URGENT FIELD SAFETY NOTICE

Date of Letter Deployment

GE HealthCare Ref. # 67949

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

RE: **"Start Scan" button active following Power Monitor trip for certain MR systems.**

Safety Issue

GE HealthCare has become aware that for certain MR systems (see affected product list below) a scan can be resumed following a Power Monitor trip when the '6-minute average SAR' is above the limit indicated on the 'SAR Display'.

If this error occurs, the 'Start Scan' button on the Scan Control Interface Module (SCIM) may become inappropriately illuminated and the user interface screen may incorrectly display 'Please press start scan button', enabling a scan to proceed earlier than intended (see **Figures 1 and 2**).

If a scan is resumed by the operator under these conditions, it can result in potential excessive tissue heating, particularly if a patient were to be in contact with a conductive material or have an implant.

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

Figure 1. Scan Control Interface Module (SCIM) showing 'Start Scan' button illuminated.

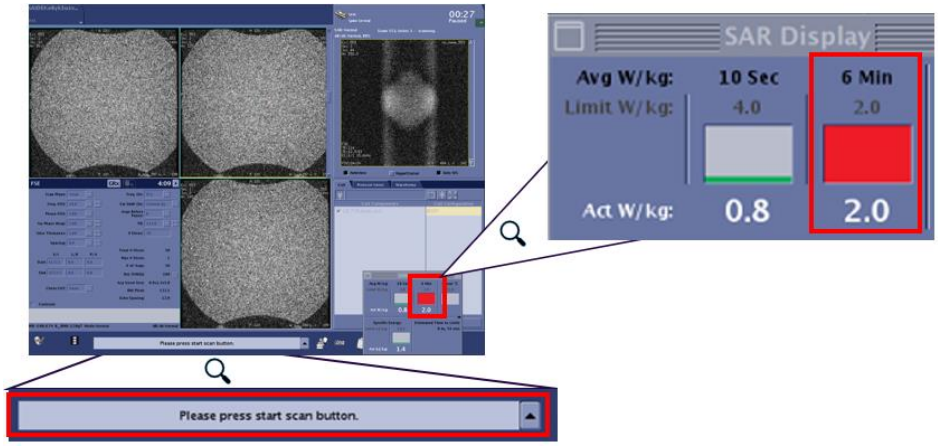

Figure 2. User Interface 'SAR Display' showing '6-minute average SAR' above the indicated limit, displaying Red, with 'Please press start scan button' message.

Actions to be taken by Customer /User

You can continue using your MR system by following these instructions:

1. Identify Power Monitor trip occurrences by noting all of the following:
    a) scanning pauses,
    b) the '6-minute SAR average' in the 'SAR Display' turns Red (**Figure 2**), and
    c) the message shown in (**Figure 3)** briefly appears on the User Interface. NOTE: this message appears and subsequently is replaced with 'Please press start scan button'.
2. Ignore the subsequent 'Please press start scan button' message (**Figure 2**) on the User Interface.
3. Do not press the illuminated 'Start Scan' button on the SCIM while the '6-minute SAR average' in the 'SAR Display' shows as Red (**Figure 2**).
4. Pay attention to the '6-minute average SAR' in the 'SAR Display'.
5. Wait until the '6-minute average SAR' is below the limit indicated on the 'SAR Display' and the indicator turns Yellow (**Figure 4**) before pressing the 'Start Scan' button on the SCIM to resume scanning.
6. Should the system Power Monitor trip again during the exam, repeat the steps above.

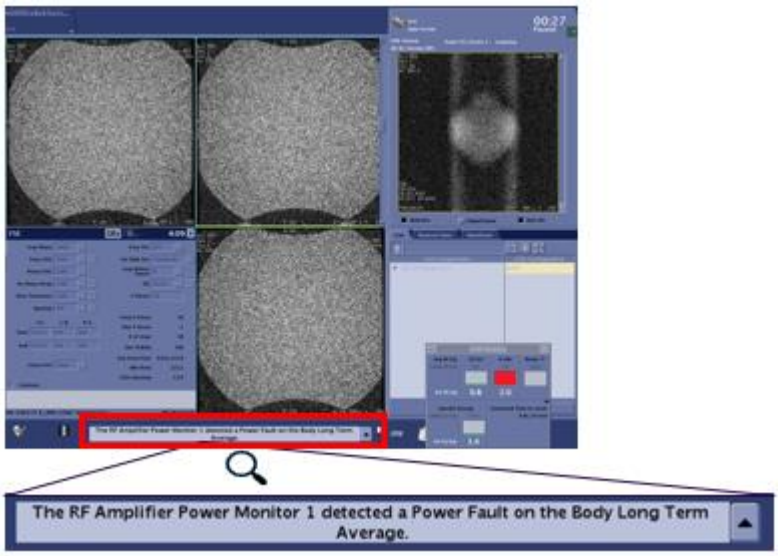

Figure 3. Message on the User Interface stating a Power Fault has been detected due to Power Monitor trip.

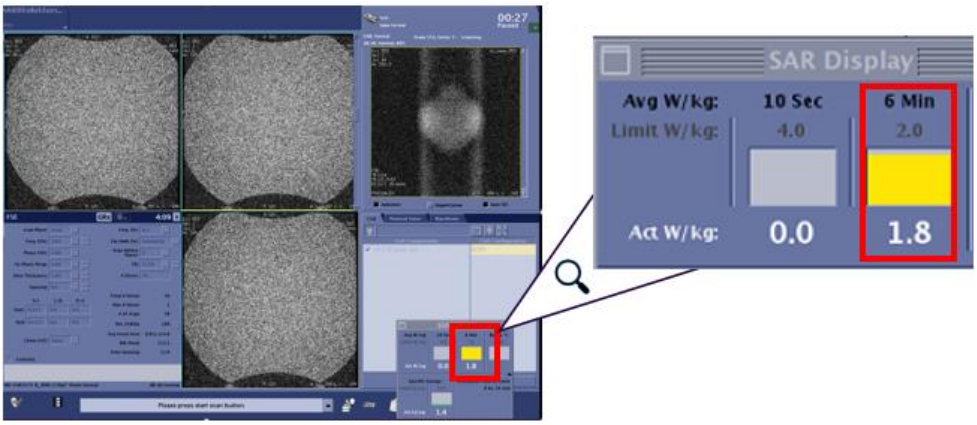

Figure 4. SAR Display showing '6-minute average SAR' displaying Yellow ready to resume scanning.

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.67949@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™ Creator	MR30.1, SV29.1, SV25.4, SV25.3	00840682113786 00195278554444 00195278577238 00195278370426
SIGNA™ Explorer	MR30.1, SV29.1, SV25.4, SV25.3	00840682113762 00840682146814 00195278370419
SIGNA™ MR380	MR30.1, SV25.3	00195278361257
SIGNA™ MR355	SV25.6, SV25.4, SV25.3	00840682144407
SIGNA™ MR360	SV25.6, SV25.4, SV25.3	00840682144445
Brivo MR355	SV20.2, SV23.2	Not applicable
Optima MR360	SV20.2, SV23.2	Not applicable

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 Safety Officer
GE HealthCare

GE HealthCare Ref. # 67949

URGENT FIELD SAFETY NOTICE 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 URGENT FIELD SAFETY NOTICE.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

System ID _____

By signing this form, we acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice, 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.67949@gehealthcare.com