Disclaimer

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

Declaration of conformity

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 10B system. It contains information related to patient safety and lists new features, known issues and possible workarounds.

Every user of RayPlan 10B 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.
This chapter describes the news and improvements in RayPlan 10B compared to RayPlan 10A SP1.

## 2.1 HIGHLIGHTS

- HDR brachytherapy planning.
- Dose calculation and planning on oblique image sets.
- Improvements regarding jaw and MLC positioning for LINACs.
- Improved support for large datasets and many simultaneous users.

## 2.2 HDR BRACHYTHERAPY PLANNING

- Creation of plans for brachytherapy High Dose Rate (HDR) treatments.
- Automatic channel reconstruction on CT image sets.
- Channel reconstruction based on predefined channel geometry.
- Dwell time optimization.
- Tools for selecting specific dwell points and editing corresponding dwell times.
- Channel reconstruction and plan evaluation using arbitrary image view rotation.
- Dwell time and dose scaling.
- Dose computation based on the TG43 formalism.

## 2.3 NON-FUNCTIONAL IMPROVEMENTS

- More robust and faster when saving to rsbak file format.

## 2.4 GENERAL SYSTEM IMPROVEMENTS

- The ROI algebra dialog can now be launched from the ROI list context menu (Shortcut Ctrl + L). No resulting ROI is preselected. For a derived ROI, the Edit derived ROI dialog is also available in the context menu and will open the relevant dialog to modify the derived ROI.
The function *Move POI to slice intersection* is now available from the context menu of the POI list in all modules where *Localize POI* is available.

Tooltips in the toolbar will now show both the tool description and the reason for it being disabled instead of just one of them. Keyboard shortcut, if any, will also be displayed.

Auto recovery data can be stored on disk to offload the database server. Storage location (database or file system) is selected in the Clinic Settings application. Default value for RayPlan 10B is file system and storage on the local disk.

The database size for a patient can now be calculated in both primary and secondary databases.

### 2.5 PATIENT DATA MANAGEMENT

- The *Edit patient data* dialog is updated to show ideographic and phonetic representations of the patient name (also supported from scripting methods). Which representations to show is selected in the Clinic Settings application.

### 2.6 PATIENT MODELING

- New keyboard shortcut for faster navigation. The shortcut Ctrl + G moves focus to the *Current ROI* or *Current POI* drop-down list (depending on visibility). Type part or the full name of the desired ROI/POI and press Ctrl + Enter to select and localize the highlighted ROI.
- Improved reconstruction from contours to voxel ROIs.
- Possible to use a limiting ROI for 3D region growing.
- It is now possible to store which image sets are selected as primary and secondary.
- Possible to use a limiting ROI in the Expand/Contract dialog.

### 2.7 PLAN SETUP

- Oblique image sets can now be used for planning. This feature requires a separate license which will only be distributed to a selected group of clinics to start with.
- Shifts to imaging/setup beam isocenters are presented in the *Patient setup* dialog and plan reports.
- Default table top pitch and roll couch angles are set from the selected planning image set if present in the DICOM data.

### 2.8 PLAN OPTIMIZATION

The VMAT algorithm has been improved. The directions from which fluence optimization is performed have been increased, which makes the representation of the target projections more exact.
2.9 GENERAL PHOTON PLANNING

- Jaw positions can now be defined to be rounded to 1, 2 or 3 decimals (defined per treatment machine in RayPlan Physics).
- Possible to define the behavior of guard leaves per treatment machine in RayPlan Physics.

2.10 PLAN EVALUATION

- Possible to calculate dose on additional oblique data sets.
- Multiple warnings at approval will now be displayed as a bullet list, with the warning icon as bullet.

2.11 PLAN REPORTS

- It is now possible to include evaluation doses in treatment plan reports. Which evaluation doses to include are selected when the report is created. DVH, clinical goals, dose statistics, dose views (T/S/C) and dose difference (one direction only) can be included. The selected report template determines which of these will be displayed in the report. The image slice to show in the dose and dose difference views can be selected before generating the report.
- The percentage outside dose grid for ROIs reported for clinical goals is now always correct. [FSN 68727, fixed in RayPlan 10A SP1]
- The values for couch pitch and couch roll for setup beams are now always reported correctly. [FSN 69129, fixed in RayPlan 10A SP1]

2.12 DICOM

- Import of oblique CT and MR image sets is now supported. [This feature requires a separate license which will only be distributed to a selected group of clinics to start with.]
- Possible to define some export properties per beam set. The new Export properties dialog is opened from the RayPlan menu, under DICOM export. The introduction of this dialog replaces the following DICOM export filters:
  - RSL-D-61-386 Rename Treatment Machine
  - RSL-D-61-359 Stereotactic with Cone to MOSAIQ
- Added support for import of open MR images with Patient Positions HLS, HLP, FLS and FLP. The Patient Positions are interpreted as follows:
  - HLS -> HFS
  - HLP -> HFP
- FLS -> FFS
- FLP -> FFP

• Added warnings in DICOM import dialog for Storage SCP if missing files are detected. [Added in RayPlan 10A SP1]

• In previous versions of RayPlan, import of corrupt DICOM data could lead to incorrectly linked prescription ROI/POI and bolus ROI. These issues have now been fixed. [FSN 66704, fixed in RayPlan 10A SP1]

### 2.13 VISUALIZATION

• Changed behavior when maximizing patient views:
  - When maximizing a patient view with a double click or by clicking the maximize window button, the patient view now only expands so that the beam list is not hidden behind the patient view. Shortcuts for various ways of expanding the patient views can be found in the shortcuts list.

• Several improvements to DVH views:
  - It is no longer possible to zoom out further than the range of visible curves in the DVH diagram. Zooming out with the mouse wheel stops when all curves are fully visible.
  - Mouse wheel zoom is centered on the position of the mouse pointer instead of in the middle of the DVH graph.
  - The visualization option Show enhanced DVH has been split into two options: Light background and Thick lines. This means that it is now possible to have thick lines on a dark background.
  - The light background color has been changed to white. ROI colors are adjusted, if necessary, to enhance visibility.
  - The additional option Text size has been added to change the font size of axis labels, axis values and header text.
  - When a curve is clicked, the thickness of the line increases to make the curve stand out.
  - It is possible to change curve style for curve sets, for example, when comparing doses in the Plan evaluation module. The preset curve style is the same as before.

• Possible to edit visualization of an ROI from the ROI properties dialog. In addition to the ROI details/POI details dialog, the user can now change the visualization of a single ROI by accessing the ROI properties dialog.

• Possible to change rotation axes when rotating in the 3D view. It is now possible to rotate along the frontal axis and the longitudinal axis or the sagittal axis and the longitudinal axis in the 3D view.
• Possible to scroll/view the Beam’s Eye View (BEV) for each degree along the arc of a newly created arc beam before optimizing.

2.14 CLINIC SETTINGS

• The setting Allow localization point as isocenter for setup beams is removed, as the selection of isocenter for setup beams is now always visible if the user selects to create setup beams for the treatment plan.

2.15 RAYPLAN PHYSICS

2.15.1 Photon beam commissioning

• Random number handling has been changed for photon Monte Carlo dose curves to make the dose curve computation deterministic regardless of which set of curves are computed.

• Rounded jaw positions:
  - Possible to define if jaw positions shall be rounded to 1, 2 or 3 decimals for plans created in RayPlan.
  - Two rounding modes are supported.

• Guard leaves:
  - Possible to define if guard leaves shall be opened for plans created in RayPlan.
  - Possible to define the distance from the y-jaw within which guard leaves shall open.
  - The updated handling of guard leaves changes the rectangular field setup used when computing dose curves for some field sizes for affected machines. This leads to slight changes in computed dose curves for these field sizes compared to the previous version.

2.16 DOSE ENGINE UPDATES

2.16.1 RayPlan 10B dose engine updates

The changes to the dose engines for RayPlan 10B are listed below.

<table>
<thead>
<tr>
<th>Dose engine</th>
<th>10A SP1</th>
<th>10B</th>
<th>Dose effect</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>-</td>
<td>-</td>
<td>Negligible</td>
<td>Changed reconstruction from contours to voxel ROIs.</td>
</tr>
</tbody>
</table>
### 2.17 Changed behavior of previously released functionality

- Clinic setting to allow different setup beam isocenter (localization point) is removed. Now the option is always available when adding/editing beam sets. Default behavior is unaffected, setup beams will be created to treatment beam isocenters if no other option is selected.
• Behavior of importing ROIs has changed. In previous versions, only the name of the ROI was compared and import of an ROI with a name that conflicted with an existing name would be disregarded. The name conflict is now resolved by adding a sequence number (e.g., ‘External’, ‘External 1’, ‘External 2’ etc.) as names must be unique within the patient model. The check if an ROI name already exists is now done by looking at the combination of ROI Number and SOP Instance UID.

• Support for DICOM Person Name in alphabetic, ideographic and phonetic representations now allows patient name to be parsed correctly according to the DICOM Person Name encoding. This will affect presentation in all places where the patient name is shown. Previous versions would include the character = which is special in DICOM and should not be displayed. This character and anything that follows up to the character ^, also special in DICOM, would be included in one of the patient name components (Last name, middle name, first name, title or suffix).

  - Example: Doe^John=Unknown

    In RayPlan 10A this would present as: John=Unknown (first name) Doe (last name)

    In RayPlan 10B this would present as: John (alphabetic first name) Doe (alphabetic last name), Unknown (ideographic first name)

• Editing of polygons and splines in the BEV can no longer be canceled with the ESC key. Instead, the Ctrl key shall be used as for other editing tools.

• It is no longer possible to select a GPU that supports ECC RAM if this is not enabled.

• Approved phantoms are no longer possible to delete from the Beam 3D modeling module in RayPlan Physics.
There are no issues related to patient safety in RayPlan 10B.

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

Report Templates must be upgraded after upgrade to RayPlan 10B
The upgrade to RayPlan 10B 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.

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.

Relative DVH x-axis not properly updated when changing number of fractions
When changing the number of fractions in a plan, the DVH x-axis is not updated correspondingly when relative dose is displayed. A workaround is to switch the Dose axis to ‘Absolute’ and then back to ‘Relative’.

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.

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
**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.

**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.

**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.

**Limitation in the auto recovery functionality**

The auto recovery functionality has a limitation when it comes to the amount of data that can be handled. Actions that produce more than 2 GB of modified data cannot be handled and RayPlan will crash to prevent memory corruption. The workaround is to turn off auto recovery in the Clinic Settings application.

**The slice position indicator might be incorrect for coronal images in the plan report**

If the first patient view included in a plan report is a coronal view, the slice position will have the incorrect sign [ +/- ]. This is due to an issue using the DICOM coordinate system for the first image, instead of the IEC coordinate system.

To avoid the issue, do not create plan report templates with a coronal view as the first patient view. Also, when including evaluation doses in a plan report, make sure the first patient view included is not coronal.
4.2 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.

4.3 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”.

[285641]

[144701]
4.4 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]
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