

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Potential incorrect dose calculation after modification of MLC shapes
Product Reference: iPlan RT Dose version 4.0 and 4.1 (including all subversions)
Date of Notification: April 9, 2013
Individual Notifying: Julia Mehlretter, MDR & Vigilance Manager
Brainlab Identifier: CAPA-20130328-000289 (B)
Type of action: Advice regarding use of device; Device modification.



www.brainlab.com

We are writing to advise you of the following effect that has been identified when using iPlan RT Dose version 4.0 or 4.1 (including all subversions: 4.0, 4.1.0, 4.1.1, 4.1.2, 4.1.3). Please note that Version 4.1 is not the latest version of iPlan RT.

The purpose of this Product Notification letter is to provide you with corrective action information and to advise you of the actions Brainlab is taking to address the issue.

This Notification is applicable when using iPlan RT Dose version 4.0 or 4.1 **in combination with Vero**. For usage with other linear accelerators, please refer to Brainlab Product Notification CAPA-20130328-000289 (A).

Effect:

iPlan RT Dose version 4.0 and 4.1 might not correctly refresh the dose calculation after certain MLC shape modifications (see below) if all of the following conditions are met:

1. The modifications are performed for a Dynamic Conformal Arc, and
2. The dose display (e.g. isodose lines) is turned on, or if the dose has already been calculated and the dose display is turned on again after the MLC shape was modified.

The effect may occur for the following modifications of the MLC shape:

- The MLC margin of the arc is modified, or
- The MLC shape is modified in the beam's eye view (BEV) in a way that also changes the MLC shapes of neighboring segments of the arc¹, or
- The Leaf Adaption is modified (Inline/Average/Outline), or
- The modified MLC shapes in the BEV are reset.

The dose calculation is not refreshed in the Physician's Review and Physicist's Verification tasks or when generating the printout or exporting the plan.

If the incorrect dose calculation is not recognized by the user, the actual delivered treatment dose might be different from the one shown in the treatment plan. If the plan is used for treatment and the deviation exceeds clinically acceptable limits, **this could result in serious patient injury and/or ineffective treatment.**

¹ For a Dynamic Conformal Arc the monitor units are delivered with a constant dose rate and constant gantry speed. Therefore, due to the leaf speed limitation of the MLC, a leaf can only travel a limited distance between two neighboring segments of a Dynamic Conformal Arc. If the MLC shape is modified in BEV in a way that one or several leaves travel more than the maximum distance, iPlan RT automatically adapts the leaves in neighboring segments until the maximum distance is no longer exceeded.

User Corrective Action:

If you use iPlan RT Dose version 4.0 or 4.1 (including all subversions) in combination with Vero, please adhere to one of the following actions:

1. Use iPlan RT 4.5 in combination with Vero

To completely avoid the occurrence of this error it is recommended to no longer use iPlan RT Dose version 4.0 or 4.1 in combination with Vero.

Please only use iPlan RT version 4.5 in combination with Vero.

2. Workaround

If, for a certain reason, it is required to continue the usage of iPlan RT Dose 4.0 or 4.1 with Vero, make sure that the dose calculation is correctly refreshed before reviewing and approving the plan.

To correctly refresh the dose calculation, please adhere to the following:

- To refresh the dose calculation after performing one of the MLC shape modifications mentioned above, increase the couch angle of the affected Dynamic Conformal Arc by five degrees (5°) and decrease the angle again².
- To finally ensure that the dose calculation for all Dynamic Conformal Arcs has been correctly refreshed, save the plan **without saving the Monte Carlo Dose matrix** and re-open it again before final dose review in the Physician's Review or Physicist's Verification tasks³.

Attention! Please note:

- Dose calculation is NOT refreshed in Physician's Review or Physicist's Verification tasks.
- Dose calculation is NOT refreshed when generating the printout.
- Dose calculation is NOT refreshed when exporting the plan.
- Dose calculation is NOT refreshed if "Refresh MU" is pressed.
- Dose calculation is NOT refreshed if the dose display is turned off and then on again.

In general, please continue to always follow the instructions and warnings as described in the iPlan RT Dose User Guide, in particular:

All information input to the iPlan RT Dose system and all information received from the iPlan RT Dose system as output must be reviewed regarding its plausibility before patient treatment.

² The dose calculation for a Dynamic Conformal Arc is correctly refreshed – also considering modifications of the MLC shape – if machine parameters like the gantry angle or couch angle are changed.

³ The Monte Carlo dose matrix should not be saved as the incorrect dose information may be contained within this matrix. After re-opening the plan, the Monte Carlo dose matrix can then be re-calculated again if applicable.



Brainlab Corrective Action:

1. Existing potentially affected iPlan RT Dose version 4.0 or 4.1 customers receive this product notification information.
2. Brainlab will provide a software update with this issue solved to affected customers. Tentative planned timeline for availability: Dec 2013.

Please advise the appropriate personnel working in your 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 Brainlab Customer Support Representative.

Customer Hotline: +49 89 99 15 68 44 or +1 800 597 5911 (for US customers)

E-mail: support@brainlab.com (for US customers: us.support@brainlab.com)

Fax: Brainlab AG: + 49 89 99 15 68 33

Address: Brainlab AG (headquarters), Kapellenstrasse 12, 85622 Feldkirchen, Germany.

April 9, 2013

Kind Regards,



Julia Mehlretter
MDR & Vigilance Manager

brainlab.vigilance@brainlab.com

Europe: The undersign confirms that this notice has been notified to the appropriate Regulatory Agency in Europe.



www.brainlab.com