BU IGT Systems

FSN: 2018-IGTBST-020 2019, 26 February
DocID: DHF338320/ XCR609-190022

URGENT – Medical Device Correction

Medical Device: MultiDiagnost-Eleva, Urodiagnost, OmniDiagnost-Eleva and OmniDiagnost-Classic

<Date>
<Hospital/Clinic Name>

Locking plate inspection

cc: Chairman Medical Board and relevant Head of Departments

Dear Customer,
A problem has been detected in the MultiDiagnost-Eleva system that if it were to re-occur, could pose a risk for the patient, user or bystander standing in the vicinity of the system.

This Medical Device Correction 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, users or bystander.
- the actions planned by Philips to inspect the system and if needed, 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 until the system is inspected by Philips.

Following two cases identified during the execution of service activities of a MultiDiagnost Eleva system where a locking plate for one of several shafts on the system was missing, Philips initiated an investigation and confirmed that MultiDiagnost Eleva, Urodiagnost, OmniDiagnost Eleva and OmniDiagnost systems in the field must be inspected for missing locking plates.

In the following pages, detailed information and actions required are provided.

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]

R. Kathuria
Head Q&R IGT systems

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AFFECTED PRODUCTS

System name:	System Code:
MultiDiagnost Eleva	708032
Urodiagnost	708033
MultiDiagnost Eleva with Flat Detector	708034
MultiDiagnost Eleva with Flat Detector	708035
MultiDiagnost Eleva	708036
MultiDiagnost Eleva with Flat Detector	708037
MultiDiagnost Eleva with Flat Detector	708038
OmniDiagnost Eleva	708026 708027 708028
OmniDiagnost Classic	70859 708023 708024 708025

PROBLEM DESCRIPTION

For the height and tilt movement of the stand/table, the MultiDiagnost-Eleva, Urodiagnost and OmniDiagnost systems have 2 actuators that are connected to the system stand by 4 shafts. The position of each of these shafts is secured by a locking plate.

During service of two MultiDiagnost Eleva systems, it was noticed that a locking plate was missing. In one of these cases, the shaft was still properly positioned after the system had been in use for 9 years. In the other case, involving a system that had been in use for 5 years, the shaft was no longer properly positioned but was still holding the actuator.

Over time, a missing locking plate may result in the shaft of the corresponding connection point becoming improperly positioned. If the shaft works its way totally out of position, it could result in unexpected stand/table tilt movement that cannot be stopped by the user.

HAZARD INVOLVED

In case of an unexpected stand/table tilt movement that cannot be stopped by the user there is a risk of injury for the patient, user or bystander standing in the vicinity of the system.

HOW TO IDENTIFY AFFECTED PRODUCTS

All units of the systems identified in the section "Affected Products" above are possibly affected.

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ACTION TO BE TAKEN BY CUSTOMER / USER	A copy of this Field Safety Notice shall be placed together with the documentation of the system until the system has been inspected by Philips.
ACTIONS PLANNED BY PHILIPS	All systems in the field that potentially could have a missing locking plate, will be inspected by Philips free of charge. If a locking plate is found missing, Philips will secure the system until a locking plate is installed so that use of the system can continue. Additionally, Philips will check three other locking plates of the system. These locking plates do not pose a safety risk. You will be contacted by our local Philips representative to schedule this inspection. This action will start effective from March 2019.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: Technical Support Line: 1-800-722-9377. Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number)