

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject: *Unexpected Overwrite of Plan Couch Parameter*
Commercial Name of Affected Product: *TrueBeam® Radiotherapy Delivery System with AlignRT®*
Affected Version(s) / Lot(s): *TrueBeam version 2.0/2.5 with any version AlignRT*
Reference / FSCA Identifier: *CP-23897*
Date of Notification: *2016-06-24*
Type of Action: *Notification and Correction*

Description of Problem:

Varian Medical Systems has been notified by Vision RT that unintended changes can be made to planned couch parameters, specifically the couch rotation parameter, during patient set-up. This can occur when a user sets a different couch rotation from the plan couch rotation while performing patient alignment with Vision RT's AlignRT® device prior to treatment with the TrueBeam® Radiotherapy Delivery System [TrueBeam]. Neither Vision RT nor Varian has received any report of patient harm due to this issue.

Details:

When a request to update the couch position is sent to the TrueBeam via the AlignRT device using the Move Couch function, the request may not be processed as expected. If the couch rotation selected by the user in the AlignRT device **does not match** the planned couch rotation of the field selected on the TrueBeam, this can result in a significant change to the planned couch rotation value for the session. When the planned value is changed, the original plan value is overwritten at the console. This will result in the treatment plan couch value being updated unintentionally and, if used for treatment, a misadministration may occur.

For example, the treatment field selected includes a planned couch rotation of 10 degrees. The patient is set-up with the actual couch and the reference image at zero (0) degrees. Using the Move Couch function will cause the plan couch rotation for this treatment field to be updated incorrectly to zero (0) degrees at the console. This overwrite will allow beam delivery at zero (0) degrees for this treatment session although the original planned value was 10 degrees. This could result in the patient being treated with fields entering at the wrong angle.

The Varian console software is designed to require a sign-off by an authorized user when the difference between actual couch and planned couch parameters exceed the defined tolerance. Because the original planned value is overwritten, there is no difference that exceeds the defined tolerance and the user is not prompted for sign off.

Recommended User Actions:

DO NOT USE the "Move Couch" function if the couch rotation value set in the AlignRT® device **DOES NOT** match the planned couch rotation for the treatment field.

Varian recommends that the user ALWAYS confirm that the patient is correctly aligned prior to commencing treatment.

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Varian Medical Systems Actions:

Varian Medical Systems is notifying all possibly affected customers with this document. Varian is providing a copy of the Vision RT notification for reference.

Varian Medical Systems and Vision RT are both investigating a solution for this issue. You will be contacted when this correction is available to schedule its installation.

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
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