



Reference: 5071

Product Advisory Notice

TomoTherapy® HI•ART System®

August 11, 2010

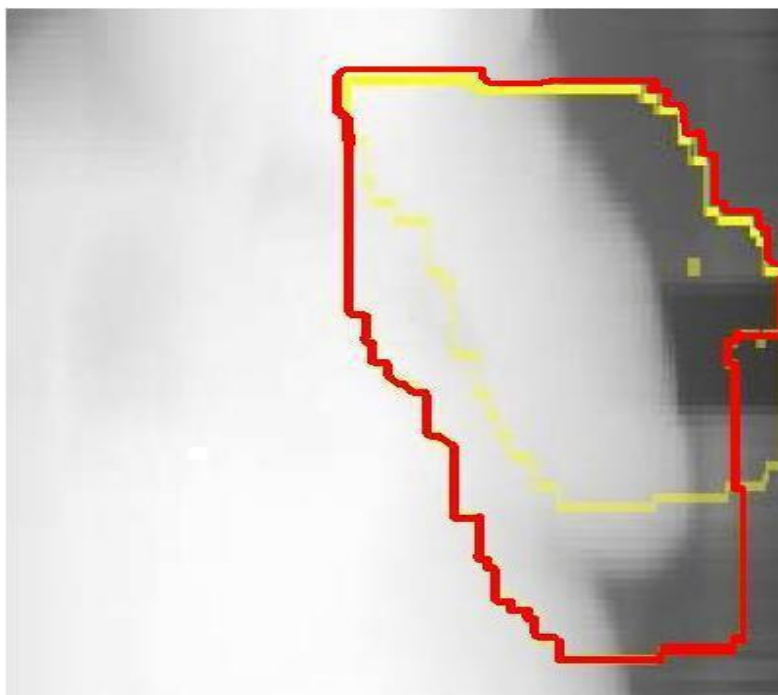
Dear TomoTherapy Customer,

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 discovered an anomaly with the 4.0.2 Plan Report during internal testing. When using TomoDirect 3DCRT, the outline of the treatment region, displayed on the digitally reconstructed radiograph (DRR) in the Plan Report will be distorted in the longitudinal direction (up to a field width). Only TomoDirect 3DCRT Plan Reports are affected by this anomaly. Below is an example of the issue on which the yellow outline represents what is currently shown in the Plan Report and the red outline represents how the DRR should appear.

All other plan information is not affected by this anomaly.





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Product Affected:

Hi-Art Systems functioning on version 4.0.2 software

Recommended Actions:

TomoTherapy recommends that you do not use the DRR to make clinical decisions.

Resolution:

TomoTherapy will correct this anomaly in version 4.0.3 software, 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



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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