

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject:	Optical Guidance Platform may not always display the correct transfer date on the patient file
Commercial Name of Affected Product:	Optical Guidance Platform, version 2.6 and 2.6.1
Reference / FSMA Identifier:	CP-03976
Date of Notification:	2011-05-10
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 Optical Guidance Platform (OGP) software may not always be displaying the correct transfer date on the patient file. The 'Date' that is displayed in the Patient List of the OGP software may not always be the date the plan was received by the OGP and may lead to confusion about the which plan is the proper plan for the treatment of the day.

Details:

The initial date assigned to the plan is the date of the data transfer. This date is updated when any **NEW** file is written into the directory. This date may change when performing other functions with a transferred patient file such as saving pre-recorded positions, fiducial registration, and report or patient settings. Therefore, exam transferred at time T, but opened for a quick review in time T+t may have the later timestamp leading to confusion at the time of exam selection. The risk is a user opens a previous exam for review and then "saves" the file. They then go to open today's exam, however they select the most recent exam (the one they just opened, reviewed, and saved) thinking it is treatment plan for the day when it is not.

Recommended User Action:

- Review the OGP Instructions For Use on Loading a treatment plan.
- Before positioning the patient, compare the plan details loaded into the OGP with the plan details printed from the treatment planning system. Verify that the patient information, isocenter, gantry and couch angles are identical as requested in the Instructions For Use.
- Varian has made other changes to the Optical Guidance Platform Instructions For Use – we strongly recommend you download the most recent version at www.MyVarian.com or request a copy from your local Varian Customer Support District or Regional Manager.

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Varian Actions:

- Varian is notifying all affected customers with this document.
- Varian is preparing a software correction which will be applied to affected units to correct this issue.

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

2011-05-10

Date

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**APPENDIX
LIST OF SERIAL NUMBERS**

HZ10003	HZ10155	HZ10333	HZ10542	HZ10703	HZ12005	HZ12060	HZ12190	HZ17007	HZ17137	HZ19013	HZ19106
HZ10008	HZ10157	HZ10335	HZ10544	HZ10706	HZ12006	HZ12061	HZ13006	HZ17010	HZ17142	HZ19014	HZ19109
HZ10013	HZ10159	HZ10337	HZ10545	HZ10712	HZ12007	HZ12062	HZ13009	HZ17011	HZ17175	HZ19015	HZ19113
HZ10014	HZ10165	HZ10343	HZ10547	HZ10715	HZ12008	HZ12063	HZ13013	HZ17012	HZ18001	HZ19017	HZ19114
HZ10015	HZ10170	HZ10347	HZ10552	HZ10717	HZ12009	HZ12064	HZ13019	HZ17013	HZ18002	HZ19018	HZ19115
HZ10017	HZ10172	HZ10352	HZ10553	HZ10722	HZ12010	HZ12065	HZ13020	HZ17016	HZ18004	HZ19019	HZ19117
HZ10019	HZ10179	HZ10357	HZ10557	HZ10724	HZ12011	HZ12066	HZ13021	HZ17017	HZ18006	HZ19020	HZ19118
HZ10023	HZ10181	HZ10368	HZ10560	HZ10728	HZ12012	HZ12067	HZ13022	HZ17018	HZ18013	HZ19022	HZ19119
HZ10024	HZ10182	HZ10372	HZ10562	HZ10730	HZ12013	HZ12068	HZ13023	HZ17019	HZ18018	HZ19023	HZ19121
HZ10025	HZ10183	HZ10376	HZ10568	HZ10731	HZ12015	HZ12069	HZ13024	HZ17020	HZ18020	HZ19025	HZ19125
HZ10026	HZ10185	HZ10378	HZ10580	HZ10733	HZ12016	HZ12070	HZ13026	HZ17021	HZ18022	HZ19026	HZ19126
HZ10027	HZ10187	HZ10379	HZ10584	HZ10737	HZ12018	HZ12071	HZ13029	HZ17023	HZ18024	HZ19028	HZ19128
HZ10029	HZ10188	HZ10387	HZ10591	HZ10740	HZ12019	HZ12072	HZ13030	HZ17024	HZ18026	HZ19029	HZ19129
HZ10044	HZ10190	HZ10392	HZ10592	HZ10743	HZ12020	HZ12073	HZ13031	HZ17027	HZ18035	HZ19033	HZ19130
HZ10046	HZ10194	HZ10394	HZ10594	HZ10744	HZ12021	HZ12074	HZ13032	HZ17028	HZ18040	HZ19034	HZ19131
HZ10048	HZ10196	HZ10398	HZ10598	HZ10759	HZ12022	HZ12075	HZ13038	HZ17030	HZ18041	HZ19035	HZ19133
HZ10051	HZ10201	HZ10401	HZ10601	HZ10762	HZ12023	HZ12076	HZ13039	HZ17032	HZ18042	HZ19036	HZ19134
HZ10052	HZ10203	HZ10403	HZ10607	HZ10764	HZ12024	HZ12077	HZ13041	HZ17034	HZ18043	HZ19040	HZ19135
HZ10054	HZ10205	HZ10404	HZ10609	HZ10766	HZ12026	HZ12078	HZ13042	HZ17035	HZ18046	HZ19041	HZ19140
HZ10055	HZ10209	HZ10408	HZ10611	HZ10771	HZ12027	HZ12080	HZ13043	HZ17036	HZ18048	HZ19043	HZ19141
HZ10058	HZ10210	HZ10409	HZ10612	HZ10774	HZ12028	HZ12081	HZ13044	HZ17037	HZ18062	HZ19044	HZ19142
HZ10061	HZ10220	HZ10411	HZ10613	HZ10776	HZ12029	HZ12082	HZ13045	HZ17039	HZ18066	HZ19045	HZ19143
HZ10063	HZ10228	HZ10412	HZ10617	HZ10778	HZ12030	HZ12083	HZ13046	HZ17040	HZ18068	HZ19046	HZ19155
HZ10065	HZ10237	HZ10425	HZ10620	HZ11001	HZ12031	HZ12084	HZ13047	HZ17041	HZ18069	HZ19051	HZ19158
HZ10068	HZ10239	HZ10426	HZ10627	HZ11002	HZ12032	HZ12085	HZ13048	HZ17042	HZ18070	HZ19052	HZ19159
HZ10070	HZ10240	HZ10430	HZ10629	HZ11003	HZ12033	HZ12086	HZ13049	HZ17043	HZ18076	HZ19053	HZ19162
HZ10073	HZ10242	HZ10434	HZ10632	HZ11004	HZ12034	HZ12087	HZ13050	HZ17044	HZ18077	HZ19055	HZ19167
HZ10076	HZ10245	HZ10438	HZ10640	HZ11005	HZ12035	HZ12088	HZ13052	HZ17046	HZ18079	HZ19056	HZ19170
HZ10083	HZ10247	HZ10442	HZ10644	HZ11006	HZ12036	HZ12089	HZ13053	HZ17048	HZ18085	HZ19059	HZ19171
HZ10084	HZ10249	HZ10450	HZ10646	HZ11007	HZ12037	HZ12090	HZ13054	HZ17049	HZ18088	HZ19060	HZ19172
HZ10086	HZ10254	HZ10453	HZ10647	HZ11008	HZ12038	HZ12091	HZ13055	HZ17051	HZ18118	HZ19062	HZ19179
HZ10088	HZ10257	HZ10460	HZ10649	HZ11010	HZ12039	HZ12092	HZ13056	HZ17057	HZ18120	HZ19065	HZ19186
HZ10090	HZ10258	HZ10467	HZ10650	HZ11011	HZ12040	HZ12093	HZ13057	HZ17058	HZ18126	HZ19066	HZ19189
HZ10092	HZ10260	HZ10479	HZ10652	HZ11013	HZ12041	HZ12094	HZ13058	HZ17059	HZ18131	HZ19068	HZ19190
HZ10095	HZ10271	HZ10489	HZ10656	HZ11014	HZ12042	HZ12095	HZ13059	HZ17061	HZ18132	HZ19069	HZ19193
HZ10098	HZ10273	HZ10493	HZ10659	HZ11015	HZ12043	HZ12096	HZ13060	HZ17062	HZ18134	HZ19071	HZ19194
HZ10102	HZ10274	HZ10495	HZ10663	HZ11016	HZ12044	HZ12097	HZ13062	HZ17065	HZ18142	HZ19072	HZ19195
HZ10108	HZ10283	HZ10496	HZ10665	HZ11017	HZ12045	HZ12098	HZ13063	HZ17067	HZ18143	HZ19076	HZ19201
HZ10110	HZ10293	HZ10497	HZ10670	HZ11018	HZ12046	HZ12099	HZ13064	HZ17068	HZ18155	HZ19078	HZ19226
HZ10116	HZ10294	HZ10500	HZ10674	HZ11019	HZ12047	HZ12100	HZ15006	HZ17069	HZ18175	HZ19079	HZ19227
HZ10117	HZ10295	HZ10501	HZ10675	HZ11020	HZ12048	HZ12101	HZ15070	HZ17070	HZ18188	HZ19086	HZ19228
HZ10121	HZ10297	HZ10507	HZ10676	HZ11021	HZ12049	HZ12102	HZ15118	HZ17071	HZ18193	HZ19087	HZ19229
HZ10126	HZ10299	HZ10508	HZ10679	HZ11022	HZ12050	HZ12103	HZ15480	HZ17072	HZ19001	HZ19088	HZ19235
HZ10138	HZ10303	HZ10509	HZ10681	HZ11023	HZ12051	HZ12104	HZ16006	HZ17074	HZ19003	HZ19089	HZ19236
HZ10144	HZ10305	HZ10513	HZ10684	HZ11024	HZ12052	HZ12107	HZ16069	HZ17078	HZ19004	HZ19091	HZ19611
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HZ10148	HZ10313	HZ10534	HZ10689	HZ12001	HZ12056	HZ12125	HZ17001	HZ17081	HZ19006	HZ19096	HZ19996
HZ10151	HZ10316	HZ10537	HZ10693	HZ12002	HZ12057	HZ12126	HZ17002	HZ17106	HZ19007	HZ19098	HZ19997
HZ10153	HZ10326	HZ10540	HZ10698	HZ12003	HZ12058	HZ12154	HZ17003	HZ17118	HZ19010	HZ19099	HZ19998
HZ10154	HZ10330	HZ10541	HZ10700	HZ12004	HZ12059	HZ12188	HZ17006	HZ17126	HZ19012	HZ19104	