

## URGENT FIELD SAFETY NOTICE

**Subject:** Inadvertent Deletion of Treatment Accessories from Treatment Fields

**Commercial Name of Affected Product:** RT Chart version 7.3.10(function in VARiS Vision)

**FSCA Identifier:** CP-00569

**Date of Notification:** 2011-02-07

**Type of Action:** Notification and Correction

**Details on Affected Devices:** See attached list.

### Description of Problem:

We are writing to advise you of the possible inadvertent deletion of accessory elements (including dynamic MLC) of a field when creating a set up field in RT Chart.

### Anomaly:

Immediately after creating a Setup field in RT Chart version 7.3.10, the focus reverts to the Treatment Field. Varian has received reports that users have sometimes failed to notice this focus, and have proceeded to delete MLC and other accessory components from the field, in the mistaken belief they were acting on the Setup field.

### Details:

For more information on this issue, please refer to CTB-TR-566, enclosed with this letter, and available at the [www.myvarian.com](http://www.myvarian.com) website.

### Recommended User Action:

- Ensure that the focus of RT Chart is on the Setup Field when attempting to edit a Setup Field. Be aware that the focus does not stay on the Setup Field when you first create it.

### Varian Actions:

- In RT Chart v7.5.49 (a function of ARIA™), Varian has introduced a completely new methodology for creating Setup Fields from Treatment Fields, reducing the chance that information is inadvertently removed from Treatment Fields.
- Varian is developing a service pack which will introduce a change in RT Chart which will hold the focus on the Setup Field when one is created, reducing the probability of inadvertent edits to the Treatment Field. You will be contacted by a Customer Service rep when this correction is available to schedule its installation on your system.

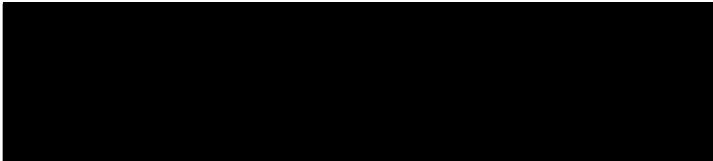
## URGENT FIELD SAFETY NOTICE

### Inadvertent Deletion of Treatment Accessories from Treatment Fields

**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 co-operation. If you require further clarification, please feel free to contact your Varian Customer Support District or Regional Manager.

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.



\_\_\_\_2011-02-07\_\_\_\_  
Date

#### 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](mailto:support-americas@varian.com)  
Australia/New Zealand: [support-anz@varian.com](mailto:support-anz@varian.com)  
Europe: [support-emea@varian.com](mailto:support-emea@varian.com)  
South East Asia: [seasia.apps.helpdesk@varian.com](mailto:seasia.apps.helpdesk@varian.com)  
China / Asia: [china.apps.helpdesk@varian.com](mailto:china.apps.helpdesk@varian.com)  
Japan: [Japan.Apps.Helpdesk@varian.com](mailto:Japan.Apps.Helpdesk@varian.com)  
Latin America: [soporte.al@varian.com](mailto:soporte.al@varian.com)

**Internet:** Oncology Systems - [www.myvarian.com](http://www.myvarian.com)  
Varian Medical Systems - [www.varian.com](http://www.varian.com)

## URGENT FIELD SAFETY NOTICE

### Inadvertent Deletion of Treatment Accessories from Treatment Fields

#### APPENDIX A LIST OF AFFECTED SERIAL NUMBERS

H831019	H831875R1	H832916	H833606	H834008	H834483	H836093	H836522	H837656
H831032	H831876	H832950M	H833635	H834009	H834488	H836095	H836524	H837657
H831048	H831898	H832950R1	H833638	H834022	H834490	H836096	H836593	H837672
H831052	H831932	H832950R2	H833652	H834028	H834491	H836106	H836595	H837684
H831055	H831971	H832969M	H833658	H834031	H834554	H836109	H836642	H837685
H831074	H831980	H832969R1	H833668	H834079	H834564	H836111	H836650	H837693
H831097	H831994	H832969R2	H833672	H834080	H834568	H836113	H836657	H837694
H831098	H832000	H832969R3	H833680	H834090	H834588	H836118	H836685	H837696
H831103	H832028	H832982	H833681	H834095	H834603	H836124	H836686	H837802
H831113	H832084	H833027	H833682	H834116	H834662	H836128	H836687	H837807
H831124	H832167	H833071	H833684	H834124	H834663	H836167	H836754	H837811
H831130	H832181	H833091	H833686	H834125	H834731	H836168	H836758	H837814
H831143	H832297	H833126	H833693	H834127	H834732	H836170	H836761	H837816
H831158	H832335	H833142	H833701	H834138	H834736	H836176	H836763	H837817
H831185	H832351	H833146	H833715	H834147	H834737	H836199	H836766	H837819
H831190M	H832358M	H833158	H833741	H834186	H834747	H836269	H836776	H837820
H831190R1	H832358R1	H833176	H833755	H834189	H834752	H836275	H836777	H837927
H831197	H832358R2	H833221	H833772	H834192	H834762	H836277	H836779	H837928
H831198	H832358R3	H833247	H833813	H834193	H834769	H836281	H836823	H837931
H831221	H832393	H833249	H833816	H834196	H834786	H836283	H836831	H837933
H831230	H832423	H833259	H833825	H834198	H834789	H836292	H836845	H837934
H831234	H832436	H833318	H833843	H834230	H834813	H836293	H836848	H837935
H831252M	H832536	H833326	H833853	H834232	H834866	H836298	H836967	H837941
H831252R1	H832561	H833329	H833856	H834255	H834869	H836311	H836972	H837942
H831252R2	H832583	H833343	H833868	H834260	H834881	H836321	H836986	H837943
H831279	H832593	H833348	H833869	H834270	H834887	H836322	H837007	H837945
H831296	H832594	H833354	H833882	H834283	H834889	H836323	H837015	H837949
H831305	H832602	H833369M	H833902	H834293	H834912	H836332	H837016	H838106
H831325	H832608M	H833369R1	H833904	H834351	H834919	H836336	H837018	H838108
H831418	H832608R1	H833370	H833905	H834353	H834926	H836347	H837024	H838112
H831437	H832618	H833391	H833924	H834355	H834929	H836402	H837031	H838113
H831446	H832653	H833399	H833934	H834369	H834934	H836404	H837042	H838114
H831452	H832698	H833402	H833946	H834384	H834948	H836406	H837058	H838115
H831502	H832710	H833404	H833950	H834394	H834958	H836419	H837072	H838118
H831512	H832713	H833429	H833951	H834399	H834967	H836424	H837146	H838119
H831559	H832715	H833433	H833952	H834405	H834972	H836430	H837289	H838120
H831611	H832728	H833445	H833953	H834409A1	H834977	H836445	H837295	H838121
H831639	H832741M	H833458	H833954	H834417	H834979	H836447	H837299	H838122
H831652	H832741R1	H833531M	H833955	H834424	H834991	H836453	H837314	H838433
H831711A4	H832755	H833538	H833956	H834449	H834994	H836454	H837357	H838435
H831714	H832771	H833551	H833957	H834451	H836003	H836471	H837374	H838437
H831724	H832830M	H833552	H833971	H834456A1	H836007	H836481	H837382	H838441
H831803	H832830R1	H833556	H833972	H834456A4	H836061	H836485	H837413	H838445
H831807	H832847	H833557	H833974	H834462	H836066	H836489	H837502	H838446
H831835	H832870	H833570	H833993	H834469	H836069	H836490	H837544	H838556
H831839	H832872	H833577	H833995A1	H834470	H836079	H836492	H837650	
H831875M	H832902	H833585	H834000	H834477	H836087	H836506	H837651	

CTB Information

Approved Release Date 11/13/07

<b>Title</b>	Creation Of Setup Fields From Treatment Fields		
<b>Drawing Number</b>	884972	CTB	TR-566A
<b>Est. labor hours</b>	N/A		
<b>Purpose</b>	The purpose of this document is to notify customers of unintended treatment parameters when creating Setup Fields		
<b>Machine Effectivity</b>	All RT-Chart versions up to and including v7.3.10		
<b>Prerequisites</b>	The CTB shall be used in conjunction with the appropriate ARIA User Manuals.		

Document Information

REV	CREATION DATE	STB	INT	DESCRIPTION OF CHANGE	FILE NAME
A	Oct. 23, 2007	N/A	MA	Initial Release	CTB-TR-566a.doc

Tools Information

<b>Tools &amp; Equip</b>	N/A
<b>Reference Documents</b>	ARIA User Manuals
<b>Modification Overview</b>	This CTB does not update or modify the core Software product. This anomaly has been addressed and in RT-Chart version 7.5.49 and is available for installation.

Order Kit Information

Order Number	Description
884972-01	The CTB has no associated parts.
<b>Order from</b>	<input type="checkbox"/> Service <input type="checkbox"/> Palo Alto <input type="checkbox"/> Baden <input type="checkbox"/> Crawley



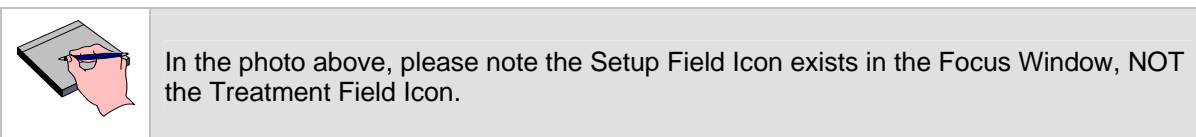
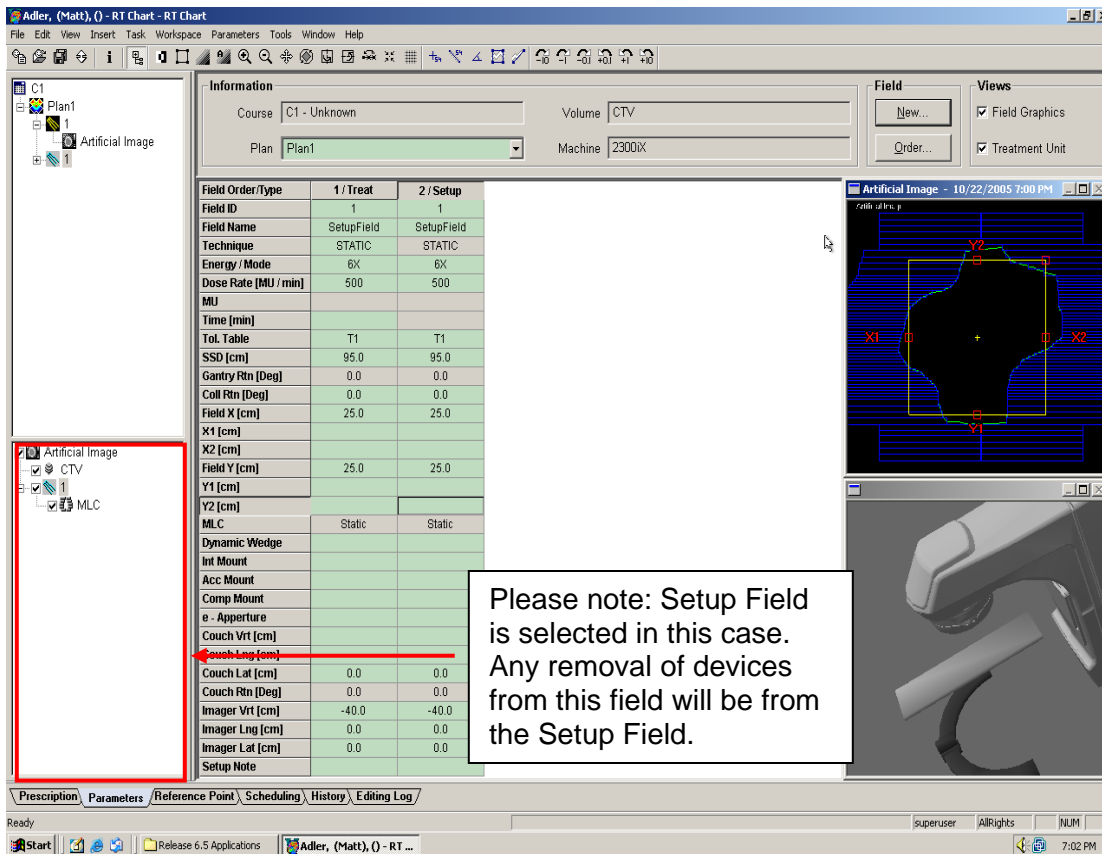
**1. DESCRIPTION**

In RT-Chart, when creating a Setup Field from a Treatment Field, the focus of the product remains on the Treatment Field, instead of shifting to the newly created Setup Field. Users are then inadvertently removing MLC and accessory information from this field, thinking they had the Setup Field selected. Although warning messages appear and user confirms warning, there are in actuality removing important information from Treatment Fields, not Setup Fields.

**2. USER CORRECTIVE ACTION**

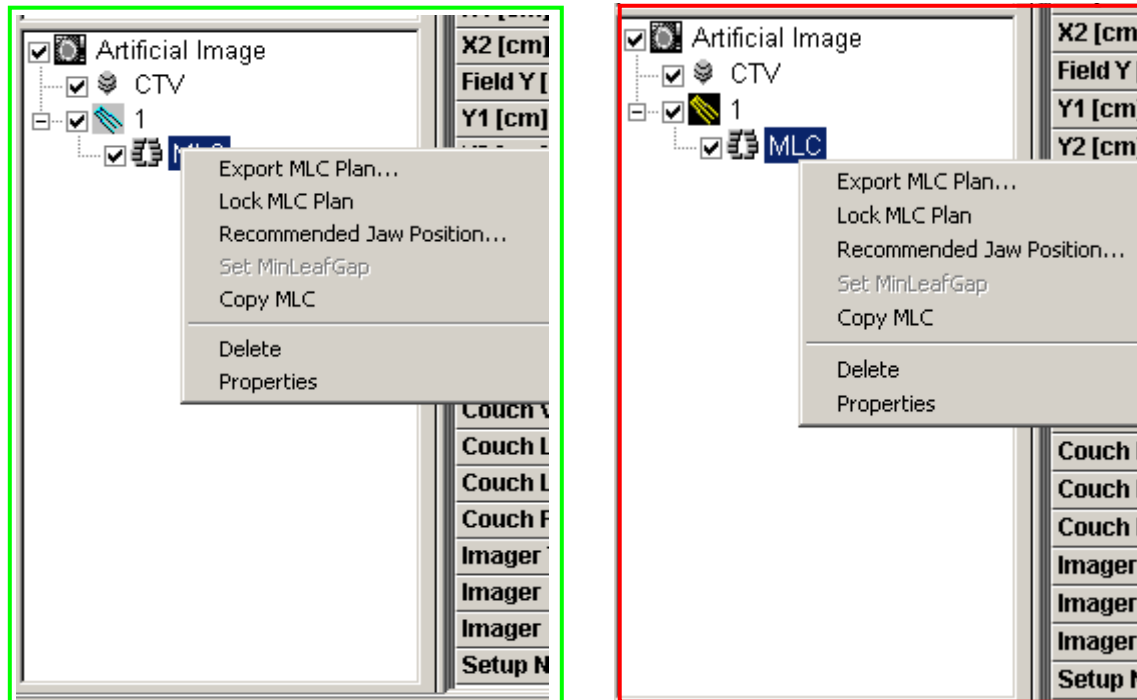
**2.1. Ensure the focus of RT-Chart is on the Setup Field**

To avoid removing accessories and objects from Treatment Fields, please ensure that the focus of the product exists on the Setup Field, not Treatment field. The photo below shows that the Setup Field is the object in focus in the product. The Setup Field icon exists in the Focus Window. All information removed now will be against this Setup Window.

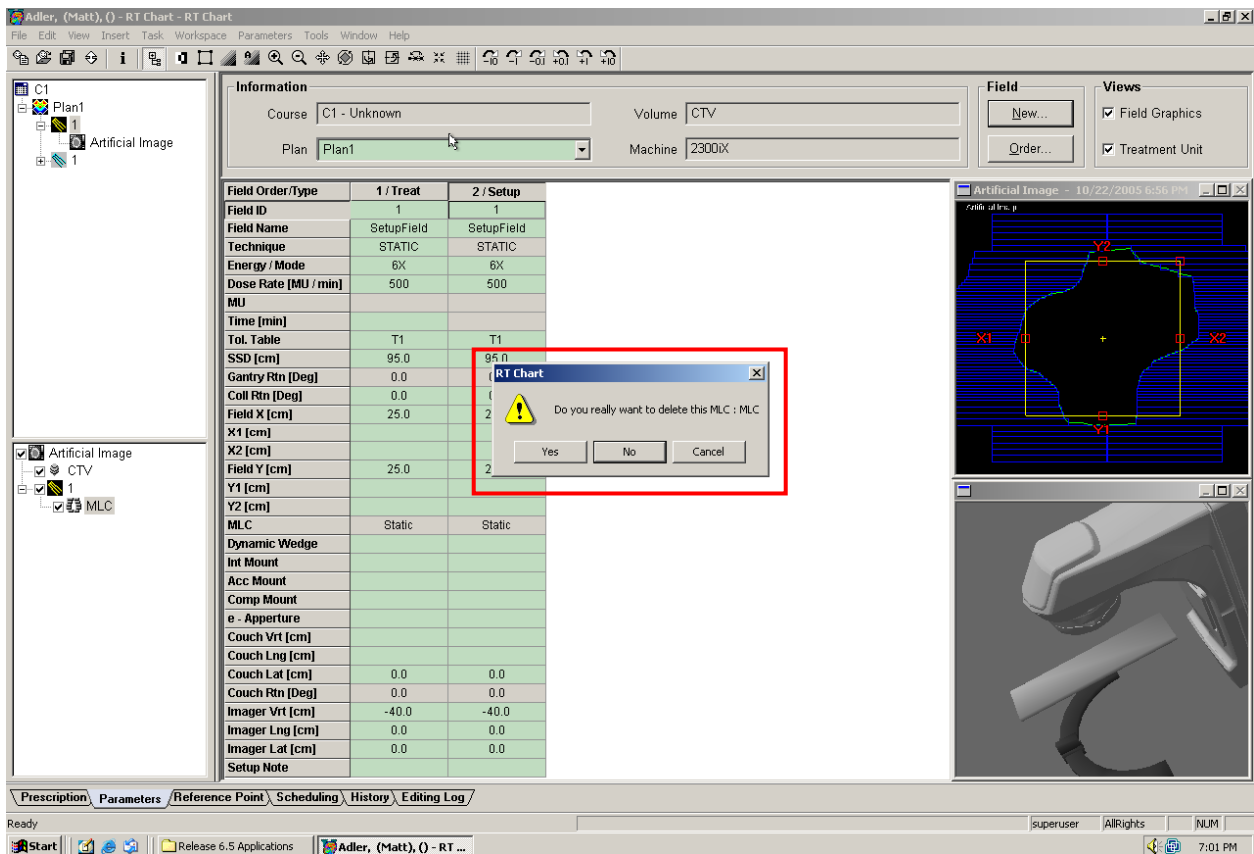


## 2.2. Ensure proper selections and confirm deletions appropriately

Please ensure that when selecting the “Delete” option from any object, the users have verified the appropriate object has been selected. Anytime the “Delete” action is requested, the user will be prompted with a 2<sup>nd</sup> message asking them to confirm the deletion. Please have your staff double check and ensure that they are deleting the appropriate information from the appropriate field selected.



The image on the left has the appropriate Setup Field selected for removal of the MLC object. The image on the right is incorrect with the Treatment Field selected for MLC removal.



It is important for the user to understand and confirm the information they are deleting is appropriate.

### 3. VARIAN CORRECTIVE ACTION

In RT-Chart v7.5.49, Varian Medical Systems has introduced a completely new methodology for creating Setup Fields from Treatment Fields, reducing the chance that information is inadvertently removed from Treatment Fields.

**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 Representative.

## Varian Oncology Systems

### United States Centers

#### Headquarters

660 North McCarthy Blvd.  
Milpitas, CA 95035  
Tel: 408.321.9400

#### Las Vegas Facility

6873 Spencer St  
Las Vegas, NV 89119  
Tel: 702.938.4700

#### Northeast

100 Walnut Ave. STE 201  
Clark, NJ 07066  
Tel: 732.381.5300

#### Southeast

2250 Newmarket Pkwy #120  
Marietta, GA 30067  
Tel: 678.255.3888

#### Midwest

200 E. Howard St. STE 202  
Des Plaines, IL 60018  
Tel: 847.296.0660

#### Southwest

403 International Pkwy STE 503  
Richardson, TX 75081  
Tel: 972.238.7017

#### West

650 E. Parkridge Ave. STE 109  
Corona, CA 92879.1092  
Tel: 909.280.4406

### International Centers

#### Australasia Pty. Ltd.

Suite 3, 13a Narabang Way  
Belrose, NSW 2085  
Tel: 61.2.9485.0121

#### Belgium

Park Hill  
Mommaertsiaan, 16B  
1831 Diegem  
Tel: 32.2.720.1008

#### Brazil Ltd A

Rua São Carlos do Pinhal,  
no 696 - 9o andar - Bela Vista  
Sao Paulo, SP - CEP 01333-000  
Tel: 55.11.3457.2655

#### China P.R.

Room 1206, Air China Plaza  
No. 36 Xiaoyun Road  
Chaoyang District, Beijing 100027  
Tel: 86.10.8447.5925

#### Denmark

Lyskaer 9  
DK-2730, Herlev  
Tel: 45.44.500.100

#### France

283 Rue de la Miniere  
78535 Buc Cedex  
Tel: 33.1.30.83.83.83

#### Germany

Alsfelder Strasse 6  
D-64289 Darmstadt  
Tel: 49.6151.731.30

#### Germany (BrachyTherapy)

Bergische Strasse 16  
42781 Haan  
Tel: 49.2129.551.0

#### Hong Kong

Room 1016-20, Tower A,  
New Mandarin Plaza  
14 Science Museum Road  
Tsimshatsui East, Kowloon  
Tel: 852.2724.2836

#### India Pvt. Ltd.

602, Pressman House,  
Plot No. 70A  
Nehru Road, Vile Parle (E)  
Mumbai 400 099  
Tel: 91.22.2613755

#### Italy

Via Brescia 28D1  
20063 Cernusco Sul Naviglio  
Milano  
Tel: 39.02.921.351

#### Japan

Keio Chofu Kojimacho Bldg.  
32-2, Kojimacho 1-Chome,  
Chofu-shi, Tokyo 182-0026  
Tel: 81.424.41.5802

#### Middle East

10 Janabiyah Gardens Arcade  
Entrance 330, Avenue 35  
Janabiyah 561,  
Kingdom of Bahrain  
Tel: 973.176.99.470

#### Netherlands

Nederland B.V,  
Kokermolen 2  
3994 DH Houten  
Tel: 31.30.6340506

#### Russia

19A, Khlebny per.,  
4th Floor, 121069 Moscow  
Tel: 7.495.204.44.23

#### Spain

Avda. de la Industria, 9  
Edificio Isósceles, 1o - 2a  
Pol. Industrial de Alcobendas  
28108 Alcobendas - Madrid  
Tel: 34.91.33.44.800

#### Switzerland

Chollerstrasse 38  
CH-6303 Zug  
Tel: 41.41.749.8844

#### United Kingdom

Gatwick Road  
Crawley  
West Sussex RH10 2RG  
Tel: 44.1293.53.12.44

January-2006