

**URGENT - Field Safety Notice**  
**Allura FC**

**Anti-collision improvement**

Dear Customer,

As part of Philips' continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Philips Allura FC, we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information regarding:

- what the issue is, and under what circumstances it may occur
- the actions you can take to avoid or minimize the occurrence of the issue
- the actions planned by Philips to correct the issue

**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, please contact your local Philips representative:

<Philips representative contact details to be completed by the KM / country>

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,

  
Director Q&R, DMC Pune, India.

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<b>AFFECTED PRODUCTS</b>	Allura FC 723003
<b>PROBLEM DESCRIPTION</b>	<ol style="list-style-type: none"><li>1) While positioning the detector close to the patient, there is a possibility that c-arm lightly touches the patient.</li><li>2) In another complaint, a patient got entrapped. One of the reasons for entrapment was that the angular motion of the c-arm was configured for more than 45 degrees. The other reason being user errors.</li><li>3) When the anti-collision function senses and stops the c-arm motion in the direction of the patient, sometimes it cannot be retracted back by the joystick but needs the operation of anti-collision override switch.</li></ol>
<b>HAZARD INVOLVED</b>	There is possibility of c-arm touching the patient and causing minor injury. Patient can also get entrapped leading to a risk of asphyxia.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	All Allura FC systems manufactured before January 2015 will be affected systems. Manufacturing date can be ascertained from the system label.
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	-Customer should be careful while positioning the detector close to the patient. -Anti-collision override switch should be used if the c-arm does not retract back using the joystick.
<b>ACTIONS PLANNED BY PHILIPS</b>	A mandatory Field Safety Corrective Action will be issued to solve these problems. This field safety corrective action identified as FCO72300014 and will be free of charge. It consists of a replacing existing anti-collision sensor and software to improve the performance of the anti-collision function. The expected date of this field safety corrective action will be 31 January 2015 for implementation within 6 months.
<b>FURTHER INFORMATION AND SUPPORT</b>	<Philips representative contact details to be completed by the KM / country>