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 manual
This manual describes the available options when upgrading to RayStation 11A. Clinical Systems should only be upgraded by RaySearch authorized service personnel.

In brief, the upgrade process starts with an evaluation phase followed by a transition phase. When transitioning from an evaluation phase to a transition phase, the evaluation license is replaced with a clinical license. When this transition happens a new patient database must be created.

With the RayStation Storage Tool application, there are three main options for the transition phase:

- "Based on" option 1: Batch upgrade of several patients (Recommended).
- "Based on" option 2: Parallel transition during upgrade.
- Full database upgrade.

The "based on" options creates a new database system based on an existing one. For more information about the upgrade process, see chapter 3 Upgrade process.

Contact information
Report errors or queries to the RaySearch support email: support@raysearchlabs.com.
2 PREPARATIONS

Before the RayStation installation engineer upgrades your system, perform the following preparations:

1. Verify in the RSL-D-RS-11A-SEG, RayStation 11A System Environment Guidelines that the hardware at your clinic is compatible with the new RayStation version.

2. Download the RayStation 11A deployment package:
   a. Go to: https://ftp.raysearchlabs.com
   b. Enter Login ID "RayStation876" in the login dialog. Contact RaySearch support to get the latest password.
   c. Download the latest version of the software deployment package "RayStation 11A Deployment Package SW V*.zip" and the manuals deployment package "RayStation 11A Deployment Package Manuals V*.zip". (The manuals deployment package includes all presently translated manuals.)

3. Make sure that all recent and scheduled RayStation database backups have been successfully completed, and that a copy of these backups has been transferred to another computer (or similar).

4. Review RSL-D-RS-11A-RN, RayStation 11A Release Notes and any other document you consider relevant to get an understanding of RayStation 11A.
IT staff should also review the RSL-D-RS-11A-SEG, RayStation 11A System Environment Guidelines and the System Administration section of the RSL-D-RS-11A-USM, RayStation 11A User Manual.

5. If you would like to get started with the evaluation phase, contact your account owner to request an evaluation license for RayStation 11A.

6. Identify which computer to host the evaluation databases on (a RayStation compatible SQL server needs to be installed). The deployment package should be transferred to this computer. The clinical databases should be reachable from the identified computer. For more information, see chapter 3 Upgrade process.

7. The RayStation Index Service can be used to refer to the present active clinical version in order to test upgrade of certain patients. The Index Service queries the systems identified in the Resource database that is referenced in the IndexService.Service.exe.config and can present this list to the user. This can be set up at installation. It is also recommended to create a Managed service account to run the indexing service. For more information about Managed service account, see chapter 4 IT considerations.
3 UPGRADE PROCESS

The upgrade process starts with an evaluation phase followed by a transition phase. This chapter describes the two phases as well as the available options for the transition phase.

In this chapter

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Note: RayStation sites with Machine Learning databases can view the Machine Learning databases with the same approach as the Machine databases. A new version of the machine learning models must be re-imported with RayMachine for use with a different version of RayStation.
3.1 EVALUATION PHASE

During the RayStation 11A evaluation phase, there are a few things to keep in mind:

- The databases that the upgrade should be based on, so called “based on” databases, need to be available.

- During evaluation, the previous Clinical system updates and the new evaluation systems are not synchronized. When you go clinical you need to decide if the clinical system should be based on the old RayStation version or the evaluation system.

- If a Primary SQL environment is used, the latest version of RayStation Launcher should be used by all users as early as possible so that user configuration only needs to be maintained in one version. The configuration is easier to administer in RayStation 8B and onwards as, for example, previous versions of RayStation can be launched from the RayStation Launcher [if they have been installed on the relevant computers].
3.2 TRANSITION PHASE

In the RayStation Storage Tool application, there are three main options for the transition phase:

- "Based on" option 1: Batch upgrade of several patients [Recommended].
- "Based on" option 2: Parallel transition during upgrade.
- Full database upgrade.

In this section

This section contains the following sub-sections:

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<td>3.2.3</td>
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3.2.1 “Based on” option 1: Batch upgrade of several patients

The Batch upgrade option will upgrade the selected patients to the RayStation 11A format. Data in the source database will not be changed. The main advantage with the Batch upgrade option is that the upgrade step when the patients are opened in RayStation 11A can be performed for several patients simultaneously and when it is most convenient for the user.

After the upgrade to RayStation 11A, it is no longer possible to open and save patients in the old version of the patient database. All patients are now opened in RayStation 11A and will also be saved in the RayStation 11A database.

Figure 1. “Based on” option 1: Batch upgrade of several patients.
### Advantages and disadvantages with batch upgrade of several patients

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upgrade of all data is not required.</td>
<td>Patients that are undergoing treatment planning during the upgrade will be upgraded to the new RayStation version and need to be reviewed before continuing the treatment planning.</td>
</tr>
<tr>
<td>With only one clinical version in use, it is less likely that two divergent patient records are created for the same patient (i.e., where a patient in RayStation 4.x and onwards and the upgraded RayStation version have had different updates made).</td>
<td></td>
</tr>
<tr>
<td>Provides a clear view of which RayStation version all clinical patients are being treated with at all times.</td>
<td></td>
</tr>
<tr>
<td>Previous RayStation version can be uninstalled.</td>
<td></td>
</tr>
</tbody>
</table>
### 3.2.2 "Based on" option 2: Parallel transition during upgrade

The Parallel transition option will complete the patients that are being treatment planned using the previous RayStation version, while RayStation 11A is used for treatment planning for new and re-occurring patients. A clinical license for both versions is issued for the transition period (usually 60 days).

**Note:** If parallel transition is used, it is possible to have two divergent versions of the same patient. This can be avoided by checking if the patient exists in RayStation 11A before any updates in the previous RayStation version are made.

![Diagram illustrating the parallel transition during upgrade](image-url)
## Advantages and disadvantages with Parallel transition during upgrade

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Upgrade of all data is not required.</td>
<td>• When using two clinical systems there is a possibility of having two divergent versions of the same patient.</td>
</tr>
<tr>
<td>• Patient treatment planning completes with the same RayStation version as commenced.</td>
<td>• Maintenance of two clinical RayStation versions, machine models, Clinic Settings and all associated backups are required during transition.</td>
</tr>
<tr>
<td></td>
<td>• Validation using RayStation Storage tool should be run regularly on the previous RayStation version during transition [requiring offline maintenance].</td>
</tr>
</tbody>
</table>
3.2.3 Full database upgrade

The Full database upgrade option updates all data within all databases to the latest RayStation version. Treatment planning for all patients proceeds with the new RayStation version.

Note that converting the databases will make them incompatible with the currently installed supported RayStation version. Upgrading an entire system is not recommended, instead a new system should be created based on the existing one (section 3.2.1 “Based on” option 1: Batch upgrade of several patients on page 14 or section 3.2.2 “Based on” option 2: Parallel transition during upgrade on page 16).

We recommend that a full backup of the previous RayStation version is retained by the clinic.

![Diagram of database upgrade](image-url)
### Advantages and disadvantages with Full database upgrade

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• All patients are upgraded and available in</td>
<td>• Patient data is affected during upgrade.</td>
</tr>
<tr>
<td>the new RayStation version.</td>
<td>• The upgrade can take some time (depending on database size). It is highly</td>
</tr>
<tr>
<td>• Previous RayStation version can be uninsta-</td>
<td>recommended that patient databases over 300 GB are not upgraded in full due to</td>
</tr>
<tr>
<td>lled.</td>
<td>the significant time to perform the upgrades.</td>
</tr>
</tbody>
</table>
4 IT CONSIDERATIONS

SQL database names
RayStation 11A prevents the use of certain characters within database names (and hence suffixes). This also applies to previously created databases, to be used in RayStation Storage Tool. Such databases should be reviewed and, where necessary, updates performed in order to comply with the following rules:

• Letters as defined in the Unicode Standard 3.2
• Decimal numbers from either Basic Latin or other national scripts
• The at sign (@), dollar ($), number sign (#), or underscore (_)
• Maximum 128 characters

Database names can be renamed from SQL Server Management Studio. RayStation Storage Tool Systems will need to be recreated to reference the new database names.

Configuration files, Index Services, Database backups and any other connections to the database should be reviewed/updated as part of the procedure.

Active Directory
In order to use the RayStation Indexing Service, an Active Directory service account is required.

A Microsoft Managed service account is recommended for the RayStation Indexing Service. A Managed service account requires Microsoft Active Directory Functional level of 2008 R2 or higher. The Microsoft guide regarding Managed service accounts can be found here: https://technet.microsoft.com/en-us/library/dd560633(v=ws.10).aspx

As an overall strategy we also recommend to create an Active Directory group of RayStation-Users (or equivalent in your domain) and assign User and Managed service accounts to this group. Permissions to databases etc. can be administered using this group. For example, RayStation-Administration, RayStation-BeamCommissioning, RayStation-PlanApproval and RayStation-IndexService ¹ can be added as members within RayStation-Users.

¹ RayStation-IndexService or equivalent service name that the Indexing Service will run under
**HIPAA**

For users who consider HIPAA, there is a considerable amount of additional requirements. These additional requirements should be in place before considering a HIPAA-targeted installation. Please contact RaySearch Support for more information.
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