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Field Safety Notice

Magnetic Resonance (MR) imaging systems with Diffusion Tensor Imaging (DTI)
Incorrect data in Enhanced MR DICOM Export

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.

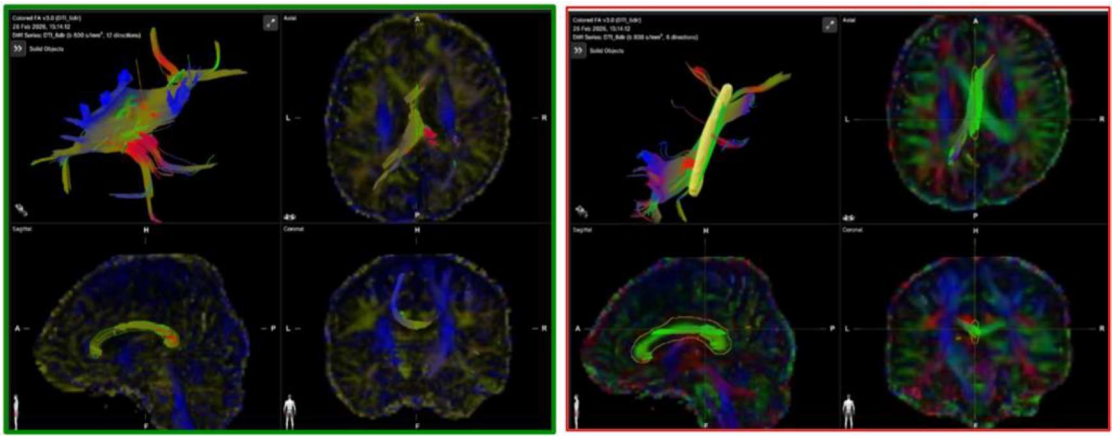
Dear Customer,

Philips has become aware of a potential safety issue affecting MR systems (see Section 3) with Diffusion Tensor Imaging (DTI) 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**

   When exporting diffusion tensor imaging (DTI) scans from a Philips MR system using the Enhanced MR DICOM format, the exports contain incorrect data (diffusion directions). If the Enhanced MR DICOM export is used in conjunction with third-party software for tractography (e.g. for mapping nerve fiber pathways in the brain), the software will not be able to correctly process the DTI data for reconstruction (see Figure 1).

   Figure 1. Example of a correct reconstruction image (Left) and an incorrect reconstruction image (Right) resulting from processing an Enhanced MR DICOM export with incorrect data. The image on the right clearly exhibits abnormal fiber tracking.



   As of August 2026, there have been 2 complaints associated with this issue. There have been no reports of injury or adverse events.

2. **Hazard/harm associated with the issue**
   If an incorrect reconstruction image is used for treatment planning, it may lead to inadequate or inappropriate treatment. A surgical procedure planned with incorrect data could result in injury to

vital structures, causing a range of neurologic injuries and deficits. In the most severe case, this could result in patient death.

If the reconstruction error is detected, the user may choose to use another method for treatment planning, which could result in a delay to treatment.

3. Affected products and how to identify them

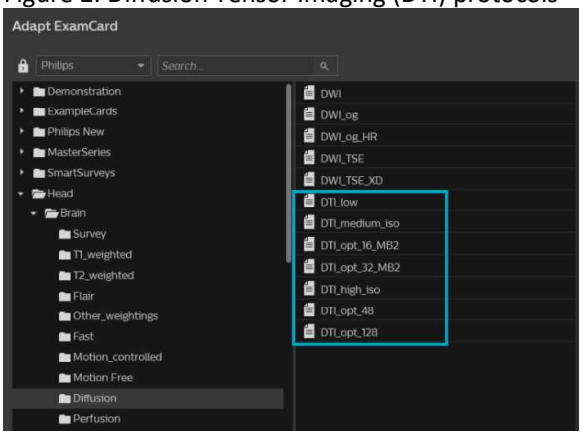
Identification of Impacted Systems:
Your Philips MR system is impacted if you have a model listed in Table 1 with Diffusion Tensor Imaging (DTI).

Table 1. Impacted MR systems

Model Name	Model Number (REF)	Software Versions
BlueSeal SE	782185	R11, R12, & R13
BlueSeal XE	782192	
Evolution upgrade 1.5T	782116, 782148, 782166, 782201	
Evolution upgrade 3.0T	782117, 782143, 782162	
Ingenia 1.5T	781315, 781341, 781396, 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, 782159, 782194	
Ingenia Ambition X	781356, 782109, 782138, 782160, 782195	
Ingenia Elition S	781357, 782106, 782137, 782157, 782180	
Ingenia Elition X	781358, 782107, 782119, 782136, 782151, 782158, 782181, 782198	
MR 5300	782110, 782152, 782156, 782196	
MR 7700	782120, 782153, 782155, 782179, 782199	
SmartPath to dStream for 1.5T	781260, 782112, 782146, 782165	
SmartPath to dStream for 3.0T	782145, 782164	
SmartPath to dStream for XR and 3.0T	781270, 782113, 782129	
SmartPath to Ingenia Elition X	782118, 782144, 782163	
SmartPath to MR 7700	782178, 782207	
Upgrade dStream	782127	
Upgrade to MR 7700	782130	

To identify if your system has Diffusion Tensor Imaging (DTI), navigate to the **Philips\Head\Brain\Diffusion** folder within the Philips protocol database and verify if your system contains the protocols shown in Figure 2.

Figure 2. Diffusion Tensor Imaging (DTI) protocols

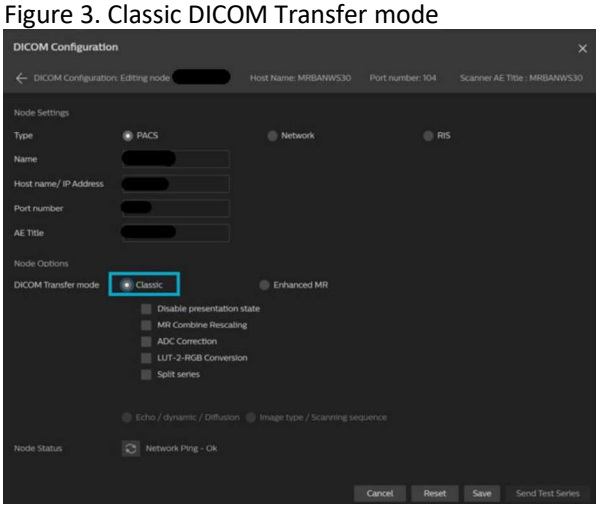


Intended Use of MR System:
Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device. This MR system enables trained physicians to obtain cross-sectional images, spectroscopic images and/or spectra of the internal structure of the head, body, or extremities, 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.

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

- To prevent the issue from occurring while Philips is developing the software solution, use the Classic DICOM transfer option for exporting DTI scans (see instructions below).
    - Open the **DICOM Configuration**, click **Settings and Tools (F10)**  in the Navigation Bar and then **DICOM Configuration**.
    - To unlock **DICOM Configuration**, enter the password. Then click **Unlock**.
        - The **DICOM Configuration** window opens. It displays the available **DICOM Nodes** with **Node Name** and **Status**.
    - To modify an existing DICOM node, select the DICOM node. Then click **Edit**  in the same line.
    - Set the DICOM Transfer mode to **Classic**
    - To save the current settings of the node and to test the connection, click **Save**.

Figure 3. Classic DICOM Transfer mode



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- 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 issue 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 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-014).

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

Sincerely,

Electronically signed by: Akivia Rivera Garcia
Reason: "I Approve"
Date: Aug 28, 2026 09:11:58 GMT+2

Akivia Rivera Garcia
Head of MR Quality

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Field Safety Notice Response Form

Reference: Magnetic Resonance (MR) imaging systems with Diffusion Tensor Imaging (DTI) - Incorrect data in Enhanced MR DICOM Export

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>*