RAYSTATION 12A

System Upgrade Options

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Disclaimer

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

Declaration of conformity

CE 2862

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

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TABLE OF CONTENTS

1 INTRODUCTION 7

2 PREPARATIONS 9

3 UPGRADE PROCESS 11

3.1 Evaluation phase 12

3.2 Transition phase 13

3.2.1 "Based on" option 1: Batch upgrade of several patients 14

3.2.2 "Based on" option 2: Parallel transition during upgrade 16

3.2.3 Full database upgrade 18

4 IT CONSIDERATIONS 21

1 INTRODUCTION

About this manual

This manual describes the available options when upgrading to RayStation 12A. 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-12A-SEG, RayStation 12A System Environment Guidelines* that the hardware at your clinic is compatible with the new RayStation version.
2. Download the RayStation 12A 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_12A_Deployment_Package_SW_V*.*.zip" and the manuals deployment package "RayStation_12A_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-12A-RN, RayStation 12A Release Notes* and any other document you consider relevant to get an understanding of RayStation 12A.

IT staff should also review the *RSL-D-RS-12A-SEG, RayStation 12A System Environment Guidelines* and the System Administration section of the *RSL-D-RS-12A-USM, RayStation 12A 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 12A.
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

This chapter contains the following sections:

3.1	Evaluation phase	p. 12
3.2	Transition phase	p. 13

RayStation 12A has introduced the ability to automatically move patients from a secondary patient database of a previous version of RayStation. This can help to reduce the amount of overall data but would require updates to backups of previous database versions, for consistency.

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.*

Note: *The additional databases that define RayStation Systems (resource database), services available to RayStation (Service database), indexed patients (Index service database) and license details (License database) are not upgraded through the same process as is described in this document. In most situations, upgrades are either not required or are performed automatically, but where necessary these databases should be upgraded during the Transition phase. It is recommended that these databases are included in the regular full backup task.*

Additional note: In RayStation 11B the Resource database underwent a "one-off" restructuring. This means that, once upgraded, any previous Indexing Services will not be able to read the resource database. Previously configured launches of other versions of RayStation (e.g. Research versions) from the same Resource database may also need to be reconfigured.

3.1 EVALUATION PHASE

During the RayStation 12A 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. A maintenance window is required to run consistencyAnalyzer/Validate prior to creation of the based-on system.
- There is no synchronization between the newly created evaluation system and the based-on system. 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:

3.2.1	"Based on" option 1: Batch upgrade of several patients	p. 14
3.2.2	"Based on" option 2: Parallel transition during upgrade	p. 16
3.2.3	Full database upgrade	p. 18

3.2.1 "Based on" option 1: Batch upgrade of several patients

The Batch upgrade option will upgrade the selected patients to the RayStation 12A 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 12A can be performed for several patients simultaneously and when it is most convenient for the user.

After the upgrade to RayStation 12A, 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 12A and will also be saved in the RayStation 12A database.

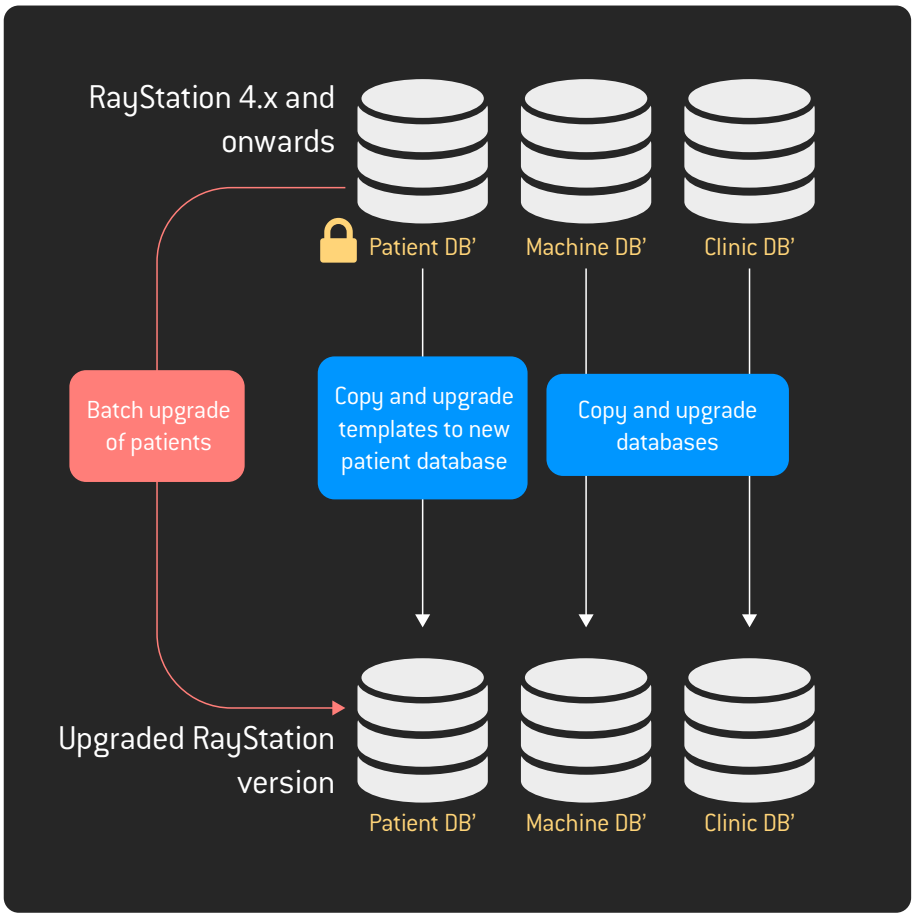

Figure 1. "Based on" option 1: Batch upgrade of several patients.

Advantages and disadvantages with batch upgrade of several patients

Advantages	Disadvantages
• Upgrade of all data is not required. • 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). • Provides a clear view of which RayStation version all clinical patients are being treated with at all times. • Previous RayStation version can be uninstalled.	• 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.

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 12A is used for treatment planning for new and re-occurring patients. A clinical license for both versions is issued for the transition period (usually 90 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 12A before any updates in the previous RayStation version are made.*

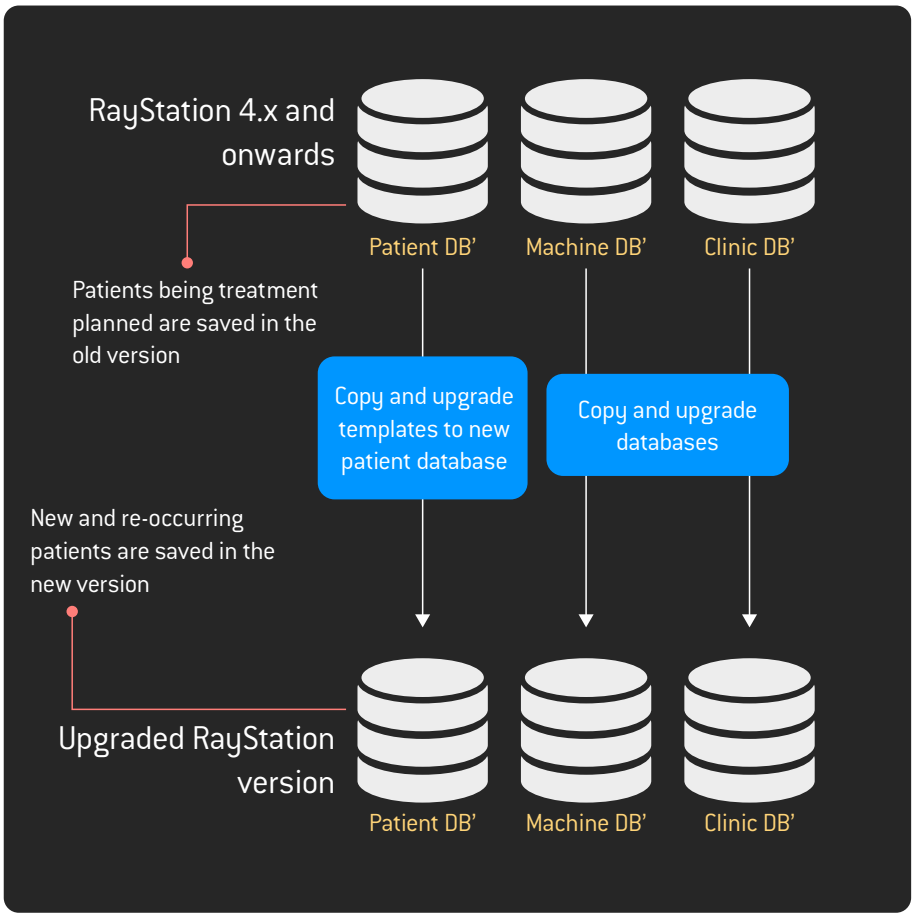

Figure 2. "Based on" option 2: Parallel transition during upgrade.

Advantages and disadvantages with Parallel transition during upgrade

Advantages	Disadvantages
• Upgrade of all data is not required. • Patient treatment planning completes with the same RayStation version as commenced.	• When using two clinical systems there is a possibility of having two divergent versions of the same patient. • Maintenance of two clinical RayStation versions, machine models, Clinic Settings and all associated backups are required during transition. • Validation using RayStation Storage tool should be run regularly on the previous RayStation version during transition (requiring offline maintenance).

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.

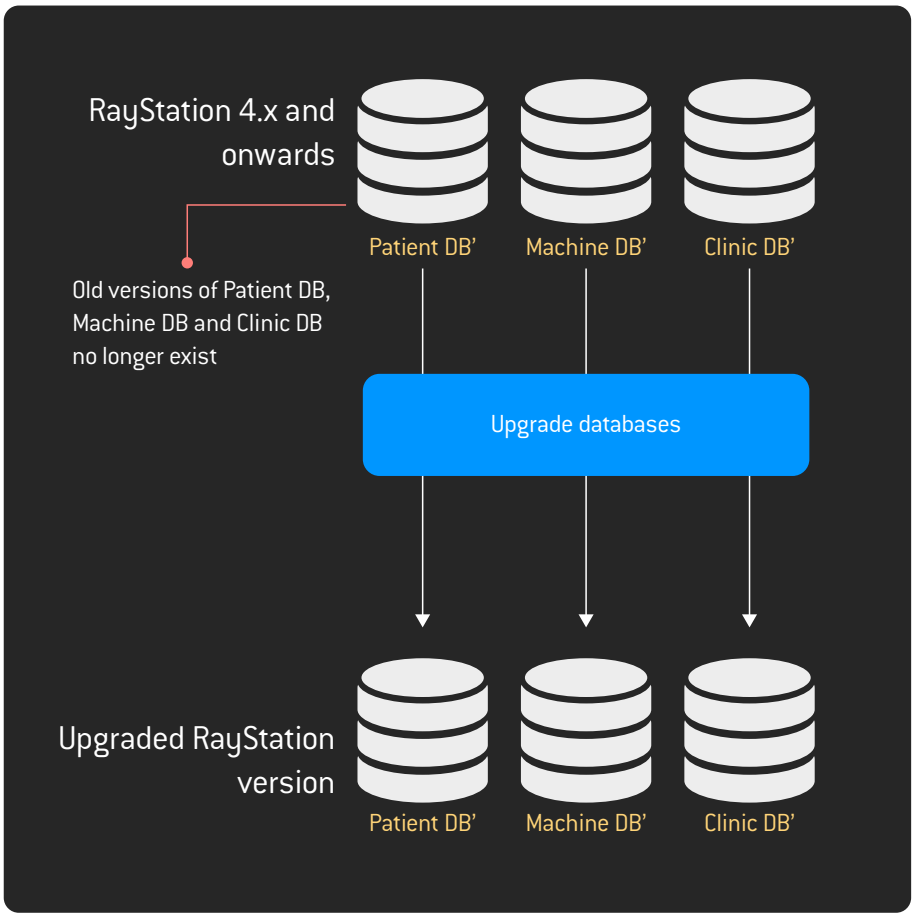

Figure 3. Full database upgrade.

Advantages and disadvantages with Full database upgrade

Advantages	Disadvantages
• All patients are upgraded and available in the new RayStation version. • Previous RayStation version can be uninstalled.	• Patient data is affected during upgrade. • The upgrade can take some time (depending on database size). Validating and upgrading large databases is time consuming and it is important to plan for maintenance windows with sufficient time. RayStation 12A has functionality to move data from old secondary databases, making full upgrade less attractive.

4 IT CONSIDERATIONS

SQL database names

RayStation 12A 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 (except the ResourceDB, LicenseDB, IndexServiceDB and ServiceDB). 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-Services [1] can be added as members within RayStation-Users.

1 RayStation-Services 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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