URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 34148

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

RE: **Unexpected shutdown of Carestation 850 and 850c Anesthesia Systems 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 800 Series Anesthesia Systems (see Affected Product Details below), if the AC mains power is unplugged or AC mains power fails. This can occur following an incomplete system startup occurring when the ON/Standby switch is not pushed long enough as indicated in the User Reference Manual.

Due to this issue, if AC mains power is interrupted for any reason, the system could shut down disrupting gas flow, mechanical ventilation, manual ventilation, and anesthetic agent delivery.

If this is not promptly addressed by the user, the loss of ventilation can 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 by following the instructions below:

1. Whenever possible, Carestation anesthesia systems should have mains power connected.
2. As stated in Section 2: Beginner's Guide of the User Reference Manual, when turning on the system, push the On/Standy switch for 1 full second.
3. Complete all preoperative checkout tests in accordance with the instructions in the User Reference Manual.
4. If unexpected system shutdown occurs:
    a. Promptly initiate ventilation using a self-inflating bag connected to an oxygen source.
    b. Assess oxygenation via pulse oximetry.
    c. Supplement with or transition to intravenous anesthetics, as needed, because anesthetic agent delivery will be disrupted.

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 electronically via FMI 34148 Digital Response Form or print, fill out manually, scan, and email to Recall.34148@gehealthcare.com

Please evaluate existing service stock for the Field Replaceable Unit (FRU) parts and dispose of all affected FRU parts.

After GE HealthCare has corrected your system, ensure that all media containing software versions of 01SP05, 01SP06, 01SP07, 01SP08 are destroyed.

Affected Product Details

All Carestation 850/850c Anesthesia Delivery Systems with software versions 01SP05, 01SP06, 01SP07, 01SP08.

Table 1: Affected Products

Product	Ref#	GTIN Number
CARESTATION 850	1012-9850-000	00195278843593
CARESTATION 850c	1012-9855-000	00195278860859

In addition to the products listed in the above table, the following Field Replaceable Unit (FRU) part and eDelivery Software versions are affected:

Table 2: Affected Field Replaceable Unit parts

Item No.	Name
5963252-S	CS800 SERIES SYSTEM SOFTWARE V01SP07 USB MEDIA

Table 3: Carestation 850/850c eDelivery Software

Ref#	Name
5963252-DWPKG	DOWNLOAD PACKAGE SVC - CS800 SW V01 SP05v41
6007047-DWPKG	DOWNLOAD PACKAGE SVC - CS800 SW V01 SP06
6009599-DLPKG	DOWNLOAD PACKAGE SVC - CS800 SW V01 SP07
6014067-DLPKG	DOWNLOAD PACKAGE SVC - CS800 SW V01 SP08

Intended Use

The Carestation 850/850c 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.

Service Centre UK - Patient Care Solutions :
Phone : 0800 387 377
Email : askuktechnicalsupport@gehealthcare.com

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 GE HealthCare per the contact information above.

Sincerely,

[redacted]

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

GE HealthCare Ref. # 34148

FIELD SAFETY NOTICE 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 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 Field Safety Notice, 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: _____

Position/Job Title: _____

Date (DD/MM/YYYY): _____

To complete this form electronically, please scan the QR Code below or click this link: FMI 34148 Digital Response Form	**To complete this form via email, scan or take a photo of the completed form and email to:** Recall.34148@gehealthcare.com