



Reference: 4679

Product Advisory Notice

TomoTherapy® HI•ART System®

July 31, 2009

Dear TomoTherapy Customer,

TomoTherapy Inc. wishes to alert you of an issue that was discovered on the Hi-Art System during the course of ongoing testing.

Issue:

Any Region of Interest (R.O.I.) contour with a name containing the word “couch” (space on both ends), will be treated as a couch contour by the system whether the contour actually is of the couch or not. As a result, if a contour exists with “couch” in the name, but is not actually a contour of the couch and is located above isocenter, the system will set the contents of that R.O.I. to air when a couch replacement is performed. This may result in an underdose of target areas.

Additionally, if there is an actual couch R.O.I. defined for a plan, but no contour exists on any given slice, the couch replacement will not occur for that slice and there is no system warning. In this case, the software assumes that the user does not want the couch replaced on slices that are missing this contour.

Product Affected:

All HI•ART Systems with version 2.x or 3.x software

Recommended Action:

- Do not use the word “couch” in the name of any non-couch R.O.I. contour.
- Check carefully to ensure that the actual couch contour exists on all desired slices of a plan.

Resolution:

These issues will be addressed in 4.0 software.

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



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Customer Support

The Customer Care 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