



Reference: 4901

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 an anomaly which may affect the performance of the Hi-Art System.

Issue:

TomoTherapy has received a few reports that the Film Analyzer Transverse Laser Point Tool can return an erroneous lateral offset indicating the sagittal laser is out of tolerance.

In the event the incorrect lateral offset is used to update both the stationary and movable laser positions and patient setup were performed based upon fiducials and laser positions alone without MVCT, patients could be improperly positioned up to 4mm.

This issue has no impact on patient registration if you're using patient MVCT imaging.

Product Affected:

TomoTherapy Film Analyzer

Recommended Actions:

TomoTherapy recommends setting up the Y-component of the overhead laser to match the (sagittal plane laser) Y-component of the bore (cooling side) stationary laser, therefore, the user should ignore the last row of the Transverse Laser Point Tool results, as reported by the film analysis software.

If the Transverse Laser Point Tool indicates the lasers are out of tolerance, image a small metal object centered on the stationary green lasers using a fine slice thickness. On the Operator Station Register tab review the position of the object with respect to the virtual sagittal plane green laser position. If the image viewer depicts the scanned object as centered on the virtual sagittal plane green laser, do not adjust the lasers based upon the Film Analyzer Transverse Laser Point Tool results.

Resolution:

TomoTherapy will correct this anomaly in the next release of Film Analyzer software, which is planned for mid 2011.



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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