

FIELD SAFETY NOTICE / PRODUCT NOTIFICATION

Subject:	iPlan RT Radiation Treatment Planning Software: MLC leaf gap leakage potentially not correctly calculated when using iPlan RT Dose treatment planning for Elekta Agility MLC.
Product Reference:	iPlan RT Dose / iPlan RT (Versions 4.5.3 and 4.5.4), only in combination with Dose Planning for Elekta Agility MLC.
Date of Notification:	September 13, 2016
Individual Notifying:	Markus Hofmann, Senior MDR & Vigilance Manager
Brainlab Identifier:	CAPA-20160909-001728
Type of action:	Advice regarding use of device; Device modification.



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We are writing to advise you of potentially incorrect dose distribution calculation when using iPlan RT Dose treatment planning for Elekta Agility Multileaf-Collimator (MLC) under specific circumstances.

There has been no report to Brainlab by any user site of undesirable dose distribution delivered to a patient due to this issue.

Affected Brainlab Software:

iPlan RT Dose / iPlan RT Versions 4.5.3 and 4.5.4, only in combination with the optional function Dose Planning for Elekta Agility MLC.

This notification letter is to provide you with the technical details and the user corrective action information, and to advise you of the actions Brainlab is taking to address the issue. At the same time we are asking you to kindly reply to our questions in the attached customer reply form, to ensure that this issue is adequately and permanently resolved at your facility.

Effect:

The Elekta Agility MLC controller automatically adds a physical gap of 1 mm (about 3 mm projected to the isocenter) between opposing closed leaf pairs. Therefore, leakage radiation through this gap must be correctly considered during treatment planning and dose calculation. Due to a software inconsistency, the Brainlab Pencil Beam dose calculation algorithm does not correctly regard and represent this gap if all of the following conditions are met:

1. iPlan RT Dose v. 4.5.3 or 4.5.4 is used.
2. The planning option for Elekta Agility MLC is used for a treatment plan.
3. The *Machine Profile* (dose profile entered in the Brainlab treatment planning SW, accessible via *Physics Administration*) for the used Elekta Agility MLC and linear accelerator combination contains a **Leaf Shift Static value different than 0 mm**.

For clarification, this issue is specific to the Pencil Beam algorithm with the Agility MLC only, and does not affect any other MLC model supported by iPlan RT Dose.

If the above described conditions are met, only specific plans irradiating multiple separate target volumes simultaneously with a single isocenter are affected, since only these plans require the closed MLC leaves to cover the area between the targets without the shielding by the primary jaws. In this case a relevant difference might occur between the displayed and the actual dose distribution that would be irradiated. For illustrations, please refer to the following page.

For such plans, the effect is highest with opposing leaf pairs closed in the middle of the radiation field. An accumulated leakage dose might occur especially for the tissue region that would remain within this leaf gap area for all beam or arc directions of the treatment plan. This applies for the close vicinity of a "virtual" isocenter placed in between the target volumes, with the MLC leaves closed in "middle" position. Brainlab simulation of this effect under these circumstances for a multiple arc plan yielded an accumulated leakage dose added by this gap at the "virtual" isocenter of ca. 33% of the prescribed dose. With the above described circumstances present, the iPlan RT treatment plan would not calculate and display this resulting added leakage dose by such leaf gaps. For all other tissue regions outside this accumulation area, no significant dose deviation (below 0.5%) can be expected. In general, the dose distribution for the target volumes (intended apertures) is not affected.

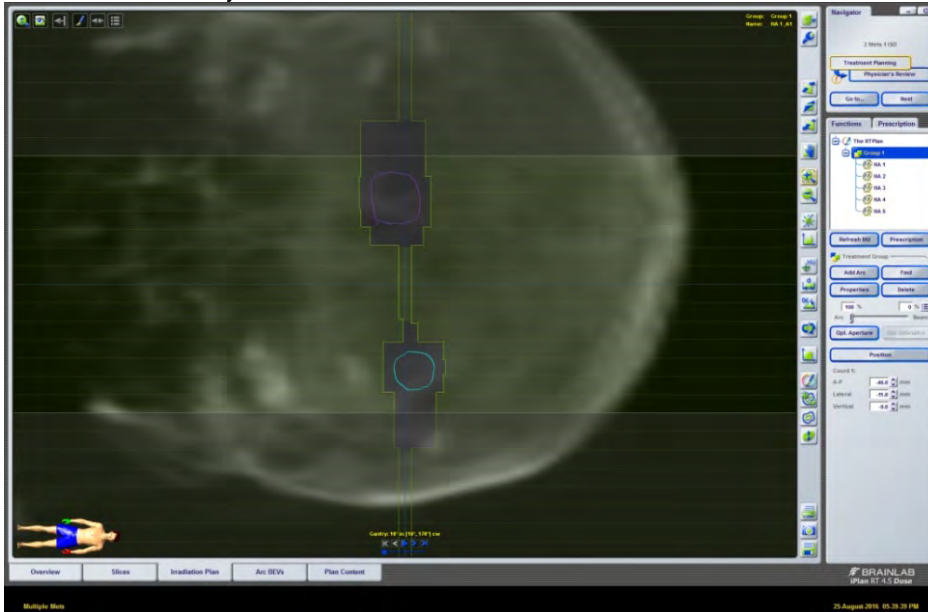
If this effect occurs for these specific treatment plans and is not detected by the user with the corresponding treatment-specific quality assurance, **this might lead to a not recognized and not considered accumulated leakage dose in small tissue regions, which could exceed clinically acceptable limits and ultimately lead to undesirable long term effects for the patient.**

If the opposing leaf pairs of the Agility MLC are closed at one side of the treatment field (left or right) instead of in the middle, this effect, even if it occurs, **is significantly reduced**: In that case, for the most common stereotactic treatment planning techniques, a potential deviation is not expected to exceed 0.5%, due to the decreased radiation gap outside the center of the divergent beam, and due to the significantly reduced likelihood of the gap intersecting at the very same tissue volume for the different radiation directions. Thus also for the described multiple target volume plans this would expectedly reduce the effect to a non-relevant level.



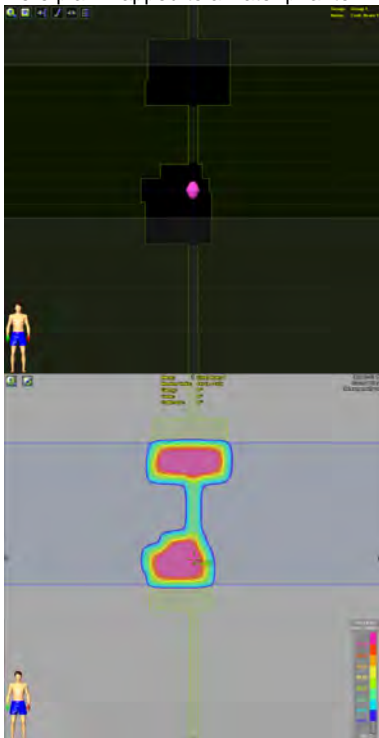
Illustrations:

I) Example of a treatment plan view of multiple separated treatment target volumes to be irradiated simultaneously, with correct display for the Agility MLC: here the remaining gap in between closed leaf pairs is regarded as intended by iPlan RT – the light green lines correctly represent the actual radiation field used by the dose calculation:

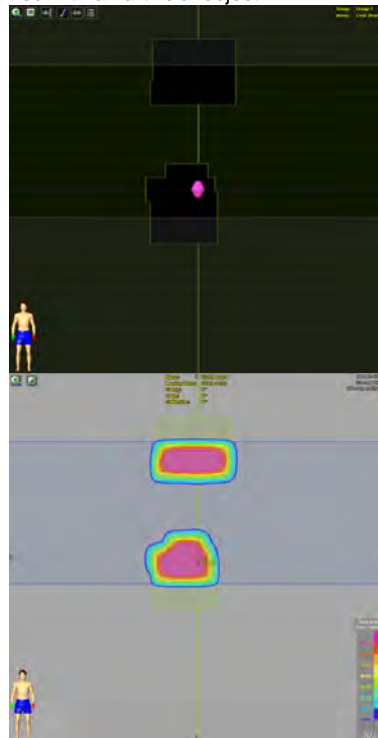


II) Examples of dose distribution displays for a single beam:

Here plan mapped to a water phantom with isocenter marked with an artificial object.



Dose calculation and display **correctly** considering the gaps of closed leaves and their leakage dose (e.g. *Leaf Shift Static* set to 0mm).



Dose calculation and display **not correctly** considering the gaps of closed leaves and their leakage dose (e.g. *Leaf Shift Static* set to 0.2 mm).

User Corrective Action:

- 1) Please immediately check the *Leaf Shift Static* value in all your machine profiles in iPlan RT Dose for an Elekta Agility MLC: **Ensure that this value is set to "0 mm"**. If another value is found, please change this specific value to 0 in order to permanently resolve the described potential issue.
- 2) Please return the attached **Customer Reply Form** to Brainlab.

Please refer to the **Appendix** for detailed information about:

- How the *Leaf Shift Static* setting only slightly influences the dose calculation for the intended radiation field (by tenths of a millimeter only).
- How to verify that the dose calculation is still as accurate as expected in case this setting was modified to 0.
- Retrospective review of already existing treatment plans.



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Reminders (as already contained in the Brainlab instructions for use):

- For any new or changed machine profiles, it is highly recommended to perform a dose verification (using a phantom) before clinical use, to ensure adequate implementation and accuracy of dose calculation.
- Patient-specific Quality Assurance of a treatment plan and verifying the dose distribution (in a suitable phantom) is highly recommended before irradiating the patient.

General recommendation:

- Selecting the preferred plan position of closed leaf pair gaps outside the middle of the MLC treatment field (e.g. specify *Left* or *Right*), generally supports to reduce radiation leakage through your MLC for iPlan RT Dose treatment plans whenever possible.

Brainlab Corrective Action:

- 1) Brainlab provides existing potentially affected customers (with iPlan RT / iPlan RT Dose and the optional Dose Planning for Elekta Agility MLC) with this product notification information and Customer Reply Form.
- 2) Despite adapting the setting as described does permanently resolve this issue preventing the described scenario from occurring, Brainlab intends to offer a software solution independent of this requirement to affected customers. Brainlab will actively contact affected customers tentatively starting November 2017 to offer the update free of charge.

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 cooperation.

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 (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.

September 13, 2016

Kind Regards,



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

Customer Reply Form

for Field Safety Notice / Product Notification CAPA-20160909-001728

Please return the completed form to Product.notifications@brainlab.com

or

Fax +49 (89) 991568 33



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[Please select one of the following]

- We do **not have** any machine profile yet for an Elekta Agility MLC within iPlan RT Dose.
- All** our existing machine profiles for an Elekta Agility MLC within iPlan RT Dose **already had the setting 0 mm** for the *Leaf Shift Static* value.
- Our machine profile(s) for an Elekta Agility MLC within iPlan RT Dose had a different setting than 0 mm for the *Leaf Shift Static* value. This value has been **changed to 0 mm in all** our corresponding machine profile(s).

We are aware that for all changes of machine profiles, a dose verification (using a phantom) before clinical use is recommended to ensure adequacy of implementation and accuracy of dose calculation.

Date:

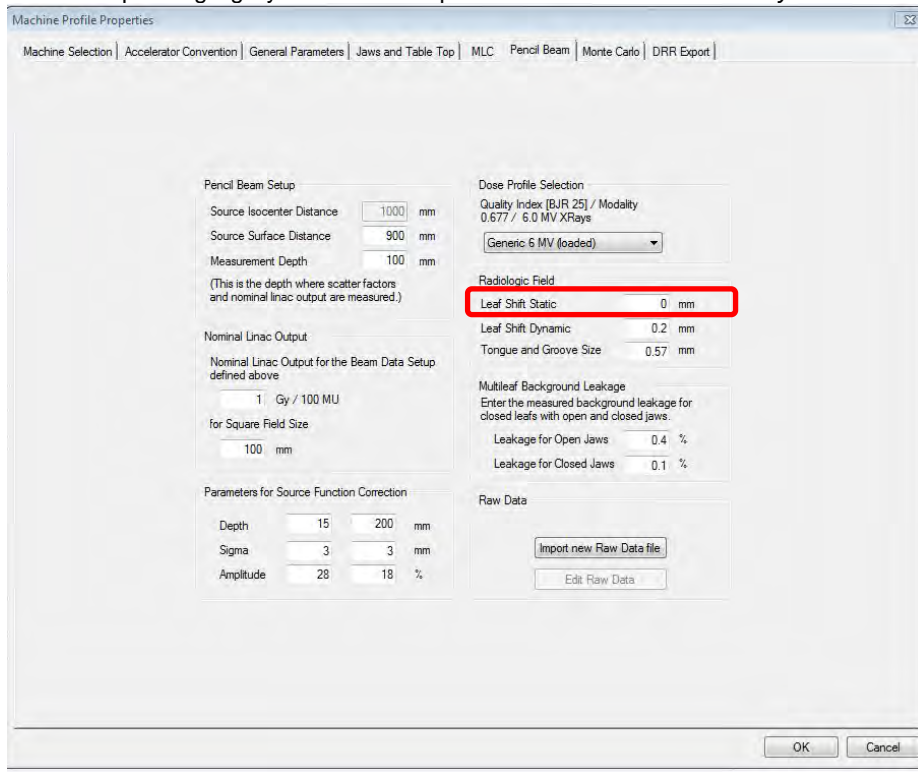
Name and Signature:

Hospital/Facility Name:

APPENDIX

Location of the *Leaf Shift Static* value

The corresponding Agility MLC machine profiles can be accessed via *Physics Administration*:



The screenshot shows the 'Machine Profile Properties' dialog box with the 'MLC' tab selected. The 'Radiologic Field' section is highlighted with a red box, showing 'Leaf Shift Static' set to '0 mm'. Other visible settings include 'Pencil Beam Setup' (Source Isocenter Distance: 1000 mm, Source Surface Distance: 900 mm, Measurement Depth: 100 mm), 'Dose Profile Selection' (Quality Index: 0.677 / 6.0 MV X Rays, Generic 6 MV (loaded)), 'Nominal Linac Output' (1 Gy / 100 MU), 'Parameters for Source Function Correction' (Depth: 15, 200 mm; Sigma: 3, 3 mm; Amplitude: 28, 18 %), and 'Multileaf Background Leakage' (Leakage for Open Jaws: 0.4 %, Leakage for Closed Jaws: 0.1 %).

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This issue only affects machine profiles for the Elekta Agility MLC, and only for the Pencil Beam dose algorithm. No other settings and no other machine profiles (for other MLCs or collimators) need to be addressed or changed to resolve this specific issue.

The *Leaf Shift Static* parameter defines the non-negative increase in the field size (per field edge) in leaf direction due to round leaf-end design. For more information about *Leaf Shift Static* and the other parameters we refer to the *Technical Reference Guide Brainlab Physics* and the *Software User Guide Physics Administration*.

Verification check in case the *Leaf Shift Static* value was changed to 0 mm from a different value
 Create a treatment plan similar to the one as illustrated in the Field Safety Notice (e.g. a single-beam plan for multiple separated target volumes). In the *Beams Eye View* (BEV) of iPlan RT Dose, check the radiation field used for dose calculation (indicated with the light green lines) of the closed leaf pairs before and after changing the *Leaf Shift Static* parameter to 0 mm. With the *Leaf Shift Static* parameter set to 0 mm, the BEV shall show the 3 mm gap. Also the Pencil Beam dose distribution shall be affected as shown in the illustrations.

The change of the *Leaf Shift Static* (LSS) parameter from a value $LSS > 0$ to $LSS = 0$ causes a sub-millimetrical decrease of the field width used for dose calculation. This can be checked by comparison of a measured and a calculated cross profile in leaf moving direction. Therefore, we recommend recalculating at least one corresponding cross profile after changing LSS in the Machine Profile. The value of $LSS = 0$ can be accepted if the measured and the calculated cross profiles are in agreement taking into account the accuracy requirements of your hospital. If agreement cannot be achieved, please contact Brainlab support.

For details of verification of dose calculation accuracy (also relevant for changed machine profiles), please consult the quality assurance chapter in your latest *Technical Reference Guide, Brainlab Physics*.

Retrospective review of existing treatment plans

If the machine profile for an Elekta Agility MLC did contain a *Leaf Shift Static* value other than 0 mm and it was used for treatment planning, it is recommended to review treatment plans where multiple objects were simultaneously treated with the same beams or arcs (one isocenter for multiple separated planned target volumes). Of these plans for an Agility MLC, especially the following treatment plans should be reviewed specifically for the area close to the leaf gaps for the actually applied leakage dose:

- Plans with multiple beams or multiple arcs from different directions (different couch positions) where the isocenter was not located within one of the planned target volumes and the gap of closed leaf pairs was set to the middle of the MLC treatment field.
- Single Arc plans where the closed leaf pairs gap was set to the middle of the MLC or the direction of the leaf gap axis (collimator rotation) did coincide with the gantry movement direction.



If this was not already reviewed with the patient specific Quality Assurance (with dose measurements in a phantom), this can be re-performed at any time for an existing plan.

As an additional option, the plan's dose distribution can be re-calculated with the changed machine profile, by keeping all other treatment plan specific parameters for plan comparison.

General Reminders:

It is strongly recommended to establish a comprehensive quality assurance program suitable for detecting errors, limitations or inaccuracies of the treatment planning and treatment delivery systems. For details, please consult the quality assurance chapter in your latest *Technical Reference Guide, Brainlab Physics*:

“Measure the absolute accuracy of the Brainlab treatment planning system in combination with the used treatment delivery systems using phantoms. The measured accuracy must be taken into account when configuring plan parameters in order to ensure accurate treatment delivery.”

“Ensure proper delivery of the treatment plan to the patient. It is strongly recommended to perform a phantom verification for every treatment plan using exactly the same parameter settings that will be used for the real patient during actual treatment.”

General Recommendation: Select the preferred plan position of closed leaf pair gaps outside the middle of the MLC treatment field

In order to reduce radiation leakage through your MLC for iPlan RT Dose treatment plans whenever possible, it is recommended to set the *Preferred Home Position* to e.g. *Left* or *Right* in the corresponding machine profiles (via *Physics Administration*):

