Customer Information
MR SENSE Head Receive Coil Assembly

Dear Customer,

The potential for a problem to develop has been detected in the Philips MR SENSE Head Receive Coil Assembly, that, if it were to re-occur, could affect the performance of the equipment. This Customer Information is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that you as a customer can take to minimize the effect of the problem
- the actions planned by Philips to correct the problem.

Receive coil assemblies are used to investigate specific anatomies of the patient. Each assembly has been designed for prolonged safe and reliable operation. The coil assembly includes the receive coil itself, cable and cable traps. The cable traps ensure safe operation of the coil assembly via RF filtering of the signal. However, it is known that RF incidents can still occur on MR scanners, which result, in some cases, in RF or thermal burns for the patient. These incidents may be the result of unwanted RF interaction with a patient or of the heating of parts of the assembly, caused by technical failures. Thermal burns are most likely to occur from patient contact with the cable trap, indicated in Figure 1.

The Instructions for Use for the MR scanner gives numerous instructions and warnings for the safe use of receive coil assemblies to avoid the unwanted RF interaction and to avoid the occurrences of injuries caused by part malfunctioning. Close attention should be paid to these instructions.

Nevertheless for a series of RF receive coils for the Philips family of MR scanners we have encountered a higher than normal occurrence of RF burns. This situation was signaled in time and has resulted in improvements that have been cut into forward production to reduce the probability.

After consideration, it was decided not to replace or revise the cable traps in the installed base of these coils because the chance on malfunctioning of the coil assembly was estimated to be unlikely. This probability can be reduced further by paying more attention to the application (positioning) of the device, as instructed in the documentation supplied with the system.

This letter is to inform you about this situation and ask you to pay extra attention to the application of these coil assemblies. Whenever you are in doubt on the performance of a coil assembly and particularly of the cable or cable trap, please contact your local Philips representative:

<Philips representative contact details to be completed by the KM / country>

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

<Signature>

<Name>

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Specifically, the cable trap housing, which includes the cable trap for RF filtering of the MR signal is affected. These cable trap housings can be recognized most easily by it's shape and warning label (see Figure 1) and by the fact that the coil assembly is produced for Philips Medical Systems by Invivo corporation (see Figure 2)

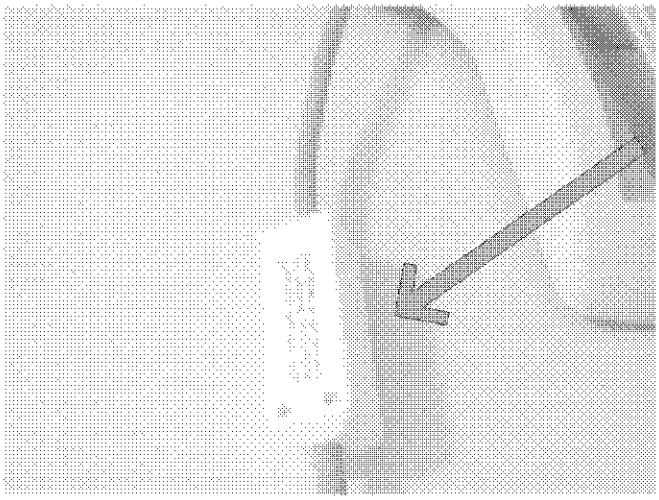

Fig. 1. The Balun Housing

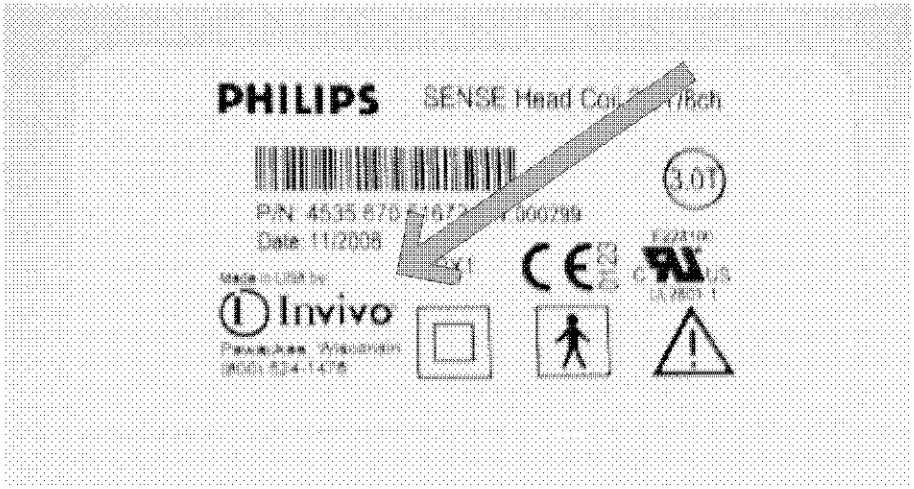

Fig. 2. Example of the product label

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AFFECTED PRODUCTS	The receive coil assemblies as depicted in the images
PROBLEM DESCRIPTION	It is known that RF incidents can occur on MR scanners, which result, in some cases, in RF or thermal burns for the patient. These incidents may be the result of unwanted RF interaction with a patient or of the heating of parts of the assembly, caused by technical failures. Thermal burns are most likely to occur from patient contact with the cable trap, indicated in Figure 1. RF burns are most likely due to the cable being positioned too close to the patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	See images
ADVICE ON ACTIONS BY CUSTOMER / USER	The Instructions for Use for the MR scanner gives numerous instructions and warnings for the safe use of receive coil assemblies to avoid the unwanted RF interaction and to avoid the occurrences of injuries caused by part malfunctioning. The user is advised to pay extra attention to these instructions.
ACTIONS PLANNED BY PHILIPS	This situation was signaled in time and has resulted in improvements that have been cut into forward production to reduce the probability. The improved versions of the units have been delivered since mid 2007.
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>