# AutoContour

# User Manual

V2.2.0, Rev 8.0

RAD formation

335 Madison Ave, 4th floor
New York, New York 10017
USA
844-723-3675
support@radformation.com

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# 1. Introduction

## 1.1. What is the AutoContour Application?

AutoContour is a .NET application that can be run either as a standalone executable or as a plugin through the Eclipse™ (by Varian Medical Systems, Palo Alto, CA) Treatment Planning System Scripting API (ESAPI Versions 15.5, 15.6, and 16.1) . It can read and modify structure sets for a patient image designated by the user, sending the de-identified image matrix to Radformation's AutoContour web services to (1) automatically contour various structures of interest for radiation therapy treatment planning using machine learning based contouring, (2) allow the user to review and modify the resulting contours, and (3) export the approved modified structures to a DICOM file or directly into the Eclipse™.

AutoContour also allows the user to perform rigid and deformable image registrations for the purposes of transferring structure contours from one image series and producing deformed dose distributions that may be used for evaluation within ClearCheck.

## 1.2. How does it benefit the users?

Radiation oncology treatment planning generally requires contouring structures such as organs-at-risk such that dose-volume histogram analysis can be performed in order to determine whether dose to these structures are within constraints that minimize dangerous side effects of radiation. AutoContour benefits the user by automatically contouring many of these structures and providing a workspace where the user can review, edit, and export these Structures back to the Eclipse™ treatment planning system or DICOM structure set file.

Further the rigid and deformable image registration tools allow the user to easily transfer previously generated contour data from one Image Set to another for adaptive treatments as well as produce deformed dose distributions that may be used for evaluation within ClearCheck.

## 1.3. Key sections of the software

AutoContour ESAPI Application consists of:

1. AutoContour, a .NET application executable.

2. A cloud-based AutoContour automatic contouring service that produces initial contours for the image set sent to it by AutoContour.

## 1.4. Indication for use

AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.

## 1.5. Developer's Information

**Manual Name:** Radformation AutoContour User Manual


AutoContour™

AutoContour Version 2.1.0
**Developed by Radformation, Inc.**
335 Madison Avenue, 16th Floor
New York, NY 10017
USA

## 1.6. Package Includes

- User Manual
- AutoContour Installer.
- All software and manuals are downloaded via https://www.radformation.com/

## 1.7. Symbols

| Symbol | Description |
|---|---|
|  | **MANUFACTURE**<br>**Manufacturer's name and address** |
|  | **Operation Instructions** |

| | |
|---|---|
|  | **Warnings** |
| Rx Only | **Prescription Only Device** |

## 1.8. Software Recommendations

Only the AutoContour.exe is installed locally.

- Operating Systems Supported: Windows 7 (32- or 64-bit), Windows 8 (32- or 64-bit), Windows 10 (32- or 64-bit, Windows 11 (32- or 64-bit), Windows Server 2008, 2008 RS, 2012, 2016, and 2019, .NET Framework version 4.5 or higher is required.
- CPU: 2.4+ GHz, Multi-core processor (2+ cores, 4+ threads)
- Hard drive space: Software components fully installed require only ~10MB, but storage requirements for patient data are much larger and vary from clinic-to-clinic. A minimum of 100 GB hard drive is suggested for larger patient sets.
- Memory (RAM): 8+ GB
- Display Resolution: A minimum of 1280 x 1024, 24- or 32- bit color depth.
- Citrix Workspace or Citrix Receiver 4.12 or higher is recommended.
- AutoContour Network Requirements: >100Mbit/s internet upload speed recommended (uploaded compressed image data is usually between 20-50MB, structure results for downloading are usually <1MB).

## 1.9. Cybersecurity

- Network firewall with port 443 open for HTTPs communication
- Radformation server HTTPs API endpoints protected by authentication token requirement; only clients with valid AutoContour license are allowed to communicate with HTTPs endpoints.
- All local storage data is encrypted using AES-256 bit encryption.
- AutoContour Plugin can only be accessed through Eclipse, as the application is an Eclipse plugin which requires users to have an Eclipse username and password.
- The Administration and DICOM standalone applications are username and password protected. Passwords are hashed using the Scrypt hashing algorithm or users can configure Windows Active Directory to restrict access to users with valid Windows Active Directory credentials.
- Recommended to update local computers to Windows 11/10, or at least the latest Windows 7 ESU service pack in order to enable usage of latest TLS versions and cipher suites.
- Recommended to remove NSA obsolete ciphers from local computers e.g. TLS_RSA_WITH_3DES_EDE_CBC_SHA to remain up to date with latest NSA security recommendations for secure HTTPs connections.

# 2. Device Description

AutoContour is software that uses image data as input to (1) automatically contour various structures of interest for radiation therapy treatment planning using machine learning based contouring, (2) allow the user to review and modify the resulting contours, and (3) generate structures that can be exported into the Eclipse™ radiation therapy treatment planning system.

## 2.1. AutoContour™ Administration Application

The AutoContour™ Administration Application is used to set department structure standards and to manage user account settings. The following are set in the administration application:

- Global Structure Templates
- Users
- Global System Settings
- Software License Key

## 2.2. Operating Environment

AutoContour ESAPI Application consists of:

- AutoContour.exe, a .NET application executable.
- A cloud-based and/or On-Prem AutoContour automatic contouring service that produces initial contours for the image set sent to it by AutoContour.exe.

**AutoContour.exe**

AutoContour.exe is a standalone Windows Application designed to run on Windows 7, Windows 10 or Windows Server 2016 Operating Systems. It is created for the .NET 4.5 runtime and is written in C#. The application may be launched directly or via another application - ClearCheck - which launches AutoContour for a specific patient structure set and also provides the current dose constraint template ID to AutoContour. AutoContour then uploads the deidentified image matrix to a Google Cloud API backend that notifies the Automatic Contouring Service when the dataset is ready to be processed. AutoContour then provides the user interface that allows the user to edit, review, and approve structures that can then be exported to the Eclipse™ treatment planning system through the Eclipse™ Scripting API (ESAPI (ESAPI Versions 15.5, 15.6, and 16.1), if launched through ClearCheck, or to a DICOM Structure Set file if launched directly .

**Cloud-based Automatic Contouring Service**

The cloud-based Automatic Contouring Service is built using Python code and the Python runtime and is served from the Google Cloud Platform from a Compute Instance (Virtual machine) running the Linux operating system.

**Windows-based Automatic Contouring Service**

AutoContour On-Prem Application consists of a Windows Service "AutoContourOnPrem" that runs at all times in the background monitoring a DICOM input directory from which DICOM image sets will be automatically processed. AutoContour On-Prem Service utilizes Python V3.6.8 running on a Windows Operating System.

**Automatic Rigid and Deformable Registration Service**

AutoContour utilizes an open source Elastix V5.0.0[1] and Simple ITK V2.0.0[2] for both automatic rigid and deformable image registrations. Full documentation of this library is available here: https://elastix.lumc.nl/download/elastix-5.0.1-manual.pdf

## 2.3. Memory Constraints

System will require at least 50MB of hard drive space to install the AutoContour.exe

## 2.4. Periodic Maintenance

When an update to the software is available, users will be notified via email. The email will have information of the changes that have occurred with the new version. As AutoContour has both a locally installed and web component, updates to the specific components are made available in different ways:

**AutoContour.exe**

To install an updated version of AutoContour.exe, open a web browser to https://www.radformation.com and log in with your account. On the right-hand side of the page, you will see a region for ClearCheck with a link to download the updated installer (with the version number identified as AutoContour.exe is bundled with the ClearCheck installer). Download the installer and run it from the target computer to update your AutoContour.exe installation.

**Cloud-based Automatic Contouring Service**

The cloud-based Automatic Contouring Service backend may be periodically updated by Radformation to improve reliability, contouring accuracy, and/or to add new features to the product. These updates are applied in a fashion where there is no disruption to service for AutoContour users.

[1] S. Klein, M. Staring, K. Murphy, M.A. Viergever and J.P.W. Pluim, "elastix: a toolbox for intensity based medical image registration," IEEE Transactions on Medical Imaging, vol. 29, no. 1, pp. 196 - 205, January 2010.
[2] https://simpleitk.readthedocs.io/en/master/index.html

**Windows-based Automatic Contouring Service**

To install an updated version of the On-Prem Automatic Contouring Service , open a web browser to https://www.radformation.com and log in with your account. On the right-hand side of the page, you will see a region for AutoContour On-Prem with a link to download the updated installer. Download the installer and run it from the target computer to update your version of the On-Prem Automatic Contouring Service.

# 3. Intended Use and Users

AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.
AutoContour is intended to be used by medical physicists, medical dosimetrists, and radiation oncologists.

# 4. Warnings

AutoContour software is not intended to contour tumors or lesions.

AutoContour software automatically generates many **INITIAL** structure contours, but the user **MUST NOT** assume that those contours are complete and accurate in all cases. It is possible for AutoContour to undercontour, overcontour or not find any structure on any scan.

AutoContour in some instances may incorrectly generate a contour for a structure that is not within the scan. Users **MUST** carefully review all structures for accuracy and remove any structures which are not correct prior to radiation treatment planning.

AutoContour structure models were trained on CT and MR Image datasets with patient demographic and scanner acquisition protocols described in further detail within Appendix A. Use of AutoContour structure models on patients or scan types outside of this scope may result in incorrect contour results.

During testing, some structure models displayed DSC standard deviation >0.1 including: A_LAD, Ear_Internal_L/R, Esophagus, Glnd_Lacrimal_L/R, Glnd_Submand_L/R, Lens_L/R, Lips_L/R, OpticNrv_L/R and OpticChiasm. Additional care should be taken when reviewing these structure models.

During testing, some structure models displayed a high percentage of False Positive Localization (Low Specificity) when presented with a scan well outside the expected anatomical region for that structure (Eg. Femur model included for prediction on a Brain Image Series). Additional care should be taken when reviewing these structure models for potential False Positive contouring including: A_Aorta, Bladder, Bowel_Bag, BrachialPlex_L, BrachialPlex_R, Breast_L, Breast_R, Bronchus, Carina, Breast_L, Breast_R, Bronchus, Carina, Femur_L, Femur_R, HDR_Cylinder, Humerus_L, Humerus_R, LN_Neck_IB-V_L, LN_Neck_IB-V_R, LN_Neck_II_L, LN_Neck_II_R, LN_Neck_II-IV_L, LN_Pelvics, LN_Sclav_L, LN_Sclav_R, Prostate, Rectum, and Stomach.

Users **MUST** carefully review all structures for accuracy and fix any structures which are not correctly contoured prior to using those structures in a radiation treatment plan. AutoContour's algorithm has the following limitations:

- IV Contrast and image artifacts may affect the accuracy of the algorithm.
- Some structures inherently lack local contrast on some aspects which may affect the accuracy of the algorithm (especially Brainstem, Parotid Glands, Submandibular Glands, Esophagus, Stomach, Bowel Bag, Bladder, Rectum).
- Scans that only include partial structures (e.g. half a brain) may result in contouring errors.

- Non-standard CT Imaging protocols (eg. 4D-CT Average, MIP, MinIP, Synthetic CTs generated from MR, CBCTs, and reduced FOV CT) were not used for the training of structure models and may affect the accuracy of the algorithm.
- Non T1-Post Axial MR Imaging protocols (eg. T2, FLAIR, etc) were not used for the training of the MR Brain structure models and should not be used with AutoContour's MR-based structure models including Brainstem, Hippocampus (L/R) OpticChiasm, and OpticNrv (L/R).
- MR and CT Imaging protocols with a slice thickness > 3mm may result in poor performance for smaller structures (Cochlea, Optic Chiasm, Optic Nerve etc).
- Long structures such as the spinal cord and esophagus may miss slices superior or inferior to the actual anatomic structure as shown on the scan.
- Patient anatomical abnormalities may affect the accuracy of the contouring algorithms for all structures (e.g. patient with high/low BMI, extensive disease overlapping with normal tissue, solitary kidney, surgical changes, heart on right side, etc.)
- Gender specific structure models including Prostate, Penile Bulb, Breast etc. may still generate results when applied to patients of the opposite sex. The user is responsible for ensuring contour models are not applied incorrectly for the patient site.
- AutoContour tends to contour structures in a particular way, and contouring is inherently subject to inter-observer variation. The user **MUST** ensure that the contoured structures are acceptable for their radiation treatment planning purposes. Be aware of the following tendencies or limitations in AutoContour's algorithm:
    - Brachial Plexus tends to be under-contoured laterally past the level of the first rib.
    - Esophagus tends to be under-contoured at the caudal aspect as there may be a gap at the level of GE junction and may not overlap with the Stomach AutoContour Structure
    - Parotids tend to be slightly under-contoured on the medial aspect which to some observers may be considered under-contouring.
    - Oral Cavity does not include teeth or air cavity which may be considered under-contoured to some observers.
    - Bowel Bag inter-observer variation is significant, and AutoContour's Bowel Bag approach represents a single style of contouring. It aims to encompass the potential extent of the bowel, but may be considered over-contouring or under-contouring to some observers. This is not intended to be a contour of the true bowel (which changes daily for many patients).
    - Femur contours do not cover the full extent of the femur inferiorly, but should be expected to end around the mid shaft. This may be considered to be over-contoured compared to some contouring standards which end either at the caudal end of ischium or just below the lesser trochanter.
- Using AutoContour on pediatric cases may result in poor performance or structures not being found because AutoContour was trained mainly on adult CT/MR data.
- AutoContour's structure models are not intended for use where the patient has additional non-anatomical hardware (Brachytherapy applicators, hip prosthesis, pacemakers etc) within the treatment image. Presence of this hardware may result in poor accuracy of structure models.

# 5. Precautions

- For maximum utilization of this software, users should read the user manual supplied with the software and follow its instructions for achieving the best results and should ensure that their computer environment matches the software specifications.
- Caution: Federal Law restricts this device usage by or on the order of a radiation therapist (or medical dosimetrist, medical physicist, radiation oncologist).

**Cybersecurity**

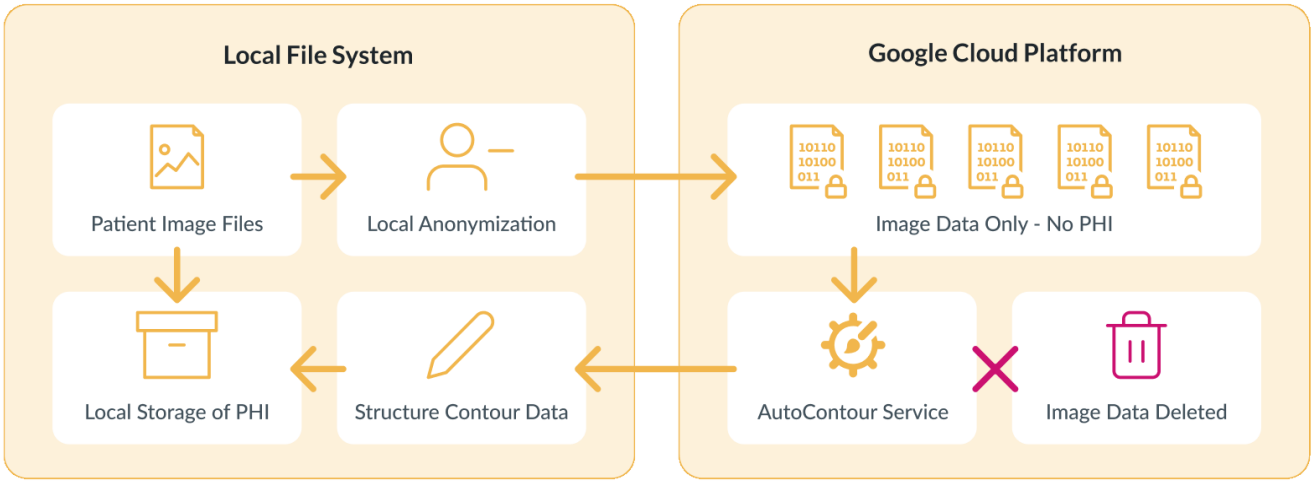
- Cloud-based resources (Auto contouring service) are accessible via HTTPS requests to Radformation's cloud endpoints. HTTPS stands for "Hypertext Transfer Protocol Secure" and is a combination of the Hypertext Transfer Protocol (HTTP) with the Secure Socket Layer (SSL)/Transport Layer Security (TLS) protocol. The addition of SSL/TLS ensures that all communication between the client web browser and the server is encrypted and is not vulnerable to snooping or man-in-the-middle attacks.

- The user must take appropriate measures to ensure that their system they install the AutoContour.exe on is protected from viruses or malware by using appropriate prevention and mitigation strategies such as installing and maintaining appropriate anti-virus software.

- AutoContour's auto-segmentation component is hosted on the Google Cloud Platform – the only data sent off-site is raw binary image data without any DICOM or other labels. In this manner, no PHI is shared with Radformation as this raw binary image data is considered to be de-identified per the "Safe Harbor Method" as defined by HHS:
  - https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html
  - Description of raw binary image information sent to GCP
    - Image dimensions (# of slices, slice x/y size)
    - Image Resolution (x, y, z dimensions)
    - Image Origin Position (x, y, z)
    - Image Pixel Values
    - Binary writer code used to send image data.

- Communication with AutoContour Google Cloud Platform (GCP) server is done using HTTPS (TLS V1.2) encryption protocol. No PHI is sent to the GCP.
- Once the autocontouring process has been completed in GCP, all datasets are deleted.
- For additional information regarding the security protocols of the Google Cloud Platform please see the following references:
  - https://cloud.google.com/storage/docs/encryption/default-keys

### Cloud-Based AutoContouring Diagram



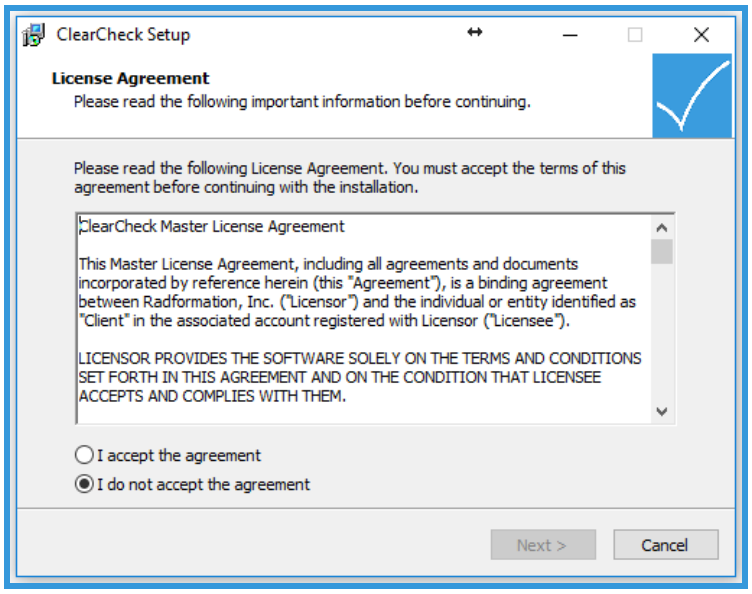
# 6. Contra-indications

None known.

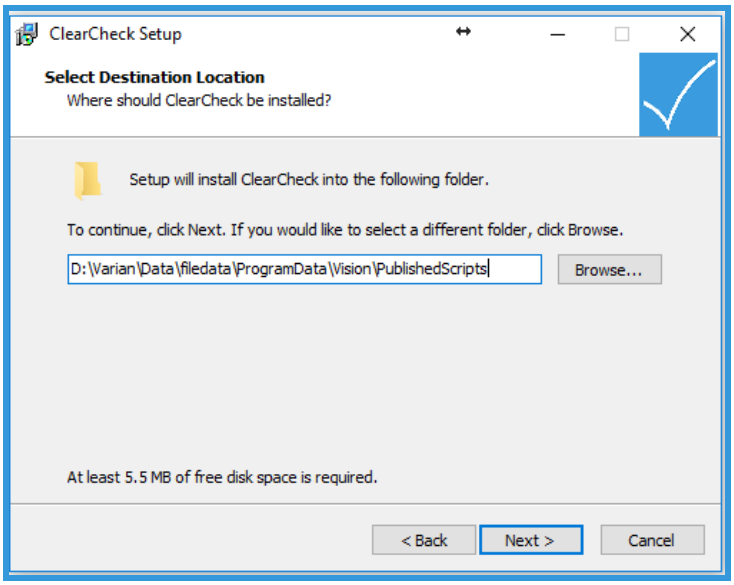
# 7. Instructions for Use

## 7.1 Installation

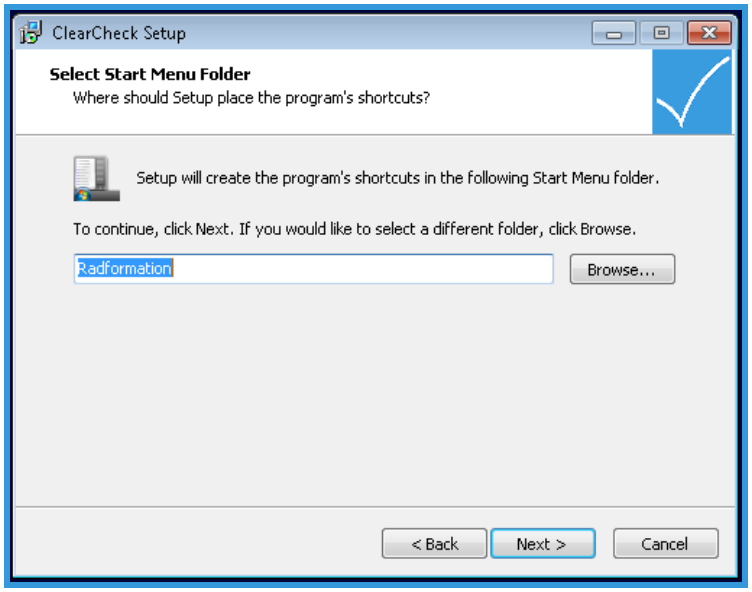
1. Download setup.exe **for ClearCheck** (AutoContour.exe is bundled with the ClearCheck installer) from Radformation website for the version of Eclipse™ you have.
2. Run setup.exe
   a. Accept ClearCheck License Agreement



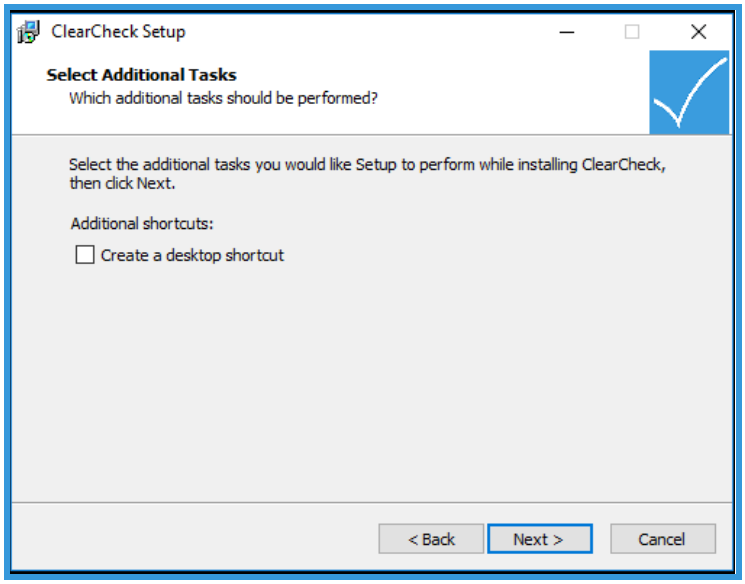

   b. Browse to your institution's PublishedScripts folder or a network folder that all Eclipse™ users have access to. The PublishedScripts folder resides on the Varian Server and can be found by going to Eclipse™->Tools->Scripts and clicking the "Open Directory" Button.



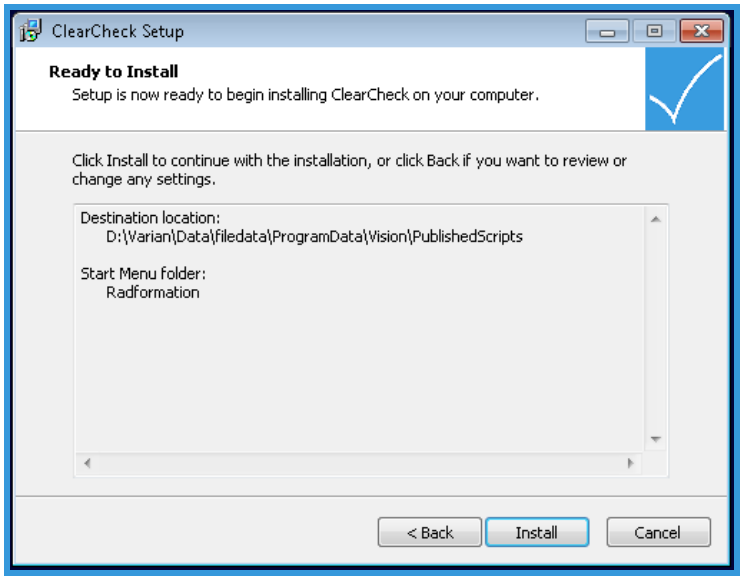

c. Select next to create start menu shortcut



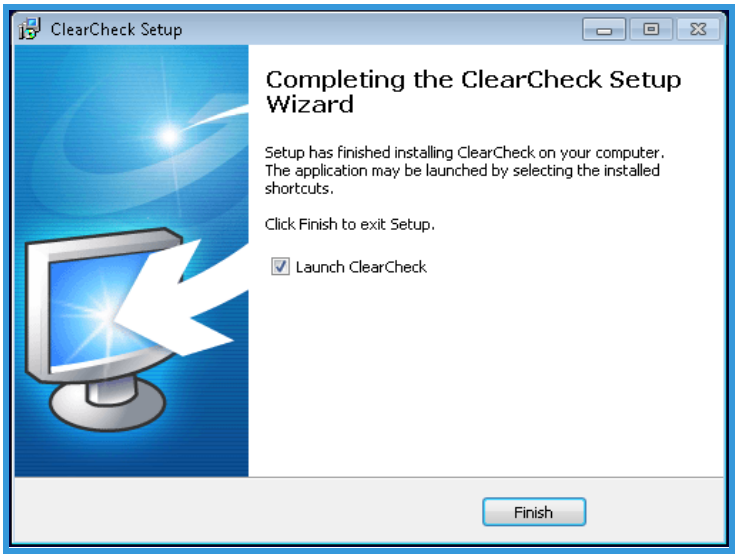

d. Select if you would like a desktop shortcut to the ClearCheck Administration Application




e. Select Install



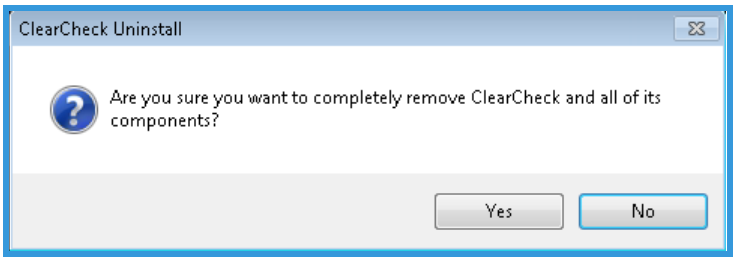

f. Launch ClearCheck Administration to set up the department templates and settings.



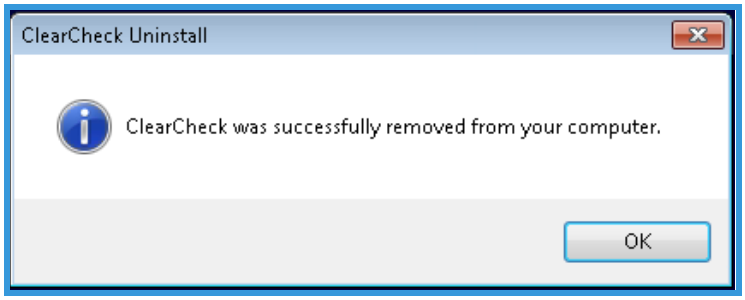

g. Approve the ClearCheck.esapi.dll script in Eclipse

## 7.2 Uninstallation

1. Navigate to ClearCheck Folder
2. Run unins000.exe
3. Select Yes to uninstall ClearCheck




4. Select OK after uninstallation



## 7.3 Using AutoContour with ClearCheck Eclipse API

**Interoperability with ClearCheck**

Currently, AutoContour launched through Eclipse by way of ClearCheck is only available to versions 15.5 and higher of Eclipse (including Eclipse V15.6, v16.1) as these are the only versions which allow the user to write structure information back to its database with the API. Earlier versions of Eclipse (including V11, 13.5, 13.6, 13.7, 15.1) are not supported by AutoContour as they are read-only APIs.

Launching AutoContour from ClearCheck provides the user with the following workflow benefits which we feel would be the optimal workflow for users of AutoContour.

1) Write access to Eclipse is available allowing direct saving of approved structure contours back to the Treatment Planning System
2) Structure Templates configured in AutoContour may be paired with previously configured Constraint templates in ClearCheck. When launching AutoContour, the appropriate set of AutoContour structures will be matched automatically, preventing possible incorrect assignment of structures to be contoured for a given patient's treatment protocol.
3) ClearCheck provides additional structure contour checks including (laterality checks, margin checks, structure holes, slice gap checks etc) which provide an additional layer of contour verification to AutoContour's built-in forced review.

**Recommended ESAPI Workflow**

Users that wish to launch AutoContour though the Eclipse API are required to do so with a previously installed version of ClearCheck. (More detailed ClearCheck instructions may be found with the user manual installed or from the link provided here). Once an active AutoContour license is activated within the AutoContour Administration application (See Section 7.1), then the user will see the AutoContour Icon appear at the top of the ClearCheck Window.

For maximum efficiency, we recommend the following workflow:

After importing a patient's scan into External Beam Planning, add a new plan to that image.
**(Eclipse V15 Optional)** Apply the desired Structure Set Template to create empty structures applicable to the plan (this will ensure that generated structure colors are your preferred colors).
**(Optional)** Contour target structures or any other structures not supported by AutoContour.
With that plan loaded in External Beam Planning, launch ClearCheck (Tools => Scripts, though setting it as a favorite makes it easier to launch either via hotkey or in the Tools drop-down).
**(Optional)** In the ClearCheck Template manager, apply the desired dose constraint template and ensure that matching structures exist for each applicable dose constraint.

Launch AutoContour by pressing  in ClearCheck.
In the Structure Table, watch for structures that change to "AutoContour" status - this means AutoContouring is complete. If any structures do not have a **Model** assigned, then set the appropriate Model from the drop-down (over time, AutoContour will learn the Structure Aliases).

Click the Play  Button on the "AutoContour" structures, and then review the structure (and edit as needed), and mark it either:

a. Approved 

b. Rejected 

After reviewing and approving / rejecting the AutoContoured structures:

c. **(Optional)** Use the Structure Generation Table (bottom right) to generate any custom structures (e.g. margin expansions, rings, overlap, cropping some structures out of others, etc.) NOTE that if you don't have all structures available (such as Targets), you can still Export the current approved structures anyway and then run AutoContour again when those structures are contoured so you can do Structure Generation with them.

d. Click the Export button to export the approved structures to Eclipse™: 

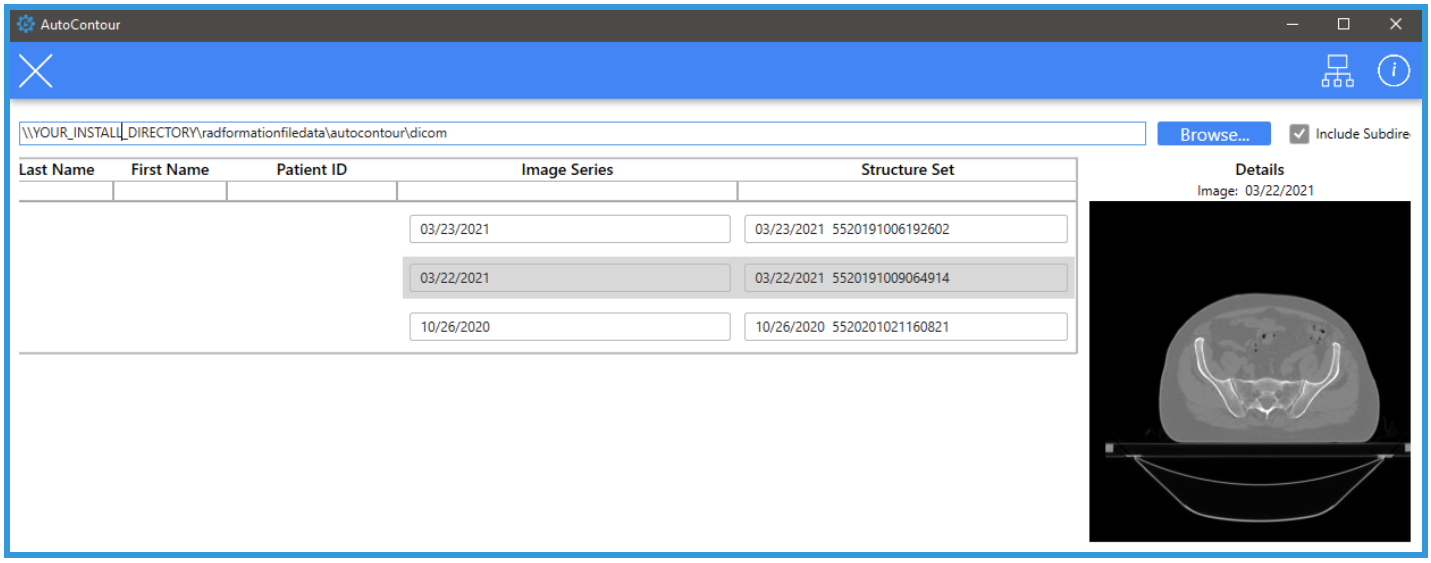
Structures Approved within AutoContour will be written directly into the original Eclipse Structure Set.

## 7.4 Using AutoContour with Dicom Standalone

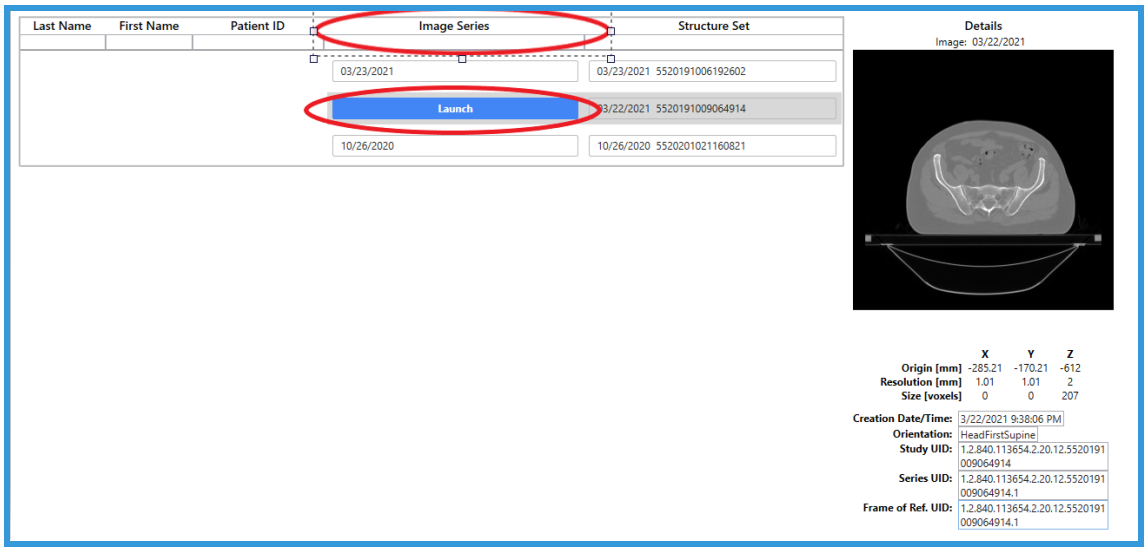
**Recommended Dicom Workflow**

For maximum efficiency, we recommend the following workflow:

1. Launch AutoContour.exe from the installed location or shortcut.

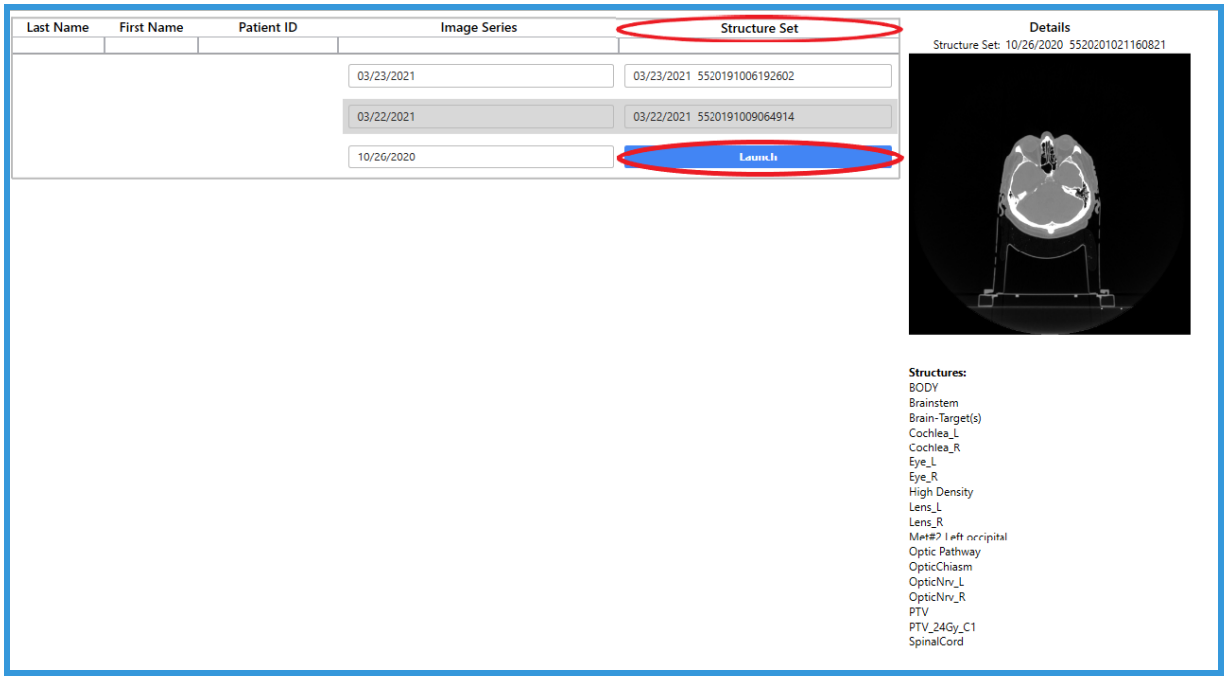



2. From the list of available DICOM files in the default Import Directory. (See Administration Application Section for further details on setting up custom User/Hospital-specific directories.)
    a. NOTE: Including subdirectories within a folder containing a large number of image sets (> 20 patient scans) may result in a slow initial load of patient scans while DICOM image information is processed. Users may Stop this loading at any time using the Abort button, and only the processed scans (most recent first) will appear on the list.
3. To create a **NEW** DICOM Structure Set, choose the desired Image Series from the Image Series Column. Any attached structure sets for that Image series will not be updated.
    a. The Image Series Icon will become active and turn into a **Launch** button.



b. A preview of the Image Series along with additional details about that Series from the DICOM header will appear on the Right side of the screen.
c. Once the user has confirmed that the Image Series is correct, then the **Launch** may be clicked to initiate the AutoContour process.

4. To update an **EXISTING** DICOM Structure Set, select DICOM RS file from the Structure Set Column.
   a. The Structure Set Icon will become active and turn into a **Launch** button.




   b. A preview of the Image Series along with a list of existing structures from the DICOM structure set will appear on the Right side of the window.
   c. Once the user has confirmed that the Image Series and Structure Set is correct, then the **Launch** may be clicked to initiate the AutoContour process.

5. In the Structure Table, watch for structures that change to "AutoContour" status - this means AutoContouring is complete. If any structures do not have a **Model** assigned, then set the appropriate Model from the drop-down (over time, AutoContour will learn the Structure Aliases).

   Click the Play ▶ Button on the "AutoContour" structures, and then review the structure (and edit as needed), and mark it either:

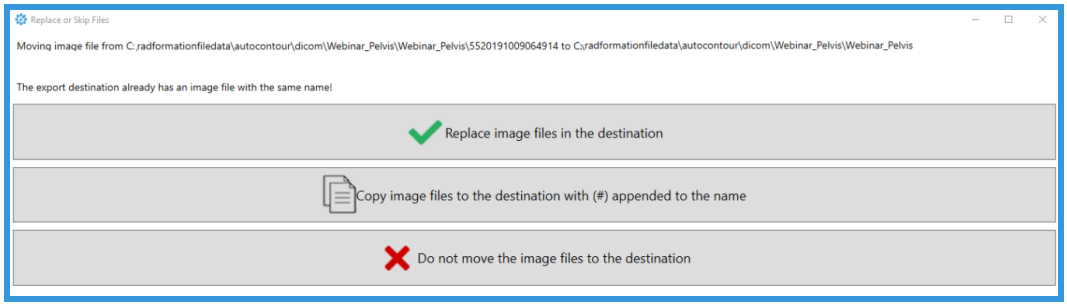
   e. Approved ✔
   f. Rejected ✖

   After reviewing and approving / rejecting the AutoContoured structures:

   **g.** **(Optional)** Use the Structure Generation Table (bottom right) to generate any custom structures (e.g. margin expansions, rings, overlap, cropping some structures out of others, etc.) NOTE that if you don't have all structures available (such as Targets), you can still Export the current approved structures anyway and then run AutoContour again when those structures are contoured so you can do Structure Generation with them.

h. Click the Export button to export the approved structures to a RS Dicom File: 

6. If a structure Set for the Image Series already exists in the default export directory, then a MessageBox will appear asking user to either replace the existing structure set or add a duplicate Structure Set to the directory with "#" added to the name.




## 7.5 AutoContour Main Window

**Reviewing and Approving Structures**

*AutoContour only exports Approved structures to Eclipse™ or to a RS structure set DICOM file.*

Approval Controls are provided in the Structure Table as well as in the center of the Three-Slice View when a structure is selected in the Structure Table.

The Approval Control shows either a Review button to begin reviewing the structure, or the approval options (as described above):


When a Review has begun, AutoContour will automatically zoom to the structure and set the viewing planes to a few slices superior to the top-most slice of the structure (or the top of the scan if at the limit). Auto-Scroll will begin, which automatically scrolls through all of the slices of the structure and beyond a few slices, back and forth.

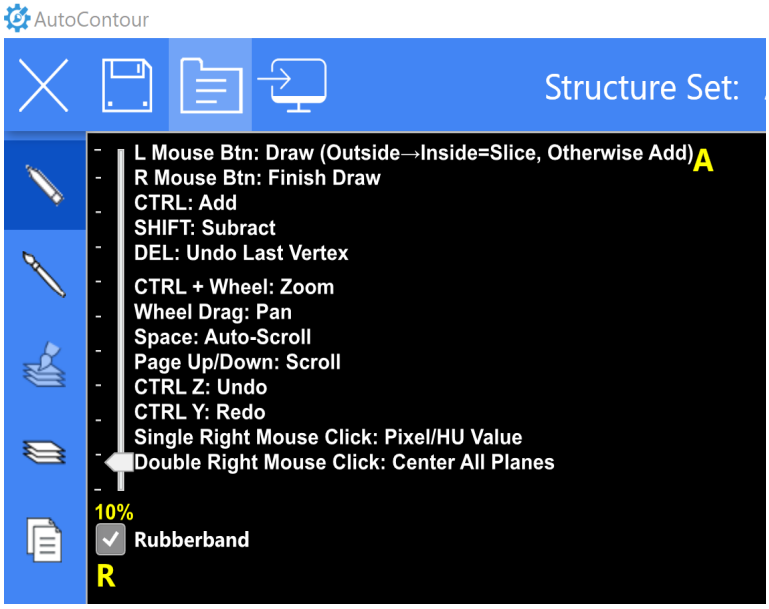
You can pause Auto-scrolling with a mouse click, mouse wheel, pressing Spacebar, or pressing the the  button, which can be continued either by pressing Spacebar or pressing the  button.

**IMPORTANT:** The Approval button of the Approval Control does not become enabled until all of the slices have been visited during review (unless one of the other buttons has already been clicked).

Any modifications to a structure after approval result in the structure being set to "Unreviewed" (though Undoing the modification reverses the approval state to the prior value).

## Three-Slice View Navigation

In the upper left corner there are instructions for hotkeys and how the currently selected tool (if any) works. By default, this is displayed:




Note that the Space Bar toggles Auto-Scrolling on or off, and it only works when a structure is selected.

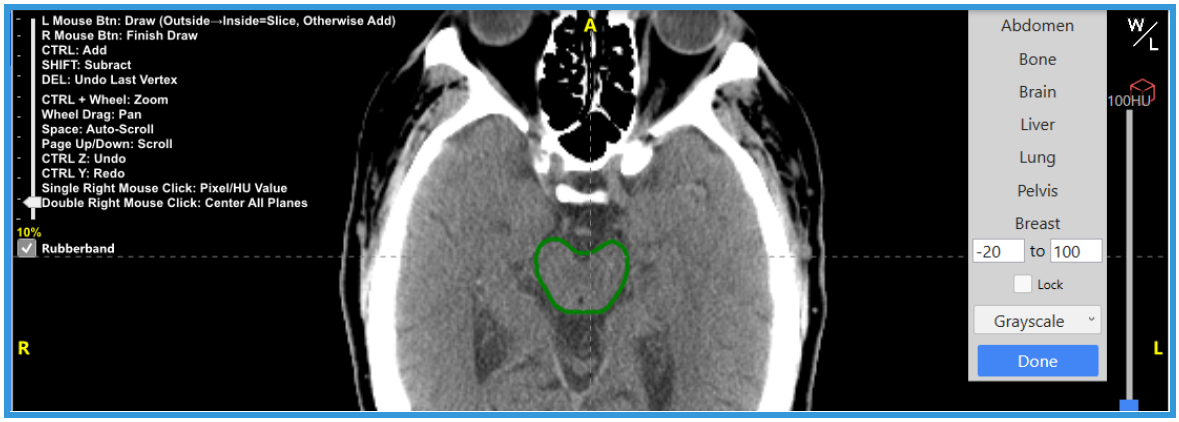
When a structure is selected in the structure table, a control panel is shown:


- The Structure ID is displayed (in the structure's color).
- < and > arrow buttons allow you to go to (and automatically begin reviewing) the next structure in the structure table.
- The  button (only visible when Auto-scrolling is paused) resumes auto scrolling just like pressing the Spacebar. If Auto-scrolling is in process, the button pause button will be shown:
- The SpeedControl slider  allows the user to adjust the review scroll speed manually.
    - 1X: 640msec/slice
    - 2X: 320 msec/slice
    - 3X: 160 msec/slice
    - 4X: 80msec/slice
    - 5X: 40 msec/slice

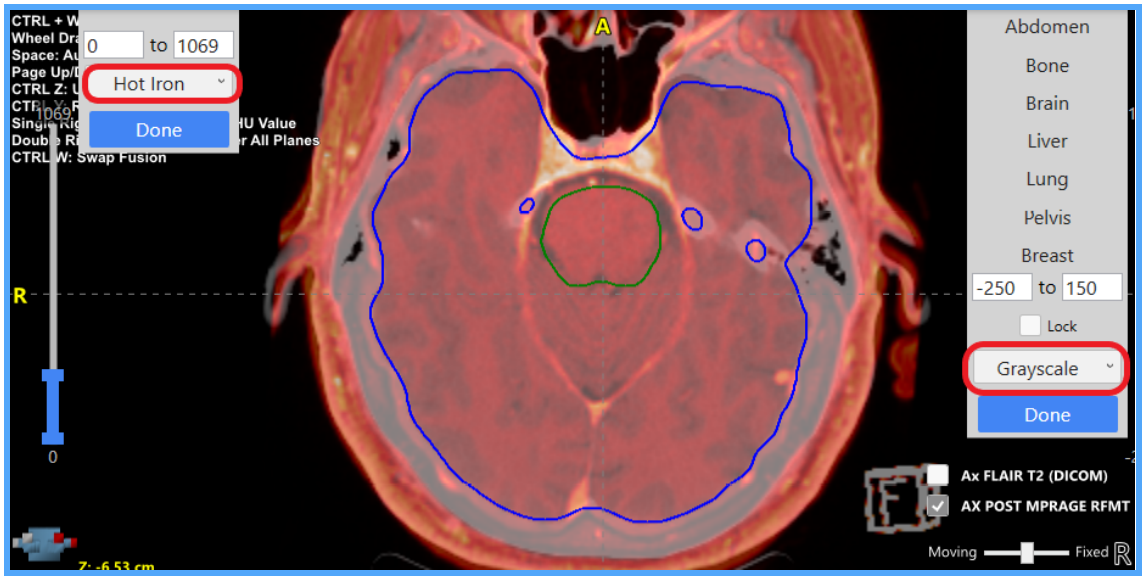
- For users with smaller screens, users may collapse the full structure table on the right side to a condensed view to allow for additional Image size using the “Shrink/Expand Structure Table Button in the Top Right. 

## Adjusting Window/Level

- During structure review, the Window/Level of the Three View Images will be adjusted automatically to the structure Window/Level specified within the current AutoContour Structure template.
- Manual adjustment may be done by clicking  in the top right corner. This will open the Window and Level control which allows you to select a preset Window and Level or type your own in.




- Adjustment to the W/L of any registered images will appear on the left side.
- checkbox will prevent structure-specific settings from updating the currently set Window/Level settings during automatic review.
- Color Palette drop-down allows the user to update the displayed image or registered image with grayscale, blue, yellow or hot iron color scales.



## Patient Orientation

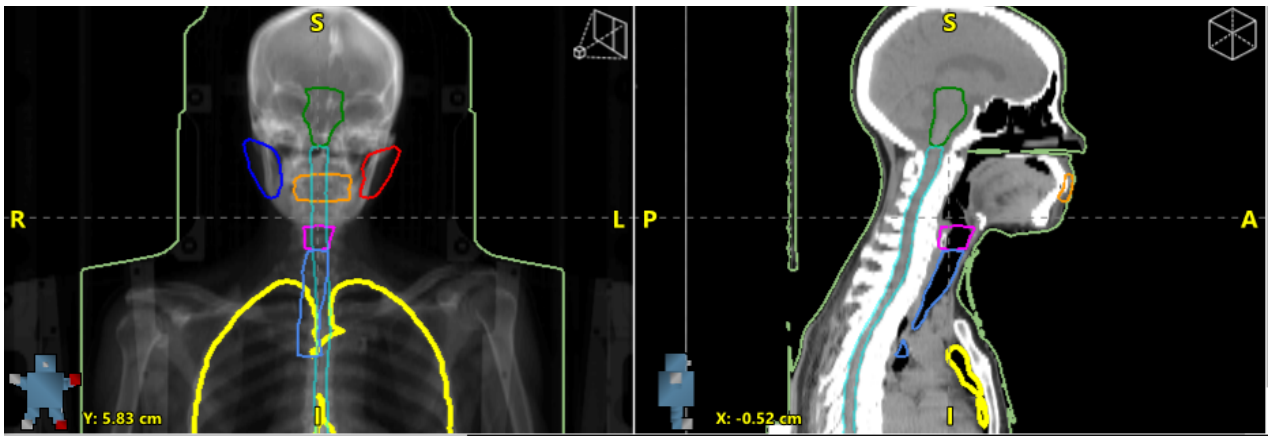
The orientation indicator  shows the orientation of the patient in the scan. Red indicates the patient's left.

WARNING: The Three-Slice view in AutoContour is always oriented relative to the patient regardless of the imaging orientation. The displayed X, Y, Z coordinates are DICOM coordinates. This means:

- For **Transverse** slices, **Patient Posterior** will always be toward the **Bottom** side of the screen.
- For T**ransverse/Coronal** slices, **Patient Left** will always be toward the **Right** side of the screen.
- For **Coronal/Sagittal** slices, Patient Superior will always be toward the **Top** side of the screen.
- For **Sagittal** slices, **Patient Posterior** will always be toward the **Left** side of the screen.

In the Eclipse™ Treatment Planning System, the default coordinate system displayed is the same as DICOM coordinates only when the patient is Head-First-Supine.

## Topogram View

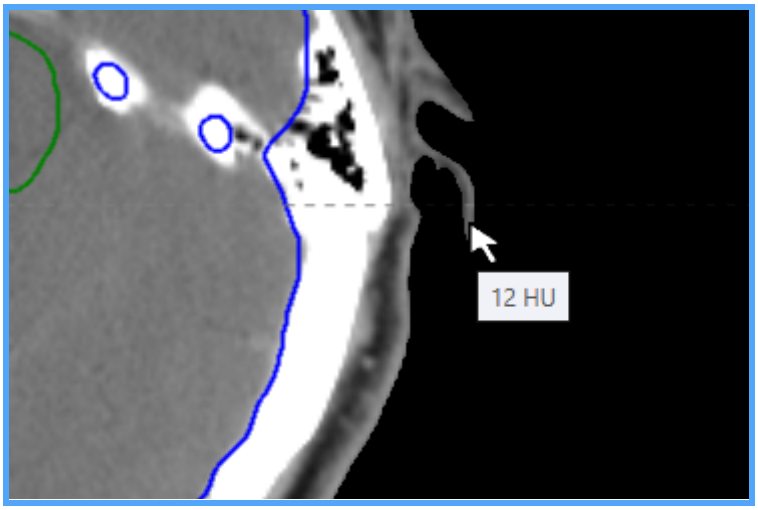



The Sagittal and Coronal Slice Views may be toggled to a 2D projection topgram view of the Image (Similar to a CT scout image) and the corresponding contour overlays. This view may be enabled by clicking on the  icon in the top right corner of the sagittal and coronal windows. To close out of the topogram view and return to standard slice view, click on the  icon.

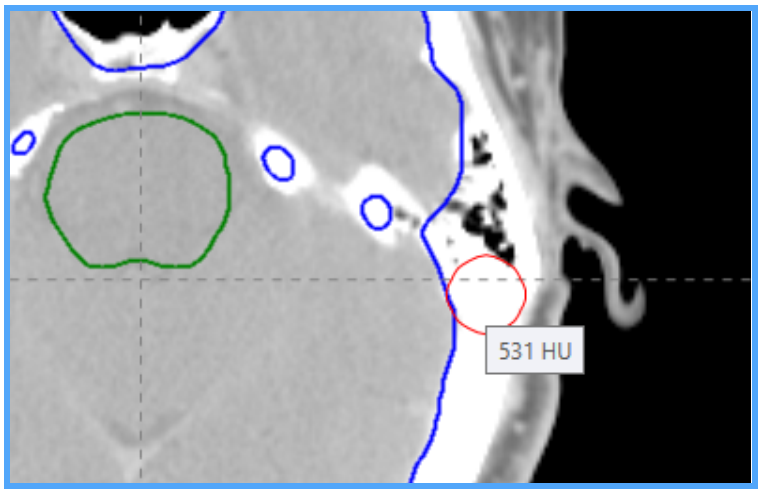
## 7.6 Structure Editing

### Pixel/HU Value Tool:

Single right-mouse Click on any pixel within the 3-Views to determine the HU (CT) or Pixel intensity (MR/PET)

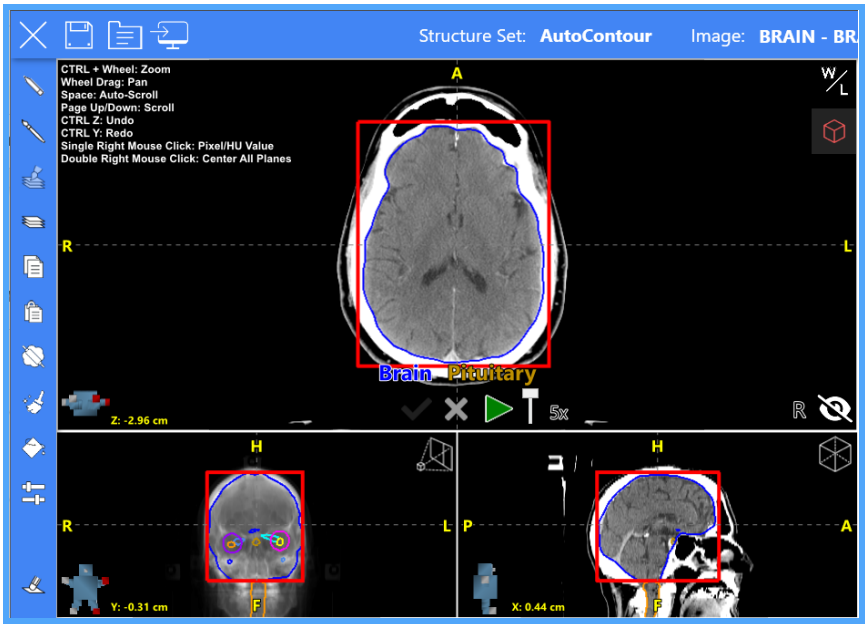



If brush tool is enabled, then the average pixel/HU intensity within the brush region will be displayed on the single right-mouse click.



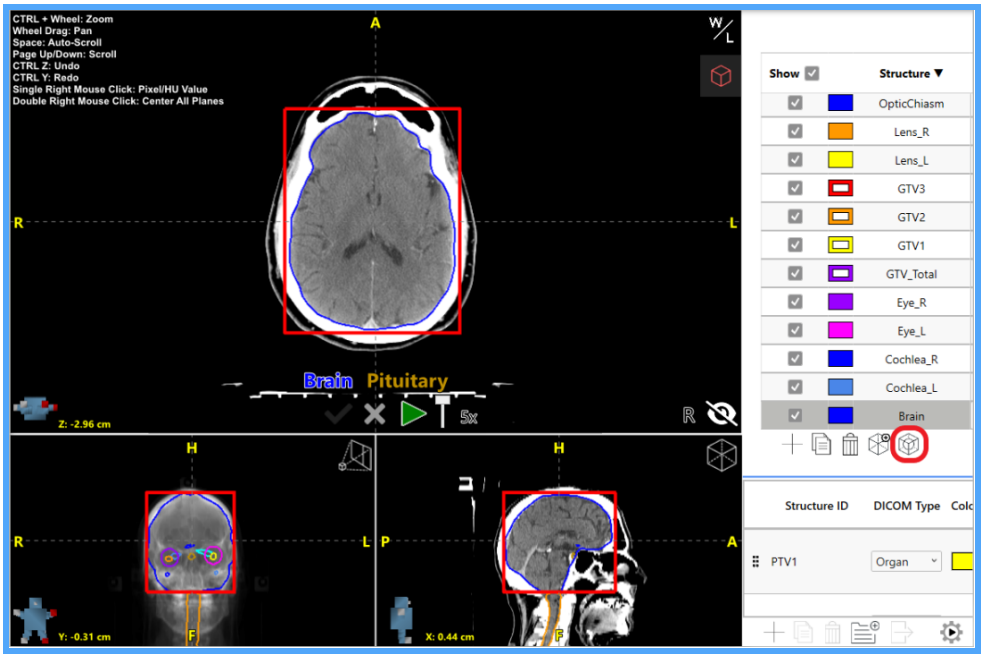

### Volume of Interest (VOI) Tool: 

When activated, the Volume of Interest tool may be used to constrain certain post-processing tools and the automatic registration tools to only apply changes within certain anatomical regions. The VOI may be activated by clicking on the VOI button in the top right corner of the axial view window.



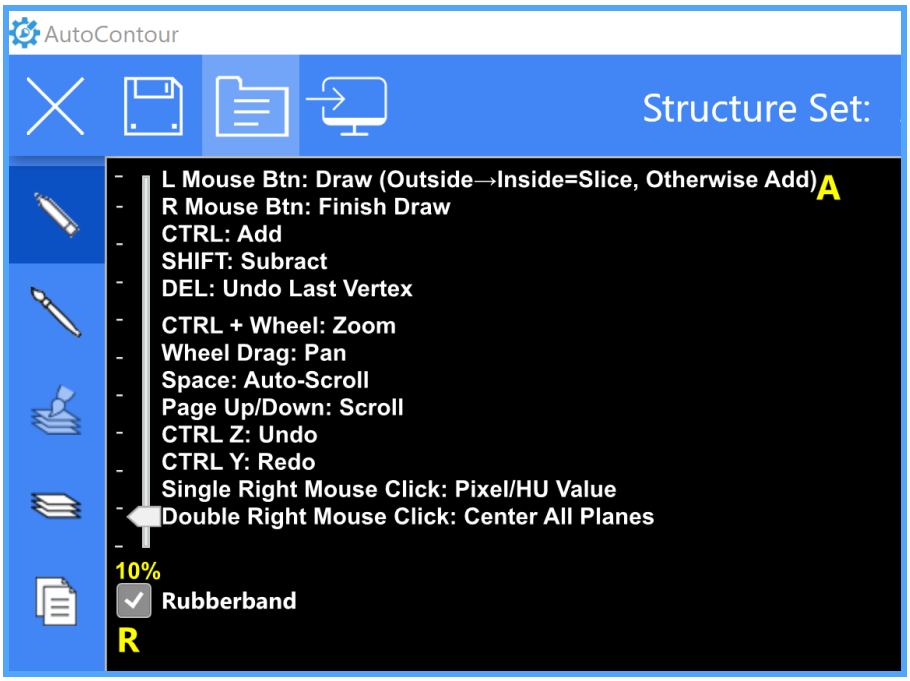

Edits to the VOI region can be made by hovering the mouse over the red VOI outline and left-mouse click and dragging within the three view planes. Adjustments may be made in either the Topogram or 3D view display for the Sagittal or Coronal views.

To automatically fit the VOI region to an existing structure, select the structure to be fit and then click on the **Update VOI to bound structure** button. 



To save the current VOI dimensions to a new structure, click on the **Save VOI as a new structure** button  .

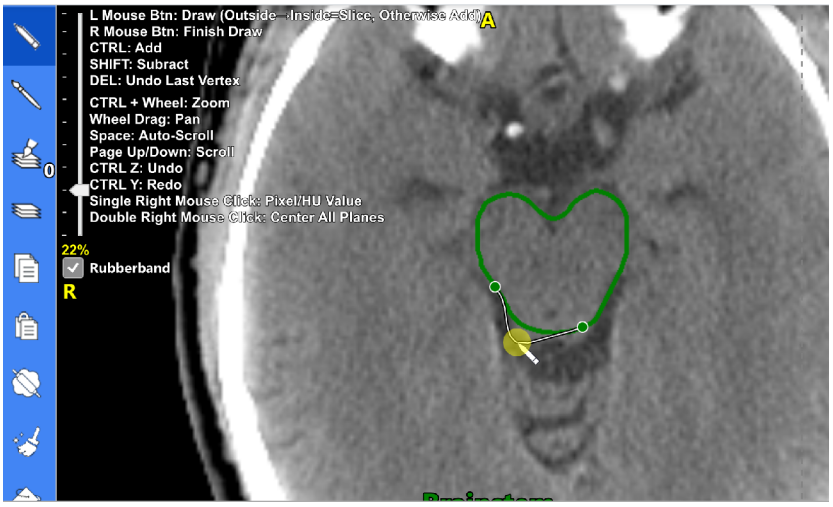
## Pencil Tool, Hotkey: [1]




To elaborate on the L Mouse Btn instruction:

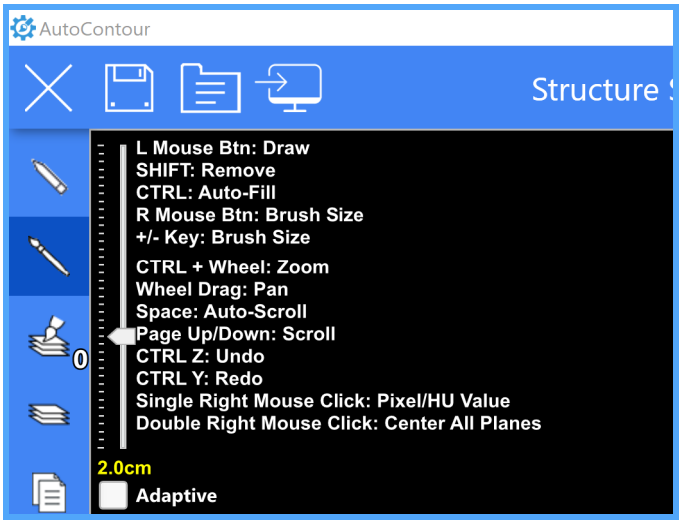
- You can **Slice** off (subtract) the smaller component of the contour if you:
  - Are NOT holding CTRL or SHIFT
  - You Left-click outside of the structure to begin drawing
  - At some point you click or draw inside the structure
  - You click or draw outside the structure again
  - You Finish Draw (R Mouse Btn)
- If you start from inside the structure or start outside the structure and never enter any existing structure, then anything you draw is added.

## Rubber Band Pencil Tool



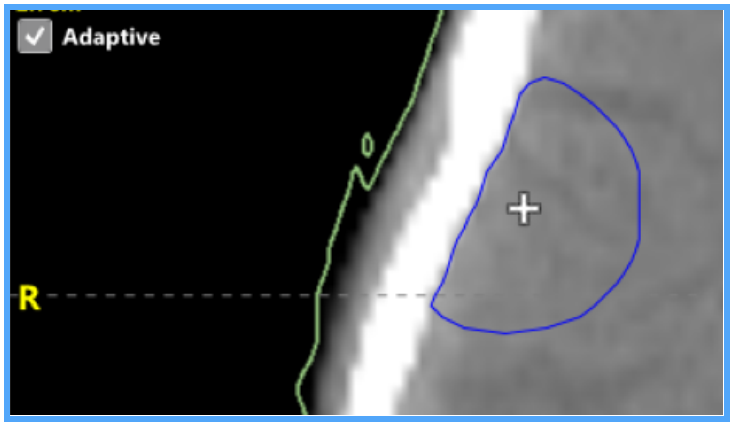

- Users may enable the Rubberband option when utilizing the pencil tool allowing for click and drag interaction with existing contours.
- The slider bar in the top right of the screen will adjust the % circumference of the highlighted contour segment that will be adjusted. Users may also Right-Mouse-Click Hold and drag Left/Right to edit this circumference.

## Brush Tool, Hotkey: [2]




Note that you can hold both SHIFT and CTRL simultaneously to Remove + Auto-Fill. The Slider allows you to change the brush size (0.125cm increments, with a 0.25cm minimum and 5cm maximum). The +/- keys (either the number pad or top row keys) increase/decrease the brush size in 0.25cm increments. Holding the Right Mouse Button and dragging to the right will increase the brush size, to the left will decrease the brush size.

- Adaptive Brush - Enable the adaptive option when utilizing the Brush tool by checking the “Adaptive” checkbox which will automatically adapt the Brush outline to any HU edges detected within the active Window/Level range.

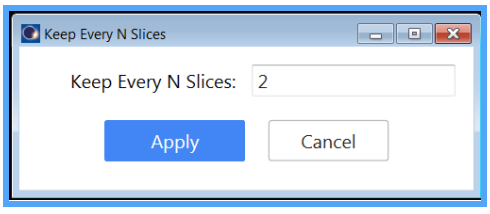



Clear Buttons, Clear Plane Hotkey: [CTRL D]  

The  button clears the structure from the current Transverse Plane, while the  button clears the structure from ALL planes.

Keep Every N Slices, Hotkey: [CTRL N] 

Keep Every N Slices button clears all but the structure contour slice frequency specified by the user. When clicked, a pop-up window will appear allowing the user to enter the desired frequency of remaining slices. After clearing, user may then edit only the remaining slices before re-interpolating the edits using the Interpolate button  .



## Recent Edit Interpolation Button, Hotkey: [CTRL A] 

Recent Edit Interpolation allows you to linearly interpolate **Pencil** (excluding the *Slice* action, so to subtract be sure you hold SHIFT when editing), **Brush**, and **Clear Plane** edits. This tool is particularly useful for correcting AutoContour results in that, rather than interpolating all missing slices (as the Structure Interpolation Button does), the recent edits -- Adding OR Subtracting -- are interpolated. A couple of examples:

1. If AutoContour overcontoured one side of a structure on 12 slices, you could use the pencil or brush tool to Subtract from every 3rd slice and then press CTRL A (or click the button) to interpolate the fix to the in-between slices.
2. The number of recorded interpolations will appear as a number next to the Recent Edit Interpolation Button. 

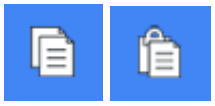
Clicking on the button will apply the interpolation and reset the counter to 0.
3. To clear out recent edits so that edits are not interpolated, the user may right mouse click on the button to revert to an inactive state. 
4. If AutoContour overcontoured the Bowel_Bag inferiorly a few slices, you could:
    a. Navigate to the most superior errant slice, press CTRL D (i.e. Clear Plane)
    b. Navigate inferiorly past the bottom and press CTRL D again
    c. Press CTRL A (or click the button) to interpolate clearing all the planes in between the two planes you applied the Clear Plane command to.

NOTE: This interpolation is only applied to the most recent edits that are:

1. same tool
2. same operation (Add or Subtract)
3. edits made on separate slices must be within 1 cm of each other on lateral planes to be considered for interpolation. For example, edits made along the anterior aspect of the Heart will be interpolated, but if user makes edits to anterior edge, and then edits on the posterior aspect, then the interpolation counter will be reverted to 0 as interpolating these changes will result in unexpected results.

## Structure Interpolation Button 

The Structure Interpolation applies a linear interpolation to fill in any missing slices that exist for the selected structure.

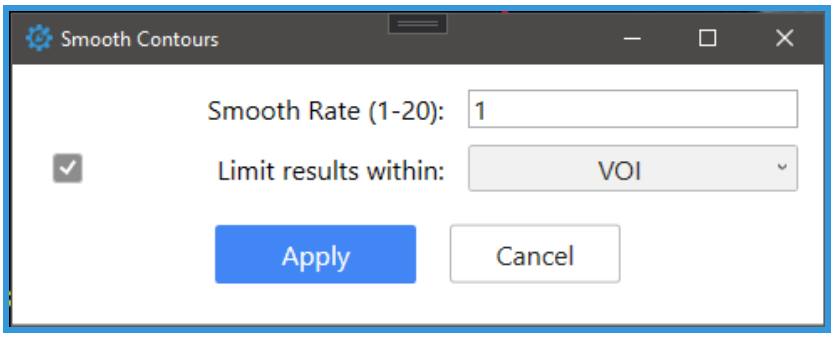
### Copy/Paste Slice Button: Hotkey [CTRL-C]/[CTRL-V] 

The Structure Copy Paste Button will allow the user to copy the contours from one slice to another. If copying to multiple slices is required as would be common with an avoidance region, the Interpolation button may then be used to fill the intermediate slices with the duplicate contours.

### Smooth Structure Button 

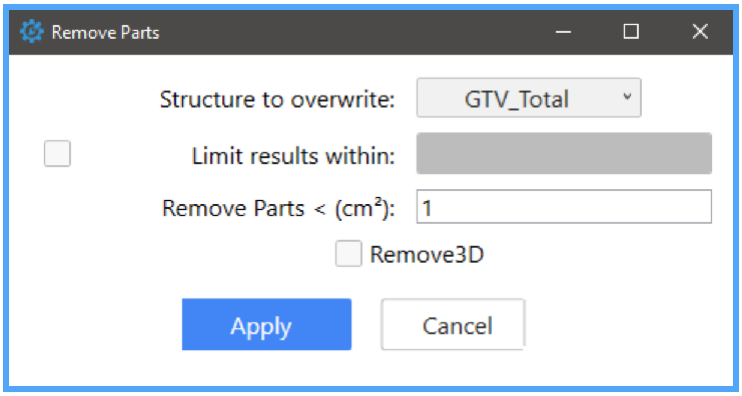
The Smooth Structure button will smooth structure contours in the Axial plane. When clicked, the Smooth Contours Window will appear allowing the user to set the smoothing level between 1-20 that is to be applied.

1. Users may optionally choose to limit the smoothing result to only occur within a specified structure or region such as the VOI bounding box.
2. Users may smooth contours multiple times, but some loss of contour fidelity, minor reduction in volume etc. may result.




### Remove Parts Button 

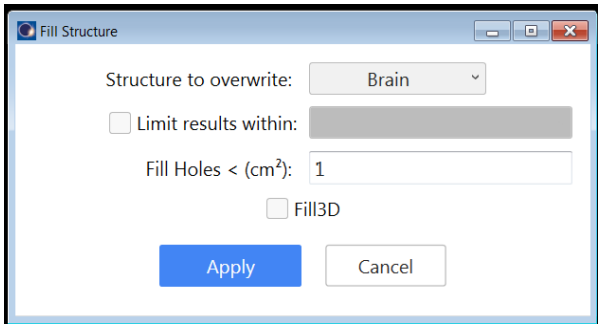
The Remove Parts button allows the user to clean up small or extraneous segments found on single (2D) and multiple (3D) image planes automatically. When clicked, a pop-up window will appear allowing user to select:




- Structure to Overwrite: the structure for which the Remove Parts changes will be applied. This will default to the structure currently selected for editing in the structure table.
- Limit results within: the structure or VOI to which the post-processing cleaning will be limited.
- Remove Parts < ($cm^3$) sets the upper Volume threshold to be removed by the tool.
- Remove 3D checkbox: allows users to switch between remove parts less than the threshold on all 2D slices (unchecked), or if threshold search should apply to structure segments in 3D (checked).

### Fill Structure Button 

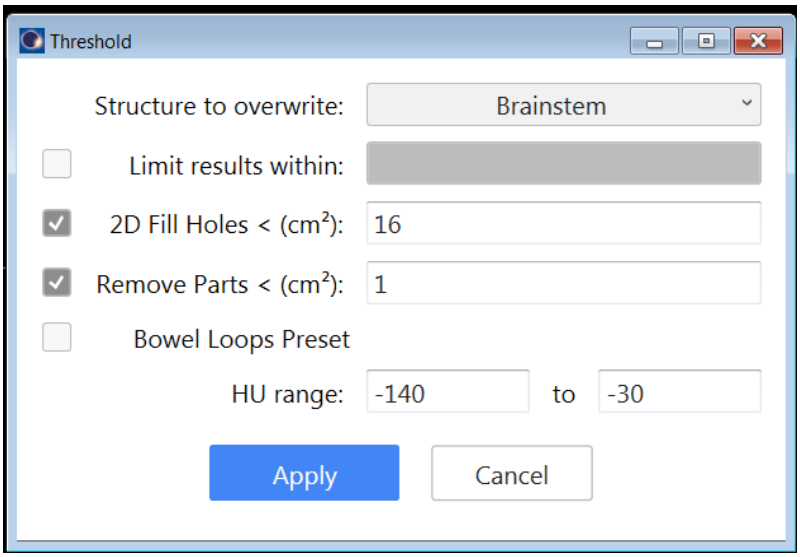
The Fill Structure button allows the user to fill contour holes/cavities found on single (2D) and multiple (3D) image planes automatically. When clicked, a pop-up window will appear allowing user to select:




- Structure to Overwrite: the structure for which the Fill Structure changes will be applied. This will default to the structure currently selected for editing in the structure table.
- Limit results within: the structure or VOI to which the post-processing fill will be limited.
- Fill Holes < ($cm^3$) sets the upper volume threshold to be filled by the tool.
- Remove 3D checkbox: allows users to switch between fill holes less than the threshold on all 2D slices (unchecked), or if threshold search should apply to only cavities found in 3D (checked).

### Threshold Button 

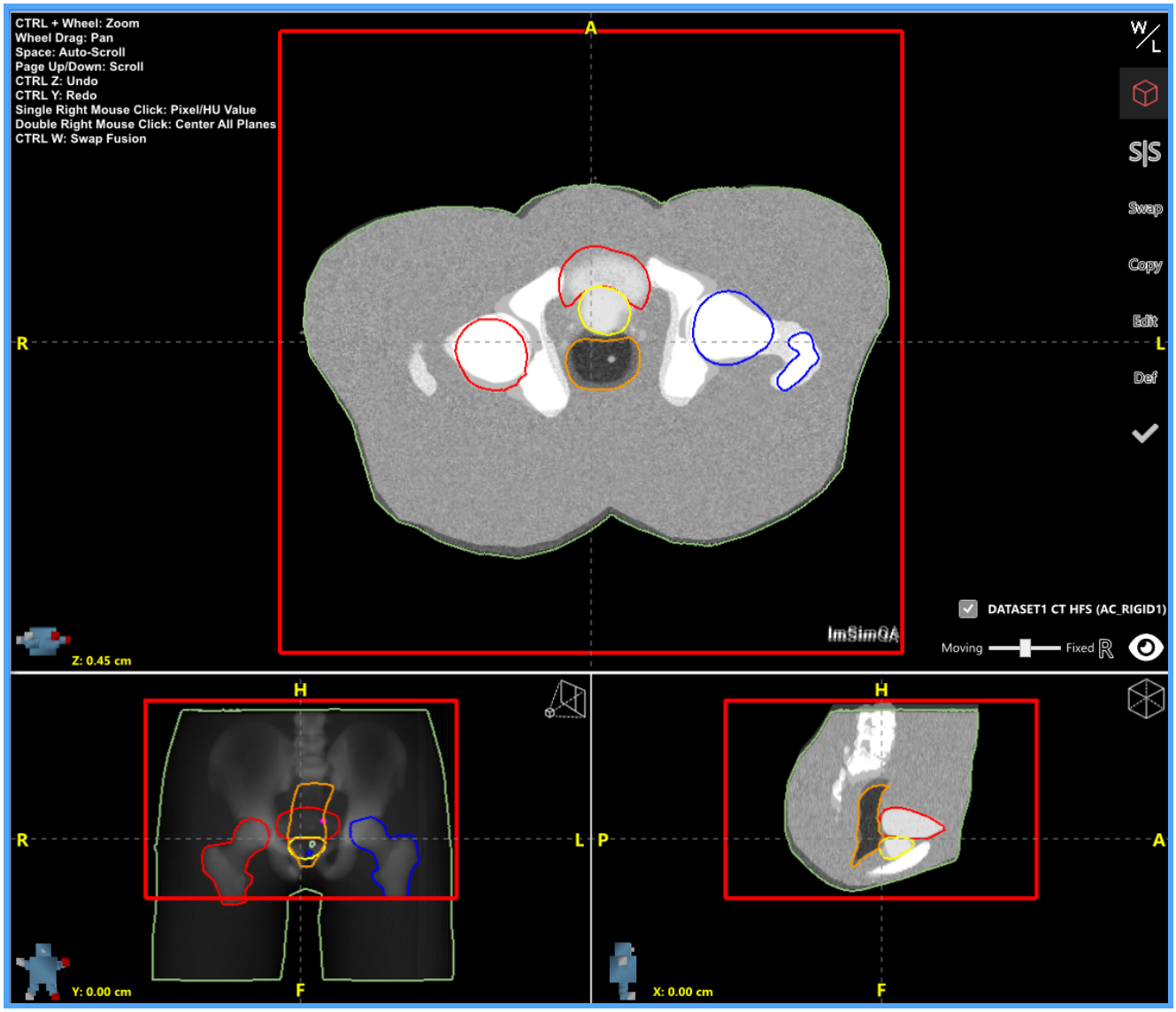
The Threshold Button allows the user to automatically segment all image voxels that fall within a specified HU Range. Common applications of this tool would be for automatic segmentation of High HU structures (fiducials, implants etc),the automatic segmentation of Bones,or Bowel Loops.




- Structure to overwrite: the structure for which the Threshold button will apply contours. This will default to the structure currently selected for editing in the structure table.
- Limit results within: will limit the threshold search to only add contours within the selected structure.
- 2D Fill Holes < ($cm^2$) sets the upper volume threshold of volume holes to be filled by the tool.
- Remove Parts < ($cm^2$): sets the upper volume threshold to be removed by the tool.
- Bowel Loops Preset: set limit results within: to the Bowel_Bag.
- HU Range: specifies the upper and lower Hounsfield Unit values to be used for the voxel search.

## The Volume of Interest (VOI) button 

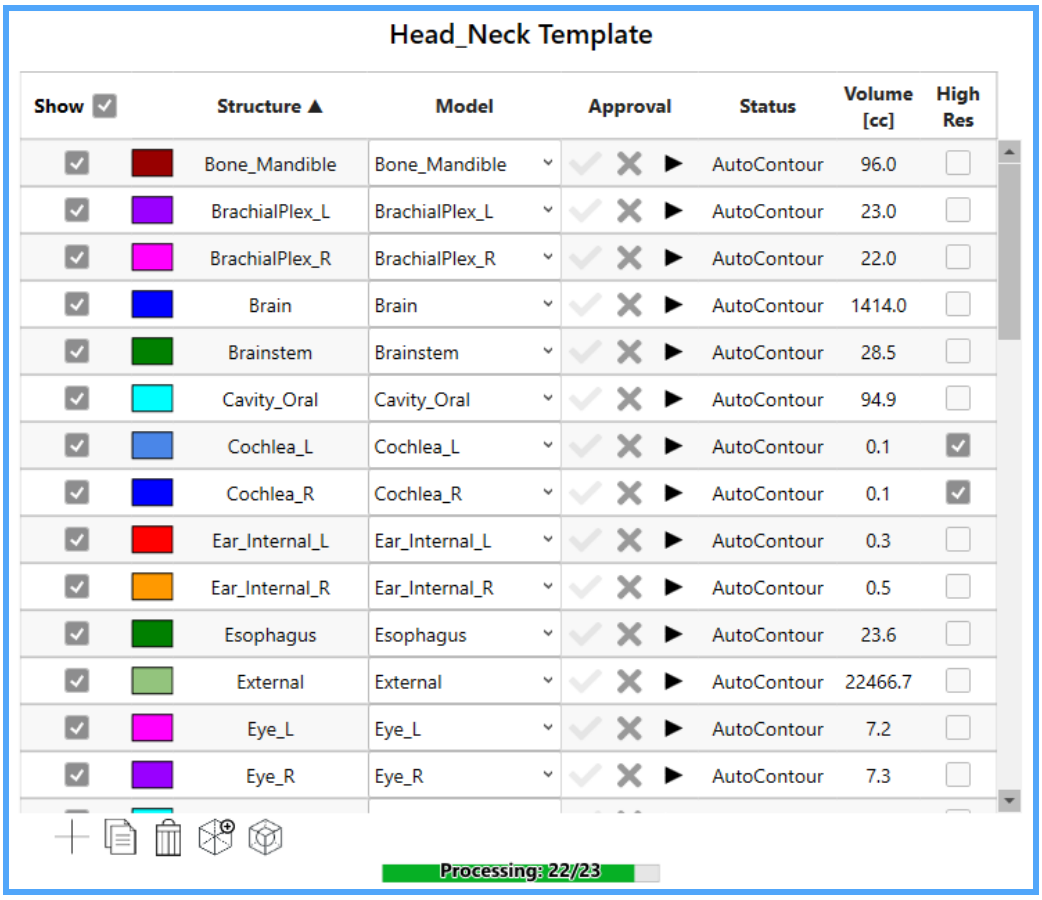
The volume of interest box tool allows the user to allow for structure changes and rigid/deformable registrations within a specified area.




## The clear structure outside VOI button 

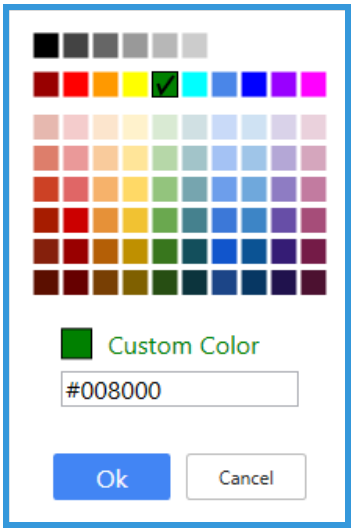
The clear structure outside VOI button allows the user to erase any part of a structure outside of this volume of interest box.

## Structure Table



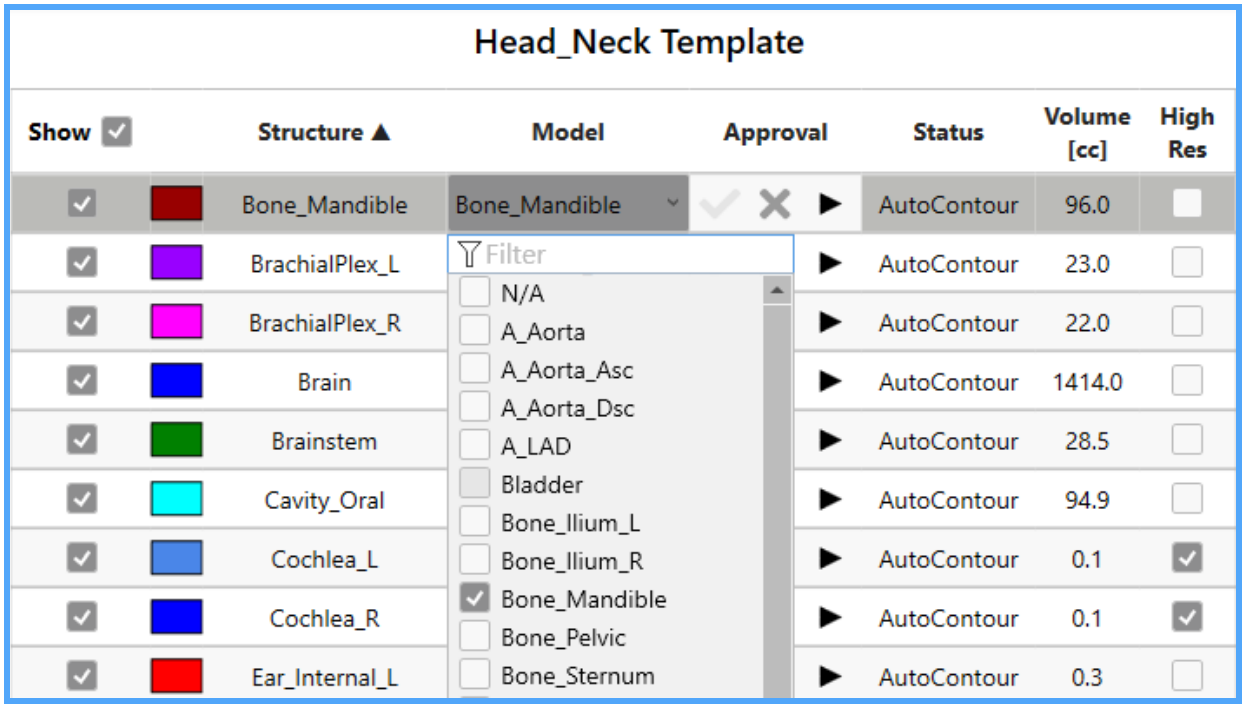

The Structure Table has the following columns:

- **Show CheckBox**: When checked, the Three-Slice View is updated to show the structure (otherwise the structure is hidden).
- **Color**: Indicates the color of the structure. For Dicom Standalone and Eclipse V16.1+, users may edit the color by right clicking on the Color Rectangle and selecting a new color or entering a Custom Color Code.

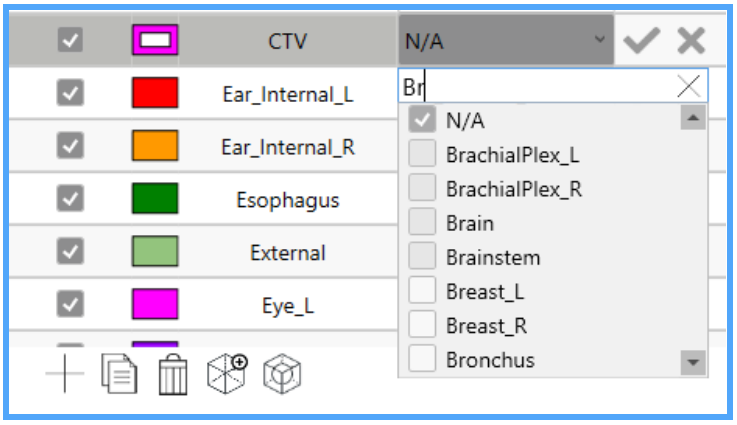


NOTE: Unfortunately the Eclipse™ V15 API does not include the ability to change the color of structures, so the color of new structures created in AutoContour that didn't already exist (e.g. from applying a Structure Template in Eclipse™ prior to running AutoContour) is determined by the structure Type (e.g. GTV is Red, ORGAN is Yellow, etc.).

- **Structure ID**
- **Model ComboBox**: Allows you to assign an AutoContour model to the structure. If the selected structure model has already been completed by AutoContour, then changing to that AutoContour model will set the contours to the AutoContour result (and set the Status to AutoContour).



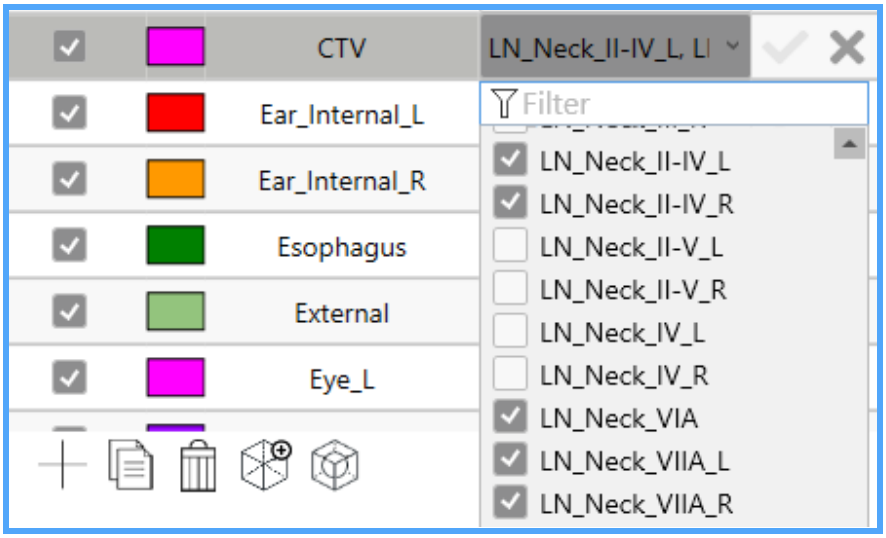

- Users may filter the list of structure models by typing into the Filter Search bar




- Only structure models that have not already been assigned to another structure may be assigned. Structure Models that have already been assigned will be grayed out as an option to prevent inconsistencies of contouring edits. If the same model is needed to be used for two different structures (eg. Lung_L and Lungs) then the Lungs structure should be

Combined using the Planning structure Table to ensure consistency between the total and individual contours.

- Structures models that have not been previously assigned, but do not yet have contour results, or if they returned with a status of "Not Found" will be grayed out as an option for selection.
- Multiple structure selection - Users may choose one or more structure models within the Model ComboBox in order to automatically combine the AutoContour results for the selected Structure ID.




- **StructureApproval Component**: (see Recommended Workflow for description)
- **Status**: Indicates the Status of the Structure from the following options:
  - **TPS**: Structure is in the state it was in when initially pulled from the Treatment Planning System (TPS)
  - **TPS_Modified:** TPS structure has been edited manually by the user or transferred to a structure set that did not previously contain that structure.
  - **Queued**: Structure has been queued for processing in the AutoContour web service.
  - **Not_Found**: AutoContour web service did not find the structure in the image data.
  - **Processing**: AutoContour web service is currently processing the structure.
  - **AutoContour**: Unmodified AutoContour result.
  - **AC_Modified:** AutoContour structure has been edited manually by the user or transferred to a structure set that previously contained that structure
  - **Generated:** Structure generated using the planning structure generation table
  - **Gen_Modified:** Generated structure that has been edited manually by the user.
  - **New**: Structure is new (does not exist in the TPS) or has not yet been queued by AutoContour for processing.
- **Volume [cc]**: Indicates the Volume of the structure in cubic centimeters (cc). NOTE: Volume is calculated on an image voxel-basis, where all voxels which have their center inside of the contours in its associated image slice are fully included in the structure volume accumulation. This will not match Eclipse™'s calculated volume exactly due to Eclipse™'s *Volume Interpolation Algorithm* (see Varian Medical System's Image Registration and Segmentation Algorithms Reference Guide for details on their implementation).

- **High Resolution CheckBox**: When checked, the Eclipse™ structure is converted to a High Resolution (if allowed by Eclipse™). This is a one-way change that (if a structure is set to High Resolution within AutoContour and not Eclipse™) can only be reverted by exiting AutoContour and launching it again.

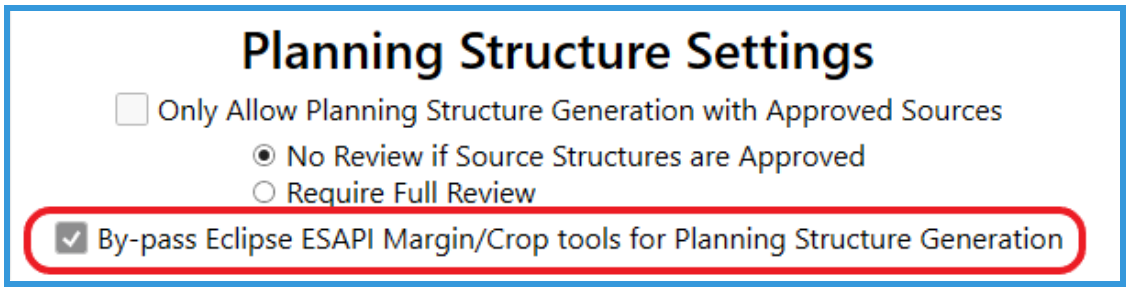
The bottom of the Structure Table has the following buttons:

- Show ☐ Shows or Hides all structures.
-  Adds a new structure.
-  Deletes the currently selected structure.

## Planning Structure Generation

The Structure Generation Table (bottom right) is useful for generating structures using Eclipse™'s built-in structure operations when in the Eclipse ESAPI environment or using AutoContours internal structure operations when using the DICOM standalone application.

**Note:** users have the option to default to using AutoContour internal structure operations for Margin, Boolean and Crop operations, if preferred by selecting the **"By-pass Eclipse ESAPI Margin/Crop tools for Planning Structure Generation"** in Adminstration Settings. This option will allow for faster generation of larger planning structures compared to Eclipse tools.



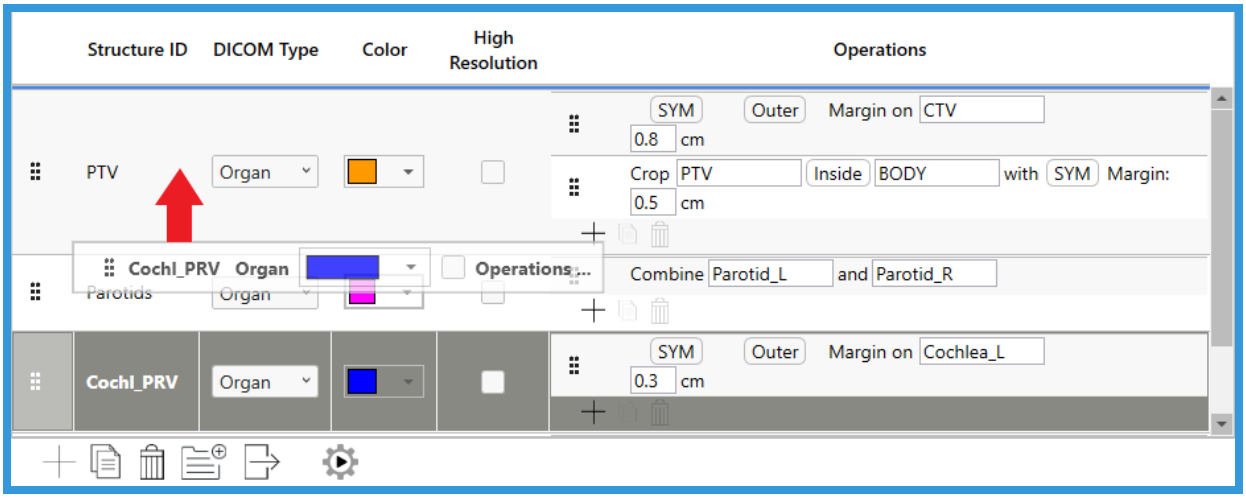

 WARNING: Small discrepancies may result between similar structure volumes generated with the Eclipse ESAPI tools, especially with small source structures and margins. Care should be taken if enabling the "By-pass Eclipse ESAPI Margin/Crop" tools option

Each Row represents a single structure to be created or modified when the  (Generate Structures) button is pressed.

Operations are performed ***sequentially*** which means that the order in which they appear is important. For example, if you want to use the structure in the 2nd row of the Structure Generation Table to generate the structure in the 1st row, you will find (unless that structure already exists in your Structure Table above)

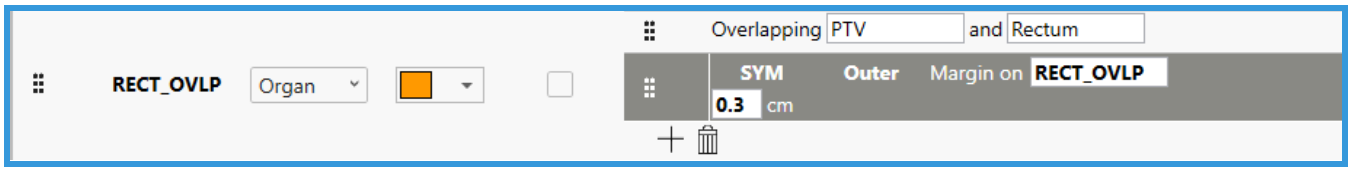
that the structure drop-down does NOT contain the structure in the 2nd row (because it doesn't exist yet as it is generated when the 2nd row is processed).

Clicking and dragging the Rows allows you to update the structure generation order.



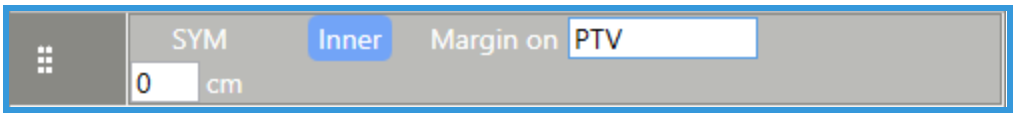

To add a Structure to Generate, click the + Button under the table and click into the left-most column to type in the Structure ID for the structure you want to add or modify (e.g. Bowel).


5 buttons are displayed in the right-most column of the row corresponding to the available operations: Margin, Ring, Overlap, Combine, and Crop. Click the button for the operation you want to perform first. The buttons in the row allow you to add or delete a Step. Multiple steps can be added in order to perform ***sequential*** operations, for example you could generate a RECT_OVLP structure from the overlap of the PTV and the Rectum and then do a margin 0.3cm from that generated overlap structure like so:




## Margin

The **SYM** / **ASYM** and **Outer** / **Inner** toggle buttons can be used to specify Symmetric or Asymmetric margins as well as Outer or Inner margins.




If **ASYM** is selected, then you must enter the margin in each cardinal direction relative to the patient:


NOTE: **SYM** margins allow for negative numbers but **ASYM** does not (negative numbers essentially invert the Outer or Inner specification).

### Ring

Ring allows you to generate a ring structure based around the surface of the selected structure:


Negative numbers are allowed (so a Ring: Outer 1cm, Inner -0.1cm would generate a ring structure 1cm larger than the structure, and 0.9cm thick)

### Overlap

Overlap is equivalent to the Boolean AND operator for two structures:

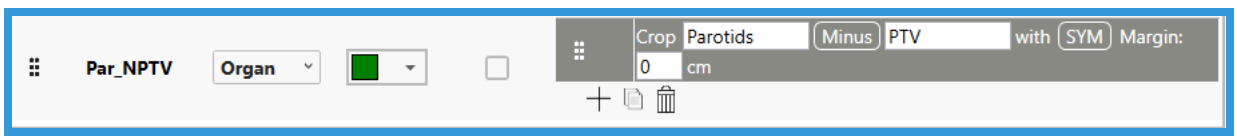

### Combine

Combine is equivalent to the Boolean OR operator for two structures:

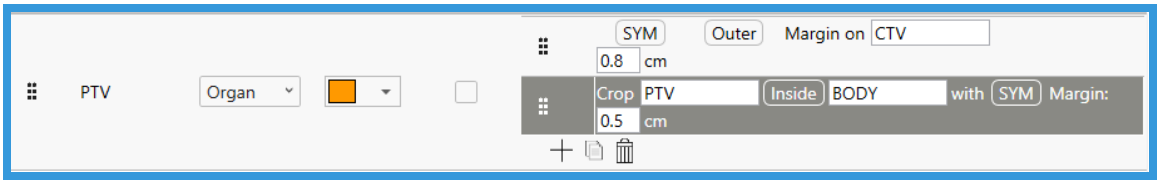

### Crop

Crop allows you to crop one structure from another with the "Minus" operation and prevent structures from extending outside of another with the "Inside" operation. Both options also allow for cropping with an additional margin (**SYM** or **ASYM** as described above) if desired. If no margin is desired, just leave it as **SYM** 0cm. Only positive cropping "Inside" margins are allowed.

Crop "Minus" example:



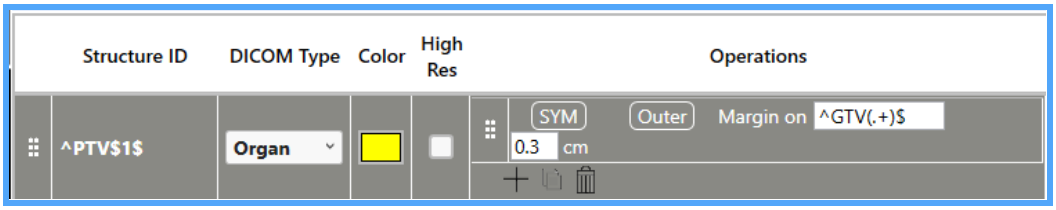

Crop "Inside" Example



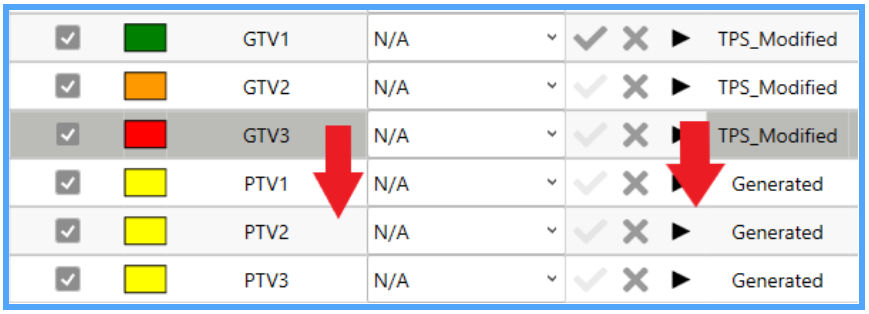

## Regular Expressions

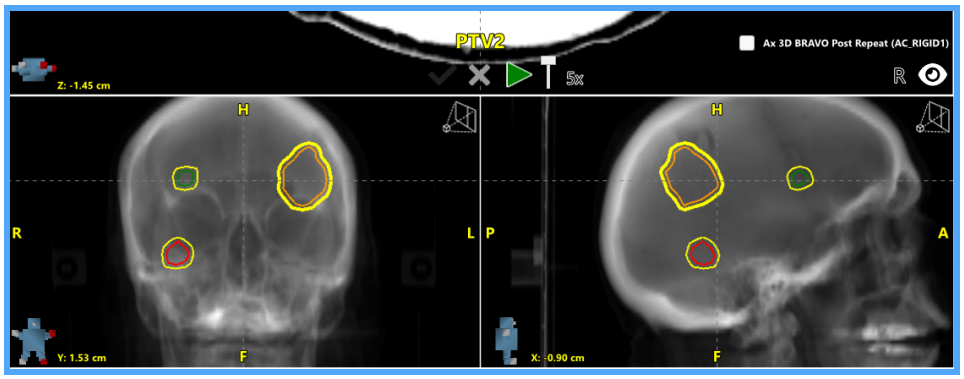
Regular expressions may be utilized to generate planning structures that follow a naming pattern. This function may be helpful when generating standard PTV expansions on CTV structures with unique trailing characters.

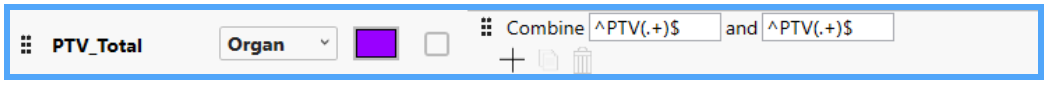
1) **Example:** Multiple Brain PTV margin expansions from GTV
   a) Use **^GTV(.+)$ in the** Margin textbox to match any source structure starting with “GTV” and end with unique ending character (GTV_L, or GTV_R, or GTV1, GTV2 etc)
   b) Use **^PTV$1$** in the Planning Structure ID column to generate a new structure that will append the trailing characters matched (eg. “PTV_L”, “PTV_R”, “PTV1”, “PTV2”) for any matched CTVs.




   c) Click on the Generate Structures button. 
   d) Structures with matching trailing characters will appear with a “Generated” status.

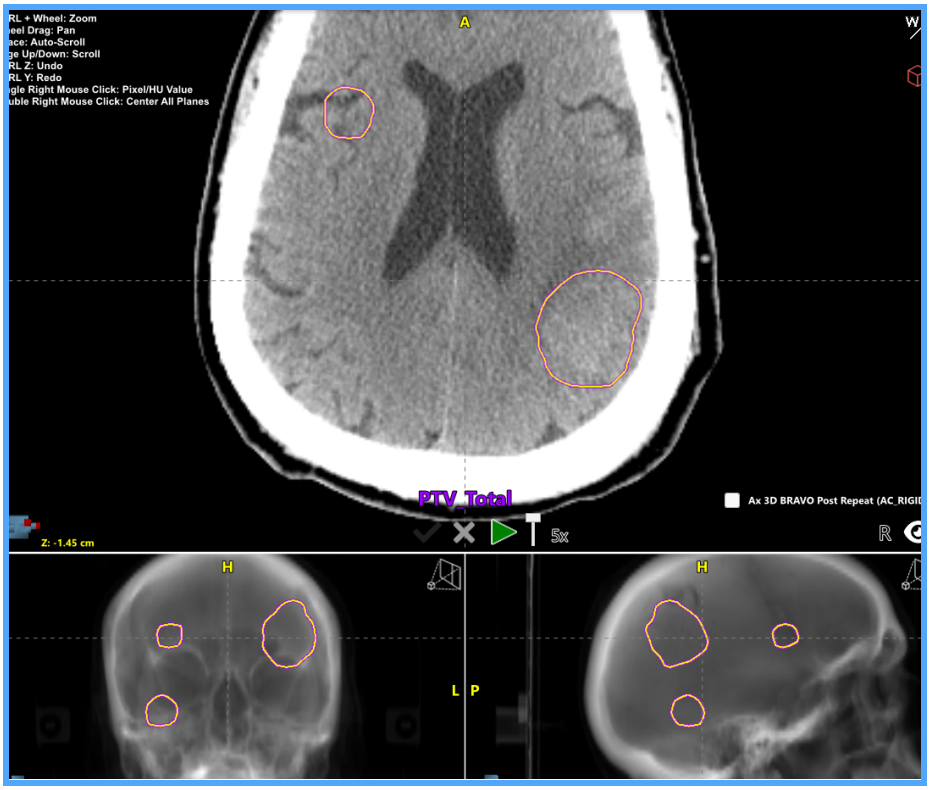


2) **Example:** Merge multiple structures with similar names to single structure
   a) Use **^PTV(.+)$** in both Combine text boxes to match any source structure starting with “PTV” and end with unique ending character (GTV_L, or GTV_R, or GTV1, GTV2 etc).
   b) Set any structure ID (eg. PTV_Total) as the target structure to which all matched PTV structures will
   c) 

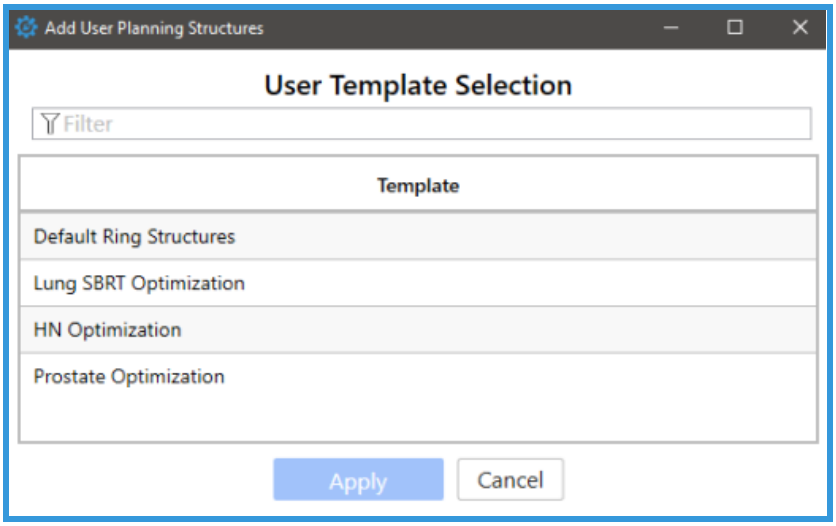
   d) Click on Generate Structure button 
   e) PTV_Total will returned with Generated Status

| | | | | | | |
|---|---|---|---|---|---|---|
| ☑ | | PTV_Total | N/A | Generated | 32.1 | ☐ |
| ☑ | | PTV1 | N/A | Generated | 2.5 | ☐ |
| ☑ | | PTV2 | N/A | Generated | 24.9 | ☐ |
| ☑ | | PTV3 | N/A | Generated | 4.7 | ☐ |



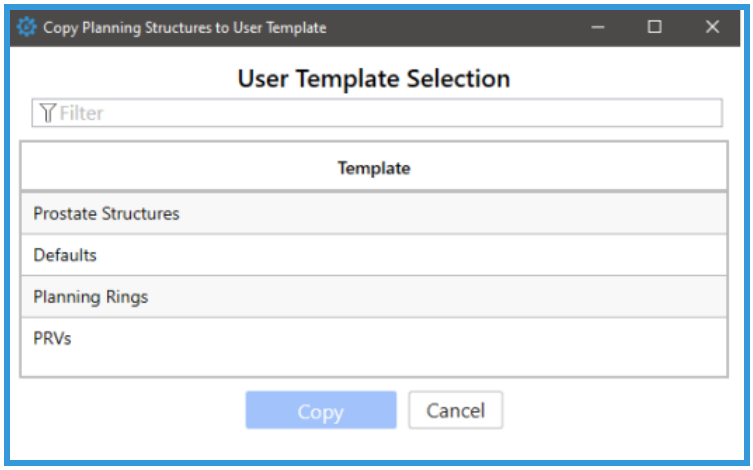
### Importing User Planning Structure Templates

The  button allows you to import previously-saved User Structure generation templates.




### Copy Planning Structures to User Template

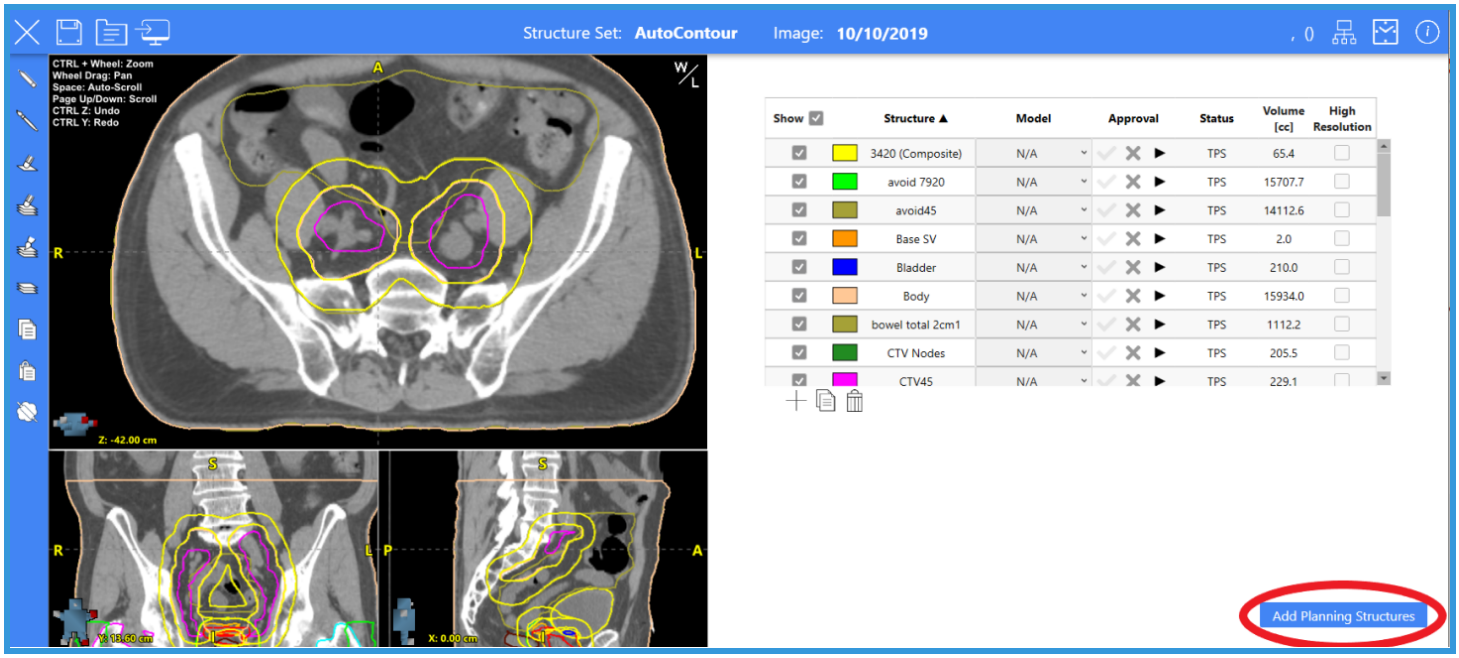
If a user adds/edits planning structures to the Main Window Planning Structure table, it is possible to save those changes to a User Template using the Copy Planning Structure to Template Button.  Any selected structures and their dependencies (source structures) will be copied to the User Structures Template(s) selected in the User Template Selection Window.



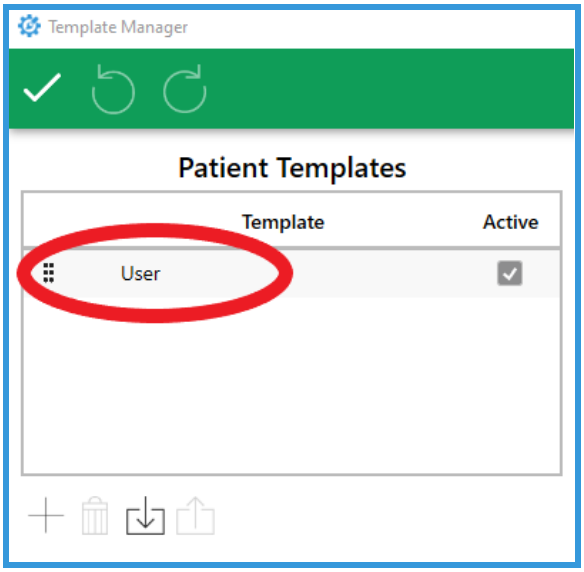

### Adding Structure Generation Templates Manually

If a Template is not initially assigned to the Image Series during initial launch, the user may still generate planning structures by clicking on the “Add Planning Structures” button in the bottom right corner of

the Main Window.

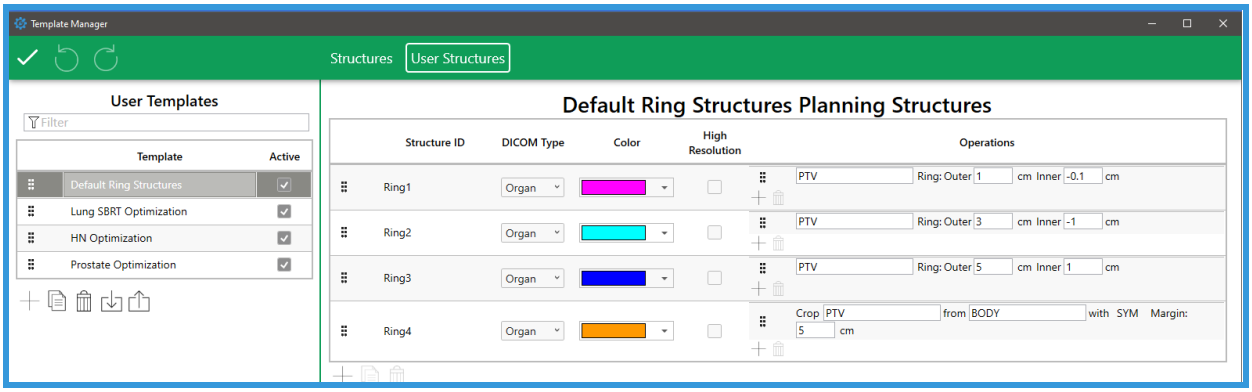



A default Patient Template with ID “User” will be automatically added to that Patient Templates List in the Template Manager so the changes to the Planning Structure table may be saved upon exit.




## Creating User Structure Generation Templates

Open the Patient Template Manager folder  button allows you to save your current Structure Generation Template. Select the User Structures Tab.



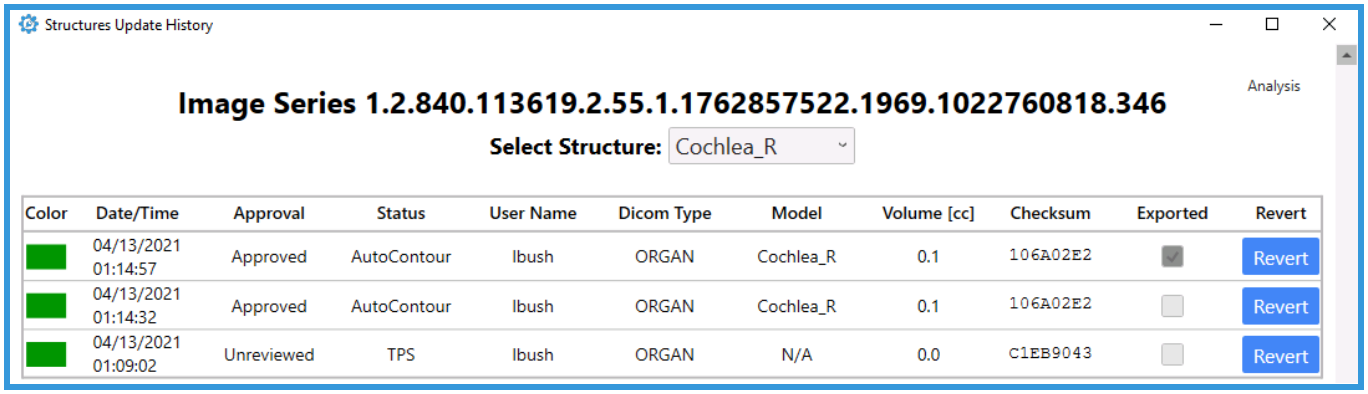

User-specific planning structure templates may be added , copied or deleted as needed. User Structure Templates will only be visible and saved based on the currently logged in User ID.

Templates may be shared between users by exporting as a **.structures** and imported into other users template list.

WARNING: If all of the structures used as inputs for structure generation are Approved, then AutoContour will automatically mark the generated structures as Approved. The user is responsible to ensure that the inputs to structure generation are correct for the desired output and that the generated structures are correct.

## Structure History

The  button under the Structure Table will display a window for viewing AutoContour's Structure History. Anytime anything is exported to Eclipse™, AutoContour will save the following information for each structure in the Structure tab

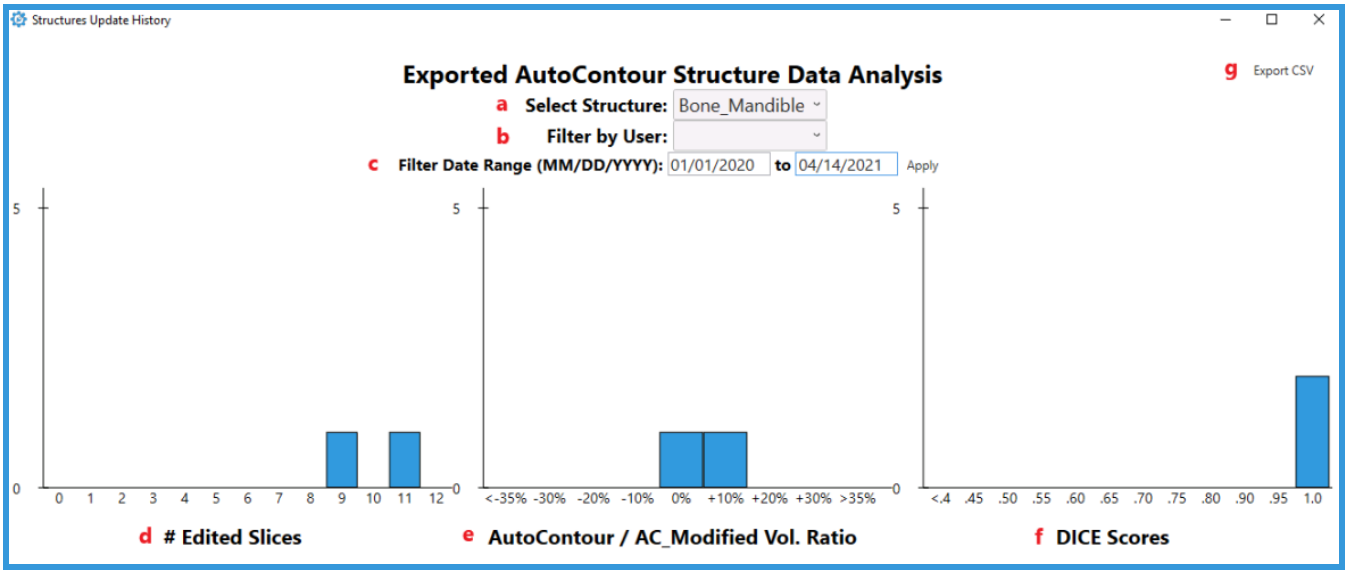



1. Color
2. Current Date/Time
3. Approval
4. Status (AutoContour, Modified, Generated etc.)
5. User Name
6. Dicom Type
7. Model
8. Volume [cc]
9. Checksum (MD5 Hash calculated from contour vertex positions)
10. Whether the structure was exported to Eclipse™.
11. Revert Button

Select the structure from the drop-down to see all history entries for that image series and structure.

## Structure Edit Analysis

Structure Edit Analytics may be viewed by clicking on the **Analysis** Button in the Top right corner of Structure History window. This window will show the # of Edited slices, Volume Ratio and Dice Similarity Coefficient Values (DICE) between the original contour generated by AutoContour and the final (AC_Modified) version of the contour approved and exported by the user.




a. Select AutoContour Structure Model
b. Filter results by user
c. Filter by Date Range
d. Histogram showing # of Manually edited Slices
e. Histogram showing ratio of AutoContour to AC/Modified Volume
f. Histogram of DICE Scores between the AutoContour and Approved AC_Modified structure contours. DICE scores are calculated using:

$$\mathrm{DSC} = \frac{2\,|X \cap Y|}{|X| + |Y|}$$

where:

$|X \cap Y|$ represents the intersection of X and Y, and
$|X| + |Y|$ represents the union of X and Y.

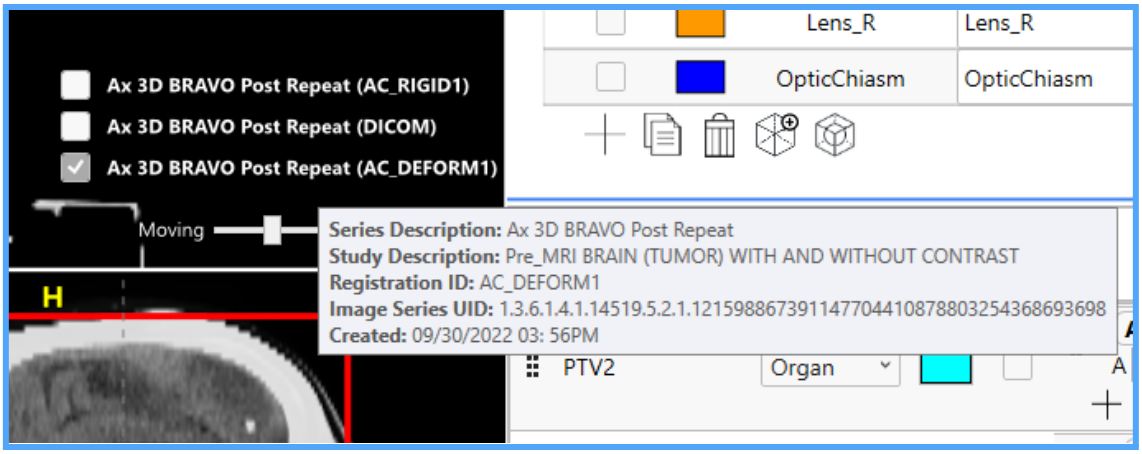
g. Export all Structure data to CSV. Data to be exported includes:
   i. Model
   ii. UserName
   iii. ExportDateTime
   iv. NumEditedSlices
   v. AutoContourVolumeCC
   vi. AC_ModifiedVolumeCC
   vii. DICE
   viii. AutoContourNumSlices
   ix. AC_ModifiedNumSlices

## 7.7 Image Registration

**Viewing Registered Images (MR/PET/CT)**

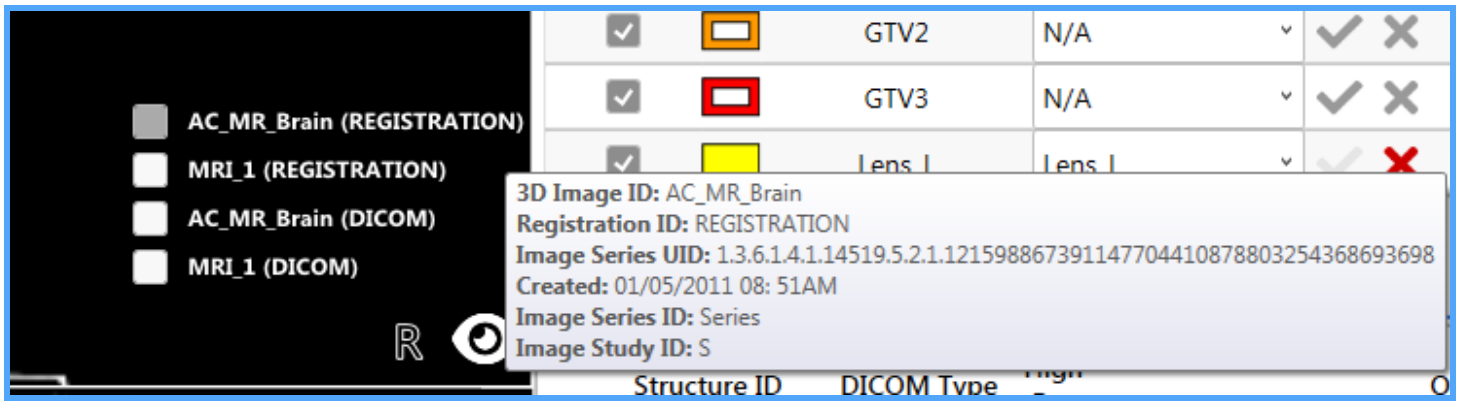
User may display any registered Image Series by clicking on the Show/Hide Registrations button  in the lower right corner of the Axial View. Activating this button will display a list of registered Images to the Primary CT.

1. In DICOM standalone mode the Series Description of each registered image or Image Series with a Shared Frame of Reference will display along with the Registration description in Parenthesis.
    a. For Registrations generated by AutoContour (Rigid or Deformed) the Registration ID will display (eg. "AC_RIGID1")
    b. For existing DICOM registrations, "DICOM" will be displayed.
    c. For Images with a Shared Frame of Reference to the current Primary Image, "Shared FOR" will display.
2. On mouse hover, additional Image Series Information will be displayed in the Tool-Tip including:
    a. Series Description
    b. Study Description
    c. Registration ID
    d. Image Series UID
    e. Created Date/Time

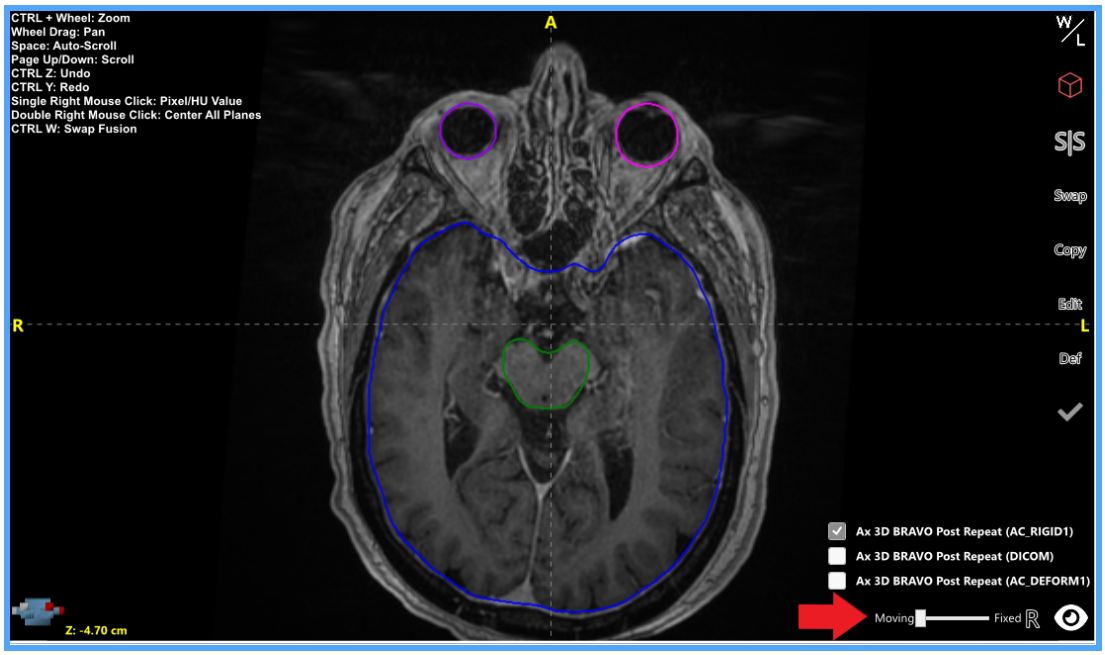



3. In ESAPI mode the Series Description of each registered image or Image Series with a Shared Frame of Reference will display along with the Registration description in Parenthesis.
    a. For Registrations generated by AutoContour (Rigid or Deformed) the Registration ID will display (eg. "AC_RIGID1")
    b. For existing Eclipse registrations, the Eclipse Registration ID will be displayed.
    c. For Images with a Shared Frame of Reference to the current Primary Image, "Shared FOR" will display.
4. On mouse hover, additional Image Series Information will be displayed in the Tool-Tip including:
    a. 3D Image ID
    b. Registration ID

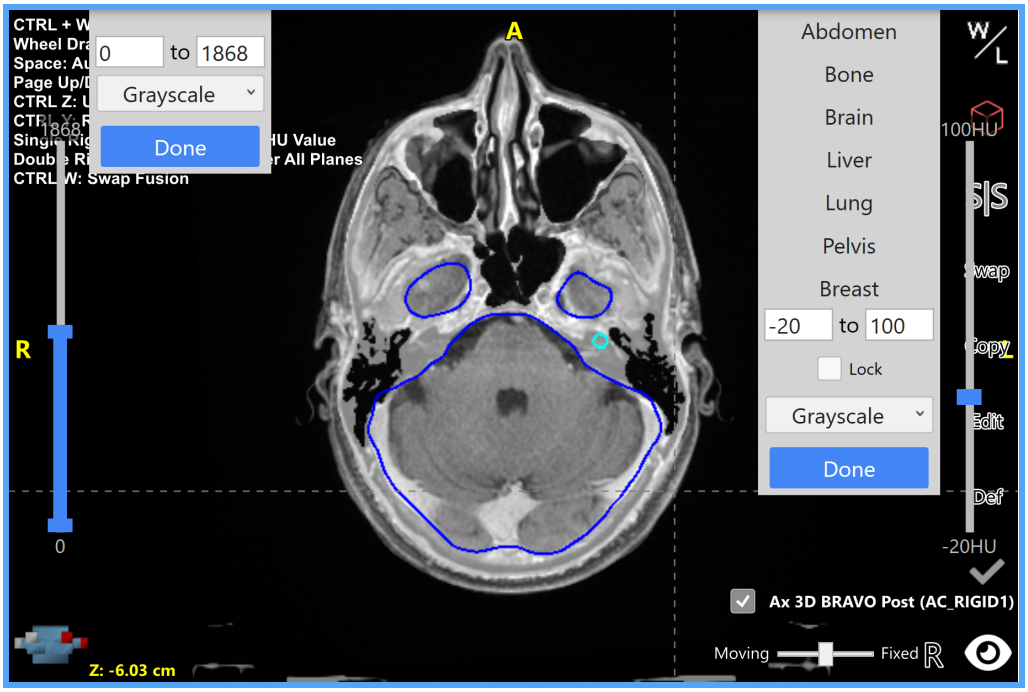
c. Image Series UID
d. Created Date/Time
e. Image Series ID
f. Image Study ID




- Overlay View
  a. By activating the checkbox next to the registered Image Series, an overlay view of the Registered (Moving) and Primary (Fixed) Image will be enabled.
  b. The overlay visibility of each of the images may be adjusted using the slider bar
     - Sliding all the way to the Left will only show the Moving Image
     - Sliding all the way to the Right will display only the Fixed Image.

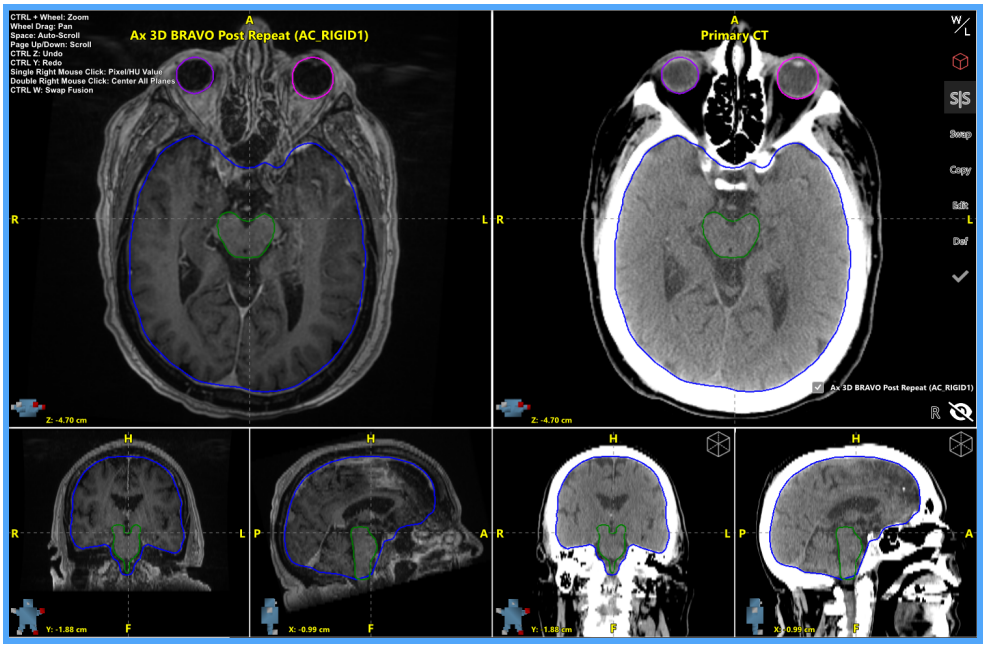



     - to adjust window/level  the moving image adjustment is on the left and the fixed image adjustment is on the right.

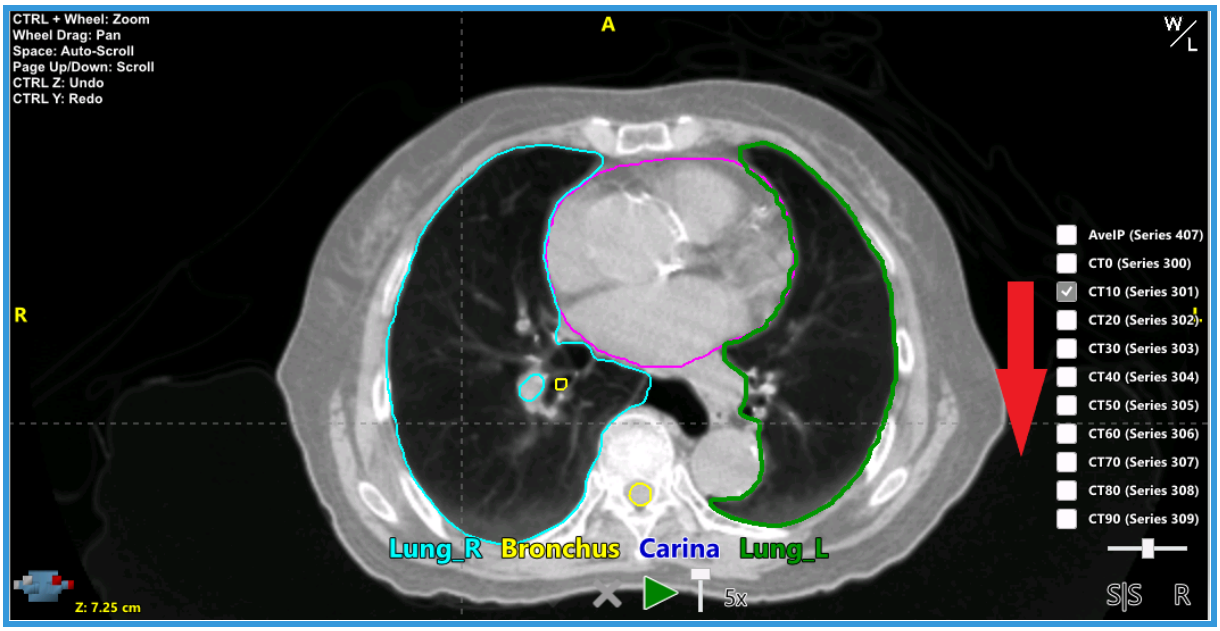



- Side-by-Side View

a. Once in overlay mode, the user may select the  button to view a locked view of the two images side-by-side.
   - Registered Image on the Left
   - Primary Image on the Right

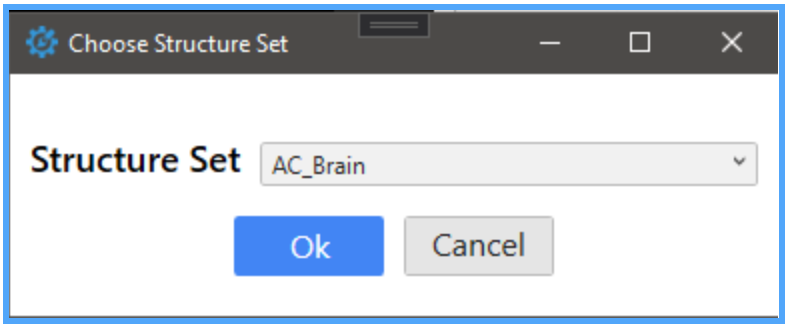


- Viewing 4D-CTs
    a. Users may switch between phases of a 4D-CT series using the UP/DOWN arrow keys.
    b. Note: An initial delay may be experienced when loading each phase into memory for the first time.




**Swap to Registered Image Series**

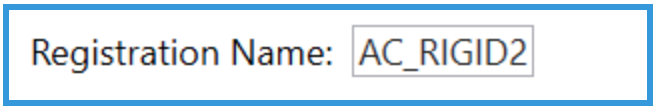
a. When viewing a registration, the user may quickly swap AutoContour to make the currently selected Moving Image as the Primary Image Set using the Swap button.
b. When clicked, the user will be asked to save any changes made to the current structure set.
c. If more than one Structure Set is attached to the selected Moving Image Series, then AutoContour will prompt the user to select the preferred structure set to be used for contour editing.



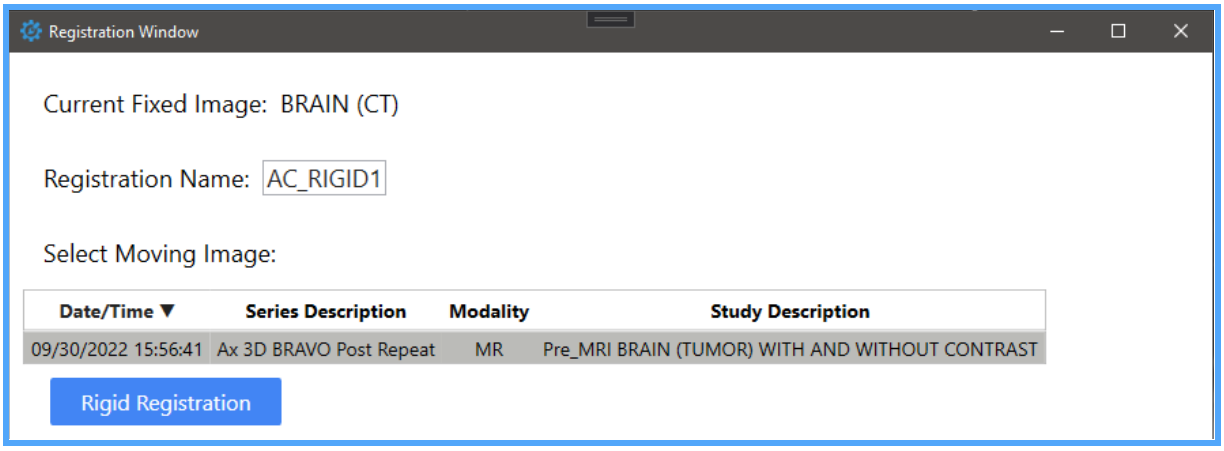

**Adding New Rigid Image Registrations**

d. Select Add Registration R to launch the Image Registration workspace window.

e. Set a Name for the Registration:




f. Select the Moving Image to be registered to the current Fixed image series. The Fixed Image will be the primary Image series paired with the Structure Set in the Main Window. The Moving Image will be the image series that is to be mapped via registration to the current Fixed Image.




g. Click the **Rigid Registration** button to launch the registration process on the selected Moving Image.
h. The Moving Image selected will be launched in Edit mode in overlay mode with the Fixed Image.
i. At this time the user can make manual adjustments to translation/rotation of the Moving Image (See Editing Existing Registration section below) and adjust the VOI box (see 7.6 structure editing above) if necessary on the anatomical area of interest to give a better starting point for the automatic registration process.

## Adding New Deformable Image Registrations

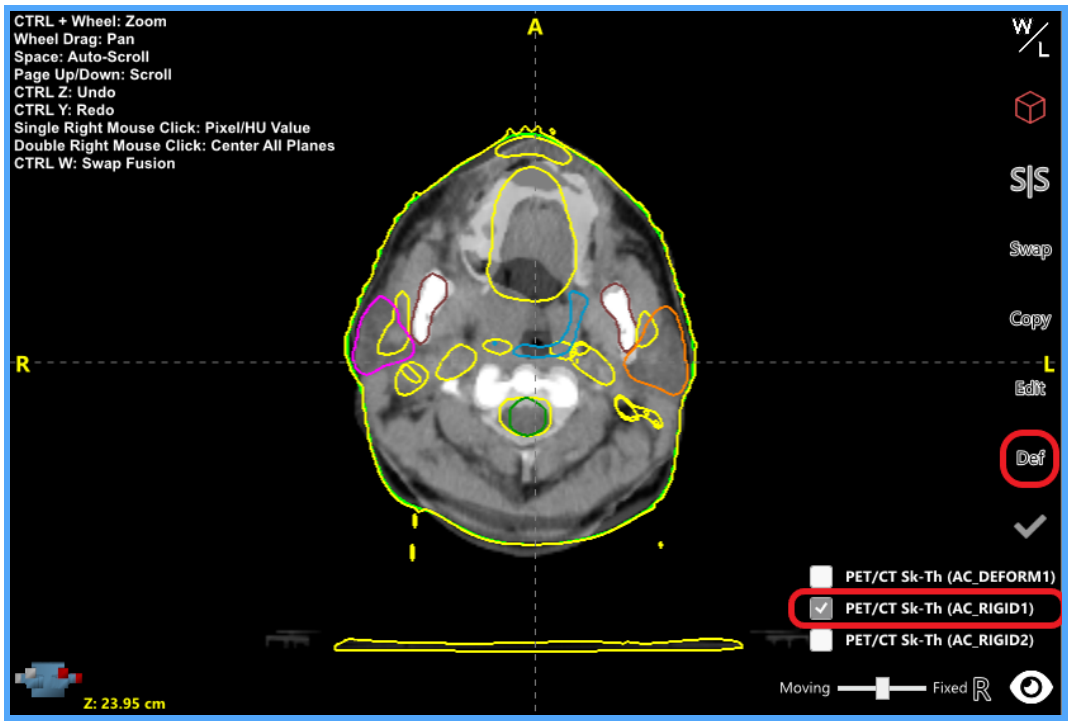
WARNING: Deformable Image Registrations are most accurate when starting with Rigid Registrations where the maximum expected deformation between anatomical landmarks is less than 2-3cm. Larger deformations may result in unexpected registration results.

WARNING: It is required that all deformable image registrations be reviewed by qualified clinical experts before use in the clinical workflow

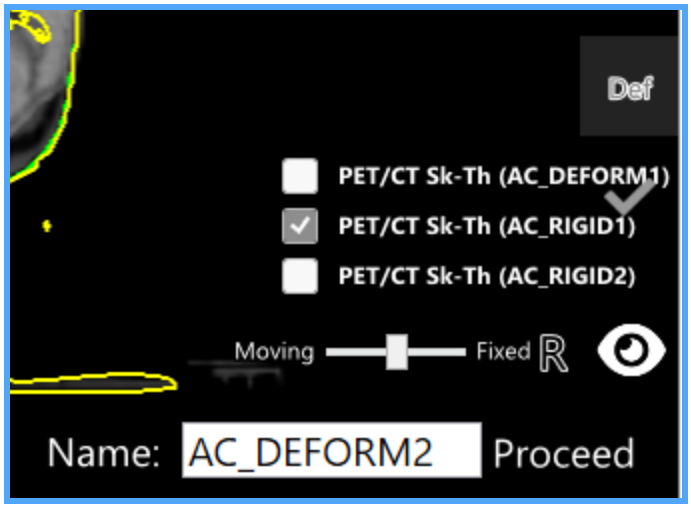
Deformable Image Registration may only be run on an existing Autocontour Image Rigid Registration.

a. Select an existing AutoContour Rigid Registration within the Main Window.

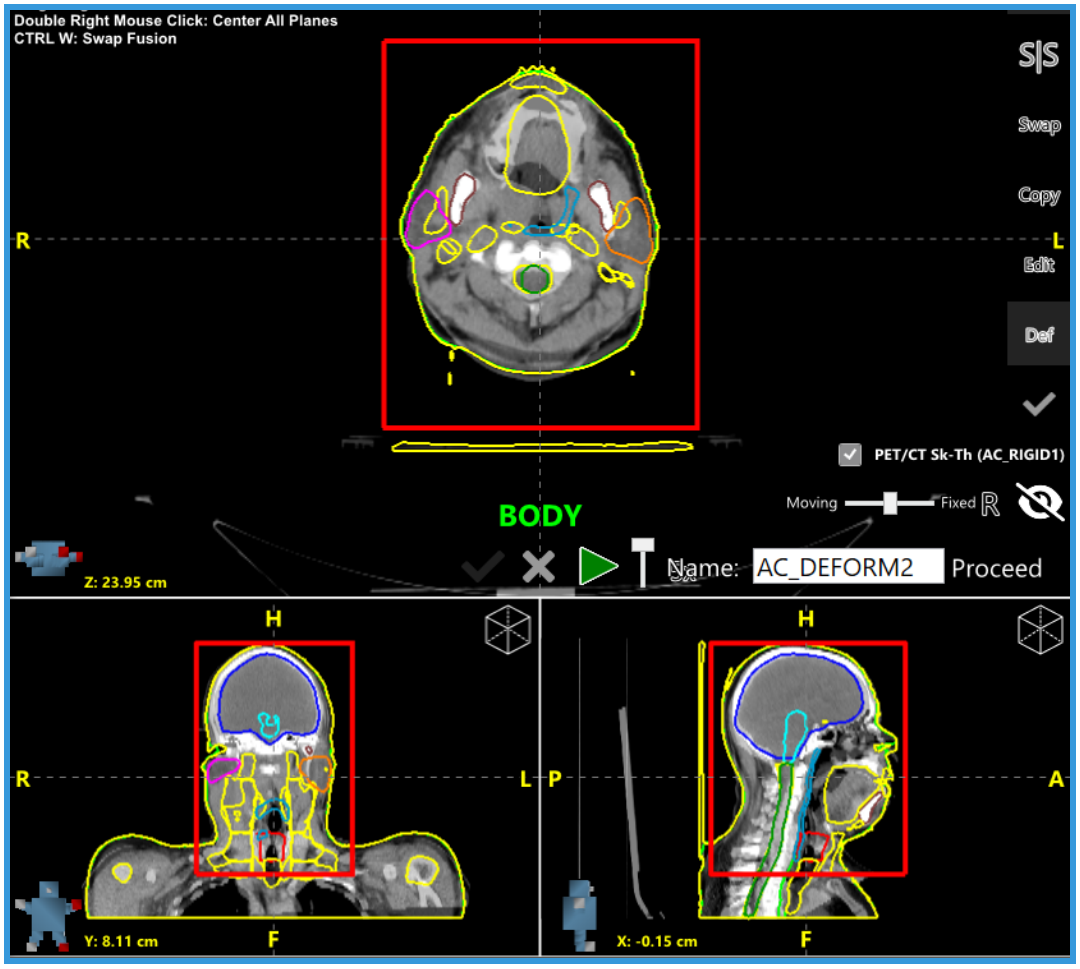
b. Click on the Def button.




c. Set a name for the Deformable Registration:




d. Adjust the VOI box (see 7.6 structure editing above) to focus the Regions of Interest in which the Deformable Registration Algorithm is applied.




e. Click 

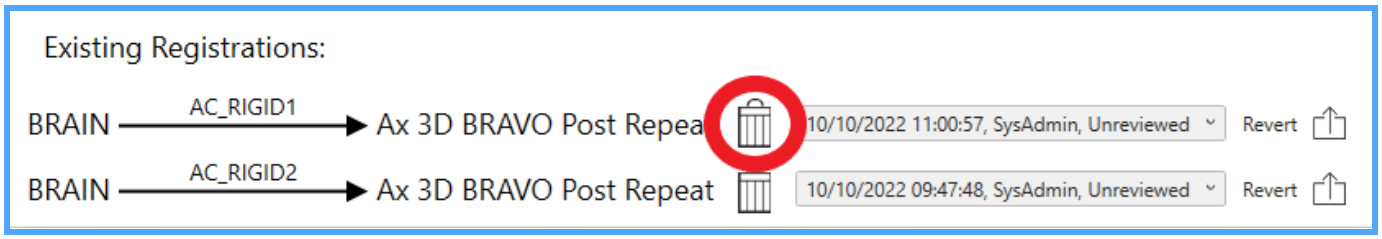
.

f. Deformable Image Registration may take a few minutes to complete depending on local computer hardware resources.

## Deleting Existing Image Registrations

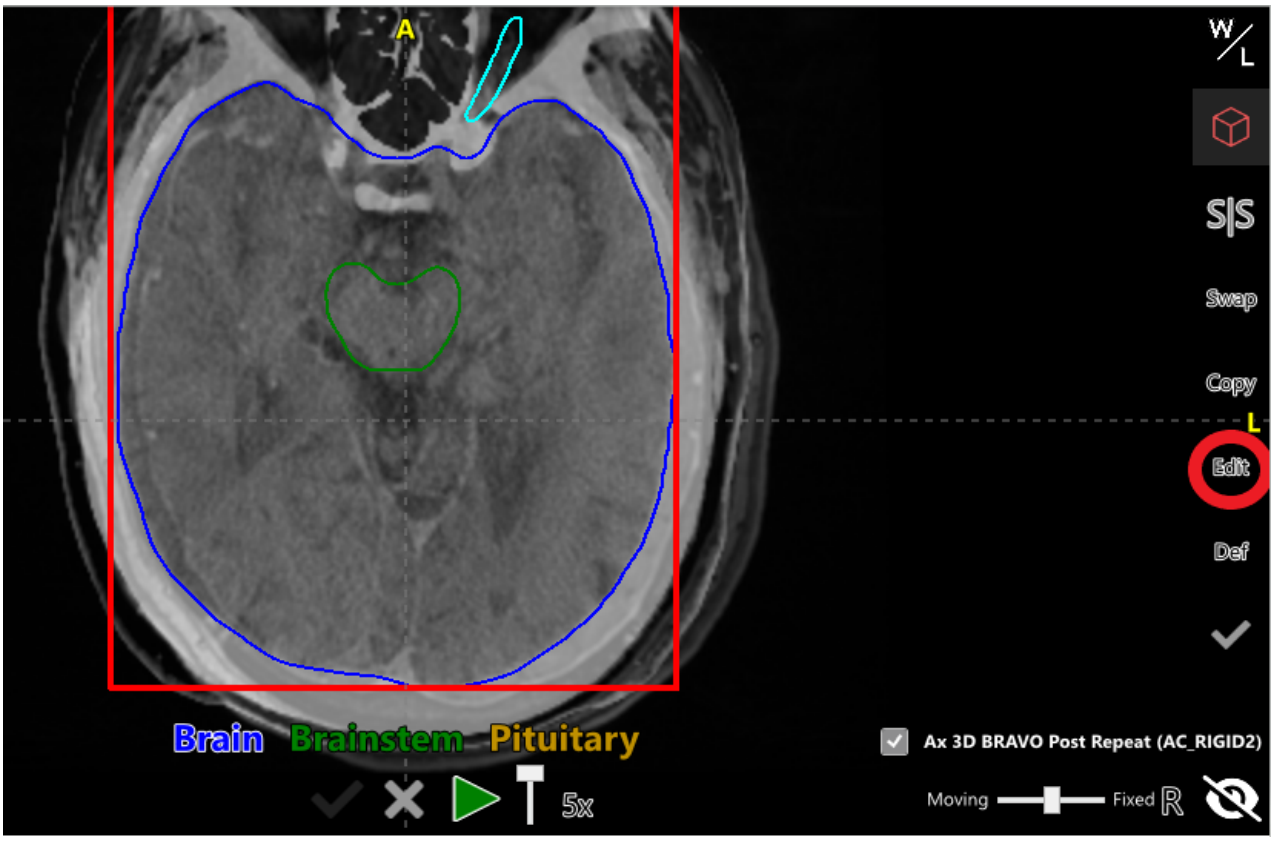
a. Select Add Registration  to launch the Image Registration workspace window.

b. Click on trash can Icon next to each of the existing registrations to delete that registration

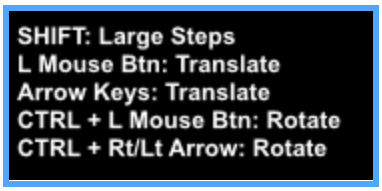


## Editing Existing Rigid Registrations

a. With a Rigid Registration selected in the Main Window select the Edit button.




b. Manual Editing Registration Tools are displayed in the upper left corner of Axial View Plane window.

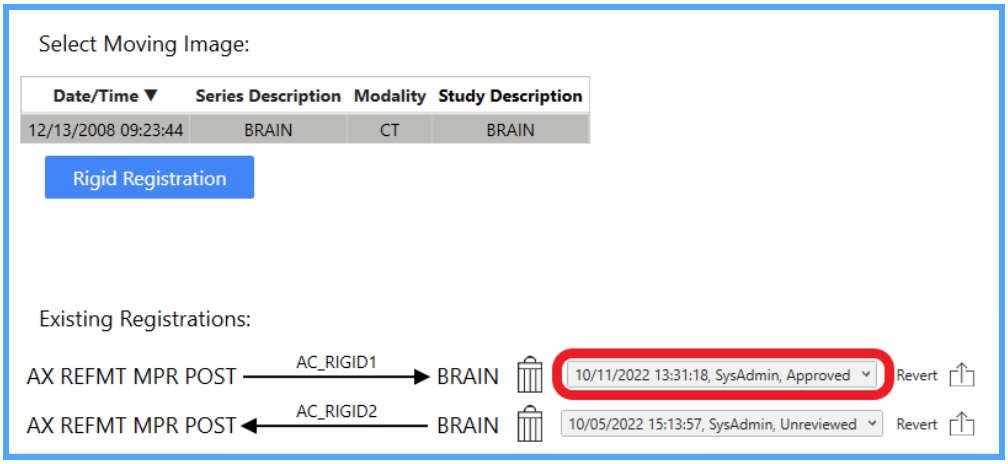



c. To adjust the translation of the Moving Image relative to the Fixed Image:
   i. Click and drag the mouse within the Axial/Sagittal/Coronal Viewing Plan windows.
   ii. Use arrow keys for fine adjustments (1 pixel)
   iii. Hold the **Shift** key and use arrow keys for coarse adjustments (5 pixels)

d. To make rotation adjustments relative to the current viewing plane intersection point.
   i. Hold the CTRL key and drag the mouse within the Axial/Sagittal/Coronal Viewing Plan windows.
   ii. Hold the CTRL key and rotate clockwise with right-arrow key, counter-clockwise with left-arrow key.

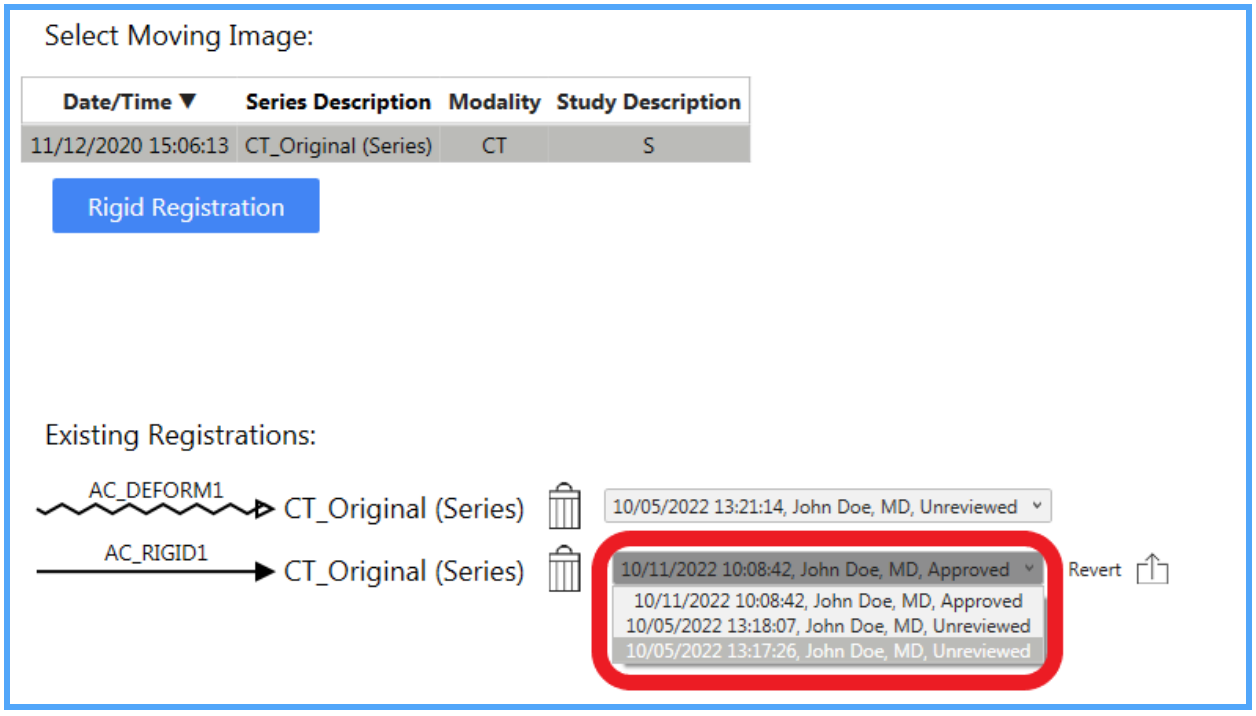
## Approving Existing Image Registrations

a. Once the moving image registration is complete, the user may approve the registration using the  button to add the current username and datetime to the registration history snapshot and to prevent users from editing the registration.
b. Registration Approval History can be reviewed within the Registration Window under the Existing Registrations section.




## Reverting Existing Image Registrations

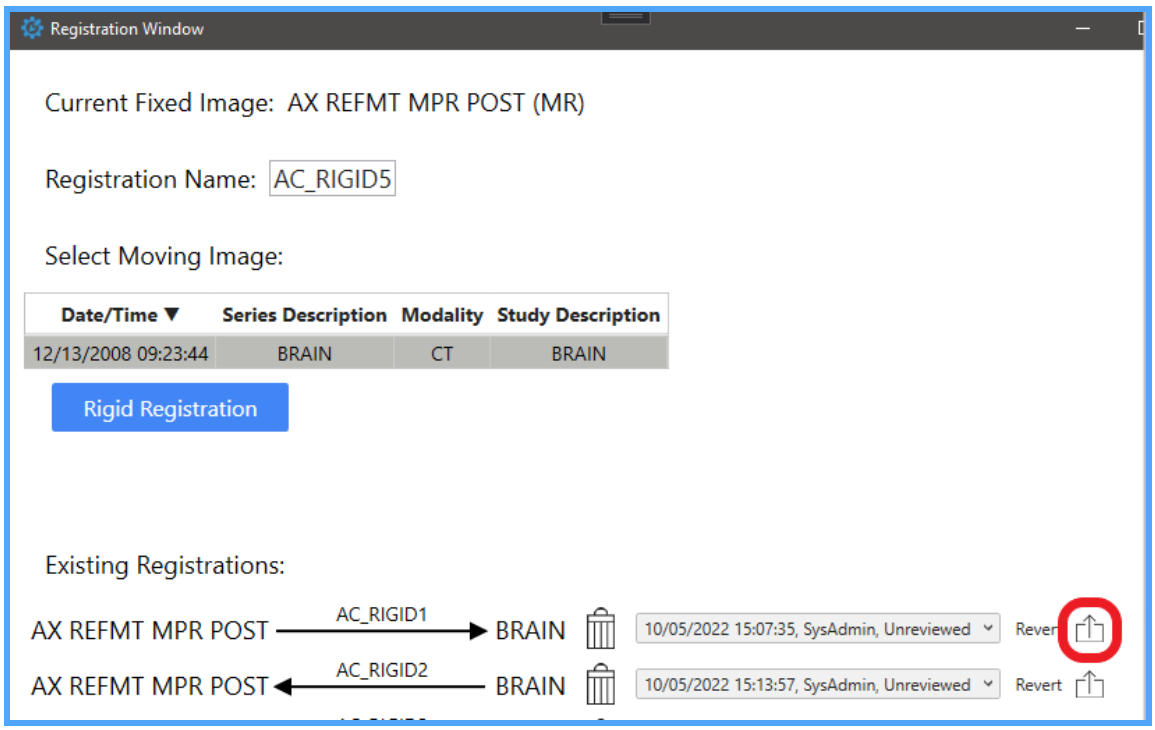
c. Select Add Registration  to launch the Image Registration workspace window.
d. Click on the Moving Image to show the list of registrations for that Image Series to the current Fixed Image Series.
e. Next to the Rigid Registration to be reverted, choose the Registration snapshot to be reverted.



f. Click on the Revert to revert that registration to a previous version. The previous version of the registration will appear with a “Reverted” status.

## Exporting Rigid Registrations to DICOM

g. Select Add Registration R to launch the Image Registration workspace window.
h. Click on the Moving Image to show the list of registrations for that Image Series to the current Fixed Image Series.
i. Click on the button to export the existing registration to the same directory as the current Primary (Fixed) Image Series.

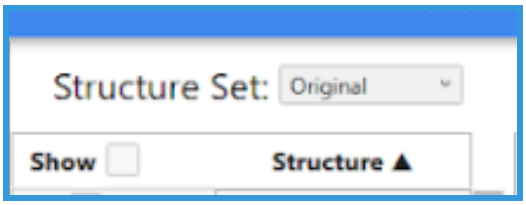



j. A message box will appear upon successful export detailing the exported Directory location

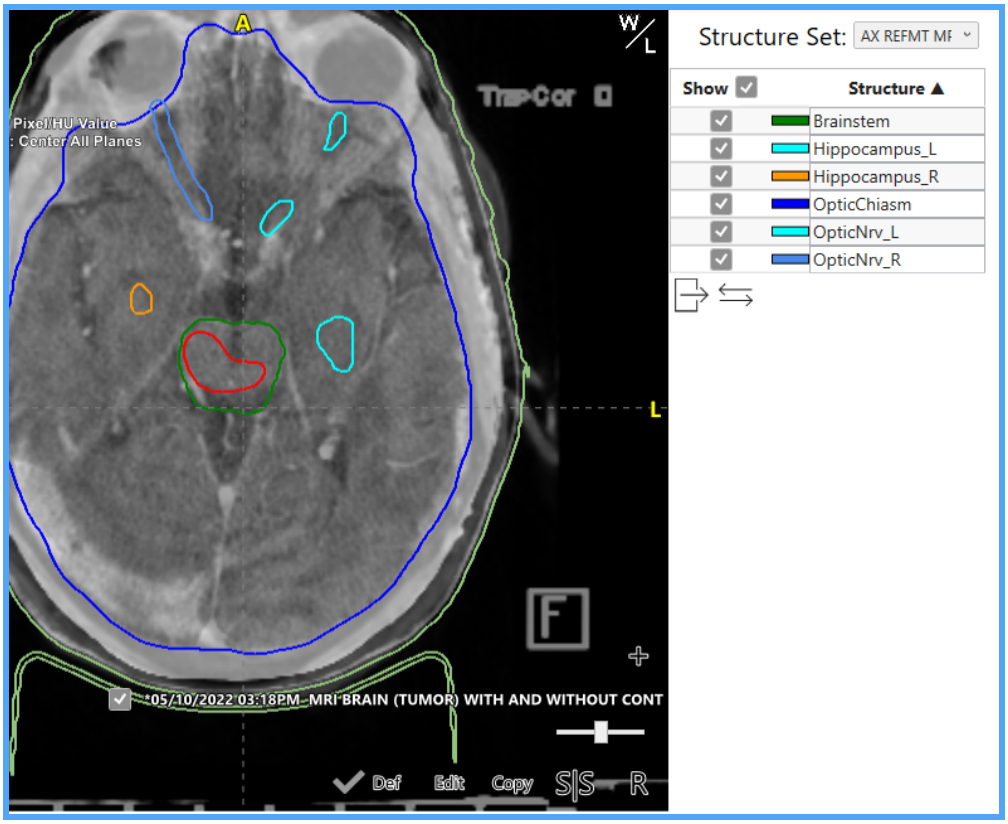
## Transferring Structures to Registered Image Structure Set

AutoContour allows the user to transfer structures on the Moving Image Series to the Primary Image Series structure set. The structure contours will be transferred based upon either the rigid or deformable transformation matrix. To send one or more structures from the Fixed to Moving Image Series:

a. Select a Registered Image/Registration pair from the list of registered Images.
b. Click the Copy button.
c. Select the appropriate Moving Image Structure Set from Drop Down if multiple are available.




d. Select one or more structures from the left structure set table.

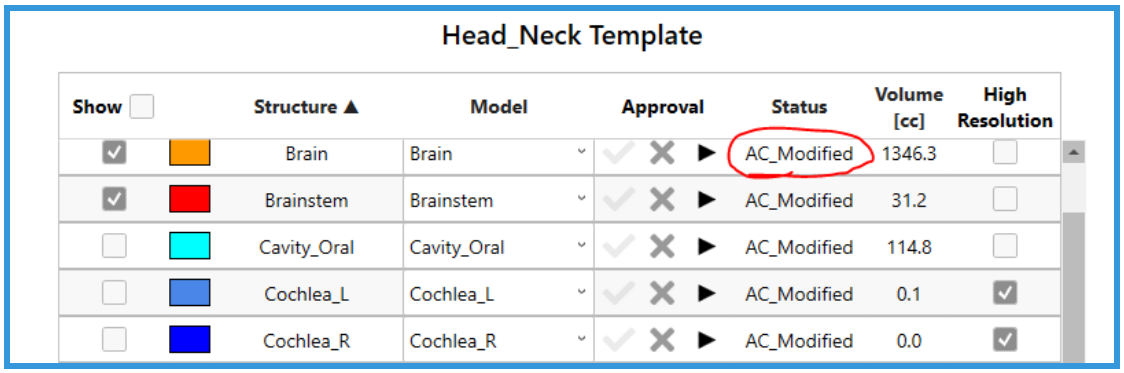



e. Structures with matching IDs may be compared directly within the Structure Comparison Tool  to evaluate Volume and Dice Similarity Coefficient.

f. Select the Transfer Structures Button  to copy the selected structures to the Primary Structure Set with a “Modified” status.

 WARNING : If a structure with the same ID is present in the Primary Structure set, then the contours for that structure will be overwritten with the contours from the Transferred Structure. To maintain the original contour, it may be necessary to copy the structure first before transferring.

g. Transferred structures will now appear with an AC_Modified Status.




h. Structures to be exported from AutoContour for use in the adaptive plan must still be reviewed on every slice for accuracy before Approval and Export to Eclipse or DICOM.

WARNING: It is possible that some loss of contour fidelity may occur during structure transfer from one registered image plane to another, especially between deformable registrations, and between scans where the axial view planes are not aligned between rigidly registered images. It is important to fully review all structures before clinical use.

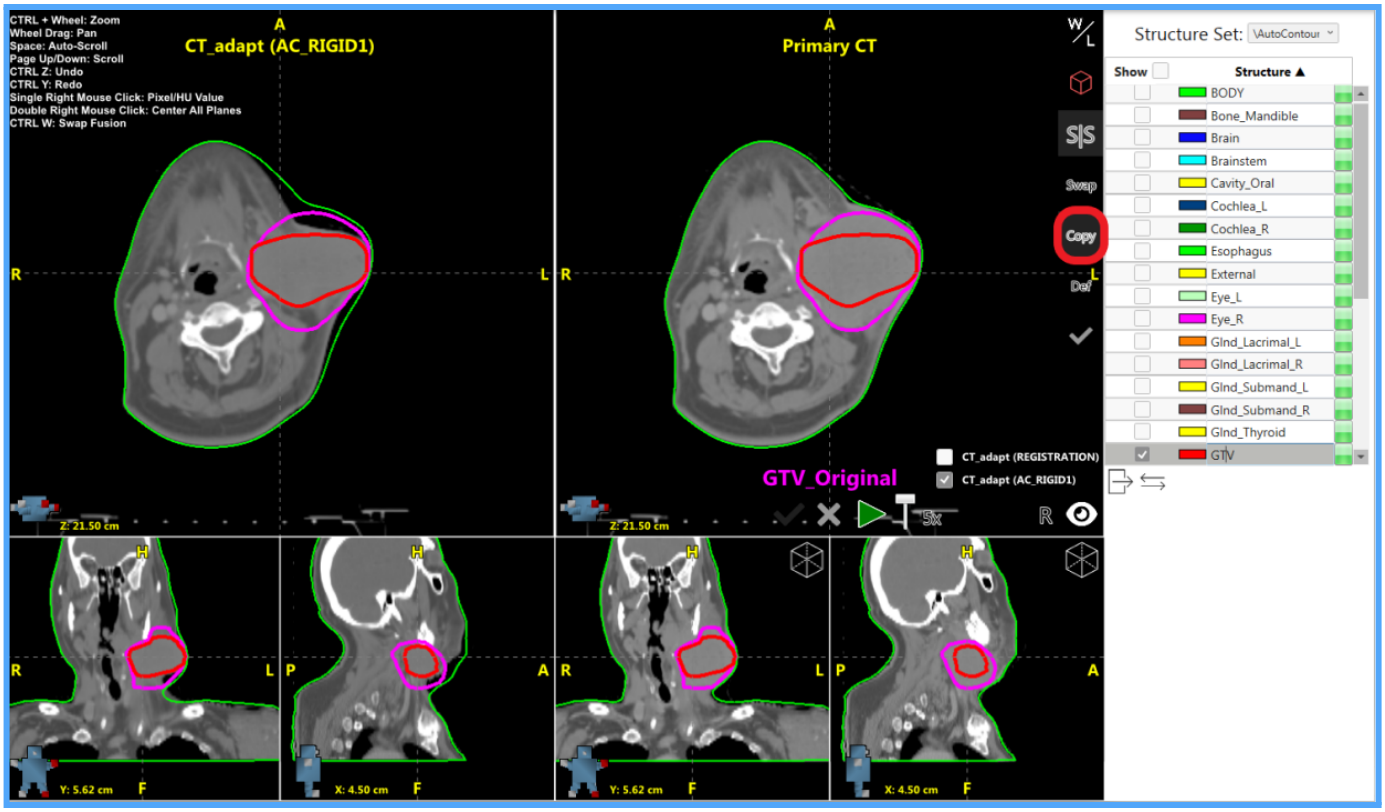
## Adaptive Workflow

AutoContour may be used within an offline adaptive workflow by taking advantage of its contouring, registration, and structure transfer tools. An adaptive workflow may consist of multiple steps including initial patient contouring, on-treatment patient contour changes. Offline adaptive Radiation therapy refers to the process of updating the patient's treatment plan after the delivery of a single or multiple fractions of treatment, often involving re-simulation, re-contouring, and re-planning in the same manner the initial treatment plan was created.

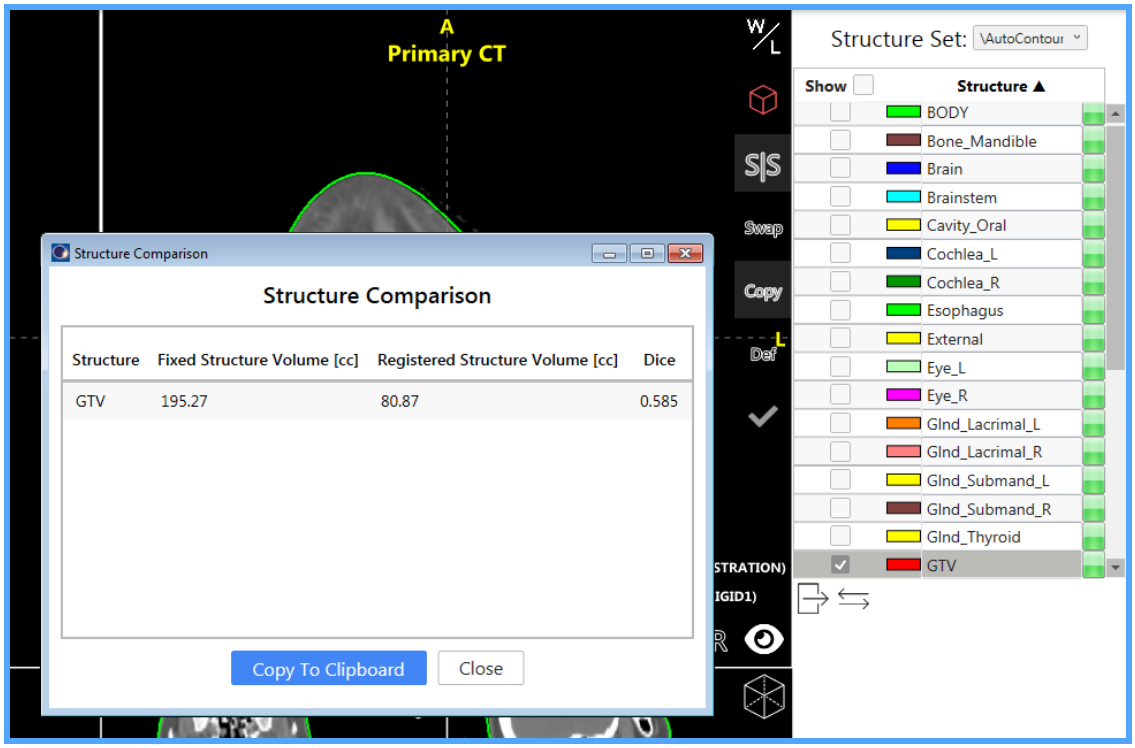
After initial contours have been approved and the patient begins treatment, any subsequent CT scans or on-treatment CBCT scans acquired during the patient course of treatment may be rigidly registered to the original planning CT for basic comparison of patient weight loss, tumor volume changes, or organ-at-risk changes.

**Patient Weight Loss/Volume change evaluation**

1) Launch AutoContour on the original Planning CT
2) Register the new Image CT or CBCT to the Fixed planning CT
3) In the overlay or side-by-side Registration view, Structures from both the Original (Fixed) and Adapted (Moving) Structures sets may be reviewed by also enabling the




4) Structure volumes may be evaluated based on Volume and Dice Similarity Coefficient (DSC) using the Structure Comparison Window.

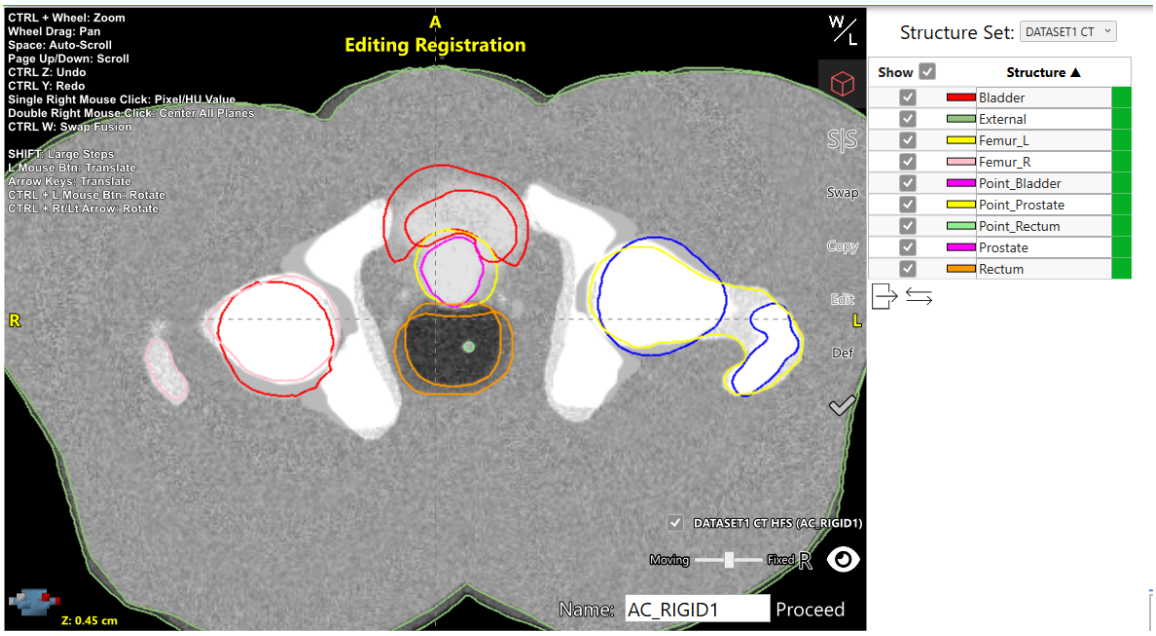


## Deformed Structure Transfer

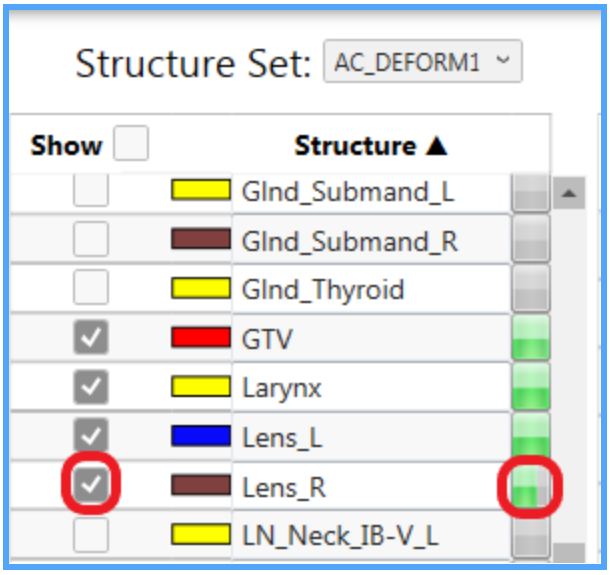
If significant changes are found in contour evaluation above, then new contours based on the latest CT images may be required for an adaptive re-plan to occur. The user may take advantage of AutoContour's automatic AI contouring directly, but it may be preferable to simply transfer the original structure contour information directly to the new scan using a Deformable registration and AutoContour Structure Transfer option. Deformed Structure Transfer Procedure.

1) Launch AutoContour with the new adaptive CT Image Series as the Primary (Fixed) Image.
2) Run a Rigid and then Deformable Image Registration with the Original Planning CT selected as the Moving Image Series.
3) Evaluate the Deformable Registration for appropriateness.
4) Click on the 

button on the right side of the Axial view to enable the display of structures from the original planning CT deformed to the current CT frame of reference.



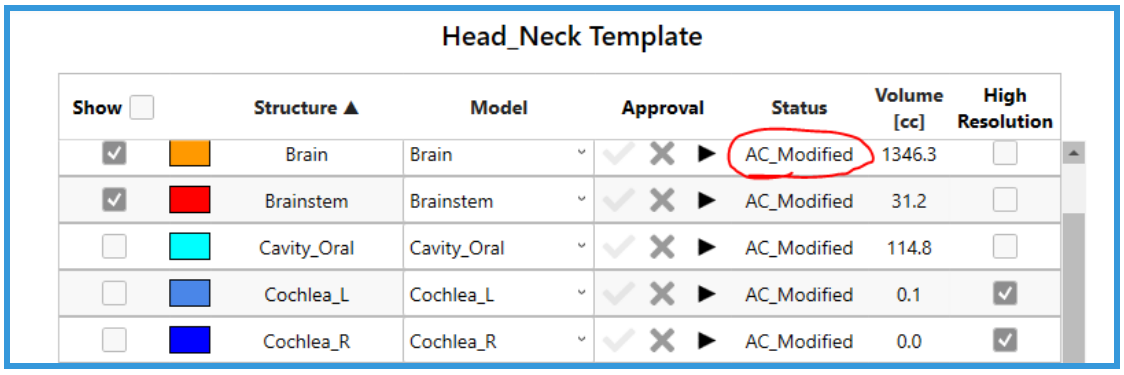

5) The user may evaluate the deformed structures in comparison to structures generated by AutoContour to further evaluate the accuracy of the deformation while in this view.
6) For deformed structure transfers, it may take additional time for each structure to be deformed to the new geometry depending on available hardware resources. The processing order may be adjusted by only checking the structures you wish to view/transfer as these will begin the deformation transformation first. The progress bar at the right hand side of the Copy Structure Table will indicate when the structure deformation is in progress or complete.




7) Structures with matching IDs may be compared directly within the Structure Comparison Tool  to evaluate Volume and Dice Similarity Coefficient.
8) To transfer the deformed original contours to the new Fixed Image, select the check box next to the structures to be transferred and hit the  button.

 WARNING : If a structure with the same ID is present in the Primary Structure set, then the contours for that structure will be overwritten with the contours from the Transferred structure. To maintain the original contour, it may be necessary to copy the structure first before transferring.

9) Transferred structures will now appear with an AC_Modified Status.

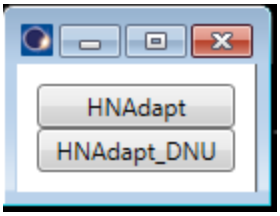



10) Structures to be exported from AutoContour for use in the adaptive plan must still be reviewed on every slice for accuracy before Approval and Export to Eclipse or DICOM.

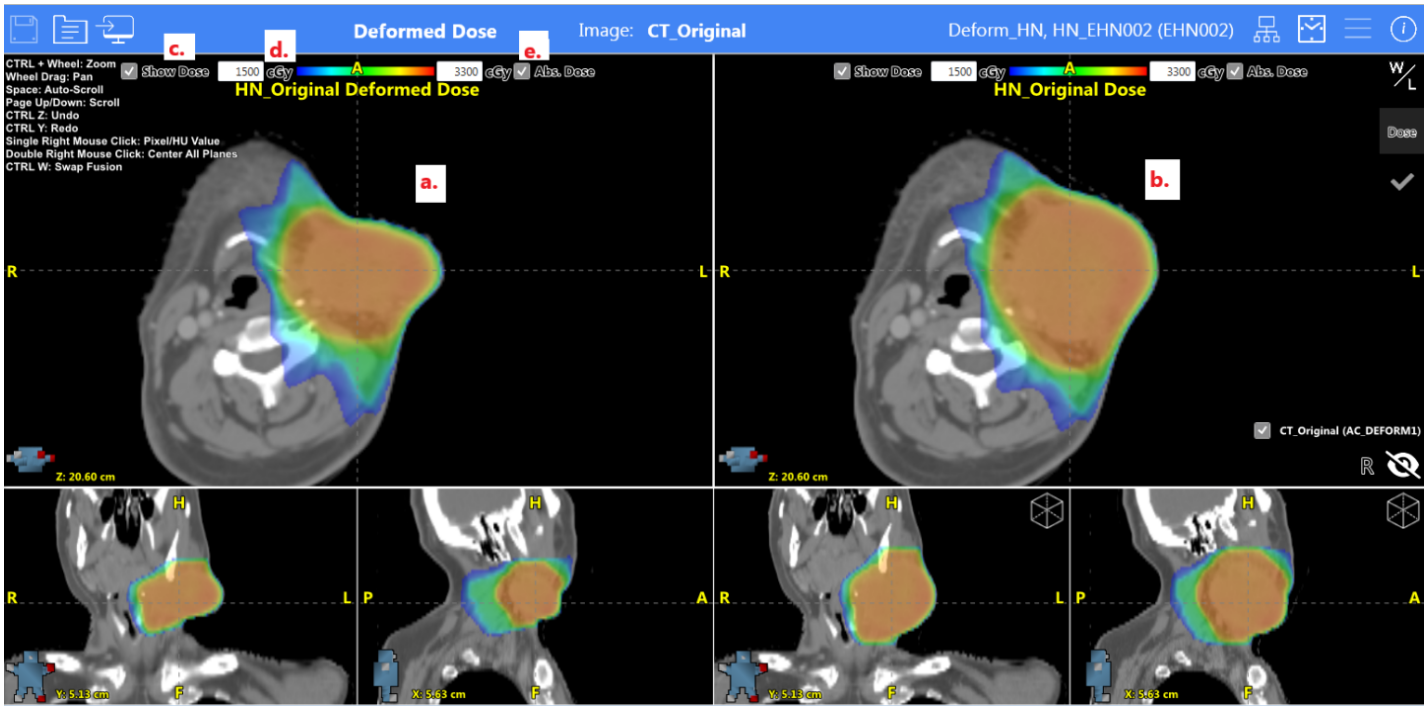
**Deformed Dose Display (Eclipse ESAPI Workflow only)**

After an existing Deformable Image Registration is performed within AutoContour, users may visualize the same image deformation mapping applied to any plan dose calculated on the Moving Image Series within Eclipse.

1) Launch AutoContor on the Primary Image Series to which you would like to see the moving image series dose mapped.
2) Perform a Rigid and then Deformed registration to the Moving Image linked with the previous Dose to be mapped to current image geometry.
    a) Note: The accuracy of the deformable registration must be performed by a trained clinical expert before Deformed Dose Transfer is performed. User may evaluate registration accuracy qualitatively using the overlay and side-by-side views or by overlaying relevant structure contours with the “Copy” button along with Structure Comparison tool.
3) Click on the 

icon.
4) If more than one Plans with Dose are linked to the current Moving Image Series, then choose the Plan Dose to be viewed within the Pop-up Plan selection window.
    a) 

5) Processing window shall appear while the dose is being deformed.
6) Deformed Dose View Window




a) Deformed Moving Image and Dose
b) Original Moving Image and Dose
c) Show Dose checkbox
d) Dose Colorwash Controls
e) Absolute/Relative Dose checkbox

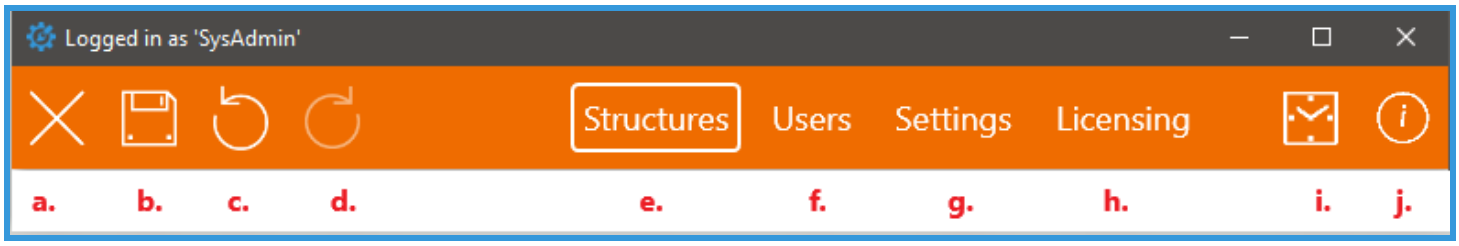
7) To make the Deformed Dose available within ClearCheck, a qualified clinical expert must set the Deformed Registration to Approved. 

8) To close out of the Deformed Dose View Window, select the  button again to revert to the Registration Side-by-side view.

## 7.8 AutoContour Administration Application

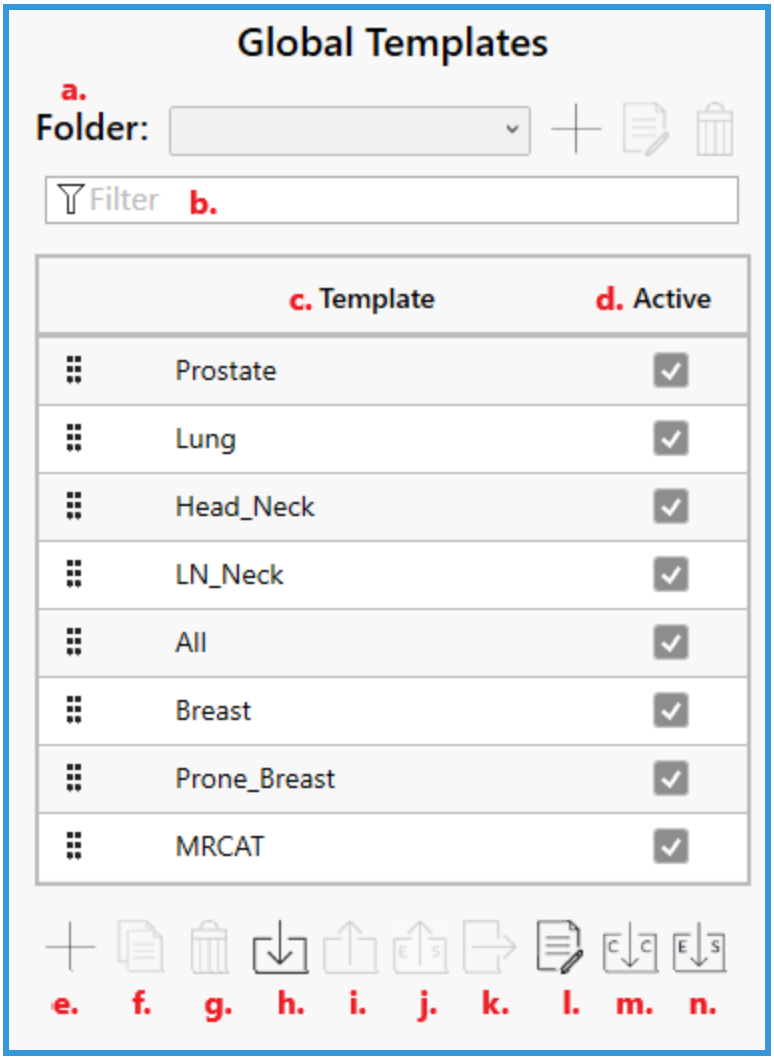
Please note that the Administration application for global structure templates has a similar layout to the patient structure template manager. Any changes made in the Administration application will be globally changed for the entire clinic. Also note that changes made are not retroactive and will only apply to future use.

1. **Access**
    a. The Administration application is available directly within the AutoContour install location (\radformationfiledata\autocontour\AutoContourAdministration.exe)
    b. Admin is also accessible within the AutoContour Software itself by clicking on the  icon in the top right corner.
2. **Administration Application Header**



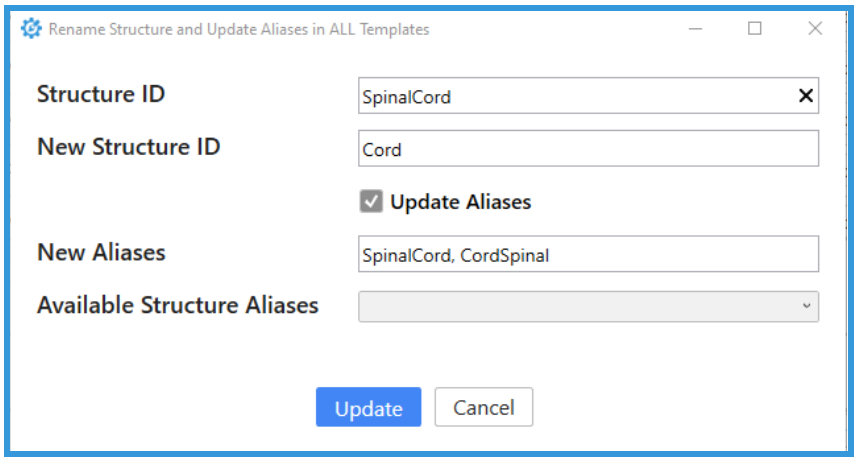

a. Close (CTRL+Q)
b. Save Changes (CTRL+S)
c. Undo (CTRL-Z)
d. Redo (CTRL_Y)
e. Global Structures Tab
f. Users Tab
g. Settings Tab
h. Licensing Tab
i. History
j. Info

### 3. Global Structures Tab - Left Window




a. Structure Templates may be filtered into folders. Users may add, rename and delete existing folders.
b. Filter Structure Templates by name
c. Structure Template Table
d. Active Checkbox specified if the template is available to users in Template Manager.
e. Add new Structure Template (CTRL+N)
f. Copy Structure Template (CTRL+C)
g. Delete Structure Template (DEL)
h. Import Structure Template
i. Export Structure Template
j. Export Structure Template as Eclipse Structure Set XML file
k. Copy Template to Folder
l. Rename Structure in all templates
    i. This button updates the Structure ID/Alias across all templates to a new string.

ii. User to choose the existing Structure ID they would like to edit, enters the New Structure ID, and any New Aliases to be used.

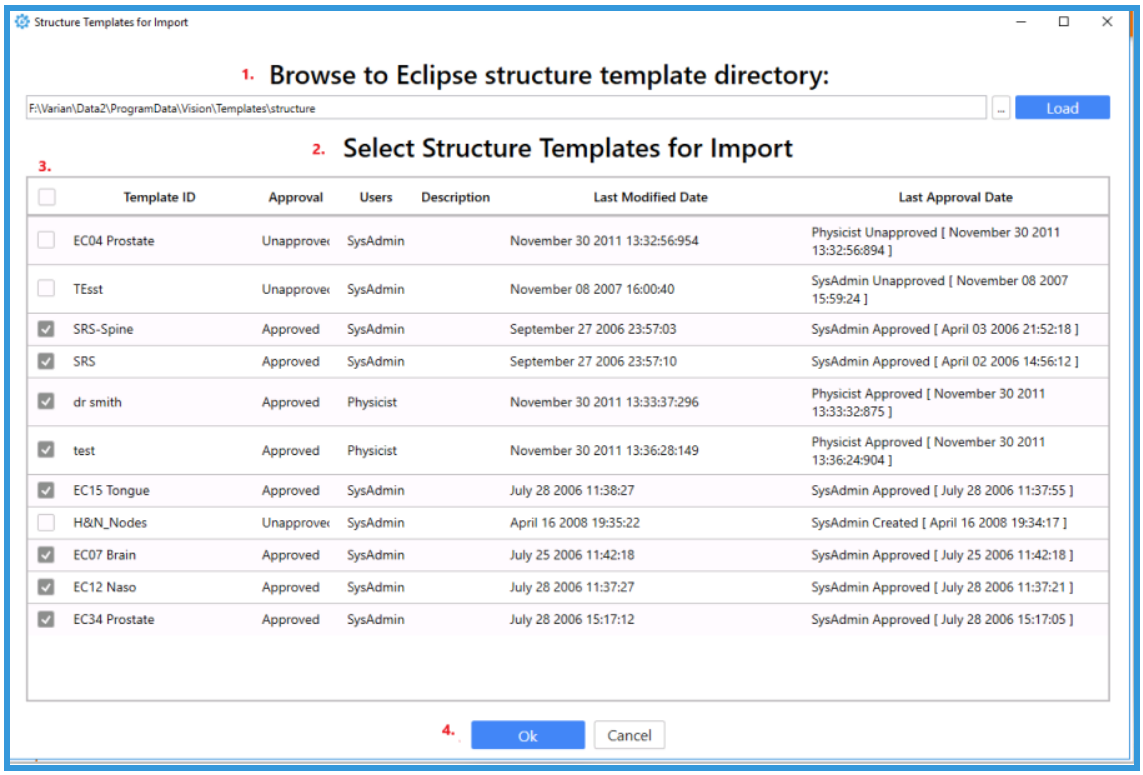



m. Import Structures from ClearCheck Constraint Templates

n. Import Structures from Eclipse Structure Set Template

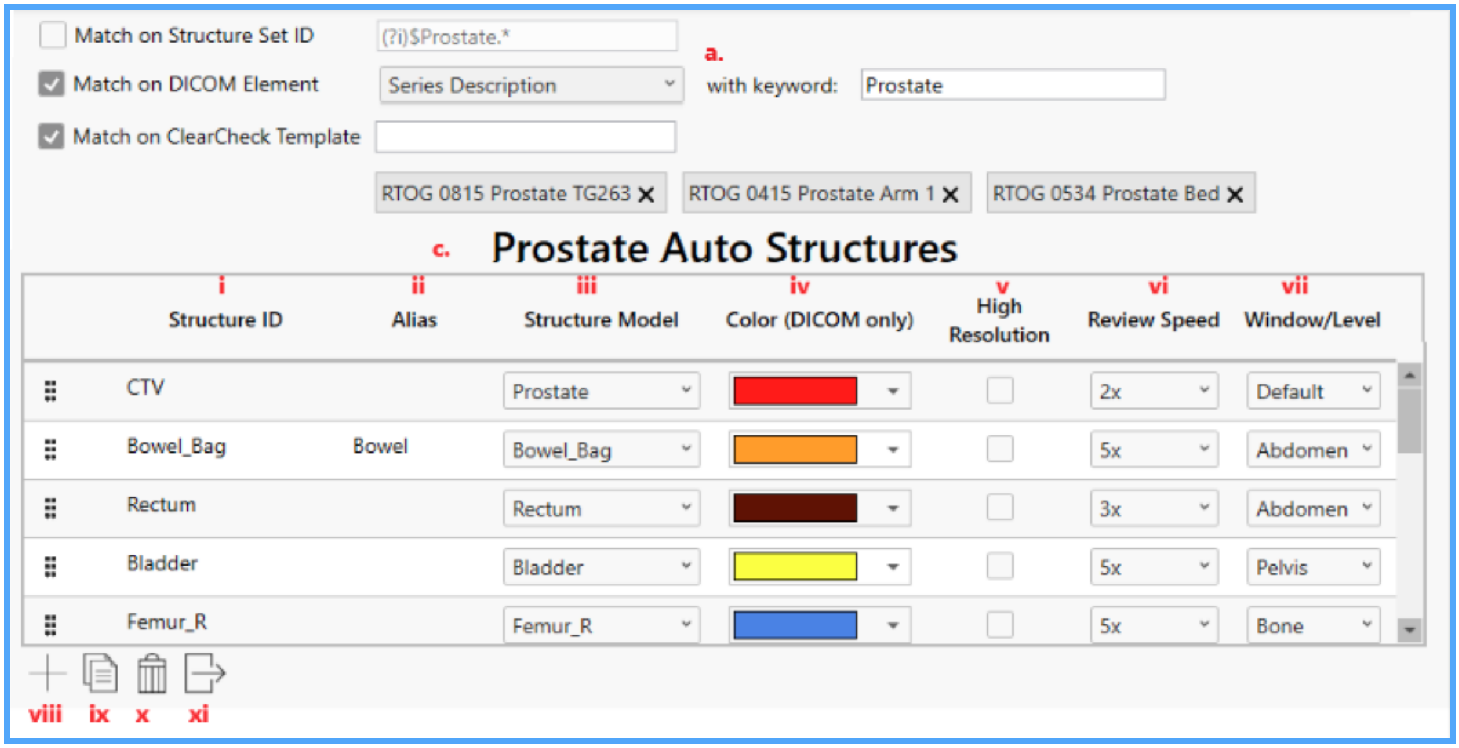
i. User may review and select Eclipse XML Structure Set to be imported as AutoStructure templates

ii. Eclipse Structure Template Import Window

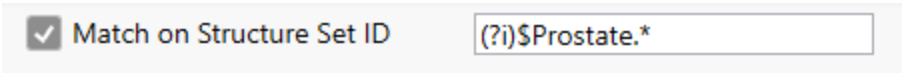



1. Browse to Eclipse Structure Directory
2. Eclipse Structure Set Template details Table
3. Template selection checkbox allowing the user to choose which templates will be imported.
4. OK button will import all selected templates as unique AutoContour templates.

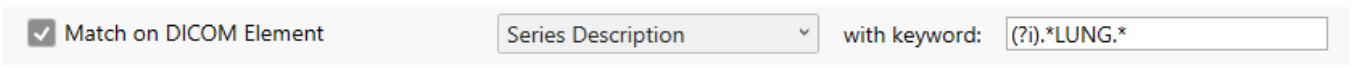
### 4. Global Structures Templates Tab - Main Window Auto Structures



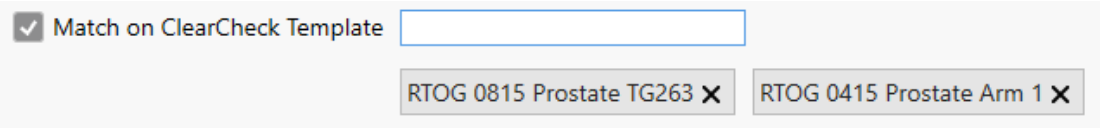

a. Automatic Template Matching
   i. Match On Structure Set ID (Regex)
      1. The AutoContour template will be automatically selected at AutoContour launch if the Structure Set ID attached to the current Image Series matches the regex string entered.




   ii. Match on DICOM Element
      1. The AutoContour template will be automatically selected at AutoContour launch if the DICOM Element specified in the ComboBox dropdown matches with keyword specified in the textbox.
      2. Available DICOM header tags that may be used for search are:
         a. Clinical Trial Protocol ID
         b. Clinical Trial Protocol Name
         c. Protocol Name
         d. Series Description
         e. Study Description
      3. Users may enter Regular Expression to match on one or more keywords.



iii. Match On ClearCheck Template
1. If launched from ClearCheck, the AutoStructure Template will be automatically matched based on the ClearCheck Constraint Global Template ID active in the ClearCheck Window



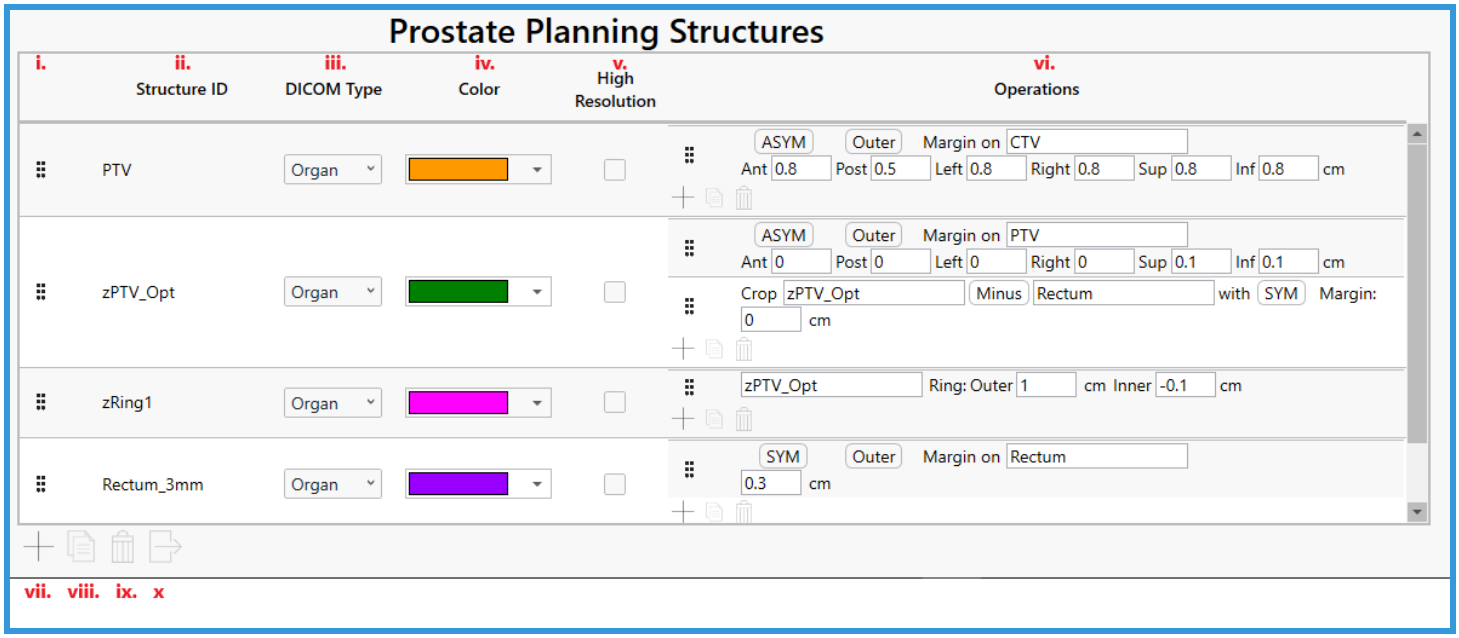

2. Multiple ClearCheck Structure Templates may be used as the matching key for the same AutoContour Template.

b. Manual Matching: The user may also choose to leave the "Match On" checkboxes blanks. This will force the user to manually select the appropriate Structure Template using the Patient Template Manger window during AutoContour Launch.

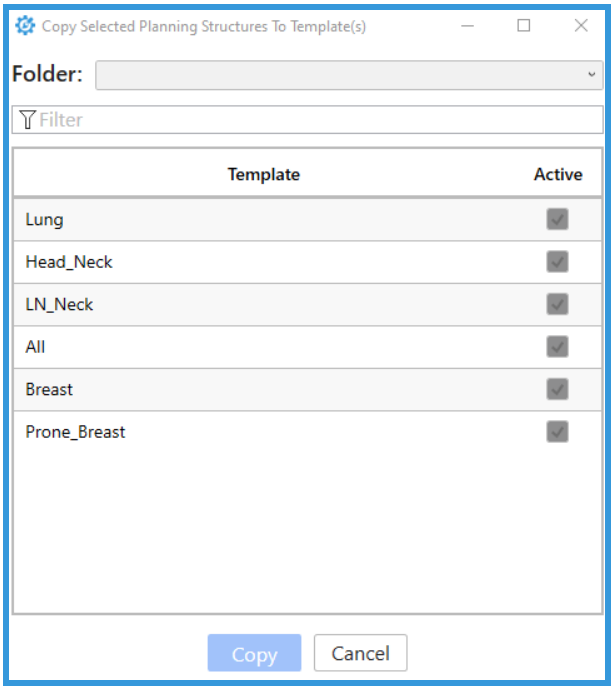
c. AutoStructure Table
i. Structure ID
ii. Structure Alias
iii. Structure Model Combo-Box
1. Combo-Box displaying all of the available AutoContour Structure Models to be generated for that structure.
iv. Color (DICOM, Eclipse V16+ only)
v. High Resolution checkbox
vi. Review Speed Combo-Box
1. 1X: 640msec/slice
2. 2X: 320 msec/slice
3. 3X: 160 msec/slice
4. 4X: 80msec/slice
5. 5X: 40 msec/slice
vii. Window/Level Defaults (HU)
1. Default (current display value in Eclipse/Dicom)
2. Abdomen (-125, 225)
3. Bone (-400, 800)
4. Brain (-20, 100)
5. Liver (-25,125)
6. Lung(-1000, 0)
7. Pelvis (-160, 240)
8. Breast (-250, 150)
viii. Add Structure
ix. Copy Structure
x. Delete Structure
xi. Move Structure to Planning Structures Table

**5. Global Structures Tab - Planning Structures**

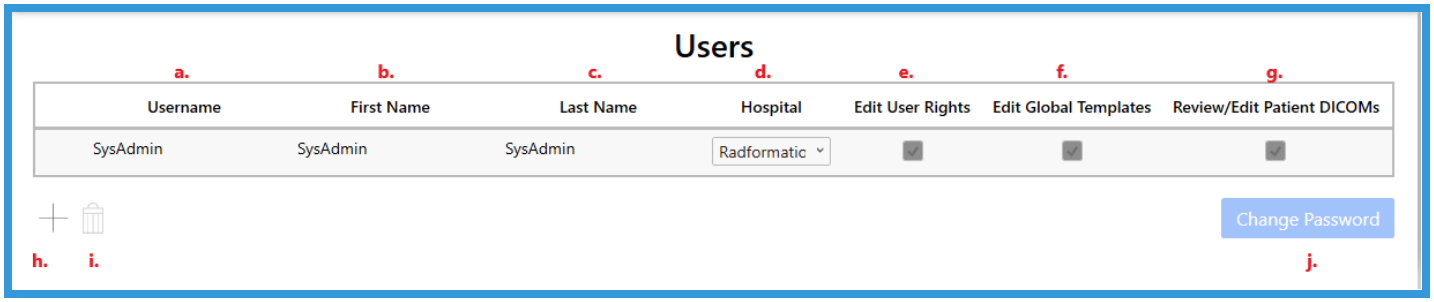
a. Planning Structures Table




i. Drag/Drop Sorting
ii. Structure ID
iii. DICOM Type
iv. Color (DICOM, Eclipse V16+ Only)
v. High Resolution
vi. Operations
    1. Margin
    2. Ring
    3. Overlap
    4. Combine
    5. Crop
vii. Add Planning Structure
viii. Copy Planning Structure
ix. Delete Planning Structure
x. Copy Planning Structures to Template(s)
    - Send selected Planning Structures along with any necessary source structures to other templates. When clicked a window will appear showing a list of templates that do not already contain the same planning structure.

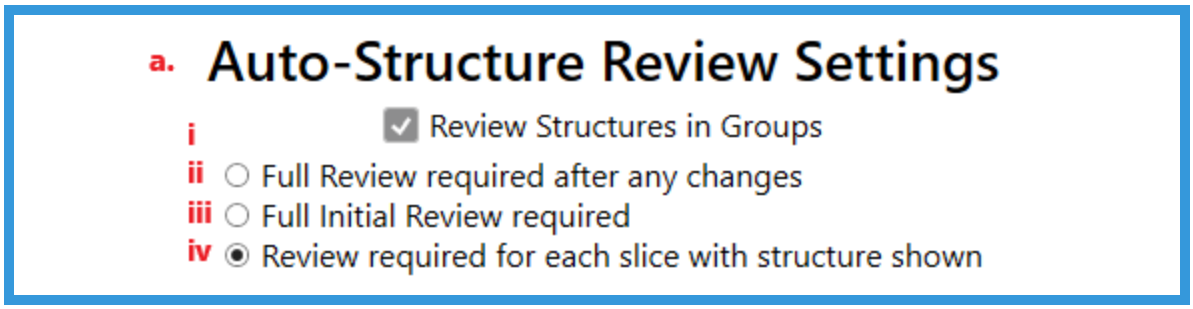



### 6. Users Tab




a. Username
    i. Note: For Login using Windows Authorization: the Domain must be included in the user name (eg: Domain\WindowUserName)
b. First Name
c. Last Name
d. Hospital ComboBox
    i. Specifies default Import/Directory at Login to Dicom Standalone Application
    ii. Configured in Setting Tab
e. Allow Edit User Rights
f. Allow Edit Global Templates
g. Allow Review/Edit Patient DICOMs
h. Add New User
i. Delete User
j. Change User Password

7. **Settings**
    a. AutoStructure Review Settings



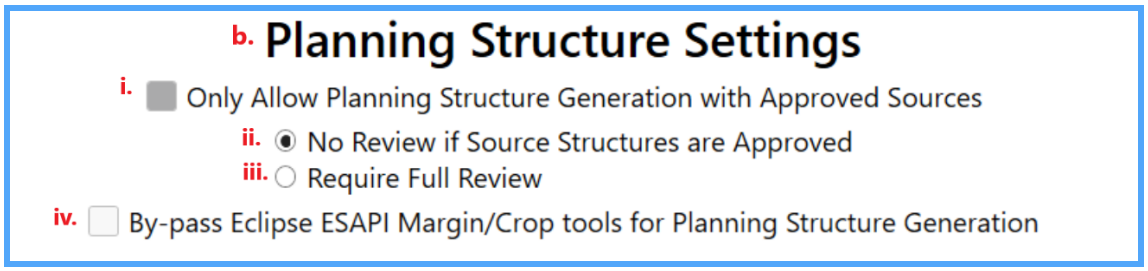

i. **Review Structure in Groups** - All structures will be visible during automatic scrolling and may be approved together. Current structure groups are as follows:
    1. Prostate+SeminalVes
    2. Bladder+PenileBulb+Rectum+Colon_Sigmoid
    3. V_Venacava_S+Heart+A_Aorta+A_LAD+A_Aorta_Asc+A_Aorta_Dsc
    4. SpinalCord+SpinalCanal+CaudaEquina
    5. Cavity_Oral+Lips+Musc_Constrict+ Buccal_Mucosa
    6. Glnd_Submand_R+Glnd_Submand_L+Parotid_R+Parotid_L
    7. Femur_R+Femur_L+Femur_RTOG_R+Femur_RTOG_L+Femur_Head_R+Femur_Head_L
    8. Larynx+Glnd_Thyroid+ Larynx_SG+ Larynx_Glottic
    9. Liver+Kidney_R+Kidney_L+Kidney_Outer_R+Kidney_Outer_L
    10. Brain+Brainstem+Pituitary
    11. Cochlea_L+Ear_Internal_L+Cochlea_R+Ear_Internal_R
    12. Lung_R+Lung_L+Bronchus+Carina+ Trachea
    13. Glnd_Lacrimal_R+Eye_R+Lens_R+Lens_L+Eye_L+Glnd_Lacrimal_L
    14. OpticNrv_R+OpticChiasm+OpticNrv_L
    15. Chestwall_OAR+Rib+Bone_Sternum+Rib_L+Rib_R
    16. Bone_Ilium_L+Bone_Ilium_R+Marrow_Ilium_L+Marrow_Ilium_R
    17. LN_IMN_L+LN_IMN_R
    18. Breast_L+Breast_R
    19. LN_Ax_L+LN_Ax_R+LN_Sclav_L+LN_Sclav_R
    20. LN_Neck_II_L+LN_Neck_II_R
    21. LN_Neck_III_L+LN_Neck_III_R
    22. LN_Neck_IV_L+LN_Neck_IV_R
    23. LN_Neck_VIIA_L+LN_Neck_VIIA_R+LN_Neck_VIIB_L+LN_Neck_VIIB_R+LN_Neck_IB-V_L+LN_Neck_IB-V_R
    24. LN_Neck_II-IV_L+LN_Neck_II-IV_R
    25. Humerus_L+Humerus_R
    26. Stomach+Spleen+ Pancreas
    27. Retina_L+Retina_R+Cornea_R+Cornea_L+Macula_L+Macula_R
    28. Body+ External
    29. LN_Pelvics_NRG+LN_Inguinofem_L+LN_Inguinofem_R

ii. **Full Review after any changes** - User must review every slice of AutoContour structures and after any manual edits made to that structure for Approval buttons to become active.

iii. **Full Initial Review Required** - User must review every slice of AutoContour structures initially. Only slices with changes will be required for Approval buttons to become active after initial review is completed.

iv. **Review required for each slice with structure shown** - Only require that every slice of a structure be viewed at least once for Approval buttons to become active

b. Planning Structure Settings




i. **Only Allow Planning Structures Generation with Approved Sources** - Do not allow Planning structures to be generated unless all structures upstream of that structure have been reviewed and approved.

ii. **No Review if Source Structures are Approved** - Planning Structures do not require review as long as all source structures upstream are Approved when generation occurs.

iii. **Require Full Review** - All Planning Structures slices must be reviewed after being generated

iv. **By-pass Eclipse ESAPI Margin/Crop tools for Planning Structure Generation** - Planning structures will be generated using AutoContour's internal structure operations when running the ESAPI workflow

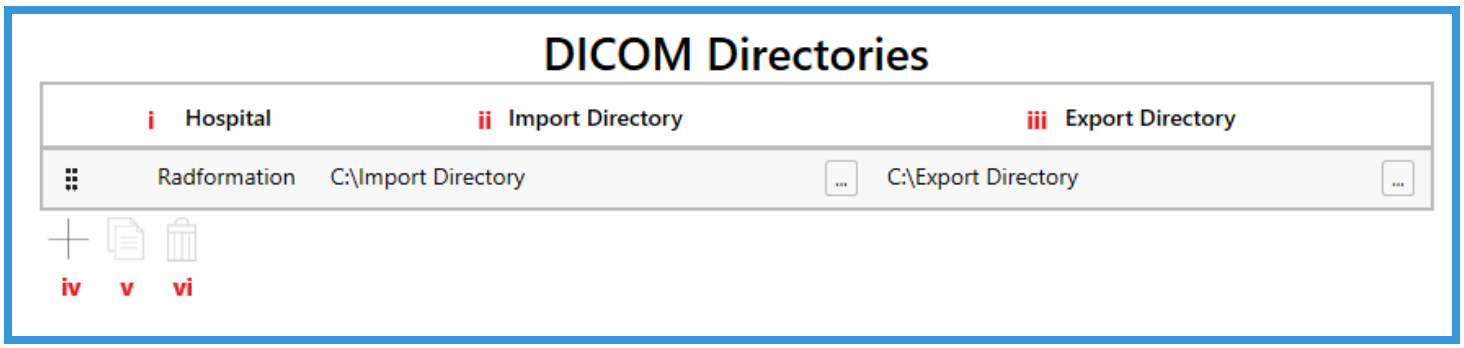
c. Approvals

i. **(DICOM Only) Export Structure Set as Approved** - Structure Set will be exported with an approved Status when exported out of AutoContour.

d. User Login

i. **Allow window authentication for user login**

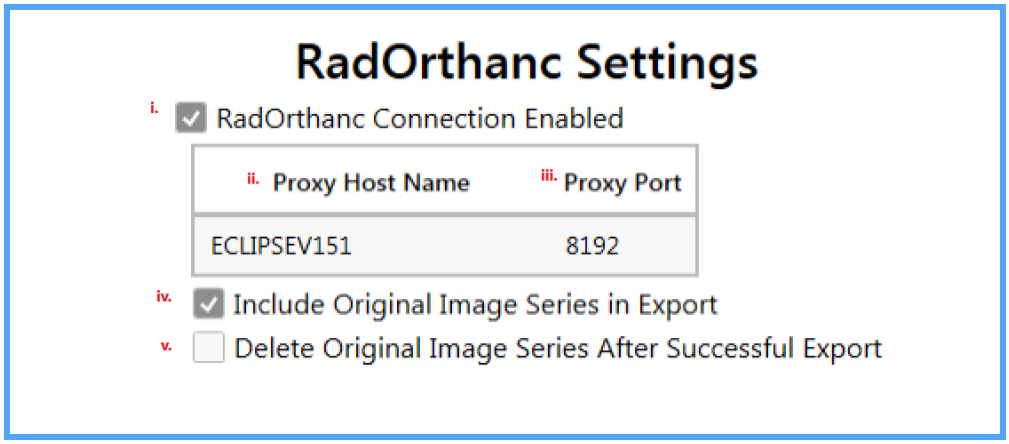
e. Dicom Directories




i. Hospital Name

ii. Import Directory
iii. Export Directory
iv. Add New Hospital
v. Copy Hospital
vi. Delete Hospital

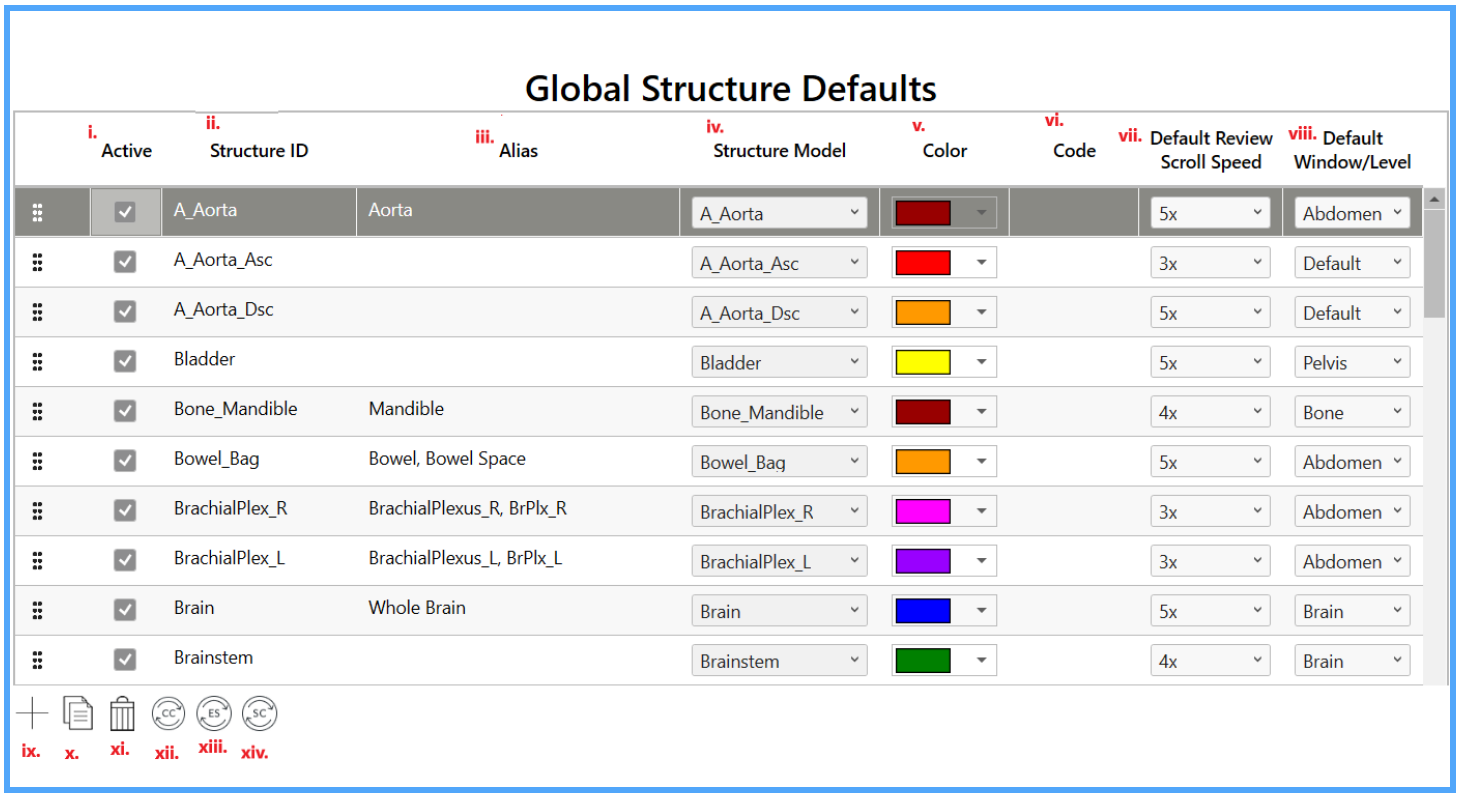
f. RadOrthanc Settings Section
   i. Enabled only after installation of the RadOrthanc Service and placement of the radorthanc.json file in the **radformationfiledata\autocontour** folder.RadOrthanc Settings (See Appendix B for more details) specify the DICOM endpoints to which approved structure sets and Image series may be exported.




   ii. RadOrthanc Connection Enabled
   iii. Proxy Host Name
   iv. Proxy Port
   v. Include Original Image Series in Export
   vi. Delete Original Image Series After Successful Export

g. Global Structure Defaults

Global Structure Defaults specify the standard AutoContour Models, Colors, Scroll Speed and Window/Level preferences to be added by default to any new Structure Templates.




i. Active
   1. Allows inactive structures to be removed from the Structure Model Drop-Down. All structure IDs with the structure model linked must be inactivated in order for the model to be removed from the Drop-Down.

ii. Structure ID

iii. Alias
   1. Allows multiple aliases with Comma Separated entries
   2. Allows Regular Expression matching

iv. Structure Model

v. Color (Dicom and Eclipse V16+ only)

vi. Code
   1. Structure codes will be assigned to structure IDs with a configured Code when exporting to DICOM structure set.
   2. Structures Codes follow the FMA 3.2 nomenclature. Structure Descriptions will automatically be linked based on the TG-263 Code Meaning and descriptions found here: https://www.aapm.org/pubs/reports/rpt_263_supplemental/TG263_Nomenclature_Worksheet_20170815.xls

vii. Default Review Scroll Speed

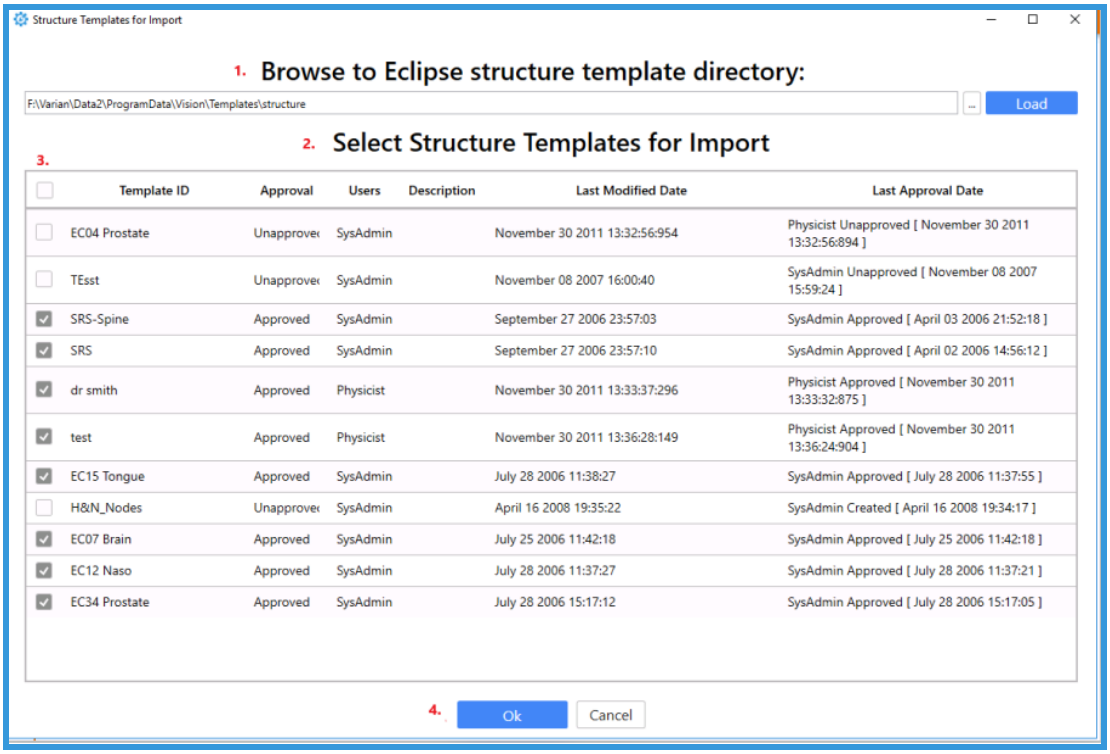
viii. Default Window/Level

ix. Add New Structure ID

x. Copy Structure

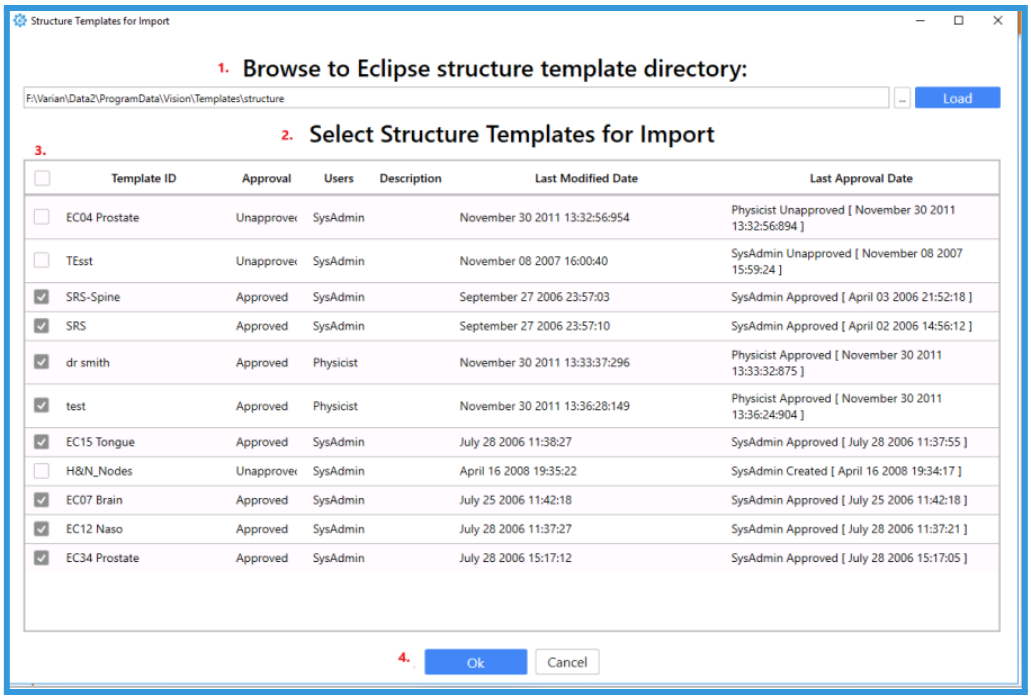
xi. Delete Structure

xii. Sync Eclipse Structure TemplatesImport Window




1. Browse to Eclipse Structure Directory
2. Eclipse Structure Set Template details Table
3. Template selection checkbox allowing the user to choose which templates will be imported.
4. OK button will import all selected templates as unique AutoContour templates.

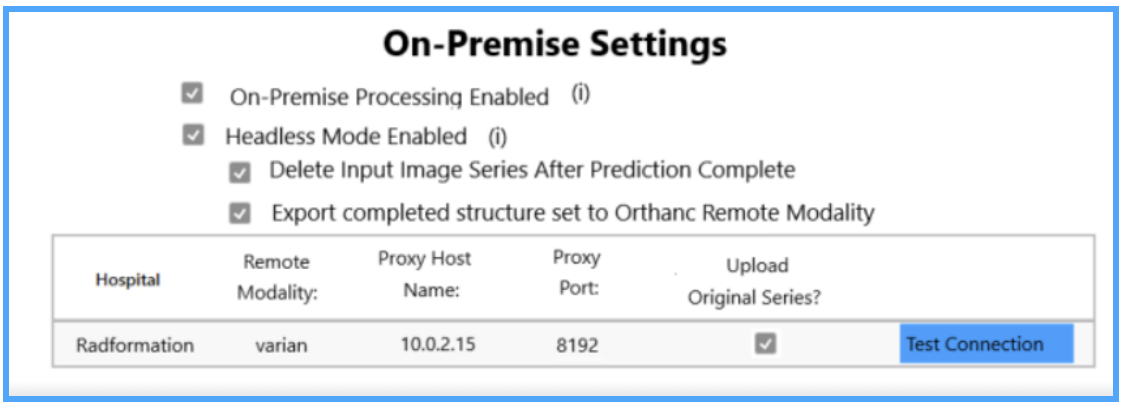
xiii. Sync ClearCheck Templates



1. Browse to Eclipse Structure Directory
2. Eclipse Structure Set Template details Table
3. Template selection checkbox allowing the user to choose which templates will be imported.
4. OK button will import all selected templates as unique AutoContour templates.
5. Any structures IDs or Aliases existing within the table that match a structure ID from the Eclipse template will be overwritten with the template ID and color.

xiv. Sync Structure Codes to AutoContour Templates

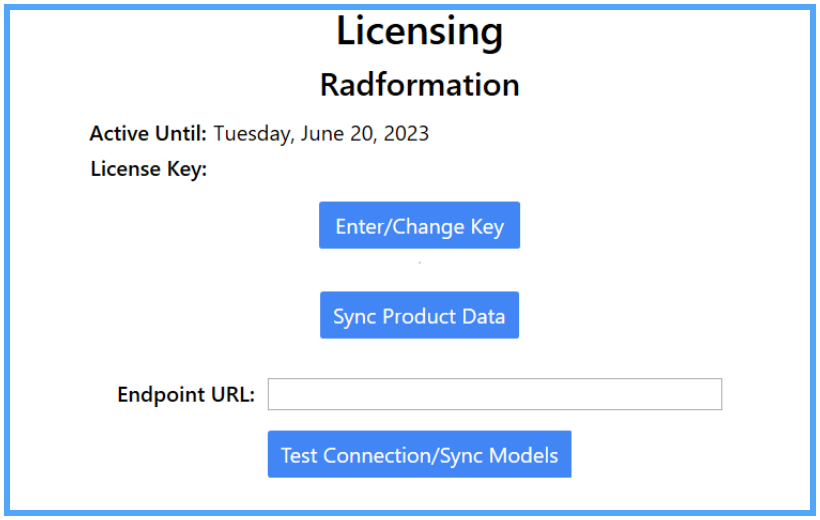
**8. On-Premise Settings**




a. On-Premise Processing Enabled
b. Zero-Click Mode Enabled
   i. Delete input image series after prediction completes.

c. Export completed structure set to Orthanc Remote Modality

**9. Licensing**



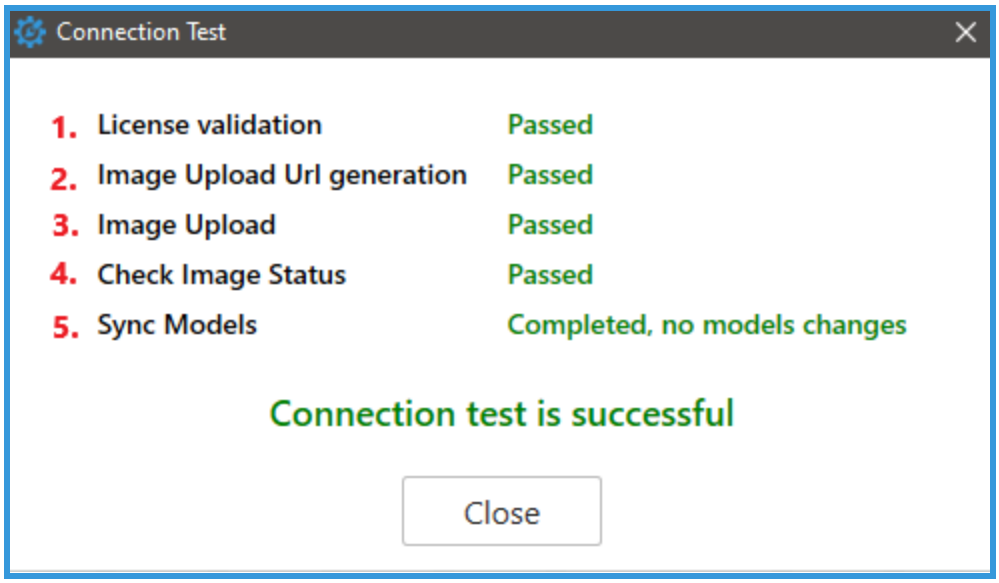

a. License Key
b. Enter/Change Key button

i. Institution Keys may be found by signing into your Account at https://www.radformation.com

c. Sync Product Data

d. Endpoint URL Textbox
   i. Default URL (GCP us-east4 region) is: https://autocontour.radformation.com

e. Test Connection/Sync Models
   i. Clicking on the Test Connection/Sync Models button will launch an end-to-end verification of all web -based endpoints required to successfully run image predictions with AutoContour.
   ii. The Test will also check for any structure model updates/additions so that new models may automatically be entered into the Administration Settings Globals templates without first running an image prediction.

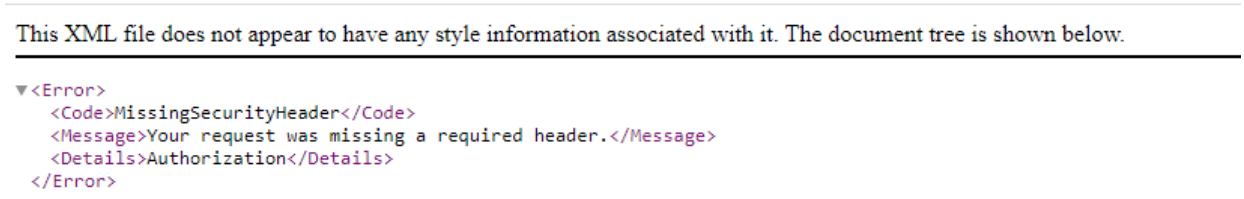



1. **License Validation** - Confirms that Product License Key is Valid
   a. https://autocontour.radformation.com (port 443)
2. **Image Upload Url Generation** - Get a signed URL location to upload binary image data.
3. **Image Upload** - Upload binary image data (empty for test) to Google cloud URL location.
   a. https://autocontour.radformation.com (port 443)
4. **Check Image Status** - Poll for updates until autocontouring is complete.
5. **Sync Models** - Check for any model updates deployed, and import into AutoContour if available.

# 8. Troubleshooting the Software

## Can't Access the AutoContour Server

1. A proxy server may be blocking access to https://www.radformation.com port 443. Check with your IT administrators and, if possible, allow access to that URL and port.
2. Confirm access to storage.googleapis.com on the computer/citrix server being used to run AutoContour. Website should return the following message:




   If the above message does not appear then storage.googleapis.com may need to be whitelisted by your IT administrators.

3. If still not resolved, contact us as shown in Support below.

# 9. Support

If you need support while using the software, please contact us:

Radformation, Inc
https://www.radformation.com/
support@radformation.com
Phone: 1-844-RADFOR5 extension 2
*(1-844-723-3675)*

# 10. Appendix A: Structure Models

## Supported CT Structure Models

### Chest & Abdomen

- ✓ Aorta (Full/Asc/Desc)
- ✓ Axillary I, II, III Nodes (L/R)
- ✓ Bowel Bag
- ✓ Brachial Plexus (L/R)
- ✓ Breast (L/R)
- ✓ Bronchus
- ✓ Carina
- ✓ Chestwall
- ✓ Esophagus
- ✓ Heart
- ✓ Humerus (L/R)
- ✓ IMN Nodes (L/R)
- ✓ Kidney (L/R)
- ✓ Kidney Minus Hilum (L/R)
- ✓ LAD Artery
- ✓ Liver
- ✓ Lung (L/R)
- ✓ Ribs
- ✓ Spinal Canal
- ✓ Spinal Cord
- ✓ Spleen
- ✓ Sternum
- ✓ Stomach
- ✓ Superior Vena Cava
- ✓ Supraclavicular Nodes (L/R)
- ✓ Trachea

### Head & Neck

- ✓ Brain
- ✓ Brainstem
- ✓ Cochlea (L/R)
- ✓ Constrictor Muscle
- ✓ Ear Internal (L/R)
- ✓ Eye (L/R)
- ✓ Lacrimal (L/R)
- ✓ Larynx
- ✓ Lens (L/R)
- ✓ Lips
- ✓ LN_Neck_IA
- ✓ LN_Neck_II (L/R)
- ✓ LN_Neck_III (L/R)
- ✓ LN_Neck_IV (L/R)
- ✓ LN_Neck_VIA
- ✓ LN_Neck_VIIA (L/R)
- ✓ LN_Neck_VIIB (L/R)
- ✓ LN_Neck_IB-V (L/R)
- ✓ LN_Neck_II-IV (L/R)
- ✓ Mandible
- ✓ Optic Chiasm
- ✓ Optic Nerve (L/R)
- ✓ Oral Cavity
- ✓ Parotid (L/R)
- ✓ Spinal Canal
- ✓ Spinal Cord
- ✓ Submandibular (L/R)
- ✓ Thyroid

### Pelvis

- ✓ Bladder
- ✓ Body
- ✓ Bowel Bag
- ✓ Cauda Equina
- ✓ Femur (L/R)
- ✓ Femur_RTOG (L/R)
- ✓ HDR Cylinder
- ✓ Iliac Crest (L/R)
- ✓ Iliac Marrow (L/R)
- ✓ Pelvic Lymph Nodes
- ✓ Penile Bulb
- ✓ Prostate
- ✓ Rectum
- ✓ Seminal Vesicles

## CT Structure Model Training

Mean Dice Similarity Coefficient (DSC) was used to validate the accuracy of structure model outputs within three size categories. As DSC can be sensitive to structure volume as structure would pass validation if the mean DSC exceeded 0.8 for large volume structures (eg. Liver, Lung) 0.65 for medium volume structures (eg. Parotid, Eye) and 0.5 for small structures (eg OpticChiasm, Lens).

The pool of images used for training and validation of CT models came from 2 institutions, both in the United States, 4230 image sets from one (Philips Big Bore CT) and 920 image sets from another (GE Optima CT).

For CT structure models there were an average of 700 training and 140 testing image sets. Datasets used for testing were removed from the training dataset pool before model training began, and used exclusively for testing. Among the patients used for CT testing 51.7% were male and 48.3% female. Patient ages range 11-30 : 0.3%, 31-50 : 6.2%, 51-70 : 43.3%, 71-100 : 50.3%. Race 84.0% White, 12.8% Black or African American, 3.2% Other. CT testing data spanned across treatment subgroups most typically found in a radiation therapy treatment clinic with the most common diagnosis being cancers of the Prostate (21%), Breast (21%), Lung (29%), Head and Neck (16%), Other (13%).

Philips Big Bore 32 slice CT simulator datasets used for testing were acquired with the majority of scans having an average slice thickness of 2mm, In-plane resolution between 1-1.2 mm, and acquisition parameters of 120kVp, 674+/-329 average mAs.

GE Optima CT simulator datasets used for testing were acquired with the majority of scans having an average slice thickness of 2.5mm, In-plane resolution between 0.6-1.3mm, and acquisition parameters of 120kVp, 671+/-352 average mAs.

Ground truthing of each test data set were generated manually using consensus (NRG/RTOG) guidelines as appropriate by three clinically experienced experts consisting of 2 radiation therapy physicists and 1 radiation dosimetrist.

For CT Structure models large, medium and small structures resulted in a mean DSC of 0.94+/-0.03, 0.82+/-0.09, and 0.61+/-0.14 respectively.

| Structure | # Training Data Sets | # Test Data Sets | DSC Mean | DSC STD |
|---|---|---|---|---|
| A_Aorta | 240 | 60 | 0.91 | 0.03 |
| A_Aorta_Asc | 240 | 60 | 0.90 | 0.03 |
| A_Aorta_Dsc | 240 | 60 | 0.93 | 0.02 |
| A_LAD | 461 | 116 | 0.57 | 0.13 |
| Bladder | 1000 | 372 | 0.92 | 0.09 |
| Bone_Ilium_L | 120 | 31 | 0.94 | 0.01 |
| Bone_Ilium_R | 120 | 31 | 0.94 | 0.01 |
| Bone_Mandible | 230 | 58 | 0.90 | 0.03 |
| Bowel_Bag | 131 | 33 | 0.93 | 0.04 |
| BrachialPlex_L | 78 | 20 | 0.73 | 0.08 |
| BrachialPlex_R | 78 | 20 | 0.73 | 0.08 |
| Brain | 1000 | 28 | 0.96 | 0.01 |
| Brainstem | 236 | 60 | 0.90 | 0.02 |
| Breast_L | 462 | 116 | 0.93 | 0.04 |
| Breast_R | 462 | 116 | 0.93 | 0.04 |
| Bronchus | 200 | 50 | 0.73 | 0.09 |
| Carina | 2312 | 578 | 0.82 | 0.08 |
| CaudaEquina | 87 | 22 | 0.90 | 0.02 |
| Cavity_Oral | 532 | 133 | 0.83 | 0.10 |
| Cochlea_L | 106 | 26 | 0.65 | 0.10 |
| Cochlea_R | 106 | 26 | 0.65 | 0.10 |
| Ear_Internal_L | 1289 | 324 | 0.64 | 0.21 |
| Ear_Internal_R | 1289 | 324 | 0.64 | 0.21 |
| Esophagus | 1116 | 279 | 0.76 | 0.13 |

| | | | | |
|---|---|---|---|---|
| External | 3173 | 826 | 0.99 | 0.04 |
| Eye_L | 336 | 85 | 0.92 | 0.02 |
| Eye_R | 336 | 85 | 0.92 | 0.02 |
| Femur_L | 1315 | 330 | 0.96 | 0.06 |
| Femur_R | 1315 | 330 | 0.96 | 0.06 |
| Femur_RTOG_L | 1315 | 330 | 0.96 | 0.06 |
| Femur_RTOG_R | 1315 | 330 | 0.96 | 0.06 |
| Glnd_Lacrimal_L | 353 | 86 | 0.54 | 0.18 |
| Glnd_Lacrimal_R | 353 | 86 | 0.54 | 0.18 |
| Glnd_Submand_L | 814 | 43 | 0.82 | 0.15 |
| Glnd_Submand_R | 814 | 43 | 0.82 | 0.15 |
| Glnd_Thyroid | 169 | 43 | 0.79 | 0.06 |
| HDR_Cylinder | 15 | 4 | 0.97 | 0.00 |
| Heart | 2060 | 515 | 0.93 | 0.05 |
| Humerus_L | 451 | 114 | 0.95 | 0.02 |
| Humerus_R | 451 | 114 | 0.95 | 0.02 |
| Kidney_L | 1083 | 271 | 0.94 | 0.03 |
| Kidney_R | 1083 | 271 | 0.94 | 0.03 |
| Kidney_Outer_L | 590 | 148 | 0.93 | 0.05 |
| Kidney_Outer_R | 590 | 148 | 0.93 | 0.05 |
| Larynx | 172 | 43 | 0.85 | 0.05 |
| Lens_L | 1114 | 278 | 0.66 | 0.14 |
| Lens_R | 1114 | 278 | 0.66 | 0.14 |
| Lips | 432 | 110 | 0.52 | 0.16 |

| | | | | |
|---|---|---|---|---|
| LN_Ax_L | 437 | 110 | 0.83 | 0.07 |
| LN_Ax_R | 437 | 110 | 0.83 | 0.07 |
| LN_IMN_L | 390 | 97 | 0.68 | 0.07 |
| LN_IMN_R | 390 | 97 | 0.68 | 0.07 |
| LN_Neck_IA | 272 | 68 | 0.78 | 0.06 |
| LN_Neck_IB-V_L | 316 | 79 | 0.86 | 0.05 |
| LN_Neck_IB-V_R | 316 | 79 | 0.86 | 0.05 |
| LN_Neck_II_L | 271 | 68 | 0.84 | 0.04 |
| LN_Neck_II_R | 271 | 68 | 0.84 | 0.04 |
| LN_Neck_II-IV_L | 325 | 82 | 0.86 | 0.03 |
| LN_Neck_II-IV_R | 325 | 82 | 0.86 | 0.03 |
| LN_Neck_III_L | 328 | 83 | 0.80 | 0.09 |
| LN_Neck_III_R | 328 | 83 | 0.80 | 0.09 |
| LN_Neck_IV_L | 328 | 82 | 0.77 | 0.07 |
| LN_Neck_IV_R | 328 | 82 | 0.77 | 0.07 |
| LN_Neck_VIA | 262 | 66 | 0.79 | 0.07 |
| LN_Neck_VIIA_L | 272 | 69 | 0.71 | 0.07 |
| LN_Neck_VIIA_R | 272 | 69 | 0.71 | 0.07 |
| LN_Neck_VIIB_L | 332 | 84 | 0.79 | 0.06 |
| LN_Neck_VIIB_R | 332 | 84 | 0.79 | 0.06 |
| LN_Pelvics | 502 | 126 | 0.87 | 0.05 |
| LN_Sclav_L | 460 | 115 | 0.88 | 0.05 |
| LN_Sclav_R | 460 | 115 | 0.88 | 0.05 |
| Liver | 480 | 120 | 0.96 | 0.02 |

| | | | | |
|---|---|---|---|---|
| Lung_L | 3491 | 748 | 0.97 | 0.02 |
| Lung_R | 3491 | 748 | 0.97 | 0.02 |
| Marrow_Ilium_L | 121 | 31 | 0.91 | 0.02 |
| Marrow_Ilium_R | 121 | 31 | 0.91 | 0.02 |
| Musc_Constrict | 272 | 69 | 0.75 | 0.06 |
| OpticChiasm | 158 | 40 | 0.63 | 0.07 |
| OpticNrv_L | 741 | 185 | 0.51 | 0.18 |
| OpticNrv_R | 741 | 185 | 0.51 | 0.18 |
| Parotid_L | 739 | 48 | 0.82 | 0.04 |
| Parotid_R | 739 | 48 | 0.82 | 0.04 |
| PenileBulb | 232 | 58 | 0.76 | 0.09 |
| Pituitary | 201 | 41 | 0.68 | 0.09 |
| Prostate | 708 | 177 | 0.86 | 0.04 |
| Rectum | 1436 | 359 | 0.88 | 0.05 |
| Rib | 64 | 17 | 0.87 | 0.02 |
| SeminalVes | 236 | 60 | 0.79 | 0.07 |
| SpinalCanal | 87 | 22 | 0.90 | 0.02 |
| SpinalCord | 1000 | 24 | 0.68 | 0.09 |
| Stomach | 431 | 83 | 0.88 | 0.07 |
| Trachea | 196 | 49 | 0.87 | 0.05 |
| V_Venacava_S | 162 | 41 | 0.81 | 0.06 |

## Supported MR Structure Models

- ✓ Brainstem
- ✓ Optic Chiasm
- ✓ Optic Nerve (L/R)
- ✓ Hippocampus (L/R)

## MR Structure Model Training Information

The MR Structure models had an average of 81 training image sets and 16 testing image sets taken from the Cancer Imaging Archive (TCIA) Glioma data set[3]. These training sets consisted primarily of glioblastoma and astrocytoma - cases. Datasets used for testing were removed from the training dataset pool before model training began, and used exclusively for testing. For MR structure model validation,. Ground truthing of each test data set were generated manually using consensus (NRG/RTOG) guidelines as appropriate by three clinically experienced experts consisting of 2 radiation therapy physicists and 1 radiation dosimetrist.For MR Structure models a mean DSC of 0.67+/-0.08 was found across all structure models.

| Structure | Size | Pass Criteria (DSC Mean) | DSC Mean | DSC STD | Lower Bound 95% Confidence Interval | Pass/Fail |
|---|---|---|---|---|---|---|
| Brainstem | Medium | **0.65** | **0.90** | 0.02 | 0.87 | Pass |
| OpticChiasm | Small | **0.50** | **0.53** | 0.11 | 0.35 | Pass |
| OpticNrv_L | Small | **0.50** | **0.64** | 0.08 | 0.51 | Pass |
| OpticNrv_R | Small | **0.50** | **0.64** | 0.08 | 0.51 | Pass |
| Hippocampus_R | Medium | **0.65** | **0.65** | 0.09 | 0.50 | Pass |
| Hippocampus_L | Medium | **0.65** | **0.65** | 0.09 | 0.50 | Pass |

[3] Shusharina, N., & Bortfeld, T. (2021). *Glioma Image Segmentation for Radiotherapy: RT targets, barriers to cancer spread, and organs at risk* [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/TCIA.T905-ZQ20

# 11. Appendix B: RadOrthanc Configuration

## Summary

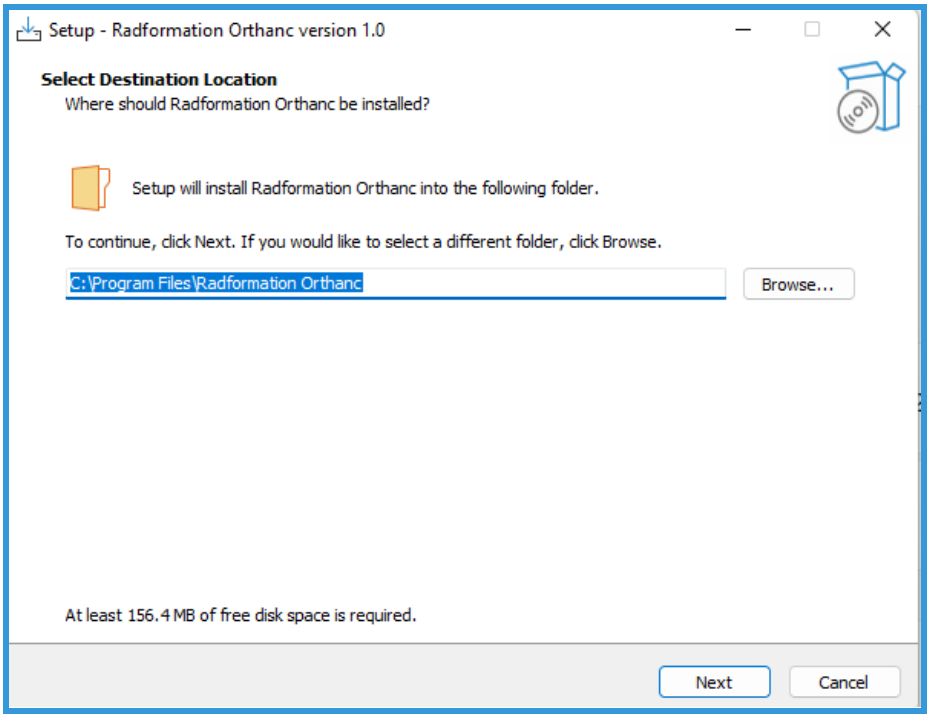
AutoContour V2.2 now allows the user to save/send completed DICOM Structure Sets and Image Data directly to pre-configured DICOM endpoints without having to manually export to local directories. In order to enable this feature, users must install the RadOrthanc DICOM service locally.

## Requirements

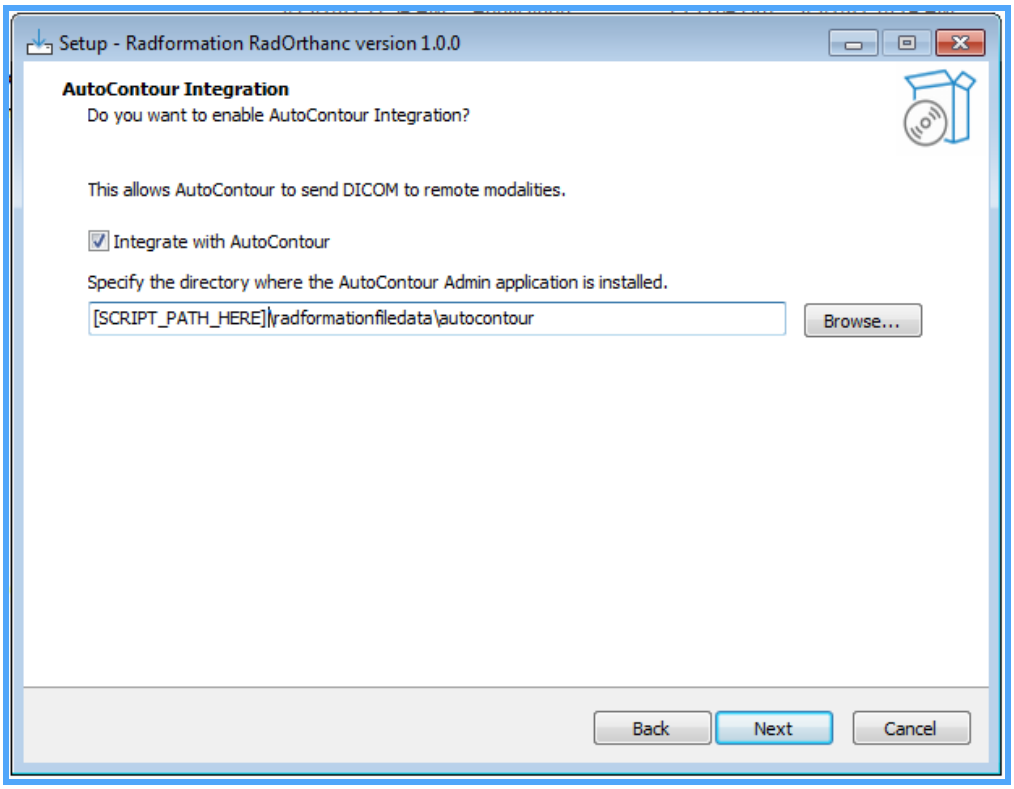
a. Operating Systems Supported: Windows 7 (32- or 64-bit), Windows 8 (32- or 64-bit), Windows 10 (32- or 64-bit), Windows Server 2008, 2008 RS, and 2012
b. CPU: 2.4+ GHz, Multi-core processor (2+ cores, 4+ threads)
c. Hard drive space: Software components fully installed require only ~300MB, but storage requirements for patient data are much larger and vary from clinic-to-clinic. A minimum of 100 GB hard drive is suggested for larger patient sets.
d. Memory (RAM): 2+ GB

## Installation Procedure

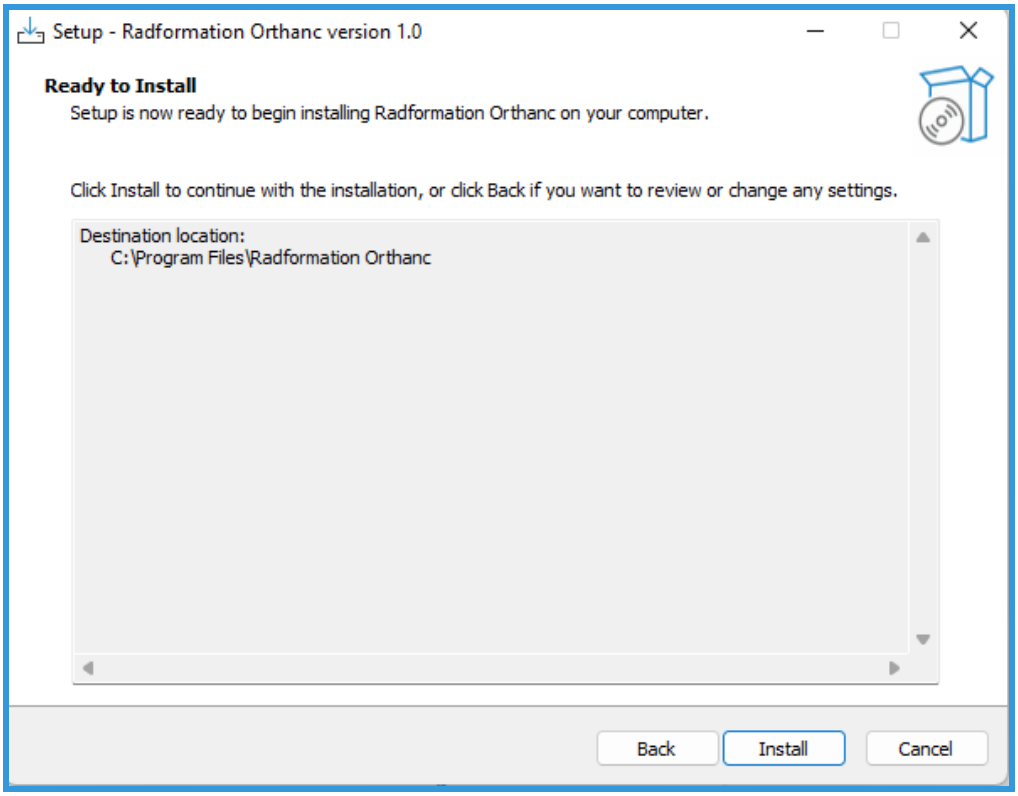
e. RadOrthanc DICOM Service must be installed when “Headless + Save to Remote Modality Workflow” is configured.
f. Download setup.exe provided by radformation.
g. Confirm User Account access
   **Note:** System Administrator account privileges are required to install RadOrthanc DICOM Service.
   1) Choose Orthanc Installation Location

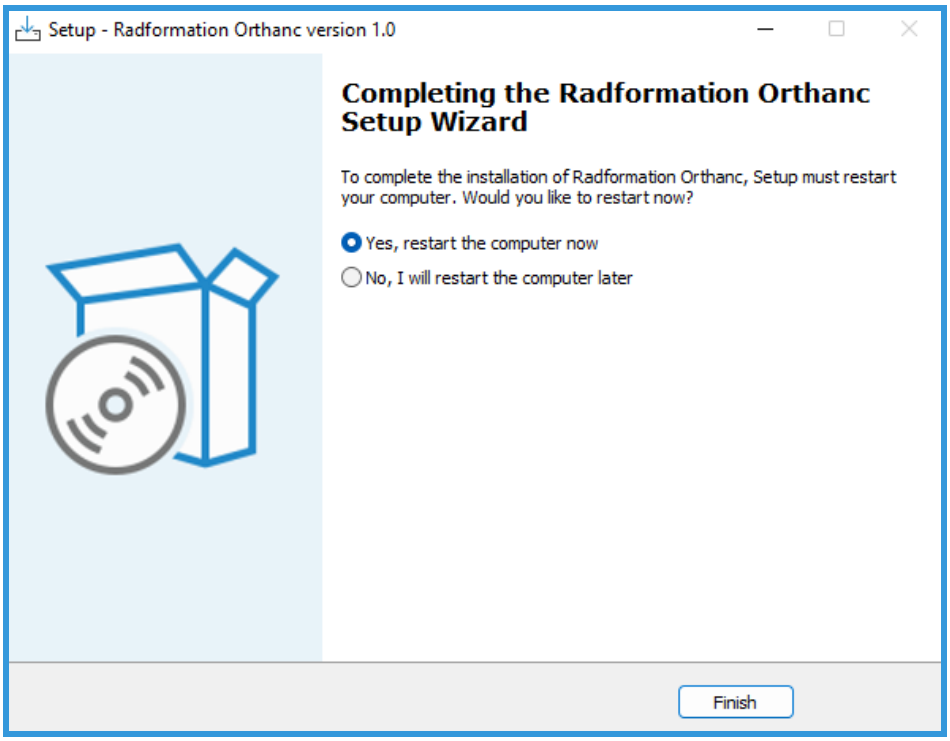



2) Check Integrate with AutoContour and Browse to **radformationfiledata\autocontour** directory.



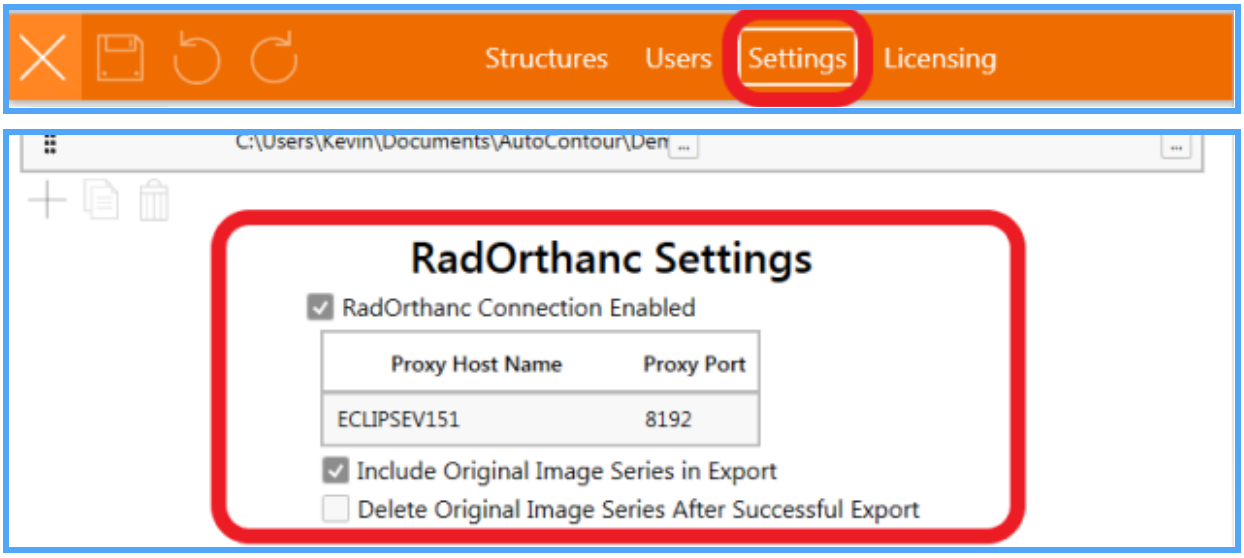

3) Click **Install**




## AutoContour Administration Application Settings Configuration

a) After successful installation, navigate to the installed directory and launch the AutoContour Administration Application, and navigate to the Settings Tab.



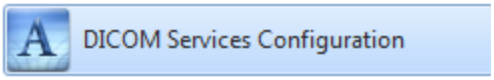

b) Verify that the RadOrthanc Connection is Enabled and that the correct Proxy Hostname and Port are configured.

c) Update the "Include Original Image Series in Export" checkbox to send the associated DICOM Image Series along with the exported DICOM structure set when exporting using RadOrthanc.

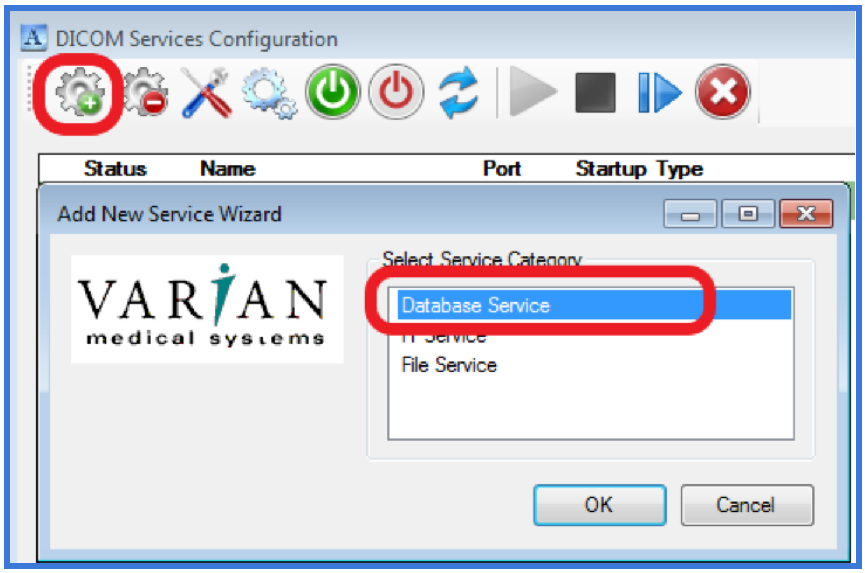
d) Update the "Delete Original Image Series After Successful Export" checkbox to delete the original DICOM Image Series after successful export to the DICOM endpoint.

## Eclipse DICOM Services Example installation

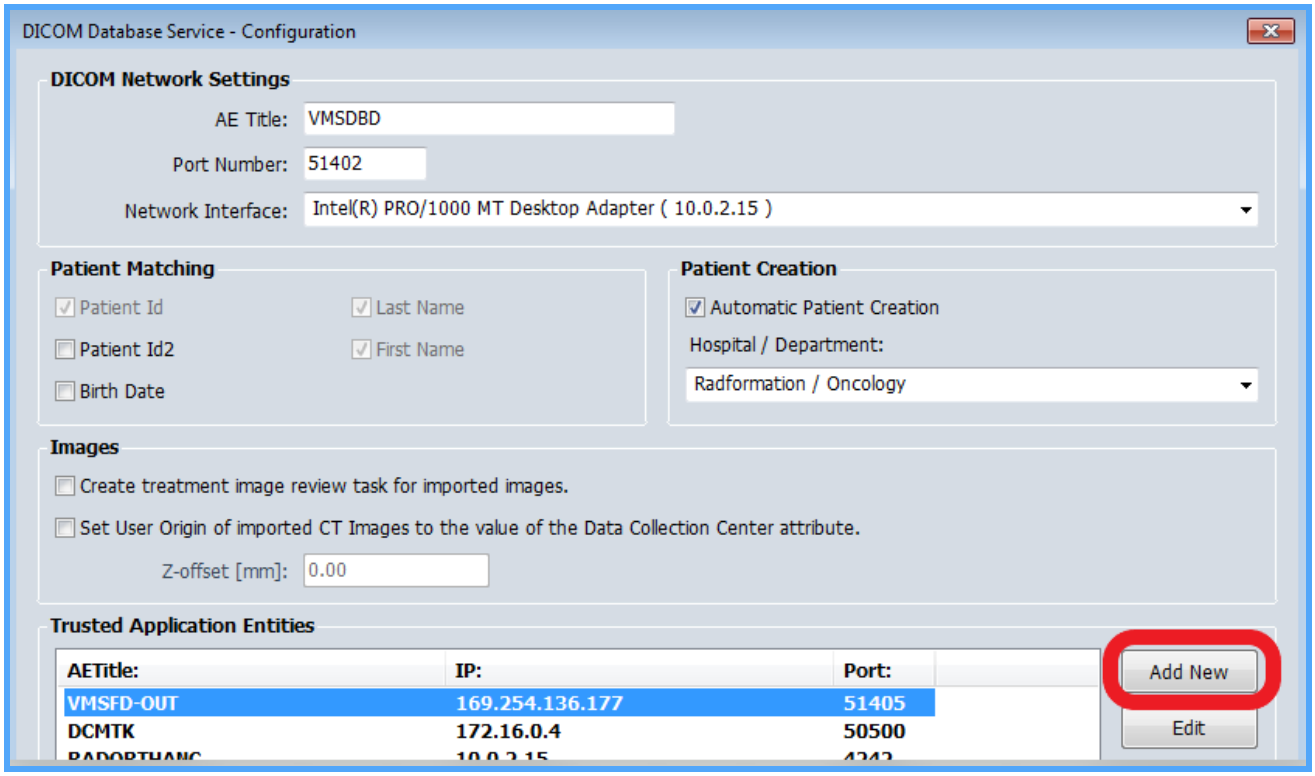
a) Launch Varian **DICOM Services Configuration** Tool



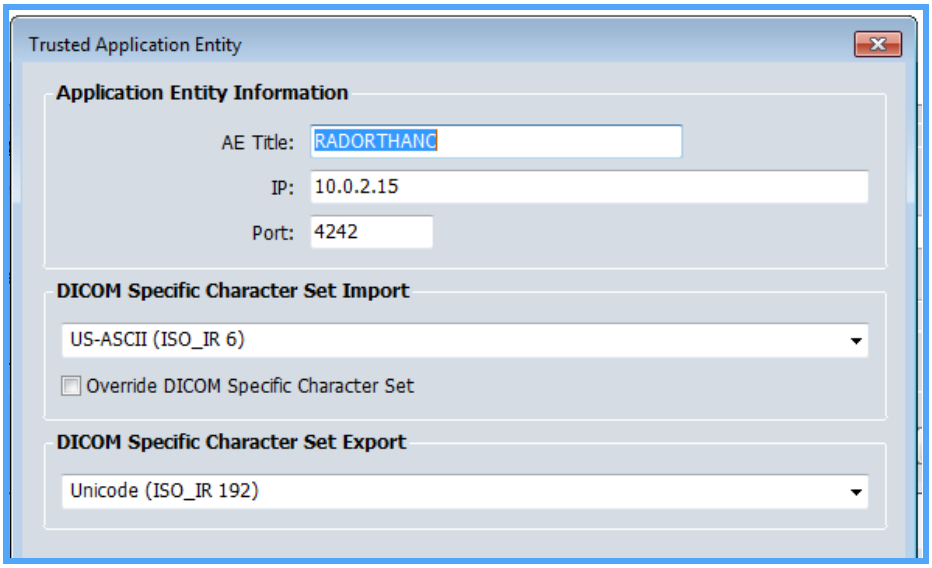

b) Add New Database Service (Only required if Import Service does not already exist)



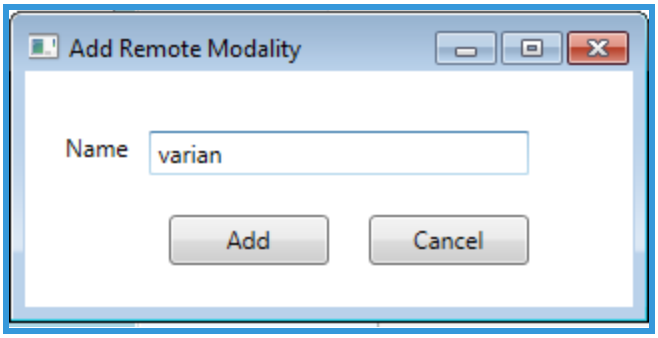

c) Add AETitle: **VMSDBD**, Port Number: **51402** and Network Interface Device as appropriate.
d) Under Trusted Application Entities, select **Add New**.



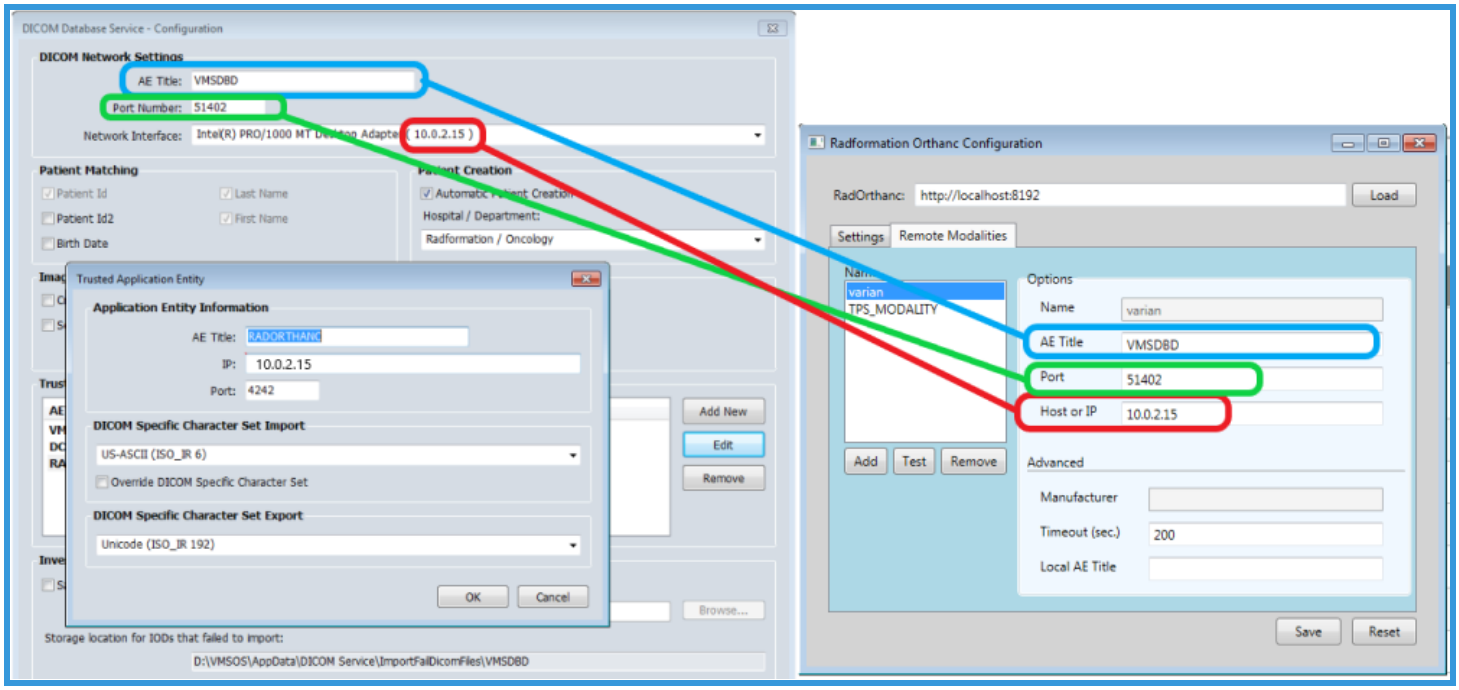

e) Configure DICOM Database Service to add RADORTHANC as trusted Entity.
    a) **AE Title**: RADORTHANC
    b) **IP:** IP Address of the PC where RadOrthanc is installed
    c) **Port:** 4242




f) Open Radformation Orthanc Administration Application (**Rad.Orthanc.Admin.exe**) included in the RadOrthanc Installation directory.
   a) Click on the **Remote Modalities** Tab.
   b) Click **Add**
      i) Add name (eg. varian)



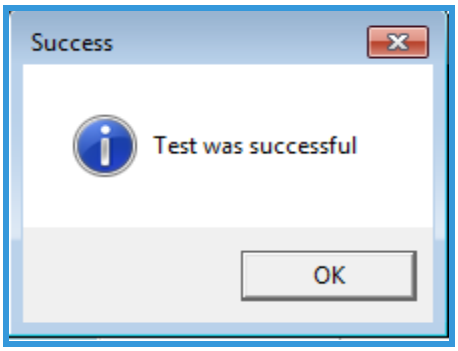

   c) Match the settings for AETitle, Port and Host/IP with those from the Varian Database Service Configuration.




g) Click **Save**

h) Click **Test** to verify that connection is established between RadOrthanc and Varian DICOM Services.

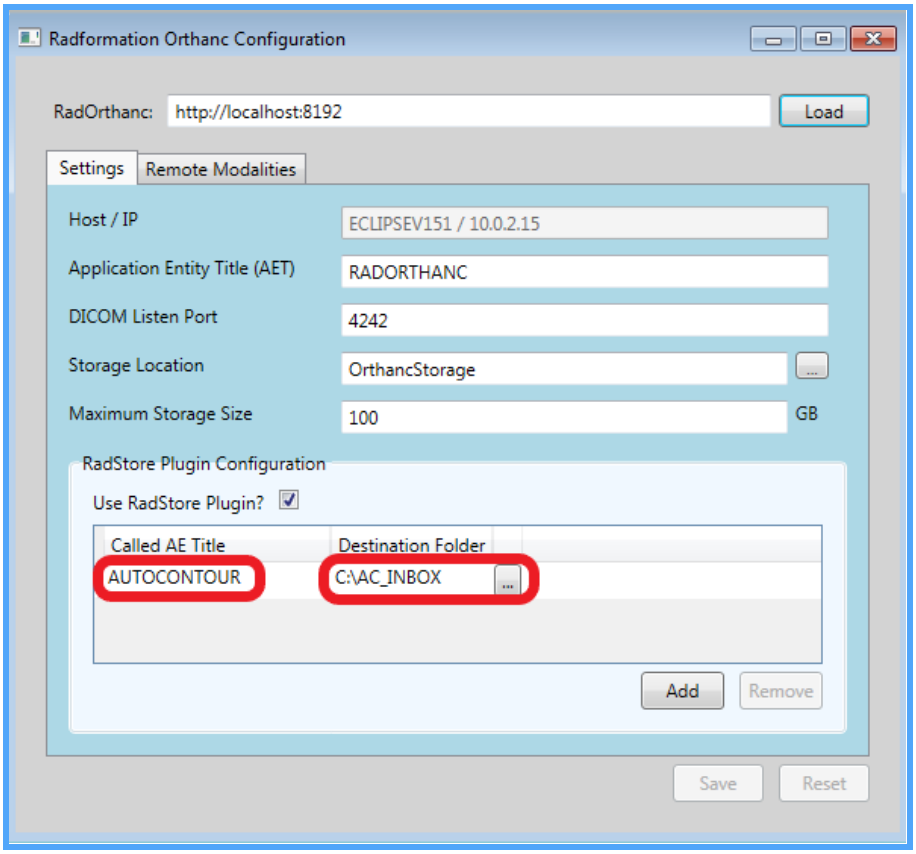
a) If a connection with the remote modality is successful, then the following window will appear.

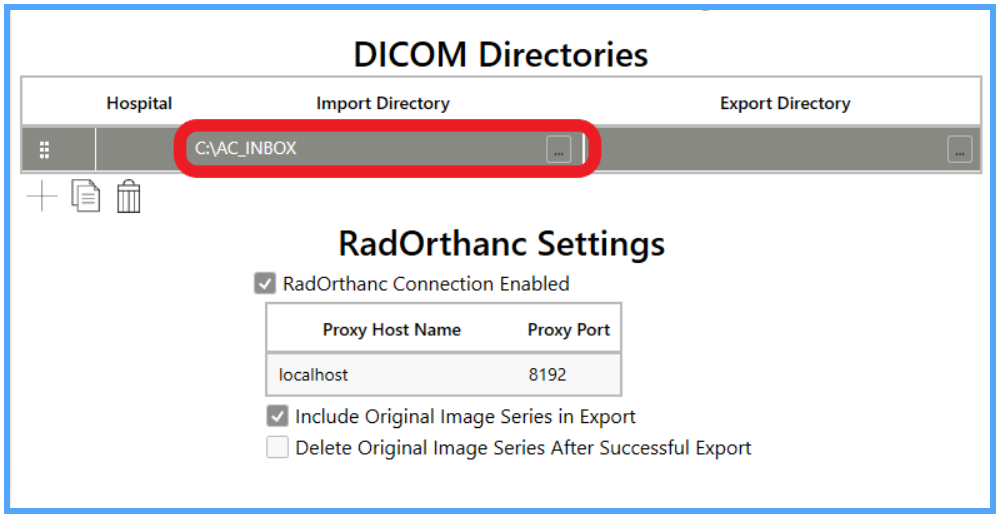


## Adding RadStore DICOM Inbox Location

In order to allow outside systems to send data automatically to the AutoContour Import Directory using RadOrthanc, the user must configure the RadStore Plugin Configuration section within the Radformation Orthanc Configuration Application.

h. Launch Rad.Orthanc.Admin in the RadOrthanc Install directory.
i. Click **Load**
j. Set AutoContour AE Title to **AUTOCONTOUR** and set AutoContour Inbox Location to match Import Directory from AutoContour Administration Application.



# 12. Regulatory and Safety Notices

## Injury Hazard

**a.** If the software is used in a manner not specified by Radformation, Inc. or is altered or modified in any way, the protection provided by the equipment may be void.

**b.** All repair or service should only be performed by qualified personnel. Please contact Radformation, Inc. at +1-844-723-3675 or support@radformation.com

## FDA 21 CFR 820

**a.** Radformation's products are designed and manufactured in accordance with this regulation.