

Field Safety Notice

MR systems with SW versions R5 & R11
Potential scan abort during an examination

August 2026

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 become aware of a potential safety issue affecting Philips Magnetic Resonance (MR) imaging systems operating with software versions R5 & R11. This Field Safety Notice is to inform you about:

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

Philips has become aware of a software issue which may terminate an examination during the image reconstruction process. If the scan parameters are manually adjusted such that reconstruction requirements exceed the available system memory, the system will freeze, preventing image generation and requiring a system re-start.

This issue can occur when the 3D Vane scan protocol is customized with a reconstruction matrix greater than 480 and/or more than 167 slices. Due to a system error in memory budgeting, the system may allow a scan to start even when there is not enough available memory to complete it.

As of June 2026, Philips has received 26 complaints potentially associated with this issue. There have been no reports of patient injury/harm.

2. Hazard/harm associated with the issue

If a scan is aborted and the examination needs to be repeated, then the patient may require additional sedation, medication, and/or contrast agent administration. There is a potential these additional interventions could result in illness or impairment.

3. Affected products and how to identify them

Your Philips MR system(s) is impacted if you have a model listed in Table 1 operating with software versions R5 & R11.

Table 1. Impacted MR systems

Product Name	Model Number (REF)
Achieva 1.5T	781196
Achieva 1.5T	781296
Achieva 1.5T	781343
Achieva 1.5T Conversion	781283
Achieva 1.5T Conversion	781346
Achieva 1.5T Initial system	781178

Achieva 3.0T	781177
Achieva 3.0T	781277
Achieva 3.0T	781278
Achieva 3.0T	781344
Achieva 3.0T	781345
Achieva XR	781153
Achieva XR	781253
Evolution upgrade 1.5T	782116
Evolution upgrade 1.5T	782148
Evolution upgrade 3.0T	782117
Evolution upgrade 3.0T	782143
Ingenia 1.5T	781315
Ingenia 1.5T	781341
Ingenia 1.5T	781396
Ingenia 1.5T	782101
Ingenia 1.5T	782115
Ingenia 1.5T	782140
Ingenia 1.5T CX	781261
Ingenia 1.5T CX	781262
Ingenia 1.5T S	781347
Ingenia 3.0T	781342
Ingenia 3.0T	781377
Ingenia 3.0T	782103
Ingenia 3.0T CX	781271
Ingenia 3.0T CX	782105
Ingenia Ambition S	781359
Ingenia Ambition S	782108
Ingenia Ambition S	782133
Ingenia Ambition S	782139
Ingenia Ambition X	781356
Ingenia Ambition X	782109
Ingenia Ambition X	782138
Ingenia Elition S	781357
Ingenia Elition S	782106
Ingenia Elition S	782137
Ingenia Elition S	782150
Ingenia Elition X	781358
Ingenia Elition X	782107
Ingenia Elition X	782119
Ingenia Elition X	782136
Ingenia Elition X	782151
Ingenia Elition X	782158
Intera 1.5T	781195
Intera 1.5T	781295
Intera 1.5T Achieva IT Nova	781175
Intera 1.5T Achieva Nova	781172
Intera 1.5T Achieva Nova-Dual	781173

Intera 1.5T Omni/Stellar	781104
Intera Achieva 1.5T Pulsar	781171
MR 5300	782110
MR 5300	782135
MR 5300	782152
MR 7700	782120
MR 7700	782153
SmartPath to dStream for 1.5T	781260
SmartPath to dStream for 1.5T	782112
SmartPath to dStream for 1.5T	782146
SmartPath to dStream for 3.0T	782145
SmartPath to dStream for XR and 3.0T	781270
SmartPath to dStream for XR and 3.0T	782113
SmartPath to dStream for XR and 3.0T	782129
SmartPath to Ingenia Elition X	782118
SmartPath to Ingenia Elition X	782144
Upgrade to MR 7700	782130

To identify the software version of your product **(R5)**:

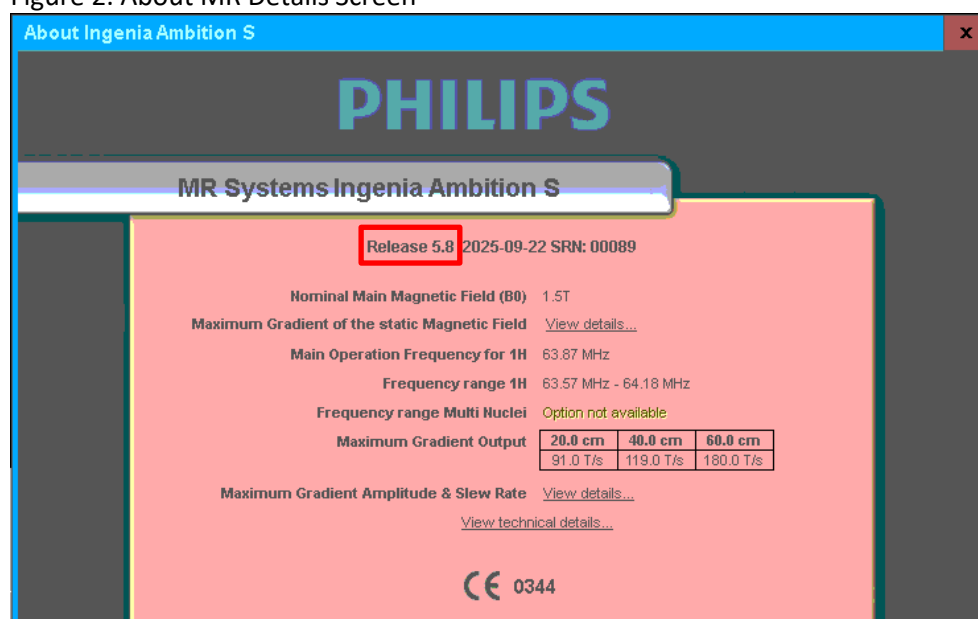
1. Navigate to the main screen of the operator(s) console and select the question mark symbol on the Patient Toolbar. Select the About option from the drop-down list (see Figure 1).

Figure 1. Initial screen on console



2. Verify the software version in the pop-up window (See Figure 2).

Figure 2. About MR Details Screen



To identify the software version of your product (**R11**):

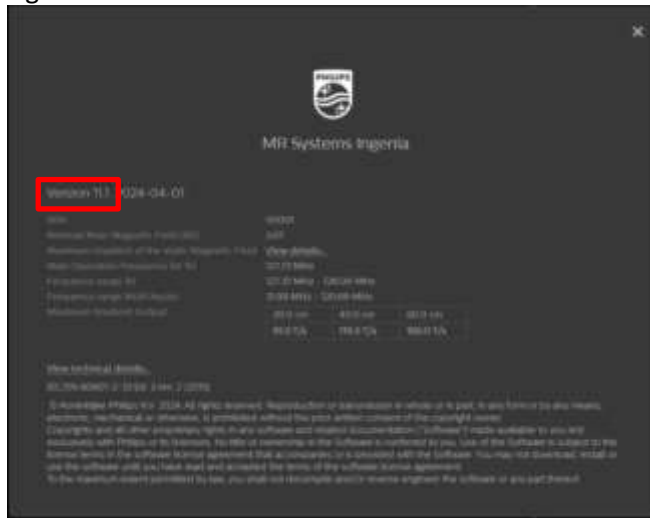
1. Navigate to the main screen of the operator(s) console and select the question mark symbol on the Patient Toolbar. Select the About - MR option from the drop-down list (see Figure 3).

Figure 3. Initial screen on console



2. Verify the software version in the pop-up window. The software version is listed next to the word Version (See Figure 4).

Figure 4. About MR Details Screen



Intended use:

Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device. This MR system 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. Image appearance is determined by many different physical properties of the tissue and the anatomy, the MR scan technique applied, and presence of contrast agents.

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

- To prevent this issue from occurring,
 - Use the standard 3D Vane scan protocol from the Philips Examcard Database, or
 - For custom 3D Vane scan protocols, use a maximum of 480 for the reconstruction matrix and use a maximum of 167 for the number of slices.
- You may continue to use affected systems in accordance with their intended use.
- Circulate this notice to all users of this device so that they are aware of the issues and associated hazard/harm.
- Please retain this Field Safety Notice with your system(s) until the software upgrade is installed; ensure the notice is in a place likely to be seen/viewed.

- Please complete and return the attached response form to Philips MR promptly and no later than 30 days from receipt of this letter via email to: **<Market to insert local contact information>**. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

5. Actions planned by Philips to correct the problem

A Philips representative will contact you to schedule time for a Field Service Engineer (FSE) to install a software upgrade to resolve the issue (reference 2026-PD-MR-006).

If you need any further information or support concerning this issue, please contact your local Philips representative.

Sincerely,

<signature, name, title>

Field Safety Notice Response Form

Reference: MR systems with SW versions R5 & R11.- Potential scan abort during an examination

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 issues, and required actions to be taken.

Customer/Consignee/Facility Name: Triomed :Limited

Street Address: Prohealth Bldg Mdina Road Zebbug

City/State/ZIP/Country: ZBG9019 Malta

Customer Actions:

- Follow the instructions provided in Section 4 of the Field Safety Notice.

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 affected MR system(s).

Name of person completing this form:

Signature: *Digitally signed by*
Andrew Paris
2026-09-18 16:30:34 +0200

Printed Name: _____

Title: Director, MDRP

Telephone Number: +35623385313

Email Address: Andrew.paris@triomed.com.mt

Date (DD / MMM / YYYY): _____

Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt via email to: Philips.Recall@Philips.com