

URGENT - Field Safety Notice
SENSE Body Coil 1.5T used with ACS NT, Intera 1.5T and Achieva 1.5T MR Systems

Elevated temperature of the SENSE Body Coil 1.5T cables.

Dear Customer,

A problem has been detected in the 1.5T SENSE Body Coils used with Philips ACS NT, Intera 1.5T and Achieva 1.5T MR products that, if it were to re-occur, could pose a risk for patients or users. This FSN781 00437 is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem.

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 a copy with the equipment's Instructions for Use.

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 Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Shawn Leo Hunsaker

Head of Quality and Regulatory Affairs
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| AFFECTED PRODUCTS | ACS NT, Intera 1.5T and Achieva 1.5T MR Systems with the SENSE Body Coil 1.5T. The SENSE Body Coil 1.5T works in conjunction with the Quadrature Body Coil (QBC). The QBC acts as the RF transmitter and the SENSE Body Coil 1.5T as the receiver. The intended use of the SENSE Body Coil is for MR imaging of the thorax, abdomen, pelvis and legs |
| PROBLEM DESCRIPTION | The Instructions for Use state how (and how not) to position the SENSE Body Coil 1.5T and its cables in relation to the patient and MR bore in order to avoid a hazardous situation. When these instructions are not followed during an examination, the positioning of the coil cables can create unintended resonances via the patient or elevated coil cable temperature due to RF coupling to the QBC. |
| HAZARD INVOLVED | Unintended resonances via the patient or elevated coil cable temperature can occur when cables are placed in any of the following ways, each of which is contrary to Instructions for use: <ul style="list-style-type: none">• coil cables are placed in loops or twisted inside the QBC (RF area);• coil cables do not run <u>directly away from</u> the region of interest;• coil cables are routed close to the QBC;• coil cables are in direct contact with patient's body;• coil interface box is in direct contact with the patient's body; or• coil cables and interface box do not have sufficient distance between them The combined use of the SENSE coil, high SAR level scanning and placement of the cables contrary to instructions for use can lead to patient burns. |

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HOW TO IDENTIFY AFFECTED PRODUCTS

All SENSE Body Coils 1.5T with one of the following identification numbers (12nc):

4522 131 5575x¹⁾
4522 132 1985x
4522 132 7619x
4598 000 5187x
4598 000 5189x
4598 003 59051

¹⁾Where x can be a number varying from 1 to 9.

The identification number (12nc) can be found on the coil interface/driver box as indicated in below example. The 12nc is listed behind 'REF':



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| <p>ACTION TO BE TAKEN BY CUSTOMER / USER</p> | <p>The Instructions for Use give safety warnings for the mentioned hazardous situations, including (without limitation) a general warning to prevent coil related burns and warnings about high SAR scanning. These kinds of events can be prevented by following the Instructions for Use, including:</p> <p>“• Avoid placing cable loops and twisted cables (RF coil cables, interface boxes and ECG leads) inside the body coil (RF area).</p> <p>Loops can cause excessive heating of the cables which may result in burns upon contact to patient’s skin.</p> <p>The cables must be routed parallel to the axis of the bore.</p> <ul style="list-style-type: none"> • Avoid routing of the RF coil cable assembly in proximity to the RF transmit coil. Avoid direct contact of the patient’s skin with the RF coil cable assembly. <p>All this may result in excessive local heating and ultimately in skin burns. Positioning of the RF coil cable assembly must therefore be done with care. Keep a distance to the patient’s skin of at least 2 cm. Use the special spacer or pads of the standard accessory set where the cable assembly may touch the skin.</p> <ul style="list-style-type: none"> • Never attempt to bend or force the coil into an abnormal shape. • Do not place the coil perpendicular to the main magnetic field. • Always run the cable directly away from the region of interest. • Position and secure the cable using the clips provided in the accessory gutter (Achieva 1.5T and 3.0T), or in the grooves under the mattress (3.0T TX systems). • Do not position any coil interface-box on the patient’s body. <p>The interface box may be positioned on the patient in exceptional cases Only. Use the special spacer or pads of the standard accessory set to create a distance to the patients skin. “</p> <p>(IFU 2.18.11 Intera 1.5T, Achieva 1.5T; 2.18.8 ACS NT)</p> |
| <p>ACTIONS PLANNED BY PHILIPS</p> | <p>Although following the Instructions for Use will prevent the occurrence of the hazard, Philips has decided to provide further protection. A sleeve is being developed that will be applied to the cable on the SENSE Body Coil 1.5T and provide consistent spacing between the cable and the patient, thereby reducing the chance of RF interaction and heating.</p> <p>This sleeve will be distributed as part of a Field Change Order with reference FCO781 00437 for SENSE Body Coils in the installed base and will be installed free of charge by the Philips Field Service Engineers. The release of this FCO is planned in the end of 2015 (Q4-2015).</p> <p>Should you need to communicate with Philips with regard to this program, please reference FCO781 00437</p> |
| <p>FURTHER INFORMATION AND SUPPORT</p> | <p>If you need any further information or support concerning this issue, please contact your local Philips representative:</p> |