Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 166 **dated** 28/11/24 **Regarding SFDA Field Safety Notice of Philips MR system breast coils from (mfr: Philips Medical Systems Nederland B.V).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

Sultanate of Oman
Ministry of Health
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سلطنة عُمان
وزارة الصحة
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مسقط

Circular No. 166 **/ 2024**

26 -05-1446 H
28 -11-2024

Field Safety Notice of Philips MR system breast coils from Philips Medical Systems Nederland B.V.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/173
Product	Philips MR system breast coils.
Manufacturer	Philips Medical Systems Nederland B.V.
Local agent	Mustafa Sultan Science & Industry Co.LLC.
The affected products	Please refer to the attachment for the affected products names and numbers.
Reason	It has been 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. 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.
Action	1. Please refer to the attachment which contains recommendations for continued use of the systems (Actions that should be taken by the customer / user in order to prevent risks for patients). 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

PHILIPS

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.

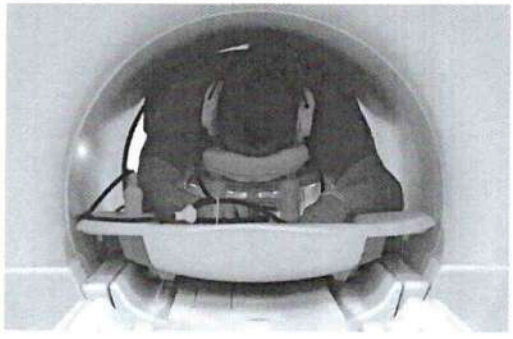
Dear Customer,

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.

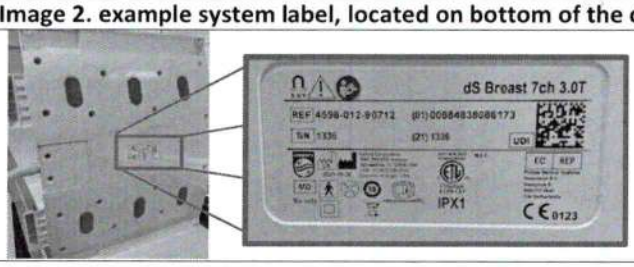
2. **Hazard/harm associated with the issue**

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.

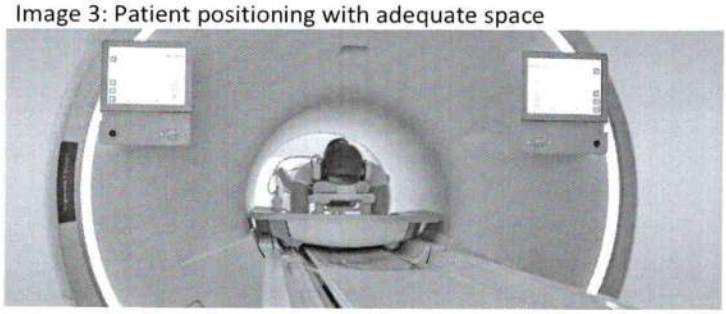
4. **Actions that should be taken by the customer / user in order to prevent risks for patients**

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 MR promptly upon receipt and no later than 30 days from receipt via email to: met.quality@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. met.quality@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Akivia Rivera Garcia
Head of MR Quality

PHILIPS

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 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:

- 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 30 days from receipt via email to: met.quality@philips.com

PHILIPS

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