PHILIPS

Urgent Field Safety Notice

Multiva 1.5T MR Systems

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.

21-Oct-2025

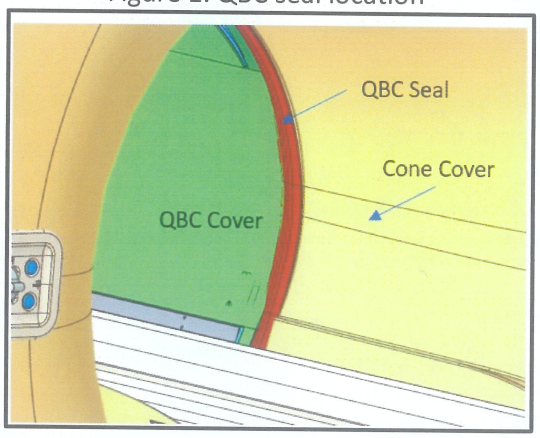
Dear Customer,

Philips has identified an issue with the Multiva 1.5T 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 not received any harm or injury associated with this issue from Multiva 1.5T systems as of Oct 2025.

2. Hazard/harm associated with the issue

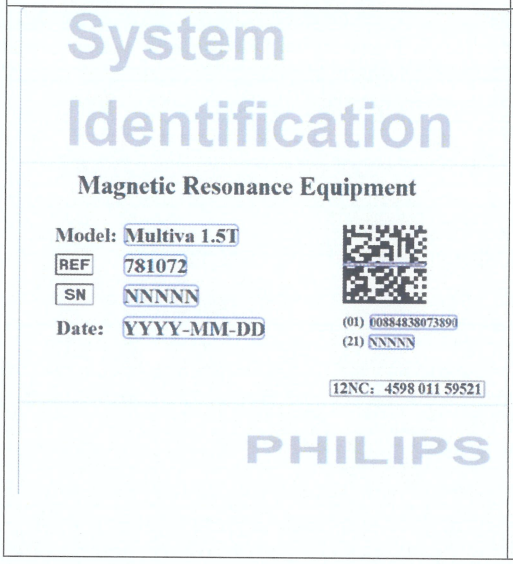
If the QBC seal becomes loose during the scanning process, the risk to the patient may include one or more of the following: skin abrasions, bruises, lacerations, hair loss/entanglement, and tissue injury.

PHILIPS

3. Affected products and how to identify them

Identification of Impacted Systems:
Refer to Tables 1 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

Figure 1. Example System Label	Product Name (Model)	Product Number (REF)	Device Identifier
	Multiva 1.5T	781072	(01)00884838073890
		781073	(01)00884838073883
		781074	(01)00884838073906
		781076	N/A
		781078	(01)00884838047631

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 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.

PHILIPS

5. **The actions planned by Philips MR** (CN-MF-000003923) **to correct the problem**

   Philips will contact you to schedule a time for a Field Service Engineer (FSE) to visit your site to inspect your system's QBC Seal and replace the QBC Seal if necessary (reference FCO78100616).

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,

Li Xin
Quality Leader
Philips Precision Diagnostics (PD) China

PHILIPS

Urgent Field Safety Notice Response Form

Reference: Multiva 1.5T MR Systems Quadrature Body Coil (QBC) seal failure (reference FCO78100616)

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 Philips promptly and no later than 30 days from receipt via email to: <Philips representative contact details to be completed by the Market/Business>.