

URGENT - Field Safety Notice

Multidiagnost Eleva, MultiDiagnost Eleva with Flat Detector and UroDiagnost Eleva systems.

C-arm may float freely and possibly sag.

Dear Customer,

This Field Safety Notice is intended to inform you that recently a problem has been detected related to our MultiDiagnost Eleva system, MultiDiagnost Eleva with Flat Detector and UroDiagnost Eleva systems. Philips has determined that two bolts in the system may break, causing the C-arm to float freely in the lateral direction and possibly sag.

If this were to occur, a patient on the examination table and anyone in the direct path of a sagging C-arm could be struck. However, the only one such failure reported to Philips occurred while the system was being serviced and did not result in injury.

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.
- the actions planned by Philips to correct the problem.

This document contains important information for the continued safe and proper use of your equipment

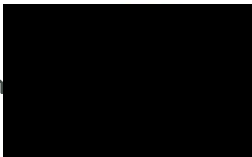
Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

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 agencies.

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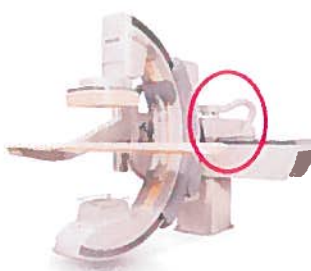
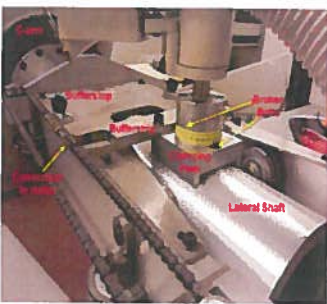
H. Weusten
Head Q&R IGT systems



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<p>AFFECTED PRODUCTS</p>	<table border="1"> <thead> <tr> <th>SystemName:</th> <th>Productcode:</th> </tr> </thead> <tbody> <tr> <td>MultiDiagnost Eleva</td> <td>708032</td> </tr> <tr> <td>UroDiagnost</td> <td>708033</td> </tr> <tr> <td>MultiDiagnost Eleva with Flat Detector</td> <td>708034</td> </tr> <tr> <td>MultiDiagnost Eleva</td> <td>708036</td> </tr> <tr> <td>MultiDiagnost Eleva with Flat Detector</td> <td>708037</td> </tr> <tr> <td>MultiDiagnost Eleva with Flat Detector</td> <td>708038</td> </tr> </tbody> </table>	SystemName:	Productcode:	MultiDiagnost Eleva	708032	UroDiagnost	708033	MultiDiagnost Eleva with Flat Detector	708034	MultiDiagnost Eleva	708036	MultiDiagnost Eleva with Flat Detector	708037	MultiDiagnost Eleva with Flat Detector	708038
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<p>PROBLEM DESCRIPTION</p>	<p>The two bolts that attach the clamping plate to the lateral shaft may break. This may cause the C-arm to float freely. Depending on the orientation of the free-floating C-arm and any other forces applied to it the C-arm could move laterally forward, slide out of its bearings and then possibly sag.</p> <div style="display: flex; justify-content: space-around;">   </div> <p>These pictures indicate where the bolts and lateral shaft are located in the scan carrier.</p>														
<p>HAZARD INVOLVED</p>	<p>If a sagging C-arm strikes a patient or operator, it could potentially result in a risk to health. However this risk to health is rarely to occur.</p> <p>To date, there have been no reports of injury associated with this event. There only has been one report of failure noted during a service call.</p>														
<p>HOW TO IDENTIFY AFFECTED PRODUCTS</p>	<p>All units of the systems identified above are affected. Your local Philips organization will help you confirm that all of your affected systems have been identified.</p>														
<p>ACTION TO BE TAKEN BY CUSTOMER / USER</p>	<ul style="list-style-type: none"> • If the C-arm moves in any unexpected manner or fails to move when directed, please contact your local Philips representative immediately. • Ensure that all staff with access to affected systems are informed of the contents of this Field Safety Notice. • Place this letter with your user documentation. 														
<p>ACTIONS PLANNED BY PHILIPS</p>	<p>You will be contacted by our service organization to schedule an appointment to make the necessary repairs.</p>														



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FURTHER INFORMATION AND SUPPORT	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>
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