

URGENT FIELD SAFETY NOTICE

Reference: Acuity ConeBeam Computed Tomography (CBCT) 2.0.11 SP2 and SP3
Date of Notification: February 5, 2008
Type of Action: Field Safety Corrective Action

This letter is to advise you of an anomaly that has been identified with the ConeBeam Computed Tomography (CBCT) software on Acuity simulators where the image orientation DICOM tag will not be set correctly if the patient has been scanned with an orientation other than Head First Supine.

Details on Affected Devices:

Listed are the affected Acuity Serial Numbers with associated CBCT Serial Numbers (Acuity # - CBCT#). The last four digits represent the serial number of the device.

H770002 – H780001	H770134 – H780026
H770012 – H780058	H770143 – H780039
H770030 – H780034	H770159 – H780062
H770055 – H780046	H770170 – H780056
H770068 – H780010	H770184 – H780061
H770107 – H780050	H770212 – H780074
H770113 – H780060	H770245 – H780086
H770119 – H780035	H770279 – H780105

Description of the Problem:

The image orientation tag for Acuity CBCT slices may not be set appropriately if the patient orientation has been set to an orientation other than Head First Supine. When such images are imported to a treatment planning system, they may appear with either a mirrored or a rotated view.

The Patient Orientation is selected on the Patient Setup wizard page of the ConeBeam CT application. The operator must select from one of the following orientations:

- Head First Supine
- Head First Prone
- Feet First Supine
- Feet First Prone
- Head First Decubitus Right
- Head First Decubitus Left
- Feet First Decubitus Right
- Feet First Decubitus Left

During DICOM export of the CBCT data, an image orientation tag is set. In the ConeBeam CT 2.0.11 SP2 release, this orientation tag is set to Head First Supine for all patient orientations. If the patient has been scanned in any one of the seven orientations other than Head First Supine, the data will appear to be mirrored or rotated when imported into a treatment planning system. The orientation of all ConeBeam CT data should be verified prior to proceeding with treatment planning.

This behavior can occur with the Acuity CBCT 2.0.11 SP2 or SP3 release. Earlier releases are unaffected. You may determine the version of CBCT software you are running by selecting 'Help' > 'About' from the ConeBeam CT Task Menu.

Recommended User Action:

To avoid this issue, the following methods are recommended:

1. Where possible, perform all ConeBeam CT scans that are to be used for treatment planning with patient positioned in the Head First Supine position.
2. When performing a ConeBeam CT scan for treatment planning using Eclipse, where the patient must be positioned in an orientation other than Head First Supine,
 - a. Select "Head First Supine" as the patient orientation within the CBCT application.
 - b. Place external fiducial markers on the patient's skin surface to assist with confirmation of appropriate orientation (i.e. place double fiducials on the left and posterior patient surfaces)
 - c. Upon completion of the scan, select "Accept and Export" Upon import of the data into Eclipse, set the patient dataset orientation using the external markers to confirm appropriate orientation.
 - i. Select the patient orientation within the properties of the CBCT Image series folder.
Note: The patient orientation should be selected and saved prior to assigning the CBCT 3D image (CT_1) to a patient plan
 - ii. Select the patient orientation within the properties of the treatment plan
3. When importing ConeBeam CT data into a third party treatment planning system, ensure the appropriate patient dataset orientation has been set as per third party planning system procedure.


Orientation of all ConeBeam CT data should be verified prior to proceeding with treatment planning.



Varian Corrective Action:

Varian is notifying all customers who have Acuity ConeBeam CT 2.0.11 SP2 & SP3 with this Urgent Field Safety Notice. A Service Pack is being created to correct this issue. Varian will contact you when it becomes available.

Please advise the appropriate personnel working in your radiotherapy department of the content of this letter.

We sincerely apologize for any inconvenience and thank you in advance for your co-operation. If you require further clarification, please feel free to contact your local Varian Customer Support Services Manager, or: Varian Oncology Helpdesk – 888-VARIAN5 (888- 827-4265), email: onc.helpdesk@varian.com.





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