

URGENT - Field Safety Notice
Diagnost 76, EasyDiagnost and EasyDiagnost Digital with
SCP Generator and tube grid switch functionality

Risk for increased patient X-Ray dose

Dear Customer,

A problem has been detected in the Philips Diagnost 76, EasyDiagnost and EasyDiagnost Digital Systems 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:

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

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

<Signature, to be signed by Senior Management of the BS/BU/BL or GS&S/KM>

<Name>

<Function>



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AFFECTED PRODUCTS	Diagnost 76, EasyDiagnost and Easy Diagnost Digital Systems using SCP Generator with Tube Grid switch functionality.
PROBLEM DESCRIPTION	The grid-switch technology considerably improves the image quality compared to the image quality by conventional fluoroscopy procedures and it implicates a reduction of the radiation dose for patients and staff. In sporadic cases (only at higher KV settings) it can come to deviations in this function, due to a limited grid-switch performance which is not always detected automatically by the System. This should lead to lower patient dose savings as expected however due to the grid switch issue the patient dose is not any more within the Philips quality tolerances of dose savings. However, during preventive maintenance each System will be recalibrated and after recalibration it will fulfill the specification with respect to patient dose rate.
HAZARD INVOLVED	Higher patient dose then normally can be achieved comparing with having full Grid-switch functionality.
HOW TO IDENTIFY AFFECTED PRODUCTS	All Diagnost 76, EasyDiagnost and Easy Diagnost Digital Systems using SCP Generator with Tube Grid switch functionality.
ACTION TO BE TAKEN BY CUSTOMER / USER	Please continue to closely monitoring the patient dose rate on the DAP meter. In case of unexpected higher readings, consult your local Philips Organization.
ACTIONS PLANNED BY PHILIPS	A mandatory FCO will be issued to solve this problem. The FCO content will be an addition of a Hardware circuit in the SCP Generator. You will be contacted by Philips for implementation of the corrective action.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: <Philips representative contact details to be completed by the KM / country>

