

Urgent
Medical Device Correction
Field Safety Notice
TomoTherapy Treatment Systems

July 12, 2011

Dear TomoTherapy Customer,

As a result of an internal review, TomoTherapy has identified an issue that we would like to bring to your attention.

Issue:

During DICOM export of plan level images with a non square exported Field of View (FOV), an anomaly in the process of squaring the plan level image may cause the image to shift with respect to ROIs and dose. When the anomaly occurs, the magnitude of the image shift can be a full IEC-X voxel, a full IEC-Z voxel, or full voxels in both IEC-X and IEC-Z.

Please note that while square images are required for successfully importing via DICOM, the process of inserting the couch and moving the patient with the couch can result in non square images internal to TomoTherapy.

Even when a plan level image is exported with non square FOV, the anomaly does not occur with every export and is dependent on specific image dimensions and voxel sizes.

Product Affected: Hi-Art versions 4.0.x, and HD versions 1.0.x

Recommended Action:

After DICOM export of images with non square FOV; carefully review the image / ROI / dose relationship for shifts.

To determine whether a subsequent DICOM export could be affected, review the number of coronal and sagittal slices on the fractionation tab. If the total number of slices differs between the two planes, the image is not square and the DICOM export of the plan level image could be affected by this issue.

Resolution:

This issue will be remedied with Hi-Art software version 4.1 and HD software version 1.1 and later.

Please forward this notice to appropriate personnel within your organization. Also, please be aware that the Competent Authority of your country has been advised of these actions. Thank you for your cooperation, and we apologize for any inconvenience. If you have any questions, please contact the TomoTherapy Customer Interaction Center by email or telephone using the

contact information provided on the last page of this notice and request to be connected to Peter De Kempeneer.



Director of Regulatory Affairs and Quality Assurance

Customer Support

The TomoTherapy Technical Solutions Center can be reached 24 hours a day, 7 days a week, by e-mail at support@tomotherapy.com or by phone at:

- **North America:** 1 866 368 4807
- **Belgium:** 0800 38783
- **France:** 0805 631 565
- **Germany:** 0800 000 7541
- **Italy:** 800 986 399
- **Netherlands:** 0800 0201364
- **Spain:** 800 300049
- **Switzerland:** 0800 001927
- **United Kingdom:** 0808 238 6035
- **China/CNC (Northern):** 10 800 712 1701
- **China (Southern):** 10 800 120 1701
- **Hong Kong:** 800 967912
- **Japan:** 0044 22 132374
- **Singapore:** 800 1204 683
- **South Korea:** 0079 81 4800 7204
- **All other locations:** +1 608 824 2900 or +32 2 400 44 44