



Reference: 4722

## **URGENT MEDICAL DEVICE CORRECTION FIELD SAFETY NOTICE**

August 10, 2009

Dear Customer:

As a result of input received from one TomoTherapy customer, TomoTherapy Inc. wishes to alert you to an issue that occurred on the Hi-Art System®.

**Issue:**

TomoTherapy received one customer report indicating that after starting a patient procedure from the Status Console, the “radiation on” light and the audible indicator on the Status Console came on as expected, however the Operator Station (OS) did not display the dose rate and the procedure time, or the couch position updates. Within a few minutes, the customer pressed the “Stop” button on the Status Console and the radiation indicators on the Status Console shut off. After rebooting the system, the procedure that had just been attempted was marked “scheduled”, indicating it had not yet been initiated.

**Product Affected:**

All TomoTherapy Hi-Art Systems

**Investigation:**

TomoTherapy’s investigation revealed that radiation was appropriately delivered up to the time the procedure was stopped by the user, even though there were no values in the Treatment Status fields on the OS display. The Hi-Art System then did not update the procedure from a "scheduled" to an "interrupted" status as expected after a system reboot. In this very rare situation, if the procedure were restarted the entire fraction will be delivered.

**Recommended Actions:**

In the very rare event that the dose rate, procedure timer, and couch position updates are not present on the OS, after pressing “Start” on the status console, yet the “radiation on” light and audible indicators are active, please immediately press the “Stop” button on the Status Console and contact your authorized TomoTherapy Service Representative for further direction.

**Resolution:**

This issue will be corrected in the next software version, which is scheduled for release in early 2010.

Please forward this notice to appropriate personnel within your organization. Also, please be aware that all relevant regulatory authorities have been or will be advised of this issue. Thank you for your cooperation, and we apologize for any inconvenience. If you have any questions, please contact the TomoTherapy Call Center by email or telephone using the contact information provided on the last page of this notice.

Sincerely,

A handwritten signature in black ink, appearing to read 'Rob Bovy'.

Rob Bovy  
Director of Regulatory Affairs

## Support

*TomoTherapy Incorporated keeps our customer sites running smoothly with proactive service plans and responsive customer support.*

The Customer Contact 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

**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