URGENT MEDICAL DEVICE CORRECTION

10 October 2024 GE HealthCare Ref. # 85478

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 Zero Footprint Client – Potential Security Vulnerability.**

Safety Issue

GE HealthCare has become aware of an issue in Centricity Universal Viewer Zero Footprint Client (ZFP) where there is a potential security vulnerability which could allow a malicious actor to access the system and potentially manipulate patient data.

There have been no injuries or unauthorized access to patient data reported 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 implement one of the actions below until your system has been corrected.

Option 1: Restrict access to these systems from the internet.

or

Option 2: Implement additional safeguards such as a VPN.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to recall.85478@gehealthcare.com.

Affected Product Details	Centricity Universal Viewer Zero Footprint Client Versions ZFP v6.0: SP7.x, SP8.x, SP9, SP9.0.1, SP9.0.1.1, SP9.0.1.2, SP9.0.1.3, SP10.0, SP10.1, SP10.2, SP11.0 GTIN 00840682102988

Intended Use:
Centricity Universal Viewer Zero Footprint Client is a device that displays medical images, data from various imaging sources, and other healthcare information sources. Medical images and data can be viewed, communicated, processed, and displayed within a computer network or on a workstation. The device may be used to provide images for diagnostic purposes by trained professionals.
Typical users of this system are authorized individuals and trained healthcare professionals who view medical images and data.
Mammographic images may only be interpreted using a monitor compliant with requirements of local regulations and must meet other technical specifications reviewed and accepted by the local regulatory agencies.

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. After the software has been corrected, be sure to destroy the installation media for affected software at your site.
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 completed form by scanning or taking a photo of the completed form and email to: recall.85478@gehealthcare.com