

URGENT - Field Safety Notice
FCO72200279

Allura systems. Actuator Monitor Ceiling Suspension (MCS)

Monitor suspension failure

Dear Customer,

We have noticed an issue with a Philips Allura System that, if it were to re-occur, could potentially pose a risk for the patient, user and/or bystanders. This Field Safety Notice notification 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.

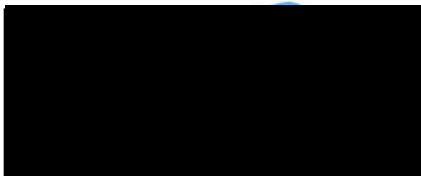
Please retain a copy with the equipment Instruction for Use.

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.



19th June 2015

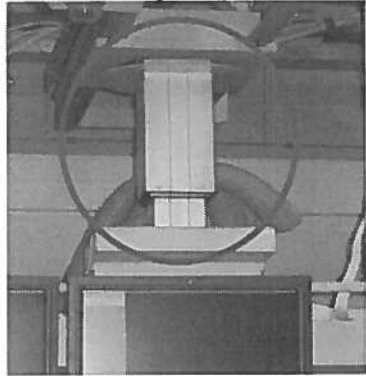
H. Weusten
Sr. Director Q&R BU IGT systems



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<p>AFFECTED PRODUCTS</p>	<p>System: Allura Xper FD10 Allura Xper FD10/10 Allura Xper FD20 Allura Xper FD20/10 Allura Xper FD10 OR Table Allura Xper FD20 OR Table Allura Xper FD10/10 OR Table Allura Xper FD20 Biplane OR Table</p> <p>Productcode: 722010, 722011, 722012, 722013, 722022, 722023, 722024, and 722025.</p> <p>Applies to: Actuator Short Assy: THC8AWDS-121 989600-184-665 Actuator Long Assy: THC8AWDS-122 989600-184-654</p> 
<p>PROBLEM DESCRIPTION</p>	<p>A call was registered at our service department with respect to an issue with a failing Monitor Ceiling Suspension (MCS) Actuator of an Allura Xper system. The actuator assembly had become detached and the monitor carriage with a flexvision monitor dropped to its lowest position. The Monitor Ceiling Suspension is designed to allow flexible positioning near the patient table when in use, and away from the patient when not in use. (park position)</p>
<p>HAZARD INVOLVED</p>	<p>When the Monitor Ceiling Suspension falls to its lowest position there is a possibility it might collide with patient or personnel in the room. There is also the possibility that the monitor ceiling suspension collides with other equipment in close proximity of the MCS.</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>All Allura Systems as mentioned above. The potential affected systems will be clearly identified by the local Philips Organization.</p>



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<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<p>In order to avoid any risk for patients, users or bystanders we recommend the following until the containment action FCO has been implemented. We recommend that you do not:</p> <ul style="list-style-type: none"> - Position or move the Monitor Ceiling Suspension above the patient. - Allow staff to stand under or close to the Monitor Ceiling Suspension. <p>Additionally avoid any unnecessary movement of the Monitor Ceiling Suspension and inform all possible System users.</p>
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>Two mandatory Field Safety Corrective Actions will be issued. Mandatory FCO72200279 as a containment action and will be free of charge. This FCO involves a check if the actuator serial number is on the affected product list. If the actuator is on the affected product list the containment action is to secure the MCS with straps to prevent the monitors to fall down in case the actuator fails. The expected date of this FCO will be June 2015. Actuators on the affected product list will be replaced with Mandatory FCO72200280 (corrective action)</p>
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>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></p>

