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URGENT Field Safety Notice

Philips MR system breast coils
Potential for harm while using a breast coil

October 31, 2024

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.

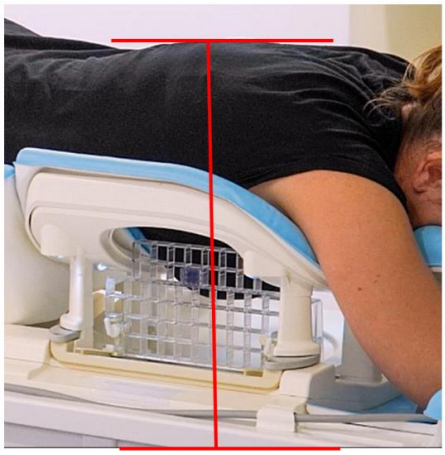
Dear Customer,

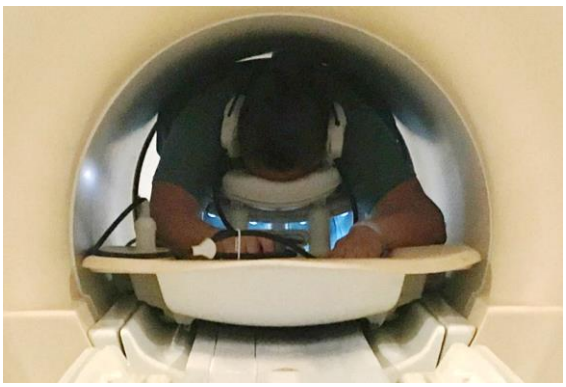
Philips has become aware of a potential safety issue with MR system breast coils where a patient may be harmed while preparing for or during a scan. This URGENT Field Safety Notice is intended to inform you about:

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

   Philips has identified an issue with patient set up while using the MR system breast coil where, if the cross-section of the prone patient, breast coil, and patient table exceeds the internal diameter of the magnet bore, the patient may be compressed between the breast coil and top of the magnet bore potentially resulting in harm to the patient (see Image 1).

   Image 1: (Left) *Cross-section: combined measurement of patient height, breast coil, and table. Must not exceed the internal diameter of the magnet bore. (Right) Incorrect patient set up: patient is touching/pressed against the side of the bore.*





   Additionally, in cases of compromised bone strength, the pressure points created between the prone patient and the breast coil could be exaggerated due to exam duration, the machines vibrations and/or patient positioning that induces pain, resulting in harm to the patient.

   Philips has received 19 reports, globally, of patient harm associated with this issue as of September 2024.

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2. Hazard/harm associated with the issue

The patient may experience friction, pain, rib fractures, contusions, bruises, abrasions, and/or dyspnea.

3. Affected products and how to identify them

Identification of product impacted by this issue:
See Appendix A for a list of Philips breast coils and Image 2. For example system label and label location.

Image 2. example system label, located on bottom of the coil

Intended Use:
The Magnetic Resonance (MR) Breast coil is to be used in conjunction with an MR Scanner to produce diagnostic images of the anatomy of interest that can be interpreted by a trained physician. The clinical environments where the MR Breast Coils can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

4. Actions that should be taken by the customer / user in order to prevent risks for patients

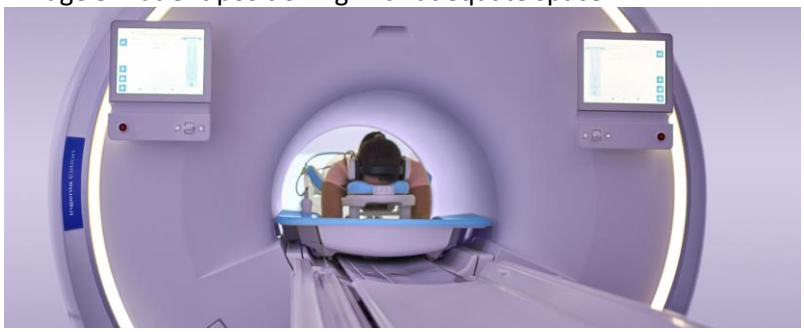
A. Customers can continue using the identified systems in accordance with the intended use.

B. When using the system:

- Follow section *PRECAUTIONS, CAUTIONS & WARNINGS* in the Instructions For Use (IFU) provided with your coil:
  - *i. When using breast coils if the patient's back touches the bore and stops the table movement, do not manually force the table to iso center, this could cause injury to the patient.*
  - *ii. When positioning the coil on the table and the patient in the coil, always check that the coil and/or the patient will not hit the bore when moving the table, this could result in patient injury. Refer to the system Instructions for Use for positioning instructions.*

- Follow section *Positioning>Safety* in the IFU: *Ensure clearance between body parts and the bore wall.*

Image 3: Patient positioning with adequate space



C. Circulate this notice to all users of this device so that they are aware of the potential issue.

D. Please complete and return the attached acknowledgment form to Philips promptly upon receipt and no later than 3 days from receipt via email to FCO.Nordic@philips.com.

5. Actions planned by Philips MR to correct the issue

Philips is providing this Field Safety Notice (FSN) Letter which contains recommendations for continued use of the systems referenced in Section 4.

If you need any further information or support concerning this issue, please contact your local Philips representative.

Telephone 80 30 30 35
Email philips.service@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Akivia Rivera Garcia
Head of MR Quality

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URGENT Field Safety Notice Response Form

Reference: Philips MR system breast coils - Potential for harm while using a breast coil

Instructions: Please complete and return this form to Philips promptly and no later than 3 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:

- See Section 4 of the Urgent Field Safety Notice.

We acknowledge receipt and understanding of the accompanying Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users that handle the system breast coil.

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 3 days from receipt via email to FCO.Nordic@philips.com

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Appendix A: Philips breast coil product List

Product name	Product Number
Achieva TX Interventional Coil 3.0T	45353026471x
dS Breast 16ch 1.5T	45353028072x 45980172988x 45980129051x
dS Breast 16ch 3.0T	45353028073x 45980172989x 45980129074x
dS Breast 7ch 1.5T	45353028088x 45980076668x 45980129043x 45980172881x 45980172990x
dS Breast 7ch 3.0T	45353028089x 45980129071x 45980172991x
Mammotrak Diagnostic Coil 1.5T	45353022887x
Mammotrak Interventional Coil 1.5T	45353022888x
Mammotrak Diagnostic Coil 3.0T	45353022891x
Mammotrak Interventional Coil 3.0T	45353022889x
SENSE Breast Coil	45353008395x
SENSE Breast Coil 3.0T 7ch	45353008930x
ST SENSE Breast Coil	45353005457x
ST SENSE Breast Dx Coil	45353026479x