URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	Unexpected MU change in Plan Parameters workspace
Commercial Name of Affected Product:	Eclipse™ Treatment Planning System, ARIA® for Radiation Oncology, ARIA® Radiation Therapy Management, and Acuity™
Affected Version(s) / Lot(s):	Versions 11 and 13
Reference / FSCA Identifier:	CP-13526
Date of Notification:	***2013-11-18***
Type of Action:	Notification and Correction

Description of Problem:

This letter is to advise you of an anomaly that has been identified with the Plan Parameters workspace within Eclipse™ Treatment Planning System, ARIA® Radiation Oncology, ARIA® Radiation Therapy Management, and Acuity™. When a dose relevant parameter is changed and "Do not clear MUs and Reference Point dose" is selected, the Monitor Units (MUs) may change. 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.

This issue does not affect BrachyVision.

Details:

A software anomaly has been identified in the Plan Parameters workspace. The Monitor Units of the plan may change without the user being aware when all of the following conditions are fulfilled:

1. The plan has a primary reference point with geometrical location AND
2. The dose prescription percentage at the primary reference point is not 100% AND
3. 3D Dose Distribution is cleared AND
4. "Do not clear MU's and reference point doses" has been selected in the "Clear 3D Dose dialog" box AND
5. Any dose relevant parameter (see Table 1 below) is changed in the Plan Parameters workspace.

When all these conditions are fulfilled, the dose is rescaled such that the 100% isodose is shifted to the primary reference point location. Consequently, the MUs for each treatment field will change and will not meet the dose prescription intended.

For example, if the dose prescription percentage was 85% in the original plan, and a dose relevant parameter is changed, the dose prescription percentage will rescale to 100%. The Monitor Units will be correspondingly increased. Thus, the plan will no longer meet the intended dose prescription.

PARAMETERS CAUSING RESCALING		
Field Technique (e.g. Static or Arc)	Collimator Rotation	Dynamic Wedge
Energy, Modality or Dose Rate	Field X, X1, X2	Internal Mount
Gantry Rotation	Field Y, Y1, Y2	Couch Rotation
Any change in dose prescription	Change of treatment unit	Change of Target Volume
Change to dosimetrically equivalent machine	Beam Modifier (e.g. MLC, block, wedge, compensator, or trays)	Any change invalidating Dose

Table 1. Parameters which can cause Rescaling of Monitor Units

Recommended User Action

DO NOT USE the Plan Parameters workspace to modify 3D Treatment Plans containing a 3D dose. When it is necessary to edit patient treatment plans containing 3D dose, this action must be performed in Eclipse™ External Beam Planning or in your applicable treatment planning system.

Varian Medical Systems recommends a thorough review of treated patient plans for plans with a primary reference point with geometric location and where modifications were made in the Plan Parameter workspace.

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 Support representative when this correction is available to schedule its installation on your system.

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.

Please complete the enclosed Recall Return Response form. In order to satisfy regulatory requirements, we request that you complete the Recall Return Response form and return it to Varian Medical Systems by email to returnresponse@varian.com.

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

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.

Jeff Semone
Sr. Director, Regulatory Affairs Post Market Safety & Surveillance

Varian Oncology Help Desk Contact Information:

Phone:	USA and Canada: 1.888.VARIAN5 (888.827.4265) Europe: +41 41 749 8844
Email:	North America: support-americas@varian.com Australia/New Zealand: support-anz@varian.com Europe: support-emea@varian.com South East Asia: support-sea@varian.com China / Asia: support-china@varian.com Japan: support-japan@varian.com Latin America: sac@varian.com.br