

## **URGENT - Field Safety Notice**

### **Allura Xper systems**

#### **7<sup>th</sup> or 8<sup>th</sup> 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 7<sup>th</sup> or 8<sup>th</sup> monitor to the Monitor Ceiling Suspension. The 7<sup>th</sup> or 8<sup>th</sup> monitor attached to the Monitor Ceiling Suspension may disengage from the suspension arm and fall down.

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

When a 7<sup>th</sup> or 8<sup>th</sup> 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 or the UK Philips Customer Care Service Centre on 0870 532 9741.

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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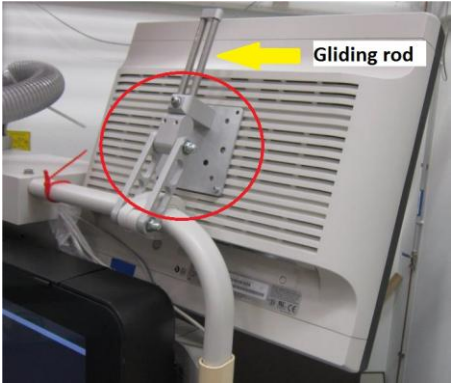

**7<sup>th</sup> or 8<sup>th</sup> monitor on the Monitor Ceiling Suspension may disengage**

| <b>AFFECTED PRODUCTS</b>          | <p>Only systems with an attached 7<sup>th</sup> or 8<sup>th</sup> monitor on the Monitor Ceiling Suspension are affected.</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;"><b>System name:</b></th> <th style="text-align: left; border-bottom: 1px solid black;"><b>System code:</b></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> | <b>System name:</b> | <b>System code:</b> | 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 |
|-----------------------------------|--|---------------------|---------------------|--------------------------|--------|------------------------|--------|------------------|----------------------------|-----------------------|----------------------------|------------------|----------------------------|--------------------------|------------------|---------------------------|----------------------------|-----------------------------------|--------|-----------------------|--------|-----------------------|--------|--------------------------------|--------|-----------------------|--------|--------------------------------|--------|
| <b>System name:</b>               | <b>System code:</b>  |                     |                     |                          |        |                        |        |                  |                            |                       |                            |                  |                            |                          |                  |                           |                            |                                   |        |                       |        |                       |        |                                |        |                       |        |                                |        |
| 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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| <p><b>PROBLEM DESCRIPTION</b></p>               | <p>Extra monitors, so called 7<sup>th</sup> or 8<sup>th</sup> 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><b>HAZARD INVOLVED</b></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><b>HOW TO IDENTIFY AFFECTED PRODUCTS</b></p> | <p>All units of the systems identified in the section "Affected Products" above with an attached 7<sup>th</sup> or 8<sup>th</sup> 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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|   |  |
|---|--|
| <p><b>ACTION TO BE TAKEN BY CUSTOMER / USER</b></p> | <ul style="list-style-type: none"> <li>• Verify if the facility has a 7<sup>th</sup> or 8<sup>th</sup> monitor attached to the Monitor Ceiling Suspensions (MCS)</li> </ul> <div style="text-align: center;">  </div> <ul style="list-style-type: none"> <li>• Position an MCS with a 7<sup>th</sup> or 8<sup>th</sup> monitor only before or after an examination.</li> <li>• Avoid positioning the MCS above a patient/sterile field during the examination.</li> <li>• Users must ensure that all staff with access to the affected system are informed of the contents of this Field Safety Notice.</li> <li>• The customer is requested to place this field safety notice with the documentation of the system until this correction has been implemented.</li> </ul> |
| <p><b>ACTIONS PLANNED BY PHILIPS</b></p>            | <ul style="list-style-type: none"> <li>• All possibly affected products in the field will be corrected free of charge.</li> <li>• 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.</li> <li>• You will be contacted by our local Philips representative to schedule an appointment to make the necessary corrective action.</li> <li>• This action will start effective December 2017.</li> </ul>   |
| <p><b>FURTHER INFORMATION AND SUPPORT</b></p>       | <p>If you need any further information or support concerning this issue, please contact your local Philips representative or the UK Philips Customer Care Service Centre on 0870 532 9741.</p>   |