StructSure™ Software

Version 1.0

User Manual
General Precautions

Warnings and Cautions alert users to dangerous conditions that can occur if instructions in the manual are not obeyed. Warnings are conditions that can cause injury to the operator, while Cautions can cause damage to the equipment.

**CAUTION:**
To minimize the potential for computer issues, do not run StructSure Software concurrently with other software programs.

**CAUTION:**
Install StructSure Software only on approved Operating Systems. The current version of StructSure is designed for use only on Windows 2000, Windows XP, Windows Vista, and Windows 7 Operating Systems.

**WARNING:**
Enter complete and correct data. Ensure that complete and correct data has been entered by viewing the data on the screen before proceeding.

**WARNING:**
Verify all printed data. Verify that printed data matches the screen display. All pages need to be accounted for and correctly collated. Correct paper size and printer conditions need to be verified for all print jobs.

**WARNING:**
Verify exported reports. After exporting a report for electronic storage, users are advised to verify the file before closing the plan.

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

**CAUTION:**
Proper use of this product depends on careful reading of all instructions and labels.

**WARNING:**
Issues identified through the use of this product must be investigated and appropriately resolved and/or noted.

Minimum System Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating System</td>
<td>Windows® XP SP1</td>
</tr>
<tr>
<td></td>
<td>Windows® 2000 SP4</td>
</tr>
<tr>
<td></td>
<td>Windows Vista®</td>
</tr>
<tr>
<td></td>
<td>Windows® 7</td>
</tr>
<tr>
<td>Processor</td>
<td>Intel® or AMD® 600 MHz or greater</td>
</tr>
<tr>
<td>Memory</td>
<td>1 GB or greater</td>
</tr>
<tr>
<td>Hard Drive</td>
<td>250 MB or greater</td>
</tr>
<tr>
<td>Screen Resolution</td>
<td>1024 x 768 or higher recommended</td>
</tr>
<tr>
<td>CD-ROM Drive</td>
<td>2X speed or greater</td>
</tr>
</tbody>
</table>

Windows® and Windows Vista® are registered trademarks of Microsoft Corporation.

Product Standards: Designed to meet IEC 60601-1-4
Each Standard Imaging software application is issued a software key. The key is a series of numbers attached to the CD-ROM packaging. Each key is capable of registering a set number of computers. In the case of a computer failure it will be necessary to contact Standard Imaging to release the license that was used on the computer before another computer can be licensed using the supplied key. **NOTE: in the case of a computer requiring repairs, any changes to the computer hardware could result in the failure of the license for that computer.**

Upon running the software for the first time you will be shown the StructSure Registration form.

If you have previously licensed a Standard Imaging product using the Nalpeiron licensing system enter the Username and Password previously created. If you do not remember your password click on the ‘Forgot Your Password’ link and you will be directed to the Nalpeiron website where you can retrieve it. If you continue to have problems please contact Standard Imaging support. **NOTE: Please do not create a second account.**

To create a new account click the ‘Create’ button and the following screen will be shown.

Create a Username and Password for the licensing system. Having an account set up will make it easier in the future if licensing issues need to be resolved. Fill in the requested information. **NOTE: First Name, Last Name, Email Address, and Company Name are also required to be filled in.**

Click the Register button to complete the registration process.
Authorization of a computer without internet access — If your computer is not connected to the internet or firewall issues prevent you from utilizing the web based registration click on the manual registration button. You will be shown the following screen:

Copy the Installation ID number shown on your screen and follow the directions to either:

1. Activate from another computer that is connected to the internet
2. Call Standard Imaging for an unlock code
3. E-mail your ID to Standard Imaging and a unlock code will be returned to you within 1 working day.

Run the software in DEMO mode — If you are evaluating the software before purchase click on the demo button and the following screen will be shown:

Clicking the ‘Start’ button will allow you to use the software application for a period of 30 days. Once this period has expired and you have not purchased a perpetual key, the registration software will disable the use of the software.

Transferring a license

All Standard Imaging software licenses are tied to the specific ID of the computer the software is installed and registered on. If your software is going to be removed from a computer, or if the computer that the software is installed on is no longer going to be utilized it is necessary to release the license that is in use for the installation.

Removing a license — Click on Help/License and the following screen will be shown:

To remove the license from the computer enter your License Code and click the ‘Release License Button’. The license can now be utilized on a different computer. If your computer is not connected to the internet, please contact Standard Imaging support for assistance.

Update License — Certain Standard Imaging software products are offered with optional modules that are activated based on a license code. If a product is purchased and in the future a new module is desired an update can be made to the license automatically. Standard Imaging support services will contact you and you will be asked to click on the ‘Update License’ button at the appropriate time.

StructSure QA Purpose

StructSure QA Software is designed to be used to assess the capabilities of both automated contouring systems and professionals involved in creating contours.

For the QA of auto-segmentation software StructSure can be utilized to test the ability of an auto-segmentation routine to delineate different types of structures allowing the user to have confidence in its ability and also to know where manual contouring needs to be performed. StructSure can also be used when a software upgrade is performed on the auto-segmentation tool as a way to identify how the software has changed and to verify it still is performing in the manner that they are used to.

StructSure QA is also a valuable tool as a teaching and testing tool for professionals involved in the contouring process such as but not limited to Radiation Oncologists, Dosimetrists and Medical Physicists.
How StructSure QA Software Works

StructSure QA Software imports pairs of DICOM-RT Structure files and volumetrically compares them qualitatively and quantitatively. The first step in the process is to create the primary dataset which the secondary dataset will be compared to. At this time there are no national or industry standards for contouring so it is left to each user of StructSure QA software to create the primary dataset. The primary dataset will be treated as the ‘ideal’ set of contours for the image dataset being used.

Once a primary dataset has been created, the same image dataset is then provided to the auto-contouring tool or the contouring professional being evaluated and a secondary DICOM-RT Structure file is created.

The primary and secondary structure datasets are then imported into the StructSure QA software. StructSure will then ‘voxelize’ each of the matching regions of interest (ROI) into a 3-dimensional structure made of 1mm x 1mm x 1mm voxels. The two voxelized ROI are then compared to determine how the two structures are alike and how they are different. See figure below.

Each missing or extra voxel is then penalized as a function of distance away from the primary based on customizable metrics and a score is produced as a quantitative comparison. A perfect score equals 100 and negative scores are possible depending on the metric that is used.

A difference region view illustrates the differences qualitatively and regions of regret are shown where extra (red) or missing (blue) voxels exist in the secondary set.

Initial Configuration

Metric Parameters

StructSure QA Software lets the user decide how penalties are assessed for each ROI pair with an intuitive metric parameter creation tool. There are several default parameters included with the software as examples but Standard Imaging does not make any recommendations for utilizing any parameter with any particular ROI pair. Each metric has independent penalty functions for missing and extra voxels giving the user an unlimited amount of versatility in creating metrics for each type of ROI pair.

Metric scores are determined by the formula:

$$100 \times \frac{\#\text{Primary Voxels} - \text{SUM(Voxel Penalties)}}{\#\text{Primary Voxels}}$$

Clicking on the ‘Define Metric Parameters’ button or choosing ‘Configuration/Metric Parameters’ from the menu bar will show the metric parameters module.

The formula used for computing the penalties is:

$$A + (B \times \text{Distance}) + (C \times \exp(D \times \text{Distance}))$$

- **mm Forgive** – This field allows the user to set a threshold that all voxels within the forgiveness region are not penalized.
- **A** – A constant penalty for all failing voxels
- **B** – Determines the arithmetic slope of the penalty function, e.g. a value of 0.25 results in an increase of .25 penalty points per 1 mm of distance.
- **C** – The minimum penalty for the exponential function
• D – The exponential rate of the penalty function. Larger values cause the exponential to increase faster so voxels further away from the primary are penalized at an ever increasing rate.

• Upper Cutoff – The value in the lower right hand corner of the metric parameter module is the upper cutoff limit for calculations and affects all parameter formulas in the same way. Whatever value is chosen (1-20 mm) the penalty created by the formula at that distance is applied to all voxels that are that distance or greater away from the primary. NOTE: Smaller upper cutoff yields faster metric calculation time

Creating a new metric parameter
To create a new metric parameter click on the ‘Add new metric method’ button. A new row will be added.

Double-click on the ‘New Metric’ name and enter a unique name for the new method. Using the ‘Tab’ key will move the cursor to each subsequent field. The first five (5) fields create the ‘missing’ voxels penalty parameters and the last five (5) create the ‘extra’ voxels penalty parameters.

Creating different metrics for missing and extra voxels
It is possible to create different penalty functions for missing and extra voxels. An example would be for an ROI that missing voxels are much more important than extra ones. A penalty function can then be created that penalizes missing voxels at a much higher rate than extra voxels as shown below.

Click the ‘Save Changes’ button to update and save the list. Clicking the Close button without saving will result in warning being shown:

Choose Yes to save your changes and No to close the module without saving.

Editing an existing metric
Any parameter of an existing metric can be edited at any time. The only exception to this is when data is loaded in which case the name of the metric parameter cannot be edited. If the metric parameter module is entered when datasets have been loaded a warning will be shown.

To edit a parameter click in the field that is to be edited. The field will be hi-lighted and typing a new value will overwrite the existing values.

Click the ‘Save Changes’ button to update and save the list. Clicking the Close button without saving will result in warning being shown:

Choose Yes to save your changes and No to close the module without saving.

Deleting an existing metric
To delete an existing metric, click on the name of the metric to be deleted to hi-light it and then click on the ‘Delete Metric Method’ button.

Click the ‘Save Changes’ button to update and save the list. Clicking the Close button without saving will result in warning being shown:

Choose Yes to save your changes and No to close the module without saving.
ROI Association Rules

StructSure QA Software imports sets of two DICOM-RT structure files which are generally created by two different individuals or an individual and an auto-contouring system. Just as no two sets of contours will be the same, often the regions of interest (ROI) in each file will not be named the same. To account for this, StructSure gives the user the ability to set up naming association conventions for typical ROI.

Click on the ROI Association Rules button or choose 'Configuration/ROI Association Rules' from the menu bar and the association module will be shown.

Adding a new set of ROI associations

To add a new set of ROI associations double-click in the first blank line shown in the list. A blinking cursor will be shown. To create associations type each ROI name that StructSure should consider equal separated by a semi-colon (;), e.g. R Lung; Right Lung; Rt Lung. The ROI associations are not case sensitive so it is not necessary to enter ‘RT Lung’; ‘rt lung’. Each ROI association can have a default metric parameter set (see Metric Parameters on page 3). Choose a metric parameter from the drop down list. NOTE: the metric method can be changed at the time of calculation.

Click the ‘Save Changes’ button to update and save the list. Clicking the Close button without saving will result in warning being shown:

Choose Yes to save your changes and No to close the module without saving.

Editing an ROI association

To edit an existing ROI association double-click in the row in which changes are to be made. Edit as necessary.

Click the ‘Save Changes’ button to update and save the list. Clicking the Close button without saving will result in warning being shown:

Choose Yes to save your changes and No to close the module without saving.

Deleting an ROI association

To delete an existing ROI association double-click in the row that is to be deleted. Hit-highlight the entire text in the row and press the ‘Delete’ key on the keyboard.

Click the ‘Save Changes’ button to update and save the list. Clicking the Close button without saving will result in warning being shown:

Choose Yes to save your changes and No to close the module without saving.
Using StructSure QA Software

StructSure QA Software imports pairs of DICOM-RT Structure files and DICOM3 image files. **NOTE: Loading DICOM3 image files is a memory intensive operation.** Your computer must have at minimum of 1 GB of memory (2 GB is recommended) if importing image datasets or extended importation times will be experienced. Most commercial treatment planning and stand-alone contouring systems include the ability to export in the DICOM-RT format and most imaging systems such as computed tomography (CT) and magnetic resonance imaging (MRI) can export image sets in the DICOM3 format. Using these systems export the appropriate files to a directory that is accessible to the StructSure software. It is advisable to save the primary dataset and subsequent secondary datasets in individual directories for ease of identification before import.

**Importing datasets**

The first step in using StructSure QA Software is importing the DICOM-RT Structure files and optionally the matching DICOM3 image set. **NOTE: Loading DICOM3 image files is a memory intensive operation.** Your computer must have at minimum of 1 GB of memory (2 GB is recommended) if importing image datasets or extended importation times will be experienced. Click on the ‘Load Data’ button or choose File/Load Data from the menu bar. The Load Data screen will be shown.

1. Click on the Load Primary button and a standard Windows file browser screen will be shown. Navigate to the primary structure set file and click ‘Open’. The structure file information along with information about all of the ROI in the file will be shown.

2. Repeat the same steps for the Secondary Structure File. After the secondary file is loaded the ROI that match between the two sets per the ROI association rules will be shown.

3. StructSure QA Software allows you to import the image set associated with the structure files for visualization verification. To import the associated image set, click on the ‘Load DICOM Images’ button. **NOTE: Loading DICOM3 image files is a memory intensive operation.** Your computer must have at minimum of 1 GB of memory (2 GB is recommended) if importing image datasets or extended importation times will be experienced.

A standard Windows file browser window will be shown. Navigate to the appropriate directory and choose the image files you would like to import. Standard Windows keyboard/mouse shortcuts are available; Shift-click for multi-select, Ctrl-click for individual multi-select, and Ctrl-A to select all files in the browser window. Click ‘Open’ to load the images.

StructSure will load each image and show a thumbnail for verification. Turning off the thumbnail image by un-clicking the ‘Show Image Thumbnails’ will speed up the image loading process. ‘Esc’ will abort image loading but keep what was loaded to that point. A message will be shown verifying that the image set has been loaded completely.

4. Click on the ‘Load Data’ button to complete the loading process.

5. Upon loading any ROI that have potentially large volumes will have the calculate status automatically turned to ‘off’ and a notification will alert the user as to which ROI have been affected.

The ROI can manually be set to calculate using the ROI Control module (see pg 7).
Using StructSure QA Software continued

### Loading additional datasets

At any point while using StructSure QA Software a new dataset can be loaded for the Primary Structure, the Secondary Structure or the images. This can be useful when comparing multiple secondary datasets to a single primary dataset such as when testing multiple auto-contouring systems or training/testing multiple professionals on the same dataset.

Click on the ‘Load Data’ button or choose File/Load Data from the menu bar. The Load Data screen will be shown.

Clicking the ‘Clear All’ button will clear all previously loaded datasets.

Clicking the ‘Clear’ button found on each ‘Load’ button will clear the data for that dataset only. After data is cleared, clicking the ‘Load’ button for the dataset will allow for the choice of a new dataset being loaded.

**NOTE:** You only need to reload the new data. Current data that is not cleared will be retained.

### StructSure QA User Interface

The StructSure QA User Interface is designed to facilitate easy navigation and quick evaluation of obtained results. After importation and calculation of datasets the following is a typical view of the user interface.

#### Slice Navigation

The Slice Navigation module displays the ROI as a 3 dimensional mesh. Arrows on either side of the module window indicate the individual axial slice shown in the Active Module window to the right and by default are set to the middle slice.

#### ROI Control

The ROI Control module allows the user to determine which ROI are shown in the Slice Navigation and Axial View windows. You can also choose which ROI pairs will be calculated and by which Metric Method they will be calculated. Default matching pairs that do not have large volumes will automatically be chosen for calculation and their rows will be shown in green.

**Controls**

- **Show Column** – determines which ROI are shown in all graphical views. Click individual ROI on or off. Clicking the box at the top of the column switches between 3 different states:
  - Show all – Check shown in box
  - Show only matched pairs – Check box is filled
  - Show none – Check box is empty

- **Calc Column** – determines which ROI matched pairs will be calculated. Click individual ROI on or off. Clicking the box at the top of the column switches between two different states:
  - Calculate all pairs – Check shown in box. **NOTE:** The body or external contour is by default turned off and will not be selected when Calculate All is chosen. If it is desired to calculate this ROI pair it will need to be manually chosen by clicking in the check box next to the ROI name. Calculation of large ROI can take extended amounts of time.
  - Calculate none – Check box is empty

- **Metric Method** – Set to the default metric set in the ROI Association rules for each ROI. Clicking on the drop down list allows the user to choose a different metric per ROI.
Using StructSure QA Software continued

Image Control

The Image Control module allows the user to adjust the window and level (contrast) of the DICOM3 image set shown in the Active Module window. This functionality is only available if images are loaded.

Controls

- Show Image Checkbox – uncheck to discontinue displaying loaded images
- Image control – Clicking on either edge of the blue box allows the user to adjust the window/level by moving the edges of the box in or out. The image changes are interactive allowing the user to adjust the window/level ‘on the fly’ to meet their needs.

Axial View Module

The first view that is shown in the Active View window after loading data is the Axial View Module. The Axial View Module displays all ROI that are set to ‘Show’ in the ROI Control Module as simple outlines. The ROI from the Primary structure set are shown with solid lines and the ROI from the Secondary set are shown with dotted lines. This view gives the user a quick qualitative overview of how the two sets of contours compare.

The user can return to this view at any time by clicking the Axial View button or choosing Modules/Axial View from the menu bar.

Controls

- Slice control – For a mouse with a scroll wheel use the wheel to scroll superiorly and inferiorly through the slices. The Page Up and Page Down buttons will move up or down a single slice each time the key is depressed. You can also use the Slice Navigation window to determine the slice position shown in the Axial View Module (see pg 7)
- Zoom control - Right-click and dragging left-to-right and/or down-to-up will zoom and un-zoom the view
- Pan control – Left-click and dragging will pan the view
- Overlay opacity – Clicking on the ‘Format ROI Foreground’ button allows the user to vary the opacity from 0 to 100% of the ROI overlays over the background images.

The Calculate Structure Metric Scores Button

After data has been loaded and the ROI controls have been used to determine which ROI are to be calculated and by which metric, the scoring and difference views can be calculated.

Click on the Calculate button to begin the calculation process. The first step in the process is to voxelize each ROI. After voxelization the metric scores are calculated. A progress bar at the bottom of the screen informs the user of the progress of each step.

Depressing the ‘Escape’ button on the keyboard or clicking the ‘Stop’ button in the progress will cancel the calculation process. The results for any ROI that have been calculated will then be shown.

Metric Scores

At the top of the module results are shown in rows which are sorted from best-to-worst metric score by default. Metric scores are color coded for a quick analysis of results with a score of 100 being pure green and a score of 0 or lower being pure red with a gradation of colors in between. The metric scores can be sorted by any of the column headings by clicking on the heading name.

Exporting Metric Scores

A comma delimited text file (.csv) of the metric scores can be created by choosing File/ Export Metric Results from the menu bar.

Distance-Volume Histogram

By clicking on any of the rows in the Metric Scores a Distance-Volume Histogram will be shown in the lower portion of the module. The histogram gives a qualitative view of the distribution of voxels that are common, extra and missing. To the right of the histogram a quantitative table of results is shown with volumetric information for each of the distance bins of the histogram. Clicking within the results table allows the user to hi-light and using Control-C copy the data. The data can then be pasted into a spreadsheet program for further analysis.

NOTE: ROI with large volumes and when a Primary and Secondary ROI are more disparate will take longer to calculate the metric.

NOTE: If the calculation process was stopped at any point, clicking the Calculate button will resume the calculation at the same point it was stopped.

Changing a metric after calculation

After metrics have been calculated it is possible to change the metric for a particular ROI. After the change has been made, clicking the Calculate button will re-calculate only the ROI pair with the metric that has been changed.

The Metric Results Module

The Metric Results Module is automatically shown after calculation of metrics is completed. It can also be shown by clicking on the ‘View Results’ button or by choosing Modules/Metric Results from the menu bar.

Metric Scores

At the top of the module results are shown in rows which are sorted from best-to-worst metric score by default. Metric scores are color coded for a quick analysis of results with a score of 100 being pure green and a score of 0 or lower being pure red with a gradation of colors in between. The metric scores can be sorted by any of the column headings by clicking on the heading name.

Exporting Metric Scores

A comma delimited text file (.csv) of the metric scores can be created by choosing File/ Export Metric Results from the menu bar.

Distance-Volume Histogram

By clicking on any of the rows in the Metric Scores a Distance-Volume Histogram will be shown in the lower portion of the module. The histogram gives a qualitative view of the distribution of voxels that are common, extra and missing. To the right of the histogram a quantitative table of results is shown with volumetric information for each of the distance bins of the histogram. Clicking within the results table allows the user to hi-light and using Control-C copy the data. The data can then be pasted into a spreadsheet program for further analysis.

NOTE: ROI with large volumes and when a Primary and Secondary ROI are more disparate will take longer to calculate the metric.

NOTE: If the calculation process was stopped at any point, clicking the Calculate button will resume the calculation at the same point it was stopped.

Changing a metric after calculation

After metrics have been calculated it is possible to change the metric for a particular ROI. After the change has been made, clicking the Calculate button will re-calculate only the ROI pair with the metric that has been changed.

The Metric Results Module

The Metric Results Module is automatically shown after calculation of metrics is completed. It can also be shown by clicking on the ‘View Results’ button or by choosing Modules/Metric Results from the menu bar.

Metric Scores

At the top of the module results are shown in rows which are sorted from best-to-worst metric score by default. Metric scores are color coded for a quick analysis of results with a score of 100 being pure green and a score of 0 or lower being pure red with a gradation of colors in between. The metric scores can be sorted by any of the column headings by clicking on the heading name.

Exporting Metric Scores

A comma delimited text file (.csv) of the metric scores can be created by choosing File/ Export Metric Results from the menu bar.

Distance-Volume Histogram

By clicking on any of the rows in the Metric Scores a Distance-Volume Histogram will be shown in the lower portion of the module. The histogram gives a qualitative view of the distribution of voxels that are common, extra and missing. To the right of the histogram a quantitative table of results is shown with volumetric information for each of the distance bins of the histogram. Clicking within the results table allows the user to hi-light and using Control-C copy the data. The data can then be pasted into a spreadsheet program for further analysis.

NOTE: ROI with large volumes and when a Primary and Secondary ROI are more disparate will take longer to calculate the metric.

NOTE: If the calculation process was stopped at any point, clicking the Calculate button will resume the calculation at the same point it was stopped.

Changing a metric after calculation

After metrics have been calculated it is possible to change the metric for a particular ROI. After the change has been made, clicking the Calculate button will re-calculate only the ROI pair with the metric that has been changed.

The Metric Results Module

The Metric Results Module is automatically shown after calculation of metrics is completed. It can also be shown by clicking on the ‘View Results’ button or by choosing Modules/Metric Results from the menu bar.

Metric Scores

At the top of the module results are shown in rows which are sorted from best-to-worst metric score by default. Metric scores are color coded for a quick analysis of results with a score of 100 being pure green and a score of 0 or lower being pure red with a gradation of colors in between. The metric scores can be sorted by any of the column headings by clicking on the heading name.

Exporting Metric Scores

A comma delimited text file (.csv) of the metric scores can be created by choosing File/ Export Metric Results from the menu bar.

Distance-Volume Histogram

By clicking on any of the rows in the Metric Scores a Distance-Volume Histogram will be shown in the lower portion of the module. The histogram gives a qualitative view of the distribution of voxels that are common, extra and missing. To the right of the histogram a quantitative table of results is shown with volumetric information for each of the distance bins of the histogram. Clicking within the results table allows the user to hi-light and using Control-C copy the data. The data can then be pasted into a spreadsheet program for further analysis.
Dice Coefficient

StructSure QA software also computes a Dice Coefficient for each ROI pair included in the analysis for use as a comparison to the computed metric scores. The Dice Coefficient is calculated as:

\[ S = \frac{2|X \cap Y|}{|X| + |Y|} \]

Clicking on the ‘Dice Coefficients’ button will display the results for each ROI pair.

ROI Difference View Module

The ROI Difference View is enabled after the calculation of metric parameters and provides the user with a graphical representation of the differences between the two imported datasets. It can be shown by clicking the ‘View ROI Difference Regions’ button or by choosing Modules/Difference View from the menu bar. A ‘region of regret’ method is utilized where matching voxels are shown in green, voxels that are in the secondary set but not in the primary set are shown in red, and voxels that are missing in the secondary set are shown in blue.

Controls

- Slice control – For a mouse with a scroll wheel use the wheel to scroll superiorly and inferiorly through the slices. The Page Up and Page Down buttons will move up or down a single slice each time the key is depressed. You can also use the Slice Navigation window to determine the slice position shown in the Axial View Module (see pg 8)
- Zoom control - Right-click and dragging left-to-right and/or down-to-up will zoom and un-zoom the view
- Pan control – Left-click and dragging will pan the view
- Overlay opacity – Clicking on the ‘Format Difference View Foreground’ button allows the user to very the opacity from 0 to 100% of the difference region overlays over the background images. If the opacity is turned down to 0, the original ROI Overlays will be shown.
- ROI selection – Clicking on the ‘Select ROIs to Display’ button allows the user to select which region of interest are shown in the display. Clicking the ‘None’ button will turn all ROI off, clicking the ‘All’ button will turn all ROI on. Clicking each of the ROI names in the list will toggle the ROI on or off in the view.

Printing Reports

Several different reports are available and can be accessed by clicking the ‘Print Active Module’ button or by choosing File/Print Active Module from the menu bar.

For each of the active modules a different report will be generated. Once the report is generated the user has the choice of either saving the report as a PDF file or sending the report to the printer of their choice.

ROI Association Module

A report will be generated with a screen capture of the ROI Association rules shown in the module window along with the date and time the report was generated.

Metric Parameters Module

A report will be generated showing the parameters list and a graph of the hi-lighted parameter along with the date and time the report was generated.

Axial View Module

A report will be generated with a screen capture of the Axial View shown in the module along with the date and time the report was generated and demographic information of the two datasets shown.

Difference View Module

A report will be generated with a screen capture of the Difference View shown in the module along with the date and time the report was generated and demographic information of the two datasets shown.

Metric Results Module

A report will be generated showing the results for each of the calculated ROI pairs along with the settings for each of the Metric Parameters used in the calculation. Demographic information about the two datasets is included at the top of the report and an area for a reviewer’s signature and comments is included at the bottom. This report can also be printed from any of the other modules by choosing File/Print StructSure Results Report from the menu bar.
Appendix A – StructSure Advanced Method Descriptions

Building 3D ROI Voxel Grids

The 3D voxel grid in StructSure is an object that converts a series of ROI contours loops on axial slices into a 3D object in space, where each voxel is True (meaning that voxel is contained in the ROI volume) or False (meaning that voxel is not contained in that ROI volume).

An understanding of the XYZ coordinate system is crucial, and that coordinate system is detailed in Appendix B. It is important to note that the StructSure coordinate system becomes independent of the patient position once the data are read into objects, i.e. it becomes analogous to a “couch coordinate system” after all the data values are read in to create objects.

The ROI voxel grid can have a specified resolution (i.e. voxel size), but in StructSure version 1.0, the resolution is set as 1 mm X 1 mm X 1 mm. This is sufficiently small to be accurate, and any smaller would result in slower performance without adding much value to the accuracy of the calculations.

Metric Results

Metric Results can be calculated for any ROI pair (one ROI from the Primary dataset, one ROI from the Secondary dataset).

ROI Metric Results is an object that includes (among other fields):
• Volume of Primary ROI
• Volume of Secondary ROI
• Common Volume (contained in both primary and secondary ROIs)
• Missing Volume (in primary ROI but not in secondary)
• Extra Volume (in secondary ROI but not in primary)
• Distance-Volume-Histogram (Missing and Extra Volumes as a function of “distance away” from nearest match
• Metric Parameters used for Metric Score
• Metric Score (defined by StructSure metric parameters employed)
• Dice Coefficient (a historical coefficient of similarity between two objects)

The volume calculations are self-explanatory – they are calculated by summing all the voxels and multiplying times an individual voxel volume.

In order to compute the Distance-Voxel-Histogram and the StructSure metric score, each error voxel (i.e. Missing or Extra) must have it’s “Distance Away” calculated. This is done by searching in 3D surface “shells” around the error voxel until the closest voxel (of the other dataset) is found. The 3D ROI Voxel Grids are used to do these distance calculations, and distances are binned in 1 mm increments, so any “Distance Away” value is rounded to the nearest integer distance (mm). If a voxel is a common voxel (in both the primary and secondary ROI volumes) then its “Distance Away” is binned as 0 mm, i.e. a matching voxel.

During the Distance-Volume-Histogram computation, the components of the eventual Metric Score are also accrued, because the Metric Score is a function of each error voxel’s “distance away” value. The penalty for each error voxel is a function of the distance according to the general equation, where Dist = Distance Away:

\[ A + B \cdot Dist + Ce^{D \cdot Dist} \]

Further comments:
• If the Distance Away is less than a “Forgiveness Distance”, the penalty is zero.
• If the Distance Away is greater than an upper threshold, the penalty is equal to that for the upper threshold distance.
• The ABCD parameters can be different for Extra voxels vs. Missing voxels.

The cumulative Metric Score is given by:

\[ MetricScore = 100 \times \left[ \frac{\#Voxels_{Primary} - \sum VoxelPenalties}{\#Voxels_{Primary}} \right] \]
Appendix A

Figure 3 gives a simple example of Missing, Extra, and Common Voxels.

![Figure 3. Simple schematic of Missing (blue), Extra (red), and Common (green) voxels.](image)

Each Missing or Extra Voxel is penalized as a function of “Distance Away” from Primary Volume.
Appendix B – StructSure Coordinate System

StructSure uses a unified coordinate system that equates to a “Couch Coordinate System”. Unlike DICOM3, whose coordinate system can vary with patient position, the Couch Coordinate System is consistent over all possible patient positions (roll angle, head-in/foot-in, etc.).

The virtual patient, defined by contours from a DICOM RT Structure Set and in some cases also by DICOM3 images, becomes a rigid body grid of voxels (image density voxels, ROI contours, and dose voxels) “fixed” to the treatment table/couch.

Transformations from DICOM3 (which is fixed to anatomy directions, i.e. +X left, +Y posterior, +Z superior) to the Couch system must be taken into account with respect to “Patient Position” of which there are eight primary options: HFS, HFP, FFS, FFP, HFDR, HFDL, FFDR, FFDL. The transformation logic can be found in the well-commented source code of StructSure.

The StructSure Coordinate System XYZ is illustrated below.

IMPORTANT NOTE: The (0,0,0) XYZ origin is not necessarily where the figure shows; the figure shows the directions of the orthogonal axes and does not imply the origin.
The Digital Imaging and Communications in Medicine (DICOM) standard is specified by parts 1 through 13 NEMA PS 3.1-13. StructSure Software does not export any DICOM files, and only supports the limited functionality of the DICOM specification that is required to import DICOM files from specific treatment planning systems. StructSure Software does not support any of the communications functions of the DICOM specification; all DICOM files to be imported must already reside on a disk drive that is accessible by StructSure Software. The license manager limits the use of the DICOM import module to file types that have been specifically validated for use with StructSure Software. For validation of other DICOM files please contact support@standardimaging.com.
Software License Agreement

Contains licensed program materials of Standard Imaging, Inc.
Copyright © Standard Imaging, Inc., Middleton, Wisconsin, USA

This software is protected by U.S. copyright laws, international treaties, FDA regulations, and other intellectual property laws and treaties.

This is a software license agreement to use the software product or products ("the product") enclosed in this package and described in the applicable purchase order or other ordering document. Standard Imaging, Inc., a Wisconsin corporation (Standard Imaging) hereby grants to the purchaser of the product ("Licensee") the right to use the product, together with its documentation and other related materials, only in connection the computers or computer network system located at the site of use ("the site") previously designated as such by Licensee and only if in strict compliance with the terms and conditions set forth below. Any purchase and installation or use of the product shall constitute acceptance of and agreement by Licensee to be bound by the terms and conditions hereof. Licensee also agrees that the agreement terms and conditions will prevail in the event of any conflict between the agreement applicable purchase order or other ordering document.

All rights not specifically granted to licensee under this software license agreement are reserved by Standard Imaging. The Standard Imaging documented Warranty and Customer Responsibility statements shall be considered to be part of this agreement. The term of this agreement and the licenses granted hereunder will continue in perpetuity, unless sooner terminated by Standard Imaging.

Licensee may:
- a. Use the product only on a single computer or single network system at the site of use; and
- b. Make backup copies of the product only for back-up, recovery and archival purposes.

Licensee may not and shall not:
- a. Make copies of the product, except as otherwise permitted herein;
- b. Rent, lease, sub-lease or otherwise permit any third party to use the product;
- c. Redistribute any portion of the product, its software programs, documentation, or other related materials;
- d. Other than as set forth in section 1.b. above, copy the product, any of its software programs, documentation or other related materials, without the express written permission of Standard Imaging;
- e. Remove or obscure copyright and/or trademark notices appearing on the product;
- f. Reverse engineer the product in order to derive or appropriate for any reason or purpose the source code or any other trade secret or other proprietary information; or
- g. Transfer the software program of the product to another site or to a third party purchaser without the express written permission of Standard Imaging and agreement to all the terms and conditions of the then current software license agreement utilized by Standard Imaging by the authorized representative of the new site or such third party.

The Licensee shall be solely responsible for the installation of the product and any updates provided by Standard Imaging. Standard Imaging shall provide telephone technical support for the product for a period of (1) one year from the date of shipment. Any updates, upgrades and new releases to the product within the period of (1) year from date of shipment will be provided at no additional costs. After the expiration of the period of (1) year from the date of shipment, Standard Imaging will provide technical support, and updates, upgrades and new releases for an additional fee.

Standard Imaging shall not be liable for any amount in excess of the product costs actually paid by the Licensee giving rise to any claims hereunder. In no event shall Standard Imaging be liable, whether in contract, tort or otherwise for any indirect, incidental or consequential damages arising out of the subject matter of this agreement.

In the event of breach by Licensee of any of the terms and conditions of this software license agreement, Standard Imaging shall be entitled to enforce all legal rights and remedies conferred upon it by State of Wisconsin, federal, and/or international law. Standard Imaging and Licensee acknowledge that because breach by Licensee of any of the terms or conditions of this agreement will likely cause irreparable harm to Standard Imaging, injunctive relief would be an appropriate remedy for Standard Imaging resulting from any such breach by Licensee. In the event that action, suit, or legal proceedings are initiated or brought to enforce any or all of the provisions of this agreement, the prevailing party shall be entitled to such attorney's fees, costs, and disbursements as are deemed reasonable and proper by a court of law or an arbitrator. In the event of an appeal of an initial decision of a court or of an arbitrator, the prevailing party shall be entitled to such attorney's fees, costs, and disbursements as are deemed reasonable and proper by such appellate court.

Notwithstanding the foregoing, in the event of any breach by Licensee of the terms and conditions of this agreement, Standard Imaging may, upon reasonable advance written notice to Licensee (which in no event shall be less than thirty days), terminate this license. Upon such termination by Standard Imaging, Licensee shall furnish Standard Imaging with a sworn affidavit stating that all of the product, including, without limitation, its software program(s), documentation and other related material and any copies thereof, have been returned by certified mail, return receipt requested to Standard Imaging or destroyed by Licensee.

This agreement shall be deemed executed in the State of Wisconsin and shall be interpreted and construed in accordance with the laws of the State of Wisconsin. If any provision of this agreement is judicially declared to be invalid, unenforceable, or void by a court of competent jurisdiction, such decision shall not have the effect of invalidating or voiding the remainder of this agreement and the part or parts of this agreement so held to be invalid, unenforceable, or void shall be deemed to be deleted from this agreement and the remainder of this agreement shall have the same force and effect as if such part or parts had never been included.
**Customer Responsibility**

This product and its components will perform properly and reliably only when operated and maintained in accordance with the instructions contained in this manual and accompanying labels. A defective device should not be used. Parts which may be broken or missing or are clearly worn, distorted or contaminated should be replaced immediately with genuine replacement parts manufactured by or made available from Standard Imaging, Inc.

⚠️ **CAUTION:** Federal law in the U.S.A. and Canadian law restrict the sale, distribution, or use of this product to, by, or on the order of a licensed medical practitioner. The use of this product should be restricted to the supervision of a qualified medical physicist. Measurement of high activity radioactive sources is potentially hazardous and should be performed by qualified personnel.

Should repair or replacement of this product become necessary after the warranty period, the customer should seek advice from Standard Imaging Inc. prior to such repair or replacement. If this product is in need of repair, it should not be used until all repairs have been made and the product is functioning properly and ready for use. After repair, the product may need to be calibrated. The owner of this product has sole responsibility for any malfunction resulting from abuse, improper use or maintenance, or repair by anyone other than Standard Imaging, Inc.

The information in this manual is subject to change without notice. No part of this manual may be copied or reproduced in any form or by any means without prior written consent of Standard Imaging, Inc.

---

**Warranty**

Standard Imaging, Inc. sells this product under the warranty herein set forth. The warranty is extended only to the buyer purchasing the product directly from Standard Imaging, Inc. or as a new product from an authorized dealer or distributor of Standard Imaging, Inc.

For a period provided in the table below from the date of original delivery to the purchaser or a distributor, this Standard Imaging, Inc. product provided in the table is warranted against functional defects in design, materials and workmanship, provided it is properly operated under conditions of normal use, and that repairs and replacements are made in accordance herewith. The foregoing warranty shall not apply if the product has been altered, disassembled or repaired other than by Standard Imaging, Inc. or if the product has been subject to abuse, misuse, negligence or accident.

<table>
<thead>
<tr>
<th>Product</th>
<th>Warranty Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Imaging Ionization Chambers</td>
<td>2 years</td>
</tr>
<tr>
<td>Standard Imaging Well Chambers</td>
<td>2 years</td>
</tr>
<tr>
<td>Standard Imaging Electrometers</td>
<td>2 years</td>
</tr>
<tr>
<td>Standard Imaging Software Products</td>
<td>1 year</td>
</tr>
<tr>
<td>All Other Standard Imaging Products</td>
<td>1 year</td>
</tr>
<tr>
<td>Standard Imaging Custom Product</td>
<td>90 days</td>
</tr>
<tr>
<td>Consumables</td>
<td>90 days</td>
</tr>
<tr>
<td>Serviced Product</td>
<td>90 days</td>
</tr>
<tr>
<td>Resale Products</td>
<td>As defined by the Original Equipment Manufacturer</td>
</tr>
<tr>
<td>ADCL Product Calibration</td>
<td>0 - 90 days = 100% of ADCL Calibration Costs</td>
</tr>
<tr>
<td>(Standard Imaging uses the UW-ADCL for recalibrations required under warranty)</td>
<td>91 - 182 days = 75% of ADCL Calibration Costs</td>
</tr>
<tr>
<td>183 – 365 days = 50% of ADCL Calibration Costs</td>
<td>366 – 639 days = 25% of ADCL Calibration Costs</td>
</tr>
</tbody>
</table>

This warranty represents the current standard warranty of Standard Imaging, Inc. Please refer to the labeling or instruction manual of your Standard Imaging, Inc. product or the Standard Imaging, Inc. web page for any warranty conditions unique to the product.

---

**Serialization Information**

Standard Imaging products that are serialized contain coded logic in the serial number which indicates the product, day and year of manufacture, and a sequential unit number for identification:

<table>
<thead>
<tr>
<th>Serial Number Format</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A YY DDD X</td>
<td>Unique unit ID</td>
</tr>
<tr>
<td>A</td>
<td>Unique product ID</td>
</tr>
<tr>
<td>YY</td>
<td>Last two digits of the year (e.g. 1999 = 99, 2000 = 00)</td>
</tr>
<tr>
<td>DDD</td>
<td>Day of the year (1 ≤ DDD ≤ 365)</td>
</tr>
<tr>
<td>X</td>
<td>Unique unit ID Number (1 ≤ X ≤ 9)</td>
</tr>
</tbody>
</table>