

URGENT FIELD SAFETY NOTICE



Date of Letter Deployment

GE HealthCare Ref. # 63003

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

RE: **Functional check of MR table caster locks during Planned Maintenance**

Safety Issue

GE HealthCare has become aware that for certain MR systems (see affected products list below), the planned maintenance steps to check the functionality of the caster locks on the MR patient table may not have been performed. The functional check is intended to proactively detect potential failure of table caster locks, which could result in unintended table movement and unstable patient support when the table is not docked to the system.

Actions to be taken by Customer/ User

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

In the "undocked" position, lock the table by pressing the pedal in the front of the table. Check to see that all casters are locked and that the table is secure. Contact your GE HealthCare representative for assistance if any of the casters do not lock.

Before each patient transfer verify that the caster locks are engaged. If you notice more than one caster is damaged or fails to lock properly, use particular caution as the table may move while in use.

No additional steps are required to continue to use your table in the "docked" position.

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.63003@gehealthcare.com.

Affected Product Details

The MR systems listed below are potentially affected if GE HealthCare performed planned maintenance of your MR system since March 1, 2023:

Product Name	GTIN
SIGNA Artist	00840682123129 00840682146104 00195278117021 00840682123457 00195278126443 00195278210036
SIGNA Voyager	00840682108607 00195278124609
Discovery MR450 1.5T	
Optima MR450w 1.5T	00840682115971
SIGNA Architect	00840682147095 00840682122702 00195278023643 00840682123440
SIGNA Premier	00195278010797 00840682135269
SIGNA UHP	
Discovery MR750 3.0T	00840682115872
Discovery MR750w 3.0T	00840682103817
SIGNA Hero	00195278486813
SIGNA PET/MR	00840682105378 00840682125697 00840682135283 00840682105699 00195278648877 00195278729224
SIGNA Artist Evo	00195278481382
SIGNA Voyager AIR (China Only)	
SIGNA Architect AIR (China Only)	
SIGNA Premier XT (China Only)	
SIGNA Premier Elite (China Only)	
SIGNA Premier MAX (China Only)	
SIGNA Hero XT (China Only)	
SIGNA Hero Elite (China Only)	
SIGNA Hero MAX (China Only)	
SIGNA PET/MR AIR (China Only)	
SIGNA PET/MR AIR Plus (China Only)	

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 inspect and if necessary, 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.

Phone: 1800 992 557

Email: healthcareserviceireland@gehealthcare.com

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,

A handwritten signature in blue ink, appearing to read 'Laila Gurney', followed by a long horizontal flourish.

Laila Gurney
Chief Quality & Regulatory Officer
GE HealthCare

A handwritten signature in blue ink, appearing to read 'Scott Kelley', followed by a long horizontal flourish.

Scott Kelley
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.

Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Email Address: _____

Customer Phone Number: _____

MR System ID _____

By signing this form, 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.63003@gehealthcare.com

