PHILIPS

Field Safety Notice

Philips MR Systems

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

<Date>

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.

Dear Customer,

Philips has identified an issue with certain models of its MR systems (see Section 3) that could pose a risk for patients and/or users. This 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 component failures in the Gradient Coil of the affected MR systems listed in Section 3 may act as a heat source with a potential to produce smoke and/or fire.

If a 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
- Burning smell
- Smoke and/or fire

Philips has received 60 complaints potentially related to this issue. There has been one (1) complaint of smoke/fire caused by this issue. There were no reports of injury or serious harm to hospital staff or patients. However, in some cases, 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 death. This issue could also lead to property damage.

3. Affected products and how to identify them

Identification of Impacted Products:
The affected products, including product name (Model) and product number (REF) are listed below. Figure 3 illustrates the location of the product name (Model) and product number (REF) on the label.

Product Name (Model)	Product Number (REF)
Achieva 3.0T	781177
	781277

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	781278
	781344
	781345
Achieva XR	781153
	781253
Evolution upgrade 1.5T	782116
	782148
Evolution upgrade 3.0T	782117
	782143
Ingenia 1.5T	781315
	781341
	781396
	782101
	782115
	782140
Ingenia 1.5T S	781347
Ingenia 3.0T	781342
	781377
	782103
Ingenia 3.0T CX	781271
	782105
Ingenia Ambition S	781359
	782108
	782133
	782139
Ingenia Ambition X	781356
	782109
	782138
Ingenia Elition S	781357
	782106
	782137
	782150
Ingenia Elition X	781358
	782107
	782119
	782136
	782151
Intera 3.0T Quasar Dual	781150
MR 5300	782110
	782135
	782152
MR 7700	782120
	782153
SmartPath to dStream for 3.0T	782145
SmartPath to dStream for XR and 3.0T	781270
	782113
	782129
SmartPath to Ingenia Elition X	782118
	782144
Upgrade to MR 7700	782130

To locate the system label for your MR system –

A. General Mains Distribution Unit (gMDU)
   3.1. Enter the Technical Room

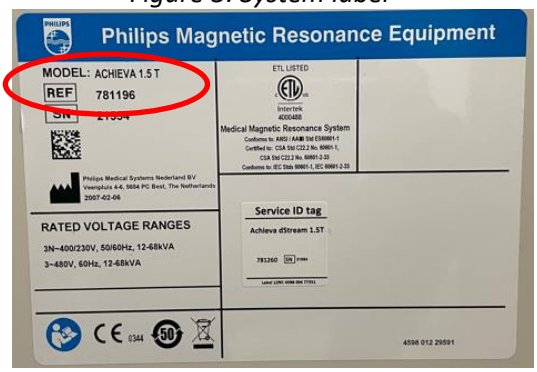
3.2. Locate the general Mains Distribution Unit (gMDU)
3.3. The system label is located on the front door of the gMDU (see Figure 1)
3.4. Locate the product name (Model) and product number (REF) on the system identification label (see Figure 3)

B. Liquid Cooling Cabinet (LCC)
3.1. Enter the Technical Room
3.2. Locate the Liquid Cooling Cabinet (LCC)
3.3. The system label is located on the front door of the LCC (see Figure 2)
3.4. Locate the product name (Model) and product number (REF) 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.

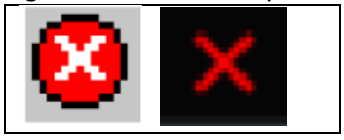
These MR systems enable trained physicians to obtain cross-sectional images, spectroscopic images and/or spectra of the internal structure of the head, body or extremities, in any orientation, representing the spatial distribution of protons or other nuclei with spin.

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 Symbols



4.3. When scan aborts occur the symbol is shown and applicable messages are presented in the message box (see Figure 5 and 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 5 and 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 5. UI example SW Version R11.

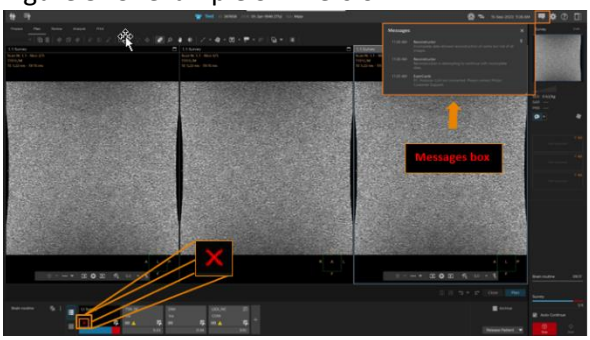
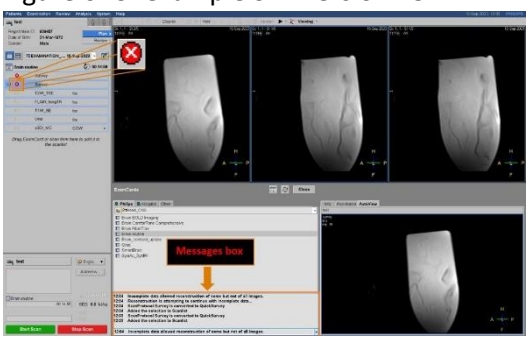


Figure 6. UI example SW Version R5.



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 Appendix A, *Actions for Customer / User: Post with System,* near the affected MR unit(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 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 Q3 2025. This feature will 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, which prevents further scanning, 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 field corrections will be implemented to deliver the solution (depending on software version):

FCO Number	Software Version	Planned Release Date
78100610	R3.2.3 Service Pack 6	Q3 2025
78100592	R4 → R5.8.2	Q4 2025
78100618	R5.1 and R5.2 → R5.8.2	Q3 2025
78100619	R5.3.X through R5.8.1 → R5.8.2	Q3 2025
78100585	R11.X → R12.2	Q3 2025
78100620	R12.1.1 → R12.2	Q3 2025

Philips is also exploring if materials in the vicinity of the gradient coil need to be replaced with better (more) flame-retardant alternatives.

The advice provided in Section 4 and the solution in Section 5 of this Field Safety Notice are applicable for systems in operational status and is intended to address the issue identified in this letter. It is not intended to extend the service life of the product or designed to address any of the risks related to continued use of the system after its service life (meaning the timespan during which the system is expected to perform and remain safe when used in accordance with its labelling).

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.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Electronically signed by:
Akivia Rivera G
Reason: "I Approve"
Date: Jun 24, 2025 18:01 GMT+2

Akivia Rivera Garcia
Head of MR Quality

PHILIPS

Field Safety Notice Response Form

Reference: Philips MR Systems - 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 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:

A. Follow the instructions provided in section 4 of the Field Safety Notice.

B. Post Appendix A, *Actions for Customer / User: Post with System,* near the affected MR unit(s) for ease of reference.

C. 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.

We acknowledge receipt and understanding of the accompanying Field Safety Notice 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 <Insert local Market contact information>

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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.

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:

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- "RF door must be closed while performing scan. Scan aborted."
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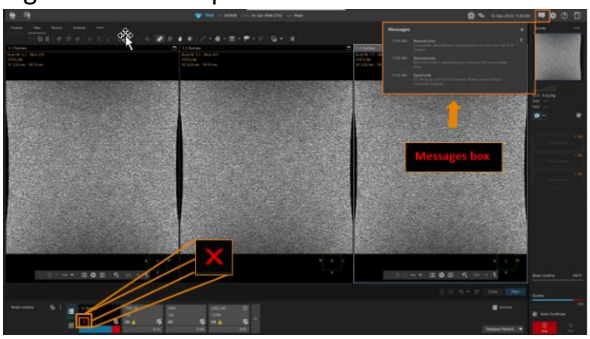
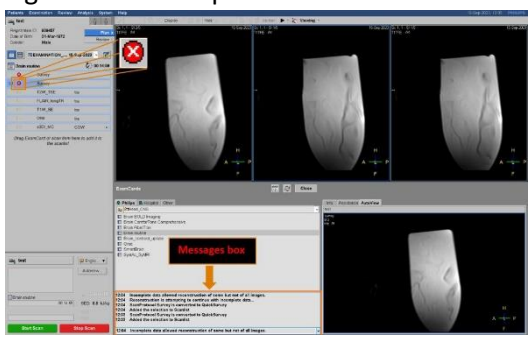


Figure 6. UI example SW Version R5.



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- 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:*
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>
> *Philips MRI systems have an Emergency Table Stop button in case there is an emergency during tabletop movement.*

4.6. Post Appendix A, *Actions for Customer / User: Post with System,* near the affected MR unit(s) for ease of reference.

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