

This document contains important information for the continued proper use of your equipment. Please pass this on to other persons who need to be aware of the contents of this update.

PRODUCT SAFETY NOTIFICATION

May 30, 2007

RE: Gemini TF 64 slice (Brilliance 64 CT scanners subcomponent): – Potential artifacts in head images

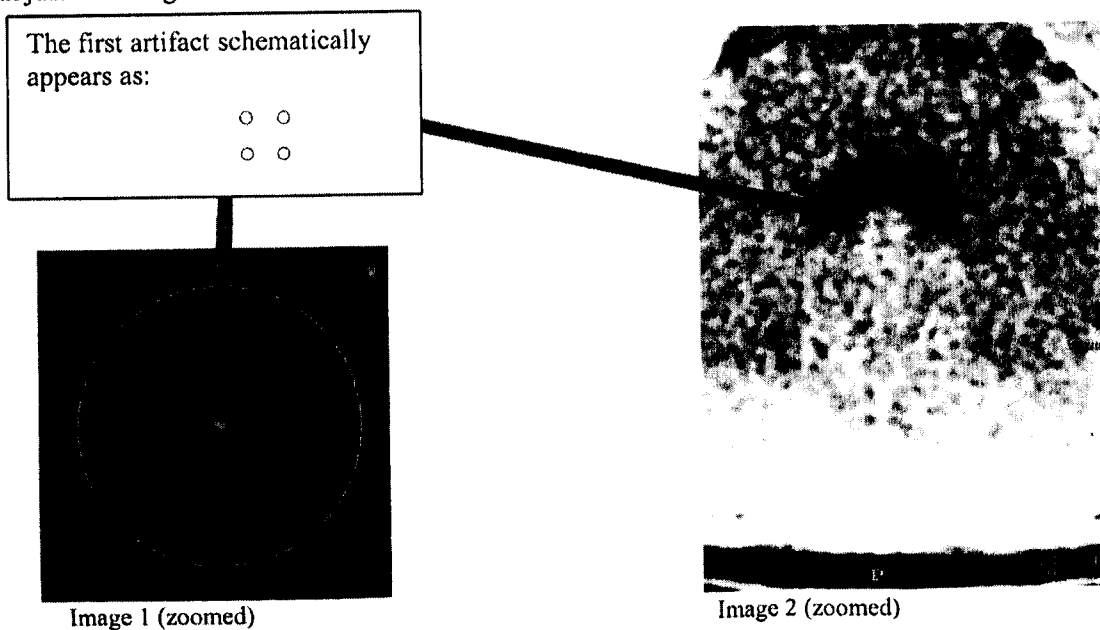
Dear Customer;

Philips Medical Systems would like to make you aware of two potential artifacts that may appear in some images from head scans on the Brilliance 64 CT systems subcomponent of the Gemini TF 64 slice system. Patient, operator, 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.

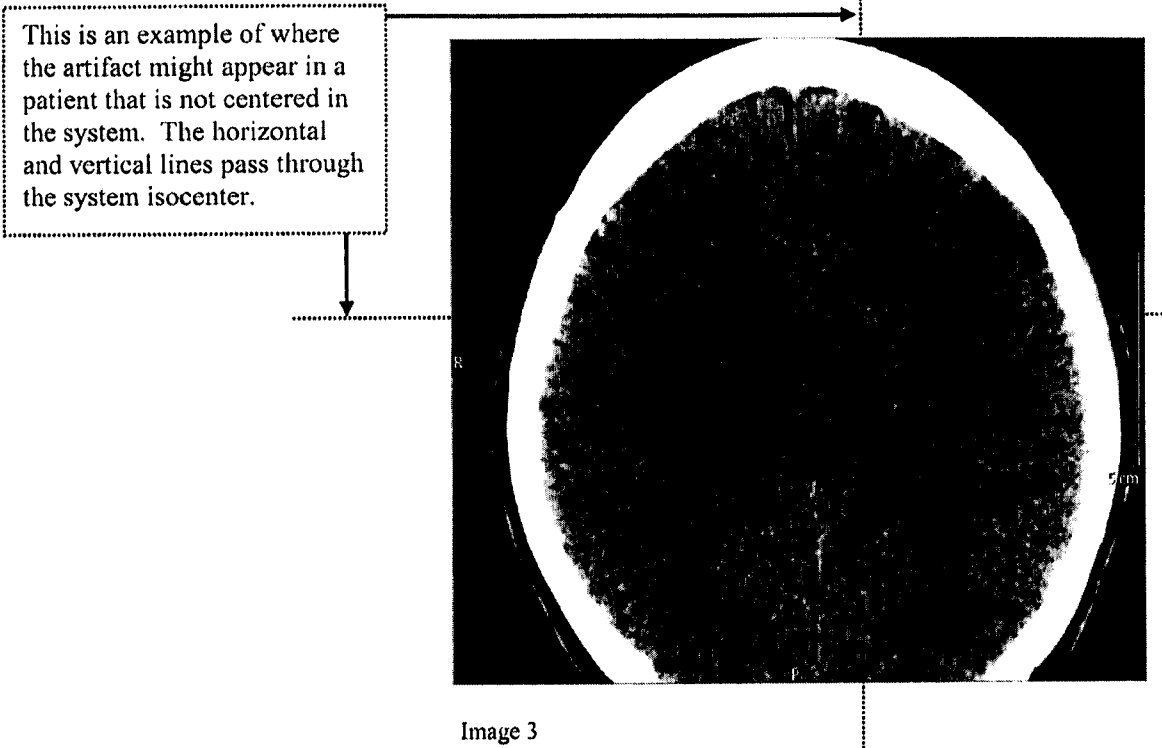
Warning: Misreading of these artifacts may lead to misdiagnosis and improper treatment.

There are common characteristics to both artifacts that will assist in identification. If present, they are always located at the system isocenter and not the image center. If the patient is positioned off-center, the artifact will also be located off-center (see Image 3). It is helpful to display the images in a sagittal or coronal view as shown in images 4 & 5 to confirm if the artifact is present.

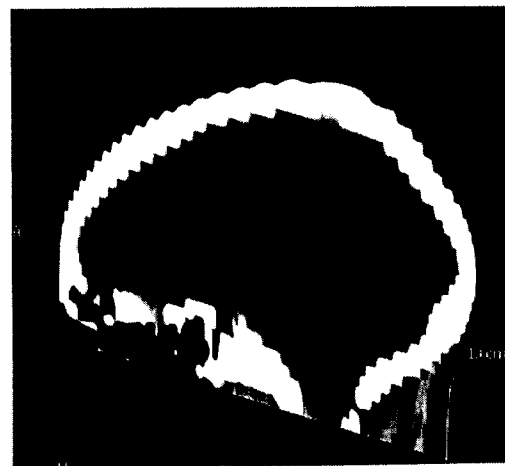
The first artifact will be visualized as a small pattern of four low contrast white or black dots as seen in images 1 and 2. There may or may not be a central dot. It typically appears in a series of images rather than just one image.



The second artifact will be visualized as a slight blush as seen in image 3. This image also provides an example of the how the artifact would be visualized if the patient was located off center.



Please see the images 4 and 5 below as an example of how to identify the appearance of an artifact as a vertical band on 5mm thick axial tilted brain studies (See Images 4, 5)



Philips is currently investigating methods for the detection and removal of this artifact, and will make any methods that may be developed available free of charge to our customers.


Please ensure that this PSN is distributed within your site to all affected users, that it is posted appropriately, and that a copy is kept with the Instructions for Use until further notice.

Please direct questions to our Remote Technical Assistant Center (RTAC) 1-800-722-9377 or to your local Philips Medical Systems office.

Sincerely,

A large black rectangular redaction box covering the signature of the sender.

Manager, Regulatory Affairs
on behalf of


Director, PET Q&R

**Philips Medical Systems (Cleveland), Inc.
595 Miner Road
Cleveland, OH 44143**