

URGENT - Field Safety Notice
Medical Device Recall
ProGrade Rel.1x

Connectivity Improvements

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 ProGrade Rel.1x 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,


Michael Mizrachi
Head of Q&R DXR

DXR

Quality Management System DXR

DXR Field Safety Notice

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FSN MA-FCO 71200166

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AFFECTED PRODUCTS	ProGrade Rel.1x
PROBLEM DESCRIPTION	It the WiFi connection between the SkyPlate detector and HP transfer point is weak, an image may fail to transfer from the SkyPlate detector to the system. The image remains in the memory of the detector, but cannot be transferred wirelessly or by use of the backup cable. To continue, the operator can reset the SkyPlate detector by removing its batteries, but the acquired image is lost and a re-take is necessary.
HAZARD INVOLVED	Information and data corruption can require an image to be retaken.
HOW TO IDENTIFY AFFECTED PRODUCTS	ProGrade Rel.1x systems are affected.
ACTION TO BE TAKEN BY CUSTOMER / USER	No action is needed on your part. There are no restrictions to usage of this device. Customers may continue to use the device according to its intended use. Should you feel uncertain regarding these instructions, please contact Philips.
ACTIONS PLANNED BY PHILIPS	Philips plans to release a new HP firmware to the installed base. In addition the existing Access Point Hardware in the field needs to be patched. 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 71200166.
FURTHER INFORMATION AND SUPPORT	If you would like any further information or support concerning this issue, please contact your local Philips representative.