URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 38018

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

RE: **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 two potential issues with certain CHA systems. These issues are described below:

Safety Issue 1 - Order and Recording Summary component used in displays and printed reports in CHA applications: When this component is configured to display "Show all sessions," the dose amounts of dry medications (for example, tablets) are not included in the medication session row. As a result, the displayed and printed dose amount for a medication session is incomplete and does not reflect the actual administered medication amount. This could lead users to make clinical decisions based on incomplete medication information, potentially resulting in underdosing or overdosing during subsequent medication administration.

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

Safety Issue 2 - Flexible Order Summary printout component: Under specific circumstances, a medication order may be omitted from the printed output due to a pagination logic error. The issue is limited to the Flexible Order Summary component in printout and does not affect the display of medication orders within the CHA application. If this occurs, the printed medication order list may be incomplete and may not accurately reflect the patient's actual medication orders. Reliance on incomplete medication information from this printout could result in incorrect decisions regarding subsequent medication orders or medication administration.

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

Actions to be taken by Customer/User:

Pending corrections from GE HealthCare, you can continue to use the CHA system in accordance with the User Manuals and the below supplemental information.

For Safety Issue 1: Continue to use CHA with “Order and Recording Summary” component configured to display “Show All Records” instead of "Show All Sessions." If the “Order and Recording Summary” component is configured to display "Show All Sessions", please verify administered medication amounts before making clinical decisions regarding subsequent

medication dosing, using alternative sources of information within the application, and particularly when reviewing printed records.

Verification can be performed through reviewing “Drug and Fluid trends” to confirm the actual administered medication amounts.

For Safety Issue 2: When using the “Flexible Order Summary” component in printed reports, please verify medication orders before making clinical decisions regarding subsequent medications or medication administration using alternative sources of information within the application.

Verification can be performed by:

- Configuring additional “Order & recording Summary” component (configured to display "Show All Records") to view a complete list of medication orders in the printout; or
- Reviewing “Drug and Fluid trends” to confirm orders and the actual administered medications.

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.

Please complete and return the attached acknowledgement form electronically via (FMI 38018 Digital Response Form) or print, fill out manually, scan, and email to Recall.38018@gehealthcare.com

Affected Product Details:

Please see Appendix 1 for details on Affected Products listed below:

CHA Product	Safety Issue 1	Safety Issue 2
Centricity High Acuity Anesthesia (CHA A)	versions 5.8.3 and 5.8.4	versions 5.8.2, 5.8.3, 5.8.4 and 5.8.5 up to patch B
Centricity High Acuity Critical Care (CHA CC)	versions 5.8.3 and 5.8.4	versions 5.8.2, 5.8.3, 5.8.4 and 5.8.5 up to patch B

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 GE HealthCare per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical & Safety Officer
GE HealthCare

Appendix 1: Affected Product Details

The following product versions of Centricity High Acuity Anesthesia (CHA A) and Centricity High Acuity Critical Care (CHA CC) systems are affected:

Product	UDI code
CHA Anesthesia 5.8.5	(01)00195278463531(10)58P55500000003
CHA Anesthesia 5.8.5 Patch A	(01)00195278463531(10)58P5A5500000003
CHA Anesthesia 5.8.5 Patch B	(01)00195278463531(10)58P5B5500000003
CHA Critical Care 5.8.5	(01)00195278463548(10)58P55500000004
CHA Critical Care 5.8.5 Patch A	(01)00195278463548(10)58P5A5500000004
CHA Critical Care 5.8.5 Patch B	(01)00195278463548(10)58P5B5500000004
CHA Anesthesia 5.8.4	(01)00195278463531(10)58P45500000003
CHA Anesthesia 5.8.4 Patch A	(01)00195278463531(10)58P4A5500000003
CHA Anesthesia 5.8.4 Patch B	(01)00195278463531(10)58P4B5500000003
CHA Anesthesia 5.8.4 Patch C	(01)00195278463531(10)58P4C5500000003
CHA Critical Care 5.8.4	(01)00195278463548(10)58P45500000004
CHA Critical Care 5.8.4 Patch A	(01)00195278463548(10)58P4A5500000004
CHA Critical Care 5.8.4 Patch B	(01)00195278463548(10)58P4B5500000004
CHA Critical Care 5.8.4 Patch C	(01)00195278463548(10)58P4C5500000004
CHA Anesthesia 5.8.3	(01)00195278463531(10)58P35500000003
CHA Anesthesia 5.8.3 Patch A	(01)00195278463531(10)58P3A5500000003
CHA Anesthesia 5.8.3 Patch B	(01)00195278463531(10)58P3B5500000003
CHA Critical Care 5.8.3	(01)00195278463548(10)58P35500000004
CHA Critical Care 5.8.3 Patch A	(01)00195278463548(10)58P3A5500000004
CHA Critical Care 5.8.3 Patch B	(01)00195278463548(10)58P3B5500000004
CHA Anesthesia 5.8.2	(01)00195278463531(10)58P25500000003
CHA Anesthesia 5.8.2 Patch A	(01)00195278463531(10)58P2A5500000003
CHA Anesthesia 5.8.2 Patch B	(01)00195278463531(10)58P2B5500000003
CHA Anesthesia 5.8.2 Patch C	(01)00195278463531(10)58P2C5500000003
CHA Critical Care 5.8.2	(01)00195278463548(10)58P25500000004
CHA Critical Care 5.8.2 Patch A	(01)00195278463548(10)58P2A5500000004
CHA Critical Care 5.8.2 Patch B	(01)00195278463548(10)58P2B5500000004
CHA Critical Care 5.8.2 Patch C	(01)00195278463548(10)58P2C5500000004

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FIELD SAFETY 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 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 Notification, 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): _____

To complete this form electronically, please scan the QR Code below or click this link: here	**To complete this form via email, scan or take a photo of the completed form and email to: recall.38018@gehealthcare.com**