

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject: Differences in IMRT field CIAO visualization in Varian applications

Commercial Name of Affected Product: 4D Integrated Treatment Console and TrueBeam

Reference / FSCA Identifier: CP-05708

Date of Notification: 2012-03-01

Type of Action: Notification only

Details on Affected Devices: Refer to appendix page.

Description of Problem:

Several Varian applications have a visualization tool for IMRT fields called CIAO (Complete Irradiated Area Outline). The purpose of the CIAO visualization is to indicate the area where the planned, therapeutic dose of the IMRT (Intensity Modulated RadioTherapy) treatment field is to be delivered in the patient. Due to the nature of the IMRT fields (sweeping leaves that are travelling from under the jaws to the therapeutic area), CIAO is not always a sufficient tool to determine where **all dose** from treatment plan will be delivered. 3D dose calculation results in treatment planning (like Eclipse) must always be used when analyzing the dose to be delivered to the patient.

This letter is to advise you of potential discrepancies in IMRT CIAO outline visualization between treatment applications (4D Integrated Treatment Console (4DITC), AM Editor, On-Board Imager, PortalVision and TrueBeam), and treatment planning & oncology information system applications (Eclipse, ARIA, RTChart, Off-line Image Review). For example, the calculation of the ad-hoc imaging CIAO differs from CIAO calculated in RTChart, Eclipse, Offline Review and On-Board Imager.

The discrepancy is a display issue that is sometimes seen when an ad-hoc image template has been added, after the plan has been loaded on the 4DITC. None of the reported discrepancies affect the delivered dose to the IMRT field, and the planned MLC and the actual MLC used for treatment are correct. Varian has not received any reports of misadministration.

This notice provides a description of the CIAO related issues, the actions you can take to avoid or mitigate the issues, and steps Varian is taking to address the issues.

Details:

Varian has received a report about the following discrepancy in CIAO visualization between 4DITC and Eclipse/ARIA:

The 4DITC ad-hoc imaging CIAO calculation results in a CIAO shape that differs from the CIAO calculated in ARIA, RTChart, Eclipse, Offline Review and On-Board Imager (see Figure 1). If the ad-hoc imaging CIAO light field edge is marked on the patient's skin and is used to set-up another abutting treatment field, the area between the projected field edge and the abutting field edge would be mismatched. The light field would not correctly project the true CIAO shape and the treatment could be delivered incorrectly. The discrepancy in the field edges are displayed in

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Figure 1 below.

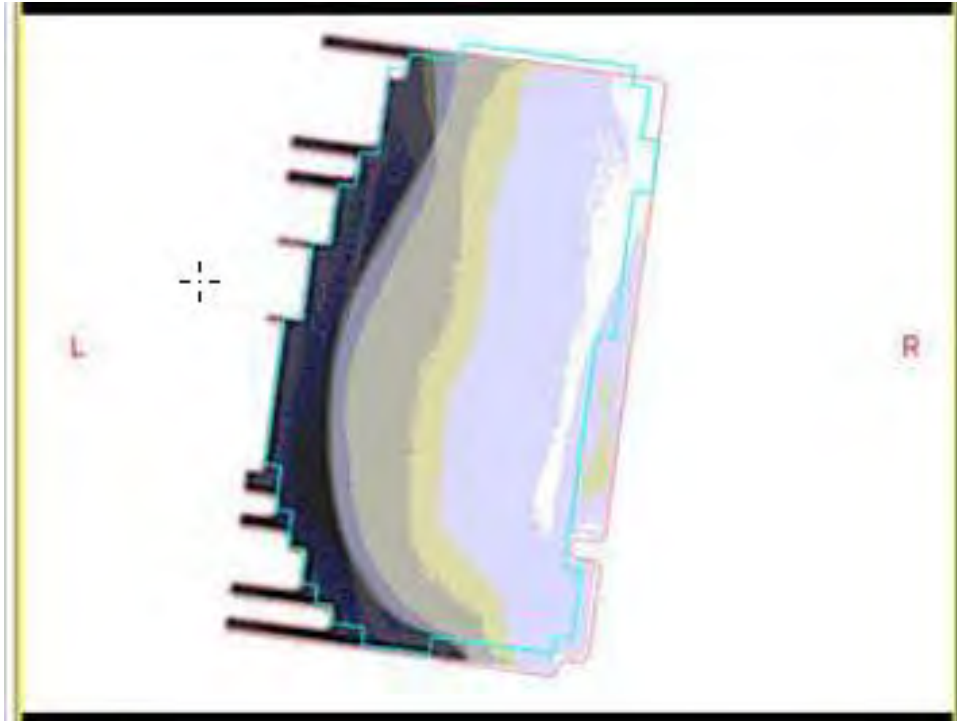


Figure 1: RTChart CIAO in blue; 4DITC Ad-hoc Imaging CIAO in red.

TrueBeam does not have the discrepancy described above, but the guidance (about using CIAO for clinical decisions) provided in document is applicable to TrueBeam as well.

Potential discrepancies (such as the reported issue above) between CIAO calculated and displayed in RTChart, Eclipse, Offline Image Review, On-board Imager, 4DITC and TrueBeam may impact your treatment planning and treatments in following ways:

- When you perform image matching for MV image based patient set-up, the CIAO outlines may differ, and you are not able to perform the image match solely based on the CIAO out-line.
- If you try to perform field edge matching between an IMRT treatment field and another treatment field (abutted fields), the field edge is not consistent for the IMRT field, and the field edge match (if performed) could lead to overdose or under dose in the area of the field seam. It is important to understand that the field edge of sliding window IMRT field is not as sharp as the penumbra of static open or MLC field, because in many cases the closed leaf pairs move from being covered by the jaws to the treatment field defined by the jaws during the treatment, and thus there is some amount of dose delivered in the outside "edge" of the CIAO. This 'outside of CIAO' dose is appropriately estimated by Eclipse treatment planning system dose calculation, and is visualized in treatment planning.

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Recommended User Action

1. 4DITC Users:
Schedule all imaging sessions in the Oncology Information System when possible. Scheduled imaging templates display the consistent CIAO.
2. All Users:
The purpose of the CIAO visualization is to indicate the area where the planned, therapeutic dose of the IMRT (Intensity Modulated RadioTherapy) treatment field is to be delivered in the patient. However, by definition CIAO is **NOT** an accurate representation of the entire area where dose is delivered by an IMRT field even if the CIAO discrepancies between different applications didn't exist.

Do not use the CIAO outline to define field edge match with another treatment field. The dose distribution in eclipse describes the true treatment field aperture, and shall be taken into account if any field edge match with IMRT field is considered. It is strongly recommended that only field edges defined by the jaws or static MLC aperture are used for field edge match.

Do not use CIAO outline as sole method to determine the patient position when image matching is done as part of the patient positioning. The image matching must be always verified using the anatomy of patient. Re-image after couch shifts to ensure that the patient is correctly positioned before treating the patient.

3. All Users:
Any discrepancies in CIAO comparison should be brought to the attention of the medical physicist for investigation before treatment continues.

Varian Actions:

Varian is notifying all possibly affected customers with this document.

Please advise the appropriate personnel working in your radiotherapy department of the content of this letter. For future reference, this document will be posted to the Varian customer support website: <http://www.MyVarian.com>.

Special Instructions for customers outside the USA and Canada: In order to satisfy regulatory requirements, we request that you complete the attached Proof of Notification or Receipt Verification Card once you have read this document and return it to Varian Medical Systems.

We sincerely apologize for any inconvenience and thank you in advance for your cooperation. If you require further clarification, please feel free to contact your local Varian Customer Support District or Regional Manager.

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The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.

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APPENDIX LIST OF SERIAL NUMBERS

H190004	H191058	H191119	H191186	H510129	H510285	H510399	H510500	H510589	H510677	H510773	H510853	H510948
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