RAYSTATION 11A

Ocular Proton Planning Instructions for Use

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Disclaimer

For information on functionality not available for regulatory reasons, see the Regulatory Information in the RayStation Instructions for Use.

Declaration of conformity

CE 0413

Complies with 93/42/EEC Medical Device Directive as amended by M1 to M5. A copy of the corresponding Declaration of Conformity is available on request.

Safety notices

This user documentation contains WARNINGS concerning the safe use of the product. These must be followed.

WARNING!

The general warning sign informs you of a risk for bodily harm. In most cases the risk is related to mistreatment of the patient.

Note: *The note gives additional information concerning a specific topic, for example, things to consider when performing a certain step in an instruction.*

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1 INTRODUCTION

About this manual

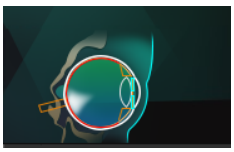
This document is an addition to *RSL-D-RS-11A-USM, RayStation 11A User Manual* and describes ocular proton planning in RayStation 11A.

Study this manual and the *RSL-D-RS-11A-IFU, RayStation 11A Instructions for Use* carefully before using ocular proton planning in RayStation 11A. Proper functioning of the device can only be guaranteed if the instructions in these documents are adhered to.

Study the Release Notes in this manual as well as the *RSL-D-RS-11A-RN, RayStation 11A Release Notes* carefully. These notes provide final instructions on how to use ocular proton planning in RayStation 11A.

The RayStation 11A system is further described in the RayStation 11A product documentation.

About ocular proton planning in RayStation



Ocular proton planning in RayStation requires the *rayOcular* license.

The scope of the ocular proton planning capabilities in RayStation is to support the treatment planning needs of clinics following the model-based ocular gaze angle method originally suggested by Massachusetts General Hospital (MGH) [1]. The functionality covered by RayOcular may be summarized as follows:

- Detailed parameterized models of the eye and clip markers
- Adaptation of the eye and clip models using CT/MR images
- Fundus view using either Polar mode or Camera mode projections with user-specified optical parameters
- Registration of fundus photos in the Fundus view

1 Goitein M, Miller T., Med Phys. 10(3), (1983) p.275-83

- Tumor modeling in the Fundus view
- Tumor modeling in the CT/MR views
- Handling of radiographs for verification of eye model clip positions
- Planning tools for generating passively scattered plans using apertures for a fixed horizontal beamline
- Eye gaze angles and eye model center position as input plan parameters
- Fixation light position computed from eye gaze angles, eye center, and fixation light arm geometry as specified in machine model
- Pencil beam dose engine
- Dose grid resolution between 0.2 mm and 1.0 mm
- Dedicated plan report for Ocular plans

The following functionality is not currently supported in RayStation:

- Clip position definition from radiographs. The clips are defined based on CT and/or MR images only, but tools are provided for verifying the clip positions using radiographs.
- Eyelid modeling.
- Wedge planning.

2 INFORMATION NEEDED FOR SAFE OPERATION

Adhere to the following warnings as well as the warnings described in *RSL-D-RS-11A-IFU, RayStation 11A Instructions for Use* for safe operation of ocular proton planning in RayStation 11A.

Safety precautions

WARNING!

Fundus photo registration in the Fundus view. An error in the registration of a fundus photo to the Fundus view will lead to an incorrect tumor volume. This error will typically be larger the farther anterior the tumor extends in the eye.

To minimize this error, the user must make sure the best possible fundus view projection settings are used in RayStation. However, it can be difficult to assess that the projection is correct, and it may in fact not be fully possible to realize. This especially applies to montage fundus photos, that is, photos that have been patched together by several individual photos.

If the registration is done using the positions of the optic disc and macula only, an error in the tumor volume is expected even for small deviations in the placement of those structures in the eye model. Note that this will occur also if the distance between the optic disc and macula is correct, but the positions in the eye model and the relative angle between them are not.

The user must be aware of these potential uncertainties, be able to quantify them, and apply margins to the tumor volume accordingly. It is not advisable to generate a target volume solely based on a fundus photo without support from other observations, such as the relation between the tumor and the clip positions.

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WARNING!

The eye model geometries and associated materials must be reviewed. All volumes of the eye model and the External ROI must be associated with a defined material. It is the responsibility of the user that the chosen materials accurately represent the materials of the modeled eye. An inappropriate choice of material will lead to an error in dose.

All eye model geometries and associated materials must therefore be carefully reviewed before they are used for planning.

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WARNING!

The user must manually make sure there is a sufficiently large air gap to avoid patient collision. For an ocular gaze treatment plan, the patient is described by the eye model and the skin plane only, making a calculation of the air gap between the delivery system and the real patient impossible. For the chosen combination of beam (gaze) direction, isocenter and beam accessories, the user must therefore manually make sure a sufficiently large air gap can be achieved to avoid collisions with the patient.

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WARNING!

All plan information not taken from DICOM must be verified before use. For ocular gaze treatments, the DICOM-exported RTIonPlan does not contain all the parameters necessary for delivery of the treatment plan. If missing information needs to be manually extracted, the treatment plan must first be approved, and a plan report printed using a report template suited for ocular gaze plans. Such a template is provided by RaySearch and can also be adapted to the needs of the clinic. The required values must be taken from the report. All manually handled plan information must be carefully verified before use.

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WARNING!

Clip positions from CT/MR images must be verified. The tantalum clips stitched to the sclera will produce large artefacts in both the CT and MR images. This introduces some uncertainty in the extracted clip positions. The clip positions determined from the CT and MR images should therefore be verified by radiographs and by measurements obtained during the clip surgery.

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WARNING!

Defining tumor from MR image. When a tumor is delineated using an MR image, while the clip positions of the eye model are defined from a CT image or have been extracted from radiographs, it is very important that the MR image is correctly registered with respect to the clip positions in the eye model. Any mismatch between the clip positions in the model and in the MR image will directly translate to a corresponding error in the tumor position. It is the responsibility of the user to make sure the registration of the MR image is done to a sufficient degree of accuracy.

Another source of uncertainty when the tumor is defined using MR images is the fact that it can be difficult to distinguish the tumor from retinal detachments in the eye. The user shall be aware of this problem.

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WARNING!

Dose outside of eye has no relation to CT/MR image. The CT and/or MR image data in RayStation only serves as input for constructing the eye model and is no longer a valid representation of the patient geometry as the eye is rotated in the plan. However, the dose in RayStation is reported in the patient coordinate system in which the CT and MR images are defined. This means that the dose observed outside of the eye model in the 2D and 3D patient views in RayStation has no relation to the patient structures observed in those views. The same also holds true for DVHs and dose statistic data for ROIs and POIs that are fully or partly outside of the eye.

The user must be aware that dose outside of the eye model has no relation to the patient geometries as seen in, or deduced from, the underlying CT/MR image data.

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WARNING!

Eye model DRR printout verification. When an eye model DRR is printed using the 'Print eye model DRR'-function in the Plan design module, the scale in the printout needs to be verified. It is the responsibility of the user to verify that the printout has been printed to correct scale by measuring the horizontal and vertical reference scales included in the printout.

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WARNING!

Grayscale data in DRRs should not be used for patient setup. The DRRs from an ocular gaze angle plan in RayStation consider the rotation of the eye according to the planned gaze and twist angles. Both the ROIs and the entire underlying CT image set are rotated with the eye. This means that the gray scale of the generated DRRs will not be correct and cannot be used for patient setup. Only contours from ROIs and aperture openings in the DRRs should be used for patient setup.

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WARNING!

Insufficient modeling of the patient outside of the eye model. It is the responsibility of the user to make sure the position of the skin plane is accurate. Plans which depend on a highly accurate description of the patient geometry outside of the eye should be avoided.

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WARNING!

Verification of the eye orientation at treatment position. As the patient is asked to look at the fixation light during the treatment, there are several reasons for a mismatch between the modeled and the actual orientation of the eye.

It is the responsibility of the user to verify the orientation of the eye at the treatment position by matching DRRs from RayStation to radiographs acquired in the treatment position. Translational errors and errors in gaze angles can be adjusted by modifying the chair position and the fixation light. However, any remaining errors caused by an effective twist of the eye must be adjusted by creating a new plan with an adjustment of the eye twist in the plan.

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WARNING!

Manual modification of the eye model must be carefully reviewed. The eye model is a detailed parametrized model that generates a set of ROI geometries representing the eye components. The size, shape, and relative placement of the components are fully determined by the eye model parameters and the hierarchical relationship between the components. Adjusting the individual component parameters will therefore update the entire eye model to make sure it is up-to-date.

It is also possible to modify the ROI geometries directly by using tools in the Structure definition module. This is only recommended for exceptional cases such as modeling significant scar tissue on the sclera. If any eye model component is manually modified, the resulting eye model must be carefully reviewed before continuing treatment planning to make sure no unintended cavities or holes or similar defects are introduced to the eye model. It is recommended to use both 2D views, 3D views, and the material visualization view for evaluation.

Also note that if any eye model parameter is adjusted after a manual modification to an eye model geometry or tumor model geometry, these components are restored and the manual modification will be lost. Also, editing tumor model parameters will reset any manual changes to the corresponding tumor model geometry.

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WARNING!

Uniform lateral dose distribution for proton ocular treatments. The pencil beam dose computation for passive proton ocular treatments will generate a dose in water that is laterally uniform inside the high-dose region. It is the user's responsibility to validate that this assumption is acceptable for the actual delivery system.

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WARNING!

Eye model alignment. It is important that the eye model is aligned correctly with respect to the underlying 3D data. This can be difficult for models that are created using CT images only where the contrast for the eye structures is low, especially for the rotational direction of the eye in the sagittal view. An incorrect alignment of the eye can lead to:

- Incorrect position of a tumor ROI defined on an MR image in relation to the clip positions.
- Incorrect position of the risk organs in relation to the clip positions.
- Incorrect registration of a fundus photo leading to an incorrect position of the tumor model.

It is the responsibility of the user to ensure that that the eye model is aligned correctly with respect to the underlying 3D data.

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3 COORDINATE SYSTEM, MOVEMENTS AND SCALES

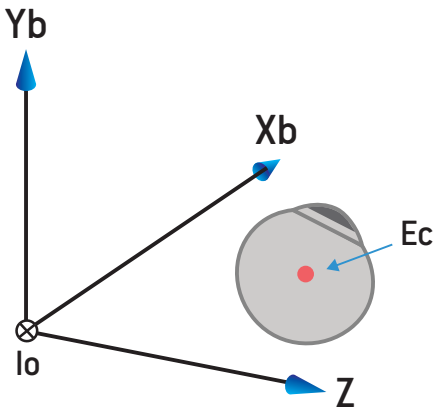
To simplify the interpretation of the eye center coordinates and also the definition of the fixation light, RayStation will only accept machine models with the following fixed angles (IEC 61217) for ocular gaze planning: gantry angle = 90 deg, chair rotation = 270 deg, and collimator (beam limiting device) angle = 90 deg. With these fixed angle settings, the x-axis is horizontal with positive values to the sitting patient's left and the y-axis is vertical with positive values upwards. The z-axis is aligned with the beam central axis, with positive values in the direction towards the beam source.

In this chapter

This chapter contains the following sections:

3.1 EYE CENTER POSITION COORDINATE SYSTEM

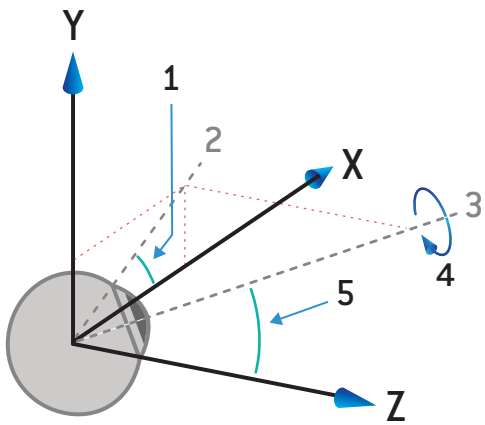
The eye center position (Ec) is defined in a coordinate system with the origin at the isocenter (Io), where the x- and y-axes coincide with the corresponding axes of the IEC 61217 beam limiting device coordinate system, and where the positive z-axis is directed towards the beam source.



3.2 GAZE ANGLES

The gaze angles are defined in a spherical coordinate system with the z-axis pointing into the beam and the x-axis pointing from the right to the left eye of the patient:

- Polar angle – measured between the gaze of the patient and the z-axis.
- Azimuthal angle – measured between the projection of the gaze of the patient onto the xy-plane and the direction of the x-axis.
- Twist (torsion) angle – clockwise rotation of the eye along the axis of the gaze direction.



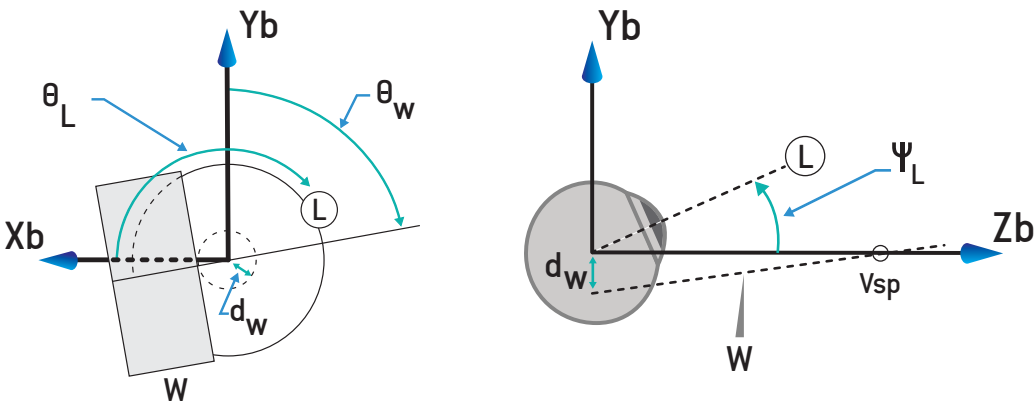
Number	Description
1	Azimuthal angle
2	Projected gaze
3	Gaze
4	Twist (torsion) angle
5	Polar angle

3.3 FIXATION LIGHT

The fixation light angles indicate the position of the light diode on the fixation light arm. The patient looks at the light diode and thereby achieves the desired gaze angle.

In RayStation, the fixation light arm is modeled as being mounted on the snout at a fixed distance from the isocenter. Different fixation light arm mounting angles are supported. Only straight (not curved) fixation light arms are supported. The fixation light position is defined in a spherical coordinate system. The grading for both the polar angle and the azimuthal angle for the fixation light is assumed to be in degrees. The rotation of the fixation light position is performed with polar angle first, azimuthal angle second.

- Polar angle – measured between the direction from the fixation light diode to the isocenter and the direction of the beam.
- Azimuthal angle – measured between the x-axis of the IEC 61217 beam limiting device coordinate system and the fixation light diode.



Symbol	Description
θ_L	Fixation light azimuthal angle
W	Wedge
d_w	Wedge position
L	Fixation light
θ_W	Wedge angle
Vsp	Virtual source position
ψ_L	Fixation light polar angle

4 RELEASE NOTES

This chapter contains important notes about ocular proton planning in RayStation 11A.

Every user of ocular proton planning in RayStation 11A must be familiar with these known issues as well as the known issues described in *RSL-D-RS-11A-RN, RayStation 11A Release Notes*. Contact the manufacturer for any questions about the content.

Note: *Beware that additional safety-related release notes may be distributed separately within a month of software installation.*

4.1 KNOWN ISSUES

Image orientation indicator in RayStation

The image orientation indicator 'Ray' is located in the lower right corner of all views displaying patient image data, including Beams Eye View (BEV) and DRRs, to indicate the image orientation in relation to the patient. For Ocular Gaze plans, Ray will still be oriented in relation to the underlying image data, irrespective of the registration of the eye model and the gaze angles of the plan. As a consequence, the relation between the fixed beam and Ray changes with the planning gaze angles and the registration of the eye model, despite the fact that the relation between the sitting patient and the beam does not change. Effectively, Ray will rotate with the eye rotation in the views. This behavior is especially pronounced in the BEV and the DRR views.

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