

URGENT FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject: Export incompatibility in specific configurations of iPlan RT Dose IMRS/IMRT treatment fields and VARiS version 6.2 or lower may result in unintended dose distribution.
Product Reference: iPlan RT Dose v. 3.0.1 and 3.0.2 in combination with IMRS/IMRT treatment planning module and export to VARiS v. 6.2 or lower.
Date of Notification: April 21, 2008
Individual Notifying: [REDACTED] BrainLAB CAPA Manager
BrainLAB Identifier: 08-03-28.ROE.1
Type of action: Device modification

We are writing to advise you of the following effect that has been identified when exporting IMRS/IMRT treatment fields from the BrainLAB iPlan RT Dose treatment planning software v. 3.0.1 and 3.0.2 to the Varian VARiS Record & Verify system v. 6.2 or lower.

This Notification letter is to provide you with corrective action information, and to advise you of the actions BrainLAB is taking to address the issue.

Effect:

An export incompatibility resulting in incorrect rounding of settings caused by the iPlan RT Dose Software during plan export may result in incorrect IMRS/IMRT treatment field segments. As a consequence

- an over- or under-dosage of parts of the planned treatment volume may occur.
- some parts of the target region are overdosed while other parts receive a dose lower than planned.

The geometric targeting accuracy and the overall dose (total number of MU) delivered to the target region are not affected by the problem.

Details:

In some cases one or more segments of an IMRS/IMRT treatment field planned by the iPlan RT Dose treatment planning software are not exported correctly to the Varian VARiS Record & Verify System version 6.2 or lower. That means, the dose fraction associated with the segments of those IMRT treatment fields may finally not be delivered as planned leading to an unintended dose distribution inside the planned target region.

This **unintended dose distribution** occurs exclusively with the IMRS/IMRT module of the BrainLAB iPlan RT Dose treatment planning software in combination with the Varian VARiS Record and Verify Software version 6.2 or lower. The BrainLAB BrainSCAN treatment planning software is not affected by this anomaly.

BrainLAB estimation of magnitude of error: The magnitude of error varies to a high degree between individual plans. In all the clinical cases we so far have evaluated only small regions of the target area were affected and the dose error within those regions was below 10%. However we have been able to create artificial scenarios, where the deviation was higher and where larger regions were affected.

The anomaly is detectable if the Quality Assurance procedure described in the iPlan RT Dose user guide (phantom treatment before each patient treatment) is followed. The dose distribution determined by these phantom treatments is always the actually delivered dose distribution.

User Corrective Action:


1. With immediate effect, stop using the iPlan RT Dose IMRS/IMRT treatment module in combination with VARiS version 6.2 or lower until BrainLAB provided the corresponding software update.
2. Please complete the attached return fax and send to the specified fax number.
3. In general, BrainLAB highly recommends users to always
 - follow the instructions provided in the BrainLAB user guide
 - perform phantom treatments evaluating the actually delivered dose distribution prior to patient treatments as described in the user guides.

BrainLAB Corrective Action:

1. Existing potentially affected iPlan RT Dose customers receive this product notification information
2. BrainLAB will provide a software update for the affected iPlan RT Dose customers. BrainLAB will actively contact those customers upon availability. Tentative planned timeline: August 2008.

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) or by
E-mail: support@brainlab.com. Fax BrainLAB AG: + 49 89 99 15 68 33
Address: BrainLAB AG (headquarters), Kapellenstrasse 12, 85622 Feldkirchen, Germany.

Thank you for paying attention to this information.

April 11, 2008
Kind Regards,



CAPA Manager


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

