STANDARD IMAGING®

IMSURE 3D™

REF 91355

UDI: (01)00850019946543(8012)1.7.2.5384

V E R S I O N 1 . 7 . 2 U S E R M A N U A L

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Doc. 80964-00 2022/12

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1 Overview

1.1 Indications for Use

IMSure 3D (IM3D) software is intended to be used for radiation dose calculation and radiation treatment plan quality assurance in radiation therapy. IMSure 3D software uses the SciMoCa Monte Carlo dose calculation engine to calculate fast and accurate radiotherapy dose computations. IMSure 3D creates a dose calculation that can be compared against the initially calculated treatment plan created by the treatment planning system for quality assurance and plan review. IMSure 3D is not a treatment planning system and may only be used by trained radiation oncology health professionals for clinical review and judgement of radiation therapy treatment plans.

⚠ WARNING: Federal law in the U.S.A., and Canadian law, restricts the sale distribution, or use of this product to, by, or on the order of a licensed medical practitioner. This product should be used under the guidance of a medical physicist.

⚠ WARNING: Where applicable, Standard Imaging products are designed to be used with the versions of common radiation delivery devices, treatment planning systems and other common computer software products or systems used in the delivery of ionizing radiation, available at the time the Standard Imaging product is released. Standard Imaging does not assume responsibility, liability and/or warrant against, problems with the use, reliability, safety or effectiveness that arise due to the evolution, updates or changes to these products or systems in the future. It is the responsibility of the customer or user to determine if the Standard Imaging product can be properly used with these products or systems.

⚠ WARNING: IMSure 3D is not intended to be used as a primary calculation for patient treatment. Should IMSure 3D results differ from the treatment planning or other primary calculation results, the planning result discrepancy will require resolution prior to treatment.

⚠ WARNING: Conduct Acceptance and routine QA Testing. It is the responsibility of the user to conduct Acceptance Testing on the machine specified for treatment, and to conduct routine QA Testing at appropriate intervals.

⚠ WARNING: Verify all physics data. Ensure that physics data is complete and correct after entering or importing data by viewing the data screens in the Physics Data Module.

⚠ WARNING: The use of IMSure QA does not preclude the need for routine machine QA.

⚠ CAUTION: Cybersecurity is a shared responsibility between Standard Imaging and the customer. Secure use of this product is dependent upon the proper utilization of passwords, firewalls, networks, computer platforms, operating systems and data storage.

⚠ CAUTION: Back up data files. Data files should be backed up on a regular basis.

⚠ CAUTION: Protect the CD-ROM surface from fingerprints, scratches and other damage. Do not store the CD-ROM in direct sunlight or warm and humid places.

⚠ CAUTION: For professional use only. As desired by IAEA, English is the default language for labeling and manuals. If translated versions are available, resolve any differences in favor of the English versions.

1.2 Software Modules

IMSure 3D is a radiotherapy dose computation, analysis and reporting service comprising a best-in-class Monte Carlo calculation algorithm. IMSure 3D is implemented in a service-oriented client-server architecture consisting of a client; a high-performance, hardware-independent dose calculation server; and proprietary beam modeling tools. The licensable modules of the IMSure 3D software program are:

- IMSure 3D Calculate: a radiotherapy dose calculation engine.
- IMSure 3D Compare: a suite of dose evaluation, analysis and reporting tools for plan review and quality assurance.

1.3 Revision History

Date	Version	Description
02/20/2018	1.0	Original release
3/14/2018	1.1	UI changes; Added support for Varian, Elekta and Siemens conventional linear accelerators. Added features, including ROI mapping, Archiving, Gamma analysis, CT Density Tables, ROI Density, and Saved Images section. Added Lock and Unlock Template feature. Enhanced error logging and user controls. Included a beam summary table.
02/06/2019	1.2	UI Changes: Added new controls to the Slice Viewer, support for Electron Density, navigation control for Patient Report view, support for user concurrency, new email notifications, and miscellaneous UI improvements.
03/20/2019	1.2.1	Updated validation ranges for certain values.
04/23/2019	1.3.0	UI Changes: Added a full screen version of the Slice Viewer. Updated recommended settings. Added TomoTherapy treatment plan support.
07/11/2019	1.4.0	UI Changes: Added Client Log access via worklist, Gamma per ROI display in the metrics section with accompanying legend, and support for CT Density recalculation in the plan settings.

07/17/2019	1.4.1	Updated gamma view of patients.
09/05/2019	1.4.2	Updated information regarding the Patient worklist and User Audit log.
02/07/2020	1.5.0	UI Changes: Added pagination for the Patient Worklist, support for processing 0 Gy prescription plans, instructions for the database configuration tool, and refreshed the information presented in the beam information table. Updated Gamma Legend.
04/08/2020	1.5.1	UI Changes: Dose cloud selection labels are now displayed in the slice viewer.
10/30/2020	1.5.2	UI Changes: New automation utilities for Worklist plan management, Email notifications, PDF generation, and Dose Export configuration. Additional UI changes were made to allow more visibility to the client log location, refreshed the beam information table and plan review menu.
12/30/2020	1.5.2.3330	Plan navigation menu will display Rx. Verify Systems page updated to show labels. Plan Label can now be displayed in the Worklist. The dose server will now check for license expiration with greater frequency.
07/22/2021	1.6.0	UI Changes: PDFs can now be opened in the Patient Report page. Server and database backup added to the Database Config Tool. Dose Difference range has been updated. Additionally, Electron and SRS cone plan support has been added.
07/30/2021	1.6.0.3650	Electron & SRS cone information added to the Review page header and Beam Information Table.
01/14/2022	1.7.0	ZAP-X treatment machine support added to the list in the Treatment Plan Type Compatibility section. Users can now access the Settings button from to the Template Editor page. Updated Header and Beam Information Table with ZAP-X support.
07/09/2022	1.7.1	Removed Internet Explorer support. Updated default global settings password and delivery device section.
12/10/2022	1.7.2	Improved logging for PDF generation. Integrated a more robust solution for users experiencing “bounded_coordinates_system_maker” issues. Fixed how electron plans parse information contained in ApplicatorIDs tags

1.4 Disclaimer

This User Guide is intended to provide a general overview and instructions for use of the IMSure 3D software. It is provided without warranty of any kind, either express or implied. Radialogica assumes no liability for use of this document if any unauthorized changes to content or format are made. Users should follow the instructions, warnings, and cautions in the guide when using Radialogica software.

Please contact Radialogica Customer Support if you have additional questions:

Tel: +1 (800) 515-9132 x999
Email: support@radialogica.com

2 Getting Started

2.1 Recommended System Requirements

The following are the minimum recommended specifications* for the server on which IMSure 3D software will be installed:

CPU	x64-based processors 4C/8T, 1.4 GHz or faster
RAM	12 GB of RAM
Free Hard Disk Space	20 GB (Installation)
Operating System	Windows** Server 2012 R2 Standard or newer with IIS enabled
Software	.NET 4.6.2, .NET 3.5 (Windows Server 2016+)
	IIS
Database	Microsoft SQL Server 2012 Express or newer
Monitor	Medical grade with minimum native display resolution of 1024x768 and 32-bit color
Input Device	Standard keyboard and wheeled mouse
Language	English (US) or English (UK)

*Minimum specifications will allow users to run typical patient data using a “Fast” Minimum Uncertainty setting with a grid voxel size of 3mm x 3mm x 3mm.

For optimal system performance, the following are the recommended specifications for the server on which IMSure 3D software will be installed:

CPU	x64-based processors 8C/16T, 1.4 GHz or faster
RAM	20 GB of RAM
Free Hard Disk Space	20 GB (installation)
Operating System	Windows** Server 2012 R2 Standard or newer with IIS enabled
Software	.NET 4.6.2, .NET 3.5 (Windows Server 2016+)
	IIS

Database	Microsoft SQL Server 2012 Standard or newer
Monitor	Medical grade with minimum native display resolution of 1024x768 and 32-bit color
Input Device	Standard keyboard and wheeled mouse
Language	English (US) or English (UK)

**Windows is a registered trademark of Microsoft Corporation.

2.2 Browser Compatibility

The IMSure 3D portal can be accessed by any computer that is connected to your network using one of the following Web browsers:

- Google Chrome
- Mozilla Firefox
- Microsoft Edge

2.3 Delivery Device Compatibility

IMSure 3D is compatible with plans designed for Varian, Elekta, Siemens, Accuray, ZAP-X, and CyberKnife delivery devices.

2.4 Treatment Planning System Compatibility

IMSure 3D requires input from a treatment planning system that can transmit CT images, structure sets, RT-Dose and RT-Plan using the DICOM-RT format. IMSure 3D requires plan and report .XML files for CyberKnife treatment plans. Treatment planning systems that generally support DICOM-RT export include Eclipse, Pinnacle, XiO, Monaco, RayStation, MultiPlan, PrecisePlan and Oncentra.

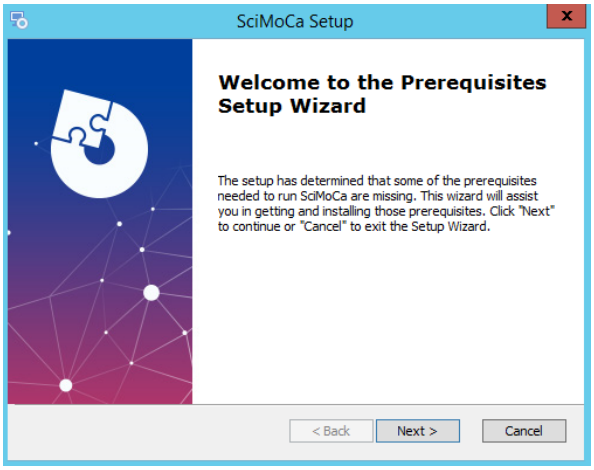
2.5 Treatment Plan Type Compatibility

IMSure 3D calculates dose for 3D conformal, IMRT, VMAT, SRS, SRS cones, SBRT (MLC-shaped treatment fields for photon plans), TomoTherapy, Halcyon, Electron, ZAP-X, and CyberKnife (cones, Iris, and MLC) plans. The following requirements are stipulated:

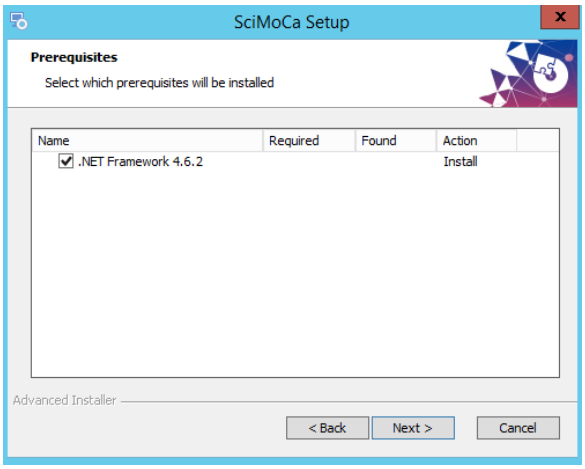
- All beams of a treatment plan are assumed to be delivered by the same treatment machine.
- All control points of a single beam are assumed to be delivered with the same beam energy.
- DICOM plans that do not adhere to these stipulations are rejected.

3 Software Installation

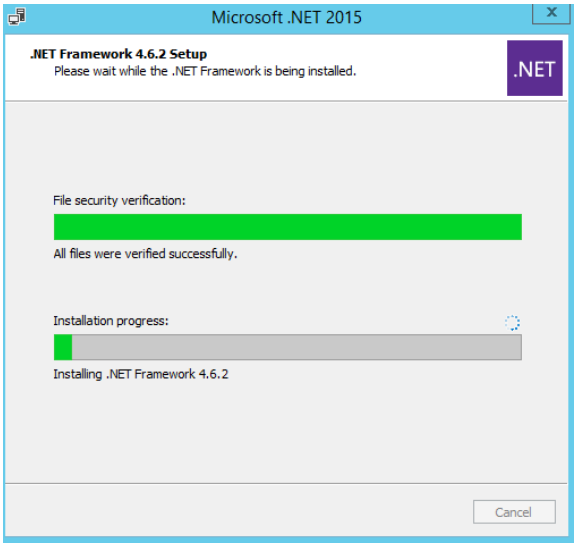
Open and run the electronic IMSure 3D Installer. The installation process should start automatically. The application will verify that the supported software .NET Framework 4.6.2 is installed on the computer. If the supported .NET Framework 4.6.2 is not installed, the application will prompt the following dialog for installing .NET Framework 4.6.2:



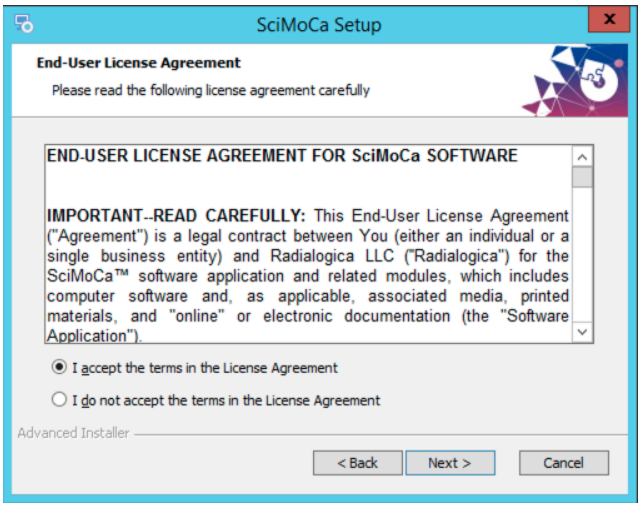
Click *Next* and the following dialog will identify the prerequisite of .NET Framework 4.6.2 must be installed. Click *Next* to continue.



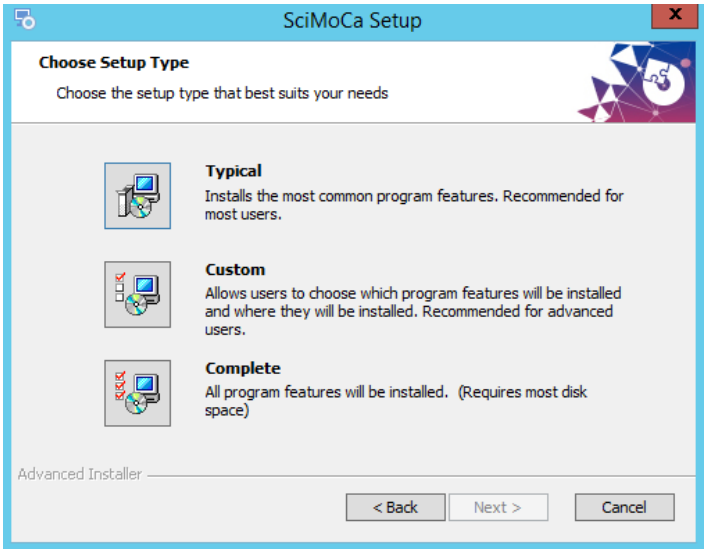
Click *Next* and the dialog will show progress for the installation process.



After .NET Framework 4.6.2 has been installed, the computer will reboot. Upon logging back in, IMSure 3D installer will resume. When the install resumes the EULA will be displayed. Accept the terms and click *Next*.



Accept the terms and clicking *Next* will present you with the following dialog:



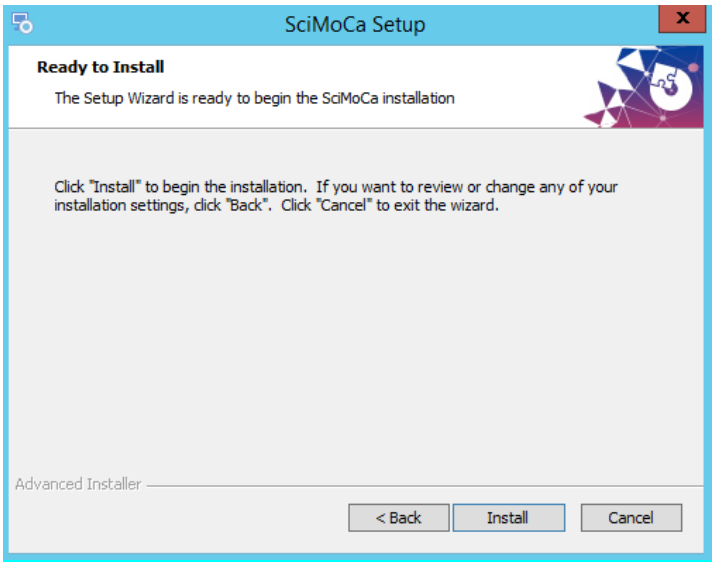
Selecting *Complete* will install both SciMoCa Calculate and SciMoCa Compare.

Selecting *Typical* will install only SciMoCa Calculate.

Selecting *Custom* will provide installation options for:

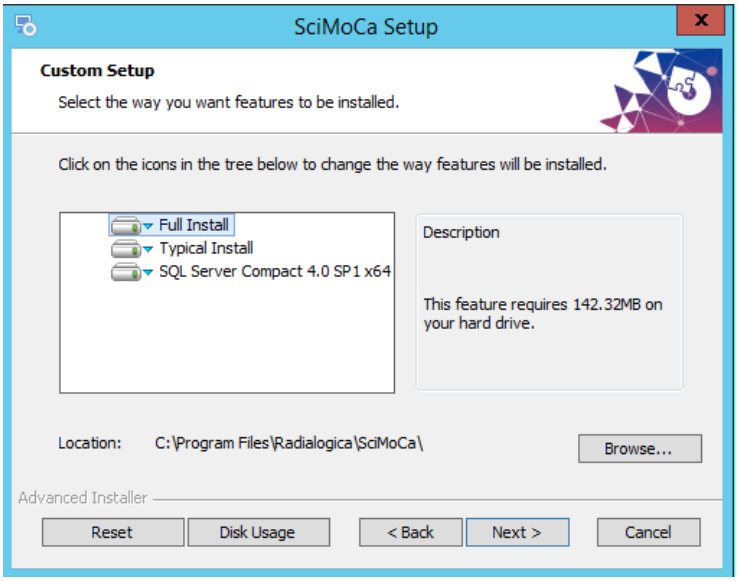
1. SciMoCa Calculate only
2. SciMoCa Compare only
3. SciMoCa Calculate and SciMoCa Compare

After making a *Typical* or *Complete* installation selection, clicking *Next* will present you with the following dialog:

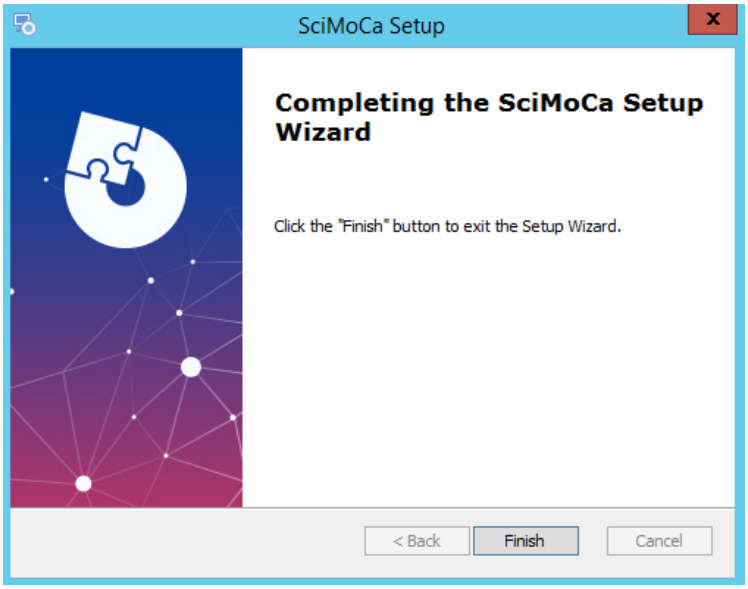


Click *Install* to initiate the installation process. During this process, the installer will check to ensure that all necessary components are installed.

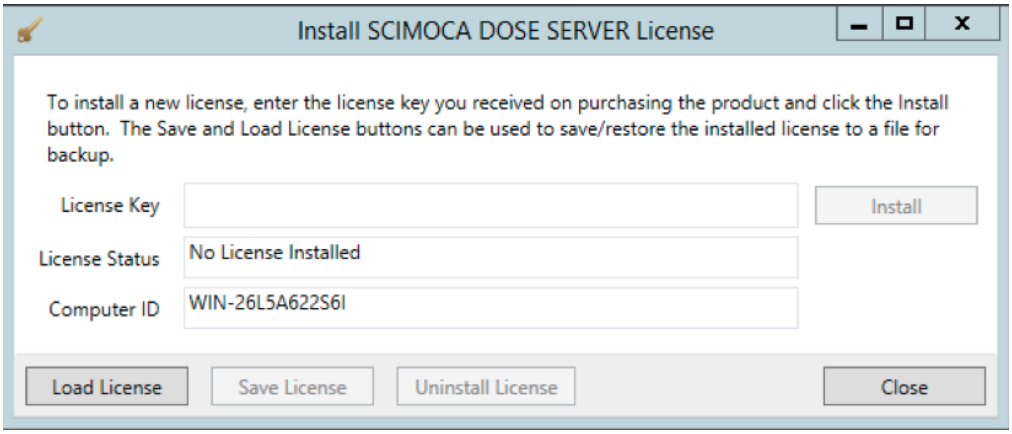
If you chose a *Custom* installation selection, clicking *Next* will present you with the following dialog:



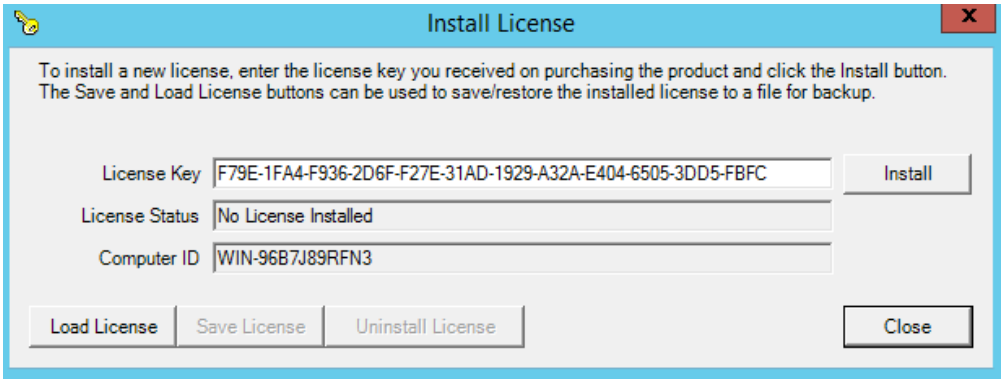
Upon completion of the installation process you will be presented with the following three dialog indicating a successful installation:



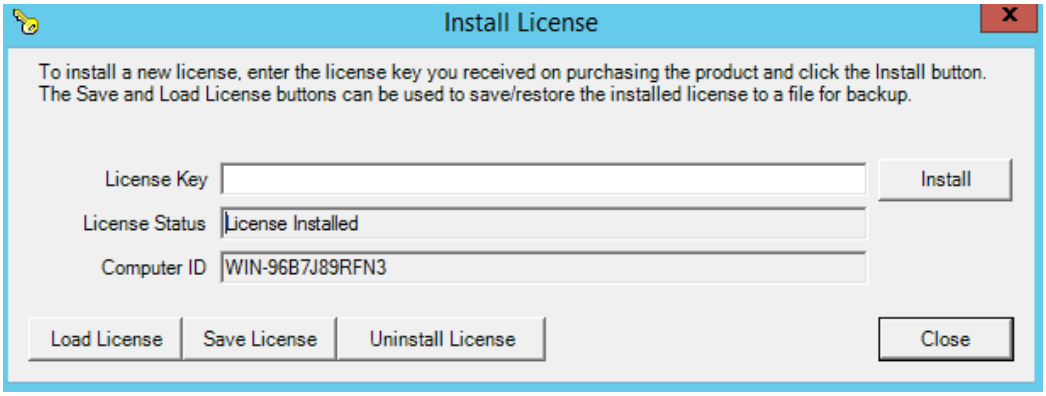
For installations with SciMoCa Calculate, after you click *Finish* you will be prompted to enter a license key for the Dose Server. Enter your license key into the text field and click *Install*.



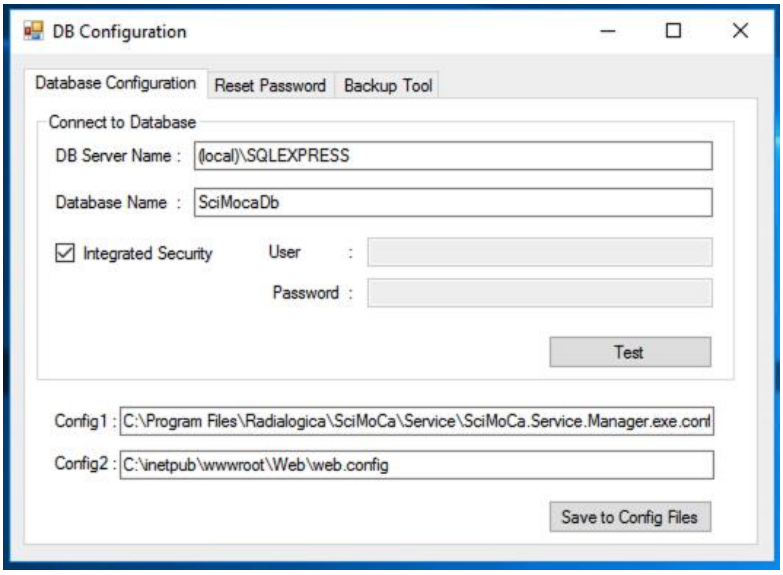
For installations with SciMoCa Compare, after you click *Finish* you will also be prompted to enter a license key for the reporting service. Enter your license key into the text field and click *Install*.



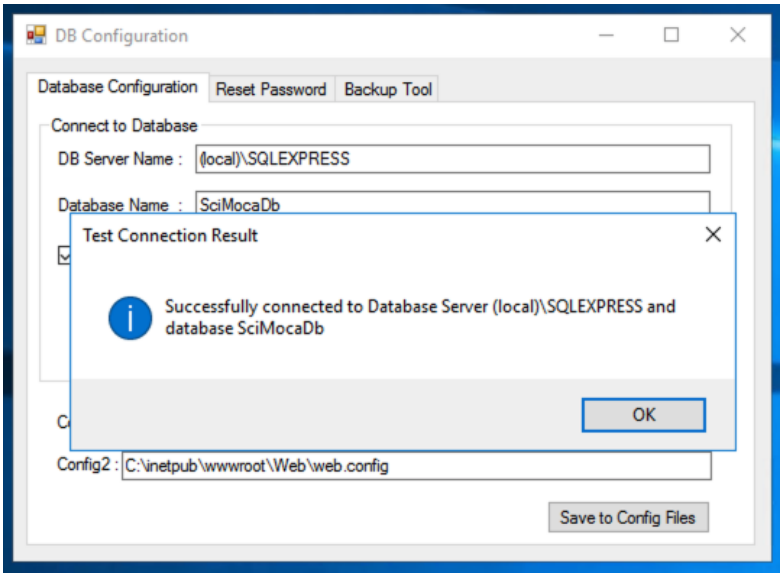
Once the application has successfully accepted the license(s), the License Status will change to *License Installed*. Click *Close* in each license window to complete the license portion of the installation.



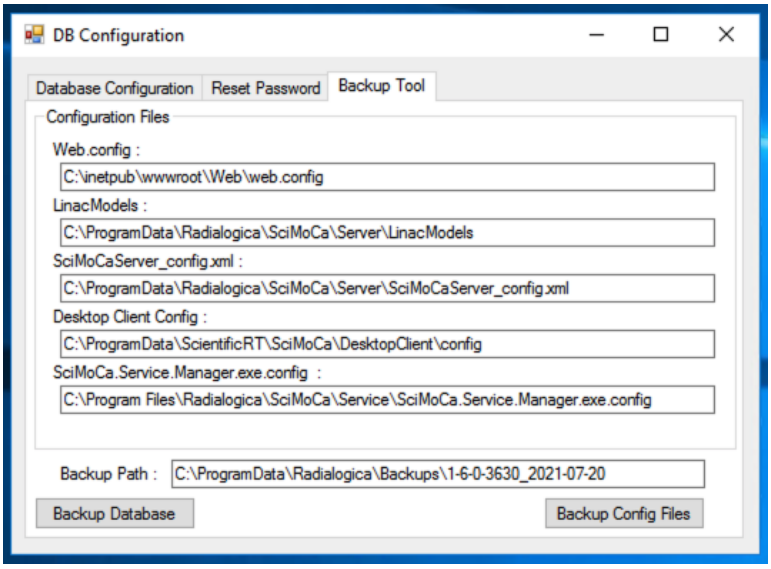
After closing the windows, you will then be shown the Database Configuration Tool. Use this tool to configure the IMSure 3D Database connection parameters.



Once editing has been completed, click on *Test* to verify that it can connect to the database.



If the connection result is successful, click *OK* to close the test window and then click *Save to Config Files* to complete the database configuration. Once completed, you may close the dialog window to conclude the installation or configure the Backup Tool section. The Backup Tool section will allow the user to save server files and the database to a specified folder.



Upon successful installation of IMSure 3D:

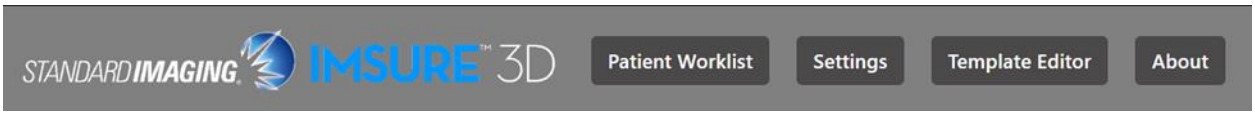
- Ensure that SciMoCa service manager is running in the Task Manager
- Ensure that SciMoCa server is running in the Task Manager
- Ensure the existence of pre-loaded plan evaluation templates
- Run SQL Server Management Studio (SSMS) and verify that there is a IM3DDb database with tables in it.
- Open up a web browser and navigate to http://localhost - the IMSure 3D website should display.

4 Home Screen

After logging into the IMSure 3D portal you will land on the IMSure 3D home page. Presented within the home page are the menu bar, patient worklist and report panel.

4.1 Menu Bar

The menu bar is displayed on the top of the IMSure 3D home page. The menu bar allows for viewing of basic information and navigating to different screens in IMSure 3D. From left to right, the elements of the menu bar are:



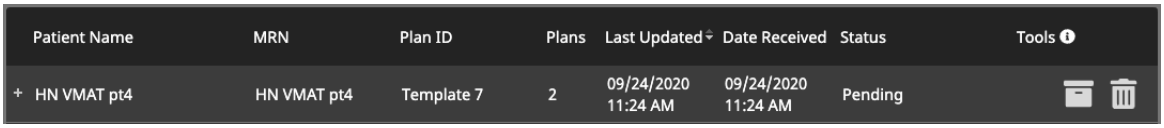
- **Patient Worklist:** Clicking *Patient Worklist* will display or reload the patient worklist.
- **Settings**: Clicking *Settings* allows you to view and edit global configuration settings (See Section 5 – Global Settings).
- **Template Editor:** Clicking *Template Editor* will present a library of plan evaluation templates. The Template Editor is used to create, edit, and delete evaluation templates used by IMSure 3D for plan evaluation purposes. See Section 6 for template management within the Template Editor.
- **About**: Clicking *About* will display information about the current installation of IMSure 3D including:
    - Software version number
    - Software Manufacturing Date
    - Information related to regulatory compliance

4.2 Patient Worklist

The patient worklist is presented below the top menu bar. New patients and new plans are automatically added to the patient worklist following completion of a dose calculation by IMSure 3D.

To initiate a dose calculation, the treatment plan must be exported from the treatment planning system to the designated IMSure 3D export location (the "DICOM Incoming Top Folder" referenced in the *Directories* tab in the *Setup* section of the *Global Settings* menu). Dose calculation requests will automatically be queued and processed by IMSure 3D, and the new patient or plan will appear on the worklist once the calculation is complete.

Patients may have multiple plans. The patient row can be expanded to view all plans for that patient by clicking the plus sign to the left of the patient's name. You can also click anywhere in the row of the patient to display all plans for the patient.



The patient worklist displays the following data elements for each patient on the worklist:

- ***Patient Name***: Displays the patient name taken from the DICOM files.
- ***Patient MRN:*** Displays the Patient ID taken from the DICOM files.
- ***Plan ID:*** Displays either the Plan Name or Plan Label taken from the DICOM files.

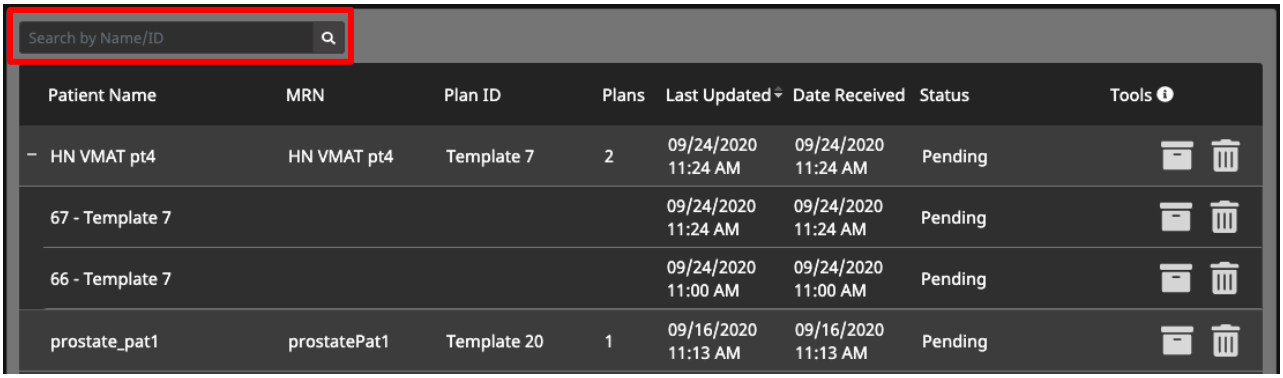
  Note: Plan Name is displayed by default. To display the Plan Label, go to the <appSettings> section of the web.config file, add in the following to have the Plan Label displayed under Plan ID: <add key="WorklistPlanKey" value="PlanLabel" />.

- ***Plans***: Displays the number of treatment plans associated with a given patient; for patients with multiple plans, click on the plus icon to the left of the patient name
- ***Last updated***: Displays a timestamp that denotes the last time a Plan Summary Report was updated due to changes in plan settings and/or calculation settings.
- **Date received**: Displays a timestamp that denotes the date and time the DICOM plan file was received by IMSure 3D.
- ***Status***: Displays a message corresponding to the status of plan review; status messages include:
  - Pending – All elements were successfully loaded; plan is awaiting review.
  - Unable to process – The DICOM did not pass due to an error; plan was not loaded. An informational icon with a functional tooltip will display the last encountered error message.
  - Approved - Plan has been reviewed and approved.
  - Rejected – Plan has been reviewed and rejected.
  - Completed – All plans for a patient have been approved or rejected.

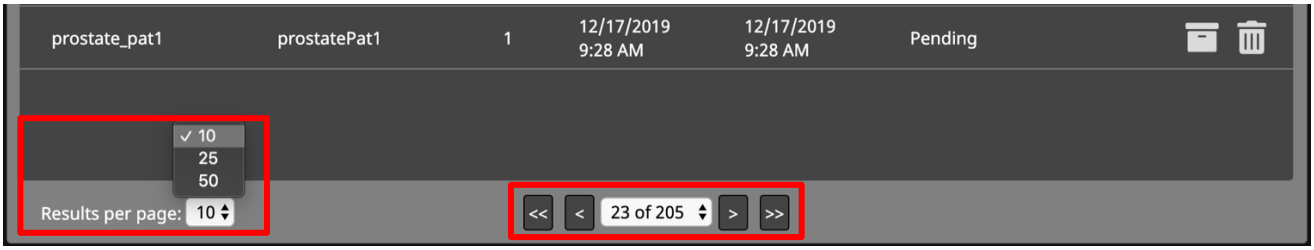
- ***Tools***: Tool icons are presented for each plan based on the status of the review
  - *Reprocessing icon:* Click the Reprocessing Icon to reprocess a plan that was unable to be processed.
  - *PDF icon*: Click the PDF icon to review a Plan Summary Report in the portable data file (PDF) format. PDF Reports are only available for approved plans.
  - *Archive*: Click the Archive icon to archive the plan or patient from the Patient List. Archived patients can be found by using the search function. Archived plans or patients may still be viewed, deleted, or unarchived using the search function.

- *Trashcan*: Click the trashcan icon to delete the patient or associated plan from the worklist.

➢ ***Search Bar***: The patient list can be filtered by Patient Name, Patient MRN, and Plan ID. The search feature allows for the patient name, MRN, and Plan ID to be typed into the search box located above the patient worklist.



➢ ***Pagination:*** At the bottom of the patient list, users can select to view either 10, 25, or 50 patients per page. Users are able to navigate between pages by using the arrow buttons to the left and right of the page indicator. They may also directly select the desired page using the page indicator selection box.



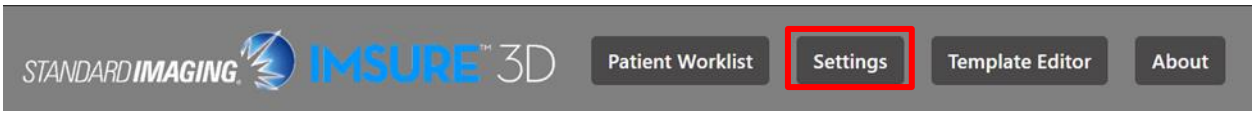
5 Global Settings

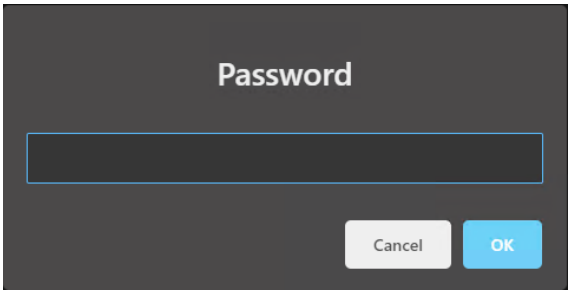
Click the *Settings* button on the top menu bar on the home screen to review and modify global configuration options. This menu is password protected by default. Users must have the password to access the Settings menu. Please contact your IMSure 3D administrator if the password needs to be reset.

Note: The default password upon installation is "montecarlo".

Within this environment global configuration options are available for:

- Setup
- Calculation Settings
- Reporting
- ROI
- Automation





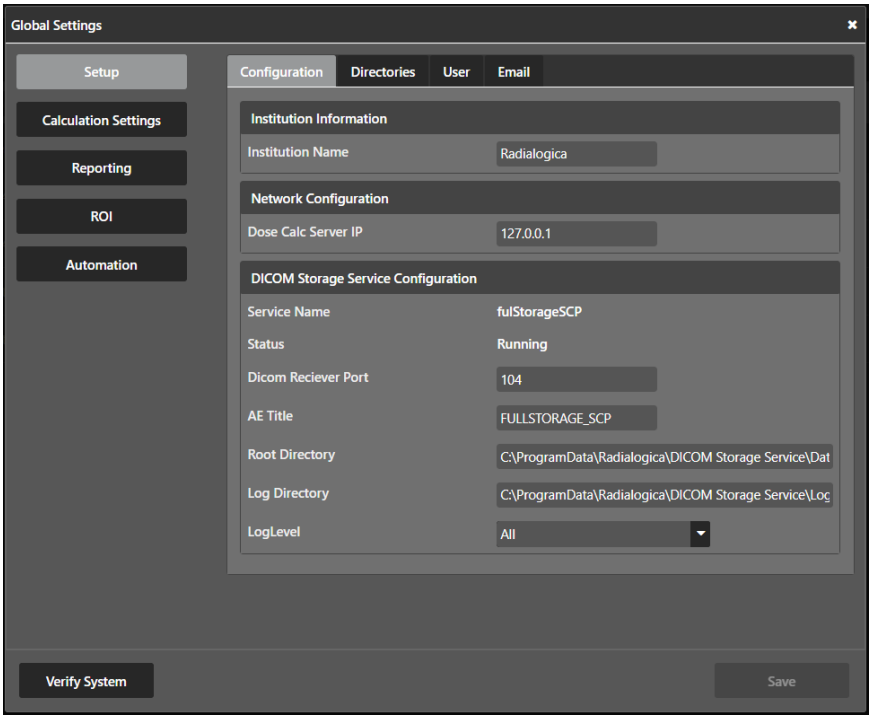
5.1 Setup

Click *Setup* to access options for the Global Settings menu.

➢ **Configuration**: In the *Configuration* tab you can review and edit the following elements:

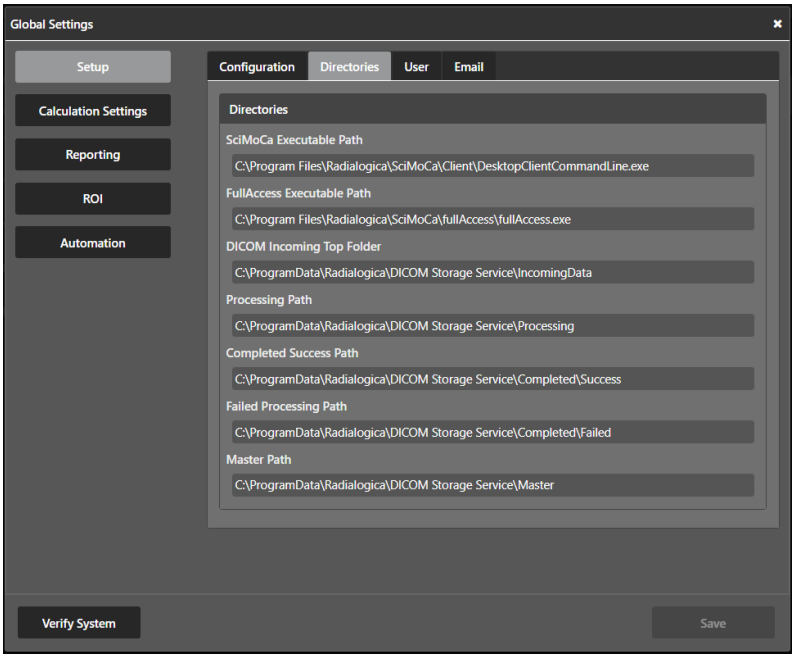
- Institution Name: Institution name appears on the IMSure 3D Plan Report. Enter the institution name in the field provided.
- Network configuration: Enter the IP address of the server on which the IMSure 3D software is installed.
- DICOM Storage Service Configuration: Enter and update configuration settings for the DICOM storage service.

You can modify configuration settings by editing the text in the corresponding text field. Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.



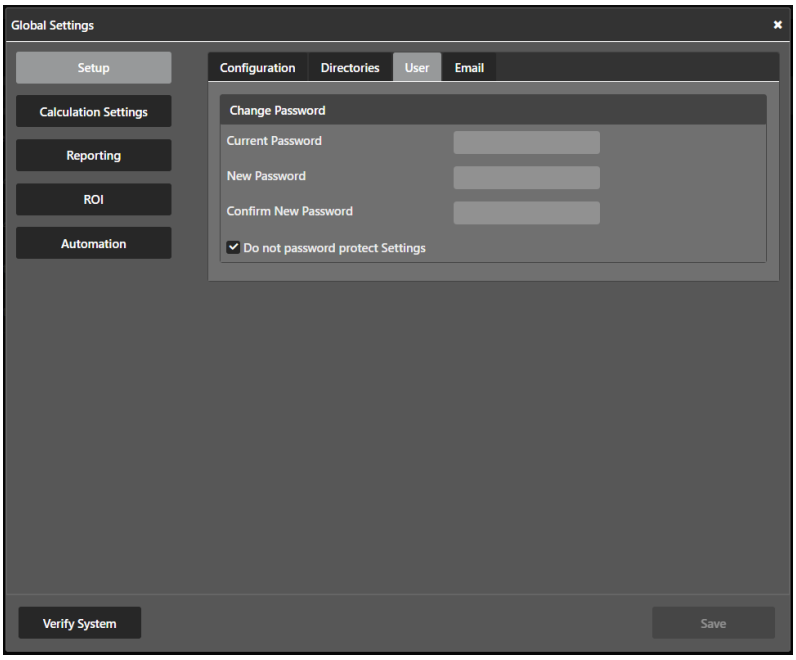
- **Directories**: In the *Directories* tab you can specify and update network directory locations for the following:
    - IMSure 3D Executable Path
    - FullAccess Executable Path
    - DICOM Incoming Top Folder
    - Processing Path
    - Completed Success Path
    - Failed Processing Path
    - Master Path

You can update directory locations by editing the text in the corresponding text field. Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "*x*" button in the top right corner of the dialog box.



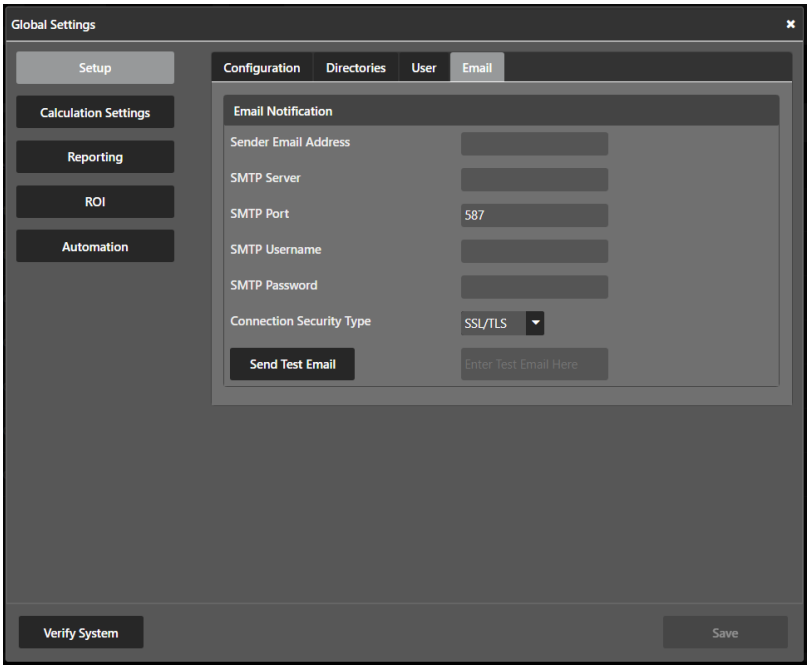
- **User**: In the *User* tab you can change the current password as well as select an option to allow users to access the Global Settings menu without a password.

You can update the password by editing the text in the corresponding text field. Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "*x*" button in the top right corner of the dialog box.



- **Email**: In the *Email* tab you can specify the email account that will send the email notifications. There is also an option to send a test email to make sure the email configuration is correct.

You can update the email fields by editing the text in the corresponding text fields. Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "*x*" button in the top right corner of the dialog box.



5.2 Calculation Settings

Click *Calculation Settings* to access plan parameters and CT Density.

➢ **Plan Parameters:** Selecting Plan Parameters presents the following options:

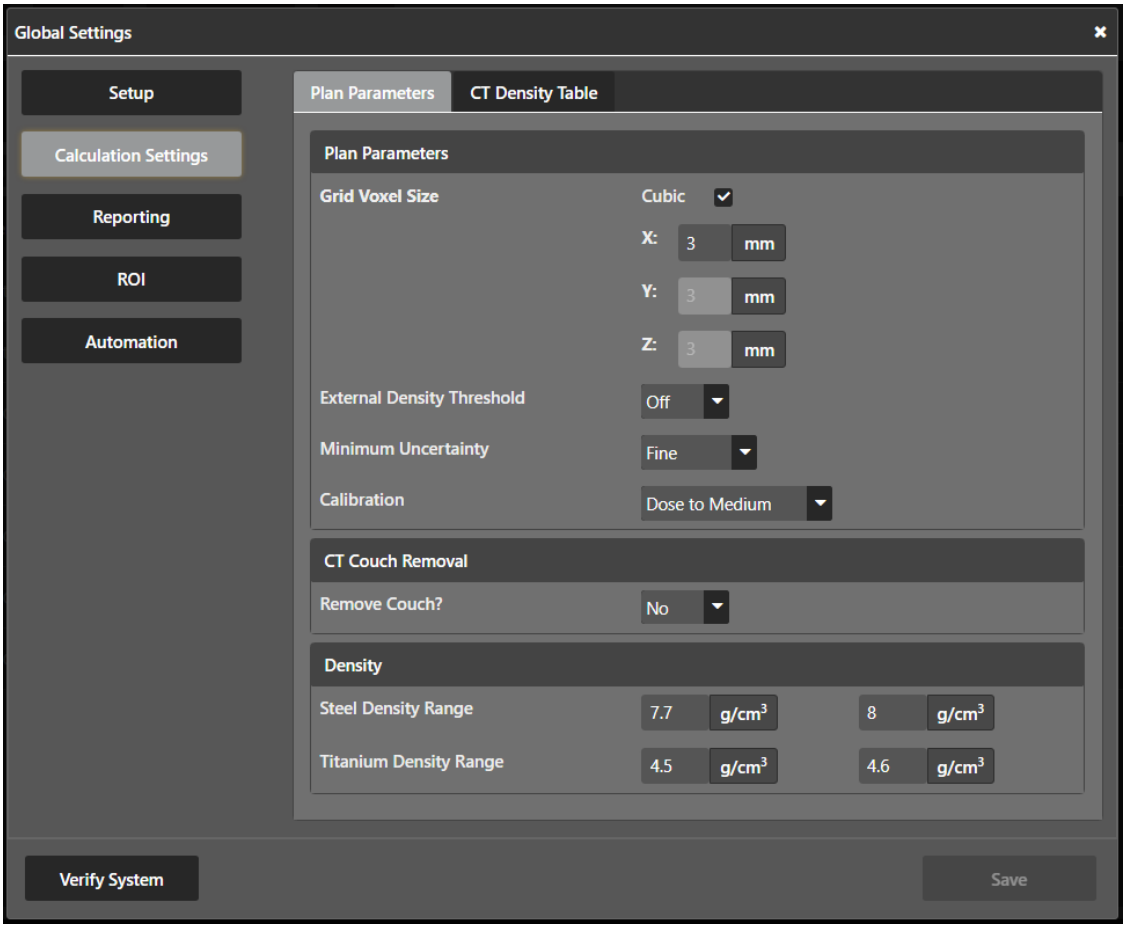
- Grid Voxel Size: Presents the dose calculation grid voxel size in millimeters. Textboxes are provided for each X, Y, Z values. Acceptable minimum value is 0.500 mm and maximum value is 10.000 mm for each. If the cubic checkbox is selected, the Y and Z fields will be disabled and assume a cubic value for the X value entered. By deselecting the cubic checkbox, all values can be edited. If no setting is specified, the default setting 3 mm^3 will be used.
- External Density Threshold: Allows the user to set a minimum external contour density threshold. Acceptable range of values is between 0 and 1 g/cm^3.
- When Off is selected for linac plans the dose calculator will not set a minimum density for an external contour.

  NOTE: For CyberKnife plans, even when Off is selected the minimum external contour density threshold is set to 0.1 g/cm^3 automatically.
- When On is selected a textbox is provided to input the threshold value.

  NOTE: When On is selected, this setting will include the treatment table as present in the CT image.

- Minimum Uncertainty: Presents a list of calculation speeds: Fast, Fine, and Extra Fine. If no setting is specified, the default setting Fine will be used.
- Calibration: Calibration options include Dose to Medium or Dose to Water for valid calibration values. Options can be selected from the drop-down menu. If no setting is specified, the default setting Dose to Medium will be used.
- CT Couch Removal: Options are presented in the drop-down menu to include or remove the couch density from the dose calculation. Dose calculations performed by the treatment planning system typically remove the CT couch from the CT scan. If the couch removal setting is selected to remove the CT couch from the calculation, a structure with a density override may still be taken into account for the dose calculation. The couch removal option is initially set to "*No*."
- When to turn on Remove Couch:
    - IF there is no skin contour AND External Density Threshold is used AND the couch needs removing
    - IF there is an indistinct calculation box around the patient that includes the couch.
- Steel Density Range: Presents the range of mass density values that are interpreted as steel in units of g/cm^3. Acceptable minimum value is 7.7 g/cm^3 and maximum value of 8.2 g/cm^3. Values can be edited by entering acceptable values in the text box. If no setting is specified, the default range 7.9 g/cm^3 to 8.1 g/cm^3 will be used.
- Titanium Density Range: Presents the range of mass density values that are interpreted as titanium in units of g/cm^3. Acceptable minimum value is 4.4 g/cm^3 and maximum value of 4.6 g/cm^3. Values can be edited by entering acceptable values in the text box. If no setting is specified, the default range 4.44 g/cm^3, 4.6 g/cm^3 will be used.

You can update calculation settings by editing the text in the corresponding text field. Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.

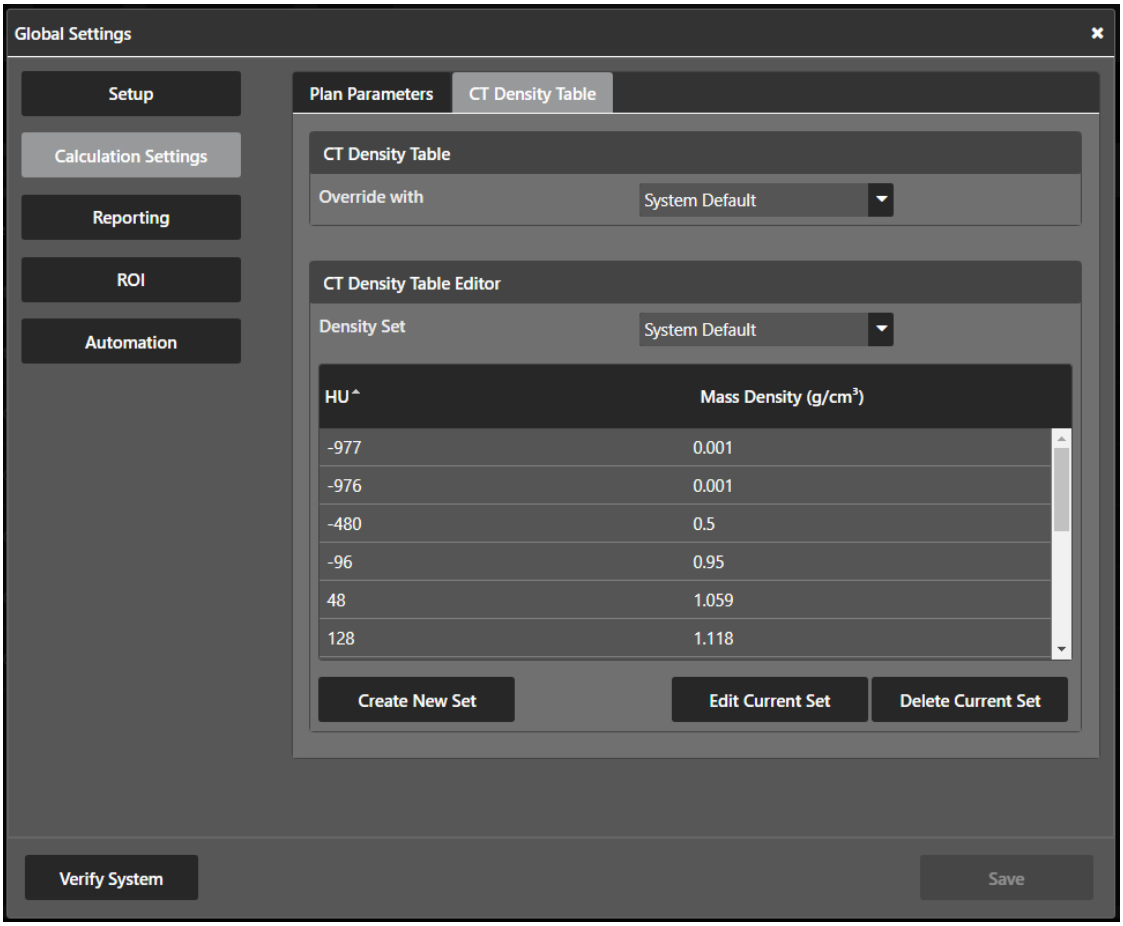


➢ **CT Density Table**: Selecting CT Density presents the following options:

- CT Density Table: Select a created CT Density table using the dropdown menu.

  Note: The creation and editing of CT Density tables are performed within the CT Density Editor.

- CT Density Editor: The following options are available within the CT Density Editor:
  - Create New Set
  - Edit Current Set
  - Delete Current Set
  - View Density Set



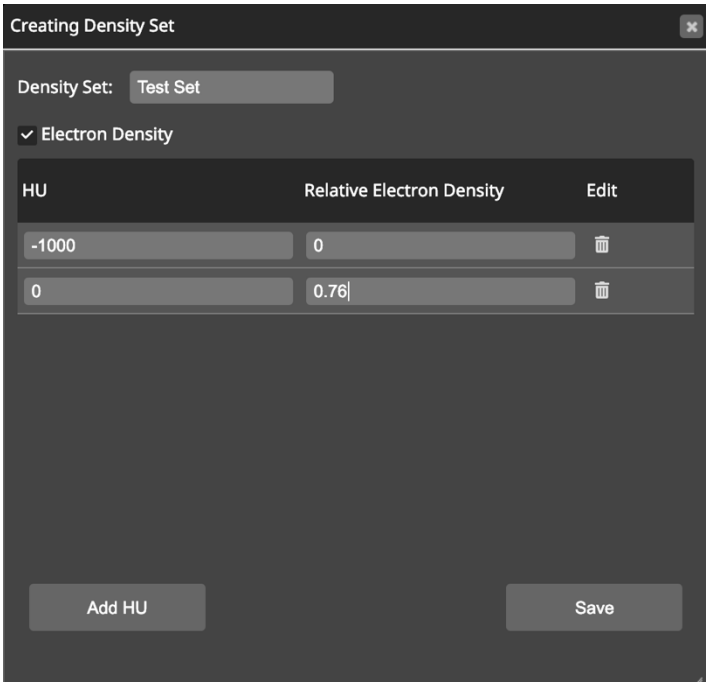
Create New Set: Click the *Create New Set* button to create a new CT Density table. A name for the Density set must be entered. Click the *Add HU* button to add HU and Density values. Press the trashcan icon to delete rows, if needed. Users also have the option to use Relative Electron Density values instead of Mass Density values.

When Electron Density is selected, IMSure 3D will automatically convert the Relative Electron Density values into Mass Density (g/cm^3) when processing a plan. In the Plan Setting menu for that plan it will display the converted values in the HU-Density table.

The valid range of values is between -1000 to 6000 for HU, 0 to 4.8 g/cm^3 for Mass Density, and 0 to 4.8 for Relative Electron Density.

Note: There must be two rows of values for the table to be saved.

Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.



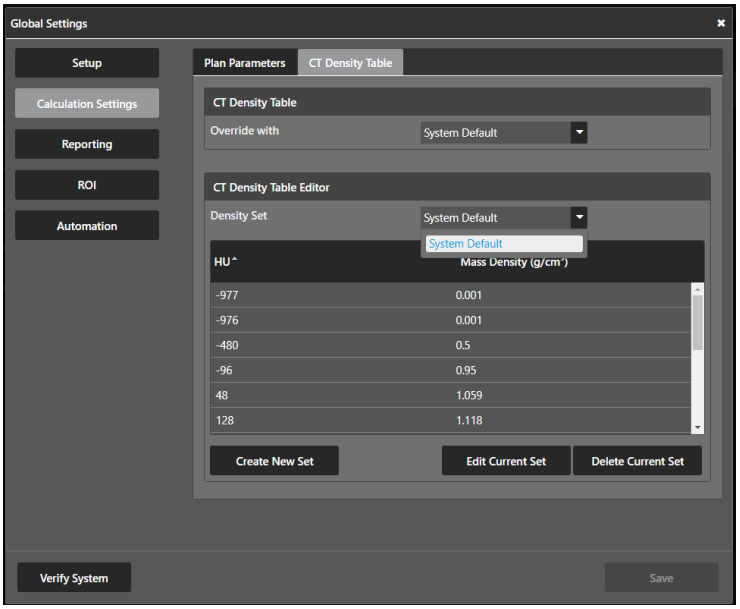
- Edit Current Set: Click the *Edit Density Set* button to edit an already created table set. In this window there are options to delete rows (Trashcan Icon), edit the values in rows, add rows (*Add HU* button), change Density Set Name, and the ability to save the current table set as a new table with a new name.

Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.

- Delete Current Set: If a custom CT Density table set is no longer needed press the Delete current set button to delete the table set.

  Note: Pressing this button will delete the table set that is selected and in view.

- View Density Set: Select a CT Density table set to view from the Density Set drop-down menu.



5.3 Reporting

Click *Reporting* to access Template Management and 3D Gamma Analysis configuration options.

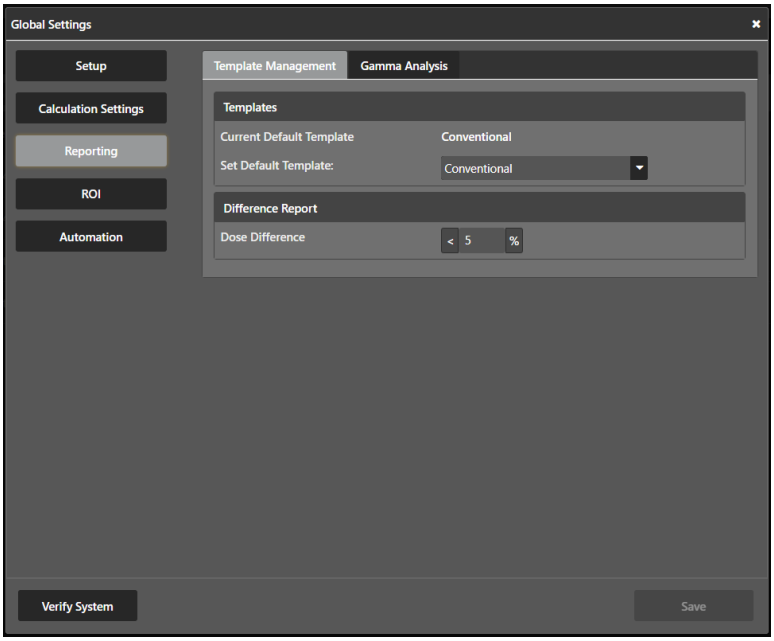
➢ **Template Management**: Selecting the *Template Management* tab presents the following options:

- Templates: Select a default evaluation template by choosing from a list of available evaluation templates from the drop-down menu.

  Note: The creation and editing of evaluation templates are performed within the Template Editor (See Section 6 – Template Management).

- Dose Difference: Presents the dose difference threshold, or percentage difference between the treatment planning system calculation value and IMSure 3D calculation value, that determines an acceptable or unacceptable deviation for a particular quality measure. The acceptable range for the dose difference is 0 – 100%.

You can update template settings by editing the text in the corresponding text field. Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.

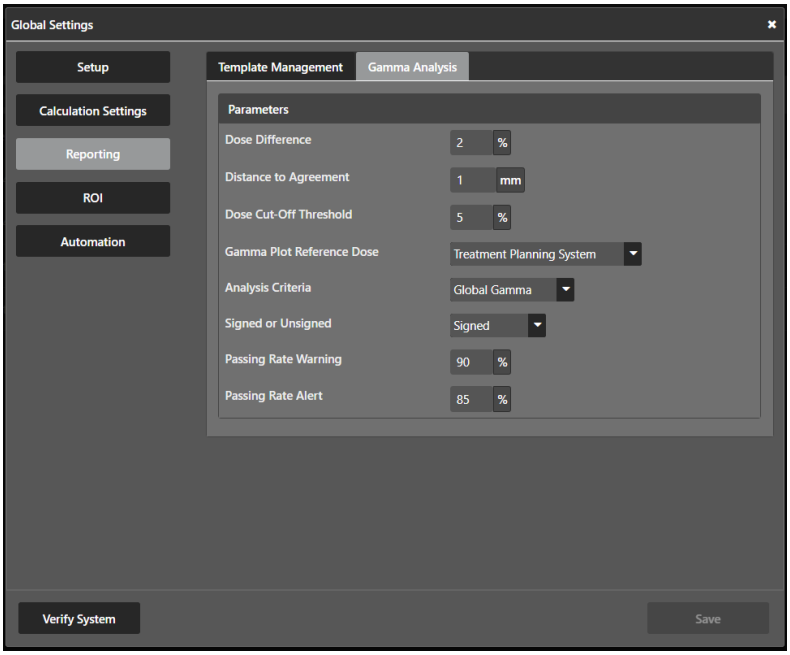


➢ **Gamma Analysis**: Selecting the *Gamma Analysis* tab presents the following options:

- Dose Difference: Used to compare the dose at corresponding points in both distributions. Values are expressed in units of percentage. You may edit the value by clicking inside the text field. The acceptable range for the dose difference is 0 – 100%.
- Distance to Agreement: Distance-to-Agreement is the nearest point in the measured distribution. Values are expressed in units of millimeters. You may edit the value by clicking inside the text field.
- Dose Cut-Off Threshold: Any dose under the set value in this field will not be considered for the gamma calculation. Values are expressed in units of percentage. You may edit the value by clicking inside the text field. The acceptable range for the dose difference is 0 – 100%.
- Gamma Plot Reference Dose: Select between the TPS or IM3D reference dose as the denominator for the dose difference calculation using the drop-down menu.
- Analysis Criteria: Select either Local or Global Gamma from the drop-down menu.
- Signed or Unsigned: Select between signed (-2 to 2) or unsigned (0 to 2) percentage comparisons values using the drop-down menu.
- Passing Rate Warning: Any rate above the value set in the Passing Rate Alert field and Below the Passing Rate Warning field will trigger a yellow alert. Values are expressed in units of percentage.

  Passing Rate Alert: Any percentage rate below the value set in this field will trigger a red alert. Values are expressed in units of percentage.

Note: The Gamma Analysis settings will be used to generate a Passing Rate for a plan as well as it's Gamma per ROI values.



You can modify the gamma analysis fields by editing the text in the corresponding text field. Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.

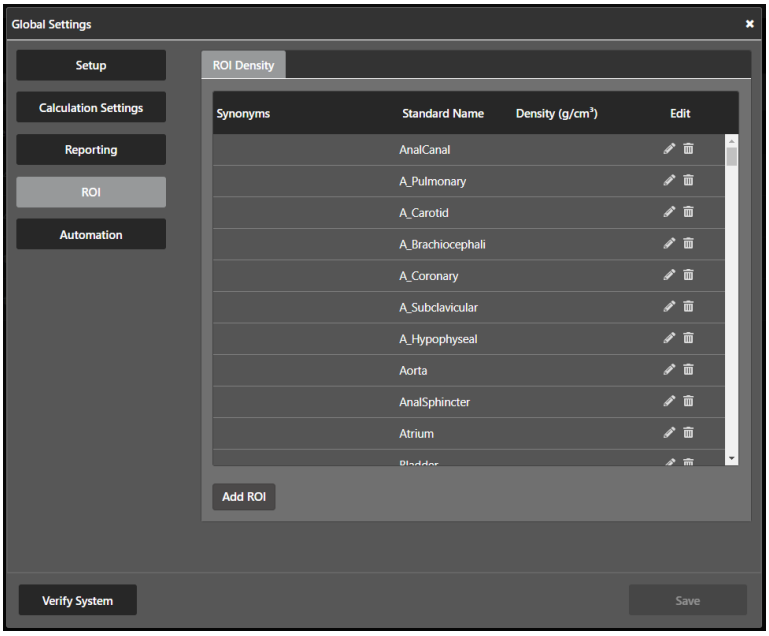
5.4 ROI

Click *ROI* to access ROI Density configuration options.

- **ROI Density**: The ROI Density tab provides the opportunity to edit information about any Region of Interest (ROI). Within the *ROI* tab you can manage list of standard structure names, create and map structure synonyms, and edit ROI density values.

  The ROI table consists of:

  - Synonyms for standard ROI names
  - Standard ROI names
  - ROI density in g/cm^3
  - Tools for editing ROIs within the global list
  - Tools for adding ROIs to the global list
  - Tools for deleting ROIs from the global list



- Synonyms: Synonyms can be associated with standard structure names for ROIs. This allows users to create a synonym library to overcome variability in structure naming.
- Standard Names: The list of standard structure names provided within IMSure 3D Compare is derived from "Standardizing naming conventions in radiation oncology," Santanam et al., Int J Radiat Oncol Biol Phys. 2012 Jul 15;83(4): 1344-9.
- ROI Density: Density values are expressed in units of g/cm^3. Acceptable minimum density value is 0.80 g/cm^3 and maximum value is 1.80 g/cm^3. Global settings allow for density overrides by region of interest (ROI) as in the structure set. Density value of zero (0) ignores the ROI in the density grid. ROI density overrides follow the order given by the structure set. The default ROI density value is obtained from the CT DICOM-RT structure set density value. This value can be overridden in IMSure 3D and will be used for dose calculation.

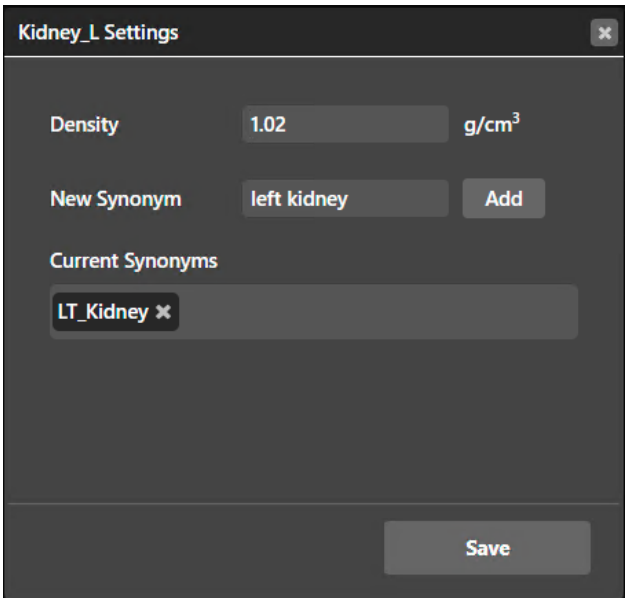
  The treatment planning system may have the option to override and export density values in its CT data for specific structures defined in the treatment plan. Density overrides are automatically transmitted in the DICOM-RT structure set. These values can be verified in the ROI section of Plan Settings. If the density override was successfully overridden and exported by the TPS, this value will always be used for calculation. The TPS will override any value defined in IM3D.

➢ **Editing ROIs:** ROIs can be edited by clicking on the pencil icon. Once the pencil icon is selected to edit ROI information, the following dialog will display:

- Density: Displays the current ROI density value. Value can be edited by changing the value in the text field.
- New Synonym: Displays the current synonyms mapped to the standard structure name. Click *Add* to create a new synonym.

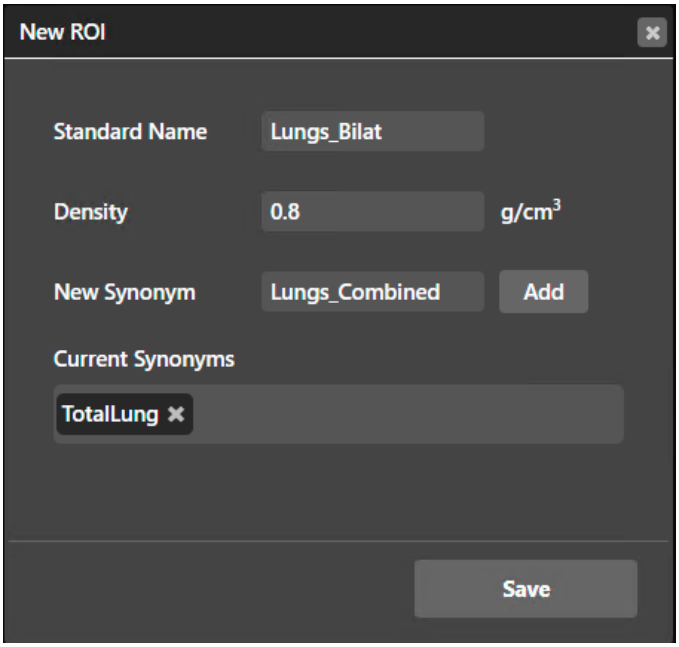
- Current Synonyms: Displays structure names previously mapped to the standard structure name. Synonyms can be deleted by clicking the "*x*" next to the mapped structure name.

You can update ROI settings by editing the text in the corresponding text field. Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.



➢ **Adding ROIs**: ROIs can be added to the global list by clicking *Add ROI* in the lower left corner of the ROI tab. After selecting *Add ROI*, the following dialog will display:

- Standard Name: Enter a value for the new standard structure name.
- Density: Enter a value for structure density in g/cm^3.
- New Synonym: Displays the current synonyms mapped to the standard structure name. To add a new synonym, enter the structure name in the text field and click *Add*.
- Current Synonyms: Displays structure names previously mapped to the standard structure name. Synonyms can be deleted by clicking the "*x*" next to the mapped structure name.



Click the *Save* button the save the new ROI. To cancel the creation of a new ROI, click the "x" button in the top right corner of the dialog box to return to the ROI tab.

➢ **Deleting ROIs**: To delete a ROI from the standard list, click on the trashcan icon located on the right end of the ROI row. You will be prompted to confirm deletion of the ROI.

5.5 Automation

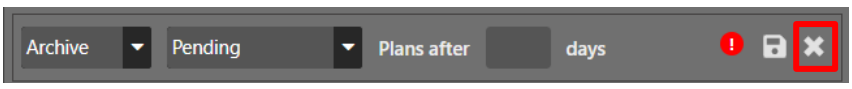
Click *Automation* to access Automation configuration options.

➢ **Worklist**: The *Worklist* tab presents the opportunity to create, edit, or delete automation rules. These rules trigger the archival or deletion of plans after a set number of days based on review status.

- *Create Rule:* To create automation rules, select *Create Rule* and then several options must be selected:
  - Action option: Archive or Delete
  - Plan status option: Pending, Approved, Rejected, or Unable to process
  - Number of days option: Numerical value set in *Days* for when the rule is to take effect *after* a specified plan status is attained.

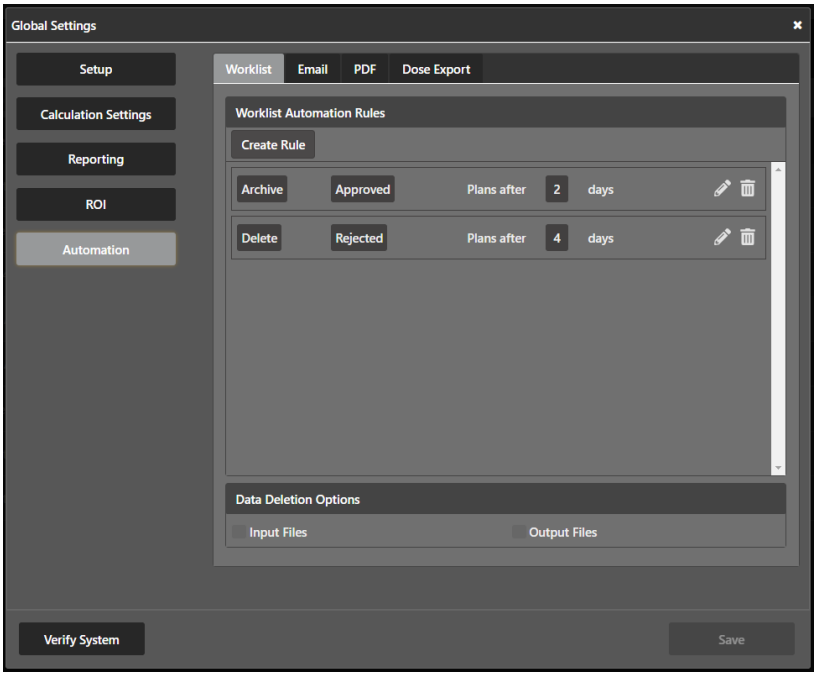
    Note: Must be a positive number.
  - Option to cancel the creation or editing of a rule and tools for saving, editing, or deleting rules.

Click the *Save* icon to save a new Worklist automation rule. To cancel the creation of a rule, click the "x" icon.



- Data Deletion Options: When a plan row is deleted, users can select whether to also delete the corresponding input files and/or output files from the server.
    - Input Files: Selecting this option will delete all patient files sent over from the TPS that was used to create a IM3D dose. These patient files are located in the Master folder of the DICOM Storage Service folder.
    - Output Files: Selecting this option will delete all patient files created by IMSure 3D. These patient files are located in the patient processing folder.

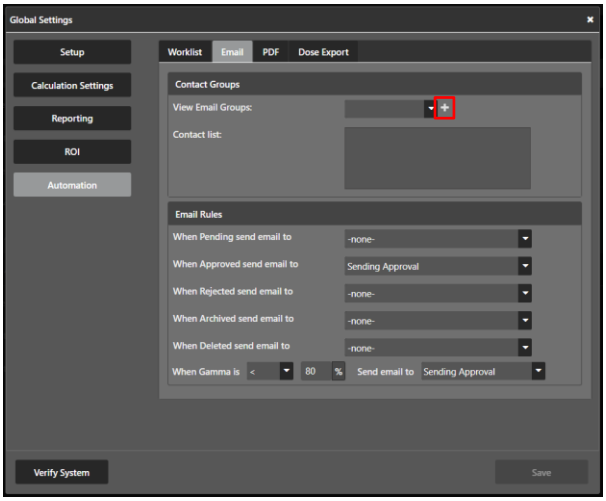
Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.

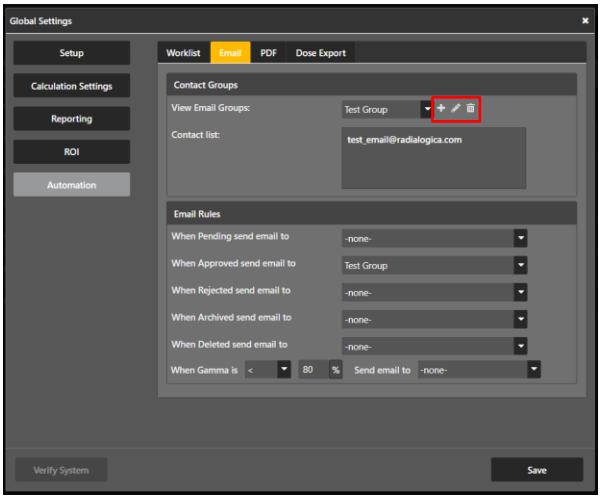


➢ **Email**: The *Email* tab presents the opportunity to create, view, edit, and delete email notification contact groups as well as set up automated email notification rules.

- Contact Groups: The following options are available within this section:
    - Create new Contact Group: Click on the *"+"* icon to create a new contact group.
    - Edit selected Contact Group: Select a contact group from the drop-down menu and then click on the *pencil* icon to edit the contents of the contact group.
    - Delete selected Contact Group: Select a contact group from the drop-down menu and then click on the *trash can* icon to delete the selected contact group.
    - View the contents of a Contact Group: Select a contact group from the drop-down menu to view the email addresses of the contact group.

Click the *Save* button the save the new Contact Group. To cancel the creation of a new Contact Group, click the "x" button in the top right corner of the dialog box to return to the Email tab.





- Email Rules: The Email Rules section allows the user to select which contact group will receive an email notification based on a plan status change. A notification email will be sent to the email addresses contained in the specified contact group. There is also an option to send an email notification based on a configurable Gamma Analysis pass rate threshold.

Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.

➢ **PDF:** The *PDF* tab presents the opportunity to automatically save a PDF to a specific folder as well as name it in a specific way.

- Include Unmapped Metric ROIs: Selecting this option will include the unmapped ROIs of the selected metric template in the PDF report.
- Save PDF As: This allows users to configure the naming scheme for the saved PDF report by selecting between different naming options.

PDF renaming schema is as follows:

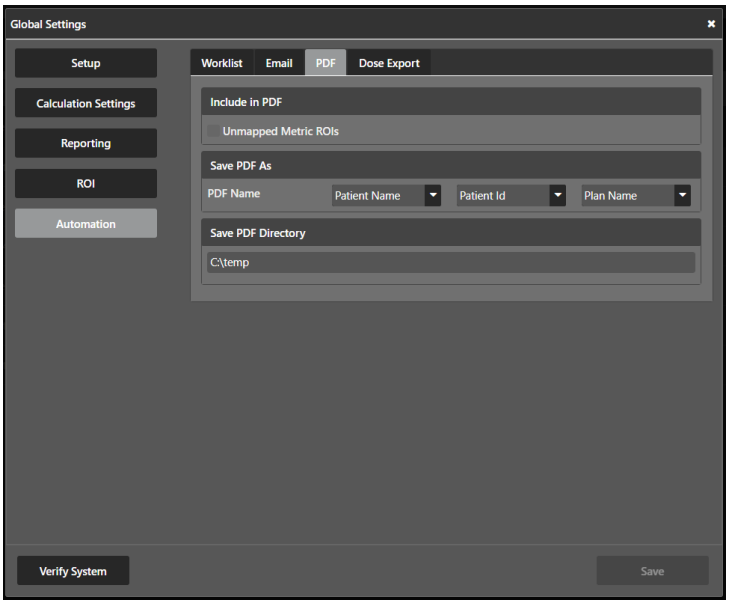
<Status>_<Patient processing ID>_<Selection1>_<Selection2>_<Selection3>.pdf

Example:

Approved_34_JohnSmith_S14323_Prostate74Gy.pdf

- Save PDF Directory: Users can configure the automatic save location for newly generated PDFs. The user specified folder location must allow IMSure 3D adequate permissions to read, write, and delete files to this folder.

Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.



➢ **Dose Export:** The Dose Export tab presents the opportunity to select whether or not to automatically rename the IMSure 3D dose file upon generation as well as save it to a specified folder location.

- Save IMSure 3D Dose As: If enabled this selection allows users to configure the naming scheme for the generated IMSure 3D Dose by selecting between different naming options.

IMSure 3D dose renaming schema is as follows:

RD.<Patient processing ID>.<Status>_<Selection1>_<Selection2>_<Selection3>.dcm

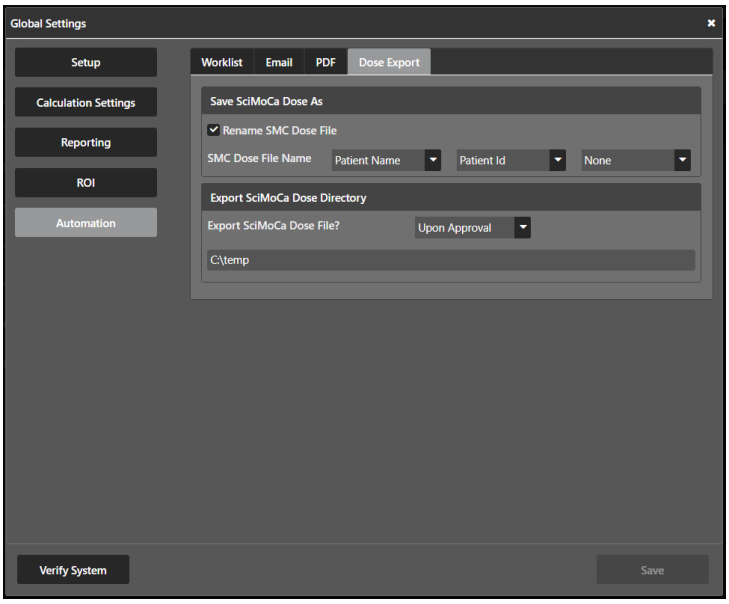
Example:

RD.34.Approved_JohnSmith_S14323_Prostate74Gy.dcm

- Export IMSure 3D Dose Directory: An option is presented for users to select when to export the IMSure 3D generated dose file. Users can select from these events:
  - Always
  - Upon Approval
  - No

Users can also configure the automatic save location for the IMSure 3D generated dose file. The user specified folder location must allow IMSure 3D adequate permissions to read, write, and delete files to this folder.

Click the *Save* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.

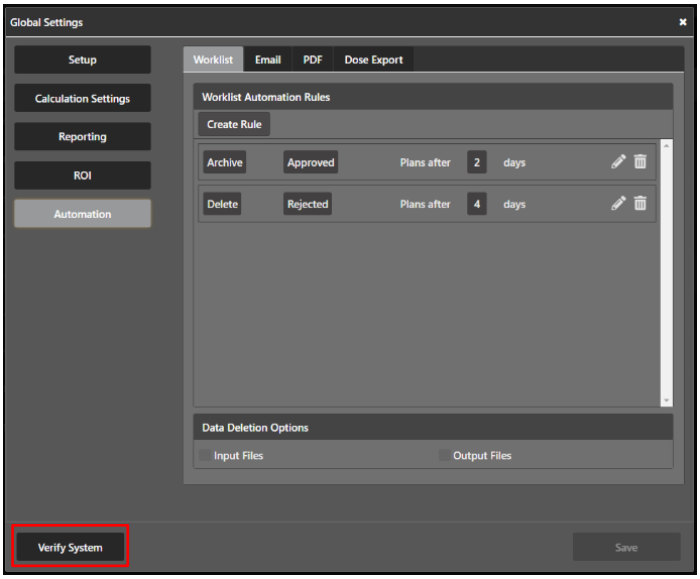


5.6 Verify Systems

Click *Verify Systems* to access a webpage that details the status of IMSure 3D operations.

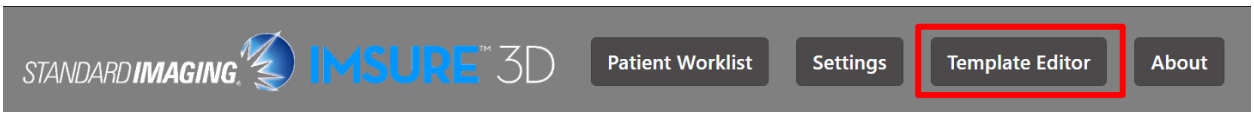
The *Verify Systems* button will open a new browser window that gives the user insight and a detailed view into the processes, files, and folders that are necessary for IMSure 3D to operate.

- Existence of Executable Files
- Activated Licenses
- Running Processes
- Directory Permissions
- Database Connection Strings

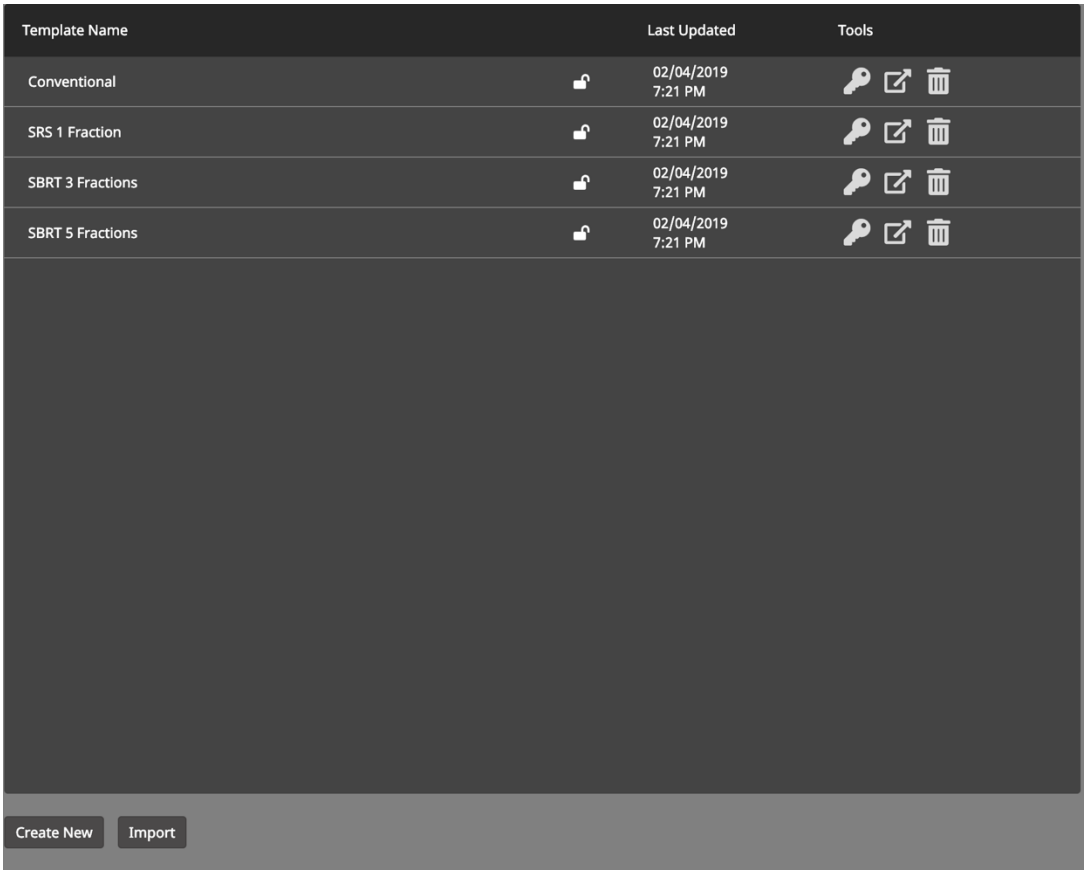


6 Template Management

To access template management, click the *Template Editor* button in the top menu bar on the home screen. Within this environment users can create, edit and delete evaluation templates, and import / export templates.



A list of saved evaluation templates is presented in the Template Editor tab.

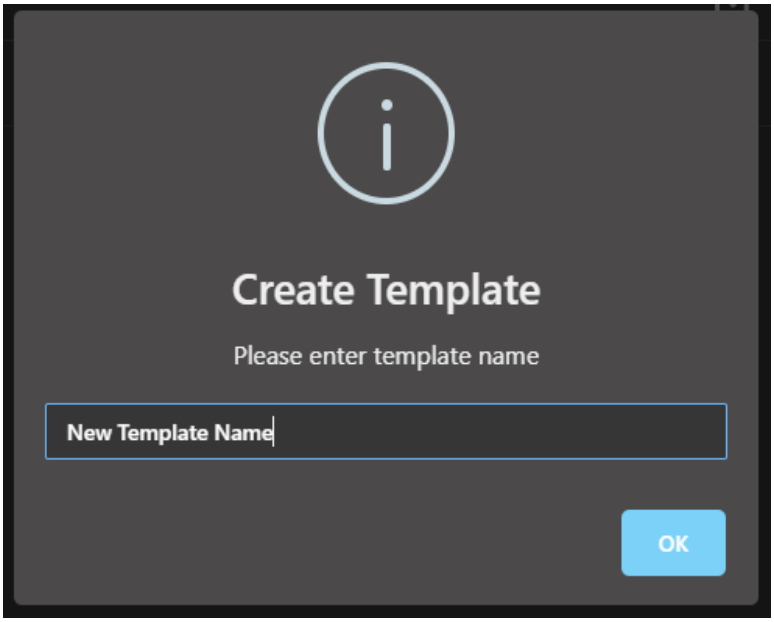


The following options are available within the Template Editor:

- Create New
- Edit
- Export
- Import
- Delete
- Lock / Unlock

6.1 Create a New Template

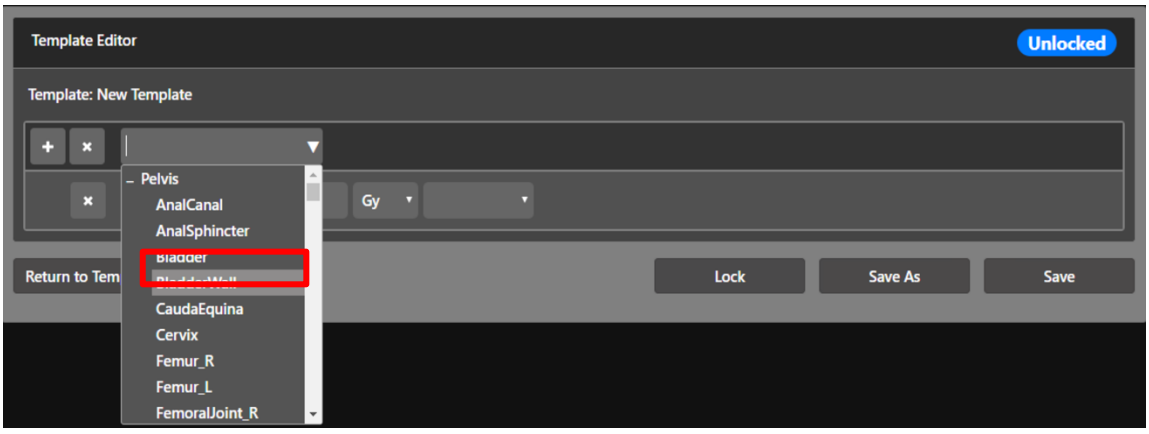
To create a new plan evaluation template, click *Create New* in the lower left portion of the dialog box. A dialog box will display. Enter a template name and click *OK or* click *Cancel* to exit.



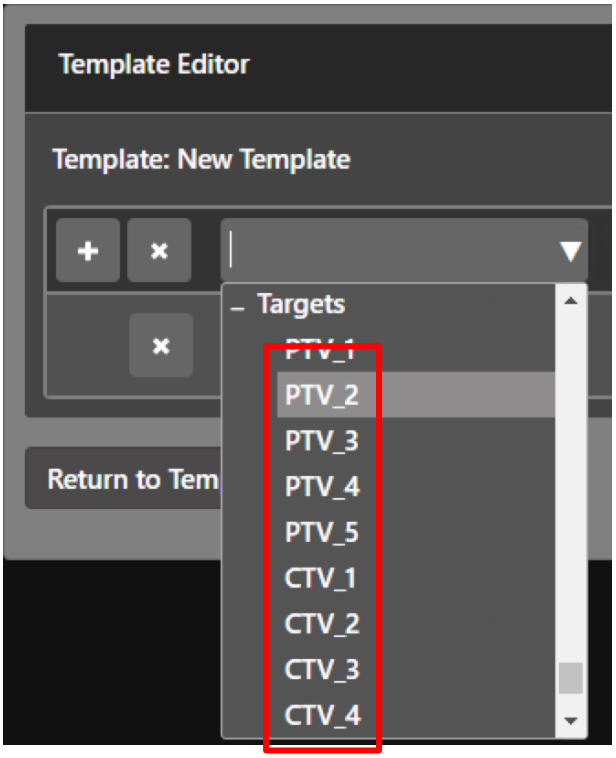
Once a new evaluation template has been created and named, the template will display in the list of available templates. The new template can be configured by specifying ROIs for reporting and adding reporting metrics. Select the template by clicking on the template row. The software will not save a template that does not contain a reporting volume and associated metric.

- **Add ROI reporting volume**: Clicking *+Add Volume* will produce a new row and present a dropdown menu with options for ROI selection.

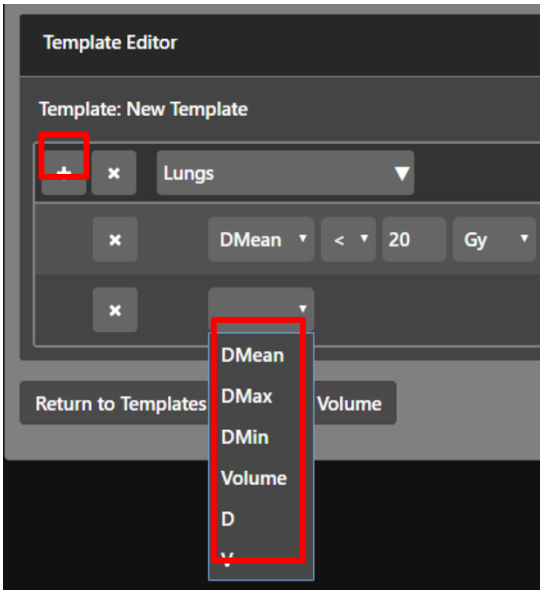
  The list of standard structure names provided was derived from "*Standardizing naming conventions in radiation oncology,*" Santanam et al., Int J Radiat Oncol Biol Phys. 2012 Jul 15;83(4): 1344-9)



  Target volume options are also presented in the ROI dropdown menu.



- **Add a metric**: To add a new metric to report, click the plus sign to the left of the corresponding ROI. This will produce a new row under the ROI and present a dropdown menu for selection of evaluation metric.

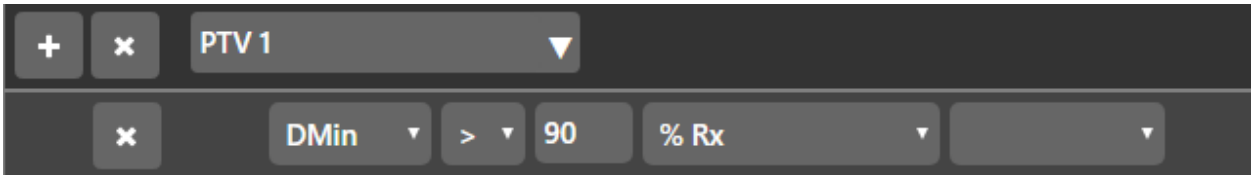


Evaluation metrics supported by IMSure 3D include:

- Dmean: DVH objective is calculated for the mean dose in the ROI in units of Gy.

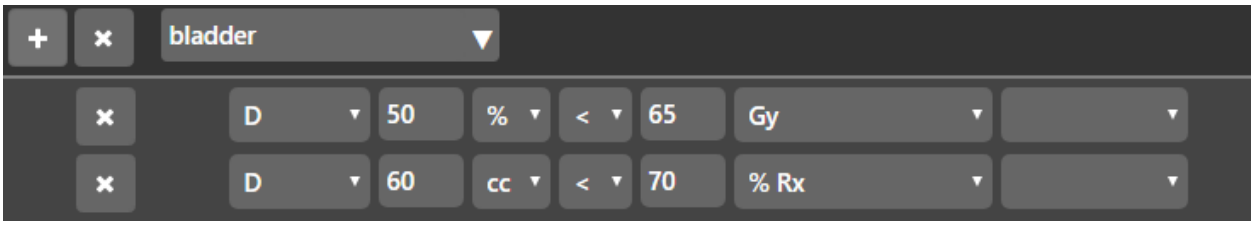
- Dmax: DVH objective is calculated for the maximum dose in the ROI in units of Gy.

- Dmin: DVH objective is calculated for the minimum dose in the ROI in units of Gy.



- Volume: Calculates the volume of the ROI in units of cc.

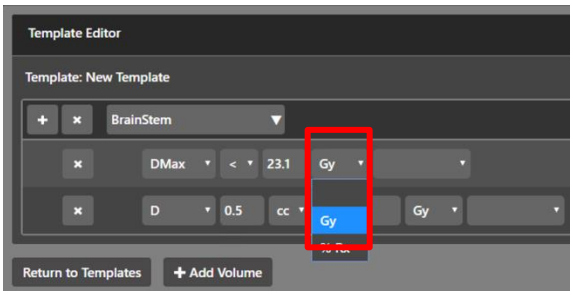
- D metrics: Calculates the minimum dose received by a sub-volume of the ROI.
- Sub-volume can be specified in units of cc or % of the ROI's total volume.
- Dose can be reported in units of Gy or % of prescription dose.
- Examples below:
  - Dose to 50% of the bladder should be less than 65 Gy.
  - Dose to 60 cc of the bladder should be less than 70% of the prescription dose



- V metrics: Calculate the sub-volume of the ROI receiving at least a certain dose.
- Dose can be specified in units of Gy or % of prescription dose.
- Sub-volume can be reported in units of cc or % of the ROI's total volume.

- Examples below:
  - Volume of the right femur receiving 60% of the prescription dose should be less than 20 cc
  - Volume of the right femur receiving 50 Gy should be less than 10% of total ROI volume

- Metric values can be reported in absolute value (Gy) or as a percentage of prescription dose.

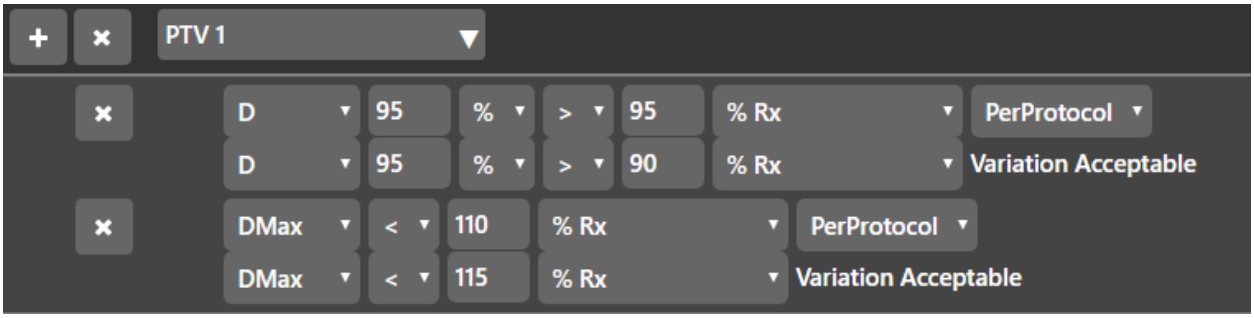


- For any given metric, either:

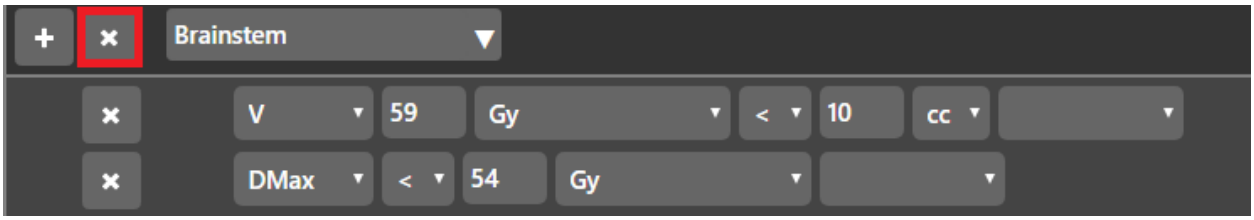
a metric value can be reported; or

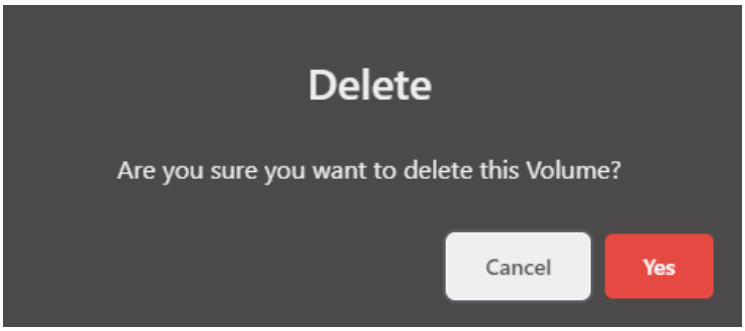
An objective/constraint for that metric can also be specified, in which case the metric value is reported along with pass/fail relative to the stated objective/constraint.

- **Per Protocol, Variation Acceptable:** Metrics can be constructed with reference to both "*per protocol*" and "*variation acceptable*" values.



- **Delete ROI Reporting Volume**: To delete a reporting volume, click the "x" button to the left of the ROI name. A dialog box will display after selecting a reporting volume to delete asking to confirm this action. Select Yes to continue to delete the reporting volume or Cancel.

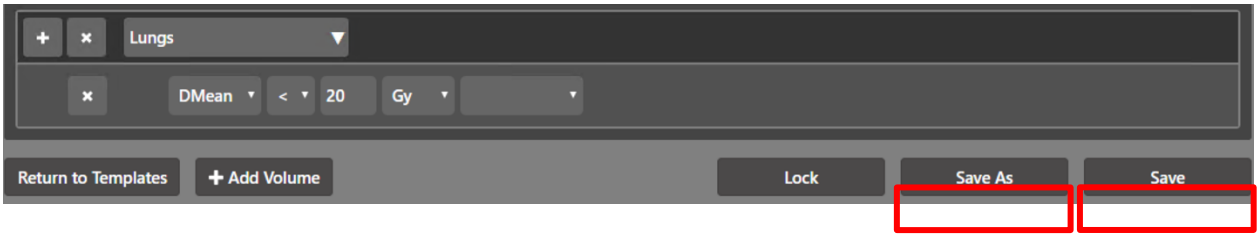




- **Delete metric:** To delete a metric, click the "x" button to the left of the metric.

6.2 Edit a Template

To edit an existing template, select that template in the list of saved templates by clicking on the template row. Within edit mode, users can create and delete ROI reporting volumes, and create / edit / delete reporting metrics. After changes are made, click *Save* in the bottom right corner of the dialog box to update the template contents. You can click *Save As* and enter a new template name to save the updated template under a new name. You will be prompted to enter a new template name, then click *OK*.

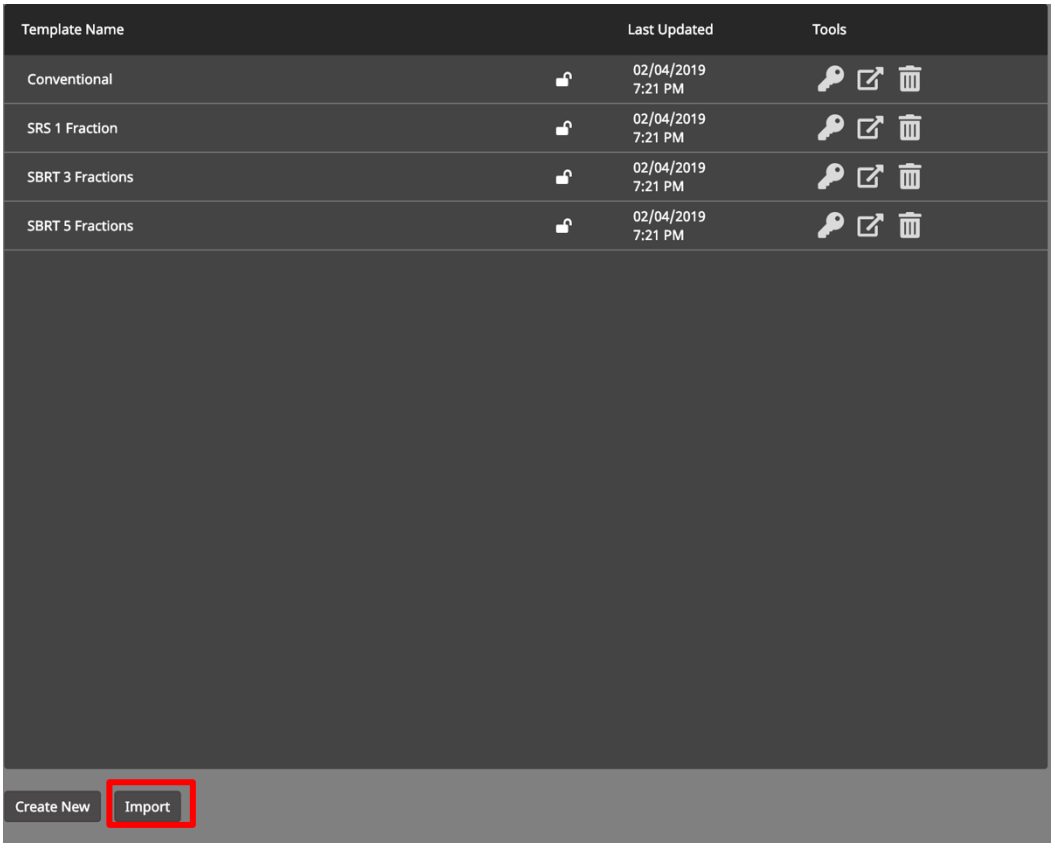


6.3 Export a Template

To export a saved evaluation template, click the *export icon* in the "Tools" column for the corresponding template. The template will be downloaded to the Downloads folder on your computer. Once the template has been exported/downloaded, it can be shared by attaching it to an email.

6.4 Import a Template

To import an evaluation template created by another IMSure 3D user, click the *Import* button on the Template Editor tab. You will then be prompted to navigate to a storage location and select the template. Select the desired template and click *Open* to add it to your IMSure 3D template library.



6.5 Delete a Template

To delete a template, click the *trash can icon* in the "Tools" column on the Template Editor tab.

6.6 Lock and Unlock a Template

Users have the ability to Lock and Unlock templates from editing. The lock icon on the template list page as well as within the template gives the user a visual representation of the locked or unlock status of the template.

- To lock a template: click the lock button at the bottom of a template or the key icon beside the template in the template list.
- To unlock a template: click the unlock button at the bottom of the template or the key icon beside the template in the template list. Enter in the password (same password used for Global Settings access) when prompted.

Note: Only users with the password may unlock a template for editing.

6.7 Return to Templates

To return to the list of templates, click the *Return to Templates* button at the lower left corner of the template dialog box or click the *Template Editor* button at the top of the page.

6.8 Return to Patient Worklist

To return to the patient worklist on the main menu, click the *Patient Worklist* button displayed on the IMSure 3D banner menu.

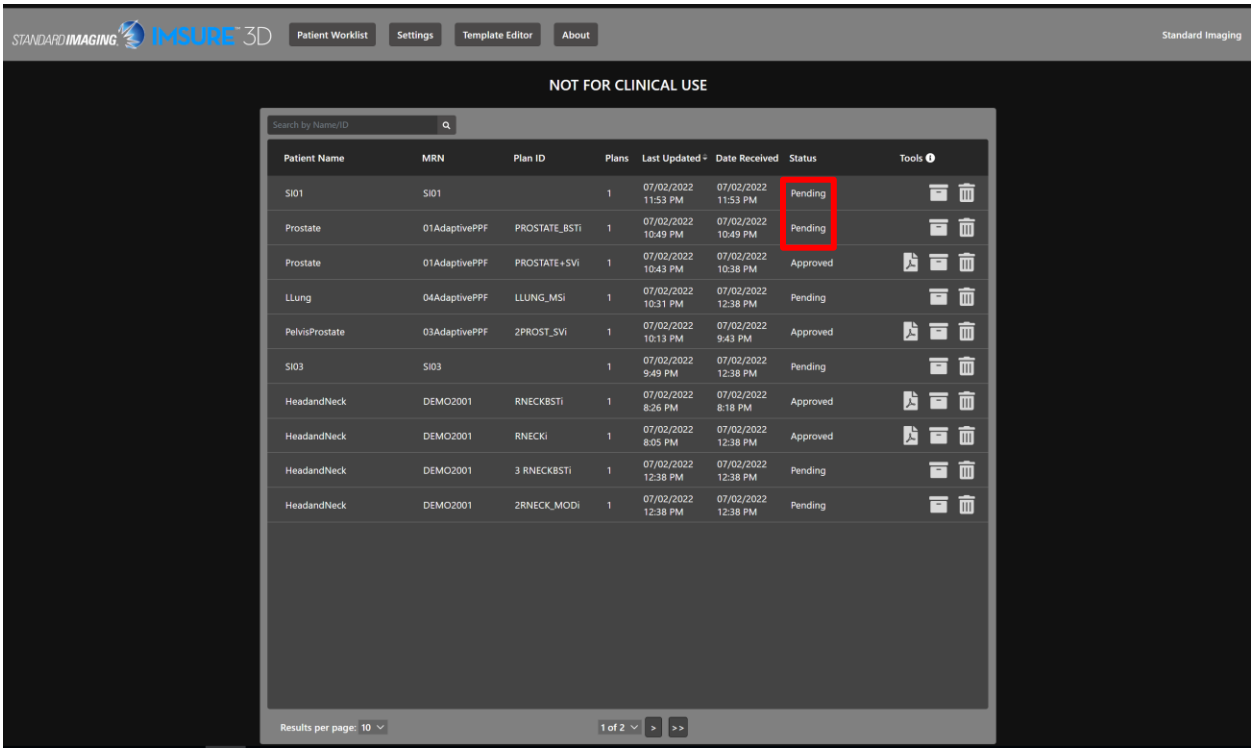
7 Data Submission

7.1 DICOM Export

IMSure 3D requires input from a treatment planning system that can transmit DICOM CT images, DICOM RT structure set, DICOM RT-Dose and RT-Plan using the DICOM-RT format. IMSure 3D requires plan and report .XML files from CyberKnife treatment planning systems. To initiate a dose calculation, the treatment plan must be exported from the treatment planning system to the designated IMSure 3D export location. Dose calculation requests will automatically be queued and processed by IMSure 3D.

7.2 Valid Submission

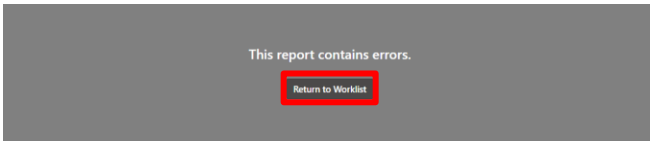
Once IMSure 3D has completed a dose calculation, the patient / plan is automatically added to the patient worklist with status designated *Pending* indicating that the plan is ready for review.



7.3 Invalid Submission

In the event IMSure 3D is unable to generate a dose calculation due to an incomplete DICOM dataset or problems encountered in the export process, the patient / plan will appear on the worklist with status designated *Unable to process*. Error details will be documented in the IMSure 3D client and server logs.

If a patient row is selected with the status designated *Unable to process*, a dialog box will display stating that the report contains errors. To return to the patient worklist, select the *Return to Worklist* button.



8 Plan Reporting

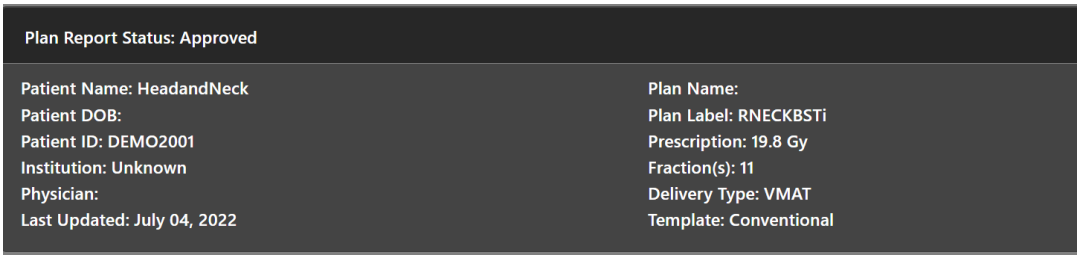
To review a patient's plan report, select the patient from the patient worklist with a status of *Pending*. Click anywhere on the row of given plan to review the plan report within the reporting panel.

8.1 Header Information

Patient Header information includes the following data elements derived from the DICOM files (if available):

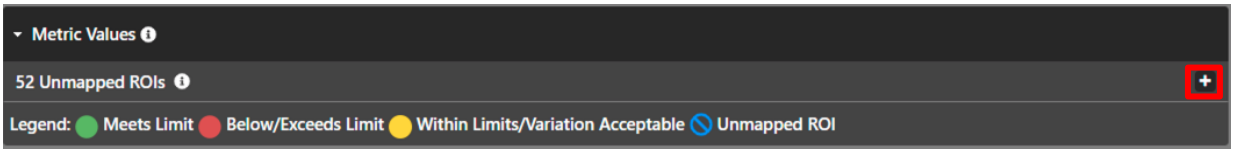
- Plan Report Status

- Patient Name
- Patient Date of Birth
- Patient ID
- Institution
- Physician
- Last Updated
- Plan Name
- Plan Label
- Prescription
- Prescription Percentage (CyberKnife plans only)
- Max Dose (CyberKnife plans only)
- Fraction(s)
- Delivery Type
- Radiation Type (Electron, SRS cone, and ZAP-X plans only)
- Applicator Type (Electron & SRS cone, and ZAP-X plans only)
- Number of Beams (Electron & SRS cone, and ZAP-X plans only)
- Template



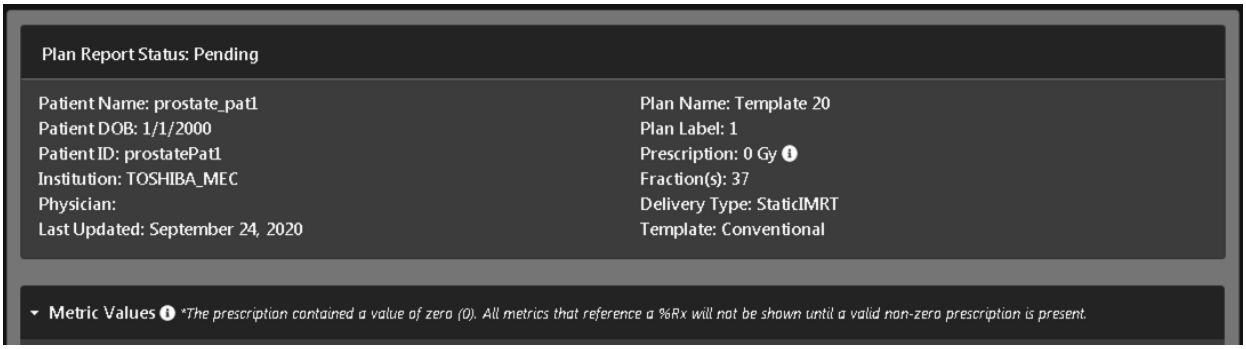
8.2 Dose Difference Report

The dose difference report presents the values and percentage difference associated with the treatment planning system (TPS) dose and IMSure 3D (IM3D) dose for the plan quality measures included in the evaluation template. Metrics will only display for ROIs included in the evaluation template that are mapped. If template volumes are not mapped to a ROI, metric values will not display. Unmapped template ROIs will be shown in the Unmapped ROIs section. Click on the + sign to expand the section to see all the unmapped ROIs for that template.



The metric values for both TPS and SMC doses are color coded, with green denoting "*Meets Limit*," red denoting "*Below / Exceeds Limit*," and yellow denoting "*Variation Acceptable*."

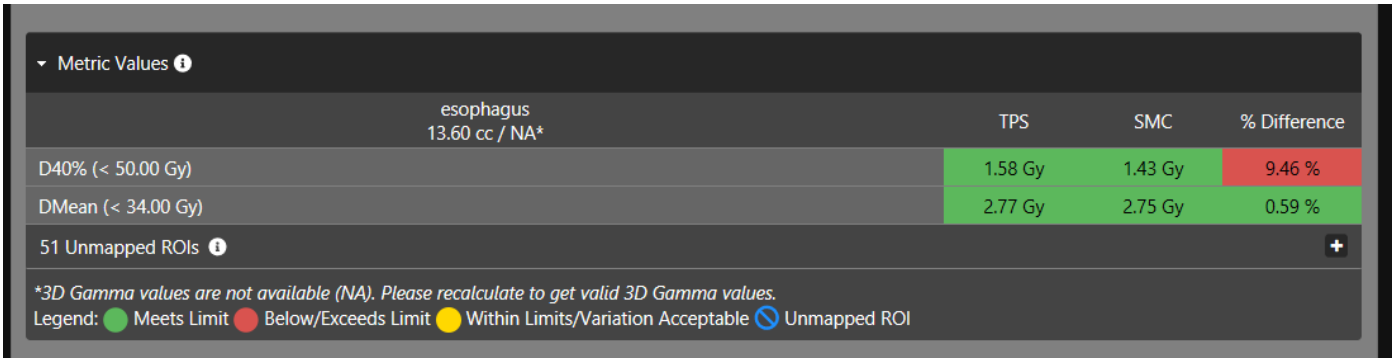
Plans containing a 0 Gy prescription dose can be processed through IMSure 3D. Metrics in the report that reference a relative dose will not be calculated and shown in the difference report until the plan is recalculated with a valid non-zero prescription.



The percentage differences between the TPS and SMC metric values are also reported. The percentage difference is color coded, with green denoting "*within tolerance*," red denoting "*outside tolerance*," and yellow denoting "*variation acceptable*" based on user-defined tolerance criteria. The % Difference tolerance criteria can be set within *Global Settings* for all plans or *Plan Settings* for a specific plan.

Each metric header will show the structure that the ROI is mapped to (if available) and will display the total volume of the structure as well as a ROI Gamma calculation value.
Within the ROI Gamma calculation there are 3 conditions that IMSure 3D recognizes which will produce the following messages:

1. NA - this means the ROI Gamma value is not calculated. The application displays NA for patients that were processed prior to the current version. To dismiss the NA message the user must recalculate the Gamma Analysis.



2. NC - this means the ROI Gamma value cannot be calculated. In calculating the value, none of the voxels for the ROI are considered for the ROI Gamma calculation, as such the ROI gamma value cannot be calculated. This typically arises when the cut-off dose threshold is high combined with many 0-dose voxels residing in the

dose cloud.

3. ND - this means the ROI Gamma value cannot be calculated due to the ROI geometries being contained outside of the dose cloud. Since the ROI Gamma calculation uses comparison between 2 dose clouds, if part of an ROI resided outside of the dose cloud, the algorithm cannot produce a valid value since it cannot use any value to calculate the gamma value for the ROI will be incorrect.

Pulm total (Bladder) 7584.59 cc / ND**	TPS	SMC	% Difference
D15% (< 80.00 Gy)	1.24 Gy	1.45 Gy	-16.87 %
D25% (< 75.00 Gy)	0.48 Gy	0.51 Gy	-6.19 %
D35% (< 70.00 Gy)	0.28 Gy	0.26 Gy	7.27 %
D50% (< 65.00 Gy)	0.14 Gy	0.12 Gy	13.79 %
DMax (< 65.00 Gy)	72.60 Gy	73.30 Gy	-0.97 %
Thrachea (BrachialPlexus) 31.57 cc / ND**	TPS	SMC	% Difference
D5% (< 60.00 Gy)	11.68 Gy	11.07 Gy	5.22 %
DMax (< 66.00 Gy)	12.92 Gy	13.46 Gy	-4.23 %
esophagus 13.60 cc / 100 %	TPS	SMC	% Difference
D40% (< 50.00 Gy)	1.58 Gy	1.43 Gy	9.46 %
DMean (< 34.00 Gy)	2.77 Gy	2.75 Gy	0.59 %
Cor (Heart) 439.23 cc / NC*	TPS	SMC	% Difference
D33% (< 60.00 Gy)	0.05 Gy	0.06 Gy	-18.18 %
D67% (< 45.00 Gy)	0.04 Gy	0.04 Gy	-28.57 %
D100% (< 40.00 Gy)	0.00 Gy	0.00 Gy	0.00 %
DMean (< 26.00 Gy)	0.05 Gy	0.06 Gy	-32.80 %
48 Unmapped ROIs			

Gamma can't be calculated due to dose voxels below cutoff dose for the whole ROI.
**Cannot calculate Gamma due to ROI extents exceeding Dose extents.*
Legend: Meets Limit Below/Exceeds Limit Within Limits/Variation Acceptable Unmapped ROI

Note: If any of the ROIs encounter the ND situation, the overall patient gamma can be incorrect. IMSure 3D still calculates the patient gamma value, but will provide a warning to indicate that with one (or more) of the ROI's gamma value cannot be evaluated. The overall patient gamma value may skew towards more positive results and should be further inspected. (See Section 8.8 – Gamma Analysis)

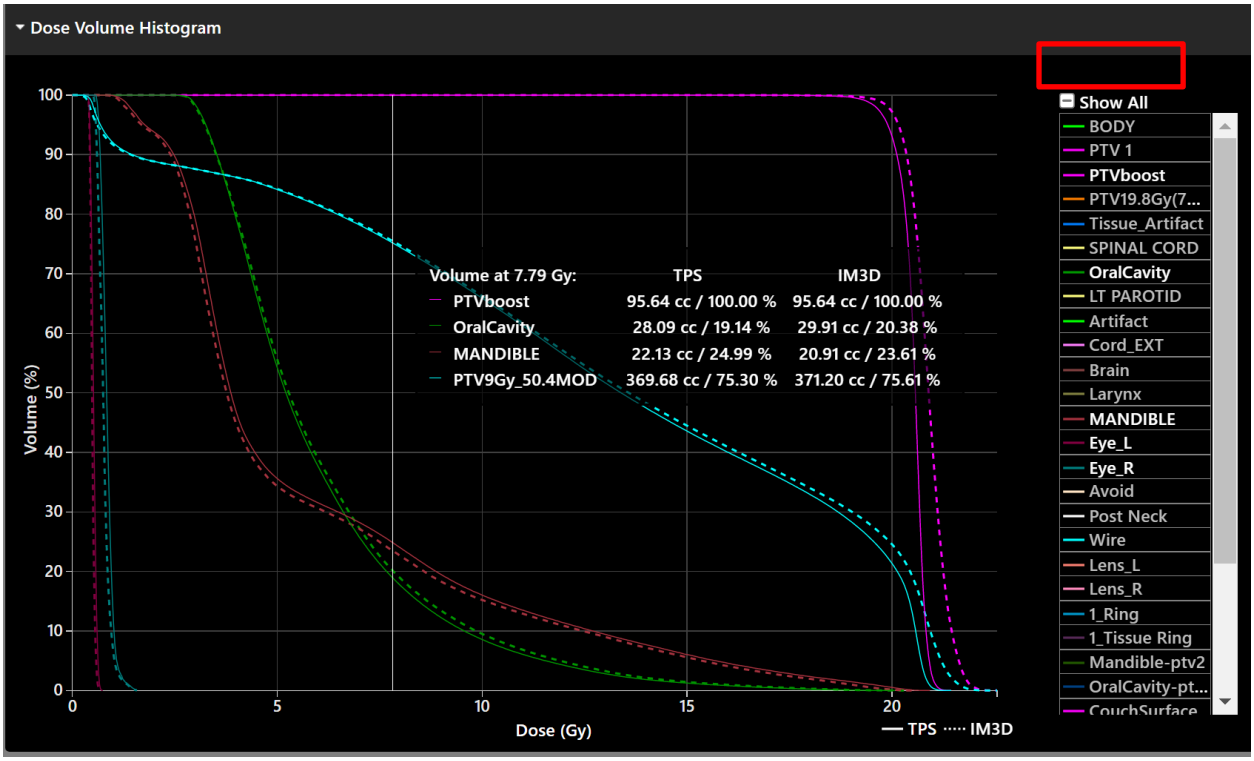
Gamma Analysis

Passing Rate	Criteria	Dose Cut-Off	Reference Dose	Analysis	TPS Voxel Size (mm)	SMC Voxel Size (mm)
76.8 %	2% / 1 mm	5%	TPS	Global	1.50, 2.00, 2.00	3.00, 3.00, 3.00

*3D Gamma Passing Rate may be adversely affected by one or more ROIs that are outside of the dose extents.

8.3 Dose Volume Histogram

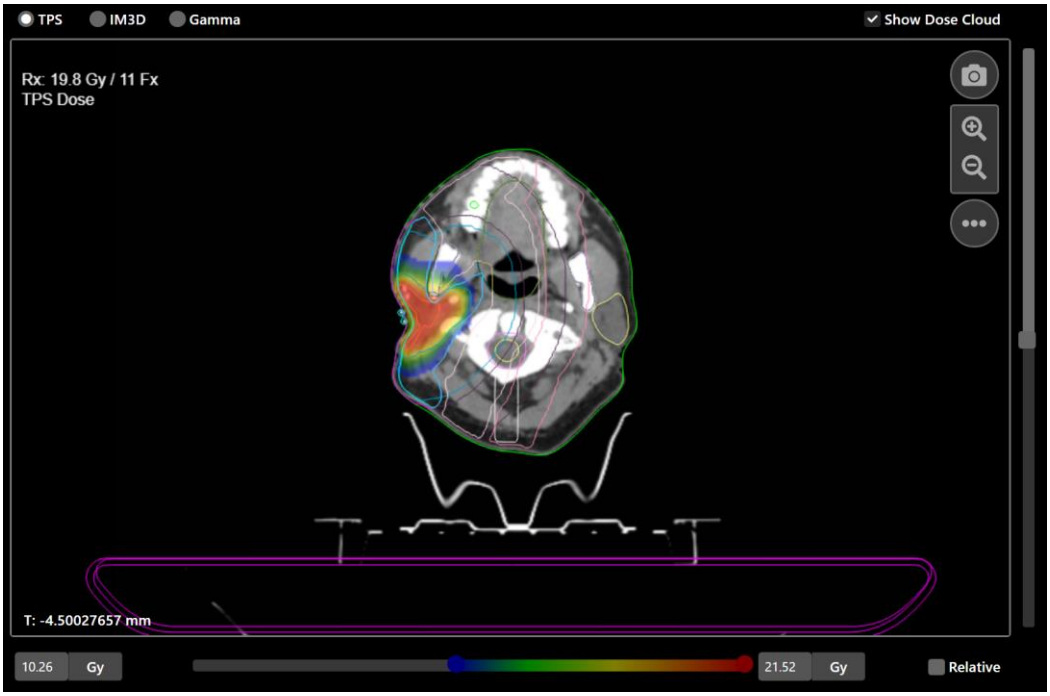
The Dose Volume Histogram (DVH) includes comparative DVH curves for the TPS dose calculation (solid line) and IMSure 3D dose calculation (dotted line). Individual structures can be added or removed from the display by clicking the structure name to the right of the DVH. All structures can be turned on or turned off by selecting the *Show All* checkbox above the structure list. Hovering the curser over the DVH will present dose volume statistics in tabular form for all active structures at that point on the graph. All structures listed in the DICOM RT SS will be displayed on the right column of the DVH.



8.4 Image Slice Viewer

The image slice viewer will display multiple views including, TPS dose, IMSure 3D dose, and Gamma Analysis in the transverse view. A corresponding gamma scale legend will be displayed in the Gamma Analysis view.

Full Screen: The image slice viewer has an option for a Full Screen mode. To enable this mode click on the expand window icon in the image slice viewer menu bar. Press the ESC key on the keyboard to exit out of the full screen mode. All slice viewer functionalities listed below can be used in the normal viewing window as well as in full screen mode.



Scrolling: The image slice viewer can be manipulated by users. To scroll through the image slices, use either the scroll bar beside the image with a mouse or the arrow keys on the keyboard. The mouse wheel can also be used for scrolling through image slices. Ensure that the mouse cursor is in the image slice viewer screen when scrolling or using the arrow keys. Slice location is displayed in the bottom left corner of the image slice viewer.

Screenshots: The camera icon in the right corner of the screen allows for a screenshot image to be saved to the patient report. Image screenshots will be saved and can be viewed below in the Saved Images section.

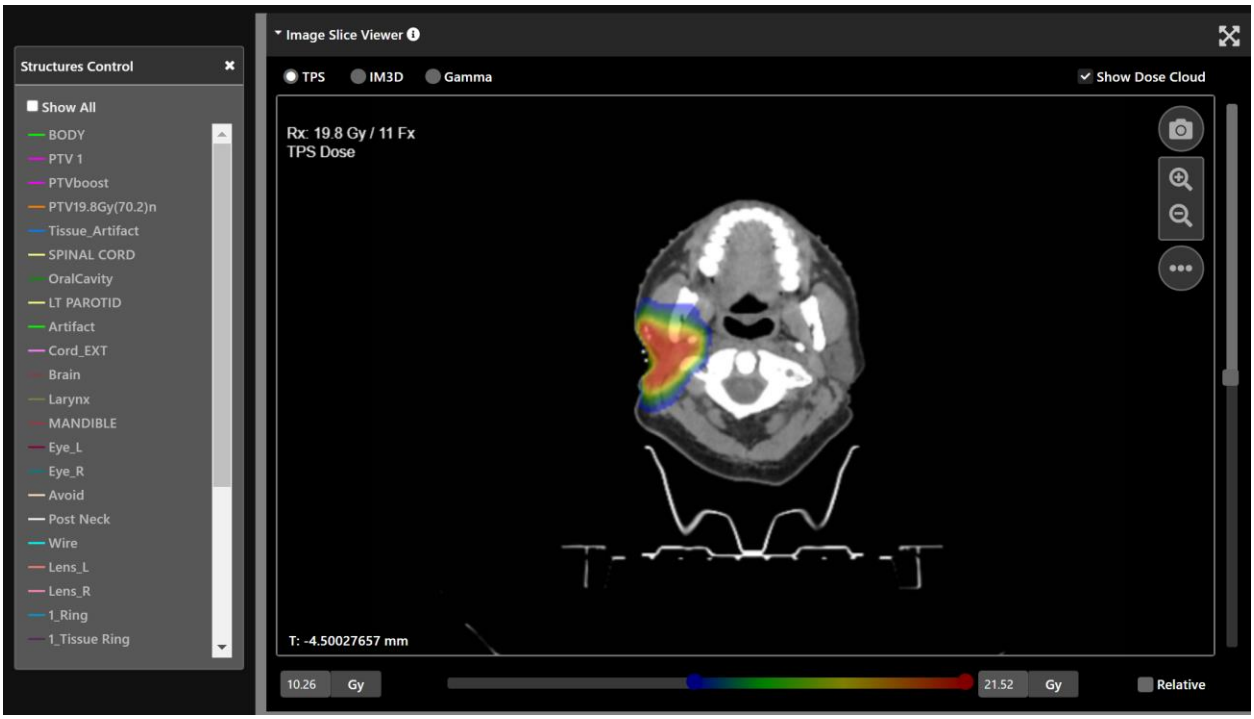
Zoom: The zoom "+" and "–" magnifying glass icons in the right corner of the screen allows for the image to be zoomed in or out in the viewer.

Pan: Using the mouse, users can grab and pan the image in the slice viewer.

Dose Cloud: In the TPS and IM3D dose views, there is checkbox option to toggle the display of the dose cloud.

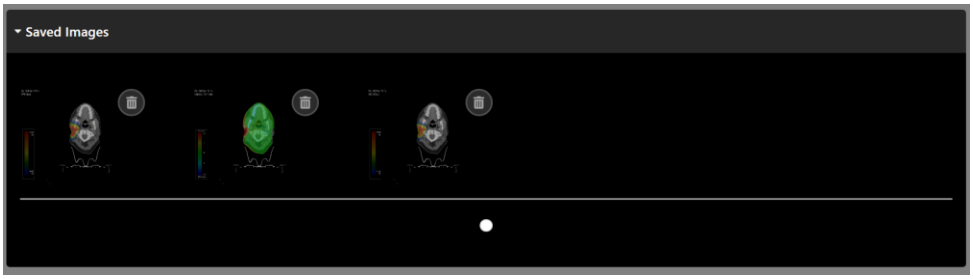
Dose Slider: The user can input dose values to control the dose cloud window level in addition to moving the slider with a mouse. There is an option to enter in either absolute or relative values. Click the checkbox marked Relative to use relative values.

Structure List: Click the "..." icon underneath the zoom buttons to access the structure list. There are options to turn on or off all structures and to toggle the view for each individual structure. The structure selections will persist between every view. To close the structure list, click the x button in the window or click the "..." icon again.



8.5 Saved Images

Saved images will be included in the patient's report. Scroll through the saved images by using the scrollbar underneath the images or page through the images by selecting the pagination (circle) buttons underneath the scrollbar. An image can be enlarged by selecting the image or be deleted from the saved images section by clicking on the trashcan icon. These images will be included in the PDF report upon plan approval.



8.6 Beam Information Table

The Beam Information Table section of the patient's report will display the relevant beam information (if available), which includes:

- Beam Name
- Beam Type
- Radiation Type
- Energy
- Fluence
- Number of Control Points
- Applicator Type (Electron, SRS cone and ZAP-X only)
- Applicator ID (Electron, SRS cone and ZAP-X only)
- Diameter (SRS cone and ZAP-X only)
- Opening X (Electron only)

- Opening Y (Electron only)
- Block Data Size (Electron only)
- Gantry
- Min Gantry (VMAT only)
- Max Gantry (VMAT only)
- Gantry Arc (VMAT only)
- Gantry Rotation (VMAT only)
- Collimator
- Couch
- TPS MU
- SMC MU
- TPS Beam Dose (Gy)
- SMC Beam Dose (Gy)
- Beam Dose Difference
- Beam Delivered Energy
- Time (min) (TomoTherapy only)
- Beam Dose Specification Point*
- Dose Gradient at Specification Point
- Density at Specification Point
- Density Gradient at Specification Point
- Field Irregularity
- Small Field Contribution
- Off Axis Contribution
- Leaf Travel Variability
- Leaf Gantry Synchronization
- Max Leaf Travel Per MU
- Max Gantry Rotation Per MU

*If the Beam Dose Specification point is not available in the DICOM, then it will look for a DoseReferenceItem Type COORDINATES in the DICOM. If both are not available then the Isocenter will be used to calculate the MU.

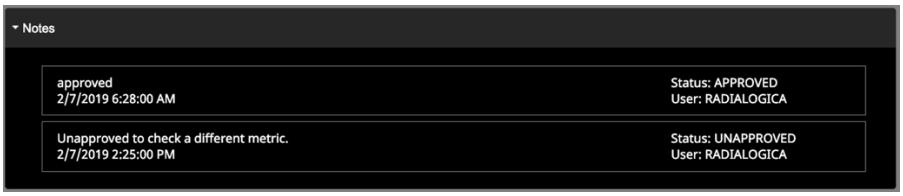
Beam Information Table

Shared Beam Information	
Energy (MV)	15 MV
Beam Type	StaticIMRT
Couch	0.00°
Collimator	0.00°
Beam Dose Specification Point	3.17, 0.72, -1545.50
Dose Gradient At Specification Point	0.55 %/mm
Density At Specification Point	1.10 g/cm³
Density Gradient At Specification Point	0.00 (g/cm³)/mm

Beam	1	2	3	4	5	6
Beam Name	1.A01	1.A02	1.A03	1.A04	1.A05	1.A06
Gantry	140.00°	100.00°	60.00°	20.00°	340.00°	300.00°
TPS MU	44.10	37.40	33.50	65.90	63.20	35.70
TPS Beam Dose	0.24 Gy	0.23 Gy	0.25 Gy	0.29 Gy	0.27 Gy	0.24 Gy
SMC MU	45.25	38.38	34.38	67.62	64.85	36.63
SMC Beam Dose	0.23 Gy	0.22 Gy	0.24 Gy	0.28 Gy	0.26 Gy	0.23 Gy
Beam Dose Difference	2.61%	2.61%	2.61%	2.61%	2.61%	2.61%
Beam Delivered Energy	6.44e4 MUcm²	4.33e4 MUcm²	4.68e4 MUcm²	1.1e5 MUcm²	8.33e4 MUcm²	5.03e4 MUcm²
Field Irregularity	38.79	28.33	25.43	42.32	39.01	25.01
Small Field Contribution	-105.66	-15.91	-24.91	-110.44	30.56	-67.19
Off Axis Contribution	-89778.13	-38573.65	-62648.27	3491.04	-21240.99	-87972.65
Leaf Travel Variability	0.00	0.00	0.00	0.00	0.00	0.00
Leaf Gantry Synchronization	0.00	0.00	0.00	0.00	0.00	0.00
Max Leaf Travel Per MU	0.00	0.00	0.00	0.00	0.00	0.00
Max Gantry Rotation Per MU	0.00	0.00	0.00	0.00	0.00	0.00

8.7 Notes

The Notes section will display any notes entered in during a patient report status change. It will display the date and time the note was entered, who made the status change, and the new status. All notes will be displayed in the patient report PDF.



8.8 Gamma Analysis

The Gamma Analysis section will display the Gamma Analysis passing rate as well as the criteria used to generate the Gamma Analysis.

The passing rate is color coded, with green denoting "*Meets or exceeds limit*," red denoting "*Below limit*," and yellow denoting "*Within limit*."

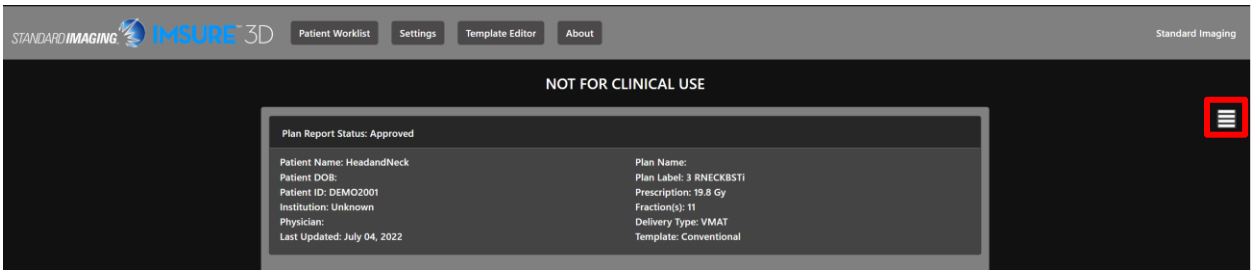
Gamma Analysis

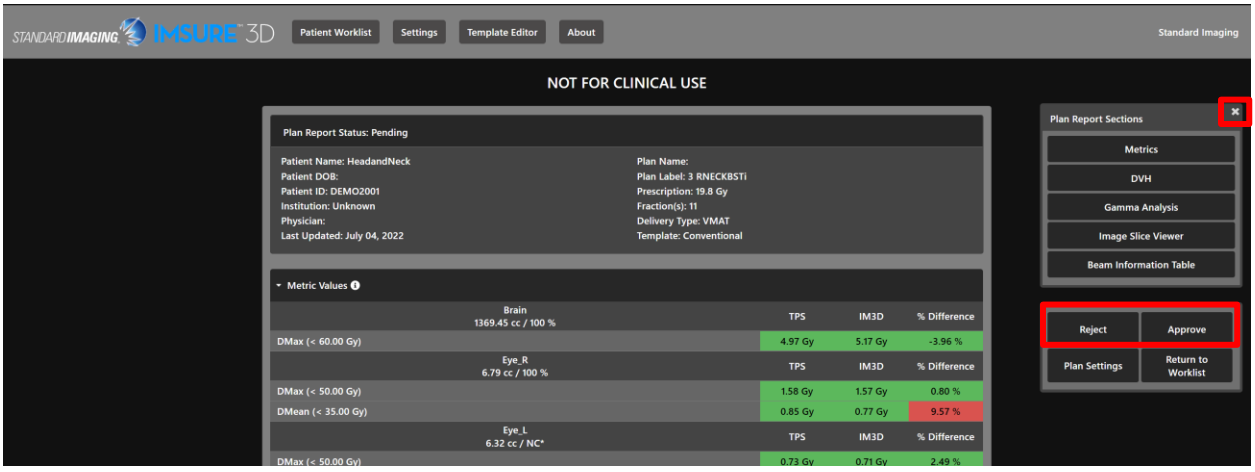
Passing Rate	Criteria	Dose Cut-Off	Reference Dose	Analysis	TPS Voxel Size (mm)	IM3D Voxel Size (mm)
94.9 %	2% / 1 mm	5%	TPS	Global	2.00, 2.00, 2.50	3.00, 3.00, 3.00

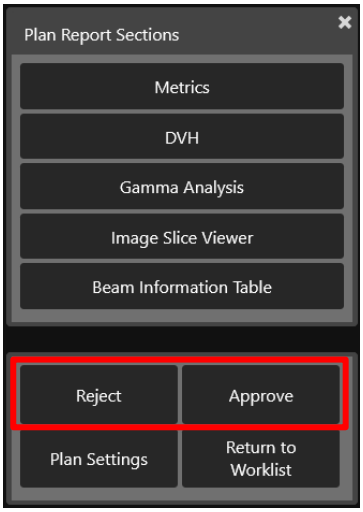
9 Plan Approval

IMSure 3D allows you to approve a plan, reject a plan, and add notes for approved and rejected plans. Plan reports in a PDF format are automatically generated for approved plans. The generated PDF can be accessed in the patient worklist or inside of the plan review page. Approval status and time stamp are recorded on the PDF report along with any notes. To approve or reject a plan, click the *Approve* or *Reject* button in the plan navigation panel to the right of the report.

Note: Plan Navigation Panel can be maximized and minimized by using the *Menu* or *X* icon in the upper right-hand corner of the plan review.

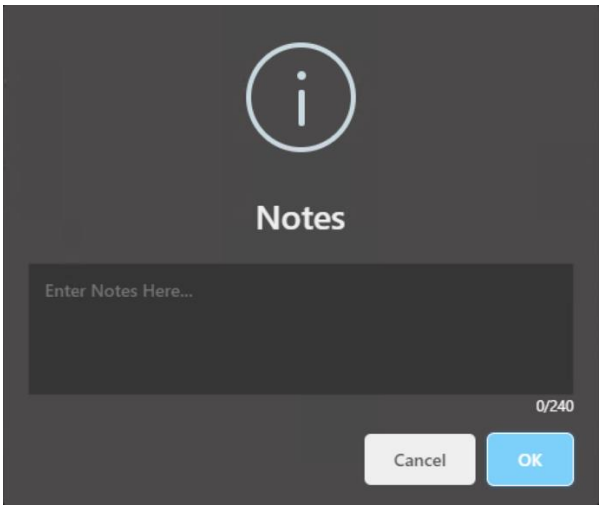




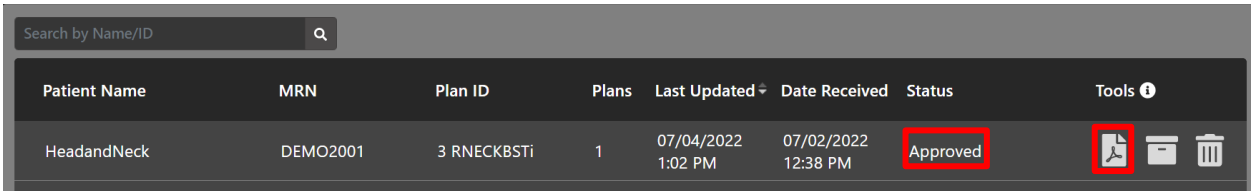


9.1 Approve

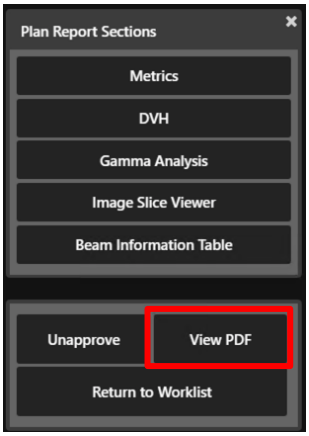
To approve a plan, click *Approve* and a dialog box will be presented for notes that will be included in the plan report. Enter notes in the free text field and click *OK* to save or click *Cancel* to exit and return to the plan panel.



Once a plan has been approved, a dialog box will display stating *Generating PDF* for successfully changing the plan status. Select OK to return to the patient worklist. The plan status will change to *Approved* and a PDF icon will appear in the Tools column of the patient worklist.



Click the PDF icon on the patient worklist to display the PDF report for the selected patient / plan.

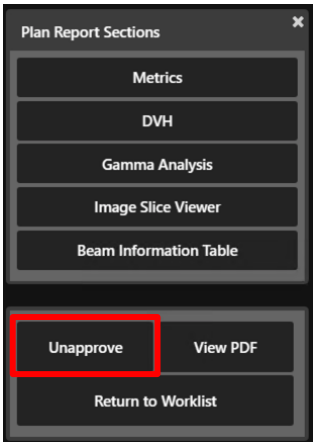


The PDF can also be viewed by opening an Approved plan report and then selecting the *View PDF* button in the Plan Navigation Menu.

After the PDF has been launched it can be saved to a connected storage location.

9.2 Unapprove

To retract approval for a plan that was previously approved, click the plan row for the patient / plan. Once the approved report displays, click the *Unapprove* button in the plan navigation panel to the right of the report.



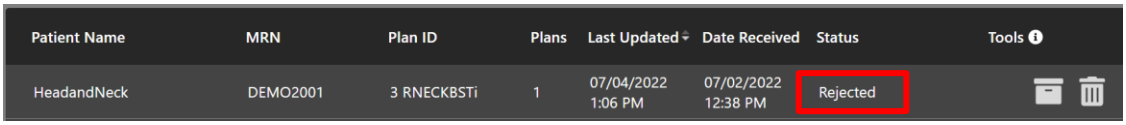
Once the plan has been unapproved, a dialog box will display stating that the plan status was successfully changed. Select *OK* to return to the patient worklist. The plan status will revert to *Pending*. The status changes including a time stamp will be recorded in the notes section of the plan report.

9.3 Reject

To reject a plan, click *Reject* and a dialog box will be presented for notes that will be included in the plan report. Enter notes in the free text field and click *OK* to save or click *Cancel* to exit and return to the report panel.

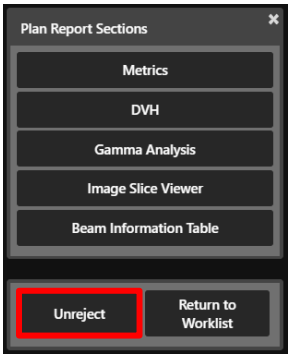
Once a plan has been rejected, a dialog box will display stating that the plan status was successfully changed. Select OK to return to the patient worklist. The plan status will change to *Rejected*.

Note: PDF copies of plan reports are not generated for rejected plans.



9.4 Unreject

To retract rejection for a plan that was previously rejected, click the plan row for the patient / plan. Once the rejected report displays, click the *Unreject* button in the bottom right corner of the dialog box.

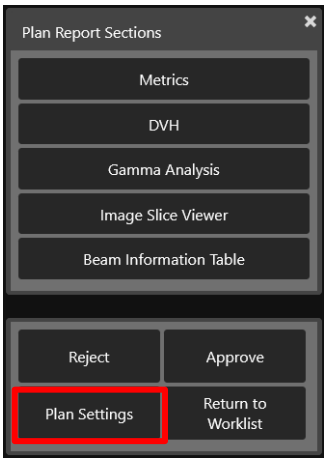


Once the plan has been unrejected, a dialog box will display stating that the plan status was successfully changed. Select *OK* to return to the patient worklist. The plan status will revert to *Pending*. The status changes including a time stamp will be recorded in the notes section of the plan report.

10 Plan Settings

While global settings are automatically applied to all plans, users can review and modify the settings for individual plans by clicking the *Plan Settings* button within the plan report. Modifying plan-specific parameters will result in the generation of a new plan report and may also prompt a new dose calculation or Gamma Analysis. Click on *Plan Settings* in the plan navigation panel to the right of the report.

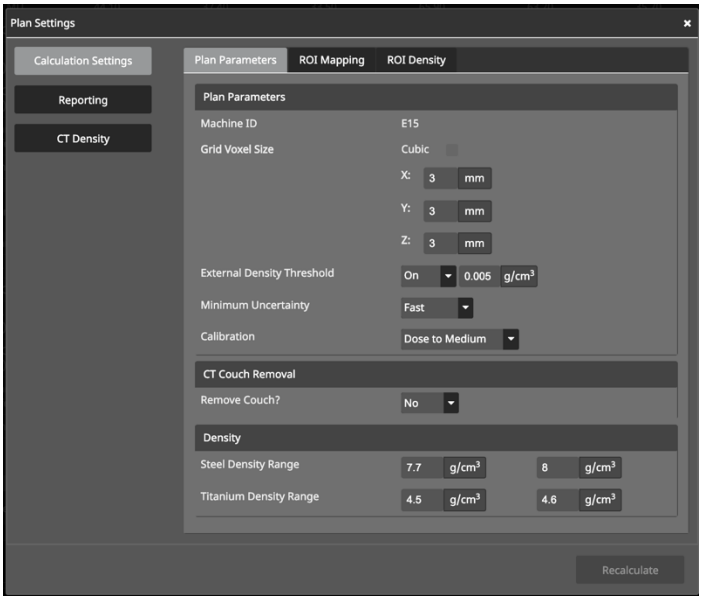
Note: If there is no prescription dose or fractions entered when *Plan Settings* is selected, then those values must be entered to continue.



10.1 Calculation Settings

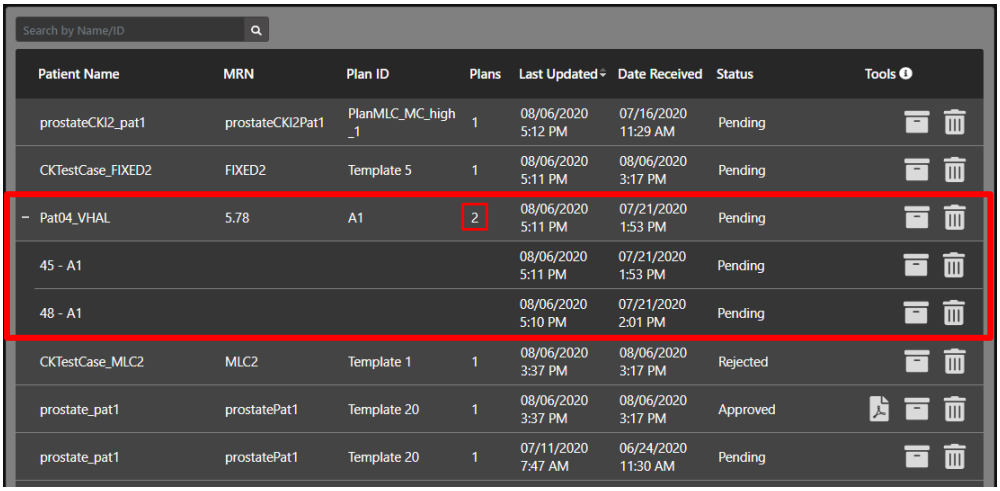
Changes in the following plan parameters within *Calculation Settings* will result in a new IMSure 3D dose calculation:

- Grid voxel size
- External Density Threshold
- Minimum uncertainty
- Calibration medium
- Couch removal
- Steel density
- Titanium density



You can modify the plan parameter fields by editing the text in the corresponding text field. Click the *Recalculate* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.

Changes in plan parameters resulting in a new dose calculation will present an additional row and plan for a given patient on the patient worklist. The patient row can be expanded to view all plans for that patient by clicking the plus sign to the left of the patient name. You can also click anywhere in the row of the patient to display all plans for the patient.



10.2 ROI Mapping

IMSure 3D includes a structure mapping file that allows you to define structure synonyms for ROIs on a per plan basis. The purpose of this mapping file is to allow the user to overcome variability in structure naming within the clinic. Structure synonyms that are not defined in the global settings can be performed on an individual plan basis. Mapping synonyms in *Plan Settings* will only save for that particular plan. To save synonyms within global mapping, define within *Settings*. (See Section 5.2 – Calculation Settings).

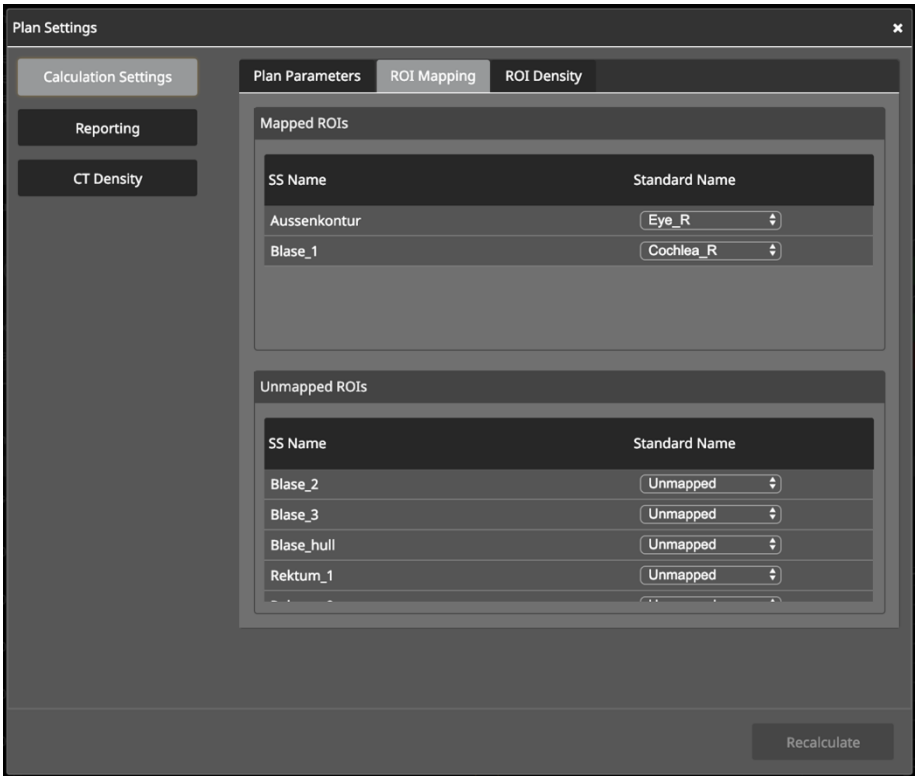
To map structures, select the *ROI Mapping* tab within *Calculation Settings*. You will be presented with the structure mapping dialog. The structures currently mapped within global mapping will display on the top half of the page. Unmapped ROIs will display on the bottom half of the page.

DVH curves will display for all structures within the dataset if the structure is selected for DVH display. Metric limits within the dose difference report only display for mapped structures for the selected evaluation template.

The left side of each mapping dialog displays a list of structures in the currently loaded dataset for the patient under the column *SS Name*. The right side of each mapping dialog contains a dropdown menu for all ROIs listed in the selected evaluation template under *Standard Name*. This dropdown menu will allow for:

- Un-mapping a structure: Select *Unmapped* from the dropdown menu.
- Remapping a structure: Select a different template structure from the dropdown menu.
- Mapping an unmapped structure: Choose a template structure from the dropdown menu.

Once mapping is complete, click *Recalculate* to generate a revised plan report. Mapping changes will be saved.



10.3 ROI Density

The ROI Density tab provides the opportunity to edit information about any Region of Interest (ROI). Changes in the following ROI Density parameters will result in a new IMSure 3D plan report. Changing the ROI Density values will result in a new dose calculation or plan row on the patient worklist.

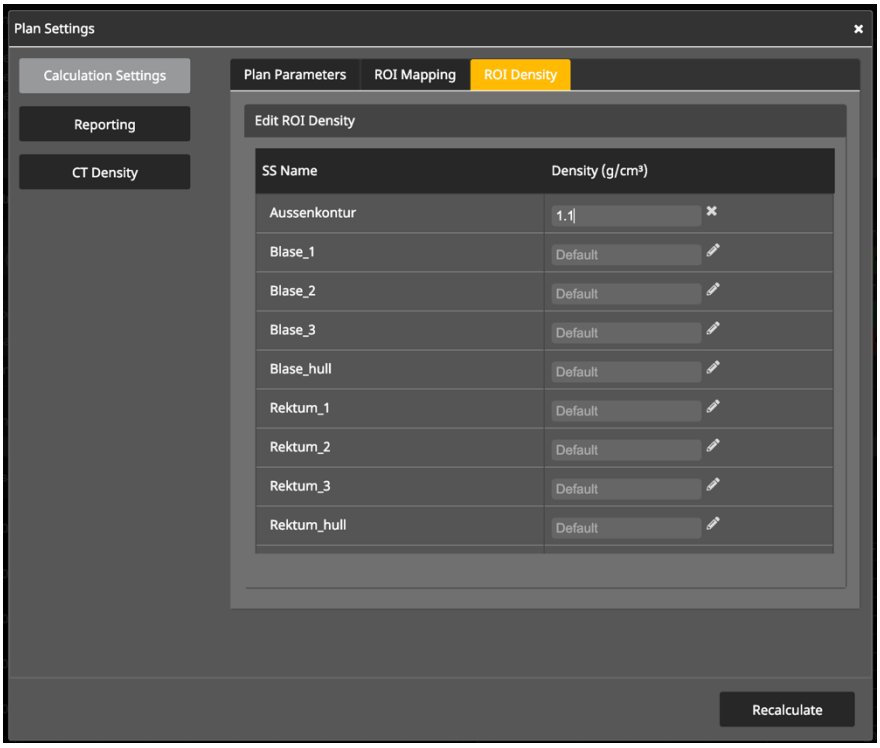
Density values are expressed in units of g/cm^3. Acceptable minimum density value is 0.80 g/cm^3 and maximum value is 1.80 g/cm^3.

The plan setting menu allows for density overrides by region of interest (ROI) as in the structure set. Density value of zero (0) ignores the ROI in the density grid. ROI density overrides follow the order given by the structure set. The default ROI density value is obtained from the CT DICOM-RT structure set density value. This value can be overridden in IMSure 3D and will be used for dose calculation.

To change an ROI Density value, click on the pencil icon and insert a new value in the text box. If the default value is desired type in “Default” into the text field of the ROI.

To cancel an ROI Density row change, click on the “x” icon which will erase the changed value and will instead display the last saved density value.

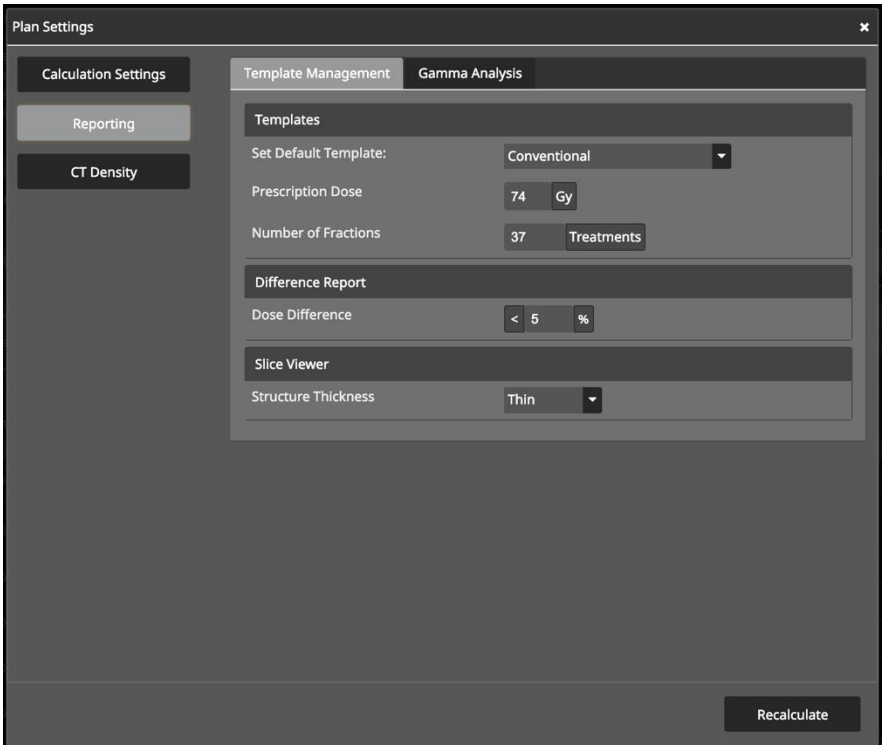
Click the *Recalculate* button to save changes. To cancel the modified selections and revert to the prior settings, click the “x” button in the top right corner of the dialog box.



10.4 Reporting Settings

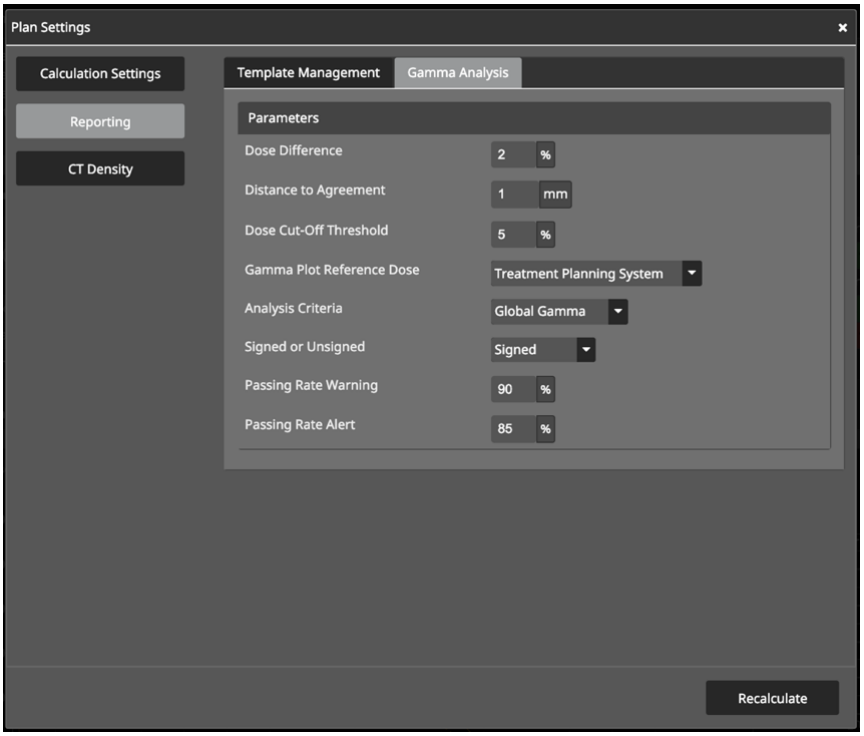
- **Template Management**: Changes in the following reporting parameters will result in a new IMSure 3D plan report. Changing only these reporting settings will not result in a new dose calculation or plan row on the patient worklist.
    - Evaluation template
    - Prescription dose
    - Number of fractions
    - Dose difference criteria
    - Structure Thickness in Slice Viewer

You can modify the Template Management fields by editing the text in the corresponding text fields or selecting a different template from the drop. Click the *Recalculate* button to save changes. To cancel the modified selections and revert to the prior settings, click the "x" button in the top right corner of the dialog box.



➢ **Gamma Analysis**: Changes in the following parameters will result in a new IMSure 3D plan report.

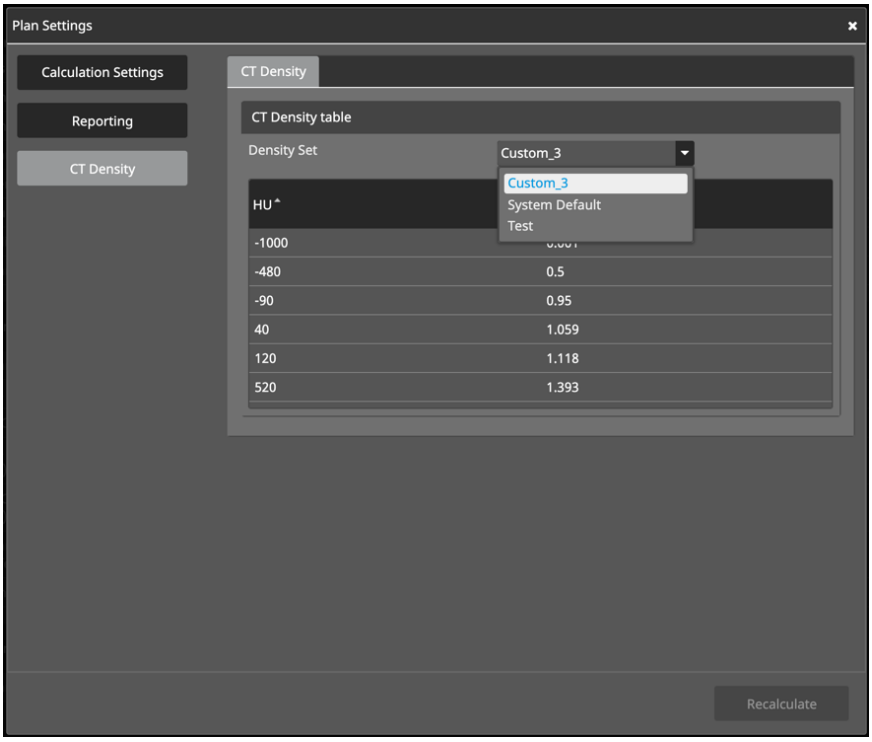
- Dose Difference: Used to compare the dose at corresponding points in both distributions. Values are expressed in units of percentage. You may edit the value by clicking inside the text field.
- Distance to Agreement: Distance-to-Agreement is the nearest point in the measured distribution. Values are expressed in units of millimeters. You may edit the value by clicking inside the text field.
- Dose Cut-Off Threshold: Any dose under the set value in this field will not be considered for the gamma calculation. Values are expressed in units of percentage. You may edit the value by clicking inside the text field.
- Gamma Plot Reference Dose: Select between the TPS or IMSure 3D reference dose as the denominator for the dose difference calculation using the drop-down menu.
- Analysis Criteria: Select either Local or Global Gamma from the drop-down menu.
- Signed or Unsigned: Select between signed (-2 to 2) or unsigned (0 to 2) percentage comparisons values using the drop-down menu.
- Passing Rate Warning: Any rate above the value set in the Passing Rate Alert field and Below the Passing Rate Warning field will trigger a yellow alert. Values are expressed in units of percentage.
- Passing Rate Alert: Any percentage rate below the value set in this field will trigger a red alert. Values are expressed in units of percentage.



10.5 CT Density

This section will allow users to select a different pre-made CT Density set. Selecting a new CT Density set will kick off a new dose recalculation which will result in a new plan review row. Within this menu, users will also be able to view the CT Density table this was used to calculate the plan and the content of other CT Density sets.

Note: When an Electron Density table is selected in Global Settings, IMSure 3D will automatically convert the Relative Electron Density values into Mass Density (g/cm3) when processing a plan. In the Plan Setting menu for that plan it will display the converted values in the HU-Density table.



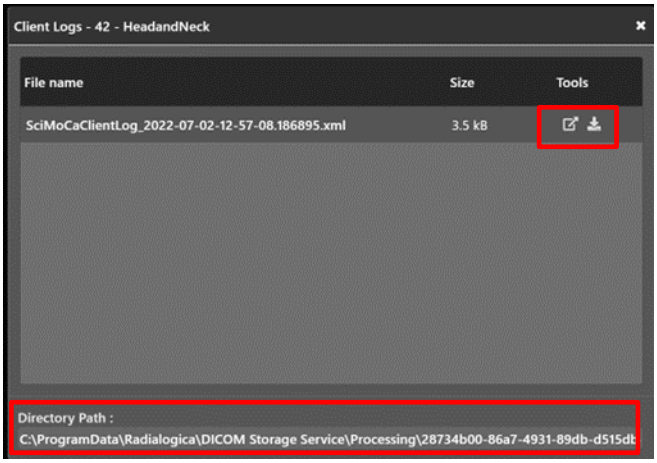
11 Logging

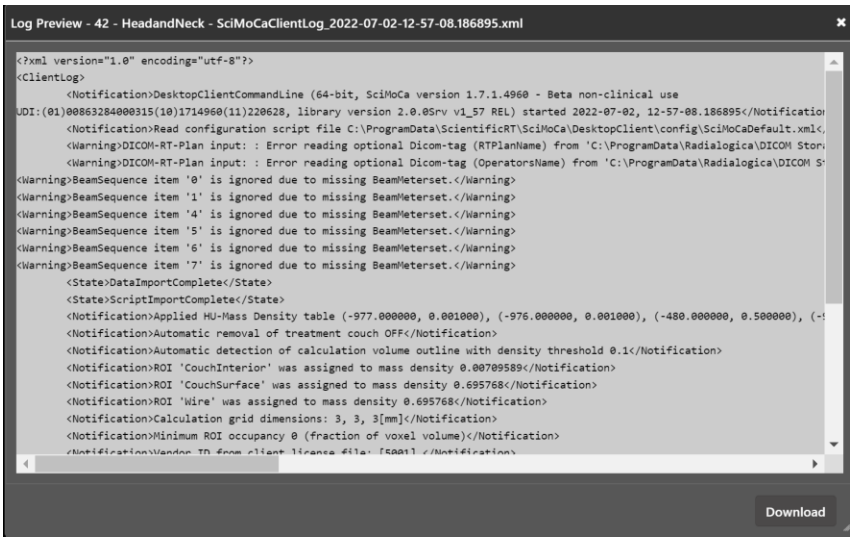
IMSure 3D creates both client and server log files. IMSure 3D will also log user interactions within the website.

11.1 Client Log Files

The log file, SciMoCaClientLog.xml file, created by the IMSure 3D client during execution, is stored in each patient's folder. The Client Log can also be accessed via the Worklist. To do this, the user must hold down the CONTROL key on the keyboard and right click using the mouse on any *Tools* icon in the chosen plan row.

Within this viewer the user will have the option to open the log, download the log, or interacting with the file such as copying information. The viewer will also display the directory path at the bottom of the viewer. The user can copy and paste this path directly in the server's file explorer to navigate to the chosen patient processing folder.





The SciMoCaClientLog.xml file will contain the following types of messages:

- State messages: Indicate the normal performance of the client and are intended to document the successful completion of internal stages.
- Notifications: Report essential information about settings that affect the dose calculation that cannot be derived from the DICOM dose object. Notifications refer to settings that concern the mass density distribution and the beam model ID.
- Warnings: Indicate that the client encountered unexpected or missing input data. IMSure 3D will continue execution, but further execution depends to some degree on the assumptions made while interpreting the data.
- Errors: Indicate that the client encountered an internal state or an input data problem that could not be resolved.

The SciMoCaClientLog.xml file contains notifications about all settings that affect dose calculation, in particular density overrides and beam model selections. This log file does not document normal actions of the client that are governed by the script input or the DICOM data.

11.2 Server Log Files

The IMSure 3D server will produce the following output which is written into the C:\ProgramData\Radialogica\SciMoCa\Server\Logs folder:

- Log file “SciMoCa.log” in ASCII text format for status and error information
- Error log file “SciMoCa_errors.log”
- For Windows, the server starts as a background process and thus does not produce console output

The logging output of the server contains three categories of messages:

- State messages: Indicate the normal performance of the server and are intended to document the successful completion of internal stages. Possible state messages include:
  - Start and termination of the server
  - Connection attempts of client sessions
  - Successful creation of client-sessions
  - Successful start of dose calculation request
  - Completion of dose calculation request
  - Successful upload of beam model data
- Notifications: Report versioning and run time information. The former includes version- and build-information of the server binary and the server-client-library used by the server. The latter include information about the configuration options and the license file, as well as information about the remaining number of allowed client connections.
- Errors: Indicate that the server encountered an internal state or an input data problem.

Error messages are written both into the error log file and the general log file. All other types of messages are written into the general log file only. All messages are tagged with timestamps using the UTC time format (time resolution: 1s). Subsequent start and termination of the server executable do not overwrite the log files but do append new logging messages to existing log files.

11.3 Other Log Files

The log files from the Service.Manager, Website, and the User Audit log will be output to the C:\ProgramData\Radialogica\SciMoCa\Logs folder.

User Audit logs will capture user interactions within the worklist, plan review, pdf report, template editor, global settings, and plan settings. To turn on the User Audit feature please contact your IMSure 3D server administrator.

12 Cybersecurity

Cybersecurity risks are considered in the risk analysis and overall design and development process. Because the application is installed and hosted in a customer's institution our focus is on providing configurability options such that the end user can configure and administer the application in a manner consistent with best privacy/security practices. In general, we consider access control, content control and trusted content as risk/failure categories. Also, in general, mitigations are focused on implementing the application with support for Windows Active Directory; an ability to require/set passwords that control access to settings options in the application, plan approval/rejection; and logging of user access and activity.

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