

## Field Safety Notice

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

September 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.

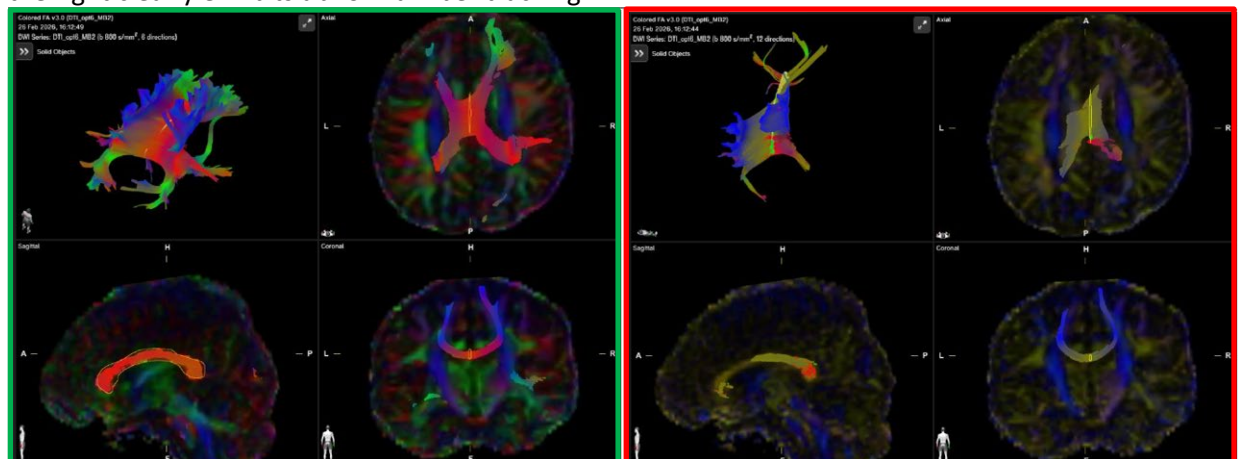
Dear Customer,

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:

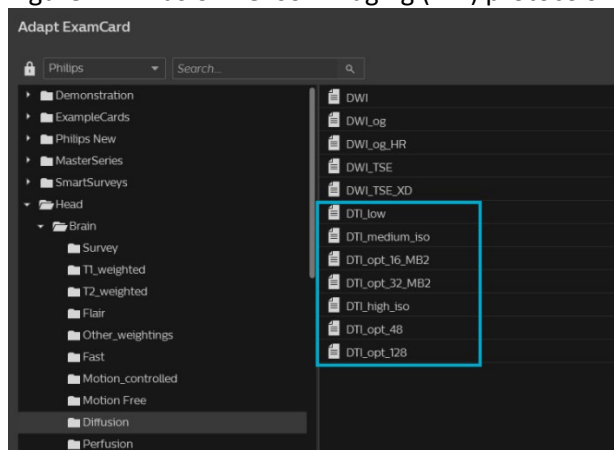
Your Philips MR system is impacted if you have a model listed in Table 1 with Diffusion Tensor Imaging (DTI).

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



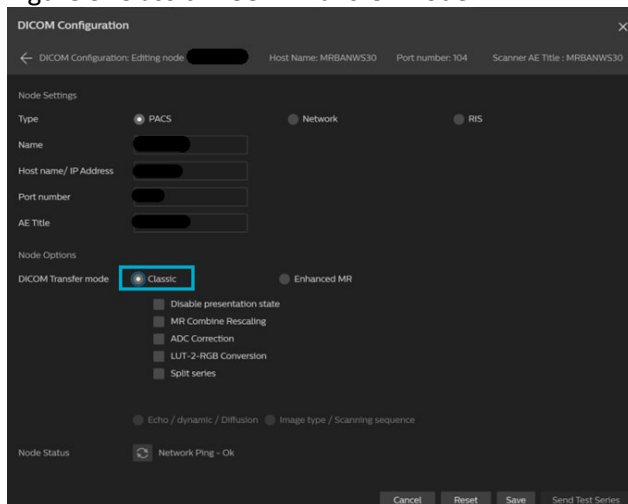
### Intended Use of MR System:

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



- 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: UKI\_Quality\_CR@philips.com. 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 at the Philips Customer Care Service Centre by:

Telephone: UKI: +448000260086  
NI: +448000260430  
ROI: +3531800832340

Email: UKFCO@philips.com

Sincerely,

Akivia Rivera Garcia  
Head of MR Quality

## 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/Postcode: \_\_\_\_\_

**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: **UKI\_Quality\_CR@philips.com**