URGENT - Field Safety Notice
MobileDiagnost wDR 2

Software Upgrade to Release 2.0.4

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 MobileDiagnost wDR 2, we have identified a potential issue that could result in unnecessary radiation exposure to the patient 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:

<Philips representative contact details to be completed by the KM / country>

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

Sincerely

[redacted]

Karmen Gruenert
Director Q&R DXR Hamburg (Print Name)

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AFFECTED PRODUCTS	MobileDiagnost wDR 2
PROBLEM DESCRIPTION	1. The system may sporadically apply the default x-ray exposure parameters for an adult (patient type: "Normal"), even though the patient type "Newborn" was selected and is displayed in the generator control area of the Eleva User Interface. 2. Under certain condition, the detector might not be ready for examination. Released x-ray might lead to an image with artifacts and a retake is required. While the attachment process is running, the detector might be too short in front of the IR (Infrared) sensor and the problem of the washed out images can appear if an exposure is taken right after that.
HAZARD INVOLVED	The only hazard is the potential for unnecessary radiation exposure to the patient.
HOW TO IDENTIFY AFFECTED PRODUCTS	All MobileDiagnost wDR 2
ACTION TO BE TAKEN BY CUSTOMER / USER	1. Check the exam parameter before exposure and change them if necessary manually. 2. Avoid this by holding the detector while the attachment is running in front of the IR (infrared) sensor until the LEDs on the detector are solid green and do not blink anymore. The second possibility why this can happen is that before an exposure the already attached detector is in sleep mode. The customer should take care that before an exposure all LEDs are also solid green at any time. When following the safety notices the system can be used according to the Instruction for Use without restrictions. If the customer feels uncertain, they can contact Philips.
ACTIONS PLANNED BY PHILIPS	Philips is preparing a Field Action Kit, which will allow a Philips Service Engineer to update the software to version 2.0.4. A Philips Service Engineer will contact you as soon as the Field Action Kit is ready to be implemented. Should you need to communicate with Philips in regards to this program, please reference FCO-71200152.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative.