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,

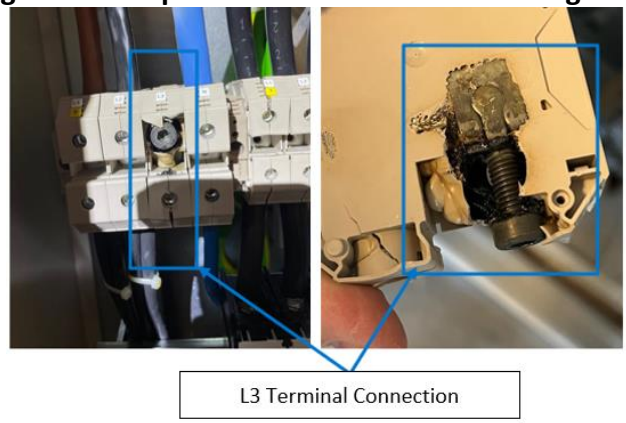
Philips has identified an issue with the Multiva 1.5T systems that could pose a risk for patients and users. This URGENT Field Safety Notice is to inform you about:

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

   Philips has identified an issue where the g-MDU (global 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

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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 3 days from receipt via email to: FCO.Nordic@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.

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.

Telephone 80 30 30 35
Email philips.service@philips.com

Sincerely,

LI XIN
Head of Quality, PD China

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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 3 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 3 days from receipt via email to: FCO.Nordic@philips.com.