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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RaySearch Laboratories AB (publ) including its subsidiaries is hereafter referred to as RaySearch.
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-10A-IFU, RayPlan 10A 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

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<tr>
<th>Definitions, acronyms and abbreviations</th>
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<tr>
<td>AD</td>
<td>Active Directory</td>
</tr>
<tr>
<td>CPU</td>
<td>Central Processing Unit</td>
</tr>
<tr>
<td>CUDA</td>
<td>Compute Unified Device Architecture. A computing platform and API developed by NVIDIA for Graphics Processing Units.</td>
</tr>
<tr>
<td>DR</td>
<td>Disaster Recovery</td>
</tr>
<tr>
<td>ECC RAM</td>
<td>Error Correcting Code Random Access Memory</td>
</tr>
<tr>
<td>GPU</td>
<td>Graphics Processing Unit</td>
</tr>
<tr>
<td>HDD</td>
<td>Hard Disk Drive</td>
</tr>
<tr>
<td>LAN</td>
<td>Local Area Network</td>
</tr>
<tr>
<td>PACS</td>
<td>Picture Archiving and Communication System</td>
</tr>
<tr>
<td>SAN</td>
<td>Storage Area Network</td>
</tr>
<tr>
<td>SSD</td>
<td>Solid State Drive</td>
</tr>
<tr>
<td>VLAN</td>
<td>A “section” of a Local Area Network exclusively for traffic of a certain type or a certain application.</td>
</tr>
<tr>
<td>WAN</td>
<td>Wide Area Network</td>
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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-10A-IFU, RayPlan 10A Instructions for use*
- *RSL-D-RP-10A-DCS, RayPlan 10A DICOM Conformance Statement*
- *RSL-D-RP-10A-SEAT, RayPlan 10A 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-10A-DCS, RayPlan 10A DICOM Conformance Statement). This information is saved to the relevant database(s).
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 10A. 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 10A 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.

<table>
<thead>
<tr>
<th>Graphic cards</th>
<th>Windows 10</th>
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<tbody>
<tr>
<td>NVIDIA RTX8000</td>
<td>441.12</td>
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<td>NVIDIA RTX6000</td>
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<td>NVIDIA RTX5000</td>
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<td>441.12</td>
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<tr>
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**Note:** Additional validations may have been performed. Certificates are available from support@raysearchlabs.com.

Please see reference information within the *RSL-D-RP-10A-IFU, RayPlan 10A 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 10A client software.

Windows 10 Professional should be a minimum of version 1709.

*Note:* The possibility of running RayPlan on Microsoft Server 2019 is intended to be assessed during 2020.

### 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.

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

RayPlan 10A is validated for Microsoft SQL Server 2016 SP2 hosting the databases. 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:** MS SQL 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-10A-SEAT, RayPlan 10A 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-10A-IFU, RayPlan 10A Instructions for use.

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)

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.

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\(^1\) 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.
**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.

In RayPlan 10A 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 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

5.8 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).
If you are not familiar with all Microsoft technologies, significant information is available from https://mva.microsoft.com.

Information related to RayPlan:


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