

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 38017

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 of a potential cybersecurity vulnerability within one of the CHA components. Exposure of this potential vulnerability is limited to the local network.

There have been no injuries, exploits of this potential vulnerability or unauthorized access to patient data 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 by ensuring that CHA systems are operated in a secure network environment that is protected from unauthorized intrusion per product documentation.

Customers are encouraged to adopt cybersecurity defense-in-depth industry best practices, implementing necessary technical and operational controls at the perimeter, network, and host levels.

Please ensure that your network administrators and personnel responsible for network security 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 quality@anandic.com.

Affected Product Details

- Centricity High Acuity Critical Care (CHA CC) versions 4.2 through 5.8.3 Patch A.
- Centricity High Acuity Anesthesia (CHA A) versions 4.2 through 5.8.3 Patch A.

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.

Anandic Medical Systems AG

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F: +41 (0)52 646 03 03

E: quality@anandic.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 per the contact information above.

Sincerely,

Chief Quality & Regulatory Officer
GE HealthCare

Chief Medical Safety Officer
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:

quality@anandic.com