

RAYPLAN 11B

Release Notes



RayPlan
RayStation



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Disclaimer

Japan: For the regulatory information in Japan, refer to RSJ-C-02-003 Disclaimer for the Japanese market.

Declaration of conformity



Complies with Medical Device Regulation (MDR) 2017/745. 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 11B system. It contains information related to patient safety and lists new features, known issues and possible workarounds.

Every user of RayPlan 11B must be familiar with these known issues. Contact the manufacturer for any questions about the content.

1.2 MANUFACTURER CONTACT INFORMATION



RaySearch Laboratories AB (publ)
Eugeniavägen 18
SE-113 68 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 must 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 must 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 11B

This chapter describes the news and improvements in RayPlan 11B compared to RayPlan 11ASP2.

2.1 NON-FUNCTIONAL IMPROVEMENTS

- The GPU (Graphics Processing Unit) environment is now validated for a GPU model instead of a particular physical GPU unit. This simplifies running RayPlan in cloud environments by removing the need to re-approve the physical GPU which can change when restarting RayPlan.
- The usage of MD5 checksums are replaced in order to make the application FIPS compatible.

2.2 GENERAL SYSTEM IMPROVEMENTS

- Directories with rsbak files now can be used as secondary databases. This will improve the workflow for restoring single patients and simplify backups. Multiple patients can be moved from the primary database to rsbak using the RayPlan Storage tool.
- The ROI list and POI list can now return to a previous combination of visible and hidden ROIs/POIs when using the visibility indicators in the headers. Clicking the checkbox once will hide all ROIs in the group, a second click will show all ROIs, and a third click will revert to the previous visibility.
- The GPU settings dialog is now accessible also from RayPlan, not only from RayPlan Physics.
- The product version is now displayed in the launcher as well as in Clinic Settings.
- It is now possible for administrators to add new common materials to be used for all patients and to define the full elemental composition for the materials.
- Material view selection has moved to the 2D view tabs. The tab also indicates if the image set view or the material view is selected.
- Material for support and fixation ROIs is now shown in the material visualization view.
- The couch pitch and roll angles can be edited interactively in the BEV.
- It is now possible to use CT density instead of material override for Support, Fixation and used Bolus ROIs.
- Dose statistics calculations are updated in RayPlan 11B. This means that small differences in evaluated dose statistics are expected when comparing to a prior version.

The dose statistics accuracy improvement is more noticeable with increasing dose range (difference between minimum and maximum dose within an ROI), and only minor differences are expected for ROIs with dose ranges smaller than 100 Gy. The updated dose statistics no longer interpolates values for Dose at volume, $D(v)$, and Volume at dose, $V(d)$. For $D(v)$, the minimum dose received by the accumulated volume v is instead returned. For $V(d)$, the accumulated volume that receives at least the dose d is returned. When the number of voxels within an ROI is small, the discretization of the volume will become apparent in the resulting dose statistics. Multiple dose statistics measures [e.g., D5 and D2] may get the same value when there are steep dose gradients within the ROI, and similarly, the dose ranges lacking volume will appear as horizontal steps in the DVH.

- Shortcuts in the shortcut dialog are now categorized and a search function is implemented.

2.3 PATIENT DATA MANAGEMENT

If a plan, or part of a plan (e.g., a beam set) is approved, deleting the plan now requires authentication by a user with the proper authority.

2.4 PATIENT MODELING

- Multiple rigid image registrations are now supported.
 - One frame-of-reference registration
 - # Only one per frame-of-reference pair allowed
 - # Used when computing dose on other data set
 - # Used when creating deformable registrations
 - Multiple image registrations
 - # Possible to create multiple registrations between two images
 - # Can be created for images in the same frame-of-reference
 - # Can be selected when contouring in fusion mode
- It is now possible to approve registrations.
- It is now possible to rename registrations. Renaming a registration will not affect approval of plans or dose calculations.
 - Renaming a registration group will update the name of all registrations in the group where the registration name starts with the group name.
- It is now possible to add a description for a registration, which is shown as tooltip in the registration tree.

- POI based rigid registrations no longer require four POIs. A registration can now be done with one (or more) POIs.
- When an ROI or POI (or the geometry of an ROI/POI) is deleted, and the ROI/POI is neither approved nor referenced by a dose calculation/derived ROI/clinical goal etc., there will no longer be a confirmation dialog. If the deletion was unintentional, Undo will restore the ROI/POI (geometry). If deleting multiple ROIs/POIs, a confirmation dialog will still appear if at least one of the selected ROI/POI would have required confirmation.
- When switching patient direction in the Structure Definition module, the camera pan and zoom level will not reset.
- The triangulation algorithm has been updated and is now faster. There may be minor differences compared to previous versions.

2.5 BRACHYTHERAPY PLANNING

- Image fusion is now also available in the Brachy planning module, to make it easier to work with multiple image sets during planning of brachytherapy treatments.
- Brachy equipment is now listed in a separate section in the ROI list for ROIs of brachy type.
- The support for rotating and translating applicator models has been extended to also include POIs and to enable moving of only selected parts. This can be used to move the ring but not the tandem, and to include Point A in the applicator model.
- It is now possible to switch visualization of channels and channel candidates on and off.
- The channel tip visualization now reflects the source applicator tip length specified in RayPlan Physics for each channel.
- Smart draw is now significantly faster.
- It is now possible to lock specific dwell points so that they do not change during an optimization.
- It is now possible to define clinical goals in two Gray equivalent dose (EQD2) based on the linear-quadratic model.

2.6 PLAN SETUP

- The handles for editing the dose grid interactively have been enlarged.
- All prescriptions are now displayed in the default beam set report.
- Nominal dose contributions to prescription are now included in the default beam set report.
- The maximum number of fractions is now 100 (reduced from 1000).
- Nominal dose contributions to prescription are rounded to always add up to the prescribed fraction dose in full cGy. This should avoid potential rounding issues in the OIS. Note that the prescribed beam set dose in cGy must be divisible by the number of fractions for the nominal contribution to match exactly.

2.7 3D-CRT BEAM DESIGN

Support is added to automatically set the jaws a distance from the MLC opening for segments created with Treat and Protect. The distance to the MLC opening is a parameter defined by the user in RayPlan Physics for the LINAC.

2.8 PLAN OPTIMIZATION

- It is now possible to map template ROIs/POIs to ROIs/POIs in the patient when loading clinical goal list templates and optimization function list templates. This is useful in cases where the ROI/POI does not have the same name in the patient as in the template.
- Support is added to automatically set the jaws a distance from the MLC opening for optimized segments (3DCRT, SMLC, DMLC, VMAT, Conformal Arc). The distance to the MLC opening is a parameter defined by the user in RayPlan Physics for the LINAC.

2.9 GENERAL PHOTON PLANNING

- Segment doses used during segment MU (Monitor Units) optimization are stored with a lower accuracy than previously. This leads to a reduced risk of using up all available memory while the changes in optimization results are small.
- New tools are added for reversing an arc beam and creating a reversed copy of an arc beam.

2.10 PLAN EVALUATION

- It is now possible to compute, deform and accumulate the 2 Gy equivalent dose (EQD2) from photon and brachy fraction doses.
- It is possible to rename summed evaluation doses and EQD2 evaluation doses.
- It is possible to manually enter maximum value for Y axis in Line graphs. Y maximum value no longer updates to maximum of all doses when changing displayed doses.
- It is now possible to compute perturbed dose with patient rotation perturbation.

2.11 DICOM

For machines configured to export the Beam Dose as the nominal contribution/part of the prescribed dose value, it is now possible to toggle whether Beam Dose (300A,0084) is to be exported as beam nominal contribution or with beam dose specification point dose at the time of the export. Previously, it has not been possible to override the setting on the machine.

2.12 VISUALIZATION

- The ROI visualization settings for 2D, 3D, BEV and DRR views are now persistent and saved together with the ROI.
- The slice indicator widget has been improved with clearer colors.

- 3D visualization of POIs, CyberKnife beams and Brachy channels has been enhanced.
- If the visualization setting for an ROI is turned off in any view, this will be indicated via the eye symbol in the ROI list.
- It is now possible to visualize setup imager DRRs on the receptor plane. The measure tool and crosshair scale are adapted to give distances on the receptor plane.
- Beam angles are written on exported DRRs, together with other annotations.

2.13 SETUP IMAGING SYSTEMS

- The source-axis distance (SAD) property for setup imaging systems has been moved to the individual setup imagers of the setup imaging system.
- A setup imager can be assigned a receptor model represented by its width, height and isocenter to receptor plane distance. Setup imager DRRs will be visualized on the receptor plane. The measure tool and crosshair scale are adapted to give distances on the receptor plane. To keep DRRs presented on isocenter plane, select an isocenter to receptor plane distance of zero, and specify the receptor size on isocenter plane.
- A setup imager can be assigned DRR export data that will tell how the DRRs will be exported.

2.14 PHOTON BEAM COMMISSIONING

- It is now possible to move uncommissioned CyberKnife and TomoTherapy treatment machines into groups in the machine tree.
- Updated template machines:
 - Beam qualities with and without flattening filter are merged into same machine.
 - Various minor corrections to machine model parameters for several template machines.
- It is now possible to compute all photon Monte Carlo dose curves for a machine.
- It is now possible to compute all dose curves for a machine at once (Collapsed Cone, photon Monte Carlo and electron Monte Carlo).
- When computing selected dose curves for photon Monte Carlo, all dose curves with the same field size and modulation (open/wedge/cone) as a selected curve will also be computed. The time required to compute all curves for the same field size and modulation is the same as the time for only computing one.
- Recommendations have been updated on the usage of detector height and depth offset for depth dose curves. If the previous recommendations were followed, the modeling of the build-up region for photon beam models could lead to surface dose overestimation in computed 3D dose. It is recommended to review and, if needed, update photon beam models with respect to the new recommendations. Refer to section *Detector height and depth offset* in *RSL-D-RP-11B-REF, RayPlan 11B Reference Manual*, section *Depth offset and detector height*

in *RSL-D-RP-11B-RPHY, RayPlan 11B RayPlan Physics Manual and Beam Commissioning Data Specification* for information about the new recommendations.

2.15 ELECTRON BEAM COMMISSIONING

It is now possible to compute all dose curves for a machine (Collapsed Cone, photon Monte Carlo and electron Monte Carlo).

2.16 DOSE ENGINE UPDATES

2.16.1 RayPlan 11B dose engine updates

The changes to the dose engines for RayPlan 11B are listed below.

Dose engine	RS 11A SP2	RS 11B	Dose effect	Comment
All	-	-	-	The issue described in FSN 84236 has been resolved, in some cases leading to noticeable changes in dose for beams passing through the interface between the External ROI and ROIs of type Support, Fixation and Bolus for beam. Updated computation for surface triangulations of ROIs, which can have minor effect on ROI voxel volumes.
Photon Collapsed Cone	5.5	5.6	Negligible	Existing machine models do not need to be re-commissioned.
Photon Monte Carlo	1.5	1.6	Negligible	The platform used for GPU computations in RayPlan (CUDA) has been upgraded to a new version. This has a minor effect on the computed Photon Monte Carlo dose, which due to the statistical nature is very sensitive to even small disturbances. For dose calculation with low statistical uncertainty, the difference in dose compared to previous version is negligible. Existing machine models do not need to be re-commissioned.

Dose engine	RS 11A SP2	RS 11B	Dose effect	Comment
Electron Monte Carlo	3.9	3.10	Negligible in most cases. Electron dose can be changed noticeably for cases affected by the issue described in FSN 84236.	Existing machine models do not need to be re-commissioned.
Brachy TG43	1.1	1.2	Negligible	Existing machine models do not need to be re-commissioned.

2.17 CHANGED BEHAVIOR OF PREVIOUSLY RELEASED FUNCTIONALITY

- Note that RayPlan 11A introduced some changes regarding prescriptions. This information is important if upgrading from a RayPlan version earlier than 11A:
 - Prescriptions will always prescribe dose for each beam set separately. Prescriptions defined in RayPlan versions prior to 11A relating to beam set + background dose are obsolete. Beam sets with such prescriptions cannot be approved and the prescription will not be included when the beam set is DICOM exported.
 - Prescription percentage is no longer included in exported prescription dose levels. In RayPlan versions prior to 11A, the Prescription percentage defined in RayPlan was included in the exported Target Prescription Dose. This has been changed so that only the Prescribed dose defined in RayPlan is exported as Target Prescription Dose. This change also affects exported nominal dose contributions.
 - In RayPlan versions prior to 11A, the Dose Reference UID exported in RayPlan plans was based on the SOP Instance UID of the RT Plan/RT Ion Plan. This has been changed so that different prescriptions can have the same Dose Reference UID. Because of this change, the Dose Reference UID of plans exported prior to 11A has been updated so that if the plan is re-exported a different value will be used.
- Note that RayPlan 11A introduced some changes regarding Setup imaging systems. This information is important if upgrading from a RayPlan version earlier than 11A:
 - A Setup imaging system (in earlier versions called Setup imaging device) can now have one or several Setup imagers. This enables multiple setup DRRs for treatment beams as well as a separate identifier name per setup imager.
 - # Setup imagers can be gantry-mounted or fixed.

- # Each setup imager has a unique name which is shown in its corresponding DRR view and is exported as a DICOM-RT Image.
 - # A beam using a setup imaging system with multiple imagers will get multiple DRRs, one for each imager. This is available for both setup beams and treatment beams.
- Note that dose statistics calculations are updated in RayPlan 11B. This means that small differences in evaluated dose statistics are expected when comparing to a prior version.

This affects:

- DVHs
- Dose statistics
- Clinical goals
- Prescription evaluation
- Optimization objective values

This change also applies to approved beam sets and plans, meaning that, for example, prescription and clinical goals fulfillment may change when opening a previously approved beam set or plan from a RayPlan version prior to 11B.

The dose statistics accuracy improvement is more noticeable with increasing dose range (difference between minimum and maximum dose within an ROI), and only minor differences are expected for ROIs with dose ranges smaller than 100 Gy. The updated dose statistics no longer interpolates values for Dose at volume, $D(v)$, and Volume at dose, $V(d)$. For $D(v)$, the minimum dose received by the accumulated volume v is instead returned. For $V(d)$, the accumulated volume that receives at least the dose d is returned. When the number of voxels within an ROI is small, the discretization of the volume will become apparent in the resulting dose statistics. Multiple dose statistics measures [e.g., D5 and D2] may get the same value when there are steep dose gradients within the ROI, and similarly, the dose ranges lacking volume will appear as horizontal steps in the DVH.

- The maximum value for the Y axis in Line graphs in Plan Evaluation no longer updates to the maximum of all displayed doses when changing doses to display.
- Recommendations have been updated on the usage of detector height and depth offset for depth dose curves. If the previous recommendations were followed, the modeling of the build-up region for photon beam models could lead to surface dose overestimation in computed 3D dose. It is recommended to review and, if needed, update photon beam models with respect to the new recommendations. Refer to section *Detector height and depth offset* in *RSL-D-RP-11B-REF, RayPlan 11B Reference Manual*, section *Depth offset and detector height* in *RSL-D-RP-11B-RPHY, RayPlan 11B RayPlan Physics Manual* and *Beam Commissioning Data Specification* for information about the new recommendations.

3 KNOWN ISSUES RELATED TO PATIENT SAFETY

There are no issues related to patient safety in RayPlan 11B.

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

4 OTHER KNOWN ISSUES

4.1 GENERAL

Slow GPU computation on Windows Server 2016 if the GPU is in VDDM mode

Some GPU computations running on Windows Server 2016 with the GPUs in WDDM mode may be significantly slower than running the computation with the GPU in TCC mode.

[283869]

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 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]

Slight inconsistency in dose display

The following applies to all patient views where dose can be viewed on a patient image slice. If a slice is positioned exactly on the border between two voxels, and dose interpolation is disabled, the dose value presented in the view by the "Dose: XX Gy" annotation can differ from the actual presented color, with regards to the dose color table.

This is caused by the text value and the rendered dose color being fetched from different voxels. Both values are essentially correct, but they are not consistent.

The same can occur in the dose difference view, where the difference might seem larger than it actually is, because of neighboring voxels being compared.

[284619]

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]

Incorrect information in the Edit plan dialog when adding a new beam set, if current beam set has deprecated prescription

When adding a new beam set and the currently selected beam set has a prescription relating to beam set + background dose (deprecated functionality), the *Edit plan* dialog will incorrectly display that the prescription for the new beam set also will be set for beam set + background dose. This is incorrect since prescriptions for a new beam set relate to the beam set dose. The information in the *Edit plan* dialog will be corrected when switching beam sets in the dialog.

[344372]

4.2 IMPORT, EXPORT AND PLAN REPORTS

Import of approved plan causes all existing ROIs to be approved

When importing an approved plan to a patient with existing unapproved ROIs, the existing ROIs may become automatically approved.

336266

Laser export not possible for decubitus patients

Using the laser export functionality in the Virtual simulation module with a decubitus patient causes RayPlan to crash.

[331880]

RayPlan sometimes reports a successful TomoTherapy plan export as failed

When sending a RayPlan TomoTherapy plan to iDMS via RayGateway, there is a timeout in the connection between RayPlan and RayGateway after 10 minutes. If the transfer is still ongoing when the timeout starts, RayPlan will report a failed plan export even though the transfer is still in progress.

If this happens, review the RayGateway log to determine if the transfer was successful or not.

338918

Report Templates must be upgraded after upgrade to RayPlan 11B

The upgrade to RayPlan 11B 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]

Warnings listed in the beam set Warnings report table might be incorrect for approved plans

If a report is generated for a plan approved in an earlier RayPlan version than 11A, the warnings displayed in the beam set *Warnings* table might not reflect the warnings displayed at the time of approval. The beam set *Warnings* table is generated by RayPlan at the time when the report is created, by performing all checks that will cause warnings in RayPlan 11A. Therefore, there might be additional warnings in the report that were not present at the time of plan approval.

[344929]

4.3 PATIENT MODELING

Floating view in Image registration module

The floating view in the Image registration module is now a fusion view that only displays the secondary image set and contours. The change of the view type has changed how the view works/displays information. The following have changed:

- If Level/window is activated from the floating view it will affect the Primary image set instead of the Secondary. The level/window in the Secondary image set can be changed via Fusion tab instead.
- It is not possible to edit the PET color table from the floating view. The PET color table in the Secondary image set can be changed via Fusion tab instead.
- Scrolling in the floating view is limited to the Primary image set, e.g., if the Secondary image set is larger or does not overlap the Primary in the fusion views it will not be possible to scroll through all slices.
- The image orientation indicator, "Ray", does not update based on the registration rotations in the floating view.
- Position, Direction (transversal/sagittal/coronal), Patient direction letters, Imaging system name and Slice number are no longer displayed in the floating view.
- Image value in the floating view is not displayed if there is no registration between the Primary and Secondary image sets.

[409518]

4.4 BRACHYTHERAPY PLANNING

Mismatch of planned number of fractions and prescription between RayPlan and SagiNova version 2.1.4.0 or earlier

There is a mismatch in the interpretation of the DICOM RT Plan attributes *Planned number of fractions* {300A, 0078} and *Target prescription dose* {300A,0026} in RayPlan 10B compared to the brachytherapy afterloading system SagiNova version 2.1.4.0 or earlier.

When exporting plans from RayPlan:

- The target prescription dose is exported as the prescription dose per fraction multiplied by the number of fractions of the beam set.
- The planned number of fractions is exported as the number of fractions for the beam set.

When importing plans into SagiNova version 2.1.4.0 or earlier for treatment delivery:

- The prescription is interpreted as the prescription dose per fraction.
- The number of fractions is interpreted as the total number of fractions, including fractions for any previously delivered plans.

Possible consequences are:

- At treatment delivery, what is displayed as prescription per fraction on the SagiNova console is actually the total prescription dose for all fractions.
- It might not be possible to deliver more than one plan for each patient.

Consult with SagiNova application specialists for appropriate solutions.

[285641]

4.5 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]

4.6 PLAN OPTIMIZATION

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

DMMLC 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]

4.7 PLAN EVALUATION

Material view in Approval window

There are no tabs to select to display the material view in the Approval window. The material view can be selected instead by clicking on the image set name in a view and then selecting material in the drop-down that appears.

[409734]

4.8 CYBERKNIFE PLANNING

Verifying deliverability of CyberKnife plans

CyberKnife plans created in RayPlan may, for about 1% of the cases, fail the deliverability validation. Such plans will not be deliverable. The affected beam angles will be identified by the deliverability checks that are run at plan approval and plan export.

[344672]



CONTACT INFORMATION



RaySearch Laboratories AB (publ)
Eugeniavägen 18
SE-113 68 Stockholm
Sweden

Contact details head office

P.O. Box 3297
SE-103 65 Stockholm, Sweden
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 1 76 53 72 02

RaySearch Korea

Phone: +82 10 2230 2046

RaySearch Australia

Phone: +61 411 534 316

RaySearch Belgium

Phone: +32 475 36 80 07

RaySearch Germany

Phone: +49 30 893 606 90

RaySearch Singapore

Phone: +65 81 28 59 80

RaySearch China

Phone: +86 137 0111 5932

RaySearch Japan

Phone: +81 3 44 05 69 02

RaySearch UK

Phone: +44 2039 076791