Urgent Field Safety Notice

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

GE Healthcare Ref: FMI 38007

June 7, 2021

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) may show overdue task notification when the task is already documented.**

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

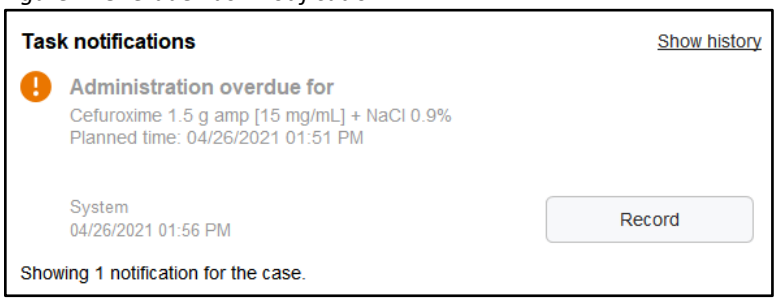
Due to a software error, there is a rare possibility that the CHA Application could display an overdue task notification for a scheduled task (e.g. as shown in Figure 1) that was already completed and documented in the system.

This issue can occur only when the Order Module feature is enabled in the CHA system and users have created orders with scheduled tasks.

The redundant overdue task notification will manifest itself within 30 seconds from the time the related task was documented, but cannot be deleted or removed.

In rare circumstances, if this duplication is not detected, it could potentially lead to inappropriate treatment (e.g. administration of an additional drug dosage or duplicate task). There have been no injuries reported as a result of this issue.

Figure 1: Overdue Task Notification



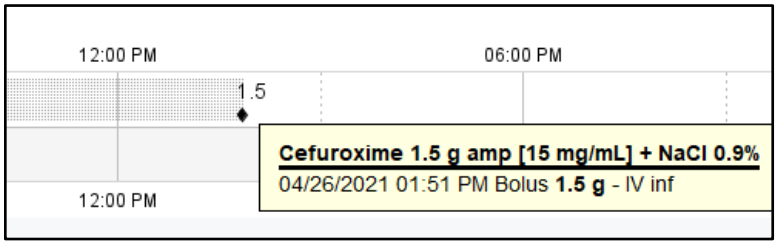
Safety Instructions

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

Always refer to the drugs and fluid trend in the CHA Application (see Figure 2 below). Actions:

1) Confirm that the drugs and fluid trend shows all documented tasks.
2) If you see an overdue task, check whether there is a record of that task already having been completed and documented.

Figure 2: Documented Task in Trend



Affected Product Details

Affected products:
Centricity High Acuity Critical Care (CHA CC) Version 4.2 and above *with the order module feature enabled.*
Centricity High Acuity Anesthesia (CHA A) Version 4.2 and above *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.

After the GE Healthcare representative has updated your system, be sure to destroy the installation media for affected software 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.38007@ge.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 us immediately.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

GE Healthcare

GEHC Ref# 38007

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# 38007.

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.38007@ge.com