

8th Jan 2018

TO: WHOM IT MAY CONCERN
CC: Chairman Medical Board and relevant Head of Department

Attached is a Field Safety Notice/Field Corrective Order pertaining to the Allura Xper FD20 Biplane due to FCO 72200354. Please note that the serial number of the units affected are stated below:



If you need any further information or support concerning this issue, please contact your local Philips Healthcare Representative/Modality Engineer: 1800-744-5477 or (Overseas Number).

This is a mandatory requirement based on 21CFR Part 820 by USA FDA, thus we seek your cooperation to acknowledge that you are thus notified of the above within 5 working days from the issuance of this letter.

Acknowledged By:

Customer Name/Signature:

Company Name/Stamp:

Date:

URGENT - Field Safety Notice

Allura Xper systems

7th or 8th monitor on the Monitor Ceiling Suspension may disengage

Dear Customer,

A problem has been detected in Philips Allura Xper Systems, that if it were to re-occur, could pose a risk for patients or users.

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.

Philips has discovered through customer complaints a problem with mounting of the 7th or 8th monitor to the Monitor Ceiling Suspension. The 7th or 8th monitor attached to the Monitor Ceiling Suspension may disengage from the suspension arm and fall down.

Only Allura Xper systems with an attached 7th or 8th monitor on the Monitor Ceiling Suspension are affected.

When a 7th or 8th monitor disengages from the suspension arm it could pose a risk for the patient, user, bystander or service engineer.

If you need any further information or support concerning this issue, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,


K. Kathuna
Head Q&R IGT systems

URGENT - Field Safety Notice

Allura Xper systems

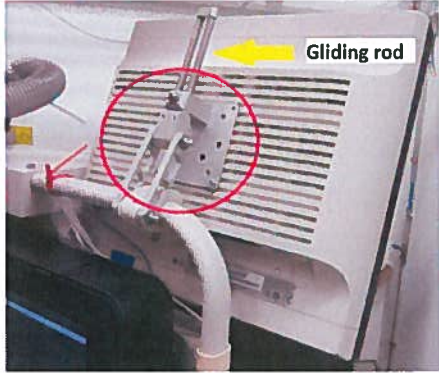

7th or 8th monitor on the Monitor Ceiling Suspension may disengage

AFFECTED PRODUCTS	<p>Only systems with an attached 7th or 8th monitor on the Monitor Ceiling Suspension are affected.</p> <table style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;">System name:</th> <th style="text-align: left; border-bottom: 1px solid black;">System code:</th> </tr> </thead> <tbody> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD10 Ceiling</td> <td style="border-bottom: 1px solid black;">722001</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD10 Floor</td> <td style="border-bottom: 1px solid black;">722002</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD10</td> <td style="border-bottom: 1px solid black;">722003 722010 722026</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD10 / 10</td> <td style="border-bottom: 1px solid black;">722005 722011 722027</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD20</td> <td style="border-bottom: 1px solid black;">722006 722012 722028</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD20 Biplane</td> <td style="border-bottom: 1px solid black;">722008 722013</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD20 OR table</td> <td style="border-bottom: 1px solid black;">722015 722023 722035</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD20 Biplane OR table</td> <td style="border-bottom: 1px solid black;">722020</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD20 / 10</td> <td style="border-bottom: 1px solid black;">722029</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD20 / 20</td> <td style="border-bottom: 1px solid black;">722038</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD20 / 20 OR table</td> <td style="border-bottom: 1px solid black;">722039</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD20 / 15</td> <td style="border-bottom: 1px solid black;">722058</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Allura Xper FD20 / 15 OR table</td> <td style="border-bottom: 1px solid black;">722059</td> </tr> </tbody> </table>	System name:	System code:	Allura Xper FD10 Ceiling	722001	Allura Xper FD10 Floor	722002	Allura Xper FD10	722003 722010 722026	Allura Xper FD10 / 10	722005 722011 722027	Allura Xper FD20	722006 722012 722028	Allura Xper FD20 Biplane	722008 722013	Allura Xper FD20 OR table	722015 722023 722035	Allura Xper FD20 Biplane OR table	722020	Allura Xper FD20 / 10	722029	Allura Xper FD20 / 20	722038	Allura Xper FD20 / 20 OR table	722039	Allura Xper FD20 / 15	722058	Allura Xper FD20 / 15 OR table	722059
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Allura Xper systems


7th or 8th monitor on the Monitor Ceiling Suspension may disengage

<p>PROBLEM DESCRIPTION</p>	<p>Extra monitors, so called 7th or 8th monitor, mounted on the Monitor Ceiling Suspension (MCS), might disengage from the MCS and fall down. The two small set screws securing the two gliding rods into an aluminum block of the support arm can come loose because of vibrations and forces exerted on them.</p> <p>If the set screws have come loose gravity can keep the rods in position. However, if a force is exerted on the monitor pushing it forward, the monitor can topple forward. Once the monitor has toppled over it is only attached with its wires. If the monitor breaks loose of its wires it will drop on the floor.</p> <div style="display: flex; justify-content: space-around;">   </div>
<p>HAZARD INVOLVED</p>	<p>If the above described problem occurs, it may lead to harm to patient, user, bystander or service engineer, that may necessitate medical intervention.</p>
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>All units of the systems identified in the section "Affected Products" above with an attached 7th or 8th monitor are affected. Your local Philips organization will help you confirm that all of your affected systems have been identified.</p>

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Allura Xper systems

7th or 8th monitor on the Monitor Ceiling Suspensions may disengage

<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<ul style="list-style-type: none"> • Verify if the facility has a 7th or 8th monitor attached to the Monitor Ceiling Suspensions (MCS) <div style="text-align: center;">  </div> <ul style="list-style-type: none"> • Position an MCS with a 7th or 8th monitor only before or after an examination. • Avoid positioning the MCS above a patient/sterile field during the examination. • Users must ensure that all staff with access to the affected system are informed of the contents of this Field Safety Notice. • The customer is requested to place this field safety notice with the documentation of the system until this correction has been implemented.
<p>ACTIONS PLANNED BY PHILIPS</p>	<ul style="list-style-type: none"> • All possibly affected products in the field will be corrected free of charge. • A Philips representative will secure the set screws in the affected systems. This will effectively make it impossible for the set screws to loosen under the prevailing conditions. • You will be contacted by our local Philips representative to schedule an appointment to make the necessary corrective action. • This action will start effective December 2017.
<p>FURTHER INFORMATION AND SUPPORT</p>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative.</p>