URGENT MEDICAL DEVICE CORRECTION

GE HealthCare

2 January 2024 GE HealthCare Ref. # 38011

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

RE: **Patient allergies deleted from external systems are displayed in Centricity Critical Care (CCC), Centricity Anesthesia (CA), Centricity High Acuity Anesthesia (CHA-A) and Centricity High Acuity Critical Care (CHA-CC) products.**

Safety Issue

Centricity Critical Care (CCC), Centricity Anesthesia (CA), Centricity High Acuity Anesthesia (CHA-A) and Centricity High Acuity Critical Care (CHA-CC) products do not support deleting patient allergies via interface messaging. Once a patient allergy is imported, the data will remain in the CCC, CA, or CHA system even when deleted from the external system, leading to a potential mismatch of patient allergy information between the two systems. This could lead to suboptimal treatment of patients.

NOTE: This issue does not impact transfer of allergy additions from external systems to CCC, CA, or CHA. It only impacts transfer of allergy deletions.

Actions to be taken by Customer /User

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

1. When reviewing patient allergies in CCC, CA and CHA, please verify the correctness of the allergies from the external allergy source system.
2. Remove any incorrect allergies from the patient record in the CCC, CA, CHA application.
3. Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.
4. Please complete and return the attached acknowledgement form to recall.38011@ge.com.

Affected Product Details

This issue affects all CCC, CA and CHA product versions.

- Centricity Critical Care (CCC), all versions
- Centricity Anesthesia (CA), all versions
- Centricity Anaesthesia (CA), all versions
- Centricity High Acuity Anesthesia (CHA-A), all versions
- Centricity High Acuity Critical Care (CHA-CC), all versions

INTENDED USE: Affected systems allow 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 the system, 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

GE HealthCare Ref. # 38011

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.38011@ge.com