URGENT FIELD SAFETY NOTICE

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188   USA

Date of Letter Deployment   GEHC Ref. # 30102-2

To: Healthcare Administrator / Risk Manager
       Cardiology IT
       Cardiology Manager

RE: **MUSE™ NX R1 systems with Web Edit option – Edits can be lost after test is confirmed**

This document contains important information for your product. 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.

Safety Issue   Edits to measurements and diagnosis statements can be lost after a test is **Signed** in the MUSE NX web client. There are two scenarios where edits can be lost after a test is **Signed**.

Scenario 1
Edits can be lost in the unlikely event a memory error occurs during the following sequence:
1.   A test is opened from the **Work List**.
2.   While editing in the **Report Editor** screen, the **QT** and/or **Vent. rate** (Ventricular rate) values are modified. (Changes to other 12SL measurements will not cause this issue to occur.)
3.   The user clicks **Sign**.

When this condition occurs, the measurement and diagnosis values will revert to the original 12SL values and diagnosis for all subsequent **Signed** tests. This occurs on subsequent tests even if **QT** and/or **Vent. rate** are not modified and remains until the user logs out of the web client.

Scenario 2
Edits can be lost when the following sequence occurs:
1.   While editing in the **Report Editor** screen, the user adds or modifies a statement. The acronym drop-down box appears as the user begins typing.
2.   The user clicks **Sign** without selecting a statement from the drop-down list.

When this condition occurs, the modifications and/or preliminary 12SL statement will not be saved for that test only.

This issue could result in a potentially delayed or inappropriate treatment.

There have been no injuries reported as a result of this issue.

Actions to be taken by Customer / User

It is recommended to use the MUSE desktop (thick) client for editing until the software correction is implemented.

Alternatively, you can continue to use your MUSE NX web client for editing with one of the following workflows until the software correction is implemented:

1.   Use the following steps when editing on the web client from the patient context:

A. Launch the MUSE web client from the Electronic Health Record (EHR) to the **Report Editor** screen (instead of the **Work List**) for editing.
B. Ensure the acronym drop-down box is closed prior to clicking **Sign**.

OR

2. Use the following steps when editing on the web client from the **Work List**:
   A. Ensure the acronym drop-down box is closed after editing.
   B. Select **More** to view the drop down list.
   C. Confirm **Update and Close** is active in the drop down list. If active, the issue did not occur, and you can select **Sign** to confirm the test. If **Update and Close** is inactive (greyed out), the issue has occurred, and you should proceed to the next step.
   D. Log out of the web client and re-log in. Then re-edit and **Sign** the test.
   E. Continue to follow steps A through C for every test.

Please complete and return the attached acknowledgement form to DCAR.30102@ge.com.

| **Affected Product Details** | All MUSE NX R1 systems SP2 and higher with Web Edit option are impacted. If you are receiving this letter, you have purchased a MUSE NX R1 system with Web Edit option. |

All MUSE NX R1 systems SP2 and higher with Web Edit option are impacted. If you are receiving this letter, you have purchased a MUSE NX R1 system with Web Edit option.

To confirm the version of your MUSE system, go to **About** in the MUSE software. Refer to the part numbers below that include the Web Edit option. If you are unsure if the Web Edit option is activated, contact your local Service Representative.

Impacted Versions:

Product	Version	UDI	GTIN
MUSE NX	R1 SP2	(01)00840682142809(10) MUSENXSP2	00840682142809
	R1 SP3	(01)00840682142809(10) MUSENXSP3	00840682142809
	R1 SP4	(01)00840682142809(10) MUSENXSP4	00840682142809

Impacted Options:

Part Number	Description
3101011-040	UPGRADE WEB EDIT MODULE
3101010-401	WEB EDIT MODULE
3101010-009	NEW ADVANCED MUSE NX R1
3101010-008	NEW ENTERPRISE MUSE NX R1

Intended use:
The MUSE Cardiology Information System is intended to store, access, and manage cardiovascular information on adult and pediatric patients. The information consists of measurements, text, and digitized waveforms. The MUSE Cardiology Information System provides the ability to review and edit electrocardiographic procedures on screen, through the use of reviewing, measuring, and editing tools, including ECG serial comparison and interpretive 12-lead analysis. The MUSE Cardiology Information System is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or facility providing patient care. The MUSE Cardiology Information System is not intended for real-time patient monitoring. The MUSE Cardiology Information System is not intended for pediatric serial comparison.

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 patched, destroy all previous versions of the locally stored MUSE application installation package immediately.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE Healthcare Service at 1-800-437-1171 or your local Service Representative.

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 immediately per the contact information above.

Sincerely,

xxx   xxx
GE Healthcare   GE Healthcare

GE Healthcare

**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.

*Customer/Consignee Name:

Street Address:

City/State/ZIP/Country:

*Customer Email Address:

*Customer Phone Number:

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have informed appropriate staff 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:

*Title:

*Date (DD/MM/YYYY):

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: DCAR.30102@ge.com.

You may obtain this e-mail address through the QR code below: