URGENT FIELD SAFETY NOTICE

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

Date of Letter Deployment

GE Healthcare Ref# 60984

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

RE: **MR Systems – Potential for images to be flipped (left to right) if the X+ and X- gradient cables on the Gradient Switch are placed incorrectly during service operations**

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 a potential issue on the affected products listed below. During the servicing of a Gradient Switch located in the Twin Speed Accessory Cabinet (TAC), it is possible for the gradient cables to be inadvertently swapped for example X+ and X- which would cause axial and coronal images to be flipped left to right.

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

Actions to be taken by Customer / User

You can continue to use your device.

1) Confirm that your device is currently working as intended with the correct image orientation by performing a Finalization Step running a geometry check with a Daily Quality Assurance (DQA) phantom, which is provided with the system (or similar).

2) During servicing of the Gradient Switch, ensure that the gradient cables for the X+ and X- are correctly installed per the service manuals. In addition, perform a Finalization Step after servicing by running a geometry check with a DQA phantom (or similar) to ensure correct image orientation and cable placement.

3) Complete and return the attached response form to **Recall.60984@ge.com**

Affected Product Details

The following MR systems with Twinspeed listed below are potentially affected:

GE Signa 1.5T TwinSpeed, 1.5T Signa Excite HD, 3.0T Signa Excite HD, GE Signa 3.0T with Excite, GE 1.5T Signa HDx, 3.0T Signa HDx, GE 1.5T HDxt, GE 3.0T Signa HDxt, 1.5T Signa HDxt Mobile Magnetic Resonance System's

Intended Use:
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 provide a revised service manual at no cost to you. The revised service manual includes a required Finalization Step that ensures a geometry check with a DQA phantom (or similar) following Gradient Switch servicing to ensure cable placement is correct and no impact to image orientation.

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

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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.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer 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): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to:
Recall.60984@ge.com