

URGENT FIELD SAFETY NOTICE

Subject: Warning Messages affecting Linear accelerators other than Clinac® were missing from Inspiration Platform 8.0 Release Notes

Type of Notification: Advice on Use – Warnings to heed during upgrade

Reference: Eclipse migration from VARIs Vision 6.5/7.x environment to Varian Inspiration Platform - Release 8.0 and above

Date of Notification: November 21, 2008

Contact Information: Varian Helpdesk – 888-VARIAN5 (888- 827-4265)
email: onc.helpdesk@varian.com , or tps.support@varian.com

This letter is to advise you of an issue relating to the orientation of Siemens® wedges, the wedge limits and SAD values for Elekta® machines, and collimator operating limits for Saturne™ machines following an upgrade from the Varian VARIs Vision 6.5/7.x environment to the Inspiration Platform. During this upgrade, a number of Varian System Server service packs are installed prior to commencement of the main database conversion. During installation of one such service pack, the orientation and operating limit attributes of Siemens, Elekta and Saturne wedges defined in the information system database will be updated to use standardized values, which may not correspond to the previously set values.

This notice provides a description of the issue, the actions that Varian advises users to take, and the steps Varian is taking to correct this occurrence.

Description:

During the server upgrade from 6.5\7.x to Inspiration 8.x, all previous server service packs are installed prior to the main db conversion taking place. One of these Server service packs implements a standard wedge configuration for Siemens machines on all existing machines defined in the database. If the existing Siemens machine wedge configuration and specifically wedge orientation, does not correspond to Siemens standard configuration, the conversion process will alter the orientation of any wedges defined in the database to use a standard value for each respective wedge type. If the orientation value of any such wedge was opposite to Siemens standard prior to conversion, the upgrade process could have the effect of reversing the orientation of the wedge in the Varian System database. Through this process any previous customized configuration with respect to Wedge orientation will be returned to standard Siemens configuration consequently any such wedges when exported as part of a RT plan would be exported with an orientation opposite to that used to calculate a treatment plan prior to the upgrade. This could lead to the use of a wedge in the treatment field delivered at the machine that was opposite to that called for by the plan developed on the treatment planning system.

Also, for Elekta and Saturne machines, a motorized wedge, with potentially incorrect limit and SAD values will be added.

A Warning message that was to be included in the release notes for the Inspiration upgrade was inadvertently missing in some versions of the release note.

User Corrective Action:

Varian advises customers to special attention to the machine configuration after an upgrade by comparing the before and after settings.

Varian Corrective Action:

Varian is providing notification of this issue to our customers by way of this Field Safety Notice. Included with this notification is a copy of the corrected Warnings page of the Inspiration Platform Customer Release Notes. Please refer to important information relating to this issue in the section "Warnings".

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 local Varian Customer Support District or Regional Manager.

Note that the appropriate regulatory agencies have been advised of this action.



21. NOV. 08

Dave Hall
Acting Manager, Regulatory Reports
Varian Medical Systems
911 Hansen Way
Palo Alto, CA 94304

Note: Users may add these new pages to their existing manual.

INSPIRATION PLATFORM

This customer release note provides application information such as:

- Warnings
- System Components and Compatibility
- New Features and Functions
- Major Changes to Previous Releases
- Known Issues

WARNINGS



WARNING: Transferring patients between machines equipped with HD120 MLC and Millennium (52, 80 and 120 leaves) MLC:

The direct conversion from Millennium to HD120 MLC is *not* supported. If a patient needs to be transferred for treatment between machines that are equipped with a HD MLC and a Millennium MLC, then the patient's plan must be redone in the treatment planning system.

Note: Up to now, it has been possible to transfer patients between machines equipped with Millennium 80 and Millennium 120 MLC's, because the leaf physics are identical. In the case of the HD120 MLC, the leaf has different physics so that it's no longer valid. For example, the leaf-end has a different radius, so that the "dosimetric leaf-end gap" is different. Also, the HD120 leaves are taller and use a dense form of tungsten, so that their leakage is less than the Millennium leaves.



WARNING: Wedge Orientation and Wedge Limits for Siemens® Machines

If a Siemens machine is configured in your system, this release modifies the wedge orientation to match the most current machine definitions. It also resets all wedge limits; therefore, all wedge limits for Siemens machines must be entered after the upgrade.

Note: Users may add these new pages to their existing manual.



WARNING: Wedge Limits and SAD for Elekta® Machines

If an Elekta machine is configured in your system, this release will add a motorized wedge if none was defined. However, this new motorized wedge has incorrect wedge limits. Therefore, the wedge limits and also the SAD (machine properties) must be verified after the upgrade and corrected if appropriate.

Note: If you are adding a new Elekta machine through the wizard, all values are correct.



WARNING: Collimator Operating Limits for Saturne® Machines

If a Saturne machine is configured in your system, this release will add a motorized wedge if none was defined. The existing machine operating limits are not modified, but may conflict with the new motorized wedge limits. Therefore, be sure to verify the collimator operating limits with this release.

Note: If you are adding a new Saturne machine through the wizard, all values are correct.