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 89 **dated** 27/6/2024 **Regarding NCMDR Field Safety Corrective Action of Multiva 1.5T systems equipped with g-MDU from (mfr: Philips Healthcare).**

Copy to:

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

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Ministry of Health
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سلطنة عُمان
وزارة الصحة
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Circular No. 89 **/ 2024**

20-12-1445 H
27-06-2024

Field Safety Corrective Action of Multiva 1.5T systems equipped with g-MDU from Philips Healthcare.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21069
Product	Multiva 1.5T systems equipped with g-MDU.
Description	Magnetic Resonance systems.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	(REF) Numbers: 781072, 781073, 781074, 781076, 781078 Please refer to the attachment for more information.
Reason	It has been identified an issue where the g-MDU (global Mains Distribution Unit) L3 terminal connection may become loose creating a hotspot that may cause smoke/fire to alarm in the hospital's technical room.
Action	1. Please follow instructions provided by Philips that should be taken by the customer / user found in the attachment. 2. You will be contacted by Philips distributor to schedule time for a Field Service Engineer (FSE) to visit your site to inspect the g-MDU connections in the technical room and apply the proper torque to the connection if necessary (reference FCO78100583). 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

Multiva 1.5T systems Terminal connections in the general Mains Distribution Unit (g-MDU) may produce a Thermal Event

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.

30-May-2024

Dear Customer,

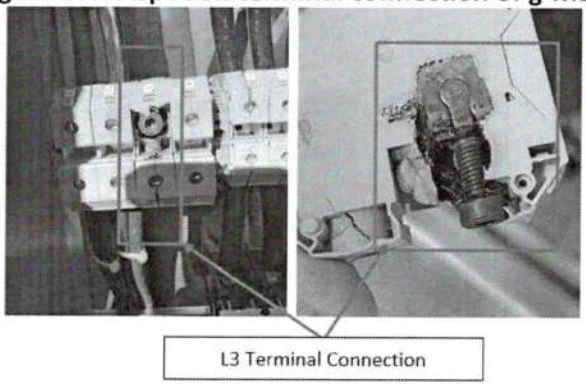
Philips has identified an issue with the Multiva 1.5T systems that could pose a risk for patients and users. **This URGENT Field Safety Notice is to inform you about:**

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

   Philips has identified an issue where the **g**-MDU (**g**lobal Mains Distribution Unit) L3 terminal connection may become loose creating a hotspot (see figure 1) that may cause smoke/fire to alarm in the hospital's technical room. The g-MDU, located in the technical room, is the single-entry point for the hospital electricity supply and distributes the electricity toward the various cabinets and components of the MR Scanner.

   If the connection failure occurs, the user may observe the following:
   - Smoke and/or fire alarm in the examination room
   - Smoke and/or fire in the hallway or technical room
   - Power being cut from the system

Figure 1. Hotspot on terminal connection of g-MDU



Philips has not received any complaints of burnt g-MDU terminal connections, and smoke /burning smell in the technical room associated with the issue from Multiva 1.5T systems. There was no report of injury or serious harm.

2. Hazard/harm associated with the issue

If smoke or fire were to occur in the technical room, the risk to patients or operators may include asphyxia, eye irritation, eye redness, and/or delay in diagnosis.

3. Affected products and how to identify them

Identification of Impacted Systems:
All Multiva 1.5T systems equipped with g-MDU listed below are affected. Refer to Figure 2 for the systems model names and model numbers (REF) and Refer to Figure 3 on how to locate the system label.

Figure 2. Sample System Label Example	Model	(REF) Numbers	UDI
	Multiva 1.5T 8 R5	781072	00884838073890
	Multiva 1.5T 16 R5	781073	00884838073883
	Multiva 1.5T 8 R5	781074	00884838073906
	Multiva 1.5T	781076	N/A
	Multiva 1.5T 16 R5	781078	00884838047631

To locate the MR system label:

- Enter the Technical Room
- Locate the Mains Distribution Unit (gMDU)
- The label is located on the front door of the gMDU, (see Figure 3)

Figure 3. 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

- If a smoke/fire alarm is detected:
  a. Immediately stop scanning and evacuate the patient and staff from the examination room.
  b. If a developing fire is detected, adhere to established hospital fire emergency procedures, **which may include switching off power to the complete system and/or removing the** magnet field by using the Emergency Magnet Off button.
  c. Do not attempt to continue scanning.
  d. Immediately contact Philips Service.

- Ensure all users are aware of facility specific Emergency Procedures as outlined in *Chapter 2: Safety* in the *Instructions for Use*

  Emergency procedures
  The User is required to establish emergency procedures for the following situations:
  - *A medical emergency*
  - *A fire*
  - *An emergency that requires immediate removal of the magnetic field*
  - *The release of helium gas into the examination room*

  Philips MRI systems have an Emergency Table Stop button in case there is an emergency during tabletop movement.

- Circulate Urgent Field Safety Notice to all users of this device so that they are aware of the issue.

- Post this notice near the affected MR system(s) for ease of reference.

- **Please complete and return the attached response form to Philips promptly and no later than 30** days from receipt via email to: pd.cnr@philips.com. 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 g-MDU connections in the technical room and apply the proper torque to the connection if necessary. (reference FCO78100583). Philips plans to start implementing corrections in July 2024.

PHILIPS

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.

Sincerely,

LI XIN
Head of Quality
PD China

PHILIPS

URGENT Field Safety Notice

Reference: Terminal connections in the general Mains Distribution Unit (g-MDU) may produce heat triggering the smoke/fire alarm (reference FCO78100583)

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: met.quality@philips.com.**