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Urgent Product Correction

via certified mail, return receipt requested.

To: All Philips iSite PACS 3.5 Customers
Date: January 23rd, 2008
Subject: iSite PACS version 3.5.0 – 3.5.65 Multi-Planar Reformation (MPR)
Generated Images. FCO #2954704-01/04/08-001-C

Philips Healthcare is writing to inform iSite PACS 3.5 users of the potential for MPR generated images to be oriented incorrectly.

Description of the Potential Problem:

Images generated using the iSite PACS native Multi-Planar Reformation (MPR) feature could be oriented incorrectly if the patient is scanned in orientations other than **Supine Head First**. Depending on your scanner and the way the reconstructed images are formatted, this behavior could vary:

For generated coronal images:

- The generated images could be flipped around the "Y-axis" (i.e., Left and Right labels are misplaced on the images).
- 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).

For generated sagittal images:

- The generated images could be flipped around the "Y-axis" (i.e., Anterior and Posterior labels are misplaced on the image).
- 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).

Required Action:

Determine which version of iSite PACS you are using by launching iSite Enterprise or Radiology and the version identifier will be shown on the login screen. If you are unsure, please contact either your customer advocate or customer care at 877-328-2808.

Philips is currently working to provide a fix for this problem as soon as possible. The upgrade is expected to be available by the end of January 2008 and we expect to complete the upgrade process within 6 months, which will be performed at no cost to you.

If your site is using an effected version of the software, Philips requires that you disable the MPR feature by performing the following actions:

1. Log into iSuite

Philips Healthcare,
Radiology Informatics
4100 East Third Avenue, Suite 101
Foster City, CA 94404



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2. Select **Sys Admin, Security**, option **Access Group**
 3. Click on an **Access Group**
 4. Click on **+ security codes** button
 5. Ensure that security code **ISTMPRACC** is unselected
 6. Click on **ok**
 7. Click on **update**
 8. Repeat steps 3 to 6 for all Access Groups
- Make sure that you always view the axial, sagittal or coronal images generated by the imaging modality scanner, these images will always have the correct orientation when displayed on the iSite PACS workstation.
 - When reviewing historical reformatted images, users **MUST** always cross reference the image orientations with the original axial images generated by the imaging modality scanner.

Please insert this notification letter into your user's manual and notify your respective users group accordingly. If you have any comments or questions regarding the information presented in this letter, please contact Philips Radiology Informatics Customer Care at (877) 328-2808. In your communication, please refer to this notification and associated FCO #2954704-01/04/08-001-C.

We at Philips sincerely apologize for this error and for the disruption and inconvenience this may cause you.

Sincerely,


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

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