URGENT MEDICAL DEVICE CORRECTION

28 February 2025

GE HealthCare Ref. # 85480

To: Director/Manager of Radiology
Director/Manager of Cardiology
Risk Manager/Hospital Administrator
Head of Radiology Department
Head of Cardiology Department
PACS Administrator
Director of IT Department
Head, Biomedical Engineering
Head of Imaging Informatics

RE: **Centricity Universal Viewer (UV), Centricity PACS-IW (PACS-IW), Centricity Radiology RA600 (RA600), & Centricity Cardiology CA1000 (CA1000) – Potential Security Vulnerability**

Safety Issue

GE HealthCare has become aware of a potential security vulnerability in Centricity Universal Viewer (UV), Centricity PACS-IW (PACS-IW), Centricity Radiology RA600 (RA600), & Centricity Cardiology CA1000 (CA1000) where the service login credentials are able to be identified which could allow a malicious actor with these credentials to access the system and potentially manipulate patient data.

There have been no injuries 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 device.

Please ensure all potential users in your facility are made aware of this safety notification.

Please ensure you have implemented the actions below:

1: Ensure your hospital network is secure
and
2: Outside of the hospital network implement additional safeguards such as a VPN.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to recall.85480@gehealthcare.com.

Affected Product Details

The following products with the software versions listed below are impacted.

Product	Device Identification Number / GTIN
Centricity Universal Viewer Software Versions 7.0 through 7.0 SP1.0.3	00840682145794
Centricity Universal Viewer Software Versions 6.0 through 6.0 SP10.4.1	00840682103800
Centricity Universal Viewer Software Versions 5.0 through 5.0 SP7.1	N/A
Centricity PACS-IW	N/A
Centricity Radiology RA600 Software Versions 7.0 through 7.0 SP13	N/A
Centricity Radiology RA600 Software Versions 8.0 through 8.0 SP14M	00840682125260
Centricity Cardiology CA1000 Software Versions 7.0 through 7.0 SP13	N/A
Centricity Cardiology CA1000 Software Versions 8.0 through 8.0 SP14M	00840682125260

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 Safety Officer
GE HealthCare

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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.

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 Medical Device 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): _____

Please return by scanning or taking a photo of the completed form and email to recall.85480@gehealthcare.com or submitting an online Customer Response Form.

Email Link

Customer Response Form