PHILIPS

URGENT Field Safety Notice

MR System Patient Support may experience restricted horizontal tabletop movement

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

23-Aug-2024

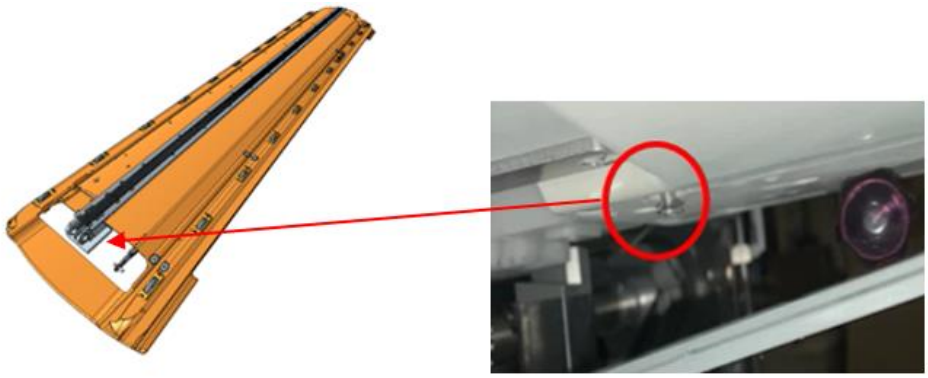
Dear Customer,

Philips has identified an issue with the MR systems identified in Section 3 of this letter, that could pose a risk for patients and users. This URGENT Field Safety Notice is to inform you about:

1. **What the problem is and under what circumstances it can occur**

   Philips has identified an issue in the MR System Patient Support where the Integrated Radio Frequency (IRF) Carrier assembly screws may come loose and protrude beyond the surface (Figure 1). This could cause the screws to interfere with other moving parts, potentially blocking the horizontal tabletop movement.

Figure 1. IRF Carrier protruding screws



The IRF Carrier (Figure 2, Item 2 and 3), a component of the Patient Support within the MR system, supports the tabletop where the patient lies. As the patient moves into the MRI tunnel, the tabletop, supported by the IRF Carrier, forms a container for positioning the posterior coil.

Figure 2. MR System (left image: 1) MR Magnet; 2) Patient Support; 3) IRF Carrier) and IRF carrier (middle and right image).

There have been no reports of adverse events reported to Philips regarding the issue as of March 2024.

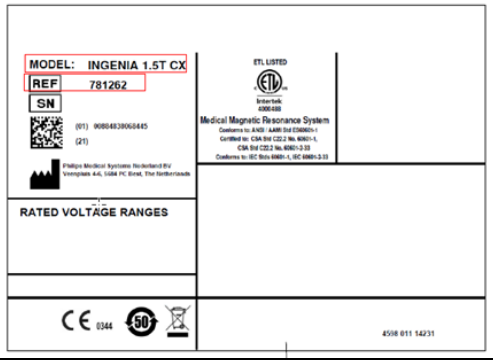
2. Hazard/harm associated with the issue

If a tabletop movement blockage occurs, it could lead to delay in diagnosis and/or may include anxiety if a patient is left on the tabletop inside the bore for a longer duration than anticipated.

3. Affected products and how to identify them

Identification of Impacted Systems:
MR systems listed below are affected. Refer to Figure 3 for the systems model names and model numbers (REF). Refer to Figure 4 on how to locate the system label.

Figure 3. Sample System Label Example



Model	(REF) Numbers
Evolution Upgrade 3.0T	782117
	782143
Ingenia 1.5T	782115
	782101
	782140
Ingenia 3.0T	782103
Ingenia 3.0T CX	782105
Ingenia Ambition S	782108
	781359
	782133
Ingenia Ambition X	782109
Ingenia Elition X	782151
	782119
	781358
	782107
	782136

Ingenia Elition S	782150
	782106
MR 5300	782110
MR 7700	782120
SmartPath to dStream for 1.5T	782112
	781260
SmartPath to dStream for XR and 3.0T	782113
	781270
	782129
SmartPath to Ingenia Elition X	782118

To locate the MR system label:

- Enter the Technical Room
- Locate the Mains Distribution Unit (MDU)
- The label is located on the front door of the MDU, (see Figure 4)

Figure 4. Label location

Intended Use:
Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device. This enables trained physicians to obtain cross-sectional images, spectroscopic images and/or spectra of the internal structure of the head, body or extremities, in any orientation, representing the spatial distribution of protons or other nuclei with spin.

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

A. Customers can continue using identified systems in accordance with the intended use.
B. As a reminder, when using MR systems, follow the warnings listed in the IFU provided with your system:

Refer to the warnings listed in the IFU section titled *Moving the patient into the magnet bore*:

- Before starting a scan which initiates tabletop movement, always check that nothing can get caught or hit during tabletop movement.
- Check patient, patient extremities, clothing, equipment and positioning aids. Guide cables and intravenous lines
- Due care must be taken to ensure that no part of the patient's body, hair, clothing cables or infusion lines can be trapped or injured by any part of the equipment.

C. If you experience resistance from the tabletop movement during patient scan, **Stop-use immediately** and contact your local Philips service representative.
D. Circulate this Urgent Field Safety Notice to all users of this device so that they are aware of the issue.
E. Please display attached 'Advisory' with your system(s); ensure the notice is in a place likely to be seen/viewed by operators.
F. Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt via email to: <Market to insert contact information>. Completing this form confirms receipt of the Urgent Field Safety Notice, understanding of the issue, and required actions to be taken.

5. The actions planned by Philips to correct the problem

Philips will contact you to schedule time for a Field Service Engineer (FSE) to visit your site to inspect the IRF carrier assembly and provide a correction if necessary (reference FCO78100588). Philips plans to start implementing corrections in Q4 2024.

If you need any further information or support concerning this issue, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Electronically signed by: Roxanne Ramirez
Reason: "I Approve"
Date: Aug 21, 2024 21:44 CDT

Roxanne Ramirez
Quality Leader

PHILIPS

URGENT Field Safety Notice Response Form

Reference: MR Systems Integrated Radio Frequency (IRF) Carrier Assembly screws (reference FCO78100588)

Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the URGENT Field Safety Notice, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name:_____

Street Address:_____

City/State/ZIP/Country:_____

Customer Actions:

Follow the instructions provided in Section 4 of the URGENT Field Safety Notice.

We acknowledge receipt and understanding of the accompanying URGENT Field Safety Notice and confirm that the information from this notification has been properly distributed to all users of the affected systems.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please complete and return the response form to Philips promptly and no later than 30 days from receipt via email to: <Market to insert contact information>

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Advisory Notice - MR Systems: Integrated Radio Frequency (IRF) Carrier Assembly screws

As a reminder, when using MR systems, follow the warnings listed in the IFU provided with your system:

Refer to the warnings listed in the IFU section titled *Moving the patient into the magnet bore*:

- Before starting a scan which initiates tabletop movement, always check that nothing can get caught or hit during tabletop movement.
- Check patient, patient extremities, clothing, equipment and positioning aids. Guide cables and intravenous lines
- Due care must be taken to ensure that no part of the patient's body, hair, clothing cables or infusion lines can be trapped or injured by any part of the equipment.

If you experience resistance from the tabletop movement during patient scan, **Stop-use immediately** and contact your local Philips service representative.