URGENT - Field Safety Notice
1.5T Intera and 1.5T Achieva systems

Risk to patient using the Synergy Flex-M / Shoulder Coil 1.5T

Dear Customer,

A problem has been detected in relation to the Philips Flex-M / Shoulder Coil for 1.5T systems, that, if it were to re-occur, could potentially pose a risk for patients. This Field Safety Notice is intended to inform you about:

- the problem and the circumstances under which it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients
- the actions planned by Philips Healthcare 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 Instruction for Use.

From this Flex-M / Shoulder Coil it is known that the combined use with other coils increases the chance for heating up because of RF interaction. An addendum to the IfU (Release 6, 7 and 8) was issued by means of Mandatory Action FCO in 2002. Additionally, in the IfU of release 9 the restriction to use the Flex-M/Shoulder coil in combination with other coils is mentioned. However in the IfU for R10/R11 the focus was on the new improved Flex-M coil and the new application that this coil brings. Because of this the restriction to combine this Flex-M coil/Shoulder Coil with other coils disappeared from the R10/R11 IfU. However the removal of this restriction from the R10/R11 IfU only applies to the 'new' improved SENSE Flex-M and not for the 'old' Flex-M/Shoulder coil that still may not be used in combination with other coils. This might be confusing to the customer and might result in the assumption that combined use with the coil is always allowed. Therefore it has been decided to replace the 'old' Flex-M / Shoulder Coils with the improved Flex-M coil for all 1.5T systems on SW level 10, 11 and 12. This will reduce the chance to possible RF interaction with the patient that may result in RF burns.

<Any further information concerning the problem and its correction the BS/BU/BL or KM might want to add. Please note that it is not allowed to incorporate sales information or promotional wording in this type of customer communication and that the KM is not allowed to include any technical or clinical details without agreement from BS/BU/BL>

If you need any further information or support concerning this issue, please contact your local Philips representative:
<Philips representative contact details to be completed by the KM / country>

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

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<Signature, to be signed by Senior Management of the BS/BU/BL or GS&S/KM>

<Name>
<Function>

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AFFECTED PRODUCTS	Trace item: 4522-131-6656x - Synergy Flex-M / Shoulder Coil 1.5T 12nc on coil: 4522-131-6656x
PROBLEM DESCRIPTION	The combined use of the Synergy Flex-M / Shoulder Coil 1.5T increase the chance of RF interaction and heating up of the coil. This may result in possible burns of the patient.
HAZARD INVOLVED	Possible burn to the patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	 The identification of the Synergy Flex-M can be found on the driver box. The 12nc of the affected systems is **4522-131-6656x**

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ACTION TO BE TAKEN BY CUSTOMER / USER	**Do not combine the 'old' Synergy Flex-M / Shoulder coil 1.5T with any other coil.** To minimize the risk please refer to the following instructions: ⚠ WARNING *The combined use of RF coils, high SAR levels and direct skin contact of the coils cables may cause local cable heating and can lead to skin burns.* Strictly follow the instructions below to avoid the risk of cable heating: • DO NOT combine the Synergy Flex-M / Shoulder coil 1.5T with any other Receive Coil. • Use high SAR levels (above 2.5 Watt/kg) only in those cases where it is absolutely necessary. • Leave a 2 cm distance between the patient's skin and the RF cables and interface boxes.
ACTIONS PLANNED BY PHILIPS	It has been decided to replace the 'old' Synergy Flex-M / Shoulder Coils with the improved Flex-M coil for all 1.5T systems on SW level 10, 11 and 12. This to reduce the chance to possible RF interaction with the patient that may result in RF burns. This will be done by means of Mandatory Action Field Change Order (FCO781 00290). The release of this FCO is planned in the third quarter of 2009 (Q3 -2009). Philips will contact you to follow up on this action.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>