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URGENT Field Safety Notice

Multiva 1.5T

Potential for System Shutdown and Magnet Bore Cover Thermostability Issue

January 13, 2025

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 Multiva 1.5T MR systems, that could pose a risk for patients and/or users. This *URGENT Field Safety Notice* is intended to inform you about:

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

Philips has identified a thermostability issue with the magnet bore cover used on Multiva 1.5T MR Systems. The cover may partly melt where the area is not covered by the Quadrature Body Coil (QBC) inside the bore if an unexpected arcing failure occurs on the Gradient Coil. The magnet bore cover acts as a barrier between the heat and the patient.

If the arcing failure occurs, the system will shut down and the user may observe the following:

- Smoke and/or fire from within the system.
- If Gradient Coil arcing occurs in a region outside of the QBC or bridge support, particles may melt through the magnet bore cover and contact the patient.

As of December 2024, Philips has received one (1) complaint associated with the magnet bore cover partially melting on a Multiva 1.5T System. There was no report of injury or serious harm to hospital staff or patients.

2. Hazard/harm associated with the issue

If the Gradient Coil arcing failure occurs with smoke and/or fire, the risk to patients may include inhalation of smoke, asphyxia, eye irritation, eye redness, burns and/or delay in diagnosis.

3. Affected products and how to identify them

Identification of Impacted Systems:
All Multiva 1.5T systems listed below are affected. Please refer to Figure 1 for the system model names and model numbers (REF) and Refer to Figure 2&3&4 on how to locate the system label.

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Figure 1. Example System Label	Product Name (Model)	Product Number (REF)
	Multiva 1.5T	781072 781073 781074 781076 781078

Please locate the serial number of your impacted MR system by:

3.1. Enter the Technical Room

3.2. Locate the general Mains Distribution Unit (gMDU) and Liquid cooling cabinet (LCC)

3.3. The system label is located on the front door of the gMDU (see figure 2) or LCC (see figure 3)

3.4. Locate the serial number on the system identification label (see figure 4)

Figure 2: Front door of gMDU

Figure 3: Front door of LCC

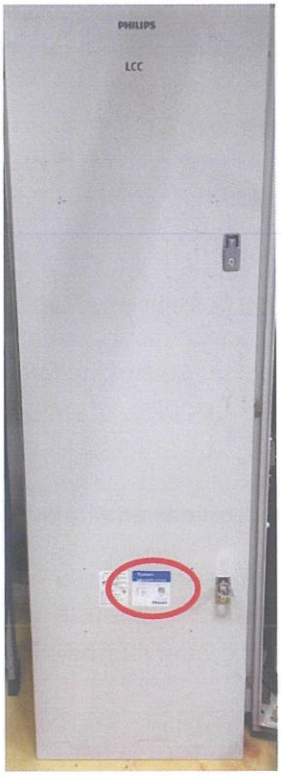
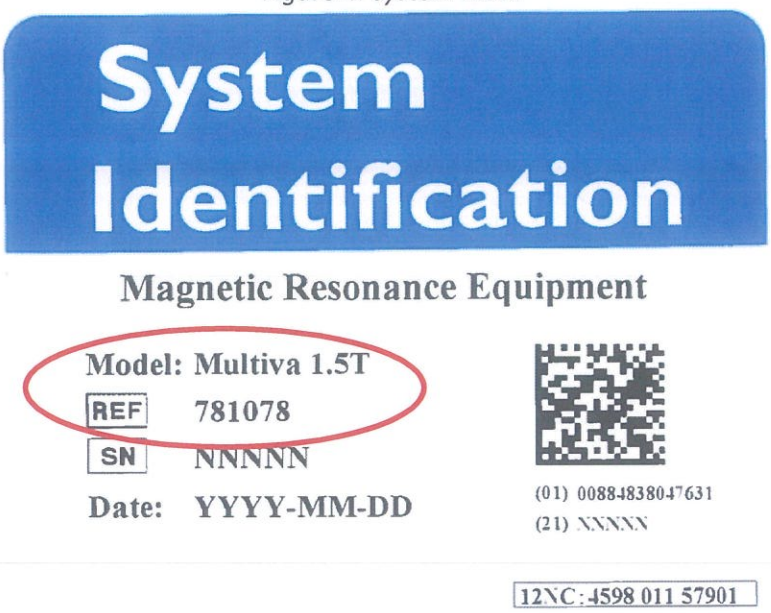


Figure 4: system label



Intended Use:
Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device.

These MR systems enable 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

4.1. If smoke and/or fire is detected:

- Immediately stop scanning and evacuate the patient and staff from the Examination Room.
- 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.
- Do not attempt to continue scanning.
- Immediately contact Philips Service.

4.2. 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.

4.3. Circulate this notice to all users of this device so that they are aware of the product issue and associated hazard/harm.

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

4.5. Please complete and return the attached updated customer response form to Philips **promptly** and no later than 30 days from receipt of this letter.

5. 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 install a hardware solution to improve the thermostability of the magnet cover (Reference FCO78100598).

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: <When a Philips representative is required, contact details to be provided by the Market>

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Li Xin
Quality Leader
Philips Precision Diagnostics (PD) China

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URGENT Field Safety Notice Response Form

Reference: Multiva 1.5T: Potential for System Shutdown and Magnet Bore Cover Thermostability Issue (Reference FCO78100598)

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 updated URGENT Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

A. Post this notice near the affected MR unit(s) for ease of reference.

B. Circulate this notice to all users of this device so that they are aware of the product issue and associated hazard/harm until this issue has been resolved.

C. Follow the instructions provided in section 4 of the URGENT Field Safety Notice Letter.

We acknowledge receipt and understanding of the accompanying URGENT Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users that handle the system.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please complete and return the attached acknowledgment form to Philips via email to: <local market email address>