

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject: Treatment field calculated with an energy other than that selected

Commercial Name of Affected Product: Eclipse 10 (Client builds 10.0.28 and 10.0.34)

Reference / FSCA Identifier: CP-05308

Date of Notification: **2011-06-30**

Type of Action: Notification

Details on Affected Devices: Refer to appendix page.

Description of Problem:

This letter is to advise you of an anomaly in Varian's Eclipse Treatment Planning System version 10. The issue is that the treatment field energy may change from the current selection to a previous selection without user intervention and without invalidating the MU or calculated dose distribution.

Details:

The energy shown or selected by the treatment planner in the **fields** tab of External Beam Planning and in the **general** tab of field properties may differ from the value actually used for dose calculation.

This issue is caused by incorrect handling of the energy mode object within the memory cache system used by Eclipse External Beam Planning Version 10. When the user changes the field energy, the memory cache anomaly may result in the use of the previously selected field energy instead of the intended field energy. This cache memory issue may arise when switching between software applications (such as between External Beam Planning and RT Chart), when using multiple sessions, or when switching between patients in a single session of the External Beam Planning application in Eclipse.

When this issue occurs, it can be identified by inspection of the **dose** log and **LMC** log (leaf-motion calculator logs are generated for IMRT and electronic compensator fields) in the "errors and warnings from last calculation" in the **calculation** tab of the field properties (Figure 1A). The MU and dose distribution will be correct for the energy shown in the **dose** and **LMC** calculation logs.

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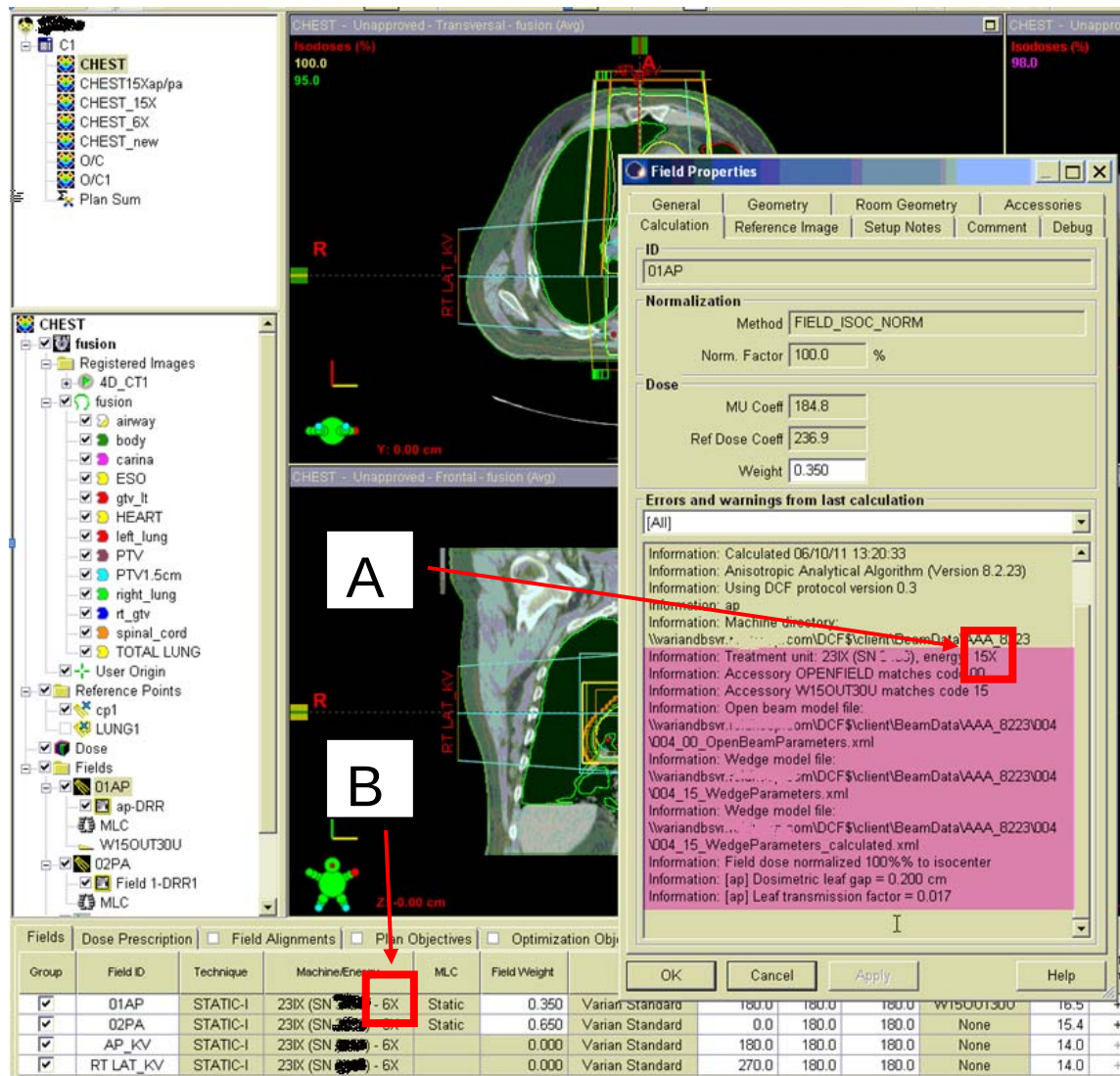


Figure 1. (A) The actual energy used in the field dose calculation disagrees with (B) the energy displayed in **Fields** tab of External Beam Planning.

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Recommended User Actions:

1. As described below under **Varian Actions**, Varian will be contacting you and will apply a database configuration script to your database. Even after Varian applies this script:
 - a. Do not use multiple sessions in Eclipse;
 - b. Always close the patient file in Eclipse after completing work on the patient record;
 - c. Always close Eclipse fully before opening a new patient.
2. Compare the energy shown in **dose** section and **LMC section** (if applicable) of the “errors and warnings from last calculation” log (see Figure 1) in the **Calculation** tab of the field properties dialog (Figure 1A) with the energy value shown in the **Fields** tab of External Beam Planning (Figure 1B) to detect a discrepancy;
3. If there is a discrepancy between the energy value shown shown in the “errors and warnings from last calculation” logs in the **calculation** tab of field properties with the energy value shown in the **fields** tab of External Beam Planning, then copy the treatment plan, invalidate the dose with **Planning → Dose Calculation → Reset Calculation Volume**, then recalculate; AND
4. Confirm all treatment planning calculations as cautioned and warned below:

From Eclipse Instructions for Use, PN B502681R01A, p.29



CAUTION: Verify the dose calculation and dose display against independent verification methods, for example, manual calculations, to ensure that the

- MU data is correctly interpolated and calibrated.
- MU calculation is correct.
- Configuration of the dosimetric data is correct.

From Eclipse Reference Guide, PN B502675R01A, p.740



WARNING: Before approving plans or plan sums for treatment,

- Always perform QA tests on a physics phantom to make sure that the plan is correctly transferred to the treatment machine.
- Always verify plans with DVH analysis when approving plans or plan sums for treatment.

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Varian Actions:

- Varian is notifying potentially affected customers with this document.
- A Varian representative will contact affected customers to apply a database configuration script that will reduce the possibility of this unintended change in selected energy when switching between applications.
- Varian is preparing a correction for Eclipse Version 10 to address this issue.
- A Varian representative will contact you to schedule the installation of the correction when it is available.

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.

Michael Pignataro
Michael Pignataro, Manager Reporting and Corrections

____2011-06-30____
Date

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APPENDIX LIST OF SERIAL NUMBERS

H480015	H480313	H480798	H481172	H481514	H481954	H482014	H482074	H482260	H482487	H482900	H483184	H483622
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H484298	H484749	H485116	H485586	H485898	H486308	H486665	H487150	H487639	H488291	H489045	H489597	H48A158
H484299	H484750	H485133	H485587	H485899	H486311	H486693	H487151	H487661	H488316	H489056	H489631	H48A202
H484300	H484751	H485134	H485589	H485900	H486312	H486694	H487152	H487676	H488371	H489062	H489663	H48A213
H484302	H484752	H485136	H485610	H485901	H486314	H486733	H487153	H487733	H488393	H489063	H489670	H48A214
H484303	H484753	H485143	H485617	H485902	H486315	H486805	H487154	H487734	H488396	H489095	H489671	H48A225
H484308	H484798	H485144	H485618	H485903	H486319	H486819	H487155	H487794	H488406	H489096	H489672	H48A226
H484310	H484799	H485145	H485628	H485904	H486320	H486820	H487156	H487847	H488423	H489097	H489673	H48A227
H484334	H484800	H485146	H485656	H485905	H486327	H486842	H487157	H487866	H488446	H489156	H489674	H48A228
H484335	H484801	H485147	H485657	H485938	H486329	H486843	H487158	H487867	H488447	H489179	H489675	H48A242
H484354	H484802	H485152	H485667	H485939	H486331	H486844	H487159	H487875	H488448	H489180	H489676	H48A254
H484356	H484803	H485163	H485671	H485941	H486337	H486845	H487160	H487876	H488449	H489186	H489718	H48A292
H484357	H484804	H485191	H485675	H485944	H486354	H486846	H487164	H487887	H488450	H489194	H489740	H48A293
H484358	H484805	H485193	H485677	H485945	H486355	H486858	H487165	H487888	H488452	H489196	H489754	H48A294
H484359	H484806	H485208	H485689	H485962	H486357	H486859	H487166	H487908	H488464	H489232	H489755	H48A348

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H48A369	H48A920	H48B294	H48B445	H48B600	H48B696	H48B789	H48B887	H48B969	H48C074	H48C160	H48C256
H48A370	H48A924	H48B295	H48B451	H48B602	H48B702	H48B790	H48B888	H48B971	H48C075	H48C161	H48C257
H48A398	H48A930	H48B298	H48B457	H48B604	H48B703	H48B791	H48B889	H48B973	H48C076	H48C162	H48C258
H48A407	H48A931	H48B299	H48B458	H48B607	H48B704	H48B792	H48B890	H48B975	H48C077	H48C163	H48C259
H48A408	H48A940	H48B300	H48B459	H48B608	H48B705	H48B793	H48B892	H48B976	H48C078	H48C168	H48C260
H48A415	H48A942	H48B302	H48B471	H48B609	H48B707	H48B794	H48B893	H48B977	H48C082	H48C170	H48C261
H48A416	H48A943	H48B309	H48B472	H48B610	H48B708	H48B795	H48B894	H48B978	H48C083	H48C171	H48C262
H48A417	H48A959	H48B312	H48B486	H48B611	H48B709	H48B797	H48B895	H48B979	H48C084	H48C173	H48C263
H48A418	H48A966	H48B331	H48B492	H48B612	H48B712	H48B798	H48B896	H48B994	H48C085	H48C174	H48C264
H48A453	H48A967	H48B332	H48B494	H48B613	H48B713	H48B799	H48B898	H48B995	H48C086	H48C175	H48C265
H48A454	H48A968	H48B333	H48B495	H48B614	H48B714	H48B800	H48B899	H48B996	H48C087	H48C176	H48C266
H48A455	H48A969	H48B334	H48B496	H48B615	H48B715	H48B801	H48B900	H48B997	H48C088	H48C177	H48C267
H48A456	H48A970	H48B335	H48B497	H48B616	H48B719	H48B802	H48B901	H48B998	H48C089	H48C178	H48C268
H48A462	H48A971	H48B336	H48B498	H48B617	H48B720	H48B803	H48B907	H48B999	H48C095	H48C179	H48C270
H48A474	H48A990	H48B340	H48B499	H48B618	H48B722	H48B804	H48B910	H48C000	H48C096	H48C180	H48C271
H48A478	H48A991	H48B341	H48B502	H48B619	H48B723	H48B805	H48B911	H48C001	H48C097	H48C183	H48C272
H48A484	H48A992	H48B342	H48B504	H48B622	H48B724	H48B806	H48B912	H48C002	H48C098	H48C184	H48C278
H48A485	H48B059	H48B343	H48B505	H48B630	H48B725	H48B807	H48B913	H48C003	H48C099	H48C185	H48C294
H48A487	H48B060	H48B344	H48B506	H48B633	H48B726	H48B808	H48B914	H48C004	H48C100	H48C186	H48C295
H48A506	H48B061	H48B345	H48B507	H48B634	H48B727	H48B809	H48B915	H48C005	H48C101	H48C187	H48C296
H48A507	H48B062	H48B349	H48B511	H48B635	H48B732	H48B810	H48B916	H48C006	H48C102	H48C188	H48C297
H48A509	H48B063	H48B350	H48B512	H48B636	H48B733	H48B812	H48B917	H48C007	H48C103	H48C194	H48C298
H48A510	H48B083	H48B351	H48B513	H48B637	H48B734	H48B813	H48B918	H48C008	H48C104	H48C195	H48C299
H48A511	H48B084	H48B352	H48B516	H48B638	H48B735	H48B816	H48B919	H48C010	H48C105	H48C197	H48C300
H48A543	H48B085	H48B362	H48B517	H48B639	H48B736	H48B817	H48B926	H48C011	H48C106	H48C198	H48C301
H48A563	H48B087	H48B363	H48B521	H48B640	H48B737	H48B818	H48B927	H48C012	H48C112	H48C199	H48C302
H48A594	H48B142	H48B367	H48B522	H48B647	H48B738	H48B819	H48B928	H48C013	H48C115	H48C200	H48C303
H48A595	H48B150	H48B369	H48B523	H48B648	H48B739	H48B820	H48B929	H48C014	H48C116	H48C203	H48C304
H48A612	H48B156	H48B370	H48B524	H48B649	H48B740	H48B821	H48B930	H48C015	H48C117	H48C204	H48C305
H48A624	H48B187	H48B371	H48B525	H48B650	H48B741	H48B822	H48B934	H48C016	H48C118	H48C205	H48C306
H48A625	H48B188	H48B372	H48B526	H48B657	H48B742	H48B828	H48B935	H48C017	H48C119	H48C206	H48C307
H48A626	H48B189	H48B373	H48B527	H48B658	H48B743	H48B829	H48B936	H48C019	H48C120	H48C207	H48C308
H48A627	H48B190	H48B374	H48B528	H48B660	H48B744	H48B830	H48B937	H48C020	H48C121	H48C208	H48C311
H48A628	H48B198	H48B375	H48B531	H48B661	H48B745	H48B831	H48B938	H48C022	H48C122	H48C212	H48C312
H48A629	H48B199	H48B377	H48B532	H48B662	H48B746	H48B832	H48B939	H48C024	H48C123	H48C217	H48C313
H48A658	H48B200	H48B378	H48B537	H48B663	H48B747	H48B833	H48B941	H48C025	H48C124	H48C218	H48C315
H48A659	H48B208	H48B379	H48B539	H48B664	H48B748	H48B839	H48B942	H48C029	H48C125	H48C219	H48C316
H48A660	H48B209	H48B380	H48B542	H48B667	H48B749	H48B840	H48B943	H48C030	H48C126	H48C220	H48C317
H48A661	H48B213	H48B381	H48B543	H48B668	H48B754	H48B841	H48B944	H48C031	H48C127	H48C221	H48C318
H48A662	H48B214	H48B382	H48B544	H48B669	H48B755	H48B846	H48B945	H48C032	H48C128	H48C222	H48C319
H48A663	H48B215	H48B385	H48B545	H48B670	H48B756	H48B847	H48B946	H48C033	H48C129	H48C225	H48C320
H48A664	H48B216	H48B386	H48B546	H48B671	H48B757	H48B848	H48B947	H48C034	H48C130	H48C226	H48C323
H48A679	H48B219	H48B387	H48B547	H48B672	H48B760	H48B849	H48B948	H48C035	H48C131	H48C227	H48C324
H48A692	H48B229	H48B388	H48B553	H48B673	H48B762	H48B850	H48B949	H48C036	H48C132	H48C228	H48C325
H48A712	H48B232	H48B399	H48B554	H48B674	H48B763	H48B852	H48B950	H48C037	H48C133	H48C229	H48C326
H48A772	H48B233	H48B407	H48B555	H48B675	H48B764	H48B853	H48B951	H48C038	H48C134	H48C239	H48C327
H48A773	H48B234	H48B408	H48B556	H48B676	H48B765	H48B854	H48B952	H48C039	H48C135	H48C240	H48C328
H48A774	H48B235	H48B419	H48B557	H48B677	H48B766	H48B855	H48B953	H48C040	H48C136	H48C241	H48C329
H48A812	H48B236	H48B424	H48B577	H48B678	H48B767	H48B866	H48B954	H48C041	H48C137	H48C242	H48C335
H48A813	H48B237	H48B426	H48B579	H48B679	H48B768	H48B867	H48B955	H48C044	H48C138	H48C243	H48C336
H48A827	H48B238	H48B429	H48B580	H48B680	H48B774	H48B868	H48B956	H48C045	H48C139	H48C244	H48C337
H48A840	H48B243	H48B431	H48B583	H48B681	H48B775	H48B869	H48B957	H48C046	H48C140	H48C245	H48C338
H48A841	H48B244	H48B432	H48B586	H48B682	H48B776	H48B870	H48B958	H48C054	H48C141	H48C246	H48C339
H48A866	H48B245	H48B436	H48B587	H48B683	H48B777	H48B873	H48B959	H48C059	H48C142	H48C247	H48C340
H48A898	H48B246	H48B437	H48B588	H48B684	H48B778	H48B875	H48B960	H48C060	H48C143	H48C248	H48C341
H48A899	H48B254	H48B438	H48B589	H48B685	H48B779	H48B876	H48B961	H48C062	H48C144	H48C249	H48C342
H48A900	H48B255	H48B439	H48B590	H48B686	H48B781	H48B877	H48B963	H48C063	H48C146	H48C250	H48C343
H48A901	H48B256	H48B440	H48B591	H48B687	H48B782	H48B879	H48B964	H48C064	H48C147	H48C251	H48C344
H48A902	H48B257	H48B441	H48B592	H48B688	H48B783	H48B880	H48B965	H48C065	H48C151	H48C252	H48C345
H48A903	H48B258	H48B442	H48B593	H48B689	H48B784	H48B881	H48B966	H48C066	H48C157	H48C253	H48C346
H48A911	H48B263	H48B443	H48B594	H48B690	H48B787	H48B885	H48B967	H48C068	H48C158	H48C254	H48C347
H48A918	H48B293	H48B444	H48B599	H48B695	H48B788	H48B886	H48B968	H48C073	H48C159	H48C255	H48C348

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H48C349	H48C363	H48C383	H48C402	H48C419	H48C441	H48C471	H48C488	H48C517	H48C527	H48C552
H48C350	H48C364	H48C384	H48C403	H48C420	H48C442	H48C472	H48C489	H48C518	H48C528	H48C555
H48C351	H48C367	H48C388	H48C406	H48C421	H48C443	H48C473	H48C490	H48C519	H48C529	H48C556
H48C352	H48C368	H48C389	H48C407	H48C422	H48C446	H48C474	H48C491	H48C520	H48C530	H48C565
H48C353	H48C373	H48C390	H48C408	H48C423	H48C447	H48C475	H48C492	H48C521	H48C531	H48C588
H48C354	H48C375	H48C397	H48C412	H48C425	H48C458	H48C477	H48C504	H48C522	H48C532	H48C589
H48C355	H48C378	H48C398	H48C413	H48C427	H48C467	H48C478	H48C505	H48C523	H48C533	
H48C358	H48C379	H48C399	H48C414	H48C428	H48C468	H48C484	H48C510	H48C524	H48C549	
H48C359	H48C380	H48C400	H48C415	H48C429	H48C469	H48C486	H48C515	H48C525	H48C550	
H48C362	H48C382	H48C401	H48C416	H48C434	H48C470	H48C487	H48C516	H48C526	H48C551	