VARIAN
medical systems

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	Changing the prescription to optimized RapidArc or VMAT plan may not achieve plan objectives
Commercial Name of Affected Product:	Eclipse™ Treatment Planning System
Affected Version(s) / Lot(s):	Versions 8.5, 8.6, 8.9, 10, and 11
Reference / FSCA Identifier:	CP-08582
Date of Notification:	***2012-06-18***
Type of Action:	Notification and Correction

Description of Problem:

This letter is to advise you of an anomaly that has been identified with the Eclipse™ Treatment Planning System where changing the prescription in a calculated VMAT or RapidArc plan may lead to Monitor Units which do not reflect the new prescription. This notice provides a description of the issue, the actions you can take to avoid or mitigate the issue, and steps Varian Medical Systems is taking to address the issue.

If the dose prescription of a VMAT or RapidArc plan is changed after the initial Dose Volume Optimization, the Monitor Units and dose distribution may not reflect the intended prescription.

Details:

When a VMAT or RapidArc plan is optimized, the Monitor Units resulting from the Dose Volume Optimization represent the dose prescription. The 3D dose calculation, dose distribution, dose volume histogram and final monitor units represent this optimization result. If the dose prescription, for example dose/fraction and/or fraction number is changed ***following optimization***, the monitor units of the optimized plan change accordingly. However, if the plan is at this point re-calculated, but **not re-optimized**, the new dose calculation will use the fixed monitor units from the existing optimization. The new absolute 3D dose distribution will be correctly calculated to correspond to these monitor units, as will DVHs and dose points. However, failure to visualise the new dose distribution and to perform DVH analysis prior to approving the plan could lead to the situation the patient is treated with monitor units inappropriate to the original plan objectives.

Recommended User Action

It is not recommended to change prescription after the dose volume optimization has been performed. If changes are made, the plans must be re-optimized and visualized.
When using VMAT or RapidArc optimization:
-Always verify the final plan using DVH analysis inside Eclipse when approving plans or plan sums for treatment.
-Evaluate dose distribution visually.
-Verify the maximum dose and its location inside the irradiated target after dose calculation.
-Always follow warnings, cautions and messages provided by the software.

Varian Medical Systems Actions:

Varian Medical Systems is notifying all possibly affected customers with this document.

Varian Medical Systems is developing a technical 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.

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This document contains important information for the continued safe and proper use of your equipment.

- Please retain a copy of this document along with your most current product labeling.
- 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 Medical Systems 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 Form 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 Medical Systems Customer Support District or Regional Manager.

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

Mika Miettinen
Director, Global Quality Assurance and Product Reliability

2012-06-18
Date (YYYY-MM-DD)

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