URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	Loose Encoders Can Lead to Inaccurate Imaging Arm Geometry
Commercial Name of Affected Product:	TrueBeam 1.0
Reference / FSCA Identifier:	CP-04185
Date of Notification:	2011-10-05
Type of Action:	Notification plus field correction
Details on Affected Devices:	Refer to Appendix page.

Description of Problem:

This letter is to advise you of an anomaly that has been identified with the imaging arms of the TrueBeam accelerator where loose encoder pulleys could lead to inaccurate readout of arm geometry. This notice provides a description of the issue, the actions you can take to avoid or mitigate the issue, and steps Varian is taking to address the issue.

Details:

This notification describes a potential problem with loose encoder pulleys in the imaging arms of the TrueBeam accelerator. To date, one loose encoder pulley for the wrist has been detected in a clinically operating TrueBeam accelerator. The problem was identified during arm initialization and the geometric error would have been ~ 0.5 mm. Importantly, loose encoder pulleys can be detected by daily checks of imager arm geometry.

The TrueBeam imaging arms employ primary, secondary and tertiary position readout encoders to monitor the position of the arms. If the difference between the readouts exceeds a threshold then faults are generated that prevent arm use until the fault condition is resolved.

The threshold between primary and secondary encoder readouts has been selected so that differences between readout values caused by mechanical elasticity and backlash do not trigger false indications of encoder failures.

The design is well suited to catch sudden and complete failures of the encoders (e.g., encoder failure, cable break, power loss). However, the primary/secondary position readout channels will not detect gradual changes in readout of the primary encoder - such as would be caused by a loose encoder pulley - if those changes do not exceed the threshold tolerance. Therefore, a loose encoder pulley has the potential to generate clinically significant geometric errors (see Table 1) before differences in the primary and secondary readout systems trigger a fault.

Axis	Shoulder	Elbow	Wrist	Hand
Vert [mm]	-	-	-	-
Long [mm]	0.7	5.4	1.6	0.0
Lat [mm]	0.0	0.0	0.0	0.7

Table 1: Geometric discrepancies before the differences in the primary and secondary readout systems would trigger a fault.

Table 1 shows the magnitude of the possible geometric errors – ranging between 0.7 – 5.4 mm in the longitudinal (superior-inferior) and lateral directions - before a fault would be generated. Errors in the vertical direction change the magnification of the images, however any geometric errors due to magnification changes will be small compared to the longitudinal or lateral errors.

Analysis suggests that any geometric errors will be generated gradually, so routine geometric checks will catch any geometric problems.

Recommended User Action
A daily check of the geometric accuracy of the imaging arms is recommended, which will catch the problem if a primary encoder pulley gradually works loose over a period of time.

- Regularly (i.e., daily) check the geometric accuracy of the imaging system using a geometric Q/A phantom such as the Isocenter cube phantom or the IsoCal phantom. Such checks verify the correct operation of the arm position readout system as well as the accuracy of the arm geometry calibration.

A weekly check of the arm position readout system is also recommended by performing the arm initialization process.

- The arm initialization uses a stable mechanical home position from which to compare all encoder readout values. The initialization process is very sensitive to encoder changes and will detect geometric errors in primary encoder readouts greater than 0.5 mm. The initialization check verifies that the readout of the primary encoder has not changed since the last arm position calibration has been performed.

Varian Actions:

- Varian is notifying all possibly affected customers with this document.
- Varian is developing a plan to inspect/replace the wrist encoder readout systems to ensure that there are no assembly problems. You will be contacted by a Customer Service rep when this plan has been finalized to schedule an inspection of your system.
- There have been no reports of loose pulleys for the elbow encoders. Nevertheless, Varian is planning to implement automated checks of the readout system, which will reduce the threshold at which an indication of a loose primary elbow encoder pulley would be detected.

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.

Pete Coronado, Global Regulatory Affairs ____2011-10-05___
Date

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APPENDIX
LIST OF SERIAL NUMBERS

H191001	H191012	H191022	H191032	H191043	H191054	H191065	H191080
H191002	H191013	H191023	H191033	H191044	H191055	H191066	H191083
H191003	H191014	H191024	H191034	H191045	H191056	H191067	H191085
H191005	H191015	H191025	H191035	H191046	H191057	H191070	H191086
H191006	H191016	H191026	H191036	H191047	H191058	H191071	H191089
H191007	H191017	H191027	H191037	H191048	H191059	H191072	H191090
H191008	H191018	H191028	H191038	H191049	H191060	H191076	H191091
H191009	H191019	H191029	H191039	H191051	H191061	H191077	H191092
H191010	H191020	H191030	H191041	H191052	H191063	H191078	
H191011	H191021	H191031	H191042	H191053	H191064	H191079	