

## URGENT FIELD SAFETY NOTICE

**Subject:** High Energy C Series Clinac® - Loose Counterweight Bolts

**Commercial Name of Affected Product:** High Energy C Series Clinac

**FSCA Identifier:** CP-00480

**Date of Notification:** 2010/12/17

**Type of Action:** Notification

**Details on Affected Devices:** See attached list.

### **Description of Problem:**

Varian has identified an installation anomaly whereby the bolts used to fasten the counterweight to the gantry may not, in some cases, be fully tightened to the required torque specification. In the worst possible scenario (which has never occurred) this could result in the counterweight detaching from the gantry; and the resulting unbalanced gantry may swing freely, posing a hazard of a collision with a patient, therapist, or service person. This notice provides a description of the issues, the actions you can take to avoid or mitigate the issues, and steps Varian is taking to address the issues.

### **Background:**

For Clinacs not covered by Varian PMI, there is a possibility that counterweight retaining bolts have not been fully tightened to Varian's latest (2009) torque specification. Such counterweight bolts potentially could become loose, eventually failing due to fatigue.

For equipment under contract to Varian for PMI inspections, an annual inspection of these bolts has been performed to ensure that they are properly tightened.

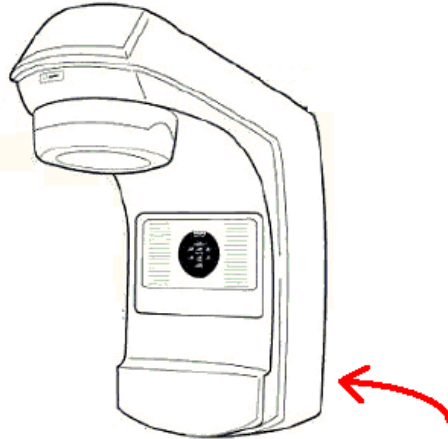
### Definitions:

#### Definition of counterweight:

For those high-energy Clinacs without a retractable beam-stopper, the counterweight is a weight attached to the lower part of the gantry (Figure 1) for the purpose of balancing the gantry. The counterweight weighs approximately 6000 lbs.

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**Figure 1 – Counterweight Location**

#### **Definition of PMI:**

Periodic Maintenance Inspection, a program of regular maintenance inspections of the Clinac performed by Varian Service.

#### **Details:**

For those high-energy Clinacs without a retractable beam-stopper, Varian installs a counterweight on the lower part of the Clinac gantry (Figure 1) for balance. This counterweight is located within the fiberglass cover, and is secured to the gantry using two alignment pins and four large bolts. Varian has become aware of several installations where one or more bolts were not properly tightened to Varian's current torque specifications by the installation team and became loose over time. In all cases the loose bolts were detected during the regular PMI or by unusual noises noticed by the customer during the Gantry rotation.

Varian is not aware of any occurrence of the counterweight detaching from the gantry. However if the loose bolts are not addressed they will be subject to fatigue stress. Depending on severity and locations of loose bolts there has been a calculated estimate of 2-2.5 years for possible bolt failures. Failure of the bolts would allow the counterweight to detach from the machine.

Due to its location on the back side of the gantry, the falling counterweight is not expected to be a hazard to patients; however it may be a hazard to therapists or service personnel. The resulting imbalanced gantry may swing freely, posing a hazard to anyone in the path of the gantry, including patient, therapists, and service personnel.

#### **Recommended User Action**

- Immediately investigate ANY unusual noises originating in the Clinac. Report any unusual noise to those responsible for servicing your Clinac (e.g. Varian Service, 3rd-party service, or in-house service).

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- If you do not maintain a Varian Service Contract:
  - Be sure to perform an annual inspection of the counterweight bolts as described in Appendix A.

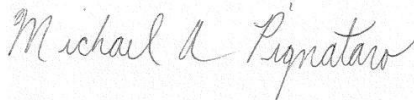
#### **Varian Actions:**

- Notification of customers is by way of this Urgent Field Safety Notice.
- For customers on Varian Service Contract, Varian service shall perform an inspection of the counterweight bolts as part of the regular Periodic Maintenance Inspection (PMI) procedure.

#### **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.

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



\_\_\_\_\_  
Michael Pignataro, Manager Reporting and Corrections

2010/12/17  
Date

#### **Varian Oncology Help Desk Contact Information:**

**Phone:** USA and Canada – 1-888-VARIAN5 (888- 827-4265)  
Europe - +41 41 749 8844

**Email:** North America: [support-americas@varian.com](mailto:support-americas@varian.com)  
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Europe: [support-emea@varian.com](mailto:support-emea@varian.com)  
South East Asia: [seasia.apps.helpdesk@varian.com](mailto:seasia.apps.helpdesk@varian.com)  
China / Asia: [china.apps.helpdesk@varian.com](mailto:china.apps.helpdesk@varian.com)  
Japan: [Japan.Apps.Helpdesk@varian.com](mailto:Japan.Apps.Helpdesk@varian.com)  
Latin America: [soporte.al@varian.com](mailto:soporte.al@varian.com)

**Internet:** Oncology Systems customer site - [www.myvarian.com](http://www.myvarian.com)  
Varian Medical Systems public site - [www.varian.com](http://www.varian.com)

## **URGENT FIELD SAFETY NOTICE**

### **High Energy C Series Clinac® - Loose Counterweight Bolts**

#### APPENDIX A: ANNUAL COUNTERWEIGHT MOUNTING BOLTS INSPECTION

1. Remove the 2 rear Counterweight covers.
2. Inspect each of the four mounting bolts for looseness. Inspect all 4 washer pairs for any cracks. [ref. Figure 2]
3. Rotate Gantry to both limits while listening for any noise created from the Counterweight area.
4. If any problems are observed, it may be necessary to replace washers or torque bolts. Contact Varian Medical Systems for part numbers and instructions.



**Figure 2: Counterweight Bolt/Washer Inspection**

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## High Energy C Series Clinac® - Loose Counterweight Bolts

### APPENDIX B LIST OF SERIAL NUMBERS

H140002	H140101	H140738	H140901	H270237	H270364	H270462	H270605	H270703	H270793	H270896
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H140009	H140115	H140744	H270001	H270245	H270371	H270470	H270616	H270710	H270800	H271002
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## High Energy C Series Clinac® - Loose Counterweight Bolts

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H272300	H272387	H272498	H272910	H273051	H290003	H290195	H290283	H290380	H290551	H291099
H272301	H272389	H272801	H272912	H273052	H290012	H290196	H290286	H290381	H290553	H291108
H272302	H272390	H272804	H272914	H273056	H290016	H290198	H290288	H290386	H290558	H291111
H272304	H272392	H272808	H272917	H273061	H290017	H290199	H290292	H290387	H290559	H291114
H272306	H272398	H272809	H272920	H273062	H290026	H290203	H290296	H290388	H290560	H291115
H272307	H272399	H272813	H272921	H273067	H290030	H290204	H290299	H290394	H290561	H291127
H272308	H272403	H272818	H272924	H273068	H290031	H290205	H290301	H290396	H290600	H291128
H272311	H272405	H272820	H272934	H273072	H290033	H290208	H290306	H290400	H291002	H291130
H272312	H272406	H272821	H272936	H273078	H290100	H290209	H290309	H290401	H291004	H291132
H272313	H272408	H272822	H272937	H273093	H290103	H290210	H290310	H290402	H291006	H291137
H272315	H272409	H272823	H272941	H273097	H290105	H290211	H290311	H290406	H291007	H291139
H272316	H272414	H272829	H272942	H273098	H290106	H290213	H290314	H290411	H291008	H291140
H272317	H272419	H272830	H272949	H273101	H290108	H290214	H290315	H290412	H291010	H291142
H272318	H272421	H272831	H272954	H273102	H290111	H290216	H290316	H290413	H291015	H291144

## URGENT FIELD SAFETY NOTICE

### High Energy C Series Clinac® - Loose Counterweight Bolts

H291148	H293308	H293406	H293556	H293678	H293791	H293910	H294073	H294235	H294393
H291151	H293311	H293416	H293559	H293679	H293794	H293924	H294083	H294237	H294394
H291152	H293315	H293417	H293560	H293681	H293795	H293929	H294091	H294248	H294395
H291154	H293316	H293421	H293562	H293682	H293796	H293935	H294095	H294256	H294397
H291157	H293320	H293423	H293567	H293684	H293802	H293938	H294098	H294265	H294399
H291158	H293321	H293424	H293568	H293687	H293803	H293942	H294100	H294284	H294403
H291159	H293323	H293427	H293571	H293691	H293804	H293947	H294101	H294288	H294407
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H291164	H293327	H293431	H293588	H293704	H293811	H293953	H294106	H294299	H294429
H291165	H293328	H293432	H293594	H293705	H293821	H293956	H294108	H294302	H294451
H291168	H293329	H293434	H293595	H293710	H293822	H293958	H294110	H294304	H294467
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H291250	H293374	H293511	H293637	H293765	H293877	H294034	H294196	H294364	
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H291264	H293379	H293516	H293639	H293770	H293882	H294038	H294200	H294368	
H291265	H293384	H293518	H293642	H293771	H293889	H294041	H294203	H294372	
H291267	H293385	H293521	H293643	H293773	H293890	H294045	H294204	H294373	
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H291272	H293387	H293532	H293648	H293776	H293900	H294056	H294209	H294380	
H293009	H293388	H293534	H293649	H293780	H293901	H294059	H294210	H294381	
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H293307	H293401	H293554	H293664	H293790	H293909	H294072	H294234	H294392	