

**URGENT - Field Safety Notice  
Product Correction – iSite PACS**

**3.5.x Multi-Planar Reformation (MPR) Generated Images.  
Incorrect scout lines and localizer crosshair display on MPR**

Dear Customer,

A problem has been detected in the Philips iSite PACS, 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.

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,

Thomas Myers  
Senior Manager, Quality & Regulatory and Business Excellence  
Philips Healthcare, Radiology Informatics.



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<b>AFFECTED PRODUCTS</b>	iSite PACS v. 3.5.x
<b>PROBLEM DESCRIPTION</b>	<p>Images generated using the iSite <u>native</u> Multi-Planar Reformation (MPR) feature could be oriented incorrectly if the patient is scanned in orientations other than <b>Supine Head First</b>. Depending on your scanner and the way the reconstructed images are formatted, this behavior could vary:</p> <p>For generated coronal images:</p> <ul style="list-style-type: none"> <li>• The generated images could be flipped around the “Y-axis” (i.e., Left and Right labels are misplaced on the images).</li> <li>• The slices could be ordered incorrectly (i.e., the scout line on the axial images is on the anterior part of the body while the coronal image displayed is of the posterior part of the body).</li> </ul> <p>For generated sagittal images:</p> <ul style="list-style-type: none"> <li>• The generated images could be flipped around the “Y-axis” (i.e., Anterior and Posterior labels are misplaced on the image).</li> <li>• The slices could be ordered incorrectly (i.e., the scout line on the axial images is on the left side of the body while the sagittal image displayed is of the right side of the body).</li> </ul>
<b>HAZARD INVOLVED</b>	This mis-sampling leads to the construction and display of a deformed 3d multi planar reconstruction, deviant from the true image by the degree of the gantry tilt (degree of obliqueness). Although no data is artificially created or omitted, the image is deformed, and the correlation to the localizer is also incorrect, again, to the degree of deviation from a true axial.
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	To determine which version of iSite PACS you are using launch iSite Enterprise or Radiology and the version identifier will be shown on the login screen.



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<b>ACTION TO BE TAKEN BY CUSTOMER / USER</b>	<p>Until a corrected version of iSite PACS is available, we <b>require</b> all customers to perform the following measures to their systems:</p> <ol style="list-style-type: none"> <li>1. Disable the MPR feature for all users until a fix is deployed.</li> <li>2. Post this product notification letter.</li> </ol> <p><b><u>Steps to Disable MPR in iSite 3.5</u></b></p> <ol style="list-style-type: none"> <li>1. Log into iSuite</li> <li>2. Select <b>Sys Admin, Security</b>, option <b>Access Group</b></li> <li>3. Click on an <b>Access Group</b></li> <li>4. Click on <b>+ security codes</b> button</li> <li>5. Ensure that security code <b>ISTMPRACC</b> is unselected</li> <li>6. Click on <b>ok</b></li> <li>7. Click on <b>update</b></li> <li>8. Repeat steps 3 to 6 for all Access Groups</li> </ol>
<b>ACTIONS PLANNED BY PHILIPS</b>	<p>Philips Radiology Informatics is working on permanently removing the MPR feature to address the aforementioned usage of the product planned for completion by the end of August 2008. This upgrade will be installed by Philips via FCO 22945704-06232008-003 and will be implemented free of charge. You, the customer, will be contacted by Philips for implementation of the corrective action.</p>
<b>FURTHER INFORMATION AND SUPPORT</b>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative: &lt;Philips representative contact details to be completed by the KM / country&gt;</p>

