



## Product Advisory Notice

TomoTherapy® HI•ART System®

June 22, 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 determined that, under certain circumstances, it is possible to generate and deliver two identical completion procedures for a single interrupted procedure. This may occur when “generate completion procedure” is selected in the Operator Station Display for the interrupted procedure, but before the completion procedure is created the user clicks on the “generate completion procedure” again. Below is an example on how this would appear on the Operator Station Display.

Scan		Register		Treat		Plan		Calibrate	
Procedures		Show types		Treatment					
Type	Nu...	Status	Date	Time	Elapsed Time				
TRMT	1	Performed	Aug 5, 2009	12:48:49 PM	112.64 sec				
TRMT	2	Interrupted	May 4, 2010	3:34:24 PM	31.79 sec				
TRMT-Completion	2.1	Scheduled							
TRMT-Completion	2.1	Scheduled							
TRMT	3	Scheduled							
TRMT	4	Scheduled							
TRMT	5	Scheduled							
TRMT	6	Scheduled							
TRMT	7	Scheduled							
TRMT	8	Scheduled							
TRMT	9	Scheduled							

**Product Affected:**

Hi-Art Systems operating on 3.x, 4.0.0, 4.0.1 & 4.0.2. There has been only one report of this anomaly.



Reference: 5025

**Recommended User Action:**

If two completion procedures with the same procedure number appear on the OS display, select only one to deliver and ignore the other one.

**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 Customer Care Center by email or telephone using the contact information provided on the following page.

Sincerely,

Rob Bovy  
Director of Regulatory Affairs and Quality Assurance



Reference: 5025

## Customer Support

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The Customer Care Center can be reached 24 hours a day, 7 days a week, by e-mail at [support@tomotherapy.com](mailto: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