VARIAN
medical systems

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	**Erroneous Conventional Arc Field Dose Calculation with Pencil Beam Convolution Algorithm**
Commercial Name of Affected Product:	**Eclipse ™ Treatment Planning System**
Affected Version(s) / Lot(s):	**Eclipse™ Treatment Planning System versions 11, 13.0, 13.5, 13.6 using Pencil Beam Convolution Algorithm 11.0.31**
Reference / FSCA Identifier:	**CP-23187**
Date of Notification:	**2016-01-11**
Type of Action:	**Notification and Correction**

Description of Problem:

Varian Medical Systems has received a report of an anomaly involving Eclipse™ Treatment Planning System Pencil Beam Convolution (PBC) 11.0.31 to compute a conventional arc dose distribution. When using PBC 11.0.31 to calculate the dose for a conventional arc field with **_more than 100 segments_** with Eclipse versions 11, 13, 13.5 or 13.6, the displayed dose does not correspond to the calculated Monitor Units (MU). Varian has not received any report of misadministration due to this issue.

Eclipse version 10 and lower using PBC are not affected. Eclipse versions 11, 13, 13.5 or 13.6 using PBC 10.0.28 are not affected. RapidArc® plans are not affected, because PBC cannot be used with RapidArc. Arc plans for TrueBeam® Radiotherapy Systems are not affected.

Details:

All Eclipse Treatment Planning Systems include the PBC algorithm; however, customers may purchase and use different dose calculation algorithms. The anomaly in PBC 11.0.31 affects Eclipse versions 11, 13, 13.5 and 13.6, for arcs consisting of **_more than 100 segments_**. The anomaly causes Eclipse to display a dose distribution that does not correspond to the calculated Monitor Units, which may lead to an overdose. *The discrepancy is easily detectable when a phantom is used to verify the treatment plan,* as is advised in the user documentation.

The discrepancy between the displayed dose distribution and MUs increases with the number of segments above 100. When the arc has few segments above 100, the discrepancy is smaller and more difficult to detect. As the number of segments increases above 100, the discrepancy between the displayed dose and the actual dose becomes more pronounced. When an arc is comprised of significantly more than 100 segments, the arc plan will not display MU, and the arc treatment plan will become invalid and cause the treatment to be blocked.

All conventional arcs supported by PBC 11.0.31 dose calculation algorithm with _more than 100 segments_ are affected including:
- Conformal arc with varying MLC
- Standard arc with static jaws only
- Standard arc with static MLC

The issue <u>does not occur</u> if the site is using PBC version 10. The user cannot perform dose calculations with version 10 if the number of segments is greater than 100.

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Recommended User Actions:

DO NOT USE Eclipse version 11, 13, 13.5, or 13.6 with PBC 11.0.31 algorithm for conventional arc field dose calculation.

Varian recommends use of the Eclipse Anisotropic Analytical Algorithm **(**AAA) or Acuros® XB advanced dose calculation algorithm for conventional arc field dose calculation.

Users can verify whether a plan generated by Eclipse version 11, 13, 13.5 or 13.6 using PBC 11.0.31 exceeds the 100 segment limit for a given field by reviewing the calculation log files. The affected fields should be evaluated by re-calculating the plan with either: AAA, Acuros® XB or PBC 10.0.28 dose calculation algorithms. For conformal arc plans, fields can also be evaluated in the properties of the dynamic MLC.

Varian Medical Systems Actions:

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

Varian Medical Systems is investigating a solution for this issue.

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.

In order to satisfy regulatory requirements, we request that you complete the attached Recall Return Response form provided. Kindly return the completed form to returnresponse@varian.com.

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. This notice has been provided to the appropriate Regulatory Authorities.

Jeff Semone, Sr. Director
Global Quality Assurance and Product Reliability
Varian Medical Systems

Varian Oncology Help Desk Contact Information:
Phone: +1.888.827.4265
Email: support_@varian.com