

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject: 4D Integrated Treatment Console mandatory upgrade
Commercial Name of Affected Product: 4D ITC versions 8.1 SP2 to 10.0 SP1
Reference / FSCA Identifier: CP-03940
Date of Notification: 2011-08-17
Type of Action: Notification and correction
Details on Affected Devices: Refer to appendix page.

Description of Problem:

We are writing to advise you that the 4D Integrated Treatment Console (4DITC) is scheduled for a mandatory upgrade from your current version to 10.2. The reason for the upgrade is to ensure customers have the most current version of 4DITC which contains several improvements to address issues related to proper recording of treatment information from Varian machines.

Details:

There are circumstances in which the 4DITC may be involved in a failure to correctly record treatment history information. The majority of the issues experienced fall into one of three general categories:

- Communication issues between the Clinac sub-systems and the 4DITC
- Communication issues between the 4DITC and the Oncology Information System (OIS)
- Unplanned shut down of the 4DITC or the Clinac during treatment

NORMAL TREATMENT WORKFLOW

Under normal conditions, treatment workflow broadly consists of the following steps:

1. A patient is selected from the daily schedule
2. The plans scheduled for treatment are loaded from the Oncology Information System (OIS) to the 4D Integrated Treatment Console (4DITC)
3. The patient setup position is verified
4. Treatment is initiated and upon completion, activity charges are captured and the treatment history is saved back to the OIS.

During the treatment delivery process, after each beam has been delivered, the treatment history is sent from the treatment machine sub-systems to the 4DITC. The history is saved locally on the 4DITC workstation until the entire treatment has been delivered. Once the treatment session has been completed, the treatment history, for all the beams, is sent to the OIS.

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ABNORMAL TREATMENT WORKFLOW

It is possible that after a treatment beam or series of beams have been delivered, an error may occur that results in a failed or incomplete electronic recording of the treatment information. Depending on where in the process the error occurs, Varian recommends different mitigation strategies be use by the clinical staff as defined below.

Recommended User Action

In the event of a non-record,

- Varian recommends that the treatment process, for the current or next patient, is temporarily paused and that all error messages are thoroughly read before proceeding.
- Varian further recommends that the user opens up the detail portion of the error message in order to understand what type of anomaly has occurred.
- Varian strongly recommends that the user verify the delivered treatment history has been recorded accurately in the local cache or in the OIS before proceeding.
- If you have any questions regarding this Product Notification Letter, please contact Varian Medical Systems Help desk at 1-888-VARIAN5 (888- 827-4265) for USA and Canada and +41 41 749 8844 for Europe. World wide e-mail addresses are listed below as well as internet support.

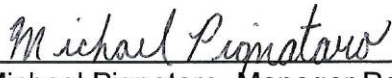
Varian Actions:

- Varian is notifying all affected customers with this document. Varian will issue a Customer Technical Bulletin to inform users of the mandatory upgrade and related information. The CTB will be posted to the customer support site: <http://www.MyVarian.com>.

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

____2011-08-17____
Date

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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
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Latin America: soporte.al@varian.com

Internet: Oncology Systems customer site - www.myvarian.com
Varian Medical Systems public site - www.varian.com

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APPENDIX

LIST OF SERIAL NUMBERS

H510001	H510172	H510344	H510480	H510575	H510682	H510788	H510906	H511000	H511098	H511199	H511286	H511377
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H511551	H511651	H511760	H511850	H511950	H512038	H512145	H512262	H512360	H512453	H512556	H512669	H512770
H511552	H511652	H511763	H511851	H511951	H512039	H512148	H512264	H512361	H512454	H512559	H512670	H512771
H511553	H511653	H511764	H511852	H511953	H512040	H512149	H512265	H512362	H512455	H512560	H512671	H512773
H511554	H511654	H511765	H511853	H511954	H512041	H512150	H512266	H512364	H512459	H512567	H512674	H512774
H511555	H511655	H511767	H511854	H511955	H512042	H512163	H512268	H512365	H512460	H512568	H512676	H512776
H511558	H511656	H511768	H511855	H511958	H512043	H512165	H512270	H512366	H512461	H512569	H512677	H512777
H511559	H511657	H511769	H511857	H511959	H512044	H512166	H512271	H512367	H512462	H512570	H512678	H512778

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H512779	H512875	H512980	H513065	H513158	H513254	H513344	H513442	H513542	H513631	H513719	H513815	H513910
H512781	H512878	H512982	H513066	H513162	H513255	H513345	H513443	H513543	H513632	H513720	H513817	H513911
H512782	H512879	H512984	H513067	H513163	H513256	H513347	H513450	H513545	H513633	H513721	H513818	H513912
H512783	H512880	H512985	H513069	H513164	H513257	H513349	H513452	H513546	H513634	H513722	H513819	H513913
H512784	H512881	H512987	H513070	H513165	H513261	H513351	H513453	H513547	H513635	H513730	H513821	H513914
H512785	H512882	H512988	H513073	H513166	H513262	H513353	H513454	H513548	H513636	H513731	H513822	H513919
H512786	H512883	H512989	H513078	H513167	H513264	H513355	H513455	H513549	H513638	H513733	H513823	H513921
H512787	H512884	H512990	H513079	H513170	H513265	H513356	H513456	H513550	H513639	H513735	H513825	H513922
H512789	H512885	H512991	H513080	H513171	H513266	H513357	H513459	H513551	H513641	H513738	H513826	H513923
H512790	H512886	H512992	H513081	H513172	H513267	H513358	H513460	H513552	H513642	H513741	H513829	H513924
H512791	H512887	H512993	H513082	H513174	H513268	H513359	H513462	H513553	H513645	H513742	H513830	H513925
H512795	H512888	H512994	H513083	H513176	H513269	H513360	H513464	H513554	H513646	H513743	H513831	H513926
H512799	H512889	H512995	H513086	H513180	H513272	H513362	H513465	H513555	H513647	H513744	H513832	H513927
H512802	H512892	H512997	H513087	H513181	H513273	H513363	H513466	H513556	H513648	H513745	H513837	H513929
H512803	H512893	H512998	H513089	H513182	H513274	H513365	H513467	H513558	H513649	H513746	H513838	H513930
H512804	H512896	H513002	H513091	H513183	H513277	H513369	H513470	H513559	H513650	H513747	H513839	H513931
H512809	H512907	H513004	H513092	H513184	H513278	H513371	H513471	H513561	H513656	H513748	H513840	H513932
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H512812	H512909	H513006	H513095	H513186	H513280	H513373	H513475	H513563	H513658	H513750	H513842	H513935
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H512816	H512916	H513011	H513103	H513192	H513289	H513379	H513483	H513569	H513663	H513757	H513847	H513941
H512817	H512917	H513012	H513104	H513193	H513290	H513382	H513485	H513570	H513664	H513758	H513850	H513942
H512818	H512918	H513015	H513105	H513195	H513291	H513383	H513493	H513571	H513665	H513759	H513853	H513943
H512819	H512920	H513018	H513106	H513196	H513292	H513384	H513494	H513574	H513667	H513761	H513854	H513944
H512821	H512926	H513019	H513107	H513197	H513293	H513385	H513495	H513575	H513668	H513763	H513855	H513945
H512822	H512929	H513020	H513109	H513200	H513294	H513386	H513496	H513579	H513669	H513764	H513857	H513947
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H512829	H512933	H513025	H513115	H513205	H513298	H513394	H513501	H513583	H513674	H513770	H513861	H513954
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H512835	H512940	H513029	H513119	H513211	H513302	H513399	H513506	H513589	H513679	H513775	H513867	H513958
H512836	H512941	H513030	H513120	H513212	H513303	H513400	H513508	H513591	H513680	H513776	H513869	H513959
H512837	H512944	H513031	H513121	H513213	H513304	H513402	H513509	H513594	H513681	H513777	H513871	H513961
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H512839	H512948	H513033	H513123	H513216	H513306	H513407	H513511	H513596	H513683	H513779	H513873	H513963
H512842	H512953	H513034	H513124	H513217	H513307	H513413	H513514	H513600	H513686	H513780	H513875	H513964
H512843	H512954	H513035	H513125	H513220	H513309	H513414	H513515	H513601	H513690	H513781	H513876	H513965
H512846	H512955	H513036	H513127	H513222	H513310	H513419	H513516	H513604	H513691	H513782	H513877	H513966
H512847	H512956	H513037	H513128	H513223	H513311	H513420	H513517	H513605	H513692	H513783	H513878	H513967
H512848	H512957	H513039	H513129	H513224	H513312	H513421	H513518	H513606	H513693	H513784	H513880	H513968
H512849	H512958	H513042	H513130	H513226	H513313	H513422	H513519	H513607	H513695	H513785	H513881	H513969
H512850	H512959	H513043	H513132	H513227	H513314	H513424	H513520	H513611	H513696	H513786	H513888	H513971
H512852	H512960	H513045	H513134	H513228	H513315	H513425	H513521	H513612	H513697	H513787	H513889	H513972
H512853	H512961	H513046	H513135	H513229	H513317	H513426	H513523	H513613	H513699	H513788	H513890	H513973
H512854	H512962	H513047	H513139	H513231	H513321	H513427	H513524	H513614	H513700	H513789	H513891	H513974
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H512856	H512966	H513049	H513144	H513240	H513323	H513429	H513526	H513617	H513704	H513791	H513893	H513976
H512858	H512967	H513050	H513145	H513241	H513325	H513430	H513527	H513618	H513706	H513793	H513896	H513977
H512859	H512969	H513051	H513146	H513242	H513326	H513431	H513528	H513619	H513707	H513794	H513898	H513978
H512861	H512970	H513052	H513148	H513244	H513327	H513432	H513529	H513621	H513709	H513795	H513899	H513979
H512862	H512971	H513054	H513150	H513245	H513329	H513433	H513530	H513622	H513710	H513797	H513901	H513980
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H512873	H512978	H513062	H513156	H513251	H513341	H513440	H513539	H513629	H513716	H513806	H513908	H513985
H512874	H512979	H513064	H513157	H513253	H513342	H513441	H513541	H513630	H513717	H513808	H513909	H513986

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H513987	H514078	H514163	H514240	H514326	H514406	H514498	H514581	H514660	H514784	H514880	H514983	H515068
H513988	H514079	H514164	H514241	H514329	H514407	H514499	H514582	H514661	H514785	H514881	H514984	H515070
H513989	H514080	H514165	H514243	H514330	H514408	H514501	H514583	H514662	H514787	H514890	H514986	H515071
H513990	H514081	H514166	H514244	H514331	H514409	H514502	H514584	H514663	H514788	H514891	H514987	H515072
H513991	H514082	H514167	H514245	H514332	H514410	H514504	H514585	H514664	H514789	H514892	H514990	H515073
H513992	H514083	H514168	H514247	H514334	H514411	H514506	H514586	H514667	H514790	H514895	H514991	H515075
H513993	H514084	H514170	H514248	H514336	H514412	H514507	H514590	H514668	H514791	H514898	H514993	H515076
H513995	H514085	H514171	H514249	H514337	H514413	H514508	H514592	H514669	H514792	H514899	H514994	H515077
H513999	H514086	H514172	H514250	H514339	H514414	H514510	H514596	H514670	H514793	H514900	H514995	H515078
H514001	H514087	H514173	H514254	H514340	H514415	H514511	H514597	H514671	H514794	H514903	H515000	H515079
H514002	H514089	H514174	H514256	H514341	H514416	H514513	H514598	H514672	H514795	H514905	H515001	H515080
H514003	H514090	H514175	H514257	H514342	H514417	H514514	H514600	H514673	H514796	H514906	H515004	H515082
H514004	H514091	H514179	H514258	H514343	H514420	H514515	H514601	H514675	H514797	H514907	H515005	H515083
H514005	H514092	H514180	H514260	H514344	H514421	H514516	H514602	H514676	H514798	H514908	H515006	H515084
H514006	H514093	H514181	H514262	H514345	H514422	H514517	H514603	H514677	H514800	H514910	H515007	H515085
H514007	H514094	H514182	H514263	H514346	H514424	H514518	H514604	H514678	H514801	H514911	H515008	H515086
H514008	H514095	H514183	H514265	H514347	H514426	H514520	H514605	H514679	H514804	H514912	H515009	H515087
H514009	H514096	H514184	H514268	H514348	H514429	H514521	H514607	H514682	H514805	H514913	H515011	H515088
H514010	H514097	H514185	H514269	H514349	H514430	H514522	H514608	H514683	H514811	H514915	H515012	H515089
H514011	H514098	H514186	H514270	H514350	H514433	H514523	H514609	H514685	H514812	H514916	H515013	H515090
H514015	H514100	H514187	H514271	H514351	H514436	H514525	H514611	H514687	H514813	H514917	H515014	H515091
H514016	H514101	H514188	H514272	H514352	H514437	H514526	H514612	H514688	H514814	H514919	H515016	H515092
H514017	H514104	H514191	H514273	H514353	H514438	H514527	H514613	H514689	H514815	H514920	H515017	H515093
H514018	H514108	H514192	H514274	H514355	H514439	H514529	H514614	H514690	H514816	H514921	H515018	H515094
H514019	H514110	H514193	H514275	H514356	H514440	H514530	H514615	H514691	H514817	H514922	H515019	H515095
H514020	H514112	H514194	H514276	H514357	H514441	H514532	H514616	H514692	H514818	H514924	H515020	H515096
H514021	H514114	H514196	H514277	H514359	H514444	H514533	H514617	H514693	H514819	H514927	H515021	H515097
H514022	H514115	H514198	H514278	H514360	H514449	H514534	H514618	H514698	H514820	H514929	H515023	H515099
H514023	H514119	H514200	H514279	H514361	H514456	H514539	H514619	H514699	H514821	H514930	H515024	H515100
H514025	H514121	H514201	H514280	H514362	H514457	H514540	H514620	H514702	H514824	H514932	H515025	H515101
H514026	H514122	H514202	H514281	H514363	H514460	H514541	H514623	H514703	H514826	H514933	H515026	H515102
H514028	H514123	H514204	H514282	H514364	H514461	H514542	H514624	H514705	H514827	H514934	H515027	H515105
H514029	H514124	H514208	H514283	H514365	H514462	H514544	H514625	H514708	H514828	H514936	H515030	H515106
H514030	H514125	H514209	H514284	H514366	H514463	H514545	H514626	H514711	H514829	H514937	H515033	H515107
H514031	H514126	H514210	H514285	H514367	H514464	H514546	H514627	H514716	H514830	H514939	H515034	H515108
H514032	H514127	H514211	H514286	H514372	H514465	H514547	H514628	H514722	H514832	H514940	H515036	H515109
H514033	H514128	H514212	H514288	H514373	H514466	H514551	H514629	H514723	H514834	H514941	H515037	H515110
H514034	H514129	H514213	H514289	H514374	H514467	H514552	H514631	H514724	H514836	H514942	H515038	H515111
H514039	H514130	H514214	H514291	H514375	H514468	H514553	H514632	H514732	H514842	H514944	H515039	H515112
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H514047	H514135	H514216	H514293	H514378	H514470	H514555	H514634	H514735	H514844	H514949	H515042	H515115
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H514050	H514137	H514219	H514297	H514381	H514472	H514559	H514636	H514750	H514849	H514952	H515044	H515117
H514051	H514138	H514220	H514300	H514382	H514474	H514560	H514637	H514752	H514851	H514953	H515045	H515118
H514052	H514141	H514221	H514301	H514383	H514478	H514561	H514638	H514753	H514852	H514954	H515046	H515120
H514053	H514142	H514222	H514303	H514385	H514479	H514562	H514639	H514754	H514854	H514955	H515047	H515121
H514054	H514143	H514223	H514304	H514386	H514480	H514563	H514640	H514756	H514855	H514958	H515048	H515122
H514055	H514144	H514224	H514305	H514387	H514481	H514564	H514641	H514758	H514856	H514959	H515049	H515123
H514056	H514146	H514225	H514306	H514388	H514482	H514565	H514642	H514759	H514857	H514961	H515050	H515124
H514060	H514147	H514226	H514307	H514389	H514483	H514566	H514643	H514763	H514862	H514962	H515052	H515125
H514062	H514148	H514227	H514310	H514390	H514484	H514567	H514644	H514765	H514863	H514963	H515054	H515127
H514064	H514149	H514228	H514311	H514391	H514485	H514568	H514645	H514766	H514865	H514967	H515055	H515128
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H514068	H514153	H514230	H514314	H514393	H514487	H514571	H514648	H514768	H514868	H514970	H515057	H515130
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H514071	H514156	H514234	H514318	H514396	H514490	H514575	H514652	H514778	H514871	H514974	H515061	H515133
H514072	H514157	H514235	H514319	H514397	H514491	H514576	H514653	H514779	H514872	H514975	H515062	H515134
H514073	H514159	H514236	H514320	H514398	H514493	H514577	H514654	H514780	H514874	H514976	H515063	H515135
H514075	H514160	H514237	H514321	H514399	H514494	H514578	H514656	H514781	H514875	H514980	H515064	H515136
H514076	H514161	H514238	H514322	H514400	H514496	H514579	H514657	H514782	H514876	H514981	H515065	H515138
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H515140	H515215	H515286	H515361	H515431	H515506	H515585	H515659	H515733	H515828	H515942	H518164
H515141	H515216	H515287	H515362	H515432	H515507	H515587	H515660	H515734	H515829	H515946	H518170
H515142	H515218	H515288	H515363	H515433	H515509	H515588	H515661	H515735	H515830	H515947	H518171
H515143	H515220	H515289	H515365	H515435	H515510	H515589	H515662	H515736	H515831	H515948	H518172
H515144	H515221	H515290	H515366	H515436	H515511	H515591	H515663	H515737	H515833	H515951	H518173
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H515158	H515231	H515301	H515377	H515446	H515523	H515602	H515673	H515749	H515850	H515977	H51A001
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