URGENT - Field Safety Notice
DigitalDiagnost X-ray System

Software Upgrade for Systems with 3.0.x Software (Revised Notice)

Dear Customer,

As part of Philips' continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Philips Digital Diagnost, we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information regarding:

- what the issue is, and under what circumstances it may occur
- the actions you can take to avoid or minimize the occurrence of the issue
- the actions planned by Philips to correct the issue

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, please contact your local Philips representative: Technical Support Line: 1-800-722-9377.

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,

Dominic Siewko
Sr. Manager of Radiation Health and Product Safety

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AFFECTED PRODUCTS	All DigitalDiagnost systems with Eleva software version 3.0.x
PROBLEM DESCRIPTION	**This FSN-71200085 is superseding CIL-71200066** **Philips previously notified owners of DigitalDiagnost systems with software releases 3.0.1 and 3.0.2, that a new software release, 3.0.3, would be installed on their systems.** **However, software release 3.0.3 contained a defect that may result in the incorrect placement of the electronic marker (left/right) indicating the patient side if an image is rotated.** **Software release 3.0.4 corrects this defect in release 3.0.3, and it will be installed on affected systems in place of release 3.0.3. If software release 3.0.3 has already been installed on a system, it will be replaced with release 3.0.4.** When the operator for a wall stand view selects an "image rotation" different from default, or such image rotation is preset in the examination database, then the resulting image may be rotated in the wrong direction. When the operator manually rotates the image back, electronic side markers (if programmed) are rotated also and as a result may be placed in a wrong position inside the image.
HAZARD INVOLVED	Electronic patient side (left/right) markers on wrong image side
HOW TO IDENTIFY AFFECTED PRODUCTS	This correction applies to the following affected units of DigitalDiagnost systems with release version: *DigitalDiagnost 3.0.1; 3.0.2 and 3.0.3*
ACTION TO BE TAKEN BY CUSTOMER / USER	If the image needs to be rotated, this can be manually done by each user with the rotation tool. Philips Healthcare recommends that customers always check whether the automatic marker is set correctly, even more carefully after a manual image rotation was performed. The image rotation can be corrected manually with the rotation tool. The marker can be corrected manually with the annotation tool. It is recommended to use a L/R lead marker to mark the patient side permanently in the image instead of using the automatic L/R markers from the EPX-database.
ACTIONS PLANNED BY PHILIPS	Philips will implement a software update to solve the image rotation and marker positioning issue.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. 1-800-722-9377. Please reference FCO 71200085 when contacting your local Philips representative.

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