URGENT MEDICAL DEVICE CORRECTION

12 April 2024 GE HealthCare Ref. # 38012

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

RE: **Order-based medication mixture details may be confusing in Centricity High Acuity Anesthesia (CHA A) and Centricity High Acuity Critical Care (CHA CC) systems (collectively CHA).**

Safety Issue

GE HealthCare has become aware of the potential for misunderstanding dosing values in the recording window of CHA application when using the order module. Specifically, the display of both "Dose amount" of a single medication and "Dose volume" may confuse clinicians during the preparation of a mixture of two medications for administration. This misunderstanding can lead to incorrect dosing of medication to a patient.

Actions to be taken by Customer /User

1. You can continue to use your CHA A and CHA CC applications in accordance with the User Manuals.

2. When preparing a mixture of medications for administration, ensure that the mixture is made as detailed in the "Composition and Order" section (See Figure 1).

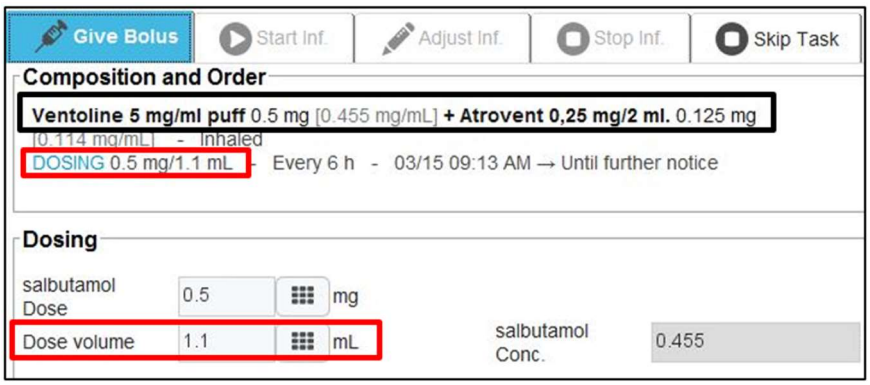

Figure 1. Picture from CHA-A application in English locale.

- Combine the medication ***amounts*** listed in the top line of the "Composition and Order" area (highlighted in black box).

- **NOTE**: The volumes displayed in the "DOSING" and "Dose volume" fields (highlighted in red boxes) describe the *total* volume of the mixture for administration and is not the volume of either medication component to be used in preparing the mixture.

3. If either the composition or dosing of the medication mixture is unclear, confirm details from corresponding order or consult with the prescribing clinician.

4. Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.

5. Please complete and return the attached acknowledgement form.

Affected Product Details

Affected products:
Centricity High Acuity Critical Care (CHA CC) Version 5.0 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.

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 per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

GE HealthCare Ref. # 38012

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:
mailto:recall.38012@gehealthcare.com