RAYPLAN 2024B

Release Notes

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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

CE 2862

Complies with Medical Device Regulation (MDR) 2017/745. A copy of the corresponding Declaration of Conformity is available on request.

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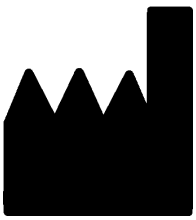
1 INTRODUCTION

1.1 ABOUT THIS DOCUMENT

This document contains important notes about the RayPlan 2024B system. It contains information related to patient safety and lists new features, known issues and possible workarounds.

Every user of RayPlan 2024B must be familiar with these known issues. Contact the manufacturer for any questions about the content.

1.2 MANUFACTURER CONTACT INFORMATION



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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 2024B

This chapter describes the news and improvements in RayPlan 2024B as compared to RayPlan 2024A.

2.1 GENERAL SYSTEM IMPROVEMENTS

- Support for secondary acceptance levels for clinical goals.
  - A third state of clinical goal fulfillment has been introduced and clinical goals are now reported as *Fulfilled* (green), *Acceptable* (yellow) or *Not fulfilled* (orange).
  - Two acceptance levels define the clinical goal fulfillment, a primary acceptance level and an optional secondary acceptance level. A clinical goal is considered *Fulfilled* if its primary acceptance level is met and *Acceptable* if only its secondary acceptance level is met.
  - If a clinical goal has no secondary acceptance level, it will either be *Fulfilled* or *Not fulfilled*.
- Clinical goal descriptions now use short format when displayed in the GUI e.g., "Dmean >= 40 Gy" instead of "At least 40 Gy average dose". The long format is available as a tooltip.
- It is now faster to load planning modules – especially for cases with a high number of visualized ROIs.
- Support for DICOM data with larger pixel data range than before.
  - Previously, import was blocked if either the minimum pixel value of a PET or MR image set, or the minimum HU value of a CT image set was less than -32768 or the maximum pixel value of a PET or MR image set, or the maximum HU value of a CT image set was more than 32767. Such images can now be imported and used in RayPlan.
  - This extended supported range removes the need for several existing import filters which rescale pixel data before import.
- Dose is now invalidated when dose computation settings are modified.
  - The *Compute dose* button is now disabled if a clinical dose computed with the latest dose engine version already exists.
- RayStorage improvements:

- It is now possible to use the command line to move patients between data sources. This makes it possible to, for example, schedule movement of patients that have not been changed for 30 days to a secondary database.
- The transfer screen in RayStorage now provides more options, including moving and copying to and from rsbak repositories.

2.1.1 Snapshots in reports

- The new snapshots functionality enables the user to take a screenshot of any part of the application window, add a title and a description, and include it in a treatment plan report.
- The *Snapshots* tab added to the left-hand panel displays all snapshots associated with the currently open treatment plan, organized into two lists: *Included in report* and *Excluded from report*. The snapshots can be moved between the lists. All snapshots added to the "included" list will be included when generating a treatment plan report, provided that the report template includes the snapshots module.

2.2 PATIENT DATA MANAGEMENT

- It is now possible to change the mass densities for the predefined levels in the CBCT to density table. Default densities are the same as in previous versions.

2.3 PATIENT MODELING

- It is now possible to add ROIs to a template in the *Structure template management* dialog. The options are to add a mapped ROI, a derived ROI or an empty ROI.
- It is now possible to use structure templates to copy or map ROIs from one image set to another. If an ROI in a template has initialization method *Mapping*, an image set from the patient can be selected when running the template and the ROI will be copied rigidly or mapped deformably from the selected image set to the new image set. It is also possible to run templates with mapped ROIs from protocols.
- In *Structure template management*, it is now possible to create a copy of a structure template and to change initialization for some types of ROIs, e.g. edit how an ROI should be mapped using the template.
- The toolbar in the *Structure definition* module now has a more compact design.
- In the *Patient modeling* module, it is possible to select *Show as supine* in the visualization settings to always display patients as Supine, regardless of scanning position.
- In RayPlan 2024B, the following template materials have been removed: Aluminum+, Aluminum2 Bone1, Bone+, Cartilage1 Bone2, Cartilage2 Bone1, LiF PE, LN10, PLA, PlasticAE C-552, PlasticBE B-100, PlasticTE A-150, RB2, SB5, Silicon [Si], Ti-6Al-4V, WT1. Existing plans will not be affected by this change.

2.4 BRACHYTHERAPY PLANNING

- The toolbar in the Brachy planning module now has a more compact design.
- It is now possible to edit the effective length of a channel.
- It is now possible to import applicator models from XML files. The imported applicator models can be saved as structure templates for fast loading during planning. Additionally, user-defined structures can be added to the structure templates, e.g. evaluation points (A-point).
- Improved rotate and translate functionality for applicator models, allowing coupled transformations of source path and applicator model ROIs.

2.5 VIRTUAL SIMULATION

- It is now possible to commission a LINAC treatment machine for Virtual simulation use only. See *section 2.9.1 Photon beam commissioning on page 12*.

2.6 PLAN OPTIMIZATION

- It is now possible to exclude beams from a co-optimized beam set. Excluded beams are not affected by the optimization, but the dose is a part of the beam set dose.
- Optimization with respect to segment MU is now supported for co-optimized beam sets.
- There was an issue where VMAT plans for wide targets, using a machine commissioned with Jaw movement rule *Per segment* (jaw tracking) and beam splitting strategy *Use multiple carriage groups* sometimes violated the *Maximum leaf out of carriage distance* constraint, resulting in one or many pauses during the delivery of an arc beam. This problem has now been resolved.

2.7 PLAN EVALUATION

- Evaluation doses are now always computed according to their own dose computation settings, not according to the current nominal beam set dose computation settings. This will affect re-computation of invalidated evaluation doses if the dose computation settings have been changed for the nominal beam set.

2.8 DICOM

- It is now possible to configure the order in which treatment beams and setup beams are exported in the Beam Sequence (300A,00B0) and Ion Beam Sequence (300A,03A2). This configuration is done when commissioning a machine. Some systems require the treatment beams to come first, others require that the setup beams come first.

2.9 RAYPHYSICS

2.9.1 Photon beam commissioning

- It is now possible to import open and standard wedge photon dose curves on W2CAD .asc format version 02.
- It is now possible to commission a LINAC treatment machine for virtual simulation use only, which allows for the virtual simulation use case without physics licenses. Such a machine contains no beam models, and it is therefore not possible to use it for dose computation.
- Template machine is updated for TrueBeam: 'T_TrueBeam'

2.9.2 Electron beam commissioning

- Template machine is updated for TrueBeam: 'T_TrueBeam'

2.10 RAYPLAN 2024B DOSE ENGINE UPDATES

The changes to the dose engines for RayPlan 2024B are listed below.

Dose engine	2024A	2024B	Requires recommissioning	Dose effect[i]	Comment
All	-	-	-	Negligible	Opened up for import of image sets which have higher pixels values than was previously allowed, i.e., densities used for dose computation can now be higher than previously in areas of the image set with high density, e.g., areas with metal artifacts that do not have a material override.
Photon Collapsed Cone	5.9	5.10	No	Negligible	
Photon Monte Carlo	3.1	3.2	No	Negligible	
Electron Monte Carlo	5.1	5.2	No	Negligible	

Dose engine	2024A	2024B	Requires recommis-sioning	Dose effect[i]	Comment
Brachy TG43	1.5	1.6	No	Negligible	

i The dose effect (Negligible/Minor/Major) refers to the effect when recommissioning of the machine model is not performed. After successful recommissioning the dose changes should be minor.

2.11 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 RayPlan 11B introduced changes in the dose statistics calculations. 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.

- Note that RayPlan 2024A introduces the possibility to associate a clinical goal to either the beam set dose or the plan dose. This information regarding existing plans and templates with clinical goals is important if upgrading from a RayPlan version earlier than 2024A:
  - Physical clinical goals in single beam set plans will now be automatically associated with that beam set.
  - For plans with multiple beam sets, physical clinical goals will be duplicated to ensure all possible associations within the plan. For example, a plan with two beam sets will yield three corresponding copies of each clinical goal: one for the plan and one for each of the two beam sets.
  - Clinical goals defined in templates will be assigned to beam set with name 'BeamSet1'. Users who plan with multiple beam sets are advised to update their templates with the correct association and beam set name.
- Note that RayPlan 2024B introduces secondary acceptance levels for clinical goals. It is important to note how this affects existing methods for clinical goal evaluation in scripting. When scripting is used to evaluate clinical goals with secondary acceptance levels, the methods will compare the clinical goal value with the secondary acceptance level and report fulfillment based on that. In other words, the methods will return *true* if a clinical goal is fulfilled (green), or *acceptable* (yellow) and *false* otherwise.

- For SMLC plans without optimization constraints, handling of leaf position bounds when continuing an optimization previously depended on whether intermediate dose was selected or not. The handling for the case with no intermediate dose has now been modified so that it is the same as when intermediate dose is selected. This typically affects the results for this type of optimization. Changes compared to previous RayPlan versions are expected to be small.
- The *Smart angles* algorithm for Conformal Arc has been modified to use a more accurate cost function when determining the optimal angle. It now accounts for closed leaf pairs that cannot be hidden behind the x-jaws.
- Function values are no longer automatically computed after running *Scale dose*.

2.12 RESOLVED FIELD SAFETY NOTICES (FSNS)

The following FSNs (Field Safety Notices) are resolved in RayPlan 2024B, as compared to RayPlan 2024A.

- FSN 130646
- FSN 133261

2.13 NEW AND SIGNIFICANTLY UPDATED WARNINGS

For the complete list of warnings, see *RSL-D-RP-2024B-IFU, RayPlan 2024B Instructions for Use*.

2.13.1 New warnings

WARNING!

Review warnings when using automatic import and segmentation workflow after automatic export to another system. Warnings generated during automatic import are displayed when opening the patient for the first time. If the automatic import and segmentation workflow is used to automatically export the created structures without opening the patient in RayStation, the exported structures must be reviewed in the consuming system. Any warnings generated at import are also accessible through scripting.

(932309)

WARNING!

Review channel lengths. The inner and effective channel lengths are critical values communicated directly to the afterloader for the execution of the treatment plan. It is imperative to recognize that any discrepancy in the channel lengths may not be detected by the machine. Errors in these values can result in significant deviations from the intended treatment.

When channel lengths are edited during treatment planning, it is essential to confirm that all edited lengths accurately reflect the intended treatment setup prior to the final approval and delivery of the treatment plan.

(936234)

2.13.2 Significantly updated warnings

WARNING!

Bolus ROIs need to be assigned to beam(s). Bolus ROIs are regarded as beam properties. In order for a bolus ROI to be used for radiation transport and dose computation for a certain beam, it must be assigned to that beam. If a bolus is to be used for all beams, it must be assigned to all beams individually. A bolus which is not assigned to any beam in a plan is not going to contribute to the dose computation at all.

A bolus ROI assigned to a beam will be:

- shown with solid line style in the 2D patient views,
- shown in the 3D patient view and
- included in the Material patient view when beam dose for the corresponding beam is selected.

(53471)

WARNING!

Review applicator models. Users are strongly advised to adhere to industry standards for quality assurance of brachytherapy applicators and treatment planning. This includes performing dosimetric verification using methods such as gafchromic film measurements, as recommended by the American Association of Physicists in Medicine (AAPM) in *Code of practice for brachytherapy physics: Report of the AAPM Radiation Therapy Committee Task Group No. 56* and in the *AAPM Medical Physics Practice Guideline 13.a*.

The user is advised to create a structure template including the applicator structures. After completing appropriate QA checks, it is crucial to approve the template to ensure that the applicator structures do not undergo unintended changes over time. During the treatment planning process, users should only use structures from these approved templates to maintain consistency and accuracy in treatment delivery.

(726082)

3 KNOWN ISSUES RELATED TO PATIENT SAFETY

There are no known issues related to patient safety in RayPlan 2024B.

Note: *Additional release notes may potentially be distributed shortly after installation.*

4 OTHER KNOWN ISSUES

4.1 GENERAL

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)

No warning is given when deleting a case containing approved plans

When a patient containing an approved plan is selected for deletion, the user will be notified and given the opportunity to cancel the deletion. However, if a case containing an approved plan is selected for deletion for a patient with multiple cases, no warning will be given to the user that an approved plan is about to be deleted.

(770318)

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 can become automatically approved. If this occurs, a UI message is given at import stating that the plan approval status will be transferred to the RTStruct.

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 2024B

The upgrade to RayPlan 2024B 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)

4.3 BRACHYTHERAPY PLANNING

Mismatch of planned number of fractions and prescription between RayPlan and SagiNova

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 compared to the brachytherapy afterloading system SagiNova. This applies specifically to SagiNova versions 2.1.4.0 or earlier. If

the clinic is using a version later that 2.1.4.0, contact customer support to verify whether the issue persists.

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 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)

Brachy Monte Carlo number of histories

The number of histories used to compute a brachy Monte Carlo dose distribution is not displayed in the patient views. This information can be retrieved through scripting. It is the responsibility of the user to ensure that a Monte Carlo dose is computed with a sufficient number of histories to reach an acceptable statistical uncertainty.

(1043893)

DICOM connectivity issue with Oncentra Brachy related to measured source paths

An issue has been identified affecting the DICOM import of measured applicator model source paths into Oncentra Brachy.

When importing an applicator model from an XML file into RayPlan, it is possible to import measured source paths. These measured source paths are characterized by absolute 3D positions of the source points that are not equidistant. The measured source paths are imported from the XML files as described in *RSL-D-RP-2024B-BAMDS, RayPlan 2024B Brachy Applicator Model Data Specification*, and the resulting 3D source positions in RayPlan correctly represent the source paths provided in the XML files. The 3D source positions are also correct in DICOM exports from RayPlan. However, when importing the file into Oncentra Brachy the measured source paths undergo a shift, causing a discrepancy between the absolute source positions in Oncentra Brachy and RayPlan. This could mean that a dose distribution recomputed in Oncentra does not match the corresponding dose distribution calculated in RayPlan.

The dose distribution computed by RayPlan is correct, provided that the applicator is correctly modeled in RayPlan. As noted in the *RSL-D-RP-2024B-IFU, RayPlan 2024B Instructions for Use* (see warning 726082, Review applicator models), users are strongly advised to adhere to industry standards on applicator model quality assurance to ensure that the applicator is accurately represented in RayPlan.

This issue is specific to measured source paths within applicator models and does not affect source paths reconstructed by other methods.

(1043992)

4.4 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)

4.5 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)

4.6 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)

The spine tracking grid smaller in Accuray TDC than the grid displayed in RayPlan

The spine tracking grid used and displayed in Accuray TDC (Treatment Delivery Console) for treatment delivery setup will be around 80% smaller than the grid visualized in RayPlan. In RayPlan, make sure to assign the grid a margin around the intended setup area. Note that the grid size is editable in Accuray TDC at delivery.

(933437)

4.7 RAYPHYSICS

Updated recommendations for detector height usage

Between RayPlan 11A and RayPlan 11B, recommendations on the usage of detector height and depth offset for depth dose curves have been updated. 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. When upgrading to a RayPlan version newer than 11A, 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-2024B-REF, RayPlan 2024B Reference Manual*, section *Depth offset and detector height* in *RSL-D-RP-2024B-RPHY, RayPlan 2024B RayPlan Physics Manual* and *RSL-D-RP-2024B-BCDS, RayPlan 2024B Beam Commissioning Data Specification* for information about the new recommendations.

(410561)

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