

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject:	Potentially Inverted RPM Respiratory Waveform
Commercial Name of Affected Product:	RPM Respiratory Gating System
Affected Version(s) / Lot(s):	RPM Gating v1.7.5 with 3D Option
Reference / FSCA Identifier:	CP-03152
Date of Notification:	2013-03-26
Type of Action:	Notification and 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 RPM Respiratory Gating System software version 1.7.5, 3D Option. While operating with the 6-dot marker block, this version of RPM Gating may produce **an inverted respiratory waveform** in amplitude and phase-gating sessions. This notice provides a description of the issue, the actions you can take to avoid or mitigate the issue, and steps Varian Medical Systems is taking to address the issue.

Trace inversion occurs when the breathing trace on the chart window moves in a phase opposite to the marker block movement. This event has been reported in an extremely limited number of times in the installed base, but users should be aware and monitor their displays carefully.

Details:

The error may be reproduced if the RPM system is induced to **frequently** lose and re-acquire tracking of the 6-dot marker block during a calibration sequence, a reference session, or a single session after tracking has begun. In practice, this has been extremely rare.

The root cause of the malfunction has been determined to lie within the SmartTrack software library used only by RPM v1.7.5 with the 3D option.

RPM v1.7.5 2D (with 2-dot marker block) is not affected.

Recommended User Action

- a. Please refer to the *RPM Respiratory Gating System Reference Guide* for recommended placement of the marker block on the patient.



Note

The system can temporarily lose tracking if the markers on the marker block are obstructed.

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b. Instructions for detecting and preventing inverted trace:

- i. When setting up the marker block, make sure to first position the marker block on the patient and verify that the marker block may be seen on the in-room view finder screen. Only then start tracking in the RPM (by pressing **Track** or **Treat** button).
- ii. After recording of the reference or treatment session has started, verify that the marker block movement in the video window is in sync with the breathing trace movement in the chart (i.e., when the marker block is moving up, the breathing trace is moving up). If they are out of sync, restart tracking.



Note

*If the marker block video is not active when the recording of the Treatment session has started, click the **Camera** button.*

- iii. After restarting tracking, if the trace continues to be inverted, repeat the system calibration from the Tools menu. After completing the calibration, verify that the trace in the video window is in sync with the breathing trace motion in the chart.

Varian Medical Systems Actions:

Varian Medical Systems has developed a technical correction for this issue. You will be contacted by a Customer Service representative to schedule its installation on your system.

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>.

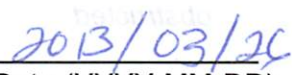
Special Instructions for customers outside the USA and Canada: In order to satisfy regulatory requirements, we request that you complete the attached Proof of Notification Form once you have read this document and return it to Varian Medical Systems.

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.


Vy Tran

Vice President, Regulatory Affairs and Quality Assurance


Date (YYYY-MM-DD)

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Varian Medical Systems public site - www.varian.com

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APPENDIX: LIST OF SERIAL NUMBERS

H500017	H500366	H500611	H500804	H501060	H501256	H501451	H501662	H501863	H502024	H502215	H502371	H502539
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H502897	H503056	H503175	H503281	H503366	H503469	H503559	H503645	H503751	H503852	H503946	H504029	H504104
H502901	H503057	H503176	H503282	H503367	H503470	H503560	H503646	H503752	H503858	H503949	H504031	H504106
H502905	H503060	H503177	H503283	H503368	H503471	H503561	H503647	H503754	H503860	H503950	H504032	H504107
H502907	H503061	H503180	H503284	H503369	H503475	H503562	H503648	H503755	H503861	H503951	H504034	H504108
H502911	H503063	H503181	H503285	H503370	H503476	H503564	H503649	H503756	H503862	H503953	H504035	H504109
H502916	H503064	H503183	H503286	H503371	H503477	H503566	H503650	H503757	H503863	H503954	H504036	H504110
H502920	H503067	H503185	H503287	H503372	H503479	H503567	H503652	H503758	H503864	H503955	H504037	H504113
H502923	H503069	H503187	H503288	H503373	H503480	H503568	H503653	H503759	H503865	H503956	H504038	H504115
H502928	H503073	H503188	H503289	H503374	H503481	H503569	H503658	H503760	H503866	H503957	H504039	H504118

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H504121	H504214	H504319	H504407	H504524	H504645	H504750	H504851	H504950	H505060	H505173	H505267	H505399
H504122	H504215	H504320	H504408	H504525	H504646	H504751	H504853	H504952	H505062	H505174	H505268	H505402
H504124	H504216	H504321	H504409	H504526	H504647	H504752	H504854	H504954	H505065	H505175	H505269	H505406
H504126	H504218	H504322	H504410	H504527	H504649	H504756	H504855	H504955	H505066	H505176	H505275	H505408
H504128	H504220	H504323	H504411	H504529	H504651	H504760	H504856	H504960	H505069	H505177	H505276	H505412
H504130	H504224	H504324	H504413	H504533	H504652	H504761	H504857	H504961	H505070	H505178	H505277	H505413
H504131	H504225	H504325	H504418	H504535	H504655	H504762	H504858	H504962	H505071	H505179	H505278	H505414
H504133	H504227	H504326	H504420	H504538	H504656	H504763	H504861	H504965	H505073	H505180	H505280	H505417
H504134	H504232	H504327	H504422	H504541	H504659	H504764	H504864	H504967	H505074	H505184	H505286	H505422
H504135	H504234	H504328	H504423	H504543	H504661	H504766	H504866	H504970	H505075	H505186	H505289	H505423
H504136	H504236	H504329	H504425	H504545	H504662	H504769	H504867	H504971	H505078	H505187	H505290	H505427
H504138	H504239	H504330	H504426	H504549	H504663	H504770	H504868	H504972	H505080	H505188	H505291	H505428
H504141	H504240	H504333	H504428	H504554	H504666	H504771	H504869	H504975	H505081	H505190	H505292	H505429
H504144	H504241	H504335	H504429	H504556	H504667	H504773	H504870	H504976	H505082	H505191	H505293	H505430
H504145	H504244	H504336	H504432	H504557	H504668	H504774	H504871	H504980	H505085	H505192	H505294	H505433
H504146	H504245	H504338	H504434	H504559	H504669	H504778	H504873	H504982	H505087	H505194	H505296	H505435
H504147	H504248	H504340	H504436	H504560	H504670	H504779	H504874	H504984	H505088	H505195	H505302	H505436
H504148	H504249	H504342	H504437	H504561	H504671	H504780	H504877	H504989	H505092	H505196	H505303	H505440
H504149	H504250	H504343	H504439	H504564	H504672	H504782	H504878	H504990	H505094	H505198	H505304	H505441
H504152	H504251	H504344	H504440	H504565	H504673	H504784	H504879	H504991	H505095	H505199	H505306	H505442
H504153	H504252	H504345	H504441	H504566	H504674	H504785	H504880	H504993	H505096	H505200	H505308	H505444
H504154	H504253	H504346	H504443	H504567	H504675	H504786	H504883	H504995	H505097	H505201	H505309	H505445
H504155	H504254	H504348	H504444	H504573	H504676	H504787	H504884	H504996	H505099	H505203	H505310	H505446
H504156	H504255	H504349	H504445	H504574	H504677	H504789	H504886	H504997	H505102	H505204	H505317	H505447
H504157	H504256	H504350	H504446	H504577	H504678	H504791	H504889	H504998	H505103	H505205	H505319	H505448
H504158	H504257	H504353	H504448	H504578	H504679	H504792	H504890	H505000	H505105	H505207	H505320	H505450
H504159	H504258	H504356	H504449	H504579	H504680	H504794	H504892	H505001	H505106	H505208	H505321	H505451
H504161	H504261	H504357	H504450	H504580	H504681	H504795	H504894	H505002	H505121	H505209	H505326	H505453
H504166	H504263	H504358	H504451	H504581	H504682	H504798	H504895	H505003	H505122	H505211	H505329	H505456
H504168	H504264	H504360	H504452	H504586	H504687	H504800	H504898	H505004	H505123	H505212	H505330	H505457
H504169	H504265	H504361	H504453	H504587	H504689	H504801	H504899	H505005	H505125	H505214	H505331	H505458
H504170	H504266	H504362	H504454	H504594	H504690	H504802	H504900	H505006	H505126	H505216	H505335	H505460
H504171	H504268	H504364	H504455	H504597	H504692	H504803	H504905	H505008	H505127	H505217	H505336	H505461
H504172	H504269	H504367	H504460	H504601	H504694	H504804	H504906	H505009	H505128	H505218	H505338	H505463
H504173	H504270	H504368	H504461	H504603	H504695	H504806	H504907	H505010	H505130	H505220	H505339	H505466
H504174	H504271	H504369	H504462	H504604	H504697	H504808	H504908	H505011	H505132	H505229	H505343	H505467
H504175	H504272	H504370	H504464	H504607	H504702	H504809	H504911	H505012	H505133	H505232	H505344	H505468
H504176	H504273	H504371	H504470	H504608	H504703	H504810	H504912	H505013	H505138	H505233	H505345	H505472
H504177	H504274	H504372	H504472	H504610	H504705	H504811	H504913	H505014	H505140	H505234	H505346	H505473
H504178	H504275	H504373	H504473	H504611	H504706	H504812	H504914	H505015	H505141	H505236	H505347	H505477
H504179	H504276	H504374	H504475	H504612	H504707	H504815	H504916	H505017	H505142	H505238	H505348	H505496
H504180	H504278	H504375	H504477	H504614	H504708	H504816	H504917	H505018	H505144	H505239	H505349	H505498
H504181	H504282	H504377	H504480	H504616	H504711	H504817	H504919	H505019	H505145	H505240	H505350	H505500
H504182	H504283	H504378	H504481	H504617	H504713	H504823	H504920	H505020	H505146	H505241	H505351	H505503
H504183	H504284	H504380	H504482	H504618	H504717	H504824	H504921	H505021	H505147	H505242	H505352	H505504
H504184	H504285	H504383	H504485	H504620	H504724	H504829	H504924	H505022	H505148	H505243	H505353	H505505
H504185	H504287	H504387	H504486	H504621	H504726	H504830	H504925	H505023	H505150	H505244	H505355	H505506
H504186	H504289	H504388	H504488	H504622	H504727	H504831	H504926	H505025	H505151	H505245	H505357	H505507
H504187	H504292	H504390	H504490	H504623	H504728	H504832	H504927	H505026	H505153	H505247	H505361	H505508
H504192	H504293	H504391	H504494	H504624	H504729	H504833	H504928	H505027	H505156	H505248	H505365	H505513
H504194	H504297	H504392	H504498	H504628	H504730	H504834	H504930	H505028	H505157	H505249	H505372	H505514
H504197	H504298	H504393	H504499	H504630	H504733	H504835	H504934	H505031	H505158	H505250	H505373	H505515
H504198	H504300	H504394	H504500	H504631	H504734	H504837	H504936	H505033	H505161	H505251	H505379	H505516
H504199	H504301	H504396	H504502	H504632	H504735	H504838	H504937	H505035	H505162	H505252	H505383	H505517
H504200	H504304	H504397	H504503	H504635	H504737	H504839	H504938	H505043	H505164	H505253	H505384	H505518
H504201	H504305	H504399	H504504	H504636	H504738	H504840	H504939	H505044	H505165	H505254	H505385	H505519
H504207	H504308	H504400	H504505	H504637	H504739	H504841	H504940	H505047	H505166	H505255	H505386	H505527
H504208	H504309	H504401	H504516	H504638	H504740	H504842	H504941	H505052	H505167	H505261	H505387	H505528
H504210	H504310	H504402	H504517	H504639	H504741	H504843	H504943	H505054	H505168	H505262	H505389	H505530
H504211	H504311	H504404	H504519	H504640	H504744	H504844	H504945	H505055	H505169	H505263	H505390	H505538
H504212	H504313	H504405	H504520	H504643	H504748	H504848	H504946	H505056	H505170	H505265	H505393	H505540
H504213	H504316	H504406	H504522	H504644	H504749	H504850	H504949	H505059	H505172	H505266	H505397	H505541

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H505542	H505706	H505896
H505543	H505707	H505897
H505544	H505708	H505905
H505554	H505710	H505906
H505558	H505712	H505910
H505562	H505723	H505917
H505563	H505724	H505918
H505577	H505729	H505925
H505578	H505733	H505926
H505579	H505735	H505955
H505580	H505738	H505966
H505588	H505739	H506000
H505592	H505741	H506434
H505593	H505745	H509004
H505600	H505746	H509158
H505604	H505748	H509181
H505605	H505749	H509182
H505606	H505750	H509960
H505607	H505755	
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H505690	H505885	
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H505696	H505889	
H505701	H505891	
H505703	H505894	
H505704	H505895	