PHILIPS

Update – Field Safety Notice

Multiva 1.5T

Gradient Coil component failure may act as a heat source with potential to produce smoke and/or fire.

Jun 23, 2025

Dear Customer,

Attached you will find an update to Philips Jul-2024 Field Safety Notice letter relating to *Gradient Coil component failure may act as a heat source with potential to produce smoke and/or fire*.

As a reminder, the instructions within the original letter (attached) Section 4, *"Actions that should be taken by the customer/user to prevent risks for patients or users"* are still advised and valid. Please continue to follow these instructions until a correction is provided.

In Section 5 of the letter "*Actions planned by Philips to correct the problem*" Philips committed to provide an update on the development of our plan to address the Gradient Coil issue. The updated action plan information is as follows:

Summary of Updates:

- Philips has identified additional Multiva 1.5T systems which are being included in the scope of this recall. These systems will be included in the delivery of a new software risk control measure to prevent smoke/fire by prohibiting customers from continued scanning if Gradient Amplifier errors reach a threshold, thus triggering a system interlock. If this system interlock occurs, an FSE will come to your site to investigate the issue and if it is identified that there is a problem with the gradient coil, it will be replaced.
  - Section 3 of the Field Safety Notice letter has been updated to include the additional model names and numbers (REF). According to our records, affected product has been distributed to your facility.

- Section 5 of the Field Safety Notice Letter has been updated to include up to date information regarding the field corrections. The release date of the field correction for the software risk control measure has been updated from Q4 2024 and will now start to be implemented in Q1 2026 through multiple FCO's (depends on SW version):

FCO Number	SW Version	Implementation
FCO78100623	Multiva R5.X	Q1 2026
FCO78100624	Multiva R5.1.5X	

- The previous plan to implement a Smoke Detector Interlock has been modified and instead, Philips is exploring if materials in the vicinity of the gradient coil need to be replaced with better (more) flame-retardant alternatives. Once all the materials are assessed a plan will be put in place to deliver this material change.

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Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning this issue, please contact your local Philips representative:

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

Sincerely,

Peter Jangenfeldt
Head of Services & Solutions Delivery, Nordic

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URGENT Field Safety Notice

Multiva 1.5T

Gradient Coil component failure may act as a heat source with potential to produce smoke and/or fire.

Jun 23, 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 an issue where a specific component failure in the Gradient Coil of the affected Multiva 1.5T MR Systems listed in this letter may act as a heat source with a potential to produce smoke and/or fire.

If the component failure occurs, the user may observe the following:

- Repeated scan abort error messages due to gradient amplifier fault detection, described in Section 4.
- Unusual noise from the system in the examination or technical room
- Smoke and/or fire from within the system

Philips has received 2 complaints of smoke/fire caused by this issue which is associated with the Gradient Coil type used in the MR Systems identified in this letter. There was no report of injury or serious harm to hospital staff or patients, however, damage to property has occurred.

2. **Hazard/harm associated with the issue**

If smoke or a fire occurs the risk to patients or operators may include inhalation of smoke, burns, and/or asphyxia which may lead to injury or even death. This issue could also lead to property damage.

3. Affected products and how to identify them

Identification of Impacted Systems:

The affected Multiva 1.5T MR Systems including product number (REF), name (Model) listed in below table. Figure 3 illustrates the location of the product number (REF) and name (Model) on the system label.

Product Name (Model)	Product Number (REF)	Device Identifier
Multiva 1.5T	781072	00884838073890
	781073	00884838073883
	781074	00884838073906
	781076	N/A
	781078	00884838047631

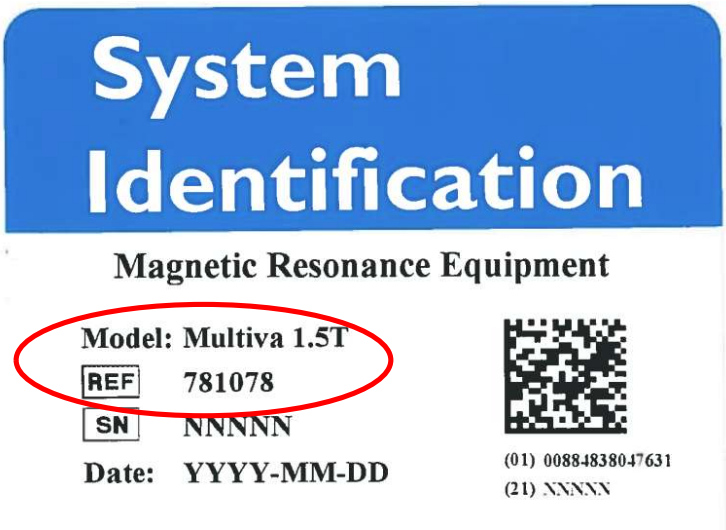
Please locate the serial number of your impacted MR system by:

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 1) or LCC (see figure 2)
3.4. Locate the serial number on the system identification label (see figure 3)

Figure 1: Front door of gMDU

Figure 2: Front door of LCC

Figure 3: system label



Intended Use:

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

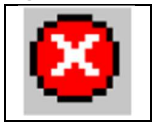
These MR systems enable trained physicians to obtain cross-sectional images, spectroscopic images and/or spectra of the internal structure of the head, body or extremities, in any orientation, representing the spatial distribution of protons or other nuclei with spin.

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

4.1. When using any affected system identified according to the information in section 3, follow the instructions below.

4.2. Pay particular attention if a scan interruption occurs and a 'scan abort' symbol is encountered, which may appear in the user interface (UI) with the symbols shown in Figure 4 below:

Figure 4. Scan Abort Symbol

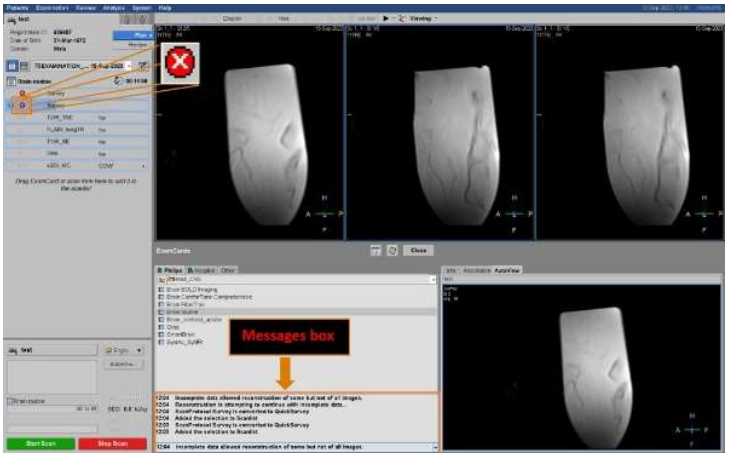


4.3. When scan aborts occur the symbol is shown and applicable messages are presented in the message box (see Figure 5 example)

4.3.1. Check the status of the error messages in the User Interface (UI) screen. Click to expand the message box in case previous messages are hidden, see orange box in Figure 5 below. If possible, correct the issue that is relevant to the error shown, and continue scanning, for example:

- "RF door must be closed while performing scan. Scan aborted."
- "Patient support is moved while scanning, scan stopped."
- "Coil A (*or B*) failure, coil disconnected?".

Figure 5. UI example SW Version R5.



4.3.2. If, after a scan abort, one of the following conditions occur five times in a row stop scanning immediately and contact Philips Service to describe the problem:

- If there is no error message in the message box
- If the error message meaning is not clear

4.3.3. If the error message “Gradient amplifier Rack Fault” is received two times in a row, or if the error message “Gradient amplifier Rack Fault” is preceded or followed by an aborted scan with no message, then stop scanning immediately and contact Philips Service to describe the problem.

4.3.4. If you encounter any of these conditions described in 4.3.2 or 4.3.3 do not attempt any additional/further scans, including without limitation do not attempt any phantom scanning until your system has been checked and released by a Philips Service representative.

4.4. 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.

4.5. 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.

4.6. Post the attached Appendix A – Actions for Customer / User: Post with System near the affected MR system(s) for ease of reference.

4.7. 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.

4.8. 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 is committed to addressing the issue and plans to start delivery of a software risk control measure starting in Q1 2026. This feature will act to prevent smoke/fire by prohibiting customers from continuing scanning if Gradient Amplifier errors reach a threshold, thus triggering a system interlock. If this system interlock occurs, an FSE will come to your site to investigate the issue and if it is identified that there is a problem with the gradient coil, it will be replaced. The following are the anticipated SW releases which will be delivered:

FCO Number	SW Version	Implementation
FCO78100623	Multiva R5.X	Q1 2026
FCO78100624	Multiva R5.1.5X	

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

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Peter Jangenfeldt
Head of Services & Solutions Delivery, Nordic

PHILIPS

URGENT Field Safety Notice Response Form

Reference: Multiva 1.5T: Gradient coil may act as a heat source with a potential to produce smoke and/or fire.

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: FCO.Nordic@philips.com

URGENT Field Safety Notice

Appendix A – Actions for Customer / User: Post with System

4. Actions that should be taken by the customer / user in order to prevent risks for patients or users

4.1. When using any affected system identified according to the information in section 3, follow the instructions below.

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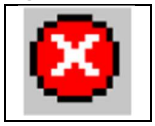

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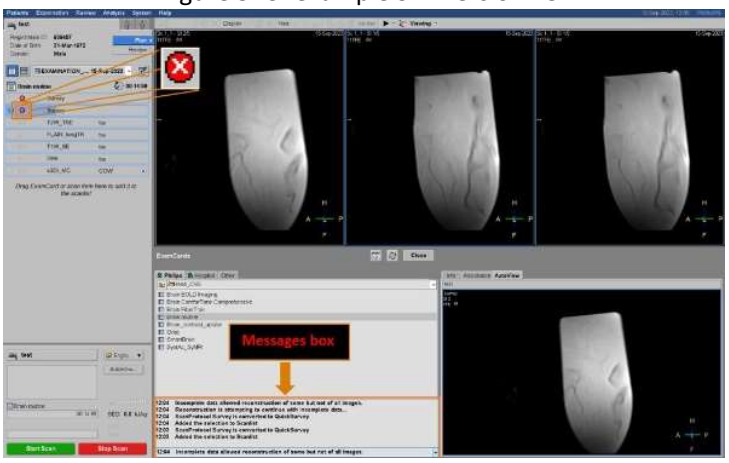

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