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Field Safety Notice

MR systems with SW version R11.1 and R12.1
Wrong stiffness values displayed with MR Elastography (MRE) in PACS

03-Dec-2025

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 through in-house testing of a potential safety issue affecting MR systems operating on software versions R11.1 to R12.1 (see Section 3) that could pose a risk for patients. 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 potential stiffness value errors when viewing exported MR Elastography (MRE) stiffness maps to viewer Picture Archiving and Communication System (PACS).

Figures 1 and 2 show the stiffness map of the human liver in the MRE viewer PACS (Figure 1) and on the MR Console viewer (Figure 2). In the screenshots, the MRE viewer PACS indicates around 2 kPa (Figure 1, wrong stiffness values), which can be associated with healthy tissue, while the general viewing environment in the MR Console viewer indicates almost 8 kPa (Figure 2, correct stiffness values), which can be an indicator of cirrhosis.

Figure 1: MRE stiffness map (lower right) in the MRE viewer PACS.

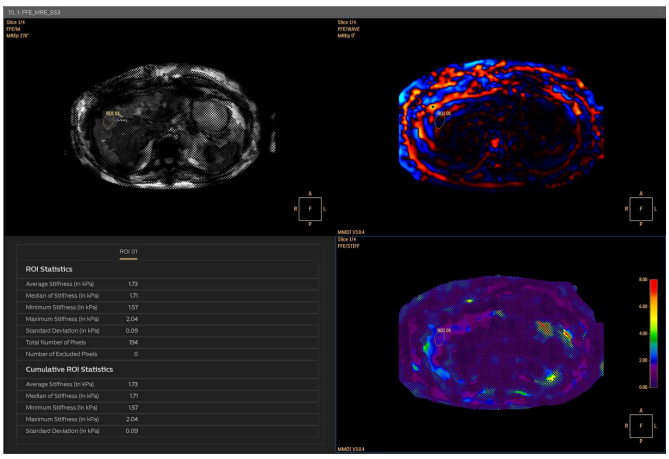
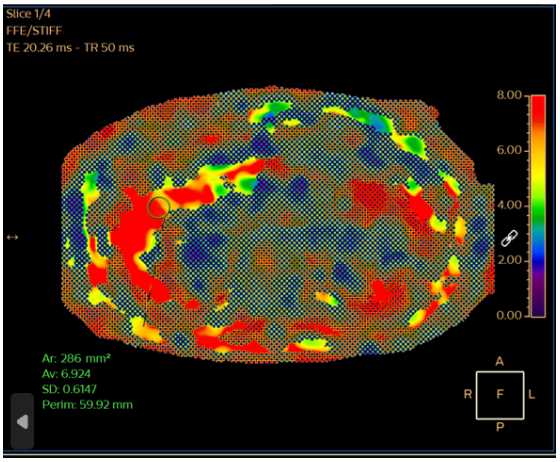


Figure 2: MRE stiffness map in the MR Console viewer



As of October 2025, Philips has received 5 complaints associated with this issue. There have been no reports of adverse events.

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2. Hazard/harm associated with the issue

There is a potential for misdiagnosis based on incorrect stiffness values displayed if the MRE stiffness maps are exported and viewed in an MRE viewer PACS. Misdiagnosis may result in untreated conditions, further diagnostic imaging, or lead to a different treatment that might not be preferable.

3. Affected products and how to identify them

The impacted MR systems can be identified by the model (#), product code (REF), and software version.

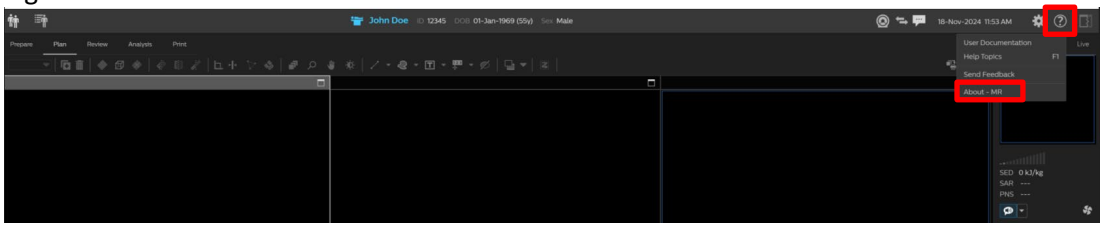
Table 1. Impacted MR systems

Model (#)	Product Code (REF)	UDI
Evolution Upgrade 1.5T	782148	00884838108714
Evolution Upgrade 3.0T	782143	00884838108660
Ingenia 1.5T	781341, 781396, 782115	00884838055322, 00884838009820, 00884838099722
Ingenia 3.0T	781342, 781377	00884838055339, 00884838009813
Ingenia 3.0T CX	781271	00884838068452
Ingenia Ambition S	782108	00884838098343
Ingenia Ambition X	781356, 782109, 782138	00884838090040, 00884838098350, 00884838108622
Ingenia Elition S	781357, 782106, 782137	00884838088108, 00884838098329, 00884838108615
Ingenia Elition X	781358, 782107, 782136	00884838088115, 00884838098336, 00884838108608
MR 7700	782120, 782153	00884838104112, 00884838112858
Upgrade to MR 7700	782130	00884838104402
SmartPath to dStream for 3.0T	782145	00884838108684
SmartPath to dStream for XR and 3.0T	781270	00884838095083

Your Philips MR system(s) is impacted if you have a model listed in Table 1 running on software version R11.1 and R12.1. To identify the model and software version of your product:

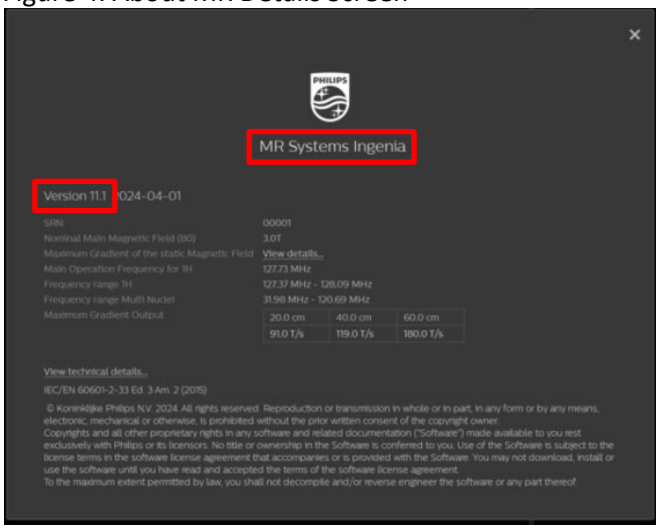
1. Navigate to the main screen of the operator(s) console and select the question mark symbol on the Patient Toolbar. Select the About - MR option from the drop-down list (see Figure 3).

Figure 3. Initial screen on console



2. Verify the model and the software version in the pop-up window (See Figure 4). The model is in the title block, after the words **MR Systems**. The software version is listed below this section, next to the word **Version**.

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

- You may continue to use your system(s) in accordance with the intended use.
    - To avoid the potential issue of MRE stiffness value errors, view stiffness maps in general viewing environment (MR Console viewer) and not MRE viewer PACS.
- 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: **FCO.Nordic@philips.com**. Completing this

form confirms receipt of the Field Safety Notice, understanding of the issues, and required actions to be taken.

5. Actions planned by Philips MR 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 issues beginning in January 2026 (reference FCO78100585, FCO78100620).

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

Sincerely,

Akivia Rivera Gracia
Head of MR Quality

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Field Safety Notice Response Form

Reference: MR systems with SW version R11.1 and R12.1 – Wrong Stiffness Values Displayed with MRE in PACS

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:

- 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: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

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: **FCO.Nordic@philips.com**