RAYCARE v2025 SP5

Instructions for Use

RayCare

v2025

Declaration of conformity

$\mathsf{C}\mathsf{E}$ 2862

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

Safety notices

Warning and caution notices in the user documentation inform about the safe use of the product and must be followed.

> ⚠️ **WARNING!**
>
> A warning notice informs about a risk for bodily harm or death. In most cases, the risk is related to mistreatment of the patient.

> △! **CAUTION!**
>
> A caution notice informs about a risk for damage to equipment, software or data.

Note: *A note provides additional helpful information, tips or reminders.*

Copyright

Printed material

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

TABLE OF CONTENTS

1   INTRODUCTION

About RayCare

RayCare is an oncology information system that supports healthcare professionals in delivering cancer care.

RayCare is a software-only system with a client part that allows the user to interact with the system, and a server part that performs the necessary processing and storage functions.

In this chapter

This chapter contains the following sections:

1.1 ABOUT THIS MANUAL

This manual contains general product information, safety related information, installation instructions, and information about system integrity and safety. This manual also contains important notes about the RayCare v2025 SP5 system. It contains information related to patient safety, and lists known issues and possible workarounds.

Study this manual carefully before using the RayCare v2025 SP5 system. Proper functioning of the device can only be guaranteed if the instructions in this guide are adhered to. Every user of RayCare v2025 SP5 must be familiar with the known issues described in this manual. These notes provide final instructions on how to use the RayCare v2025 SP5 system. Feel free to contact the manufacturer for any questions about the content.

Copyright notice for AJCC Staging System
Cancer staging information in RayCare is used with permission from the American College of Surgeons, Chicago, Illinois. The data is sourced from the AJCC Cancer Staging System (2023 edition).

1.2 RAYCARE DOCUMENTATION

1.2.1 RayCare system documentation

The RayCare v2025 SP5 system documentation consists of:

Document	Description
RSL-D-RC-v2025-IFU, RayCare v2025 SP5 Instructions for Use	This manual contains regulatory information, safety information and a summary of known issues concerning the RayCare v2025 SP5 system.
RSL-D-RC-v2025-USM, RayCare v2025 User Manual	This manual describes the functionality of the RayCare v2025 SP5 system and gives step by step instructions on how to perform the most common operations.
RSL-D-RC-v2025-TAUSM, RayCare v2025 Treatment Application User Manual	This manual describes the RayCare v2025 SP5 treatment application.

1.2.2 Other associated documentation

- *RSL-D-RC-v2025-NI, RayCare v2025 News and Improvements*

- *RSL-D-RC-v2025-SEG, RayCare v2025 System Environment Guidelines*

- *RSL-D-RC-v2025-TPL, RayCare v2025 Third-Party Licenses*

- *RSL-D-RC-v2025-RPDCS, RayCare v2025 RayCare PACS DICOM Conformance Statement*

- *RSL-D-RC-v2025-ATP, RayCare v2025 Acceptance Test Protocol*

- *RSL-D-RC-v2025-CIT, RayCare v2025 Clinic IT Instructions*

- *RSL-D-RC-v2025-PDFIMIN, RayCare v2025 Document and Photo File Import Interface Specification*

- *RSL-D-RC-v2025-SAPI, RayCare v2025 Scripting API*

- *RSL-D-RC-v2025-UPG, RayCare v2025 Upgrade Manual*

- *RSL-D-RC-v2025-XRTS, RayCare v2025 XRTS Integration Configuration Manual*

- *RSL-D-RC-v2025-SBOM, RayCare v2025 Software Bill of Materials*

- *RSL-D-RC-v2025-CSG, RayCare v2025 Cyber Security Guidelines*

- *RSL-D-RC-v2025-IHL7ADT, RayCare v2025 Inbound HL7 ADT Interface Specification*

- *RSL-D-RC-v2025-IHL7ORU, RayCare v2025 Inbound HL7 ORU Documents Interface Specification*

- *RSL-D-RC-v2025-IHL7ORUR40, RayCare v2025 Inbound HL7 ORU Flags Interface Specification*

- *RSL-D-RC-v2025-IHL7SIU, RayCare v2025 Inbound HL7 SIU Interface Specification*

- *RSL-D-RC-v2025-OHL7ADT, RayCare v2025 Outbound HL7 ADT Interface Specification*

- *RSL-D-RC-v2025-OHL7DFT, RayCare v2025 Outbound HL7 DFT Interface Specification*

- *RSL-D-RC-v2025-OHL7DOC, RayCare v2025 Outbound HL7 DOC Document Interface Specification*

- *RSL-D-RC-v2025-OHL7SIU, RayCare v2025 Outbound HL7 SIU Interface Specification*

- *RSL-D-RC-v2025-CKATP, Accuray CyberKnife Acceptance Test Protocol*

- *RSL-D-RC-v2025-CKITS, Accuray CyberKnife Integration Test Specification*

- *RSL-D-RC-v2025-ARATP, Accuray Radixact Acceptance Test Protocol*

- *RSL-D-RC-v2025-ARITS Accuray Radixact Integration Test Specification*

- *RSL-D-RC-v2025-IBAPOATP, IBA ProteusOne Acceptance Test Protocol*

- *RSL-D-RC-v2025-IBAPOITS IBA ProteusOne Integration Test Specification*

- *RSL-D-RC-v2025-DCSAR RayCare treatment driver DICOM Conformance Statement - Accuray Radixact*

- *RSL-D-RC-v2025-DCSAR RayCare treatment driver DICOM Conformance Statement - Accuray CybrKnife*

- *RSL-D-RC-v2025-DCSIBA RayCare treatment driver DICOM Conformance Statement - IBA Proteus*

2 PRODUCT INFORMATION

This chapter describes important information about the RayCare v2025 SP5 system.

In this chapter

This chapter contains the following sections:

2.1   DEVICE TYPE

RayCare is a stand-alone software Oncology Information System (OIS).

2.2   INTENDED USE

RayCare is an oncology information system intended to provide information which is used to take decisions for diagnosis, treatment management, treatment planning, scheduling, treatment and follow-up of radiation therapy, medical oncology and surgical oncology.

For these disciplines, as applicable, RayCare enables the user to define the clinical treatment intent, prescribe treatment, specify the detailed course of treatment delivery, manage the treatment course and monitor the treatment course. RayCare may also be used to aid in treatment by providing and recording treatment delivery data for safe and effective treatment delivery.

In the context of radiation therapy, the RayCare image viewer can be used for viewing images, annotating images, performing and saving image registrations as well as image fusion to enable offline image review of patient positioning during treatment delivery.

RayCare is not intended for use in diagnostic activities.

2.3   INTENDED USER

The intended users of RayCare are cancer care clinic personnel including clinical, technical and administrative personnel.

User group access is controlled according to their defined usage needs, training and education requirements are defined per group. For safety related activities, the user of the system must also have appropriate training in using the system.

The users must have a working knowledge of English.

2.4   INTENDED PATIENTS AND INDICATIONS

RayCare is an Oncology Information System (OIS), aimed at professionals managing information, diagnosis and treatment related to patients who are considerd for or treated with radiation therapy, medical oncology, surgical oncology or liver ablation.

2.5   INTENDED ENVIRONMENT

RayCare servers are located within the hospital IT environment. RayCare clients are used within the internal hospital network or within a secure wireless network in the hospital.

2.6   CLINICAL BENEFIT

RayCare provides the benefit of digitalization of patient related data and management and visualization of the clinical workflows. Automation features included in RayCare could enhance the efficiency of the clinical workflows and potentially lead to a reduced number of errors due to a reduced number of manual activities.

2.7   USER RESPONSIBILITIES

The user organization shall ensure that:

- Individuals authorized to use RayCare according to the specified intended use, are appropriately trained for the functions they perform.

- The user shall be aware that the quality of the output depends critically of the input of data and any irregularities or uncertainties about input data units, identification, or quality of any other nature shall be thoroughly investigated before the data are used.

2.8 HARDWARE AND OPERATING SYSTEM

RayCare clients shall be installed on a modern PC, with a minimum of 16 GB RAM and a recommended screen resolution of 1920 x 1200 pixels (or 1920 x 1080). Windows scaling on clients shall always be set to 100%. RayCare v2025 SP5 clients can be used with Windows 11 64-bit operating system. For the image viewer to operate correctly, an NVIDIA graphics card must be used. It is recommended to use the versions 581.42 (only) of the NVIDIA GPU drivers.

The RayCare server shall be installed on servers running Windows Server 2016, 2019, 2022 or 2025 operating system. In case of virtualization, only supported virtualization software shall be used. For a large Clinic installation, the RayCare server should have 64 GB of RAM, 8 CPU cores and at least 500 GB of disc space. All RayCare backend services shall be configured to run on the same server instance. The SQL server should have 64 GB of RAM, 8 CPU cores and at least 1 GB of SSD storage per patient. The treatment driver server should have at least 16 GB RAM, 4 CPU cores and 40 GB of SSD storage.

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.

The system must only be used with a computer that meets applicable hardware safety standards with respect to electric failure and electromagnetic radiation. It is recommended to install new Windows Service Packs on both client computers and servers. These are tested, cumulative sets of security and critical updates widely released by Microsoft. It is also recommended to install the Security Updates, which are widely released fixes for operating system security related vulnerabilities. Installing any other updates is discouraged. After all updates have been performed, system performance must be verified.

2.9 CONTRAINDICATIONS

None known.

2.10 MANUFACTURER CONTACT INFORMATION
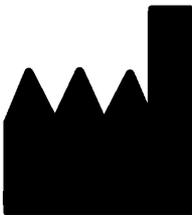
RaySearch Laboratories AB (publ)
Eugeniavägen 18C
SE-113 68 Stockholm
Sweden
Telephone: +46 8 510 530 00
E-mail: info@raysearchlabs.com
Country of origin: Sweden

2.11 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.

2.12 REGULATORY REPRESENTATIVE

The table below specifies the contact information of the regulatory representative.

Regulatory representative	Contact information
Australian Sponsor	Emergo Australia Level 20, Tower II Darling Park 201 Sussex Street Sydney, NSW 2000 Australia
New Zealand Sponsor	CARSL Consulting P O Box 766 Hastings New Zealand
US Agent	RaySearch Americas, Inc. The Empire State Building 350 5th Avenue, Suite 5000 New York, New York 10118 USA

2.13 PRODUCT LABEL

The version number of an installed RayCare v2025 SP5 system can be found by choosing **About** in the RayCare menu.

The following information can be identified:

- Product name = RayCare

- Release version = **9.0**

- Marketing name = RayCare v2025 SP5

- Software build number = **9.0.5.60021**

- Clinical build = Indicates that this is a product for clinical use

- Environment name = The name of the environment where the RayCare services are run

- Product Lifetime = The lifetime per market is one year after the next major release, but no less than three years

- Licensed to [Hospital name] until [date]. This will be updated for each clinic and installation.

- Oncology Information System = The generic name of the product

- **MD** = Indicates that the product is a medical device

- **UDI** = Unique Device Identification number

- **CH REP** = The Swiss authorized representative and importer

- Driver information = To be used for treatment interoperability

- CE_{2862} = 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

2

Figure 1.   The **About RayCare** dialog.

2.14   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.

2.15   REGULATORY INFORMATION

European SRN-number

The single registration number (SRN) = SE-MF-000001908 has been issued to RaySearch Laboratories AB (publ), as required by the EU MDR — Regulation (EU) 2017/745.

3   INFORMATION NEEDED FOR SAFE OPERATION

This chapter describes information needed for safe operation of the RayCare v2025 SP5 system.

In this chapter

This chapter contains the following sections:

3

3.1 DISPLAY FORMAT

In RayCare, date and time can be configured to be displayed in two different formats:

- **EU format**: "ddMMMYYYY, HH:mm", e.g., "14 Jan 1975, 13:20".

- **US format**: "ddMMMYYYY, h:mm a", e.g., "14 Jan 1975, 01:20 pm".

This configuration is system-wide and affects all clients, regardless of local Windows settings.

3.2 RESOLVED FIELD SAFETY NOTICES (FSN:S)

There are no resolved FSNs in RayCare v2025 as compared to RayCare 2024A.

3.3 SAFETY PRECAUTIONS

Adhere to the following warnings and known issues for safe operation of the RayCare v2025 SP5 system.

Note: *Additional release notes may potentially be distributed shortly after installation.*

In this section

This section contains the following sub-sections:

3

3.3.1 General warnings and known issues

> ⚠️ **WARNING!**
>
> **Changes that are not saved may be lost.** Changes that have not been saved may be lost without warning if the user navigates away from a workspace, closes an input window or moves to another row in a table. (55572)

> ⚠️ **WARNING!**
>
> **Image viewer.** The Image viewer is not intended for diagnostic use. (61637)

> ⚠️ **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. (149255)

> ⚠️ **WARNING!**
>
> **Broken patient record.** A broken patient record occurs when RayCare detects an error or inconsistency in data related to a specific patient. If RayCare cannot automatically recover from the error, the patient is flagged as a broken patient record. When this happens, a banner is displayed in the patient panel stating that 'The patient record is broken'. The patient data displayed may not be up to date and/or correct. The user should not continue working with this patient in RayCare until the issue has been cleared. RaySearch support must be contacted to resolve the issue.(573275)

> ⚠️ **WARNING!**
>
> **RayCare system blocked.** If an error is detected that RayCare cannot recover from automatically, the system will be set in a blocked state. When this happens, a banner is displayed in RayCare stating that 'An error has occurred and the system is blocked. Please contact the system administrator.' At this time, all users except system administrators are logged out of the system. System administrators can access the system but need to be aware that the system is not safe to use, and that the data displayed may not be up to date and/or correct. RaySearch support must be contacted to resolve the issue. (573274)

> ⚠️ **WARNING!**
>
> **System upgrade.** After an upgrade of the RayCare system to a newer version, the clinic is responsible for validation of the system before continued clinical use. (97332)

> ⚠️ **WARNING!**
>
> **Unprocessed patient information.** A warning will be displayed on the patient panel when RayCare detects patient information that is flagged as outdated. This indicates that certain data is still being processed and pending updates to the patient record are anticipated. Until the information is fully updated, some data may be inaccurate, and additional caution is required. Users should refrain from taking action based on non-updated patient data. The warning message will automatically disappear once the data has been successfully updated. (2163535)

3.3.2 Warnings and known issues concerning patient chart

> ⚠️ **WARNING!**
>
> **Additional patient identifiers.** When editing additional patient identifiers, the user needs to consider if any other system references the patient by that ID and in that case update the other systems accordingly. (148497)

> ⚠️ **WARNING!**
>
> **RayCare and RayStation shall be configured to use the same dose unit.** Ensure that RayCare and RayStation are configured to use the same unit for displaying radiation dose, either cGy or Gy. (55838)

> ⚠️ **WARNING!**
>
> **Editing values in RayCare Documents do not change the corresponding values in RayCare.** When changing values in a document in the RayCare Document workspace the corresponding values in RayCare do not change. (58837)

> ⚠️ **WARNING!**
>
> **Fixed number of decimals for stored values.** When entering numeric measurement data the user shall be aware that even though RayCare does not limit the number of decimals that can be entered, the values will only be displayed with the pre-defined number of decimals for each type of measurement. For example, the body temperature of a patient is always displayed with one decimal. Always check how the values you enter are represented after being saved. (122636)

> ⚠️ **WARNING!**
>
> **Notes and remarks.** In the Documentation Overview tab, all RayCare patient notes, task and appointment comments, and messages relating to the patient can be found. Remarks pertaining to specific workspaces/tabs are not displayed in the Documentation Overview tab. (227121)

> ⚠️ **WARNING!**
>
> **Medication substance allergies.** Warnings for medication substance allergies may not be displayed if the allergy is entered as free-text. The warning for medication substance allergies will only be displayed if the spelling of the allergy exactly matches that of the substance. (227236)

> ⚠️ **WARNING!**
>
> **RayCare treatment site prescriptions are not connected to RayStation beam set prescriptions.** Prescription values entered in RayCare are not propagated to RayStation. No validation between systems is performed on the entered prescription values. The user is expected to manually enter beam set prescriptions in RayStation that match the RayCare treatment site prescriptions. The user must carefully review that the RayStation beam set prescriptions fulfill the RayCare treatment site prescriptions. (570679, 570675)

> ⚠️ **WARNING!**
>
> **RayCare case status.** The RayCare case status has no effect on RayCare, RayStation, RayCare Treatment or RayCommand. It is still possible to modify data and continue the treatment course. (574262)

> ⚠️ **WARNING!**
>
> **Dose is displayed as RBE when RBE and physical dose are displayed together.**
> When dose is displayed for a treatment site, all dose is displayed as RBE dose if any prescribed or delivered dose for that treatment site is RBE weighted. (574458)

> ⚠️ **WARNING!**
>
> **Value selected in draft document removed if removed from RayCare.** If a RayCare domain object has been selected in a dropdown in a document and one of the selected values has been removed from the patient record, the removed value will not be displayed in the document. (686519)

> ⚠️ **WARNING!**
>
> **Extended domain objects share data between documents.** Extended domain objects are designed to extend the possibility of structured data storage for patient-specific data. The data in the user-specified extended domain objects will be shared between documents.
>
> When setting the context level (patient, case or care plan) on extended domain objects, the user should be aware that the extended domain objects will be shared between all documents on the same or more specific context level when the document is completed or approved. The extended domain object values are not shared between documents until the document is completed or approved. Depending on the extended domain object configuration, the following will apply:
>
> - Patient level extended domain objects will share data to all documents for that patient.
> - Case level extended domain objects will share data to documents on the same case and documents on care plans belonging to that case.
> - Care plan level extended domain objects will only share data to documents on the same care plan.
>
> When creating the document from patient chart, the user will be prompted to enter the required context information, i.e., case and/or care plan as needed. (573616, 686660, 1441544)

3

⚠️ **WARNING!**

Data in open or minimized documents is updated only on save or reload. RayCare domain object and Extended domain object fields will not be updated with new values until the document has been saved or closed (not minimized) and then reopened.

If the user has minimized a document and updated data included in the minimized document, the document needs to be saved or closed and reopened for the values to be updated. (1441563)

⚠️ **WARNING!**

Updating RayCare domain objects and extended domain objects in Word documents. RayCare domain objects and extended domain objects in a Word document are only updated when opening the Word document in edit mode or when the values are refreshed using the RayCare Word add-in. RayCare domain objects and extended domain objects are not updated when the Word document is opened in view only mode. Make sure to open the Word document in edit mode when the RayCare domain objects and extended domain objects need to be updated. (2152671)

⚠️ **WARNING!**

Modifying the content of the RayCare domain objects and extended domain objects in the Word document. References to RayCare domain objects and extended domain objects are added to a Word document by the RayCare Word add-in as 'content controls'. Modifying the content control properties added by the RayCare Word add-in may result in values not being updated as expected. Do not update the properties of the content controls. (2162794)

Other known issues concerning patient chart

- The crown icon, indicating that the image is used as planning image, is not removed from the image series in the Images workspace in the patient chart and the PACS workspace when the corresponding planning instruction is set to Entered in error. (686261)

- Deprecating an order document does not cancel the order. Cancel the order manually from the Order workspace to prevent the order from being performed. (687393)

- In the Edit appointment dialog, appointment notes can be added to an appointment. The appointment notes are displayed in the Recent messages and comments in the Patient summary and the in the Documentation workspace when filtering on All or on Appointments. (1337828)

- The formatting of exported PDFs of documents using long static or input text might be unexpected. Verify the layout and content of the exported PDF. (1343794, 1343798)

- When exporting a plan report from RayStation with more than one beam set, the plan report is displayed as connected to only one of the beam sets. Open the Plan report to view which other beam sets in the treatment plan it applies to. (1344848)

- Charges from the appointment template used originally for an appointment series will also be used for appointments added to the series, even if the appointment template is changed when scheduling the new appointments. (1438254)

- In RayCare documents, the RayCare Domain Object for "Treatment start" and "Treatment end" dates reflect the treatment start and end date for the case and not the dates for a treatment course for the patient. Review the use of these values in RayCare documents to ensure that they are not misleading to users of the documents. (1433245)

3.3.3 Warnings and known issues concerning offline image review

⚠️ **WARNING!**

Manually imported treatment images for offline image review. Manually importing treatment images and corresponding registrations will be available in the Offline image review workspace for all cases for that patient. It is the responsibility of the user to link the treatment images manually to the correct RayCare case. (573886)

⚠️ **WARNING!**

The primary and secondary images differ in the 2D/3D case as compared to the 3D/3D and 2D/2D cases. When performing offline image review based on 2D/3D fusion, the user must be aware that the primary and secondary images are reversed as compared to 3D/3D and 2D/2D fusion.

In the 2D/3D case, the RT image is used as primary image and the planning CT is used as secondary image.

In the 3D/3D case the planning CT is used as primary image and in the 2D/2D case the planning RT image is used as primary image. (227770)

⚠️ **WARNING!**

2D/3D fusion. Offline image review for 2D/3D fusion is only supported and validated for RT images originating from an image system manufactured by MedPhoton. (226036)

> ⚠️ **WARNING!**
>
> **RT Image Display.** For kV Images, the Gantry Angle text annotation will describe the angle of the kV radiation source with respect to the IEC Fixed coordinate system and may not coincide with the gantry angle displayed in the treatment console of the treatment device. (1438541)

> ⚠️ **WARNING!**
>
> **2D/3D and 2D/2D fusion tools.** Updates to the registration made using the fusion tools will affect all image pairs, including ones not currently being displayed. (1440334)

> ⚠️ **WARNING!**
>
> **2D/2D fusion.** Review of 2D/2D fusion in the Image viewer is only supported and validated for RT images originating from an image system manufactured by Varian Medical Systems. (1434934)

Other known issues concerning offline image review

- Comments made during offline image review are not displayed in RayCare Treatment until a status has been set on the offline image review result. (573181)

- A treatment plan used for fraction is not clearly marked when performing offline image review. All approved treatment plans are listed in the Image viewer RT Plan/RT Ion Plan drop-down list. The user must actively select the correct treatment plan from the drop-down list. (72681)

- The completeness of treatment images in the Offline image review workspace is not automatically verified. In rare circumstances, there can be a difference between the number of slices for the treatment image in RayCare and the source location of those image sets. When reviewing the treatment images in offline image review, verify that the number of slices is as expected for the used imaging protocol. (1068366)

3.3.4   Warnings and known issues concerning scheduling

⚠ **WARNING!**

Treatment appointment scheduling rules are not always enforced when manually modifying appointments. When manually booking an appointment, or editing a suggested time slot for a treatment appointment, the temporal rules specified for the appointment type may be violated. (55702)

⚠ **WARNING!**

Appointment template suggestion rules are not applied when rescheduling parts of series. Appointment template suggestion rules are only applied when using the scheduling or rescheduling functionality. They are only used to provide scheduling suggestions for the complete series of appointments before any changes have been made. The rules are not verified when manually editing appointments. If one or more appointments have been manually modified, the suggestion rules will not be applied. (572967)

⚠ **WARNING!**

Treatment appointment frequency. It is the responsibility of the user to schedule treatment appointments with the appropriate time intervals. (573563)

⚠ **WARNING!**

Treatment appointment to treatment session connection may change. Treatment sessions are connected to treatment appointments based on the current order of treatment sessions and appointments. Treatment sessions are expected to be delivered in the order indicated by the treatment course index. Changing the scheduled order of treatment appointments will update which treatment sessions are connected to which treatment appointments. Also, changing the relationships between treatment series will update the connection to treatment appointments according to the updated order of treatment sessions. (1343284)

3

⚠️ **WARNING!**

Notes and comments for treatment appointments are connected to the appointment, not the session. The connection between treatment appointments and treatment sessions may change based on scheduling or changes in the treatment course index. Notes and comments added to a treatment appointment will stay on the appointment if the treatment appointment is connected to another treatment session, they will not be moved with the treatment session. The user must take care to not add any treatment session specific information in the notes and comments. (1344341)

⚠️ **WARNING!**

Scheduling tasks for continuation sessions. When continuations sessions are added, they are automatically connected to a new treatment appointment that must be scheduled. The newly added pending treatment appointment will have an associated scheduling task. The scheduling task will be assigned to the logged in user who added the continuation session and the booking administrator role. If the logged in user is not a RayCare user, the task will only be assigned to the booking administrator role. To ensure that the task is displayed for users, ensure that continuation sessions are always added by a RayCare user or that there are individuals assigned to the booking administrator role. (1343937)

Other known issues concerning scheduling

- It is not possible to reschedule appointments that have been added manually. The rescheduling functionality is only available for appointments that are booked based on tasks. (98221)

- When scheduling appointments, the name of the clinic that the patient belongs to is not displayed in the user interface. (472174)

- It is not possible to get scheduling suggestions for a resource that does not have a clinic specified. (571975)

- Charges configured on an appointment template will not be included when adding the activity or module to a patient. Do not configure charges on an appointment template when the appointment will be used in an activity or module. Configure the charges on the appointment in the module or activity instead. (1337932)

- The status of the appointment is not displayed for appointment notes or comments in the patient chart or when reviewing All comments in the Edit appointment dialog. Open the appointment linked to the comment or note to see the status of the appointment. The appointment may have been set to removed. (1341009)

- The allowed weekday and the starting on weekday settings can be set during the appointment series template configuration in the Admin workspace. The suggestion rules specified for appointment series will not be considered when scheduling appointment series using appointment template configured using these settings. Do not use allowed weekdays or starting on weekdays when configuring appointment series templates. (1343382)

- Not possible to create a new treatment appointment series on care plan level if one already exists for the same care plan, even if all appointments in the latter series are canceled or entered in error. Add new appointments to the already existing treatment appointment series instead. (1439710)

- When saving but not closing the Edit appointment dialog, any changes regarding scheduling and room validation alerts will not be updated in the dialog. Close and re-open the Edit appointment dialog to see the updated scheduling and room validation alerts. (1437931)

- When attempting to reschedule after completing a scheduling task using the Get suggestions functionality, the validation message 'Time is not set' might appear. To avoid this issue, switch to the 'Book specific time' tab and then switch back. No time needs to be specified in the 'Book specific time' tab. (2163633)

- The selected start and/or end appointment(s) in the Rescheduling workspace may be unexpectedly reset to the default values when changing other scheduling parameters, e.g. by selecting the 'Get suggestions' tab. This may lead to accidentally rescheduling the entire appointment series when only rescheduling of a subset was intended. Verify the selected start and end appointments during rescheduling as well as the generated appointment suggestions. (2163101)

- If the time field is modified and the Book button is clicked immediately afterward when using the Book specific time functionality, new appointment suggestions will be retrieved, but the appointment series will not be booked. To complete the booking, click the Book button again after the suggestions have been updated. Note that if the booking confirmation dialog does not appear, no (re)scheduling has taken place. (2163326)

- An appointment series where some of the appointments have been set to Entered in error and others are Completed in a non-chronological order may cause a crash when trying to reschedule the appointment series. Reschedule the appointments manually using the Edit appointment dialog. (2163536)

3

3.3.5 Warnings and known issues concerning workflow

> ⚠️ **WARNING!**
>
> **Manual changes of task states.** RayCare supports tasks that can be either updated by manual interaction with the task or by automatic updates based on the availability of information in the system. There is no verification that the manual interaction is consistent with the availability of information. Therefore, when manually updating the state of the task, check that the state is consistent with the actual state of all related information. (16084)

> ⚠️ **WARNING!**
>
> **Due dates for tasks may have dependencies.** RayCare supports the management of due dates for tasks which are often defined relative to other tasks. Therefore, changing a due date for one task may result in a change of due dates for other tasks. For your specific workflows, make sure that you understand how the due dates are related. (16099)

> ⚠️ **WARNING!**
>
> **Undo and redo of tasks.** To provide flexibility and allow the user to correct mistakes, the completion of a tasks can be undone. Most tasks are representations of clinical activities that were performed as part of the task completion. Be aware that those activities are not automatically reverted when changing state of a task but may require additional compensatory activities. (16104)

> ⚠️ **WARNING!**
>
> **Due date anchors and target dates are not updated when appointment is canceled.** When setting an appointment linked to a due date anchor to status canceled or entered in error or when it becomes annulled or removed e.g. by canceling the module in which it is contained, the due date anchor date and target date will not be automatically updated accordingly. (1436068)

> ⚠️ **WARNING!**
>
> **Reducing treatment series fraction count may cause completed fraction tasks to be removed.** When reducing the fraction count of a treatment series with a connected treatment delivery module, fraction activities and tasks corresponding to the removed sessions will also be removed. This removal includes fraction activities and tasks which may have been set to completed. (1439054)

Other known issues concerning workflow

- The patient chart task list does not display an icon indicating that a workflow module or an order has comments. Only comments on tasks and appointments are indicated by an icon. (367581)

- Opening the Edit task dialog without saving any changes will not add the task to the Recent task list in the Home workspace. (368675)

- Problem resolution tasks without a case are not displayed in the patient chart task list. These tasks can be accessed by a system administrator from the patient chart left panel task list. (572510)

- Comments made when performing one task that is part of a review cycle such as treatment plan creation and review are not displayed in subsequent tasks in the same review cycle if the tasks are separate. The user must review the comments in, for example, Create dose plan task when working with the Review dose plan task. (573287)

- Separate plan and beam set target dates for each plan and beam set module will be created in the Edit workflow properties dialog even if the plan used in both workflow modules is the same. The user must take care to set all target dates. Canceling a plan or beam set module will not remove the plan or beam set target date. (688148, 688161, 688470)

- It is not possible to add a second workflow module of a specific module type even though the existing module of that type has been completed. (687986)

- When an insertable forms task on care plan level is inserted in an activity on case, the form will be created on case level and it will not be possible to complete the form. Avoid manually inserting a care plan level document task in a module on case or patient level or a case level document tasks in a module on patient level. (1068216)

- The plan and beam set icons are not displayed in the task list in RayStation for tasks that do not require a plan or beam set to be specified before being completed. (1069108)

- It is not possible to remove task configuration options when including a task in a module, it is only possible to add additional options on the module level. (1069383)

- Due date anchors on care plan level without a specified due date will not use the due date of their case level counterpart. Make sure to add the due date to the due date anchor on the appropriate context level. (1339161)

- When a care plan is specified for a treatment appointment series, the case treatment target date is kept. Both the case and care plan treatment start date will be updated when the care plan treatment appointment series is rescheduled. The scheduled case or care plan treatment start date are only linked when a scheduling task is used to book the treatment appointment series. (1342016)

- The scheduled treatment start date will not be displayed on the Planning or QA whiteboard when the related treatment appointment series is not scheduled using a scheduling task. Use the scheduling tasks to make sure the scheduled treatment start date is displayed. The treatment start date is not displayed on the Active patients whiteboard when the patient has a case and care plan and the treatment appointment series is booked on case level. (1341631)

- It is possible to select a combination of care plan and beam set for a workflow module that does not correspond to the care plan connected to that beam set in Treatment course management. Take care to select the appropriate care plan and beam set combination when selecting workflow modules. (1437909)

- When inserting multiple blocking tasks and performing the first inserted blocking task, the other linked blocked tasks are unblocked even though the tasks should still be blocked by the other inserted blocking tasks. Review the blocked status of tasks carefully after completion. (1448665)

- It is not possible to add a new treatment delivery module for a given care plan when at least one completed task per treatment session exists in the current treatment delivery module. To be able to add the new treatment module, add an additional treatment session, add the new treatment delivery module and then remove the additional treatment session. (2163435)

3.3.6   Warnings and known issues concerning treatment planning integration with RayStation

> ⚠ **WARNING!**
>
> **DICOM warnings in RayStation must be reviewed.** Always review if there are any DICOM import warnings after automatic import of an image to RayStation. Warnings can be reviewed in the RayStation DICOM import log, or in the problem resolution task that will be generated in RayCare. (14590)

> ⚠️ **WARNING!**
>
> **Interruption of communication between RayStation and RayCare.** On rare occasions, the communication between RayCare and RayStation fails in a way that prohibits any further communication between the systems for a specific patient. If this happens, contact RaySearch support to resolve the problem. (14846)

> ⚠️ **WARNING!**
>
> **RayStation does not store optimization information in DICOM.** When a treatment plan is approved in RayStation and stored in RayCare PACS, some detailed information related to the optimization process in RayStation is not transferred. To make sure that this information is retained, do not delete the plan in RayStation after exporting. (15060)

> ⚠️ **WARNING!**
>
> **Unapproval of image registrations in RayStation will not be reflected in RayCare.** Always verify the approval status of image registrations in RayStation. Treatment planning tasks in RayCare workflows will not reflect unapproval of these items. (15088)

> ⚠️ **WARNING!**
>
> **Unapproval and replanning shall not be initiated from RayCare.** The status of the treatment planning tasks in RayCare does not affect the approval status of structure sets and plans in RayStation. Never attempt to unapprove structure sets or plans by modifying the status of a treatment planning task in RayCare. (16749)

> ⚠️ **WARNING!**
>
> **RayStation comments.** Comments created in RayStation will only be transferred to RayCare when they are linked to a RayStation task, added from the RayCare task list in RayStation, added from the Ready for review, added from the plan/beam set approval dialog, or added to the beam set comment field in the New/Edit plan dialog. (573283)

3

> ⚠️ **WARNING!**
>
> **Data synchronization between RayCare and RayStation.** During normal operation of RayCare and RayStation, data is automatically synchronized between the systems. In the event that the synchronization fails, a warning message is displayed in the patient panel. If RayCare and RayStation data for a patient record is not in sync due to an unsupported or unexpected actions performed in either system, no warnings are automatically displayed to the user. (1343950)

Other known issues concerning treatment planning integration with RayStation

- The primary planning image in RayCare is not pre-selected in RayStation when opening a case in RayStation. (472819)

- The names of DICOM images are not consistently used between RayCare and RayStation. (472754)

- The 'Make available for planning' function in the Images workspace in the patient chart does not always work for treatment plans (RTPLAN) and structure sets (RTSTRUCT). The user needs to manually import the DICOM RTPLAN or RTSTRUCT into RayStation instead. (567891)

- A workflow module for a specific care plan can be linked to a treatment plan and a beam set belonging to a different care plan. (687323)

- The date and time of approval of a RayStation beam set displayed in the status tooltip in the Plan overview workspace may differ from the beam set approval time in RayStation. Make sure to verify the approval time in RayStation Patient data management. (903675)

- The patient panel in RayStation does not give an indication if the corresponding RayCare patient has been removed. (1067695)

- Comments added after the setting a plan in ready for review or approving the plan in RayStation will not be added to the related task unless the status of the task is also changed. The comments are available in Plan overview. (749502, 1069225)

- In the event that data for a RayCare patient needs to be synchronized between RayCare and RayStation, all updates as a result of the synchronization will be performed as one action and thereby reduce traceability in RayCare. (1339103)

- The patient first or last name of a patient treated with an Accuray treatment device is restricted to 30 characters. It will not be possible to approve the treatment plan in RayStation. Make sure the first or last name is shorter than 30 characters. (685046)

- Treatment plan and beam set details from RayStation cannot be displayed correctly after removing the case or patient from RayStation. (474559)

- When an ION machine model is used for a beam set planned in RayStation and the Dose Type for the machine model is set to RBE, the nominal progress dose values for treatment sites defined by the RayStation prescription are displayed as physical dose, even though

they represent RBE dose. The issue only occurs for treatment sites without corresponding RayCare prescription with RBE dose. (1449021)

- In the Treatment Course workspace, the first record in the Online Couch Corrections table for a session displays the shift between the planned table top position (if assigned in RayCare for a single isocenter beam set) and the actual table top position at the time of that first record. Each subsequent record in the table shows the shift between the actual position and rotation of the current record and the previous record. This means that:

    - Each shift reflects the actual couch movement performed between each imaging and/ or beam delivery event (represented as one record for each event).

    - The shifts do not represent corrections relative to the original planned positions and rotations for each event, but rather the incremental changes made during the session.

    This does not apply to shifts displayed for RayCommand deliveries. (1728507)

- Consider a patient that has been treated using RayCare 6A or earlier. When performing offline recording for such a patient for the same or a different treatment course, the treatment records (RT Records) from both the online and offline recorded sessions treated in RayCare 6A or earlier will be available for selection and will not be filtered out in the treatment record selector in the offline recording dialog. Make sure to carefully select the correct RT record when offline recording new fractions for these patients. (2163713)

3.3.7   Warnings and known issues concerning treatment management

> ⚠ **WARNING!**
>
> It is recommended that all set-up instructions linked to the same planning image are described in the same setup instruction. (74052)

> ⚠ **WARNING!**
>
> **Treatment records imported to PACS are not automatically transferred to and imported in the RayCare treatment course.** The user should always import the relevant treatment records in the RayCare treatment course. (369254)

> ⚠ **WARNING!**
>
> **Nominal dose progress.** It is possible to track nominal dose progress towards one or more prescriptions during treatment delivery performed using RayCare Treatment or RayCommand.

RayCare presents nominal dose progress per treatment site and prescription type for a selected case. RayCare and RayStation prescriptions will be displayed as one item when they have identical treatment site names and prescription types.

Nominal dose progress is not related to the calculated dose in RayStation. It is based solely on the beam set prescription in RayStation and has no dependency on whether the beam set prescription is fulfilled or not. (574154)

⚠️ **WARNING!**

Beam set is assigned the same care plan as the treatment series it is used in.
Beam sets are assigned a care plan context from the treatment series that it is assigned to. The care plan from that treatment series must be added to the setup instruction that is used for the delivery of that beam set, to enable treatment delivery. (1340092)

⚠️ **WARNING!**

Fraction numbering and treatment course index. The fraction number represents the initial order of fractions within a treatment series and is constant for a given fraction. The treatment course index represents the current order of fractions in a treatment course and may update when fractionation pattern or when scheduling of treatment appointments change. This includes changing the relationship between two treatment series or rescheduling fractions that have been locked for treatment. The treatment course index will update to reflect the actual order of delivery and may change after a session has been checked in. Always use the fraction number and treatment series to uniquely identify a treatment fraction. (1342250)

⚠️ **WARNING!**

Fraction pattern display. The fraction pattern table in the Treatment course management workspace displays delivered fractions on the day they were delivered, not on the day they were originally specified in the fraction table. (1342258)

⚠️ **WARNING!**

Schedule alerts do not take continuation sessions into consideration. Schedule alerts are displayed when treatment appointments are not scheduled according to the fraction pattern specified for the treatment course. Continuation sessions are not considered part of the fraction pattern and do not generate schedule alerts. (1344336)

⚠️ **WARNING!**

Management of parallel treatments in multiple care plans. RayCare supports parallel independent treatments in separate care plans. Each care plan has a separate treatment course and it is not possible to define relationships between these treatment courses. Review all active care plans for treatment information. (1344060)

⚠️ **WARNING!**

Always consider all treatment series in a care plan when approving a treatment series. Treatment series are managed and approved individually, and the user must take care to consider all treatment series included in the treatment course at approval of any treatment series. User must also review the fraction pattern for the complete treatment course when editing any of the treatment series included in the treatment course. This applies when including or excluding treatment series in treatment course, changing the number of fractions in the treatment course or changing beam set assignment. (1343222)

⚠️ **WARNING!**

Treatment series and fraction cancelation. When a planned treatment course is discontinued or canceled, it will only be possible to cancel a treatment series after minimally one fraction for that series has been delivered. If a treatment series is canceled then all remaining fractions will be set to canceled and sessions will be removed, this will remove the fractions from the treatment course overview and it will not be clear that there was any remaining delivery left before the planned treatment was discontinued. It will not be possible to cancel individual fractions. (1344896)

> ⚠️ **WARNING!**
>
> **Editing number of fractions in treatment series.** It is possible to edit the number of fractions in New or Unapproved treatment series from the Edit treatment series dialog. Increasing the number of fractions will add more fractions to the treatment series. Decreasing the number of fractions in the treatment series will remove fractions from the end of the treatment series, the fractions will not be set to state Cancelled. It is not possible to reduce the number of fractions in a way where delivered fractions are removed. (1344898)

> ⚠️ **WARNING!**
>
> **Treatment plan fractionation is not enforced.** It is possible to use different number of fractions and fractionation than what has been specified in the treatment plan. Warnings are displayed when assigning a different number of fractions to a treatment series than the number of fractions specified for a beam set. (1343665)

> ⚠️ **WARNING!**
>
> **Beam set treatment settings.** The beam set table in Treatment course management workspace displays the latest applied settings for the displayed beam sets. Already performed treatment deliveries may have used other settings than the currently displayed in the table. The settings for the performed deliveries can be viewed in the beam set assignment dialog.
>
> Beam set treatment settings always update all non-delivered fractions with that beam set assigned, regardless of which fractions are selected in the beam set assignment dialog when applying the new setting. (1343683, 1343660)

> ⚠️ **WARNING!**
>
> **Treatment series approval does not compare fraction dose.** The tables in Treatment series approval compare dose in treatment series to dose in the prescription or a linked series prescription. Dose is only compared for the sum of all included fractions, not per fraction. Also, the total number of fractions in the treatment series is compared to the linked treatment series prescriptions. (1343469)

> ⚠️ **WARNING!**
>
> **Prescriptions included in treatment series approval.** The table displaying treatment series dose compared to prescription displays the linked prescription or treatment series prescription regardless of the status of the treatment series prescription. The table displaying the treatment course dose compared to prescription displays all new or approved prescriptions in the care plan depending on user filtering. Unapproved prescriptions are not displayed in the table even if they are linked to the treatment series. (1343532)

> ⚠️ **WARNING!**
>
> **Beam set delivery approval.** Beam set delivery approval is an approval of a beam set in addition to the plan approval performed in RayStation. Whether delivery approval is required or not is a configurable option for the clinic. If beam set delivery approval is configured to be required, beam sets must have been delivery approved before it is possible to use them for treatment delivery. (1339661)

> ⚠️ **WARNING!**
>
> **Review the setup instruction to ensure that it matches the isocenter and the plan.** Always approve that the setup instructions, applicable setup photos and main planning image are correct and correspond to each other. When creating a new plan with another isocenter than originally described in the setup information, the setup instruction must be updated to avoid mismatch between the current plan and the setup instruction. (58607)

> ⚠️ **WARNING!**
>
> **Configuration changes require validation.** Changes of the configuration in the treatment delivery device software, RayCare, RayStation or the machine model can affect the treatment device interoperability. Rerun the Installation Test Specification in case of any configuration changes related to the treatment device interoperability. (1449330)

3

⚠️ **WARNING!**

Machine model commissioning and treatment room configuration. The commissioning of machine models and configuration of machine models assigned to RayCare treatment rooms must be performed with care. The configuration requires in-depth understanding of the capabilities of the treatment device and treatment room. (1449327)

⚠️ **WARNING!**

Clinical use case testing. The user is required to validate the clinic specific treatment use cases before clinical use of RayCare interoperability with treatment devices. (1449331)

⚠️ **WARNING!**

Offline recording does not affect specified meterset in delivered sessions in same fraction. Offline recording treatment results for a session will not update the specified meterset for delivered sessions in the same fraction. When modifying the delivered dose for a treatment session, the specified meterset for any already delivered continuation session in the same fraction will not be updated according to the modified dose. (1442606)

⚠️ **WARNING!**

Offline recording is not supported for RayCommand. It is not possible to perform administrative unlock or offline recording of RayCommand treatment sessions. If needed, the user must instead perform manual recording of the session in RayCommand. (1445873)

⚠️ **WARNING!**

Prescribed dose from unapproved prescriptions is not displayed in treatment course approval dialog. The treatment course approval dialog displays prescribed dose from prescriptions linked to the treatment course. If any linked prescription is unapproved, dose from that prescription will not be displayed in the dialog. (1432822)

WARNING!

Tabletop positions are always displayed in IEC tabletop coordinate system. The tabletop positions are always displayed in IEC tabletop coordinates regardless of the coordinate system used on the treatment device console or other treatment device application. (1443136)

WARNING!

Configured meterset tolerance must match meterset tolerance of treatment device. RayCare will use the meterset tolerance configured on the machine model to calculate the delivery status for sessions delivered on the linked treatment device. To ensure a matching delivery status in RayCare and the treatment device, the meterset tolerance must be configured to the same value in RayCare as on the device. (1441174)

WARNING!

Tabletop propagation to future sessions. When selecting to propagate tabletop positions to later treatment sessions, the propagated tabletop position will not contain any couch angle corrections. To compensate for the removal of the couch angle corrections, the couch positions (translations) are recalculated to better match the position at isocenter. As a result, the propagated tabletop positions will not be the same as the delivered tabletop position. Only the tabletop position of the first delivered beam is used for tabletop propagation in case of a multi isocenter treatment. The positions for other isocenters are calculated based on the relative position of the isocenters in the beam set. (1443272)

WARNING!

Offline recording must be performed with care. It is possible to offline record a treatment delivery using treatment records that do not match the treatment fraction. The system cannot fully verify whether the treatment records used during offline recording correspond to the fraction being recorded. Therefore, the user must ensure that the correct RT Record is selected or that the appropriate manual record is provided for the fraction delivery. The result of the offline recording must be carefully reviewed before approval. (1445952)

> ⚠️ **WARNING!**
>
> **Rescheduling treatment appointment after an imaging only session.** If a treatment session is completed after setup images are acquired but before delivery is performed, the status of the treatment fraction delivery for that session will be changed back to 'Not delivered' and the session will be marked as completed. However, the appointment will remain linked to the completed treatment session even if treatment appointments are rescheduled or the treatment course is updated. Manually reschedule the treatment appointment for the completed session to perform the remaining delivery for that session. (2156410)

Other known issues concerning treatment management

- When decreasing number of fractions in multiple treatment series by a large number of fractions within a short period of time, RayCare can become unresponsive. (1340155)

- It is not possible to open and review the treatment series approval information after the treatment series has been approved. (1344948)

- When working in the beam set assignment dialog, the status of the treatment series is not displayed. Also, the status of the respective fractions in the treatment series is not displayed. Review the treatment series and fraction table in the Treatment course management workspace. (1344890)

- When adapting a beam set in RayStation the "Starting at fraction" information is not used in RayCare. It is possible to assign a beam set to a different fraction and no information or warning is displayed to the user. The user must take care to note the starting fraction information and assign the beam set to the treatment course accordingly. (1437671)

- Starting offline recording for treatment sessions with status "Not delivered" will prevent the delivery of that session on a treatment device. The offline recording must be completed and treatment results must be approved in RayCare before treatment can continue for the patient. The user will be informed of this consequence when starting offline recording. (1437860)

- Beam delivery results in the Treatment course workspace in RayCare displays "-" for accessories, bolus, dose rate and collimator angle for deliveries that are not performed on the Varian TrueBeam even though the accessories could have been used during the treatment. (1438606)

- When a bolus is assigned to a beam in RayStation, the bolus information will not be displayed in the RayCare setup instructions for the related beam set. The bolus information is available in RayCare Treatment, RayCommand and the Varian TrueBeam console. (1438928)

- When an ion machine model is used to create a beam set in RayStation and the Dose type in the machine model is set to RBE, it is not clear that the dose value displayed related to

nominal progress for the dose reference coming from the RayStation prescription is RBE dose. The dose is displayed as physical dose. (1449021)

- When the offline recording dialog is closed before approving the offline recording, the treatment start time, treatment device and final note will be removed and needs to be readded. Verify the offline recording carefully before approving. (1442641)

- If snout or gantry positions used during delivery are different from the planned positions then it is not highlighted in the Treatment course workspace that those positions are different. (1440781)

- If the patient details are updated in RayCare between the check-in of the first session in a fraction and the check-in of a continuation session in the same fraction, it will not be possible to start the delivery of the continuation session. The user should undo the check-in for the continuation session and revert the patient detail changes in RayCare. (1013271)

- When 2D images are used for offline image review, it is not always clear if the image set is a kV or MV image. RayCare will, depending on the configuration, either show Portal, MV or kV even if the 2D image set is of a different type. (1068655)

3.3.8   Warnings and known issues concerning RayCare PACS and Image viewer

> ⚠️ **WARNING!**
>
> **Completeness of DICOM import.** The RayCare PACS supports import of DICOM objects from media files from a specified directory. It is not possible for that function to validate that all files that are intended for the import are present in the specified directory. Therefore, always ensure that all files are present in the specified directory before the import and also verify that the DICOM objects were correctly imported after the import has been performed. (13052)

> ⚠️ **WARNING!**
>
> **Check for successful storage before deleting.** After image acquisition on a modality, the resulting DICOM objects may be stored in the RayCare PACS. The RayCare PACS may also be set up to forward the images to another PACS through an automatic forwarding rule. To minimize the risk of loss of image data at the modality, verify that the images have been successfully stored in the RayCare PACS and also verify that the forwarded entities have successfully stored the images before deleting them at the modality. (13055)

> ⚠️ **WARNING!**
>
> **Validation of successful DICOM export.** The RayCare PACS can be used to export DICOM series to DICOM media files stored in a directory specified by the user. The export will create one file for each DICOM instance in the series. To make sure that all files have been successfully stored, verify that the number of files in the directory corresponds to the number of images in the series after the export has been completed. (13057)

> ⚠️ **WARNING!**
>
> **Patient information updates in RayCare PACS.** The RayCare PACS has a built-in function to allow the user to update the patient information to match the information in RayCare. The user must manually confirm those updates for each series. If a user accidentally only updates the patient information in a subset of the series in a study, RayCare will consider that as a DICOM study with multiple patient information and reject some operations on those series. Make sure to update all series in a study when using this function. (10828)

> ⚠️ **WARNING!**
>
> **Planning images must be associated.** To ensure that patient information is consistent with DICOM, RayCare has the function to associate DICOM series with RayCare and correct errors in the DICOM information. Be aware that only image series that have been associated can be used as planning images in RayCare. (16331)

> ⚠️ **WARNING!**
>
> **Validate successful import of non-DICOM data.** RayCare PACS can import non-DICOM data such as PDF files, JPEG images and ZIP files. When the import has been completed, make sure to confirm that the imported non-DICOM data belongs to the selected patient. (52135)

> ⚠️ **WARNING!**
>
> **Validate PACS scripts.** RayCare provides clinics with the functionality to develop PACS scripts that can modify DICOM data. It is the responsibility of each clinic to validate all PACS scripts and verify the proper usage of the scripts. (52959)

> ⚠️ **WARNING!**
>
> **Validate DICOM data updates done by PACS scripts.** When DICOM data is imported to or exported from RayCare PACS, PACS scripts developed by the clinic can be used to modify the DICOM data. It is the clinic's responsibility to ensure that the DICOM data updates or filtering done by the PACS script are as expected. (52954)

> ⚠️ **WARNING!**
>
> **Validate number of imported images.** RayCare PACS supports C-Get request for retrieving images from the PACS. When images are retrieved using C-Get, there will be no check that images can be stored successfully. To make sure that all images have been successfully stored, verify that the number of images correspond to the number of images in the series in RayCare PACS. (17730)

> ⚠️ **WARNING!**
>
> **PACS scripts require update after upgrade.** PACS scripts require update after upgrade. The DICOM interface used in scripting for accessing DICOM data has been updated compared to previous versions of RayCare. This means that the script code may need to be updated. The script must be imported and activated again after update. (149921, 55295)

> ⚠️ **WARNING!**
>
> **Restoring data from external archive.** Archived DICOM data cannot be restored to RayCare if the data in the archive are removed or if patient identifiers no longer match. If patient identifiers are changed, the update needs to be performed in both the archive and RayCare to be able to restore the data. (368836)

Known issues related to patient safety concerning RayCare PACS and Image viewer

- The completeness of the planning images is not automatically verified between RayCare and RayStation. In rare circumstances, there can be a difference between the number of slices c in a planning image RayCare PACS and RayStation. Make sure that all slices related to the planning image have been imported before it is used for treatment delivery. Compare the number of instances for the image set in the RayCare images workspace with the number of slices displayed in the patient modeling workspace in RayStation. (1331648)

Other known issues concerning RayCare PACS and Image viewer

- Information logged while running PACS scripts is not stored to disk. (567902)

- It is not possible to use the PACS script test tool for validation of PACS scripts. The user should instead validate the scripts in a non-clinical RayCare environment. (567542)

- When RayCare PACS scripts, used in for example PACS rules, are not found or are not possible to load, the actions related to the script do not present as failed. Make sure to validate the PACS scripts and actions before clinical use and verify the PACS data regularly. (1332044)

3.3.9 Warnings and known issues concerning integrations with external systems

> ⚠️ **WARNING!**
>
> **RayCare patient data updated via an external system.** If RayCare is configured to receive patient data (such as patient demographics, allergies or insurances) via HL7 from an external system, be aware that it will only be possible to update that data via the external system. An administrator user is able to override and edit the data, but any changes to that data in RayCare may then be overwritten if the patient data is changed later in the sending system. (16055)

> ⚠️ **WARNING!**
>
> **Patient details updated in an external system by RayCare.** If RayCare is configured to send patient details via HL7 to an external system, be aware that any changes made manually to patient details in the external system may be overwritten if the patient details are then changed in RayCare. In such an integration RayCare should be considered the master of the patient information. Moreover, RayCare should not be configured to send patient data via HL7 if it is also configured to receive data. Bidirectional integration is not supported. It is the clinic's responsibility to ensure that patient details are updated correctly. (58745)

> ⚠️ **WARNING!**
>
> **Patient alias.** Using a patient alias together with an Outbound ADT interface may cause the patient alias to overwrite the real patient name in the receiving system depending on the configuration. (369463)

WARNING!

Case and care plan. Information about RayCare case and care plan is not exported to external systems when sending information via HL7 integrations to external systems about documents, charges or appointments. (474443)

WARNING!

Inbound data integrations must be validated by the clinic. When a an inbound integration is enabled in RayCare, the customer needs to validate that the integration works as expected with the external system and that imported data is correctly imported into RayCare. The customer must also re-validate all inbound integrations if RayCare has been upgraded to a newer version to ensure that it works correctly. (1013580)

WARNING!

Mirth channels or code may not be modified by the clinic. Only RaySearch staff may modify or edit deployed channels and code in Mirth. Unapproved modifications could have unexpected consequences for the clinics integration and may lead to erroneous data being imported/export or even system crashes. (1014089)

WARNING!

Mirth logs must be monitored by the clinic. If an external integration is active that uses the integration engine Mirth, the Mirth logs need to be monitored by the clinic in addition to the regular RayCare health monitoring. Errors specific to channel/message processing might only occur in the Mirth logs and may not be detected through the RayCare health monitoring and it is therefore important that the clinic IT staff monitors the Mirths logs as well. (1014175)

WARNING!

Allergies received via ADT do not trigger medication warnings. If using an inbound ADT integration for RayCare in which allergies are received from a master system, be aware that no check for allergy - medication contraindications is performed in RayCare when new allergies are received from the master system. This check must be performed in the master system. (1331696)

3.3.10 Warnings and known issues concerning scripting

> ⚠️ **WARNING!**
>
> **Validate RayCare or RayWorld scripts.** RayCare provides clinics with the functionality to develop scripts that can read and modify selected RayCare data. It is the responsibility of each clinic to validate all RayCare scripts and verify the proper usage of the scripts including error handling. (366877)

> ⚠️ **WARNING!**
>
> **RayCare scripts are validated for accessing and editing RayCare data.** If RayCare scripts are used to access or modify any other sources of data than RayCare data, any effects of the scripts on other systems is are the responsibility of the clinic. (366887)

> ⚠️ **WARNING!**
>
> **If a RayCare or RayWorld script fails, data affected by the script run will not be reset.** Always review failed script runs and verify that RayCare data is not in an unexpected state. (370678)

> ⚠️ **WARNING!**
>
> **RayCare script user input limitation.** User input in RayCare scripts is not supported. Attempting to do so will cause the script to run until it times out and subsequently fails. Do not use scripts that open dialogs to receive user input. (2043529)

> ⚠️ **WARNING!**
>
> **Limitations of the RayCare ScriptRunner tool.** Be cautious when using the ScriptRunner tool. Take the following scenarios into account:
>
> - Running multiple scripts for the same patient in parallel can lead to unexpected outcomes. Avoid running scripts in parallel for the same patient.
> - If a script execution is canceled (e.g., by closing the ScriptRunner window) or times out, it will remain in the 'Running' status in RayCare and cannot be completed. Avoid canceling scripts in the ScriptRunner tool.

- Any non-admin user with access to the ScriptRunner tool can write and run scripts. Make sure the correct users have access to the ScriptRunner tool.

- The content of scripts ran by the ScriptRunner is not visible in RayCare. Make sure to take a local copy of the scripts used in the ScriptRunner tool.

- Avoid spamming RayCare with requests by running multiple scripts simultaneously, as this can cause system issues.

(2162256)

Other known issues concerning scripting

- Script actions performed from RayWorld script run in RayStation background service are not run as the user who requested the script. (473788)

3.3.11   Warnings and known issues concerning system administration

> ⚠️ **WARNING!**
>
> **Validation of the clinic-specific configuration.** It is the responsibility of the clinic to validate that the clinic-specific configuration of RayCare works as expected in a non-clinical setting before clinical use. This includes validation of the function of RayCare workflows, tasks, appointments, forms, documents and value sets. (14764)

> ⚠️ **WARNING!**
>
> **Modifying code sets and value sets will affect the behavior of RayCare.** Use caution when managing code systems and value sets such as diagnoses or charge capture codes as modifications of the value sets will have effect on the options available to the user in RayCare. All changes to the value sets in the user interface must be validated by the clinic as applicable. (51793)

> ⚠️ **WARNING!**
>
> **Treatment device names in RayCare and RayCare Treatment must match.** The treatment device name in RayCare must be the same as the one used in RayCare Treatment. (58255)

3

> ⚠️ **WARNING!**
>
> **Updating templates will not update any instances that have already been created based on the template.** The administration workspace contains several features that are based on templates configured by RaySearch (task, workflow and document templates) or by the clinics (flags). Be aware that updating any of these templates will not lead to updates in already created tasks, workflows, document templates or flags in RayCare. For example, a flag or a clinical trial that has been added to a patient that is based on a template will not be updated when the template is updated. (8183)

> ⚠️ **WARNING!**
>
> **Deactivated resources will not be removed from assigned tasks or appointments.** Deactivation of users, teams, groups, devices, locations or the organization will not lead to these objects being removed from tasks or appointments that they have already been assigned to. The clinic must reassign any tasks or appointments to active resources upon deactivation. The deactivated resources will not be available for selection of new assignments. (58785)

> ⚠️ **WARNING!**
>
> **RayCare reporting database.** The clinic is responsible for report generation and validation of the resulting reports. Also, it is the responsibility of the clinic to audit log access to the report database. (97061)

> ⚠️ **WARNING!**
>
> **Modifying extended domain objects will affect the behavior of form templates and forms.** Use caution when updating extended domain objects. Any changes will be directly updated in form templates and actively used forms. (574101)

> ⚠️ **WARNING!**
>
> **Avoid duplication between RayCare domain objects and Extended domain objects.** For every RayCare version, the user should review the RayCare domain objects to identify duplication with clinic-defined Extended domain objects. If duplicates are identified, the clinic should consider using the RayCare domain object instead of the Extended domain object to avoid two sources of the same data. (573748)

> ⚠️ **WARNING!**
>
> **Report database contains data removed by the user.** When constructing queries to access data from the report database, the user must consider the status of each item. (573997)

> ⚠️ **WARNING!**
>
> **Use of additional databases for reporting purposes.** The clinic is allowed to add additional databases to the RayCare SQL server for RayCare related reporting purposes only. The added databases must not use "raycare" as part of the database name. Any additional databases added will not be part of RayCare backups and may be out of sync with RayCare report database after disaster recovery. The clinic is responsible for backups of additional databases. (628722, 628723, 684736)

> ⚠️ **WARNING!**
>
> **RayCare performance may be affected by querying report databases.** Queries against the report database can result in degraded RayCare performance since the reporting database is running on the same SQL server as all other RayCare databases. The clinic is responsible for any performance impact reporting queries may have on the SQL server. For advanced report queries where the performance could be affected, it is recommended to replicate the reporting database to another SQL server and run all queries against the replicated database. Clinic shall not use an isolation level higher than read committed when reading from the RayCare report database. (628726, 628727, 1338933)

> ⚠️ **WARNING!**
>
> **Import of document templates with extended domain objects**. When a RayCare document template is imported to the system, the external domain object that is included in the document template will be mapped to an existing extended domain object in the system if they have the same name. The user must validate the document template after import. (1014188)

3

> ⚠️ **WARNING!**
>
> **String values in the report database.** The value for an object of type string will be an empty string instead of NULL in the report database if the value is cleared in RayCare. If the value has never been filled in, the value of the string object will be NULL in the report database. (1339433)

Other known issues concerning system administration

- When viewing or editing a module template in the Administration workspace, no task preview will be displayed for tasks added to a module using a predefined activity. The task will be indicated with a lock symbol. The task preview will be visualized when viewing the configured activity from the Activity workspace. (1012112)

- When configuring a new module or activity, a predefined form task can be added. When the form task is added to a module or activity on a less specific level, the linked form template selection field will be empty. Avoid adding a form task to a module or activity on a less specific level. (1068464)

- When a default team is specified for a module during workflow configuration, it is not possible to remove the default team from a task defined in the module. Do not use a default team when a task in the module should not have a team assigned. (749315)

- An external program configured to open .txt files will not open as expected. The default program for the specific file on system level will be started instead. (1067920)

- It is not possible to extract information about due date triggers, status triggers or event triggers from the report database. (1344766)

- It is not possible to extract all properties related to treatment planning and treatment delivery from the report database. (1344915)

- When importing user configured workflow templates which have the same name as existing non-user configured workflow templates, the user configured workflow templates will be added as new versions of the non-user configured workflow templates making them impossible to activate. Modify the name of the user configured workflow template to avoid this issue. (1438196)

- No warning is displayed when importing a medication in Admin with the same drug label as exists in RayCare, resulting in GenericName and Ingredients to be overwritten for an active medication. (1014861)

3.3.12 Warnings and known issues concerning system environment

> ⚠️ **WARNING!**
>
> **Changes may be lost if RayCare services restart.** In the event of a restart of one of the RayCare services, the very latest user actions before the restart may not have been saved and will consequently be lost. (11626)

> ⚠️ **WARNING!**
>
> **Time zone configuration.** The time zone configuration for all RayCare and RayStation servers shall be the same and set to the local time zone. Imaging modalities and treatment delivery devices connected to RayCare must also be configured to use the local time zone. (15336)

> ⚠️ **WARNING!**
>
> **The clinic shall not attempt to modify or upgrade the RayCare databases.** Only RaySearch authorized personnel shall upgrade or modify the RayCare databases. (61621)

> ⚠️ **WARNING!**
>
> **RayCare and RayStation configuration.** When RayCare and RayStation are configured to provide integrated treatment planning and delivery features they must both be clinical. Never attempt to use a clinical version of RayCare with a non-clinical version of RayStation. (13790)

> ⚠️ **WARNING!**
>
> **Use compatible versions of RayCare and RayStation.** When using RayCare with RayStation, the versions of the products must be compatible. Only use RayCare v2025 SP5 with RayStation v2025 and subsequently validated service packs. Check the specific versions with RaySearch service. (15608)

> ⚠️ **WARNING!**
>
> **User properties from Active Directory.** RayCare supports user management through an Active Directory and also synchronization of a subset of user properties managed in the Active Directory. Be aware that not all properties are synchronized. Only the user's name, user name, e-mail and mobile phone number are synchronized from Active Directory to RayCare. (16805)

> ⚠️ **WARNING!**
>
> **The clinic shall not use any of the command line tools included in the RayCare installation.** Only RaySearch authorized personnel shall use the command line tools included in the RayCare installation. (55431)

> ⚠️ **WARNING!**
>
> **The clinic shall not modify the RayCare system configuration files.** Only RaySearch authorized personnel shall modify the RayCare system configuration files. (61620)

> ⚠️ **WARNING!**
>
> **Monitoring shall be reviewed and updated after upgrade.** After an upgrade of RayCare, the clinic is responsible for verifying that the monitoring is up-to-date with respect to the monitoring instructions for the new version. Pay special attention to any service-specific monitoring, since the set of services might change between releases. (149554)

> ⚠️ **WARNING!**
>
> **User access prohibited during upgrade or maintenance.** It is the responsibility of the clinic to ensure that users do not access RayCare, RayCare Treatment or RayStation during upgrade or maintenance. (226192)

> ⚠️ **WARNING!**
>
> **The clinic shall not restore RayCare databases without support from RaySearch personnel.** All restores from backup must be supervised by RaySearch authorized personnel. If any anomalies appear after restore, contact RaySearch authorized personnel. (15094)

> ⚠️ **WARNING!**
>
> **Organization must be configured with the same time zone as the servers and clients.** Only one organization may be created in resource management and it must be configured in the same time zone as the RayCare system. (61511)

> ⚠️ **WARNING!**
>
> **Disaster recovery.** In the event of need for disaster recovery, contact RaySearch support. To be able to perform disaster recovery, all information stored in RayCare must be backed up frequently to a safe location.
>
> It is the responsibility of the clinic to ensure that any non-RaySearch data and/ or databases (if any) are synchronized with RaySearch databases after disaster recovery.
>
> After a system restore it is the responsibility of the clinic to verify that the system behaves as expected and any abnormalities must be investigated by authorized RaySearch personnel. (1344400, 1337000)

> ⚠️ **WARNING!**
>
> **Backup and restore**. The clinic is responsible for performing backups of all data that is required for restoring the system to a consistent state. At a minimum, the following information must be backed up:
>
> • All RaySearch databases (full database backups and transaction log backups)
>
> • PACS blob storage (file system backup)
>
> • Application log files
>
> BLOB storage backups must be performed at least as frequently as transaction log backups.
>
> The clinic is also responsible for ensuring that the data can be restored according to RaySearch instructions using database management tools available at the

clinic. Restore operations must be performed supervised by authorized RaySearch personnel. (1338976, 1336867)

⚠️ **WARNING!**

RaySearch environment for troubleshooting. The clinic is responsible for providing access to a RSL Verification environment (sandbox) for verifying and troubleshooting problems in the clinical environment. The clinic must ensure that it is possible to restore clinical data from the clinical environment to the RSL Verification environment in a timely manner. It must be possible for RaySearch personnel to access the environment remotely. (1338663)

⚠️ **WARNING!**

Retention of RayCare log files. RayCare writes system logs to facilitate troubleshooting activities. RayCare log files shall be backed up regularly and possible to retrieve for a minimum of 3 months, preferably 6 months or longer. The clinic must ensure that the log files are periodically archived to prevent disk space outage. (1337248)

⚠️ **WARNING!**

Monitoring of certificate expiration. RayCare relies on several certificates for normal operation which have expiration dates. To prevent unexpected interruption of service, the clinic must make sure that the expiration dates of all certificates are known and that they are renewed before they expire. (1339178)

⚠️ **WARNING!**

Windows Event Log shall be monitored. The clinic is responsible for monitoring the Windows Event Log and to take prompt action to resolve any errors. If a message is logged with 'Fatal' log level, contact RaySearch support immediately. Fatal errors may lead to that the RayCare system or specific patients in RayCare are unavailable for continued use. (13692)

⚠️ **WARNING!**

System health shall be monitored. The clinic shall monitor the RayCare service's health API, using a monitoring system of their choice. If errors are reported,

authorized RaySearch personnel shall be contacted. Database (SQL Server) logs should be monitored for errors.

If RayStation is used in the environment, the clinic shall also monitor the health of RayStation services and treatment drivers as applicable according to RaySearch instructions. (73644)

⚠️ **WARNING!**

Server resources shall be monitored. To make sure that RayCare maintains performance over time, the server resource utilization must be monitored to prevent critical resources from being depleted. Memory, CPU and available disk space shall be monitored on the servers hosting RayCare services, database servers and on Citrix application servers hosting RayCare clients. When an UNC path (e.g., \\server\blob-storage) is used for the PACS BLOB storage, then disk space cannot be checked automatically in RayCare. The clinic is responsible for keeping track of the available disk space. (13430, 72258)

⚠️ **WARNING!**

PACS recycle bin retention. Archived or deleted blob storage data is moved to a recycle bin and is automatically deleted after a configurable number of days. The configured number of days in the recycle bin must exceed the number of days between database backups. (370072)

⚠️ **WARNING!**

Mandatory to perform RayCare Acceptance Test Protocol. The user is required to run the RayCare Acceptance Test Protocol in the Production Validation and Test (PVT) environment before migration of the configuration to the Production Clinical (PC) environment where the final clinical acceptance testing shall be performed. The tests shall be performed for newly installed systems as well as upgraded systems. (1449332)

3.3.13   Warnings and known issues concerning upgraded RayCare systems

⚠️ **WARNING!**

Task automation in review cycles after upgrade. Tasks previously configured to be automatically assigned to the user who had a task assigned before a review will no longer be automatically re-assigned after the upgrade from RayCare 5A or earlier versions to RayCare 5B or later versions. The task must be manually assigned using the Edit task dialog or the RayStation task list. (685610)

⚠️ **WARNING!**

Data-driven tasks may be manual after upgrade. Some tasks configured to be completed by addition of data must be manually completed after the upgrade from RayCare 5A or earlier versions to RayCare 5B or later versions. This is applicable to tasks related to data in the patient chart or RayStation which has been assigned to the care plan, treatment plan or beam set contexts instead of the case context. (688186)

⚠️ **WARNING!**

Due date anchors removed after upgrade. Due date anchors specified on workflow modules or based on due date anchor tasks will be lost during the upgrade from RayCare 5A or earlier versions to RayCare 5B or later versions. The due date anchors will not be available in the workflow properties in the Workflow management workspace. Due dates on the tasks dependent on due date anchors must be updated manually using the Edit task dialog. (685628)

⚠️ **WARNING!**

Treatment course on care plan level. Before RayCare 2024A, treatment courses were managed on case level. In RayCare 2024A, the treatment course is instead managed on care plan level. Treatment courses that existed before RayCare 2024A are moved to care plan level and split over different care plans as needed when multiple care plans exist as part of the upgrade to RayCare 2024A. The treatment series and treatment courses must be approved after the upgrade to RayCare 2024A. (1449333)

> ⚠️ **WARNING!**
>
> **Out of order scheduling.** Upgraded booked treatment appointments are locked to the same session they were connected to before upgrade. Therefore, the sessions may still be scheduled out of order using rescheduling or by manually editing the appointment. No warning will be displayed to the user that the sessions are scheduled out of order. (1441476)

Other known issues concerning upgraded RayCare systems

- The treatment intent functionality no longer supports entering dose delivery information for treatment sites. This information should now be entered via the Prescriptions workspace. For treatment intents created before RayCare 6A, the dose delivery information for treatment sites will be available in the Description field after upgrade to RayCare v2025 SP5. All values will be displayed in cGy. (574321)

- The workflow configuration allows for the configuration of one treatment appointment series per treatment delivery module. Additional appointment series cannot be created. (686588)

- The maximum length rules for selected text input fields in RayCare have been changed to prevent text values to become too long. Some of these values may have been truncated in the corresponding report database tables if these values were longer than the new maximum length rule. The truncated values are clearly marked in the report database. (685682)

- The modified date for treatment plans created in RayCare 4A or earlier will be displayed in the Plan overview workspace with the default value of 1 Jan 1970. (688498)

- The user who saved and approved the planning instructions in RayCare versions before 6A will be shown as the user who signed the planning instructions on the information icon in RayCare v2025 SP5. (1014845)

- Ready triggers for activities will no longer re-open already completed activities after upgrade from versions before RayCare 6A to RayCare v2025 SP5. Review ready triggers and add re-open triggers as applicable. (1068055, 1014192)

- After upgrade from versions before RayCare 6A to RayCare v2025 SP5, insertable tasks configured to be data-driven will be completed by data. (1067904)

- During the upgrade of RayCare 6A to RayCare 2024A, the treatment appointments are moved from the treatment modules and new treatment appointment series are created for each care plan connected to the treatment of the patient. For the treatment appointment series created during this upgrade, it is not possible to cancel the treatment appointment series. It is however possible to cancel each appointment within the appointment series. (1448966)

- When treatment sessions without nominal delivered dose exist for sessions that were partially or fully delivered in versions before RayCare 2024A, nominal progress will never be

displayed after the upgrade for the treatment sites that the beam set for those sessions is contributing to. The fields for delivered dose, remaining dose and expected total dose will be empty for those treatment sites in the nominal progress tables for that patient's case. (1432165)

- The care plan information for a diagnosis in state Entered in error will be removed when upgrading from RayCare 6A or earlier to RayCare v2025. (1449285)

- Certain data in upgraded documents displayed in the Other documentation workspace for patients created before RayCare 5B will not be loaded when opening the document after upgrade. Edit the document for the data to be updated and save the document. Also, primary planning image information will never be available. (1441383)

- During the upgrade from RayCare 6A to RayCare 2024A, the orders that have been canceled before the upgrade are displayed with status Completed after the upgrade if some tasks in the order were completed before the upgrade. For orders that were canceled before the upgrade and contain tasks that are not completed, those tasks will show as Annulled after the upgrade. (1449367)

3.3.14   Warnings and known issues concerning treatment interoperability

Mandatory test sites

Before using the treatment interoperability clinically with a new treatment delivery device or after an upgrade of any relevant software or hardware, the test cases in the Installation Test Specification must be run on the Production Validation and Test (PVT) and Production Clinical (PC) environment. The Installation Test Specification tests must be repeated for every treatment device.

In addition, the Acceptance Test Protocol (ATP) for the integration must be run on the Production Validation and Test (PVT) environment before clinical use. As long as the software versions of RayCare, RayStation and the treatment driver as well as the treatment device hardware and software are used with the same version and clinic configurations in the Production Clinical (PC) environment, these tests will not have to be repeated there.

The clinic is required to perform additional test cases relevant for the clinical implementation of the integration before the start of clinical use.

Supported versions

Compatible software versions for treatment integrations. Only versions of the treatment delivery device software that have been validated shall be used together with RayCare Treatment.

RayCare v2025 SP5 can only be used in conjunction with the following validated treatment machine software versions:

Machine vendor	Machine type/software	Vendor software and version
Accuray	CyberKnife	11.2.2.0

Machine vendor	Machine type/software	Vendor software and version
Accuray	iDMS	3.5.0.3, 3.5.1.0
Accuray	Radixact	8.5.0.1.10
IBA	Proteus	12.2, 12.4
IBA	AdaptInsight	2.4.0

Other versions

Running the treatment interoperability against any vendor software version that has not been validated is strongly prohibited. If a new validation has to be performed, contact RaySearch.

Warnings concerning the RayCare Treatment application

> ⚠️ **WARNING!**
>
> **No automatic opening of a treatment session.** Opening a session on the treatment delivery device (TDD) does not automatically open the session in the RayCare Treatment application. Always ensure that the session is opened on the RayCare Treatment application before opening it on the treatment delivery device to maintain proper synchronization and workflow. (2152658)

Known issues related to patient safety concerning the RayCare Treatment application

• Continuation sessions created in RayCare 6A are not possible to be delivered after an upgrade to RayCare v2025. Make sure no continuation sessions remain when upgrading from RayCare 6A to RayCare v2025. (2162495)

Other known issues concerning the RayCare Treatment application

• The overrides displayed in the RayCare treatment course include overrides performed in RayCare Treatment and some overrides that have been performed on the treatment delivery console. Not all overrides performed on the treatment delivery device might be displayed. (1438616)

Warnings concerning the Accuray treatment interoperability

> ⚠️ **WARNING!**
>
> **Refreshing the Patients List on Accuray TDC.** The Patient list does not automatically refresh on the Accuray Treatment Delivery Console (TDC). To ensure the most up to date information is displayed after opening a treatment session on the RayCare Treatment application, always reopen the Patients list dialog. Once opened, the list will continue to display the information available at the time of opening and will not refresh automatically. (2160746)

> ⚠️ **WARNING!**
>
> **Verifying Treatment Session.** Treatment session content may not match between the Accuray Treatment Delivery Console (TDC) and RayCare. The TDC does not automatically receive the fraction number or continuation status from RayCare.
>
> Imaging-only sessions are marked as completed on the TDC, while the same fraction can be reopened in RayCare, causing a mismatch in fraction numbers (e.g., Fx 2 in RayCare vs. Fx 2.1 on TDC).
>
> If the TDC encounters an error and the session gets an 'Invalid' status in iDMS, the session can be manually recorded without delivered meterset in RayCare, and a continuation session can be created and opened in RayCare Treatment. The invalid session in TDC cannot be treated, and the user must select the upcoming session, leading to mismatched fraction numbers for remaining fractions. Avoid creating continuation sessions in RayCare for this scenario.
>
> Additionally, the TDC shows fraction numbers for a specific plan, while RayCare considers fractions in the entire treatment course. For example, if a treatment course has plan A assigned to fractions 1-4, 6-9, and plan B assigned to fractions 5 and 10, fractions 1-4 will match on the TDC, fraction 5 will show as fraction 1 on the TDC, fractions 6-9 will show as fractions 5-8 on the TDC, and fraction 10 will show as fraction 2 on the TDC. Use the Fx in beam set number to verify the fraction number between the console and the RayCare treatment session.
>
> Therefore, manually verify the status of a treatment session for consistency between the TDC and RayCare, considering continuation status, fraction number, and plan content. (2152653)

> ⚠️ **WARNING!**
>
> **Show OIS Scheduled Patients and Plans on TDC.** Always ensure that 'Show only OIS scheduled patients and plans' is selected on the Treatment Delivery Console (TDC) when selecting a patient and plan ready for treatment in RayCare. If this option is not selected, any fraction available for delivery in iDMS can be selected for delivery. Fractions delivered outside of the OIS mode will not be available anymore for delivery on the treatment console in OIS mode and must be recorded by importing the corresponding treatment record or by manually recording the session in RayCare. (2152654)

Known issues related to patient safety concerning Accuray treatment interoperability

• RayStation treatment plans are not transferred to iDMS via DICOM. Instead, the RayStation DICOM file is stored in iDMS using the RayGateway functionality. During this storage process, some non-dose affecting plan properties are not retained.

  Be aware that some non dosimetrical data might be different in RayStation/RayCare/RayCare Treatment application and iDMS. (2155617)

• iDMS will store all the fractions specified in the RT PLAN while, in RayCare, a beam set can be assigned to the treatment course for a different number of fractions. The Treatment Delivery Console (TDC) can display all fractions from the RT plan outside the OIS mode. Make sure that the RT PLAN contains equal or more fractions than the number of fractions assigned in the RayCare treatment course. To prevent this issue from occuring, make sure that:

  - The RT PLAN contains equal or more fractions than the number of fractions assigned in the RayCare treatment course.

  - The OIS mode in iDMS is used.

  (2162382)

Other known issues concerning the Accuray treatment interoperability

• When gender Other is used for a RayCare patient, Accuray will interpret the gender as Unspecified. Due to this, the treatment data will not to be linked to the treated patient in RayCare PACS. Do not use gender Other for patients treated with an Accuray interoperability. (2155639)

• Treatment images taken at the end of a treatment session after a completed delivery are not sent to RayCare from the Accuray software. Contact Accuray for more information about this issue. (2155928)

• When performing imaging on the Radixact treatment delivery device, all treatment images will be indicated with type CBCT. Refer to Accuray for more information about this error. (2155608)

Other known issues concerning the IBA treatment interoperability

- If offline recording is performed on a treatment session that was completed before the upgrade to RayCare v2025 then the already recorded delivery status might change from delivered to partially delivered due to a change in the calculation of the session status. (2162933)

- A continuation session cannot be delivered when it is based on a partial treatment in IBA ProteusOne Standalone Mode where the treatment records have been imported using offline recording in RayCare or when the partial delivery is manually recorded without treatment records. (2690432)

4 RAYCARE INSTALLATION INSTRUCTIONS

The RayCare system shall only be installed and configured by RaySearch authorized personnel.

The installation preparation steps, including hardware specification and configuration, shall be reviewed by and agreed with RaySearch. Contact RaySearch for detailed instructions on installation preparations and prerequisites described below.

RayCare services are based on the Microsoft .NET platform and require a specific version of the Microsoft .NET runtime to be present on the server. RayCare requires a specific server setup as well as a specific setup for users on the servers and in the configured Active Directory. RayCare relies on several certificates for normal operation, which need to be obtained before the installation.

All RayCare data, except DICOM images, are stored in a Microsoft SQL Server database. The database must have version 2016 SP1, 2019 or 2022 and have the specific configuration required by RayCare. The database must be configured to use full recovery model and transaction logging must be enabled.

DICOM images are stored in an NTFS or UNC file system. The security and data integrity policies for this file system must be configured to meet appropriate department guidelines for encryption and backup. DICOM images can be archived to a remote archive location. The remote archive must support the DICOM DIMSE protocol for data transfer. After image data have been successfully moved to the remote archive and the archive has committed that image data have been received, the image data will be removed from RayCare. The remote archive must support that DICOM images can be archived multiple times.

RayCare, RayStation and the treatment drivers are highly integrated. The configuration of all DICOM application entities used for DICOM data transfer between RayCare, RayStation and the RayCare treatment drivers shall be performed by RaySearch authorized personnel.

4

5 DISPLAY OF COORDINATES, MOVEMENTS AND SCALES

RayCare v2025 SP5 uses the IEC61217[1] standard for display of coordinates, movements and scales.

Patient positions and measurement lines are shown in the patient coordinate system defined in the IEC 61217 standard and are projected onto the primary image plane for all image modalities except RT images. For RT images, displayed patient positions and measured distances are always projected from the RT image plane onto the isocenter plane.

RayCare uses the 'Away from zero' rule for tie breaks when rounding display values. This means that values are rounded to the nearest integer away from zero. For example, when a value needs to be rounded to one decimal, 2.75 will become 2.8 and -3.35 will become -3.4.

5

---

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

6 SYSTEM INTEGRITY AND SAFETY

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

In this chapter

This chapter contains the following sections:

6

6.1   SYSTEM MONITORING AND MAINTENANCE

To make sure that RayCare maintains performance over time, the server resource utilization must be monitored to prevent critical resources from being depleted. Memory, CPU and available disk space shall be monitored on the servers hosting RayCare services, and on Citrix application servers hosting RayCare clients. On resource shortage, the corresponding resource shall be increased.

The clinic is responsible for monitoring the event log and to take prompt action to resolve any errors. If the error is tagged as "Fatal", contact RaySearch support immediately. Fatal errors may lead to that the RayCare system or specific patients in RayCare are unavailable for continued use.

When an UNC path (e.g., \\server\blob-storage) is used for the PACS BLOB storage, then disk space cannot be checked automatically in RayCare. The clinic is responsible for keeping track of the available disk space.

The clinic shall monitor the RayCare service's health API, using a monitoring system of their choice. If errors are reported, RaySearch authorized personnel shall be contacted.

RayCare writes system logs to facilitate troubleshooting activities if necessary. Since the log files can grow quite large over time, the clinic must ensure that the log files are periodically archived to prevent disk space outage. On the server hosting the RayCare services, the log files to be transferred can be found in %programdata%\RaySearch_Laboratories_AB\RayCare\archive.

RayCare relies on several certificates for normal operation which have expiration dates. To prevent unexpected interruption of service, the clinic must make sure that the expiration dates of all certificates are known and that they are renewed before they expire.

6.2   BACKUP AND RESTORE

All information stored in RayCare must be periodically backed up to a safe location to enable recovery in the event of a disaster. This includes the backup information files, which must be stored together with the backups. The backups must be scheduled according to the specifications provided by RaySearch. Since RayCare stores information in multiple databases, all those databases and the NTFS or UNC file system used to store image data must be included in the backup. Database backup plans must be updated after upgrade. Regular full backups as well as frequent transaction log backups are required to minimize data loss and decrease time required to restore the system. RayStationPatientDB log backup must happen directly after checkpoints have been created. The images stored in the NTFS or UNC file system must be backed up continuously or in regular intervals with high enough frequency to minimize data loss otherwise it will not be possible to correctly restore the RayCare PACS in RayCare. Archived and deleted image data are moved to a recycle bin and are automatically deleted after a configurable number of days. The configured number of days in the recycle bin must exceed the time between database backups. If a system restore must be performed, contact RaySearch authorized service personnel. The NTFS or UNC file system used to store image data shall always be restored to the point in time more recent than the database restore. After image data have been restored, image data in the recycle bin must be manually copied back to the original storage location. When RayCare is configured with RayStation, the two systems must always be restored to the same time to operate correctly after the restore. Database restore requires intervention from RaySearch

staff before the system is turned back on, actions need to be taken by RaySearch to ensure that the system is in a consistent state. After a system restore it is the clinic's responsibility to verify that the system behaves as expected and any abnormalities must be investigated by RaySearch authorized service personnel.

6.3   SECURITY CONFIGURATION

It is required that the data-in-motion (SQL connections, HTTP communication) is encrypted. It is highly recommended, and required for the installation to be HIPAA compliant, that data-at-rest in SQL is encrypted (using for example SQL TDE or BitLocker). In order to make tampering of audit data detectable, SQL audit logs shall be enabled on the dbo.event table in the audit logging database (raycare_audit_write) database. As an additional measure to restrict access to the database, database access rights should be limited to service and system administration accounts. When accessing the RayCare report database, the pre-defined database role "ReadReportViews" shall be used.

RayCare backups may be encrypted to prevent unauthorized access. This requires the use of encryption keys configured in the SQL Server. To successfully recover an encrypted backup, the user must have access to the keys. The clinic is responsible for managing the encryption keys to prevent loss of information.

DIMSE and HL7 connections are not encrypted by application layer security. The clinic is responsible for using additional network layer encryption such as VPN or IPsec to secure communication for such connections according to the clinic security policies.

6.4   SYSTEM DECOMMISSIONING

RayCare stores personal and health-related data. When decommissioning a system, contact RaySearch support if needed to make sure that all storage locations for such data are identified.

6

CONTACT INFORMATION

 RaySearch Laboratories AB (publ)
Eugeniavägen 18C
SE-113 68 Stockholm
Sweden

Contact details head office
P.O. Box 45169
SE-104 30 Stockholm, Sweden
Phone: +46 8 510 530 00
Fax: +46 8 510 530 30
info@raysearchlabs.com
www.raysearchlabs.com

RaySearch Americas
Phone: +1 347 477 1935

RaySearch China
Phone: +86 137 0111 5932

RaySearch India
E-mail:
manish.jaiswal@raysearchlabs.com

RaySearch Singapore
Phone: +65 8181 6082

RaySearch Australia
Phone: +61 411 534 316

RaySearch France
Phone: +33 (0)1 76 53 72 02

RaySearch Japan
Phone: +81 (0)3 44 05 69 02

RaySearch UK
Phone: +44 (0)2039 076791

RaySearch Belgium
Phone: +32 475 36 80 07

RaySearch Germany
Phone: +49 (0)172 7660837

RaySearch Korea
Phone: +82 01 9492 6432