# RAYSTATION 11A

Combination with IDCAS Modules, Instructions for Use

RayStation

## Disclaimer

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

## Declaration of conformity

Complies with 93/42/EEC Medical Device Directive as amended by M1 to M5, Article 12 and 2017/745 Medical Device Regulation, Article 22.

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.*

## Copyright

## Printed material

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

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# 1 INTRODUCTION

## *About this manual*

This document is an addition to *RSL-D-RS-11A-USM, RayStation 11A User Manual* and describes the combination of RayStation 11A and the Imaging Definition and Collision-Avoidance Software Suite (IDCAS) modules from medPhoton GmbH. The IDCAS modules are only available to customers who have purchased this specific license. For more information about the IDCAS modules, refer to the IDCAS product documentation.

Study this manual and the *RSL-D-RS-11A-IFU, RayStation 11A Instructions for Use* carefully before using the combination of RayStation 11A and the IDCAS modules. Proper functioning of the device can only be guaranteed if the instructions in these documents are adhered to.

Study the Release Notes in this manual as well as the *RSL-D-RS-11A-RN, RayStation 11A Release Notes* carefully. These notes provide final instructions on how to use the combination of RayStation 11A and the IDCAS modules.

The RayStation 11A system is further described in the RayStation 11A product documentation.

# 2 PRODUCT INFORMATION

## 2.1 INTENDED USE

The combination of RayStation 11A and the IDCAS modules is a software system for radiation therapy and medical oncology. Based on user input, RayStation proposes treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, RayStation may also be used to administer treatments.

The system functionality can be configured based on user needs.

## 2.2 INTENDED USER

The intended users of the combination of RayStation 11A and the IDCAS modules shall be clinically qualified staff trained in using the system.

> **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)

## 2.3 INTENDED PATIENT POPULATION AND MEDICAL CONDITIONS

The intended patients for RayStation 11A and the IDCAS modules are patients where a qualified and licensed medical practitioner has decided it is appropriate to give radiation therapy or medical oncology treatment for tumors, lesions and other conditions.

## 2.4 INTENDED ENVIRONMENT

The intended environment of the combination of RayStation 11A and the IDCAS modules is a general office environment. The combination shall not be placed close to patients.

## 2.5 CONTRAINDICATIONS

None known.

## 2.6 HARDWARE AND OPERATING SYSTEM

For information, refer to *RSL-D-RS-11A-IFU, RayStation 11A Instructions for Use*.

## 2.7    CONTACT INFORMATION

The combination of RayStation 11A and the IDCAS modules is placed on the market by:

RaySearch Laboratories AB (publ)
Sveavägen 44
SE - 111 34 Stockholm
Sweden
Telephone: +46 8 510 530 00
E-mail: info@raysearchlabs.com

## 2.8    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 should 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 shall be reported to the competent authority of the European Union Member State in which the user and/or patient is established.

# 3   INFORMATION NEEDED FOR SAFE OPERATION

Adhere to the following warnings as well as the warnings described in *RSL-D-RS-11A-IFU, RayStation 11A Instructions for Use* for safe operation of the combination of RayStation 11A and the IDCAS modules.

## *Safety precautions*

> **WARNING!**
>
> If the patient setup or imaging definition is in any way modified outside RayStation, e.g., by directly calling the IDCAS modules, the collision result in RayStation will not be invalidated and may not be correct until the next collision check call. (125092)

> **WARNING!**
>
> The Collision Visualizer window may display a different patient/plan than the current one since a new instance is created when a new treatment machine is used and the previous Collision Visualizer window must be closed manually. (147942)

> **WARNING!**
>
> The IDCAS collision software is only a treatment planning tool. It does not in any way prevent collisions from occurring during treatment. Therefore, the hardware in the treatment room must be equipped with touch-guard safety measures for physical body collision detection. (126040)

# 4   RELEASE NOTES

This chapter contains important notes about the use of the combination of RayStation 11A and the IDCAS modules. None of the notes described in this chapter are related to patient safety.

**Every user of the combination of RayStation 11A and the IDCAS modules must be familiar with these known issues as well as the known issues described in** *RSL-D-RS-11A-RN, RayStation 11A Release Notes*. Contact the manufacturer for any questions about the content.

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

## 4.1   KNOWN ISSUES

### Not possible to launch the Path Checking module for beams with spots and with zero beam meterset

When launching the Path Checking Module there will be an error message if there are beams with spots and with zero beam meterset. This typically occurs when an optimized beam is copied. The workaround is to avoid this workflow and run the collision check only on empty beams. It is also possible to run an optimization or to manually set the beam meterset to a value larger than zero in the beam list. (603727)

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# 5   COMBINATION OF RAYSTATION 11A AND THE IDCAS MODULES

The combination of RayStation 11A and the IDCAS modules is a treatment planning system capable of checking plan feasibility with respect to collision issues. For treatment plan creation, refer to the RayStation documentation. The collision detection is based on detailed models of the treatment room, the treatment machine, the robot, couch, the imaging ring, support devices etc. The patient is modeled using an avatar selected from a library based on the height, weight and physique of the patient.

Note that the combination of RayStation 11A and the IDCAS modules is a tool for reducing the risk of collisions at treatment delivery already during treatment planning. However, it does not eliminate the collision risks. There are many uncertainties involved that simply cannot be eliminated by software, e.g., the patient avatar is an approximation of the real patient, the models do not include human operators, chairs or similar objects, and there is no way to guarantee that the patient setup modeled in IDCAS is actually used.

Therefore, the collision avoidance does not only take the configured 3D models (couch, patient avatar etc.) into consideration, but also considers a configurable safety margin around the objects (typically 1 to 3 cm) to yield a conservative collision prediction.

> **WARNING!**
>
> The IDCAS collision software is only a treatment planning tool. It does not in any way prevent collisions from occurring during treatment. Therefore, the hardware in the treatment room must be equipped with touch-guard safety measures for physical body collision detection. (126040)

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## 5.1 IDCAS MODULES

There are four IDCAS modules that can be accessed from RayStation 11A:

- **Patient Setup Module (PS-M)** - where the patient avatar is selected and where the case type and indexing of the support devices are specified.

- **Imaging Definition Module (ID-M)** - where the imaging protocol is defined.

- **Path Checking Module (PC-M)** - where the actual collision check is performed for the given treatment setup. The PC-M is indirectly used by the Path Checking Module client (PC-Mc) application.

- **Collision Visualizer (CV)** - where the collisions are visualized in a 3D room model. The CV is indirectly used by the Path Checking Module client (PC-Mc) application.

## 5.2 INTEGRATION INTO RAYSTATION

The integration of the modules into RayStation relies on proper configuration of the paths to the modules (see *section 5.2.1 Module configuration on page 16*). To the user, this integration is seamless, but it may be worth noting that all communication between RayStation and the IDCAS modules relies on a DICOM export of the current plan containing private tags for identifying the current patient setup and imaging protocol.
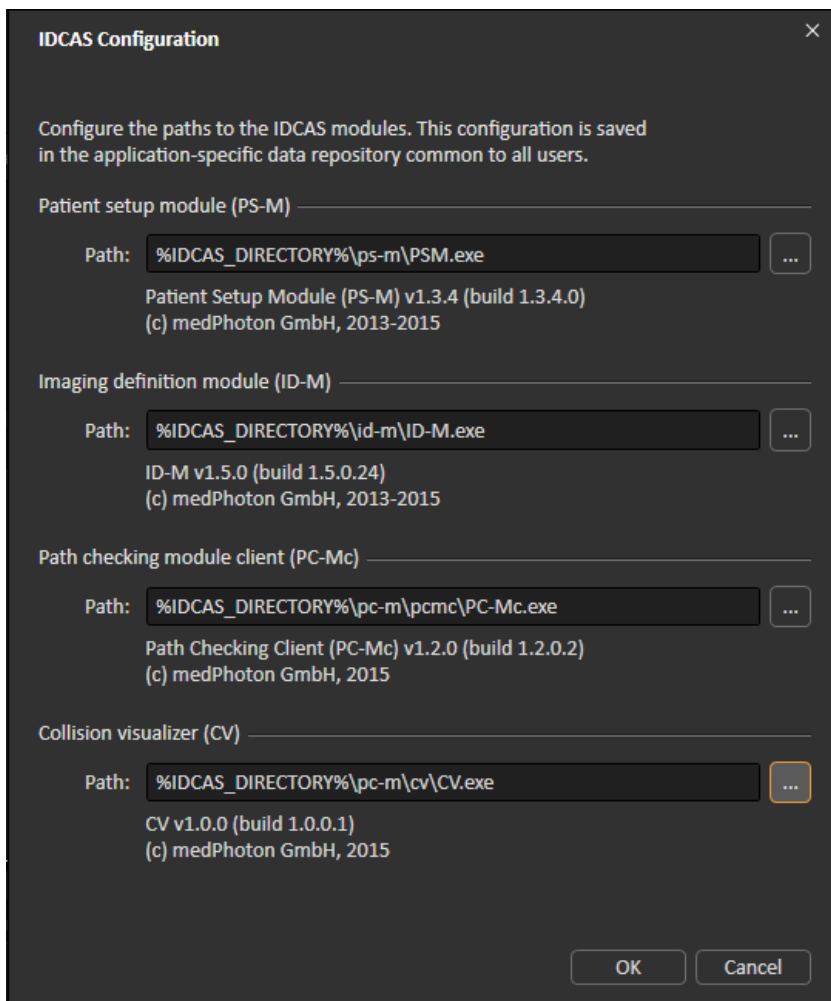
### 5.2.1 Module configuration

In order to use the IDCAS modules in RayStation, the paths to the executables must be defined properly. For users with the IDCAS license, the **IDCAS configuration** option is available in the RayStation main menu.

To define the paths to the executables:

1. Select the **IDCAS configuration** option in the RayStation main menu **Settings**.
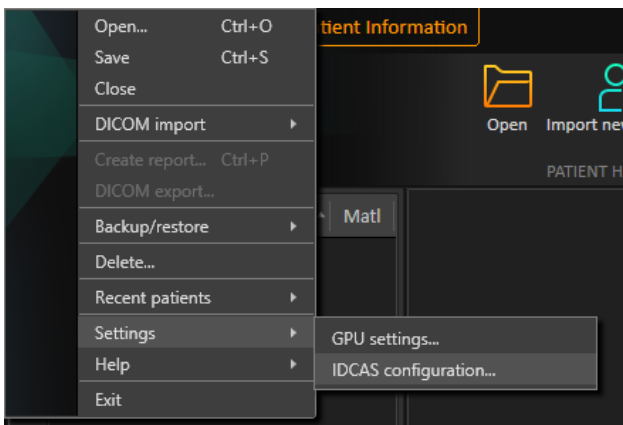
This opens the IDCAS Configuration dialog.



2.   Specify the paths to the modules in the IDCAS Configuration dialog.

*Note:*       *As this configuration is saved in the application specific data-repository common to all users, it is important to verify that the correct module version is used.*

*Note:*       *This configuration must be done for each client. If the location of the IDCAS modules always is on the same network folder, the configuration does not have to be changed when the modules are updated.*

3.   Click **OK**.

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### 5.2.2    The IDCAS Collision Avoidance tab

The IDCAS modules are accessed in the **IDCAS Collision Avoidance** tab that is available in the Plan Design, Plan Optimization, and Multi Criteria Optimization modules.

| Beams | Beam Dose Specification Points | IDCAS Collision Avoidance |

| IDCAS setup | Collision check | ☐ Ignore imaging ring | Collision status: **Beam collision** |

IDCAS setup

- Patient setup...
- Patient setup: **Done**

- Imaging definition...
- Imaging def.: **Done**

- Reset PS    Reset ID

- Margins...
- Margins:    **Specified**

| No. | Name | Air gap [cm] Min | CAX | Collision status |
|-----|-------|------|--------|------------------|
| 1 | Beam1 | -15.80 | -15.17 | **Colliding** |
| 2 | Beam2 | 41.62 | 42.18 | **OK** |

## Patient Setup Module (PS-M)

To enter the Patient Setup Module, click the **Patient setup...** button in the **IDCAS Collision Avoidance** tab. Any ROIs that have been created in RayStation will be imported into the Patient Setup Module upon entry.
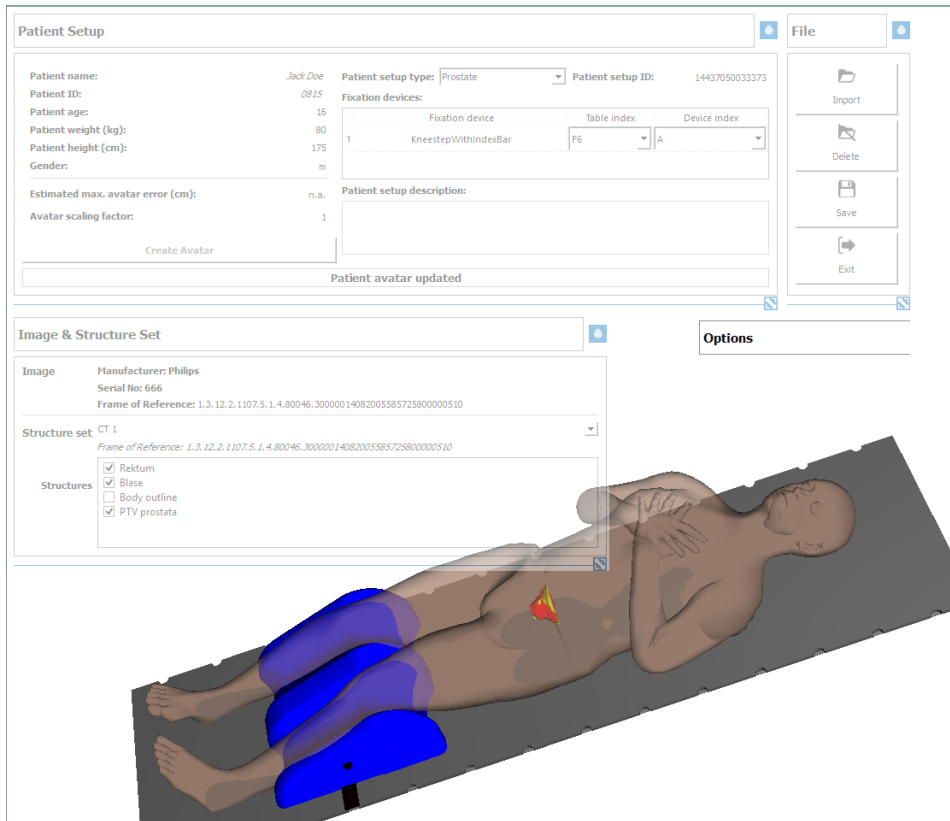
## Imaging Definition Module (ID-M)

To enter the Imaging Definition Module, click the **Imaging definition...** button in the **IDCAS Collision Avoidance** tab. Any ROIs that have been created in RayStation will be imported into the Imaging Definition Module upon entry.
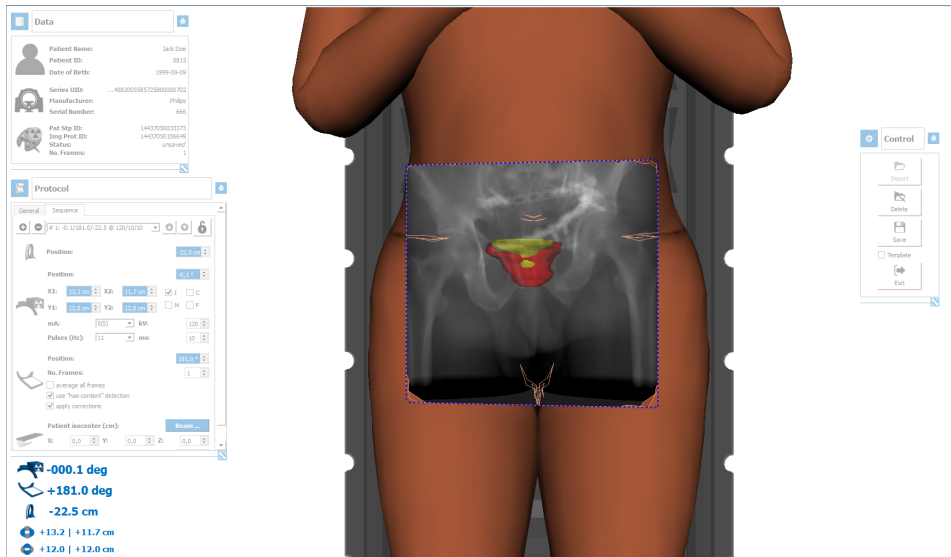


## Path Checking Module (collision check) (PC-M)

The **Collision check** button launches the PC-Mc application. Based on the patient setup, imaging definition, and the current plan, it performs a collision check and returns whether the beam configuration causes collisions or if the imaging protocol causes collisions.

To check for collision, click the **Collision check** button in the **IDCAS Collision Avoidance** tab.

- If no collision is detected, the **Collision status** will be **OK**.

- If a collision is detected, the **Collision status** will be **Colliding**. Try adjusting the **Gap** value of the beam to avoid collision.

The **Ignore imaging ring** option might be used for cases where the imaging ring is not relevant and can be manually positioned in a non-colliding position.

## Margins

It is possible to specify rotational and translational offsets for the collision check in order to obtain desired margins for position vector correction. To specify the margins, click the **Margins...** button.

***Note:***      *The margins functionality is available only for PC-Mc version 1.5 or later.*

## Collision Visualizer (CV)

The Collision Visualizer is launched along with the collision check when clicking the **Collision check** button. The Collision Visualizer displays the collision check result as a 3D model.
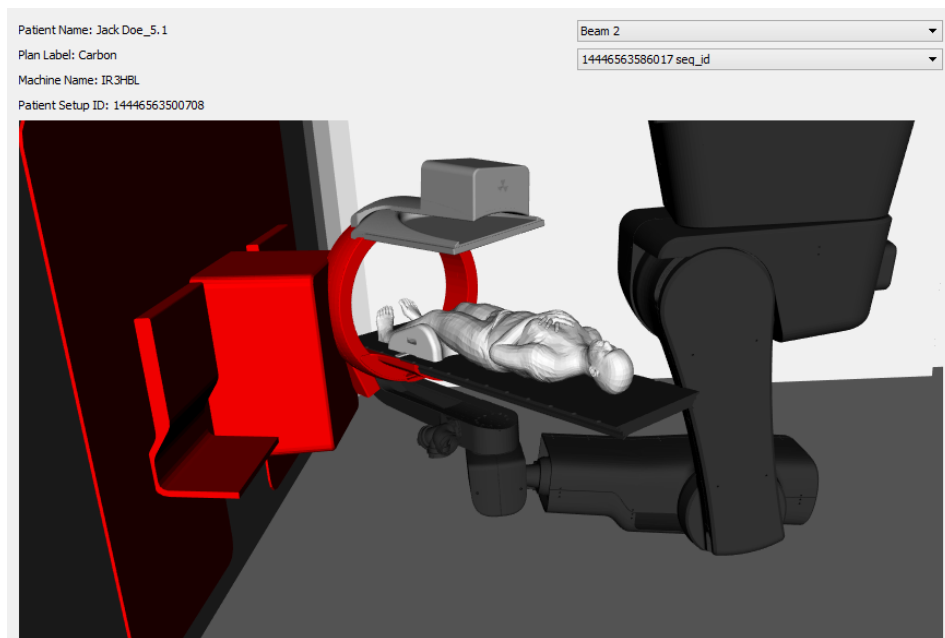


For an approved beam set it is possible to perform a read-only collision check to be able to view the collision result in the Collision Visualizer. The result from the read-only collision check will not be saved in RayStation.

## Resetting the setup

In rare cases, the patient setup or imaging protocol ID:s can be out-of-sync with the patient database, for instance due to an unexpected system failure. In order to resolve this it might be needed to reset the ID:s. To reset the setup, click the **Reset** button and then re-open the PS-M and/or ID-M in order to create new ID:s or to import existing ones.

### 5.2.3     Main workflow using collision check

The main workflow for creating plans in RayStation where collision is taken into account is described in this section.

If the patient setup and imaging definition is done prior to creating the plan in RayStation, perform all the steps in the main workflow, but import existing setups instead of defining new setups in steps 3 and 6.

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*Main workflow*

1.  Create a new plan. Beams can be added now or in step 5. (For more information, refer to *RSL-D-RS-11A-USM, RayStation 11A User Manual.*)

2.  Click **Patient setup…** to open the PS-M.

3.  Define the patient setup, save and close the PS-M (ref to the PS-M manual).

    *Result:* **Patient setup** changes state to "Done" in the **IDCAS Collision Avoidance** tab.

4.  Add beams if this has not been done in step 1.

5.  If an imaging protocol should be defined, click **Imaging definition…** to open the ID-M.

6.  Define the imaging protocol, save and close the ID-M (ref to the ID-M manual).

    *Result:* **Imaging def** changes state to "Done" in the **IDCAS Collision Avoidance** tab.

7.  If margins should be specifed, click **Margins...** to open the **Collision Check Margins** dialog.

8.  Specifiy the desired translational and rotational margins and click **OK**.

    *Result:* **Margins** changes state to "Specified" in the **IDCAS Collision Avoidance** tab.

9.  Choose whether to include the imaging ring in the collision result or not.

10. Click **Collision check** to perform a collision check.

11. The Collision Visualizer is displayed in a separate window and displays the collision result in a 3D model of the treatment room.

12. Adjust beam parameters (angles, gap, etc.) if necessary using the Collision Visualizer as a guide to identify the cause of the collisions.

13. Iterate steps 9 and 12 until satisfied.

## 5.2.4 Adjust the gap

The adjustment of the gap (see *RSL-D-RS-11A-USM, RayStation 11A User Manual*) provides an intuitive way to adjust the beams for non-isocentric plans. Both the gap adjustment and the collision check can be adjusted through scripting, which provides a way to automate the workflow.

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