Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمان وزارة الصحة مركز سلامة الدواء مسقط

Moving Forward with Confidence

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 17 dated 10/6/2025 Regarding SFDA Field Safety Corrective Action of Centricity High Acuity Critical Care (CHA CC) and Centricity High Acuity Anesthesia (CHA A) systems (collectively CHA) from (mfr: GE Healthcare).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information





Sultanate of Oman Ministry of Health Drug Safety Center Muscat



وزارة الصحــة مركز سلامة الدواء

Circular No. 117/2025 Moving Forward with Confidence

14 -12-1446 H 0 -06-2025

Field Safety Corrective Action of Centricity High Acuity Critical Care (CHA CC) and Centricity High Acuity Anesthesia (CHA A) systems (collectively CHA) from GE Healthcare.

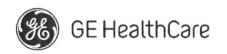
Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/379		
Product	Centricity High Acuity Critical Care (CHA CC) and Centricity High Acuity Anesthesia (CHA A) systems (collectively CHA).		
Manufacturer	GE Healthcare.		
Local agent	Muscat Pharmacy & Stores LLC.		
The affected products	 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. 		
Reason	A potential cybersecurity vulnerability within one of the CHA components.		
Action	Please refer to the attachment. Contact the local agent for remedial action.		
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om		

Ph. Ibrahim Nasser Al Rashd Director General





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 recall.38017@gehealthcare.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.

8004292222

SaudiArabiaServiceCenter@gehealthcare.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,

Laila Gurney

Chief Quality & Regulatory Officer

GE HealthCare

Scott Kelley

Chief Medical Safety Officer

GE HealthCare



GE HealthCare Ref. # 38017

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: recall.38017@gehealthcare.com and SaudiArabiaServiceCenter@gehealthcare.com				