

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 38016

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

RE: **Centricity High Acuity Critical Care (CHA CC) and Centricity High Acuity Anesthesia (CHA A) systems (collectively CHA)**

Safety Issue

GE HealthCare has become aware that the CHA system discontinues infusion orders with a 'Continuous' timing schedule once the ordered amount is given even if the prescribed time duration is not met. This can lead to undermedication if the intention was for the medication administration to continue until further notice or for a set duration.

There have been no injuries reported to GE HealthCare as a result of this issue.

Actions to be taken by Customer /User

You can continue to use your CHA applications in accordance with the User Manuals and the below supplemental information.

When using the '**Continuous**' timing for infusion orders, be aware that the order will automatically discontinue once the specified amount has been administered to the patient, even if the defined end time has not yet been reached.

If you intend to order an infusion to continue until further notice or for a set duration, please use the 'Continuous' timing schedule and follow the instructions below:

- For infusion orders with a single preparation, leave the **Amount** field empty and only enter the rate into the **Rate** field.
- For infusion orders of a mixture, use the **Mixture Dosing** button to enable mixture dosing. In the **Mixture Dosing** section that appears, leave the **Amount** field empty and enter only the rate into the **Rate** field.

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 to recall.38016@gehealthcare.com.

Affected Product Details

- Centricity High Acuity Critical Care (CHA CC) versions 4.2 through 5.8.2 with the order module feature enabled.
- Centricity High Acuity Anesthesia (CHA A) versions 4.2 through 5.8.2 with the order module feature enabled.

Intended Use: The CHA 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.

Contact Information If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.

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 us per the contact information above.

Sincerely,



GE HealthCare



GE HealthCare

**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): _____

Please return completed form by scanning or taking a photo of the completed form and email to: (e.g., recall.38016@gehealthcare.com)

