

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 30116

To: Healthcare Administrator
Network Administrator
Director of IT Department

RE: Potential security vulnerability for MUSE 5 systems

Safety Issue GE HealthCare has become aware of a potential security vulnerability for MUSE 5 systems. The MUSE Administrator Account active directory or local credential could potentially be used from your local network to log into a GE HealthCare MUSE 5 system and potentially manipulate recorded 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 MUSE 5 systems have reached their End of Sales/Service Support as of November 1, 2014. Please see attached for the End of Sales/Service Support letter that was previously distributed. GE HealthCare recommends that customers replace or upgrade these systems.

If you wish to continue using your MUSE 5 system, you should ensure your IT Department provides ongoing prevention of unauthorized access to the system such as not using a well-known password.

If passwords are well-known, please update the credentials according to your organization's password policies or contact GE HealthCare Service or your local Service Representative if necessary.

Please ensure 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 Medical Device Notification Acknowledgement Response Form to DCAR.Recall@gehealthcare.com.

**Affected
Product Details**

MUSE 5 systems

Intended Use:

Large capacity client-server-based computer system that accesses stores and manages cardiovascular information. The information can consist of measurements, text, digitized waveforms and angiographic images. The AccuSketch Image Capture software in conjunction with the frame grabber board provides a computer-based method for digitizing angiographic images to allow for quantitative analysis. The system accepts video image inputs and performs manipulations on the digitized images to analyze vessel stenoses and ventricular wall motion.

The editable coronary tree is a tool used to electronically annotate and document the anatomy of the patient's vessels.

**Product
Correction**

Please refer to the instructions above under "Actions to be taken by Customer / User".

**Contact
Information**

If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.

01707 263570 or askuktechnicalsupport@gehealthcare.com

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.# 30116

**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): _____

Please return completed form by scanning or taking a photo of the completed form and email to: DCAR.Recall@gehealthcare.com

