RAYPLAN 10A

Release Notes



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Disclaimer

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

Declaration of conformity

CE₀₄₁₃

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.

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1 INTRODUCTION

1.1 ABOUT THIS DOCUMENT

This document contains important notes about the RayPlan 10A system. It contains information related to patient safety and lists new features, known issues and possible workarounds.

Every user of RayPlan 10A must be familiar with these known issues. Feel free to contact the manufacturer for any questions about the content.

1.2 MANUFACTURER CONTACT INFORMATION



RaySearch Laboratories AB (publ) Sveavägen 44 SE-111 34 Stockholm Sweden Telephone: +46 8 510 530 00 E-mail: info@raysearchlabs.com Country of origin: Sweden

1.3 REPORTING OF INCIDENTS AND ERRORS IN SYSTEM OPERATION

Report incidents and errors to the RaySearch support email: support@raysearchlabs.com or to your local support organization via telephone.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer.

Depending on applicable regulations, incidents may also need to be reported to national authorities. For the European Union, serious incidents shall be reported to the competent authority of the European Union Member State in which the user and/or patient is established.

2 NEWS AND IMPROVEMENTS IN RAYPLAN 10A

This chapter describes the news and improvements in RayPlan 10A compared to RayPlan 9B SP1.

2.1 GENERAL SYSTEM IMPROVEMENTS

- Close plan is now available from the RayPlan menu.
- When selecting an ROI or POI from a drop-down list it is now possible to more easily find the
 desired ROI/POI by typing one or more characters to filter the list of ROIs/POIs. When the
 drop-down list is opened, the current selection is replaced with a text entry field, initially showing
 the name of the currently selected ROI/POI. Start typing to reduce the size of the drop-down
 list. If only one ROI/POI remains in the list, it will be automatically selected. If the list becomes
 empty, the selection is cleared.

2.2 PATIENT MODELING

- The move POI tool has a new mode to prevent the POI to snap to the clicked slice. When pressing the ALT key while interacting, the POI remains at the distance to the current slice.
- The New ROI drop-down menu has been reordered for improved usability.
- Structure definition has a new workspace layout available. This layout is denoted *Combined* and enables the user to see both the primary and secondary image sets for all patient directions at once. The top left area can be switched between primary and fusion view.

2.3 GENERAL IMPROVEMENTS FOR LINAC TREATMENTS MACHINES

- Possibility to define minimum and maximum tip positions per leaf pair for MLCs in RayPlan Physics.
- Possibility to define minimum and maximum MU allowed for beams that use wedges. This is specified per wedge in RayPlan Physics. The functionality is mainly intended for Siemens virtual and Varian enhanced dynamic wedges, but it is possible to define minimum and maximum MU for all wedge types. For Elekta motorized wedge, the minimum/maximum MU will apply to the total MU per fraction and not to the wedge-in MU.

2.4 QA PREPARATION

Possibility to compute relative EPID response for pre-treatment QA of photon plans. The response
is exported as a DICOM RTImage, which can be compared to the measured EPID response in
an external comparison software. The EPID QA functionality has been validated for Varian
machines.

2.5 VIRTUAL SIMULATION

- Possibility to configure creation of external ROI geometry as well as dose grid assignment for the default plan creation. Configuration is done in Clinic Settings.
- Conformed beams will by default get no MU.

2.6 3D-CRT BEAM DESIGN

- Support for automated collimator angle selection for conformal arcs to facilitate stereotactic planning. The angle selection is based on target projection with the goal to minimize the exposure of healthy tissue in-between targets. The feature, Smart angles, is an option in the Treat tab and is used in combination with the Conform function.
- Improved positioning of closed leaf pairs for Conformal Arcs.
- Workflow improvement for copied beams. Dose computations performed in the 3D-CRT Beam Design module will assign a default value of 1 MU to 3D-CRT beams.
- Aperture creation for new 3D-CRT-beams no longer give the new beam a default MU value. Computed plan dose for existing beams will be preserved.
- Reset beam(s) in the 3D-CRT beam design module will preserve beam MU.
- When adding/copying a beam with a wedge with a defined minimum MU, the new beam will get MU set to the minimum wedge MU.
- When assigning a wedge with a defined minimum MU to a beam in the Beams list, the beam MU will be set to the minimum wedge MU if the beam MU is below the minimum wedge MU.

2.7 PLAN OPTIMIZATION

• Improved jaw positioning during optimization for LINACs with jaw positions per segment.

2.8 CLINIC SETTINGS

- Clinic Settings now uses the same dark theme as RayPlan.
- The tab System admin has been added. It contains settings related to system administrative tasks, most of which were previously found in the Preferences tab.
- General dose settings have moved to the Preferences tab.

- The layout of Clinic Settings has been changed to reduce the amount of scrolling and make better use of the window area.
- All tabs now handle resizing of the window. Most tabs have two columns instead of one and the columns can be resized.
- Possibility to select if an external ROI geometry should be created and if a dose grid should be applied when a default Virtual simulation plan is created.

2.9 RAYPLAN PHYSICS

2.9.1 Photon beam commissioning

- Possibility to set statistical uncertainty per auto modeling step for Photon MC beam models.
- Support for arbitrary field openings in dose curve computation and auto-modeling. Corresponding dose curves can be imported.
- Possibility to set leaf tip width, tongue-and-groove width, offset, gain, curvature and orthogonal offset per MLC layer for dual layer MLC machines.
- The random number generator used for the photon MC dose engine has been changed. This will lead to differences in computed dose curves for Photon MC beam models in RayPlan 10A compared to previous versions. For a dose calculation with high statistical uncertainty, differences up to 10% have been seen in individual points. When running the dose calculation with low statistical uncertainty, the differences are negligible. It is not required to re-commission previous beam models.
- Possibility to define minimum and maximum tip positions per leaf pair for MLCs.
- Possibility to define minimum and maximum allowed beam MU for wedges.

2.9.2 Electron beam commissioning

• The auto-modeling dialog is now available for electrons. There are new auto-modeling steps to optimize the electron source phase space parameters and the energy spectrum parameters using the applicator curves. Note that MC calculation of the applicator curves is slow, so these steps are long-running. Resolution and number of histories can be set per step.

2.10 DOSE ENGINE UPDATES

2.10.1 RayPlan 10A dose engine updates

The changes to the dose engines for RayPlan 10A are listed below.

Dose engine	RS 9B SP1	RS 10A	Dose effect	Comment
All	-	-	Minor	A performance optimization and refactoring of material handling has been done, which might give small differences in dose computed in RayPlan for all modalities. It is not required to re-commission existing beam models based on this change. For additional changes in each dose engine, see below.
Photon Collapsed Cone	5.2	5.3	Negligible	For LINACs with dual layer MLCs, the transmission is changed in the inter- section of the leaf tip and the tongue-and-groove region for a sin- gle leaf. No changes to dose curves in beam commissioning. Machines are upgraded to give identical dose in all cases if leaf tip is zero and/or tongue and groove is zero. Existing machine models do not need to be re-commissioned.

Dose engine	RS 9B SP1	RS 10A	Dose effect	Comment
Photon Monte Carlo	1.2	1.3	Minor if calcu- lated with low uncertainty	For LINACs with dual layer MLCs, the transmission is changed in the intersection of the leaf tip and the tongue-and-groove region for a single leaf. No changes to dose curves in beam commissioning. Machines are upgraded to give identical dose in all cases if leaf tip is zero and/or tongue and groove is zero. The random number generator used for the photon MC dose engine has been changed. This will lead to differences in computed dose for Photon MC in RayPlan 10A compared to previous versions. For a dose calculation with high statistical uncertainty, differences up to 10% has been seen in individual points. When running the dose calculation with low statistical uncertainty, the differences are negligible. Example dose curves calculated with the different random number generators are shown in the section below. Existing machine models do not need to be re-commissioned.
Electron Monte Carlo	3.6	3.7	Negligible	Existing machine models do not need to be re-commissioned.

2.10.2 Example of differences in dose curves for Photon Monte Carlo between RayPlan 10A and previous versions

In RayPlan 10A the random number generator for the Photon Monte Carlo dose engine has been changed. The reason for the change is that the Proton Monte Carlo dose engine has been migrated to GPU, and testing revealed that the random number generator used for Photon Monte Carlo did not suffice for Proton Monte Carlo. No issues with using the previous random number generator for Photon Monte Carlo have been found, but it was nevertheless decided to change so that Photon Monte Carlo uses the same random number generator as Proton Monte Carlo. This will lead to differences in the Photon Monte Carlo dose computed in RayPlan 10A compared to previous versions. The Photon Monte Carlo dose calculation itself has not changed, but for calculations with high statistical uncertainty, there can be large differences in individual voxels. When running the dose calculation with low statistical uncertainty, the differences are negligible.

Figure 1 and Figure 2 below show examples of dose curves computed with the previous and current random number generator. The field is 10x10 cm2 and one depth dose curve and an x-profile at 10 cm depth is visualized. In Figure 1, the uncertainty is 2% and large differences can be seen. In Figure 2, uncertainty 0.2% has been used, and the dose curves are almost identical.



Figure 1. Dose curves computed with uncertainty 2%. Curves for the random number generator in RayPlan 10A are shown in blue, and for previous versions in red. The curves to the left show dose related to depth, and to the right dose related to x-position.



Figure 2. Dose curves computed with uncertainty 0.2%. Curves for the random number generator in RayPlan 10A are shown in blue, and for previous versions in red. The curves to the left show dose related to depth, and to the right dose related to x-position.

2.10.3 Changed behavior of previously relseased functionality

- The allowed field opening for dose calculation with Siemens virtual wedge has been limited. The y-jaw positions in the fully open field are limited to retracted positions between 3 cm and 10 cm. This is a safety precaution introduced due to the problem described in FSN #56089.
- The Compute Function Values button has moved from the toolbar to just above the list of objectives/constraints and is now named Compute values.

3 KNOWN ISSUES RELATED TO PATIENT SAFETY

Note: Be aware that additional safety related release notes may be distributed separately within a month of software installation.

Elekta guard leaf behavior

Elekta guard leaves are the first leaves behind the y-jaws that are moved to the same position as the last leaf pair in the field. All leaf positions must be fully specified in the prescription. Because of this, guard leaves are set by the Treatment Planning System (TPS).

However, the R&V system or the Treatment Control System (TCS) can have a feature that automatically sets guard leaf positions that will override the prescription from the TPS for those leaves. It might be possible to select this feature in the R&V system or in the TCS. Contact the suppliers of your R&V system and TCS for more information.

Be aware that the guard leaf positions in RayPlan may vary for different plan types:

- When openings are created in the 3D-CRT module using "Treat and protect", RayPlan does not open any additional leaf pair behind the y-jaws for Elekta machines. Similarly, when segments are manually edited (Edit MLC and jaws) – no additional leaf pair is opened.
- However, RayPlan does open one additional leaf pair for Elekta machines in some other workflows:
 - Optimization: only for 3D-CRT and SMLC, not for DMLC and VMAT.
 - Create rectangular field

Note that this will only occur for segments where the y-jaws are positioned exactly at the edge of a leaf.

There is no setting in RayPlan Physics that allows the user to set if an additional leaf pair shall be opened. The decision is based on the relative positions of the MLC and the jaws; if the MLC is closer to the source than the jaws, the jaws are considered to be "the primary collimator" and the leaves open to get a sharper penumbra.

[146818]

DICOM import may be missing image slices

The RayPlan import dialog may be missing image slices when importing image series using the Storage SCP. The correct number of files in the Storage SCP folder must be compared to the number of instances displayed in the import dialog.

If an incorrect number of instances is displayed in the import dialog, the user should search again until the correct number is displayed. Alternatively, the image series can be imported using file based import.

If an image series with an incorrect number of slices has been imported into RayPlan, the series must be deleted from the patient in RayPlan and reimported.

When comparing the number of files, note that the Storage SCP adds an extra xml file to the folder beside the DICOM files. If for example a single CT set is pushed to the Storage SCP and imported, the number of instances in the import dialog should be the number of files in the Storage SCP folder minus one.

273212

4 OTHER KNOWN ISSUES

4.1 GENERAL

Do not use Fiducial in ROI/POI names when using TomoHelical with Synchrony

For TomoHelical plans using real-time tracking and motion management support - avoid having POIs with "Fiducial" in the name. The Treatment delivery system identifies which fiducials to track by this naming convention. Using the name "Fiducial" in POI names might cause problems on the delivery side with incorrect POIs to be set as tracked as well as duplicate POI names.

Incorrect fiducial usage will result in failure to deliver.

(146823)

Report Templates must be upgraded after upgrade to RayPlan 10A

The upgrade to RayPlan 10A requires upgrade of all Report Templates. Also note that if a Report Template from an older version is added using Clinic Settings, this template must be upgraded to be used for report generation.

Report Templates are upgraded using the Report Designer. Export the Report Template from Clinic Settings and open it in the Report Designer. Save the upgraded Report Template and add it in Clinic Settings. Do not forget to delete the old version of the Report Template.

(138338)

No Room View machine model displayed if couch pitch angle or couch roll angle differ from zero

The Room View does not yet have support for pitch and roll of the treatment couch. Therefore, if couch pitch angle or couch roll angle differ from zero the Room View machine model will not be shown.

(144697)

Relative DVH x-axis not properly updated when changing number of fractions

When changing the number of fractions in a plan, the DVH x-axis is not updated correspondingly when relative dose is displayed. A workaround is to switch the Dose axis to 'Absolute' and then back to 'Relative'.

(138539)

The auto recovery feature does not handle all types of crashes

The auto recovery feature does not handle all types of crashes and sometimes when trying to recover from a crash RayPlan will show an error message with the text "Unfortunately auto recovery"

4

does not work for this case yet". If RayPlan crashes during auto recovery, the auto recovery screen will pop up next time RayPlan is started. If this is the case, discard the changes or try to apply a limited number of actions to prevent RayPlan from crashing.

(144699)

Limitations when using RayPlan with large image set

RayPlan now supports import of large image sets (>2GB), but some functionality will be slow or cause crashes when using such large image sets:

- Smart brush/Smart contour/2D region growing are slow when a new slice is loaded
- Creating large ROIs with gray-level thresholding might cause a crash

(144212)

Cut plane indicators are not displayed in 2D patient views

The cut planes, used to limit the CT data used for computing a DRR, are not visualized in regular 2D patient views. To be able to view and use cut planes, use the DRR settings window.

(146375)

Calculating dose on a copy of an imported approved plan can lead to a crash

Importing an approved plan, copying it, and subsequently unchecking "Consider imported dose clinical" can lead to a state where RayPlan crashes if optimization or final dose calculation is performed. To be able to continue with optimization and dose computation, either unapprove the imported plan, or do a small edit of the dose grid in the copied plan.

(139944)

4.2 PLAN DESIGN AND 3D-CRT BEAM DESIGN

Center beam in field and collimator rotation may not keep the desired beam openings for certain MLCs

Center beam in field and collimator rotation in combination with "Keep edited opening" might expand the opening. Review apertures after use and if possible use a collimator rotation state with "Auto conform".

[144701]

4.3 PLAN OPTIMIZATION

No feasibility check of max leaf speed performed for DMLC beams after dose scaling

DMLC plans that result from an optimization are feasible with respect to all machine constraints. However, manual rescaling of dose (MU) after optimization may result in violation of the maximum leaf speed depending on the dose rate used during treatment delivery.

(138830)

4.4 DICOM

Failed SCP import wrongly deletes files

If importing data from DICOM storage SCP when the checkbox "Delete files after successful import" is checked, files that were not possible to import may also be removed. When sending data from external systems to RayPlan SCP, do not delete the data in the external system until it is verified that it has been successfully imported to RayPlan.

(138336)

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CONTACT INFORMATION



Contact details head office

P.O. Box 3297 SE-103 65 Stockholm, Sweder Phone: +46 8 510 530 00 Fax: +46 8 510 530 30 info@raysearchlabs.com www.raysearchlabs.com

RaySearch Americas Phone: +1 877 778 3849

RaySearch France Phone: +33 975 433 632

RaySearch Korea Phone: +82 10 2230 2046 RaySearch Belgium Phone: +32 2 213 83 65

RaySearch Germany Phone: +49 30 89 36 06 90

RaySearch Singapore Phone: +65 81 28 59 80 **RaySearch China** Phone: +86 137 0111 5932

RaySearch Japan Phone: +81 3 4405 6902

RaySearch UK Phone: +44 7508 426 563

