

**URGENT - Field Safety Notice**  
**Medical Device Correction**  
***Azurion Interventional Fluoroscopic X-ray system***  
***Loosening screws on the C-arm roll motor***

Dear Customer,

A problem has been detected in the Philips Azurion 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 until the problem is solved by Philips.

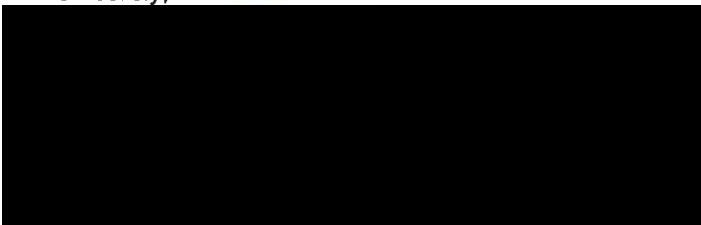
Philips has identified that no torque was specified for the four screws that connect the gearbox and the mounting flange within the C-arm roll motor. If the torque is too low, the movement of the system may lead to stress on the screws, which potentially could result in the four screws becoming loose. If this occurs, the C-arm could rotate freely over the "roll" movement and the system would not be available for use. No harm has been reported to Philips.

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.

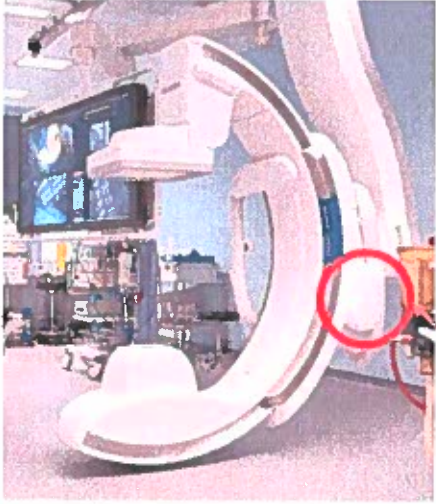
Sincerely,



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<b>AFFECTED PRODUCTS</b>	Philips Azurion 7 M20 systems distributed between October 2018 and July 2019.
<b>PROBLEM DESCRIPTION</b>	<p>Philips has identified that no torque was specified for the four screws that connect the gearbox and the mounting flange within the C-arm roll motor. If the torque is too low, the movement of the system may lead to stress on the screws, which potentially could result in the four screws becoming loose. If this occurs, the C-arm could rotate freely over the "roll" movement and the system would not be available for use.</p>  <p>The roll motor is under the encircled cover</p>
<b>HAZARD INVOLVED</b>	<p>If the four screws of the C-arm roll motor assembly become totally loose, the C-arm could rotate freely over the "roll" movement. The system would not be available for use and there could be a delay of the treatment. An uncontrolled movement of the C-arm could result in collision and/or entrapment.</p>
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<p>The affected systems are the Philips Azurion model 7 M20 distributed between October 2018 and July 2019. Philips will be contacting directly customers with affected systems.</p>
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	<p>Ensure all system users are aware of this issue and place a copy of this Field Safety Notice with the Instructions for Use of the system until it has been corrected by Philips.</p>

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<b>ACTIONS PLANNED BY PHILIPS</b>	Philips will exchange the roll motor in all affected systems, free of charge. This action will start in March 2020. You will be contacted by our local Philips representative to schedule an appointment to replace the roll motor.
<b>FURTHER INFORMATION AND SUPPORT</b>	If you need any further information or support concerning this issue, please contact your local Philips representative.



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