

Philips Medical Systems

Number: CNL070927

## ***Urgent Device Notification***

*This document contains important information for the continued proper use of your equipment. Please pass this on to technologists, reading physicians and other persons who need to be aware of the contents of this update, and maintain a copy with the system instructions for use.*

September 27, 2007

RE: Maximum Intensity Projection (MIP) images produced from respiratory gated images by Tumor Localization (Tumor LOC) on Brilliance Big Bore scanner console will have incorrect Left /Right (L/R) labels for certain patient orientations and view conventions.

Affected Products: The Tumor Localization application that can be run on Brilliance Big Bore CT scanners using software v2.2.1 through v2.2.5.

Dear Customer:

Philips Medical Systems would like to inform you of a L/R image labeling issue that can occur when the Tumor Localization Application is used to create and export MIP images generated from certain patient orientations and view conventions.

### **WARNING: Failure to follow these instructions may lead to improper treatment.**

When the operator uses the Tumor Localization application function to create MIP (or Average IP, or Minimum IP) images from retrospective pulmonary gated image datasets for certain patient orientations and view conventions, and exports these images, the Left / Right (L/R) patient orientation labels will be incorrect on the stored images.

The table below identifies combinations of patient orientation and view convention which will cause the problem. Any combination of patient orientation and viewing convention denoted in green produces MIP images with L/R labels which are correct. Any combination of patient orientation and viewing convention denoted in red produces MIP images with L/R labels which are incorrect.

To avoid incorrect patient orientation labeling, only use the combinations of patient orientation and viewing convention denoted in green.

Note that data previously acquired with the incorrect combinations should not be used to create MIP (or AvgIP, or MinIP) images.



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# PHILIPS

**RE: Incorrect L/R orientation labeling on MIP images produced from respiratory gated images by Tumor Localization (Tumor LOC) on Brilliance Big Bore scanner console.**

## Correctness of L/R orientation labels by combination of Patient Position and View Convention

	RoL (Right on Left)	VfB (View from Bed)	VfF (View from Feet)
Head First Supine			
Head First Prone			
Feet First Supine			
Feet First Prone			



Please ensure that this letter is distributed to all affected users including referring physicians, that it is posted appropriately, and that a copy is kept with the Instructions for Use until otherwise notified in writing by Philips that a corrected software version has been installed on your system.

Patient, technologist, and product safety continues to be our overriding concern. As a valued customer of Philips Medical Systems, we want to ensure that your Philips equipment is being used in a safe manner.

Philips is currently correcting this issue and will provide updates free of charge to our customers.

**Please direct questions to our Customer Care Center (1-800-722-9377, option 5: Diagnostic Imaging, option 1: CT) or to your local Philips Medical Systems office.**

Sincerely,

[Redacted Signature]

[Redacted Title]

Director, CT Regulatory Affairs & Compliance  
Philips Medical Systems

