URGENT FIELD SAFETY NOTICE

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

2 July 2021

GE Healthcare Ref# 60978-2B

To: Director of Clinical/Radiology
Risk Manager/Hospital Administrator

RE: **Incorrect Image Annotation and/or Flipped Images as a result of Inadvertently Changing the Prescribed Patient Orientation. SIGNA Premier, Signa Pioneer, SIGNA Architect, Discovery MR750w 3.0T, Discovery MR750 3.0T, SIGNA PET/MR, SIGNA Voyager, Optima MR450w 1.5T, SIGNA Artist, SIGNA Creator, SIGNA Explorer, SIGNA MR355, SIGNA MR360, SIGNA MR380, Discovery MR450 1.5T, 1.5T Signa HDxt (HD28)**

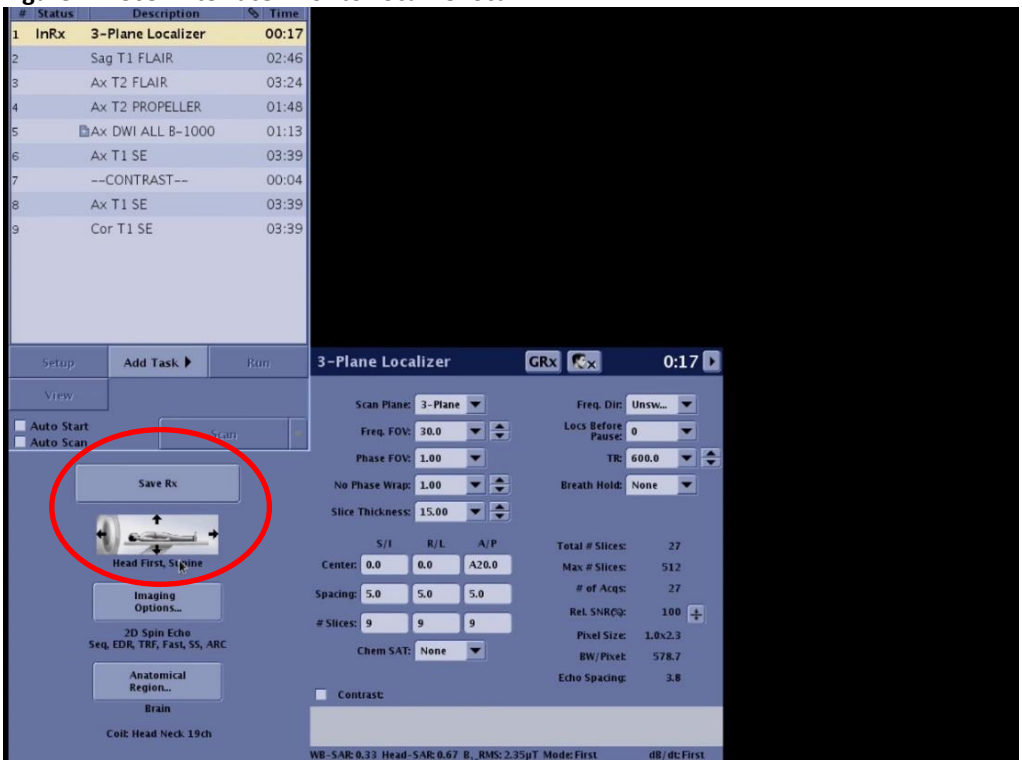
This document contains important information for your product. Please ensure all potential Users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

GE Healthcare has recently become aware of an issue on the affected products listed below where the "**Patient Orientation**" button can inadvertently be clicked when intending to click on the "**Save RX**" button. This changes the prescribed patient orientation on the system prior to running the initial 3-Plane Localizer Scan (See Figure 1 for reference to buttons.) Selecting and saving a patient orientation that does not match the patient's actual position can result in incorrectly annotated and/or flipped images. In the unlikely situation where this is not identified, it can potentially result in improper medical treatment. **Please ensure users review and confirm that the actual patient orientation matches the prescribed patient orientation before initiating the scan. To make users aware of this issue, GE Healthcare recommends you post this letter in your facility on or near the MR operator console until GE Healthcare corrects your affected product.**

There have been no injuries reported to GE Healthcare as a result of this issue**.**

Figure 1 – User Interface Prior to Localizer Scan

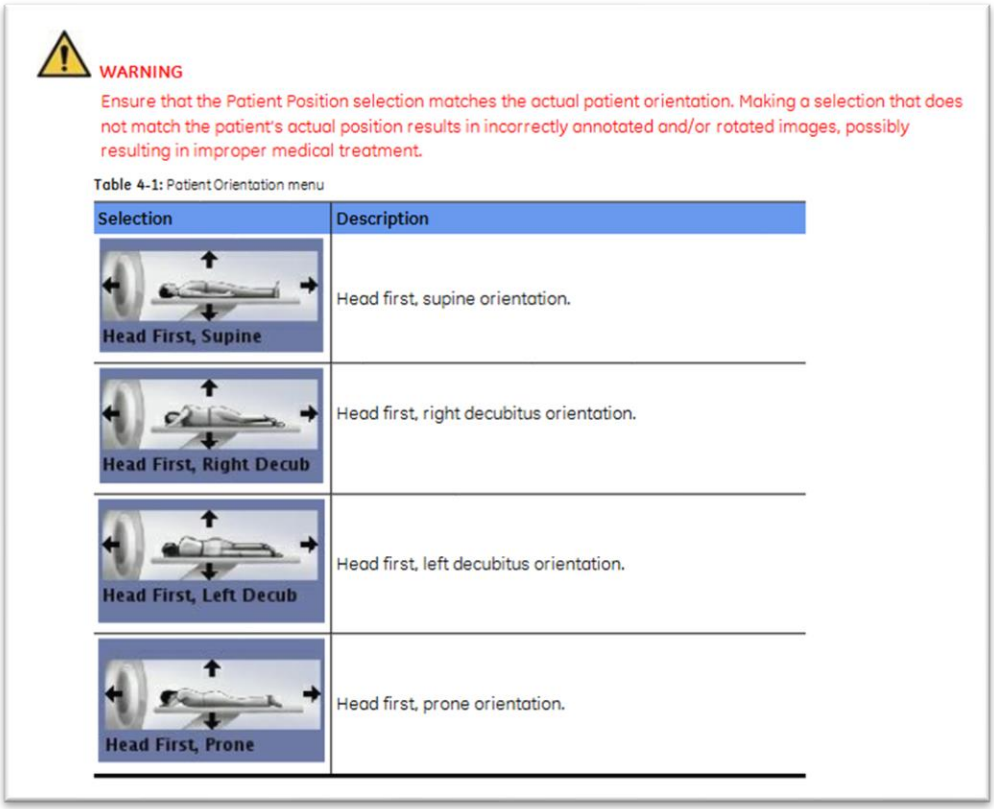


Safety Instructions

You can continue to use your device.

1) Please ensure users review and confirm that the actual patient orientation matches the prescribed patient orientation before initiating the scan. As outlined in the Product Labeling, it is important to confirm the correct patient orientation is selected prior to scanning. This information is found in the Patient Position Procedure within Chapter 4, Section 4 of your Operator Manual (See Figure 2 for reference).

Figure 2 – Chapter 4, Section 4 of Operator Manual



WARNING

Ensure that the Patient Position selection matches the actual patient orientation. Making a selection that does not match the patient's actual position results in incorrectly annotated and/or rotated images, possibly resulting in improper medical treatment.

Table 4-1: Patient Orientation menu

Selection	Description
Head First, Supine	Head first, supine orientation.
Head First, Right Decub	Head first, right decubitus orientation.
Head First, Left Decub	Head first, left decubitus orientation.
Head First, Prone	Head first, prone orientation.

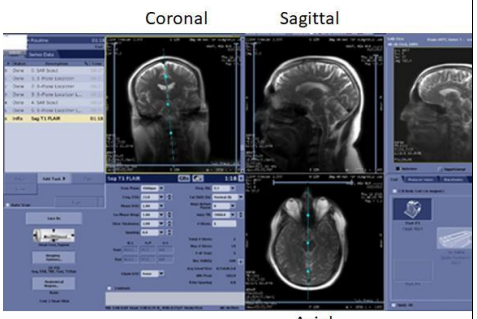
2) When the **correct** patient orientation is prescribed, the resulting localizer images are displayed in the viewport (Figure 3a).

If the patient orientation is in the "Head-First Supine" position but the patient orientation is **incorrectly** prescribed as "Head-First Left Decubitus":

- The Sagittal image is displayed as Coronal and vice versa and annotations on the Coronal and Sagittal images will be incorrect (Figure 3b)
- The labeled imaging plane will also be incorrect (Figure 4)
- The Axial image will be annotated as A/P and not L/R (Figure 5).

Figure 3 – User Interface with Viewport showing (a) Correct and (b) Incorrect Image Display

(a) CORRECT: Coronal & Sagittal Display



(b) INCORRECT: Sagittal Displayed as Coronal

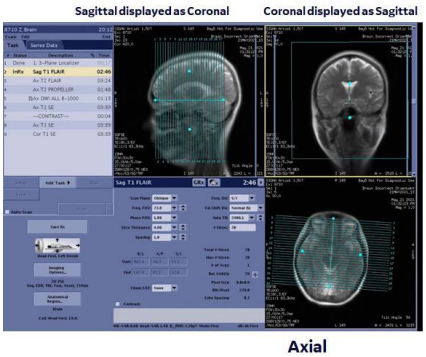


Figure 4: Incorrect Orientation Per Annotations [3-Plane Localizer Sag]

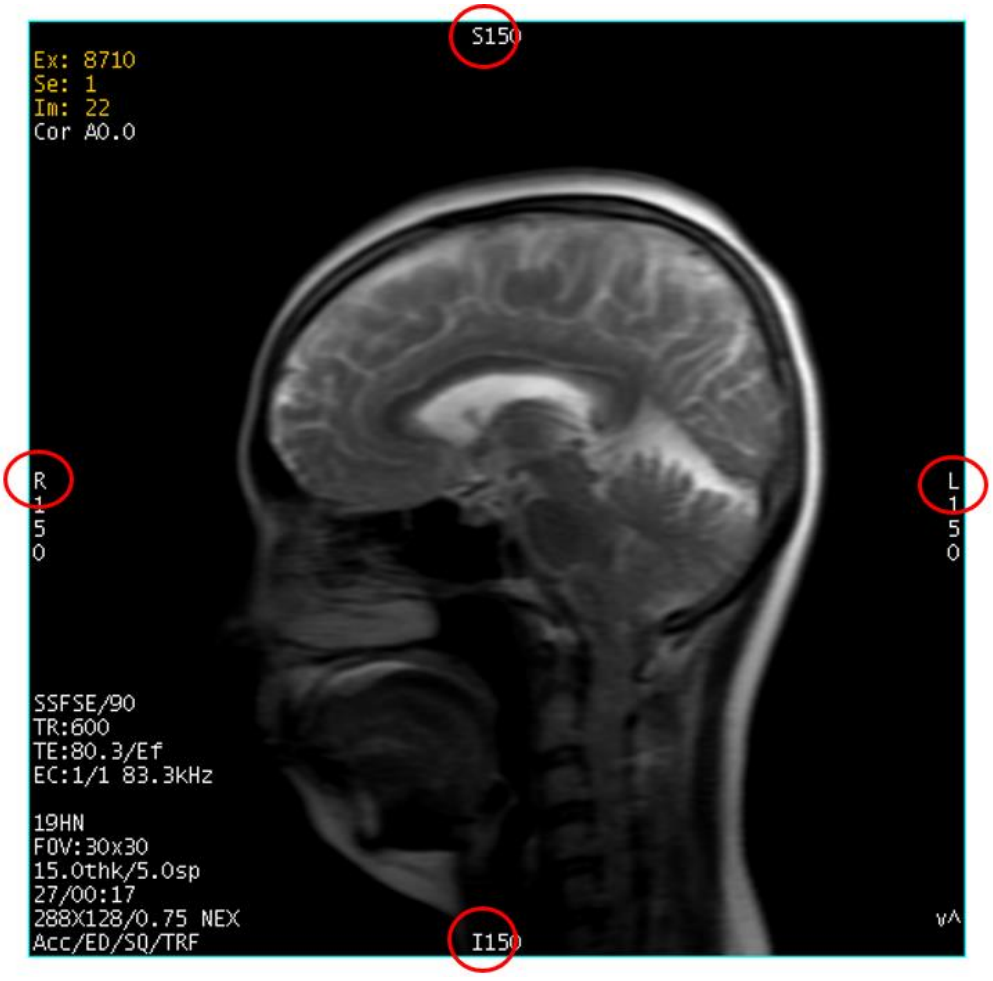
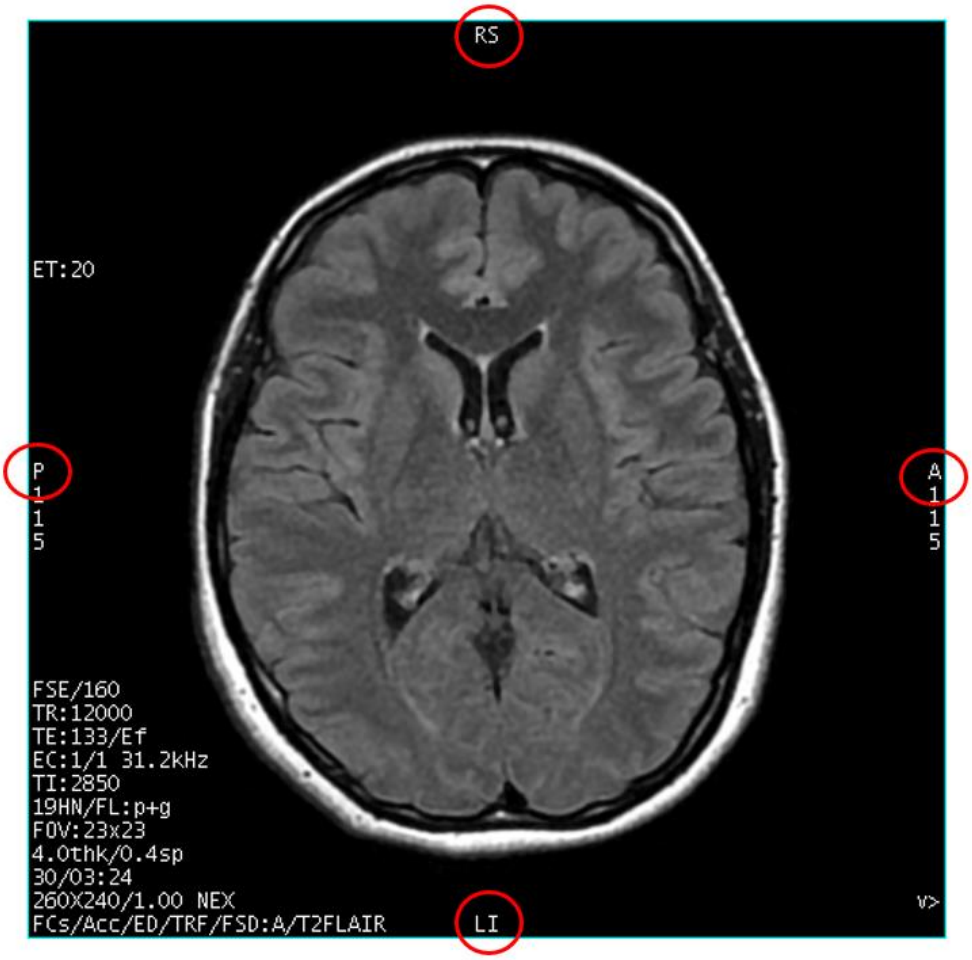


Figure 5: Axial image Incorrectly Annotated as A/P and not L/R



3) Complete and return the attached response form to **Recall.60978@ge.com**

Affected Product Details

The following MR systems with the software versions listed below are potentially affected:

Product Name	Affected Software Versions	GTIN
SIGNA Architect	DV26, DV27, DV28, DV29, DV29.1 DV26.2, DV26.3	00840682147095
		00840682122702
		00195278023643
		00840682123440
SIGNA Pioneer	PX25.1, PX25.2, PX26.1, PX28, PX29, PX29.1	00840682145770
		00840682104401
		00195278005502
		00195278271594
SIGNA Premier	RX27, RX27.1, RX27.2, RX28, RX29, RX29.1	00840682135269
		00195278010797
Discovery MR750 3.0T	DV25.1, DV26, DV29.1	00840682115872
		00195278229519
Discovery MR750w 3.0T	DV25.1, DV26, DV29.1	00840682103817
		00195278229519
Optima MR450w 1.5T	DV25.1, DV26, DV29.1	00840682115971
		00195278229519
Discovery MR450 1.5T	DV25.1, DV26	Not applicable
SIGNA Artist	DV26, DV27.1, DV28.1, DV29.1	00195278210036
		00840682146104
		00840682123129
		00840682123457
SIGNA PET/MR	MP26	00840682105378
		00840682125697
		00840682135283
SIGNA Voyager	PX26.0, PX26.2, PX26.3, PX26.4, VX28.0, VX29.1	00840682108607
1.5T SIGNA HDxt Family	HD16.1, HD16.2, HD28, HD29.1	00840682144261
SIGNA Creator	SV25.1, SV25.2, SV25.3, SV25.4, SV29.1	00840682113786
SIGNA Explorer	SV25.1, SV25.2, SV25.3, SV25.4, SV29.1	00840682113762
		00840682146814
SIGNA MR380	SV25.3	00195278361257
SIGNA MR355	SV25.3, SV25.4	00840682144407
SIGNA MR360	SV25.3, SV25.4	00840682144445

Device Use in the Clinical Setting:
GE Healthcare Whole-Body MR scanners are used to produce images of the inside of the human body that help aid the diagnosis of disease. In a clinical setting, Magnetic Resonance imaging (MRI) can be used to distinguish diseased or compromised tissue from normal tissue.

MRI technology is routinely used to help the diagnosis in diseases such as oncology, stroke, heart and peripheral vascular disease, pediatric diseases, etc. MRI technology in general, however, is not limited to specific diseases, stage and condition of diseases, or clinical forms.

MRI technology is intended to be used by the healthcare professionals (clinicians and trained technologists) following good clinical practice. It can be used in broad patient population including adults, children and infants, following good clinical practice

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.

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,

Laila Gurney
Chief Quality & Regulatory Officer
GE Healthcare

Jeff Hersh, PhD MD
Chief Medical Officer
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: _____

Email Address: _____

Phone Number: _____

System ID _____

☐ 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): _____

Please return completed form by scanning or taking a photo of the completed form and email to: Recall.60978@ge.com