

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject: **Automatic Partial Fraction Incorrect After Forced Logoff**

Commercial Name of Affected Product: **VariSource™ iX Control Software**

Affected Version(s) / Lot(s): **Version 1.2.1, Build 3726**
Version 1.2, Build 2.4336

Reference / FSCA Identifier: **BT-01822**

Date of Notification: **2015-09-29**

Type of Action: **Notification and Correction**

This letter and guidance supersedes and replaces the guidance provided in PN BT-01822 Rev A, Automatic Partial Fraction Incorrect After Application Freeze dated 2015-08-15. Only VariSource iX afterloader systems with magnetic hard disk drives and Windows XP are affected by this specific application freeze scenario. Other situations, as discussed below, may also lead to an incorrect partial fraction.

Description of Problem:

This letter is to advise you of an anomaly that has been identified with the VariSource™ iX Control Software versions 1.2.1 Build 3726 and 1.2, Build 2.4336. When a forced logoff occurs while the dummy wire is extended during a treatment session, the Partial Fraction generated by the system will be incorrect. This notice provides a description of the issues, the actions you can take to avoid or mitigate the issues, and the steps Varian Medical Systems is taking to address the issues.

There have been no reports of patient injury due to this issue.

Details:

In certain circumstances, the VariSource™ iX control software can log the user off during a treatment session. When this log off occurs, the user will have to log back in. Specific circumstances that can result in a treatment session forced logoff include:

1. System is unable to retract the dummy wire after a set time-out interval.
2. Loss of power for any reason.
3. Loss of communication between the system components for any reason.

The issue occurs only if the site has the Control Software is set to “Dummy All / Active All“. With this setting, all channels are checked with the dummy wire prior to extending the active wire for treatment. When a session interruption occurs after any dwell positions have been delivered, the User will be prompted to choose a partial treatment option. When treatment is restarted, the re-start dummy check is initialized. If a forced logoff occurs, while this re-start dummy check is in process, the Partial Fraction created after the user has logged back in will be incorrect. The control software does not differentiate the re-start dummy sweep from the dummy sweep at the beginning of the treatment session. The control software assumes no treatment has been delivered.

The Partial Fraction generated will be equivalent to the original full fraction. If this Partial Fraction is treated, this would result in re-treatment of any dwell positions actually delivered prior to the session interrupt and result in a dose greater than intended. The Treatment Recovery Report will incorrectly indicate that **no** dwell positions have been treated. Both the Treatment Delivery Report and the Treatment History Report do correctly indicate the dwell positions treated.

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

When the Control Software dummy sequence is set to “Dummy Each / Active Each”, immediately after the dummy clears a channel, the active wire treats that channel. In this scenario, the issue **does not occur**.

Recommended User Action

Users **MUST REVIEW** the Partial Fraction created and **ASSESS** whether the treatment plan should be modified to treat ONLY the untreated dwell times and positions. The treatment plan may be modified via the Control Software’s channel editor or via the planning system.

- a) Users **SHOULD** refer to the Treatment Delivery Report and the Treatment History Report which will accurately reflect the actual dwell times and dwell positions delivered.
- b) **DO NOT USE** the Treatment Recovery Report. It will indicate that no dwell positions were treated.
- c) **DO NOT USE** the Planned Treatment Report for the Partial Fraction. It will show all channels and dwells matching the original fraction channels and dwell positions.

DO NOT disconnect the afterloader USB cable from the back of the PC and re-insert it to address the log off. This has no effect. User will still need to log back in. The Partial Fraction generated will be incorrect due to the forced logoff.

The reports and user interface item listed in the table below are generated after Control Software restart.

Report or User Interface Item	Visible	Characteristics after Forced LogOff System restart LogIn
Treatment Recovery Report	After Control Software login	Incorrectly indicates that no dwell positions were treated.
Channel Display Screen – while displaying the partial treatment options	After Control Software login	Correctly displays all dwell positions treated for each channel in the treatment.
Treatment Delivery Report	After choosing one of the options on the Partial Treatment Strip	Correctly shows all channels and dwell times that were treated in this fraction prior to interrupt.
Fraction View Page	Prior to choosing the Partial Fraction	The Partial Fraction row indicates that it matches the original fraction. This Partial Fraction is an exact duplicate of the original and will result in an over dose if delivered.
Planned Treatment Report for the Partial Fraction	Prior to treating the Partial Fraction	Shows all channels and dwells matching the original fraction and will result in an over dose if delivered.

To assess whether this scenario may have occurred in previous treatments, review the Treatment History Report. This record contains all of the treatments delivered to patients and can be used to detect if you have encountered this issue in the past.

Varian Medical Systems Actions:

Varian Medical Systems is notifying all possibly affected customers with this document.

Varian Medical Systems is developing a technical correction for this issue. A Technical Service representative will contact your site when this correction is available to schedule its installation.

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This document contains important information for the continued safe and proper use of your equipment.

- Please retain a copy of this document along with your most current product labeling.
- Advise the appropriate personnel working in your radiotherapy department of the content of this letter.
- For future reference, this document is posted at MyVarian.com.

In order to satisfy regulatory requirements, we request that you complete the attached Recall Return Response form and return it to Varian Medical Systems to returnresponse@varian.com.

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 Medical Systems Customer Support District or Regional Manager.

Varian confirms that this notice has been provided to the appropriate Regulatory Authorities.

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