

RAYPLAN 12A

Release Notes

12A



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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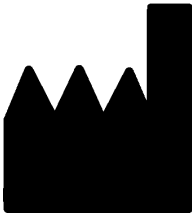
1 INTRODUCTION

1.1 ABOUT THIS DOCUMENT

This document contains important notes about the RayPlan 12A system. It contains information related to patient safety and lists new features, known issues and possible workarounds.

Every user of RayPlan 12A 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 12A

This chapter describes the news and improvements in RayPlan 12A compared to RayPlan 11B.

2.1 HIGHLIGHTS

- Brachy planning for Elekta Flexitron afterloaders.
- New, much faster electron Monte Carlo dose engine.
- CyberKnife planning improvements.

2.2 NON-FUNCTIONAL IMPROVEMENTS

- The audit log for a patient is now visible in RayPlan. Any major change of the patient is visible. It is possible to search and filter logs on time, user and category, as well as on free text.
- The index service now holds a cache of patients to make restarting RayPlan faster.

2.3 GENERAL SYSTEM IMPROVEMENTS

- Beam entry validation is now performed at dose computation, to ensure that warnings are displayed earlier in the planning process.
- It is now possible to add tags on plans and structure sets. The tags can be used to find or filter out specific patients, either in the *Open* dialog or when moving patient data between different systems using the RayStation Storage Tool.

2.4 PATIENT MODELING

- It is now possible to view inverse image registrations.
 - If there exists an image registration from image set A to image set B, the registration will be viewed in fusion views or side-by-side views and will be used when copying ROI geometries (no matter which of the image sets are primary/secondary).
- It is now possible to set an image registration as *Default for fusion*. The registration selected as *Default for fusion* will be automatically selected when activating fusion or side-by-side views, or when copying ROI geometries.

- Expand/contract margin computations for ROIs have been updated and are now faster. There may be minor differences to the computed margins compared to previous versions.
- It is now possible to set a default initialization method for a structure template.

2.5 BRACHYTHERAPY PLANNING

- It is now possible to create plans for Elekta Flexitron afterloaders. Plans created in RayPlan can be imported into Oncentra Brachy, and then be delivered on the afterloader.
- A new dwell time graph makes it possible to see all dwell times more accurately, and to easily modify dwell times manually.
- It is now possible to easily set dwell times for every second, fourth, fifth or tenth selected dwell point.

2.6 PLAN SETUP

- It is now possible to copy a beam set. A beam set can be copied within a plan or from another plan, if both plans use the same planning image set and patient treatment position.
- It is now possible to create a new plan by copying beam sets from other plans.
- The Plan setup module now includes two setup DRR views.
 - For imaging systems with multiple imagers, it is now possible to visualize different imagers in each DRR to support easier imaging isocenter positioning.

2.7 3D-CRT BEAM DESIGN

- The *Smart angles* algorithm for Conformal Arc has been modified to use a more accurate cost function when determining the optimal angle. Now, the cost is defined as the area of the smallest aperture fully containing all selected targets. This makes the algorithm useful for single targets as well.

2.8 PLAN OPTIMIZATION

- It is now possible to exclude DMLC beams (Sliding window) from the optimization and only optimize the other beams.
- The functions *Merge* and *Split* (unmerge) beams are now available for the treatment technique SMLC.
- Min or Max DVH objectives/constraints can now be specified either in relative or in absolute volume.
- When adding a clinical goal, *At most* is selected by default if the selected ROI is an OAR. This applies to *Average dose*, *Volume at dose* and *Dose at volume*.

2.9 GENERAL PHOTON PLANNING

- Beam templates created for the treatment technique SMLC can now be used for DMLC and vice versa. Beam templates created for VMAT/Conformal Arc can be used for Static Arc and vice versa.
- Monte Carlo dose computation inside and around low-density regions is improved, and statistical noise is reduced in these regions.
- In RayPlan Physics, it is now possible to configure an Elekta machine with an Agility head so that the minimum tip gap between opposing leaves is defined as a function of the displacement of the leaf pair center from the Y-axis. Thereby, dose leakage can be reduced, and normal tissue can be spared.
- In RayPlan Physics, the minimum field size (minimum distance between opposing jaws) can now be specified.
- It is now possible to specify accessory codes for photon blocks in the Beams list. The accessory code is required in plan reports for IEC 62083 compliance. If clinic specific report templates are used, add the accessory code to the template to avoid compliance warning in plan reports.

2.10 TOMOTHERAPY PLANNING

- The machine constraint *Max active leaf cycles per second* is now considered in the optimization of Tomo plans.
- When a new TomoHelical or TomoDirect plan is created, the delivery time factor gets the default value 1.50.

2.11 CYBERKNIFE PLANNING

- It is now possible to restrict the MU of a beam set or a segment when a CyberKnife plan is optimized.
- Candidate beam directions have been modified for cone/iris plans, to improve dose conformity. Beams with larger cones are more centrally positioned in the targets.
- It is now possible to view DRRs for both imagers when editing the align center and imaged volume.
- Support is added to create a 1-view margin ROI and base the motion on geometries from multiple phases of a 4DCT, and/or give the magnitude of organ motion as input. A margin in the imager coordinate space can be added.

2.12 ELECTRON PLANNING

- The previously used plug-in for in-patient transport for the electron Monte Carlo dose engine, called VMC++, has been exchanged with a version fully developed by RaySearch, which gives several advantages.

- The new electron Monte Carlo dose engine is implemented to run on the GPU, resulting in much faster dose computations.
- It is now possible to use user-specified material overrides.
- It is now possible to compute density perturbed dose for electrons.
- It is now possible to specify statistical uncertainty directly instead of number of histories for the electron Monte Carlo dose computation.
- It is now possible to specify accessory code for electron cutouts in the Beams list. The accessory code is required in plan reports for IEC 62083 compliance. If clinic specific report templates are used, add the accessory code to the template to avoid compliance warning in plan reports.

2.13 PLAN EVALUATION

- The tool *Create ROI from dose* can now also be used to create an ROI from an evaluation dose.
- Optimization objectives and constraints are now displayed in the Plan evaluation module.

2.14 DICOM

- It is now possible to export and import Deformable Spatial Registration objects.
- It is now possible to configure the DICOM export to enable increased precision in exported attributes with Value Representation (VR) Decimal String (DS). This is controlled by a setting and the old behavior is still default.
 - If increased precision is activated, DS attributes exported may be longer than what is allowed in DICOM (16 bytes). Exported DICOM files containing DS attributes (e.g., RT Structure Set and RT Plan) will also have a larger data size.
- The tolerance when importing image stacks that are not located exactly along a straight line, or with slightly varying Image Orientation, is improved. This solves three of five issues previously adjusted by the "MR Import" filter.
- The generation of the Dose Reference Description for the primary prescription is updated. The Dose Reference Description for this item will be set to the same value as the RT Plan Label. This replaces the previously existing filter "Edit Dose Reference Description for Mosaicq".
- (For clinics using RayCare only) DRRs can now be included in the automatic DICOM export when approving a beam set/treatment plan. The automatic export of DRRs is configured in Clinic settings.

2.15 PLAN REPORTS

- The generation of the Warnings table for plan reports has been updated. In previous RayPlan versions, the warnings that were produced for approved objects (plans, structure sets, etc.) were generated at the time of report creation. In RayPlan 12A, the warnings presented to the

user during approval are stored and displayed in the plan report. For objects approved in previous RayPlan versions, the previous behavior with warnings generated at the time of report creation remains.

- Series description is now reported for the planning image set in the default plan report.
- The full username from Active Directory will be used for approvals and in reports to make it easier to identify who made the approval.

2.16 VISUALIZATION

- View rotation in 3D and Room view has been improved to allow for more precise control of the view.

2.17 CLINIC SETTINGS

- It is now possible to configure the authentication behavior for the different security operations defined in RayPlan. The default is to prompt for username and password but it is possible to allow single sign on and allow the operation without entering the password.

2.18 RAYPLAN STORAGE TOOL

- Secondary data sources can now be configured to move patient records instead of copying the data. This will reduce data duplication and the setting will affect the behavior in the RayPlan *Open case* dialog.

2.19 PHOTON BEAM COMMISSIONING

- The commissioning wizard has been removed.
- It is now possible to specify accessory codes for cones and standard wedges.

2.20 ELECTRON BEAM COMMISSIONING

- The previously used plug-in for in-patient transport for the electron Monte Carlo dose engine, called VMC++, has been exchanged with a version fully developed by RaySearch which gives several advantages.
 - The computation is now performed using the GPU and is much faster.
 - It is now possible to specify statistical uncertainty directly instead of number of histories for the dose curve computation.
- A new step has been added to the auto modeling list, which computes all applicator curves with dose contributions. This step can be added after another auto-modeling step if curves computed with contributions are desired.
- The commissioning wizard has been removed.

- It is now possible to specify accessory code and tray ID for applicators.

2.21 CT COMMISSIONING

- The UI is improved, allowing a much larger HU to mass-density/SPR conversion plot.

2.22 DOSE ENGINE UPDATES

2.22.1 RayPlan 12A dose engine updates

To support an increased HU value range [-2000, 100 000], the list of reference materials for all dose engines except Collapsed Cone has been updated. Iron has been removed. Ti-6Al-4V, titanium, steel, CoCrMo, silver, tantalum and gold have been added. The consequence is that the dose computation for CTs containing pixels with densities above aluminum may yield significantly different results.

The changes to the dose engines for RayPlan 12A are listed below.

Dose engine	RS 11B	RS 12A	Dose effect	Comment
All	-	-	-	New voxel volume algorithm version due to an update of the density computation from CT image data. In cases where the External extends all the way out to the image stack border, voxels at the image stack border will generally get a lower density than before, since the part of such voxels that extends outside of the image border is now assumed to have density 0 g/cm ³ , while it previously was assumed to be 1 g/cm ³ .
Photon Collapsed Cone	5.6	5.7	Negligible	Existing machine models do not need to be re-commissioned.
Photon Monte Carlo	1.6	2.0	Small	Improvements to dose computation inside and around low-density regions. Adjustments have been made to the photon Monte Carlo engine to better handle low energy physics. For external beam treatment energies, the effect is small, but existing machine models need to be re-commissioned.

Dose engine	RS 11B	RS 12A	Dose effect	Comment
Electron Monte Carlo	3.10	4.0	Large	The previously used plug-in for in-patient transport for the electron Monte Carlo dose engine has been exchanged with a version developed by RaySearch. Existing machine models need to be re-commissioned.
Brachy TG43	1.2	1.3	Negligible	Existing machine models do not need to be re-commissioned.

2.23 CHANGED BEHAVIOR OF PREVIOUSLY RELEASED FUNCTIONALITY

- The generation of the Warnings table for plan reports has been updated. In previous RayPlan versions, the warnings that were produced for approved objects (plans, structure sets, etc.) were generated at the time of report creation. In RayPlan 12A, the warnings displayed during approval are stored and displayed in the plan report. For objects approved in previous RayPlan versions, the previous behavior with warnings generated at the time of report creation remains.
- All sequentially approved versions of a structure set will now be possible to export. All (sub) structure sets will be available for selection in the DICOM export dialog.
Exported approved plans will, as previously, always be exported with the (sub) structure set that includes the structures that were available at the time of plan approval.
- The CyberKnife functionality used to add an imager specific margin ROI has been removed. It is exchanged for the Add 1-view margin ROI functionality.
- Line doses in the plan evaluation module are no longer cleared when switching plan.
- 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.

3 KNOWN ISSUES RELATED TO PATIENT SAFETY

There are no issues related to patient safety in RayPlan 12A.

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]

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 12A

The upgrade to RayPlan 12A 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 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:

- 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.
- 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 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 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]

4.7 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]



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