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URGENT Field Safety Notice

MR 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.

19-April-2024

Dear Customer,

Philips has identified an issue with the MR systems identified in section 3 of the letter that could pose a risk for patients and users. This URGENT Medical Device Correction Notice is to inform you about:

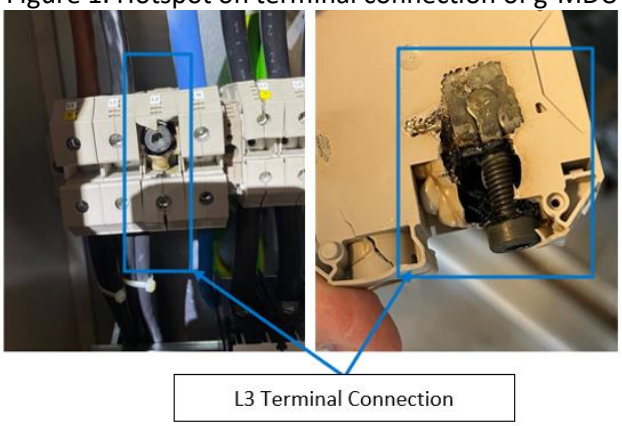
1. What the problem is and under what circumstances it can occur

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 received five (5) complaints of burnt g-MDU terminal connections, and smoke /burning smell in the technical room associated with the issue. There was no report of injury or serious harm.

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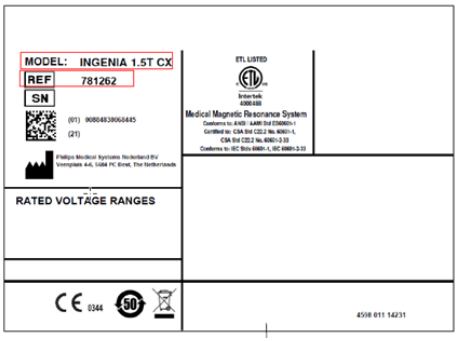
2. Hazard/harm associated with the issue

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 MR systems listed below are affected. Refer to Figure 2 for the systems model names and model numbers (REF). Refer to Figure 3 on how to locate the system label.

Figure 2. Sample System Label Example



Model	(REF) Numbers
Achieva 1.5T	781343
	781296
Achieva 1.5T Conversion	781346
	781283
Achieva 1.5T Initial system	781178
Achieva 3.0T	781345
	781344
	781278
	781277
	781177
Achieva 3.0T for PET	781477
Achieva 3.0T TX for PET	781479
Achieva XR	781253
Evolution upgrade 1.5T	782116
	782148
Evolution upgrade 3.0T	782117
	782143
Ingenia 1.5T	782140
	782115
	782101
	781396
	781341
	781315
Ingenia 1.5T CX	781262
	781261

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Model	(REF) Numbers
Ingenia 1.5T S	781347
Ingenia 3.0T	782103
	781377
	781342
Ingenia 3.0T CX	782105
	781271
Ingenia Ambition S	782139
	782133
	782108
	781359
Ingenia Ambition X	782138
	782109
	781356
Ingenia Elition X	781358
INGENUITY TF PET MR	882380
Intera 1.5T	781295
Marlin 1.5T	781474
MR 5300	782152
	782110
MR system 1.5T Marlin	781483
MR-RT	781439
MR-RT Upgrades	781440
Panorama HFO	781350
SmartPath to dStream for 1.5T	782146
	782112
	781260
SmartPath to dStream for 3.0T	782145
SmartPath to dStream for XR and 3.0T	782129
	782113
	781270
SmartPath to Ingenia Elition X	782118
Sonalleve MR-HIFU 3.0T	781361
Upgrade dStream	782127

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 2)

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.

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- 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 FCO78100582). 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: For North America, contact the Customer Care Solutions Center (1-800-722-9377).

Sincerely,

David Hanly 19Apr2024

David Hanly
Quality Leader

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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 FCO78100582)

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: pd.cnr@philips.com.