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URGENT MEDICAL DEVICE CORRECTION FIELD SAFETY NOTICE

Subject: *MLC Leaves Do Not Move During Arc Treatment*
Commercial Name: *Varian Multileaf Collimator with C-Series Linac*
Affected Version(s) / Lot(s): *MLC version 8.5*
Reference / FSCA Identifier: *NC-2019-00343*
Date of Notification: *2019-08-08*
Type of Action: *Notification and Correction*

DESCRIPTION OF ISSUE:

After a recent upgrade to Multileaf Collimator [MLC] software version 8.5, a site reported that the MLC leaves did not move during an arc treatment. The issue is related to a transient carriage primary-secondary interlock due to carriage fault on the MLC that immediately preceded the initiation of the arc treatment. The issue will occur ONLY with MLC software version 8.5.

MLC versions below 8.5 are not affected. This issue does not affect static gantry dynamic MLC treatments such as IMRT. The issue only affects conformal arc treatments, including VMAT and RapidArc.

There have been no reports of adverse health consequences due to this issue.

DETAILS:

Transient primary-secondary carriage interlocks are activated when a secondary feedback position error has occurred. This will be recorded as a carriage fault. The interlock automatically clears when the condition clears. In this case, the interlock was activated after the MLC leaves had correctly reached the intended start position prior to treatment [beam on]. In the process of asserting and clearing the interlock, the MLC state incorrectly changed from dynamic to static. Treatment can be initiated but the MLC leaves do not move. This unintended MLC state change will occur ONLY if the interlock was activated after the MLC leaves are at their planned start position and prior to treatment [beam on].

The interlock can last for as little as 50 msec. If the interlock lasts sufficiently long, an icon will be displayed on the 4DITC taskbar. When a user clicks on the icon, the depicted error message is displayed. See Photo 1.

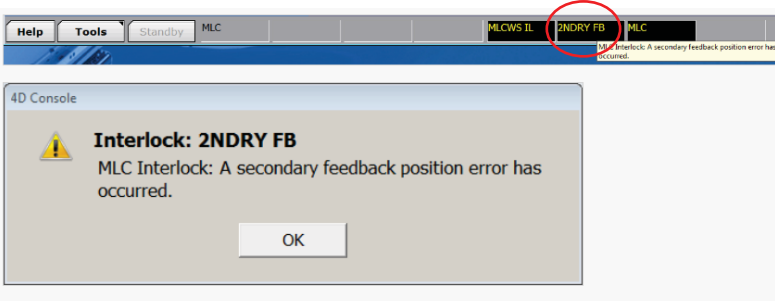


Photo 1. MLC Interlock error message displayed on 4DITC console. Shown after clicking on circled icon.

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This error message clears when the carriage fault condition clears. Therefore, the icon may only flash on the screen. Neither the taskbar icon nor the error message indicates that the MLC state has changed. The MLC leaves will not move during treatment. A record of the carriage fault can be found in the TerminalLog files. The files can be viewed with the LogViewer application.

RECOMMENDED USER ACTION:

Varian highly recommends that users monitor MLC leaf movement on the 4DITC console screen. Users **MUST** observe the start of every arc treatment and verify that the leaves are moving as intended.

Users should stop treatment immediately if MLC leaves are not moving. Contact Varian to assess the MLC status.

Users may contact Varian Support for help to verify whether carriage faults have been recorded for the MLC. If carriage fault is confirmed in the TerminalLog file, contact Varian Service Representative to assess the MLC status

VARIAN MEDICAL SYSTEMS ACTION:

Varian is developing a software solution to address this issue. You will be contacted by Varian Customer Service to schedule the upgrade when the solution is 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.

In compliance with regulatory requirements, we request that you complete the Return Response form provided with this notification. 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 service manager. This notice will be provided to the appropriate Regulatory Authorities as required.

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