PHILIPS

<Name and Address of Hospital>

<Date>

TO: WHOM IT MAY CONCERN
CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Change Order pertaining to the Philips Ingenia 1.5T, and 3.0T due to FCO 78100484. Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: <Serial number>

If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:
Customer Name/Signature:
Company Name/Stamp:
Date:

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Reg. No 199705989C

Field Safety Notice

Magnetic Resonance FSN781 00484 December 2018

URGENT - Field Safety Notice
Medical Device Correction

Intera, Enterprise, Achieva, Achieva XT, Achieva Conversion, Panorama HFO, Ingenia, Smarthpath to dStream, Multiva, Prodiva, MR-OR, MR-RT, MR-Linac, MR-Marlin

Additional fixation (grip) of the ceiling speakers of the MR system

Dear Customer,

A problem has been detected in Philips MR systems that, if it were to re-occur, could pose a risk for patients or users. This FSN 781 00484 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 Instruction 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.

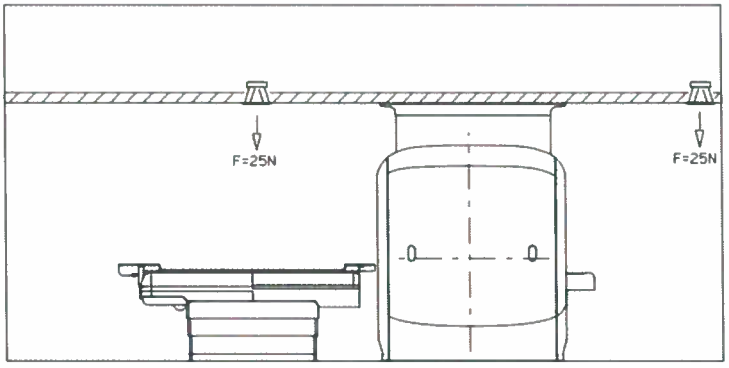
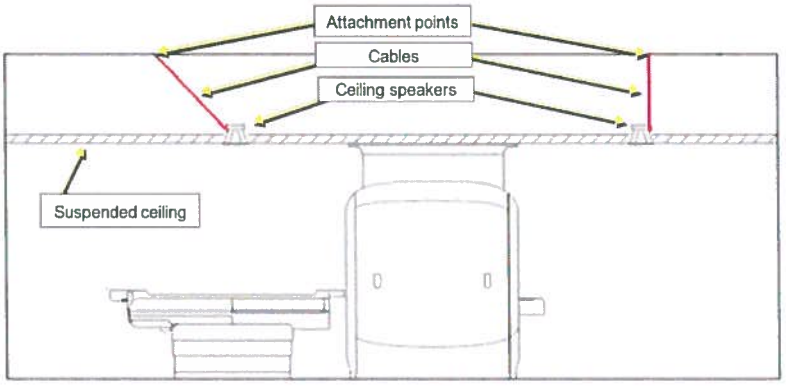
Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

Paul Sherlock
Head of Quality and Regulatory BIU,
Magnetic Resonance Imaging

AFFECTED PRODUCTS	Intera, Omniva, Enterprise, Achieva, Achieva XR, Achieva Conversion, Panorama HFO, Ingenia, SmartPath to dStream, Multiva, Prodiva, MR-OR, MR-RT, MR-Linac, MR-Marlin systems
PROBLEM DESCRIPTION	Philips MR systems are standard equipped with two ceiling speakers, positioned in the front and/or rear of the MR system. These speakers enable communication between the operator in the examination room and the patient and offer stereo music or ambient experience audio. These speakers are in most cases fixated in the suspended ceiling of the MR examination room according the Philips service instructions. The Philips Planning Reference Data (PRD) prescribes the suspended ceiling must be strong enough to hold 25 N speakers. However in very rare cases, due to external influences (hospital facility maintenance, water leakage, degradation of speaker fixation) during the lifetime of the MR system, the ceiling speaker(s) could fall from their position and be pulled to the MR system by the magnetic field.
HAZARD INVOLVED	In case the ceiling speaker or ceiling tile with speaker drops down, it will get pulled to the MR system by the magnetic field. This potentially can result in: - serious injury to a patient, operator or other persons in the examination room - damage to the MR system, e.g. covers The severity of such event depends on where, how and if the ceiling speaker or tile hits a person or system.
HOW TO IDENTIFY AFFECTED PRODUCTS	All MR systems listed above have been delivered with two Philips speakers. The customer can visually check if these ceiling speakers are mounted in the ceiling. Note: At some customers, ceiling speakers are mounted to the wall with a wall mounting box, which does not present a similar risk. Therefore, wall-mounted speakers are out of scope for this notification.

ACTION TO BE TAKEN BY CUSTOMER / USER	Following checks/actions by the customer are recommended: - Check if the speakers are mounted in the ceiling. - Visually check for signs of fixation degradation: e.g. water leakage, color changes of ceiling tiles, poorly positioned tiles. - In case of suspected insufficient fixation, do not correct the fixation yourself, but immediately contact your local Service/Philips representative. 
ACTIONS PLANNED BY PHILIPS	Via FCO78100484 an additional fixation will be installed. This 'non-magnetic' mechanical safety connection will be fixated to the ceiling speaker(s) and anchored to an external fixation point e.g. the ceiling roof, suspended ceiling rods, etc.  FCO78100484, with a required downtime of 0,5 hours, is free of charge. Please contact your local Philips representative, for further details.
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 Market>*