



**Urgent
Field Safety Notice
Medical Device Correction**
Hi-Art® Treatment System

Nov 8, 2010

Dear TomoTherapy Customer,

TomoTherapy Inc. is sending this Field Safety Notice to make you aware of an anomaly which may affect the performance of the Hi-Art System.

Issue:

TomoTherapy has discovered an anomaly during internal testing. When a TomoDirect procedure has an unrecoverable interrupt or Emergency Stop in between beam angles, there is a small possibility that the procedure will indicate a “Performed” status rather than “Interrupted” on the Operator Station.

If you experience this anomaly, a Completion Procedure will not be able to be created, resulting in the remaining dose being undeliverable. In the unlikely event this occurs you should immediately contact the TomoTherapy Customer Interaction Center for assistance in generating a completion procedure.

Product Affected:

All TomoDirect Treatment Delivery licensed systems; **TomoHelical Treatment Delivery procedures are not affected.**

Recommended Action:

If you experience an unrecoverable interrupt during a TomoDirect treatment procedure with one or more beams remaining and observe that the procedure has been incorrectly marked “Performed”, contact the TomoTherapy Customer Interaction Center for further instruction and assistance in generating a completion procedure.

If you are uncertain about the status of any TomoDirect procedure, you can verify that the expected and actual procedure times match on the Treat Tab of the OS as well as check for a Beam Delivery Status of “Not Performed” in the Delivery Report.

Resolution:

This anomaly will be addressed in Hi-Art system software version 4.0.4 and TomoHD software version 1.0.1. TomoTherapy Hi-Art version 4.0.4 software and TomoHD software version 1.0.1 will be a field action upgrade provided at no charge. This software is scheduled for release in the first quarter of 2011.

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

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