

IMPORTANT USER NOTICE

We are providing the information in this Notice to notify you of an important issue that may exist on your equipment, and to inform you of any actions needed to safeguard both your staff and your patients. We ask that you please read and understand the content of this notice and implement any recommendations provided.

We also need you to acknowledge and accept this Notice by signing and returning the statement on the Acknowledgement page.

We advise you to insert this Notice in the applicable copy of the User Manual.

Incorrect dose calculation for Regions Of Interest (ROIs) defined on a secondary image series

Product: Oncentra Brachy versions 3.x (excluding v3.0) and 4.x

Reference number (Field Change Order, FCO): 806-03-BTP-001

Field Corrective Action (FCA) number (if applicable): Not applicable

Scope:	Oncentra Brachy versions 3.x (excluding v3.0) and 4.x.
Description:	In Oncentra Brachy (Brachy Planning (BP) module and Plan Analysis (PA) module) dose may be incorrectly calculated for Regions Of Interest (ROIs) defined on a secondary image series when using specific registration methods.
Clinical impact:	The magnitude of the dose calculation error depends on the registration transformation and can vary between 0 and 100% of the correct dose value.
Solution:	To resample Regions of Interest defined on a secondary image series onto the primary image series prior to dose evaluation.
Technical Reference:	Not applicable
Contact:	If you have any queries about this Notice, please contact your local Elekta representative.

IMPORTANT USER NOTICE

1 Scope

Oncentra Brachy versions 3.x (excluding v3.0) and 4.x

2 Description

Dose may be incorrectly calculated in case the following three conditions are true:

- I. a treatment plan contains a primary image series A and one or more secondary image series B,
- II. image series B is registered to image series A by means of one of the following image registration procedures: surface matching, landmark, mutual information or manual registration,
- III. an ROI is defined on image series B, for example by creating a new ROI or copy and pasting the ROI from the primary image series A,

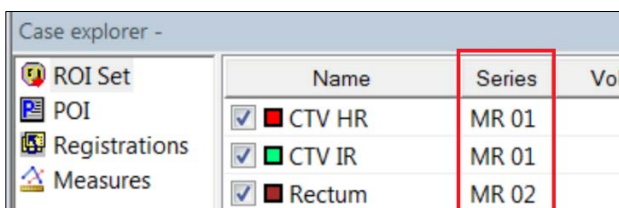
The issue occurs because the registration transformation is not applied to the dose sampling points. The issue can result in incorrect dose values or incorrect dose displayed for a number of functions applied to the secondary image series or ROIs defined on the secondary image series, see Table 1.

Function	When applied to:	
	Primary Image Series	Secondary Image Series
Dwell positions and applicator positions	Not affected	Not affected
Isodose lines	Not affected	Not affected
Live dose in 3D view (isodose surface)	Not affected	Turned off
Live dose (isodose line) in image slice	Not affected	Not affected
Patient points dose values	Not affected	Not affected
3D dose cloud	Not affected	Not affected (turned off in version > 4.1)
Dose profile	Not affected	Affected (Brachy Planning, Plan Analysis)
Function	When applied to:	
	ROIs defined on Primary Image Series	ROIs defined on Secondary Image Series
DVH graph values	Not affected	Affected (Brachy Planning only)
DVH table values	Not affected	Affected (Brachy Planning only)
Dose statistics in case explorer	Not affected	Affected (Brachy Planning only)
IPSA	Not affected	Turned off
HIPO	Not affected	Affected (Brachy Planning only)

Table 1 Overview of affected functions

IMPORTANT USER NOTICE

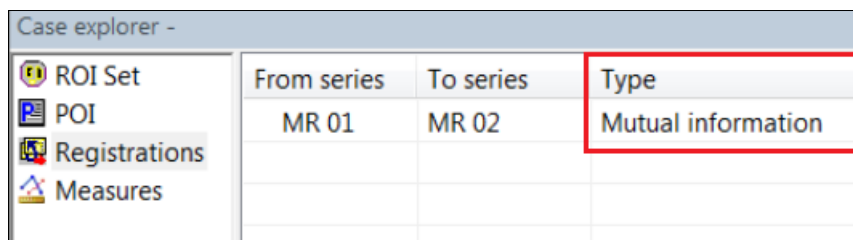
On which image series a ROI is defined can be checked in the case explorer of the Anatomy Modeling (AM) module by inspecting the **Series** column in the **ROI Set** tab, see Figure 1.



Name	Series	Vol
<input checked="" type="checkbox"/> CTV HR	MR 01	
<input checked="" type="checkbox"/> CTV IR	MR 01	
<input checked="" type="checkbox"/> Rectum	MR 02	

Figure 1 The image series on which a ROI is defined is displayed in the case explorer (AM)

The type of registration that is used can be checked by inspecting the **Registrations** tab in the case explorer of the AM module, see Figure 2. If the registration **Type** reads Surface Matching, Landmark, Mutual Information, Matrix or Manual, treatment planning may have been affected by the issue described in this Important User Notice. If the registration **Type** reads Identity the dose calculation issue reported in this Important User Notice does *not* occur.



From series	To series	Type
MR 01	MR 02	Mutual information

Figure 2 Registration method can be found in the case explorer.

The primary image series of the patient case is listed in the **From series** field of the **Registrations** tab, see Figure 2.

3 Consequences

The magnitude of the dose calculation error depends on the registration transformation and can vary between 0 and 100% of the correct dose value. We have identified two clinical scenarios in which the issue may impact patient treatment:

1. Multimodality imaging prior to the first fraction, in which secondary image series are used for contouring and dose evaluation.
2. Pre-treatment imaging and plan adaptation based on contouring and dose evaluation on the secondary (pre-treatment) image series.

IMPORTANT USER NOTICE

4 What actions to take?

4.1 Retrospective actions

If you suspect that the issue outlined in this Important User Notice may have affected treatment planning in your clinic, please do the following:

- Check for the suspected treatment plan whether the three conditions as described in the section *Description* are true.
- Determine if dose evaluation was done based (solely) on one of the affected features listed in Table 1.
- Inspect the impact of the error by copy and pasting the ROIs from the secondary image series onto the primary image series and re-evaluating the dose.

To copy and paste an ROI onto the primary image series, do the following:

1. Right click on an ROI in the case explorer of the AM module.
2. In the drop-down menu, click **Copy ROI**.
3. Type an appropriate name, color, and select the primary image series. Note: type a name which is unambiguous and different from the original name.
4. Click **OK**.

Warning: Copying the ROI can change the alignment of the new contours with the image slices if the ROI is copied to the primary image series. Be aware that if you choose to simplify the ROI the shape and volume of the copied ROI can change.

4.2 Future actions and cautions

Make sure to resample all ROIs from the secondary image series onto the primary image series before dose evaluation with one of the affected features listed in Table 1.

In order to resample an ROI, do the following:

1. Right click on the new ROI in the case explorer of the AM module.
2. Choose **Resample**.
3. Check 'Original Slices'.
4. Select the primary image series.
5. Click **Resample**.
6. Select ROI template and type an appropriate name, color, and select the primary image series.
Note: Type a name which is unambiguous and different from the original name.
7. Click **OK**.

IMPORTANT USER NOTICE

Warning: Resampling an ROI can change the shape and volume of the ROI. When you resample the ROI, the new contours in the ROI volume may not coincide with the original contours. Therefore, parts of the original ROI can be left out in the resampled ROI so that the resampled ROI is smaller than the original ROI.

For more information about the Copy ROI and Resample functionality, you are referred to the Oncentra Brachy Help that you can start from the Oncentra Brachy application.

Evaluation of a treatment plan should be done by qualified personnel using multiple dose reporting tools. For more information about what to check prior to approving a treatment plan, you are referred to the Treatment Plan Approval Checklist in Appendix A of the Oncentra Brachy v4.5 User Manual.

Because of possible incorrect dose values:

- Do not use dose profiles on secondary image series (when the image series is not registered using an identity transformation) in the Brachy Planning module and the Plan Analysis module.
- Do not include ROIs in DVH views (and DVH tables) that are defined on secondary image series (when the image series is not registered using an identity transformation) in the Brachy Planning. A workaround is to first copy (or resample) the ROIs from the secondary image series to the primary image series within the Anatomy Modeling module.
- Do not use dose statistics on ROIs in the case explorer that are defined on secondary image series (when the image series is not registered using an identity transformation) in the Brachy Planning module. A workaround is to copy (or resample) the ROIs from the secondary image series to the primary image series within the Anatomy Modeling module.
- Do not include ROIs in a HIPO optimization that are defined on secondary image series (when the image series is not registered using an identity transformation) in the Brachy Planning module. A workaround is to copy (or resample) the ROIs from the secondary image series to the primary image series within the AM module.

IMPORTANT USER NOTICE ACKNOWLEDGEMENT

Please complete the details below and sign the appropriate acknowledgement section:

- Existing installations; Acknowledgement by the customer
- New installations: New installation confirmation by the installing Elekta or Representative employee

Please return this report to your local Elekta Office or Representative, as soon as possible and within 30 days at the latest.

***The information in this Notice has been provided to address an issue and therefore the customer is expected to acknowledge and accept the recommendations given, and ensure they are implemented. By refusing to implement the recommendations, the customer assumes full responsibility and liability for all matters (including costs, losses, claims, and expenses) resulting, whether directly or indirectly from not implementing such recommendations. Further the customer will hold Elekta harmless from all matters (including costs, losses, claims and expenses) resulting, whether directly or indirectly from not implementing such recommendations.**

Failure to sign and return the acknowledgement may affect any follow-up actions necessary for us to take.

Classification: Important User Notice	FCO Ref: 806-03-BTP-001
Description: Oncentra Incorrect dose calculation for Regions of Interest (ROIs) defined on a secondary image series.	
Scope: Oncentra Brachy versions 3.x (excluding v3.0) and 4.x.	

Hospital:	
Device Serial No(s): (e.g. linac - if applicable)	Location or Site No:

Acknowledgement to be signed by customer*: I acknowledge that I have read and understood this Notice and accept implementation of any given recommendations:	
Name:	Title:
Signature:	Date:

New installation confirmation to be signed only by the installing Elekta or Representative employee: I acknowledge that the customer is informed on content of this notice and has been inserted in the applicable copy of the User Manual:	
Name:	Title:
Signature:	Date: