BIU MR Therapy FSN781 00452 April 2016

URGENT - Field Safety Notice
Sonalleve MR-HIFU Fibroid Therapy System with R2.1 L3 Application Software

Heating offset with 2 mm sonication cells.

Dear Customer,

A problem has been detected in the Philips Sonalleve MR-HIFU Fibroid Therapy System with R2.1 L3 Application SW that, if it were to re-occur, could pose a risk for patients. This FSN781 00452 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
- 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:
<Philips representative contact details to be completed by the Market Group >

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,
<Name>, <Function>, <Signature>

AFFECTED PRODUCTS	Philips Sonalleve MR-HIFU Fibroid Therapy System with R2.1 L3 Application SW. The Philips Sonalleve MR-HIFU Fibroid Therapy System is used to perform non-invasive thermal ablation. It has the CE Mark for treatment of uterine fibroids and palliation of pain from bone metastases.
PROBLEM DESCRIPTION	When performing sonication with treatment cells of 2 mm in size, there is a possibility that the depth of the sonication is not as shown on the user interface due to a software defect. In a worst case scenario, maximum possible positioning error is 4 cm but only in longitudinal direction (along transducer axis). If this scenario were to occur, it could pose a risk for patients. For this scenario to occur, it is necessary that the previous sonication is performed at a different depth than the currently planned sonication, and that either of the sonications is targeted so far or close to transducer that the software uses longitudinal deflection compensation. The defect can occur either in the Uterine Fibroid or the Bone Application. The issue was discovered through R&D testing and there have been no reports of patient harm.
HAZARD INVOLVED	When sonicating deep inside the body, the heating may take closer to skin than intended and skin, fat, bladder or abdominal muscle may be heated unintendedly. When sonicating close to skin, the heating may take place deeper than intended, but in this case no sensitive structures is likely to be present at the heating location.
HOW TO IDENTIFY AFFECTED PRODUCTS	All Philips Sonalleve MR-HIFU Fibroid Therapy Systems on R2.1 L3 Application SW. User can identify their version from the splash screen that appears when they start the application SW.
ACTION TO BE TAKEN BY CUSTOMER / USER	In order to prevent the problem from occurring, avoid using treatment cells of 2 mm in size with R2.1 L3 Application SW. Instead, use the 4 mm treatment cells.
ACTIONS PLANNED BY PHILIPS	To help prevent the above stated problem from occurring, Philips has fixed this software defect and revised the Sonalleve Application software R2.1 L4. The corresponding software upgrade will be distributed as part of a Field Change Order with reference FCO781 00452 in the installed base and installed on all Sonalleve MR-HIFU Fibroid Therapy Systems running R2.1 L3 software by a Philips service engineer. The release of this FCO is planned in April 2016. Should you need to communicate with Philips with regard to this program, please reference FCO781 00452.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: