

RAYPLAN 10A SP1

Instructions for Use

Radiotherapy Edition



RayPlan
RayStation

10A

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Declaration of conformity




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.

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 RayPlan

RayPlan is a pre-determined configuration of RayStation. It supports the full range of treatment planning activities for 3D-CRT, SMLC, DMLC, VMAT, TomoTherapy and electron beam radiation therapy and includes highly accurate dose engines for photon and electron therapy.

RayPlan is compatible with all linear accelerators commercially available.

In this chapter

This chapter contains the following sections:

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1.1 ABOUT THIS MANUAL

This manual contains general product information, safety-related information, installation instructions, information about coordinate systems and machine scales and information about system integrity and safety. Please study this guide carefully before using the RayPlan 10A system. Proper functioning of the device can only be guaranteed if the instructions in this guide are adhered to. Study the Release Notes carefully, these notes provide final instructions on how to use the RayPlan 10A system.

Some modules described in this manual are not included in the standard configuration of RayPlan 10A and may require additional licenses.

1.2 RAYPLAN SYSTEM MAIN APPLICATIONS

The RayPlan system consists of the following main applications:



RayPlan – the main application where all the activities associated with treatment planning can be performed.

The RayPlan application is described in *RSL-D-RP-10A-USM, RayPlan 10A User Manual*.



RayPlan Physics – the beam commissioning application where activities such as beam commissioning, CT commissioning and beam 3D modeling activities can be performed.

The RayPlan Physics application is described in *RSL-D-RP-10A-RPHY, RayPlan 10A RayPlan Physics Manual*.



Clinic Settings – the clinic settings administration tool.

The Clinic Settings application is described in *RSL-D-RP-10A-USM, RayPlan 10A User Manual*.



RayPlan Storage Tool – the database administration tool.

The RayPlan Storage Tool application is described in *RSL-D-RP-10A-USM, RayPlan 10A User Manual*.

1.3 RAYPLAN DOCUMENTATION

1.3.1 RayPlan system documentation

The RayPlan 10A system documentation consists of:

Document	Description
<i>RSL-D-RP-10A-IFU, RayPlan 10A SP1 Instructions for Use</i>	This manual contains regulatory information and safety information concerning the RayPlan 10A system.
<i>RSL-D-RP-10A-RN, RayPlan 10A SP1 Release Notes</i>	This document provides a summary of new features, known issues and changes since the previous version of RayPlan.
<i>RSL-D-RP-10A-USM, RayPlan 10A User Manual</i>	This manual describes the functionality of the RayPlan 10A system and gives step by step instructions on how to perform the most common operations.
<i>RSL-D-RP-10A-RPHY, RayPlan 10A RayPlan Physics Manual</i>	This manual describes the RayPlan Physics application.
<i>RSL-D-RP-10A-REF, RayPlan 10A Reference Manual</i>	This manual contains algorithm descriptions and physics reference information.
<i>RSL-D-RP-10A-OPT, A Guide to Optimization in RayPlan 10A</i>	This manual contains detailed information about optimization in RayPlan 10A.

Note: *In the case of a service pack, only the affected manuals will be updated. For a complete list of the manuals that have been updated in the service pack, refer to the Release Notes document for that specific service pack.*

1.3.2 Other associated documentation

- *RSL-D-RP-10A-SEAT, RayPlan 10A System Environment Acceptance Test Protocol*
- *RSL-D-RP-10A-BCDS, RayPlan 10A Beam Commissioning Data Specification*
- *RSL-D-RP-10A-TPL, RayPlan 10A Third-Party Licenses*
- *RSL-D-RP-10A-DCS, RayPlan 10A DICOM Conformance Statement*
- *RSL-D-RP-10A-SEG, RayPlan 10A System Environment Guidelines*

2 PRODUCT INFORMATION

This chapter describes important information about the RayPlan 10A system.

In this chapter

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2.1 INTENDED USE

RayStation is a software system designed for treatment planning and analysis of radiation therapy. The treatment plans provide treatment unit set-up parameters and estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by the intended user.

The system functionality can be configured based on user needs.

Japan: For the intended use in Japan, refer to RSJ-C-00-03 Japanese regulatory IFU for RayStation.

2.2 INTENDED USER

The intended users of RayStation shall be clinically qualified radiation therapy staff trained in using the system.

2.3 CONTRAINDICATIONS

None known.

2.4 HARDWARE AND OPERATING SYSTEM

RayPlan 10A shall be installed on a high end PC, with a minimum of 16 GB ECC RAM (recommended 32 GB or higher depending on machine function) and a recommended screen resolution of 1920 x 1200 pixels (or 1920 x 1080). RayPlan 10A can be used with Windows 8.1 or Windows 10.

The system must only be used with a computer approved to applicable hardware safety standards with respect to electric failure and electromagnetic radiation.

It is recommended to install new Windows Service Packs. These are tested, cumulative sets of security and critical updates widely released by Microsoft. Also, the Security Updates, which are widely released fixes for operating system security-related vulnerabilities are recommended to install. It is discouraged from installing any other updates. After all updates, system performance must be verified, see *section 4.2 System environment acceptance test on page 52*.

2.5 MANUFACTURER CONTACT INFORMATION



RaySearch Laboratories AB (publ)
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SE-111 34 Stockholm
Sweden
Telephone: +46 8 510 530 00
E-mail: info@raysearchlabs.com
Country of origin: Sweden

2.6 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.

2.7 REGULATORY REPRESENTATIVES

The table below describes the regulatory representatives and their contact information.

Regulatory representatives	Contact information
Australian Sponsor	Emergo Australia Level 20, Tower II Darling Park 201 Sussex Street Sydney, NSW 2000 Australia
Chinese representative	RaySearch (Shanghai) Medical Device Co., Ltd Room 605, No. 1118, Pudong South Road Pilot Free Trade Zone, Shanghai China
Hong Kong representative	Emergo Hong Kong Limited 6/F, 100QRC 100 Queen's Road Central Hong Kong
Israeli representative	I.L Emergo Israel Ltd. Andrei Sakharov 9 Matam Park Haifa 3508409 P.O.B. 15054 Haifa 3190501 Israel
Japanese representative	RaySearch Japan K.K. Saiwai building, 1-3-1 Uchisaiwaicho Chiyoda-ku Tokyo 100-0011 Japan
Korean representative	RaySearch Korea, LLC 11F, Sin-il Building 131 oegye-ro (Chungmu-ro-2-ga) Jung-gu, Seoul, P.O. Box 04537 Korea
New Zealand Sponsor	CARSL Consulting PO Box 480 Pukekohe New Zealand

Regulatory representatives	Contact information
Singapore representative	RaySearch Singapore Pte. Ltd. 260 Orchard Road #07-01/04 The Heeren, Singapore 238855 Singapore
Taiwanese representative	Tomorrow Medical System Co., Ltd. 6F, No. 366, Chang Chun Road Taipei, 104 Taiwan
Thai representative	Kamol Sukosol Electric Co., Ltd. 665 Mahachai Road, 2nd Floor Samranraj, Pranakorn Bangkok 10200 Thailand
US Agent	RaySearch Americas, Inc. The Empire State Building 350 5th Avenue, Suite 5000 New York, New York 10118 USA

2.8 ACCURACY OF DOSE COMPUTATIONS

All dose engines in RayPlan 10A have been verified to be at the same level of accuracy as that of independent well-renowned treatment planning systems. Dose computations must still be validated by the user for all clinically relevant situations, refer to *section 3.1.1 Warnings concerning user responsibility on page 25* for more information.

Note: *RayPlan beam models are general with respect to machine type and properties. It may be possible to create beam models for treatment machine setups that have not been explicitly validated by RaySearch.*

2.8.1 Accuracy for the photon dose engines

RayPlan has two photon dose engines: collapsed cone and Monte Carlo. The validation strategies for the two dose engines are described below, followed by a description of the validation scope for different machines and treatment techniques. The Monte Carlo dose engine does not support TomoTherapy machines.

Validation strategy for the collapsed cone photon dose engine

RayPlan validation has been performed against a substantial set of measurements including point doses in homogeneous and heterogeneous phantoms, line doses, film and measurements using the Delta4, MapCheck, ArcCheck, MatriXX, Octavius1500 and PTW 729 detectors. This includes the IAEA test suite, which includes measured doses for an Elekta machine for a number of test cases for energies 6 MV, 10 MV and 18 MV¹. The acceptance criteria of the validations against measurements are formulated in terms such as the gamma criterion (pass if the gamma value is below 1 for 95% of the data points for gamma 3%, 3 mm), point dose differences and confidence levels¹. The overall accuracy is acceptable. Some algorithm limitations have been identified and are described in this section, in the warning 4001 in *section 3.1.1 Warnings concerning user responsibility on page 25* and in the Algorithm weaknesses section in *RSL-D-RP-10A-REF, RayPlan 10A Reference Manual*.

The collapsed cone photon dose engine in RayPlan 10A has also been compared to classical well-renowned treatment planning systems, such as Eclipse (Varian), Pinnacle³ Radiation Treatment Planning System 7.2 (Philips), Monaco (Elekta) and Oncentra (Elekta). The comparison includes plans for Siemens, Elekta and Varian machines. Agreement between the dose computed by the independent treatment planning systems and the RayPlan dose is defined to mean that the global gamma² value is below 1 for 95% of the volume for gamma criterion (3%, 3 mm), and for 98% of the volume for gamma criterion (5%, 5 mm). Since all cases return gamma distributions within the acceptance criteria, the dose engine computations can be regarded as equivalent to the clinical systems to which they were compared.

¹ IAEA-TECDOC-1540, Specification and Acceptance Testing of Radiotherapy Treatment Planning Systems, April 2007.

² Low D.A., Harms W.B., Mutic S, and Purdy J.A., A technique for the qualitative evaluation of dose distributions, Med. Phys. 25 (1998) 656-661.

The validation has focused on typical clinical usage, with common LINAC models such as Varian (600 CD, CLINAC, 2100, 2100 EX, 2300C/D, Trilogy, TrueBeam with MLCs MLC120, HD120, Millennium MLC, m3 and Halcyon), Elekta (with MLCi/MLCi2, Beam Modulator and Agility heads), and Siemens (Primus with 3D-MLC and Artiste), for energies between 4 MV and 20 MV, and water phantoms and patient geometries. Flattening filter free delivery is validated using Siemens Artiste and Varian Halcyon. Most data is collected using MLCs with leaf widths of 5 mm and 10 mm. RayPlan 10A has also been validated with the Brainlab m3 add-on MLC on a Varian Novalis machine. The m3 MLC has not been validated with any other machine, for example a machine without backup jaw such as the Siemens machines. No other add-on MLC has been validated.

Validation for wedges, blocks and cones

For wedges the validation is performed solely in water. The validation is focused on central square fields with a few exceptions. Validation of Varian standard wedges shows deviations between RayPlan 10A computed dose and measured dose in the build-up region of depth dose curves, especially for higher energies. This is important to be aware of and special care should be taken when verifying and evaluating such beam models. Block validation is performed by comparing RayPlan 10A to Eclipse (Varian) and Oncentra (Elekta) returning gamma distributions within the acceptance criteria and as part of the IAEA test suite. The IAEA test suite also includes Elekta wedges. Only divergent photon blocks are supported. Cone validation is limited to Elekta LINACs.

Dose calculation for rotational plans

Standard VMAT delivery technique has been validated for Varian, Elekta and Vero LINACs. Sliding window VMAT sequencing is supported for Elekta Agility, Elekta MLCi2 and Varian. VMAT sequencing should be considered on par with a new treatment technique and therefore beam model and machine behavior validation, and per-patient QA must be performed.

The validation has shown that the RayPlan dose calculation for small field rotational plans is highly sensitive to beam model MLC parameters.

RayPlan 10A offers the VMAT burst mode technique, where every second segment contains MLC motion without beam on and every other segment has beam on without MLC motion. The burst mode technique is only intended and validated for Siemens machines.

Dose calculation for Vero

For RayPlan 10A, validation for the Vero machine has been performed. The CC dose engine has been successfully validated in comparison to measurements for static MLC and VMAT plans.

Dynamic IMRT (DMC) for Vero has not been validated and DMC is not available for Vero machines in RayPlan 10A. The Vero validation is limited to the Vero MLC with 30 leaf pairs with all leaf widths 0.5 cm. Dynamic tracking delivery has not been part of the RayPlan 10A validation. It is up to the user to validate the delivered dose for Vero plans with dynamic tracking enabled.

Validation strategy for the photon Monte Carlo dose engine

The photon Monte Carlo dose engine uses the same fluence computation in the LINAC head as the collapsed cone dose engine. The description of MLC details, blocks, cones, virtual wedges and physical wedge transmission has been validated thoroughly in combination with the collapsed cone dose engine. The same fluence computation has been validated also in combination with the Monte

Carlo dose computation using a representative subset of the measurements from the collapsed cone dose computation. The subset is selected to cover different energies (4 MV to 20 MV), LINAC models (Varian with MLC120, HD120 and m3 and Elekta with MLC Agility and MLCi/i2), wedges (Varian standard wedge, EDW and Elekta motorized wedge), cones and blocks, treatment techniques (3D-CRT, SMLC, DMLC and arc treatments) and homogenous and heterogeneous geometries. The IAEA test suite (Elekta 6 MV, 10 MV, 18 MV) was included and a high resolution AAPM TG105 test suite (TrueBeam with 6 MV, 10 MV, 10 MV FFF) with heterogeneous inserts for different geometries (slabs, inclined incidence, nose-shaped surfaces, steps) in water was added compared to the collapsed cone dose validation.

Measurements included scanned profiles, depth doses and point measurements in water and in the CIRS phantom, and Delta4, ArcCheck and MapCheck measurements. The acceptance criteria were the same as the ones used for the collapsed cone validation and the overall accuracy was acceptable. Most limitations described in *section 2.8.1 Accuracy for the photon dose engines on page 15* also apply for the photon Monte Carlo dose engine. For details see *RSL-D-RP-10A-REF, RayPlan 10A Reference Manual*. See also warning 4001 in *section 3.1.1 Warnings concerning user responsibility on page 25*.

In addition to the measurement based validation, the photon Monte Carlo computation in patient has been cross-checked against EGSnrc for different geometries (slabs, off-axis heterogeneous inserts, curved surfaces), materials (water, lung, bone, aluminum, titanium), energies (0.5 MeV to 20 MeV) and fields sizes (0.4 cm x 0.4 cm to 40 cm x 40 cm). Since the measurement uncertainty is no longer present, the acceptance criteria in the validation tests using simulated dose are stricter than those for measurement; 95% of all voxels are required to have a gamma value below 1 for gamma 2%, 2mm.

The Monte Carlo dose engine does not support TomoTherapy machines. The computation has not been validated for Vero and Siemens LINACs. It is up to the user to validate RayPlan 10A Monte Carlo dose computation with Vero and Siemens machines.

2.8.2 Accuracy for the electron dose engine

The electron Monte Carlo dose engine in RayPlan 10A has been compared to the Oncentra (Elekta) treatment planning system using the same gamma criteria as for photons. The comparison with Oncentra includes plans for an Elekta Synergy machine. Since all cases return gamma distributions within the acceptance criteria, the electron dose computations can be regarded as equivalent to the clinical system to which it was compared.

In addition, the electron dose engine in RayPlan 10A has been compared to measurements for treatment machines with x and y jaws (Elekta and Varian), Elekta machines with Beam Modulator and machines without x jaws (Elekta Agility and Siemens).

The RayPlan 10A system has been validated for typical clinical usage of applicator with cutout collimated fields. Only Cerrobend cutouts with straight edges, i.e. parallel to the beam axis line, are supported and validated.

The electron dose calculation in RayPlan allows for energies between 4 MeV and 25 MeV. Validation has been performed in the range 4-20 MeV. The same algorithm and code are used for high energies

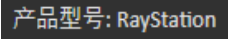
and for low energies and there are no reasons to expect any change in performance for nominal energies between 20 MeV and 25 MeV. The energy ranges for the VMC++ code covers energies from 0.1 MeV up to and above 25 MeV.

However, special care should be taken when using electrons with energies higher than 20 MeV.

2.9 PRODUCT LABEL

The version number of an installed RayPlan 10A system can be found by choosing **Help: About RayStation** in the RayPlan menu.

The following information can be identified:

- Product name = RayStation
-  (for the Chinese market only)
- Release version = **10.0**
- Marketing name = RayPlan 10A SP1
- Software build number = **10.0.1.52**
- Clinical build = Indicates that this is a product for clinical use
- 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)
- **MD** = Indicates that the product is a medical device
- **UDI** = Unique Device Identification number
- **CE**₀₄₁₃ = The CE mark and the notified body number
- **📅** = Production date
- **📖** = Consult instructions for use
- **🏭** = The name and address of the manufacturer
- **@** = The support e-mail address

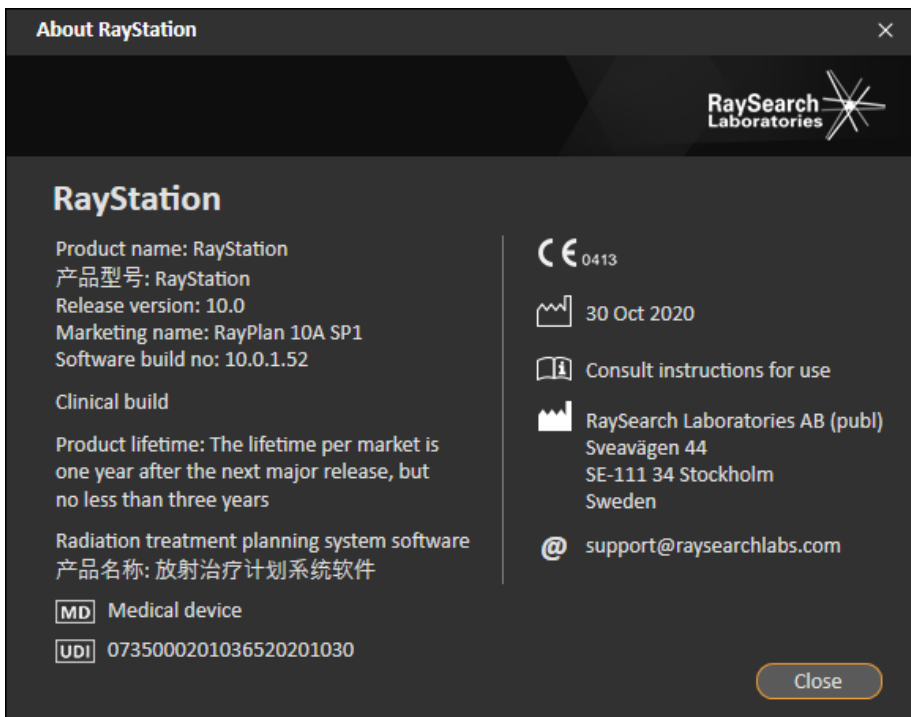


Figure 1. The **About RayStation** dialog for RayPlan.

2.10 LIFETIME

The lifetime per market is one year after the next major release, but no less than three years. Support for a product version in a market ends 36 months after market clearance, provided a new major version is released within 24 months. If not, support is prolonged and ends 12 months after the next major version is released in that market. When a version is no longer supported in a given market, it is considered to be end of life in that market.

2.11 REGULATORY INFORMATION

Disclaimer

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

Printed material

A hard copy of the Instructions For Use and other applicable manuals are available upon request.

3 INFORMATION NEEDED FOR SAFE OPERATION

This chapter describes information needed for safe operation of the RayPlan 10A system.

Note: *Be aware that additional safety-related release notes may be distributed separately within a month of software installation.*

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3.1 SAFETY PRECAUTIONS

Adhere to the following warnings for safe operation of the RayPlan 10A system.

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3.1.1 Warnings concerning user responsibility

WARNING!

Ensure sufficient training. The user organization shall ensure that individuals authorized to perform treatment planning functions are appropriately trained for the functions they perform. Only individuals authorized to perform treatment planning 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. {508813}

WARNING!

Input data quality. Always be aware that the quality of the output depends critically on the quality of the input data. Any irregularities in the imported data or uncertainties about input data units, identification, image orientation or quality of any other nature shall be thoroughly investigated before the data is used. {508811}

WARNING!

Plan review and approval. All treatment plan data shall be carefully reviewed and approved by a qualified person before it is used for radiotherapy treatment purposes. A plan (beam set) that is 'optimal' with respect to the optimization goals may still be inappropriate for clinical use. {508826, 508814}

WARNING!

Beam models must be validated before clinical use. It is the responsibility of the user to validate and commission all beam models before they are used to create clinical treatment plans.

RayPlan 10A is developed to be used by trained Radiation Oncology professionals. We strongly suggest that users adhere to recommendations published in AAPM TG40, TG142, TG53, IAEA TRS 430, IAEA TRS 483 and other standards to assure accurate treatment plans.

Computed dose accuracy depends directly on the beam model quality. Beam model insufficiency may lead to deviations between approved and delivered dose. All parameter values and plan QA and QC shall be reviewed and approved by qualified physicists. The dose calculation must be validated for all commissioned CT machines.

- The computed dose shall be validated for all relevant clinical situations including, but not limited to, variation in SAD, SSD, field-size, field-shape, off-axis position (x, y and diagonal), collimation type, degree of modulation, leakage dose (variation in MU/Gy or NP/Gy), couch/gantry/collimator angles, patient/phantom material composition and patient/phantom material geometry.
- Known limitations are described in the *RSL-D-RP-10A-REF, RayPlan 10A Reference Manual*. Additional limits of operation for each beam model must be identified during validation and adhered to during planning.

For photons:

Special care should be taken before using RayPlan 10A with MLC leaves smaller than 5 mm, materials that differ from common patient materials, blocks, wedges (in particular off-axis wedges), complex VMAT plans, rotational plans with small field sizes, Siemens mARC plans and wave arc plans, especially with larger ring rotation than 15 degrees.

Note that:

- a beam model validated for 3D-CRT is not necessarily suitable for IMRT plans.
- a beam model validated for SMLC is not necessarily suitable for DMLC plans.
- a beam model validated for SMLC or DMLC is not necessarily suitable for VMAT plans.
- a beam model validated for VMAT is not necessarily suitable for plans created using sliding window VMAT sequencing.

Validation must be performed for each selected treatment technique using Beam 3D modeling or RayPlan. For C-arm LINACs, see warning 9356 and 3438. For TomoTherapy treatment machines, see also warning 10172.

For electrons:

Validation shall include relevant applicator geometries, field sizes without cutout, field shape orientation for rectangular applicators, cutout material and thickness, correct air gap to isocenter, correct D50 water range per nominal beam energy, correct field shape for field with cutout. Only Cerrobend cutouts with straight edges, i.e., parallel to the beam axis line, are supported.

(4001)

WARNING!

TomoTherapy machine commissioning. When commissioning a TomoTherapy machine, most parameters are read from iDMS and only minor changes are expected to be required in the machine model in RayPlan Physics. The transverse profile, jaw fluence output factors and leaf latency offsets are overwritten in this process and may need to be updated.



Note that for TomoTherapy machines the computed dose curves in the Beam commissioning module are normalized against the measured curves, i.e., the measured and computed dose curves will match in output regardless of the output of the beam model. The output of the model must therefore be adjusted and verified for all field widths using TomoHelical beams. For more information, refer to the *RSL-D-RP-10A-BCDS, RayPlan 10A Beam Commissioning Data Specification*.

Note also that the MLC filters are not part of the dose curve calculation in the Beam commissioning module in RayPlan Physics and their usage can only be verified using TomoHelical or TomoDirect beams.

The dose calculation must be validated for the relevant range of clinical treatment fields before clinical use. In addition to what is listed in warning 4001, validation shall include different jaw sizes and modes, projection times, opening fractions and pitches.

(10172)

WARNING!

Block/cutout verification. Always verify that the blocks and electron beam cutouts created in the Beam design modules are physically realizable. It is not possible to define any block manufacturing constraints in RayPlan.

Always check the created block against the block aperture printout. (508816)

WARNING!



Verify the scale of the block/cutout printout. The printer settings will affect the actual size of the block/cutout in the printout. Before using the block/cutout printout for block/cutout manufacturing or verification, always check that the scale of the x- and y-axes are equal and that 1 cm on the verification scale corresponds to 1 cm using a ruler. {508818}

WARNING!



ROI/POI verification. Always review all regions of interest (ROIs) and points of interest (POIs) carefully before using them for treatment planning or evaluation purposes. {508820}

WARNING!



Review 4DCT projections. The user shall review the resulting image set from a 4DCT projection before using it for treatment planning or evaluation purposes. The projected image set shall be compared against the image sets in the 4DCT group in order to verify that the Hounsfield Units and corresponding densities are as expected. This can be performed by examining HU values in the patient views and by computing evaluation doses in the Plan Evaluation module.

The geometrical properties of the projected image set, such as orientation, position and size shall also be compared against the original 4DCT. This can be performed by fusing the projected image sets with the original 4DCT image sets in the Structure Definition module or the Image Registration module and verify that they are aligned correctly. {117566}

WARNING!



Image specific density table obtained through HU rescaling. When using an image set specific density table obtained through HU rescaling it is highly important that the user reviews the resulting density table properly before using it for dose computation. The rescaled density table will directly affect the dose computation. {125272}

WARNING!

Patient setup. Couch shift (table top translation) instructions for positioning the patient are displayed in the Patient setup dialog and in the plan report.

The default couch shift presentation is "Patient", i.e., the couch shift instructions in the Patient setup dialog are expressed in terms of patient anatomical directions.



If desired, the couch shift presentation can be changed to "Couch", i.e., the couch shift instructions in the Patient setup dialog are expressed in couch directions. The couch shift presentation is changed in the Clinic Settings application.

Before clinical use, always verify that the couch shift displayed in RayPlan and in the plan report are as intended and in accordance with clinical practice.

Note that another option for patient setup is to export the couch shift according to the DICOM standard. This option can be selected in RayPlan Physics. {252059}

WARNING!

Review frame-of-reference registration before dose computation. It is especially important that frame-of-reference registrations that have been imported are reviewed before computing dose on additional image sets. {360380}

WARNING!

Restricted sale in the U.S. Federal (U.S.) and State laws restrict the sale of this product to a physician or on a physician's order.

{4782}

WARNING!

Report template naming. User-created report templates do not necessarily need to include all information about patient, plan, beamsets, etc. For example, a report template may only include the currently selected beam set. Use a clear naming convention when creating report templates. {5147}

3.1.2 Warnings concerning installation

WARNING!



Display settings. Be aware that the RayPlan 10A system's visual output depends on monitor calibration, resolution and other hardware specific parameters. Ensure that the monitor output is appropriate for the clinical tasks. (366562)

WARNING!



Hardware/Software platform. The System Environment Acceptance Test shall be performed whenever the hardware or software platform is changed. (366563)

WARNING!



Installation tests. The user must add additional tests specific for the installation and configuration of the RayPlan 10A system at the user organization. (366564)

WARNING!



Use of non-ECC GPU memory. GPUs used for computations must have ECC RAM and the ECC state must be enabled in the GPU driver settings. Deformable image registration may however be computed on GPUs without ECC RAM.

(8453)

WARNING!



Dose calculation on GPU may be affected by computer/driver updates. If GPU is used, the dose calculation on GPU must be revalidated after any hardware or software platform changes, including operating system Service Packs. This can be done by running the *RSL-D-RP-10A-SEAT, RayPlan 10A System Environment Acceptance Test Protocol*. For photon dose computation, additional validation should be performed by recalculating dose curves for all commissioned treatment machines in the database.

(4039)

3.1.3 Warnings concerning general system use

WARNING!

Running multiple instances of RayPlan 10A. Take extra care when running multiple instances of RayPlan 10A. Always make sure that you are working on the correct patient. {508895}

WARNING!

Independent dose calculation. Ensure that the independent dose calculation system that is used really is independent. There are systems that may appear to be suitable for independent dose calculation that are in fact not independent at all since the dose engine is manufactured by RaySearch and uses the same algorithm for photon dose computation and possibly also the same code as RayPlan (e.g., Compass (IBA)). {113204}

3.1.4 Warnings concerning DICOM import

WARNING!

Image set integrity. DICOM provides no way of verifying that all image slices in an image series are included. The user must always verify this manually after import. {508830}

WARNING!

Imported dose. An imported dose for an approved plan will automatically be considered clinical. {508831}

WARNING!



For imported dose, no assumptions on how the dose was calculated are made.

The dose will not be invalidated when data that is used for calculating dose in RayPlan is different from the data the imported dose was calculated on. This applies even if the imported dose was originally calculated in RayPlan. For example, if the structure set is modified with density overrides or with changes to the External ROI, the imported dose will not be invalidated.

[224134]

WARNING!



Fractionation scheme is discarded in DICOM import. When a DICOM plan is imported to RayPlan the fractionation scheme is discarded. As a result, the beam sets created during the import will always be set for sequential delivery even if the original plan indicated an interleaved pattern.

In addition, the delivery order indicated by the beam set order may not match the intended delivery order. As a consequence, no activities that rely on a correct fractionation scheme shall be performed after the import. [119127]

WARNING!



Export after using DICOM import filter. Avoid exporting data that has been modified by DICOM import filters during DICOM import. This will prevent creating different files with the same DICOM UID. [508832]

WARNING!



No error indication when using Storage SCP. There is no indication in RayPlan 10A if patient data import using Storage SCP is incomplete due to e.g., errors during the transfer session or failure with writing file to disc. [508833]

3.1.5 Warnings concerning DICOM export

WARNING!



Export failure. When exporting data from the system, always verify that the export was successful. If the export is interrupted due to e.g., hardware failure or operation systems errors, delete any exported data and restart the export. {508805}

WARNING!



DICOM RT Structure set export. The DICOM export of the RT Structure set will convert all ROIs to contours and any structure parts outside the upper or lower image set slice will not be included.

This applies to ROI geometries with mesh or voxel representation. Such geometries are typically created by using model-based segmentation or by using 3D ROI interaction tools in RayPlan. The DICOM export only handles contours on image slices, which means that the parts that extend outside the first or last slice of the image set will not be included in the export. Thereby they will not be identical after a DICOM export/import roundtrip into RayPlan or an external system. {508804}

WARNING!



Treatment parameters shall be transferred from the RayPlan system using DICOM export. Ensure that control points for a treatment plan are exported from the RayPlan system using DICOM export. The user shall not manually transfer these settings. {508803}

WARNING!



DICOM export of Vero plans. Extra care must be taken when DICOM exporting a plan with multiple isocenters to the Vero R&V system. It is necessary to perform the DICOM export twice, once with the ExacTrac Vero checkbox checked and once with the checkbox unchecked. {125706}

WARNING!



Transaction errors when exporting to iDMS. If an error occurs during plan export there might be no indication in RayPlan. The patient and plan state must be verified by the operator in iDMS. (261843)

3.1.6 Warnings concerning dose computation

General dose computation warnings

WARNING!



Dose computation region. Radiation transport and dose is computed only inside a region consisting of ROIs of type External, Bolus for beam, Support and Fixation. Image data not included in this region will be omitted from dose computation and is regarded as a vacuum (no interactions).

If the beam Field Of View covers part of the patient not inside the External ROI or any equipment not defined by Bolus, Support or Fixation ROIs, the dose computation will be incorrect.

Note also that the computation is limited to the dose grid. There is no warning if the dose grid does not cover the appropriate region. (508993)

WARNING!



Ensure that the correct ROI has been assigned as the External ROI. Always verify that the External ROI covers all target ROIs and OARs. Dose volume histograms might be computed erroneously if the entire ROI is not included in the External ROI. (508994)

WARNING!



Ensure that the dose grid covers all intended ROIs. Only the part of an ROI covered by the dose grid is included in the DVH and in the dose statistics computation.

(9358)

WARNING!

Dose grid resolution affects dose. Both dose output and shape can be significantly affected by dose grid resolution and alignment. Make sure to use an appropriate dose grid considering factors such as e.g., field size, modulation and patient geometry. (512955)

WARNING!

CBCT values to density table. RayPlan uses an image-specific CBCT values to density table. Always review the density table before it is used in dose computation. The review can be performed through spot check of selected slices in the Create Density Table for CBCT dialog where the effect of the density table is visualized. (508999)

WARNING!

Pixel padding. If pixel padding is present in the region used for dose computation, the calculated dose may be incorrect. Make sure that the pixel padded Hounsfield Units map to the desired density or make sure to add a material override to the pixel padded region.

If the CT-image has excluded material which will be present at treatment and which is inside the radiation scatter region, it is not recommended to use pixel padded values. Instead, add a material override to each material to include them in the dose computation. Failure to do so might lead to errors in the dose computation.

If everything that is important for radiation transport is inside the CT-image, but the External ROI covers image parts with pixel padding values that correspond to high density Hounsfield Units, this could also lead to errors in the dose computation. (509000)

WARNING!

Material override for multiple structure sets. If material override is defined for an ROI which does not have any geometry defined in the used image set, there will be no warning when computing dose. (509001)

WARNING!

Bolus ROIs need to be assigned to beam(s). Bolus ROIs are regarded as beam properties. In order for a bolus ROI to be used for radiation transport and dose computation for a certain beam, it must be explicitly assigned to that beam. If a bolus is to be used for all beams, it must be assigned to all beams individually. A bolus which is not assigned to any beam in a plan is not going to be included in the dose computation at all. [136280]

WARNING!

The use of ROIs of type Fixation and Support. ROIs of type Fixation and Support are intended to be used for regions with patient support, fixation or immobilization devices, and should only be used for structures that are mainly outside of the patient outline. Always use other ROI types for material override within the External ROI. A small overlap with the External ROI is acceptable if the Fixation or Support ROI is mainly outside the External ROI. The use of Fixation or Support ROIs that are mainly within the patient outline, can lead to errors in the calculation of the mass density of voxels that are intersected by both the External and the Fixation/Support ROIs. Refer to the *RSL-D-RP-10A-REF, RayPlan 10A Reference Manual* for more details about these effects. [262427]

WARNING!

MR planning: Bulk density assignment. RayPlan planning based only on MR images relies on the user specified bulk-density assignment. Note that for certain configurations/regions, a bulk-density assignment using a homogeneous material will produce an unacceptable dosimetric error. [254454]

WARNING!

MR planning: Geometric distortion and field-of-view. MR images intended for planning must have negligible geometric distortion. RayPlan does not include any algorithm for distortion correction. The MR image should cover the patient outline. [261538]

Electron dose computation warnings

WARNING!



Maximum allowed statistical uncertainty does not affect already computed clinical Monte Carlo dose. When changing the Maximum allowed statistical uncertainty in Clinic Settings for clinical Monte Carlo electron dose, be aware that already computed doses are not affected. Doses computed prior to the change may therefore be marked as clinical although they have a statistical uncertainty that would not result in clinical dose if they were recomputed. (509008)

WARNING!



Electron dose calculation for small cutout sizes. Limited accuracy in calculated output for small cutout sizes has been reported for the RayPlan electron dose calculation. A difference between measured and computed output of more than 3% has been reported for cutout sizes of 4x4 cm², and more than 5% for cutout sizes of 2x2 cm².

The user needs to be aware of this limitation and thoroughly verify the output of the calculated electron dose for small cutout sizes.

(142165)

Photon dose computation warnings

WARNING!



CBCT photon dose calculation. Dose calculation using a CBCT imaging system may be less accurate than using a CT imaging system since there is a limited set of density levels specified for a CBCT compared to what is normally specified for a CT. The accuracy of the dose calculation using CBCT relates to the tuning of the CBCT scale to density, and how well the real density maps against the selected CBCT density. This must be validated by the clinic before using CBCT doses for clinical decisions. Dose calculation on CBCT image data sets is not supported for electrons.

(9356)

WARNING!



Maximum allowed statistical uncertainty does not affect clinical status of already computed Monte Carlo dose. When changing the Maximum allowed statistical uncertainty in Clinic Settings for clinical Monte Carlo photon dose, be aware that already computed doses are not affected. Doses computed prior to the change may therefore be marked as clinical although they have a statistical uncertainty that would not result in clinical dose if they were recomputed. [620870]

3.1.7 Warnings concerning patient modeling

WARNING!



Automatic ROI generation and modification. Always verify the outcome of automatic ROI generation and modification. Special attention should be given to choosing the appropriate organ model for the patient based on characteristic model properties such as body region, patient position, and image modality. This applies to all automatic segmentation methods including model-based segmentation, atlas-based segmentation, and deep learning segmentation.

Note that no automatic organ segmentation may be used to identify lesions in RayPlan.

[9662]

WARNING!



Automatic image registration. Always verify the outcome of automatic image registration. [360374]

WARNING!

Image set slice spacing and extrapolation of contours. In RayPlan, the 3D reconstruction of an ROI from contours assumes that the first and last contours extend half a slice distance. The first and last contours of an ROI are therefore extrapolated half a slice distance from the outermost drawn contours. Note that there is no limit for this extrapolation, it is always half a slice distance. For typical image sets with a slice distance of about 2-3 mm this means that RayPlan extrapolates 1-1.5 mm, but in an image set with wide slice spacing, this extrapolation may lead to unexpected behavior. It is therefore highly recommended to always use planning CTs reconstructed with a slice spacing less than or equal to 3 mm. {125440}

WARNING!

Missing intermediate ROI contours. If there are missing intermediate ROI contours, the gap is NOT filled in automatically.

If there are image slices with missing contours between the outermost contours of the ROI geometry, no automatic interpolation is performed between the contours. This applies to imported contours as well as contours generated in RayPlan. {360375}

WARNING!

ROI geometry extending outside the image set. When performing a contour operation (e.g., manual drawing, simplify contours etc.) on an ROI that extends outside the top or bottom of the image set, the ROI will be cut at the top and bottom slices of the image set. {240137}

3.1.8 Warnings concerning treatment planning**WARNING!**

Collision avoidance: Always verify patient position, gantry angles and couch angles (ring angles instead of couch angles for the Vero machine). The patient/machine setup must be manually verified for all beams to avoid collisions causing patient injury or equipment damage. The Room view shall not be used to verify that no collisions will occur with current patient/machine set up. For TomoTherapy treatments, see also warning 254787. {508898}

WARNING!

Select correct treatment position. Make sure that the correct treatment position (head first/feet first) is selected for the patient when creating a treatment plan. The selected treatment position will affect how beams are oriented relative to the patient. Incorrect specification may lead to mistreatment of the patient.

Note that a treatment position different from the patient position in the CT data (patient scanning position) can be selected when a plan is created. Only use this option if the patient is to be treated in a different position than he/she was positioned in during scanning. [508900]

WARNING!

Collimator angle for VMAT, Conformal Arc and Static Arc. Collimator angles 0, 90, 180 and 270 degrees should if possible be avoided for arc beams as these may lead to accumulated dose leakage. The collimator angles should preferably be shifted at least 10 degrees from the above values. The accumulated dose leakage due to interleaf transmission is not reproduced by the clinical dose computation. Be aware of this when making clinical decisions. Closed leaf pairs are likely to be positioned in the middle of the target projection which may accumulate the leakage to the center of the target at these collimator angles.

3305

WARNING!

Computing dose for small structures. It is important to choose dose grid resolution based on the smallest structures that need to be reconstructed. When structures are reconstructed for visualization in patient views, a structure specific high-resolution grid is used in order to represent the structure accurately. However, for plan optimization, dose computation and dose statistics, the structures are reconstructed on the dose grid. If the dose grid voxels are too large, the reconstruction may represent the structures inaccurately. Furthermore, there will be a discrepancy between the visualized structures and what is actually used for dose computations. It is therefore highly recommended to use a dose grid resolution such that the size of one dose grid voxel does not exceed half the size of the smallest structure to be reconstructed. [254767]

WARNING!

Density visualization. Note that if selecting to visualize density, this does not include ROIs of type bolus, support and fixation. {259822}

3.1.9 Warnings concerning TomoHelical and TomoDirect planning

WARNING!

Collision avoidance for TomoHelical and TomoDirect. After isocenter adjustments, always make sure that the patient will fit comfortably on the couch in the gantry bore. The 2D and 3D views include machine specific FOV and Bore visualization that can be used to verify that no collisions will occur. Do not use the Room view to verify collision avoidance. {254787}

WARNING!

TomoDirect treatment through the couch. The TomoTherapy couch consist of a fixed lower pallet and a movable upper pallet. The upper pallet position during delivery can be different from the planning position due to lateral patient setup adjustments. This can influence dose for beams entering through or close to the edge of the upper pallet. Daily gantry roll corrections can also change the path of the beam through the couch. Avoid creating TomoDirect plans with a large fraction of the dose from beams entering through or close to the edge of the upper pallet.

{5062}

WARNING!

Beam Entry Validation for TomoHelical plans. Be aware that there is no image stack entrance control performed for TomoHelical plans. {254782}

WARNING!

Single Patient DB per iDMS. An iDMS shall only receive data from one Patient DB in order to avoid consistency errors. A patient lock in Patient DB assures that the same patient is not exported to iDMS simultaneously from two RayPlan instances. {261846}

WARNING!



Motion synchronization for TomoHelical plans. When motion synchronization is used for a TomoHelical plan, three imaging angles (0, 90, 270 degrees) are created as a starting point. The user needs to manually edit the angles, evaluate them and make sure that they are appropriate for imaging of the selected targets to track.

At approval or export, the angles are validated to ensure that they do not violate some constraints. For example, all angles need to be separated by at least 30 degrees. However, note that there is no validation that the angles are well-suited to be used for target tracking.

(143545)

3.1.10 Warnings concerning dose evaluation

WARNING!



Interpolated dose values are shown in the patient views. Interpolated dose values are shown in the patient views by default. Ensure that an appropriate dose grid resolution for the specific treatment planning situation is used. (508958)

WARNING!



Display of total dose. It is always the total dose for all planned fractions that is displayed in the patient views, the DVH graph, the dose statistics and in the clinical goals list.

The exception is the QA module, where the dose is displayed for one fraction. (508959)

WARNING!

System checks at approval. Be aware that the following checks before approval are only performed for planning doses:

- Beam entry validation.
- A Bolus ROI geometry exists.
- A Support ROI geometry exists.
- A Fixation ROI geometry exists.
- The Dose grid resolution is smaller than 5 mm in all directions.



For evaluation doses, the user is responsible for performing these checks.

Note that having a planning dose grid which encloses the External ROI, support ROIs, fixation ROIs and bolus ROIs does not guarantee that all relevant regions are included for dose computation on additional datasets. {508962}

WARNING!**Approximate dose is only intended for intermediate treatment planning steps.**

Approximate dose has lower accuracy compared to the dose displayed as "Clinical" and it must not be used for clinical decisions. A plan with approximate dose cannot be approved or exported. {126034}

3.1.11 Warnings concerning beam commissioning

General beam commissioning

WARNING!



Beam model quality depends on beam data. The quality of the beam model depends critically on the quality and scope of the beam data, for example, dose curves, output and wedge factors, absolute calibration, phantom size and collimation settings which influence the curve field setup. The entered measurement conditions must match the measurement technique. The sizes of the measured fields should cover the field sizes of the future applications of the beam model.

All input data, such as measured curves and output factors, must be coherent and correspond to the delivery system which is to be commissioned. Otherwise the generated beam model will not be able to calculate a correct dose.

For more information, refer to the *RSL-D-RP-10A-BCDS, RayPlan 10A Beam Commissioning Data Specification*. {508979}

WARNING!



Machine constraints. If the machine constraints defined in RayPlan Physics do not reflect the treatment machine and R&V-system behavior, the plans can either be stopped at delivery or adjusted outside RayPlan giving a situation where the delivered dose differs from the approved dose. When creating a machine model from a template, ensure that all machine constraint parameters are adapted to your specific treatment machine.

Even if RayPlan adheres to all machine constraints specified in RayPlan Physics, there is no guarantee that all plans will be possible to deliver. Ensure that plans are not modified outside RayPlan in a way that significantly affects dose without proper evaluation.

{3185}

WARNING!



Beam model parameters. The accuracy of the dose computation depends critically on the beam model parameters established during beam commissioning. Before a machine is commissioned, all beam model parameters must be carefully reviewed by a person with proper training. {508983}

WARNING!

Always review curves after import. Always review curves after import to ensure consistency with the measurement situation. The beam model quality depends critically on correctness of the imported data. [508984]

*LINAC beam commissioning***WARNING!**

Modulated dynamic arc machines require information about collimator motion, gantry motion and dose rates. Deviation between the selected values and LINAC/R&V-system behavior may result in differences between delivered dose and dose approved in RayPlan. [508981]

WARNING!

Siemens virtual wedge. The Siemens virtual wedge parameters mean linear attenuation and calibration shall be adjusted from the default values to the proper values for your LINAC. Failure to do so may lead to error in the computed clinical dose. [3180]

WARNING!

Dose curve wedge orientation. The wedge orientation for wedged curves is determined from the curve at import. All wedge angles must have been measured with the same orientation. If all curves do not have the same wedge orientation, then no curves will be imported. For curves where the orientation cannot be determined, it is assumed to be identical to other curves imported at the same time. [508987]

WARNING!

Collimator calibration. The collimator calibrations (offset, gain and curvature) are used to shift the collimator positions from the plan positions (shown in the Beam's Eye View, in beam lists, in reports, exported in DICOM etc.) to an effective position used in dose computation. For dose curves this only shifts the penumbra, but for a VMAT, SMLC or DMLC field with many segments adding up, this can change the overall dose level. Ensure that the collimator shift in the beam model is really intended. Be extra careful with gain and curvature shifts which increase with increasing distances from the origin. Results from the auto-modeling collimator calibration step must be reviewed before clinical use. [508988]

WARNING!

Beam profile correction and off-axis softening at large field radii. The photon beam model parameters *Beam profile correction* and *Off-axis softening* cannot be evaluated at large radii in the Beam commissioning module without having imported diagonal profiles which extend to the corners of the field. Special care must be taken when using auto-modeling for the *Beam profile correction* and *Off-axis softening* parameters if there are only x- and y-profile curves imported into the Beam commissioning module. Be aware that manual adjustments of these parameters at large radii will be necessary after using auto-modeling without diagonal curves. The Beam 3D modeling module can be used to check the calculated dose of the entire field, including corners, before commissioning a machine.

[3438]

WARNING!

Non-standard fluence mode. When modelling a photon beam quality with non-standard fluence mode (FFF/SRS), it is essential to select the correct fluence mode when adding the beam quality. If the fluence mode is not set correctly, plans using the beam quality may be misinterpreted by the LINAC, leading to incorrect delivered dose.

If standard fluence mode is used for the beam quality, RT Plans will set Fluence mode to "STANDARD" and the Fluence mode ID is not exported.

If non-standard fluence mode is selected, RT Plans will set Fluence mode to "NON_STANDARD" and the Fluence mode ID to the selected fluence mode (FFF/SRS). [508990]

WARNING!

Dose computation photon beam energy and nominal photon beam energy. The RayPlan photon dose computation internally uses a photon energy definition according to BJR #11 (British Journal of Radiology supplement number 11). It is possible to specify a nominal photon beam energy which is different from the dose computation energy, for example to use a photon energy definition according to BJR #17.

The nominal energy will be displayed in the RayPlan user interface, used in reports and as DICOM Nominal Beam Energy in both DICOM import and export.

The dose computation energy will be used for photon dose computation, including to get the correct GSTT parameters for dose computation with Varian Enhanced Dynamic wedge. It is therefore crucial to set a correct dose computation energy regardless of the selected energy definition. {149206}

WARNING!

TomoTherapy leaf latency offsets affect both dose output and shape. Leaf latency offsets are imported from iDMS, and can also be edited in RayPlan Physics. Changes to leaf latency offsets may have different effect for different jaw field sizes, projection times and leaf opening times. Ensure that dose accuracy is validated for all jaw openings and over the full range of clinically relevant projection times and leaf opening times before using the model clinically. {530101}

WARNING!

TomoTherapy dose computation accuracy for short leaf open times and short leaf close times. For TomoHelical and TomoDirect plans with a large number of short leaf open times or a large number of short leaf close times, the delivered dose may differ significantly from the computed dose. The reason is that for fast leaf movements, the treatment machine will not open/close the leaves in accordance with the model used in the dose computation.



To avoid short leaf open times and short leaf close times when creating plans in RayPlan, use the beam model parameters *Minimum leaf open time* and *Minimum leaf close time*. The issue will occur with certain machine-specific leaf open/close time characteristics, but around 50 ms can normally be an appropriate value for both *Minimum leaf open time* and *Minimum leaf close time*.

To find the appropriate values for *Minimum leaf open time* and *Minimum leaf close time* for each TomoTherapy treatment unit, leaf latency data can be measured as described in *Westerly DC, Soisson E, Chen Q, Woch K, Schubert L, Olivera G and Mackie TR, Treatment planning to improve delivery accuracy and patient throughput in helical tomotherapy, Int J Radiat Oncol Biol Phys. 2009;74(4):1290–1297. [361442]*

3.1.12 Warnings concerning QA

WARNING!

Use the exported treatment plan for plan verification. Using the treatment plan for QA measurements provides an opportunity to detect errors in data transfer or dose calculation. It is recommended to only use the QA plan for computing QA dose and to perform QA measurements using the treatment plan. If it, for some reason, is not possible to use the treatment plan for performing QA measurements, make sure that the QA plan setup is as close as possible to the treatment plan setup and that the effects of the differences are understood. [53985]

WARNING!

Collapse of gantry angles for arc beam QA. Collapse of gantry angles to a single angle for arc beams (VMAT and Conformal Arc) in the QA Preparation module is intended for QA with a detector mounted perpendicular to the treatment beam and rotating with the gantry. The dose computed in the QA Preparation module can be used, but the QA delivery shall be performed with a rotating gantry to detect any delivery problems related to gantry rotation. For details about dose computation for arc beams and collapsed arc beams, refer to the *RSL-D-RP-10A-REF, RayPlan 10A Reference Manual*. {369355}

3.1.13 Warnings concerning RayPlan Storage Tool**WARNING!**

Verify database consistency before upgrade. In the RayPlan Storage Tool it is possible to create a new database system based on an existing system. Before creating a new system based on an existing system, make sure to run the ConsistencyAnalyzer tool. {231801}

WARNING!

RayPlan Storage Tool. When RayPlan Storage Tool opens a previous version of ResourceDB, the ResourceDB will be upgraded and cannot be used with earlier versions. {261396}

3.2 IMPORT OF PATIENT DATA

All patient data is imported using DICOM. The patient data import procedure is described in the User Manual, *RSL-D-RP-10A-USM, RayPlan 10A User Manual*, and the DICOM Conformance Statement, *RSL-D-RP-10A-DCS, RayPlan 10A DICOM Conformance Statement*.

3.3 INPUT DATA

All user input data is validated at the time of input. Incorrect values or text are rejected, correct limits or format is displayed and the user is prompted for new input.

3.4 DISPLAY FORMAT

In RayPlan date and time is displayed in format "dd MMM YYYY, hh:mm:ss (hr:min:sec)", e.g., "14 Jan 1975, 08:20:42 (hr:min:sec)".

4 INSTALLATION INSTRUCTIONS

This chapter describes the processes and tests related to the installation of the RayPlan 10A system.

In this chapter

This chapter contains the following sections:

4.1	Installation manual	p. 52
4.2	System environment acceptance test	p. 52
4.3	Hardware diagnostics checks	p. 52
4.4	Data communication environment	p. 52

4.1 INSTALLATION MANUAL

N/A. RayPlan 10A is installed by RaySearch authorized service personnel.

4.2 SYSTEM ENVIRONMENT ACCEPTANCE TEST

The system environment acceptance test must be run for each installation or change in hardware or software platform hosting the application (e.g., operating system update) to verify application installation and performance. The test is defined by *RSL-D-RP-10A-SEAT, RayPlan 10A System Environment Acceptance Test Protocol*.

4.3 HARDWARE DIAGNOSTICS CHECKS

To prevent RayPlan or RayPhysics from running in a faulty hardware environment, a self-test is run when launching RayPlan or RayPhysics. The test consists of dose computations and deformable registration calculations compared with predefined results.

If the test fails the user is notified and no GPU computations will be possible.

The test will also be run when selecting/changing GPU(s) to use for accelerated computations. Nevertheless, it is the responsibility of the user to absolutely ensure that the selected cards together with OS version, driver version and other environment details are listed as valid combinations in the *RSL-D-RP-10A-SEG, RayPlan 10A System Environment Guidelines*. Additionally, before clinical use, the operation of GPU computations must be verified by a qualified physicist using the *RSL-D-RP-10A-SEAT, RayPlan 10A System Environment Acceptance Test Protocol*.

4.4 DATA COMMUNICATION ENVIRONMENT

The RayPlan 10A system communicates with other systems using DICOM. For detailed information, see *RSL-D-RP-10A-DCS, RayPlan 10A DICOM Conformance Statement*. It is the responsibility of the user clinic to establish that the connectivity between RayPlan and the systems it imports data from works according to expectations and that exported data is correctly handled by the receiving systems.

5 DISPLAY OF COORDINATES, MOVEMENTS AND SCALES

RayPlan 10A uses the IEC 61217³ standard for display of coordinates, movements and scales during treatment planning, with a few exceptions that are user-defined. The gantry, collimator and couch angles, as well as the field coordinate system may be configured, per LINAC, to be non-IEC see section 5.3 *The treatment machine coordinate system on page 56.*

Note: *Patient positions Head First Supine (HFS), Head First Prone (HFP), Feet First Supine (FFS), Feet First Prone (FFP), Head First Decubitus Left (HFDL), Head First Decubitus Right (HFDR), Feet First Decubitus Left (FFDL), and Feet First Decubitus Right (FFDR) are supported by RayPlan 10A.*

In this chapter

This chapter contains the following sections:

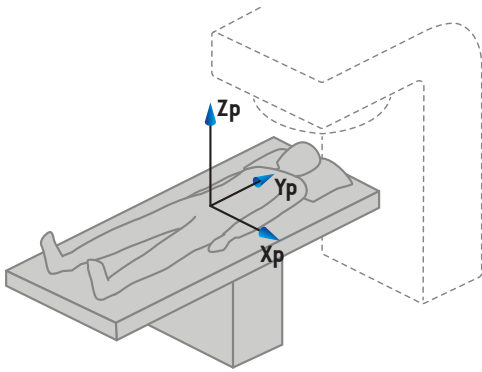
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5.2	Patient coordinate system in the DICOM export	p. 55
5.3	The treatment machine coordinate system	p. 56
5.4	The jaw and MLC labeling standard	p. 67

³ IEC 61217:2011 Radiotherapy equipment – Coordinates, movements and scales.

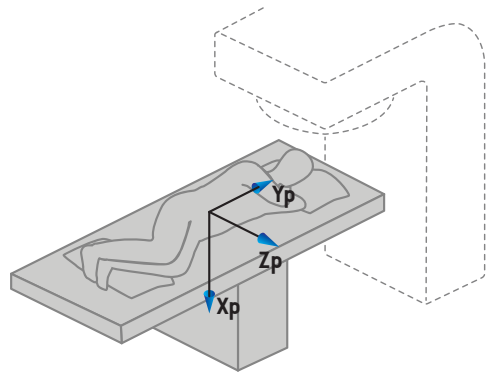
5.1 THE PATIENT COORDINATE SYSTEM

The patient coordinate system is oriented with the positive x-axis towards the patient's left arm, the positive y-axis towards the patient head and the positive z-axis in the anterior direction. The coordinate system follows the patient orientation: head first or feet first, supine or prone, decubitus right or decubitus left. In the hierarchy of IEC 61217 coordinate systems, the patient coordinate system has the table top coordinate system as its mother system.

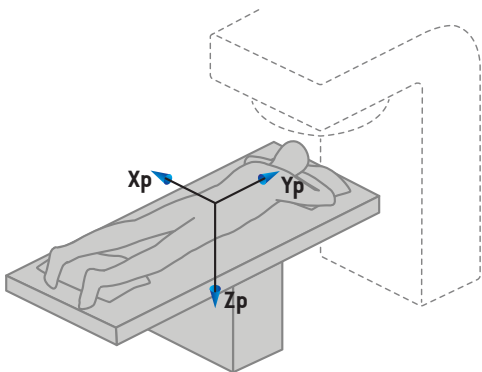
The RayPlan 10A dose and the dose difference distributions are all visualized in the patient coordinate system. In general, in RayPlan 10A the patient coordinates are reported as **Right-Left, R-L** (right-left = x -/+), **Inf-Sup, I-S** (inferior-superior = y -/+) and **Post-Ant, P-A** (posterior-anterior = z -/+).



A) Head First Supine



B) Head First Decubitus Left



C) Head First Prone

Figure 2. The patient coordinate system. Some examples of supported positions are illustrated: A) Head First Supine (HFS), B) Head First Decubitus Left (HFDL), and C) Head First Prone (HFP).

5.2 PATIENT COORDINATE SYSTEM IN THE DICOM EXPORT

Patient coordinates in DICOM exported data sets follow the DICOM standard, with the positive x-axis towards the patient's left arm, the positive z-axis towards the patient head and the positive y-axis in the posterior direction. The coordinate system follows the patient orientation: head first or feet first, supine or prone, decubitus right or decubitus left.

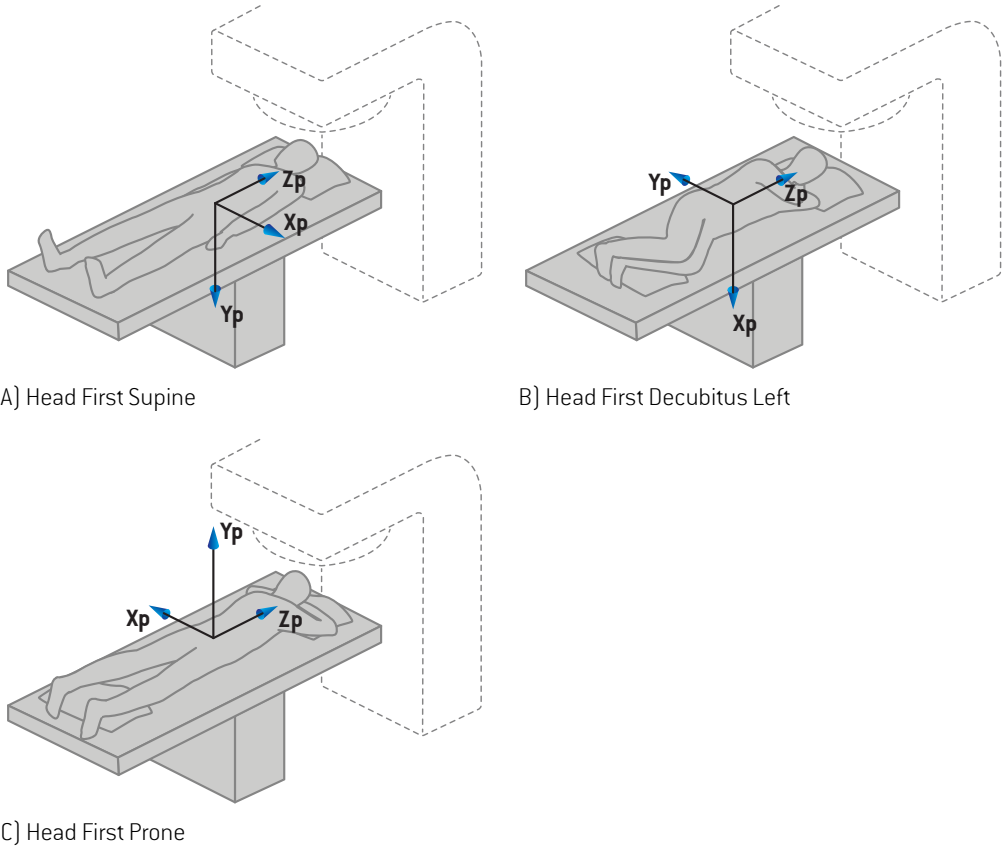


Figure 3. The patient coordinate system in the DICOM export follows the DICOM standard. Some examples of supported positions are illustrated: A) Head First Supine (HFS), B) Head First Decubitus Left (HFDL) and C) Head First Prone (HFP).

5.3 THE TREATMENT MACHINE COORDINATE SYSTEM

RayPlan 10A uses the IEC 61217 standard for display of LINAC coordinates, movements and scales during treatment planning, with the exception of gantry, collimator and couch angles as well as the field coordinate systems, which may be configured, per LINAC, to be non-IEC. There are also two options for jaw labeling. Setup imaging devices may also be described using non-IEC rotations, refer to section 5.3.9 Setup imaging device coordinate systems on page 65.

5.3.1 The machine coordinate systems overview

The machine coordinate systems in IEC 61217 are a set of coordinate systems, each defined in relation to its mother coordinate system, starting with a fixed coordinate system which has the origin at the isocenter, the positive x direction to the right for an observer facing the gantry, the positive y-axis from the isocenter towards the gantry along the axis of gantry rotation and the positive z-axis directed upwards from the isocenter.

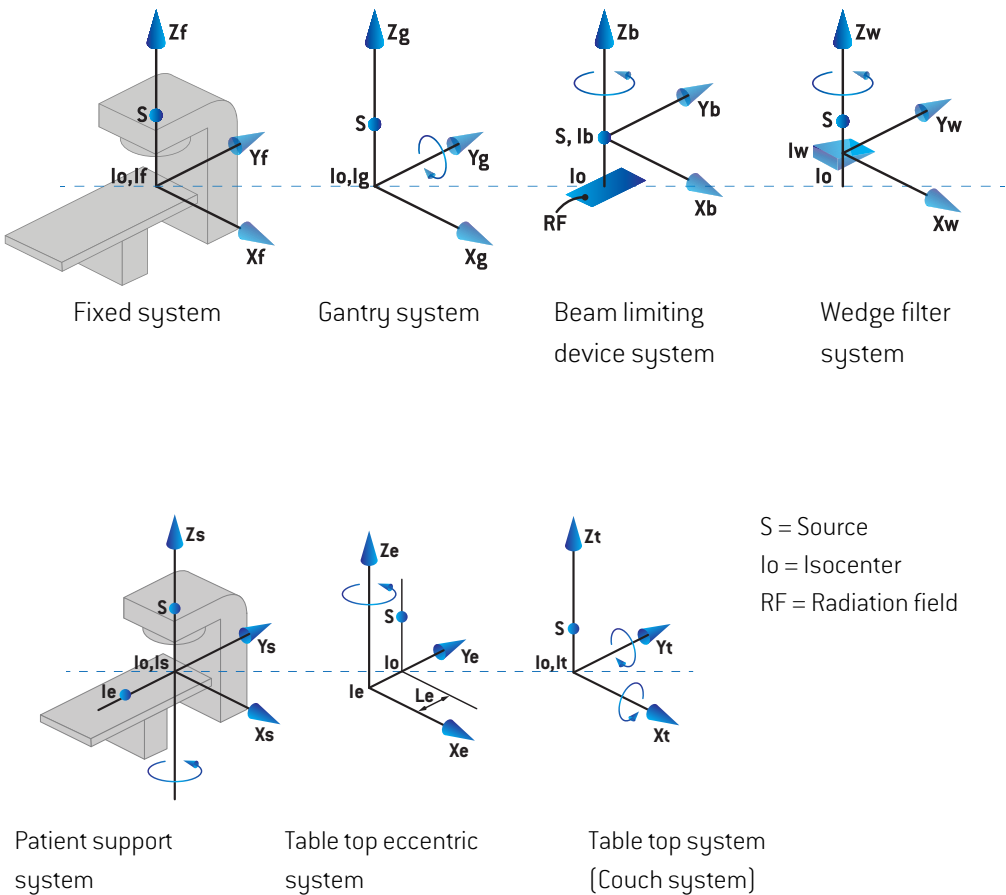


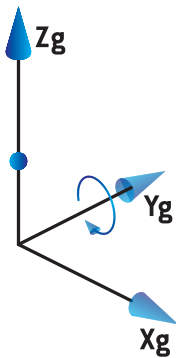
Figure 4. The machine coordinate systems according to the IEC 61217 standard.

If the machine is commissioned to replace the couch rotation by the ring rotation (e.g., the Vero machine), the rotation around the Zs axis in the patient support coordinate system is replaced by a rotation in the opposite direction around the Zg axis in the gantry coordinate system. The relationship between the patient and the gantry systems is thus maintained.

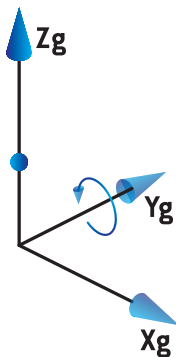
5.3.2 The gantry coordinate system

The gantry coordinate system rotates with the gantry. The gantry coordinate system has the fixed coordinate system as its mother system.

- For **IEC standard**, it is defined to coincide with the fixed coordinate system when the gantry angle is zero. The gantry angle increases gradually for clockwise rotation as viewed by an observer facing the gantry.



- For **Non-IEC gantry scale (Varian Standard)**, the gantry angle is 180 degrees when the beam enters from above. The gantry angle increases gradually for counter clockwise rotation as viewed by an observer facing the gantry.



Note: *If a LINAC is configured to use gantry angle as IEC 61217, the angle unit is given as [deg].*

Note: *If a LINAC is configured to use gantry angle as Non-IEC ("Varian Standard"), the angle unit is given as [deg Non-IEC].*

5.3.3 The beam limiting device coordinate system

The beam limiting device coordinate system is fixed in the gantry beam limiting device. The beam limiting device coordinate system has the gantry coordinate system as its mother system.

There are three settings in RayPlan Physics that affect the behavior of angles, positions and names in this coordinate system; the **Gantry and collimator coordinate system definitions**, the **Field coordinate system definitions** and the **Jaw labeling standard**. If all three settings are set to "IEC 61217", the definitions are consistent with those in the IEC 61217 standard.

The Gantry and collimator coordinate system definitions setting

The **Gantry and collimator coordinate system definitions** setting in RayPlan Physics controls the reporting of the beam limiting device rotation angle:

- For **IEC standard**, the axes coincide with the gantry system when the collimator angle is zero. The collimator angle is defined to be positive for counterclockwise rotation in the Beam's eye view, i.e. when viewed from the source. For this coordinate system, the collimator angle is usually 180 degrees when the tray opening is facing the gantry for Varian machines.
- The **Non-IEC (Varian Standard)** collimator coordinate system is rotated 180 degrees compared to the IEC standard and the collimator angle is defined to be positive for a clockwise rotation in the Beam's eye view, i.e. when viewed from the source. For this coordinate system, the collimator angle is usually zero degrees when the tray opening is facing the gantry for Varian machines.

Note: *If a LINAC is configured to use a collimator angle as IEC 61217, the angle unit is given as [deg].*

Note: *If a LINAC is configured to use a collimator angle as Non-IEC, the angle unit is given as [deg Non-IEC].*

The Field coordinate system definitions setting

The **Field coordinate system definitions** setting in RayPlan Physics defines how jaw and MLC leaf positions are reported and defined. The following description uses jaw naming convention according to the IEC 61217 standard.

Note: *If a LINAC is configured to use field coordinate system as IEC 61217, the unit for jaw and leaf positions are given as [cm].*

Note: *If a LINAC is configured to use field coordinate system as Non-IEC, the unit for jaw and leaf positions is given as [cm Non-IEC].*

Collimator positions according to IEC 61217

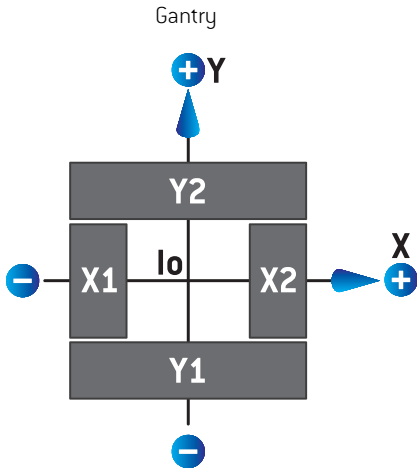


Figure 5. The collimator positions in the Beam's eye view according to the IEC 61217 standard.

The collimator positions according to the IEC 61217 standard, for a beam with (IEC) collimator angle 0 when viewed from the source, are described in the table below.

When the edge of...	is positioned to the ...	of the isocenter axis, its position reading value is ...
X1, X2 (jaw or MLCX leaf)	right	positive
X1, X2 (jaw or MLCX leaf)	left	negative
Y1, Y2 (jaw or MLCY leaf)	gantry side	positive
Y1, Y2 (jaw or MLCY leaf)	non-gantry side	negative

Collimator positions according to Non-IEC (Varian Standard)

For Non-IEC, positive position coordinates are reported in all directions for jaws and leaves that have not crossed the center line. That is, negative coordinates are reported for overtravel.

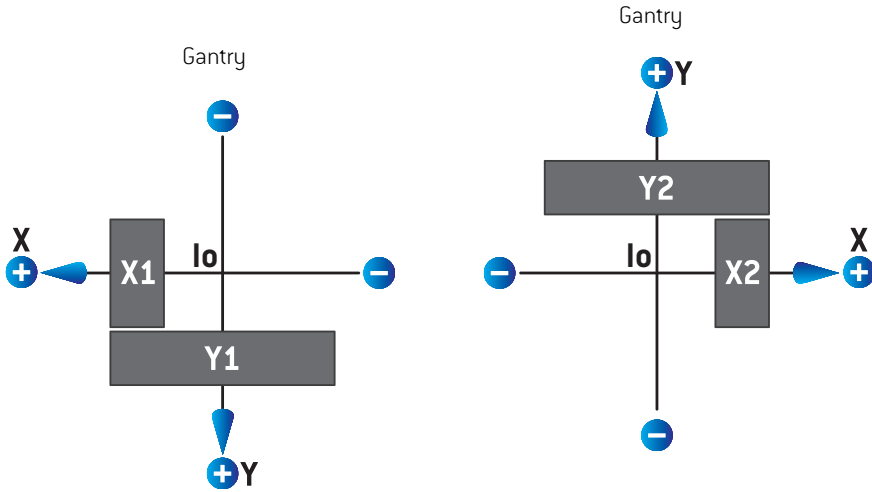


Figure 6. The collimator positions in the Beam's eye view according to the Non-IEC (Varian Standard). Note that the coordinates visualized in the Beam's eye view in RayPlan always uses the IEC 61217 coordinate system.

The collimator positions according to Non-IEC (Varian Standard), for a beam with (IEC) collimator angle 0 when viewed from the source, are described in the table below.

When the edge of ...	is positioned to the ...	of the isocenter axis, its position reading value is ...
X1 (jaw or MLCX leaf)	right	negative
X1 (jaw or MLCX leaf)	left	positive
X2 (jaw or MLCX leaf)	right	positive
X2 (jaw or MLCX leaf)	left	negative
Y1 (jaw or MLCY leaf)	gantry side	negative
Y1 (jaw or MLCY leaf)	non-gantry side	positive
Y2 (jaw or MLCY leaf)	gantry side	positive
Y2 (jaw or MLCY leaf)	non-gantry side	negative

The Jaw labeling standard setting

The **Jaw labeling standard** setting in RayPlan Physics is described in section 5.4 *The jaw and MLC labeling standard on page 67*.

5.3.4 The wedge filter coordinate system

The wedge filter coordinate system rotates with the wedge and the positive y axis points from heel to toe of the wedge. The wedge filter coordinate system has the beam limiting device coordinate system as its mother system. In RayPlan Physics and the main RayPlan 10A application, the wedge coordinate system is defined to coincide with the selected collimator coordinate system (IEC 61217 or Non-IEC) for a wedge orientation of zero degrees.

- For collimator coordinate system **IEC 61217**, the wedge orientation is zero degrees when the toe points towards the gantry for collimator angle zero.
- For collimator coordinate system **Non-IEC**, the wedge orientation is zero degrees Non-IEC when the toe points away from the gantry for collimator angle zero degrees Non-IEC.

The wedge orientation increases gradually for a counter-clockwise rotation.

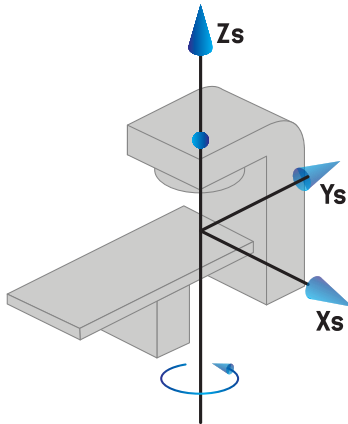
Note: *If a LINAC is configured to use a collimator angle as IEC 61217, the wedge orientation angle unit is given as [deg].*

Note: *If a LINAC is configured to use a collimator angle as Non-IEC, the wedge orientation angle unit is given as [deg Non-IEC].*

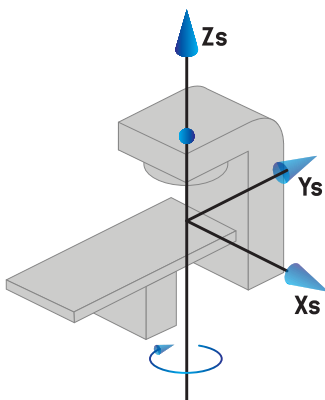
5.3.5 The patient support coordinate system

The patient support coordinate system rotates with the part of the patient support that rotates around the vertical axis Z_s . The patient support coordinate system has the fixed coordinate system as its mother system.

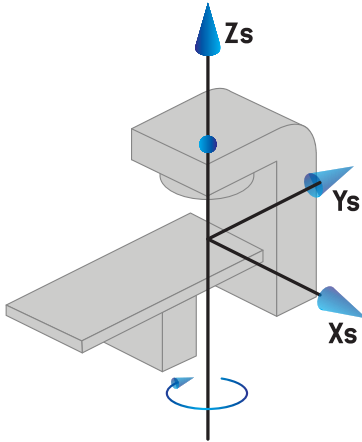
- For **IEC standard**, the patient support system coincides with the fixed system when the couch angle is zero. The positive rotation direction is defined to be counter-clockwise as seen from above.



- For **Non-IEC 1 (Varian IEC)** machine scale, the patient support system coincides with the fixed system when the couch angle is zero. The positive rotation direction is defined to be clockwise as seen from above.



- For **Non-IEC 2 (Varian Standard)** machine scale, the couch angle is 180 degrees when the IEC couch angle is zero degrees. The positive rotation direction is defined to be clockwise as seen from above.



Note: If a LINAC is configured to use couch angle as IEC 61217, the angle unit is given as [deg].

Note: If a LINAC is configured to use couch angle as Non-IEC 1 (“Varian IEC”), the angle unit is given as [deg Non-IEC] in the user interface and as [deg Non-IEC CW] in plan reports.

Note: If a LINAC is configured to use couch angle as Non-IEC 2 (“Varian Standard”), the angle unit is given as [deg Non-IEC] in the user interface and as [deg Non-IEC CW] in plan reports.

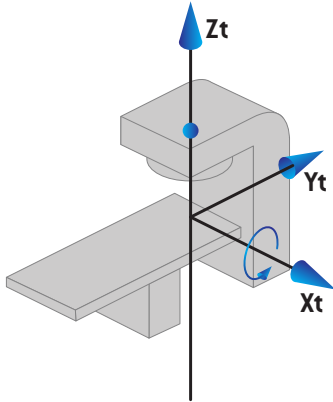
5.3.6 The table top eccentric coordinate system

In RayPlan, only zero degrees eccentric table top rotation angle and zero translation distance are supported, and thus the table top eccentric coordinate system always coincides with the patient support coordinate system. The table top eccentric coordinate system has the patient support coordinate system as its mother system.

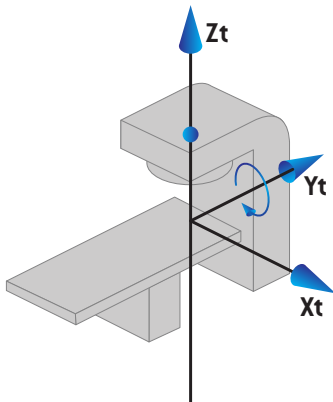
5.3.7 The table top coordinate system

In RayPlan, the table top coordinate system has the table top eccentric coordinate system as its mother system. Pitch and roll angles are always expressed using the IEC standard. Subsequent rotations are defined in the order pitch angle followed by roll angle.

- The table top pitch angle is defined as the rotation about axis X_t . An increase in the pitch angle corresponds to the clockwise rotation of the table top as viewed from the table top coordinate system origin along the positive X_t axis.



- The table top roll angle is defined as the rotation about axis Y_t . An increase in the roll angle corresponds to the clockwise rotation of the table top as viewed from the table top coordinate system origin along the positive Y_t axis.



5.3.8 Dose curve coordinate system in RayPlan Physics

The Beam Commissioning module has a dose curve coordinate system corresponding to the IEC gantry coordinate system, translated so that the origin is on the central axis at the surface of the water phantom. The x-axis is aligned with the cross-line axis. The y-axis is aligned with the inline axis, with the positive direction towards the gantry. The negative z-direction, from source towards isocenter, is aligned with the depth direction. The gantry and collimator angles are always assumed to be zero degrees for the dose curves in the Beam Commissioning module. The model is fully reflection symmetric in the xz- and the yz-plane, whereas measurements can sometimes be mildly asymmetric.

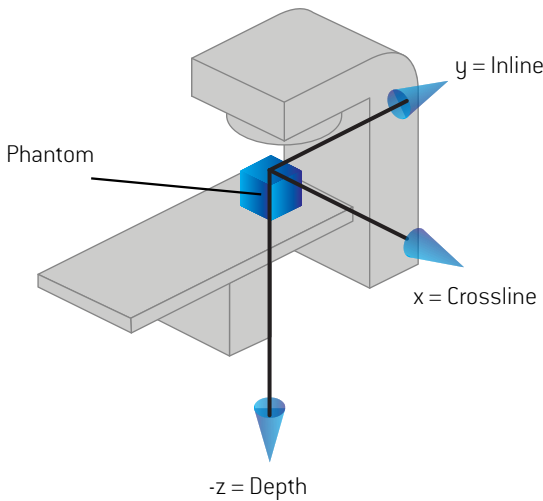


Figure 7. The dose curve coordinate system.

5.3.9 Setup imaging device coordinate systems

Setup imaging devices in RayPlan are described by the X-ray image receptor coordinate system. It is fixed in relation to the setup imaging device. It is a result of three rotations, each represented by a coordinate system, starting with the IEC fixed coordinate system.

The first rotation is a gantry rotation about the y-axis of the fixed coordinate system, described in *section 5.3.2 The gantry coordinate system on page 57*.

Note: *The rotation is not necessarily a rotation of the treatment gantry, but a rotation about the y-axis of the fixed coordinate system. Setup imaging devices only support IEC gantry rotations.*

The second coordinate system, the gantry pitch coordinate system, has the gantry coordinate system as its mother system and is a rotation about the x-axis of the gantry coordinate system. When the gantry pitch angle is zero, the gantry pitch coordinate system coincides with the gantry

coordinate system. The positive rotation direction is clockwise when viewed from the origin along the positive x-axis of the gantry coordinate system. S_r is the imager radiation source.

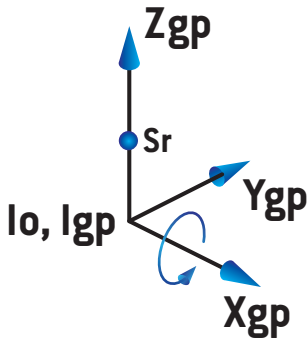


Figure 8. The gantry pitch coordinate system.

The X-ray image receptor coordinate system has the gantry pitch coordinate system as its mother system and is a rotation about the z-axis of the gantry pitch coordinate system. When the X-ray image receptor angle is zero, the X-ray image receptor coordinate system coincides with the gantry pitch coordinate system. The positive rotation direction is counter-clockwise when viewed from a point on the positive z-axis facing towards the origin. S_r is the imager radiation source.

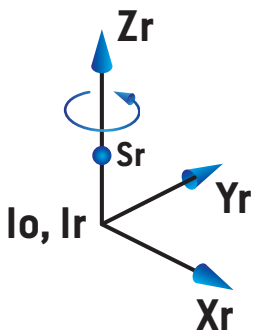


Figure 9. The X-Ray image receptor coordinate system.

Gantry-mounted setup imaging devices

A gantry-mounted setup imaging device moves with a gantry (treatment gantry or imaging gantry). A gantry-mounted setup imaging device can have one or more imagers, each with an imager gantry angle offset. Each imager is an image radiation source with an associated image receptor.

A gantry-mounted imager only has a gantry rotation, i.e., the X-ray image receptor coordinate system coincides with the gantry coordinate system. The gantry rotation is given by the gantry angle of the beam or setup beam plus the imager gantry angle offset.

Fixed setup imaging devices

A fixed setup imaging device is fixed in the treatment room. In RayPlan there are two types of fixed setup imaging devices; **Fixed with offsets** and **Fixed**.

A setup imaging device that is **Fixed with offsets** can have one or more imagers, each with an imager gantry angle offset. Each imager is an image radiation source with an associated image receptor. An imager in a setup imaging device that is **Fixed with offsets**, only has a gantry rotation, i.e., the X-ray image receptor coordinate system coincides with the gantry coordinate system. The gantry rotation is given by the fixed gantry angle of the setup imaging device plus the imager gantry angle offset.

A setup imaging device that is **Fixed** represents one single imager, i.e., an image radiation source with an associated image receptor. It can have all three rotations, i.e., gantry rotation, gantry pitch rotation and X-ray image receptor rotation.

5.4 THE JAW AND MLC LABELING STANDARD

In RayPlan 10A the jaws can be labeled according to one of the standards IEC 61217 or IEC 601-2-1. The description in this section uses the IEC 61217 Field coordinate system definitions setting.

5.4.1 The IEC 61217 jaw labeling standard

In **IEC 61217**, Y2 is close to the gantry and Y1 is away from the gantry, X1 is to the left and X2 to the right for an observer facing the gantry with gantry and collimator angle zero in the IEC 61217 coordinate system.

Gantry irradiating
from above

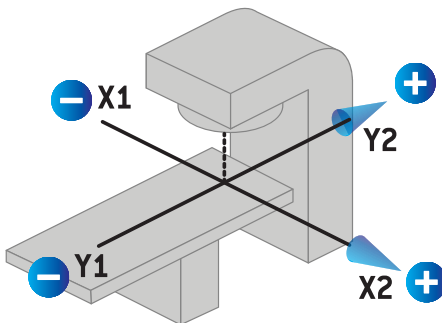


Figure 10. The jaw and MLC labels (IEC 61217).

5.4.2 The IEC 601 jaw labeling standard

In **IEC 601**, X1 is close to the gantry and X2 is away from the gantry, Y2 is to the left and Y1 to the right for an observer facing the gantry with gantry and collimator angle zero in the IEC 61217 coordinate system.

Gantry
irradiating from
above

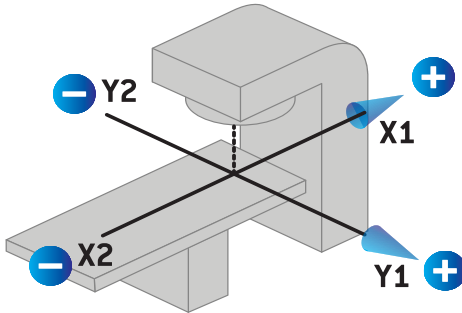


Figure 11. The jaw and MLC labels (IEC 601).

Note: *The jaw labeling standard setting only affects the names of the collimators in RayPlan and the Machine properties workspace in RayPlan Physics. Note that the coordinate axes are still labeled according to IEC 61217, examples being the dose curve labels and parameters in the Beam model workspace in RayPlan Physics.*

6 SYSTEM INTEGRITY AND SAFETY

This chapter describes the relevant processes related to system integrity and safety.

There is no need for the user to edit, add or remove parts of the system data. All modifications shall be performed by specially trained service personnel. Service personnel can assist in adjusting the system according to local IT policies.

In this chapter

This chapter contains the following sections:

6.1	Protection against unauthorized use	p. 70
6.2	Backup routines and database maintenance	p. 70
6.3	Database access permissions	p. 71
6.4	ECC RAM	p. 71

6.1 PROTECTION AGAINST UNAUTHORIZED USE

The table below lists the various protection types in RayPlan 10A.

Protection type	Description
Password protection	All operating system user accounts must be password protected to prevent unauthorized access to the system and databases.
Network security	The risk of unauthorized network access needs to be assessed by the user organization. It is recommended to use security best practices to protect the integrity of the environment, for example, use of a fire-wall on the network and regular security patching of the computers.
Protection against unauthorized physical access	The risk of unauthorized physical access to an unattended session needs to be assessed by the user organization. It is recommended to use session time-out which can be set by the user using features of the Windows Active Directory.
Virus protection	State-of-the-art virus protection shall be enabled for all parts of the system including the entire computer network if present. This shall include automatic updates or similar to keep the protection up-to-date.
License protection	RayPlan 10A uses a hardware-based license protection system to prohibit usable copies of the system to be made.
Databases and checksums	To prohibit use of program or data files not belonging to the installed version of RayPlan 10A, the files are protected from exchange using checksums. The database design prevents modification of data storage other than using RayPlan 10A programs. The checksums on physics data files prevents modification of the files, or the application will not start.
Operating system administrator privileges	Tools enabling direct access to data stored in the databases shall be set up so as to require operating system administrator privileges.
Program code protection	RayPlan 10A program code and data shall only be accessed and modified as described in the manuals. Do not to tamper with program code or data!

6.2 BACKUP ROUTINES AND DATABASE MAINTENANCE

Database backup and restore shall be performed using a standard SQL database management tool. It is recommended that all RayPlan 10A databases (RayStationPatientDB, RayStationMachineDB, RayStationClinicDB and RayStationResourceDB) are set to recovery model full. This option makes it possible to run frequent backups and minimizes the risk of losing data in a database crash.

Maintenance type	Description
Regular backups	<p>Regular backups of all RayPlan databases should be scheduled and the success of these backups should be verified on a regular basis.</p> <ul style="list-style-type: none"> • Full backups: We recommend that full backups are performed as often as time, space and system usage allows. • Differential backups: We recommend that differential backups are performed as often as time, space and system usage allows. • Transaction Log Backups: We recommend that Transaction Log Backups are performed on an hourly basis – but the frequency can be increased or decreased based on the specific clinic needs. <p>It is recommended to bring a database backup off-site on a daily basis.</p>
SQL Server OS maintenance	<p>We recommend that the fragmentation on drives hosting the SQL data files should be checked for defragmentation. Where defragmentation is required this should be performed during maintenance windows.</p>
Indexing	<p>With additions, edits and changes to patient plans, the databases (particularly the Patient Database) can become fragmented. We recommend that an additional task to re-organize the databases is included in the database maintenance plan at an appropriate time (e.g., immediately following a full backup once a week).</p>

6.3 DATABASE ACCESS PERMISSIONS

The default permissions for database access include all Domain Users of the Active Directory within which the databases are installed. If preferred or required, the access rights of the individual databases can be controlled when created (refer to the RayPlan Storage Tool section in the *RSL-D-RP-10A-USM, RayPlan 10A User Manual*). For changes on ResourceDB, a procedure is available from support@raysearchlabs.com to restrict access to an appropriate AD group of users. The procedure will need to be repeated and access reviewed and confirmed as part of any RayPlan 10A upgrade activity.

6.4 ECC RAM

An Error-correcting code memory (ECC RAM) is required for CPU memory. This is a type of computer data storage that can detect and correct the most common kinds of internal data corruption.

A DEFINITIONS

Term	Meaning
BEV	Beam's Eye View
CBCT	Cone Beam Computed Tomography
CT	Computed Tomography
DCR	Digitally Composited Radiograph
DVH	Dose Volume Histogram
deg	When the term deg is seen in RayPlan 10A this refers to degrees
DMLC	Dynamic Multi-Leaf Collimator
DRR	Digitally Reconstructed Radiograph
EUD	Equivalent Uniform Dose
External ROI	The ROI used to define patient outline. Defines the region used for dose computation, together with BOLUS for beam, SUPPORT and FIXATION ROIs.
FoR	Frame of Reference
GUI	Graphical User Interface
IMRT	Intensity Modulated Radiation Therapy
LINAC	Linear accelerator, conventional radiation therapy treatment unit.
MBS	Model-Based Segmentation
MU	Monitor Units
OAR	Organ at risk
POI	Point of Interest
ROI	Region of Interest
ROI Geometry	The image set-specific geometric representation of an ROI
SMLC	Segmental Multi-Leaf Collimator
SSD	Source to Skin Distance

Term	Meaning
SUV	Standardized Uptake Value
UI	User Interface
VMAT	Volumetric Modulated Arc Therapy

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