RAYCARE 5B

Instructions for Use

Declaration of conformity

CE 2862

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

Safety notices

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

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

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

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RaySearch Laboratories

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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 5B system. It contains information related to patient safety, and lists known issues and possible workarounds.

Study this manual carefully before using the RayCare 5B system. Proper functioning of the device can only be guaranteed if the instructions in this guide are adhered to. Every user of RayCare 5B must be familiar with the known issues described in this manual. These notes provide final instructions on how to use the RayCare 5B system. Feel free to contact the manufacturer for any questions about the content.

1.2   RAYCARE DOCUMENTATION

1.2.1   RayCare system documentation

The RayCare 5B system documentation consists of:

Document	Description
RSL-D-RC-5B-IFU, RayCare 5B Instructions for Use	This manual contains regulatory information, safety information and a summary of known issues concerning the RayCare 5B system.
RSL-D-RC-5B-USM, RayCare 5B User Manual	This manual describes the functionality of the RayCare system and gives step by step instructions on how to perform the most common operations.

1.2.2   Other associated documentation

- *RSL-D-RC-5B-NI, RayCare 5B News and Improvements*

- *RSL-D-RC-5B-SEG, RayCare 5B System Environment Guidelines*

- *RSL-D-RC-5B-TPL, RayCare 5B Third-Party Licenses*

- *RSL-D-RC-5B-RPDCS, RayCare 5B RayCare PACS DICOM Conformance Statement*

2   PRODUCT INFORMATION

This chapter describes important information about the RayCare 5B 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 used to support workflows and scheduling, as well as clinical information, planning and treatment management for oncology care. RayCare may be used in the transfer, storage, conversion and display of patient data in all areas of cancer care including radiation therapy, medical oncology and surgical oncology.

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.

2.4   INTENDED PATIENTS AND INDICATIONS

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

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   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.

2.7   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). RayCare 5B clients can be used with Windows 10 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 472.12 and 471.68 of the NVIDIA GPU drivers or the latest drivers published by NVIDIA with Vulkan support.

The RayCare server shall be installed on servers running Windows Server 2016 or 2019 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.

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.

2.8   CONTRAINDICATIONS

None known.

2.9   MANUFACTURER CONTACT INFORMATION
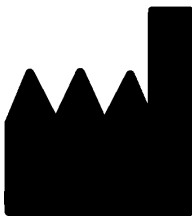
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Country of origin: Sweden

2.10   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.

2.11   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 PO Box 480 Pukekohe New Zealand
US Agent	RaySearch Americas, Inc. The Empire State Building 350 5th Avenue, Suite 5000 New York, New York 10118 USA

2.12   PRODUCT LABEL

The version number of an installed RayCare 5B system can be found by choosing **About** in the RayCare menu.

The following information can be identified:

- Product name = RayCare

- Release version = **5.1**

- Marketing name = RayCare 5B

- Software build number = **5.1.0.61073**

- 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

- **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

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

2.13   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.

2.14   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 5B 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 SAFETY PRECAUTIONS

Adhere to the following warnings and known issues for safe operation of the RayCare 5B system.

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

In this section

This section contains the following sub-sections:

3.2.1   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!**
>
> **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!**
>
> **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)

3

> **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)

3.2.2 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!**
>
> **Review Treatment intent and Setup instructions after approval.** After having signed Treatment intent or Setup instructions, validate that the displayed data and status are correct. (61397)

> **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!

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!

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)

3

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, RayTreat or RayCommand. It is still possible to modify data and continue the treatment course. (574262)

WARNING!

Setup instructions specify the care plan for all treatment session related items. The care plan associated with treatment sessions in the treatment course of the patient is defined by the approved setup instruction. The care plan specified for the approved setup instruction will be associated with all treatment sessions that have beam sets planned on the planning image selected in the setup instruction. All items related to the treatment sessions will be associated with that care plan, this includes treatment appointments, tasks and offline image reviews.

It is possible to change the care plan for the treatment session related items by unapproving the setup instructions and creating a new setup instruction and specifying another care plan for that setup instruction. (574264)

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)

Other known issues concerning patient chart

- When updating document meta data such as title or associated workflow for a document in the RayCare Document workspace, the changes are applied to all previous versions of the document. (59153)

- A comment added to a planning module in the Add/Edit workflow module dialog will not be displayed in the Plan overview. (572460)

- 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)

- No comment icon is shown for an appointment with comments in the Appointments workspace in the patient chart. (685910)

- Documents are denoted "forms" in multiple workspaces and dialogs in RayCare. (688070)

- The latest state of a RayCare domain object value will not be shown in a deprecated document when the document is not saved after the RayCare domain object is updated and before it is deprecated. Take care to save before setting status to deprecated or enter in error to not lose information. (688482)

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

Known issues related to patient safety concerning offline image review

- 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)

Other known issues concerning offline image review

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

- Offline image review cannot be performed on archived treatment images. A crash will occur in the image viewer. Restore the images from the archive to perform offline image review. (629140)

3.2.4   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. No alert is displayed when multiple treatments for the same patient are scheduled in a short time interval. (573563)

Known issues related to patient safety concerning scheduling

- When rescheduling a treatment appointment with information about treatment plan and beam set to another treatment machine, the treatment plan and beamset information is not updated until saving. (474409)

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)

- It is not possible to reschedule partially booked appointment series. In order to reschedule an appointment series using the "Reschedule" functionality in the Calendar workspace, all of the appointments in the series must first be booked. (149254)

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

- When scheduling and re-scheduling treatment appointments from the Scheduling workspace, the care plan information is only displayed when the treatment sessions have been connected to RayTreat and have approved setup instructions. (472575)

- When cancelling an appointment in an appointment series as a system administrator and selecting to not cancel the complete series, followed by clicking Cancel in the confirmation dialog, the single appointment is cancelled anyway instead of staying booked. (568887)

- No scheduling suggestions are provided if appointments in an appointment series have been manually modified in a way that the appointment template suggestion rules are not met, including if the treatment appointments are not in sequential order. The user should manually schedule the appointments from the Treatment calendar workspace. (573071)

- Manual changes to the appointments such as duration or participants will be overridden when the scheduling or rescheduling functionality is used. (573874)

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

- Treatment appointments which are cancelled in RayCare will still be displayed in RayTreat and RayCommand. (574131)

- It is not possible to set a specific start time in the Scheduling workspace outside of the organization's available hours. If attempting to do this, a suggestion will be given during the available hours. (573220)

- The plan and beam set name are not displayed when viewing suggestions for rescheduling of treatment appointments from the Scheduling workspace. Hover over the plan and beam set icon to see the plan and beam set information in the plan and beam set tooltip. (628401)

- The target treatment start date is only shown on the first treatment appointment of the treatment appointment series when the first treatment appointment is scheduled on a later date than the set target treatment start date. The target date information can be found in the Edit workflow properties dialog of the Workflow management workspace. (685935)

3.2.5   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!**
>
> **Review treatment appointment status before cancelling a treatment workflow module or RayCare case.** Always review RayCare for any treatment appointments that are not completed before cancelling the treatment workflow module or closing a RayCare case. Always verify the status of the treatment course in RayTreat. (14655)

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)

- There is no indication that a subtask has a checklist configured. Open the Edit task dialog for the subtask to see the checklist of the subtask. (569515)

- 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)

- A treatment delivery workflow module for a case cannot be canceled or replaced after a treatment plan has been set for use in the treatment course for that case. If the intent is to permanently cancel the treatment course, the user can instead cancel all tasks and appointments in the workflow module and then set the status of the module to 'Completed'. Instead of creating a new treatment delivery module for the case, consider adapting the existing module by inserting tasks and changing appointment templates as needed. (573374)

- When a task is both overdue and prioritized, only the prioritized icon will be shown in the Task list in the patient chart. The number of days the task is overdue will be indicated next to the prioritized icon. (628427)

- No comment icon is displayed on the Charges whiteboard when a task or appointment contains comments. Open the Edit task or appointment dialog to see the comments. (686895)

- A task in status Pending with subtasks and/or linked checklist items is not updated to the status Started when an action is performed on the subtasks and/or checklist items. The status should be updated manually to Started from Pending. (687124)

- 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)

- Due dates of tasks related to a target date in the Edit workflow properties dialog are not recalculated based on the target date when the linked appointment is canceled or entered in error. (688177)

- No comment icon is displayed on the task cards in the Edit order dialog or the Edit module dialog when the task has linked comments. Review the task comments in the Comments or All comments tab or on the individual tasks. (688133)

- 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)

- Comments added to tasks or modules on patient level will not be displayed in the All comments tab of the Edit module and Edit task dialog of modules and tasks on case, care plan, plan or beam set level. Verify the comments on patient level in the modules and tasks on patient level. (687900)

- Inserting an activity to an order from the patient chart Task list will cause RayCare to crash. Insert individual tasks to the order instead. (687691)

- The task or appointment comment icon in the Planning, QA and Appointment whiteboards is placed in the patient column instead of the task column. (686893)

- It is not possible to add tasks for documents which are added on the patient context level from the Documents workspace. (685362)

- When a treatment delivery module has been added it is not possible to add a workflow module containing treatment scheduling tasks. Modules containing treatment scheduling tasks must be added before the treatment delivery module. (688501)

- When inserting a task from the patient chart Task list, the plan and beam set selectors will not always be displayed in the Insert task dialog depending on configuration. The plan and beam set are correctly added to the task and are displayed after saving the task. (688454)

3.2.6 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)

3

> **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)

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. In the Treatment course view, the naming convention used in RayStation is used. (472754)

- Treatment plan and beam set details from RayStation cannot be displayed correctly after removing the treatment plan, case or patient from RayStation. Also, if the patient is restored using a RayStation backup file the information will not be updated in RayCare. (474559)

- 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)

- When a comment is added in the comment section of a task in the task list in RayStation without clicking the Save comment button, then the comment will be removed without a warning to the user when the user approves or completes the task. (628616)

- 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. The selection of planning images for a setup instruction for the care plan may be inconsistent with the linked plan and beam set in a workflow module. (687323)

3.2.7   Warnings and known issues concerning treatment management integration with RayTreat and RayCommand

> **WARNING!**
>
> **Modifying treatment appointments in RayCare does not change the treatment course in RayTreat.** The number of fractions in the treatment course is managed in RayStation and RayTreat and cannot be updated or changed from the RayCare user interface. Removal of treatment appointments in RayCare can accidentally be interpreted as influencing the treatment course. Therefore, always perform updates of the treatment course and verify the status of the treatment course in RayStation and RayTreat. (14395)

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

> **WARNING!**
>
> **RayStation or RayTreat data.** Treatment plans and treatment delivery data displayed in RayCare originates from the RayStation and the RayTreat systems. Make sure to always check the data in the original system. (228134)

> **WARNING!**
>
> **Treatment records imported to RayCare PACS are not automatically transferred to RayTreat.** The user should always import relevant treatment records to RayStation. (369254)

3

> **WARNING!**
>
> **Nominal dose progress.** It is possible to track nominal dose progress towards one or more prescriptions during treatment delivery performed using RayTreat 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!**
>
> **Order of treatment appointments and sessions.** The treatment course has a continuous session numbering in a patient case. The use of different care plans, prescriptions or treatment sites is not reflected in the numbering. Verify the treatment course and appointment list with respect to ordering of treatment appointments and sessions when different plans and/or beam sets have been assigned to the treatment course. Make sure to consider using informative naming of the plan and beam set. (574218)

Known issues related to patient safety concerning treatment management integration with RayTreat and RayCommand

- The treatment fraction and session status in RayCare is not always consistent with the corresponding status in the RayStation treatment course when treatment sessions are *first cancelled and then* manually recorded in RayStation/RayTreat/RayCommand. This could result in different treatment progress being displayed in the RayCare workspaces (patient panel, treatment course overview and summary, plan overview and treatment whiteboard). (683942, 683943, 686712, 681899, 684735, 687196)

- Online couch corrections are set to 0 for all corrections in the Treatment course overview workspace when the treatment is performed with a Varian TrueBeam treatment device. (685099)

- RayCommand does not have an image review workspace where offline image review information can be displayed. The status and potential comments for offline image review from RayCare will therefore not be visible to the user in RayCommand. The user will need to review the offline image review status of a previous fraction in RayCare before the next fraction is delivered in RayCommand. (683912)

Other known issues concerning treatment management integration with RayTreat and RayCommand

- Fractionation patterns are not synchronized between RayCare and RayStation (150035):

    - RayStation does not use scheduled fractionation patterns, or number of fractions, from RayCare.

    - When using a RayStation plan for treatment in RayTreat, the planned fractionation pattern in RayStation is not validated against the scheduled fractions in RayCare. The number of planned fractions in a RayStation treatment plan will be scheduled for treatment, with automated request for schedule updates in RayCare in case more appointments are needed.

    - Biological evaluation and optimization will only be evaluated for the planned fractionation pattern in RayStation regardless of the treatment sessions scheduled in RayCare.

- It is not possible to check in to a treatment appointment if the treatment plan set for use in treatment was already approved when imported into RayStation. The user must re-approve the plan in RayStation to be able to check in. (472608)

- Rounding of values in the RayCare treatment course view may in some cases differ from the rounding displayed in RayTreat. (567401)

- When reducing the number of treatment appointments from workflow management after a treatment course has been discontinued, the treatment appointments are still visible in the calendar in RayTreat. (568386)

- It is not possible to cancel a treatment session in RayStation until a treatment device is scheduled on the corresponding treatment appointment in RayCare. (628866)

- Both the beam set planning remark and the beam set treatment remark that are displayed in the RayCare plan overview have different names in both RayStation and RayCommand. The beam set planning remark is called "comment" for the corresponding beam set in the RayStation plan edit dialog. The beam set treatment remark is either called "beam set note" or "treatment note" in RayStation and RayCommand. (683913)

- The beam set planning remark and the beam set treatment remark that are displayed in the RayCare plan overview, are not displayed in RayTreat. (684848)

- No comment icon is displayed on the appointment in the RayTreat/RayCommand schedule when the appointment in RayCare has comments. The comments are displayed in the appointment comment section in RayTreat/RayCommand. (685205)

- Information on the signing user for the final treatment note is not available in the Treatment course overview workspace when the treatment is performed with a Varian TrueBeam treatment device. (686776)

- The nominal progress in RayCare reports no delivered dose for patients that have a treatment course created in RayCare 4B and earlier and because of that the expected total dose is not

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completely correct. The expected total dose is the sum of the delivered dose and remaining dose so for these patients the expected total dose will then always be the same as the remaining dose. (684602)

3.2.8   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!**
>
> **Manually link DICOM data to RayCare patient.** DICOM data imported and automatically associated to a RayCare patient in previous versions of RayCare (version 2C and earlier) must be manually linked to the RayCare patient in order to receive automatic updates of RayCare patient information. Note that new imported DICOM data will be automatically linked to a RayCare patient if the patient information matches. (149915)

> **WARNING!**
>
> **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)

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)

3.2.9   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)

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Other known issues concerning integrations with external systems

- When insurance information is imported and updated in RayCare via HL7, the policy holder details are not displayed in RayCare. Only system administrators can access this information by double-clicking the insurance. (574332)

- The name of the user who performed the charge export is not explicitly available in the audit log entry. It is still possible to track who the user was in the RayCare charge details view (Exported by field and matching the charge by timestamp in the audit log). It is also possible to infer the user name from adjacent log entries. (685195)

3.2.10 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)

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)

3.2.11   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 RayTreat must match. The treatment device name in RayCare must be the same as the one used in RayTreat. (58255)

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!

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. 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)

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. (628726, 628727)

Other known issues concerning system administration

- A RayCare document cannot be configured with more than one RayCare domain object of the same type. (686304)

- The data from the treatment alerts table in the reports database can differ from the treatment alerts displayed in the RayCare user interface. The treatment alerts in the report database are stored per treatment session and will not be updated after the session is completed. (685190)

- When multiple users are working in the Activities workspace in the administrator user interface with the same type of configuration templates, the changes made by one user will be discarded when another user starts editing templates of the same type. (686949)

- The workflow module type Order is available for selection in the Activities workspace of the administration user interface for users with the RayCare Flow license, but the module type cannot be used and will be removed in a later version of RayCare. (687007)

- When working with configuration of document templates with a large number of fields with references to RayCare domain objects or extended domain objects, RayCare may occasionally crash. (688494)

- It is not possible to run the RayCare script runner tool with RayCare 5A. Instead the user can run RayCare scripts from the Script workspace in Patient chart. (687090)

3.2.12 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 5B with RayStation 11B 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!

Database backup plans must be updated after upgrade. After an upgrade of RayCare, the clinic is responsible for verifying that the backup plans are up-to-date with respect to the backup instructions for the new version. Pay special attention to database-specific steps, since the set of databases might change between releases. (149553)

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

> **WARNING!**
>
> **The clinic must not restore RayCare databases.** All restores from backup must be performed 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)

3.2.13   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 to RayCare 5B. 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 to RayCare 5B. 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 to RayCare 5B. 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)

Known issues related to patient safety concerning upgraded RayCare systems

- Offline image review (OIR) tasks that have been inserted using the "Insert task" function in previous versions of RayCare will after the upgrade to RayCare 5A not become connected to OIR items in the OIR workspace. Changing the status or adding comments to these OIR tasks will not be reflected in the OIR items and vice versa. Before upgrading to RayCare 5A, carefully review if such tasks exist in active workflows and consider adding a remark in these tasks. (370135)

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 5B, the dose delivery information for treatment sites will be available in the Description field after upgrade to RayCare 5B. 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 estimated treatment start delay, defined as the delay between the module selection and the treatment start target date, configured on the treatment scheduling or treatment delivery module has been removed. Therefore, the scheduling suggestions made for treatment appointments will differ compared to previous RayCare versions. Adjust the suggested appointments as needed. (683952)

- Existing treatment plans and beam sets in RayCare will not have remark, machine model or beamlines from the corresponding plans and beam set in RayStation set after the upgrade to RayCare 5B. Correct values will be displayed in RayCare after the patient has been updated in RayStation after the upgrade. (683908)

- 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)

- Tasks configured to be automatically linked to documents when the document is created will no longer be linked to the document. The user must add the task using the document select menu instead. (685193)

- It is not possible to configure that a workflow module is compatible with a workflow module which is deactivated. All modules are deactivated during the upgrade to RayCare 5B. Modules can be configured without any compatibility requirements. (686565)

- 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)

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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 or 2019 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 is highly integrated with RayStation and RayTreat. The configuration of all DICOM application entities used for DICOM data transfer between RayCare, RayStation and RayTreat shall be performed by RaySearch authorized personnel.

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5   SYSTEM INTEGRITY AND SAFETY

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

In this chapter

This chapter contains the following sections:

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5.1   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.

5.2   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.

As part of the backup procedure, RayCare will create checkpoints in the databases. Those shall be created at intervals specified by RaySearch documentation. This document describes the detailed configuration of RayCare backups and can be requested from RaySearch service. Checkpoints must be created after full backup but before backup of transaction logs. RayStationPatientDB log backup must happen directly after checkpoints have been created. If the creation of a checkpoint for some reason fails, another attempt to create the checkpoint must be made. It is not possible to restore data using a checkpoint that has failed, and that shall never be attempted. Checkpoints shall never be created during a time of ongoing treatment delivery.

The images stored in the NTFS or UNC file system must be backed up after the checkpoints have been created, 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 number of days 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 checkpoint. 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 checkpoint to operate correctly after the restore. 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.

5.3   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.

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