

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject:	Incorrect Position Readout Values Caused by Excessive Connector Resistance
Commercial Name of Affected Product:	C-Series Clinac or Trilogy, versions 7.x and 8.x
Reference / FSCA Identifier:	CP-06611
Date of Notification:	2012-01-24
Type of Action:	Notification only
Details on Affected Devices:	Refer to appendix page

Description of Problem:

This letter is to advise you that an event has been reported to Varian involving a C-Series Clinac® accelerator. The event entails excessive connector resistance, which caused the actual jaw positions to differ from the intended jaw positions without warning the operator. Normal morning daily quality assurance testing and light field verification detected the discrepancy. Varian has not received any report of misadministration as a result of the discrepancy. Investigation found that a similar issue could arise on the gantry or couch axes. This does not affect the MLC. This notice provides pertinent details, and actions you can take to avoid or mitigate the issue.

Details:

Excessive connector resistance in the lines providing reference voltages to the potentiometers can cause a discrepancy between the actual physical positions compared to the corresponding position readouts; leading to an incorrect setting such as treatment field size. The voltage is monitored at the supply but not at the potentiometers. A measurable drop in voltage may create a situation in which the actual position might differ from the intended position, in either direction.

The wires carrying both +/- voltage reference signals are used for both primary and secondary position readout indicators. Therefore, a change in resistance to the connector would result in the same offset in both readouts. A change in resistance that occurred while the machine is in the ready or beam on state would trigger an interlock interrupting treatment.

Even though it is very unlikely that the discrepancy would go undetected by routine quality assurance checks and recommend use of the light field, if for example a jaw position error went unnoticed, the effective field size would be larger or smaller than intended. Treatments where the field is fully shaped by a tertiary collimator would limit the effect of small errors in jaw positions. This includes fields shaped by an MLC, (including Dynamic MLC and RapidArc) SRS treatments using a conical collimator and electron treatments using an electron cone. Undetected large errors in jaw positions could however lead to serious injury regardless of the tertiary collimation method.

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Quality assurance measures and standard use of the light field can identify the problem. It is imperative that both be followed routinely. A daily QA consistency check using the light field and mechanical scales can determine any difference in the projected and actual field size; collimator gantry or couch rotation and couch position. The light field also provides verification of the field size, field shape and match line, and should be used for each and every field. Morning QA should include collimator size indicator check according to the AAPM recommended daily quality assurance procedures. A light field check and mechanical scale check would identify any readout deviation.

Recommended User Action

All departments should establish a comprehensive quality assurance program. References to such programs are:

1. "AAPM code of practice for radiotherapy accelerators: Report of AAPM Radiation Therapy Committee Task Group." Medical Physics, Vol. 21, No. 7, July 1994
2. "Comprehensive Quality Assurance for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group," Medical Physics, Vol. 21, No. 4, April 1994

Before beginning treatments for the day, quality assurance tests must be performed. The AAPM Task Group 142 recommends that a collimator size indicator check be performed daily for all treatment types.¹

Additionally, any discrepancies in imaging field size vs. planned field size should be brought to the attention of the medical physicist for investigation before treatment continues.

Varian Actions:

Varian is notifying all possibly affected customers with this document.

Varian is continuing to evaluate possible technical solutions for this issue.

Please 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 customer support website: <http://www.MyVarian.com>.

Special Instructions for customers outside the USA and Canada: In order to satisfy regulatory requirements, we request that you complete the attached Proof of Notification or Receipt Verification Card once you have read this document and return it to Varian Medical Systems.

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 Customer Support District or Regional Manager.

¹ Klein et al.: 'QA of Medical Accelerator: Report of Task Group', Medical Physics, Vol.36, No. 9, September 2009,

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



Peter J. Coronado,
Acting Director, Global Regulatory Affairs
on behalf of
Mika Miettinen,
Director, Global Quality Assurance and Product Reliability

24-Jan-2012

Date

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Varian Medical Systems public site - www.varian.com

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APPENDIX

LIST OF SERIAL NUMBERS

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H293618	H293682	H293745	H293808	H293871	H293934	H293998	H294061	H294125	H294188	H294250	H294313	H294377
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H293620	H293684	H293747	H293810	H293873	H293936	H294000	H294063	H294127	H294190	H294252	H	

H294414	H294479	H294541	H294611	H294673	H294739	H294801	H294867	H294932	H295001	H295065	H295134	H295216
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