

**BIU MRI**

CIL781 00450

October 2016

**Customer Information**  
**Achieva 3.0T and Ingenia 3.0T MR systems with rear passive shielding**

**Too high attraction forces between magnet and rear passive shielding wall**

Dear Customer,

A problem has been detected in the Philips Achieva 3.0T and Ingenia 3.0T MR products on sites with rear wall passive shielding that, if it were to re-occur, could affect the performance of the equipment. This Customer Information is intended to inform you about:

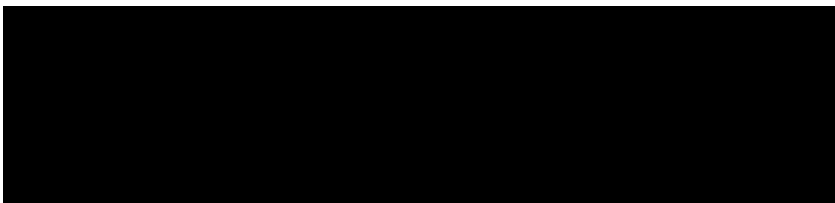
- what the problem is and under what circumstances it can occur
- the actions that you as a customer can take to minimize the effect of the problem
- the actions planned by Philips to correct the problem.

If you need any further information or support concerning this issue, please contact your local Philips representative:

If you need any further information or support concerning this issue, please contact your local Philips representative: Technical Support Line: 1-800-722-9377

Philips apologizes for any inconveniences caused by this problem.

Sincerely,



Shawn Leo Hunsaker

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<b>AFFECTED PRODUCTS</b>	<p>Achieva 3.0T and Ingenia 3.0T MR systems with passive shielding in the rear wall.</p> <p>MR systems have a strong magnetic field around the magnet, the so called fringe field. Reduction of this fringe field (e.g. 0.5-mT area) can be required under certain circumstances. A reduction can be achieved with ferromagnetic plates mounted to the parent walls, under the construction floor and above the RF-ceiling. These plates are called passive shielding.</p> <p>Passive shielding calculations require dedicated Philips Healthcare software. As documented in the Planning Reference Documentation, these calculations must be performed by Philips. It provides the requirements for the thickness and the location of the shielding material which are to be implemented, preferably by Philips' selected RF cage suppliers.</p>
<b>PROBLEM DESCRIPTION</b>	<p>The thickness and location of the shielding material must be installed according to the shielding requirements provided by Philips. In cases where the requirements are not followed, the distance between the passive shielding rear wall and the magnet could be insufficient. An insufficient distance leads to stronger attraction forces between the magnet and the passive shielding. These stronger forces may lead to shearing of the magnet vibration pads. In a worst case scenario, it may result in displacement of the magnet.</p> <p>Displacement of a magnet can result in image quality issues and mechanical fitting problems with the table. These functional issues affect the clinical usage of the MR system.</p>
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<p>Achieva 3.0T and Ingenia 3.0T MR systems with passive shielding in the rear wall.</p> <p>If the distance between magnet covers and finished rear wall is larger than 1.3m, the system is not affected.</p>
<b>ADVICE ON ACTIONS BY CUSTOMER / USER</b>	<p>None, the customer will be contacted by Philips.</p>
<b>ACTIONS PLANNED BY PHILIPS</b>	<p>A magnet vibration pad has been developed that can resist higher attraction forces.</p>

	<p>Achieva 3.0T and Ingenia 3.0T sites will be checked by the Philips Field Service Engineers. This check consists of measuring the exact distance between magnet and rear passive shielding wall. This distance is a measure for the attraction force, the risk of sheared magnet vibration pads, and magnet displacement.</p> <p>One of the following actions is to be taken, depending of the outcome of the check:</p> <ol style="list-style-type: none"> <li>1) <input type="checkbox"/> No action needed.</li> <li>2) <input type="checkbox"/> Replacement of magnet vibration pads</li> <li>3) <input type="checkbox"/> Replacement of magnet vibration pads and installation of seismic brackets</li> <li>4) <input type="checkbox"/> Replacement of magnet vibration pads (Further clinical use not advised)*</li> <li>5) <input type="checkbox"/> Replacement of magnet vibration pads and installation of seismic brackets. (Further clinical use not advised)*</li> </ol> <p>The MR magnet must be ramped down to replace the magnet vibration pads.</p> <p><b>*Note:</b> Further clinical use is not advised and the magnet must be ramped down as soon as possible by Philips at sites where all of the following is applicable:</p> <ul style="list-style-type: none"> <li>- The distance between the magnet and the passive shielding rear wall is insufficient,</li> <li>- The magnet vibration pads are sheared,</li> <li>- No seismic brackets are installed.</li> </ul> <p>The described checks and possible corrective actions are part of a free of charge Field Change Order with reference FCO781 00450. The release of this FCO is planned for Q4 - 2016.</p> <p>Should you need to communicate with Philips with regard to this program, please reference FCO781 00450.</p>
<b>FURTHER INFORMATION AND SUPPORT</b>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative: Technical Support Line:1-800-722-9377</p>