Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 41 **dated** 24/3/2024 **Regarding NCMDR Field Safety Notice of Philips MR Systems from (mfr: Philips Medical Systems).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 41 **/ 2024**

13 -09-1445 H
24 -03-2024

Field Safety Notice of Philips MR Systems from Philips Medical Systems.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20965
Product	Philips MR Systems.
Description	Magnetic resonance imaging.
Manufacturer	Philips Medical Systems.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Please refer to the affected products in the attachment.
Reason	The patient support floor plates for MR systems may not have been anchored to the floor during construction of the MR suite according to Philips requirements causing the patient support to become unstable with the potential for tipping.
Action	1. Please refer to the attachment for actions that should be taken by the customer / user in order to prevent risks for patients or users. 2. You will be contacted by Philips distributor to schedule time for an FSE to visit your site to perform an inspection regarding the patient support stability (Reference FCO 78100570). 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

PHILIPS

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,

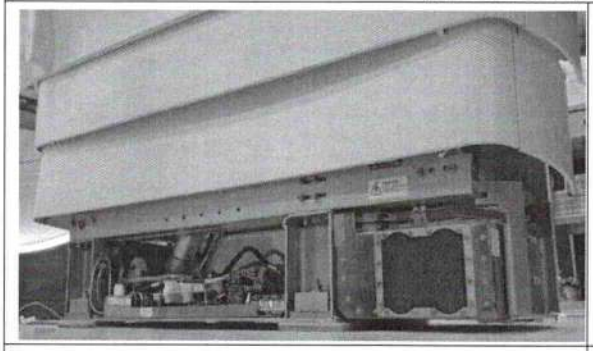
Philips has identified an issue with certain MR room cage installations where the patient support (table) floor plate may have been incorrectly installed during construction of the MR suite. This may cause the table to become dislodged from the floor and potentially cause harm to the patient and/or operator. 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

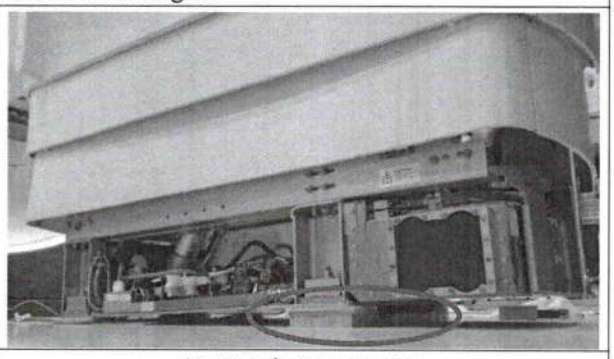
The patient support floor plates for MR systems may not have been anchored to the floor according to Philips requirements causing the patient support to become unstable with the potential for tipping (see Figure 1). This movement can inadvertently lead to harm to the patient and/or operator under certain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

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.

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
		781196
		781343
	Achieva 1.5T Conversion	781346
		781283
	Achieva 1.5T Initial system	781178
	Achieva 3.0T	781177
		781277
		781278
		781344
		781345
	Achieva 3.0T for PET	781477
	Achieva 3.0T TX for PET	781479
	Achieva XR	781153
		781253
	Enterprise 1.5T	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
		781315
		782115
		781341
		782101
	Ingenia 1.5T CX	781261
		781262
	Ingenia 1.5T S	781347
	Ingenia 3.0T	781377
		781342
		782103
	Ingenia 3.0T CX	781271
		782105
	Ingenia Ambition S	782133
		782139
		781359
		782108

	Ingenia Ambition X	781356
		782109
		782138
	Ingenia Elition S	781357
		782106
	Ingenia Elition X	782136
		781358
		782107
		782119
	Intera 0.5T Standard	781101
	Intera 1.0T Omni/Stellar	781102
	Intera 1.0T Power/Pulsar	781103
	Intera 1.5T	781195
		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

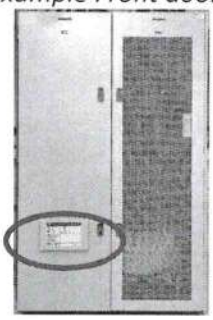
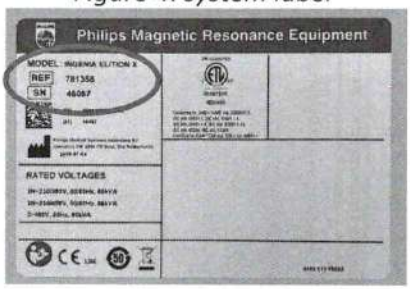


Figure 4: system label



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, 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	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: met.quality @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. met.quality @philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

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

PHILIPS

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 via email to: met.quality @philips.com.

PHILIPS

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:*

Table 1. Safe Working Load per applicable IFU

Product name	Product number	Trolley safe working load	Patient support safe working load
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, 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.