

URGENT MEDICAL DEVICE CORRECTION

Subject: Unexpected loss of Treatment Field Add-Ons (Wedges, Blocks, etc) during Ximatron simulation

Reference: Ximatron Digital Imaging v7.5.51 with Service Pack (SP) 2

Date of Notification: TBD

Contact Information: Oncology Helpdesk 888-VARIAN5 (888- 827-4265)
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This letter is to advise you that an anomaly has been identified regarding the simulation and verification of certain treatment fields containing add-on devices. This notice provides a description of the issue, actions available to the user to mitigate the effects of the issue, and steps Varian is taking to address the issue.

Definitions:

Add-ons: Accessories that can be added to a treatment plan to further shape the beam for intended treatment. These can include fixed wedges, block trays, dynamic wedges, electron applicators, etc.

MLC: MultiLeaf Collimator

Description:

If a treatment field is created (for example in Eclipse or RT Chart), is unapproved, and does not contain an MLC but does contain a different add-on, then upon acquiring a Ximatron Digital Image the add-on will be deleted without warning.

However, if the treatment field is unapproved and does contain an MLC, as well as other add-ons, then on acquiring an image all add-ons remain. The system saves all parameters correctly.

Details:

This problem will occur when the active, unapproved Treatment Field contains any add-on except MLCs. These planned add-ons will be lost when a fluoroscopic image is acquired on the Ximatron using Ximatron Digital Imaging. The system will not warn the user of this loss, and upon saving the plan the add-on will be permanently lost from the treatment field.

If this loss of an add-on is not detected through appropriate Quality Assurance review of the treatment plan then incorrect dose delivery will occur.

The anomaly was introduced in Ximatron Digital Imaging 7.5.51 (SP2). It does not exist on earlier software versions or on other Varian products.

Affected Serial Numbers:

H720291, H720441, H720621, H720637, H720672, H720702, H720781, H720804, H720865, H720873, H720894, H720895, H720916, H720932, H720973

User Corrective Action:

This anomaly can be avoided by using a copy of the unapproved treatment plan for the simulation. The simulation images may then be manually re-assigned to the original treatment plan.

See *Addendum A* for details on actions the user can follow to mitigate this anomaly until a revised version of the software can be distributed.

Varian Corrective Action:

Notification of customers is by means of this Product Notification Letter.

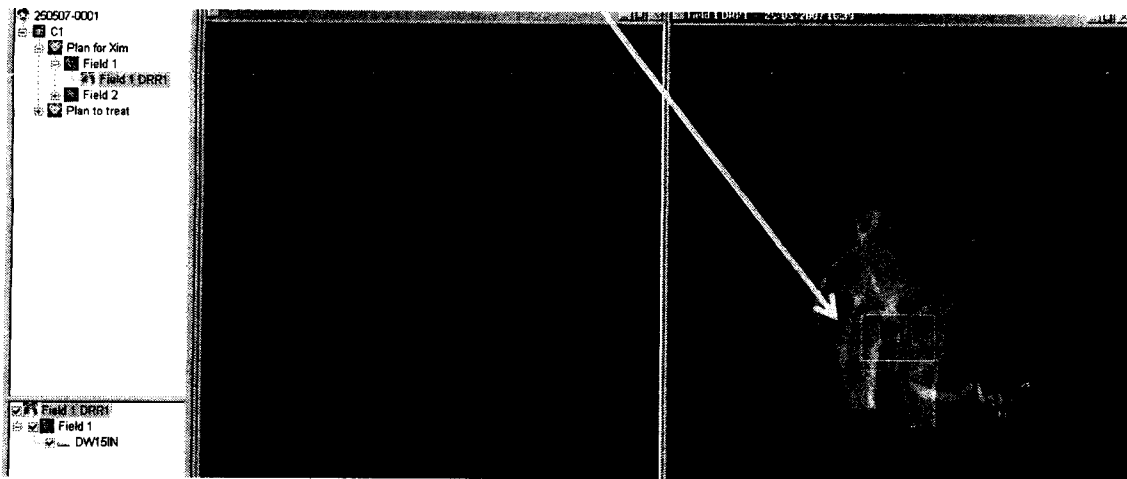
Varian is currently validating a software modification to address this problem. This modification will be distributed to all affected customers.

Please advise the appropriate personnel working in your Radiotherapy Department of the content of this letter.

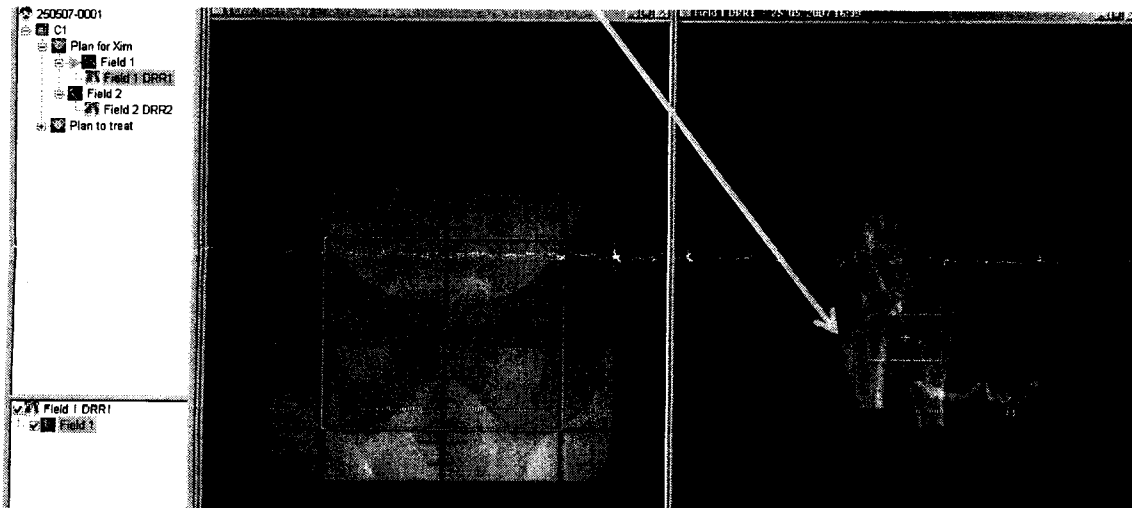
We sincerely apologize for any inconvenience and thank you in advance for your co-operation. If you require further clarification, please feel free to contact your local Varian Customer Support Representative.

Addendum A:

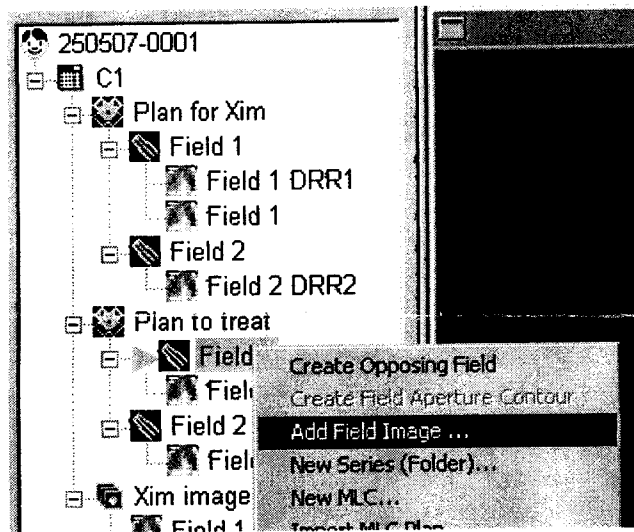
1. In the *RT Chart* task, select the PLAN. Right mouse click and choose “Copy Plan”
2. Select the COURSE. Right mouse click and choose “Paste plan with reference images”.
3. It is recommended to rename the pasted plan so that it is clearly identifiable.
4. Save the plan.
5. Switch to *Simulation Acquisition*
6. Select the COPIED PLAN
7. Select the FIELD to be verified and download it to the Ximatron. Optionally drag the DRR to the right-hand viewing panel. The add-ons (block, wedge, etc) will still be visible on the field overlay.



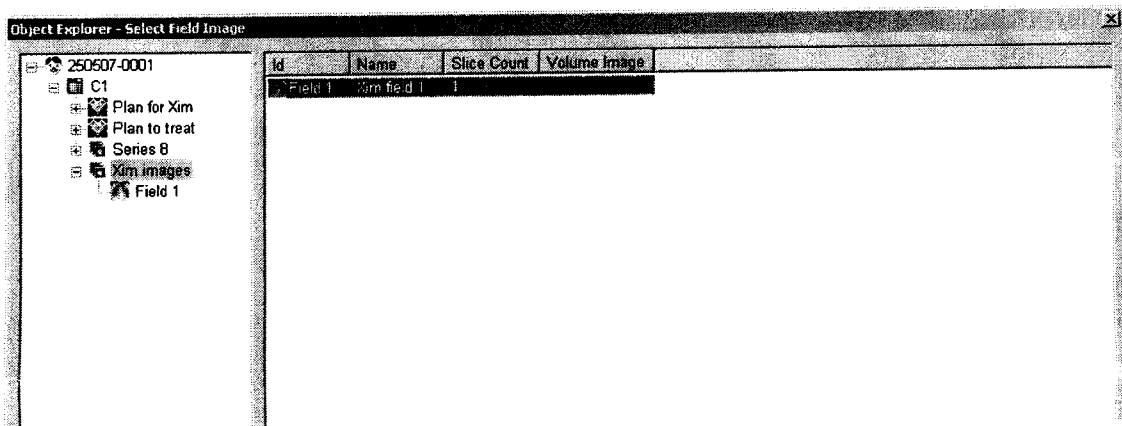
8. Acquire an image. At this point the add-ons will have disappeared.



9. Grab the image to the gallery and name it appropriately. A new image series will be created for the first image. Name this series appropriately (e.g. "Xim images").
10. Repeat steps 6 to 9 for the remaining fields.
11. Select the ORIGINAL PLAN.
12. Select the first field of the plan. Right mouse click and select "Add Field Image"



13. In the Object Explorer, select the simulation image series ("Xim images"). Select the image associated with the first field.



14. The image will now be associated to the first field of the original plan. Verify that the correct image has been selected. Dragging the simulation image to the first viewing pane, and the DRR to the second viewing plan will enable complete verification to be performed.
15. Steps 14 – 16 should be performed for subsequent fields.
16. Save all changes.