URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	***Unexpected 6MV Beam Output Variations***
***Commercial Name of Affected Product*:**	**C-Series High Energy Linear Accelerator**
	Affected Version(s) / Lot(s): Novalis Tx, Trilogy, Trilogy Tx, Clinac iX, Clinac CX, Clinac 2100 C/D, Clinac 2300C/D, Clinac DX, Clinac 21 EX, Clinac 23 EX
	6MV configurations only
Reference / FSCA Identifier:	**CP-12459**
Date of Notification:	***2014-06-17***
Type of Action:	**Notification and Correction**

Description of Problem:
Varian has seen a trend in reports of unexpected decrease in beam output in C-Series High Energy [HE] Linear Accelerators for 6MV photon treatment mode. To-date Varian has not received any report of misadministration or injury due to this 6MV target degradation or failure.

- TrueBeam™ and Varian Low Energy Linear Accelerators [e.g., 600C series, Unique] are *NOT AFFECTED*.

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:
Varian has determined the cause of the unexpected variations in beam output to be degradation of the 6MV target. Specifically, the effects of modern, highly modulated treatment modes can create high levels and frequency of stress cycles in the targets particularly if the beam spot size is small. This can lead to the targets' deterioration and failure at an accelerated rate resulting in a rapid change in the beam output and symmetry. Specifically:

1. The photon generation, or bremsstrahlung yield, decreases as fewer electrons are converted to photons in the target, and;
2. Due to a resulting escape of primary electrons the output of photons, as measured by the ion chamber, might appear to be constant, but the actual photon output is decreasing.

This failure mode in the target only affects the 6 MV photon treatment modes (6SRS, 6FFF and 6X). *No other energies are affected*.

Recommended User Action:
Varian ***strongly recommends*** that all sites implement ***daily output constancy checks*** of photon beams as recommended by the AAPM. Specifically those provided by:

1. *AAPM*, *Task Group 142 Report: Quality Assurance of Medical Accelerators,* Medical Physics publication 36 (9), September 2009, and
2. *AAPM Report No. 46, Comprehensive QA for Radiation Oncology*, Report of Task Group No. 40 Radiation Therapy Committee, April 1994.

It is particularly important that these daily output constancy checks include all 6MV beams [6SRS, 6FFF and 6X]. Sites should particularly check for any **sudden decrease in dose output ≥ 3% per day, or ≥6% per week**.

- Measurements should be made with buildup (5 cm water equivalent) which is beyond the electron range to avoid electron contamination of measurements.
- If any sudden decrease in dose output is observed, **CEASE USE of all 6MV beams** AND CONTACT VARIAN IMMEDIATELY. A Varian service representative will visit the site and investigate whether the target is degrading, or has failed.

Varian recommends that a service call be requested in the event system faults are generated for target cooling to investigate and determine whether a cooling circulation problem exists.

NOTE: Absolute dosimetry calibration at depths greater than the dose maximum depth (D_{max}) specified by Varian can compromise the reliability of the system. Clinac control systems are designed to deliver a specified number of monitor units (MU) per minute. The Dosimetry System Calibration is set at installation so that one MU displayed on the console corresponds to the delivery of one centigray (cGY) of dose to D_{max} in water for a 10 centimeter by 10 centimeter field at 100 centimeter target-to-surface distance (TSD). Varian ***strongly recommends*** the Dosimetry System Calibration be maintained as 1 MU to 1cGY delivered to D_{max} for a 10x10 cm^2 field at 100 cm TSD. See, CTB-GE-228, available from MyVarian.com.

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

Varian Medical Systems is investigating the implementation of a technical correction 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 is posted at MyVarian.com.

In order to satisfy regulatory requirements, we request that you complete the attached Recall Return Response form and return it to Varian Medical Systems 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.

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

Vy Tran
Vice President, Regulatory Affairs and Quality Systems

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