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URGENT Field Safety Notice

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

12-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.

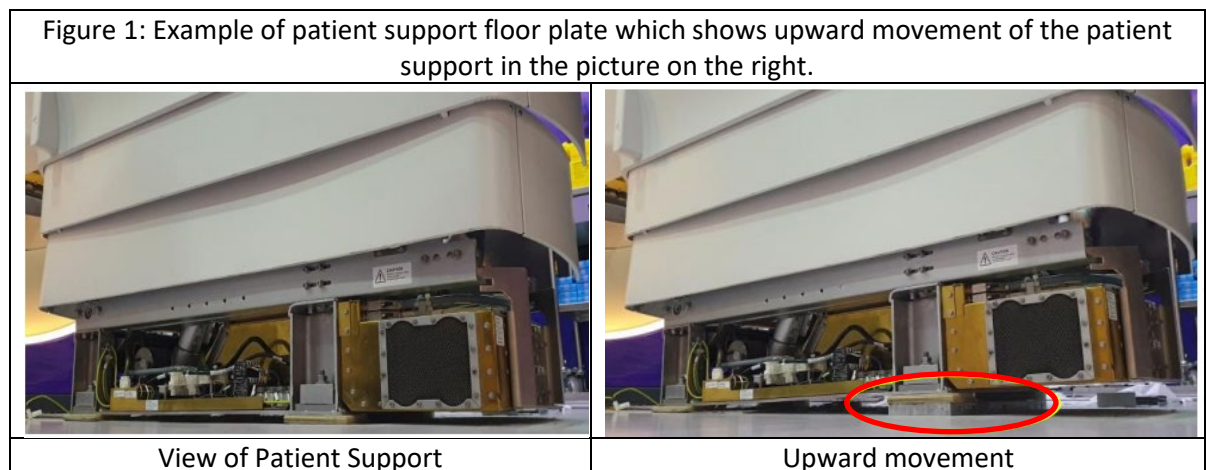
Dear Customer,

Philips has identified an issue with certain MR room cage installations where the patient support (table) floor plate may have been incorrectly installed during 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.

There have been 25 complaints reported to Philips associated with the patient support floor plate issue for MR systems and no reports of harm or injury as of February 2024.



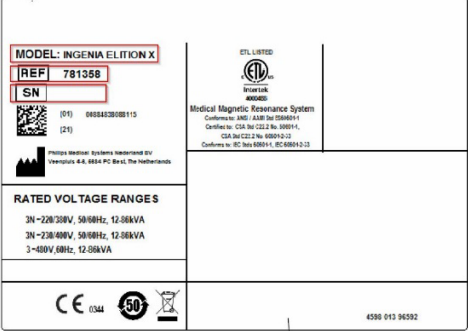
2. Hazard/harm associated with the issue.

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.

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.

Example System Label Location	Model	REF number
	Achieva 1.5T	781296
	Achieva 1.5T	781196
	Achieva 1.5T Conversion	781343
	Achieva 1.5T Initial system	781346
	Achieva 1.5T Initial system	781283
	Achieva 3.0T	781177
	Achieva 3.0T	781177
	Achieva 3.0T	781277
	Achieva 3.0T	781278
	Achieva 3.0T	781344
	Achieva 3.0T for PET	781345
	Achieva 3.0T TX for PET	781477
	Achieva 3.0T TX for PET	781479
	Achieva XR	781153
	Achieva XR	781253
	Enterprise 1.5T	781145
	Evolution upgrade 3.0T	781145
	Evolution upgrade 3.0T	782143
	GYROSCAN ACS-NT	78107
	GYROSCAN T10-NT	78108
	GYROSCAN T5	78104
	GYROSCAN T5-NT	78106
	Ingenia 1.5T	781396
	Ingenia 1.5T	781315
	Ingenia 1.5T	782115
	Ingenia 1.5T	781341
	Ingenia 1.5T	782101
	Ingenia 1.5T CX	781261
Ingenia 1.5T CX	781262	
Ingenia 1.5T S	781347	
Ingenia 3.0T	781377	
Ingenia 3.0T	781342	
Ingenia 3.0T	782103	
Ingenia 3.0T CX	781271	
Ingenia 3.0T CX	782105	
Ingenia Ambition S	782133	
Ingenia Ambition S	782139	
Ingenia Ambition S	781359	
Ingenia Ambition S	782108	

		781356
		782109
	Ingenia Ambition X	782138
		781357
	Ingenia Elition S	782106
		782136
		781358
		782107
	Ingenia Elition X	782119
	Intera 0.5T Standard	781101
	Intera 1.0T Omni/Stellar	781102
	Intera 1.0T Power/Pulsar	781103
		781195
	Intera 1.5T	781295
	Intera 1.5T Achieva IT Nova	781175
	Intera 1.5T Achieva Nova	781172
	Intera 1.5T Achieva Nova- Dual	781173
	Intera 1.5T Explorer/Nova Dual	781108
	Intera 1.5T Master/Nova	781106
	Intera 1.5T Omni/Stellar	781104
	Intera 1.5T Power/Pulsar	781105
	Intera 1.5T R11	781170
	Intera 3.0T Quasar Dual	781150
	Intera Achieva 1.5T Pulsar	781171
	Intera CV	781107
	MR 5300	782110
	MR 7700	782120
	SmartPath to dStream for 1.5T	781260
		782112
	SmartPath to dStream for XR and 3.0T	781270
		782113
		782129

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

1. Enter the Technical Room
2. Locate the system label (see Figure 3) which can be found on the cabinet door
3. Locate the model and reference number on the system label (see Figure 4)

Figure 3: Example Front door of cabinet

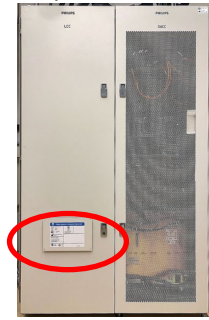
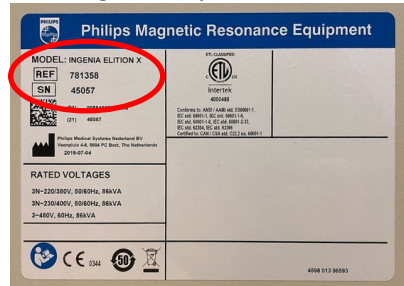


Figure 4: system label



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 horizontal and vertical movement of the tabletop on the patient support and the maximum allowed weight load of the table top on the FlexTrack in Table 1 below are taken from their respective IFU:*

Table 1. Safe Working Load per applicable IFU

Product name	Product number	Trolley safe working load (Kg)	Patient support safe working load (Kg)
Achieva 1.5T, Achieva 3.0T, Achieva XR, Intera 1.5T, Intera 1.5T Achieva Nova and Intera 1.5T Achieva Nova-Dual	781296, 781177, 781277, 781253, 781295, 781172, 781173	150 kg 330 lbs	250 kg 550 lbs
SmartPath to dStream for XR and 3.0T, Ingenua 1.5T, Ingenua 3.0T, SmartPath to dStream for 1.5T, Ingenua 3.0T CX, Ingenua Elition S, Ingenua Elition X, Ingenua Ambition X, Ingenua Ambition S, Upgrades dStream to R5.7, MR 7700 and SmartPath to Ingenua Elition X	781270, 781396, 781341, 781377, 781342, 781260, 781271, 781357, 782106, 781358, 782107, 781356, 782109, 781359, 782108, 782111, 782120, 782118	250 kg 550 lbs	250 kg 550 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 78100570).

Please be assured that maintaining a high level of safety and quality is our highest priority. 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,



David Hanly
Head of Quality, Philips Magnetic Resonance (MR)

URGENT Field Safety Notice Response Form

Reference: Patient Support for MR systems (FCO 78100570)

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 complete and return the attached acknowledgement form to Philips MR via email to: pd.cnr@philips.com.

**Advisory Notice - MR 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 FlexTrack in Table 1 below are taken from their respective IFU:*

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SmartPath to dStream for XR and 3.0T, Ingenia 1.5T, Ingenia 3.0T, SmartPath to dStream for 1.5T, Ingenia 3.0T CX, Ingenia Elition S, Ingenia Elition X, Ingenia Ambition X, Ingenia Ambition S, Upgrades dStream to R5.7, MR 7700 and SmartPath to Ingenia Elition X	781270, 781396, 781341, 781377, 781342, 781260, 781271, 781357, 782106, 781358, 782107, 781356, 782109, 781359, 782108, 782111, 782120, 782118	250kg 550 lbs	250kg 550 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.