

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject:	Absent Wedge filter on the 4D Integrated Treatment Console after a plan has been loaded from the ARIA Oncology Information System
Commercial Name of Affected Product:	4D Integrated Treatment Console (4DITC) versions 8.1.3 to 8.8
Reference / FSCA Identifier:	CP-03556
Date of Notification:	2012-04-09
Type of Action:	Notification and Correction
Details on Affected Devices:	Refer to Appendix page.

Description of Problem:

This letter is to provide all users of the 4D Integrated Treatment Console (4DITC) with notification and instructions regarding the use of wedges and Secondary Channel Integrity Check (SCIC). You may have previously received a notification; however, please read the document in its entirety. Further explanation regarding affected versions has been added.

This letter will also address all users by system configuration 4DITC and Oncology Information System (OIS) and explain what has occurred and what steps to be taken. The correction strategy will all apply to 4DITC users, regardless of OIS vendor. Varian has been notified that a plan containing a wedge was treatment approved in ARIA and loaded on the 4DITC for treatment. The wedge data was present upon loading the treatment plan. However, when the wedge field was to be treated, the wedge was not present and treatment was allowed without the presence of the wedge.

The following configurations could potentially allow treatment without the presence of a wedge:

- The 4DITC version 8.1.3 when using ARIA version 8.5 to 8.8. (4DITC 8.1.3 does not support SCIC) or;
- The 4DITC version 8.3 to 8.8 with ARIA version 8.3 to 8.9 when the SCIC feature is not enabled in 4DITC Treatment Administration and/or in ARIA Radiation Oncology Administration. Both 4DITC and ARIA administration must have SCIC enabled at the same time in order for SCIC to work.

Details:

After a plan with wedge field has been opened in 4D Integrated Treatment Console, users may not notice that the wedge filter may actually be missing from a selected field, and the treatment application will not notify the user of this anomaly and will not prevent beam delivery. The user may come to understand that the wedge filter is missing only after the treatment field has been partially or completely delivered and when the user attempts to close the patient from the treatment application. With this situation the treatment application forces the user to unload the patient, requires user authorization, and informs the user that the treatment record for the missing wedge field will not be saved to the OIS.

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Delivery of a treatment field without the planned and calculated wedge filter could result in an over dosage for that beam and potentially an unintended dose uniformity of the target treatment volume.

This errant behavior may occur with these releases of 4D Integrated Treatment Console v8.6 or earlier. However, no reported events have occurred with a 3rd party OIS.

Additionally, Varian updated the 4DITC DICOM library in version 8.8 and no reported events have occurred with the wedge being dropped for treatment in version 8.8 or higher.

Secondary Channel Integrity Check (SCIC)

Implementation of Treatment Plan Data Integrity

In the ARIA system the treatment plan is stored in the central system database (Varian system database) and accessed by multiple applications. Treatment delivery commences after plan has been transferred over to the 4D integrated treatment console. To further ensure safety of the radiation beam delivery, Varian Medical Systems has introduced a data integrity check for treatment plan data after plans have been approved. This check (if enabled by user) is applied any time the approved plan is opened from the database or after any data transfer from one application to another (e.g. data transfer from Varian system database to 4D ITC).

The check is achieved by a verification of a checksum or “plan signature” of most important plan parameters. The initial “plan signature” is calculated and stored at the time of plan approval and it is recalculated and verified any time the approved plan is accessed or transferred to another application. If the mismatch in the “plan signature” is detected, the receiving application will issue a warning and prevent user from further action until the warning has been acknowledged by an authorized user. The following figure below illustrates the use of the plan signature. In addition to treatment delivery the check is applied by any application accessing treatment plan data after approval.

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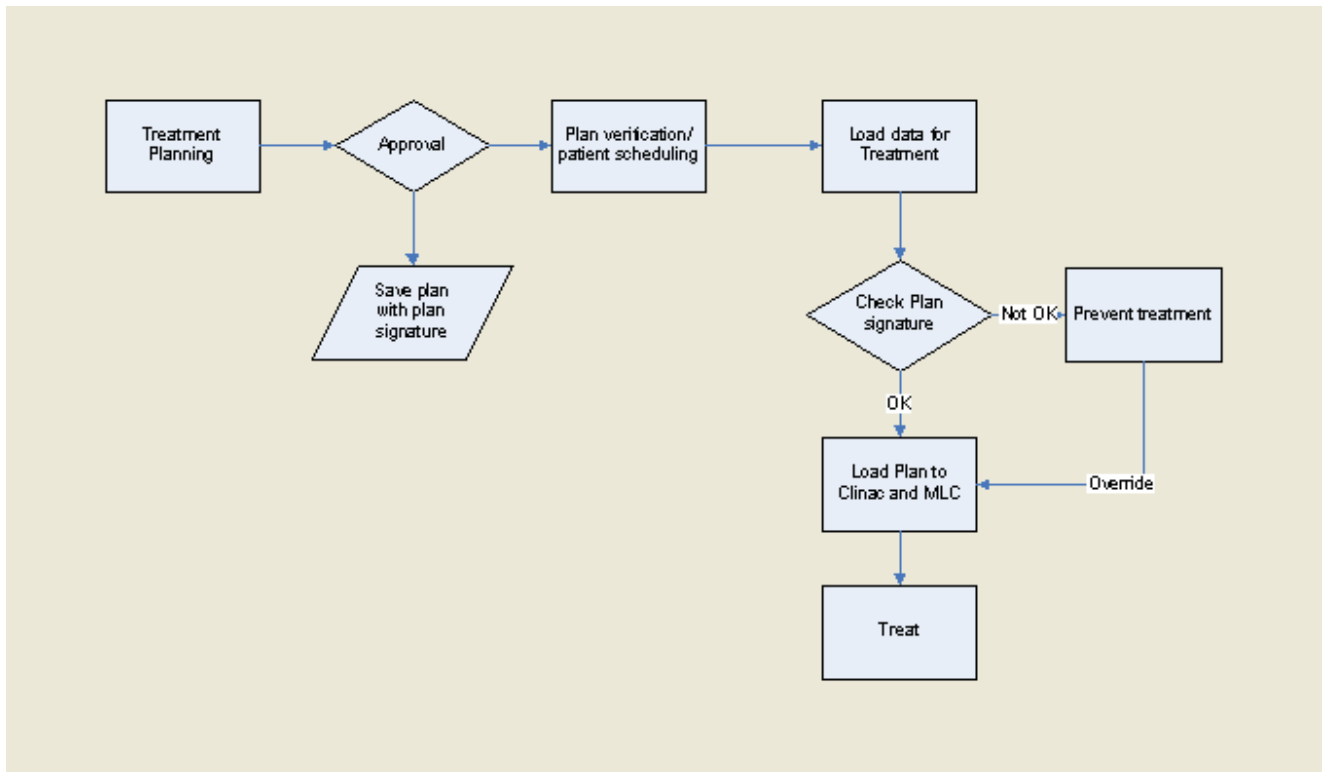


Figure 1: SCIC workflow and plan signature generation

SCIC was introduced in 4DITC version 8.3 and ARIA Radiation Oncology version 8.5. See the table below for SCIC support.

Product	SCIC not supported	SCIC supported
4DITC	8.1	8.3 to present
ARIA	8.0 to 8.3	8.5 to present
3 rd party OIS with 4DITC and Eclipse	-----	Eclipse (ARIA Radiation Oncology) 8.5 to present 4DITC 8.3 to present

Table 1: SCIC support

Figure 2 below displays where to check that SCIC Plan Integrity Checking has been enabled in ARIA Radiation Oncology Administration.

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In order to enable this functionality, the administrator must log into Radiation Oncology Administration > System Properties > General System Properties > Preferences > Enable Plan Integrity Checking.

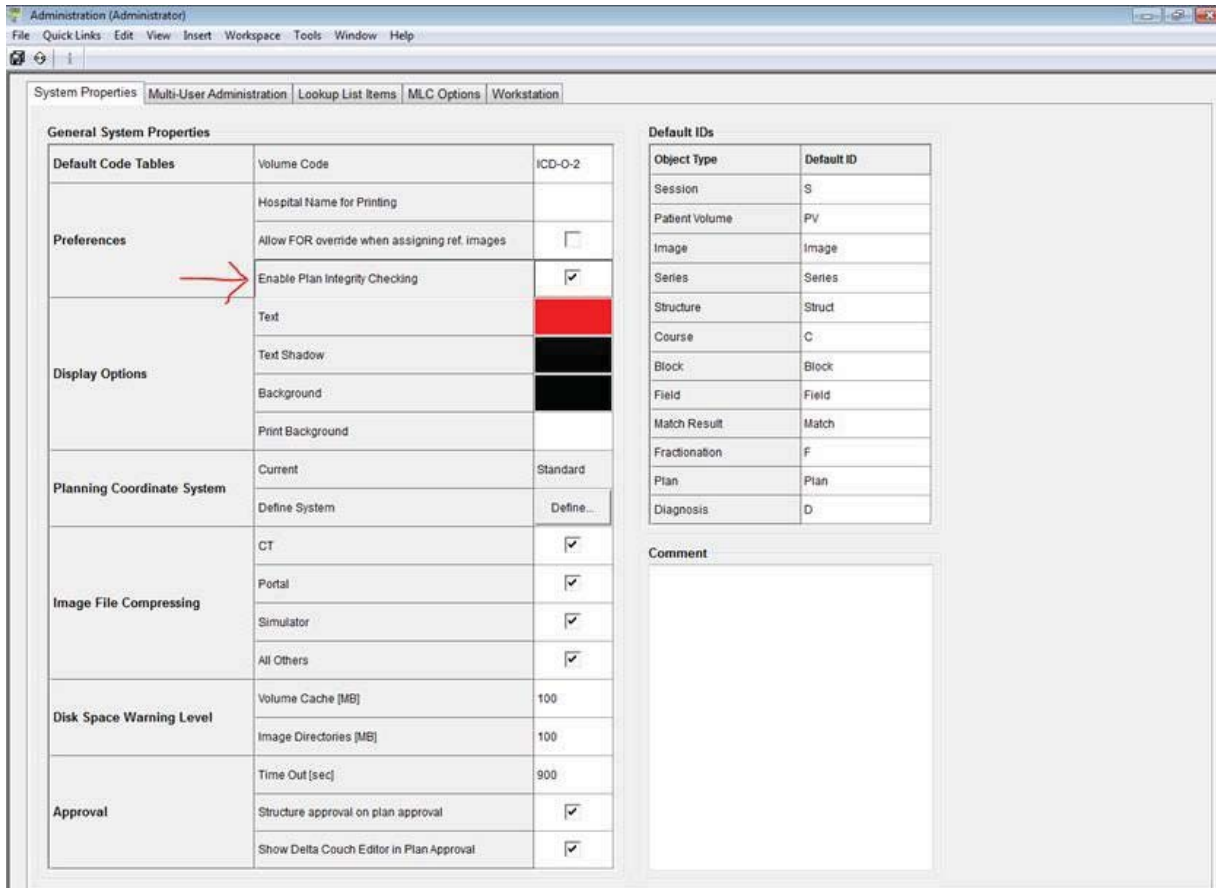


Figure 2: Radiation Oncology Administration SCIC configuration

Recommended User Action

To avoid this issue, we recommend that customers make workflow adjustments in their planning, scheduling, and delivery portions prior to delivering a wedge field treatment as follows:

Planning

1. A *Setup Note* is recommended for each field that requires a physical, virtual, or motorized wedge, and should contain the ID and Name of the wedge as well as the Field Name. {*Setup Notes* are added in RT Chart▶Parameters Tab▶select Field▶SetUp Note▶select [..]▶enter wedge specifics in the text box▶save.}
 - ✓ The *Setup Note* entry is presented to the user inside the treatment room on the In-Room Monitor (IRM), which is utilized by the user during the patient set-up process.

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- ✓ The *Setup Note* entry is also available to the user from the Treatment application.
 - ❖ Show Setup Note... button.

Scheduling

1. A *Patient Alert* will be needed for the patient when one or more fields in her/his treatment plan requires a physical, virtual, or motorized wedge. {*Patient Alerts* are added in Patient Manager ► Summary tab ► right-click the Patient Alert(s) section ► select New Alert... ► save.}
 - ✓ At the treatment machine user authorization is required to acknowledge the *Patient Alert* with username and password. The *Patient Alert* must not be checked-off (Sign Off); only then will it be available for every session prior to the patient's plan being loaded in to the Treatment application.

Delivery

1. The user will review and acknowledge the *Patient Alert*.
2. The user will only mark this particular *Patient Alert* as complete (Sign Off) on the last session for the patient's treatment plan.
3. When the radiation therapy therapist (RTT) sets up the patient inside the treatment room, s/he will review the *Setup Note* contents on the IRM and will understand that a wedge is required for the current moded-up field. See figure 1 below.
 - a. In the unlikely event that the IRM—*Internal Mount* field—does not call for the planned wedge filter for the current moded up field while the *Setup Note* calls for the wedge filter follow these steps:
 - i. Select Clear Mode Up from the Treatment application to remove the prescription from the linac control system.
 - ii. Close the patient from the Treatment application.
 - iii. Open the patient again in the Treatment application.
 - This will clear the errant plan loading in the Treatment application, which now includes the wedge for the respective field(s).
- ✓ Users may also use RT Chart ► Parameters workspace or the Treatment Field Setup report to assist with wedge fields prior to beam delivery.

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ID: 00IGRT44		Breast, Brigitte		1-RAS LT BREAST	
	Plan	Actual		Plan	
Y1(cm)	5.3	0.0	MLC	Static	
Y2(cm)	4.5		EDW(deg)		
X1(cm)	4.3	0.0		3RW15	20
X2(cm)	4.5				
Coll Rtn(deg)	59.0	0.0			
Gantry Rtn(deg)	305.0	0.0			

Internal Mount
Wedge ID/Name for the prescribed field

Setup Note
content that includes the Wedge ID/Name for the prescribed field

Set Up Note
Field (1-RAS LT BREAST) requ
Wed: **3RW1** .5

Figure 1. Screen capture of the In-Room Monitor located inside of the treatment room.

Varian Actions:

Varian is notifying all customers who have 4D Integrated Treatment Console releases 8.1, 8.3, 8.6, and 8.8 with this letter. This issue has been corrected in 4DITC 8.8 but all 4DITC customers will receive an upgrade of 4DITC v10.2 or higher. Varian service will contact to arrange to perform the upgrade.

For MOSAIQ users, please check with your Elekta representative in order to confirm compatibility with 4DITC v10.2 or higher.

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.

Date

Director, Global Quality Assurance and Product Reliability

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Varian Medical Systems public site - www.varian.com

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APPENDIX LIST OF SERIAL NUMBERS

H510010	H510807	H511260	H511614	H511939	H512265	H512652	H513009	H513261	H513547	H513830	H514051	H514285
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H514620	H514863	H515072	H515210	H515382	H515554	H515730	H515902	H518169	H51A012	H51B132	H51B267
H514623	H514868	H515075	H515211	H515384	H515559	H515732	H515904	H518170	H51A013	H51B139	H51B268
H514624	H514876	H515076	H515213	H515388	H515562	H515733	H515906	H518171	H51A014	H51B140	H51B269
H514626	H514890	H515079	H515214	H515394	H515563	H515739	H515908	H518182	H51A015	H51B141	H51B275
H514627	H514892	H515080	H515218	H515398	H515565	H515740	H515911	H518183	H51A018	H51B144	H51B276
H514628	H514895	H515083	H515220	H515401	H515579	H515742	H515914	H518184	H51A019	H51B146	H51B281
H514640	H514903	H515084	H515224	H515412	H515582	H515743	H515915	H518185	H51A021	H51B148	H51B282
H514641	H514905	H515085	H515227	H515413	H515585	H515747	H515929	H518190	H51B002	H51B150	H51B283
H514642	H514907	H515086	H515231	H515414	H515587	H515751	H515935	H518194	H51B004	H51B151	H51B287
H514653	H514912	H515088	H515232	H515417	H515592	H515754	H515938	H518197	H51B005	H51B152	H51B288
H514654	H514913	H515089	H515236	H515419	H515594	H515755	H515941	H518198	H51B006	H51B157	H51B289
H514660	H514921	H515090	H515240	H515422	H515595	H515758	H515944	H518199	H51B007	H51B159	H51B290
H514677	H514922	H515099	H515241	H515424	H515597	H515761	H515951	H518200	H51B008	H51B162	H51B292
H514682	H514924	H515100	H515242	H515431	H515599	H515762	H515959	H518201	H51B009	H51B165	H51B297
H514685	H514927	H515101	H515244	H515433	H515601	H515768	H515960	H518207	H51B010	H51B169	H51B301
H514687	H514930	H515108	H515245	H515435	H515604	H515776	H515962	H518210	H51B011	H51B172	H51B303
H514688	H514941	H515110	H515249	H515438	H515605	H515779	H515963	H518211	H51B012	H51B174	H51B310
H514699	H514942	H515111	H515256	H515440	H515609	H515780	H515965	H518212	H51B013	H51B177	H51B314
H514711	H514949	H515113	H515258	H515441	H515610	H515781	H515967	H518213	H51B016	H51B179	H51B315
H514722	H514951	H515116	H515264	H515442	H515612	H515787	H515969	H518218	H51B018	H51B183	H51B328
H514724	H514952	H515117	H515266	H515443	H515613	H515791	H515971	H518220	H51B020	H51B184	H51B330
H514734	H514953	H515118	H515271	H515451	H515614	H515792	H515972	H518223	H51B024	H51B185	H51B335
H514735	H514954	H515120	H515272	H515453	H515617	H515795	H515978	H518225	H51B025	H51B186	H51B336
H514736	H514955	H515121	H515273	H515454	H515622	H515796	H515981	H518228	H51B035	H51B187	H51B343
H514750	H514958	H515123	H515274	H515455	H515623	H515797	H515982	H518230	H51B037	H51B188	H51B347
H514753	H514959	H515124	H515276	H515456	H515625	H515798	H515983	H518236	H51B038	H51B191	H51B350
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H514756	H514963	H515129	H515285	H515464	H515632	H515803	H515985	H518247	H51B045	H51B194	H51B364
H514758	H514968	H515130	H515290	H515465	H515638	H515805	H515987	H518249	H51B046	H51B195	