

URGENT FIELD SAFETY NOTICE

Subject: RapidArc™ and VVMAT Treatment may deliver as Dynamic Arc on Incorrectly Configured System

Commercial Name of Affected Product: Clinac 2100

FSCA Identifier: CP-02334

Date of Notification: 2010-07-20

Type of Action: Notification

Details on Affected Devices:

All C series Clinacs Equipped for Rapid Arc Treatment delivery
see Appendix for serial numbers

Description of Problem:

We are writing to advise you about a possible configuration issue on RapidArc and VVMAT systems, including information on how to identify that your system does not have this issue.

In the rest of this letter, 'VMAT' is used as a generic term to represent RapidArc or VVMAT treatments.

Anomaly:

A system was discovered where VMAT plans were delivered as Dynamic Arc. On investigation, it was determined that an older configuration of the Clinac and older version and configuration of the LVI software ('Linac VI' –the interface computer between the Clinac and the 4DITC), which did not recognize VMAT plans was inadvertently installed.

Under these circumstances, dynamic dose rate and gantry speed features as well as avoidance sectors (range of gantry rotation where no dose should be delivered) that may be part of a VMAT plan are not recognized, and dose delivered does not match the treatment plan.

We believe that this system configuration issue was unique, but are issuing this letter as a cautionary measure.

Recommended User Action:

- Users should observe the C-series display during delivery of a test VMAT plan. The words 'RapidArc X' or 'VMAT X' should appear under Treatment Type during dose delivery. If the words 'RapidArc' or 'VMAT' are not seen, call Varian service and discontinue use of the device for VMAT treatments. Note you can also determine the version of Linac VI software installed – refer to the 4DITC Administrative Reference Guide.
- It is also recommended that users establish routine machine QA checks for VMAT. The VMAT machine QA should be performed at least every time the software configuration of any component on the Clinac, i.e. 4DITC, Linac VI, C-series, MLC, is modified. For a discussion on VMAT machine QA, users are encouraged to refer to: *Ling et al., Commissioning and Quality Assurance of RapidArc™ Radiotherapy Delivery System, Int. J. Radiation Oncology Biol. Phys., Vol. 72, No. 2, pp. 575–581, 2008*

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- Users are encouraged to take advantage of the RapidArc Bibliography and Commissioning information available at www.MyVarian.com
- If you have a pre-treatment plan QA program for VMAT plans established in your clinic, please note the following:
 - o Some treatment planning systems, like Eclipse, have a function that allows calculation of VMAT fields as if the dose was delivered from a single gantry angle, typically 0 degrees. This function is used to simulate measurement conditions where a radiation detector is attached to the machine's head and rotates with the gantry during VMAT delivery. If such a plan, stripped from the gantry rotation information, is delivered on the machine, it will be delivered as a static gantry IMRT plan. Caution should be used if this approach is selected for pre-treatment plan QA. The machine is not operating in VMAT mode when delivering such a plan. The QA method is thus not fully verifying the capabilities required to deliver VMAT plans.

Varian Actions:

- Varian is notifying all possibly affected customers with this document.
- Varian is modifying user documents, installation instructions, and the Customer Acceptance Test Plan in order to prevent a recurrence of this system configuration problem.

Please advise the appropriate personnel working in your radiotherapy department of the content of this letter.

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.

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

Michael Pignataro on behalf of Dave Hall *7/20/2010*
Dave Hall, Manager Reporting and Corrections /Date

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APPENDIX LIST OF AFFECTED DEVICE SERIAL NUMBERS

Listed are the affected system Serial Numbers. The last four digits represent the serial number of the device.

H140025	H140753	H140845	H140896	H272157	H272963	H291040	H291187	H293443	H293691
H140038	H140769	H140846	H140901	H272158	H272981	H291048	H291190	H293447	H293696
H140045	H140772	H140848	H140902	H272165	H272982	H291050	H291206	H293475	H293700
H140047	H140773	H140849	H140904	H272178	H272985	H291051	H291226	H293496	H293709
H140078	H140777	H140850	H140906	H272187	H273049	H291053	H291230	H293507	H293725
H140092	H140780	H140851	H182012	H272188	H273065	H291060	H291234	H293519	H293726
H140096	H140781	H140853	H271167	H272216	H273162	H291067	H291242	H293538	H293727
H140097	H140783	H140854	H271370	H272220	H273170	H291072	H291247	H293541	H293728
H140122	H140787	H140855	H271378	H272231	H273202	H291081	H291248	H293560	H293736
H140124	H140790	H140856	H271385	H272309	H273203	H291084	H291251	H293565	H293737
H140125	H140794	H140857	H271531	H272310	H290278	H291088	H291253	H293577	H293749
H140144	H140795	H140858	H271588	H272325	H290282	H291096	H291254	H293581	H293769
H140146	H140797	H140863	H271607	H272360	H290362	H291099	H291262	H293592	H293773
H140148	H140799	H140864	H271618	H272377	H290399	H291107	H291270	H293596	H293774
H140201	H140800	H140865	H271662	H272401	H290400	H291115	H291271	H293611	H293775
H140202	H140801	H140866	H271663	H272426	H290402	H291116	H291272	H293624	H293778
H140206	H140808	H140867	H271729	H272427	H290501	H291117	H293312	H293627	H293779
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H140216	H140816	H140869	H271825	H272456	H290510	H291119	H293327	H293636	H293781
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H140222	H140818	H140874	H271906	H272491	H290519	H291133	H293342	H293642	H293802
H140223	H140819	H140876	H271926	H272497	H291007	H291136	H293353	H293644	H293804
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H140233	H140824	H140881	H271951	H272826	H291011	H291143	H293363	H293649	H293818
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H140749	H140843	H140893	H272081	H272946	H291035	H291178	H293438	H293686	H293846
H140751	H140844	H140895	H272111	H272960	H291037	H291184	H293439	H293690	H293847

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H293848	H294007	H294135	H294244	H294332	H294415	H294500	H294567	H294656	H294732
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H294004	H294134	H294238	H294331	H294414	H294499	H294565	H294654	H294729	