URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	***Unexpected Auxiliary Device Authorization***
***Commercial Name of Affected Product*:**	**4D Integrated Treatment Console**
***Affected Version(s) / Lot(s)*:**	**4DITC version 10 and 11**
Reference / FSCA Identifier:	**CP-16026**
Date of Notification:	***19-08-2014***
***Type of Action*:**	**Notification and Correction**

Description of Problem:

Varian recently received two reports of treatment workflows for a C-Series High Energy (HE) linear accelerator with two auxiliary devices, specifically Brainlab's ExacTrac® patient positioning device and Varian's Barcode Conical Collimator Verification (BCCV) device. In both these cases, the user sent successive ready [authorization] signals from the ExacTrac® to the 4D Integrated Treatment Console [4DITC]. The signals are sent through the Auxiliary Device Interface [ADI]. These successive signals unexpectedly cleared both the ExacTrac® interlock and the BCCV interlock on the linac. It was possible to initiate treatment delivery with the linac even though BCCV still showed "pending" status. Varian has not received any report of patient injury due to these workflows.

- TrueBeam™ is not affected because the TrueBeam™ treatment application system differentiates the ADI devices, and waits for specific authorization from each and every ADI device.

This notice provides details 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.

Details:

BCCV works with and through Varian's Auxiliary Device Interface (ADI) to maintain an interlock preventing irradiation until the planned cone is verified by BCCV. If the mounted cone does not match the treatment plan, or no cone is mounted, the interlock will not clear and irradiation will be prevented. The ADI may also be employed by other third-party verification systems to prevent irradiation if certain other treatment parameters are not within treatment plan defined values (e.g. patient position).

The 4DITC does not identify and distinguish signals sent from ADI device. If there are multiple devices in simultaneous use, a single ADI device can send successive signals and clear pending authorizations for other devices. Any extra authorization is counted toward another ADI device. A list of third-party systems that perform verifications and communicate authorizations via the ADI appears in Table 1. This issue is only known to occur with the ExacTrac® positioning system in combination with a C-Series HE linac with BCCV.

In both reported cases, the user was employing a C-Series HE linac with 4DITC and both ExacTrac® and BCCV. The user was authorizing the ExacTrac® to the linac 4DITC. Successive signals were sent from the ExacTrac® to the 4DITC. The first signal cleared the ExacTrac® interlock as intended. The ExacTrac® console requested user confirmation of the second command to authorize. The user responded affirmatively. The signal was sent to the 4DITC, and the linac interlock associated with BCCV was released. This was not intended.

The receipt of two sequential authorizations from the ExacTrac® system resulted in the linac interlock being released (cleared) even though a BCCV authorization had not yet been transmitted. In such a

situation, it may be possible to irradiate the patient using a cone other than what is specified by the treatment plan because the BCCV verification was not completed.

Table 1. *Third Party devices issued ADI client codes for use with Varian C-Series linacs*

Third Party Vendor	Third Party ADI Device
Vision RT Ltd	AlignRT® 3D imaging and motion management system
C-RAD AB	Catalyst™ System and Sentinel™ System
Brainlab AG	ExacTrac® patient positioning system
Micropos Medical	RayPilot® electromagnetic positioning system
Civco Medical Solutions	Protura™ robotic patient positioning system

Recommended User Action:

Varian reminds users using auxiliary devices requiring the ADI interface of the following.

- The BCCV system is intended to ***assist*** users of radiation therapy devices by preventing irradiation until the conical collimator required by the treatment plan is in place. The user must verify cone size and placement independently. Users must ***always*** perform redundant visual verification in addition to the verification performed by BCCV. *Barcode Conical Collimator Verification Instructions for Use*, PN 100050506-05, Feb 2011, p 12.

- When more than one device employing the ADI are incorporated into the treatment workflow (e.g. BCCV plus ExacTrac®), it is important that users ***verify independently*** that each device authorization is appropriate before proceeding to treatment.

For users performing SRS/SBRT:

- Varian ***strongly recommends*** that users implement and document independent visual verification of the installed cone size by two individuals.

- Varian ***strongly recommends*** that users develop and use checklists for all aspects of SRS/SBRT processes. See Solberg et al., *Quality and Safety Considerations in Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy, Table 1, Recommendation Five,* Practical Radiation Oncology: August 2011 Supplement.

- Varian ***strongly recommends*** that users, prior to initiating treatment, verify adequate information is available to ensure the process is correct. QA methods used must verify the integrity of data transfer from treatment planning system to treatment management system. See Solberg et al., *Quality and Safety Considerations in Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy, Table 7, Recommendation Six,* Practical Radiation Oncology: August 2011 Supplement.

Varian Medical Systems Actions:

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

Varian Medical Systems has developed a fix for this issue and a customer service representative will be contacting you to schedule installation.

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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 is posted at MyVarian.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.

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

Jeff Semone
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