

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject: Dual MLC with Shared Workstation
Commercial Name of Affected Product: Varian Clinac® accelerators with Mark or Millennium MLC and BrainLAB m3 MLC
Reference / FSCA Identifier: CP-05591
Date of Notification: 2012-02-16
Type of Action: Notification and Correction
Details on Affected Devices: Refer to appendix page.

Description of Problem:

This letter is to advise you of the possibility of a Varian MLC interfering with the treatment field of a demountable BrainLAB m3 micro-MLC without an interlock being asserted.

This notice provides information about the problem and actions you can take to avoid or mitigate the problem.

Details:

Failure to retract or park the Varian MLC leaves prior to use of the demountable BrainLAB m3 could result in the Varian MLC leaves interfering with the treatment field defined by the BrainLAB m3 without an interlock being asserted.

When a demountable BrainLAB m3 MLC is installed on a Varian accelerator, the use of two A-B switches is required to deploy the desired MLC. Both switches must be set to the correct position prior to use.

- The first A-B switch box connects the MLC workstation to either the Varian MLC Controller or to the BrainLAB m3 Controller.
- The second A-B switch box connects the Clinac console to either the Varian MLC Controller or the BrainLAB m3 Controller. This connection includes the MLC interlock used to inhibit radiation from the Clinac accelerator. The MLC that is *not* selected on this A-B switch is disconnected from the interlock circuitry.

Recommended User Actions:

1. Read and understand all relevant user documentation that accompanied your BrainLAB m3 MLC.
2. Prior to installing a BrainLAB m3 MLC, and switching the communication and interlock paths from the Varian MLC controller to the BrainLAB m3 MLC controller the user **MUST** verify the Varian MLC leaves are parked and not interfering with the BrainLAB m3 treatment field.

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3. After switching the communication path to the BrainLAB m3 MLC controller the user **MUST** verify that the projected field is correct by using the field light.

Varian Actions:

1. Varian is notifying all possibly affected customers with this document.
2. Varian has notified BrainLAB of this event involving the BrainLAB m3 MLC.
3. Customers with 4DITC, BrainLAB m3 and a Varian Millennium MLC:
 - will be upgraded to 4DITC v10.2 which provides a warning to park the Millennium MLC when switching the active MLC to the BrainLAB m3.
 - will be upgraded to MLC v7.x. which allows for the simultaneous communications between the MLC (or 4DITC) workstation and both the MLC controllers.
 - Add warning decals to the A/B boxes reminding users to park the Millennium MLC before using the BrainLAB m3
4. Customers with:
 - Varian Millennium MLC and a BrainLAB m3 but without 4DITC
 - OR
 - Varian Mark-series MLC and BrainLAB m3
 - Add warning decals to the A/B boxes reminding users to park the Millennium MLC before using the BrainLAB m3.

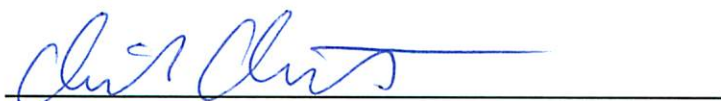
Once these modifications are available, Varian Service will contact you to arrange installation.

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.

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



Mika Miettinen
Director, Global Quality Assurance and Product Reliability

2012-02-16

Date

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Varian Medical Systems public site - www.varian.com

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APPENDIX LIST OF SERIAL NUMBERS

H530001	H530075	H530439	H533043	H535023	H535082	H535128	H535180	H535220
H530004	H530078	H531008	H534004	H535024	H535084	H535131	H535181	H535867
H530008	H530082	H531010	H534015	H535025	H535085	H535133	H535182	H536005
H530012	H530084	H531020	H534020	H535030	H535086	H535135	H535183	H536452
H530014	H530085	H531025	H534021	H535031	H535087	H535137	H535184	H536465
H530018	H530087	H531029	H534022	H535033	H535088	H535141	H535186	H536479
H530021	H530104	H531033	H534026	H535035	H535091	H535142	H535188	
H530022	H530204	H531035	H534032	H535036	H535094	H535144	H535190	
H530023	H530231	H531038	H534036	H535039	H535098	H535147	H535191	
H530024	H530250	H531041	H534040	H535043	H535099	H535149	H535192	
H530030	H530311	H531043	H534223	H535044	H535100	H535151	H535193	
H530034	H530323	H531044	H535003	H535045	H535104	H535154	H535194	
H530035	H530339	H532005	H535004	H535046	H535105	H535157	H535195	
H530036	H530340	H532006	H535005	H535047	H535106	H535159	H535197	
H530045	H530396	H532014	H535008	H535053	H535108	H535161	H535199	
H530046	H530401	H532021	H535009	H535054	H535109	H535162	H535200	
H530049	H530405	H532027	H535012	H535055	H535111	H535164	H535201	
H530050	H530417	H533004	H535013	H535056	H535115	H535166	H535207	
H530051	H530423	H533008	H535014	H535058	H535116	H535167	H535209	
H530055	H530425	H533014	H535015	H535068	H535117	H535168	H535211	
H530057	H530427	H533027	H535016	H535070	H535120	H535169	H535213	
H530063	H530428	H533028	H535017	H535072	H535121	H535173	H535214	
H530064	H530429	H533029	H535018	H535073	H535122	H535176	H535215	
H530066	H530430	H533036	H535020	H535076	H535123	H535177	H535218	
H530068	H530433	H533037	H535021	H535081	H535124	H535178	H535219	