



Reference: 3449 - supplement

URGENT MEDICAL DEVICE CORRECTION FIELD SAFETY NOTICE

December 2, 2008

Dear Customer:

This notice provides updated information relative to the issue previously described in the Field Safety Notice reference number 3449. A copy of this original notice is included for your reference.

Issue:

It has been identified that treatment plans involving very small structures (volume <2 cc), residing in a high dose gradient region, may exhibit inaccuracies with the DVH curve and the Dose Statistics for the small structures. The investigation testing conducted at the time of the original notice indicated that this issue could only occur in plans with very small voxels (1mm or less) in the transverse plane and that planning either with 512x512 images or 256x256 images with a reconstructed field of view of 25 cm or less, were the only ways to produce these small voxels.

Subsequent to the original notice, this issue has very recently been observed in a plan using a 256x256 image and a standard field of view of 50 cm and not a reconstructed field of view of 25 cm or less. The aspects of this plan that were consistent with the information in the original notice include:

- Very small structures (volume <2 cc), residing in a high dose gradient region
- The isodose displays were accurate and discrepancies between the dose reported in the isodose display, the DVH curve and the dose statistics were observed

Product Affected:

All Tomotherapy Hi-Art Systems with 3.1.2, 3.1.3, or 3.2.1 software. The affected applications include Planning Station, Planned Adaptive, Data Management System, and TomoPortal.

Recommended Actions:

In addition to the recommendations outlined in the original notice, it is further recommended to carefully check the dose reported in the isodose display, the DVH curve and the dose statistics to ensure these are consistent for plans that contain very small structures (volume <2 cc). If you have cases that you wish to have analyzed or have any questions, please contact the Tomotherapy Call Center by email or telephone using the contact information provided on the last page of this notice.



Resolution:

This issue will be corrected in software versions 3.2.2 and 3.1.4, which are scheduled for release in January and February, 2009 respectively.

We would ask that you forward this notice to appropriate personnel within your organization. Also, please be aware that all relevant regulatory authorities have been or will very soon be advised of this issue. Thank you for your cooperation, and we apologize for any inconvenience. If you have any questions, please contact the TomoTherapy Call Center by email or telephone using the contact information provided on the following page and request to be connected [REDACTED]

Sincerely,

[REDACTED]

Director of Regulatory Affairs



Reference: 3449

URGENT MEDICAL DEVICE CORRECTION FIELD SAFETY NOTICE

September 17, 2008

Dear Customer:

TomoTherapy Inc. wishes to alert you of an issue that was discovered on the Hi-Art System during the course of ongoing testing.

Issue:

It has been identified that treatment plans involving very small structures (volume <2 cc), residing in a high dose gradient region, may exhibit inaccuracies with the DVH curve and the Dose Statistics for the small structures. This error can only happen if planning was performed using very small voxels (1mm or less) in the transverse plane, independent of longitudinal resolution, under one of the following conditions:

1. Planning with images at 512x512 resolution. As detailed in the TomoTherapy User's Guide, 512x512 resolution images are downsampled by default to 256x256 resolution. Unless changes were made to the default 256x256 resolution, this condition will not apply.
2. Planning with images at 256x256 resolution with a reconstructed field of view of 25cm or less coupled with the use of the Fine dose calculation grid.

The error can result in up to 30% inaccuracy in the DVH curve and Dose Statistics, which could result in a treatment to the patient that is different than the plan.

Please note: The Isodose displays are accurate and can be cross referenced against the DVH curve.

Product Affected:

All TomoTherapy Hi-Art Systems with 3.1.2, 3.1.3, or 3.2.1 software. The affected applications include Planning Station, Planned Adaptive, Data Management System, and TomoPortal.

Recommended Actions:

- Leave the image import resolution settings set at the default settings of 256x256. Do not change the image import resolution to 512x512 and if this resolution has been previously changed, set the resolution back to the 256x256 default. This setting should be left at the default setting of 256x256 or changed only to 128x128 if required. If you currently have plans developed using imported images with a 512x512 resolution in the TomoTherapy dataserver delete the plan and re-import the image at 256x256 resolution (Please see TomoTherapy Planning Guide 3.x, pages 5-5 thru 5-7).
- Do not use a Fine dose calculation grid on a planning image that has a reconstructed field of view of 25cm or less.

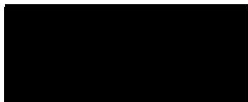


Resolution:

This issue will be corrected in software versions 3.1.4 and 3.2.2, which is scheduled for release in November 2008. If you have cases that you wish to have analyzed or have any questions, please contact the TomoTherapy Call Center by email or telephone using the contact information provided on the following page.

We would ask that you forward this notice to appropriate personnel within your organization. Also, please be aware that all relevant regulatory authorities have been or will very soon be advised of this issue. Thank you for your cooperation, and we apologize for any inconvenience. If you have any questions, please contact the TomoTherapy Call Center by email or telephone using the contact information provided on the following page and request to be connected [REDACTED]

Sincerely,



Director of Regulatory Affairs

Support

TomoTherapy Incorporated keeps our customer sites running smoothly with proactive service plans and responsive customer support.

The Customer Contact 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

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