

# 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.

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,



**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](mailto:Recall.63003@gehealthcare.com)**

