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IMPORTANT PRODUCT NOTICE

January 17, 2025

RE: Image orientation incorrect (patient hands), nurse call system pinch ball may not function, and other software issues affecting Philips MR systems with SW versions R11.1 and R12.1

Dear Customer,

Philips has identified multiple issues affecting MR systems with SW versions R11.1 and R12.1 that could affect the performance of the equipment. This Important Product Notice is intended to inform you about:

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

   Issue 1: Image orientation incorrect (patient hands)
   Philips has identified that MRI images may display an incorrect orientation, where the patient's hands are reversed showing the left hand as the right and the right hand as the left. This issue may occur if both of the following conditions are met:
   - The patient is head-first (head facing the bore of the MRI scanner) in the superman-prone or superman-supine position with both hands raised over their head and placed inside a coil.
   - The exam is set up for prone position (laterality set to 'both'; anatomic region set to 'hand (arm)').

   Issue 2: Nurse call system pinch ball may not function
   Philips has identified that the nurse call pinch ball may not function as intended, which is to alert the operator in cases of patient anxiety or discomfort. Pressing the nurse call pinch ball should activate a buzzer that can be heard as long as the ball is squeezed. When the pinch ball is pressed more than once within 4 seconds or for more than 1.5 seconds, a flashing yellow light should be activated in the control room to draw the operator's attention.

   Philips has identified additional software defects that have no associated safety impact but may impact clinical workflow. Refer to the Release Notes provided in Appendix A for details on the additional software defects.

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

2. **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

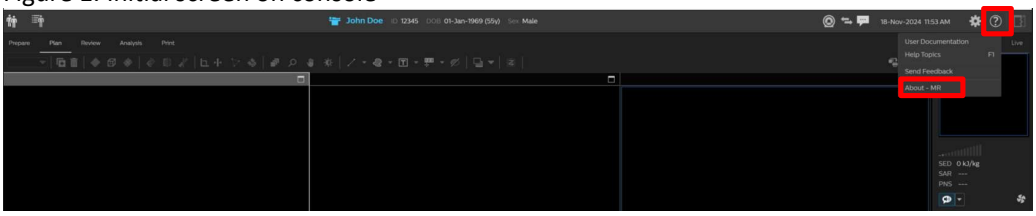
Model (#)	Product Code (REF)
Evolution Upgrade 1.5T	782116, 782148
Evolution Upgrade 3.0T	782117, 782143
Ingenia 1.5T	781315, 781341, 781396, 782101, 782115, 782140
Ingenia 1.5T CX	781262
Ingenia 1.5T S	781347
Ingenia 3.0T	781342, 781377, 782103

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:

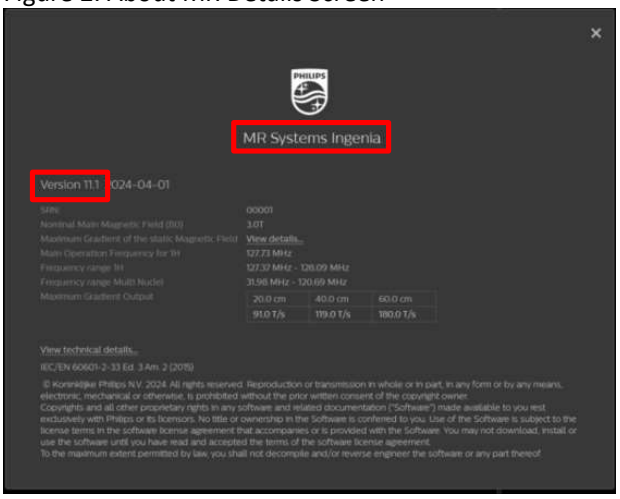
1. Navigate to the main screen of the operator(s) console and select the question mark symbol on the Patient Toolbar. Select the About - MR option from the drop-down list (see Figure 1).

   Figure 1. Initial screen on console



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

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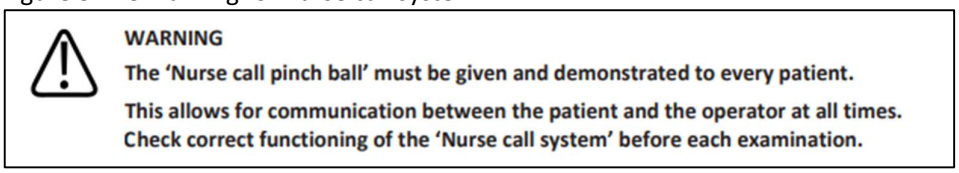
3. **The actions that you as a customer can take to minimize the effect of the problem**

- You may continue to use your system(s) in accordance with the intended use.
- **Issue 1:** To avoid the potential issue of incorrect orientation, set laterality to 'unpaired' or perform an exam where only a single hand is scanned with laterality set to 'left' or 'right'.
- **Issue 2:** As indicated in the Instructions for Use, verify the 'nurse call system' is functioning correctly before each examination.

  Figure 3. IFU warning for nurse call system

  If it is identified that the 'nurse call system' is not functioning properly:
  - Please ensure a program is in place for appropriate routine patient observation.
  - Please contact Philips service.
- Circulate this notice to all users of this device so that they are aware of the issues and software upgrades.
- Please retain this Important Product 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 upon receipt and no later than 30 days from receipt via email to: philips.recall@philips.com. Completing this form confirms receipt of the Important Product Notice, understanding of the issue, and required actions to be taken.

4. **The actions planned by Philips to correct the problem**

Philips will contact you to schedule time for a Field Service Engineer (FSE) to install a software upgrade to resolve the software issues.

- For the issue of nurse call system pinch ball may not function, a software guidance (pop-up message) is being implemented to remind the operator to test the nurse call pinch ball before every examination, as indicated in the IFU.

5. **Additional Information and Support**

If you need any further information or support concerning this issue, please contact your local Philips representative (reference FCO78100566, FCO78100604, and FCO78100585).

Sincerely,

Akivia Rivera Gracia
Head of MR Quality

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IMPORTANT PRODUCT NOTICE RESPONSE FORM

Reference: Image orientation incorrect (patient hands), nurse call system pinch ball may not function, and other software issues affecting Philips MR systems with SW versions R11.1 and R12.1 (Reference FCO78100566, FCO78100604, and FCO78100585).

Instructions: Please complete and return this form to Philips promptly upon receipt and no later than 30 days from receipt. Completing this form confirms receipt of the Important Product 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 3 of the Important Product Notice.
- Circulate this notice to all users of this device so that they are aware of the issues and software upgrades.

We acknowledge receipt and understanding of the accompanying Important Product Notice and confirm that the information from this notification 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/MM/YYYY):_____

Please complete and return the attached response form to Philips MR via email to: philips.recall@philips.com.

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Appendix A – R12.1.1 Release Notes January 2025

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Introduction

This document the high-level content for Software release R12.1.1. The document describes the solutions and provides an overview of the customer complaints and issues that are addressed.

Release Identification

Release number: Release 12.1.1

Solutions in R12.1.1

- SW-solutions in MobiView
- SW-solutions in Subtraction
- Solutions for multiple customer issues in MR Workspace (R10, R11 and R12.1)
- IoT on Cloud
- MRTC multi-client support
- Compatibility check of Profound applications (Sonalleve & Tulsa Pro) using MRTC
- Microsoft security patches up to January ‘24
- Software support for the smoke detector on all system configurations

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SW-solutions in MobiView

1. Improvement to the automatic Windowing algorithm by applying normalization between scans at different stations, based on pixel values from the overlap region between stations.
    - Normalization is not applied for quantitative data (e.g. ADC) to preserve the ROI values after fuse. Manual windowing is not allowed on quantitative data.
2. Allow stitch (fuse/merge) for more series types such as single-slice, different image types, scans without geo-link.
3. UI guidance in PlanScan when scans are not geometrically aligned:
    - Information icon at the ScanAlign button in the PlanScan toolbar.
    - Informational text message in the Message Center.

SW-solutions in MR-Subtraction

1. Normalization of pixel values when subtracting different scans to ensure correct scaling in the subtracted images.
    a. The normalization factor is automatically calculated. Normalization can be switched off based on user preference.
2. Remove restriction on image types in the subtraction package: allow all operations in e.g. image types, diffusion values, echoes, ASL
3. For multi-dimensional data, allow selection of primary and secondary dimensions for the selected operation.
    a. Two dimensions per imaging slice/volume are supported.

Solutions for (customer) issues in MR Workspace

This section provides a short description of the solutions implemented to the User Interface and to user workflow.

- Echo accumulation:
    - Extended functionality to allow accumulation of diffusion b-values.
- MR-viewer 3D and slab application:
    - Re-introduced the ‘set center point’-functionality to the toolbar of the application to define the center of rotation for a radial batch.
    - Solution is implemented for a reported issue in presets: it is now allowed to use the same name for a preset in 3D and slab.
    - Rotate preview is possible while pressing the right-mouse button.
    - Scroll in Preview to show the exact image position of the slices as defined for the batch.
    - Allow generation of single-image batch.
- Gradient Reversal Fat suppression:
    - Can now be enabled in combination with SPIR/SPAIR also for non-diffusion sequences to improve fat suppression.

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- ExamCards:
  - Delete function implemented for non-used geometry names in the Exam Overview.
  - Laterality for newly added scans will automatically be taken over from the previous scans in Exam Overview.
- Message center:
  - The number of info messages on screen is reduced. Instead, these are stored in the Message center.
  - An icon indicates the number of unread messages in the Message center.
- Patient directory:
  - Additional status columns are added to show status for Print, Export to folder and MPPS.
- Planscan:
  - The functionality of 'Center' and 'Ortho' buttons in the PlanScan toolbar is improved.
  - A reported issue that scan angulation was no longer possible after planning a spectroscopy scan is resolved.
- Review:
  - Survey scans are excluded from AutoLoad in the Review tab during the examination.
    - 'Survey' is defined as scan without geo name and with three orthogonal stacks.
  - SmartSurvey Patient Aligned MPRs are also excluded from AutoLoad, to prevent a reported issue that vertebrae labeling in SmartSpine is not visible in Review.
  - 'Close all' button is implemented at the top right corner of the Review toolbar to close all opened viewers at once.
  - XY-line functionality is re-implemented in the Measurements-functionality on the toolbar.
- Screen capture:
  - Functionality to capture the entire screen is re-introduced. It can be enabled under System settings. The function is password-protected and requires user-confirmation to secure proper protection of privacy. The function cannot be used on the Patient Directory or Patient Dashboard.
  - Viewport selection is implemented under Advanced Screen capture to support capture of views with reference lines.
- SpectroView:
  - A Compare mode is introduced to compare two spectroscopy scans within one analysis view.