

URGENT FIELD SAFETY NOTICE

Subject: **The dose distribution for a “Fit and Shield” plan is not cleared after changes are made to one or more MLC segments**

Commercial Name of Affected Product: Eclipse™ Client software versions with build numbers from 7.3.10 through 8.6.15 (i.e. excluding 8.6.17)

FSCA Identifier: CP-01785

Date of Notification: *tbd*

Type of Action: Notification and Correction

Details on Affected Devices: See attached list.

Description of Problem:

We are writing to inform you about an anomaly in certain Eclipse versions in which, under certain specific sequences of user actions, the dose distribution may fail to be re-calculated even though changes have been made which affect dose.

Anomaly:

In certain cases, a user may edit multi-leaf collimator (MLC) field positions after treatment plan calculation and the dose distribution display will not be cleared or updated when edited. This occurs when the user has created two or more MLC fields using the “Fit and Shield” technique, and the user manually edits MLC leaf positions in any field but the first one created. The result is a mismatch between the displayed dose distribution and the dose which would be delivered through the changed MLC apertures. This defect affects Eclipse software versions with build numbers from 7.3.10 through 8.6.15.

Details:

Potential risk arises from this defect when the calculated dose distribution shown in Eclipse becomes inconsistent with the MLC setting of one or more fields in the plan and this calculated dose distribution is used by the clinician to evaluate the treatment plan. What follows is a typical scenario where this issue could be encountered:

When a user is creating “Fit and Shield” plan, fields are created with MLC leaves automatically positioned to cover the target while shielding the critical structures, both with a user-specified margin. After evaluating the resulting fields visually, the user is manually adjusting the MLC shapes for one or more of the fields, because the shielding or aperture is not what they desire. This leads to two potentially hazardous situations:

- 1) The user examines the MLC shape(s), and then decides to modify the leaf positions to expose more of the target. If the dose distribution is not removed and the user fails to recalculate dose after the modifications, then there is a possibility that the plan will be approved based on the unmodified dose distribution and the treatment will over-irradiate the target volume and surrounding tissue. Furthermore, if the patient returns for subsequent treatments of the same region, and the new treatment plan is designed based on the previously stored incorrect dose distribution, then the subsequent plan will lead to a higher than intended dose to the region.

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- 2) The user examines the MLC shape(s), and then decides to modify the leaf positions to shield more of the critical structure(s) or normal tissue. If the dose distribution is not removed and the user fails to recalculate dose after the modifications, then there is a possibility that the plan will be approved based on the unmodified dose distribution and the treatment will shield the critical volume(s) and/or normal tissue more than intended. If the patient returns for subsequent treatments of the same region, and the new treatment plan is designed based on the previously stored incorrect dose distribution, then the subsequent plan will lead to a lower than intended dose to the region.

On the other hand, if the physician is basing their decision solely on the shape of the MLC with the help of the beam’s-eye-view (BEV), the shape would be based on clinical imaging only and possibly continue to treatment without further dose evaluations. This does not change the fact that the calculated dose distribution would be incorrect, but the changes to the MLC would be based on a clinical decision, and the patient would therefore receive the physician’s intended dose even though the calculated dose distribution does not match what is delivered.

Note that in all these cases the difference in monitor units from such MLC changes should be minimal. Therefore, the expected effects are all due to structure and/or target coverage and not gross over/under-exposure.

Also note that if the changes to the MLC shapes are motivated by an evaluation of the calculated dose distribution, it is less likely that the issue would go unnoticed since the expected effect of the MLC shape change will not be observed. The user is then more likely to recalculate the dose than when the MLC shape change is only based on visual inspection of the MLC shapes.

Recommended User Action:

- To determine which version of Eclipse software you have:
From External Beam Planning, select ‘Help>About>System Info’.
From the system info window scroll down until you locate the entry for “Tasks”
An Eclipse 8.n.m system will describe each of the listed tasks as having a version value of “8.n.m..xxxxx”
(The trailing x values appended to the build number are not significant).
- When modifying MLC leaf positions in “Fit and Shield” plans, always recalculate the 3D dose and review the new dose distribution prior to approving the plan for treatment.

Varian Actions:

- Varian is notifying all possibly affected customers with this document.
- Varian is developing a correction for this issue. You will be contacted by a Customer Service rep when this correction is available to schedule its installation on your system.

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 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.

Dave Hall, Manager Reporting and Corrections

Date

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APPENDIX LIST OF AFFECTED DEVICE SERIAL NUMBERS

Listed are the affected system Serial Numbers. The last four digits represent the serial number of the device.