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Field Safety Notice

MR systems with SW versions R11.1 and R12.1
MobiView cross reference alignment errors

<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 become aware of a potential safety issue affecting MR systems operating on software versions R11.1 and 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 alignment errors in the cross reference line functionality when reviewing images generated by the MobiView application.

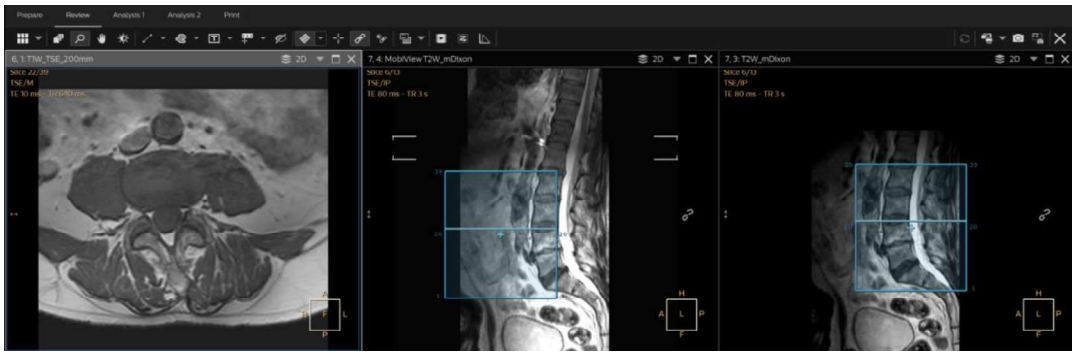
A. The cross reference line and/or box may be shown at an incorrect location when displayed on a MobiView generated image (see examples in Figure 1 and 2).

The alignment errors may occur only if both of the following conditions are met:

- Multi-station scans that require stitching 3 or more station images, and
- Scan protocol is used where stations have different voxel size or field of view (i.e. voxel size or field of view is customized based on anatomy per station).

Figure 1. Cross reference line of the axial image (left) is at the incorrect location on the MobiView generated image (middle). The correct location is shown on the non-fused sagittal source image (right).

Figure 2. Cross reference box of the axial image (left) is at the incorrect location on the MobiView generated image (middle). The slice position in the box is correct, while the box off-center is incorrect. The correct location is shown on the non-fused sagittal source image (right).



B. The cross reference box of a MobiView generated image may be shown at an incorrect location when mirrored on to another image (see examples in Figures 3 and 4), if:
   - the MobiView images are acquired with reversed slice scan order (i.e. image display settings are customized), or
   - displaying the cross reference box of a MobiView generated merged series (axial stations), or
   - displaying the cross reference box of multi-planar reformats generated from multi-stack data.

Figure 3. Cross reference box of a MobiView generated image with reversed slice scan order (left) is mirrored on another image (middle). The box position is correct, while the slice position and slice numbering are incorrect. The correct location is shown for a MobiView generated image with default slice scan order (right).

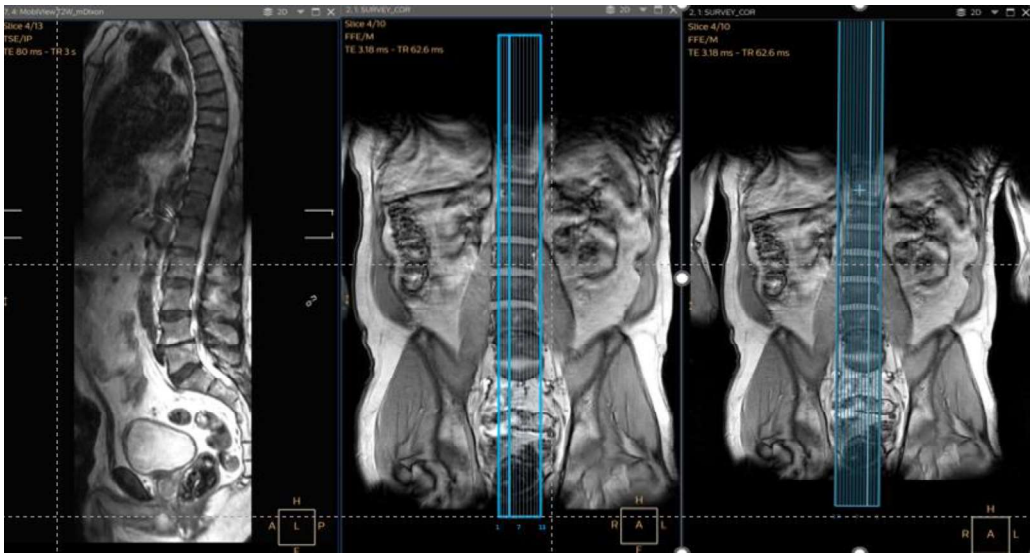
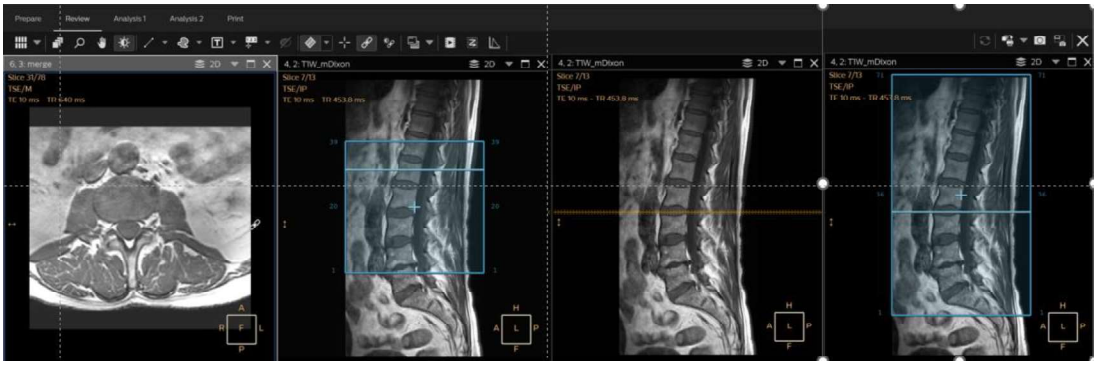


Figure 4. Cross-reference box of a MobiView generated axial merged series (left) displays with incorrect size and location on another scan (mid-left). The cross-reference line of the same MobiView generated axial merged series is at the correct location (mid-right). The correct box size and location is shown for a Mobiview generated axial fused series (right).



Philips has identified additional software defects that have no associated safety impact but may impact clinical workflow. Refer to Appendix A for details.

As of April 2025, Philips has received no reports of adverse events associated with these issues.

2. Hazard/harm associated with the issue

There is a potential for misdiagnosis if the cross reference information from MobiView generated images is shown at an incorrect location.

3. Affected products and how to identify them

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

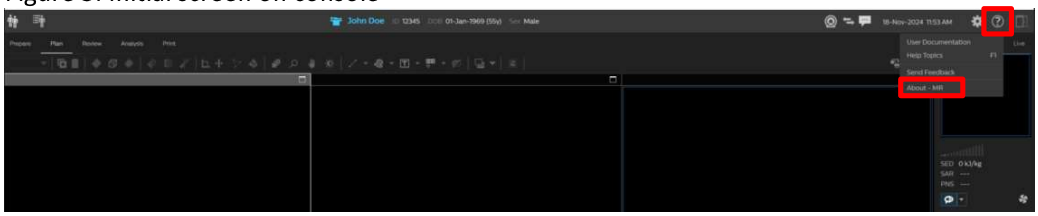
Table 1. Impacted MR systems

Model (#)	Product Code (REF)
Evolution Upgrade 1.5T	782116, 782148
Evolution Upgrade 3.0T	782117, 782143
Ingenia 1.5T	781315, 781341, 781396, 782101, 782115, 782140
Ingenia 1.5T CX	781262
Ingenia 1.5T S	781347
Ingenia 3.0T	781342, 781377, 782103
Ingenia 3.0T CX	781271
Ingenia Ambition S	781359, 782108, 782139
Ingenia Ambition X	781356, 782109, 782138
Ingenia Elition S	781357, 782106, 782137
Ingenia Elition X	781358, 782107, 782136
MR 5300	782110, 782152
MR 7700	782120, 782153
SmartPath to dStream for 1.5T	781260, 782112, 782146
SmartPath to dStream for 3.0T	782145
SmartPath to dStream for XR and 3.0T	781270, 782113
SmartPath to Ingenia Elition X	782118, 782144
Upgrade to MR 7700	782130

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

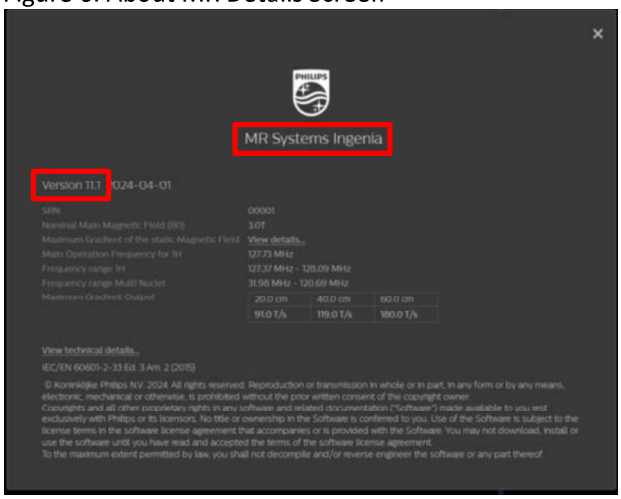
1. Navigate to the main screen of the operator(s) console and select the question mark symbol on the Patient Toolbar. Select the About - MR option from the drop-down list (see Figure 5).

Figure 5. Initial screen on console



2. Verify the model and the software version in the pop-up window (See Figure 6). 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 6. 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.

  A. To avoid the potential issue of an incorrect cross reference line in MobiView generated images, use the same voxel size and field of view across all station scans.

  B. Do not use cross reference line functionality in box mode, all slices mode, or 3D mode. Use the cross reference line functionality in single slice mode.

- 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 issues, and required actions to be taken.

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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 (reference FCO78100566, FCO78100584, FCO78100585, FCO78100620, FCO78100621).

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

Sincerely,

Electronically signed by:
Akivia Rivera G
Reason: "I Approve"
Date: Apr 28, 2025 13:46 EDT

Akivia Rivera Gracia
Head of MR Quality

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Field Safety Notice Response Form

Reference: MR systems with SW versions R11.1 and R12.1 – MobiView cross reference alignment errors

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>*.

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Appendix A – Additional Software Solutions

Additional Software Solutions

Subtraction

Two solutions are implemented for reported differences in scaling between dynamics in subtracted dynamic images:

- Propagation of correct scaling for windowing to all dynamics during series generation.
- When subtracting a scan from a different dynamic scan, the same normalization will be automatically applied between all dynamics and the reference scan.

ADC correction

A solution is implemented for a reported issue that ADC correction was not applied for all exported ADC images. This solution ensures that ADC correction is always applied when enabled in export.

mDIXON

A solution is implemented for reported water-fat swap artifacts in dynamic mDIXON dynamic images, most notably in patients with breast implants. This occurred due to an error in how the B0 map was computed for scans with > 1 dynamic.

General software improvements

- A solution is implemented to minimize the occurrence of an intermittent scan application freeze, which could only be resolved by restarting the application.
- A solution is implemented for an exception error that caused the RIS list to be empty, and scheduled patients were not visible after the upgrade to R12.1.1.