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URGENT 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.

28-December-2023

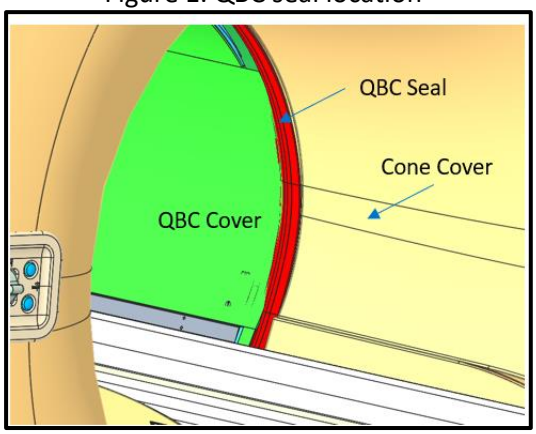
Dear Customer,

Philips has identified an issue with the MR systems identified in Appendix A of this letter, that could pose a risk for patients and users. This URGENT 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 three (3) 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 one patient received lacerations to the upper left arm.

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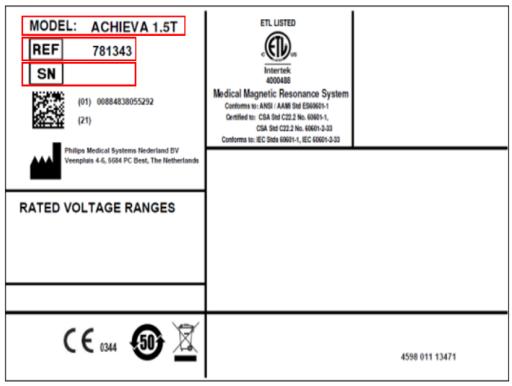
2. Hazard/harm associated with the issue

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.

3. Affected products and how to identify them

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

Figure 1: Impacted 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

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.

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 URGENT 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: **safetynoticeuki@philips.com**. Completing this form confirms receipt of the URGENT 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). Philips plans to start implementing corrections in Q3 2024.

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 at the Philips Customer Care Service Centre by:

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

Email: ukisfco@philips.com

Sincerely,

David Hanly
Quality Leader

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URGENT Field Safety Notice Response Form

Reference: MR Systems Quadrature Body Coil (QBC) seal failure (reference FCO78100573)

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 URGENT Field Safety Notice, 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 URGENT Field Safety Notice.

We acknowledge receipt and understanding of the accompanying URGENT Field Safety Notice 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 return the completed and signed reply form to **safetynoticeuki@philips.com**