URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	Respiratory gating in TrueBeam with prone patients
Commercial Name of Affected Product:	TrueBeam
Affected Version(s) / Lot(s):	1.0, 1.5.12.0 and below, 1.6.9.5 and below
Reference / FSCA Identifier:	CP-07919
Date of Notification:	***2012-05-29***
Type of Action:	Notification and correction
Details on Affected Devices:	Refer to appendix page.

Description of Problem:

This letter is to advise you of a software anomaly that has been identified in TrueBeam when using respiratory gating with patients treated in the prone position. 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:

In TrueBeam, the patient orientation is taken into account when enabling the respiratory gating system. The anomaly is the respiratory gating curve is inverted when a prone patient plan is loaded into TrueBeam.

A respiratory gating curve for a supine patient is shown correctly in Figure 1. The anomaly is shown in Figure 2, which shows the same curve as shown in Figure 1 for a prone patient. The baseline (zero amplitude) for both curves is located at the bottom of each curve. For the supine patient, the baseline is located correctly at end exhalation of the patient. For the inverted respiratory gating curve corresponding to the prone patient shown in Figure 2, the baseline is located incorrectly at end inhalation.

A gating reference curve generated in RPM is inverted when imported into TrueBeam as part of a prone treatment plan. Therefore, the amplitude of the RPM generated reference curve will have the opposite orientation compared to respiratory gating curves generated in TrueBeam. Any imported respiratory gating thresholds are not inverted. Therefore, any gating thresholds established in RPM will not trigger the beam at the same time in the respiratory cycle in TrueBeam, where the gating curve is inverted.

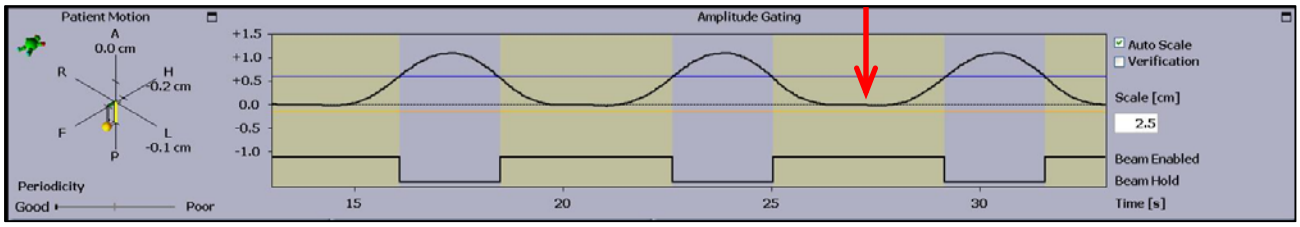

Figure 1: Respiratory gating curve with Head-First Supine patient orientation. The red arrow points to when the patient has exhaled.

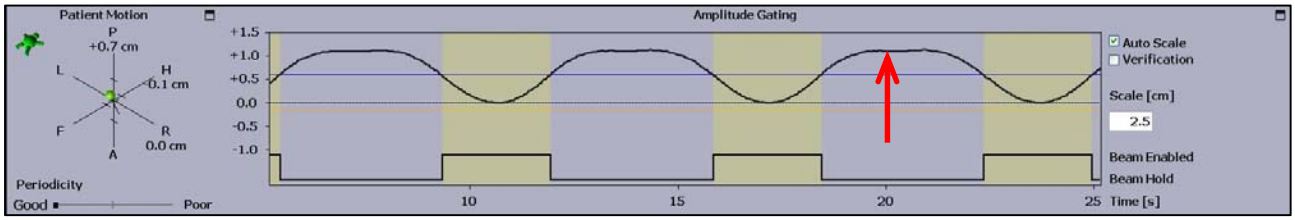

Figure 2: Respiratory gating curve with Head-First Prone patient orientation. The respiratory gating curve is inverted with exhale being at the top of the curve rather than the bottom. The red arrow points to when the patient has exhaled.

Recommended User Action

It is **strongly** recommended not to use TrueBeam when treating a prone patient who requires respiratory gating because it is possible to mix up exhale and inhale regions of the respiratory curve.

Varian Medical Systems Actions:

1. Varian Medical Systems is notifying all possibly affected customers with this document.
2. Varian will provide a software version that will mitigate the issue described in this letter. Varian Customer Support Services will contact you when the software is available.

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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.
- For future reference, this document will be posted to the Varian Medical Systems 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 Form 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 Medical Systems 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

2012-05-29
Date (YYYY-MM-DD)

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APPENDIX
LIST OF SERIAL NUMBERS

H191001	H191061	H191121	H191180
H191002	H191063	H191122	H191181
H191003	H191064	H191123	H191182
H191005	H191065	H191124	H191183
H191006	H191066	H191125	H191184
H191007	H191067	H191126	H191185
H191008	H191068	H191127	H191186
H191009	H191069	H191128	H191187
H191010	H191070	H191129	H191188
H191011	H191071	H191130	H191189
H191012	H191072	H191131	H191190
H191013	H191073	H191132	H191191
H191014	H191074	H191133	H191192
H191015	H191076	H191134	H191194
H191016	H191077	H191135	H191195
H191017	H191078	H191136	H191197
H191018	H191079	H191137	H191198
H191019	H191080	H191138	H191199
H191020	H191081	H191139	H191201
H191021	H191082	H191140	H191202
H191022	H191083	H191141	H191203
H191023	H191084	H191142	H191205
H191024	H191085	H191143	H191206
H191025	H191086	H191144	H191207
H191026	H191087	H191145	H191209
H191027	H191088	H191146	H191210
H191028	H191089	H191147	H191213
H191029	H191090	H191148	H191215
H191030	H191091	H191149	H191221
H191031	H191092	H191150	H191225
H191032	H191093	H191151	H191226
H191033	H191094	H191152	H191227
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H191042	H191103	H191161	
H191043	H191104	H191162	
H191044	H191105	H191163	
H191045	H191106	H191164	
H191046	H191107	H191165	
H191047	H191108	H191166	
H191048	H191109	H191167	
H191049	H191110	H191168	
H191051	H191111	H191169	
H191052	H191112	H191170	
H191053	H191113	H191171	
H191054	H191114	H191172	
H191055	H191115	H191174	
H191056	H191116	H191175	
H191057	H191117	H191176	
H191058	H191118	H191177	
H191059	H191119	H191178	
H191060	H191120	H191179	