VARIAN
medical systems

URGENT MEDICAL DEVICE CORRECTION
URGENT FIELD SAFETY NOTICE

Subject:	***Automatic Partial Fraction Incorrect After Application Freeze***
Commercial Name of Affected Product:	**VariSource™ iX Console software with Magnetic Hard Disk Drive ONLY**
Affected Version(s) / Lot(s):	**Version 1.2, Build 2.4336**
Reference / FSCA Identifier:	**BT-01822**
Date of Notification:	***2015-05-18***
Type of Action:	**Notification and Correction**

Description of Problem:

This letter is to advise you of an anomaly that has been identified with the VariSource™ iX Console software version 1.2, Build 2.4336. After an application freeze and restart, the Partial Fraction generated by the system will not be correct. The application freeze issue affects only systems equipped with magnetic Hard Disk Drives (HDD). 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 misadministration due to this issue.

Details:

VariSource iX Console software version 1.2, Build 2.4336 will occasionally freeze during the treatment initiation sequence. An application freeze is a condition when, after pressing the Deliver Treatment button on the Treatment Delivery Strip, the Treatment Delivery Strip becomes blank and the Afterloader remains in idle mode and does not switch to treatment delivery mode. No other buttons on the control software user interface will respond.

The application freeze issue affects only the systems equipped with magnetic Hard Disk Drives (HDD). The Partial Fraction generated by the system is incorrect if ***all*** of the following steps occur.

1. The control console has been set to check all channels with the dummy wire, prior to the active wire treatment ("Dummy All / Active All"),
2. AND an interruption occurs during treatment after dwell positions have been treated,
3. AND the User chooses either of these partial treatment options:
    a. Continue from the dwell position that was interrupted; or
    b. Skip to the next channel;
4. AND Treatment is restarted and the application freezes prior to the dummy checks,
5. AND User cycles power to the control PC to resolve the application freeze:
    a. By removing the power cord from the computer and re-inserting it, and/or
    b. Turning the computer off and on again at the power switch.
6. The control software is reinitialized and displays the Treatment Recovery Report. User chooses "Print" or "Close";
7. AND the User chooses the Partial Treatment option: *Abort this fraction, but create a new fraction, consisting of the undelivered portion of this fraction.* The Treatment Delivery report is displayed. User chooses "Print" or "Close";

8. The Partial Fraction created will be incorrect.

The control software proceeds as if the power outage occurred during the initial dummy sweep of the intended fraction, and assumes no treatment has been delivered. **It will generate a Partial Fraction equivalent to the original full fraction.** If treated without further modification, this would result in re-treatment of any dwell positions actually treated prior to the interrupt.

The above sequence of events **does not occur** if the control software dummy sequence is configured to treat each channel immediately after the dummy clears that channel, "Dummy Each / Active Each".

Recommended User Action

- In the event of an application freeze and power cycling the control PC, **DO NOT USE** the Partial Fraction automatically created by the control software.

- The reports and user interface items in the table below are generated after control software restart. 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 Delivery Report and the Treatment History Report do accurately reflect the actual dwell times and dwell positions delivered.

Report or User Interface Item	Visible	Characteristics
Treatment Recovery Report	After control software restart	Incorrectly indicates that no dwell positions were treated.
Channel Display Screen – while displaying the partial treatment options	After control software restart	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 has 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.

Application Freeze Resolution

In the event you encounter an application freeze, it is possible to continue treatment from the interrupted dwell position without cycling power.

1. Remove the afterloader USB cable from the back of the control PC, and re-insert it. The afterloader USB cable is generally white, with a large ferrite on the end, and includes a label indicating "Console PC".

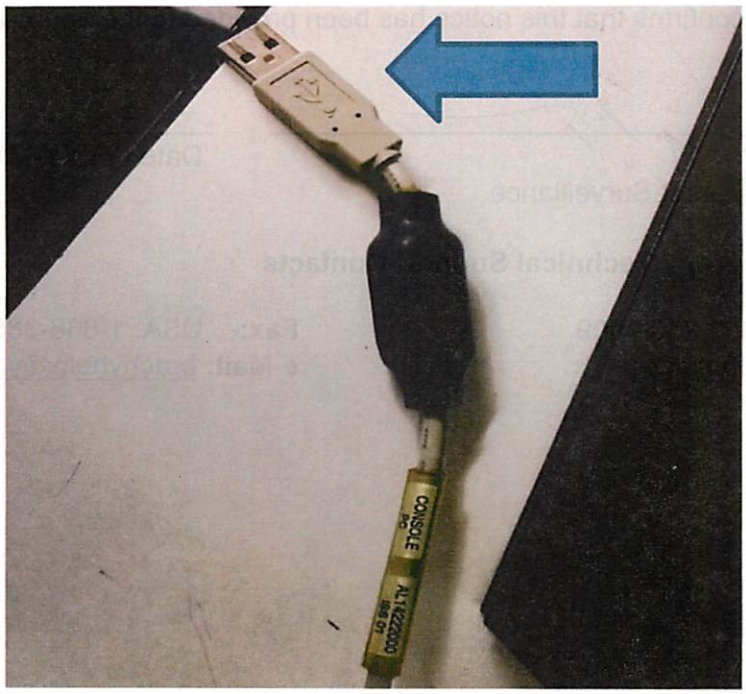

Figure 1: Console PC USB cable

2. The control software will now display a "7C" communication error. Clear this error and you will be taken through the normal treatment recovery process at this point.

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.

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.

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

[redacted]

2015-MAY-18
Date (YYYY-MM-DD)

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