MDRL FCO-MA 70900045 2019-Nov-25

URGENT — Medical Device
CombiDiagnost R90

CombiDiagnost Upgrade GCF systems to Rel. 1.0.5 + check of mains transformer thermo contact

Dear Customer,
cc: Chairman Medical Board and relevant Head of Departments
A problem has been detected in the Philips *CombiDiagnost R90* GCF that, if it were to re-occur, could pose a risk for patients or users. This *Medical Device Recall/Correction Letter* 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: Technical Support Line: 1-800-722-9377.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

[redacted]

Michael Mizrachi
Head of Q&R DXR

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AFFECTED PRODUCTS	All CombiDiagnost R90 GCF systems are affected
PROBLEM DESCRIPTION	**Error 80 issue:** The table can be tilted by pressing the corresponding + or - tilt motion buttons ("Table Tilt Left/Right") or using the table up/down button ("Table Up/Down"). If using the Table Up/Down button, the table moves down and tilts back to horizontal position at the same time. When using the Table Up/Down button, the system can experience Error 80, which locks the geometry in that specific state. System operation cannot be restored by system reboot, but requires the intervention of a service engineer. **SPDU issue:** The SPDU (system power distribution unit) is the main power supply for the complete system without the x-ray generator. It contains a three-phase transformer with a power rate of about 7kVA, containing a thermo switch per phase to aid in powering down the unit in case of overheating. These switches may be incorrectly installed and not working.
HAZARD INVOLVED	**Error 80 issue:** The hazard associated with this defect is that the system gets stuck in negative or positive tilt / table does not move anymore. When imaging using contrast agent, if the patient is lying on the table with legs elevated above the head, the contrast agent may enter the brain, causing a headache unless the patient is removed from the system. **SPDU issue:** If the transformer overheats due to a first failure and the thermo switch is not activated, the device may begin to generate smoke. Should this occur, there is a risk of smoke inhalation and related issues to patients, operators or bystanders.
HOW TO IDENTIFY AFFECTED PRODUCTS	All CombiDiagnost R90 GCF systems are affected. The label at the backside of table identifies if it is a GCF system.
ACTION TO BE TAKEN BY CUSTOMER / USER	The customer can use the system according to the IfU (Instruction for Use). **Error 80 issue:** The issue can be prevented if the operator avoids tilting the table by Table Up/Down joystick and instead uses the Table Tilt Left/Right joystick. If the issue occurs, the operator should remove the patient from the table and bring him/her to upright position so that the contrast agent does not enter the brain. **SPDU issue:** The user should pay attention to whether it smells of smoke in the room. If this is the case, immediately engage the system emergency stop button on the table or geometry control console, remove patient, stop using the system for further examinations and contact customer service.

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ACTIONS PLANNED BY PHILIPS	Philips plans to install a system software version upgrade and to perform an On-Site check of the SPDU thermo contact at affected systems, which will eliminate these issues. 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 70900045.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative. Healthcare Representative/Modality Engineer: 1800-744-5477 or (overseas Number)