PHILIPS

URGENT Field Safety Notice

Multiva 1.5T:

Patient support floor plate cage installation issue leading to potential for tipping

22-Mar-2024

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.

Dear Customer,

Philips has identified an issue with certain MR room cage installations where the patient support (table) floor plate may have been incorrectly installed during the construction of the MR suite. This may cause the table to become dislodged from the floor and potentially cause harm to the patient and/or operator. Note: The MR system will perform per its intended use. This issue is not related to a device malfunction. Refer to section 3 for potentially impacted systems. This URGENT Field Safety Notice is intended to inform you about:

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

   The patient support floor plates for MR systems may not have been anchored to the floor according to Philips requirements causing the patient support to become unstable with the potential for tipping (see Figure 1). This movement can inadvertently lead to harm to the patient and/or operator under certain circumstances.

   Philips has not received any harm or injury associated with this issue as of February 2024.

Figure 1: Example of patient support floor plate which shows upward movement of the patient support in the picture on the right.

View of Patient Support

Upward movement

2. **Hazard/harm associated with the issue.**

   If the patient support were to become dislodged from the floor, the risk to patients or operators may include physical harm from falling from the table, pinching of extremities or other body parts between the patient support and system or floor, and/or delayed diagnosis.

PHILIPS

3. Affected products and how to identify them.

Identification of Impacted Systems:
Potentially impacted systems can be identified by the Model and REF number (REF). The Model name and REF can be found on the system label, as indicated by the red boxes in Figure 2.

Figure 2. System label Example
Multiva 1.5T systems

Figure 2. Example System Label	Product Name (Model)	Product Number (REF)	Device Identifier
	Multiva 1.5T	781072	00884838073890
		781073	00884838073883
		781074	00884838073906
		781076	N/A
		781078	00884838047631

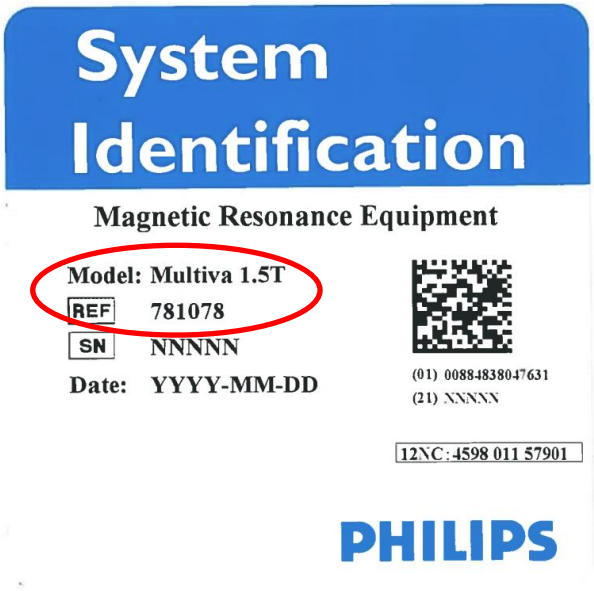
Please locate the system label of your impacted MR system according to the following steps:

1. Enter the Technical Room
2. Locate the general Mains Distribution Unit (gMDU) and Liquid cooling cabinet (LCC)
3. The system label is located on the front door of the gMDU (see figure 3) or LCC (see figure 4)
4. Locate the serial number on the system identification label (see figure 5)

Figure 3: Front door of gMDU

Figure 4: Front door of LCC

Figure 5: system label



Intended Use:

Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device. This MR system 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 the identified systems in accordance with the intended use.

B. As a reminder: When using the system, follow section Patient Support and Tabletop in the Instructions For Use (IFU) provided with your system:

The safe working load as labeled on patient support and trolley is based on the sum of the maximum allowable patient weight and the mass of accessories and coils. The weights mentioned are equal to the safe working load.

- The maximum weight load allowed for the tabletop on the patient support is 250 kg (550 lbs) for horizontal movement and 150 kg (330 lbs) for vertical movement.
- The maximum allowed weight load for the tabletop on the trolley is 150 kg (330 lbs).

C. If the patient's weight is at (or near) the maximum load mentioned above, take care that:
   - They do not sit on the end of the tabletop opposite the bore entrance.
   - From their seated position along the edge of the tabletop, they do not hop down from their sitting position while the support is at its highest position.

D. If the patient support has any unexpected movement and / or becomes unstable (dislodged movement between the system and the floor), immediately stop use and contact your Philips service representative for interim support.

E. Circulate this notice to all users of this device so that they are aware of the potential issue.

F. Please display attached 'Advisory' with your system(s); ensure the notice is in a place likely to be seen/viewed by operators.

G. Please complete and return the attached acknowledgment form to Philips MR promptly upon receipt and no later than 30 days from receipt via email to: pd.cnr@philips.com.

5. Actions planned by Philips to correct the problem.

Philips is providing this Field Service Notice (FSN) Letter which contains recommendations for continued use of the systems referenced in Section 4.

A Philips representative will contact you to schedule time for an FSE to visit your site to perform an inspection regarding the patient support stability. (Reference FCO 78100581).

If you need any further information or support concerning this issue, please contact your local Philips representative at the Philips Customer Care Service Centre by:

Telephone: UKI : +448000260086
NI: +448000260430
ROI: +3531800832340

Email: ukisfco@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Li Xin
Quality Leader
Philips Precision Diagnostics (PD) China

PHILIPS

URGENT Field Safety Notice Response Form

Reference: Patient Support for MR systems (FCO78100581)

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:

A. Customers can continue using the identified systems in accordance with the intended use.

B. Follow the instructions provided in section 4 of the Field Safety Notice Letter.

C. Circulate this notice to all users of this device so that they are aware of the issue.

D. Please display attached 'Advisory' with your system(s); ensure the notice is in a place likely to be seen/viewed by operators.

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

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return the completed and signed reply form to **safetynoticeuki@philips.com**

PHILIPS

Advisory Notice – Multiva 1.5T Systems:
Patient support floor plate cage installation issue leading to potential for tipping

As a reminder: When using the system, follow section Patient Support and Tabletop in the Instructions For Use (IFU) provided with your system: The safe working load as labeled on patient support and trolley is based on the sum of the maximum allowable patient weight and the mass of accessories and coils. The weights mentioned are equal to the safe working load.

- The maximum weight load allowed for horizontal and vertical movement of the tabletop on the patient support and the maximum allowed weight load of the tabletop on the trolley below are taken from their respective IFU:

  The safe working load as labeled on patient support and trolley is based on the sum of the maximum allowable patient weight and the mass of accessories and coils. The weights mentioned above are equal to the safe working load.

  - The maximum weight load allowed for the tabletop on the patient support is 250 kg (550 lbs) for horizontal movement and 150 kg (330 lbs) for vertical movement.
  - The maximum allowed weight load for the tabletop on the trolley is 150 kg (330 lbs).

If the patient's weight is at (or near) the maximum load mentioned above, take care that:

- They do not sit on the end of the tabletop opposite the bore entrance.
- From their seated position along the edge of the tabletop, they do not hop down from their sitting position while the support is at its highest position.

If the patient support has any unexpected movement and / or becomes unstable (dislodged movement between the system and the floor), immediately stop use and contact your Philips service representative for interim support.