

URGENT - Field Safety Notice
DigitalDiagnost 4.0.x

DigitalDiagnost Upgrade Release 4.0.x to 4.0.4

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 *DigitalDiagnost 4.0.x*, 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:

<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,


Stephanie Berger
Director Q&R DXR Hamburg

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AFFECTED PRODUCTS	DigitalDiagnost Release 4.0.x
PROBLEM DESCRIPTION	The system is designed to emit an acoustic signal (beep) upon termination of an exposure. However, if the system has been powered on for more than 12 hours, the system will no longer emit this signal.
HAZARD INVOLVED	If the system does not provide the expected acoustic signal upon the completion of an exposure, the system operator may be unsure that the exposure was correctly obtained, which may result in the decision to repeat an exposure.
HOW TO IDENTIFY AFFECTED PRODUCTS	All DigitalDiagnost systems Release 4.0.x
ACTION TO BE TAKEN BY CUSTOMER / USER	Until your system software is upgraded to release 4.0.4 to eliminate the potential loss of the acoustic signal upon termination of an exposure, Philips recommends that the system is rebooted at least every 11 hours. Should you feel uncertain regarding these instructions, please contact Philips.
ACTIONS PLANNED BY PHILIPS	Philips plans to install a software 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 71200134.
FURTHER INFORMATION AND SUPPORT	If you would like any further information or support concerning this issue, please contact your local Philips representative.