

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

Subject: Outdated HU value used in calculation
Commercial Name of Affected Product: Eclipse™ Treatment Planning System
Affected Version(s) / Lot(s): Eclipse 8.9 and 10.0
Reference / FSCA Identifier: CP-08922
Date of Notification: 2012-08-21
Type of Action: Notification and Correction

Description of Problem:

This letter is to advise you of an anomaly that has been identified with the Eclipse Treatment Planning System where an outdated assigned Hounsfield Unit [HU] value can be used for dose calculation when the clock on the Eclipse Client Workstation is not synchronized with the Database/System Server. This notice provides a description of the issue, the actions you can take to avoid or mitigate the issue, and steps Varian Medical Systems is taking to address the issue. No patient injury or misadministration has been reported to Varian due to the issue.

Details:

When the Eclipse client workstation clock is running behind the clock on the Database/System server, it is possible that a change to the assigned HU value for a structure does not invalidate the density image stored in the cache, and for the subsequent dose and Monitor Unit [MU] calculation to be based on the outdated HU assignment. The resultant MUs may be higher or lower than expected, dependent on the specific HU assignments. Treatment of the patient using these values can therefore lead to under- or over-dose.

For this situation to arise, the Eclipse Workstation client clock must show an earlier time than that on the Database/System Server clock (for example, Client time shows 09:05:17, Server time shows 09:13:47). The following activities must take place on that Client workstation for the discrepancy to occur:

1. An HU value must be assigned to one or more structures.
2. The plan must be saved. This places a timestamp (**S**) on the DCF cache files, where **S** is the current server time.
3. The dose is then calculated.
4. The dose is cleared (for example by resetting the calculation area).
5. Then either a new HU value is assigned to a structure, or an existing HU value is modified.
6. Before the current client time reaches the time the server showed at **S**, the plan must be recalculated. The calculation will then be based on the outdated HU value that existed at time **S**.

An independent verification of the MUs will highlight the discrepancy.

Recommended User Action

For each Eclipse client workstation, ensure that the workstation clock is synchronized with the Database/System server clock. Contact Varian service for assistance with time synchronization if required.

As recommended in the Eclipse Instructions for Use, always verify the dose calculation using independent verification methods to ensure the MU calculation is correct.

Varian Medical Systems Actions:

Varian PN CP-08922 Rev B

Page 1 of 2

URGENT MEDICAL DEVICE CORRECTION URGENT FIELD SAFETY NOTICE

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

Varian Medical Systems is developing a technical correction for this issue. You will be contacted by a Customer Service Representative when this correction is available to schedule its installation on your system.

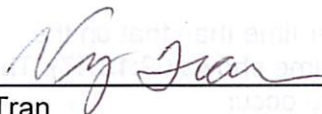
This document contains important information for the continued safe and proper use of your equipment.

- 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 will be posted to the Varian Medical Systems 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 Form 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 Medical Systems Customer Support District or Regional Manager.

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


Vy Tran
Vice-President, Regulatory Affairs/Quality Assurance
Varian Medical Systems

2012-08-21
Date (YYYY-MM-DD)

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
Australia/New Zealand: support-anz@varian.com
Europe: support-emea@varian.com
South East Asia: support-sea@varian.com
China / Asia: support-china@varian.com
Japan: support-japan@varian.com
Latin America: soporte.al@varian.com

Internet: Oncology Systems customer site - www.myvarian.com
Varian Medical Systems public site - www.varian.com