RAYPLAN 11A SP2

Release Notes

Traceback information:
Workspace Main version a674
Checked in 2021-10-07
Skribenta version 5.4.033

Disclaimer

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

Declaration of conformity

CE 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.

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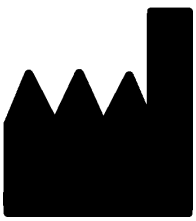
1 INTRODUCTION

1.1 ABOUT THIS DOCUMENT

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

Every user of RayPlan 11A 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 11A

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

2.1 CYBERKNIFE PLANNING

- Similar workflow as for other treatment techniques in RayPlan.
- 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 RayPlan versions with such prescriptions cannot be approved and the prescription will not be included when the beam set is DICOM exported.
- RayPlan 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.
- 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 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).

2.9 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.

2.10 PLAN EVALUATION

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

2.11 TOLERANCE TABLES

- It is now possible to create and approve tolerance tables in RayPlan Physics.
- A tolerance table can be assigned in RayPlan 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.

2.12 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.

2.13 DICOM

- Updated behavior when assigning a Dose Reference UID to a RayPlan prescription.
  - The Dose Reference UID is now used to identify a dose reference across multiple RT Plans. From RayPlan 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.

2.14 CLINIC SETTINGS

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

2.15 RAYPLAN PHYSICS

2.15.1 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.

2.16 DOSE ENGINE UPDATES

2.16.1 RayPlan 11A dose engine updates

The changes to the dose engines for RayPlan 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.
Brachy TG43	1.0	1.1	Negligible	Existing machine models do not need to be re-commissioned.

2.17 CHANGED BEHAVIOR OF PREVIOUSLY RELEASED FUNCTIONALITY

- Note that RayPlan 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 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.

- 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 RayPlan Physics. 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-RP-11A-RPHY, RayPlan 11A RayPlan Physics Manual* for details.
    - Note that when upgrading to RayPlan 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 RayPlan 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.

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 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 RayPlan Physics, 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 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 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 RayPlan 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 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 11A

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

(344929)

Only the primary prescription is included in plan reports

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

(341616)

Nominal dose contributions missing in plan report

RayPlan 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 RayPlan 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-RP-11A-USM, RayPlan 11A User Manual*, to *RSL-D-RP-11A-RPHY, RayPlan 11A RayPlan Physics Manual* and to *RSL-D-RP-11A-DCS, RayPlan 11A DICOM Conformance Statement* for more information.

(344518)

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.

(343404)

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.

(338248)

4.3 BRACHYTHERAPY PLANNING

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

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

When exporting plans from RayPlan:

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

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

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

Possible consequences are:

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

Consult with SagiNova application specialists for appropriate solutions.

(285641)

4.4 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)

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)

4.5 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)

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)

5 UPDATES IN RAYPLAN 11A SP2

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

5.1 NEWS AND IMPROVEMENTS IN RAYPLAN 11A SP2

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 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*.

5.3 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: 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

RayPlan 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.

All candidate beams running risk of causing beam entry validation failure due to image set entrance (see *RSL-D-RP-11A-USM, RayPlan 11A User Manual*, section *6.1.14 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: 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)

5.4 UPDATED MANUALS

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

- RSL-D-RP-11A-IFU-2.0 RayPlan 11A SP2 Instructions For Use
- RSL-D-RP-11A-RN-2.0 RayPlan 11A SP2 Release Notes
- RSL-D-RP-11A-ATP-2.0 RayPlan 11A Product Acceptance Test Protocol
- RSL-D-RP-11A-SEG-2.0 RayPlan 11A System Environment Guidelines

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 RayPlan 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.

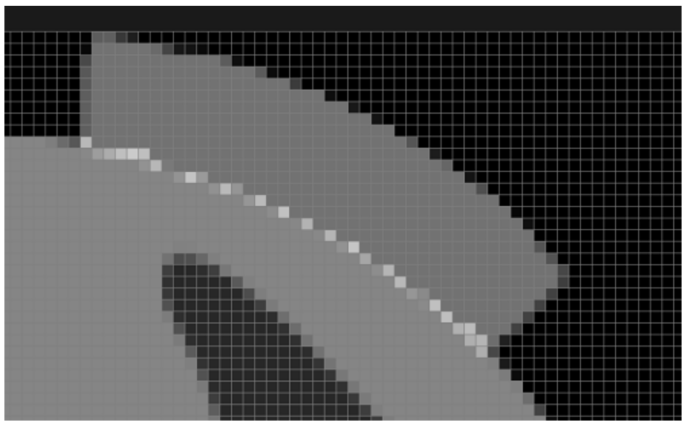

Figure 1. An example where the density is overestimated at the border between a Bolus ROI and the External ROI. The image shows density re-sampled to dose grid voxel resolution. This is the resolution used during dose computation.

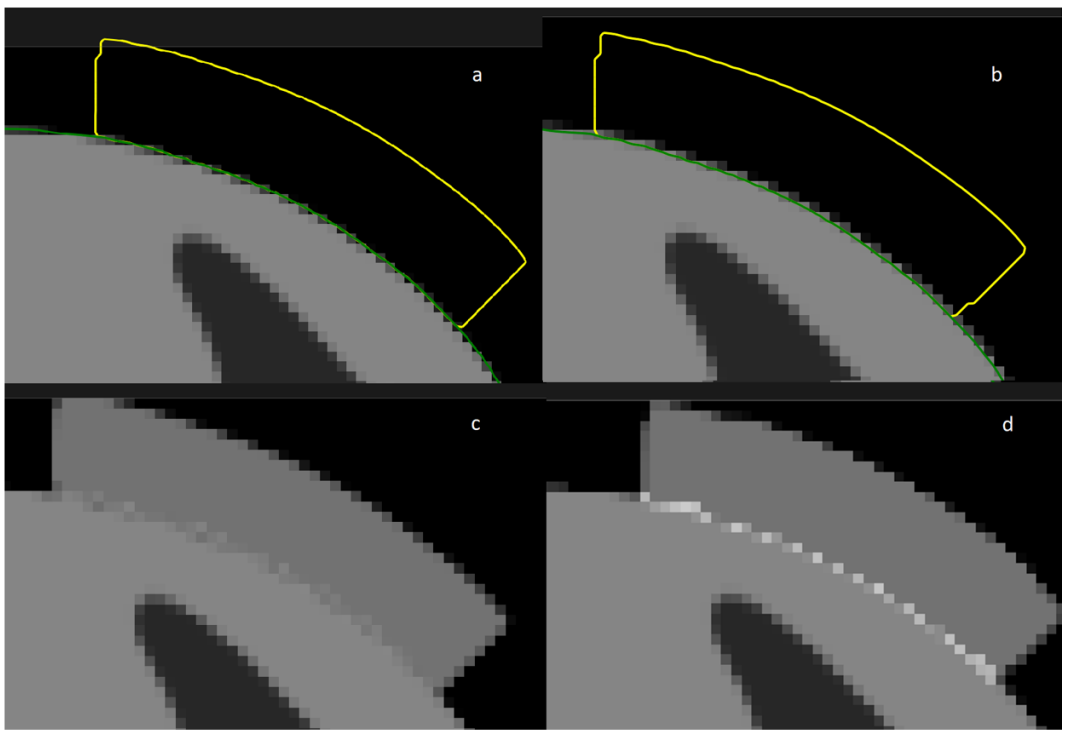

Figure 2. Density at the External ROI/Bolus ROI border for different External ROI contours. (a) External ROI contour (green) in relation to the CT data for an External ROI created with the automatic tool with default settings in RayPlan. (b) External contour (green) in relation to the CT data for an 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 users have previously been informed about this issue in RayPlan 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. In addition, no information about this issue can be found in the RayPlan 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 RayPlan 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.

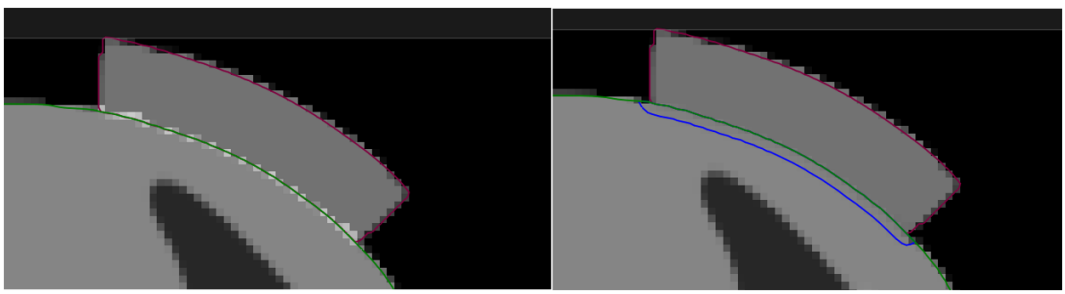

Figure 3. To the left, CT density is used for the entire External ROI (green contour) and a material override is set on the Bolus ROI (purple contour), with the resulting overestimated density at the border. To the right, a help ROI (blue contour) with material override has been added inside the External 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.

- Educate planning staff and all users about this workaround.

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RSL-D-RP-11A-RN-EN-2.0-2021-10-07
RayPlan 11A SP2 Release Notes

RaySearch Laboratories