



Product Advisory Notice

TomoTherapy® HI•ART System®

August 11, 2010

Dear TomoTherapy Customer,

TomoTherapy Inc. is sending this Product Advisory Notice to make you aware of information concerning the performance of the Hi-Art System.

Issue:

TomoTherapy has discovered an anomaly during internal testing. New in software version 4.0 is the ability of Planned Adaptive to shift the couch top to match the lateral offset of the couch applied at time of treatment. While implementing a similar feature into Planning Station for a future release, it was discovered that the couch base (lower pallet) is not properly being inserted into the merged image in Planned Adaptive. This affects the calculation of the verification dose. The dose effect is negligible for helical plans but potentially as large as 10% for TomoDirect plans depending on the angles used.

The couch top (upper pallet or carbon fiber portion) is being properly shifted in Planned Adaptive. However, the lower pallet (couch base) image is being shifted incorrectly by half the distance of the accepted lateral offset at the time of image registration in the opposite direction (up to 1.25cm due to physical lateral couch movement limitations). For example, if a +1.0 cm shift in the X direction is accepted and applied, in Planned Adaptive the couch top would correctly move to account for the +1.0 cm X shift but the couch base would incorrectly move -0.5 cm from the original couch isocenter. The couch base image should not move as the base is in a fixed physical position with respect to the machine isocenter.

The error would be difficult for customers to detect or measure because Planned Adaptive only shows machine isocenter (green lasers) during the couch insertion process. Additionally, since the couch top is correctly shifted, the resulting image appears correct.

Product Affected:

Hi-Art Systems functioning on version 4.0.2 software in combination with any version of Planned Adaptive.

Recommended Actions:

TomoTherapy recommends that you do not use Planned Adaptive with TomoDirect plans in software version 4.0.2. Helical plans should continue to be used with Planned Adaptive as the effect is negligible.



Reference: 5075

Resolution:

TomoTherapy will correct this anomaly in software version 4.0.3, which will be a field action upgrade provided at no charge. Version 4.0.3 software is scheduled for release in late 2010.

We apologize for any inconvenience this may have caused you. As always, if you have any questions, please contact the TomoTherapy Call Center by email or telephone using the contact information provided on the following page.

Sincerely,

A handwritten signature in black ink, appearing to read "Rob Bovy".

Rob Bovy
Director of Regulatory Affairs and Quality Assurance



Customer Support

The Customer Interaction 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