BU IGT Systems

FSN: 2018-IGTBST-005 May 2018
DocID: DHF312811
XCR609-180010

URGENT - Field Safety Notice

Medical Device: OmniDiagnost-Eleva and OmniDiagnost-Classic

Tilt actuator base unit

Dear Customer,
A problem has been detected in the OmniDiagnost-Eleva and OmniDiagnost-Classic systems that if it were to re-occur, could pose a risk for the patient, user or bystanders.

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 until the system is corrected by Philips.

Philips has been reported instances in which the table of the OmniDiagnost system (OD-Eleva) suddenly started to rotate from 0 to 90 degree (table arm down) with high speed. The cause of this unexpected rotation movement is related to an issue with the fixation of the upper and lower tilt actuator.

If the system rotates uncontrolled, there is a risk of injury for the patient on the table.
A rotating table also might hit the user or bystander standing near the system.

If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

R. Kathuria
Head Q&R IGT systems

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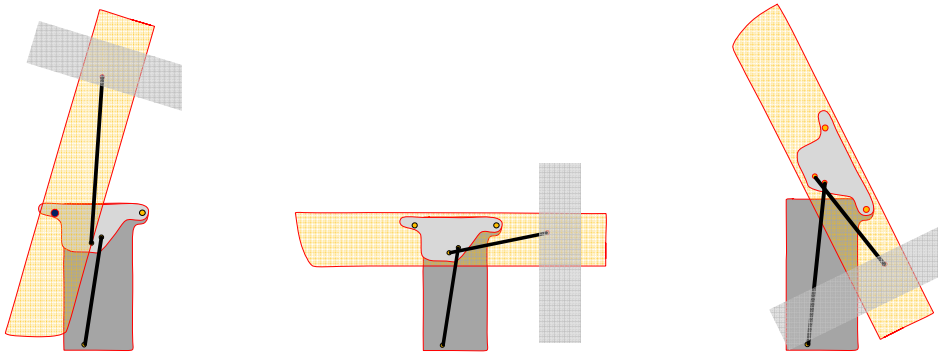
AFFECTED PRODUCTS	**System name:** / **System Code:** OmniDiagnost Eleva: 708026, 708027, 708028 OmniDiagnost Classic: 70859, 708023, 708024, 708025
PROBLEM DESCRIPTION	The fixation of the upper and lower tilt actuator, of the Omnidiagnost system might break off and the table will start to rotate from 0 to + 90 /- 90 degree with high speed. This rotating movement can not be stopped by the user.  Tilt towards - 90° Table horizontal Tilt towards + 90°
HAZARD INVOLVED	If the fixation of the actuator breaks off and if the point of gravity of the table is beyond its rotation point, the table starts to rotate uncontrolled to its + / - 90 degree end point, potentially leading to the patient falling off the table. During procedures, the system is remotely operated from the control room. In case of an uncontrolled rotation, there is a risk of injury for the patient, user or bystander standing in the vicinity of the system (e.g. the tube may hit the legs of that person). This might lead to harm that necessitates medical intervention for the person involved.
HOW TO IDENTIFY AFFECTED PRODUCTS	All units of the systems identified in the section “Affected Products” above are affected.

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ACTION TO BE TAKEN BY CUSTOMER / USER	Stop using the system and call your Philips representative if any of the following situations occurs: • the table height or tilt movement is not working. • you notice a cracking sound or snapping sound different than the normal sound during height or tilt movement. • you experience a blockade in the table height or tilt movement during system movements. • the system is having an unexpected collision or the system had an unexpected collision in the past 2 months. • you have used a CPR stand that obstructed the system, or • you notice any (other) unusual system behavior beyond the normal use of the system. Avoid collisions with the table and base stand of the system by ensuring that no obstacles are placed around the system. Customer shall ensure that all staff with access to the affected systems are informed of the content of this Field Safety Notice. A copy of this Field Safety Notice shall be placed together with the documentation of the system until the system has been corrected by Philips.
ACTIONS PLANNED BY PHILIPS	All possibly affected products in the field will be corrected by means of a field change order free of charge. A Philips representative will replace affected material on the upper and lower tilt actuator in the affected systems. You will be contacted by our local Philips representative to schedule this corrective action. This action will start effective July 2018.
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact your local Philips representative: **0800 80 3000**