RAYTREAT 2024A SP2

Instructions for Use



Disclaimer

For information on functionality not available for regulatory reasons, see the Regulatory Information in the RayStation Instructions for Use.

Declaration of conformity



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

Safety notices

This user documentation contains WARNINGS concerning the safe use of the product. These must be followed.



WARNING!

The general warning sign informs you of a risk for bodily harm. In most cases the risk is related to mistreatment of the patient.

Note:

The note gives additional information concerning a specific topic, for example, things to consider when performing a certain step in an instruction.

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1 INTRODUCTION

About RayTreat

RayTreat is used to deliver treatment plans that have been added to the treatment course in RayCare, and for which treatment appointments have been scheduled in RayCare. RayCare, together with the RayTreat application, provides a comprehensive system capable of managing patients' treatments all the way from registration for radiation treatment to delivery of the radiation treatment.

RayTreat is a RayStation client application launched with the Treatment delivery GUI interface or equivalent service and is normally installed on a computer in the treatment control room at a clinic.

This manual describes the parts of the workflow that are directly related to the delivery of treatment plans:

- Managing treatment plans in RayCare for treatment delivery in RayTreat
- Performing plan-specific QA delivery in RayTreat
- Performing treatment delivery in RayTreat

About this manual

It is possible to install RayTreat both as an application and as a Service (RTaaS). The choice of installation depends on the machine vendor software with which RayTreat will integrate. RayTreat connects to RayStation and RayCare the same way both when it is installed as an application and as a Service.

Before using RayTreat clinically with a new machine or after an upgrade of any relevant software or hardware, the test cases in the Treatment Device Integration Test Specification shall be run on at least an evaluation environment to verify the correctness of the clinical integration:

• RSL-D-RS-2024SP2-RTTDITS, RayTreat 2024A SP2 Treatment Device Integration Test Specification - if RayTreat is installed as an application.

In addition, the Installation Test Specification must be run on the clinical environment to verify the correctness of the clinical installation:

• RSL-D-RS-2024ASP2-RTITS, RayTreat 2024A SP2 Installation Test Specification - if RayTreat is installed as an application.

This document is an addition to RSL-D-RS-2024A-USM, RayStation 2024A User Manual and summarizes some of the most important features of the RayTreat application.

Study this manual and the RSL-D-RS-2024A-IFU, RayStation 2024A SP2 Instructions for Use carefully before using the RayTreat application. Proper functioning of the device can only be guaranteed if the instructions in these documents are adhered to.

Study the Release Notes in this manual as well as the RSL-D-RS-2024A-RN, RayStation 2024A SP2 Release Notes carefully. These notes provide final instructions on how to use the RayTreat application.

The RayStation 2024A system is further described in the RayStation 2024A product documentation. RayTreat Installation Instructions and Test Specification provide instructions for installing and configuring RayTreat as well as tests for verifying the installation.

Refer to the RayCare 2024A product documentation for information about the RayCare 2024A system.

2 PRODUCT INFORMATION

This chapter describes the RayTreat product label. For product information regarding the RayStation 2024A system, refer to the RSL-D-RS-2024A-IFU, RayStation 2024A SP2 Instructions for Use.

2.1 RAYTREAT PRODUCT LABEL

The version number of an installed RayStation 2024A system can be found by choosing **Help: About RayStation** in the RayTreat menu.

The following information can be identified:

- Product name = RayStation
- 产品型号: RayStation (for the Chinese market only)
- Release version = 15.2
- Marketing name = RayStation RayTreat 2024A SP2
- Software build number = 15.2.0.107
- Clinical build = Indicates that the software is designed for clinical use.
 - Note: A clinical installation requires both a clinical build and a clinical license. Otherwise, 'Not for clinical use' will be displayed in the title bar.
- Product lifetime = The lifetime per market is one year after the next major release, but no less than three years
- Radiation treatment planning system software = The generic name of the product
- 产品名称: 放射治疗计划系统软件 (for the Chinese market only)
- Indicates that the product is a medical device
- Unique Device Identification number
- The Swiss authorized representative and importer
- Driver information = The qualified driver versions. Expand this field by clicking the arrow. Note that for the RayTreat drivers, only the first three numbers are significant.

- \mathfrak{C}_{2862} = The CE mark and the notified body number
- = Production date
- = Consult instructions for use
- = The name and address of the manufacturer
- e The support e-mail address



Figure 1. The **About RayStation** dialog for RayTreat.

3 INFORMATION NEEDED FOR SAFE OPERATION

Adhere to the following warnings as well as the warnings described in RSL-D-RS-2024A-IFU, RayStation 2024A SP2 Instructions for Use for safe operation of the RayTreat application.

Note:

RayTreat 2024A SP2 is compatible with RayCare 2024A and subsequently validated RayCare 2024A service packs. Check service pack versions with RaySearch Service.

3.1 MANDATORY SITE TESTS

Before using RayTreat clinically with a new machine or after an upgrade of any relevant software or hardware, the test cases in the Treatment Device Integration Test Specification shall be run on at least an evaluation environment to verify the correctness of the clinical integration:

 RSL-D-RS-2024SP2-RTTDITS, RayTreat 2024A SP2 Treatment Device Integration Test Specification - if RayTreat is installed as an application.

In addition, the Installation Test Specification must be run on the clinical environment to verify the correctness of the clinical installation:

• RSL-D-RS-2024ASP2-RTITS, RayTreat 2024A SP2 Installation Test Specification - if RayTreat is installed as an application.

3.2 SUPPORTED MACHINE VENDOR VERSIONS

RayTreat 2024A SP2 can only be used in conjunction with the following validated treatment machine vendor software versions:

Machine vendor	Machine type/SW	Vendor SW and version
Toshiba	CI-1000-RMS	RMS v. 01.00.07.

Other versions

Additional validations of versions might have been performed after release. Please contact support@raysearchlabs.com to get information about all the latest supported versions. Running RayTreat against any vendor software version that has not been validated is strongly prohibited. If a new validation has to be performed, please contact RaySearch.

3.3 SAFETY PRECAUTIONS

3.3.1 **General warnings**



WARNING!

Machine models. The user who configures which machine models are supported in which rooms shall have a very clear understanding of the clinic and its rooms and machine models. It is strongly discouraged to remove or rename any machine model in the configuration of a room. Instead, it is recommended to deprecate the machine in RayPhysics if a machine model is not to be used anymore. It is still possible to add new machine models to a room.

(341177)



WARNING!

Ensure sufficient training. The user organization shall ensure that individuals authorized to perform treatment functions are appropriately trained for the functions they perform. Only individuals authorized to perform treatment functions and appropriately trained in treatment planning techniques should use this software. Carefully read all instructions prior to use. The user is responsible for proper clinical use and the prescribed radiation dose.

[1696]



WARNING!

Configuration changes require testing. The correct functioning of RayTreat depends on the connection to the treatment delivery system, RayPacs and the RayStation database. Changes to the configuration of any of these components require testing according to the RayTreat Installation Test Specification to confirm correct functioning. [8849]



WARNING!

Make sure that the intended plan is used. All plans can be included in the treatment course, regardless of the prescription or the planned number of fractions. Exercise caution when assigning different plans to different fractions.

(7190)



WARNING!

Verify table top positioning. If the table top positions have been entered or propagated, use the "Updated table top positions" dialog together with the treatment delivery system and the patient positioning system to verify that the table top displacement from localization point to setup and treatment isocenter table top positions are consistent.

This warning does not apply to the integration with the Toshiba delivery system. The table top position set in RayStation or propagated in RayTreat is not used by the Toshiba delivery system.

[10711]



WARNING!

Only results from signed sessions are displayed in RayCare. The results of the treatment session will not be displayed in RayCare until the session is signed in RayTreat. If it is not possible to complete the session, the result will not be displayed in RayCare.

Note that in RayTreat, treatment delivery results are displayed both for completed and non-completed sessions.

[220412]



WARNING!

User is responsible to record delivery correctly. The user completing a session is responsible for ensuring that the delivery is correctly recorded. If the recording is not received automatically, a manual recording must always be performed. This is needed to make sure that a continuation session does not lead to a radiation overdose.

(285060)



WARNING!

Propagation of table top positions to continuation sessions. Propagation of table top positions to continuation sessions is not supported by all drivers. If propagation is performed, new table top positions will only be set on sessions in upcoming fractions, not to continuation sessions unless the driver supports this. Whether this driver feature is supported or not can be verified by checking if the feature "Can propagate table top positions to continuation sessions" for the rooms in Clinic Settings is selected.

[408169]



WARNING!

Content in setup instructions preview may change before delivery. The setup instruction can be changed in RayCare after the setup instruction preview has been displayed in the Schedule workspace. The user should refer to the setup instructions in the Preparation workspace when setting up the patient for treatment.

(928807)



WARNING!

Offline import when delivering an unused plan without status change to 'In progress'. Delivery of a previously unused plan without the session status changing to In progress in RayTreat will make offline import of treatment records impossible for the session. The delivery results will have to be manually recorded.

(934421)



WARNING!

Session not automatically opened in RayTreat via treatment delivery device.

Opening the session on the treatment delivery device does not automatically open the session in RayTreat.

(935206)

14

3.3.2 Toshiba related warnings



WARNING!

Compatible Toshiba system software versions. Only versions of the Toshiba system software that have been validated shall be used together with RayTreat. For information about supported versions, see $section\ 3.2\ Supported\ machine\ vendor\ versions\ on\ page\ 11.$

(578700)

4 RELEASE NOTES

This chapter contains important notes about the use of the RayTreat application. It contains information related to patient safety and lists new features, known issues and possible workarounds.

Every user of the RayTreat application must be familiar with these known issues as well as the known issues described in RSL-D-RS-2024A-RN, RayStation 2024A SP2 Release Notes. Contact the manufacturer for any questions about the content.

Note:

Beware that additional safety-related release notes may be distributed separately within a month of software installation.

In this chapter

This chapter contains the following sections:

4.1	News and improvements in RayTreat 2024A SP1	p. 18
4.2	Resolved issues	p. 20
4.3	Known issues related to patient safety	p. 24
4.4	Other known issues	p. 25
4.5	Updates in RayTreat 2024A SP2	p. 27

4.1 **NEWS AND IMPROVEMENTS IN RAYTREAT 2024A SP1**

This chapter describes the news and improvements in RayTreat 2024ASP1 as compared to RayTreat 6A SP1 and 6A SP2 (RayStation 12A SP1 and 12A SP2).

4.1.1 Resolved Field Safety Notices (FSNs)

There are no resolved field safety notices (FSNs) in RayTreat 2024A SP1.

4.1.2 New and significantly updated warnings

For the complete list of warnings, see section 3.3 Safety precautions on page 12.

New warnings



WARNING!

Content in setup instructions preview may change before delivery. The setup instruction can be changed in RayCare after the setup instruction preview has been displayed in the Schedule workspace. The user should refer to the setup instructions in the Preparation workspace when setting up the patient for treatment.

(928807)



WARNING!

Offline import when delivering an unused plan without status change to 'In progress'. Delivery of a previously unused plan without the session status changing to In progress in RayTreat will make offline import of treatment records impossible for the session. The delivery results will have to be manually recorded.

(934421)



WARNING!

Session not automatically opened in RayTreat via treatment delivery device.

Opening the session on the treatment delivery device does not automatically open the session in RayTreat.

(935206)

Significantly updated warnings



WARNING!

Verify table top positioning. If the table top positions have been entered or propagated, use the "Updated table top positions" dialog together with the treatment delivery system and the patient positioning system to verify that the table top displacement from localization point to setup and treatment isocenter table top positions are consistent.

This warning does not apply to the integration with the Toshiba delivery system. The table top position set in RayStation or propagated in RayTreat is not used by the Toshiba delivery system.

[10711]

4.1.3 General news

- RayTreat is now session focused. Treatment course information is no longer displayed in RayTreat, this information is displayed in RayCare.
- Usability improvements:
 - Activity status indicator is shown in all workspaces to give the user the session status.
 - Room information is displayed in all modules, compared to previously only in the Schedule module.

4.1.4 Scheduling workspace

- Beam set delivery notes are now displayed.
- Preview of setup instructions with notes and fixation devices are now up to date with RayCare.
- The handling of overrides is improved. Session scheduling alerts are added, and the possibility to override warnings. Validation status is displayed with a warning that can be overridden with a motivation (e.g., Time between adjacent treatment appointments, Too many fractions, Rejected offline image review).
- Appointment cards in the calendar are now the same as displayed in RayCare.
- Plan details: Modality and Nominal contribution are now displayed.

4.1.5 Preparation workspace

- Possibility to edit and save beam set delivery notes is added.
- Possibility to check in checkboxes for applied Fixation and Boli devices is added.

- The overview of setup notes and setup photos is improved.
- Setup remarks are displayed.

416 **Results workspace**

The Results workspace replaces the previous *Delivery* workspace. The information that was previously displayed in the Delivery workspace is now displayed in RayCare.

- QA results are displayed in the Results workspace.
- Simplified GUI: Only session beam delivery results are displayed. Fraction treatment course results are now displayed in RayCare.
- Position propagation is now shown as a table in accordance with the other delivery results.

4.2 **RESOLVED ISSUES**

Resolved: Importing treatment record for a continuation session

When modifying the delivery and importing a treatment record for a continuation session following a partial delivery in which non-zero meterset was delivered, the beam record will display the wrong Planned Meterset. This will be shown as an error and as a faulted beam even when everything has been delivered correctly. Hovering the cursor over the status icon will display the correct Planned Meterset

[143582]

Resolved: Canceling session through RayStation may update the delivered date

A canceled session without any delivered meterset will show the delivery date as the last time the session's delivery was approved. If the delivery of a session is modified in RayStation, the displayed date will be incorrectly updated.

[145286]

Resolved: Offline recording through RayStation

Modifying the treatment record for a session that is not the last for a fraction and changing the total delivered meterset for a beam will not affect the list of omitted beams for any of the upcoming already existing sessions in the fraction.

In the case where a beam was previously considered completely delivered, but has since then been updated to be undelivered or partially delivered, the continuation session will incorrectly omit the updated beam. This will cause RayTreat to crash when trying to create another continuation session. To deliver the remaining beams, the incorrect record must be restored and a new beam set must be created and appended to the plan.

In the case where a beam was previously considered undelivered or partially delivered, but has since then been updated to be completely delivered, the beam will not be included in the list of omitted beams. Thus, zero or near-zero remaining meterset will remain to be delivered in a continuation for that beam.

[146246]

Resolved: Suggested online couch correction when imaging against treatment beam

The suggested online couch correction displayed in RayTreat might be wrong when imaging is performed on any other beam than the setup beam. The setup beam position and rotation will always be used when calculating the suggested online couch corrections. Make sure to only use the suggested online couch correction for verification when imaging against the setup beam.

[344436]

Resolved: Do not rename a plan after the beam set has been approved

RayTreat will use the plan name that was used when it was assigned to the treatment course. If the plan name is changed after the beam set has been approved, this could result in beam sets of the same plan being displayed with different plan names depending on when they were assigned.

(344738)

Resolved: Changing patient name can cause missing information in RayTreat

Changing the patient name in RayCare while the patient is open in RayStation can cause missing patient data (including missing flags) in RayTreat. If this happens, an error message is displayed. To correct the issue, close the patient in RayStation and then change session selection in RayTreat.

[408401]

Resolved: Changing room name prevents usage of already approved plans

After updating the name of a room or creating a new room, previously approved plans for treatment machines supported by the room cannot be used in this new or updated room. The user must either unapprove the plan, approve and assign the plan again, or copy the plan and use the copy instead.

[409606]

Resolved: Changing room name affects appearance of previous deliveries

After updating the name of a room, previous treatments in that room will be displayed as out of tolerance in RayStation and RayTreat. The delivered dose is displayed in red and the tooltip of the status icon will inform that no tolerances can be fetched for the room.

(409607)

Resolved: Planned meterset with multiple beam contributions in a session

The planned meterset value shown for a beam does not take previous beam contributions within the same session into consideration. For all beams, the planned meterset value shown for the beam is the full amount planned to be delivered in the current session.

(576258)

Resolved: Nominal progess for upgraded patients

The nominal progress reports no delivered dose for patients with a treatment course created using a combination of RayStation 10B and RayCare 4B or earlier versions. Due to this, Expected total dose will be incorrectly calculated to always equal the Remaining dose. Do not make decisions based on nominal progress for patients that have been treated but where Delivered dose is still shown as "-". This issue applies to all occurrences of nominal progress in the GUI, including RayTreat Delivery module, RayStation Approve treatment course dialog and RayCare Treatment course overview.

(580171)

Resolved: Previously used beam sets cannot be reassigned after an upgrade

After an upgrade, beam sets previously used for treatment can no longer be assigned to fractions. The previous beam set assignment is kept but the dose for beam sets created before the upgrade must be recalculated before the beam sets can be assigned, and this is not allowed for beam sets used for treatment. To assign the beam set, create a copy of the beam set/plan and use the copy for new beam set assignments.

[580225]

Resolved: Task comments removed without notification if entered without saving

If task comments are entered in RayTreat without saving, the comments will be removed without any notification when closing the task, when leaving the module or when selecting another session.

(712699)

Resolved: Planned gantry angle for TomoHelical plans is always displayed as "0"

The planned gantry angle for TomoHelical plans is always displayed as "0" (zero) in the Delivery module in RayTreat and in the Result view in RayStation. The actual start angle of the delivery is shown in RayStation and on the treatment delivery console.

[713146]

Resolved: Beamset not updated in delivery device after Undo check-in and change of beamset

When a treatment session is checked in and loaded on the treatment console, Undo check-in of the session can be performed before the session status in RayTreat has been set to In progress. It is possible to update the beamset related to the session, check-in for the same session and continue the treatment with the already loaded session on the treatment console. To update the session information on the treatment console, close the session on the treatment console when a new beam set has been assigned to the session in the treatment course.

(820067)

Resolved: Always select Show only OIS scheduled patients and plans on the Treatment Delivery Console (TDC)

When selecting a patient and plan ready for treatment in RayTreat, always verify that Show only OIS scheduled patients and plans is selected on the Treatment Delivery Console (TDC). If this option is not selected, any fraction available for delivery at iDMS can be selected for delivery. Any fraction

delivered outside of OIS mode will not be available for delivery on the treatment console in OIS mode and must be recorded by importing the corresponding treatment record or by manually recording it in RayStation.

[822620]

Resolved: Displayed status of a QA beam may differ after signing the QA session

The displayed status of a QA beam might differ between when performing the QA and after signing the QA session. The indicator that a beam was invalid during the delivery may not be displayed after signing. The specified and delivered meterset will however always be correct.

(69236)

Resolved: Canceling an unscheduled session through RayStation

When canceling an unscheduled treatment session through RayStation, that session's scheduling information will be set in RayTreat. As a consequence, the canceled session will appear as a session in the calendar on the room from which it was canceled. However, this information will not be visible in RayCare.

[145299]

Resolved: Schedule information can remain in RayTreat after changing number of fractions

Treatment appointments for sessions that have been removed and added again after changing the number of fractions can incorrectly be displayed on their previously scheduled time slots. The time slots are corrected when the appointments are scheduled in RayCare.

(339203)

Resolved: It is not possible to cancel a treatment course

It is not possible to cancel a treatment course in RayTreat. Instead, each fraction must be canceled manually, either through RayTreat or RayStation.

[342758]

Resolved: Unapproved alternative plans may appear possible to be assigned to fractions

If trying to assign alternative plans which each has one unapproved beam set, the information in the *Use plan in treatment course* dialog will be incorrectly displayed. It will show that one of the unapproved beam sets will become assigned to fractions. When clicking OK, the plan assignment will fail and be rolled back. Make sure that all beam sets are approved before assigning alternative plans.

[577123]

4.3 KNOWN ISSUES RELATED TO PATIENT SAFETY

4.3.1 RayTreat installed as a desktop application

Setup instructions are applicable to all plans with the same planning image set instead of only a single plan

If a setup instruction is available for one beam set in RayTreat, that setup instruction will automatically be used for any other beam set defined on the same planning image set. If setup details specific to the first beam set are mentioned in the setup instruction, those will also incorrectly be displayed in the preparation workspace for other beam sets. Therefore, if there are multiple beam sets or plans that have the same planning image set, describe the setup for all beam sets and plans in the same setup instruction.

(69240)

Unoverridden session validation warnings can be added to a locked session

A session that is open in RayTreat but not yet started on the delivery device may receive new session warnings from RayCare that need to be overridden to allow delivery. For example:

- Re-scheduling of other sessions activating a 'too many fractions on one day' warning
- Offline image review rejection for a previous session
- Rejection of previously accepted QA for the beam set

RayTreat will display a status message stating that there are validation warnings that need to be overridden.

Actions to take in RayTreat: Leave the session, override the warnings in the Schedule workspace and open the session again.

[937267]

Treatment records with non-zero tabletop eccentric rotation or distance not supported

RayTreat and RayCare support couch positions and rotations only when the tabletop eccentric axis distance (300A, 0124) and the tabletop eccentric angle (300A, 0125) are zero. If treatment records contain any non-zero values in these attributes, RayTreat and RayCare will disregard them. This could impact the propagated positions and OCC calculations, potentially resulting in inaccuracies in the final positioning. The delivery records will still be processed, ignoring those attributes, and stored in PACS.

(935845)

4.4 OTHER KNOWN ISSUES

4.4.1 RayTreat installed as a desktop application

RayTreat freeze can cause a faulted session

If the RayTreat GUI freezes during treatment, there is a risk that the session becomes faulted. Faulted sessions do not accept new treatment records from the delivery device. The treatment can be completed on the delivery device but no delivery information will be saved by RayTreat. The user is forced to stop the session in RayTreat. If the session becomes faulted, check the received images and all treatment records (if any) and add manual recording in RayCare to match the treatment. After that, perform offline import of the treatment record(s) stored by RayTreat and remove the manual recording.

(226095)

Meterset tolerance set in RayCare Admin is not taken into account when beam and session status is shown in RayCare and RayTreat

The displayed beam and session delivery status in RayTreat and RayCare is not based on the configured meterset tolerance in RayCare, but rather the delivery status from the treatment device. If a beam is delivered within the configured meterset tolerance but is interrupted on the treatment device before fully finished, the beam and session status displayed in RayTreat and RayCare will be *Partially delivered* instead of *Delivered*. The configured meterset tolerance in RayCare must be the same as used by the treatment device.

(934505)

Misleading status in RayTreat Downloading session - user needs to take action

In some situations, a session may not become ready for delivery on the driver. This manifests as RayTreat getting stuck with the status display *Downloading session data*. The following steps may address the issue:

For a QA session, QA mode may have been ended and then re-initiated before the session was delivered. Stop and complete the session in RayTreat, and then do *Repeat QA Delivery* for the plan in the QA Schedule workspace.

A common cause is that data necessary for delivery cannot be downloaded from RayPACS. Ensure all data for the plan to be treated is exported from RayStation to RayPACS. Verify the network connection to the computer where the driver resides.

If the above does not help, inspect the driver log for more detailed information. This may require support from RaySearch Service.

(932524)

Beam records have the same specified meterset and same treatment time in all beam records for the same recorded beam

For in-session continuations of an individual beam, when there are multiple beam records for one beam, the specified meterset for all beam records will be the total specified meterset for the beam in the session.

(932525)

Treatment series name and session number missing in offline image review section

The offline image review results, shown in the Image review tab in the Preparation workspace in RayTreat, do not specify which treatment series each offline image review pertains to, only the fraction number. A session number is only shown for continuation sessions. If no session number is shown, the offline image review pertains to the first session in the fraction. To view the full details of offline image review, see the Offline image review tab in RayCare.

(937422)

Overrides performed on the treatment machine are not documented in RayTreat or the RayCare treatment course

The overrides shown in the RayCare treatment course only include overrides performed in RayCare or RayTreat, and will not show any overrides that have been performed on the treatment delivery console.

(934486)

No data persistence for bolus devices in Preparation workspace

In case of a RayTreat crash when preparation is confirmed, the selected checkboxes for applied boli in the Preparation workspace will be cleared when the session is re-opened. Users shall ensure that all necessary boli are applied.

(929863)

Not possible to deliver a second continuation if there exists a previous canceled continuation session in the same session

It is not possible to deliver a second continuation session if there exists a previous canceled continuation session in the same session. This is manifested by that the session does not get ready for delivery in RayTreat. The workaround is to handle the remaining dose in an extra fraction.

[1152210]

4.4.2 RayTreat installed as a desktop application (Toshiba)

Possible to assign and propagate table top positions even though they are not used by the Toshiba system

The Toshiba integration supports assign and propagation of treatment delivery table top positions, in RayCare and RayTreat respectively, even though the positions are not used by the Toshiba treatment delivery system (TDD).

[1152211]

4.5 UPDATES IN RAYTREAT 2024A SP2

This chapter describes the updates in RayTreat 2024A SP2 as compared to RayTreat 2024A SP1.

4.5.1 News and improvements in RayTreat 2024A SP2

The scope is to release the RayTreat Toshiba driver. The only changes compared to RayTreat 11B SPT1 (when the Toshiba driver was last released) are:

- Support for plans with multiple isocenters.
- RayTreat Toshiba driver accepts Spatial Registration Object (SRO) from the Toshiba system. In RayTreat, a list of acquired images and associated registration objects are displayed.

Resolved Field Safety Notices (FSNs)

There are no resolved field safety notices (FSNs) in RayTreat 2024A SP2.

New and significantly updated warnings

There are no new or significantly updated warnings in RayTreat 2024A SP2.

For new and significantly updated warnings in RayTreat 2024A SP1, see section 4.1.2 New and significantly updated warnings on page 18.

For the complete list of warnings, see section 3.3 Safety precautions on page 12.

4.5.2 Found issues

Two new issues (not safety related) have been found, 1152210 and 1152211. It is described in detail in section 4.4 Other known issues on page 25.

4.5.3 Resolved issues

Resolved: Different outcomes on session status depending on the order of steps in online manual recording

Manually recording a treatment session which has previously been canceled results in the session status 'Canceled' instead of 'Delivered' or 'Partially Delivered'. The delivered meterset is saved as it was manually recorded and future fraction deliveries are determined by the previously delivered meterset (not the session status). The Toshiba driver does not allow subsequent fraction deliveries without first uploading a valid treatment record for the manual recording, which will correctly update the delivery status for the canceled fraction.

When there is a loss of connection to the treatment device, manual recording can be performed before the cancelation of the session. In this circumstance the session status is correctly set to 'Delivered' or 'Partially Delivered'.

(407003)

4.5.4 Updated manuals

The following manuals have been updated in RayTreat 2024A SP2:

- - RSL-D-RS-2024A-RTIFU-2.0 RayTreat 2024A SP2 Instructions for Use
 - RSL-D-RS-2024ASP2-RTITS-1.0 RayTreat 2024A SP2 Installation Test Specification
 - RSL-D-RS-2024ASP2-RTTDITS-1.0 RayTreat 2024A SP2 Treatment Device Integration Test Specification
 - RSL-D-RS-2024A SP2-DCSTD-1.0 RayTreat 2024A SP2 DICOM Conformance Statement for Toshiba Driver

5 RAYTREAT

In this chapter

This chapter contains the following sections:

5.1	Clinic Settings configuration for RayTreat	p. 30
5.2	Tolerance table management	p. 34
5.3	RayTreat activities	p. 35

5.1 **CLINIC SETTINGS CONFIGURATION FOR RAYTREAT**

In order to use RayTreat, configuration of the treatment settings in the Clinic settings application is needed. Most of the settings are configured at installation and are therefore described in the RayTreat installation documents. This section describes some important points of which the user should be aware.

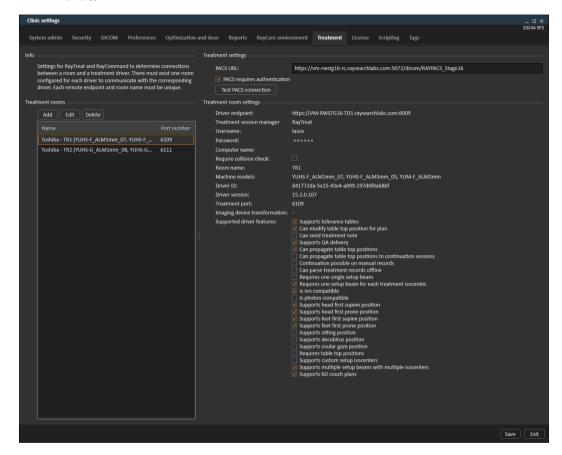


Figure 2. The Treatment tab in Clinic settings.

The configuration has a list of rooms. These reflect the rooms for which the user can schedule an appointment in RayCare. Each room also has a list of machine models. These reflect the models of the machine setup in RayPhysics and are used when creating a beam set in RayStation. The same machine model can be referenced in multiple rooms. It is also possible to let a single room support multiple machine models.

WARNING!

Machine models. The user who configures which machine models are supported in which rooms shall have a very clear understanding of the clinic and its rooms and machine models. It is strongly discouraged to remove or rename any machine model in the configuration of a room. Instead, it is recommended to deprecate the machine in RayPhysics if a machine model is not to be used anymore. It is still possible to add new machine models to a room.

(341177)

To edit treatment room settings, click the **Edit** button. This opens the **Edit treatment room settings** dialog.

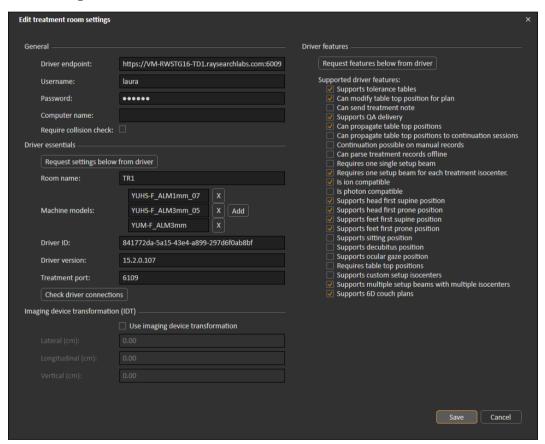


Figure 3. The Edit treatment room settings dialog.

In Imaging device system it is possible to enter an imaging device transformation in case the patient coordinate system and the imaging device do not match. If IDT is set to 0,0,0 the coordinate system for the patient and the imaging system is coinciding.

5 1 1 Configure PACS DICOM entity in Clinic settings (Toshiba)

For a Toshiba system:

From the DICOM page, verify that the Used for auto export option of the DICOM entity associated with the RayCare PACS is selected. Click the **Edit** button in the **DICOM application entities** tab to access the option.

Also ensure that the Auto export setup DRRs and Auto export treatment DRRs options are selected.

Note:

In the Toshiba integration, the setup imaging procedure is implemented by the Toshiba system and does not use RayStation setup DRRs or setup beam information. Therefore, RayStation setup DRRs may not represent the clinical setup and should not be included in clinical documentation.

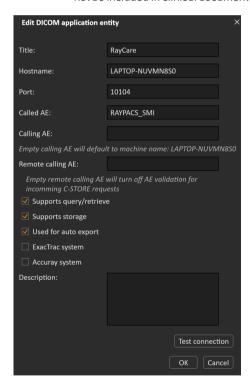


Figure 4. Clinic settings: The **Used for auto export** option.

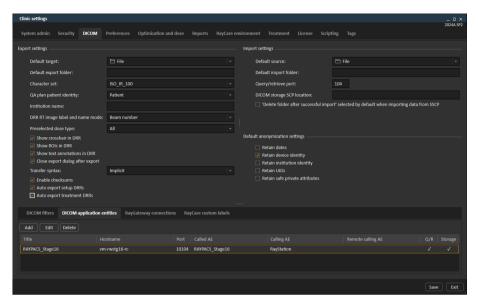


Figure 5. Clinic settings: The Auto export setup DRRs and Auto export treatment DRRs options.

5.2 **TOLERANCE TABLE MANAGEMENT**

For treatment machines that support the transmission of a tolerance table in the RT Plan, it is necessary to define at least one tolerance table in the Tolerance table management dialog in the application menu in RayPhysics or in RayCare. For further information, refer to the sections about tolerance tables in RSL-D-RS-2024A-RPHY, RayStation 2024A RayPhysics Manual and RSL-D-RC-2024A-USM, RayCare 2024A User Manual.

When selecting a tolerance table for a plan in the Assign beam set dialog in RayCare, only the approved tolerance tables for the corresponding treatment machine are displayed.

5.3 RAYTREAT ACTIVITIES

If RayTreat is installed to run as a Service, this chapter is not applicable.

The RayTreat application is divided into different parts, called treatment activities:

- Schedule
- QA schedule
- Preparation
- Results

The user can toggle between the different activities by clicking the tabs in the user interface top bar.

5.3.1 User interface top bar

The top bar of the user interface contains the RayTreat menu and the treatment activity tabs Schedule, QA schedule, Preparation and Results.

Each treatment activity tab holds functionality related to that treatment activity. The workspaces for the activities contain toolbars showing information about the selected patient and the selected treatment plan, as well as other information relevant when performing the activity.

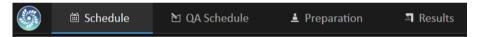


Figure 6. The treatment activity tabs, where Schedule is currently active.

The RayTreat menu provides access to global functions such as saving, accessing Patient audit log, help and exiting the application. The RayTreat menu is opened by clicking the RayTreat icon in the upper left corner.

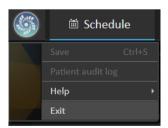


Figure 7. The RayTreat menu.

The session status is displayed, showing the treatment machine, the state of the currently selected appointment in the calendar control on the **Schedule** tab and a description of any appointment session that is currently active (in progress for treatment).

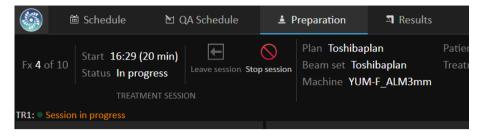


Figure 8. The session status.

5.3.2 Schedule

RayTreat displays a list of scheduled treatment appointments for the room it is configured for.

Workspace

Today's treatment appointments are listed to the left in the Schedule workspace (by default). It is possible to display the schedule for other days by clicking the arrow to the right of today's date.

Note:

A stoplight indicator next to the room indicates network connection status to the treatment machine. The connection status indicator is only available for the Toshiba treatment delivery device. (Requires support for C-ECHO response at the device at a configurable polling rate).

Patient information is located to the left of the workspace. It contains the patient photo, details, and flags and alerts that could be relevant during the treatment.

A list of tasks to be performed during the selected treatment session is displayed. To the right is the detailed session information and details regarding the plan to deliver (e.g., number of fractions, modality and treatment technique).

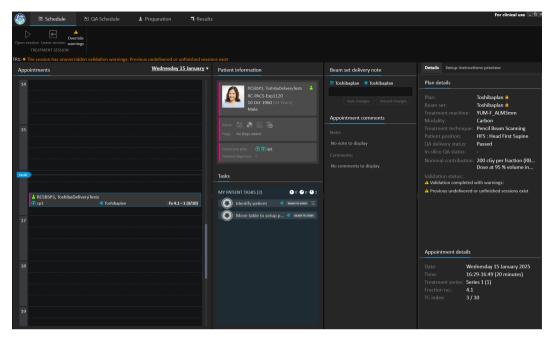
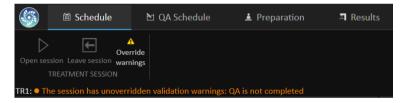
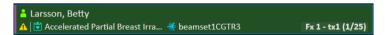


Figure 9. The Schedule workspace.



Treatment appointments

The treatment appointments are listed to the left in the Schedule workspace. Each appointment is summarized in a treatment appointment bar.



The treatment appointment bar contains the following information:

- Scheduled start time for the treatment appointment
- Estimated duration of the appointment
- · Check-in status
- Patient name

Fraction number out of the total number of fractions. Fraction one is explicitly indicated by the background color green.

Click an appointment in the schedule to get an overview of the treatment appointment. The overview consists of Patient information, Appointment comments from RayCare and Session information.

The patient information is managed and synchronized with the information entered into RayCare and the plan information is managed via the **Treatment course management** workspace in RayCare.

Checking in a patient

Before the session can be opened in RayTreat, the user might in some cases (for example if there are more than one fraction on the current day) need to override validation warnings by clicking the Override validation warning button.

Before delivering a treatment session, the patient must be checked in. The patient is checked in by selecting the corresponding appointment in the **Treatment** schedule in RayCare and then clicking the Check-in button. Once the patient has been checked in, the session is available for sending to the treatment machine. If there are warnings that need to be acknowledged by the user, the session has to be sent manually to the treatment machine.

The dot to the left of the patient name in the treatment appointment bar indicates the status for patient check-in. It is possible to open the treatment session by clicking Open session. The user is then navigated to the Preparation workspace to prepare the patient for treatment delivery.

Note: For the Toshiba system, Open session notifies the treatment system to initiate the associated session at the treatment console.

In some cases (for example if there are more than one fraction on the current day), a validation warning appears in the toolbar. Before the session can be opened in RayTreat, click the Override validation warning button.



The following patient check-in statuses exist:

Status indicator color	Description
Transparent patient icon	The status indicator is transparent if the patient has not been checked in.
	△ Larsson, Betty ▲

5.3.3 OA schedule

Workspace

The QA schedule workspace contains tools for sending QA plans to the treatment machine. All plans that are scheduled to start and have the QA status set to **Pending QA delivery** are shown in the **Plans to QA** list.

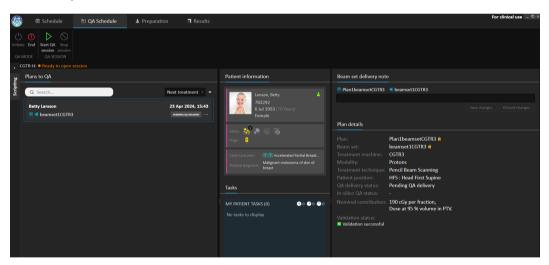


Figure 10. The QA schedule workspace.

Deliver plans in QA mode

To deliver plans in QA mode, RayTreat needs to be set in QA mode. To enter QA mode, click the **Initiate** button in the toolbar.

In QA mode, the QA session must be started before it is available to the treatment delivery system. Once the QA delivery is done, the session should be completed in the same way as for treatment sessions (*Treatment session completion on page 52*). The QA status of the plan can then be changed to one of the following options:

- Pending QA delivery
- Pending analysis
- Not needed
- **Pass**
- Failed measurements
- Failed plan

5.3.4 **Preparation**

Workspace

The Preparation workspace contains setup notes and patient setup information needed to position the patient prior to position verification imaging and treatment delivery.

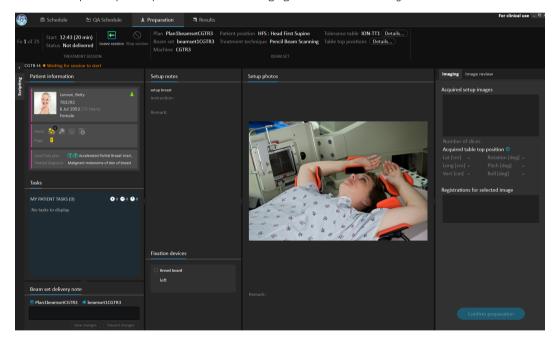
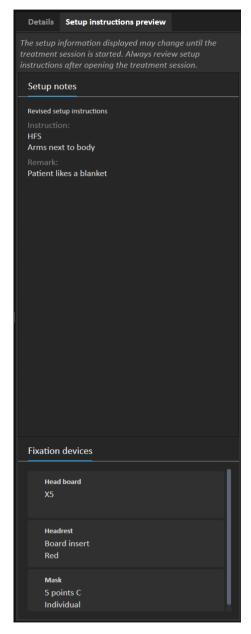


Figure 11. The Preparation workspace.

Preparing a patient for treatment delivery

In the Patient setup instructions section of the workspace, the setup instructions defined in RayCare are shown. This includes patient setup photo(s) and if any fixations devices must be used. In the lower left corner of the section, bolus information is displayed for the beams that have a bolus assigned.

In the setup instructions preview tab it is possible to view setup notes and fixation devices for the session without opening the treatment session. Note that this is only a preview, both the notes and fixation devices might change until the treatment session is started.



When setup images (position verification images) have been received from the treatment delivery system, they are listed in the **Imaging** tab to the right, together with the table top position where

the images were acquired. If registrations between the reference planning images and the acquired setup images have been received, they are listed in the Registrations for selected image list.

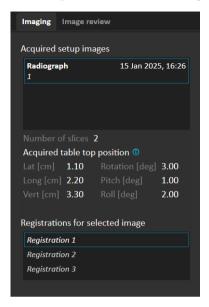


Figure 12. Setup images with multiple SRO (Spatial Registration Object) for the Toshiba system.

Note:

In the Toshiba integration, the setup imaging procedure is implemented by the Toshiba system and does not use RayStation setup DRRs or setup beam information. Therefore, RayStation setup DRRs may not represent the clinical setup and should not be included in clinical documentation.

Once patient setup and imaging has been completed, the preparation phase can be completed by clicking the Confirm preparation button in the bottom right corner. If there are multiple acquired setup images, select the one to use for calculation of setup corrections before clicking the Confirm preparation button.

Note:

The setup image selection affects offline image review. For the Toshiba system, the most recent setup verification image table top position is always used as the setup position for the next fraction.

Image review

In the Image review tab, all the related offline image reviews made in RayCare are visible. This view will show reviews for all fractions related to the patient and the current treatment course. Only reviews that have been handled in RayCare are visible. By selecting a fraction in the top list, it is possible to view the details for the related image review. If the status has been set to Rejected, the

review will be marked with a yellow warning triangle 🖴 and a dialog will be triggered when opening the session, which informs that the review has been rejected. The user should look at the details for the rejected review and read the notes. If the details do not provide enough information, it is possible to open the review in RayCare for additional information. When appropriate actions have

been made, it is possible to **Dismiss the warning** by clicking the **Dismiss warning** button at the bottom of the tab. This will remove the yellow warning triangle for the selected review and replace

Note: The Toshiba system creates a DICOM secondary capture image of the registration software which can be viewed in RayCare. Offline image review is not recorded for these images.

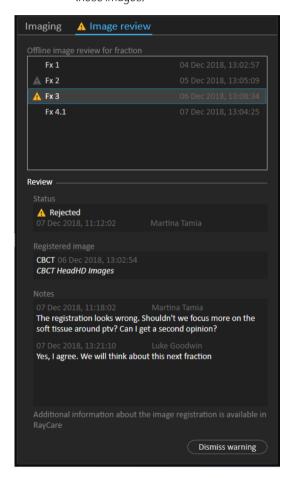


Figure 13. The Image review tab.

Nominal contribution/fx

The toolbar shows the planned nominal contribution for the current fraction. Note that the full fraction value is shown also for a session where only a partial fraction is treated.



Presence of multiple nominal contributions is indicated by a grey circle with the number of nominal contributions in it. All nominal contributions will be displayed in a tooltip when hovering over this icon.

Tolerance table

In the top bar, it is possible to verify that the correct tolerance table has been selected for the plan by viewing the tolerance table details. Click the **Details...** button to open the tolerance table details.

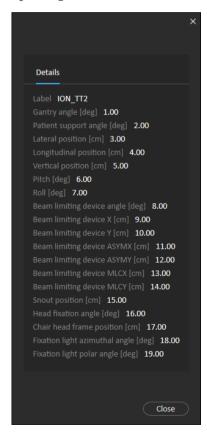


Figure 14. The tolerance table details.

Table top positions

If the machine is set to support modifying table top positions, and the table top positions have been manually edited in Treatment delivery settings or propagated through Treatment session completion, it is possible to view the updated table top position details. Click the **Details...** button next to the **Table top positions** in the top bar to open the **Updated table top positions** dialog. If the updated positions are altered when pressing **Use in treatment course**, it is updated when opening a session in RayTreat. However, if the **Set delivery table top position** is unchecked it will not be updated unless the plan is discontinued first.

Note:

For the Toshiba system, the most recent setup verification table top position is used as the setup position for the next fraction. If a setup record is not available (e.g. the first fraction), the setup position is set at the Toshiba system. The treatment table top position which can be set in the Assign beam set to treatment series dialog, or by propagating the table top position in RayTreat, is not used by the Toshiba system. The positions are, however, presented as the planned couch positions in Beam Delivery Results presentations. The planned table top position in RayStation/RayTreat may be different than the setup or actual delivery position at the Toshiba system.



WARNING!

Verify table top positioning. If the table top positions have been entered or propagated, use the "Updated table top positions" dialog together with the treatment delivery system and the patient positioning system to verify that the table top displacement from localization point to setup and treatment isocenter table top positions are consistent.

This warning does not apply to the integration with the Toshiba delivery system. The table top position set in RayStation or propagated in RayTreat is not used by the Toshiba delivery system.

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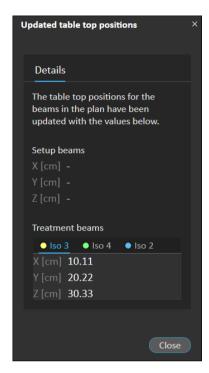


Figure 15. The **Updated table top positions** dialog.

5.3.5 Results

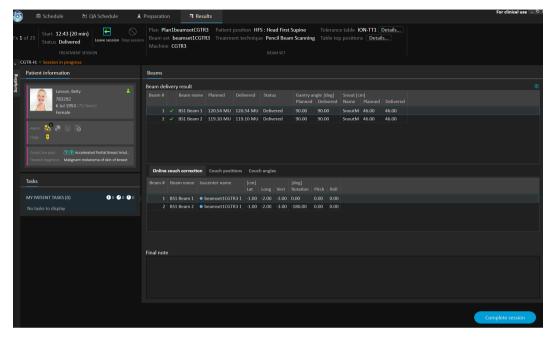


Figure 16. The Results workspace.

Beam delivery result

The delivery details for the selected treatment session are shown to the right in two separate tables — one for the beam delivery result and one with separate tabs for the online couch corrections, the absolute prescribed and recorded couch positions and couch angles. There is also a text area for writing notes about the delivered session.

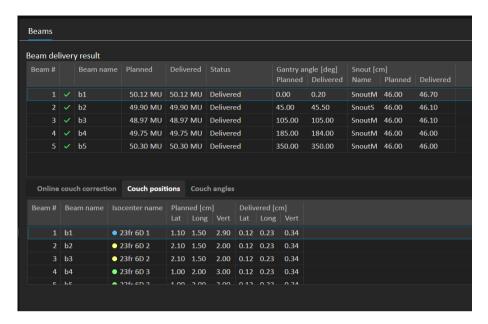


Figure 17. The Beam delivery result and Couch positions tables.

Note:

For the Toshiba delivery system, metersets with dosimeter unit NP (Number of Particles) are presented in unit 10^6 NP with four decimals. This means that it is not possible to distinguish differences between planned and delivered metersets below 100 NP. If the tolerance is set lower than this, the GUI will still indicate that there is a difference outside the tolerance.

Note:

Table top positions set in RayStation or propagated in RayTreat are not used by the Toshiba delivery system. However, they will be presented as the planned couch positions in the Beam Delivery Results presentation. (In the image, the header for planned values is shown as Prescribed).

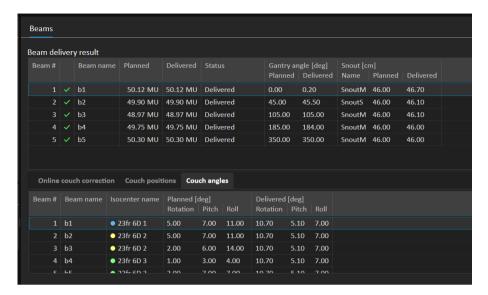


Figure 18. The Beam delivery result and Couch angles tables.



Figure 19. The Beam delivery result table with three incorrectly delivered beams.



Figure 20. The **Beam delivery result** table with a delivered dose above accepted tolerance.

If there are problems with the integration between RayTreat and the delivery system, an error icon will be displayed next to the beam in the beam delivery results, indicating that the beam is invalid.



Figure 21. The error icon.

Online couch correction

Note: For Toshiba integration, online couch correction is not displayed.

The online couch correction will be calculated as the difference between the recorded table top position and the image acquisition point shifted by the displacement from the setup beam to the treatment beam if all of the following conditions are fulfilled:

- There is an acquired setup image with a recorded table top position
- There is one setup beam
- The delivery table top position is recorded
- The preparation has been confirmed

If any of those conditions are not fulfilled, an alternative algorithm is tried. The alternative algorithm calculates the online couch correction as the difference between the planned table top position and the recorded table top position. If those positions are not available, no online couch correction will be calculated.

If the first algorithm is used, the tool tip "Shift from the setup imaging position to the treated table top position" is shown over the beam list. If the second algorithm is used, the tool tip is instead "Shift from initial planned table top position to treated table top position".

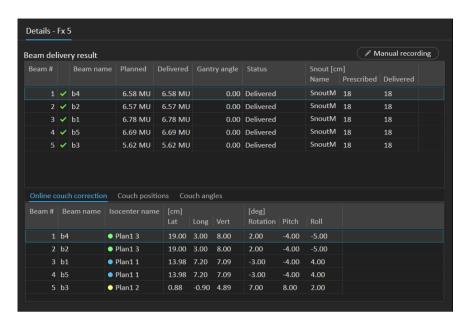


Figure 22. The Beam delivery result and Online couch correction tables.

Note: For the Toshiba system, images received are post-correction verification images. Therefore, the image acquisition table positions will generally be the delivery position for single isocenter plans.

leam de	liver	y result											
Beam #		Beam nan	ne Planned		Delivere		Status			ngle [deg] Delivered	Snout [c		Delivered
		b1	84.7668 10 ⁶	NP	84.7668	3 10 ⁶ NP	Delivere	ed	90.00	90.00	Snout1	65.00	65.00
2		b2	85.1430 10 ⁶	NP	85.1430	10 ⁶ NP	Delivere	ed	90.00	90.00	Snout1	65.00	65.00
		b3	85.2203 10 ⁶	NP	85.2203	3 10 ⁶ NP	Delivere	ed	90.00	90.00	Snout1	65.00	65.00
		b4	84.9756 10 ⁶	NP	84.9756	5 10 ⁶ NP	Delivere	ed	90.00	90.00	Snout1	65.00	65.00
			n Couch positio		Couch a		[deg]						
			n Couch position		n]		[deg] Rotation	Pitch	Roll				
Beam #				[cn	n] : Long		Rotation	Pitch	Roll				
Beam #	Ве		lsocenter name	[cn Lat	n] : Long		Rotation -	Pitch 	Roll				
Beam #	Be b1 b2		Isocenter name 2iso_2beam1 1	[cn Lat -	n] : Long -		Rotation -	Pitch 	Roll				

Figure 23. The Beam delivery result and Online couch correction tables for the Toshiba system.

Stop session

If a treatment session cannot be either completed or canceled through the treatment console (machine vendor software), or if the changes to the session status are not forwarded correctly to RayTreat, it is possible to stop the session through the **Stop session** button in the RayTreat top bar.



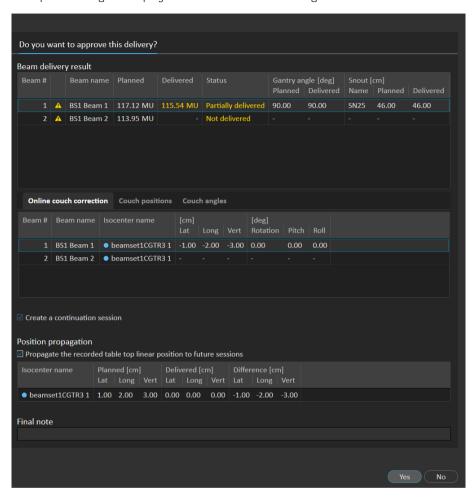
Once a session is stopped, no more deliveries can be performed. Manual recording can still be done in RayCare and completion of the session is needed to be able to continue with the next delivery.

Treatment session completion

Once the treatment has been completed by the treatment delivery system, the treatment session must also be completed in RayTreat:

Click the **Complete session** button in the bottom right part of the Results workspace.





This opens a dialog that displays all the recorded beams during this treatment session.

- 2. Verify that the recorded data is correct.
- Complete the treatment session by clicking Yes. This opens the authentication dialog.
 Alternatively, if there is an error in the treatment recording, click No and correct the recording before completing the session.
- 4. Enter user name and password in the authentication dialog.

Note: The user who completes the session is responsible for ensuring that all of the delivery is correctly recorded. If the recording is not received automatically, a manual recording must always be performed in RayCare. This is necessary to ensure that an overdose will not occur in a continuation session.

Note: The user must complete an active session before continuing treatment with another

session.

Continuation session

If the fraction was not completely delivered in the first treatment session, the status Partially delivered will be displayed for one or more beams as well as for the entire treatment session. When completing a treatment session that is only partially delivered, it is possible to select the option to Create a continuation session in the Do you want to approve this delivery dialog. The planned meterset in the continuation session will be the difference between the planned values for the original treatment fraction and what was delivered.

After completing a treatment session and creating a continuation session, that session will need to be scheduled in RayCare.

Note:

For the Toshiba system, delivery of a continuation session is not possible based on a manual recording. The check-in of a continuation session in RayCare will be blocked if a partial session for the same fraction has been manually recorded. The manual recording of a previous fraction will not block the treatment of any upcoming fraction. Replace the manual recording of the partial session with the treatment record of the corresponding partial fraction in RayCare.

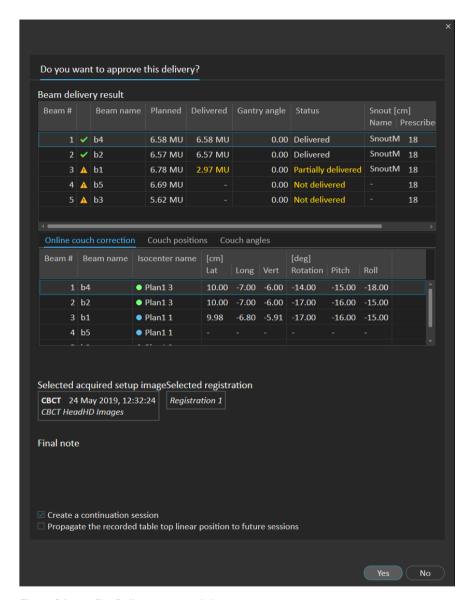


Figure 24. The Delivery approval dialog.

Propagate table top position

If the machine is set to support modifying table top positions, it is possible to propagate the recorded delivery table top linear position gained from the treatment record for all future fractions. This is done by checking the option **Propagate the recorded table top linear position to future sessions** and verifying the displayed absolute positions. If several beams are delivered, all beams must have

been delivered within the corresponding tolerances defined in the tolerance table used for the fraction. Lateral, longitudinal and vertical differences must all be within the tolerance.

Note: The Toshiba delivery system will not use table top positions set in RayStation or propagated in RayTreat. These values will, however, be presented as the planned couch positions in Beam Delivery Results presentations. Tolerance tables are applied to intended delivery parameters.

For plans with multiple isocenters, all delivered beams are considered in the validation of the tolerances. However, only the first delivered beam for the first isocenter is used to calculate the position for the propagated position. If no beam was delivered to the first isocenter, propagation is not possible.



Figure 25. The table top position propagation section of the **Delivery approval** dialog.



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