



Reference: 5029

URGENT
Field Safety Notice
Medical Device Correction

Hi-Art® Treatment System

June 23, 2010

Dear TomoTherapy Customer,

As a result of input received from one TomoTherapy Hi-Art® Treatment System customer, an issue has been identified that we would like to bring to your attention.

Issue: With a particular workflow, the Planning Station's Draft and/or final Plan Report can provide incorrect dose statistics. The workflow necessary to observe incorrect dose statistics involves performing the following steps without closing and reopening the plan at any point: creating a plan, adding a new ROI, performing optimization and generating a draft Plan Report and/or continuing to approving a plan and generating a final Plan Report.

In the event a Plan Report with incorrect dose statistics was used to guide therapy, for instance in the event of re-treatment, improper therapy could result.

DVH, isodose and dose statistics information on the user interface is not affected by this issue.

Product Affected: Hi-Art software versions 4.0.0, 4.0.1, 4.0.2

Recommended Action:

1. Prior to generating a draft or final Plan Report for a given plan, the plan must be closed and reopened at least once.
2. Review the dose statistics on Plan Reports carefully

Resolution: This issue will be remedied by Hi-Art software version 4.0.3, scheduled for release in late 2010.

Please forward this notice to the appropriate personnel in your organization. TomoTherapy is in the process of notifying relevant regulatory authorities.

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,

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
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