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URGENT MEDICAL DEVICE CORRECTION FIELD SAFETY NOTICE

Subject: *PCS Dose Calculation Error with Non-Square 3D CT Images*

Commercial Name of Affected Product: *Eclipse™ Treatment Planning System*

Affected Version(s) / Lot(s): *13.0, 13.5, 13.6 and 13.7*

Reference / FSCA Identifier: *NC-2018-00342*

Date of Notification: *2018-12-17*

Type of Action: *Notification and Correction*

DESCRIPTION OF PROBLEM:

Varian has discovered an anomaly with the Eclipse™ Treatment Planning System [TPS] Proton Convolution Superposition [PCS] dose calculation algorithm. The PCS algorithm calculates the water equivalent range incorrectly for non-square 3D CT images (either different number of pixels in X and Y, or non-square pixels). This issue may occur with dose calculations performed with PCS and Eclipse version 10 or higher.

Varian has not received any report of serious injury due to this issue. You are receiving this notification because your site was identified as holding a license for the Eclipse Proton Convolution Superposition dose calculation algorithm and Eclipse TPS version 13.0, 13.5, 13.6 and 13.7.

DETAILS:

Before the dose is calculated, Eclipse resamples the CT images to create a calculation image with a maximum resolution of 256 x 256. The PCS algorithm assumes uniform resolution in X and Y directions, or that $X = Y$ for all images, and erroneously sets the $Y = X$ for dose calculation. For images that are not square, where either $X \neq Y$, or the length of X does not equal the length of Y, the computed water equivalent range R' is erroneous compared to the correct range R:

1. $X=Y$; $R'=R$ (R' is correct)
2. $X<Y$; $R'<R$ (R' is too small)
3. $X>Y$; $R'>R$ (R' is too big)

The anomaly will result in a systemic error in the calculated dose distribution only for non-square 3D images. The magnitude of the error is dependent on the difference between the values of the actual dimensions, X and Y. The effect increases as the voxel density along the beam direction deviates further from the density of water. Note, user will not see an effect in a homogenous phantom.

Non-Square 3D CT images may be constructed via the following workflows. An alternative workflow is provided to avoid the non-square image PCS dose calculation error.

1. Importing DICOM data in Eclipse

- 1.1. Importing CT data: When CT slices are generated with different pixels sizes and resolutions in X and Y direction the 3D image will be a non-square image.

Alternative Workflow: When acquiring a proton planning CT, use a scanner protocol that ensures that the X pixel size = Y pixel size and that the X resolution [cm] = Y resolution [cm].

- 1.2. Importing CT data and structure set: When Importing images and structure sets with the DICOM import (DCIE) application, if the structure set contains a contour larger than the total image size, the 3D image

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will be expanded anisotropically.

Alternative Workflow:

1.2.1. Use the Eclipse Import Wizard to import the images and structure sets. The image and volume will be expanded isotropically as required.

RECOMMENDED USER ACTION:

Users MUST use the Eclipse Import Wizard in TPS for proton plans using the PCS algorithm.

Varian recommends that users **ensure** that the 3D images used for proton planning are **square images**. When using the PCS algorithm, verify that both:

1. X pixel size = Y pixel size and
2. X resolution cm = Y resolution cm.

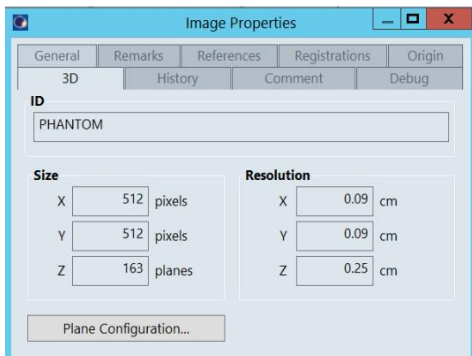


Figure 1. Square image size and resolution example.

Note, BOTH size and resolution values for X and Y are equal, X=Y.

VARIAN MEDICAL SYSTEMS ACTION:

Varian Medical Systems has provided workflow adjustments that will avoid the non-square image dose calculation when utilizing the PCS algorithm. Varian is investigating a technical solution for this issue. You will be contacted by a Varian Customer Service Representative to schedule upgrade of your system when it is available.

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>.

In compliance with regulatory requirements, we request that you complete the attached Recall Return Response form provided. Kindly return the completed form 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. This notice has been provided to the appropriate Regulatory Authorities as required.

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