URGENT - Field Safety Notice
DigitalDiagnost

Software Upgrade to DigitalDiagnost Rel 4.1.9 / 4.2.6

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 *DigitalDiagnost*, 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:

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

Sincerely,

Michael Mizrachi
Head of Q&R DXR Hamburg

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AFFECTED PRODUCTS	**Stitching run on SkyPlate detector interrupted intermittently:** Affects all DigitalDiagnost systems with system software versions 4.1.x or 4.2.x and stitching license **Stitching with SkyPlate aborts after first image:** Affects all DigitalDiagnost with system software versions 4.1.x or 4.2.x and stitching license **System software CD contains wrong baseline: Affects** All DigitalDiagnost systems with system software versions 4.1.8 and 4.2.5
PROBLEM DESCRIPTION	**Stitching run on SkyPlate detector interrupted intermittently:** When stitching image acquisition by means of the SkyPlate detector, the system software is designed such that the expected interval between two consecutive images is not smaller than eight seconds. If the detector readout time is faster so that the next image could be read in a time interval shorter than eight seconds, the synchronization between the detector and the system software results in a system abort of the stitching run. If this occurs, the stitching run needs to be repeated from the beginning. **Stitching with SkyPlate aborts after first image:** If there is an improper synchronization between the SkyPlate detector and the system, the preview offset image will have artifacts. If this happens, the system software identifies the preview image buffer as not usable during the first part image acquisition of the stitching run and as a result will abort the run. The stitching run has to be repeated. **System software CD contains wrong baseline:** DigitalDiagnost systems with system software versions 4.1.8 and 4.2.5 were delivered with a wrong system application software version on the CD. This wrong application software contains an error resulting in a failure that the mirrored image is not indicated as a mirrored image.
HAZARD INVOLVED	**Stitching run on SkyPlate detector interrupted intermittently and Stitching with SkyPlate aborts after first image:** The hazard associated with these defects is excessive radiation. In both circumstances, the image is not usable and a retake of the stitching examination is necessary. **System software CD contains wrong baseline:** The hazard associated to this defect is a wrong treatment due to mirrored image(s) which are not indicated as mirrored. Should you have any questions about this notice, please contact Philips.

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HOW TO IDENTIFY AFFECTED PRODUCTS	For the systems with the issues: - **Stitching run on SkyPlate detector interrupted intermittently:** All DigitalDiagnost with system software version 4.1.x or 4.2.x and stitching license - **Stitching with SkyPlate aborts after first image:** All DigitalDiagnost with system software version 4.1.x or 4.2.x and stitching license Availability of the stitching license it is indicated in the general system tab in the Eleva User Interface. For the systems with the issue: - **System software CD contains wrong baseline:** All DigitalDiagnost with system software version 4.1.8 and 4.2.5 will get the software upgrade to 4.1.9 or 4.2.6 respectively. The issue is not identifiable on the CD label but can be identified on the installed software on the system. The system software version is indicated in the general system tab in the Eleva User Interface.
ACTION TO BE TAKEN BY CUSTOMER / USER	**Stitching run on SkyPlate detector interrupted intermittently and Stitching with SkyPlate aborts after first image:** There are no actions to be taken by the user in these situations. The customer is notified at the end of the stitching run that the run failed. Customers can continue to use the device in accordance with this notice and the IfU. **System software CD contains wrong baseline:** Philips Healthcare recommends that customers always check the mirrored image to avoid a misdiagnosis.
ACTIONS PLANNED BY PHILIPS	Philips plans to install a system software version upgrade in affected systems, which will eliminate this issue. A Philips Service Engineer will contact you when the Field Action Kit is available to be implemented. Should you need to communicate with Philips with regard to this program, please reference Field Change Order 71200177.
FURTHER INFORMATION AND SUPPORT	If you would like any further information or support concerning this issue, please contact your local Philips representative.

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 Corrective Order pertaining to the DigitalDiagnost 4 High Performance due to FCO 71200177. Please note that the serial number of the units affected are stated below:

Affected Serial Numbers: <Serial numbers>

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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