URGENT FIELD SAFETY NOTICE

GE Healthcare
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Waukesha, WI 53188 USA

Date of Letter Deployment

GEHC Ref. # 38008

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

RE: **Safety issues in Centricity High Acuity Critical Care (CHA CC) and Centricity High Acuity Anesthesia (CHA A):**
#1. Incorrect infusion total volume displayed when restarting device connection after pump occlusion
#2. Incorrect cumulative output balance displayed in second Perioperative Case within same Visit
#3. Incorrect Renal Replacement Therapy fluid balance displayed when Application Server service is restarted
#4. Incorrect Renal Replacement Therapy fluid balance displayed when device connection is restarted after driver variable configuration

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 #1

The Centricity High Acuity (CHA) system calculates an incorrect infusion total volume when a pump connection is restarted after a pump occlusion.

Some pump devices are known to back off a little volume in an occlusion state and this lower infused volume causes a device connection error in CHA system. When the same pump connection is restarted in CHA after the occlusion has been cleared in the pump, the CHA system calculates total volume incorrectly. This happens if the pump is not reset or zeroed before restarting the pump connection in CHA.

The incorrect total volume displayed in CHA will be approximately two times greater than actual infused volume at the time of occlusion. If the occlusion occurs multiple times for the same infusion, then incorrect total volume displayed in CHA will be multiplied accordingly. As a result, the total volume for the infusion and total fluid balance as calculated in CHA will be incorrect.

In rare circumstances, if this incorrect display of infused volume is not detected, it could potentially lead a clinician to administer inappropriate treatment (e.g. under-dosing the patient by missing the intended volume of fluids or dose of medications). There have been no injuries reported as a result of this issue.

Actions to be taken by Customer/User for Issue #1

You can continue to use your system in accordance with the User Manuals and the actions below.
To prevent the occurrence of the issue the user can select either of the two following options after occlusion has been cleared in the pump:

- Reset the pump, or zero the total infused volume in the pump before restarting the pump connection in CHA.

OR

- Continue documenting the infusion manually without pump device connection in CHA.

Affected Product Details for Issue #1

The issue affects all supported infusion pump devices that have backoff functionality in occlusion state. Affected CHA product versions are listed in the table below.

Affected CHA CC and CHA A Product Versions	**Version Number in About Box**
Centricity High Acuity 5.5 Centricity High Acuity 5.5 patch A	5.5.0.0.5-1257 5.5.0.1.1-1341
Centricity High Acuity 5.6 Centricity High Acuity 5.6 patch A Centricity High Acuity 5.6 patch B	5.6.0.0.3-1345 5.6.0.1.2-1495 5.6.0.2.1-1520
Centricity High Acuity 5.7	5.7.0.0.3-3095

Note: The following CHA CC and CHA A versions are **not** impacted:

- Centricity High Acuity 5.4 and older versions

Safety Issue #2

The CHA system displays an incorrect cumulative output balance for the current Perioperative Case if the same patient Visit has a previous Perioperative Case and the same cumulative output variable was documented in the previous Case.

In this situation, the total output volume and fluid balance as displayed in CHA will be incorrect.

In rare circumstances, if this display of an incorrect cumulative output balance is not detected, it could potentially lead a clinician to administer inappropriate treatment (e.g., changes to fluid inputs). There have been no injuries reported as a result of this issue.

Actions to be taken by Customer/User for Issue #2

You can continue to use your system in accordance with the User Manuals and the actions below.
The issue occurs when more than one Perioperative Case is documented within the same patient Visit.
When the first two cumulative output variable values are documented, double check the carried over output balance from the previousPerioperative Case.

The appearance of an incorrect balance volume can be corrected to the patient documentation by additional recordings to cancel out an erroneous volume.

Affected Product Details for Issue #2

Affected CHA A Product Versions	**Version Number in About Box**
Centricity High Acuity 5.6 Centricity High Acuity 5.6 patch A Centricity High Acuity 5.6 patch B	5.6.0.0.3-1345 5.6.0.1.2-1495 5.6.0.2.1-1520
Centricity High Acuity 5.7	5.7.0.0.3-3095

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

- Centricity High Acuity 5.5 and older versions

Safety Issue #3

The CHA system displays an incorrect fluid balance when the Application Server service is shutdown while there are ongoing Renal Replacement Therapy device connections. This issue occurs when restarting the Application Server after downtime and buffered device data is saved to the system.

In rare circumstances, if this incorrect Renal Replacement Therapy fluid balance is not detected, it could potentially lead a clinician to administer inappropriate treatment (e.g. reducing the rate of fluid removal). There have been no injuries reported as a result of this issue.

Actions to be taken by Customer/User for Issue #3

Before a planned downtime for the Application Server service:

1. Open the Device Management window in the CHA application.
2. Stop the ongoing Renal Replacement Therapy device connection.

When system is again operational after downtime:

1. Open the Device Management window in the CHA application.
2. Restart the existing Renal Replacement Therapy device connection.
3. Select the choice “Device was not reset. Continuing the previous therapy.”

The incorrect display of balance volume can be correctedby additional recordings to cancel out an erroneous volume.

Affected Product Details for Issue #3

The issue affects all supported Renal Replacement Therapy devices. Affected CHA product versions are listed in the table below.

Affected CHA CC Product Versions	**Version Number in About Box**
Centricity High Acuity 5.1 Centricity High Acuity 5.1 patch A Centricity High Acuity 5.1 patch C	5.1.0.0.5-1199 5.1.0.1.3-1200 5.1.0.3.1-1277
Centricity High Acuity 5.2 Centricity High Acuity 5.2 patch A	5.2.0.0.4-1026 5.2.0.1.1-1134
Centricity High Acuity 5.3 Centricity High Acuity 5.3 patch A Centricity High Acuity 5.3 patch B	5.3.0.0.5-828 5.3.0.1.2-1013 5.3.0.2.1-1044
Centricity High Acuity 5.4 Centricity High Acuity 5.4 patch A	5.4.0.0.4-1420 5.4.0.1.2-1542
Centricity High Acuity 5.5 Centricity High Acuity 5.5 patch A	5.5.0.0.5-1257 5.5.0.1.1-1341
Centricity High Acuity 5.6 Centricity High Acuity 5.6 patch A Centricity High Acuity 5.6 patch B	5.6.0.0.3-1345 5.6.0.1.2-1495 5.6.0.2.1-1520
Centricity High Acuity 5.7	5.7.0.0.3-3095

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

- Centricity High Acuity 5.0 and older: RRT device connections are not supported in these versions.

Safety Issue #4

The CHA system displays an incorrect fluid balance when ongoing Renal Replacement Therapy device connections are stopped and restarted without removing the connection. This issue occurs when the device connection is restarted after configuration changes are done to the Renal Replacement Therapy device driver variable mappings.

In rare circumstances, if this incorrect display of Renal Replacement Therapy fluid balance is not detected, it could potentially lead a clinician to administer inappropriate treatment (e.g. reducing the rate of fluid removal). There have been no injuries reported as a result of this issue

Actions to be taken by Customer/User for Issue #4

When there are changes to Renal Replacement Therapy device driver variable mappings, apply the steps below to ongoing device connections:

1. Open the Device Management window in the CHA application.
2. Stop the ongoing Renal Replacement Therapy device connection.
3. Remove the connection after it has stopped.
4. Add a new connection to the same device and start the connection.
5. Select the choice “Device was not reset. Continuing the previous therapy.”

These actions will prevent the safety issue.

The incorrect display of balance volume can be correctedby additional recordings to cancel out an erroneous volume

Affected Product Details for Issue #4

The issue affects all supported Renal Replacement Therapy devices. Affected CHA product versions are listed in the table below.

Affected CHA CC Product Versions	**Version Number in About Box**
Centricity High Acuity 5.4 Centricity High Acuity 5.4 patch A	5.4.0.0.4-1420 5.4.0.1.2-1542
Centricity High Acuity 5.5 Centricity High Acuity 5.5 patch A	5.5.0.0.5-1257 5.5.0.1.1-1341
Centricity High Acuity 5.6 Centricity High Acuity 5.6 patch A Centricity High Acuity 5.6 patch B	5.6.0.0.3-1345 5.6.0.1.2-1495 5.6.0.2.1-1520

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

- Centricity High Acuity 5.3 and older versions do not have this software issue.
- Centricity High Acuity 5.7 version contains software correction.

Intended use: Centricity High Acuity system allows trained clinical professional users to retrieve, enter, record, store, transfer, view and trend patient data in an efficient and structured manner as well as to plan for therapy. The documentation managed by CHA, in combination with the physiological information available from the primary diagnosis and monitoring systems, as well as other medical examination results, may be used to influence/support future clinical decision making and treatment.

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 old installation media at your site unless needed for disaster recovery purposes.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.
Please complete and return the attached "Customer Response" form via e-mail to recall.38008@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,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

GEHC Ref. # 38008

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.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer 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 completed this form.

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: recall.38008@ge.com