



Varian Medical Systems

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URGENT MEDICAL DEVICE CORRECTION FIELD SAFETY NOTICE

Subject: *Unintended Override of Gated Treatment Plan*
Affected Product: *TrueBeam, TrueBeam STx, VitalBeam and EDGE treatment delivery systems*
Version: *2.0 and 2.5 [below 2.5MR2]*
Reference/Identifier: *CP-2018-01713*
Date of Notification: *2018-08-21*
Type of Action: *Notification and Correction*

DESCRIPTION OF PROBLEM:

Varian Medical Systems has received reports of an anomaly that can result in a treatment without intended gating. This issue occurs when a patient planned with gating is treated on more than one TrueBeam system [includes: TrueBeam, TrueBeam STx, VitalBeam or EDGE].

Varian has not received any reports of injury due to this issue. The issue only affects TrueBeam systems version 2.0, 2.5 and 2.5 MR1.

DETAILS:

The issue occurs when a patient with a gated treatment plan assigned to a TrueBeam (TrueBeam A) is moved to a second TrueBeam (TrueBeam B) for treatment delivery. If the TrueBeam A gating device was permanently selected for the initial treatment on a gated treatment plan, when that plan or another gating plan for the same patient is loaded on TrueBeam B, an orange message is displayed in the Treatment application. See, Figure 1.

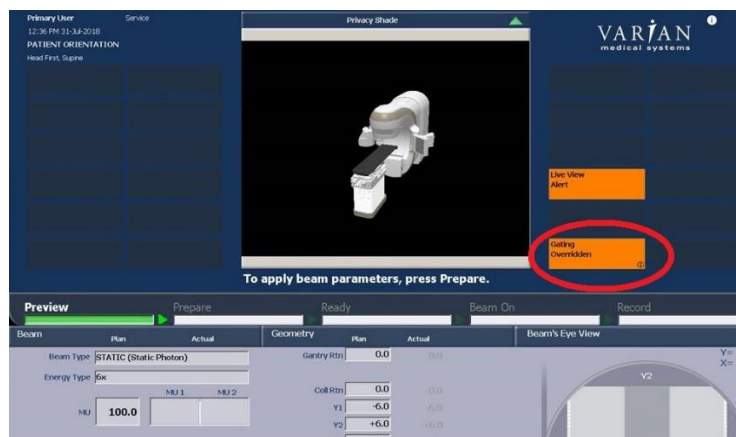


Figure 1 Gating override message, circled in red.

This orange message indicates that intended ***gating is overridden***. The Motion Management Interface will not prompt the user to select a gating device. If the user does not add gating to the workflow after this

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message is displayed, treatment can proceed without the beam being gated. Gating must be added to the workflow from the Tools Menu. Treating the plan without gating may lead to mistreatment and patient harm.

ARIA users are impacted as gating flags can be set in the system. This flag is stored in the plan between machines.

RECOMMENDED USER ACTION:

For treatment plans with intended gating, Varian recommends users monitor and pay attention to the system status message. When a patient with a gated treatment plan is moved to a second TrueBeam system, users must verify that intending gating was not overridden.

If gating is overridden, users should reselect it from the Tools menu. Contact Varian Support if you have questions regarding selecting gating from the Tools menu.

VARIAN MEDICAL SYSTEMS ACTIONS:

Varian Medical Systems is notifying all affected users with this document.

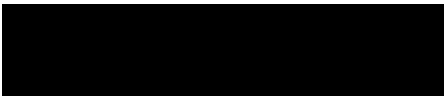
Varian Medical Systems is investigating a solution for this issue. You will be contacted by a Customer Service Representative to schedule upgrade to the correction when available.

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.



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