URGENT - Field Safety Notice
CombiDiagnost

Exchange collimator screws and PE cable check for CombiDiagnost GCF tubes

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 CombiDiagnost 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,

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AFFECTED PRODUCTS	CombiDiagnost
PROBLEM DESCRIPTION	1. It happened in some CombiDiagnost deliveries that the tube adapter-plate green/yellow protective earthing wire was removed 2. During GCF tubes assembly, spacers with different thickness are used to position pre-loc ring in respect to focal spot in specified distance.
HAZARD INVOLVED	1. There is a potential of an electrical shock if following factors occurs: - An electrical failure leads to an electrical potential on the adapter plate - The earth resistance based on mechanical connection is beyond limit - Person removes the tube cover. (not allowed for the customer) - Person touches the life wired part during exposure/fluoroscopy. 2. The hazard associated to this defect is a mechanical fault which can led to a falling collimator, which may hit a patient or another person below the source assembly. The x-ray tube assembly can be used as described in the intended use of the Instruction for Use.
HOW TO IDENTIFY AFFECTED PRODUCTS	All CombiDiagnost
ACTION TO BE TAKEN BY CUSTOMER / USER	1. There is no action to be taken by the user 2. If the customer detects a loosen screw of the tubes assembly, contact the local service engineer. In general the system can be used according to the Instruction for Use without restrictions. Should the customer feel uncertain regarding this action, please contact Philips.
ACTIONS PLANNED BY PHILIPS	Philips will provide: 1. the PE cable and 2. a modified screw fixation. 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 70900041.
FURTHER INFORMATION AND SUPPORT	If you would like any further information or support concerning this issue, please contact your local Philips representative.