PHILIPS

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.

October 23, 2023

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 one (1) complaint 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) and serial number (SN) are listed in Appendix A. Figure 1 illustrates the location of the product number (REF), name (Model), and serial number (SN).

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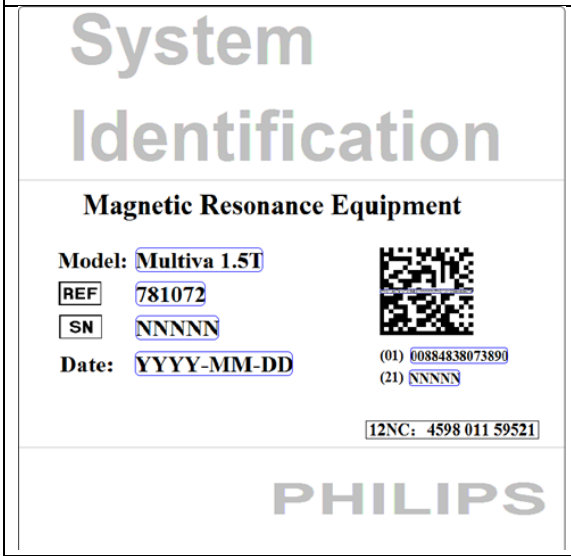
Figure 1. Example System Label	Product Name (Model)	Product Number (REF)
	Multiva 1.5T	781072
		781073
		781074
		781076
		781078

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.

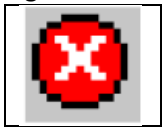
These MR systems enable trained physicians to obtain cross-sectional images, spectroscopic images and/or spectra of the internal structure of the head, body or extremities, in any orientation, representing the spatial distribution of protons or other nuclei with spin.

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

4.1. 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 5 below:

Figure 5. Scan Abort Symbol

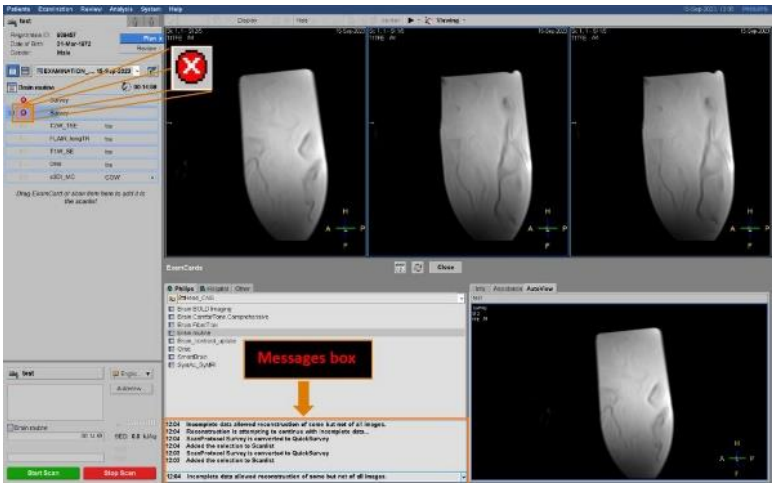


4.3. When scan aborts occur the symbol is shown and applicable messages are presented in the message box (see Figure 6 examples)

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 6 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 6. 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 B – 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 3 days from receipt of this letter.

5. Actions planned by Philips to correct the problem

Philips is providing this customer letter containing guidance until the investigation into this issue is complete.

Philips is committed to addressing the issue and continues to investigate its root cause. We anticipate providing an update to you on the development of our plan to address the issue by in early 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

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: 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 3 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

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Appendix A – Units Affected List

Serial Numbers for Multiva 1.5T (REF: 781072) Unique Device Identifier Rule: (01) 00884838073890(21) + Serial number								
80030	80047	80605	80035	80051	80055	80033	80063	80081
80067	80059	80068	80056	80054	80071	80078	80080	80075

Serial Numbers for Multiva 1.5T 16 (REF: 781073) Unique Device Identifier Rule: (01) 00884838073883 (21) + Serial number								
80609	80601	80504	80513	80521	80506	80514	80539	80529
80547	80542	80534	80560	80567	80551	80571	80531	80559
80562	80508	80523	80566	80602	80608	80615	80600	80613
80612	80620	80623	80603	80643	80610	80665	80647	80626
80652	80693	80645	80686	80704	80588	80703	80722	80726
80614	80651	80748	80729	80723	80725	80646	80779	80662
80772	80799	80906	80791	80819	80606	80775	80809	80792
80832	80835	80807	80732	80932	-	-	-	-

Serial Numbers for Multiva 1.5T (REF: 781074) Unique Device Identifier Rule: (01) 884838073906 (21) + Serial number	
76003	76008

Serial Numbers for Multiva 1.5T (REF: 781076) Unique Device Identifier Rule: N/A								
44001	44046	44014	44013	44008	44022	44038	44034	44024
44031	44045	-	-	-	-	-	-	-

Serial Numbers for Multiva 1.5T (REF: 781078) Unique Device Identifier Rule: (01) 884838047631 (21) + Serial number								
80565	44231	44245	44200	44247	44631	44207	44218	44623
44233	44602	44243	44604	44610	44613	44230	44636	-

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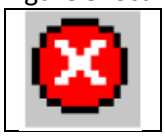

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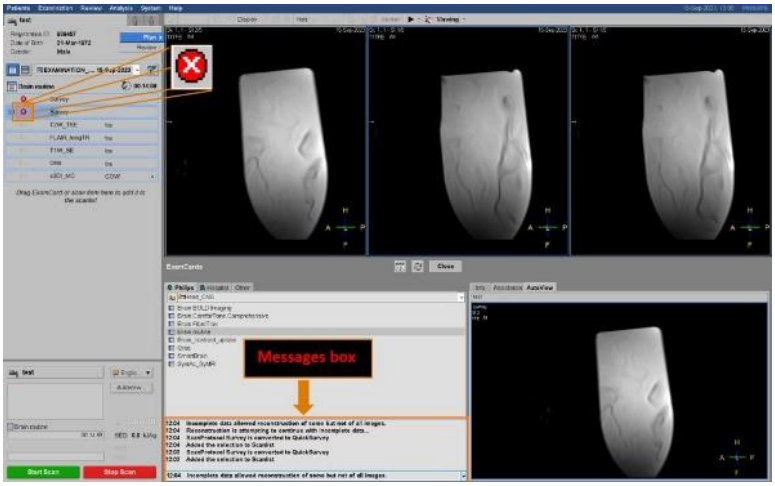

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