URGENT MEDICAL DEVICE CORRECTION

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

<Date of Letter Deployment>

GEHC Ref# 38004

To: Hospital Administrators / Risk Manager
Hospital IT Department
Managers of Anesthesia Departments and Critical Care Departments

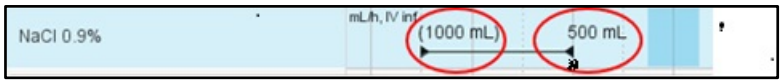
RE: Centricity High Acuity Anesthesia and Centricity High Acuity Critical Care Systems: Restarting infusions

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

This issue occurs when an infusion is started and then stopped before the entire volume is given to patient, see Figure 1, below, and then the same infusion is restarted.

Figure 1: 1000 mL infusion was started and stopped with 500 mL given.



When restarting a previously stopped infusion, the Start Infusion window displays the full volume. The system should instead display the Volume Left value from the previously stopped infusion. Due to a software issue, the default value in the Start Infusion window incorrectly displays the original full started volume, see Figure 2, below.

Figure 2: When same infusion is restarted, the dose in the Start Infusion window incorrectly displays 1000 mL; dose should display as 500 ml.

This safety issue has the potential to mislead the care provider, and can result in overdosing or underdosing the patient.

Safety Instructions

You can continue to use your system in accordance with the User Manuals and the actions below.

If a previously stopped infusion is restarted:

- Check the volume to be started in the Start Infusion display window (shown in Figure 2, above); and
- Modify the dose so that it is the actual volume being started/continued.

The Comment field may be used to enter in any additional information if needed.

Affected Product Details

Affected Product Versions	Version Number in About Box
Centricity High Acuity Anesthesia 4.5 patch C	4.5.0.3.1-1775
Centricity High Acuity Anesthesia 5.0 patch C	5.0.0.3.1-1374
Centricity High Acuity Anesthesia 5.1 patch C	5.1.0.3.1-1277
Centricity High Acuity Critical Care 5.0 patch C	5.0.0.3.1-1374
Centricity High Acuity Critical Care 5.1 patch C	5.1.0.3.1-1277

Note: The following CHA versions are **not** impacted:

- CHA 4.4 and older versions
- CHA 5.2 and newer versions

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.

After the GE Healthcare representative has updated your system, be sure to delete the affected installation media at your site.

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 complete and return the attached "Customer Response" form via e-mail to Recall.38004@ge.com.

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

GE Healthcare

GEHC Ref# 38004

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# 38004.

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 the completed form e-mailing to:
Recall.38004@ge.com