



## URGENT MEDICAL DEVICE CORRECTION

GE Healthcare

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Waukesha, WI 53188 USA

<Date of Letter Deployment>

GEHC Ref# 38000

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

RE: Centricity High Acuity Anesthesia, Centricity High Acuity Critical Care Systems with versions 4.5, 5.0 and 5.1 - Drug Infusion Volumes

*This document contains important information for the continued safe and proper use of 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

The Stop Infusion window is prepopulated with a zero volume in the Volume given field for drug infusions when a drug/fluid infusion is recorded manually and rate has not been entered by the user. The user then may inappropriately accept an incorrect value as the delivered volume (volume given) when manually recording a free-flowing drug infusion. This documentation error may lead to confusion during further care and management which may result in overmedication to the patient.

**Note: The following drug and fluid records are not impacted by this issue:**

1. For fluid infusions where the Stop Infusion window is prepopulated with the whole started volume in the volume given field when infusion rate has not been provided.
2. If drug/fluid infusion rate has been provided by the user, then the system will calculate the given volume based in the rate and times. In this case the Stop Infusion window is prepopulated with the calculated volume in the volume given field.

### Safety Instructions

You may continue to use your system in accordance with the instructions below. Always confirm the volume in the Volume given field in Stop Infusion window before accepting your recording to stop the drug/fluid infusion. If the actual administered volume is different than what the system is pre-populating, you need to manually edit it.

**Affected Product Details**

Centricity High Acuity Anesthesia and Centricity High Acuity Critical Care systems with versions 4.5, 5.0 and 5.1

Affected Product Versions	Version Number (in About Box)	Installation Media
Centricity High Acuity Anesthesia 4.5	4.5.0.0.5-1643	CHA4.5 S4.5.0.0.5-1643.zip
Centricity High Acuity Anesthesia 4.5 Patch A	4.5.0.1.3-1709	CHA4.5 S4.5.0.1.3-1709.zip
Centricity High Acuity Anesthesia 5.0, Centricity High Acuity Critical Care 5.0	5.0.0.0.5-1160	CHA5.0_S5.0.0.0.5-1160.zip
Patch A for Centricity High Acuity Anesthesia 5.0 and Centricity High Acuity Critical Care 5.0	5.0.0.1.2-1320	CHA S5.0.0.1.2-1320.zip
Centricity High Acuity Anesthesia 5.1, Centricity High Acuity Critical Care 5.1	5.1.0.0.4-1057 or 5.1.0.0.5-1199	CHA5.1_S5.1.0.0.4-1057.zip or CHA5.1_S5.1.0.0.5-1199.zip
Patch A for Centricity High Acuity Anesthesia 5.1 and Centricity High Acuity Critical Care 5.1	5.1.0.1.3-1200	CHA S5.1.0.1.3-1200.zip

**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 representative has updated your system, delete the affected installation media on site if not needed for disaster recovery.

**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 immediately per the contact information above.

Sincerely,



James W. Dennison  
Vice President - Quality Assurance  
GE Healthcare



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# 38000.**

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 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.38000@ge.com](mailto:Recall.38000@ge.com)

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

