

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject:	Eclipse modeling of treatment machines with MLC device that replaces collimator jaws (e.g. Siemens MLC and GE MLC)
Commercial Name of Affected Product:	Eclipse Treatment Planning System, 7.3, 8.0, 8.1, 8.2, 8.6, 8.9, 10.0
Reference / FSCA Identifier:	CP-07007
Date of Notification:	2012-02-27
Type of Action:	Notification
Details on Affected Devices:	Refer to appendix page.

Description of Problem:

This letter is to advise you of an anomaly that has been identified with the Eclipse Treatment Planning System (in both *External Beam Planning* and *IRREG* tasks) when planning for the machines that have Multileaf Collimator (MLC) device replacing upper and/or lower collimator jaws. Examples of these treatment machines are Siemens and GE treatment machine models, which are not equipped with back-up jaws for MLC device (in the direction of leaf travel). These “collimator jaws” replaced by MLC are referred as “virtual jaws” in this document. This notice provides a description of the issue, the actions you can take to avoid or mitigate the issue, and steps Varian is taking to address the issue.

For these machines modeled with “virtual jaws”, positioning a virtual jaw inside the MLC aperture will result in an incorrect dose distribution within Eclipse. Only treatment plans that include “virtual jaw” modeling are affected by this issue.

Details:

In Eclipse, the model for linear accelerator treatment head consists of both upper and lower jaws with an optional MLC. In the case of a treatment machine, where the MLC replaces the lower moveable jaws (e.g. Siemens MLC and GE MLC), the lower jaw and MLC is represented in Eclipse by combination of virtual jaws and an MLC. The calculation will treat the virtual jaw as a beam limiting device such that the resultant dose distribution will be bounded by the virtual jaw if it lies within the MLC aperture.

When calculating or approving a treatment plan, if a virtual jaw is positioned inside the MLC aperture, a warning will be displayed in *External Beam Planning* task when planning for Siemens MLC accelerator. This warning states that the virtual collimator jaws are positioned inside the MLC aperture, a position which is not physically possible. This warning message is not displayed in case of other accelerator types without back-up jaws (e.g. GE Saturne with GE MLC), or when *IRREG* planning task is being used.

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If the user proceeds with the calculation, the virtual jaws will remain in the current position and will be handled as a beam limiting device for the dose calculation. This will result in the region under the virtual jaw but within the MLC aperture showing no or low dose.

Treatment using such a plan will result in dose being delivered to the patient outside of the area indicated in the planned dose distribution and within the entire MLC aperture.

Recommended User Action

For each field, **ALWAYS** verify that the virtual jaws are positioned outside the MLC aperture, adjusting the virtual jaw position to achieve this as necessary.

Pay careful attention to any warnings displayed regarding the virtual collimator jaws when the plan is calculated or plan is approved. If the warning indicates that the virtual collimator jaws are **inside** the MLC aperture, do not proceed with the calculation.

Varian Actions:

Varian is notifying all possibly affected customers with this document.

Varian is continuing to evaluate possible technical solutions for this issue.

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.

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

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