RAYPLAN 10A

System Upgrade Options

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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

CE 0413

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 RayPlan 10A. 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 RayPlan 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 RayPlan installation engineer upgrades your system, perform the following preparations:

1. Verify in the *RSL-D-RP-10A-SEG, RayPlan 10A System Environment Guidelines* that the hardware at your clinic is compatible with the new RayPlan version.
2. Download the RayPlan 10A 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 "RayPlan_10A_Deployment_Package_SW_V*.*.zip" and the manuals deployment package "RayPlan_10A_Deployment_Package_Manuals_V*.*.zip". (The manuals deployment package includes all presently translated manuals.)
3. Make sure that all recent and scheduled RayPlan 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-RP-10A-RN, RayPlan 10A Release Notes* and any other document you consider relevant to get an understanding of RayPlan 10A.

   IT staff should also review the *RSL-D-RP-10A-SEG, RayPlan 10A System Environment Guidelines* and the System Administration section of the *RSL-D-RP-10A-USM, RayPlan 10A User Manual*.

5. If you would like to get started with the evaluation phase, contact your account owner to request an evaluation license for RayPlan 10A.
6. Identify which computer to host the evaluation databases on (a RayPlan 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 RayPlan 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

3.1 EVALUATION PHASE

During the RayPlan 10A 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 RayPlan version or the evaluation system.
- If a Primary SQL environment is used, the latest version of RayPlan 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 RayPlan 8B and onwards as, for example, previous versions of RayPlan can be launched from the RayPlan Launcher (if they have been installed on the relevant computers).

3.2 TRANSITION PHASE

In the RayPlan 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
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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 RayPlan 10A 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 RayPlan 10A can be performed for several patients simultaneously and when it is most convenient for the user.

After the upgrade to RayPlan 10A, it is no longer possible to open and save patients in the old version of the patient database. All patients are now opened in RayPlan 10A and will also be saved in the RayPlan 10A database.

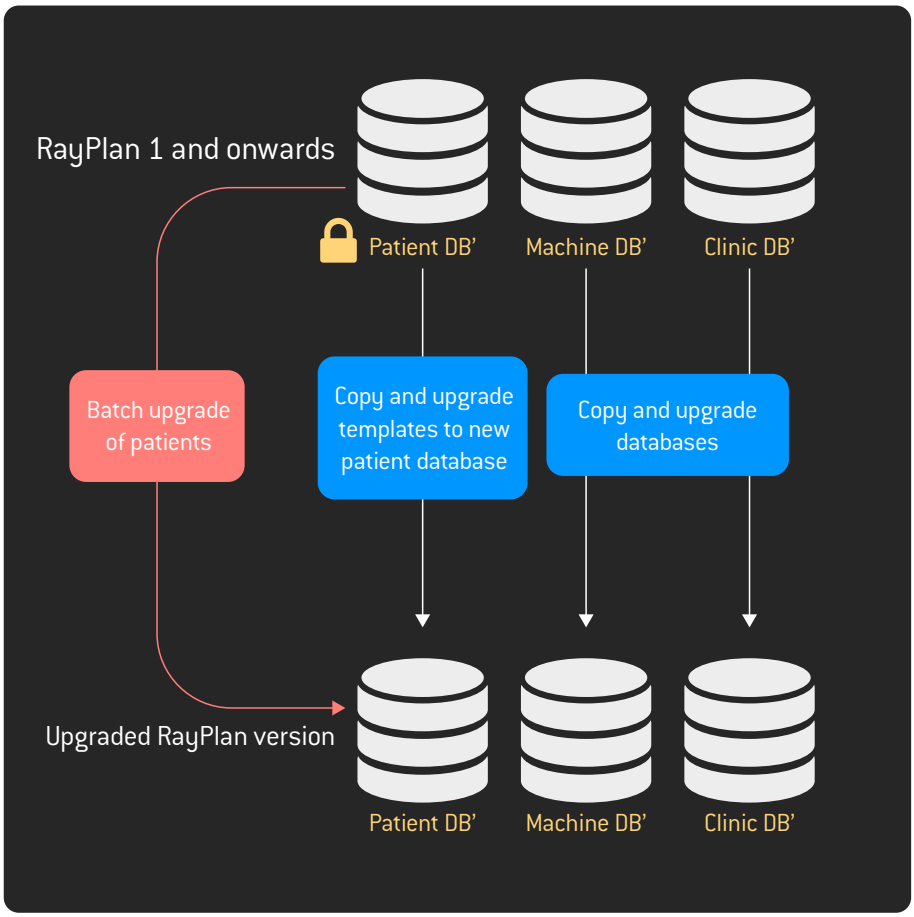

Figure 1. "Based on" option 1: Batch upgrade of several patients.

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 *RayPlan 1 and onwards* and the *upgraded RayPlan version* have had different updates made). • Provides a clear view of which RayPlan version all clinical patients are being treated with at all times. • Previous RayPlan version can be uninstalled.	• Patients that are undergoing treatment planning during the upgrade will be upgraded to the new RayPlan 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 RayPlan version, while RayPlan 10A 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 RayPlan 10A before any updates in the previous RayPlan version are made.*

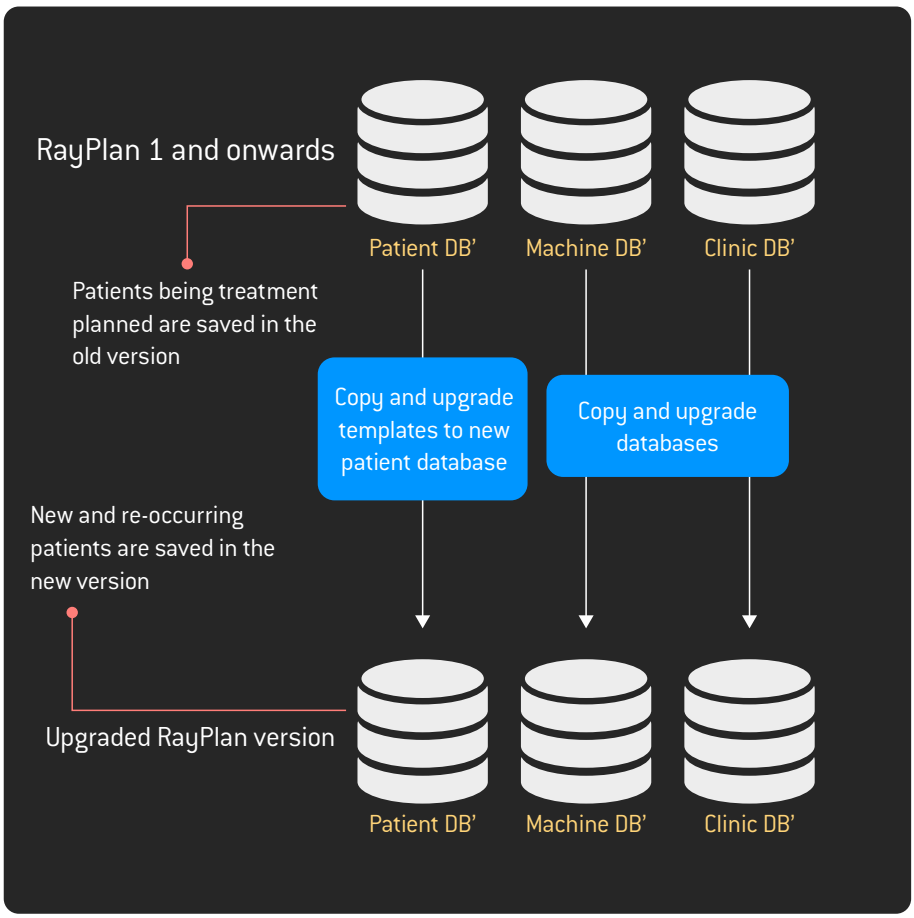

Figure 2. "Based on" option 2: Parallel transition during upgrade.

Advantages and disadvantages with Parallel transition during upgrade

Advantages	Disadvantages
• Upgrade of all data is not required. • Patient treatment planning completes with the same RayPlan 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 RayPlan versions, machine models, Clinic Settings and all associated backups are required during transition. • Consistency check should be run regularly on the previous RayPlan 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 RayPlan version. Treatment planning for all patients proceeds with the new RayPlan version.

Note that converting the databases will make them incompatible with the currently installed supported RayPlan 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 RayPlan version is retained by the clinic.

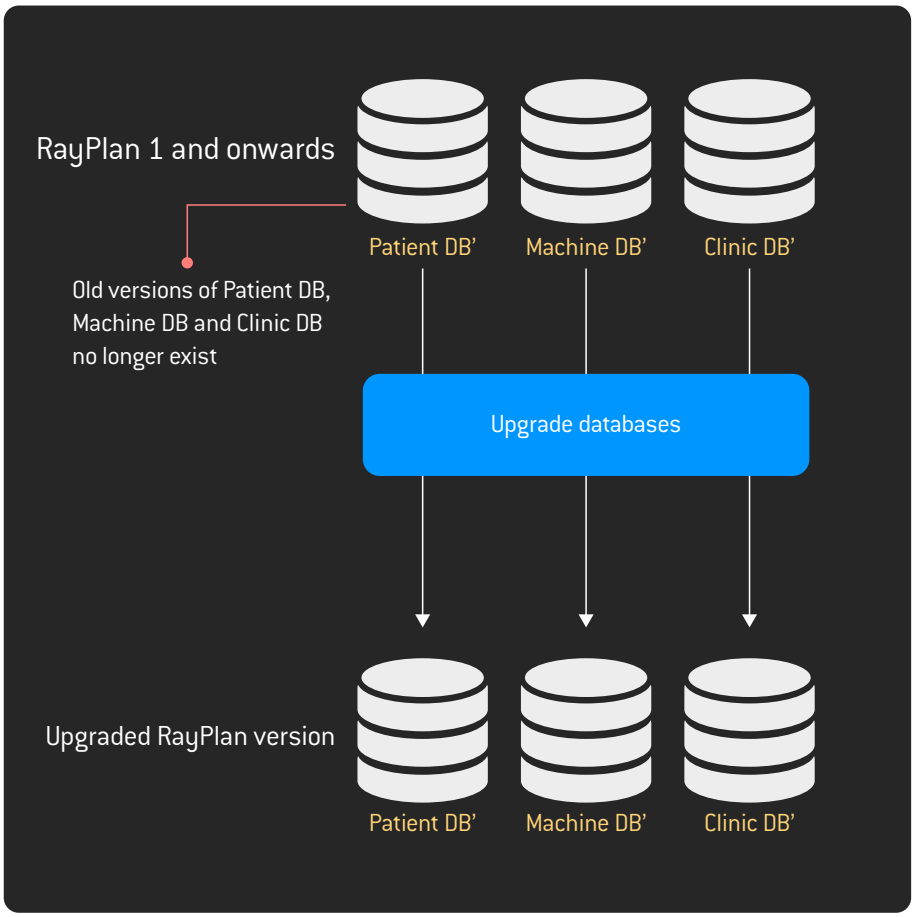

Figure 3. Full database upgrade.

Advantages and disadvantages with Full database upgrade

Advantages	Disadvantages
• All patients are upgraded and available in the new RayPlan version. • Previous RayPlan version can be uninstalled.	• Patient data is affected during upgrade. • The upgrade can take some time (depending on database size). It is highly recommended that patient databases over 300 GB are not upgraded in full due to the significant time to perform the upgrades.

4 IT CONSIDERATIONS

SQL database names

RayPlan 10A prevents the use of certain characters within database names (and hence suffixes). This also applies to previously created databases, to be used in RayPlan 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. RayPlan 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 RayPlan Indexing Service, an Active Directory service account is required.

A Microsoft Managed service account is recommended for the RayPlan 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 RayPlan-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 [1],

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

RayStation-BeamCommissioning[2], RayStation-PlanApproval[3] and RayPlan-IndexService[4] can be added as members within RayPlan-Users.

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.

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.
4 RayPlan-IndexService or equivalent service name that the Indexing Service will run under.

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