URGENT
FIELD SAFETY NOTICE

Subject:	**Language Locale Dynamic Link Library of Varian Treatment for Non-Varian linear accelerators incorrectly adjusts values for Gantry Rotation, Collimator Rotation, Couch Rotation, and Wedge Monitor Unit (MU)**
Product Name:	VARiS Vision / System 6.5; ARIA
Details of Affected Devices:	Varian Treatment for Non-Varian Linacs Version 6.6.5042 and 6.6.5043 serial numbers: **H462082, H462040, H462031, H463016, H462001, H462075, H462079, H462005, H462006, H462016, H462017, H462021, H462022, H462023, H462024, H463024, H463377**
FSCA Identifier/ Date of Notification:	TBD
Type of Action:	Notification followed by device modification via field upgrade of affected units
Contact Information:	Varian Oncology Helpdesk – 888-VARIAN5 (888- 827-4265) email: onc.helpdesk@varian.com

This letter is to advise you of an anomaly that has been identified with Varian Treatment software for Non-Varian Linear Accelerators when users elect to use the comma (,) separator instead of the dot or period (.) between the integer part and the fractional part of a decimal number (also known as the radix point) on the Treatment computer.

Description:

Using the comma (,) separator as the radix point will either truncate the fractional part of the decimal number if the integer portion is greater than zero (0), or, if the integer portion is zero (0), the fractional part will be multiplied by a factor of 10 followed by the truncation of the fractional part.

Details:

The comma (,) separator is used. The first patient plan will not be affected when Varian Treatment is first launched, but subsequent patient plans that are loaded into Varian Treatment for Non-Varian Linacs will experience this anomaly. Examples:

- Decimal number 0,1 will become 1,0
- Decimal number 0,6 will become 6,0
- Decimal number 0,9 will become 9,0
- Decimal number 2,1 will become 2,0
- Decimal number 2,6 will become 2,0
- Decimal number 2,9 will become 2,0
- Etc.

Varian Treatment for non-Varian Linacs Version 6.0.5042

When using the comma separator (,), users will be able to see these altered field values in Varian Treatment software for Gantry Rotation, Collimator Rotation, and Couch Rotation; however users will not notice that Wedge MU value for Elekta or GE Saturne motorized wedge has been altered since the graphical user interface remains the same. The treatment field values recorded back to Varian's Oncology Information System will be the planned values instead of these altered values, which can be viewed in RTChart under the History workspace. Treatment fields with motorized wedge on the Elekta or GE Saturne machines could result in an undetectable under dosage approaching 100% with the motorized wedge in place. The Wedge MU number is a divisor of planned MU to be delivered to a single field. Since this number is typically less than one, it has the effect of increasing the MU setting to achieve the desired delivered dose. The malfunction, however causes 0,9 to become 9 – reducing MU by 90% instead of increasing by 11%. Physical external wedges are not affected by this issue.

This behavior can occur with the Varian Treatment for Non-Varian Linear Accelerators 6.6.5042 release. Earlier releases are unaffected.

You may determine the version of Varian Treatment software you are running by selecting 'Help' > 'About' from within *Treatment Administration.*

Recommended User Action:

To avoid this issue, the following methods are recommended:
1. Have every user change his or her regional settings on the Varian Treatment computer as follows for Microsoft® Windows® XP Professional:

    a. Start ► Settings ► Control Panels

    b. Open *Regional and Language Options*

    c. Select *Regional Options* tab

    d. Click Customize button

    e. Select the *Numbers* tab

    f. Activate the *Decimal symbol*, and choose the decimal or dot (.) instead of the comma (,)

    g. Click APPLY

    h. Click OK

    i. Click OK

2. Have every user change his or her regional settings on the Varian Treatment computer as follows for Microsoft® Windows® 2000:

    a. Start ► Settings ► Control Panels

    b. Open *Regional Options*

    c. Select the *Numbers* tab

d. Activate the *Decimal symbol*, and choose the decimal or dot (.) instead of the comma (,)

e. Click APPLY

f. Click OK

Once this action has been completed for all users of Varian Treatment release 6.6.5042, the anomaly will no longer occur.

Varian Corrective Action:

Varian is notifying all customers who have Varian Treatment release 6.6.5042 and 6.6.5043 with this Field safety Notice. A new release version is being created to correct this issue. Varian will contact you when it becomes available.

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 Manager.

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

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Manager Reporting and Corrections