

**URGENT - Field Safety Notice  
EasyVision RAD**

**Inaccurate image processing using EasyVision Release 4.2 V2**

Dear Customer,

A problem has been detected on our Radiography system EasyVision RAD.

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.

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 Agency.

Philips apologizes for any inconveniences caused by this problem.

Sincerely,

<Signature, to be signed by Senior Management of the BS/BU/BL or GS&S/KM>

<Name>

<Function>



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<b>AFFECTED PRODUCTS</b>	EasyVision RAD Release 4.2 V2 Level 2 ... 7
<b>PROBLEM DESCRIPTION</b>	<p>Releases up to 4.2 Level 7 <u>service pack 3</u> Wrong measurements at viewing station when images are zoomed to shutter before they are sent to PACS. A potential misinterpretation of object / anatomy size can only happen when:</p> <ul style="list-style-type: none"> <li>▪ the "zoom to shutter" or "numeric zoom" function is applied on the image and</li> <li>▪ the image is exported afterwards and</li> <li>▪ measurements are performed on an image reading workstation without further calibration on the workstation</li> </ul> <p>Release 4.2 Level 7 <u>service pack 4</u> In case of images are automatically sent to PACS and are rotated or mirrored at the EV RAD they are exported in flipped orientation. Last setting / view of manipulated image are applied to all following images.</p>
<b>HAZARD INVOLVED</b>	See details above.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	All systems EasyVision RAD systems which export images to a PACS or similar destinations.
<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	<p>In order to avoid misinterpretations of object / anatomy size the zooming function of the EasyVision RAD may not be used when ...</p> <ul style="list-style-type: none"> <li>▪ images are exported to a PACS or similar destination and</li> <li>▪ the EasyVison RAD is configured to 'rotate/mirror/zoom = burn in'</li> </ul> <p>To avoid an unconscious rotation or mirroring of images such function may never be used at the EasyVision RAD if the images have been configured for autoexport.</p>
<b>ACTIONS PLANNED BY PHILIPS</b>	Current systems need to be upgraded to latest release.
<b>FURTHER INFORMATION AND SUPPORT</b>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative:</p> <p>&lt;Philips representative contact details to be completed by the KM / country&gt;</p>

