PHILIPS

Updated Field Safety Notice

Philips MR systems with MR Elastography (MRE)
Potential for inaccurate (lower) liver stiffness measurements

May 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,

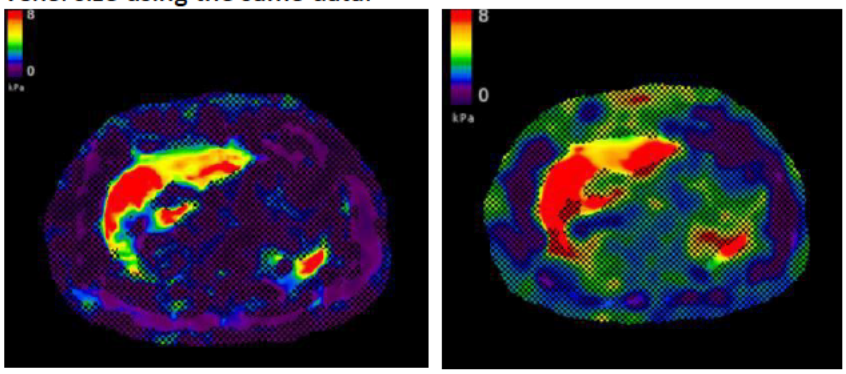
The April 2026 Field Safety Notice has been updated to include additional information. Please refer to the newly added Sections 6 and 7 below.

Philips has become aware of a potential safety issue affecting MRE systems in combination with MR systems (see Section 3) that could impact diagnostic accuracy. This Field Safety Notice is intended to inform you about:

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

Philips has become aware through the MRE software system developer Resoundant about an issue affecting MRE stiffness measurements when a specific range of image reconstruction parameters is used in combination with Resoundant's algorithm. Specifically, the reconstruction voxel size settings in the default MRE scan protocol are too small, which can potentially lead to inaccurate liver stiffness measurements (lower values). See Figure 1.

Figure 1. An example of what may occur. The left Elastogram was obtained with 1.17mm reconstruction voxel size from default MRE protocol and shows stiffness measurements in the liver are biased toward lower values. The right Elastogram was obtained with 1.65mm reconstruction voxel size using the same data.



As of March 2026, there have been 6 complaints associated with this issue. There have been no reports of injury or adverse events.

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2. **Hazard/harm associated with the issue**
   If the liver stiffness measurement is underestimated, there is a potential for misdiagnosis of the fibrosis stage. This could then result in a delay of appropriate management and/or increased risk of patient harm due to unsuitable treatment.

3. **Affected products and how to identify them**

   Identification of Impacted Systems:
   Your Philips MR system(s) is impacted if you have a model listed in Table 1 with MR Elastography (MRE).

   Table 1. Impacted MR systems

Model Name	Model Number (REF)
Achieva 1.5T	781178, 781196, 781296
Achieva 3.0T	781278
Evolution Upgrade 1.5T	782116, 782148, 782166
Evolution Upgrade 3.0T	782143, 782162
Ingenia 1.5T	781315, 781341, 781396, 782115
Ingenia 1.5T CX	781262
Ingenia 3.0T	781342, 781377, 782103
Ingenia 3.0T CX	781271, 782105
Ingenia Ambition S	781359, 782108, 782139
Ingenia Ambition X	781356, 782109, 782138, 782160
Ingenia Elition S	781357, 782106, 782137
Ingenia Elition X	781358, 782107, 782136
MR 7700	782120, 782153
SmartPath to dStream for 1.5T	781260, 782112
SmartPath to dStream for 3.0T	782145
SmartPath to dStream for XR and 3.0T	781270, 782113
SmartPath to Ingenia Elition X	782118, 782144, 782163
Upgrade to MR 7700	782130

   To identify if your system has MR Elastography (MRE), navigate to the **Philips\Abdomen\Liver\Specials** folder within the Philips protocol database and verify if your system contains the protocols shown in Figure 2.

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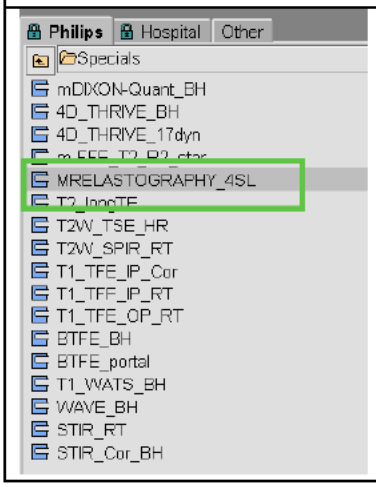
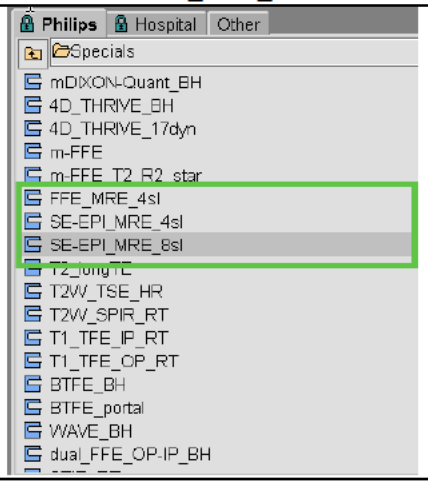
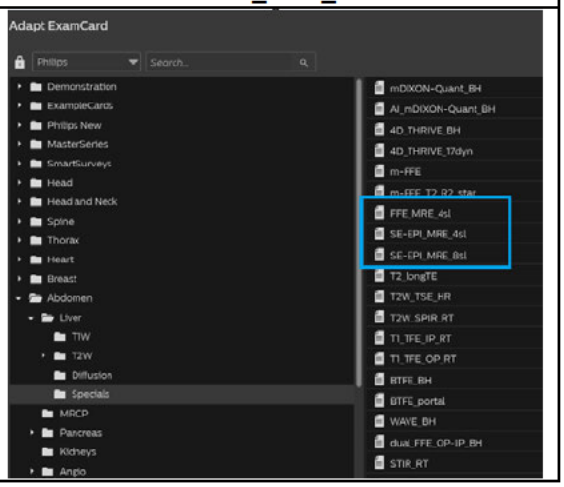
Figure 2. Default MRE scan protocols

A) SW < R5.7	B) SW R5.7	C) For SW R5.8 – R12.3
MRELASTOGRAPHY_4SL	FFE_MRE_4sl SE-EPI_MRE_4sl SE-EPI_MRE_8sl	FFE_MRE_4sl SE-EPI_MRE_4sl SE-EPI_MRE_8sl
		

Intended Use of MR System:
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.

Functional Description of MR Elastography:
MR Elastography (MRE) is a software and hardware option intended for use on Philips MRI Systems for producing images representing tissue stiffness of the abdominal area, such as liver and muscle. MRE allows for FFE and/or SE-EPI acquisition, depending on the configuration. MRE relies on a phase-sensitive gradient echo or spin echo acquisition, acquired at multiple time points for each planned slice. This acquisition is performed while an external device (Resoundant device) provides vibration at a predetermined frequency.

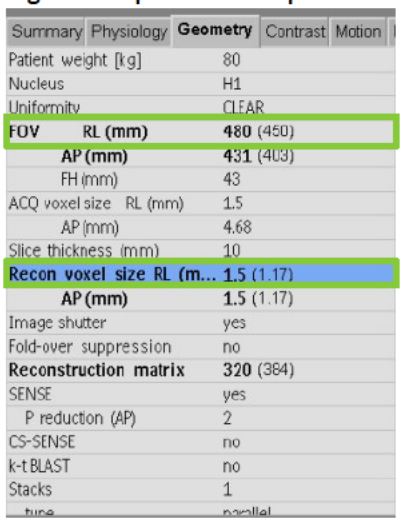
4. **Actions that should be taken by the customer / user** Follow guidelines for use as outlined in the IFU.
   - To manually update the scan protocol settings as described below. These steps will ensure that the MRE workflow only operates within Resoundant's acceptable performance through defined protocol parameters.

   A. MR systems on software R5

   1. Perform one of the following:
      - If you have an existing MRE ExamCard, add it to the ScanList
      - If you are creating a new MRE ExamCard:
        a. With an ExamCard in the ScanList, select **Add New Protocol item.**
        b. Navigate to the required MRE protocol from the **Philips\Abdomen\Liver\Specials** folder (refer to Figure 2 above)
        c. Add the MRE protocol to the ScanList.
   2. Double-click the MRE protocol to edit it.

3. On the Geometry tab make the following changes:
   - Change the **FOV RL** to 480 mm
   - Change the **Recon voxel size RL** to 1.5mm
   - Accept the changes

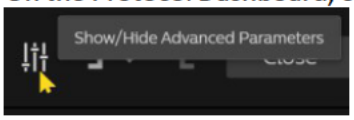
Figure 3. Updated MRE protocol settings in the Geometry tab



4. Right-click the ExamCard name and select Save ExamCard.

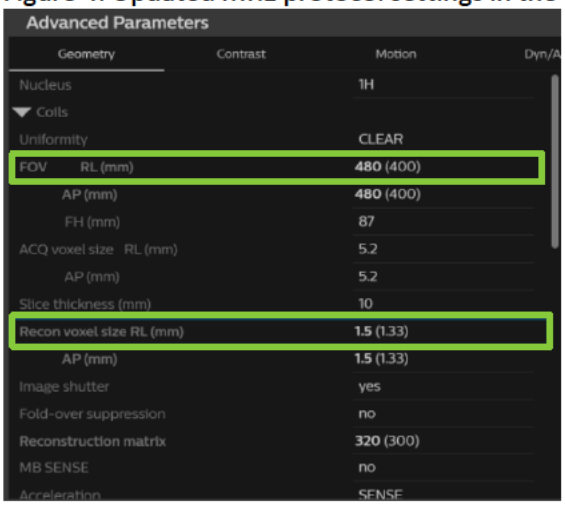
B. MR systems on software R11 and R12

1. Perform one of the following:
   - If you have an existing MRE ExamCard, add it to the Exam Overview
   - If you are creating a new MRE ExamCard:
     a. With an ExamCard in the Exam Overview, select **Add New Protocol item.**
     b. Navigate to the required MRE protocol from the **Philips\Abdomen\Liver\Specials** folder (refer to Figure 2 above)
     c. Add the MRE protocol to the Exam Overview.
2. Double-click the MRE protocol to edit it.
3. On the Protocol Dashboard, click the **Show/Hide Advanced Parameters** button.



4. On the Geometry tab make the following changes
   - Change the **FOV RL** to 480 mm
   - Change the **Recon voxel size RL** to 1.5mm
   - Accept the changes
   - NOTE: For the FFE_MRE_4sl protocol on Release 12 systems, it may be necessary to re-enter the Recon voxel size RL of 1.5mm if the system defaults to 1.48mm.

Figure 4. Updated MRE protocol settings in the Geometry tab



5. Save the ExamCard:
   - In the Exam Overview toolbar, next to the ExamCard name, click the **More** options icon
   - Click Save ExamCard.

- You may continue to use your system(s) in accordance with the 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.
- Please ensure this information reaches all staff and departments within your organization that might have interacted with the affected systems.
- Post this notice in areas where it can be read by users of the Philips MRI system in combination with MRE functionality.
- Report any Serious Incidents or quality concerns related to the use of MRE to Philips through the standard complaint-reporting process.

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 issue (reference 2026-PD-MR-003). The software upgrade is expected to be available by March 2027 (dependent on regulatory approval per country).

6. Actions required by Physicians

MRE is used to evaluate liver stiffness. According to instructions for use, MRE Stiffness images—when interpreted by a qualified physician—offer supplementary information that may support diagnosis. Established clinical guidelines recommend that MRE should not be the sole determinant

in patient treatment plans - it is intended as a second-line or confirmatory test. Decisions about reassessment actions should be made by the patient's care team. Because historical MRE results may be inaccurate, physicians who prescribed MRE scans for their patients using MRI systems should determine if those patients need their MRE scans reprocessed or rescanned. If reprocessing is preferred, it must be carried out by the radiology department, as the region of interest for measuring stiffness values must be selected by the treating physician.

7. **Considerations for reassessment:**

   If reprocessing of prior examinations is considered: this can only be performed once the corrective software solution has been deployed on the system.

   If a re-scan is considered: the scan protocol must be adjusted in accordance with the parameters specified in Section 4 of this field safety notice.

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

Personal information

Confidential business information

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Updated Field Safety Notice Response Form

Reference: Philips MR systems with MR Elastography (MRE) - Potential for inaccurate (lower) liver stiffness measurements

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: _____

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: *<Market to insert local contact information>*