URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 60996

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

RE: **B_{1+}RMS predicted value may exceed user prescribed limit in Low SAR Mode for certain MR systems**

Safety Issue

GE HealthCare has become aware that for certain MR systems (see affected products list below), the system predicted B_{1+}RMS value (see Figure 2) can exceed the B_{1+}RMS user prescribed limit (see Figure 1) when scanning in Low SAR Mode and the following two conditions are met:

1. 2D FSE T2 FLAIR OR T2 FLAIR Propeller imaging sequence is selected, **AND**
2. the Optimized T2 FLAIR sequence option is turned off OR not included in the MR configuration.

If this occurs, it can result in overheating of an MR conditional implant.

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

Figure 1. Low SAR Mode User Interface showing the user prescribed B_{1+}RMS limit

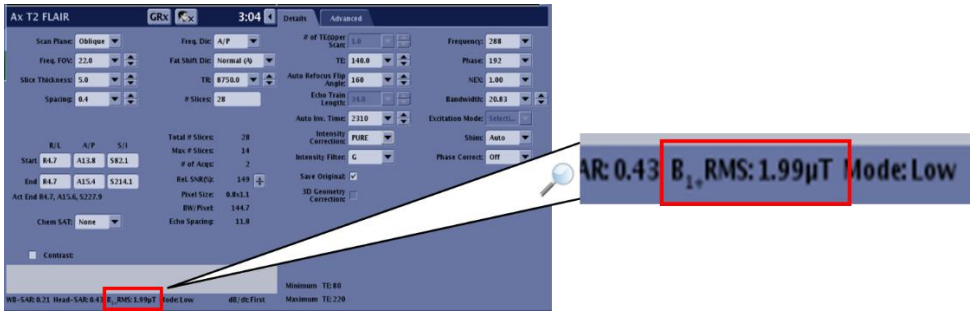

Figure 2. Scan Prescription User Interface showing the system predicted B_{1+}RMS limit

Actions to be taken by Customer/ User

You can continue to use your MR system by following the instructions below:

To ensure that the displayed B_{1+}RMS value on the Scan Prescription User Interface (Figure 2) does not exceed the user prescribed limit (Figure 1) specified in the Low SAR Mode User Interface:

- If your software version includes the Optimized T2 FLAIR Sequence option, enable this option by setting the value to 1.00. This option is present on the Advanced Tab of the Scan Prescription User Interface. Please see Figure 3 for T2 FLAIR FSE and Figure 4 for T2 FLAIR Propeller.

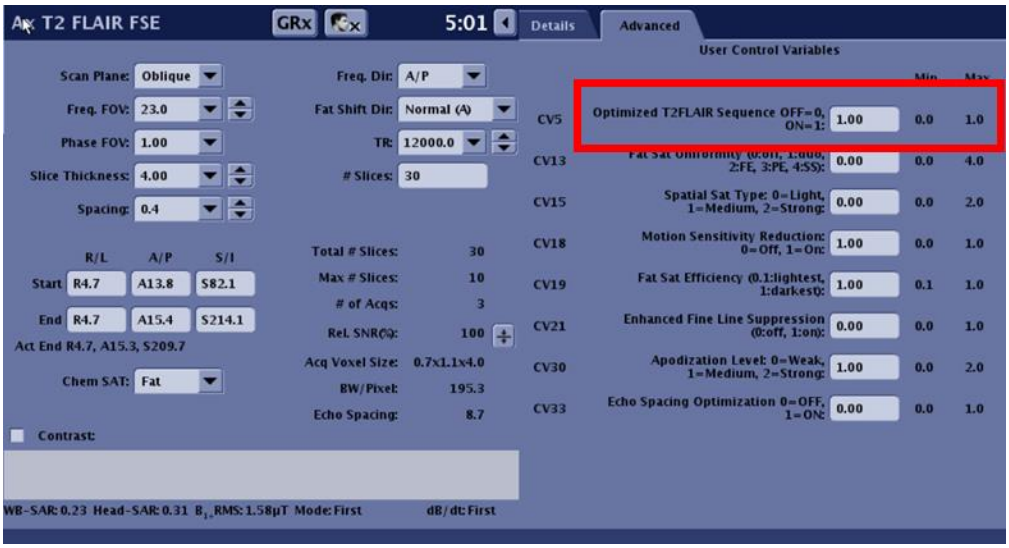

Figure 3. Optimized T2 FLAIR Sequence enabled (set to 1.00) in the Advanced Tab for T2 FLAIR FSE

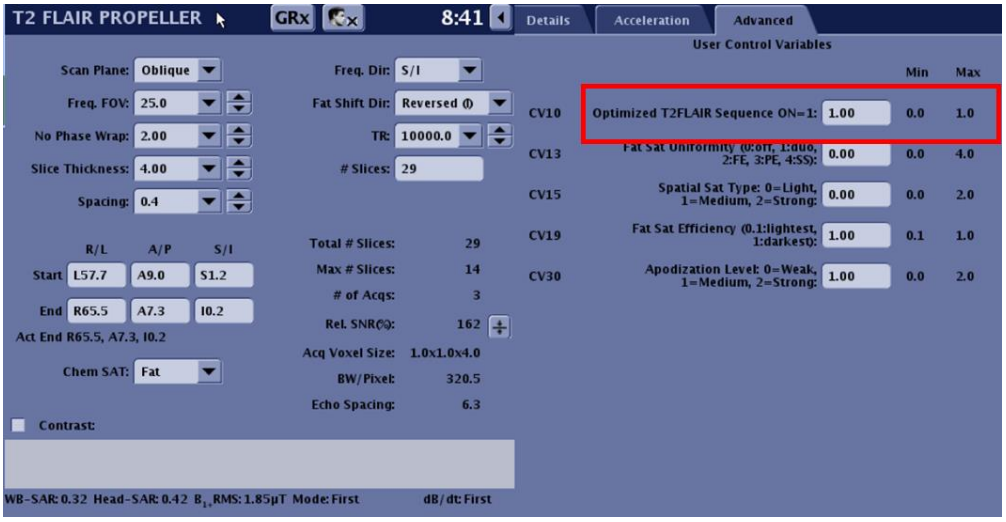

Figure 4. Optimized T2 FLAIR Sequence enabled (set to 1.00) in the Advanced Tab for T2 FLAIR Propeller

- If your software version does <u>not</u> include the Optimized T2 FLAIR Sequence option, adjust scan parameters such as “TR”, “# Slices” or “Auto Refocus Flip Angle” until the displayed B_{1+}RMS value on the Scan Prescription User Interface (Figure 2) does not exceed the user prescribed limit.

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 acknowledgement form to Recall.60996@gehealthcare.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	DV26.0 to DV26.3, DV27.0 to DV27.3, DV28.0 to DV28.5, DV29.0, DV29.1, DV29.2, MR30.0, MR30.1	00840682147095 00840682122702 00195278023643 00840682123440 00195278283481
SIGNA™ Pioneer	PX25.0 to PX25.5, PX26.0, PX26.1, PX28.0 to PX28.4, PX29.0, PX29.1, MR30.0, MR30.1	00840682145770 00840682104401 00195278005502 00195278271594
SIGNA™ Hero	PX29.1, MR30.0, MR30.1	00195278486813
SIGNA™ Premier	RX27.0 to RX27.3, RX28.0, RX29.0 to RX29.2, MR30.0, MR30.1	00840682135269 00195278010797
3.0T SIGNA™ HDxt Family	HD16.0_V03, HD23.0_V03	
Discovery MR750 3.0T	DV24.0, DV25.0, DV25.1, DV26.0 to DV26.4, DV29.1, MR30.0, MR30.1	00840682115872 00195278229519
Discovery MR750w 3.0T	DV24.0, DV25.0, DV25.1, DV26.0 to DV26.5, DV29.1, MR30.0, MR30.1	00840682103817 00195278229519
SIGNA™ PET/MR	MP24.0, MP26.0, MP26.1, MR30.0, MR30.1	00840682105378 00840682125697 00840682135283 00195278554512 00195278648877 00195278729224 00840682105699
Discovery MR450 1.5T	DV24.0, DV25.0, DV25.1, DV26.0	
Optima MR450w 1.5T	DV24.0, DV25.0, DV25.1, DV26.0, DV29.1, MR30.0, MR30.1	00840682115971 00195278229519
SIGNA™ Artist	DV26.0, DV27.1, DV28.1, DV29.1, MR30.0, MR30.1	00195278210036 00840682146104 00840682123129 00840682123457 00195278117021 00195278126443 00195278144331 00195278481382
SIGNA™ Voyager	PX26.0 to PX26.6, VX28.0, VX29.1, VX29.2, MR30.0, MR30.1	00840682108607 00195278124609 00195278372307
1.5T SIGNA™ HDxt Family	HD16.0_V03 to HD16.4, HD23.0_V03, HD28.0, HD29.1, MR30.0, MR30.1	00840682144261 00195278416339

Product Name	Affected Software Versions	GTIN
SIGNA™ Creator	SV25.5, SV25.6, SV29.2, MR30.0, MR30.1	00840682113786 00195278554444 00195278577238 00195278370426
SIGNA™ Explorer	SV25.5, SV25.6, SV29.2, MR30.0, MR30.1	00840682113762 00840682146814 00195278370419
SIGNA™ MR380	SV25.5, SV25.6	00195278361257
SIGNA™ MR355	SV25.5, SV25.6	00840682144407
SIGNA™ MR360	SV25.5, SV25.6	00840682144445
Brivo MR355	SV20.3, SV23.3, MR30.0, MR30.1	
Optima MR360	SV20.3, SV23.3, MR30.0, MR30.1	
SIGNA™ Prime	MR30.1	00840682146302
SIGNA™ Victor	MR30.1	00195278616845
SIGNA™ UHP	RX28.0, MR30.1	
Discovery MR950	7T23.0	
SIGNA™ 7.0T	7T29.1, MR30.1	00195278483713
SIGNA™ MAGNUS	MR29.1, RX29.1	

Intended Use

MR Scanner 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 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 per the contact information above.

Sincerely,

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

Scott Kelley
Chief Medical Officer
GE HealthCare

GE HealthCare Ref. # 60996

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: _____

☐ 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.60996@gehealthcare.com