FSN *MA-FCO-70900042* *2018-Oct-16*

URGENT - Field Safety Notice
Medical Device *Recall*

CombiDiagnost

Upgrade CombiDiagnost R90 to Rel.1.0.3

Dear Customer,

A problem has been detected in the Philips CombiDiagnost, that, if it were to re-occur, could pose a risk for patients or users. This *Field Safety Notice* 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:

0800 80 3000

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

Michael Mizrachi
Head of Q&R DXR Hamburg

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AFFECTED PRODUCTS	All CombiDiagnost systems with software version 1.0.0, 1.0.1 and 1.0.2
PROBLEM DESCRIPTION	**kV/mA lockin not functioning as specified:** The lock-in function is a fluoroscopy only function. When this function is enabled, the current radiation parameters, (kV and mA values), are retained to keep a consistent image impression. This is relevant for examinations of anatomies such as knee or shoulder, where the amount of dose at the detector is strongly influenced by the amount of direct radiation. Due to a software bug, the mA values are not locked, but increase when the operator restarts pulsed fluoroscopy several times after activation of the lock-in function. As a result, the patient received an increased radiation dose **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.
HAZARD INVOLVED	**kV/mA lockin not functioning as specified:** The hazard associated to this defect is that the patient receives additional radiation dose during their fluoroscopy procedure. In total the dose to the patient per fluoroscopy sequence may be increased by 50-60% compared to the intended dose. **Stitching with SkyPlate aborts after first image:** The hazard associated with this defect is excessive radiation. The image is not usable and a retake of the stitching examination is necessary.
HOW TO IDENTIFY AFFECTED PRODUCTS	All CombiDiagnost systems with software version 1.0.0, 1.0.1 and 1.0.2
ACTION TO BE TAKEN BY CUSTOMER / USER	**kV/mA lockin not functioning as specified:** The operator can recognize the issue by observing the increasing mA value. In general the system can be used according to the Instruction for Use without restrictions. **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.

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ACTIONS PLANNED BY PHILIPS	Philips will provide an upgrade of all CombiDiagnost R90 systems in the field to Rel.1.0.3 (Eleva package incl. improved clinical EPX database). 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 70900042.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**