

RAYPLAN 10B

System Environment Guidelines



RayPlan
RayStation

10B

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Disclaimer

For information on functionality not available for regulatory reasons, see the Regulatory Information in the RayPlan 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 RayPlan. A summary of the ongoing maintenance tasks that should be considered from an IT management perspective is also included.

Any recommendations in this guideline shall be in adherence with *RSL-D-RP-10B-IFU, RayPlan 10B 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.
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
PII	Personally Identifiable Information is any information relating to an identifiable person or equivalent terms relating to personal data such as GDPR.
SAN	Storage Area Network

Definitions, acronyms and abbreviations	Meaning
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 RayPlan Launcher or in the RayPlan Deployment Package.

- *RSL-D-RP-10B-IFU, RayPlan 10B Instructions for Use*
- *RSL-D-RP-10B-DCS, RayPlan 10B DICOM Conformance Statement*
- *RSL-D-RP-10B-SEAT, RayPlan 10B System Environment Acceptance Test Protocol*

2 HARDWARE ENVIRONMENT

Introduction

RayPlan operates within a Microsoft Windows environment with Microsoft SQL Server hosting information relating to the clinic, machines and patients in separate databases. The RayPlan client machine obtains the relevant information from the databases. There is also an additional resource database which defines RayPlan Systems. A System is made up of a single clinic and machine database and one or more patient databases.

Additionally, information can be queried, imported or otherwise from application entities (e.g., PACS) using the DICOM format (see details within the *RSL-D-RP-10B-DCS, RayPlan 10B DICOM Conformance Statement*). This information is saved to the relevant database(s).

RayPlan Client at desk

The RayPlan software is installed on a machine that is located at the users' "desk".

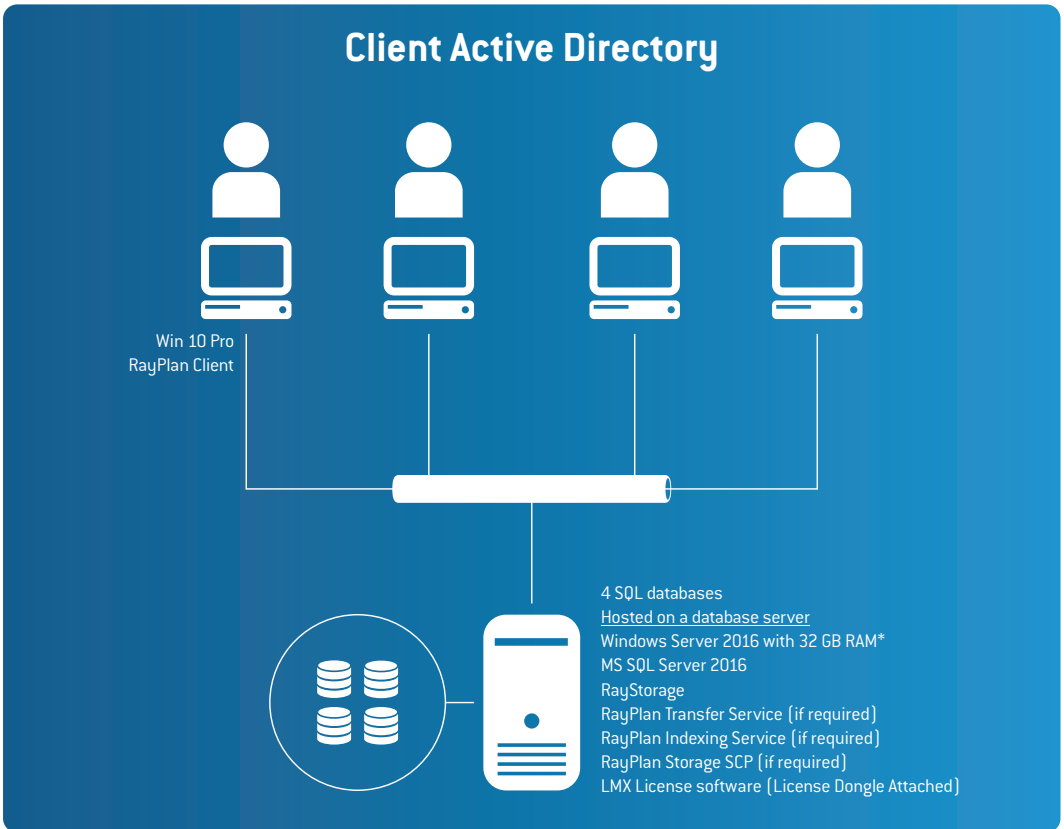


Figure 1. The RayPlan Client at desk. **Note that 64 GB RAM is preferred where possible. RAM DIMMs should be installed to provide optimal RAM usage, i.e., units of 6 for Intel Xeon Scalable (48/96 GB) or units of 4 for Intel Xeon E5 (32/64 GB).*

3 RAYPLAN MACHINES

Introduction

The sections in this chapter should be considered in relation to physical RayPlan workstations.

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

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3.1 RAYPLAN CLIENT MACHINES

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

Processor(s)

For RayPlan systems that will not include RayArc (VMAT) operations a single 6 core, 3.0GHz or higher processor is sufficient. Where RayArc (VMAT) is to be used a 2nd processor of similar specification should be included. 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 RayPlan 10B. For enterprise operations, RaySearch recommends the NVIDIA Quadro cards, principally based on reliability and recommendations from NVIDIA.

Graphics card (GPU) for accelerated computations

In certain RayPlan 10B configurations RayPlan can run certain aspects of the software computations 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
NVIDIA RTX8000 (active)	452.39
NVIDIA RTX8000 (passive)	452.39
NVIDIA RTX6000 (active)	452.39
NVIDIA RTX6000 (passive)	452.39
NVIDIA RTX5000	452.39
NVIDIA P6000	452.39
NVIDIA P5000	452.39
NVIDIA M6000 24 GB	452.39
NVIDIA M6000 12 GB	452.39
NVIDIA M5000	452.39

Note: *Additional validations may have been performed. Certificates are available from support@raysearchlabs.com. Validation of running RayPlan 10B using NVIDIA Quadro 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 RayPlan.*

Please see reference information within the *RSL-D-RP-10B-IFU, RayPlan 10B Instructions for Use* regarding GPU implementation.

Display

The recommended resolution for the display used together with RayPlan 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).

HDD

The main considerations with respect to HDD for client machines are: hosting the OS (including swap file, drivers, etc.), RayPlan 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 RayPlan clients and the SQL server is within a separate VLAN or similarly segregated network to avoid contention issues.

OS

It is recommended to use Windows 10 Professional or higher to host RayPlan 10B client software.

Windows 10 Professional should be a minimum of version 20H2.

3.2 STAND-ALONE MACHINES

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

4 SQL SERVERS

Introduction

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 RayPlan 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 RayPlan 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

Software

As a guideline for storage, 1 GB per patient can be taken as a reasonable indicator. This may change with 4DCT image sets and is also directly related to the nature and number of image sets added during treatment.

Processor(s)

Single 4 core 3.47 GHz, Xeon CPU or better.

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 SQL Databases, however a basic NVIDIA Graphics card may be considered for DR purposes.

RAM

32 GB of DDR3 ECC 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).

RAM requirements depend mainly on the profile of patients.

HDD

Entry point: OS: 200 GB SSD (RAID 1) Data: 2 TB or higher (RAID 10).

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

Minimum 1 Gb/s Ethernet (With teaming considered).

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-RayPlan client related activity should not use the same communications routes as RayPlan Client communications.

OS

Windows Server 2019 or 2016 or Windows Server 2012 R2 can be used for hosting the RayPlan SQL software.

SQL Server Software

RayPlan 10B is validated for Microsoft SQL Server 2016 SP2 hosting the databases. Microsoft SQL Server 2019, Microsoft SQL Server 2017, Microsoft SQL Server 2014 SP3 and Microsoft SQL Server 2012 SP4 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: *MSSQL Server 2012 may no longer be supported in upcoming releases of RayPlan.*

5 IT CONSIDERATIONS AND MAINTENANCE

Introduction

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

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

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5.1 GENERAL

Power options

The Microsoft Power Options (in the Windows Control Panel) for machines running RayPlan 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 RayPlan 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 and DICOM Storage SCP 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 RayPlan software or hardware is updated or in any way altered, the RayPlan System Environment Acceptance Test shall be performed (*RSL-D-RP-10B-SEAT, RayPlan 10B System Environment Acceptance Test Protocol*).

Disaster Recovery (DR) strategies

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

5.2 RAYPLAN STORAGE SCP SERVER

Where DICOM data is to be hosted by RaySearch software, the program can be run on the SQL server. The primary use case for the Storage SCP service is where a DICOM entity needs to "push" data to RayPlan. This is achieved by "pushing" to the service and (when configured in RayPlan) the data is available to the RayPlan users. Care should be taken regarding the port to be used by the service if any other software is installed on the machine.

5.3 THIRD PARTY SOFTWARE

Anti-Virus

Any Anti-Virus software installed on systems with RayPlan should have exemptions included for the RayPlan 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-RP-10B-IFU, RayPlan 10B 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

A PDF reader software should be installed on every machine with RayPlan to enable users to read RayPlan documentation. An example would be Adobe Reader.

5.4 ACTIVE DIRECTORY (AD)

AD requirements and recommendations

Active Directory is required for all RayPlan installations with the exception of stand-alone machines. Where Active Directory is to be installed as part of an overall RayPlan 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 RayPlan following any Active Directory maintenance.

AD groups

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

- **RayStation-Administration**¹ (access to Clinic Settings, ability to delete patients and other administrative tasks)
- **RayStation-BeamCommissioning**² (ability to commission machines within RayPhysics)
- **RayStation-PlanApproval**³ (ability to approve plans)

1 RayPlan-Administration or equivalent group name can be used with a group mapping in Clinic Settings for consistency if required.

2 RayPlan-BeamCommissioning or equivalent group name can be used with a group mapping in Clinic Settings for consistency if required.

3 RayPlan-PlanApproval or equivalent group name can be used with a group mapping in Clinic Settings for consistency if required.

It is also recommended to create a RayPlan-Users group which can be used to provide basic access to RayPlan. 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. RayPlan deployments not involving HIPAA related functionality can function within a Microsoft Active Directory Server 2008 R2 Functional level.

5.5 AD ORGANIZATIONAL UNIT

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

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

SQL Indexing

It is highly recommended that re-indexing of the RayPlan 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.

5.7 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 RayPlan 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 RayPlan 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 RayPlan 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 RayPlan clients and servers.	Yes	
	Deploy 3rd party file integrity tools to detect unauthorized file changes on RayPlan 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 RayPlan 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 RayPlan Storage Tool.</p>
	Enable SQL server AD user group authorization to limit access to sensitive data (PII, clinical data) stored in RayPlan databases.	Yes	
	Enable AD user group authorization to limit access to sensitive information through RayPlan 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 (RayPlan 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 RayPlan 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	

5.8 LICENSING OF THIRD PARTY SOFTWARE

Obtaining licenses for the Operating System and other supporting software such as SQL related to RayPlan 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

5.9 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).

6 MICROSOFT REFERENCE INFORMATION

If you are not familiar with all Microsoft technologies, significant information is available from <https://mva.microsoft.com>.

Information related to RayPlan:

Active Directory: <https://mva.microsoft.com/en-US/training-courses/understanding-active-directory-8233>

SQL Server: <https://mva.microsoft.com/en-US/training-courses/sql-database-fundamentals-16944>



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