



## Product Advisory Notice

TomoTherapy® HI•ART System®

July 31, 2009

Dear TomoTherapy Customer,

As a result of ongoing review and analysis by TomoTherapy, an issue has been identified that we would like to bring to your attention.

**Issue:**

In the rare event density replacement is performed to assign *high density* values to an ROI *and* that plan's Image Value to Density Table (IVDT) is subsequently changed in a particular manner, an anomaly could cause the replaced density values to be incorrect.

The maximum density value available in the Uniform ROI Density Editor is IVDT dependent. An IVDT may have a maximum density value of 22.6g/cc. If an IVDT's maximum entered value is less than 22.6 g/cc, the system derives a maximum density value by extrapolating the last two points in the IVDT to the maximum HU value 31,743.

When a density replacement value is assigned to a ROI, the Uniform ROI Density Editor modifies the HU value of the ROI in order to achieve the replacement density. If the IVDT is subsequently changed, the ROI will retain the previous replacement HU value, but the density of the ROI will depend on the new IVDT, and may be different than what was previously entered in the Uniform ROI Density Editor. Thus, it is necessary to re-apply density replacement following an IVDT change, as the Tomo Planning Guide instructs. In typical density replacement workflows not involving a change to an IVDT, the density value field is edited manually. The manual entry of a density value triggers the software to verify the value against the IVDT table's maximum extrapolated value when **Preview** is clicked. Because changes to the referenced IVDT occur outside of the Uniform Density ROI Editor, it is possible to bypass density replacement value verification if the IVDT is changed.

As a result, if the newly applied IVDT has a maximum extrapolated density which is lower than the previous table's maximum density *and* the density values assigned are above the new table's maximum extrapolated value, the HU values assigned when density replacement is re-applied are out of bounds of the new IVDT and a density of zero is assigned.

For example, consider the following IVDTs:

**IVDT A**

HU Value	Density
-1024	0
-681	0.343
0	1
2406	2.588
2749	2.744

**IVDT B**

HU Value	Density
-1024	0
0	1
762	1.47
1135	1.69
2756	2.21



Reference: 4672

Extrapolating from the final two points in each table, the above IVDTs have the following maximum extrapolated densities:

- IVDT A: 15.9
- IVDT B: 11.5

IVDT A is initially selected. Density replacement is subsequently performed and a density override of 12.0 is specified for an ROI. The ROI is correctly filled with HU 23,100. The plan's IVDT is then changed and IVDT B (with a lower maximum extrapolated density) is selected. In the density image viewer, the HU remains the same but the density now shows as 8.736 due to the lower density/HU gradient of table B.

Because the density value 12.0 was not entered manually during this instance of the Uniform ROI Density Editor, the value of 12.0 can be re-applied despite it being higher than the maximum extrapolated value for IVDT B. If density replacement with the value of 12.0 is re-applied, the ROI will be incorrectly assigned an HU of -32,262 and density of zero.

**Product Affected:** All HI•ART systems with version 3.x software.

**Recommended Action:**

1. Density replacement **Preview** properly displays the density values assigned. In the event a plan's IVDT needs to be changed post density replacement as described above, carefully review the changes to verify the densities applied are correct.

**Resolution:**

This issue will be remedied with software release 4.0.

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

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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
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