

RAYSTATION 11A

System Environment Guidelines

11A



RayStation

Traceback information:
Workspace Main version a662
Checked in 2021-06-04
Skribenta version 5.4.004

Disclaimer

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

Declaration of conformity



Complies with 93/42/EEC Medical Device Directive as amended by M1 to M5. A copy of the corresponding Declaration of Conformity is available on request.

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1 INTRODUCTION

About this guideline

This document provides a description of the primary requirements of the hardware and additional software required to run RayStation. A summary of the ongoing maintenance tasks that should be considered from an IT management perspective is also included.

This document is not intended to be a document where a full RayStation deployment strategy is defined. Instead, it is intended to provide overviews from both clinical and IT perspectives about the available options and the operational areas to be examined during the development of a solution.

This guideline describes multiple alternatives for the RayStation system environment. All options may not be suitable for all clinics depending on clinic specific details.

Any recommendations in this guideline shall be in adherence with *RSL-D-RS-11A-IFU, RayStation 11A Instructions for Use*. If there is any doubt regarding a configuration please contact RaySearch Laboratories.

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1.1 CONTACT INFORMATION

Please raise any questions with your local RaySearch Laboratories representative or contact RaySearch Support on support@raysearchlabs.com.

1.2 DEFINITIONS, ACRONYMS AND ABBREVIATIONS

Definitions, acronyms and abbreviations	Meaning
AD	Active Directory
CPU	Central Processing Unit
CUDA	Compute Unified Device Architecture. A computing platform and API developed by NVIDIA for Graphics Processing Units.
DR	Disaster Recovery
ECC RAM	Error Correcting Code Random Access Memory
GPU	Graphics Processing Unit
HDD	Hard Disk Drive
HIPAA	The Health Insurance Portability and Accountability Act is a federal statute in the United States of America to modernize the flow of healthcare information, stipulate how personally identifiable information maintained by the healthcare and healthcare insurance industries should be protected from fraud and theft and additional aspects of Healthcare in the US. It can be viewed as a best practice guide in relation to patient information security.
Hypervisor	A hypervisor or virtual machine monitor (VMM) is a piece of computer software, firmware or hardware that creates and runs virtual machines.
IIS	Internet Information Services
LAN	Local Area Network
LDAP	The Lightweight Directory Access Protocol (LDAP) is an open, vendor-neutral, industry standard application protocol for accessing and maintaining distributed directory information services over an Internet Protocol network.
LTSR	The Long Term Service Release program for Citrix Virtual Apps and Desktops (previously XenApp and XenDesktop) provides stability and long-term support for remote access to RaySearch Products.
PACS	Picture Archiving and Communication System

Definitions, acronyms and abbreviations	Meaning
PII	Personally Identifiable Information is any information relating to an identifiable person or equivalent terms relating to personal data such as GDPR.
RayStation help	An integrated version of the RayStation User Manual in HTML format. (Optional.)
RDS	Remote Desktop Services
SAN	Storage Area Network
SIEM	Security information and event management is software products and services combine security information management (SIM) and security event management (SEM). They provide real-time analysis of security alerts generated by applications and network hardware.
SSD	Solid State Drive
TDE	Transparent Data Encryption is a technology employed by Microsoft to encrypt database files.
VLAN	A "section" of a Local Area Network exclusively for traffic of a certain type or a certain application.
WAN	Wide Area Network

1.3 REFERENCES AND RELATED DOCUMENTS

The documents referenced in the following list can be found in **Documentation** that can be launched from the RayStation Launcher or in the RayStation Deployment Package.

- *RSL-D-RS-11A-IFU, RayStation 11A Instructions for Use*
- *RSL-D-RS-11A-DCS, RayStation 11A DICOM Conformance Statement*
- *RSL-D-RS-11A-SEAT, RayStation 11A System Environment Acceptance Test Protocol*

2 HARDWARE ENVIRONMENT

Introduction

RayStation can either be run from the installation PC or from a client with remote access to the installation PC, where the remote access software operates at a level suitable for assessment of medical imagery, including lossless data transfer.

RayStation operates within a Microsoft Windows environment with Microsoft SQL Server hosting information relating to the clinic, machines, machine learning models (optional) and patients in separate databases. The RayStation client machine obtains the relevant information from the databases. There are additional databases that define RayStation Systems (resource database), services available to RayStation (Service database) and license details (License database). A System is made up of a single clinic and machine database, one or more patient databases and an optional machine learning database.

Additionally, information can be queried, imported or otherwise from application entities (e.g., PACS) using the DICOM format (see details within the *RSL-D-RS-11A-DCS, RayStation 11A DICOM Conformance Statement*). This information is saved to the relevant database(s).

Three different types of client machines can be used:

- **Basic/Review** machines - lower specification machines that are primarily aimed at reviewing plans and not running any registrations, optimizations or similar processor intensive tasks.
- **Advanced/Planning** machines - machines on which a single user can run all functionality included within the RayStation Client. This does not include Plan Explorer.
- **Shared Application Servers** - servers that enable sharing of the resources of one machine to a number of concurrent users, by installing RayStation and then publishing the RayStation Launcher application using the Citrix Virtual Apps & Desktops software.

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2.3 CENTRAL RAYSTATION WITH VIRTUAL DESKTOP CONNECTION - CITRIX VIRTUAL & APPS DESKTOPS

This involves deploying RayStation on centrally located machines (usually in a rack format or can be located in a planning room but also available for remote access) and providing user access to the machines through remote desktop brokering software such as Citrix Virtual Apps and Desktops. Please contact RaySearch regarding the validated versions of Citrix Virtual Apps and Desktops for this option. This software provides the required 3D Pro HDX technology to transfer the complex graphical images to the end point device with a lossless connection. As each user running RayStation will engage all of the resources of the machine that they are logged in to, the number of concurrent RayStation sessions is equal to the number of physical machines.

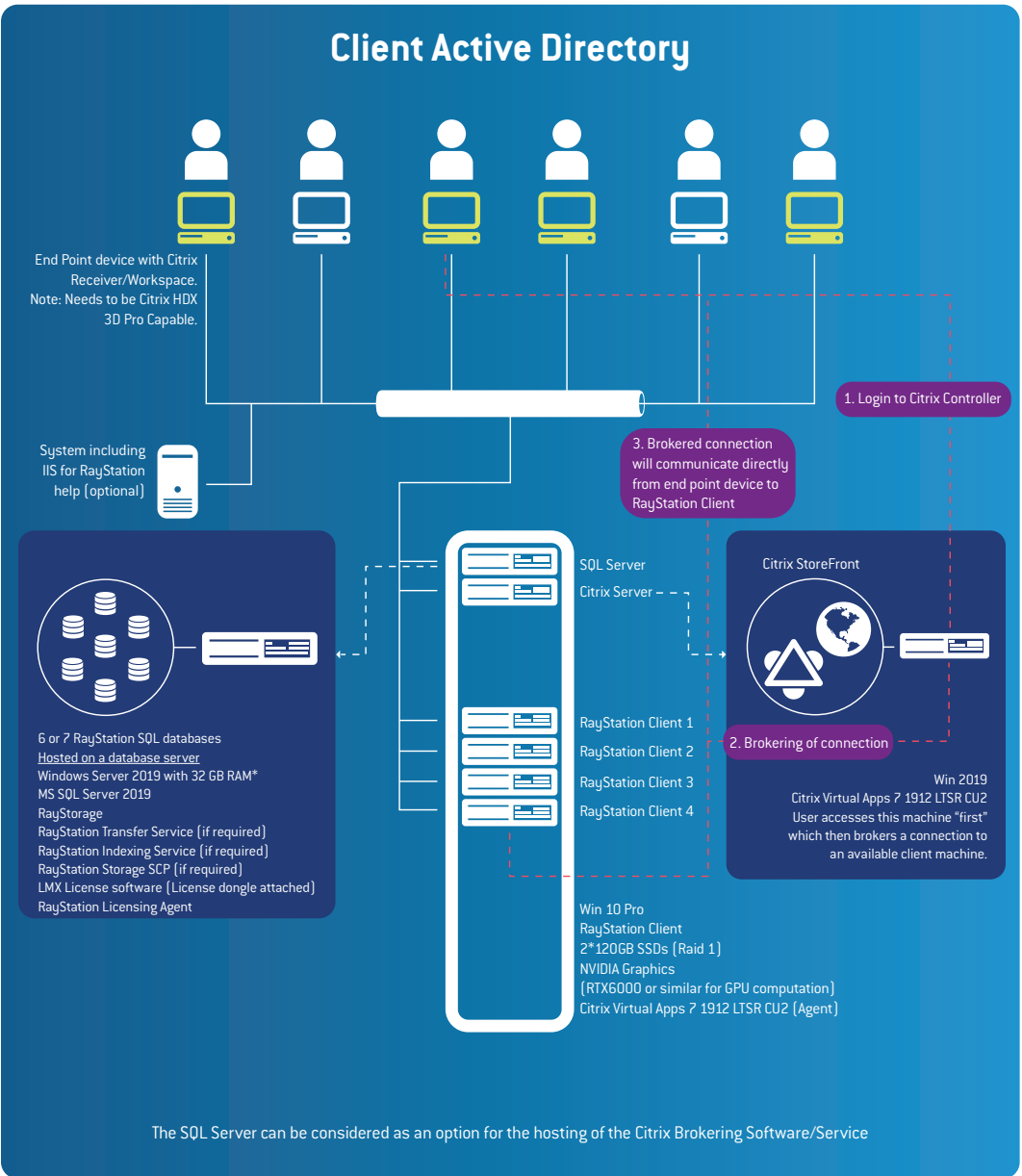


Figure 2. Central RayStation with virtual desktop connection. **Note that RAM DIMMs should be installed to provide optimal RAM usage, i.e. units of 6 for Intel Xeon Scalable (48/96 GB) or units of 4 for Intel Xeon E5 (32/64 GB).*

2.4 SHARED APPLICATION SERVER - CITRIX VIRTUAL APPS & DESKTOPS

Using Citrix Virtual Apps and Desktops, it is possible to deploy RayStation on central machines and publish the application for end users. All of the resources, for the machine that the software is installed on, are then available to the user(s) – and are managed by the operating system in relation to scheduling of operations. So while the program is "controlled" by the remote session, all of the operations occur on the central machine. Multiple graphics cards can be recognized in a native Windows Server operating system (required for this approach), i.e., these are available to RayStation and shared between multiple users. As GPU computations may saturate the load of the used GPUs, RaySearch recommends separate cards for application rendering and GPU computations. The render card can be of lower specification, but it should be noted that the rendering performance for all of the users is related to the specification of this card. (Note: The NVIDIA Quadro RTX4000 would be a candidate for hosting of multiple user render sessions). Multiple computation GPU configurations are supported, contact RaySearch support for more information on valid configurations.

Note: *With the sharing of resources (CPU and potentially GPU) between users within a Shared Application Server, there may be situations where significant demands from a single or combination of users can have an effect on other users. If this becomes an issue the user density should be reviewed. Updates to user density should be considered as an option at all stages of implementation and operation. This may require additional hardware, e.g., providing a specific power user with a dedicated machine.*

Note: *The combination of 2 mixed Quadro cards (from the same generation) within Server grade hardware may not be available directly from hardware vendors in a fully supported fashion, however these options are available through RaySearch Laboratories. Due to these possible support issues, we recommend that these systems are purchased through RaySearch Laboratories. Contact your RaySearch Laboratories account manager for further details.*

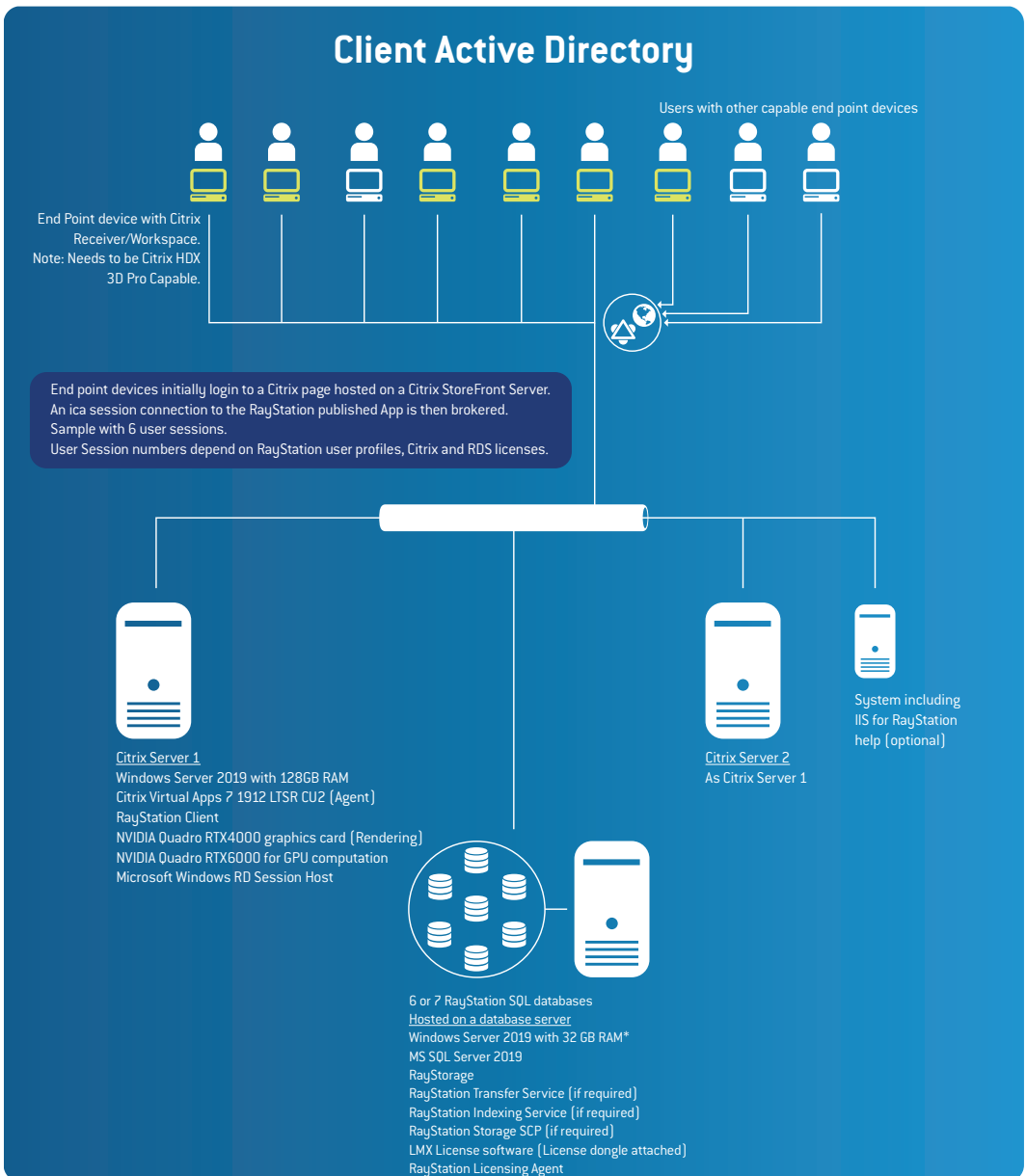


Figure 3. SQL Server. **Note that 64 GB RAM is preferred where possible.*
Shared Application Server. ***RAM DIMMs should be installed to provide optimal RAM usage, i.e, units of 6 for Intel Xeon Scalable (192/384 GB) or units of 4 for Intel Xeon E5 (128/256 GB).*

2.5 VIRTUAL MACHINE (VM) HOSTED RAYSTATION

With the advances in hypervisor possibilities, graphics cards can be passed through to Virtual machines. Virtual machine operation of RayStation has been confirmed on a restricted number of hypervisors. Clinics that want to assess this option should contact RaySearch Laboratories for further information. A high level of understanding of the hypervisor is expected within the clinic before considering this approach – particularly for support of the hypervisor environment.

3 RAYSTATION MACHINES

Introduction

The sections in this chapter should be considered in relation to physical RayStation workstations. Virtual machines should be similar but have more flexibility, e.g., in relation to amount of RAM.

Note: *For performance, update and operation reasons we highly recommend that only RayStation related software is installed on a client machine.*

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3.1 RAYSTATION CLIENT MACHINES

The specifications in this section apply to machines being used to host the RayStation Client software.

Processor(s)

Single or dual socket Intel 2.6 GHz CPUs with a total of at least 8 physical cores or better (12 physical cores preferred). The latest CPUs in the Intel Xeon Scalable Processor series should be considered when investing in new hardware.

Graphics card (GPU) for graphics rendering

An NVIDIA graphics card with a minimum of 1GB RAM is required for the basic rendering operations within RayStation 11A. For enterprise operations, RaySearch recommends the NVIDIA Quadro cards, principally based on reliability and recommendations from NVIDIA.

Graphics card (GPU) for accelerated computations

Certain aspects of the RayStation computations are run on GPU instead of the CPU. The primary advantage with this is performance.

The graphic card/operating system combinations populated with a GPU driver version in the following table have been verified for GPU accelerated computation operations. **Bold** options are recommended for new purchases.

Graphic cards	Windows 10	Windows Server 2012 R2	Windows Server 2016	Windows Server 2019
NVIDIA RTX8000 (active or pas- sive)	461.40		461.40	461.40
NVIDIA RTX6000 (active or pas- sive)	461.40		461.40	461.40
NVIDIA RTX5000	461.40			
NVIDIA P6000	461.40		461.40	
NVIDIA P5000	461.40			
NVIDIA M6000 24 GB	461.40	461.40		
NVIDIA M6000 12 GB	461.40	461.40		
NVIDIA M5000	461.40	461.40		

Note: Additional validations may have been performed. Certificates are available from support@raysearchlabs.com. Validation of running RayStation 11A using NVIDIA RTX A-series card is intended to be assessed during 2021. Note that NVIDIA Quadro M-series cards may no longer be supported in upcoming releases of RayStation.

Note: When running gpu computations on Windows Server 2016 the performance may improve if the computation card is configured to run in TCC mode.

Please see reference information within the *RSL-D-RS-11A-IFU, RayStation 11A Instructions for Use* regarding GPU implementation.

As long as the GPU is used by a single user only, it may be used for both graphics rendering and accelerated computations. However, user interface rendering lag may be experienced while a GPU computation is running. Multiple computation GPU configurations are supported, contact RaySearch support for more information on valid configurations.

Display

The recommended resolution for the display used together with RayStation is 1920 x 1200 (preferred) or 1920 x 1080 pixels.

RAM

32/48 GB of DDR3 ECC RAM. ECC RAM is required for system memory in all machines. RAM DIMMs should be installed to provide optimal RAM usage, i.e., units of 6 for Intel Xeon Scalable (48/96 GB) or units of 4 for Intel Xeon E5 (32/64 GB). For support of some use cases additional RAM can be beneficial (especially in ion planning).

HDD

The main considerations with respect to HDD for client machines are: hosting the OS (including swap file, drivers, etc.), RayStation client software, and potentially patient exports.

Local drives are recommended for client machines. Where possible RAID 1 (or potentially higher) should be implemented with SSD drives, if practical. 150 GB per drive or higher is recommended.

Network

1 Gb/s Ethernet is required, and where possible 10Gb/s connectivity between SQL Server and clients would be beneficial. Where possible, it is recommended that the link between the RayStation clients and the SQL server is within a separate VLAN or similarly segregated network to avoid contention issues.

For Citrix setups it should be remembered that the Citrix Virtual Apps & Desktops software (section 2.3 *Central RayStation with virtual desktop connection - Citrix Virtual & Apps Desktops on page 14*) acts only as a broker to establish the session between endpoint and host. Network connections between the endpoint and the host will affect the experience for the end user. Teaming of NICs can benefit interactions with SQL on Shared Application Servers (section 2.4 *Shared application server - Citrix Virtual Apps & Desktops on page 16*). Note that network infrastructure specifications may restrict the ability to team NICs.

OS

It is recommended to use Windows 10 Professional or higher to host RayStation 11A client software.

Windows Server 2019, Windows Server 2016 and Windows Server 2012 R2 can also be used to host RayStation 11A client software (64 bit versions). The intended use of Windows Server 2019, Windows Server 2016 or Windows Server 2012 R2 is the installation of Virtual Apps & Desktops and access from one or more suitable end point devices.

The OS versions should be of the following versions: Windows 10: version 20H2 (minimum), Windows Server 2019: version 1809, Windows Server 2016: version 1607.

Remote Citrix Access

The remote access options available for RayStation 11A are using Citrix Virtual Apps & Desktops 7 1912 LTSR CU2. For more information, see www.citrix.com. It should be noted that an end point device that supports Citrix XenDesktop HDX 3D Pro and the appropriate resolution is required.

3.2 STAND-ALONE MACHINES

Where the machine will act as a stand-alone machine, i.e., host the SQL databases and RayStation, additional processor power, RAM and hard drive space can be considered.

3.3 LOWER REQUIREMENT MACHINES

When the purpose of a machine is Plan Evaluation and basic Anatomy functions, a lower specification machine can be used. Please note that Intel CPU(s), ECC system RAM and an NVIDIA GPU are required for clinical operations.

4 SQL SERVERS

Introduction

SQL Server recommendations can be subdivided into three types of installations:

- RayStation SQL Server Entry Level (1-10 RayStation)
- RayStation SQL Server Advanced (11-25 RayStation)
- RayStation SQL Server Enterprise (25- ~50 RayStation)

If the present virtual infrastructure has the necessary resources, capacity and connectivity, then it can be considered for the hosting of the SQL Server instance(s). The performance and connectivity of the SQL Server host is a critical factor in the performance of opening, saving and closing patients.

SQL tools are available to assess the viability of SAN resources for hosting the RayStation Databases. Traffic will also be generated for Auto Recovery. The Auto Recovery feature can be turned off or recovery files can be written to the local filesystem based on the option selected in Clinic Settings.

Using the RayStation Storage Tool, databases can be moved to other database servers and remain visible to end users via the indexing service.

4.1 SQL SERVER SPECIFICATIONS

The table below provides guidelines for the hosting of SQL Server:

Aspect \ Installation Type	Entry	Advanced	Enterprise
Processor	Single 4 core 2.6 GHz, Xeon CPU or better	Single 4 core 3.0 GHz, Xeon CPU or better	Single 4 core 3.47 GHz, Xeon CPU or better
RAM	32 GB of DDR3 ECC RAM ⁱ	48 GB of DDR3 ECC RAM ⁱ	64 or above GB of DDR3 ECC RAM
HDD ⁱⁱ	OS: 200 GB SSD (RAID 1) Data: 2 TB (RAID 10)	OS: 200 GB SSD (RAID 1) Data: 4 TB (RAID 10)	Based on anticipated number of patients
Network	Minimum 1 Gb/s Ethernet with teaming considered	Minimum 1 Gb/s Ethernet with teaming considered	Minimum 1 Gb/s Ethernet with teaming considered
OS	MS Server 2019 (Alt: MS Server 2016 or MS Server2012 R2)	MS Server 2019 (Alt: MS Server 2016 or MS Server2012 R2)	MS Server 2019 (Alt: MS Server 2016 or MS Server2012 R2)
Software ⁱⁱⁱ	MS SQL Server 2019 (Alt: MS SQL Server 2017 or MS SQL Server 2016 SP2 or MS SQL Server 2014 SP3)	MS SQL Server 2019 (Alt: MS SQL Server 2017 or MS SQL Server 2016 SP2 or MS SQL Server 2014 SP3)	MS SQL Server 2019 (Alt: MS SQL Server 2017 or MS SQL Server 2016 SP2 or MS SQL Server 2014 SP3)

- i Note that 64GB RAM is preferred were possible. RAM DIMMs should be installed to provide optimal RAM usage, i.e., units of 6 for Intel Xeon Scalable (48/96 GB) or units of 4 for Intel Xeon E5 (32/64 GB).
- ii As a guideline for storage, 1 GB per patient can be taken as a reasonable indicator. This may change with 4D CT image sets and is also directly related to the nature and number of image sets added during treatment.
- iii Software service packs can be the relevant service pack mentioned or higher. Note that MS SQL Server 2014 may no longer be supported in upcoming releases of RayStation.

Processor(s)

The key aspects in the specification decision for the processor on the SQL Server are data upgrades and SQL maintenance. As RayStorage can reduce the burden of upgrading patients, the planned approach can impact the processor drive requirements for the SQL Server.

Graphics Card

The graphics card on the SQL Server is not important for the operation of RayStation Databases, however a basic NVIDIA Graphics card may be considered for DR purposes.

RAM

RAM requirements depend mainly on the profile of patients.

HDD

The numbers and complexities of patients may require a higher level of SQL Server or increased hard drive space to store data files, log files and file streams. This will need to be reviewed as part of the planning process. If available, SSDs can be considered for the hosting of Operating System and (full or partial) storage at all levels. Resilience is a key factor in the decision making process. 64k Block size formatting is recommended by Microsoft for SQL data storage drives. The SQL temp database should also be hosted on SSD where possible.

Network

It may be beneficial to team one or more network cards specifically for the SQL Server Service, multiple network cards would then be required. Please note that network infrastructure specifications may restrict the ability to team NICs.

Where possible, backups and any other non-RayStation client related activity should not use the same communications routes as RayStation Client communications.

OS

Windows Server 2019 or 2016 can be used for hosting the RayStation SQL software.

SQL Server Software

RayStation 11A is validated for Microsoft SQL Server 2016 SP2 hosting the databases. Microsoft SQL Server 2019, Microsoft SQL Server 2017 and Microsoft SQL Server 2014 SP3 can also be used, but may not support integration installations with other RaySearch products. In general Microsoft only sells the latest version – with downgrade rights, but where there is a choice RaySearch recommends the purchase of the latest version with downgrade rights. Purchase of the latest version is also encouraged as it appears that operational performance is an area of focus for development, for Microsoft, in relation to SQL.

Note: *Aspects of a RayStation HIPAA implementation require a Microsoft SQL Enterprise version.*

5 RAYTREAT: SUPPORTED MACHINE VENDOR VERSIONS

RayTreat is the RayStation client application launched with the Treatment delivery GUI interface or equivalent service and is normally installed on a computer in the Treatment Control room at a clinic. RayTreat is intended to only be used to deliver plans that were both created in RayStation and scheduled through RayCare - the next-generation oncology information system (OIS) from RaySearch Laboratories. RayTreat 5A can only be used in conjunction with the following validated treatment machine vendor software versions:

IBA

RayTreat 5A is compatible with IBA system PTS Release 12.

ProNova

RayTreat 5A is compatible with ProNova TRCS version: 1.1.3.59.

Varian

RayTreat 5A is compatible with Varian Treatment Interface 01.00.00906.0 and TrueBeam control system 2.8.30.76.

Accuray Tomo

RayTreat 5A is compatible with Accuray iDMS version 3.3, Accuray Treatment Delivery Console version 8.0.0.10 and Accuray Radixact version 3.0.0.10.

Accuray CyberKnife

RayTreat 5A is compatible with Accuray iDMS version 3.3 and Cyberknife M6 version 11.2.

Other versions

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

6 RAYSTATION HELP

RayStation includes an integrated help package that makes it possible for users to access the User Manual through a browser opened from the RayStation application by clicking F1 or through the RayStation menu option. This approach to opening the User Manual is optional, as the documentation should also be available through the RayStation Launcher.

The integrated help will require a Web Hosting engine such as Microsoft Internet Information Services (IIS), which is the primary version that has been tested.

Default OS browser versions and widely used browser versions such as Chrome, Firefox and Microsoft Edge have been tested but we recommend testing a browser version before implementation. While formatting may vary the content should always be displayed.

If no url for the RayStation help files is included in Clinic Settings, the F1 button is redundant and the option is not available from the RayStation menu.

7 IT CONSIDERATIONS AND MAINTENANCE

Introduction

This section describes the IT considerations and maintenance for RayStation and the RayStation system environment.

Note: *For performance, update and operation reasons we highly recommend that only RayStation related software is installed on a client machine.*

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7.1 GENERAL

Power options

The Microsoft Power Options (in the Windows Control Panel) for machines running RayStation should be set to "High Performance" at all times. This ensures that maximum processor performance is available for processor operations.

System monitoring

It is highly recommended to monitor the service operation, disk space availability, processor usage and additional key performance indicators on all RayStation machines (Database and clients) with alerting of relevant resources where acceptable levels are breached. When parameters are outside acceptable levels, remedial actions should be assessed/performed as required. Services critical to the function of SQL, DICOM Storage SCP and Citrix should be considered high priority for monitoring.

Whenever an issue is detected, there should always be a follow-up to identify the root cause following the resolution of the issue. Actions to address the root cause should be considered for implementation.

System Environment Acceptance Test

Whenever the RayStation software or hardware is updated or in any way altered, the RayStation System Environment Acceptance Test shall be performed (*RSL-D-RS-11A-SEAT, RayStation 11A System Environment Acceptance Test Protocol*).

Disaster Recovery (DR) strategies

It is highly recommended that DR options are assessed, considered and where applicable implemented for RayStation environments. These should be in line with the organization's policy for DR.

7.2 RAYSTATION STORAGE SCP SERVER

Where DICOM data is to be hosted by RaySearch software, it is recommended to use a separate machine for the hosting of the SCP service. Either a minimal specification machine or a Virtual machine (potentially hosted by the SQL server) would be required with access to adequate disk space for the files to be stored. If the use case for Storage (from a data and/or frequency perspective) is not significant, the program could be run on the SQL server directly. The primary use case for the Storage SCP service is where a DICOM entity needs to "push" data to RayStation. This is achieved by "pushing" to the service and (when configured in RayStation) the data is available to the RayStation users. Care should be taken regarding the port to be used by the service if any other software is installed on the machine.

7.3 THIRD PARTY SOFTWARE

Anti-Virus

Any Anti-Virus software installed on systems with RayStation should have exemptions included for the RayStation software. It is highly recommended that exceptions are applied on the RaySearch Laboratories folder within %programfiles% as well as all subfolders.

Windows updates

Windows updates should be assessed and applied in line with *RSL-D-RS-11A-IFU, RayStation 11A Instructions for Use*.

To turn off automatic driver updates from Windows update with group policy, use the Group Policy Management Console to go to: Computer Configuration > Administrative Templates > Windows Components > Windows Update > Do not include drivers with Windows Updates and enable the policy.

PDF Reader

It is mandatory to have a PDF reader installed to be able to access and read safety critical information as well as other product information provided by RaySearch Laboratories.

Citrix Software Licensing

Citrix have updated their licensing and product references in recent times. While older licensing models purchased will still be recognized, any new licenses will require signing up to a subscription model. This entitles the purchaser to use the latest released version of Citrix or the latest LTSR. RaySearch recommends that IT organizations review and consider the advice from Citrix regarding LTSR in the following document: <https://support.citrix.com/article/CTX205549>.

7.4 ACTIVE DIRECTORY (AD)

AD requirements and recommendations

Active Directory is required for all RayStation installations with the exception of stand-alone machines. Where Active Directory is to be installed as part of an overall RayStation installation (i.e., it is not present already) it should be noted that the installation of SQL Server and Active Directory on the same machine is not recommended by Microsoft or RaySearch. It is required to use a separate machine for Active Directory and SQL Server.

AD maintenance

It is highly recommended to test the authentication mechanisms in RayStation following any Active Directory maintenance.

AD groups

The following AD groups are used for RayStation operations that require additional authentication:

- **RayStation-Administration** (access to Clinic Settings, ability to delete patients and other administrative tasks)
- **RayStation-BeamCommissioning** (ability to commission machines within RayPhysics)
- **RayStation-PlanApproval** (ability to approve plans)
- **RayStation-MachineLearningAdmin** (ability to add, remove, edit and approve machine learning models)

It is also recommended to create a RayStation-Users group which can be used to provide basic access to RayStation. The groups listed above can be nested to facilitate maintenance. Relevant subgroups can also be added for specific user profiles.

AD Service accounts

Active Directory Service, Managed Service or Group Managed Service accounts can be considered for running SQL, Indexing, SCP or other services. The relevant file, folder, database or similar permissions should be granted to these service accounts.

AD Functional level

Windows Active Directory Functional level of Server 2012 R2 is required. RayStation deployments not involving HIPAA related functionality can function within a Microsoft Active Directory Server 2008 R2 Functional level.

7.5 AD ORGANIZATIONAL UNIT

The creation of a specific Organisational Unit for RayStation within an existing Domain should be considered as a best practice. This allows for AD policies to be tailored to the RayStation environment.

7.6 SQL

SQL Backups

Details of how to set up scheduled SQL backups are available from RaySearch Laboratories. Existing SQL backup agents can be used by the clinic. All backup operations should be monitored and reviewed on a regular basis. Databases may grow at an accelerated rate where MS SQL internal processes are not triggered by MS SQL backups.

The initial view of RayStation (before opening a patient) provides alerts where full, partial or transaction log backups have not been successful for the system that RayStation is connected to (Primary Patient DB only).

SQL Indexing

It is highly recommended that re-indexing of the RayStation Databases occurs on a regular basis, e.g., following every full database backup.

Note: *Failure to re-index databases can lead to data corruption.*

SQL Access

When creating databases, all domain users have theoretical database access. This should be reviewed to ensure the correct user sets have access to the databases. When upgrading or creating additional databases access permissions should also be reviewed.

7.7 CYBERSECURITY AND HIPAA CONSIDERATIONS

To meet regulatory requirements (HIPAA) and deliver an acceptable level of confidentiality, integrity and availability, the security measures listed in the table below should be implemented in the target environment. Failing to implement all or parts of the required actions in this section may lead to

noncompliance. The security measures described in this section are in relation to the RayStation product and may not be enough to ensure HIPAA compliance for the target environment (if other products and services are used).

When assessing the current security posture of your target environment, the Department of Health and Human Services (HHS) Security Risk Assessment Tool (SRA) can provide guidance and be a good starting point. For further information, see the HHS homepage Security Risk Assessment Tool | HealthIT.gov <https://www.healthit.gov/topic/security-risk-assessment-tool>.

For specific questions on how to secure the RayStation product you may contact RaySearch Service to get more technical implementation guidance for the action described in the table below:

Area	Additional Clinic Actions	HIPAA Required	Comments
Secure Communications Implemented methods to encrypt data in motion (PII, clinical data)	Enable SQL Server Connection Encryption.	Yes	
	Enable SSL/TLS Connection Encryption for all RayStation back-end services (e.g. Index Service, RaaS etc).	Yes	
	Enable LDAPs Connection Encryption for secure Active Directory communications.	No	
	Implement network segmentation or VPN tunnels to protect communications with legacy medical (DICOM) devices that natively does not support secure/modern communications encryption technologies.	Yes	
Data Protection Implement methods to ensure data protection for data at rest (PII, clinical data)	Enable SQL Server Full Disk Encryption (BitLocker) or enable SQL Server Transparent Data Encryption (TDE).	Yes	Implementing both BitLocker and TDE mechanisms in tandem is recommended and provides defense in depth.
	Implement SQL Server Backup Encryption or similar technologies to protect data stored on backups.	Yes	
	Implement method to secure data on removable media if used (e.g., DICOM data on USB sticks etc).	Yes	

Area	Additional Clinic Actions	HIPAA Required	Comments
<p>Device Integrity Implement methods to detect and prevent changes to the device</p>	Deploy updated antivirus/malware protection on all RayStation clients and servers.	Yes	
	Deploy 3rd party file integrity tools to detect unauthorized file changes on RayStation client and server.	No	
	Implement tools and methods to secure logs and other audit information in case of an incident or breach (i.e., aggregating Windows logs to an external SIEM or log server).	No	
<p>User Authentication and Authorization Implement user authentication and authorization for RayStation clients and back-end services</p>	Make sure user authentication and account lockout policies are implemented in the Active Directory (AD), specifically user’s workstation should be automatically logged out/locked in case of inactivity.	Yes	<p>Make sure to use the HIPAA configuration options in the RayStation Storage Tool.</p>
	Enable SQL server AD user group authorization to limit access to sensitive data (PII, clinical data) stored in RayStation databases.	Yes	
	Enable AD user group authorization to limit access to sensitive information through RayStation back-end services (Index Service, RaaS etc).	Yes	
	<p>Implement security controls to protect sensitive accounts, for example:</p> <ul style="list-style-type: none"> • Use managed service accounts (gMSA/MSA) to prevent unauthorized service account take overs • Do not use high privileged default accounts such as “NT Authority\LocalSystem”, “Domain Administrator” or SQL server’s “sa” accounts in your environment for operations or management, instead use dedicated management and service accounts with restricted permissions. • Implement multi-tier Administrative Active Directory domains to prevent AD domain takeovers. 	No	

Area	Additional Clinic Actions	HIPAA Required	Comments
Software Maintenance Implement methods to keep infrastructure and applications up-to-date.	Establish process to ensure that required IT infrastructure (RayStation clients and servers, network infrastructure and SQL servers) are regularly patched with security updates.	Yes	
	Establish a documented process to test and deploy latest service packs to RaySearch software.	Yes	
Physical Access	Establish authorization procedures and security controls to prevent unauthorized physical access to RayStation clients and servers.	Yes	
Reliability and Availability	Establish and test a Disaster Recovery (DR) plan that can be executed in case of cyber security attack or breach.	Yes	Testing the DR plan is essential to get assurance that all applications and data successfully can be restored in case of breach.
	Periodically assess the security posture of the target environment, for example using external auditor or penetration testing team.	No	

7.8 LICENSING OF THIRD PARTY SOFTWARE

Obtaining licenses for the Operating System and other supporting software such as SQL related to RayStation is the responsibility of the customer clinic. The clinic should confirm that they have the correct numbers of applicable licenses with their local license vendor on a regular basis.

Licenses include (but are not limited to):

- Microsoft Server and Client Operating System Licenses – including annual fees under certain OS licenses
- Microsoft Server Client Access Licenses
- Microsoft SQL Server Client Access Licenses
- Microsoft RDS Licenses
- Citrix Virtual Apps and Desktops

7.9 RAM

RAM DIMMs should be installed to provide optimal RAM usage, i.e., units of 6 for Intel Xeon Scalable (48/96 GB) or units of 4 for Intel Xeon E5 (32/64 GB).

7.10 RAYSTATION LICENSES

RayStation 11A uses a hybrid license model consisting of concurrent user licenses and patient volume licenses for machine learning products. The patient volume license model is required to be able to run machine learning. The concurrent user licenses have an automation limit on the number of patients for which highly automated actions may be performed. Hardware dongle and LMX License software installed on at least one server is required. High availability configuration is possible for LMX. To monitor the use of patient volume licenses and the use of highly automated actions, an additional installation of one or more License agents is required.

The License agent handles RayStation license checkouts and caches the product usage. The usage data is reported to RaySearch using three options: automatic reporting directly from the License agent, automatic reporting using the License agent proxy or offline reporting using files. Automatic reporting requires internet access. The License agent, and thus RayStation, will work without internet connection for a limited time.

In an environment where the License agent does not have internet access, there is a License agent proxy, which can be installed in the DMZ. The License agent proxy relays all messages to/from the License agent and does not need access to the database. The License agent proxy runs as the LocalSystem account.

7.10.1 License monitoring prerequisites

- License monitoring requires installation of a License Agent Windows service. This can be done on the SQL Server machine or another server machine on the domain. OS requirements equal the general RayStation requirements.
- The License agent software requires access to the Microsoft SQL server hosting the RayStation databases.
- The License agent will collect license usage and post to <https://rslicense.raysearchlabs.com> using SSL on port 443. The application will create a certificate to be used when posting data to RaySearch.
 - If internet access is not possible from the domain hosting the RayStation environment a License agent proxy can be installed in the DMZ area to forward outgoing traffic from the License agent.
- Data posted to <https://rslicense.raysearchlabs.com>:

Key	Data type	Description	Sample
SoftwareVersion	string	RayStation software version	9.1.0.933

Key	Data type	Description	Sample
LicenseType	string	License type	clinical, eval
SerialNumber	string	Numberspecifying the dongle identifier	4567892345
ApplicationGuid	Guid ⁱ	Application/Profile identifier	4B79AC7A-ADF5-4E1E-87F9-AC345ECDA85E
ProductGuid	Guid ⁱ	Product identifier	D7843D07-C871-4EE5-9935-DDB6DF132CF4
MessageId	Guid ⁱ	Message identifier	324FE6B5-FB3B-47B0-AC02-E790F4B076AD
PatientGuid	Guid ⁱ	Patient identifier, the value does not expose any sensitive patient information	E22AEA88-D4D5-4CEF-B107-9498F813F98B
CaseId	integer	Case/Study identifier, the id is a database id and case details are not exposed	-2147439316
UsageDateTime	string	Date and time of the usage, UTC time	2019-11-20 07:58:51

- ⁱ Globally Unique Identifier. A GUID is a 128-bit (16 byte) number used by software programs to uniquely identify the location of a data object.

7.10.2 RayStation offline reporting

Offline reporting involves a series of steps which revolve around transferring files back and forth between the RayStation License agent and the Report station. The Report station is a machine with internet connection that will host a License agent service proxy. The required cadence of reporting is defined during installation and RayStation will notify the user when it is time to report license usage. License usage must regularly be reported to RaySearch for RayStation to continue to function.

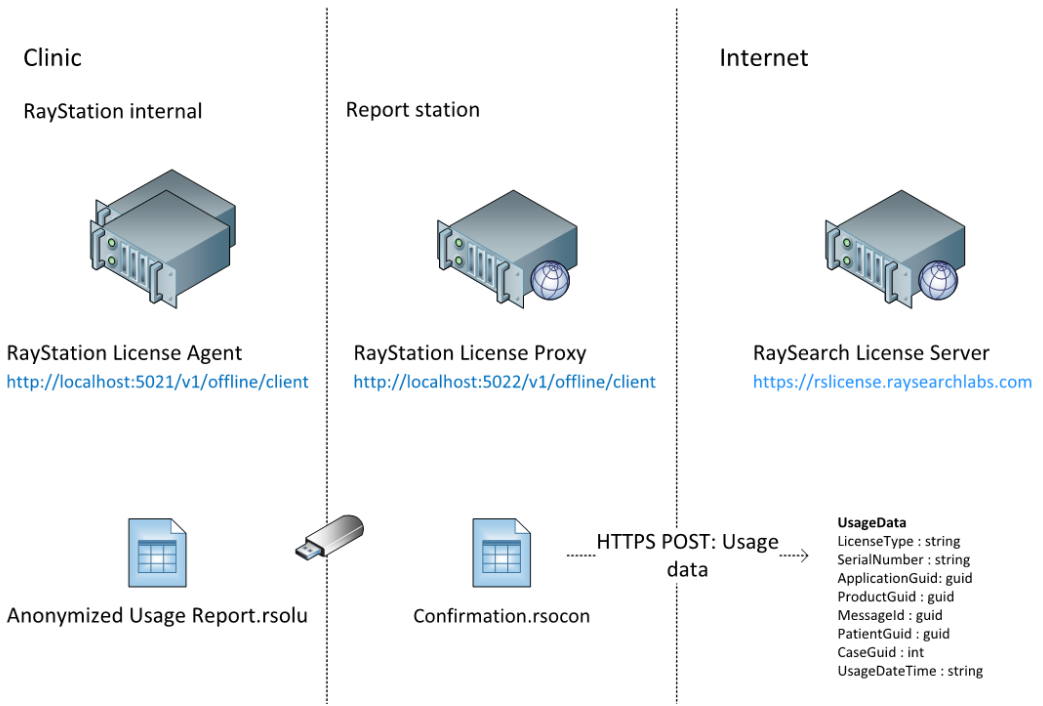


Figure 4. Configuration of offline site licenses

How to report license usage

1. On the RayStation License agent:
 - a. Attach the transfer medium, for example a USB stick.
 - b. One-time setup: Open a browser and enter *localhost:5021/v1/offline/client*. A save file dialog will appear for 'AgentClient.html'. Save the file to disk.
 - c. Open the AgentClient.html in a browser.
 - d. Click the **Download license usage file** button under the Download license usage section. A save file dialog will appear for a '.rsolu' file. Save the file to the transfer medium.
 - e. Detach the transfer medium.
2. On the Report station:
 - a. Attach the transfer medium.
 - b. One-time setup: Open a browser and enter *localhost:5022/v1/offline/client*. A save file dialog will appear for 'ServiceClient.html'. Save the file to disk.
 - c. Open the ServiceClient.html in a browser.

- d. Click the **Choose file** button under Report license usage. Select the '.rsolu' file that you previously saved to the transfer medium and then click the **Report** button. A save file dialog will appear for a file called 'confirmation.rsocon'. Save this file to the transfer medium.
 - e. Detach the transfer medium.
3. On the RayStation License agent:
 - a. Attach the transfer medium.
 - b. Open the file AgentClient.html.
 - c. Click the **Choose file** button under Confirm reported license usage. Select the 'confirmation.rsocon' file that you previously saved to the transfer medium and then click the **Confirm** button. A message indicating that the confirmation has been accepted should appear in the **Result** column on the right-hand side.
 - d. Start a new instance of RayStation and verify that no warnings related to reporting license usage are shown.

8 HIGH PERFORMANCE COMPUTING (HPC)

With the high computational profile of Plan Explorer in RayStation 11A, RaySearch Laboratories have created a HPC structure to enable increased hardware to reduce the result times for Plan Explorer.

This chapter includes the requirements of the HPC environment if Plan Explorer is to be used. For any questions, please contact your RaySearch Account manager.

8.1 HIGH PERFORMANCE COMPUTING (HPC) SOFTWARE

With the introduction of Plan Explorer, a number of treatment machine/technique combinations can be defined for a patient with a specific set of clinical goals. The different plans are then computed and evaluated with regards to how well they fulfil these goals. To handle the computation of these explorations in the most efficient manner, the optimizations are separated and run in parallel on a compute cluster. RayStation 11A utilizes the Microsoft 2012 R2 HPC Pack as cluster software.

Note: *It is recommended that compute nodes are all of the same specification.*

The following illustration gives an overview of the RayStation 11A HPC computer cluster solution:

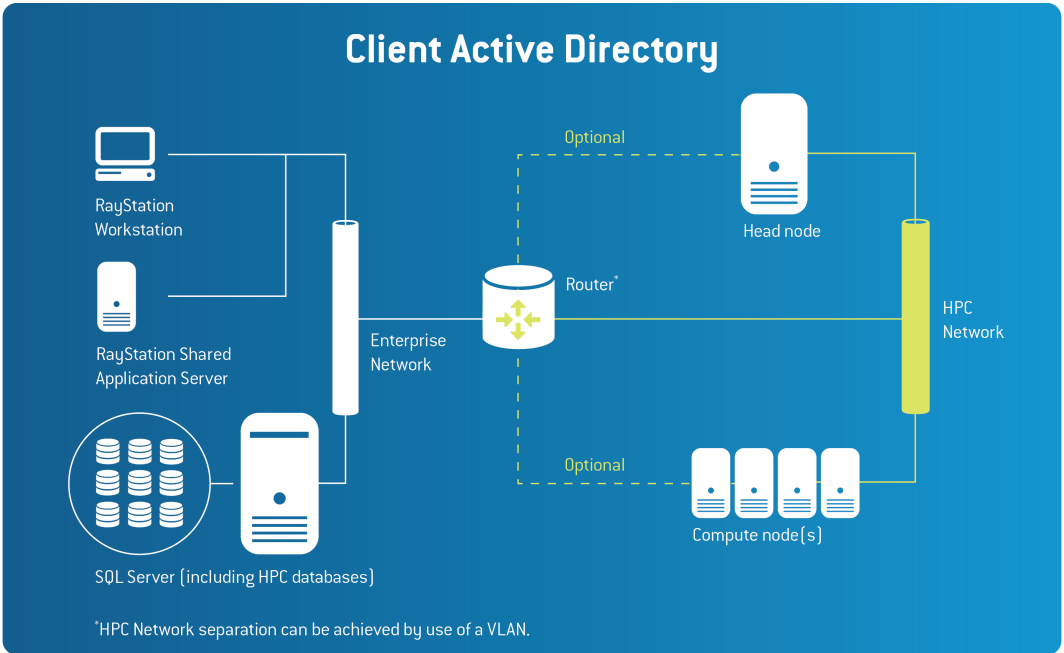


Figure 5. Overview of RayStation 11A HPC computer cluster solution.

8.2 DETAILED REQUIREMENTS

The paragraphs in this section explain the requirements and server roles for the cluster.

Head node

The Head node provides management and job scheduling services to the cluster. Where Virtual machine infrastructure is available this can be considered for hosting the Head node.

The following table lists the recommended hardware specifications for the Head node:

Aspect \ Installation Type	Description
Processor	1x Intel 5122 or similar
RAM	32 GB RAM (this will allow for possible future additional functions)
HDD	2x 240 GB SSD (RAID 1)
Network	At least 2x 1 Gb/s connections are required for the recommended installation approach. If a 10 Gb/s network is available this can be considered.

HPC Compute nodes

This is where the computation of the exploration(s) created in RayStation are run. The aim of the specification for HPC Compute nodes is to provide as much CPU processing as possible and provide an appropriate amount of GPU to balance performance.

The following table lists the recommended hardware specifications for a Compute node¹:

Aspect \ Installation Type	Description
Processor	2x Intel 6254
RAM	256 GB RAM
HDD	2x 400 GB SSD (RAID 1)
Graphics card	2x NVIDIA Quadro RTX6000. A dual RTX5000 can be also be considered, however, note that if using a dual RTX5000 the computations would be 10%-15% slower.

Operating Systems

All HPC nodes (head and compute) require Windows Server 2012 R2.

Where available volume licensing of Windows Server is more convenient for the compute nodes to make it simple to re-image them automatically.

SQL Server

The HPC solution supports SQL Server 2014 or higher. It is recommended to use the same database instance as RayStation to host the five HPC databases. These should be included in weekly backup maintenance tasks.

Active Directory requirements and recommendations

Active Directory is required for HPC. The Head and Compute nodes must be joined to the same domain as RayStation. While documentation from Microsoft indicates that Windows Server 2012 functional level is required, we have successfully tested the RayStation deployment of HPC with an Active Directory functional level of Windows Server 2008 R2.

It is recommended to create an Organizational Unit (OU) for all HPC related computer and service accounts.

¹ This hardware specification may not be available off-the-shelf from all vendors. Contact your RaySearch Account Manager for more information.

Networking

The Head and Compute nodes are connected to the enterprise network and to an additional private HPC network. All HPC administrative and task related traffic flows through the private network after receipt from RayStation.

This private network allows the Head node to automatically provision Compute node(s) from bare-metal using Windows Deployment Services (WDS), DHCP and PXE-boot in the preferred installation option. This private network can be achieved by a VLAN.

There are other networking alternatives available for an HPC installation. Please contact your RaySearch Account Manager for more information.

Firewall configuration

The installation of HPC also configures the Windows Firewall to open the ports needed.

For detailed info about ports see:

[https://technet.microsoft.com/en-us/library/ff919486\(v=ws.11\).aspx](https://technet.microsoft.com/en-us/library/ff919486(v=ws.11).aspx)

HPC Job Management

The status and progress of jobs can be tracked using HPC Pack R2 Job Manager. This tool can either be installed on a client with connectivity to the Head node and with relevant permissions, or it could be installed in a Citrix environment and published to the relevant personnel from there.

9 MICROSOFT REFERENCE INFORMATION

If you are not familiar with all Microsoft technologies, significant information is available from <https://docs.microsoft.com/en-us/learn/>.

Information related to RayStation:

Active Directory: <https://docs.microsoft.com/en-us/learn/modules/introduction-to-ad-ds/>



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