



Reference: 5081

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:

It has been reported by one customer that while performing a TomoDirect patient procedure, the gantry angles read zero on the Operator Station (OS) Display during the procedure and also displayed zero on the Delivery Report printed after the completion of the procedure.

It was discovered through an internal investigation that the gantry did actually move to the planned positions correctly. The gantry angle data was not successfully sent to the OS due to a communication interruption during the system initialization state. This communication interruption does not affect the functionality of the delivery system so the gantry will move to the requested angles and the treatment would be delivered as planned. The treatment angle values on the Treatment Report will also not be available when this communication interruption occurs. All other data for the treatment report will be populated.

This communication issue also has no effect on the delivery system interlocks, so a system interlock will occur if the actual position of the gantry is out of specification.

Product Affected:

Hi-Art Systems operating on 4.0.0, 4.0.1 & 4.0.2. There has been only one report of this anomaly.

Recommended User Action:

If this anomaly occurs, shutdown and restart the machine and this will resolve the communication interruption for the next procedure.

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.



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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 Customer Care 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