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URGENT Field Safety Notice

SENSE XL Torso (1.5T and 3.0T) Coils - All Serial Numbers for Specific Models
Potential for patients to sustain burns resulting from heated coil

31-MAY-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 been made aware through customer complaints of a potential safety issue with specific SENSE XL Torso (1.5T and 3.0T) coils that could pose a risk for patients. The affected coils are identified in Section 3 of this letter can only be used with Philips MR Intera and Achieva System. This URGENT Field Safety Notice is intended to inform you about:

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

   Philips has identified an issue in the SENSE XL Torso (1.5T and 3.0T) coils which may result in localized heating during the scan, resulting in potential harm to patients.

   Philips has received 64 complaints of coil heating events, including 52 reports of patient harm (See section 2) associated with this issue as of April 2024.

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

   If the patient is exposed to localized heating there is a potential for a heating sensation and/or 1st, 2nd, or 3rd degree burns around the area covered by the coil.

3. **Affected products and how to identify them**

   Identification of Impacted Coils:
   All serial numbers of the specific SENSE XL Torso (1.5T and 3.0T) coils identified in Figure 1 are affected. (See Figure 1 for Product Name and Model). Figure 2 illustrates the location of the product label.

Figure 1. Impacted Coils (all serial numbers)

Product Name	Model
SENSE XL TORSO COIL 1.5T	453567141882
SENSE XL TORSO COIL 1.5T	453567141883
SENSE XL TORSO COIL 1.5T Mk2	453567502281
SENSE XL TORSO COIL 3.0T	453567394942
SENSE XL TORSO COIL 3.0T	453567394943
SENSE XL TORSO COIL 3.0T	453567394945

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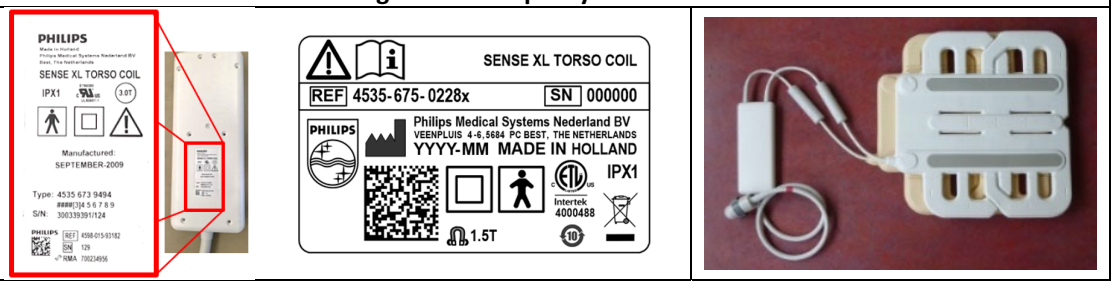
Figure 2. Example System Labels



Intended Use:
The SENSE XL Torso coil (1.5T and 3.0T) coil is a 16-element, receive only coil. The coil consists of a posterior coil, an anterior coil, and a connection/driver box. This coil is designed for torso and abdomen imaging. This coil is used independently and cannot be combined with any other coils. These coils are available in both 1.5T and 3.0T. The Magnetic Resonance (MR) coil is intended 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.

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

- Customers can continue using the identified coils with your system in accordance with the Instructions for Use (IFU).
    1. **Avoid First Level Operating Mode/High SAR scans**
       Per the system IFU, when using the SENSE XL (1.5T and 3.0T) Torso Coils, follow section "*Safety>Guidance for Specific Absorption Rate (SAR)*":
       To restrict all scan protocols of an examination to Normal Operating Mode for SAR, set Allowed SAR Mode to Normal in the New Examination window.

    2. **Use dedicated pads**
       Per the system IFU, when using the SENSE XL (1.5T and 3.0T) Torso Coils, follow section "*Safety>Coil and Cable positioning*":
       Always use dedicated pads and mattresses provide with the coils.

- Additionally, Philips is providing the updated instructions below.
    1. **Avoid positioning the coil close to the bore**
       When using the SENSE XL (1.5T and 3.0T) Torso Coils, ensure the anterior portion of the coil is positioned greater than 2 inches (5 cm) away from the bore.

    2. **Do not exceed 45 minutes of examination time**
       Do not exceed 45 minutes of examination time (excluding setup time) for a single patient.

- For ease of use and understanding, this information has been summarized in '*Advisory Notice - Using SENSE XL Torso Coils'* attached to this document. Please display the attachment with your system(s); ensure the notice is in a place likely to be seen/viewed by operators.

- Circulate this notice to all users of this device so that they are aware of the product issue and associated hazard/harm.

- Please complete and return the attached customer response form to Philips **promptly** and no later than 30 days from receipt of this letter.

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5. Actions planned by Philips to correct the problem

Philips is providing this customer letter containing guidance for this issue.

Philips is developing field corrections which include: potential software risk control measures to limit scan settings while using the SENSE XL Torso Coils, hardware updates to include additional padding. Philips is also initiating design of an improved coil. Philips anticipates providing an update to you on the development of our plan by end of 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.

This notice has been reported to the appropriate Regulatory Agencies.

Sincerely,

Electronically signed by: Roxanne Ramirez
Reason: "I Approve"
Date: May 29, 2024 20:38 CDT

Roxanne Ramirez
Quality Leader

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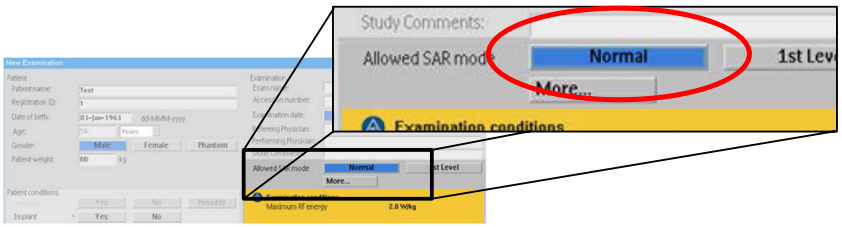
Advisory Notice - Using SENSE XL Torso Coils:

SENSE XL Torso (1.5T and 3.0T) Coils - All Serial Numbers for Specific Models

Potential for patients to sustain burns resulting from heated coil

As a reminder:

Customers can continue using the identified SENSE XL Torso (1.5T and 3.0T) coils in accordance with the intended use and the current and updated instructions below:

	Customer Action	IFU section	Operator Instructions	Additional Details
1	**Avoid First Level Operating Mode/High SAR scans**	*Safety > Guidance for Specific Absorption Rate (SAR)*	*To restrict all scan protocols of an examination to Normal Operating Mode for SAR, set Allowed SAR Mode to Normal in the New Examination window. (see Image A1)*	Image A1: New Examination Window, Normal circled in red 
2	**Use dedicated pads**	*Safety>Coil and Cable positioning*	*Notice Always use dedicated pads and mattresses provide with the coils. (see Image A2)*	Image A2: Padding provided with coil  • Direct contact of patient's skin with coil can lead to RF burns in the form of heat sensation, skin reddening or even blisters.
3	**Avoid positioning the coil close to the bore**	*N/A*	When using the SENSE XL (1.5T and 3.0T) Torso Coils, ensure the anterior portion of the coil is positioned greater than 2 inches (5 cm) away from the bore. (see Image A3)	Image A3: Coil (left) showing anterior part of the coil, System front view illustration (right) Showing space required between anterior portion and bore surface 
4	**Do not exceed 45 minutes of examination time**	*N/A*	Do not exceed 45 minutes of examination time (excluding setup time) for a single patient.	N/A

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URGENT Field Safety Notice Response Form

RE: SENSE XL Torso (1.5T and 3.0T) coils - All Serial Numbers for Specific Models: Potential for patients to sustain burns resulting from heated 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 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 Medical Device Correction.

We acknowledge receipt and understanding of the accompanying Urgent Medical Device Recall Letter and confirm that the information from this Letter has been properly distributed to all users.

- ☐ I no longer have this coil, please contact me at the number below to complete the process of updating Philips' records.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please complete and return the response form to Philips promptly and no later than 30 days from receipt via email to: