RAYSTATION 11A SP2

Release Notes

Disclaimer

Canada: Carbon and helium ion treatment planning, proton Wobbling, proton Line Scanning, BNCT planning and the Microdosimetric Kinetic Model are not available in Canada for regulatory reasons. These features are controlled by licenses and these licenses (rayCarbonPhysics, rayHeliumPhysics, rayWobbling, rayLineScanning, rayBoron and rayMKM) are not available in Canada. In Canada, machine learning models for treatment planning must be cleared by Health Canada prior to clinical use. User training of machine learning planning models is not available in Canada. Deep Learning Segmentation is limited to Computed Tomography imaging in Canada. Training machine learning segmentation models using multiple image sets is not allowed in Canada.

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

The United States: Carbon and helium ion treatment planning, BNCT planning and the Microdosimetric Kinetic Model are not available in the United States for regulatory reasons. These features are controlled by licenses and these licenses (rayCarbonPhysics, rayHeliumPhysics, rayBoron and rayMKM) are not available in the United States. In the United States, machine learning models for treatment planning must be cleared by the FDA prior to clinical use. Training machine learning segmentation models using multiple image sets is not allowed in the United States.

Declaration of conformity

$C\,\epsilon$ 0413

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

Copyright

Printed material

Hard copies of Instructions for Use and Release Notes related documents are available upon request.

RaySearch
Laboratories

TABLE OF CONTENTS

1   INTRODUCTION

1.1   ABOUT THIS DOCUMENT

This document contains important notes about the RayStation 11A system. It contains information related to patient safety and lists new features, known issues and possible workarounds.

Every user of RayStation 11A 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)
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 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 RAYSTATION 11A

This chapter describes the news and improvements in RayStation 11A compared to RayStation 10B.

2.1 CYBERKNIFE PLANNING

- Similar workflow as for other treatment techniques in RayStation.

- CyberKnife M6 and S7 systems are supported.

- Planning and optimization for machines equipped with fixed cones, iris cones and MLC.

- Collapsed Cone and Monte Carlo dose computation.

- Support for all CyberKnife Synchrony techniques for target tracking and real-time motion synchronization.

2.2 GENERAL SYSTEM IMPROVEMENTS

- Support for multiple prescriptions. It is now possible to setup multiple prescriptions for a beam set.

- Prescriptions will now always prescribe dose for each beam set separately. Prescriptions relating to beam set + background dose are obsolete. Beam sets from previous RayStation versions with such prescriptions cannot be approved and the prescription will not be included when the beam set is DICOM exported.

- RayStation now presents the nominal dose contribution per treatment beam for all prescriptions defined on a beam set. This information is found in the new Prescriptions tab and will be DICOM exported if this plan export setting is selected for the treatment machine.

- It is now possible to have more decimals displayed for dose values. The default is 0 decimals if the unit is cGy and 2 decimals if the unit is Gy. This can be increased up to 5 decimals for cGy and 7 decimals for Gy. Dose/fraction is displayed with a few extra decimals.

- The ROI-list and the POI-list now display the ROI/POI geometry status for the active image set.

- Filterable combo boxes are used in more places including, but not limited to, selection of image set, templates, treatment machine, ROI type and POI type.

2.3   PATIENT MODELING

- A new fusion mode, the difference fusion, has been added. With the difference fusion, the difference in image values between the primary and secondary image sets is displayed.

- The tools Create field-of-view ROI and Create external ROI on limited FOV data are now available for oblique image sets.

- An issue where the Create wall, Expand/Contract, and ROI algebra tools produced erroneous results for Deep Learning-segmented ROIs, has been fixed (FSN 73474).

2.4   BRACHYTHERAPY PLANNING

- A new additional workspace layout simplifies channel reconstruction.

- Possible to change image view rotation directly in the patient views.

- Support for complete 3D applicator models including outer applicator geometry as well as channels.

- A new smart draw tool makes it possible to semi-automatically reconstruct applicator channels.

- POIs can now be created, moved and deleted in the Brachy planning module.

- It is now possible to modify the geometry of a channel candidate.

- A channel candidate can now be flipped, to enable reconstructing either from tip or the connector.

- Possible to copy dwell time distribution from another plan, or from one channel to another in the current plan.

- Possible to update to current source for a plan having a deprecated source. Dwell times are automatically rescaled.

- Possible to automatically create a dose grid that covers active dwell points with user specified margin.

2.5   PLAN SETUP

- The plan overview tab (list of beam sets and plan information) has moved from the upper left corner to the bottom tab group.

- A new Prescriptions tab is added to all planning modules, and it displays all prescriptions and nominal contributions for the current beam set.

- It is now possible to define a custom imaging isocenter position for setup beams.

- The option to not create a dose grid when setting up a plan is removed. A dose grid covering the external, bolus, support and fixation ROIs will always be set for all beam sets when creating a plan.

- There is an additional Room view tab in the Plan setup module as well as in the beam design modules, so the Room view is now possible to view side-by-side with the 3D view.

2.6 3D-CRT BEAM DESIGN

- Support for restricting collimator angles when using the smart angles function for conformal arc plans.

2.7 PLAN OPTIMIZATION

- Improved optimization speed for some plans. Reduced memory usage when optimizing plans that have dose grids with many voxels. The frequency of user interface updates during optimization may differ from previous versions.
- Guard leaves are now supported for the DMLC treatment technique.
- Optimization with respect to Segment MU requires substantially less memory than in previous versions.

2.8 MULTI-CRITERIA OPTIMIZATION

- The sliders in the MCO navigator can now also be adjusted using the arrow keys.

2.9 GENERAL PHOTON PLANNING

- Support for Monte Carlo dose computation on multiple GPUs.
- An unwanted behavior, where dose could be marked as clinical after merging a beam with clinical dose with a beam with non-clinical dose, has been fixed (FSN 74977).

2.10 TOMOTHERAPY PLANNING

- It is now possible to export simulation plans for TomoHelical treatment plans that have motion synchronization selected. The export is done from the Imaging Angles tab.

2.11 PROTON BROAD BEAM PLANNING

- Scripting support for most parts of broad beam planning workflow allowing for more automation. This includes beam creation as well as creation and conformance of block and compensator. The compensator pixel thicknesses, and many other properties, are now editable from scripting.
- Support for snouts where the block is positioned 'upstream of the compensator' and the position of the block tray depends on the compensator thickness.
- Support for snouts where there is a gap between the block and compensator for setups where the compensator tray position is 'downstream of the block' or the block tray position is 'upstream of the compensator'.

2.12 PLAN EVALUATION

- The line dose graph no longer resets the zoom level when scrolling between slices in the patient view.

2.13 ROBUST EVALUATION

- A new UI toolbar displays the used final dose settings for the nominal plan and for the doses in the scenario group. If the settings are mixed within a scenario group, a warning is displayed. If the settings for the nominal dose differ from the settings for the scenario groups, an information text is displayed in the toolbar.

- If mixed dose algorithm settings are used within a scenario group the voxel wise min/max dose will be null.

- An unwanted behavior, where the voxelwise worst value of a clinical goal was not updated after editing the clinical goal, has been fixed (FSN 78320).

2.14 TOLERANCE TABLES

- It is now possible to create and approve tolerance tables in RayPhysics. RtPlan and RtIonPlan tables are supported.

- A tolerance table can be assigned in RayStation for each beam set from a list of approved tolerance tables for the selected machine.

- It is now possible to view the values of the tolerance table selected for the beam set.

2.15 SETUP IMAGING SYSTEMS AND SETUP IMAGERS

- 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.

2.16 DICOM

- Import of IONTRIS plans is now possible. The correct machine needs to exist in the database to be able to import.

- Updated behavior when assigning a Dose Reference UID to a RayStation prescription.

- The Dose Reference UID is now used to identify a dose reference across multiple RT Plans. From RayStation 11A prescriptions that share the same treatment site and prescription type, will also share the same Dose Reference UID. This means that their beam sets will be interpreted as giving nominal contribution to the same prescription object (i.e., dose reference).

  Note that for some OIS this will affect how a beam set will tie to the OIS prescription. In some OIS, subsequently exported beam sets, that have prescriptions with the same dose reference UID, will automatically report nominal progress to the same OIS prescription.

- A dose reference is defined within a case, and only prescriptions within that case will refer to the same dose reference. The prescribed dose levels are allowed to differ, and prescriptions with different dose levels but sharing the same treatment site (ROI/POI/SITE-name) and prescription type (AverageDose, DoseAtVolume + 'volume percentage', DoseAtPoint or DoseAtSite) will refer to the same dose reference.

  Example: One beam set with a prescription of 38 Gy D98% to 'PTV' and another beam set prescribing 20 Gy D98% also to 'PTV' will relate to the same dose reference while a third beam set prescribing 40 Gy D50% to 'PTV' will not.

2.17 SCRIPTING

- RayStation 11A includes scripting APIs for RayStation version 8A and higher. The APIs are installed together with RayStation in the folder \RaySearch Laboratories\RayStation Script Api Html Documentation. RayStation also includes scripts to help upgrade scripts to version 11A.

- RayStation now supports CPython 3.8 including pdf, Excel, WPF and WinForms. The support for IronPython 2.7 will be removed in future RayStation versions.

- RayStation now includes IPython console.

2.18 CLINIC SETTINGS

- New settings for number of decimals for dose display, has been added.

2.19 RAAS (RAYSTATION AS A SERVICE)

- All RaaS services now use the RayCareEnvironment in ClinicSettings for configuration. The RayCare configuration dialog in the RaaS installer has been removed.

2.20 RAYPHYSICS

2.20.1 Photon beam commissioning

- Possible to import diagonal profiles on *.mcc format with arbitrary scan angle for rectangular fields.

- Possible to model a CyberKnife treatment machine.

2.20.2   Ion beam commissioning

- Support for snouts where the block is positioned 'upstream of the compensator' and the position of the block tray depends on the compensator thickness.

- Support for snouts where there is a gap between the block and compensator when the compensator tray position is 'downstream of the block' or the block tray position is 'upstream of the compensator'.

2.21   DOSE ENGINE UPDATES

2.21.1   RayStation 11A dose engine updates

The changes to the dose engines for RayStation 11A are listed below.

Dose engine	10B	11A	Dose effect	Comment
All	-	-	Negligible	Changed reconstruction from contours to voxel ROIs for contours on oblique image sets.
Photon Collapsed Cone	5.4	5.5	Negligible	Existing machine models do not need to be re-commissioned.
Photon Monte Carlo	1.4	1.5	Negligible	Support for computation on multiple GPUs. Existing machine models do not need to be re-commissioned.
Electron Monte Carlo	3.8	3.9	Negligible	Existing machine models do not need to be re-commissioned.
Proton PBS Monte Carlo	5.1	5.2	Negligible	Existing machine models do not need to be re-commissioned.
Proton PBS Pencil Beam	6.1	6.2	Negligible	Existing machine models do not need to be re-commissioned.
Proton US/DS/Wob-bling Pencil Beam	4.6	4.7	Negligible	Existing machine models do not need to be re-commissioned.
Carbon PBS Pencil Beam	4.2	4.3	Negligible	Existing machine models do not need to be re-commissioned.
Brachy TG43	1.0	1.1	Negligible	Existing machine models do not need to be re-commissioned.

2.22 CHANGED BEHAVIOR OF PREVIOUSLY RELEASED FUNCTIONALITY

- Note that RayStation 11A introduces some changes regarding prescriptions. This information is important when upgrading to 11A:

  - Prescriptions will always prescribe dose for each beam set separately. Prescriptions defined in RayStation 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.

  - Prescriptions that are set using a plan generation protocol will now always relate to the beam set dose only. Make sure to review existing plan generation protocols when upgrading.

  - Prescription percentage is no longer included in exported prescription dose levels. In RayStation versions prior to 11A, the Prescription percentage defined in RayStation was included in the exported Target Prescription Dose. This has been changed so that only the Prescribed dose defined in RayStation is exported as Target Prescription Dose. This change also affects exported nominal dose contributions.

  - In RayStation versions prior to 11A, the Dose Reference UID exported in RayStation 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 RayStation 8B introduced handling of effective dose (RBE dose) for protons. This information is important for proton users if upgrading from a RayStation version earlier than 8B:

  - Existing proton machines in the system will be converted to RBE type, that is, it is assumed that a constant factor of 1.1 has been used. Contact RaySearch if this is not valid for any machine in the database.

  - Import of RayStation RT Ion Plan and RT Dose of modality proton and with dose type PHYSICAL that was exported from RayStation versions earlier than 8B will be treated as RBE level if the machine name in the RT Ion Plan refers to an existing RBE machine.

  - RT Dose of dose type PHYSICAL from other systems or from RayStation versions earlier than 8B with a machine that does not have the RBE included in the beam model will be imported as in earlier versions and will not be displayed as RBE dose in RayStation. The same applies if the referenced machine does not exist in the database. It is the responsibility of the user to know if the dose should be treated as physical or as RBE/photon equivalent. However, if such a dose is used as background dose in subsequent planning, it will be treated as an effective dose.

  For more details, refer to *Appendix B Effective dose for protons*.

- An unwanted behavior in the robust optimization of proton/ion plans has been fixed. When computing the range error caused by a given density error in the patient, the thickness of a potential range shifter was included, which is not correct since the density of the range shifter is accurately known. This bug affects the approximate scenario doses and leads to somewhat overly robust plans. It also gives slightly larger margins in the initial spot selection. With a range shifter of 7 cm WET and a density uncertainty of 3.5%, the dose will extend 2.5 mm WET too deep for the low-density scenarios, and 2.5 mm WET too shallow for the high-density scenarios.

  The algorithms for approximate scenario dose calculation and for selecting the extra spots in the robust optimization have also been updated for plans without a range shifter. These changes are small, however, and should not affect plan quality.

- For TomoHelical and TomoDirect plans, the number of projections displayed in the beam list has been increased by one. This also means that the estimated delivery time and the planned meterset for these treatment techniques has been increased by one projection time.

- It is no longer possible to re-compute photon dose curves for all commissioned LINAC machines from the Select GPUs … dialog in RayPhysics. Instead, self-tests for all computations using GPU can be run from this dialog.

- Setup imaging device is renamed Setup imaging system and can now have one or several Setup imagers. Refer to the *RSL-D-RS-11A-RPHY, RayStation 11A RayPhysics Manual* for details.

  - Note that when upgrading to RayStation 11A, each existing setup imaging device will be converted to a setup imaging system with one or several setup imagers. If the original setup imaging device includes multiple imaging gantry angle offsets, one setup imager per gantry angle offset will be created. The setup imagers will be named after the setup imaging device they were converted from, plus an index. For example, a setup imaging device with name 'Device' and three imaging gantry angle offsets will be converted to a setup imaging system with three setup imagers named: 'Device', 'Device (2)', 'Device (3)'

  - It is recommended to manually inspect the names of the generated setup imagers and update them as found suitable. Pay extra attention if the generated name has more than 16 characters. The names can have a length of up to 64 characters in RayStation but they are exported in the DICOM attribute 'RT Image Radiation Machine Name (3002,0020)', which according to the standard shall have a maximum length of 16 characters. Some external systems might crop the names to 16 characters, resulting in that originally unique names appear identical, leading to a potential risk of mix-up of the setup imager DRRs.

- In previous versions of RayStation, when using the functionality *Compute beam set parameters* in the Proton beam design module, the SOBP Modulation chosen by the system was determined under the assumption that a range compensator was included in the beam. This could yield sub optimal modulations for beams that do not use a range compensator which is commonly the case in, for example, ocular PT. This problem has now been fixed in RayStation 11A.

3   KNOWN ISSUES RELATED TO PATIENT SAFETY

Density may be incorrect in voxels intersected by both the External ROI and an ROI of type Support, Fixation or Bolus, FSN 84236

There is an issue where the combined density in a dose grid voxel partially covered by the External ROI and also partially covered by an ROI of type Bolus, Support or Fixation may be unexpected. The density in the voxel can be both under- and overestimated.

This issue concerns electron, proton, helium and carbon planning. For photons the effect of the error will be negligible compared to other uncertainties.

Make sure to read the details about this issue and perform all actions as described in *Appendix A Density in voxels intersected by both the External ROI and an ROI of type Support, Fixation or Bolus*.

(403058)

Setup imager name length

The name of a setup imager, specified in RayPhysics, is allowed to be 64 characters long. However, it is exported in the DICOM attribute 'RT Image Radiation Machine Name (3002,0020)', which according to the standard shall have a maximum length of 16 characters. Some external systems might crop the names to 16 characters, resulting in that originally unique names appear identical, leading to a potential risk of mix-up of setup imager DRRs. Always ensure that the setup imager name length is a maximum of 16 characters.

(344751)

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

(144699)

Limitations when using RayStation with large image set
RayStation 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

- Hybrid deformable registration might run out of memory for large image sets

- Biomechanical deformable registration might crash for large image sets

- Automated Breast Planning does not work with large image sets

- Creating large ROIs with gray-level thresholding might cause a crash

(144212)

Limitations when using multiple image sets in a treatment plan
Plan total dose is not available for plans with multiple beam sets that have different planning image sets. Without plan dose it is not possible to:

- Approve the plan

- Generate plan report

- Enable the plan for dose tracking

- Use the plan in adaptive replanning

(341059)

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 being fetched from the nearby voxel A, while the rendered dose color gets its value from the neighboring voxel B. 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)

Crash if deleting beam set with deprecated prescription

Deleting a beam set with a prescription on beam set + background dose (deprecated functionality) leads to a crash. The RayStation crash can be avoided by deleting the prescription before attempting to delete the beam set. Note that when the prescription is deleted in the *Edit plan* dialog, the dialog needs to be closed and re-opened before removing the beam set.

(344803)

Incorrect rotation angle in Room view visualization of ring gantry for Vero

For Vero treatments, the 3D visualization of the ring gantry in the *Room view* has an incorrect rotation angle.

(403630)

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 RayStation to crash.

(331880)

RayStation sometimes reports a successful TomoTherapy plan export as failed

When sending a RayStation TomoTherapy plan to iDMS via RayGateway, there is a timeout in the connection between RayStation and RayGateway after 10 minutes. If the transfer is still ongoing when the timeout starts, RayStation 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 RayStation 11A

The upgrade to RayStation 11A 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 RayStation 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 RayStation at the time when the report is created, by performing all checks that will cause warnings in RayStation 11A. Therefore, there might be additional warnings in the report that were not present at the time of plan approval.

(344929)

Only the primary prescription is included in plan reports

In RayStation 11A it is possible to have multiple prescriptions on a beam set. Only the primary prescription will be included in the *Prescription* section in the plan report. If any prescription is not

4

fulfilled, the user will get a warning at report generation and the warning will be present in the plan report.

<div align="right">(341616)</div>

Nominal dose contributions missing in plan report

RayStation presents the nominal dose contribution per treatment beam for all prescriptions defined on a beam set. This information is found in the *Prescriptions* tab in RayStation and will be DICOM exported if this setting is included in the beam model. However, the information is not present in the plan report. Refer to *RSL-D-RS-11A-USM, RayStation 11A User Manual*, to *RSL-D-RS-11A-RPHY, RayStation 11A RayPhysics Manual* and to *RSL-D-RS-11A-DCS, RayStation 11A DICOM Conformance Statement* for more information.

<div align="right">(344518)</div>

On rare occasions ROI contours might be missing in patient views in the plan report

If creating a plan report immediately after opening a patient, and the patient only has been open in the Patient data management module, the reconstruction of ROI contours for patient 2D/3D images may not be completed in the report. This is visualized in the report images where *Reconstructing ROIs* is displayed in the images.

<div align="right">(343404)</div>

Rescaled CT to density graph displayed incorrectly in plan reports

The rescaled CT to density graph is displayed incorrectly if it is included in the plan report. The scaling of the axes becomes incorrect, and the graph content cannot be seen.

<div align="right">(338248)</div>

4.3   PATIENT MODELING

Memory crashes can occur when running large hybrid deformable registration computations on GPU

GPU computation of deformable registration on large cases can result in memory related crashes when using the highest grid resolution. The occurrence depends on the GPU specification and the grid size.

<div align="right">(69150)</div>

4.4   BRACHYTHERAPY PLANNING

Mismatch of planned number of fractions and prescription between RayStation 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 RayStation 10B compared to the brachytherapy afterloading system SagiNova version 2.1.4.0 or earlier.

When exporting plans from RayStation:

- 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

Tolerance tables can only be selected in the Plan design modules

Tolerance tables can only be selected from the *Edit plan* dialog in the Plan design modules. In other modules, the functionality for selecting a tolerance table or viewing its values in *Edit plan* dialogs is missing. The workaround is to use the Plan design module to select tolerance table.

For adapted plans, the Edit plan dialog in Plan design is locked and no changes can be made. By default, the adapted plan will get the tolerance table of the original plan. The button for viewing the tolerance table values will be greyed out. The workaround for changing the tolerance table or viewing its values is to use scripting.

The label of the currently selected tolerance table is always shown correctly in Plan setup and approval modules. If the user changes the machine so that the selected tolerance table does not match an approved template, a warning will be displayed at plan approval.

(340631)

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)

No full beam entry validation for 3D-CRT and Static Arc cone plans

The beam entry validation, performed at plan approval, plan export and report generation, will not properly validate 3D-CRT and Static Arc beams using cones. It will not validate that the fluence enters the body and dose grid in an area that gives correct dose computation. The user must manually validate the proper beam and dose grid setup.

(344799)

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)

Plan approval and DICOM export of robust optimized plans might crash

After using robust optimization over additional image sets, some actions performed on the plan will cause subsequent plan approval and DICOM export to crash. Performing an optimization (zero iterations is enough) or unchecking the secondary image sets in the Robustness Settings dialog will correct this. Examples of actions that can trigger a crash are dose grid edits and version upgrade of RayStation.

(138537)

Robust optimization with respect to organ motion does not work for beam sets with background dose

It is not possible to robustly optimize a plan with respect to organ motion uncertainty if the beam set has a background dose, even though the background dose is not taken into account in the optimization functions. This may, for example, prevent adaptive workflows. A workaround is to create a new beam set without background dose, perform the robust optimization, and sum the background and beam set doses in the Plan evaluation module.

(284485)

4.7   PLAN EVALUATION

Prescription evaluation shown in the Robust evaluation module

When multiple prescriptions are present for a beam set, the prescription fulfillment status may not be displayed properly for all prescriptions in the Robust evaluation module. Refer to other modules (e.g., Plan optimization or Plan evaluation) when prescription fulfillment is to be evaluated. Also note that the prescriptions always are evaluated on the nominal beam set dose and never will show the fulfillment status for any of the evaluated robust scenario doses.

(344714)

4.8   CYBERKNIFE PLANNING

Verifying deliverability of CyberKnife plans

CyberKnife plans created in RayStation 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.

To check if a plan is affected by this issue before approval, the script method `beam_set.CheckCyberKnifeDeliverability()` can be run. The affected segments can be manually removed before running a continued optimization for the last adjustments.

(344672)

Moving the spine grid after optimization will move the treated volume for spine techniques

It is possible to move the spine grid (by using *Edit imaged volume*) after optimization. For spine techniques, this will lead to a movement of the treated volume, that is, all segment isocenters will move accordingly. For spine techniques, make sure to reset the optimization before editing the spine grid.

(344785)

4.9   PROTON AND LIGHT ION PLANNING

Beam line objects and beam parameters not updated when changing machine for an adapted plan

If the machine is changed when either creating a new adapted plan or when editing an existing adapted plan, then the beam line objects and spot tune ID of the beams in the adapted plan will not be updated automatically. The snout of the previous machine will remain in the beam list, which might be incompatible with the new machine. The range shifter might be listed as [Unknown]. In the case that the machine was changed when creating a new adapted plan, the range modulator might also be listed as [Unknown].

For any affected beam, open the Edit beam dialog and update the necessary beam line objects and spot tune ID and then click OK. Note that if only the range modulator is missing, it is enough to open the Edit beam dialog and close it again by clicking OK. This workaround will update the beam line objects and allow continued use of the beam.

(224066)

4.10   TREATMENT DELIVERY

CT-reference in treatment course

In the Plan Evaluation module, the "Image set" column shows the image set for the computed dose. However, the "Images" column of a Treatment Course shows the acquired images on that fraction, not the image sets that were used for dose computation. The image set used for dose computation and the image set for deformed doses are displayed by clicking the arrow in the Dose column.

(62376)

Mixed beam sets in plan fraction schedule

For plans with multiple beam sets where the plan fraction schedule has been manually edited for a subsequent beam set, a change to the number of fractions for a preceding beam set will result in a faulty fraction schedule where beam sets are no longer planned in sequence. This can lead to issues in dose tracking and adaptive replanning. To prevent this, always reset the plan fraction schedule to default before changing number of fractions for beam sets in a multi beam set plan after the fractionation pattern has been manually edited.

(331775)

Treatment course list is not correctly updated when a new deformable registration is approved

When a new deformable registration is approved for dose accumulation, and a deformed dose already exists, the information about the dose deformations in the treatment course list is not displayed correctly. However, the updated deformed dose is displayed correctly. The list is updated by recalculating the deformed dose.

(341739)

4.11   AUTOMATED PLANNING

Protect setting always set to None in beam list after TomoTherapy optimization running HPC in Plan Explorer

After optimization of a TomoTherapy treatment plan using HPC in Plan Explorer, the Protect setting is always set to 'None'. However, protect settings selected prior to optimization are correctly used during the optimization.

(136436)

Incorrect Beam on interval might be set back without notification

In the Plan Explorer Edit Exploration Plan dialog, when editing the Beam on interval value in the Beam Optimization Settings tab, the value will change back to the previous value without notice if the entered value is out of range. This could easily be missed, for example if the dialog is closed directly after entering an incorrect value. The Beam on interval value is only applicable for VMAT treatment machines commissioned for burst mode (mArc).

(144086)

4.12   BIOLOGICAL EVALUATION AND OPTIMIZATION

Biological evaluation of fractionation schedule can lead to crash when creating new adapted plan

If the fractionation schedule is edited from the Biological Evaluation module, the system will crash when creating an adapted plan. To perform biological evaluation, copy the plan and do the fractionation schedule changes on the copy.

(138535)

Undo/redo invalidates response curves in the Biological Evaluation module

In the Biological Evaluation module, the response curves are removed on undo/redo. Recompute the function values to restore the response curves.

(138536)

4.13   MEDICAL ONCOLOGY PLANNING

No regimen information shown in Open Case dialog

When selecting a patient plan with a regimen in the Open Case dialog, which is used for opening a patient case that is already in the database, there is no information shown indicating that the plan has a regimen. There is a list of beam sets of the patient plan, which is empty for plans with regimens.

(146680)

Backup and restore does not work correctly for medical oncology patients

When performing a backup of a medical oncology patient, not all referenced data is included in the backup. Vitals, medication statements, active substances and regimen templates are not included in backups. However, these can be backed up using the RayStation Storage tool, see section D.3.12 Export data in *RSL-D-RS-11A-USM, RayStation 11A User Manual*.

To back up a patient, start by backing up all referenced active substances, regimen templates, vitals and medication statements in the RayStation Storage tool. Vitals and medication statements are combined and backed up as observations. When this is done, back up the patient in RayStation. To restore the patient, start by restoring active substances, regimen templates and observations in RayStation Storage Tool, see section D.3.11 Import data in *RSL-D-RS-11A-USM, RayStation 11A User Manual*, and then restore the patient in RayStation.

(143750)

4.14   SCRIPTING

Limitations regarding scripted reference functions

It is not possible to approve a beam set that includes a scripted reference dose function referencing an unlocked dose. This will lead to a crash. Also, approving a beam set that includes a scripted reference dose function referencing a locked dose, and consecutively unlocking the referenced dose will lead to a crash.

If a scripted reference dose function refers to an unlocked dose, there will be no notifications if the referenced dose is changed or removed. Finally, there is no guarantee when upgrading to new versions of RayStation that upgrades of optimization problems including scripted reference dose functions will retain the dose references.

(285544)

4

5   UPDATES IN RAYSTATION 11A SP1

This chapter describes the updates in RayStation 11A SP1 as compared to RayStation 11A.

5.1   NEWS AND IMPROVEMENTS IN RAYSTATION 11A SP1

Improved beam angle selection in CyberKnife optimization

The algorithm for creating CyberKnife plans has been improved by increasing the number of beam directions that are considered during optimization, and by formulating the beam angle selection problem in a more efficient manner.

5.2   RESOLVED ISSUES

Resolved: Unable to run optimization after adding robust objective functions using template

There was an issue when using templates to add robust objectives to an optimization problem where robustness parameters were already defined. In these situations, the optimization could not be started without a special license. This has now been resolved.

(345081)

Resolved: Task with checklist makes RayStation crash (RayCare users only)

There was an issue with the planning task list where tasks with checklists made RayStation crash. This has now been resolved.

(398547)

5.3   UPDATED MANUALS

The following manuals have been updated in RayStation 11A SP1:

- RSL-D-RS-11A-IFU-2.0 RayStation 11A SP1 Instructions For Use

- RSL-D-RS-11A-RN-2.0 RayStation 11A SP1 Release Notes

- RSL-D-RS-11A-RTIFU-2.0 RayStation 11A SP1 RayTreat 5A SP1 Instructions For Use

Note: *The RayCommand Instructions for Use for 2A is not applicable for RayStation 11A SP1 since RayCommand 2A is not compatible with RayStation 11A SP1.*

5

6   UPDATES IN RAYSTATION 11A SP2

This chapter describes the updates in RayStation 11A SP2 as compared to RayStation 11A SP1.

6.1   FOUND ISSUES

One new safety related issue has been found, 403058. It is described in detail in *chapter 3 Known issues related to patient safety*.

One new issue (not safety related) has been found, 403630. It is described in detail in *chapter 4 Other known issues*.

6.2   RESOLVED ISSUES

Resolved: Incorrect jaw positions for TomoTherapy plans after changing dose grid and continuing an optimization, FSN 83773

There was an issue with TomoTherapy optimization where the positions of the jaws could change unexpectedly for some control points. This could occur if the dynamic jaw mode was used and an optimization was continued after changing the dose grid or modifying the target ROI. This has now been resolved.

(401428)

Resolved: Issue with robust optimization with respect to organ motion for VMAT

There was an issue with robust optimization with respect to organ motion for VMAT, making the plan less robust than intended. This has now been resolved.

(402875)

Resolved: Incorrect dose color table reference value for some plans

The reference value for the dose color table was incorrect for some dose display modes when prescription was used as reference. This has now been resolved.

(344471, 398938)

Resolved: CyberKnife optimization does not filter out beam directions with invalid beam entry in the patient

RayStation CyberKnife optimization did not filter out beam directions that enter through an area where the image set cuts the patient (e.g., the upper or lower parts of the scan). This has now been resolved.

6

All candidate beams running risk of causing beam entry validation failure due to image set entrance (see *RSL-D-RS-11A-USM, RayStation 11A User Manual*, section *6.1.15 Beam entry validation*) will be filtered out at the initial parts of the optimization. For cone plans, only beam directions where the open area of each cone has a correct entrance are passed on to the optimizer. For MLC plans, only beam directions where the fully open MLC area gives a correct entrance are passed on to the optimizer.

As for standard validation, the restriction can be remedied by adding material override ROIs outside of the image set.

(344676)

Resolved: CyberKnife beams unnecessarily directed to outer parts of the target when MLC collimation is applied

For cases with a relatively small target that well fits within the size of the MLC, some beams were directed to the outer parts of the target although this was not necessary. This has now been resolved.

(402882)

Resolved: Cone visualization is reset after CyberKnife optimization

If the cone visualization was turned off it was always turned on after CyberKnife optimization. This has now been resolved.

(401707)

Resolved: Error if no ROI is created by a deep learning segmentation model

When a deep learning segmentation model could not create an ROI, an error was shown when saving the model generated ROI copies. This has now been resolved.

(345270)

Resolved: Isocenter is sometimes moved incorrectly

Moving isocenter interactively in Beam's Eye View (BEV) or in Setup DRR view could sometimes make the isocenter move using wrong coordinates. This has now been resolved.

(399550)

Resolved: Crash in QA module when using tools for moving setup beam isocenter or target tracking grid

There were system crashes when using the tools for moving setup beam isocenter or target tracking grid in the QA module in combination with deleting the QA plan or changing the motion synchronization mode. This has now been resolved.

(344464)

6.3   UPDATED MANUALS

The following manuals have been updated in RayStation 11A SP2:

• RSL-D-RS-11A-IFU-3.0 RayStation 11A SP2 Instructions For Use

• RSL-D-RS-11A-RN-3.0 RayStation 11A SP2 Release Notes

- [RSL-D-RS-11A-RTIFU-3.0 RayStation 11A SP2 RayTreat 5A SP2 Instructions For Use](#)

- [RSL-D-RS-11A-RTAASTDITS-2.0 RayStation 11A RayTreat 5A as a Service Treatment Device Integration Test Specification](#)

- [RSL-D-RS-11A-RTTDITS-2.0 RayStation 11A RayTreat 5A Treatment Device Integration Test Specification](#)

- [RSL-D-RS-11A-ATP-2.0 RayStation 11A Product Acceptance Test Protocol](#)

- [RSL-D-RS-11A-SEG-2.0 RayStation 11A System Environment Guidelines](#)

Note: *The RayCommand Instructions for Use for 2A is not applicable for RayStation 11A SP2 since RayCommand 2A is not compatible with RayStation 11A SP2.*

6

A DENSITY IN VOXELS INTERSECTED BY BOTH THE EXTERNAL ROI AND AN ROI OF TYPE SUPPORT, FIXATION OR BOLUS

A.1 DESCRIPTION

For all dose computations, a density is assigned to each dose grid voxel. The density in a voxel is a combination of underlying CT voxels resampled to the dose grid resolution, and density from ROIs with material override that cover at least part of the voxel. This notice concerns an issue where the combined density in a dose grid voxel partially covered by the External ROI and also partially covered by an ROI of type Bolus, Support or Fixation may be unexpected. The density in the voxel can be both under- and overestimated. An example where the density is overestimated at the border between a Bolus ROI and the External ROI is shown in Figure 1.

The magnitude of the issue will depend on how the External ROI contour cuts the dose grid voxels at the CT density/air border. The issue will be smaller or non-existent, if the External ROI corresponds well with the CT density/air border. See Figure 2 for an example of the effect for different External ROI contours. It is recommended to use the automatic tool in RayStation to create the External ROI, but the issue might still be present. Larger problems can occur if the External ROI is imported from another system or manually edited.
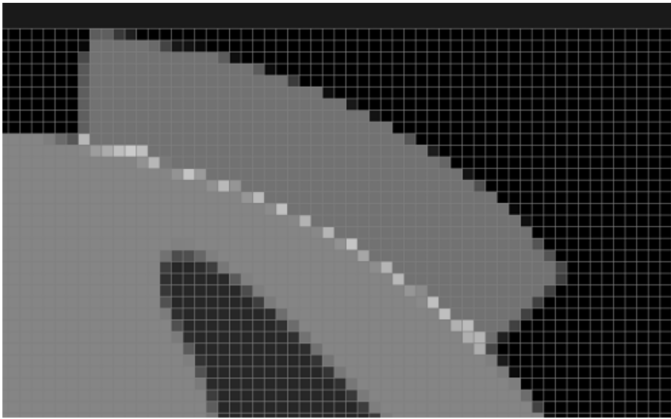
Figure 1.   An example where the density is overestimated at the border between a Bolus ROI and the External ROI. The image shows density re-sampled to dose grid voxel resolution. This is the resolution used during dose computation.
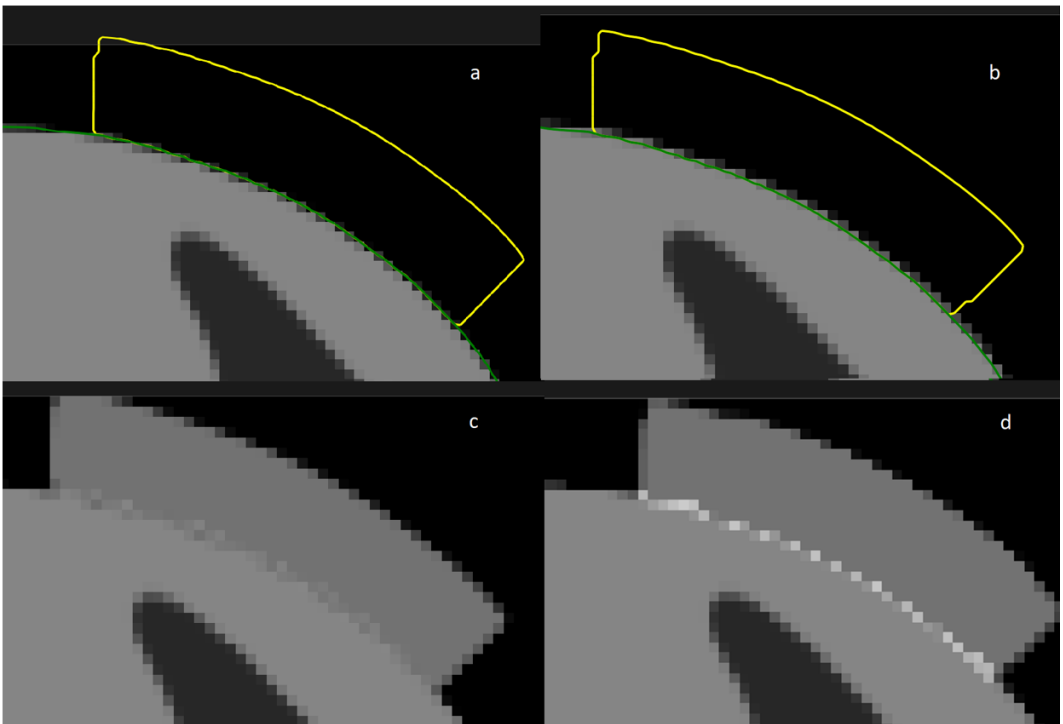

Figure 2.   Density at the External ROI/Bolus ROI border for different External ROI contours. (a) External ROI contour (green) in relation to the CT data for an External ROI created with the automatic tool with default settings in RayStation. (b) External contour (green) in relation to the CT data for an External ROI not created with the automatic tool function. (c) The combined density of

the CT data and the Bolus ROI (yellow contour) for case (a), with mixed density at the border. (d) The combined density of the CT data and the Bolus ROI (yellow contour) for case (b). The density is clearly overestimated at the border between the External ROI and the Bolus ROI. The images show density re-sampled to dose grid voxel resolution. This is the resolution used during dose computation.

The same issue as described above for density handling exists when stopping power ratios are used instead of densities.

The users have previously been informed about this issue in RayStation Physics training courses, but only for the combination of electron planning and Bolus ROIs. It has come to our attention that it has not been adequately described for the combination of electron planning and Support and Fixation ROIs, and not described at all for other charged particles, such as protons and carbon ions. In addition, no information about this issue can be found in the RayStation labeling.

The issue could lead to a maximum density of a surface voxel that equals the sum of the CT density and the bolus/support/fixation density in that voxel. In most cases, the effect will be much smaller.

A.2   ACTIONS TO BE TAKEN BY THE USER

- Use the automatic tool in RayStation to create the External ROI.

- When using a Support or Fixation ROI of tissue-like material (density around 1), extend this ROI a few millimeters inside the External ROI to cover the surface voxels of the patient.

- If the Support or Fixation ROI differs significantly from the adjacent body tissue, an extra help ROI with material override set to a suitable material, for example, 'Skin', can be created inside the External ROI. The help ROI must have a width of a few millimeters and extend along the part of the patient surface connected to the Support or Fixation ROI. The same workflow can be used for Bolus ROIs in combination with electron beams. See Figure 3 for an example.
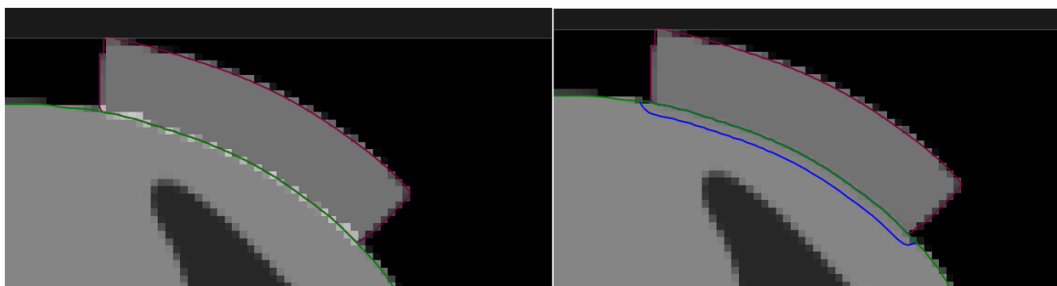

Figure 3.   To the left, CT density is used for the entire External ROI (green contour) and a material override is set on the Bolus ROI (purple contour), with the resulting overestimated density at the border. To the right, a help ROI (blue contour) with material override has been added inside the External ROI so that the External/Bolus ROI border is between two material overrides instead of CT density and material override. In the second case, the density is not overestimated. The images show density re-sampled to dose grid voxel resolution. This is the resolution used during dose computation.

- If the bolus/support/fixation device is part of the CT data, an alternative solution is to include its structure inside the External ROI. In this case the structure should not be defined as a Bolus, Support or Fixation ROI, but as a normal ROI, by setting the ROI type to, for example 'Other'. When included in the External ROI, the user can choose to use the CT densities or to apply a material override to the structure. If this method is applied for a bolus, the user must make sure that only the applicable beams pass through the structure.

- For protons and light ions, the user should consider using a higher density uncertainty than normal in robust optimization for active scanning techniques and larger proximal and distal margins for the target in passive techniques, when shooting through a Fixation or Support ROI.

- Educate planning staff and all users about this workaround.

B EFFECTIVE DOSE FOR PROTONS

B.1 BACKGROUND

Starting with RayStation 8B the effective dose of proton treatments is treated explicitly, either by including a constant factor in the absolute dosimetry in the machine model or by combining a machine model based on physical dose in the absolute dosimetry with a constant factor RBE model. When upgrading from a RayStation version prior to RayStation 8B to RayStation 8B or later, all existing machine models in the database will be assumed to have been modeled with a constant factor of 1.1 in the absolute dosimetry to take the relative biological effects of protons into account. Contact RaySearch support if this is not valid for any machine in the database.

B.2 DESCRIPTION

- The RBE factor can either be included in the machine model (as was the standard workflow in RayStation versions prior to 8B) or be set in an RBE model.

  - If the RBE factor is included in the machine model, it is assumed to be 1.1. These machines are referred to as 'RBE'.

  - A clinical RBE model with factor 1.1 is included in every proton RayStation package. This is to be combined with machine models based on physical dose. These machines are referred to as 'PHY'.

  - For other constant factors than 1.1, the user needs to specify and commission a new RBE model in RayBiology. This option can only be used for PHY machines.

- **All existing proton machines in the system will be converted to dose type RBE, where it is assumed that a constant factor of 1.1 has been used to scale absolute dosimetry measurements. Correspondingly, the dose in all existing plans will be converted to RBE dose.**

- Display of RBE/PHY for PHY machine in the RayStation modules Plan design, Plan optimization and Plan evaluation.

  - Possible to toggle between physical and RBE dose in these modules.

  - Possible to view the RBE factor in the Difference view in Plan evaluation.

- For RBE machines, the only existing dose object is RBE dose. For PHY machines, RBE dose is the primary dose in all modules with the following exceptions:

- Display of Beam Dose Specification Points (BDSP) will be in physical dose.

- All doses in the QA preparation module will be in physical dose.

- DICOM import:

  - Import of RayStation RtIonPlan and RtDose of modality proton and with dose type PHYSICAL from earlier versions of RayStation than RayStation 8B will be treated as RBE dose if the machine name in the RtIonPlan refers to an existing machine with RBE included in the model.

  - RtDose of dose type PHYSICAL from other systems or from RayStation versions prior to 8B with a machine that does not have the RBE included in the beam model will be imported as in earlier versions and will not be displayed as RBE dose in RayStation. The same applies if the referenced machine does not exist in the database. It is the responsibility of the user to know if the dose should be treated as physical or RBE/photon equivalent. However, if such a dose is used as background dose in subsequent planning, it will be treated as an effective dose.

  Note: *Plans for machines from Mitsubishi Electric Co follow different rules and the behavior has not been changed from versions prior to RayStation 8B.*

- DICOM export:

  - Treatment plans and QA plans for proton machines with dose type RBE (changed behavior compared to RayStation versions prior to 8B where all proton doses were exported as PHYSICAL):

    # Only EFFECTIVE RT Dose elements will be exported.

    # BDSP in RT Plan elements will be exported as EFFECTIVE.

  - Treatment plans for machines with dose type PHY:

    # Both EFFECTIVE and PHYSICAL RT Dose elements will be exported.

    # BDSP in RT Plan elements will be exported as PHYSICAL.

  - QA plans for machines with dose type PHY:

    # Only PHYSICAL RT Dose elements will be exported.

    # BDSP in RT Plan elements will be exported as PHYSICAL.

  Note: *Plans for machines from Mitsubishi Electric Co follow different rules and the behavior has not been changed from versions prior to RayStation 8B.*

CONTACT INFORMATION

RaySearch Laboratories AB (publ)
Sveavägen 44
SE-111 34 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 Belgium
Phone: +32 475 36 80 07

RaySearch China
Phone: +86 137 0111 5932

RaySearch France
Phone: +33 1 76 53 72 02

RaySearch Germany
Phone: +49 30 893 606 90

RaySearch Japan
Phone: +81 3 44 05 69 02

RaySearch Korea
Phone: +82 10 2230 2046

RaySearch Singapore
Phone: +65 81 28 59 80

RaySearch UK
Phone: +44 2039 076791

RaySearch Australia
Phone: +61 411 534 316

RaySearch Laboratories