



Reference: 4895

April 23, 2010

Product Advisory Notice

Dear 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 during internal testing that the median structure dose reported by the software may be larger than the true median. For an affected structure, the incorrect median will appear everywhere it is reported by the software, (e.g. on the Planning Station display, on the Plan Report).

This does not affect the mean (average) dose or the DVH curve.

Product Affected: All TomoTherapy Hi-Art Systems with Version 3.x and 4.0.x software

Recommended Actions:

Before using a structure's median dose in a clinical decision, compare the reported median with D50 on the DVH curve for that structure. D50 as displayed on the curve is accurate and in case of a discrepancy should be used in place of the reported median.

Resolution:

TomoTherapy will correct this issue in version 4.1 software, which is scheduled for release in the late 2010.

We apologize for any inconvenience this may have caused you. As always, if you have any questions, please contact the TomoTherapy Customer Interaction 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

Support

TomoTherapy Incorporated keeps our customer sites running smoothly with proactive service plans and responsive 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: 1 866 363 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