Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Achieva 3.0T TX
Device Model	Achieva 3.0T TX
Manufacturer	Philips Medical Systems
Country of Origin	Netherlands
Reference	Attached
Reason of Alert	NHRA initiates this FSN due to potential adhesive failure in the Quadrature Body Coil (QBC) seal of Philips MR systems with 60 cm bores, which may result in exposure to sharp edges and cause patient injuries such as cuts, lacerations, or entanglement during scanning procedures.
Action should be taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative Mohammed fakhroo & Bros W.L.L. at Sandeep@fakhroo.com.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

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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

15-April-2025

Dear Customer,

Attached you will find an update to Philips 28-Dec-2023 Field Safety Notice relating to the potential for Quadrature Body Coil (QBC) seal adhesive to fail, creating sharp edges that may come in contact with patients.

Summary of Updates:

- Philips has identified additional MR systems where the issue may occur. Section 3 of the Field Safety Notice has been updated to include the additional model names and numbers (REF) listed below. According to our records, affected product identified below has been distributed to your facility.

Model	(REF) Numbers
Enterprise 1.5T	781145
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

- Section 1 of the Field Safety Notice has been updated to include the number of reported adverse events Philips has received for this issue as of February 2025.
- Section 5 of the Field Safety Notice has been updated to include an additional field correction reference number (FCO78100615) for newly identified MR systems.
  * Note: SmartPath to dStream for 1.5T and SmartPath to dStream for 3.0T will be addressed via FCO78100573. The other MR systems listed above will be addressed via FCO78100615.

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,

PHILIPS

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.

15-April-2025

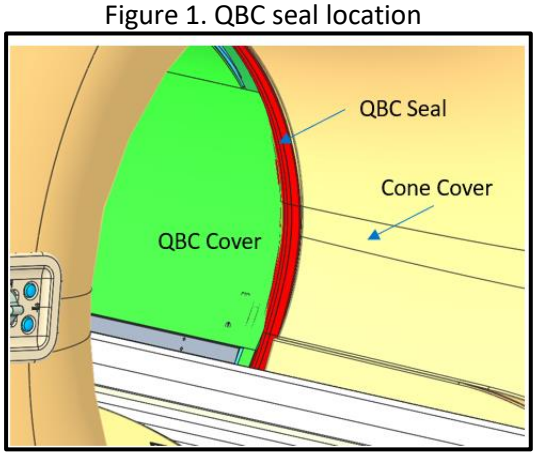
Dear Customer,

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

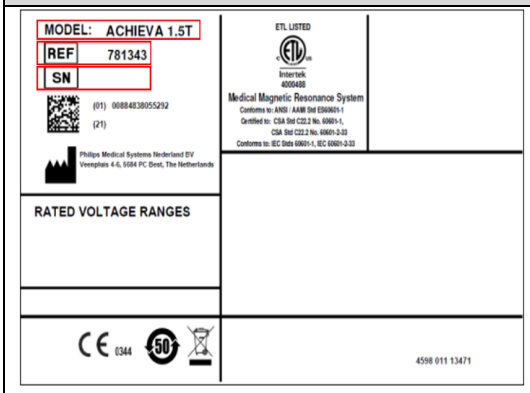
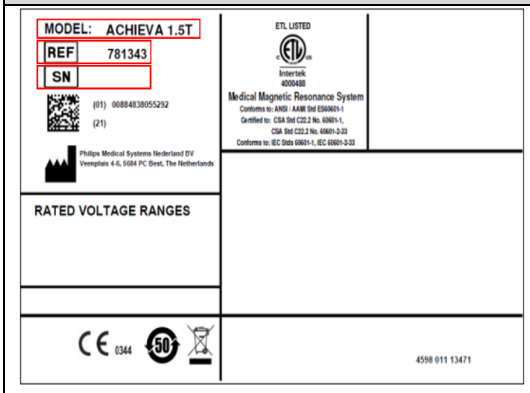
Sample System Label Example	Model	(REF) Numbers
	Achieva 1.5T	781196, 781343, 781296
	Achieva 1.5T Conversion	781346, 781283
	Achieva 1.5T Initial system	781178
	Achieva 3.0T	781277, 781177, 781278, 781344, 781345
	Achieva XR	781153, 781253
	Ingenia 1.5T CX	781262, 781261
	Ingenia 3.0T CX	781271, 782105
	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
	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: met.quality@philips.com. 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,

PHILIPS

Updated Field Safety Notice Response Form

Reference: MR Systems Quadrature Body Coil (QBC) seal failure (reference FCO78100573, FCO78100615)

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 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 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 met.quality@philips.com