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Update – Field Safety Notice

MR systems with 60cm wide bore

Quadrature Body Coil (QBC) seal adhesive failure may result in exposure of sharp edges

June 23, 2025

Dear Customer,

This notification is an update to Philips previous Field Safety Notice relating to *Quadrature Body Coil (QBC) seal adhesive failure may result in exposure of sharp edges.*

Philips has received reported complaints following QBC seal replacement via field correction FCO78100573. Based on investigation, Philips has determined to develop a new solution to address the issue (reference FCO78100633).

- Section 5 of the letter (actions planned by Philips to correct the problem) included the following: Philips will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site and replace your system's QBC Seal (reference FCO78100573).

Our records show that field correction FCO78100573 was implemented on your system. Therefore, we are sending you this notification to inform you that your system requires the new field correction FCO78100633. When FCO78100633 is released, Philips will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site for implementation of the correction.

Key Message: Until a Philips Field Service Engineer (FSE) visits your site to complete FCO78100633, please continue to follow the instructions in Section 4 of the Field Safety Notice (actions that should be taken by the customer / user in order to prevent risks for patients or users).

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need additional information or support concerning this issue, please contact your local Philips representative.

Sincerely,

Akivia Rivera Garcia
Head of MR Quality

Updated Field Safety Notice Response Form

Reference: MR Systems Quadrature Body Coil (QBC) seal failure – June 23, 2025 Update

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 update, understanding of the issue, 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 update and confirm that the information from this notification has been properly distributed to all users of the affected systems.

Name of person completing this form:

Signature:_____

Printed Name:_____

Title:_____

Telephone Number:_____

Email Address:_____

Date
(DD/MM/YYYY):_____

Please complete and return the 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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Updated Field Safety Notice

MR systems with 60cm wide bore

Quadrature Body Coil (QBC) seal adhesive failure may result in exposure of sharp edges

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.

<Date>

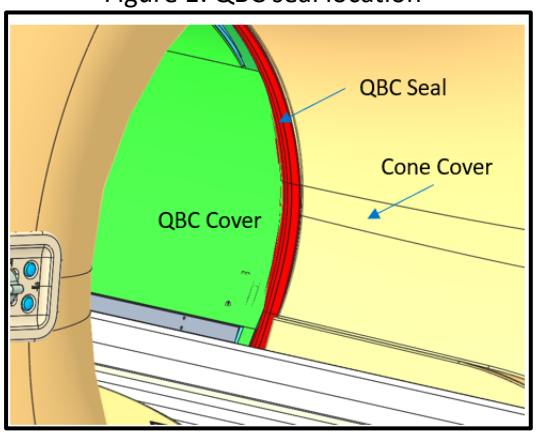
Dear Customer,

Philips has identified an issue with the MR systems identified in Section 3 of this letter, that could pose a risk for patients and users. This Field Safety Notice is to inform you about:

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

The Quadrature Body Coil (QBC) seal adhesive may fail creating sharp edges that may come in contact with patients. The QBC seal may become loose as the patient table travels in a horizontal motion in and out of the system bore. The QBC seal (Figure 1) is a rubber seal that is glued between the cone cover and QBC cover and functions to prevent sharp edges of the QBC cover from contacting patients during an examination.

Figure 1. QBC seal location



Philips has received five (5) reports of adverse events associated with this issue: one patient received a cut on the hand, one patient's hair became entangled resulting in a scalp injury, and three patients received lacerations to their arm.

2. Hazard/harm associated with the issue

If the QBC seal becomes loose during the scanning process, the risk to the patient may include one or more of the following: skin abrasions, bruises, lacerations, hair loss/entanglement, and tissue injury.

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3. Affected products and how to identify them

Identification of Impacted Systems:
MR systems with 60cm wide bore are affected. Refer to Tables 1 and 2 for the system model names and model numbers (REF). The model name and model number (REF) can be found on the system label.

Table 1. Impacted MR Systems

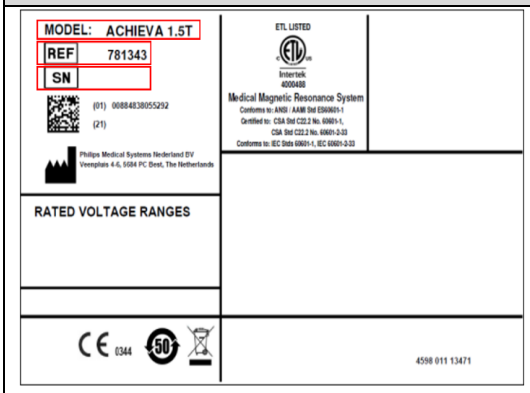
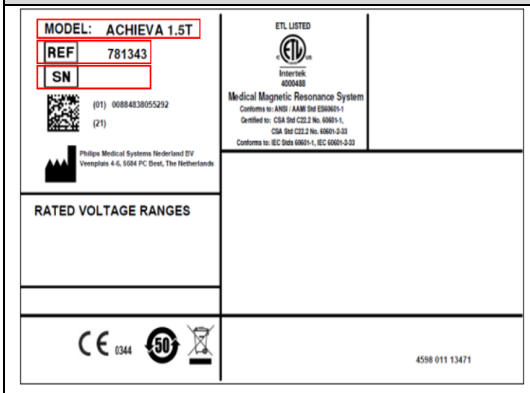
Sample System Label Example	Model	(REF) Numbers
	Achieva 1.5T	781196, 781343, 781296
	Achieva 1.5T Conversion	781346, 781283
	Achieva 1.5T Initial system	781178
	Achieva 3.0T	781277, 781177, 781278, 781344, 781345
	Achieva XR	781153, 781253
	Ingenia 1.5T CX	781262, 781261
	Ingenia 3.0T CX	781271, 782105
	Intera 1.5T Achieva Nova	781172
	Intera 1.5T Achieva Nova-Dual	781173
	Intera Achieva 1.5T Pulsar	781171
	SmartPath to dStream for 1.5T	781260, 782112
	SmartPath to dStream for XR and 3.0T	781270, 782113, 782129

Table 2. Additional impacted MR Systems

Sample System Label Example	Model	(REF) Numbers
	Enterprise 1.5T	781145
	Ingenia 1.5T	781341
	Ingenia 3.0T	781377
	Ingenia Ambition X	782109
	Intera 0.5T Standard	781101
	Intera 1.0T Omni/Stellar	781102
	Intera 1.0T Power/Pulsar	781103
	Intera 1.5T	781195, 781295
	Intera 1.5T Achieva Nova-Dual	781108
	Intera 1.5T Master/Nova	781106
	Intera 1.5T Omni/Stellar	781104
	Intera 1.5T Power/Pulsar	781105
	Intera 1.5T R11	781170
	Intera 3.0T Quasar Dual	781150
	Intera CV	781107
	SmartPath to dStream for 1.5T	782146
	SmartPath to dStream for 3.0T	782145

Intended Use:
Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device. This 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.

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4. **Actions that should be taken by the customer / user in order to prevent risks for patients or users**
   - As part of the preparation before a patient scan:
     1. Inspect the QBC seal for separation between the cone cover and QBC cover.
     2. If QBC seal is found detached or loose, **Stop-use immediately.**
     3. Contact your local Philips service representative.
   - If QBC seal becomes loose during a patient scan:
     1. **Immediately stop scanning** and carefully remove patient from the system.
     2. Contact your local Philips service representative.
   - Circulate this Field Safety Notice to all users of this device so that they are aware of the issue.
   - Please retain this letter with your system(s) until a solution is installed on your system; ensure the letter is in a place likely to be seen/viewed.
   - Please complete and return the attached response form to Philips promptly and no later than 30 days from receipt via email to: <Philips representative contact details to be completed by the Market/Business>. Completing this form confirms receipt of the Field Safety Notice, understanding of the issue, and required actions to be taken.

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

   Philips will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site and replace your system's QBC Seal (reference FCO78100573, FCO78100615).

Please be assured that maintaining a high level of safety and quality is our highest priority. If you need any further information or support concerning this issue, please contact your local Philips representative.

Sincerely,

Akivia Rivera Garcia
Head of MR Quality