

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject: Physician's Intent Total Dose
Commercial Name of Affected Product: ARIA versions 10.0.39 and below
Reference / FSCA Identifier: CP-06070
Date of Notification: 2012-03-12
Type of Action: Notification
Details on Affected Devices: Refer to appendix page.

Description of Problem:

This letter is to advise you that an anomaly has been reported to Varian involving ARIA Oncology Information Systems where, in two reported cases, the **Planned Total Dose** did not calculate correctly in **Physician's Intent**. This notice provides information about what is known about this anomaly and actions you can take to avoid or mitigate the anomaly that was reported. Varian is continuing to actively investigate this anomaly and will provide additional information as available.

Details:

In the **Physician's Intent** workspace, users manually enter the **Prescribed Dose / Fraction** and the **Planned No. Fractions** (planned number of fractions), while ARIA calculates the **Planned Total Dose**. This is done by storing the above values in a table in the database. It was identified that incorrect values were being stored for **Planned No. Fractions**, leading to an unexpected calculation.

The values **Prescribed Dose / Fraction**, **Planned No. Fractions** and **Planned Total Dose** are recalculated each time the **Prescribed Dose / Fraction** or the **Planned No. Fractions** are updated in the grid in the RT Chart **Prescription** workspace. The **Planned Total Dose** is a read-only field. However, this field is not calculated in real time for the display in RT Chart, but is actually stored as a value in the database. This redundant data may contribute to the incorrect summation of the **Planned Total Dose**. This anomaly can be seen in Figure 1 below.

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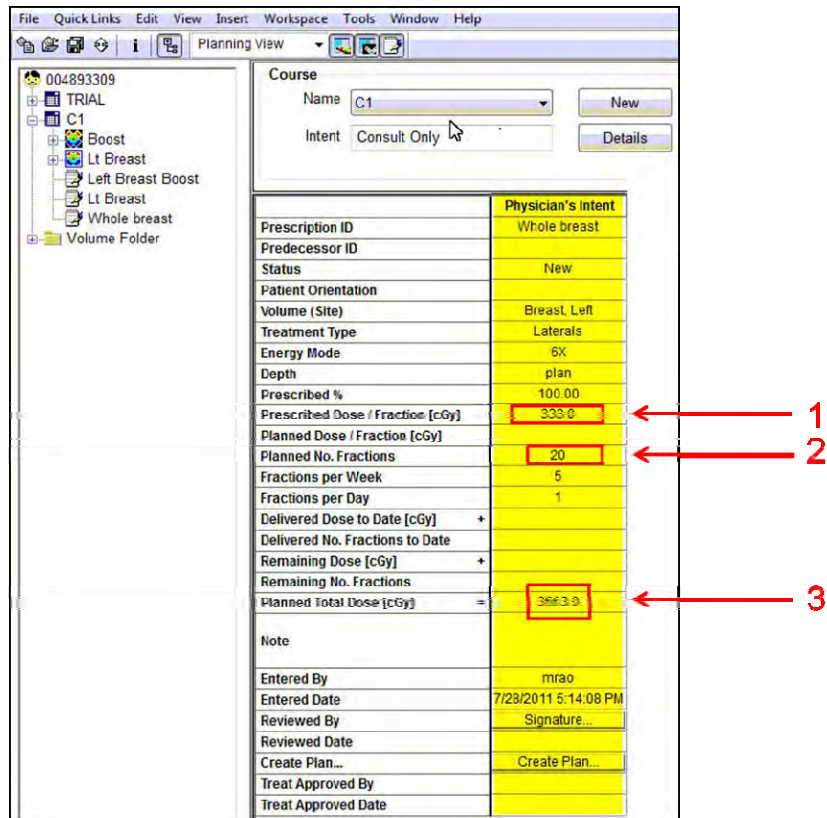


Figure 1: Physician's Intent where doses do not calculate properly

1 = Prescribed Dose / Fraction. 2 = Planned No. Fractions. 3 = Planned Total Dose.

Recommended User Action

1. Varian is recommending users of ARIA versions 10.0.39 and below using **Physician's Intent** to ensure that all doses that appear in the **Physician's Intent** are correctly calculated. Users should also ensure that when creating a plan from the **Physician's Intent** that the correct doses are entered into the plan and proper plan dose calculations are completed.

Varian Actions:

1. Varian is notifying all possibly affected customers with this document.
2. This notice provides information about what is known about this anomaly and actions you can take to avoid or mitigate the anomaly that was reported.
3. Varian is continuing to actively investigate this anomaly and will provide information to the users as available.

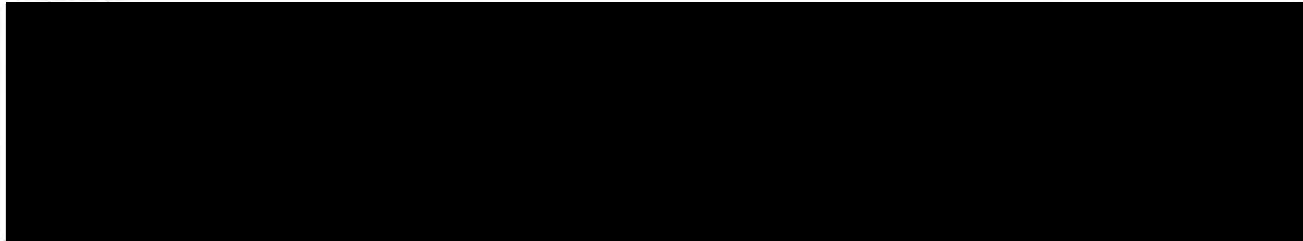
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Please advise the appropriate personnel working in your radiotherapy department of the content of this letter. For future reference, this document will be posted to the Varian customer support website: <http://www.MyVarian.com>.

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.



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Varian Medical Systems public site - www.varian.com

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APPENDIX LIST OF SERIAL NUMBERS

HIT0001	HIT0120	HIT0214	HIT0317	HIT0422	HIT0516	HIT0622	HIT0737	HIT0838	HIT0933	HIT1030	HIT1131
HIT0002	HIT0121	HIT0215	HIT0318M	HIT0424	HIT0517	HIT0624	HIT0738M	HIT0839M	HIT0937	HIT1035	HIT1132M
HIT0003	HIT0122	HIT0217	HIT0319M	HIT0426	HIT0519	HIT0625	HIT0739M	HIT0840	HIT0938	HIT1036	HIT1134
HIT0004M	HIT0123M	HIT0219	HIT0323	HIT0427	HIT0520M	HIT0627	HIT0740	HIT0842	HIT0940	HIT1039	HIT1135
HIT0005	HIT0124	HIT0223	HIT0326	HIT0428	HIT0522	HIT0629M	HIT0742M	HIT0843	HIT0942	HIT1041	HIT1137
HIT0011	HIT0125	HIT0225	HIT0328M	HIT0429M	HIT0523	HIT0630	HIT0746	HIT0844	HIT0944	HIT1043	HIT1139
HIT0013	HIT0126	HIT0227	HIT0329	HIT0430	HIT0525M	HIT0631	HIT0748	HIT0846	HIT0946	HIT1044	HIT1141
HIT0021	HIT0127	HIT0229	HIT0331	HIT0432M	HIT0527	HIT0632M	HIT0749	HIT0848	HIT0948A1	HIT1046	HIT1142M
HIT0023	HIT0130	HIT0231	HIT0333	HIT0434M	HIT0528	HIT0633	HIT0750	HIT0849	HIT0948M	HIT1047	HIT1144
HIT0025	HIT0132	HIT0234	HIT0335	HIT0436M	HIT0531	HIT0637	HIT0754	HIT0850	HIT0949M	HIT1049	HIT1145M
HIT0027	HIT0134	HIT0236	HIT0337M	HIT0437	HIT0532	HIT0639	HIT0756M	HIT0851	HIT0950	HIT1050	HIT1149M
HIT0028	HIT0137	HIT0238	HIT0339M	HIT0441	HIT0533	HIT0641M	HIT0757	HIT0852	HIT0951M	HIT1052	HIT1151
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HIT0032	HIT0143M	HIT0246	HIT0347	HIT0446	HIT0540	HIT0647	HIT0764	HIT0858	HIT0958	HIT1058	HIT1159
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HIT0040	HIT0145	HIT0249	HIT0350	HIT0450	HIT0542	HIT0650	HIT0767	HIT0863	HIT0960	HIT1060	HIT1163
HIT0041	HIT0147	HIT0251M	HIT0351	HIT0452	HIT0544	HIT0651	HIT0769	HIT0864	HIT0962	HIT1062	HIT1164
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HIT0045	HIT0150	HIT0255	HIT0355M	HIT0456	HIT0549	HIT0653	HIT0773M	HIT0868	HIT0965	HIT1065	HIT1168
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HIT0055	HIT0158	HIT0265	HIT0366M	HIT0464	HIT0558	HIT0662	HIT0782	HIT0876	HIT0975	HIT1074	HIT1179M
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HIT1365M	HIT1469	HIT1581	HIT1688	HIT1799	HIT1898	HIT2002	HIT2102	HIT2222	HIT2348	HIT2471M	HIT2596
HIT1369	HIT1470M	HIT1582	HIT1690	HIT1800	HIT1899	HIT2003	HIT2105	HIT2223	HIT2350	HIT2473	HIT2598
HIT1371	HIT1473	HIT1584	HIT1691	HIT1801	HIT1900	HIT2004	HIT2107	HIT2225	HIT2353	HIT2475	HIT2600
HIT1373	HIT1475	HIT1585	HIT1693	HIT1802	HIT1901	HIT2005M	HIT2109	HIT2226	HIT2355	HIT2477M	HIT2602
HIT1375	HIT1478	HIT1587M	HIT1696	HIT1803	HIT1903	HIT2006	HIT2110	HIT2228	HIT2357	HIT2480	HIT2603
HIT1376	HIT1481	HIT1589M	HIT1697M	HIT1804M	HIT1904M	HIT2007	HIT2111M	HIT2229	HIT2358	HIT2482	HIT2605
HIT1379	HIT1483	HIT1591	HIT1698	HIT1805	HIT1905	HIT2008	HIT2112	HIT2231	HIT2359	HIT2484	HIT2606
HIT1380	HIT1486	HIT1592	HIT1700	HIT1806	HIT1907	HIT2009	HIT2113M	HIT2233	HIT2361	HIT2491	HIT2609
HIT1381	HIT1488	HIT1594	HIT1701M	HIT1808	HIT1911	HIT2010M	HIT2115	HIT2236	HIT2362M	HIT2493	HIT2612
HIT1383	HIT1489	HIT1597	HIT1703	HIT1809	HIT1913	HIT2011	HIT2117	HIT2237M	HIT2364	HIT2498	HIT2615

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

HIT2620	HIT2740	HIT2889	HIT3016	HIT3139	HIT3270	HIT3403	HIT3526	HIT3668	HIT3795	HIT3934	HIT4108
HIT2621	HIT2741	HIT2891	HIT3018	HIT3140	HIT3274	HIT3404M	HIT3527	HIT3671	HIT3796	HIT3936	HIT4112
HIT2622	HIT2742	HIT2892	HIT3019	HIT3145	HIT3277	HIT3406	HIT3529	HIT3675	HIT3798	HIT3939	HIT4114
HIT2623A1	HIT2744	HIT2894M	HIT3020	HIT3147	HIT3279	HIT3407	HIT3531	HIT3677	HIT3799	HIT3941	HIT4116
HIT2623M	HIT2747	HIT2895	HIT3021	HIT3153	HIT3282	HIT3409	HIT3535	HIT3679	HIT3801	HIT3943	HIT4117
HIT2625	HIT2749	HIT2896	HIT3025	HIT3154	HIT3288	HIT3411	HIT3537	HIT3680	HIT3802	HIT3945	HIT4118M
HIT2627	HIT2752	HIT2897	HIT3027	HIT3157M	HIT3290	HIT3412	HIT3539	HIT3682	HIT3803	HIT3946	HIT4122
HIT2629	HIT2754	HIT2899	HIT3028	HIT3160	HIT3293	HIT3413	HIT3541	HIT3684	HIT3804	HIT3952	HIT4123
HIT2630	HIT2757	HIT2900	HIT3032	HIT3162	HIT3295	HIT3423	HIT3546	HIT3686	HIT3807	HIT3954	HIT4129
HIT2633	HIT2759	HIT2902	HIT3033	HIT3165	HIT3296	HIT3424	HIT3549	HIT3690	HIT3813	HIT3955	HIT4130
HIT2635	HIT2761	HIT2903	HIT3034	HIT3168	HIT3298M	HIT3425	HIT3551	HIT3691	HIT3815	HIT3957	HIT4132
HIT2637	HIT2763	HIT2906	HIT3039	HIT3172	HIT3299M	HIT3427	HIT3555	HIT3692	HIT3816	HIT3962	HIT4133
HIT2639	HIT2764	HIT2908M	HIT3040	HIT3173	HIT3302	HIT3428	HIT3560	HIT3697	HIT3822	HIT3964	HIT4136
HIT2640M	HIT2766	HIT2911	HIT3042	HIT3174	HIT3304	HIT3432	HIT3563M	HIT3700	HIT3823	HIT3965	HIT4139
HIT2643	HIT2767	HIT2915	HIT3044	HIT3177	HIT3308	HIT3434	HIT3564	HIT3702	HIT3826	HIT3967	HIT4144
HIT2645	HIT2768	HIT2918M	HIT3045	HIT3179	HIT3309	HIT3435	HIT3573	HIT3705	HIT3828	HIT3969	HIT4146
HIT2647	HIT2769	HIT2919	HIT3048	HIT3184	HIT3311	HIT3438	HIT3575	HIT3706	HIT3829	HIT3970	HIT4149
HIT2649M	HIT2770	HIT2923	HIT3050	HIT3186	HIT3314	HIT3439	HIT3578	HIT3708	HIT3832	HIT3973	HIT4151
HIT2650	HIT2772	HIT2929	HIT3052	HIT3187	HIT3315	HIT3441	HIT3579	HIT3710	HIT3837	HIT3975	HIT4154
HIT2652	HIT2774	HIT2930	HIT3054	HIT3188	HIT3319	HIT3446	HIT3580	HIT3713	HIT3841	HIT3977	HIT4156
HIT2655	HIT2777	HIT2932	HIT3055	HIT3192M	HIT3320	HIT3448	HIT3582	HIT3714	HIT3843	HIT3980	HIT4158
HIT2657	HIT2779	HIT2934	HIT3057	HIT3194	HIT3322	HIT3449M	HIT3583	HIT3717	HIT3844	HIT3984	HIT4159
HIT2658	HIT2780	HIT2935	HIT3058	HIT3195	HIT3324	HIT3454	HIT3585	HIT3718	HIT3845	HIT3988	HIT4160M
HIT2659	HIT2783	HIT2937	HIT3059	HIT3198	HIT3326	HIT3455	HIT3587	HIT3719	HIT3847	HIT3989	HIT4163M
HIT2660	HIT2788	HIT2939	HIT3061	HIT3199	HIT3327	HIT3456	HIT3588	HIT3720	HIT3849	HIT3992	HIT4165
HIT2662	HIT2790	HIT2941	HIT3063	HIT3201	HIT3328	HIT3457	HIT3591	HIT3722	HIT3852	HIT3994	HIT4167
HIT2666	HIT2793	HIT2942	HIT3064	HIT3204	HIT3329	HIT3459	HIT3592	HIT3724	HIT3854	HIT3997	HIT4168
HIT2668	HIT2794	HIT2943	HIT3070	HIT3206	HIT3333	HIT3460	HIT3595	HIT3725	HIT3856	HIT3998	HIT4169
HIT2670	HIT2795	HIT2945	HIT3072	HIT3209	HIT3336	HIT3461	HIT3598M	HIT3726	HIT3860	HIT4001	HIT4171
HIT2676	HIT2797	HIT2950	HIT3073	HIT3216	HIT3338	HIT3463	HIT3601	HIT3727	HIT3862	HIT4003	HIT4178
HIT2681	HIT2812	HIT2951	HIT3074	HIT3218	HIT3340	HIT3464	HIT3603	HIT3731	HIT3863	HIT4007	HIT4181
HIT2686	HIT2813	HIT2953	HIT3077	HIT3219	HIT3341	HIT3466M	HIT3605	HIT3732	HIT3865	HIT4009	HIT4188
HIT2687	HIT2816	HIT2954	HIT3081	HIT3220	HIT3342	HIT3468	HIT3607	HIT3735	HIT3867	HIT4010	HIT4190
HIT2688	HIT2818	HIT2961	HIT3084	HIT3221M	HIT3344	HIT3469	HIT3609	HIT3736	HIT3869	HIT4011	HIT4191
HIT2689	HIT2823	HIT2965	HIT3087	HIT3222	HIT3349	HIT3470M	HIT3612	HIT3738	HIT3871	HIT4013	HIT4193
HIT2690	HIT2825	HIT2966	HIT3088M	HIT3224	HIT3354	HIT3473	HIT3614	HIT3739M	HIT3873	HIT4014	HIT4196
HIT2692	HIT2826	HIT2968	HIT3089	HIT3226	HIT3355	HIT3474	HIT3615	HIT3740	HIT3875	HIT4015	HIT4204
HIT2693	HIT2828	HIT2970	HIT3091	HIT3227	HIT3356	HIT3476	HIT3618	HIT3741M	HIT3876	HIT4016	HIT4206M
HIT2694	HIT2830	HIT2973	HIT3092	HIT3230	HIT3359	HIT3478	HIT3624	HIT3742	HIT3879	HIT4017	HIT4232
HIT2695	HIT2831	HIT2974	HIT3093	HIT3232	HIT3360	HIT3479	HIT3625	HIT3744	HIT3881	HIT4020	HIT4234
HIT2699	HIT2834	HIT2975	HIT3095	HIT3233	HIT3362M	HIT3481	HIT3627	HIT3752	HIT3883	HIT4027	HIT4235
HIT2701M	HIT2835	HIT2977	HIT3097	HIT3234	HIT3364	HIT3483	HIT3628	HIT3753	HIT3887	HIT4030	HIT4237
HIT2702	HIT2836	HIT2980	HIT3100	HIT3236	HIT3365	HIT3484	HIT3629	HIT3754	HIT3888	HIT4034	HIT4240
HIT2703	HIT2840	HIT2981	HIT3102	HIT3237	HIT3366	HIT3486	HIT3630	HIT3755	HIT3891M	HIT4038	HIT4242
HIT2704	HIT2842	HIT2982	HIT3106	HIT3239	HIT3367	HIT3489	HIT3631	HIT3757	HIT3896	HIT4043	HIT4245
HIT2705	HIT2843	HIT2984	HIT3109	HIT3240	HIT3369	HIT3492	HIT3633	HIT3758M	HIT3897	HIT4045	HIT4251
HIT2706	HIT2852	HIT2985	HIT3110	HIT3241	HIT3370	HIT3494	HIT3635	HIT3759	HIT3899	HIT4047	HIT4252
HIT2710M	HIT2854M	HIT2987	HIT3112M	HIT3242	HIT3373	HIT3495	HIT3638	HIT3764M	HIT3901	HIT4051	HIT4253
HIT2711	HIT2856M	HIT2988	HIT3116M	HIT3244	HIT3376	HIT3498	HIT3640	HIT3766	HIT3902	HIT4053	HIT4254
HIT2715	HIT2860	HIT2991	HIT3117	HIT3245	HIT3379	HIT3499	HIT3641	HIT3767	HIT3904	HIT4057	HIT4255
HIT2716	HIT2863	HIT2992	HIT3118	HIT3250	HIT3384	HIT3501	HIT3642	HIT3769	HIT3906	HIT4062M	HIT4257
HIT2717	HIT2865	HIT2993	HIT3119	HIT3251	HIT3386	HIT3503	HIT3644	HIT3771	HIT3908	HIT4065	HIT4262
HIT2720	HIT2867	HIT2995	HIT3121	HIT3254	HIT3388	HIT3505	HIT3646	HIT3775	HIT3910	HIT4071	HIT4263
HIT2722	HIT2868	HIT2997	HIT3125	HIT3257	HIT3391	HIT3509	HIT3648	HIT3778	HIT3911	HIT4074M	HIT4264
HIT2724	HIT2875	HIT2999	HIT3126	HIT3259	HIT3393M	HIT3513	HIT3652	HIT3780	HIT3913	HIT4075	HIT4270
HIT2726	HIT2878	HIT3000	HIT3127	HIT3260	HIT3394	HIT3514	HIT3653	HIT3782	HIT3918	HIT4078	HIT4271
HIT2728	HIT2879	HIT3004	HIT3128	HIT3261	HIT3395	HIT3515	HIT3658	HIT3784	HIT3920	HIT4080	HIT4272
HIT2731	HIT2880	HIT3006	HIT3130	HIT3262	HIT3396	HIT3516	HIT3659	HIT3786	HIT3923	HIT4082	HIT4273
HIT2732	HIT2883	HIT3008	HIT3131M	HIT3264	HIT3397	HIT3517	HIT3660	HIT3787	HIT3925	HIT4087	HIT4276
HIT2737	HIT2884	HIT3010	HIT3134	HIT3265	HIT3400	HIT3519	HIT3661	HIT3788	HIT3927M	HIT4090	HIT4277
HIT2738	HIT2887	HIT3012	HIT3135	HIT3267	HIT3401	HIT3521M	HIT3664	HIT3790	HIT3928	HIT4105	HIT4282
HIT2739	HIT2888	HIT3013	HIT3136	HIT3268	HIT3402	HIT3524	HIT3667	HIT3792	HIT3931	HIT4107	HIT4283

**URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE**

**URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE**

HIT4285	HIT4313	HIT4349	HIT4394	HIT4439M
HIT4286	HIT4317	HIT4350	HIT4395	HIT4449
HIT4287	HIT4323	HIT4356	HIT4396	HIT4450
HIT4289	HIT4324M	HIT4357	HIT4397	HIT4451
HIT4293	HIT4326	HIT4358	HIT4400	HIT4452
HIT4299	HIT4328	HIT4360	HIT4402	HIT4453
HIT4303	HIT4331	HIT4381	HIT4404	HIT4454
HIT4306	HIT4332	HIT4385	HIT4434	HIT4455
HIT4309	HIT4334	HIT4390	HIT4436	HIT4492
HIT4310	HIT4335	HIT4391	HIT4437	HIT4517
HIT4311	HIT4348	HIT4392	HIT4438	