connection inside specific manufactured anesthesia devices. This would cause a loss of mechanical ventilation and the system will provide high priority audio and visual alarms. Loss of mechanical ventilation could lead to hypoxia if the clinician does not intervene. There have been no injuries reported as a result of this issue.

Safety Instructions

You can continue to use the anesthesia system.

- If you observe the message – "Ventilate Manually!", change from mechanical to manual ventilation. At any time, the clinician may use a self-inflating bag to ventilate the patient and/or switch to another anesthesia device. Contact your GE Healthcare representative for repair of the device.

- Perform the planned maintenance (PM) every 12-months at a minimum per the User's Reference Manual which includes inspection of the cable connection. Note: This inspection step is included in the annual PM described in the Technical Reference Manual. Performing this step in the PM would confirm the integrity of the cable connection.

Affected Product Details

Specific Anesthesia systems:

- Carestation 620 A1 (GTIN: 00840682103985)
- Carestation 650 A1 (GTIN: 00840682103947)
- Carestation 650c A1 (GTIN: 00840682103954)
- Carestation 620/650/650c A2 Anesthesia systems (China only)

Please see the table below to identify the affected device serial numbers which are located on the product label affixed to the left side of the unit. Identify the affected product by the Year (YY) Fiscal Week (FW) and Manufacture Site (SA) as described below.

Affected Devices - WU Manufactured		
Year (YY)	**Fiscal Week (FW)**	**Manufacture Site (SA)**
2018	34 to 52	WA
2019	01 to 24	WA
Affected Devices - MA Manufactured		
Year (YY)	**Fiscal Week (FW)**	**Manufacture Site (SA)**
2018	34 to 52	MA
2019	01 to 30	MA

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 inspection and correct your system if required.

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,

[redacted]

Laila Gurney
Senior Executive, Quality & Regulatory
GE Healthcare

[redacted]

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

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 Medical Device Correction Notice Ref# 34104.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff and have taken and will take appropriate actions in accordance with that Notification.

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

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

Please return completed form by scanning or taking a photo of

FMI34104.SIBCABLE@ge.com

You may obtain this e-mail address through the QR code below: