URGENT – Field Safety Notice
Ingenia, Intera Achieva and Achieva dStream MR systems using R5.1.1 and R5.1.2 version of software

Incorrect cross-reference lines on spine scans after post-processing using MobiView software option

Dear Customer,

A problem has been detected in the Ingenia, Intera, Achieva and Achieva dStream MR Systems using R5.1.1 and R5.1.2 version of software that, if it were to occur, could pose a risk for the patient. This FSN781 00426 supersedes FSN781 00431 and 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 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 Instruction 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 KM / country>

This notice will be reported to the appropriate Regulatory Agency pursuant to applicable regulations

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

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

<Name>
<Function>

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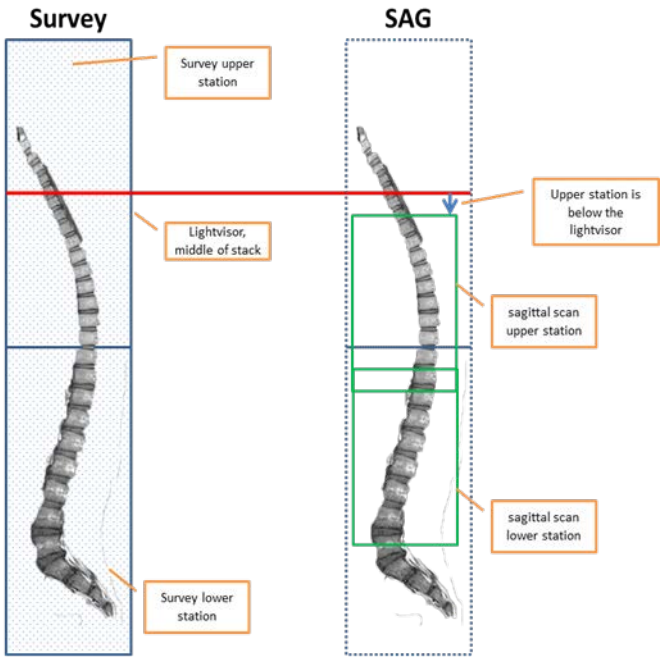
AFFECTED PRODUCTS	Ingenia, Intera, Achieva and Achieva MR systems on R5.1.1 and R5.1.2 with the MobiView software option.
PROBLEM DESCRIPTION	The cross reference lines of transversal images are displayed in an incorrect position on a fused image which has been generated through MobiView post processing. The cross reference lines are ***correctly*** displayed on the unfused stations. The problem can occur when the field of view of the clinical scan stations is below (more towards the feet) the light visor position. In such situation an error is made in calculating the position information. This causes incorrect positioning of cross-reference lines on fused sagittal images. This situation is illustrated below:  The hazard is only expected in spine examinations, when using a whole spine survey, while the cervical spine is skipped for the clinical scan.

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HAZARD INVOLVED	Risk of misdiagnosis, which could lead to incorrect therapy. The risk occurs when cross-reference lines on fused images are relied upon to determine location of transversal images. The hazard is only expected in spine examinations. In MobiView applications other than spine, reference lines are not commonly used to identify or label anatomy because anatomical landmarks are used instead.
HOW TO IDENTIFY AFFECTED PRODUCTS	All Ingenia, Intera, Achieva and Achieva dStream MR systems running on software version R5.1.1 and R5.1.2. The software version of the system can be found in the 'About' function, accessible through the Help menu of the User Interface.
ACTION TO BE TAKEN BY CUSTOMER / USER	Do not perform planning or review planning of transversal images on fused sagittal images which were generated through MobiView postprocessing Instead, review the planning of transversal scans only on the unfused stations.
ACTIONS PLANNED BY PHILIPS	A Field Change Order with reference FCO781 00426 is being released that requires Philips field service engineers to install Software release R5.1.7 which addresses the reference line positioning issue with MobiView. Next to solving the MobiView issue this software update enhances ease-of-use and scanning performance by improvements made based on the feedback from worldwide users. Should you need to communicate with Philips with regard to this program, please reference FCO781 00426.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative.