Segmental perfusion scores	17/20 segment perfusion and reversibility scores and percentages (SSS, SRS, SDS, SS%, SR%, SD%)	Slomka PJ, Nishina H, Berman DS, Akincioglu C, Abidov A, Friedman JD, Hayes SW, Germano G. Automated quantification of myocardial perfusion SPECT using simplified normal limits. J Nucl Cardiol. 2005 Jan-Feb;12(1):66-77. doi: 10.1016/j.nuclcard.2004.10.006. PMID: 15682367.
Summed perfusion scores	Summed perfusion and reversibility scores and percentages (SSS, SRS, SDS, SS%, SR%, SD%)	
Severity	Abnormal perfusion magnitude	
Extent	Abnormal perfusion area	
TPD	Total perfusion deficit, a measure that combines defect severity and extent	
Function analysis		
Segmental function scores	17/20 segment motion and thickening scores and percentages (SMS, STS, SM%, ST%)	Slomka PJ, Berman DS, Xu Y, Kavanagh P, Hayes SW, Dorbala S, Fish M, Germano G. Fully automated wall motion and thickening scoring system for myocardial perfusion SPECT: method development and validation in large population. J Nucl Cardiol. 2012 Apr;19(2):291-302. doi: 10.1007/s12350-011-9502-9. Epub 2012 Jan 26. PMID: 22278774; PMCID: PMC3320854.
Summed function scores	Summed motion and thickening scores and percentages (SMS, STS, SM%, ST%)	
Severity	Abnormal motion and thickening magnitude	
Extent	Abnormal motion and thickening area	
Quant	Quant, a measure that combines motion and thickening severity and extent	
Diastolic function		
PER	Peak emptying rate.	Slomka PJ, Berman DS, Xu Y, Kavanagh P, Hayes SW, Dorbala S, Fish M, Germano G. Fully automated wall motion and thickening scoring system for myocardial perfusion SPECT: method development and validation in large population. J Nucl Cardiol. 2012 Apr;19(2):291-302. doi:
PFR	Peak filling rate.	
PFR2	Secondary peak filling rate.	
BPM	Heart rate in heart beats per minute (if available).	

MFR/3	Mean filling rate over the first third of the end-systolic to end-diastolic phase.	10.1007/s12350-011-9502-9. Epub 2012 Jan 26. PMID: 22278774; PMCID: PMC3320854.
TTPF	Time to peak filling from end-systole.	
Flow		
MBF	Myocardial blood flow, blood flow through myocardium in ml/g/min.	Dekemp RA, Declerck J, Klein R, Pan XB, Nakazato R, Tonge C, Arumugam P, Berman DS, Germano G, Beanlands RS, Slomka PJ. Multisoftware reproducibility study of stress and rest myocardial blood flow assessed with 3D dynamic PET/CT and a 1-tissue-compartment model of 82Rb kinetics. J Nucl Med. 2013 Apr;54(4):571-7. doi: 10.2967/jnumed.112.112219. Epub 2013 Feb 27. PMID: 23447656. Slomka PJ, Alexanderson E, Jácome R, Jiménez M, Romero E, Meave A, Le Meunier L, Dalhbom M, Berman DS, Germano G, Schelbert H. Comparison of clinical tools for measurements of regional stress and rest myocardial blood flow assessed with 13N-ammonia PET/CT. J Nucl Med. 2012 Feb;53(2):171-81. doi: 10.2967/jnumed.111.095398. Epub 2012 Jan 6. PMID: 22228795.
MFR	Myocardial flow reserve, stress MBF divided by rest MBF.	
Spillover	Spillover fraction, the amount of radiotracer that spilled over from blood pool into myocardium.	
Motion correction	Automatic and manual dynamic data inter-frame motion correction	Otaki Y, Van Kriekinge SD, Wei CC, Kavanagh P, Singh A, Parekh T, Di Carli M, Maddahi J, Sitek A, Buckley C, Berman DS, Slomka PJ. Improved myocardial blood flow estimation with residual activity correction and motion correction in 18F-flurpiridaz PET myocardial perfusion imaging. Eur J Nucl Med Mol Imaging. 2022 May;49(6):1881-1893. doi: 10.1007/s00259-021-05643-2. Epub 2021 Dec 30. PMID: 34967914.
Residual activity correction	Automatic and manual dynamic data residual activity correction 6.1.11	
Viability		

Scar	Nonviable myocardium	Slomka P, Berman DS, Alexanderson E, Germano G. The role of PET quantification in cardiovascular imaging. Clin Transl Imaging. 2014 Aug 1;2(4):343-358. doi: 10.1007/s40336-014-0070-2. PMID: 26247005; PMCID: PMC4523308.
Mismatch	Hibernating myocardium	
Phase analysis		
Bandwidth	Smallest angle range on the histogram that includes 95% of the histogram measurements	Van Kriekinge SD, Nishina H, Ohba M, Berman DS, Germano G. Automatic global and regional phase analysis from gated myocardial perfusion SPECT imaging: application to the characterization of ventricular contraction in patients with left bundle branch block. J Nucl Med. 2008 Nov;49(11):1790-7. doi: 10.2967/jnumed.108.055160. Epub 2008 Oct 16. PMID: 18927331. Boogers MM, Van Kriekinge SD, Henneman MM, Ypenburg C, Van Bommel RJ, Boersma E, Dibbets-Schneider P, Stokkel MP, Schalij MJ, Berman DS, Germano G, Bax JJ. Quantitative gated SPECT-derived phase analysis on gated myocardial perfusion SPECT detects left ventricular dyssynchrony and predicts response to cardiac resynchronization therapy. J Nucl Med. 2009 May;50(5):718-25. doi: 10.2967/jnumed.108.060657. PMID: 19403876.
Mean	Entire global LV broken down into segments that allow a comparison of the LV contraction between the segments	
Mode	Location of the peak of the histogram (global or regional)	
Standard deviation	Amount of variation or dispersion from the average	
Entropy	Measure of variability rather than the dispersion (%)	
Miscellaneous		
TID	Transient ischemic dilation	Abidov A, Bax JJ, Hayes SW, Hachamovitch R, Cohen I, Gerlach J, Kang X, Friedman JD, Germano G, Berman DS. Transient ischemic dilation ratio of the left ventricle is a

		significant predictor of future cardiac events in patients with otherwise normal myocardial perfusion SPECT. J Am Coll Cardiol. 2003 Nov 19;42(10):1818-25. doi: 10.1016/j.jacc.2003.07.010. PMID: 14642694.
LHR	Lung/heart ratio	Bacher-Stier C, Sharir T, Kavanagh PB, Lewin HC, Friedman JD, Miranda R, Germano G, Berman DS. Postexercise lung uptake of 99mTc-sestamibi determined by a new automatic technique: validation and application in detection of severe and extensive coronary artery disease and reduced left ventricular function. J Nucl Med. 2000 Jul;41(7):1190-7. PMID: 10914908.
Eccentricity	LV eccentricity for the current frame, a measure of elongation that varies from 0 (sphere) to 1 (line).	Germano G, Kavanagh PB, Slomka PJ, Van Kriekinge SD, Pollard G, Berman DS. Quantitation in gated perfusion SPECT imaging: the Cedars-Sinai approach. J Nucl Cardiol. 2007 Jul;14(4):433-54. doi: 10.1016/j.nuclcard.2007.06.008. PMID: 17679052.
Shape Index	LV shape index for ED and ES. Shape index is the ratio between the maximum dimension of the LV in all short-axis planes and the length of the mid-ventricular long axis.	Abidov A, Slomka PJ, Nishina H, Hayes SW, Kang X, Yoda S, Yang LD, Gerlach J, Aboul-Enein F, Cohen I, Friedman JD, Kavanagh PB, Germano G, Berman DS. Left ventricular shape index assessed by gated stress myocardial perfusion SPECT: initial description of a new variable. J Nucl Cardiol. 2006 Sep;13(5):652-9. doi: 10.1016/j.nuclcard.2006.05.020. PMID: 16945745.

QC	LV segmentation quality control metric	Xu Y, Kavanagh P, Fish M, Gerlach J, Ramesh A, Lemley M, Hayes S, Berman DS, Germano G, Slomka PJ. Automated quality control for segmentation of myocardial perfusion SPECT. J Nucl Med. 2009 Sep;50(9):1418-26. doi: 10.2967/jnumed.108.061333. Epub 2009 Aug 18. PMID: 19690019; PMCID: PMC2935909.
Motion frozen	Generates ungated SPECT/PET datasets from gated ones by warping multiple frames into the end-diastolic frame	Slomka PJ, Nishina H, Berman DS, Kang X, Akincioglu C, Friedman JD, Hayes SW, Aladl UE, Germano G. "Motion-frozen" display and quantification of myocardial perfusion. J Nucl Med. 2004 Jul;45(7):1128-34. PMID: 15235058.
Serial change	Direct quantification of perfusion changes between two datasets through 3D elastic registration and count normalization	Slomka PJ, Berman DS, Germano G. Quantification of serial changes in myocardial perfusion. J Nucl Med. 2004 Dec;45(12):1978-80. PMID: 15585470.
Prone+	Combined supine/prone analysis	Nishina H, Slomka PJ, Abidov A, Yoda S, Akincioglu C, Kang X, Cohen I, Hayes SW, Friedman JD, Germano G, Berman DS. Combined supine and prone quantitative myocardial perfusion SPECT: method development and clinical validation in patients with no known coronary artery disease. J Nucl Med. 2006 Jan;47(1):51-8. PMID: 16391187.
RV segmentation		
RV volume	RV chamber volume, gated or ungated	Kavanagh P. QGS RV Validation 2010. Technical Report Entezarmahdi SM, Faghihi R, Yazdi M, Shahamiri N, Geramifar P, Haghighatafshar M. QCard-NM: Developing a semiautomatic segmentation method for quantitative analysis of the right ventricle in non-
RV EDV	RV chamber volume at end-diastole	
RV ESV	RV chamber volume at end-systole	
RV SV	RV Stroke volume	
RV EF	RV Ejection fraction	

		gated myocardial perfusion SPECT imaging. EJNMMI Phys. 2023 Mar 23;10(1):21. doi: 10.1186/s40658-023-00539-6. PMID: 36959409; PMCID: PMC10036722.
QBS segmentation		
LV Volume	LV chamber volume, gated or ungated	Van Kriekinge SD, Berman DS, Germano G. Automatic quantification of left ventricular ejection fraction from gated blood pool SPECT. J Nucl Cardiol. 1999 Sep-Oct;6(5):498-506. doi: 10.1016/s1071-3581(99)90022-3. PMID: 10548145.
LV EDV	LV chamber volume at end-diastole	
LV ESV	LV chamber volume at end-systole	
LV SV	LV stroke volume	
LV EF	LV ejection fraction	
RV Volume	RV chamber volume, gated or ungated	Daou D, Van Kriekinge SD, Coaguila C, Lebtahi R, Fourme T, Sitbon O, Parent F, Slama M, Le Guludec D, Simonneau G. Automatic quantification of right ventricular function with gated blood pool SPECT. J Nucl Cardiol. 2004 May-Jun;11(3):293-304. doi: 10.1016/j.nuclcard.2004.01.008. PMID: 15173776.
RV EDV	RV chamber volume at end-diastole	
RV ESV	RV chamber volume at end-systole	
RV SV	RV stroke volume	
RV EF	RV ejection fraction	
MoCo motion correction		
Motion correction	Automatic and manual inter-projection motion correction of perfusion SPECT data	Matsumoto N, Berman DS, Kavanagh PB, Gerlach J, Hayes SW, Lewin HC, Friedman JD, Germano G. Quantitative assessment of motion artifacts and validation of a new motion-correction program for myocardial perfusion SPECT. J Nucl Med. 2001 May;42(5):687-94. PMID: 11337561.

1.11 Manual Conventions

The following typographical conventions are followed throughout the manual:

- **User interface (UI) elements** (menu items, buttons, etc…) are depicted in **this style** (bold, light-colored serif type).
  The paths to menu items and sub-items are abbreviated as **Menu > Item** or **Menu > Submenu > Item**.
  Similarly, a tab **Tab** on a dialog opened by selecting a menu option **Option** may be referenced as **Menu > Option > Tab**.
- **User input**, including single keys such as shortcuts, is depicted using **this style** (bold, bright-colored sans-serif type).
- **Code or information found in configuration files** is depicted using `this style` (bold, colored fixed-width type).
- **Other items of interest**, such as references to other sections, are depicted using ***this style*** (bold, italicized, colored sans-serif type).

The following symbols are also used to draw attention to certain information:

NOTE: This is an example of a note. The note describes something related to the behavior of the application that does not pose an inherent risk.

CAUTION: This is an example of a caution statement. Review this information carefully. Misuse of a feature may lead to unwanted consequences and possible minor or moderate injury, data loss, or material damage.

1.12 General Warnings and Cautions

CAUTION: Software is designed to manage and analyze data that contains sensitive patient information. Oblige to all applicable local standards (e.g., HIPAA in the United States) in safeguarding all patient information and allow access to authorized users only. It is recommended to create password protection where offered within the program or device on which the software is installed.

CAUTION: Program is designed to automatically process data and generate quantification results; it is not meant to offer a standalone diagnosis. A qualified physician's assessment of the results is required.

While every effort has been made to ensure the accuracy of the information in this manual, you may occasionally notice slight differences between screen captures and the actual software.

2 Setup Instructions

This section summarizes the installation instructions and assumes you are familiar with various concepts such as installing programs.

2.1 Prerequisites

You will need:

- A computer running one of the supported Microsoft Windows Operating Systems (see the *Release Notes* for version-specific OS requirements).
- The installation file (downloaded from a supplied URL or provided by QUAD support staff).
- *Administrator* privileges on the computer where the software installation is to be performed.

2.2 Optional download verification

Optional download verification steps if you have a *.md5* file for your download. You must be familiar with using command-line tools.

1. Download the installer zip file and the MD5 checksum to the same location, e.g., **C:\Downloads**.
2. Open a Windows command prompt.
3. Change directory to the download location:

```
cd C:\Downloads
```

4. Compute and print the MD5 checksum for the downloaded file:

```
certutil -hashfile <downloaded-zip-file> MD5
```

   For example:

```
certutil -hashfile csmcdirect_x64_2017_37136.zip MD5
```

5. The output should look like this (MD5 hash highlighted in red):

```
C:\Downloads> certutil -hashfile csmcdirect_x64_2017_37136.zip MD5
MD5 hash of csmcdirect_x64_2017_37136.zip:
b919768e96da5300958e54e518b6928c
CertUtil: -hashfile command completed successfully.
```

6. Display the contents of the downloaded MD5 checksum file using the command below and compare with the output of the `certutil` command:

```
type <downloaded-md5-file>
```

For example:

```
type csmcdirect_x64_2017_37136.md5
```

7. The output should look like this (matching MD5 hash highlighted in red):

```
C:\Downloads> type csmcdirect_x64_2017_37136.md5
//
// File Checksum Integrity Verifier version 2.05.
//
b919768e96da5300958e54e518b6928c csmcdirect_x64_2017_37136.zip
```

8. If the outputs match verification is complete. If there is a discrepancy, re-download both files from the source and perform the verification tasks again. If the discrepancy persists or if tyour computer does not have the `certutil` application, contact QUAD support.

2.3 Installation

1. Log into the system as a user with *Administrator* privileges.
2. UnZip the download file, then double-click ***CSMC_Setup.exe***.
3. When the setup program starts, go through all steps accepting the default values or check the boxes for the specific software options purchased.
4. The setup program will automatically update the necessary registry keys if you have administrative privileges.
5. When the setup program is finished, reboot the computer if necessary (as suggested by the setup program).
6. Double-click on the ***CSImport*** icon shortcut on your desktop.
7. Send the system identifier to your CSMC support representative for obtaining a license registration key.
8. Enter the registration key in the licensing dialog.
9. Follow the initial setup steps to create an ‘admin’ password and a user. Password and user information can be modified at a later time, but please keep the admin password safe.
10. You’re done! The data browser ***CSI*** will now start and bring you to the main data browser screen.

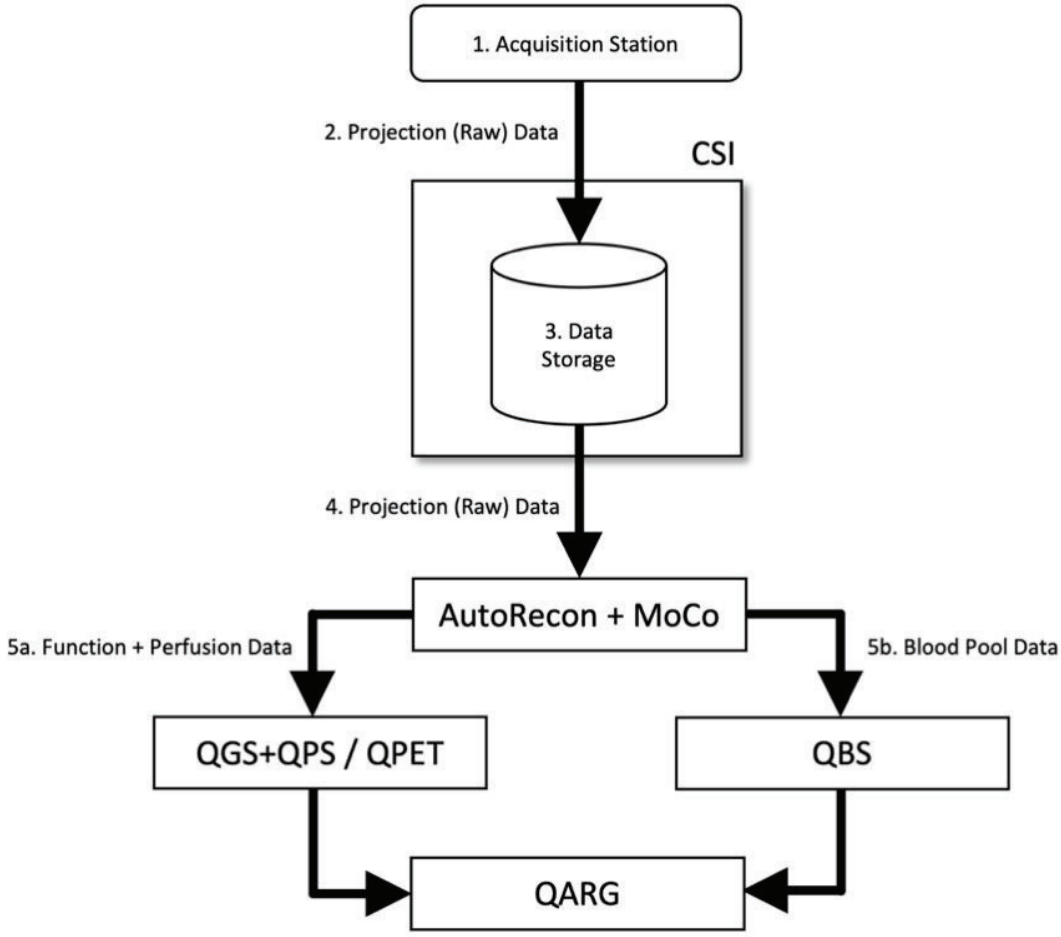
This user manual and other reference manuals are automatically copied to the system during installation. You may also consult documentation at our web site:

`http://www.csaim.com/ifu`

3 Operating Instructions

3.1 CSImport

Cedars-Sinai Import (CSI) is primarily an image database front-end that is also commonly used for launching external applications. It is designed to allow the user to retrieve datasets from a variety of sources such as the Philips Pegasys, Jet Stream, and EBW workstations, FTP servers, and DICOM Query/Retrieve servers. CSI also provides a variety of data management tools, and includes a DICOM Store Service Class Provider (SCP) service that allows DICOM-compliant systems to push images to your PC for processing and review. Details of the DICOM interactions can be found in the DICOM Conformance Statement.



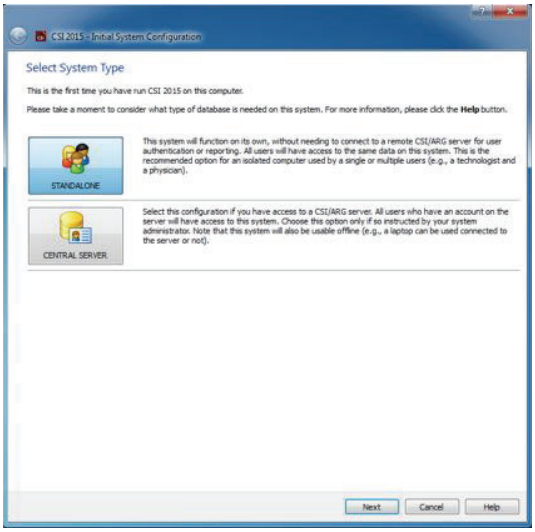
Legend

1. Acquisition Station
2. Projection (Raw) Data
3. Data Storage

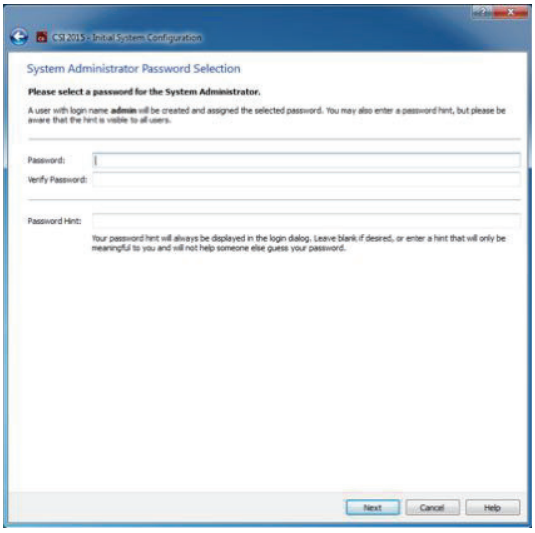
4. Projection (Raw) Data
5a. Function + Perfusion Data
5b. Blood Pool Data

3.1.1 Initial setup

CSImport controls data accessibility via user credentials. The image data base maybe setup as a standalone or Central Server. When CSI is run for the first time, it allows the ability to select the system type that is desired.

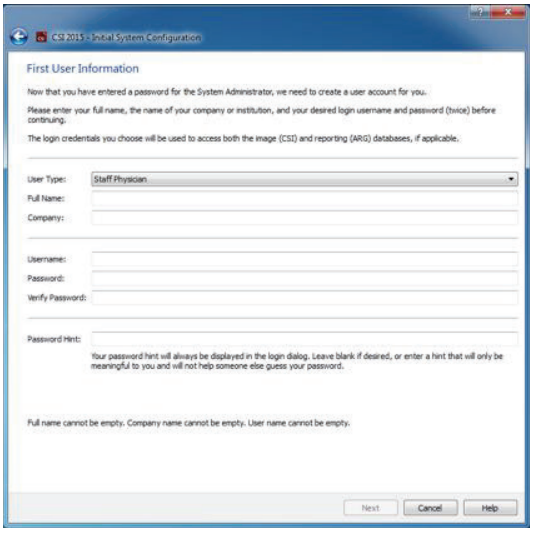


STANDALONE is the default selection unless you have multiple computers running the same version of CSImport and you would like to connect to a SQL server based CSImport/ARG database.

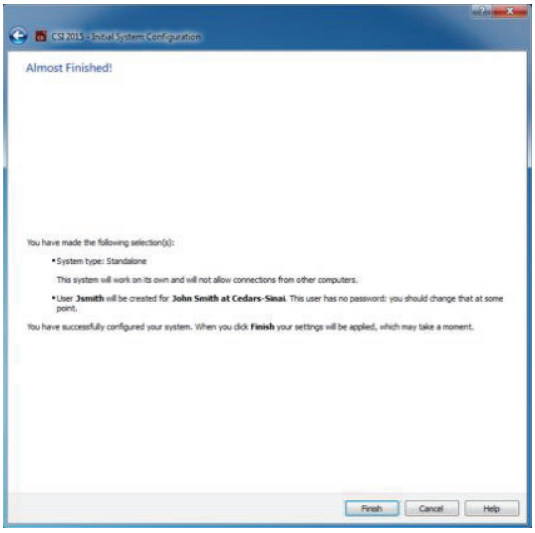


Once **STANDALONE** or **CENTRAL SERVER** database selection is made, the next step is setting up the System Administrator user account. The login user name for the Administrator account is *admin*. Enter the password information on this dialog and click **Next**.

The last step is to setup the first user information. Select desired User Type and complete the information on this dialog before clicking **Next**.



A final confirmation dialog indicates the conclusion of the initial setup process. Verify the information for accuracy and click **Finish**. To make modifications to any of the information, click on the back arrow show in the top left corner of the confirmation dialog.



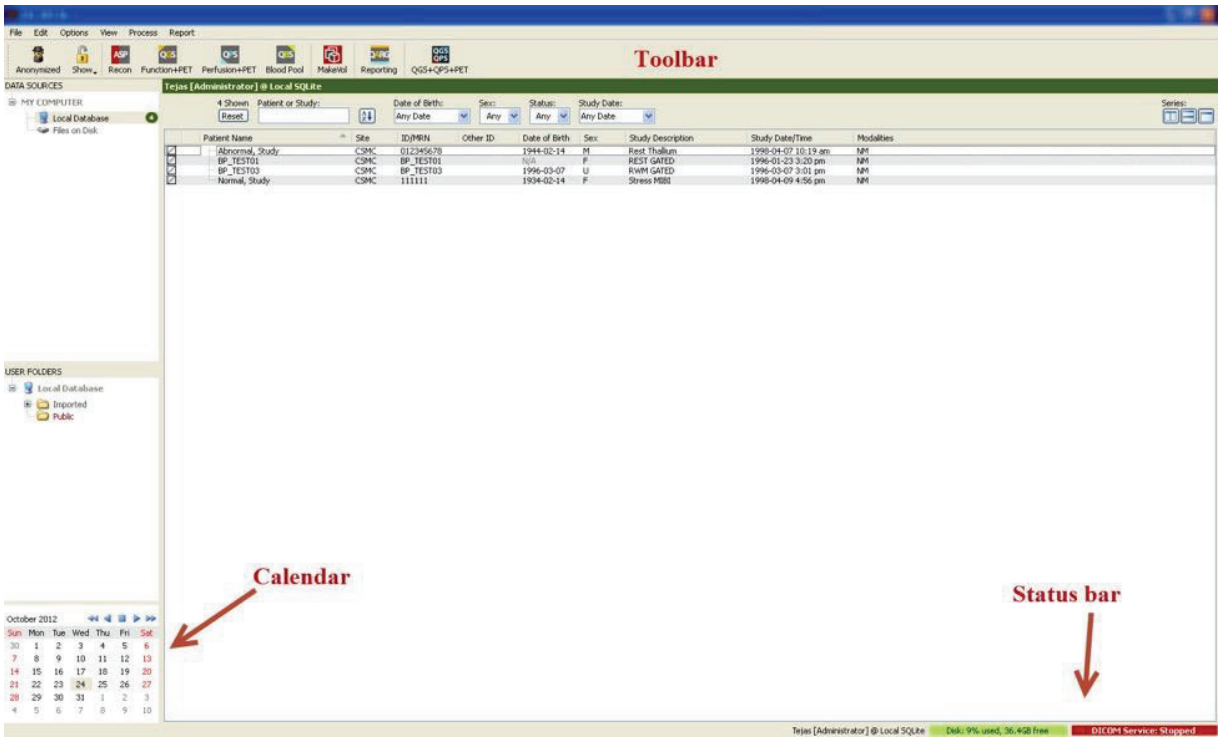
3.1.2 Launching an application

You can select one or more folders that represents DICOM series, studies, or patients, or any other type of data organization (e.g., a folder that contains studies for multiple patients suffering from the same pathology), and launch the application with all datasets contained within the selected folders by clicking the toolbar button for that application (e.g., QGS+QPS, QBS, Arecon, etc).

Note that having launched one application does not prevent you from going back to the data browser and launching another application, either for the same data or for a different selection.

Data selection follows the same conventions as Windows Explorer: clicking an item selects it, clicking another item selects that item instead of the previous selection, and keys such as Shift

and Ctrl can be used in conjunction with mouse clicks to extend or modify the selection, respectively.



3.1.3 Importing data

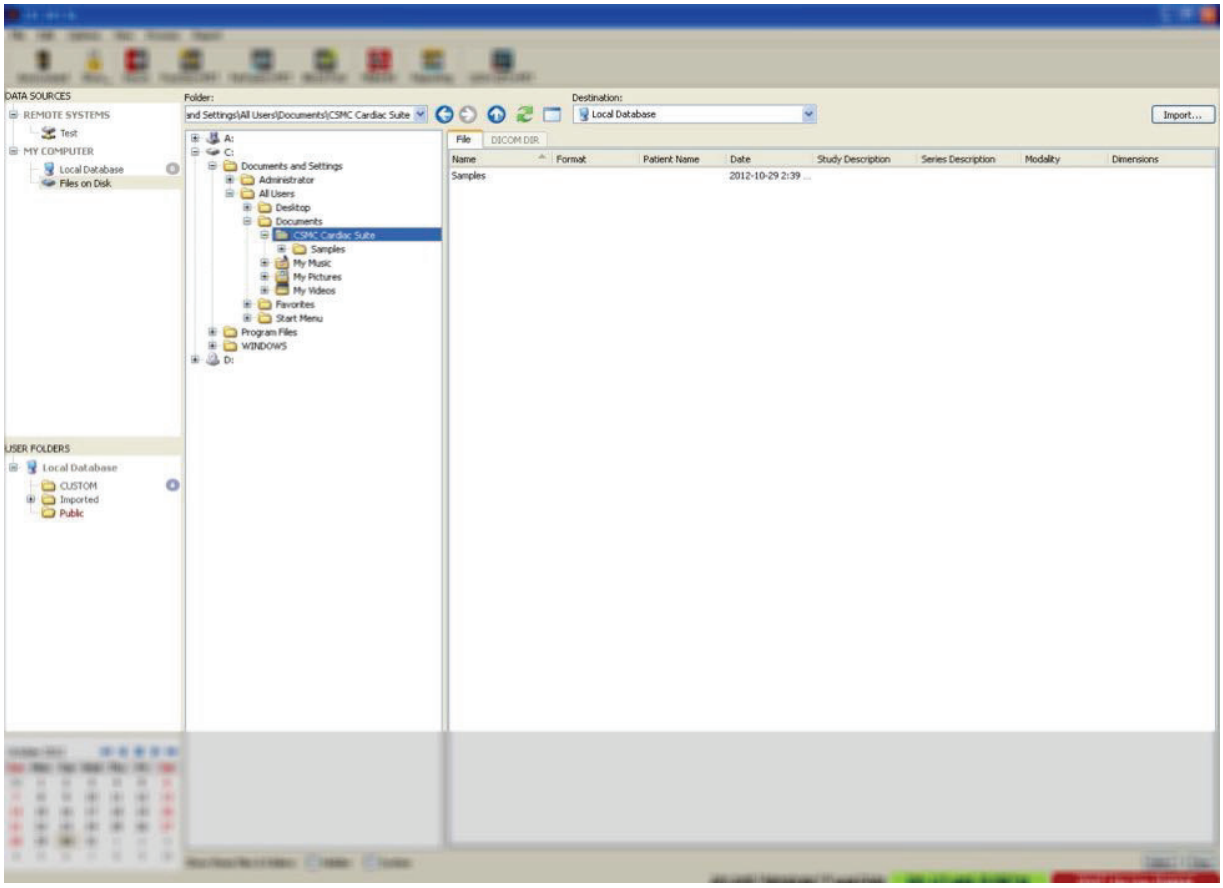
There are multiple options for importing images based on where the data is located. For purposes of this example, let's assume that the data resides on a locally accessible disk (i.e. a local hard disk, mapped drive from another computer, CD or DVD, portable USB drive, etc).

3.1.4 Importing data from a local disk

This option should be used to import data that resides on a disk accessible through the computer's file system. This includes data residing on:

- hard disks;
- CDs or DVDs;
- flash drives;
- Remote disks accessed by mapping a drive letter to a remote folder.

The image below depicts a typical display when a folder has been opened and its contents are displayed. Local disk files can be browsed by clicking **Files on Disk** from the Data Sources section and navigating to the location of the files using the windows file explorer like view.



Note the folder selection control to the left (a path can also be typed directly in the text field at the top). To the right, files that are recognized as images are displayed. Enough information is displayed for each file to allow the selection of the appropriate image(s).

There are two ways to import files: by selecting individual files, or by importing entire folders.

To import selected files, click, click-drag, or control-click files. Select the appropriate import options, and then click **import**. After the import process is complete, either navigate to another folder to import more files or click on local database option from Data Sources to go back to the original view.

To import entire folders, select the folder and click import. If **Do not recurse into sub-folders** is checked from the Import Options dialog, only files inside the selected folders will be imported. If it is unchecked and if the selected folders contain sub-folders, all datasets within all sub-folders will be imported as well.

The following import options are available:

Make data private – this option can be checked to hide the imported data from other users.

Recursive Import – this option can be checked if only data in the selected folders, not from their subfolders, should be imported.

Tags – Options to add customized tags to the imported data at the patient or study level.

3.1.5 Importing data from a remote system

The four types of supported remote systems are:

- Philips (ADAC) Pegasys
- Philips (Marconi) Odyssey
- FTP server
- DICOM Query/Retrieve server/Store Server

3.1.5.1 Creating remote system configurations

Each remote system must be configured in CSI before it can be contacted to import/export data. DICOM Q/R servers also often require server-side configuration. This will generally need to be performed by the PACS administrator (for Picture Archiving and Communication Systems) or by technical support personnel (for non-PACS imaging workstations such as acquisition systems).

The beginning of the procedure for creating a new configuration for a remote system is the same for all system types:

- Select **Options > Manage Remote Systems…**
- Click **Add…** in the Remote Computer Systems window

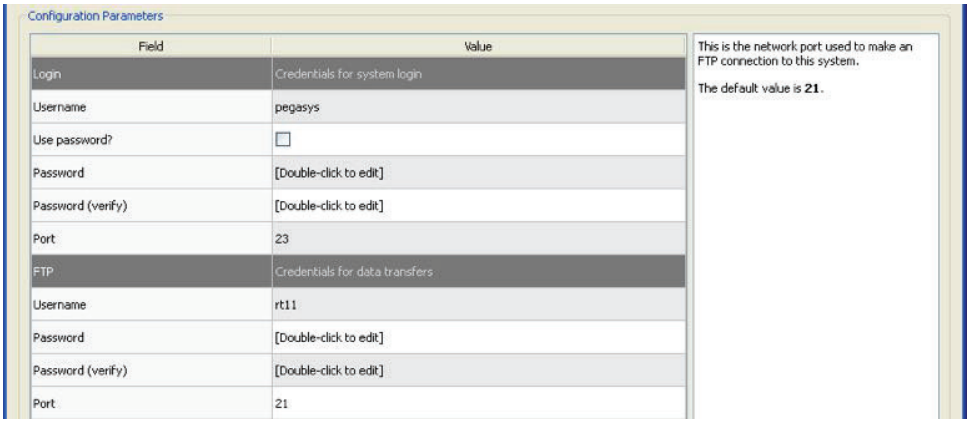
The next step is to set basic information for the system in the Remote Computer Systems window:

- Select the “Remote Computer Type”
- Enter a “Display Name” that will be used throughout the program to identify the system
- Enter the IP address of the remote system. It is recommended to use IP addresses instead of names, unless the remote system’s address is likely to change due to dynamic address allocation

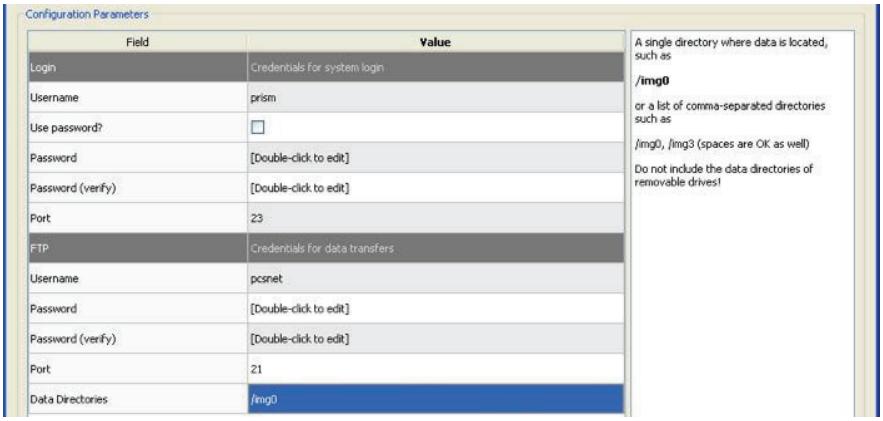
Once the remote computer type has been set, the lower portion of the dialog will update to reflect the specific settings required by that type of system.

In general:

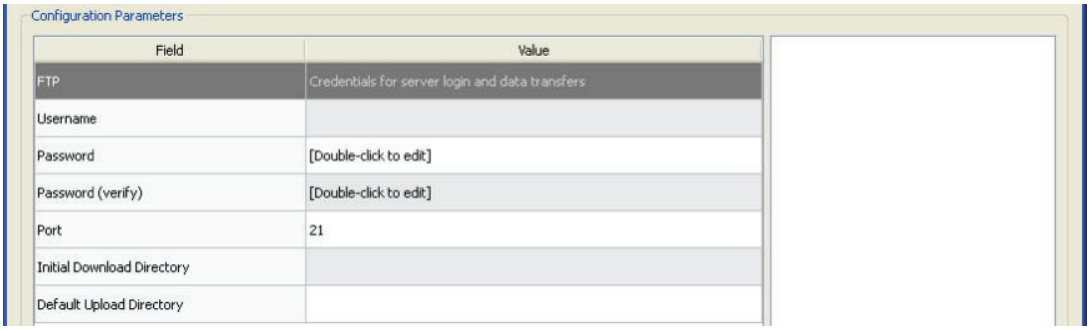
- For Pegasys systems no changes are required;



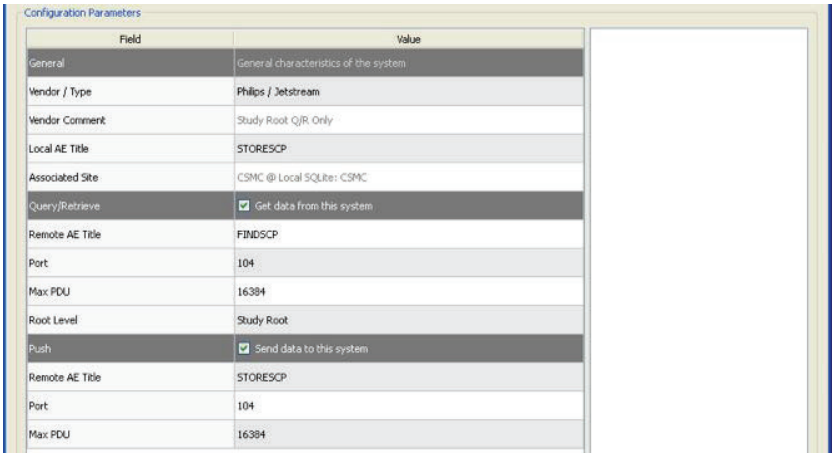
- For Odyssey systems, only the data directories need to be updated (usually one or more of the form “/imgX” where “X” is a number);



- For FTP servers, the appropriate account information (username and password) must be entered. “Port” and “Initial Directory” can often be left to default values.



- For DICOM Query/Retrieve/Store servers, the AE titles, port number, and query root level need to be set to values as prescribed by the remote system’s administrator. Setting the system’s “Vendor” type will in some cases allow CSI to restrict itself to operations that are known to function for those systems (not all DICOM systems offer the same level of functionality).

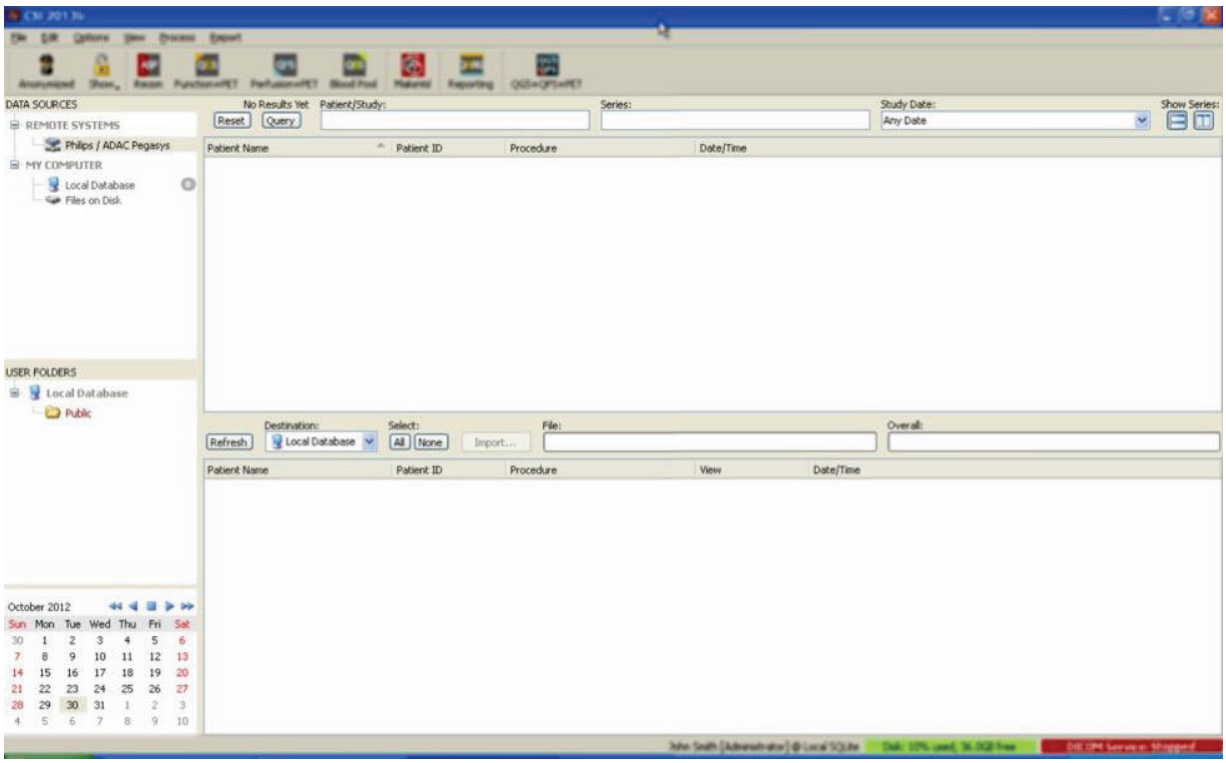


Default values can be reset by clicking **Reset**, and basic connectivity tests can be run by clicking **Test**.

Click **OK** to accept the settings when the configuration information of the new remote system is satisfactory. The new system will appear in the remote computer list, where it can be used to retrieve data.

3.1.5.2 Philips Pegasys

To import data from a Pegasys system, click the name of the system from the remote systems list. This will bring up the Pegasys dialog and start the connection to retrieve the study list.



To import entire studies, select one or more desired studies (click, click-drag or control-click in the list), set the import options and click **Import…**.

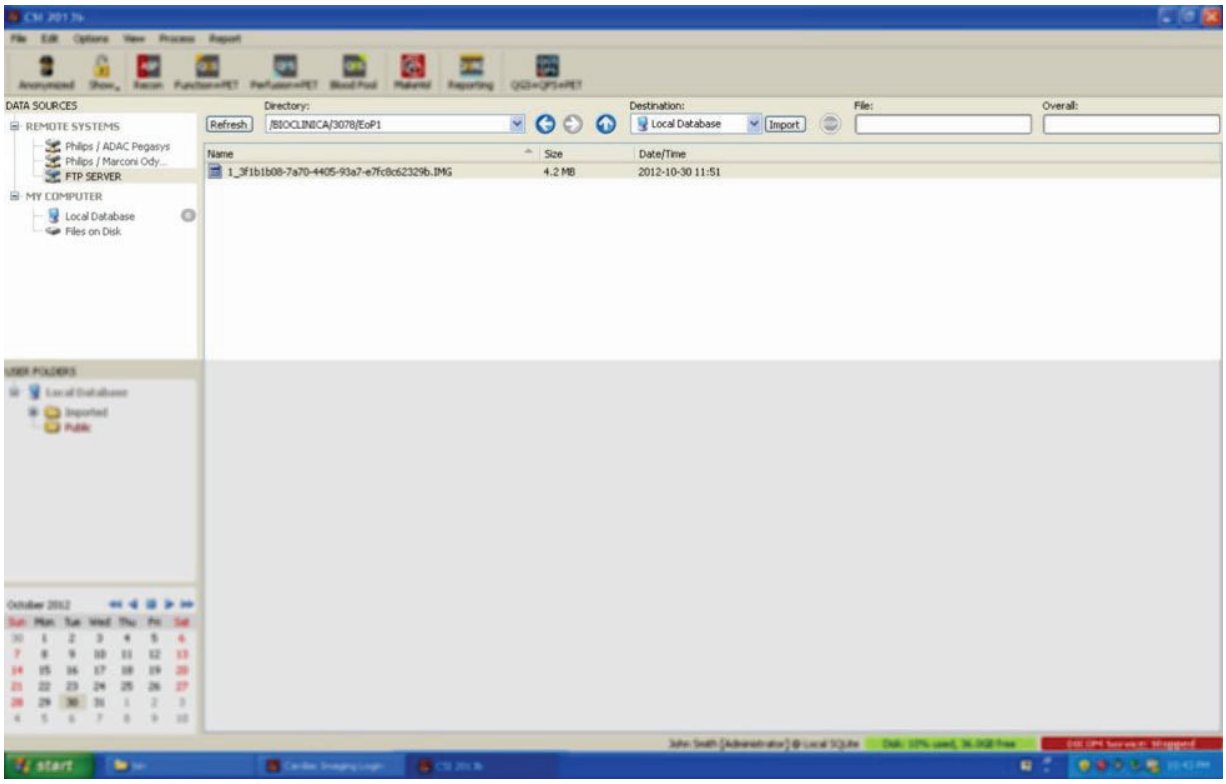
When done importing, either select more datasets, return to the studies selection page by clicking on Local Database.

3.1.5.3 Philips Odyssey

Odyssey connectivity is very similar to Pegasys connectivity. Only the information is presented slightly differently, reflecting the naming conventions and fields available on Philips Odyssey systems.

3.1.5.4 FTP Server

The main downside of using a FTP server to retrieve data is that images can only be selected by file name, without added information such as patient name, study description, etc. A typical file list is shown in the figure below.

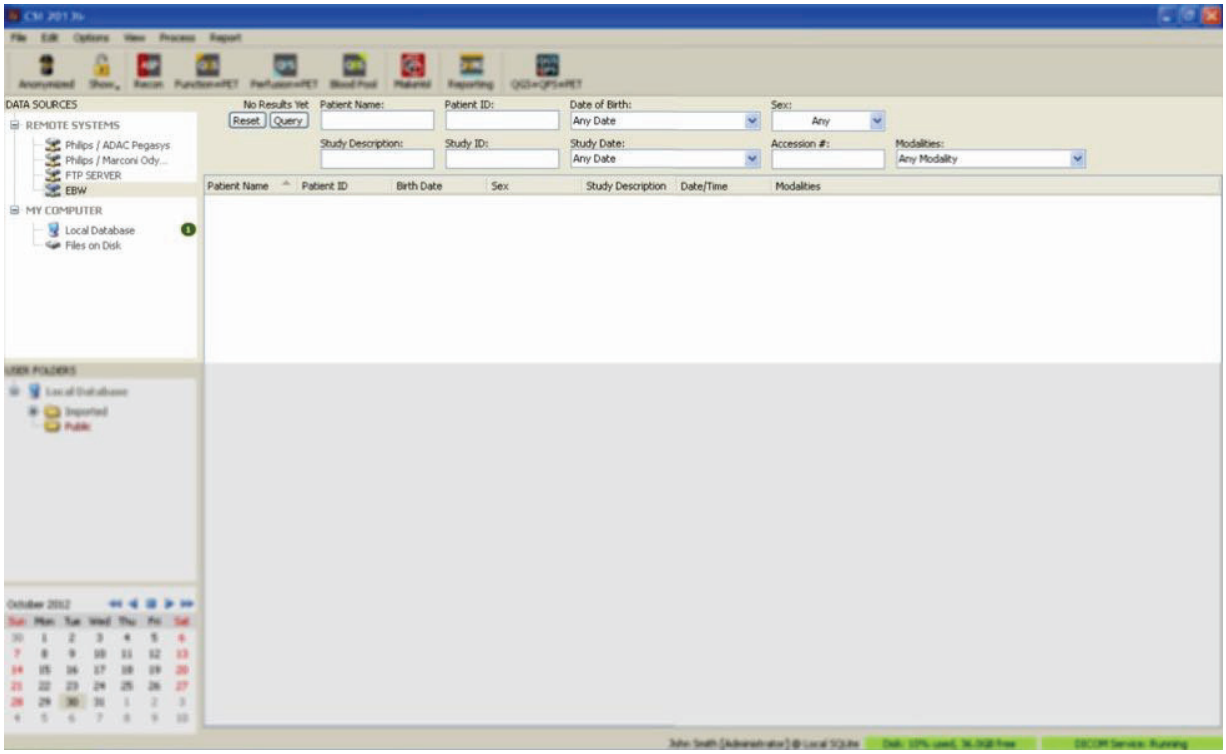


To navigate to another folder, either type the path in the Directory box or double-click folder names in the list (including the special “<UP>” folder to navigate to the parent directory).

By default, all datasets are selected. Use control-click to remove individual items from the selection. When ready, click **Import** to import the selected datasets.

3.1.5.5 DICOM Query/Retrieve Server

Importing data from a DICOM Q/R/S server requires more configuration than any other type of remote system, but it is the only method to gain access to PACS and other DICOM-based systems. Once the system has been configured and a connection established, the following dialog is presented:



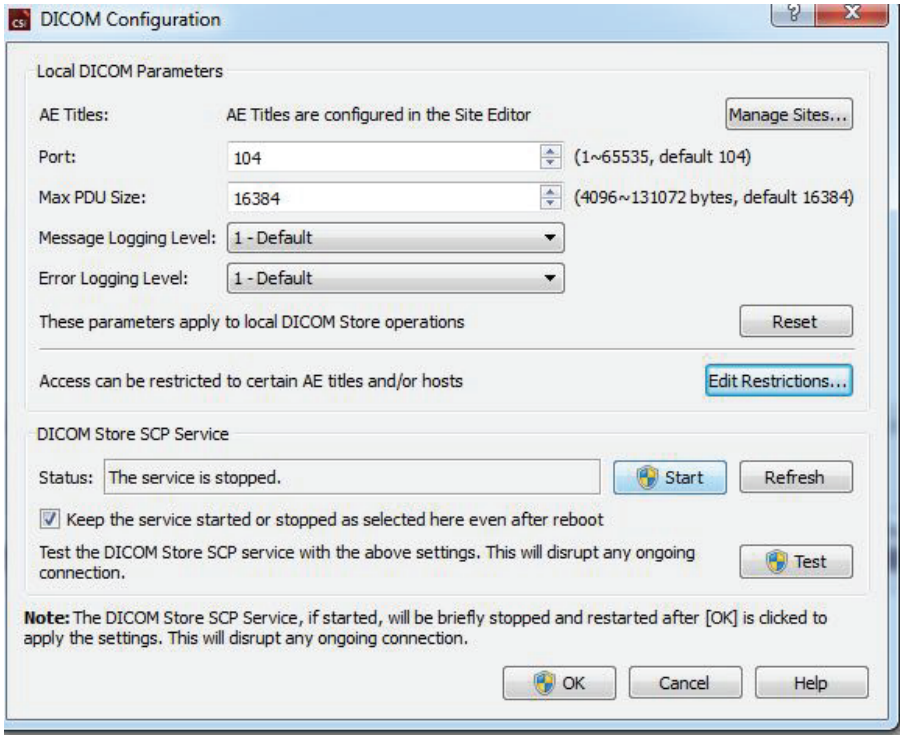
Because PACS systems often store very large amounts of data, no query is sent to the server until **Query** is pressed. This allows for the selection of a study filter to limit the number of results.

For a more detailed explanation of the other capabilities of the DICOM import dialog, please consult the Reference Manual.

3.1.5.6 Pushing DICOM datasets from a remote system

In addition to the ability to pull data from a variety of sources, it is also possible to push images from other DICOM-compliant systems to the system running CSI. CSI includes a Windows service called “Cedars-Sinai DICOM Store SCP” that listens for incoming connections. Most modern imaging platforms can connect to this service and send images which are then stored locally on your PC and inserted in the local image database.

To use this mechanism, you need to configure the DICOM Store SCP service with the appropriate parameters. The configuration dialog that is shown below can be launched from **Options > DICOM Networking**.



To configure the DICOM Store SCP, follow these steps:

1. Go to **Options > DICOM Networking**
2. Choose an application entity title (AE Title) for your computer. AE Titles are managed by the site manager and can be accessed by clicking **Manage Sites…**.
3. Choose a port number on which source systems will contact your computer (default: 104).
4. To limit access to selected remote systems, click **Edit Restrictions…** and enter the acceptable AE title information. By default the system accepts connections from all remote systems.
5. Leave the rest of the options unchanged.
6. Click **Start** to start the DICOM Store SCP service.
7. Click **OK** to apply the changes and restart the service.

You will now need to configure any source system with the appropriate settings to be able to send data. In general, configuration of the source systems will require the following information:

- The IP address of your computer
- The AE Title selected in step 2 above

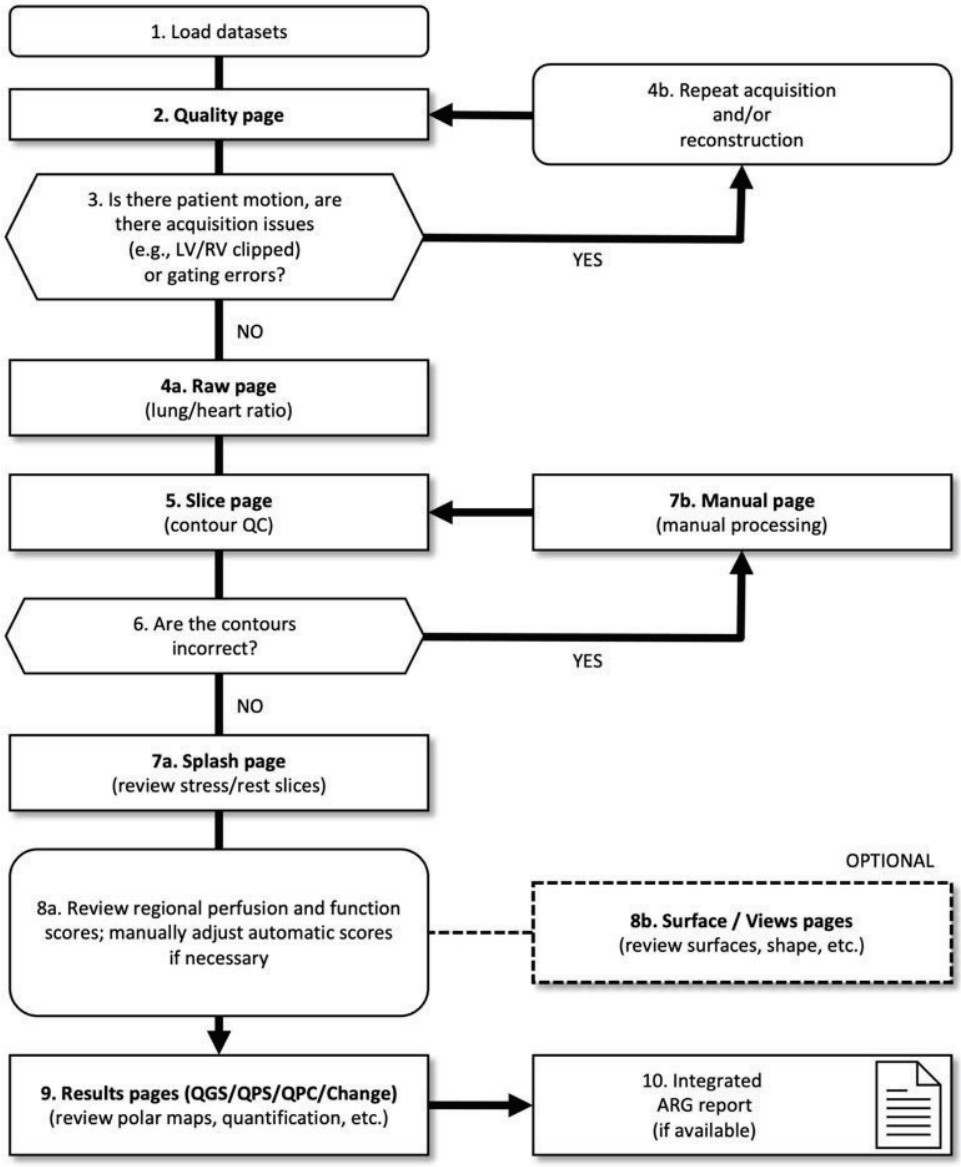
- The port number selected in step 3 above

DICOM systems usually have the ability to perform a few connectivity tests (often called “echo” in reference to the DICOM C-ECHO message) to ensure the parameters are correctly configured. These tests should succeed if the DICOM Store SCP service is running on your system.

Users on the remote systems can then select data and send it to your PC. The data should appear in the selected location. It may be necessary to refresh the list and/or modify data filters to see the data. For instance, if you have selected to view only today’s studies and the study sent from the source system was acquired yesterday, it won’t show up in your list until you remove the date filter.

4 Quantitative SPECT/PET Applications – QGS+QPS/QPET

The workflow is intentionally modeless. As such, no particular processing sequence is dictated to the user. A typical sequence might proceed as follows:



Legend

1. Load datasets
2. Quality page
3. Is there patient motion, are there acquisition issues (e.g., LV/RV clipped) or gating errors?

4a. Raw page (lung/heart ratio)

4b. Repeat acquisition and/or reconstruction
5. Slice page (contour QC)
6. Are the contours correct?
7a. Splash page (review stress/rest slices)
7b. Manual page (manual processing)
8a. Review regional perfusion and function scores; manually adjust automatic scores if necessary
8b. Surface / Views pages (review surfaces, shape, etc.)
9. Results pages (QGS/QPS/QPC/Change) (review polar maps, quantification, etc.)
10. Integrated ARG report (if available)

OPTIONAL = Recommended but not required.

4.1 Language Selection

CSMC Cardiac Suite supports user interface localization. Some languages may not be available on all platforms. To select a language open **Defaults** dialog, click the **Language** tab and select the desired language from the drop-down menu.

The new language setting will take effect when the program is restarted. Note that this setting affects all CSMC Cardiac Suite applications.

Changing the language setting within CSMC Cardiac Suite will not affect the language settings of the operating system or any other applications not part of the suite.

4.2 File Selection (using patient example)

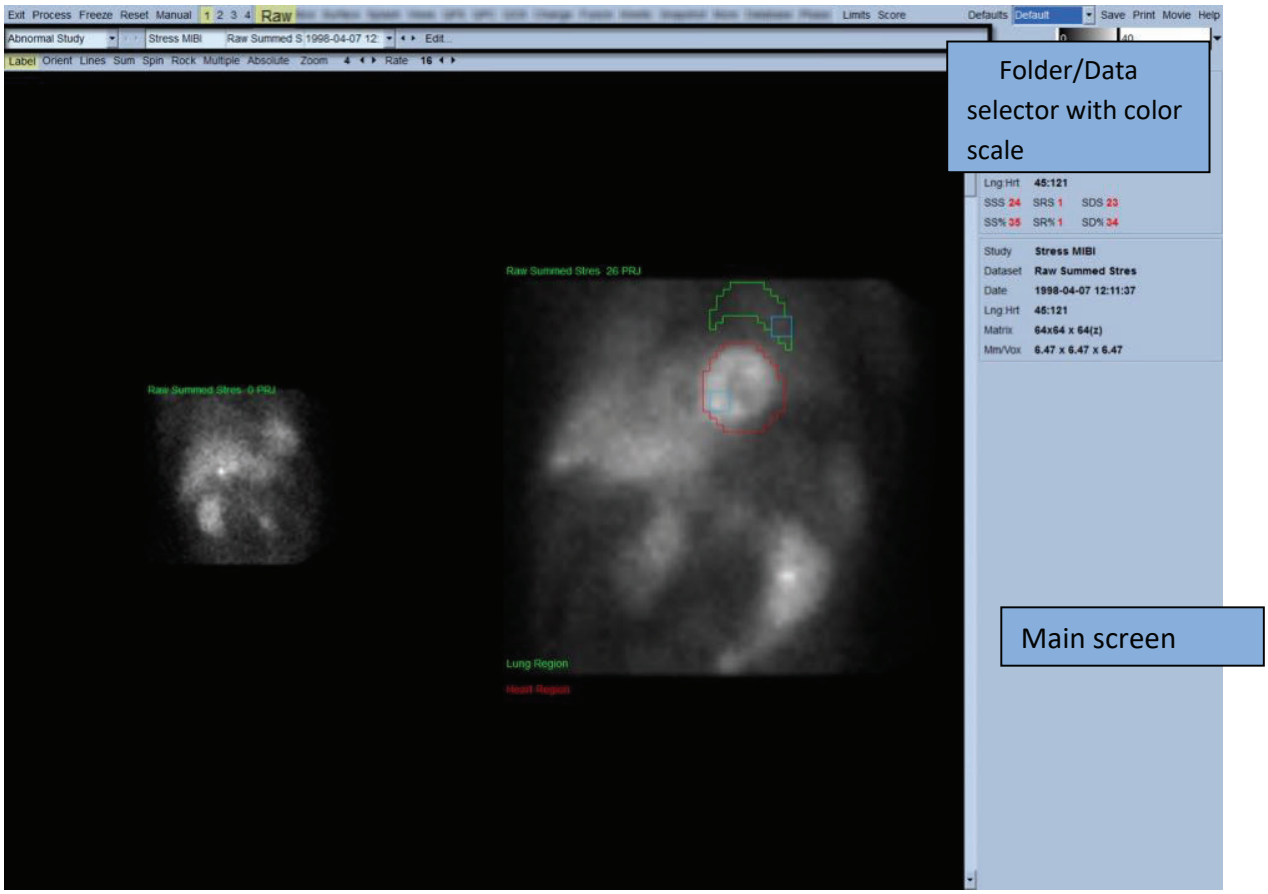
QGS+QPS is able to quantify global and regional parameters of perfusion and function using one or more, gated or summed short axis data set. For perfusion analysis, typically two data sets - stress/rest, stress/redistribution, rest/redistribution, etc. are used. If possible, it is also advisable to select the related projection data set(s), so as to be able to assess acquisition artifacts at the earliest possible stage in the processing/analysis chain. For the purposes of this example, we'll assume to have selected the following files for the patient ABNORMAL STUDY:

Study	Dataset	Description
STRESS MIBI	Raw Summed Stress	(Summed stress projection image set)
STRESS MIBI	Raw Gated Stress	(Gated stress projection image set)
STRESS MIBI	SA Gated Stress	(Gated stress short axis image set)
STRESS MIBI	SA Summed Stress	(Summed stress short axis image set)
REST THALLIUM	Raw Summed Rest	(Summed rest projection image set)
REST THALLIUM	Raw Gated Rest	(Summed rest projection image set)

REST THALLIUM	SA Gated Rest	(Gated rest short axis image set)
REST THALLIUM	SA Summed Rest	(Summed rest short axis image set)

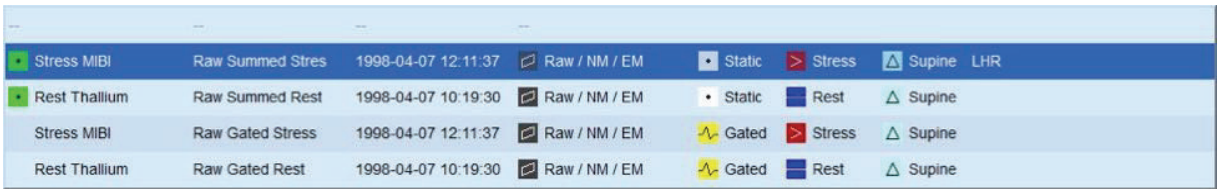
4.3 Launching

Launching QGS+QPS in its standard configuration will bring up the Main screen as shown below with the **Raw** page indicator and the **Label** toggle highlighted. A representative projection image from the **Raw Summed Stress** dataset is shown, with the number to its left showing its order in the dataset. Left-clicking on **Label** toggles that number on and off. Left-clicking on and dragging the vertical black stripe rightmost in the scale will "saturate" the scale and make the LV visible in cases where strong extra cardiac activity exists.

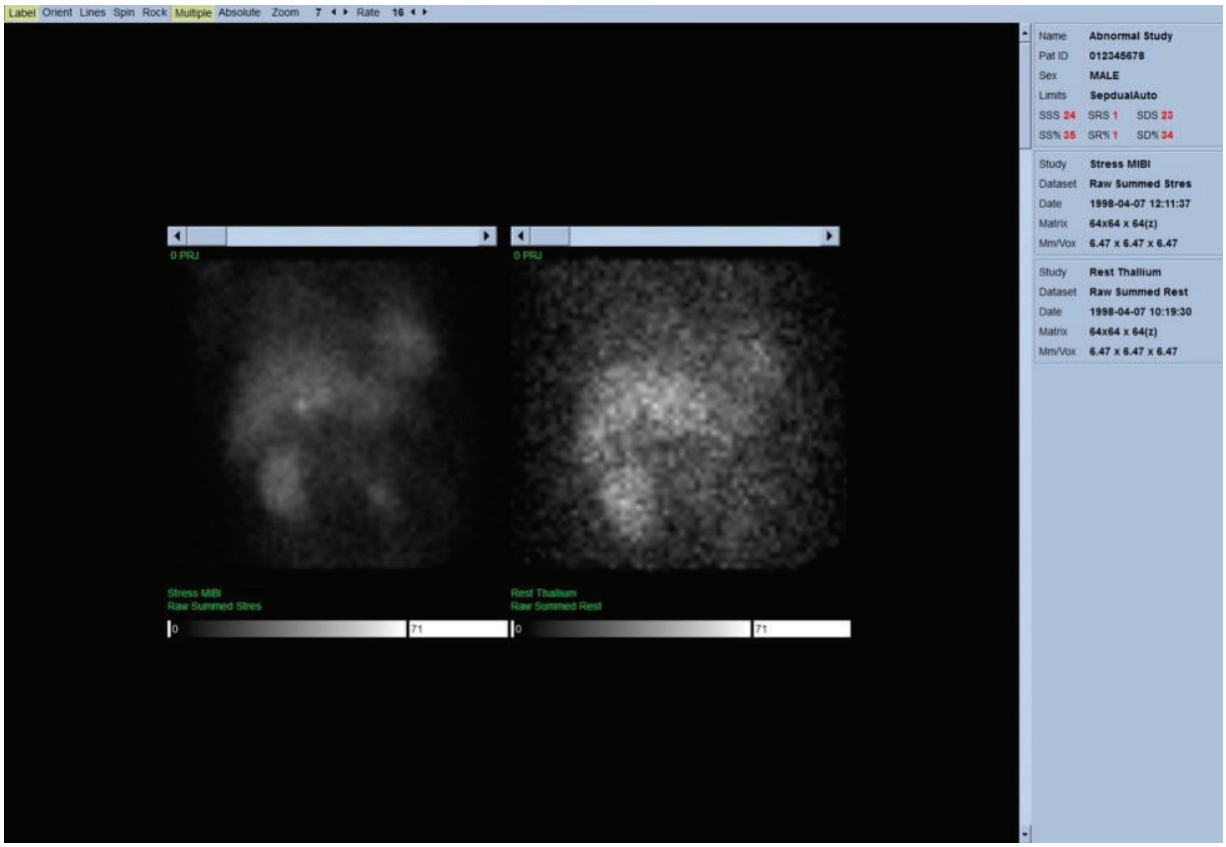


The name of the Folder (generally, a patient name) and that of the projection data set are displayed in the horizontal section that also contains the data set selector, the data set editor and the color scale.

Left-clicking on the data set selector will bring up a pull-down menu listing all selected data sets as seen below, from which any projection data set can be chosen and displayed.



Finally, the two projection datasets (or more, when applicable) can be displayed side-by-side by left-clicking **Multiple** on the page control bar. While the color scale still acts on both images, an individual color scale is also provided underneath each image. The number of controls on the page control bar is specific to the page selected on the Main screen toolbar.

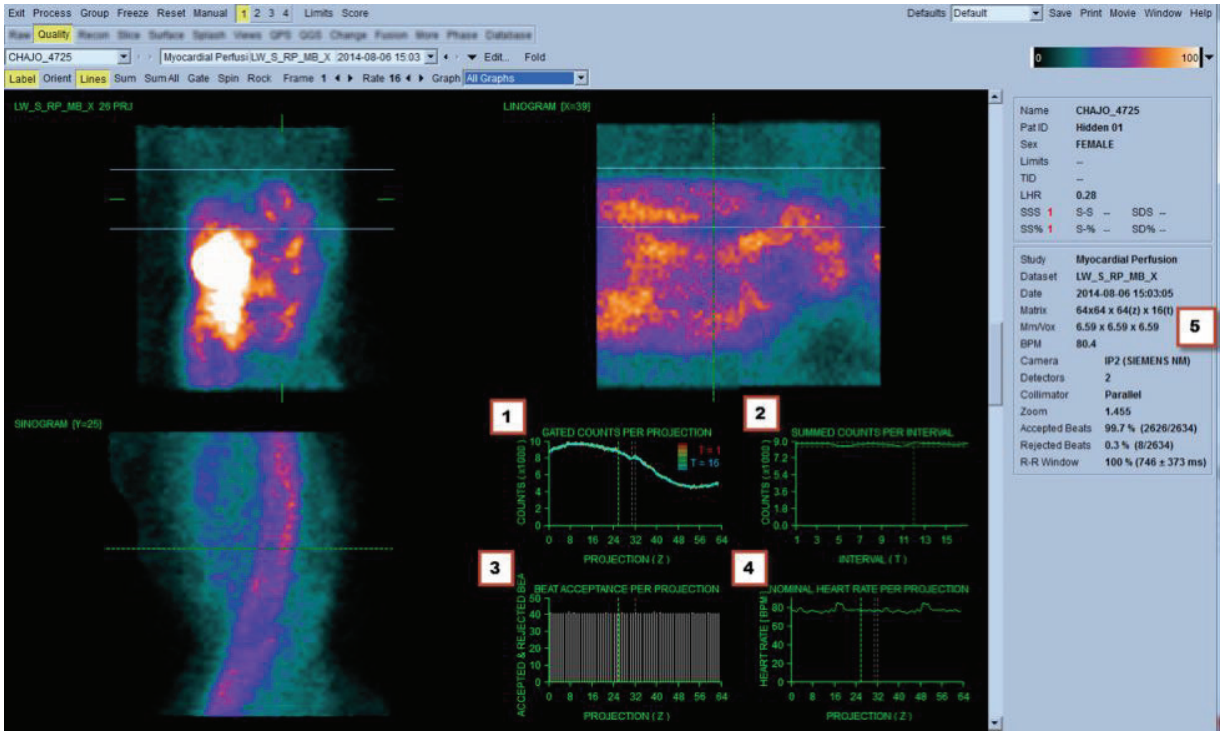


4.4 Assessing image quality

The quality page displays projection images and contains several quality-control tools to help users identify potential problems (e.g., motion artifacts, poor count density, gating errors, etc…) to assess the overall quality of the loaded study. The QC information will only be available on the **Quality** page if it is included in the dataset headers by the vendor.

In addition to the raw projection images, sinograms and linograms, the quality page can also display:

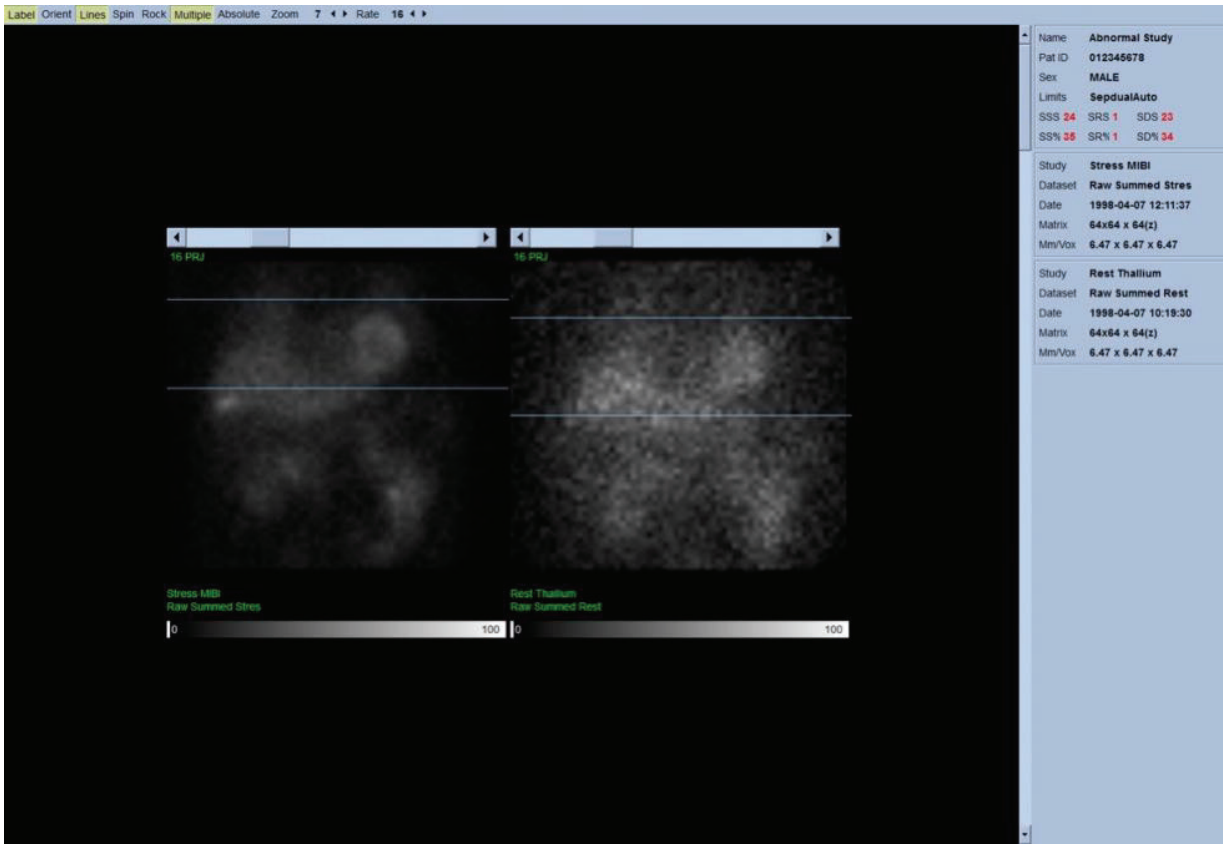
1. Gated counts per projection
2. Summed counts per gating interval
3. Accepted/rejected beats
4. Nominal heart rate per projection
5. Additional information – average heart rate, camera, collimator, zoom, accepted/rejected beats percentage and R-R window.



4.5 Reviewing the Rotating Projection Images

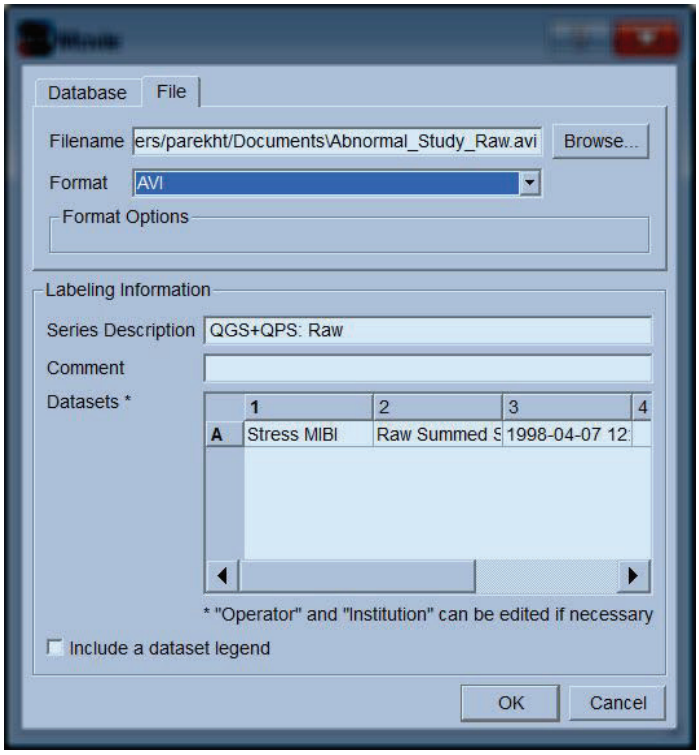
Clicking **Lines** toggle brings up two horizontal lines that should be manually positioned so that they tightly straddle the LV shown below. A continuous loop cine display of the projection data sets can then be started by clicking **Spin** (0 to 360 degrees continuous rotation). Clicking **Rock** toggle (in addition to the **Spin** toggle) will display an alternating cine (0 to 180 degrees and 180 to 0 degrees rotation). The cine speed can be adjusted by clicking the ◄ ► symbols on the right side of the **Rate** label. Any sudden movement of the LV's perceived boundaries towards or away from the lines should be noted, as should a uniform upward drift (upward creep of the heart, often associated with the diaphragm's return to its normal position soon after exercise). With dual detector cameras in the 90 degree configuration, upward creep may produce a sudden "jump" in correspondence of the middle of the projection data set, as can detector

misalignment. Major motion may affect the quantitative parameters; if such motion is detected, it would be prudent to repeat the acquisition.



In addition to patient or organ motion, flickering (sudden variations in brightness between adjacent projections) can be assessed by reviewing the projections cine. Flickering is often an indication of gating errors, which are reflected in the ungated projection images when the latter are built through summation of the gated projection datasets.

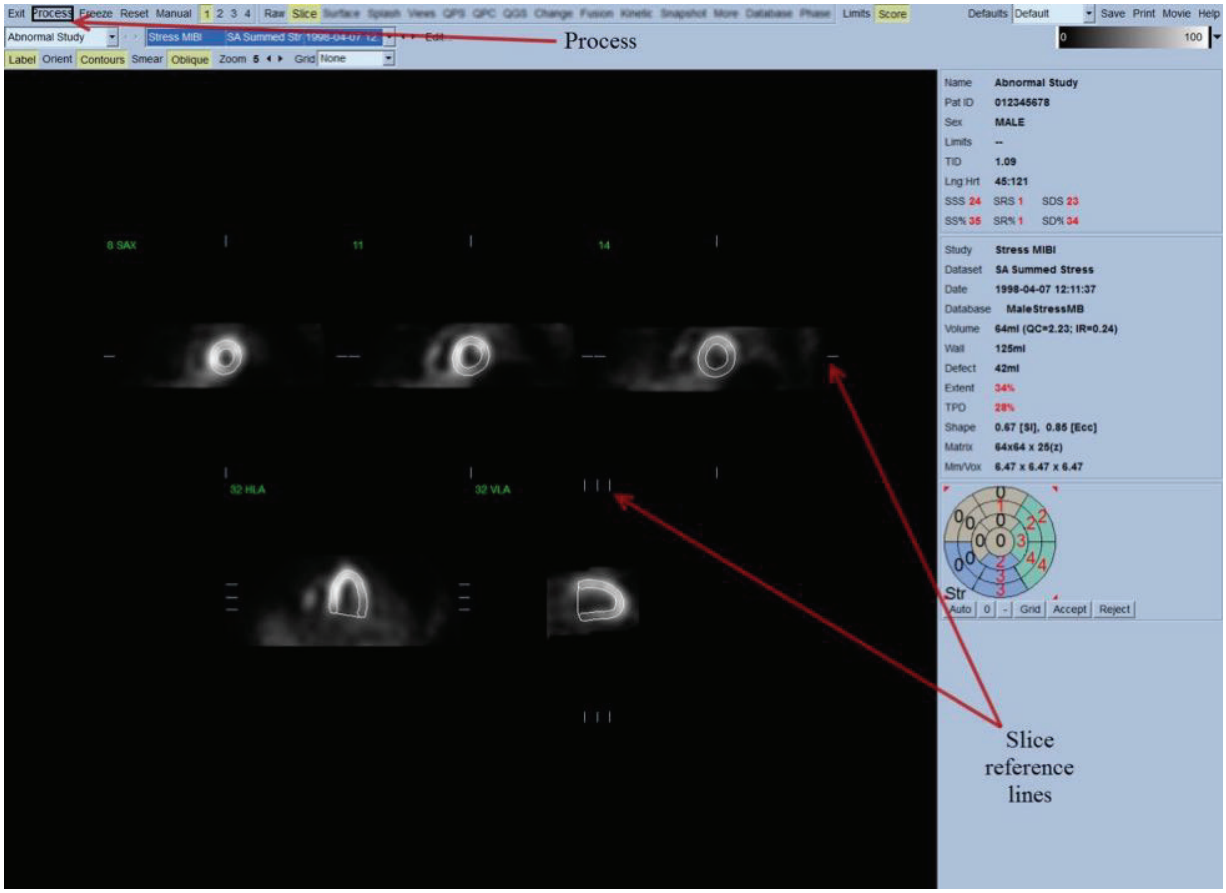
To generate a “movie” file of the raw data, click on the **Movie** button located on the global bar at the top right of the page to bring up the “movie” dialog box. Under the **File** tab page enter an appropriate path and file name for the newly created movie (AVI) file. Click **OK**.



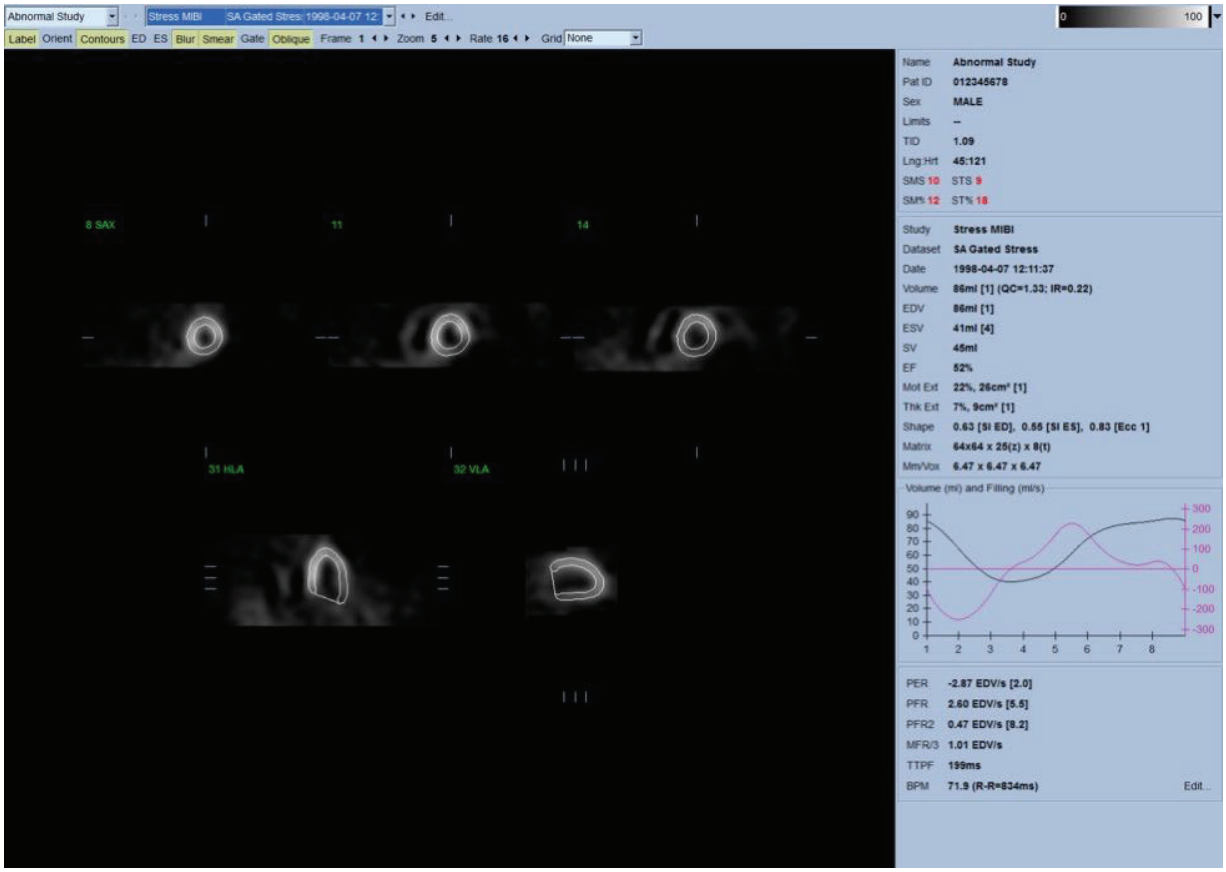
4.6 Processing the images

Clicking on the **Slice** page indicator will highlight it and advance QGS+QPS to the **Slice** page view shown below. As a result, the SA Stress Gated data set or the Short Axis (SA) data set will be automatically selected and displayed. Five 2D images or “slices” are presented in standard ACC orientation, i.e., left to right = apex to base for three short axis images (top row), with the bottom row consisting of a horizontal and a vertical long axis image.

Clicking the **Process** button will automatically apply the applicable algorithms to the data, segmenting the LV, calculating the endocardial and epicardial 3D surfaces and the valve plane, and determining all the global and regional quantitative cardiac parameters. The intersection of the 3D surfaces and the valve plane in the 2D slices planes are displayed as “contours” overlaid onto the five slices, which are now representative of equally spaced (short axis images) or mid-ventricular (long axis images) portions of the LV.



Moreover, all quantitative parameter fields in the right portion of the screen should now be filled with numeric values, in addition to the creation of time-volume and filling curves (for gated short axis datasets). We'll examine and discuss the quantitative measurements in more detail later.

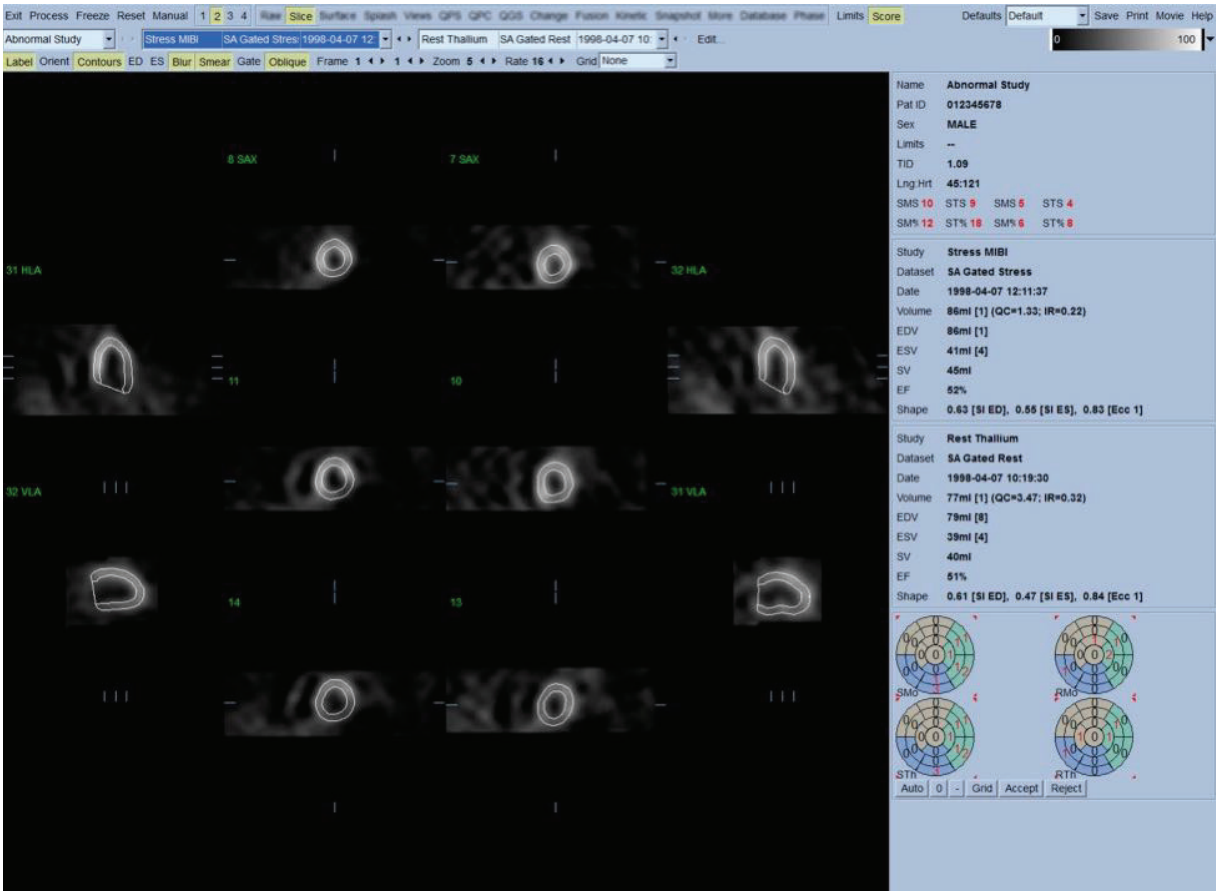


4.6.1 Group Processing

Group processing allows for simultaneously solving left ventricular geometry for all of the available datasets. It allows the algorithms, in regions where structure cannot be definitively determined for one or more of the datasets, to make decisions that exploit all the available information and that do not introduce arbitrary inter-study inconsistencies. When **Group** is ON, datasets belonging to the same patient are processed as a "pair" (or, if more than two studies are involved, as a "group").

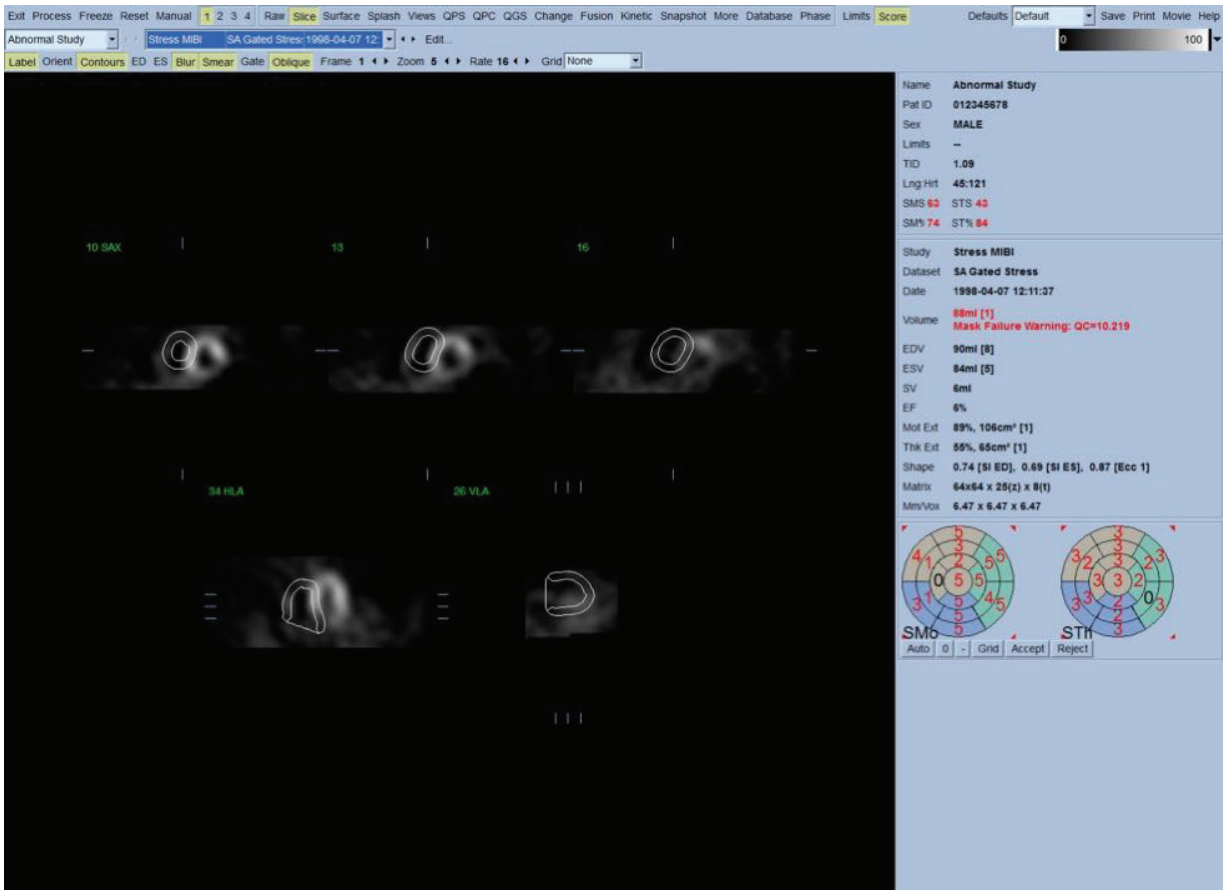
4.6.2 Checking the contours

The location of the five slices displayed can be interactively adjusted by moving their corresponding slice reference lines in orthogonal views; however, in most patient studies this will not be necessary. Both the stress and the rest short axis datasets can be visualized by clicking the **2** (dual) buttons, which also splits the display in two as shown below. The stress images are displayed on the left half and the rest images on the right half of the display.



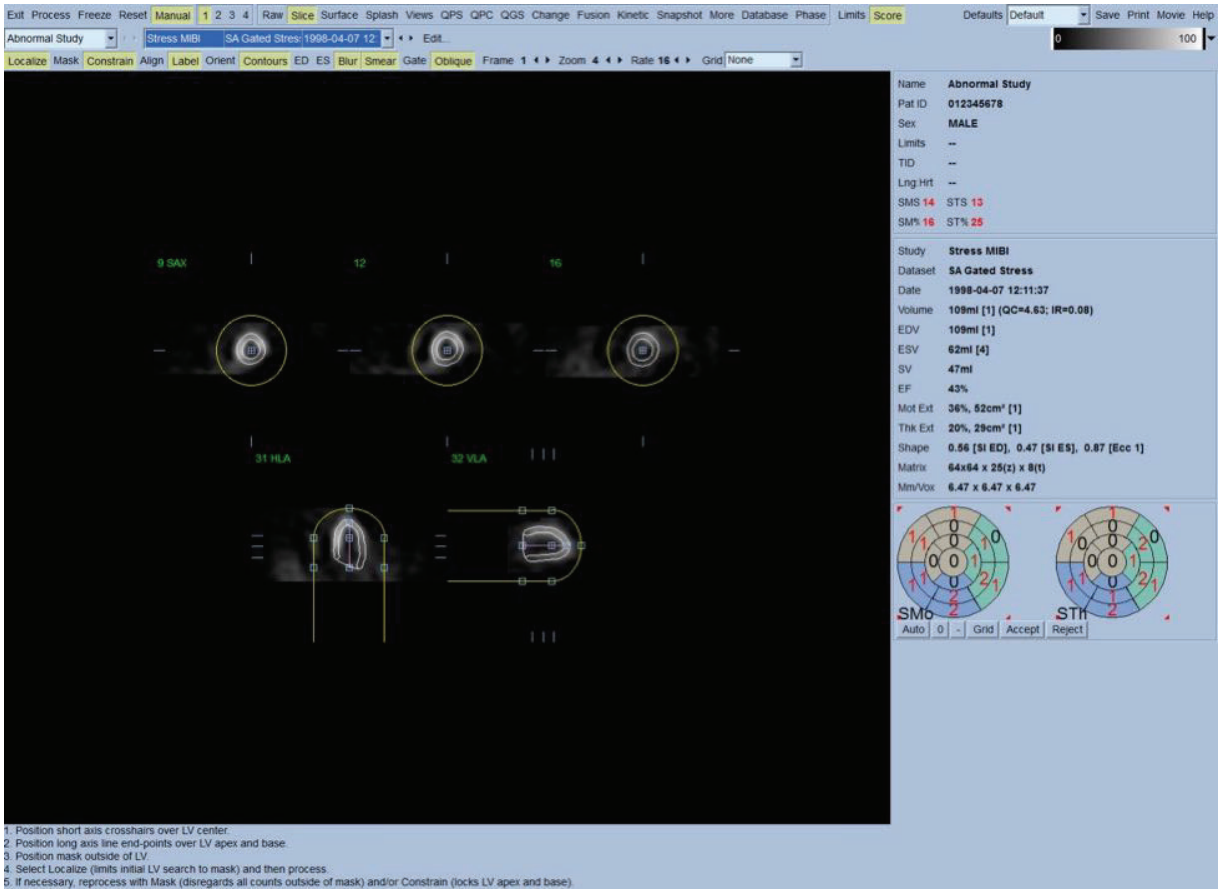
At this point, a visual check for obvious inaccuracies in the way the contours follow the LV must be performed. This will likely involve clicking the **Contours** toggle on and off, and possibly setting the images in motion (cine) by clicking the **Gate** toggle. Most major inaccuracies are due to the presence of extra cardiac activity, and will be immediately apparent from the display as seen below. In particular, one would expect to see the contours centered on a structure other than the LV, or see the contours "pulled away" from the LV to follow closely adjacent activity, especially in the inferior wall region. Both of these occurrences are extremely infrequent (0-5% in the published literature), and can be readily dealt with using the "Manual" option.

CAUTION: If a failure rate higher than 10% consistently occurs, there may be a systematic problem with the way the data is acquired, patient positioning (too high/too low) or other errors.



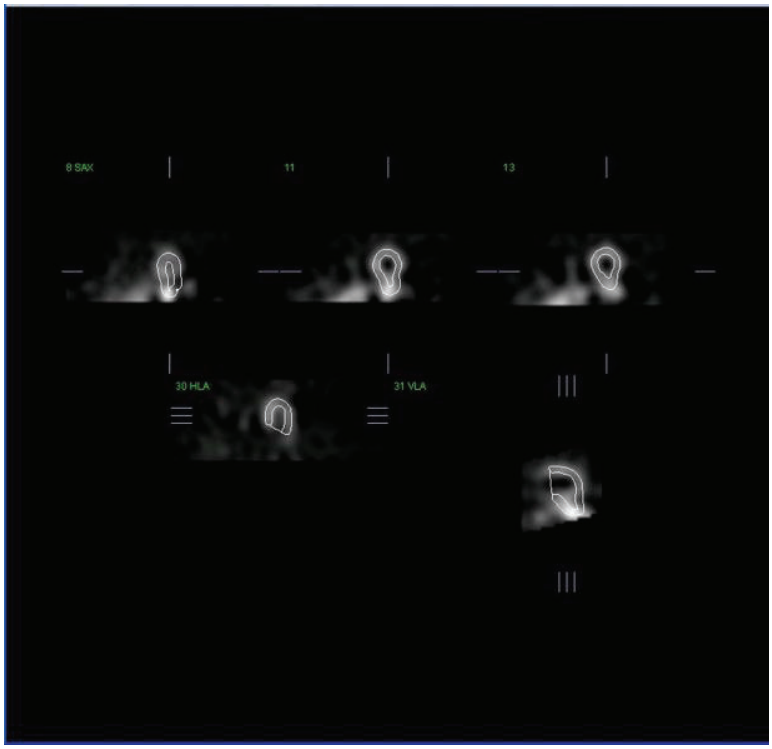
4.7 Modifying the Contours (Manual Page)

Clicking the **Manual** toggle will bring up a modified version of the Slice page, with masking graphics superimposed upon the slices. It is possible to modify the shape and position of the masking graphics by left-clicking and dragging the masking graphic handles, small squares placed at various points on the masking graphics shown below. The mask should be shaped and positioned so that it encompasses the LV and excludes all extra cardiac activity. Before doing so, it may be advisable to toggle the incorrect contours off by clicking the **Contours** button. Clicking the **Mask** toggle and clicking the **Process** button will force the automatic algorithm to operate on the portion of the 3D image inside the mask, and new contours plus new quantitative measurements will be generated and displayed.



Note that the segment positioned on the LV's long axis serves only as a reference. In cases where simple masking has not produced satisfactory contours as show below, one has the option of setting two exact locations through which the apical and basal portion of the contours must pass; this is done by clicking the **Constrain** toggle to highlight it, then clicking again on the **Process** button.

CAUTION: The "Constrain" option should not be used unless absolutely necessary, as it can greatly affect the reproducibility of the quantitative measurements. Please make sure the Constrain button is NOT highlighted when starting the masking process in the Manual page. One instance in which Constrain is used is when the valve plane is incorrectly identified and the stress and/or rest contours clearly exceed its location. This will typically result in a "ring" of artifactual hypoperfusion at the periphery of the perfusion polar map(s), not associated with a standard coronary territory.



4.8 Reviewing Gated SPECT images on the Slice page

An initial visual assessment of LV function can be performed by left-clicking the Gate toggle to display cine of the five slices while clicking the **Contours** toggle on and off. The cine speed can be adjusted by clicking the ◄ ► symbols on the right side of **Rate**. Moreover, a temporal and a spatial smoothing filter can be applied to the images by left-clicking the **Blur** and **Smear** toggles, respectively. This is especially useful to reduce statistical noise in low-counts images for visual assessment, and it will not affect the quantitative results.

NOTE: The "Blur" and "Smear" functions only affect image display. The QGS algorithms operate on the original, unsmoothed data regardless of Blur and Smear settings.

NOTE: At Cedars-Sinai Medical Center (CSMC), a gray or thermal scale is typically used to assess motion, and a 10-point scale (Step10) is used to assess thickening. A comprehensive description of the CSMC segmental scoring method can be found in "*Berman D, Germano G. An approach to the interpretation and reporting of gated myocardial perfusion SPECT. In: G Germano and D Berman, eds. Clinical gated cardiac SPECT. Futura Publishing Company, Armonk; 1999:147-182*." Essentially, images are scored based on a

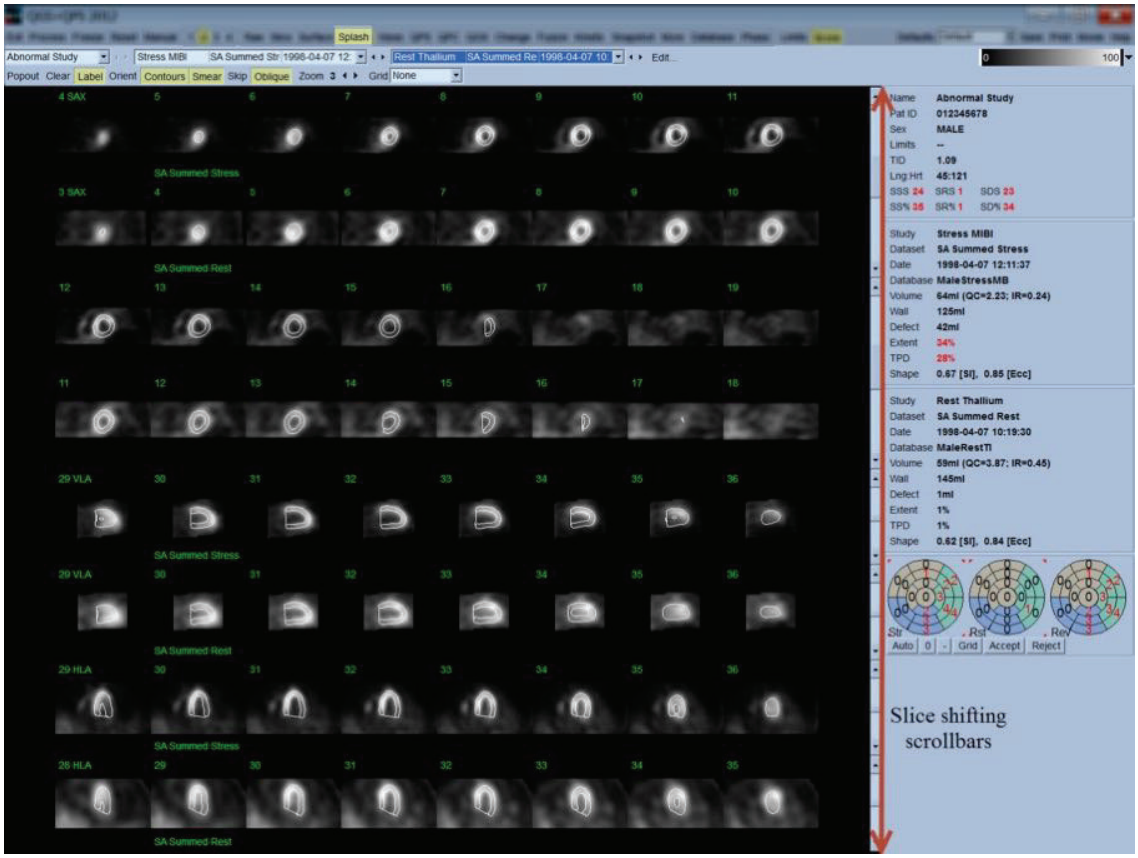
20 or 17 segment model and a categorical scale of 0-5 (motion) or 0-3 (thickening).

4.9 Reviewing Gated or Summed SPECT Images on the Splash page

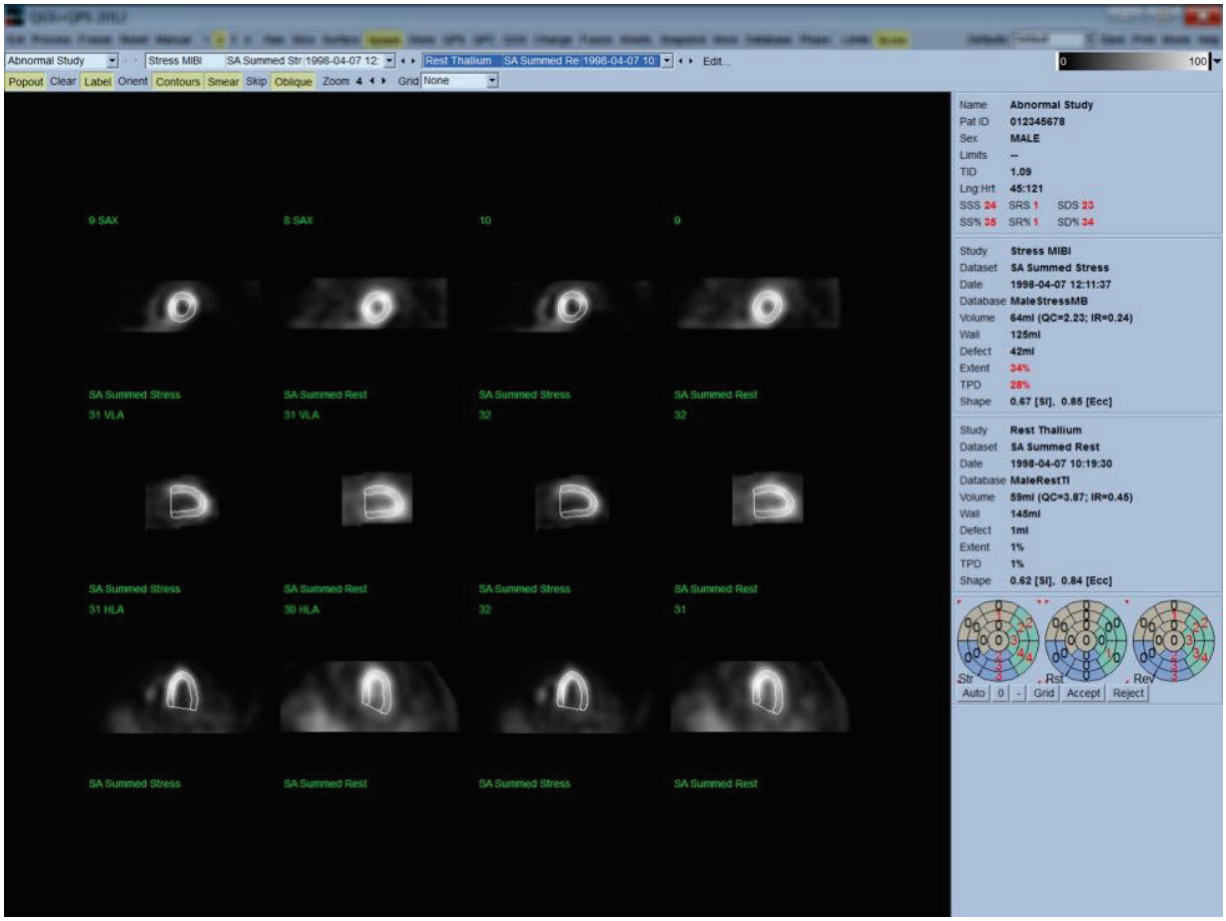
Although the **Slice** page can be useful to make a quick initial determination of the presence and location of perfusion abnormalities, accurate perfusion assessment must precede from the entire short axis datasets. Clicking on the **Splash** page indicator will bring up all the available short axis images, which (if the **2** button is on) will be displayed in interleaved fashion for the stress and the rest studies as show below. In essence, the first dataset to appear in the **Info** box will correspond to rows 1, 3, 5 and 7 of the display, the second dataset to rows 2, 4, 6 and 8. Stress and rest images are automatically chosen, and ought to be well aligned; to manual shifting of a dataset by one or more slice(s) can be achieved by clicking and dragging the appropriate scrollbars to the right of the images. Images (gated only) can be viewed simultaneously as cine by clicking the **Gate** toggle.

A spatial smoothing filter can be applied to the images by turning on the **Smear** toggle on the page control bar. This is especially useful to reduce statistical noise in low-counts images for visual assessment, and it will not affect the quantitative results.

Clicking on the dataset selector on the **Splash** page will bring up all the available short axis images. A spatial and/or temporal smoothing filter can be applied to the images by clicking the **Smear** and **Blur** (gated datasets only) toggles respectively. This is especially useful to reduce statistical noise in low-counts images for visual assessment, and it will not affect the quantitative results.



Optionally, key slices may be “blown up” for further review. This is achieved by right-clicking on the desired images to select/deselect them (the corners of the selected items are highlighted in blue), then left-clicking on the **Popout** toggle on the page control bar. To de-select all the selected slices click **Clear**. The images below show four short axis, horizontal and vertical long axis images for each of the stress and rest data sets that can be displayed using the **Popout** toggle in the **Splash** page.



NOTE: At Cedars-Sinai Medical Center (CSMC), a gray or thermal scale is typically used to assess perfusion. A comprehensive description of the CSMC segmental scoring method can be found in "*Berman D, Germano G. An approach to the interpretation and reporting of gated myocardial perfusion SPECT. In: G Germano and D Berman, eds. Clinical gated cardiac SPECT. Futura Publishing Company, Armonk; 1999:147-182.*". Essentially, images are scored based on a 20 or 17 segment model and a categorical scale of 0-4 (0=normal to 4=absent perfusion).

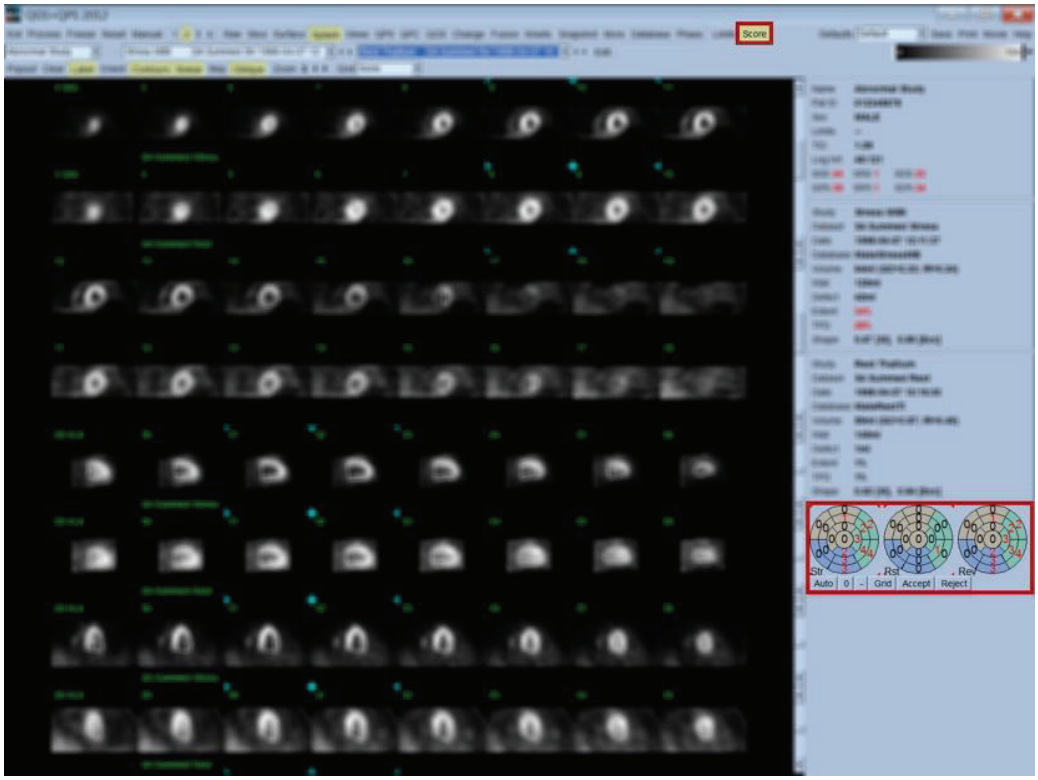
4.9.1 Using the Score Box

Clicking on the **Score** toggle will bring up the **Score Box** with its 20-segment or 17-segment polar maps with segment demarcation outlines for the stress, rest and difference portion of the study, shown below is a 20 segment score example. Each ring in these "categorical polar maps" is related to the displayed images as follows: apex to base = inner to outer rings.

The display scheme aims at making it easier for the physician to identify the 20 (or 17) segments for which perfusion must be scored. Selecting the **Segments** option from the **Grid**

pull-down menu on the page control bar will overlay demarcations onto the stress and rest images, clarifying which portion of which slice belongs to which segment. Alternating between the **Segments** and **None** options of the **Grid** pull-down menu facilitates the visual assessment of segmental scores, which can then be entered in the Score box to override automatic scoring, if so desired.

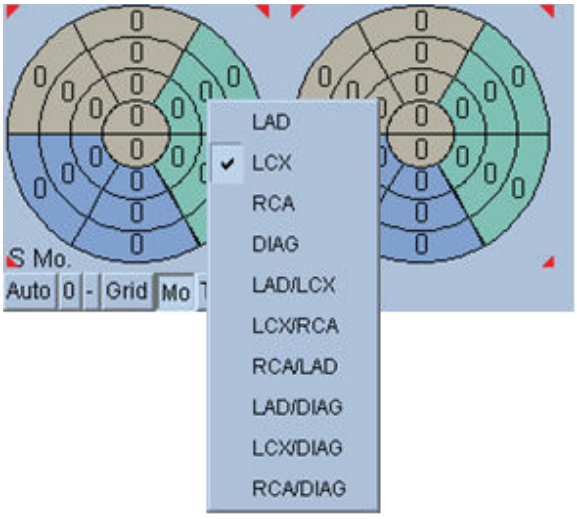
A universal set of normal limits is applied to all gated short axis datasets to automatically calculate motion and thickening scores for all segments, as well as the summed motion and thickening scores (SMS and STS), the percent summed motion and thickening scores (SM% and ST%) and the extent of motion and thickening abnormality (Mot Ext and Th Ext) expressed both as area in cm^2, and as a percent of the mid-myocardial surface area. If any of the segmental scores is deemed inaccurate by the reviewing clinician, he/she can increase it or decrease it by left or right clicking on its numeric value in the box. SMS, STS, SM% and ST% will adjust automatically.



If the appropriate normal limits are preset for this patient, the program will automatically calculate perfusion scores for all segments, as well as the summed stress, rest and difference scores (SSS, SRS and SDS) and the corresponding summed percent scores (SS%, SR% and SD%) and the extent of perfusion abnormality. Otherwise, the normal limits database to apply to the dataset will have to be selected by clicking on the **Edit…** button, located next to the dataset selector, and selecting the appropriate limits file from the dropdown menu. The user selects

one of the displayed normal limits selections in the dialog window and clicks **OK**. If any of the segmental scores is deemed inaccurate by the reviewing clinician, he/she can increase it or decrease it by left or right clicking on its numeric value on the respective score polar map. SSS, SRS, SDS, SS%, SR%, and SD% will adjust automatically.

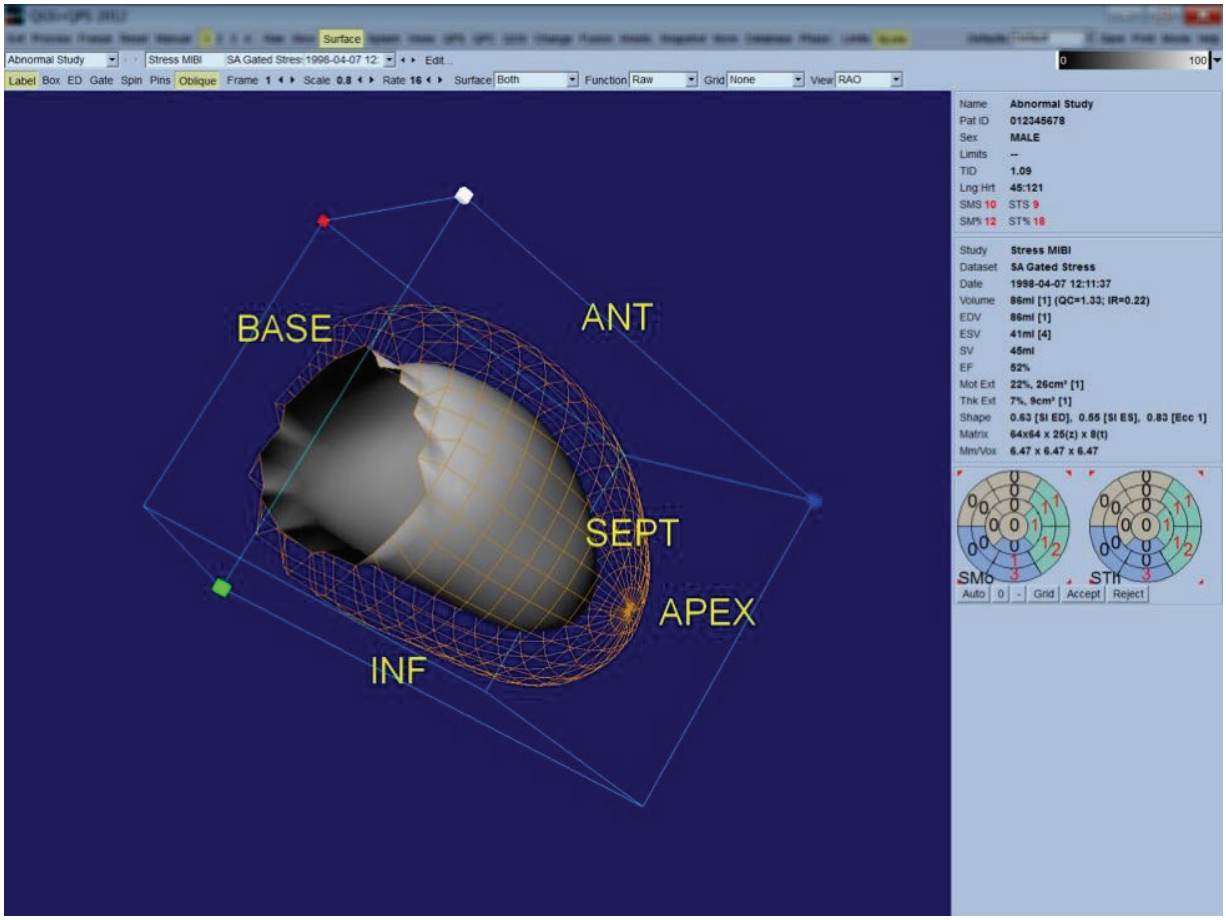
NOTE: The summed percent scores represent the summed scores normalized to the worst possible score obtainable in the model chosen (i.e., 80 for the 5-point, 20-segment model and 68 for the 5-point, 17-segment model), as described in Berman et al., JACC 2003;41(6):445A.



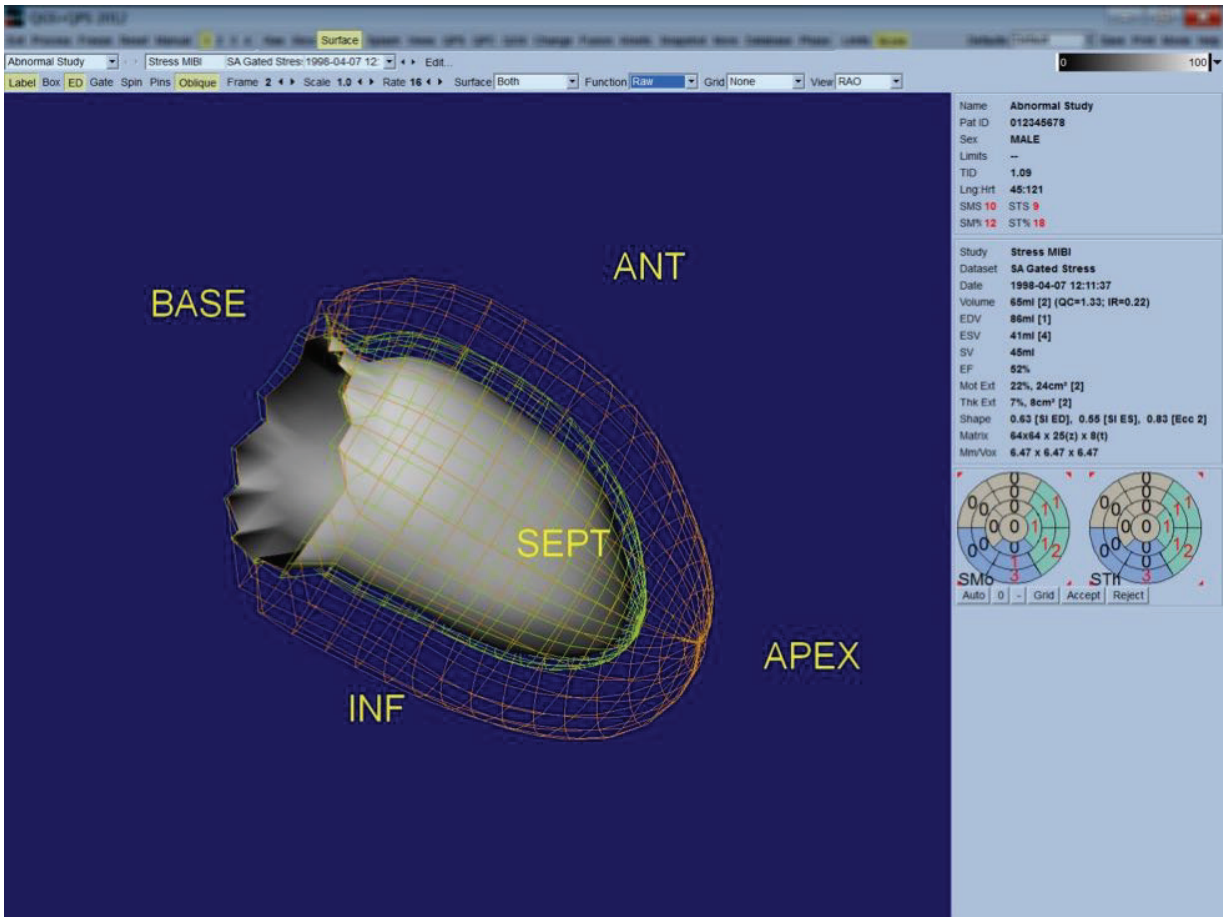
Scoring is further enhanced by the color coding of segments based on the coronary vessels supplying that segment. The Tan colored segments are assigned to the LAD, Green to the LCX, and Blue to the RCA. By default, the application will attempt to choose the coronary vessel based on the visual scores. This can be overwritten by right-clicking on a segment and selecting the appropriate vessel from the list of vessels. In some cases it is unclear to which vessel the defect belongs. When this occurs, select the abnormal segment in question and choose a combination of vessels. The **Auto** button will load the automatically generated scores.

4.10 Reviewing SPECT Images in the Surface Page

Clicking on the **Surface** page indicator will bring up the Surface page shown below, a parametric representation of the LV, consisting of a wireframe surface (epicardium) and a shaded surface (endocardium). This type of display is not as useful for perfusion as it is for gated SPECT data, but can nevertheless aid in assessing LV size and shape. Clicking **Gate** allows cine display to follow the 3D endocardium and epicardium movement throughout the cardiac cycle, while clicking and dragging on the image will interactively and in real time position it to the observer's liking.



While myocardial thickening can be conceivably assessed from the epi-/endocardial display, it is easier to assess motion from a display containing the endocardium as well as its position at end-diastole. This is achieved by selecting the **Inner** option from the Surface pull-down menu, and clicking **ED** on the page control bar to highlight it. With this type of display and **Gate** toggle on, a good proxy for regional motion is how well the endocardium pulls away from its fixed position at end-diastole. It is a good idea to display all three surfaces by selecting **Both** in the Surface pull-down menu.

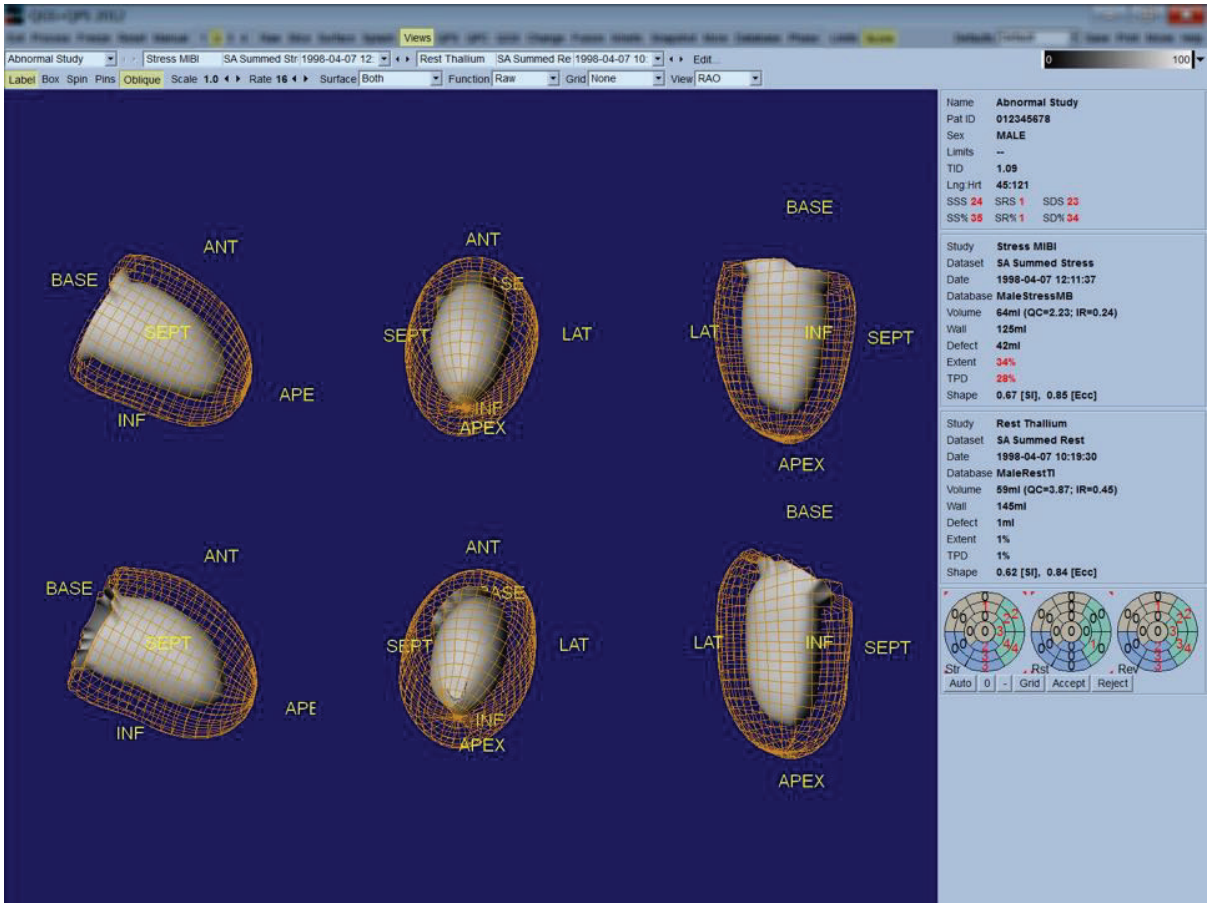


For function evaluation, the endocardial surface does not have counts mapped onto it, because it would make it harder to evaluate regional function in patients with large perfusion defects. If one wants to visualize the evolution of perfusion during the cardiac cycle, selecting the **Counts** option from the Surface pull-down menu will display the mid-myocardial surface with maximal counts mapped onto it.

Similarly, for perfusion evaluation, the endocardial surface does not have counts mapped onto it, because it would make it harder to evaluate LV size and shape in patients with large perfusion defects. If one wants to visualize 3D perfusion, selecting the Function option from the Surface pull-down menu will display the mid-myocardial surface with maximal counts mapped onto it.

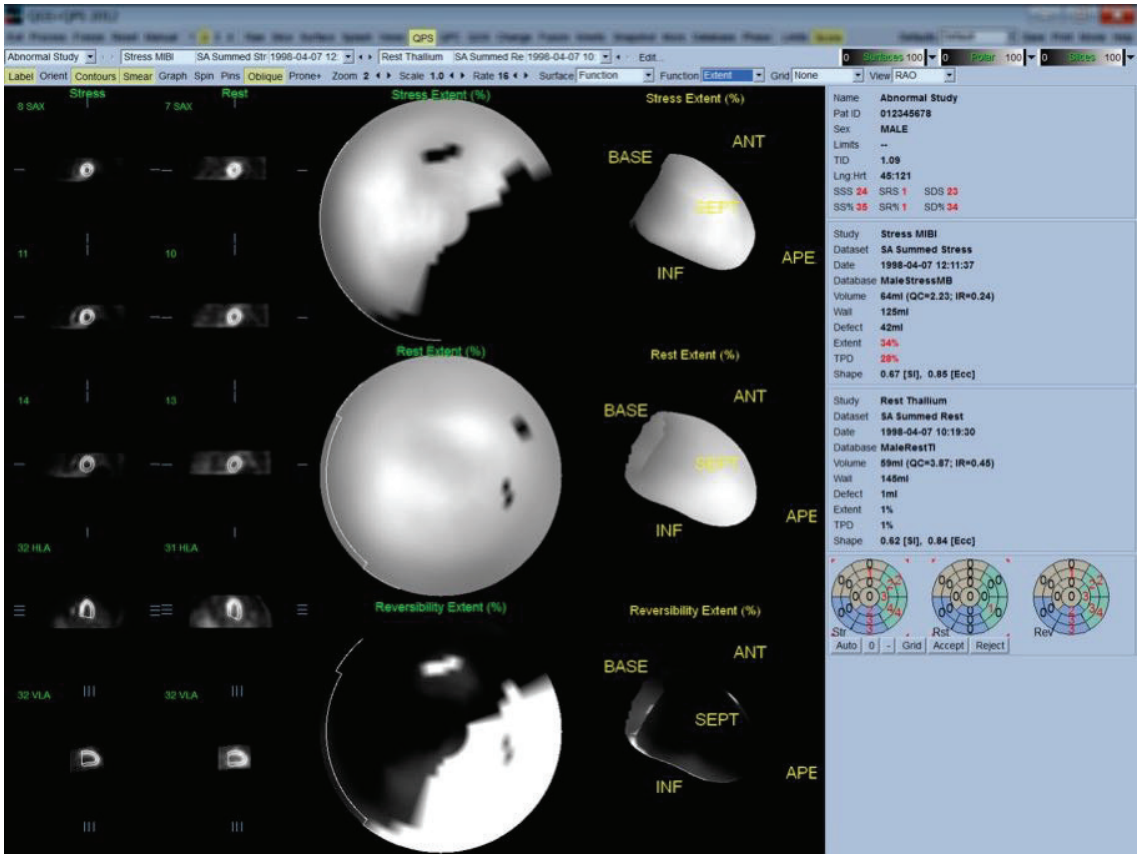
4.11 Reviewing gated SPECT images on the Views page

Clicking on the **Views** page indicator will bring up the Views page shown below, with six 3D viewports very similar to that in the Surface page. The main purpose of this page is to allow full coverage of the LV (albeit with smaller images compared to the one in the Surface page), and to facilitate comparison of stress and rest images by manipulating them in lockstep through left-clicking and dragging. Again, selecting the **Function** option from the **Surface** pull-down menu is recommended if perfusion needs to be assessed. For gated SA datasets the top row represents the end-diastolic views of the RAO, LAO and inferior orientations. The bottom row represents the same views and surfaces at end-systole. The images can be viewed as a cine display of the cardiac cycle by clicking the **Gate** toggle. If more than one dataset is selected, three orientations per dataset will be displayed and cined, with each column of images manipulable in lockstep by left-clicking and dragging.



4.12 Putting it All Together: the QPS Results Page

Clicking the **QPS** button in will bring up the QPS Results page, which aims at presenting, in synthetic format, all information related to the perfusion SPECT study for the patient. When available, two datasets are always displayed on the Results page (**1**, **3**, and **4** display options are inactive). Clicking the **Score** toggle will replace the score box with either a table showing the amount of stress and rest defect extent and TPD as well as defect reversibility (**Graph** toggle off), or a bar graph showing percent stress defect extent and reversibility (**Graph** toggle on). If a screen capture is taken of this page with the **Contours** toggle off, the **Smear** toggle on and the **Extent** option selected from the **Function** pull-down menu, it would represent a good image to send the referring physician. The following rule is applied to all pixel based scores (TPD, extent and defect) and segment based scores (visual scores): whenever rest scores contain values that are higher on rest than on stress (when comparing stress/rest pair pixel by pixel or segment by segment); in these situations the rest segment or pixel will be assigned the stress score values.



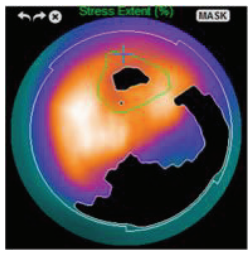
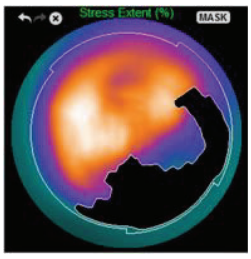
4.12.1 Assessing the Polar Maps

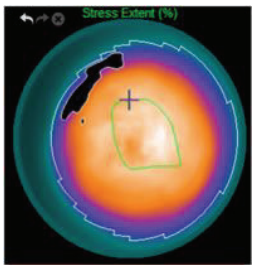
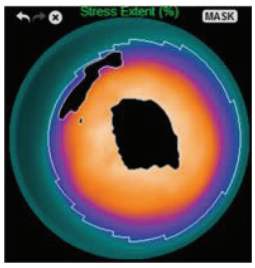
The results page provides three perfusion polar maps and three 3D parametric surfaces (stress, rest and reversibility). The **Function** pull-down menu contains the options **Raw**, **Severity**, and **Extent**, all of which apply to both 2D and 3D displays. A grid of 20 or 17 segments (**Segments**), 3

vascular territories (**Vessels**) or 5 regions (**Walls**) can be overlaid onto all polar maps and surfaces from the **Grid** pull-down menu. For polar maps, the numbers associated with the overlay represent the average value of the parameter measured by each map within the segment, territory or region in which they lie. Both stress and rest perfusion values are normalized to 100.

4.12.2 Smart defect editor

Smart defect editor can be used to manually edit the extent polar maps. The tool allows users to add, remove or modify defects. Manual edits will also affect the quantitative results such as defect, extent, TPD, segmental visual scores and summed scores. To use the defect editor, click on the **Mask** toggle on the **QPS** page. Abnormal areas can be made normal by holding down the left mouse button and drawing a region around the abnormal pixels. Similarly, normal areas can be made abnormal by holding down the right mouse button and drawing a region.

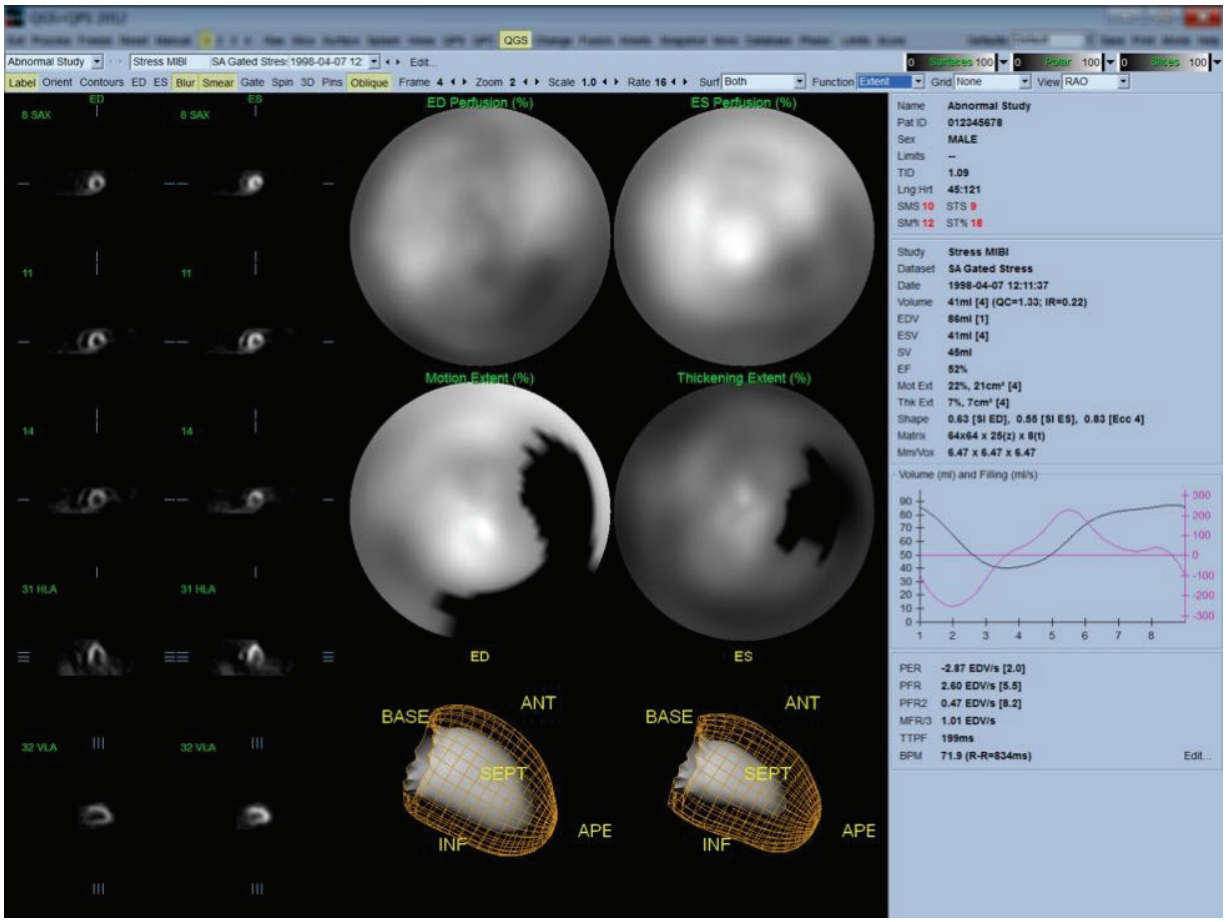
Marking an abnormal area as normal	
	
BEFORE Using the left mouse button, ROI manually drawn around defect in the anterior wall	AFTER Defect encompassed by the ROI is now considered normal

Marking a normal area as abnormal	
	
BEFORE Using the right mouse button, ROI manually drawn in the apical wall	AFTER Area encompassed by the ROI is now considered abnormal

4.13 Putting it all together: the QGS Results page

Clicking the **QGS** button will bring up the QGS Results page shown below, which aims at presenting, in synthetic format, all information related to the gated SPECT study in this patient. QGS Results page only supports single dataset mode (the **2**, **3** and **4** display mode buttons are inactive). Both the end-diastolic and end-systolic representative short axis slices and 3-D surfaces will be displayed and the latter can be cined by clicking **Gate**. Clicking the **Score** toggle off will replace the score box with a graph showing the time-volume curve (in black) and its derivative (filling curve), from which diastolic parameters are computed. The time-volume curve should be used to evaluate the existence of gating errors. If a screen capture is taken of this page with the **Contours** toggle off, the **Blur** and **Smear** toggles on and the **Extent** option

selected from the **Function** pull-down menu, it would represent a good image to send the referring physician.

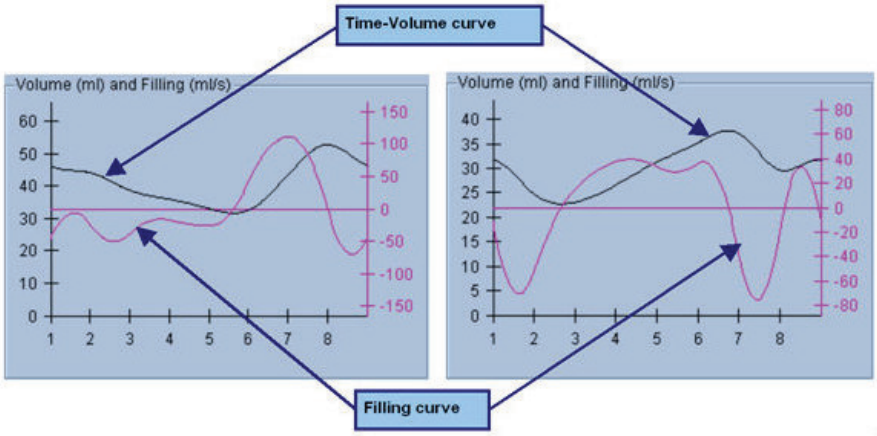


4.13.1 Assessing the time-volume curve

A valid time-volume curve would be expected to have its minimum (end-systole) at frame 3 or 4, and its maximum (end-diastole) at frame 1 or 8 of a 8-frame gated acquisition. For a 16-frame gated acquisition, the minimum (end-systole) would be expected to be at frame 7 or 8 and its maximum (end-diastole) at frame 1 or 16. If major deviations from this expected behavior occur, the prudent assumption is that the gating was unsuccessful and the study needs to be repeated. Two examples of invalid time-volume curves are shown below.

It should be noted that any errors in the time-volume curve (gating errors) will be propagated to the filling curve, since the filling curve is the first derivative of the time-volume curve.

NOTE: In the time-volume curve graph, the volumetric value for interval 1 is also “appended” to the curve after interval 8 or 16, respectively, for 8-frame and 16-frame gated acquisitions.



4.13.2 Assessing the Polar Maps

The QGS Results page provides two perfusion polar maps (at end-diastole and end-systole) and two function polar maps (regional motion and thickening). The **Function** pull-down menu contains the options **Raw**, **Extent** and **Severity**, all of which apply only to the function polar maps. Of those, only **Raw** is meaningful in the absence of motion/thickening normal limits. A grid of 20 or 17 segments (**Segments**), 3 vascular territories (**Vessels**) or 4 regions (**Walls**) can be overlaid onto all polar maps from the **Grid** pull-down menu: in every case, the numbers associated with the overlay represent the average value of the parameter measured by each map within the segment, territory or region in which they lie.

Mapping of the endocardial motion in the motion polar map follows a linear model from 0 mm to 10 mm. Motion greater than 10 mm is assumed to be = 10 mm (the scale "saturates" at 10 mm), while motion <0 mm (dyskinesia) is assumed to be = 0 mm. Likewise, thickening greater than 100% is assumed to be = 100% (the scale "saturates" at 100%), while thickening <0% (paradoxical thinning) is assumed to be = 0% in the thickening polar map. Unlike the motion map, which is "absolute" (millimeters), the thickening map is "relative" (thickness increase from end-diastole to end-systole).

CAUTION: While the presence of perfusion defects can be reasonably well assessed by “eyeballing” the perfusion polar maps, the same is not true of the motion and thickening maps! Indeed, it is well known that, even in normal patients, the septum typically moves less than the lateral wall (resulting in a “dark” area in the motion map), and the apex thickens more than the base (resulting in the “egg sunny-side-up” look of the thickening map). Function polar maps are best assessed by choosing the Extent option in the Function pull-down menu, which will black-out abnormal areas.

4.13.3 Pixel (Voxel) Size

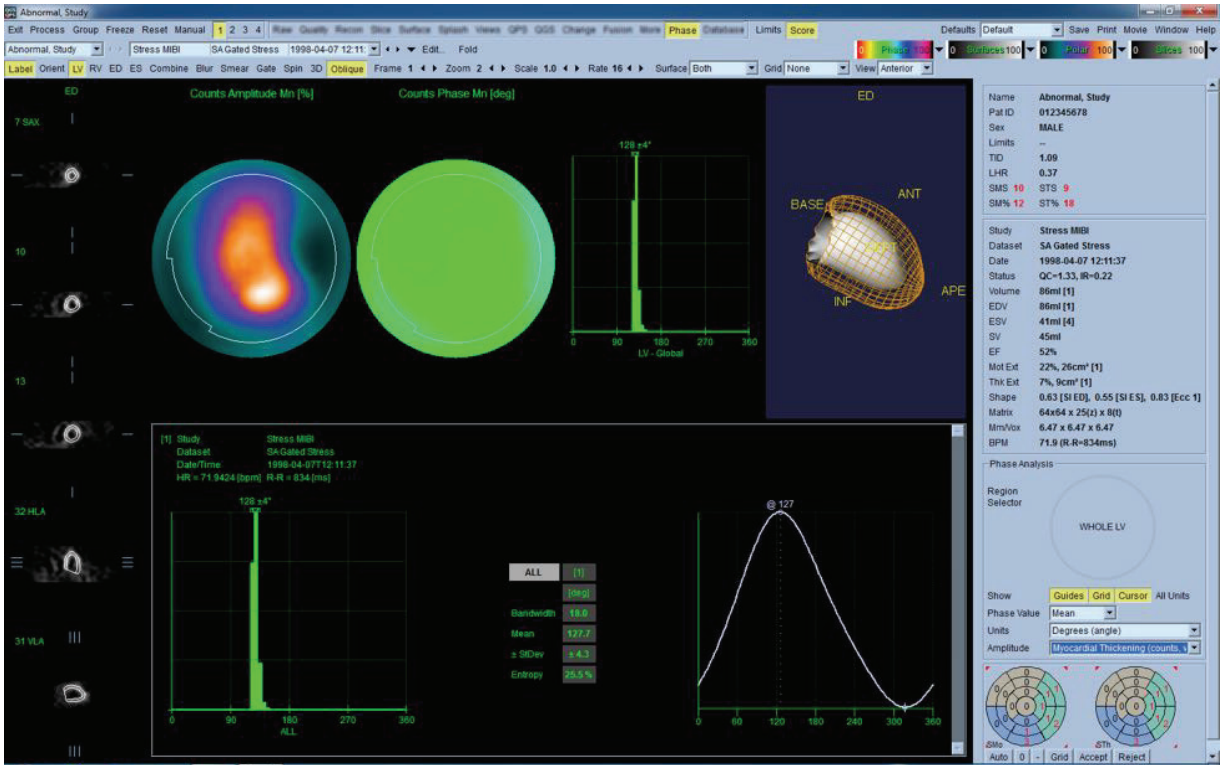
Area and volume measurements can be hampered by incorrect listing of the pixel size in the image header. This is usually not a problem with the LVEF, which is derived from a ratio of volumes. Similarly, perfusion measurements such as the absolute area of perfusion defects (but not the measurements of defects area as a percent of that of the LV!) can be hampered by incorrect listing of the pixel size in the image. Pixel size is usually automatically calculated by modern cameras, based on knowledge of field of view and zoom information. However, older cameras or "hybrid" systems (where one manufacturer's camera is interfaced to another manufacturer's computer) may not be set up to transfer pixel size information from the gantry, or may take a "standard" size (i.e., 1 cm) as default. In these cases, a correction factor should be manually calculated by imaging a known pattern (for example, two line sources separated by an exact distance), and counting the number of pixels between the lines' centroids in the reconstructed transaxial image. Key portions of an image header (including the pixel or voxel dimensions) can be viewed by selecting the **More** page.

CAUTION: One should be particularly wary of pixel sizes listed in the More page as integer numbers (0 and 1 being frequent occurrences), since they often indicate a transfer problem.

4.14 Phase Analysis

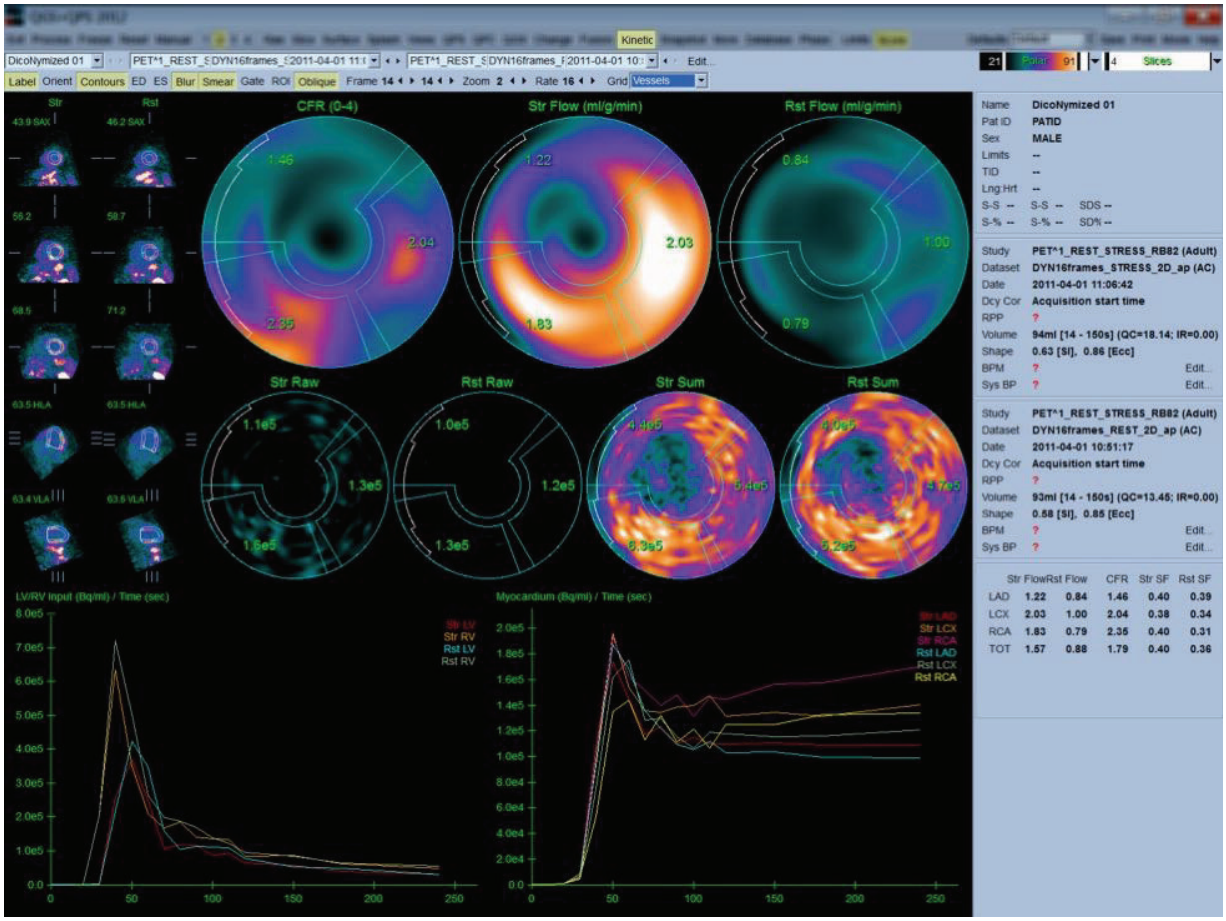
To view global and regional phase information for gated studies, click the **Phase** page button. Global statistics will be displayed if the **Grid** toolbar setting is set to **None**. If a grid such as **Vessels** (shown below) is selected, statistics are shown for each region. Use the **Combine** toolbar toggle to switch between separate and combined phase and amplitude polar maps or parametric surfaces. The additional controls made available in the info box (right side of the application) control display options such as a real-time graph cursor or display units, and the polar map toggle allows the regional display to be restricted to certain regions only. In 2 dataset mode the time-activity curves are hidden to make room for another set of histograms, and in 3 or 4 dataset mode the regional displays are hidden completely. Please refer to the ***Reference Manual*** for additional information.

NOTE: Phase analysis algorithm in version 2015 and newer was modified in order to exclude basal count variations that do not correspond to actual myocardial thickening but instead are caused by valve plane motion between diastole and systole.



4.15 Kinetic Analysis - Coronary Flow Reserve

The Kinetic analysis feature for dynamic PET and SPECT studies allows for automated quantification of absolute stress and rest blood flow within the myocardium using algorithms specifically developed for PET Rb and NH3 and SPECT Tc99m based tracers. It also allows for non-invasive determination of absolute coronary flow reserve (CFR). The kinetic modeling method for Rb-82 is the 1-tissue compartment model (Lortie et al., EJNM 34:1765-1774, 2007). Whereas the kinetic modeling method for Nitrogen-13 ammonia uses simplified 2-compartment model (Choi et al., JNM 34(3):488-497, 1993). The kinetic modeling method for Tc-99m SPECT images uses the 1-compartment model (Leppo et al., Circ Res. 1989;65:632-639).



4.15.1 Kinetic page requirements

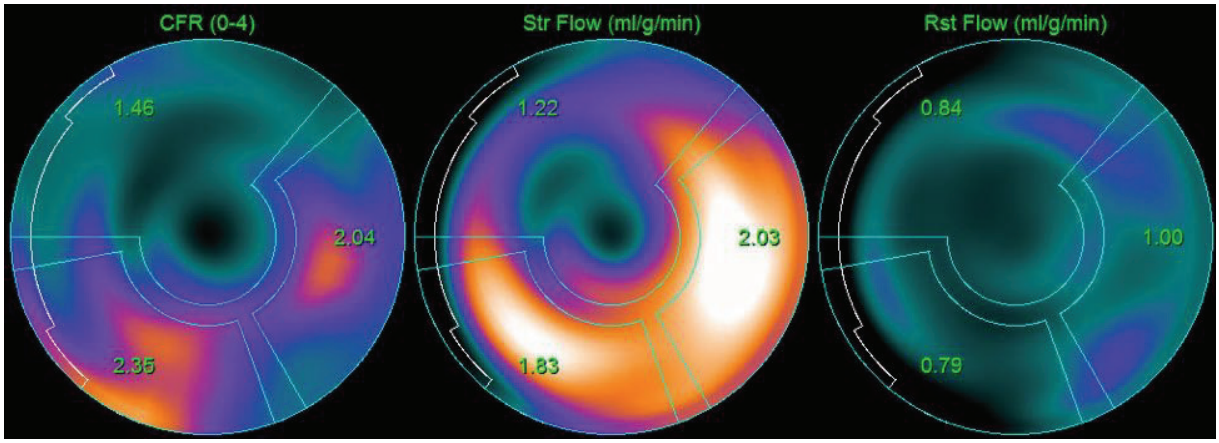
The Kinetic feature requires at a minimum one processed transverse dynamic cardiac PET or SPECT dataset. For CFR results, both Rest and Stress dynamic cardiac PET datasets in the transverse format are required. Kinetic analysis is designed to function with any number of frames but typically 16-26 frames are most commonly used in clinical settings.

4.15.2 Kinetic page displays

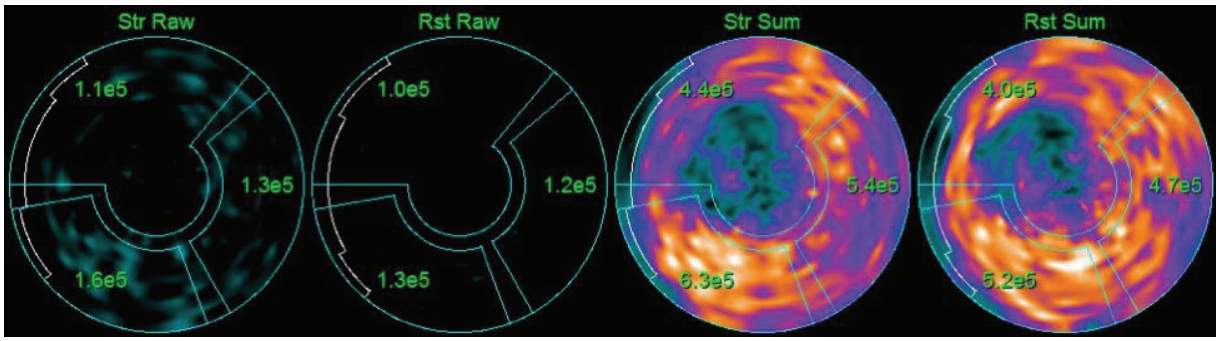
The Kinetic page displays quantitative results utilizing polar map, time/activity graph, and score chart formats.

- **Polar Maps**: there are two rows of polar maps displayed on the Kinetic page.
    - The polar maps displayed towards the top of the page show the stress and rest absolute blood flow in the Myocardium for the loaded datasets in ml/g/min. If both Rest and Stress dynamic flow datasets are loaded, an additional CFR polar map showing the coronary flow reserve is also displayed. The polar maps can be segmented into Vessels, Groups, Walls, and Segments using the **grid** pull down

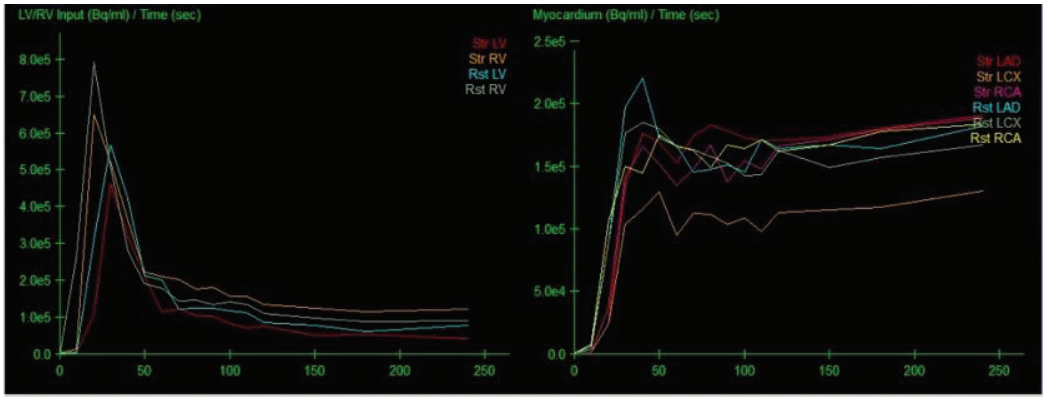
menu. The values are averaged for the polar map pixels for each user defined segment.



- The Polar maps displayed in the middle of the page show radiotracer activity within the myocardium in [(Bq/ml)/Time(Sec)]. There are up to 4 polar maps displayed in this region if both the rest and stress flow datasets are loaded. Two of the polar maps show summed data that sums the information from all frames; the remaining two polar maps show data for the specific frame being displayed.



- **Time/Activity graphs-**The time/activity curves (TACs) display radiotracer activity both within the blood pool of the right and left ventricles (left) and for the Myocardium (right). When the **Grid** setting is set to **Vessels**, the Myocardium graph will also display the curves for each of the 3 main coronary blood vessels (LAD, LCX, and RCA). The values in the time/activity graphs represent absolute radiotracer activity [Bq/ml]/Time[sec].



- **Results** (Scores)-The bottom right side of the screen shows results for absolute flow, CFR, and the spill-over fraction (SF) for each area of the Myocardium. SF is the amount of radiotracer that has "spilled-over" into the Myocardium (as defined by the segmentation or contours) from the blood pool region for stress and rest. The SF value helps the clinician QC the technical quality of the dataset. A SF value of ≥ 60% or 0.60 is considered to be of poor quality.

	Str Flow	Rst Flow	CFR	Str SF	Rst SF
LAD	1.11	1.07	1.08	0.30	0.30
LCX	1.28	1.02	1.30	0.30	0.29
RCA	1.20	0.72	1.70	0.30	0.29
TOT	1.18	1.00	1.25	0.30	0.30

4.15.3 New Kinetic page features

Cardiac Suite 2017.23 (and later versions) includes additional features for residual activity correction, automatic motion correction, and flow model configuration. Please consult the reference manual for additional details.

NOTE: Residual activity correction: both corrected and uncorrected curves should be reviewed. Use the **No RAC** toggle to view the uncorrected and corrected curves simultaneously and assess whether the subtraction is justified.

NOTE: Motion correction: each frame of both datasets (stress and rest) should be checked for patient motion, *even after automatic motion correction*. This step is as important as verifying the quality of the LV contours. If the position of the myocardium with respect to the contours (which are

computed from the last frame of the image) is unsatisfactory, use manual correction to achieve the best possible results.

NOTE: Flow model configuration: modifying the model type or model parameters will change the resulting flow values. Such modification should only be performed for the following reasons:

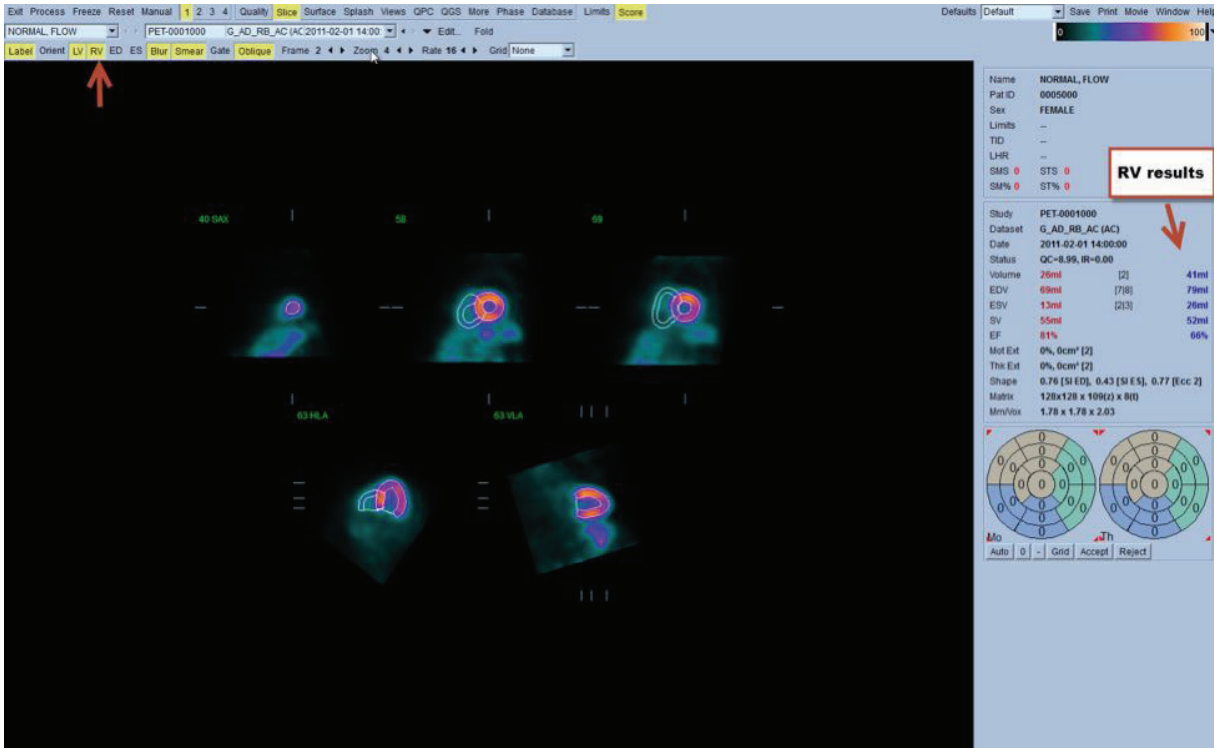
- To adhere to best practices as published in guidance/guideline documents from appropriate professional societies.
- For research purposes in an investigational, non-clinical setting.
- As instructed by Cedars-Sinai clinical support staff.

Consult the appropriate peer-reviewed publications for additional information on kinetic models.

The feature is disabled by default and requires a password to enable. Please contact **support@csaim.com** for further information and reference "**flow model configuration password request**" in your message.

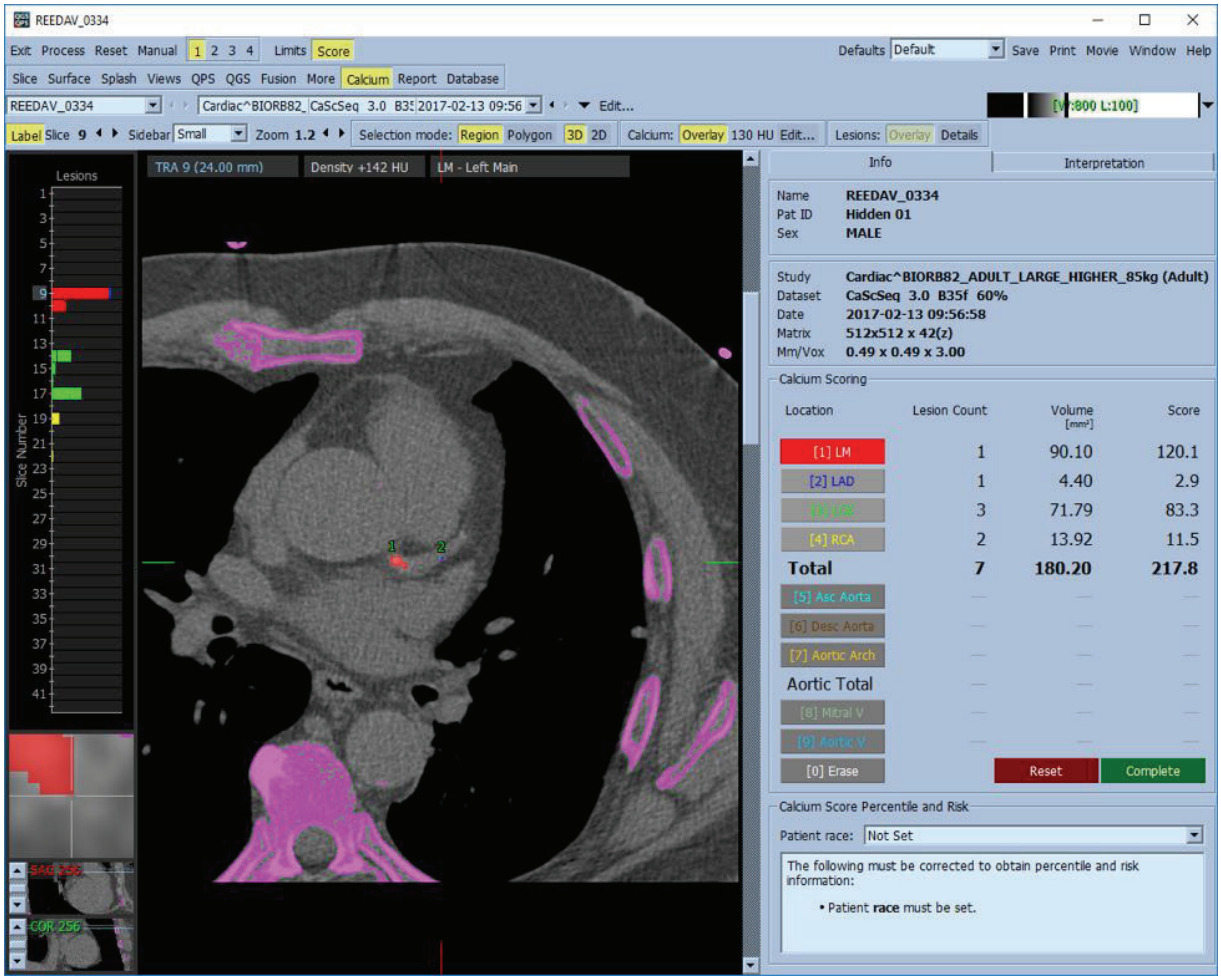
4.16 Right ventricle (RV) quantification

Automated right ventricular quantification and analysis is now available for supported gated datasets. Toggle on **RV** and then click **Process** to generate RV contours and quantitative results.



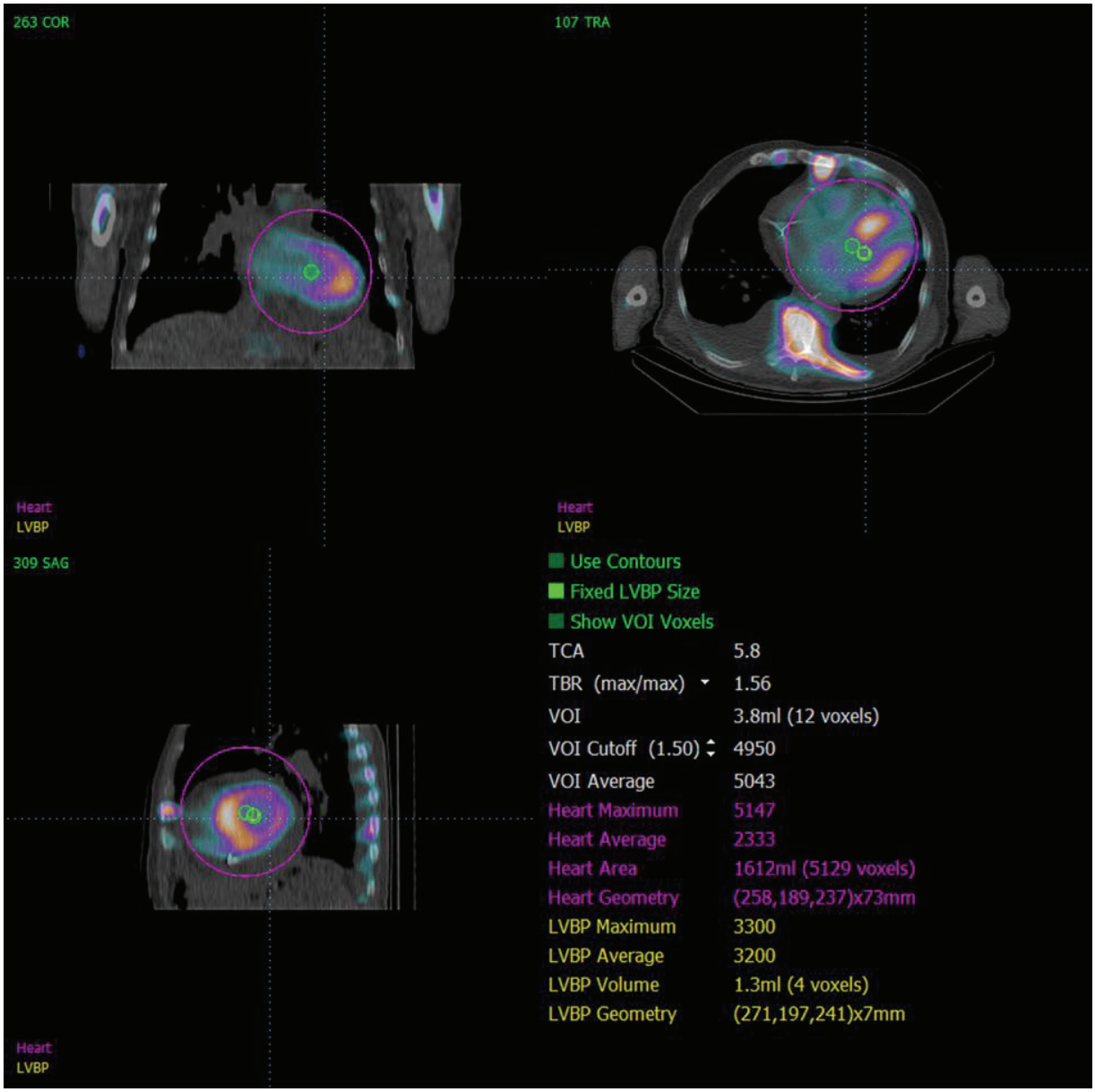
4.17 Calcium Scoring

The Calcium page is used for quantification and review of coronary artery calcium deposits. A diagnostic quality non-contrast CT dataset is required for the calcium page. The page provides tools for identifying calcium lesions throughout the scan. Only lesions assigned to one of the coronary arteries (LM, LAD, LCX or RCA) are used for computing the total coronary calcium Agatston score. Additional details for the Calcium page are described in the QGS+QPS / QPET reference guide.



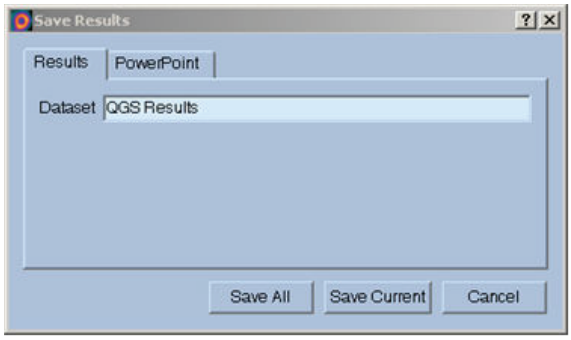
4.18 Uptake Analysis

Starting with version 2017.24, the **Raw** and **Fusion** pages have both gained new measurement modes to assist with the assessment of patients with amyloidosis, sarcoidosis, or other conditions that may be evaluated by analyzing quantitative measurements such as ROI ratios. Additional details for the analysis of tracer uptake are described in the QGS+QPS / QPET reference guide.



4.19 Saving your Results

With completion of the processing and reviewing steps outlined above, the user has the option of saving the results to a composite results file. From the main tool bar click **Save** to display the **Save Results** dialog window**.**



There are two main choices available for saving results files, **Results** and **PowerPoint**. Selecting the **Results** tab (default) allows saving of processed results as a single file within the patient study.

Selecting the **PowerPoint** tab allows saving of results and application configuration information in a format that allows for fast and easy launching of case studies directly from a PowerPoint presentation. The PowerPoint saving feature is described in the reference guide.

The following actions are supported:

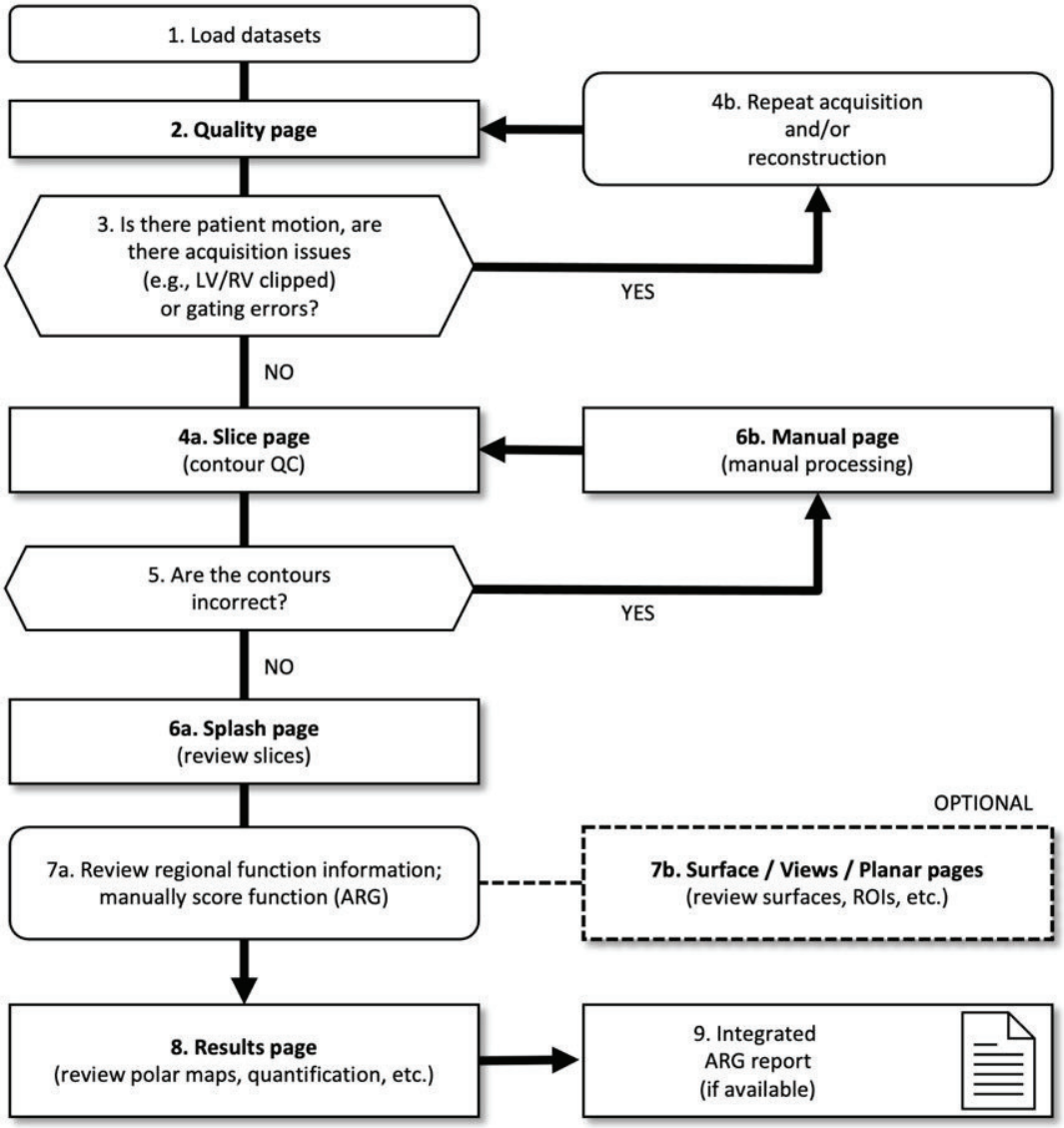
Save All	Saves results for all selected studies
Save Current	Saves results for the currently display study.
Cancel	Exits the dialog without saving results. The user may also exit the dialog by clicking the "X" in the upper right-hand corner of the dialog window.

4.20 Exiting

To exit from any of the programs, click the **Exit** button.

5 QBS Application (Quantitative Blood Pool)

The QBS workflow is intentionally modeless. As such, no particular processing sequence is dictated to the user. A typical sequence might proceed as follows:



Legend

1. Load datasets
2. Quality page
3. Is there patient motion, are there acquisition issues (e.g., LV/RV clipped) or gating errors?

4a. Slice page (contour QC)

4b. Repeat acquisition and/or reconstruction

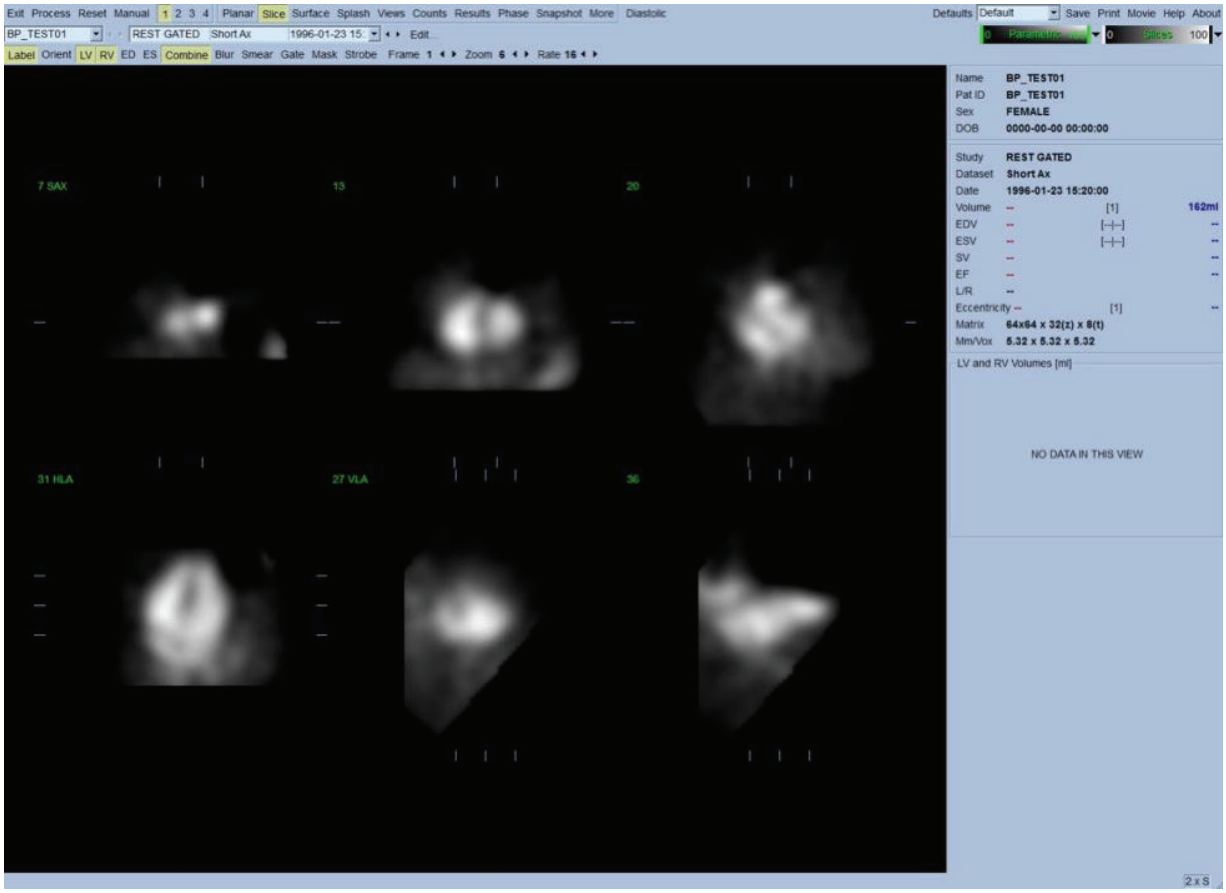
5. Are the contours correct?
6a. Splash page (review stress/rest slices)
6b. Manual page (manual processing)
7a. Review regional function information; manually score function (ARG)
7b. Surface / Views / Planar pages (review surfaces, ROIs, etc.)
8. Results pages (review polar maps, quantification, etc.)
9. Integrated ARG report (if available)

OPTIONAL = Recommended but not required.

NOTE: QBS is able to quantify parameters of global and regional LV and RV function using only a short axis gated blood pool dataset.

5.1 Launching QBS

Launching QBS in its standard configuration will bring up the Main screen with the **Slice** page indicator and the **Label, LV** and **RV** toggles highlighted shown below. Representative slices are shown, with the number to the top-left of each slice showing its order in the short axis dataset. Left-clicking on Label toggles that number and the slice reference lines on and off.



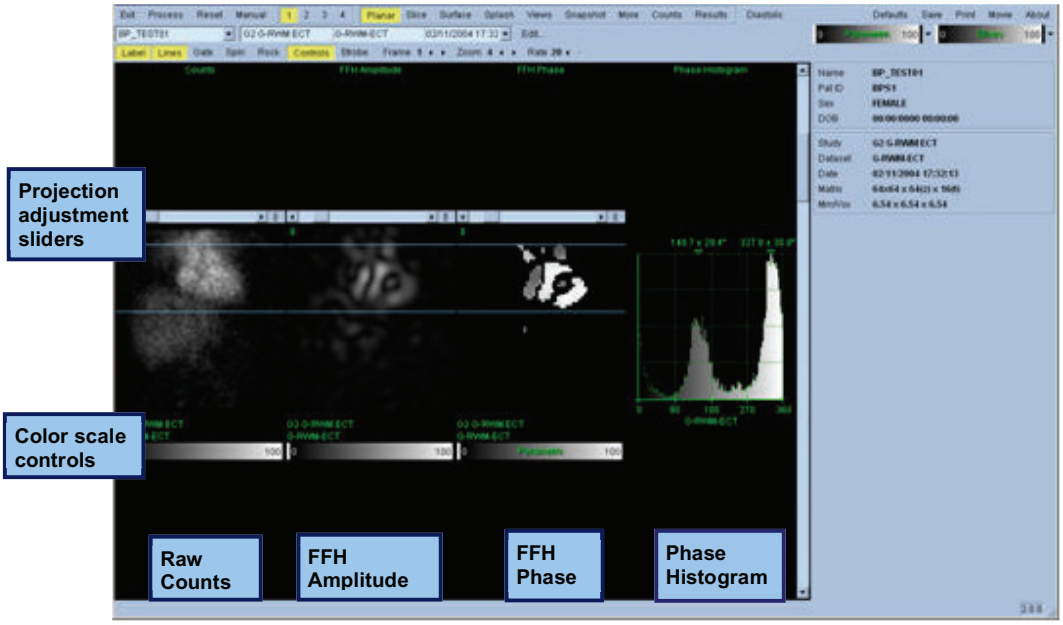
The name of the folder (generally, a patient name) and a description of the dataset are displayed in the horizontal section that also contains the color scales shown below. Left-clicking and dragging (in the **Slices** color scale) the vertical black stripe to the rightmost will “saturate” the scale and make the heart visible in cases where strong extra-cardiac activity exists. The ***Parametric*** color scale is available only if FFH Phase images are displayed on the **Slice** page.

5.2 Reviewing the Rotation Projection Images

Clicking the **Planar** page indicator will bring up the Planar page shown below. The Planar page consists of four display areas; the raw Counts projection area, the FFH Amplitude area, the FFH Phase area, and the Phase Histogram area (FFH = First Fourier Harmonic).

Prior to processing the data, it is always a good idea to view the raw projection data in cine fashion to assess patient motion. Clicking the **Lines** toggle brings up two horizontal lines, that should be manually positioned so that they tightly straddle the heart. Clicking the **Controls** toggle will bring up individual color scale and projection slider adjustment controls for the ***Counts***, ***FFH Amplitude*** and ***FFH Phase*** display areas. A continuous loop cine display of the projection dataset(s) can then be started by clicking the **Spin** toggle (continuous rotation).

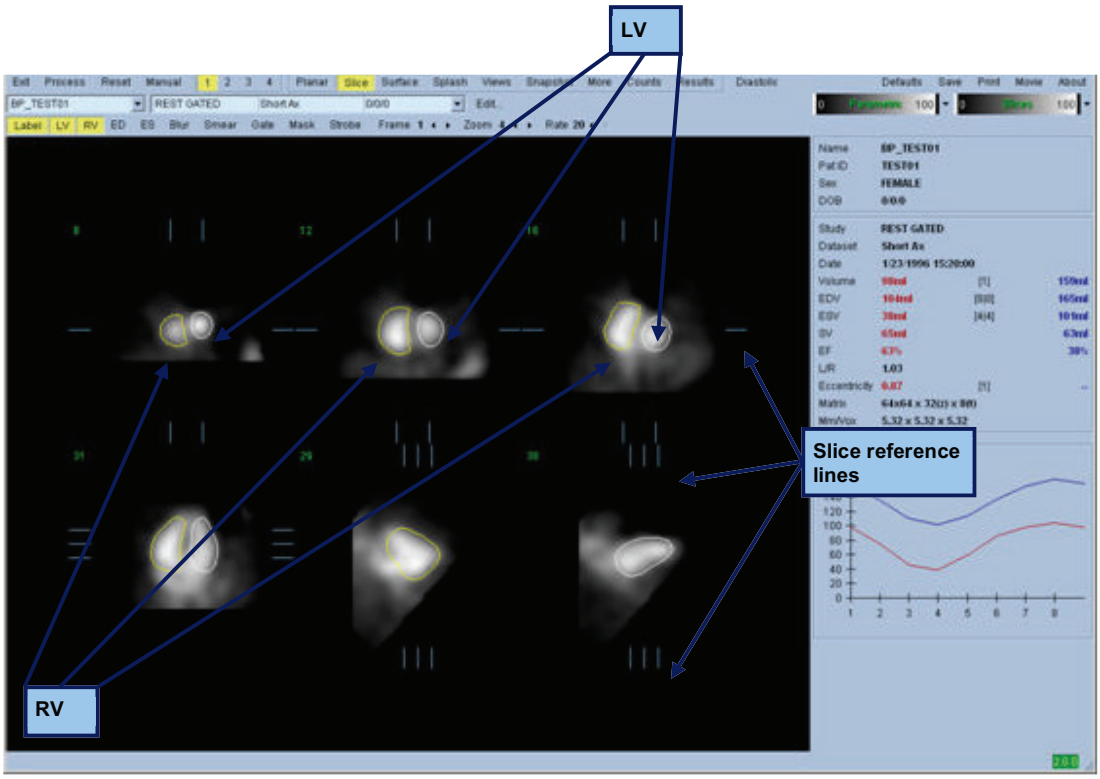
Clicking the **Rock** toggle (in addition to the **Spin** toggle) will display an alternating, back-and-forth cine. The cine speed can be adjusted by clicking the ◄ ► symbols on the right side of the **Rate** label. Any sudden movement of the heart's perceived boundaries towards, or away from the lines should be noted. Major motion may affect the quantitative parameters measured by QBS; if such motion is detected, it would be prudent to repeat the gated acquisition.



In addition to patient or organ motion, flickering (sudden variations in brightness between adjacent projections) can be assessed by reviewing the projections cine. Flickering is often an indication of gating errors, and can be accompanied by alterations of the time-volume curves shown in the Results page.

5.3 Processing the Images

Clicking on the **Slice** page indicator will highlight it and advance QBS to the **Slice** page. Clicking **Process** will automatically apply the QBS algorithms to the data, segmenting the LV and RV, calculating the endocardial 3D surfaces, and determining all the global and regional quantitative cardiac parameters. The intersection of the 3D surfaces with the 2D slices planes are displayed as "contours" overlaid onto the six slices (yellow = RV, white = LV), which are now representative of equally spaced (short axis images) or mid-ventricular (long axis images) portions of the ***LV*** and ***RV***. Moreover, all quantitative parameter fields in the right portion of the screen should now be filled with numeric values shown below. We'll examine and discuss the quantitative measurements in more detail later.



5.4 Checking the QBS Contours

The location of the six slices displayed can be interactively adjusted by moving their corresponding slice reference lines in orthogonal views shown above; however, in most patient studies this will not be necessary.

At this point, a visual check for obvious inaccuracies in the way the contours follow the LV and RV must be performed. This will likely involve toggling the **LV** and **RV** contour toggles on and off, and setting the images in motion (cine) by left-clicking the **Gate** toggle. Most major inaccuracies are due to the presence of extra-cardiac activity. In particular, one would expect to a) see the contours centered on a structure other than the heart, or b) see the contours "pulled away" from the ventricles to follow closely adjacent activity. These occurrences are infrequent, and should be dealt with using the Manual option discussed in the next section.

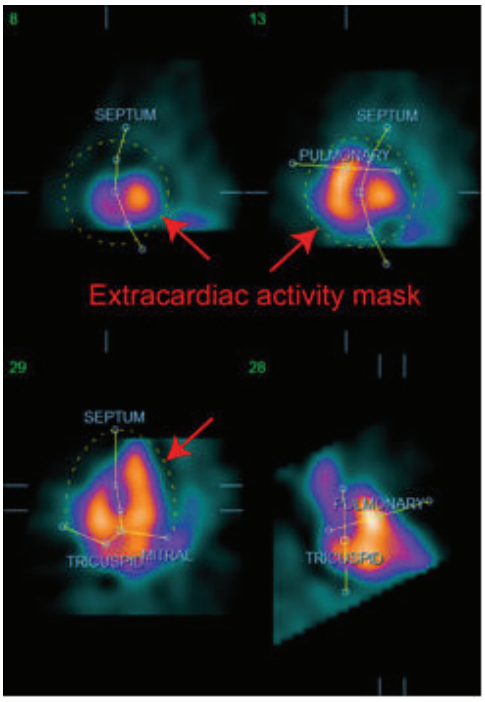
Another potential source of error is excessive blurring of the short axis data. If the dataset was over filtered during reconstruction, it is possible that the algorithm will fail to differentiate between the left and right ventricles correctly. The ventricular contours may interpenetrate, or be completely erroneous.

NOTE: Since the algorithm requires a phase difference between the ventricles and atria to correctly identify these structures, at this time it is not possible to obtain measurements from a static phantom, even if a gated acquisition was performed.

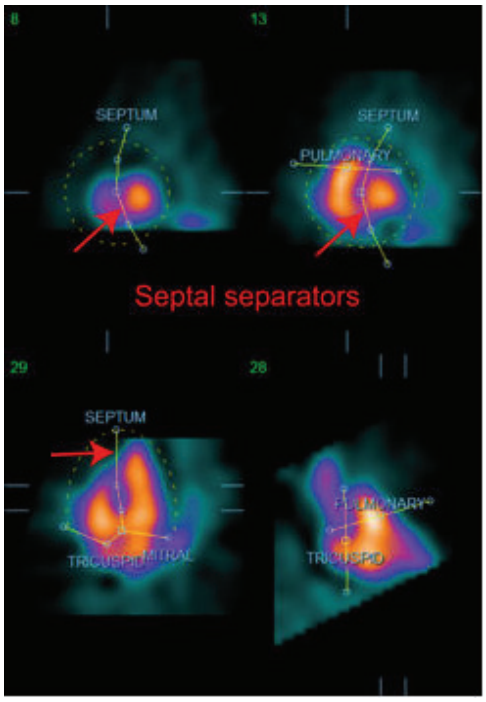
5.5 Modifying the Contours (Manual Page)

Clicking the **Manual** toggle will bring up a modified version of the **Slice** page, with 4 slices for the ***ED*** interval and 4 slices for the ***ES*** interval, as well as masking graphics superimposed upon the slices. It is possible to modify the shape and position of the masking graphics by left-clicking and dragging the masking graphic handles, small squares and circles placed at various points on the masking graphics.

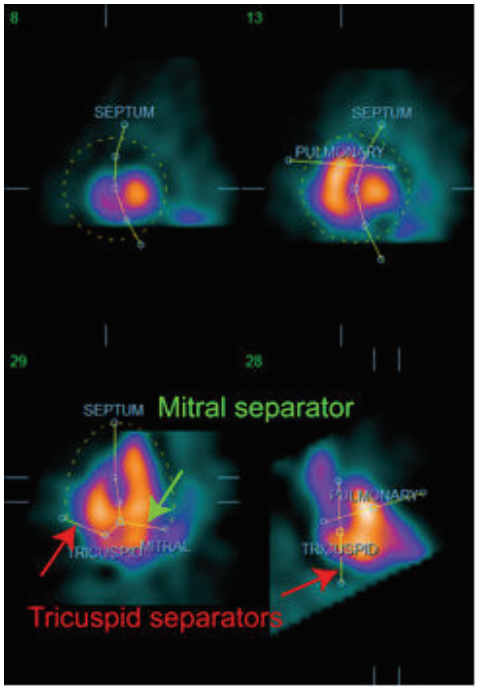
For each interval, two short-axis slices (mid-ventricular and apical), one mid-ventricular long axis and one mid-RV vertical long axis slice. Because of constraints imposed between the various points that constitute the mask, selection of the slices may be limited (as compared to slice selection in other pages). The masking graphics are designed to achieve:



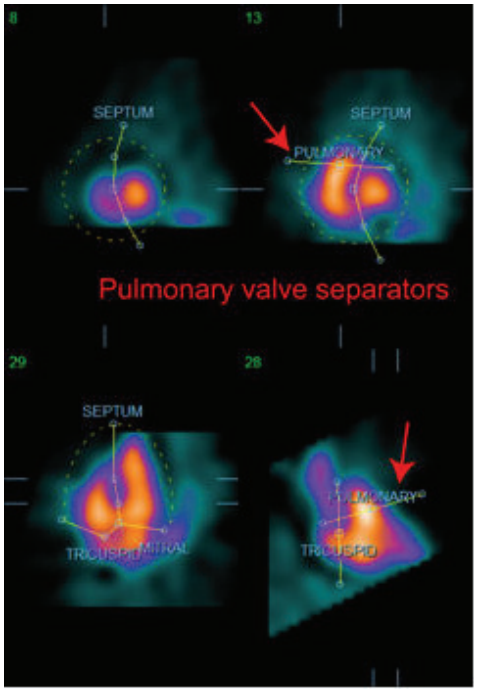
Masking of extra-cardiac activity



Separating between the LV and RV



Separation of the ventricles from the atria (Tricuspid and mitral separators)

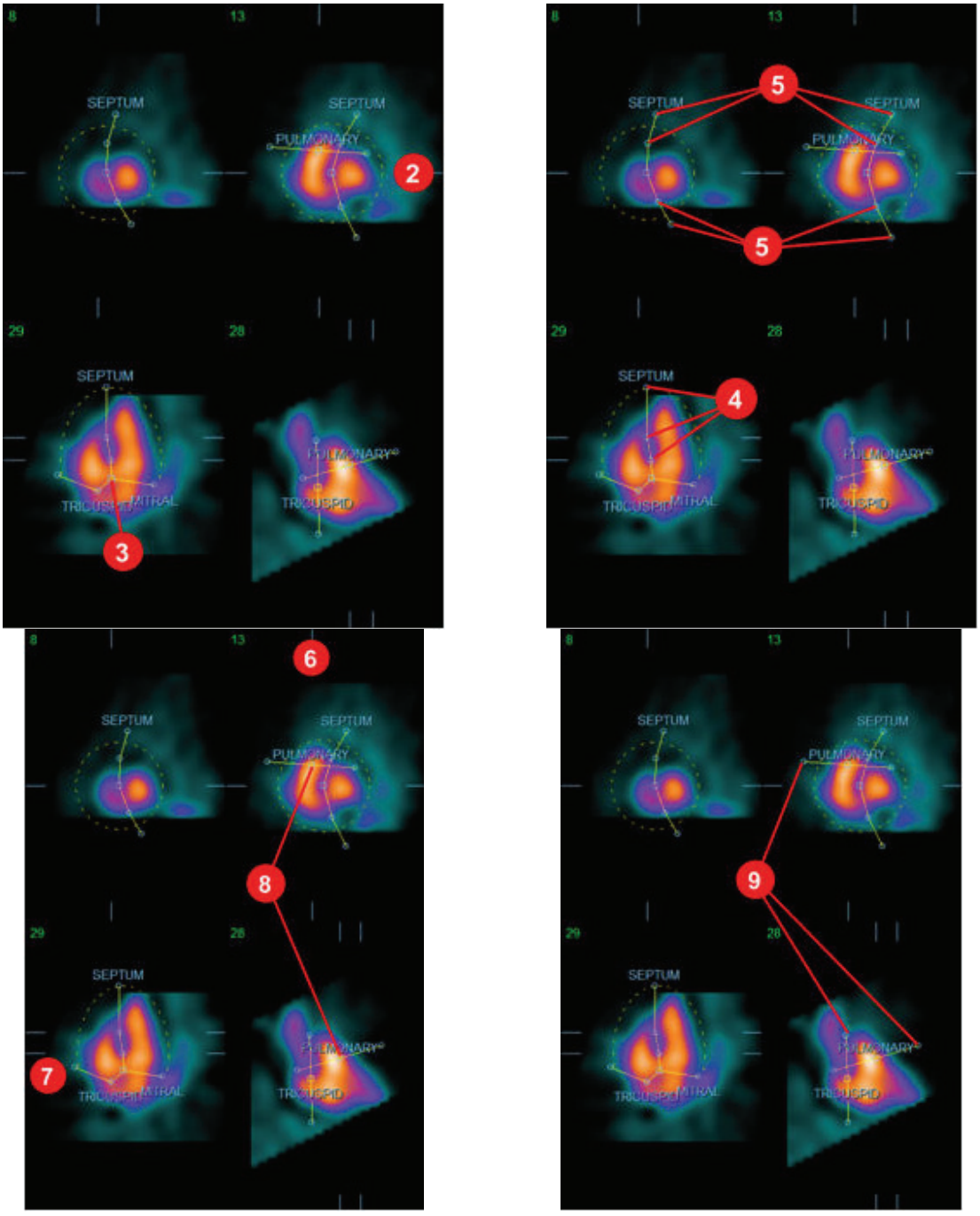


Separation of the RV from the pulmonary trunk (Pulmonary valve separator)

In general, the following sequence should be followed for optimal placement of the mask:

1. Start with the ***ED*** interval (left half of the page);
2. adjust the HLA guide in the basal SAX slice to select a mid-ventricular HLA slice;
3. move the whole mask in the HLA slice by dragging the square handle;
4. adjust the circular handles for the septal and mitral separators in the HLA slice (this process may cause the selection of different SAX slices, just place the handles and slices in a way that allows for a good delineation of the septum in SAX and HLA views);
5. adjust the circular handles for the septal separators in the SAX slices
6. adjust the VLA guide in the basal SAX slice to select a mid-RV VLA slice, this will automatically adjust the first tricuspid handle in the HLA view;
7. adjust the second tricuspid handle in the HLA view to correctly separate the RV from the RA;
8. if **RV Truncation** is on, move the square pulmonary valve handle to the appropriate location;
9. Adjust the orientation of the pulmonary and tricuspid valves in the SAX and VLA slices using the circular handles.

Using a non-linear color lookup table may help in determining the best location for the various mask separators (in the example images, the “Cool” colormap is used). The following gives a graphical depiction of the mask placement steps.

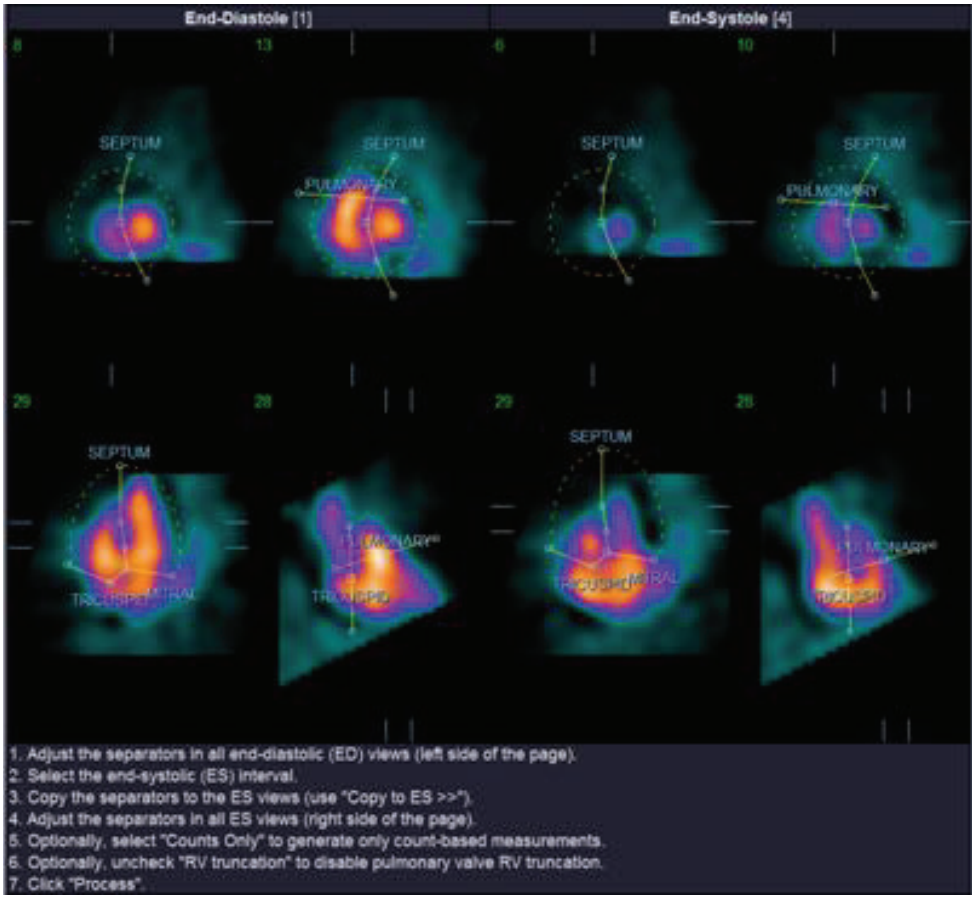


Having correctly positioned the ED mask, use the **Copy to ES >>** button to copy the mask's position to the ES interval. The correct ES interval should be selected manually by examining the image and visually determining in which frame the ventricles seem fully contracted. The program will automatically attempt to select the appropriate interval, but manual adjustment may be required. Is so desired, the mask can also be adjusted in the ES interval and copied back

to the ED interval using the **<< Copy to ED** button (note that the ES mask will completely replace the ED mask).

When the mask has been copied and the interval adjusted, repeat the above procedure for the ES interval.

Shown below are the viewports from the manual page after positioning the ED and ES masks.



Once the mask has been correctly positioned, click **Process** to process the data using the mask, or select **Counts Only** then click **Process** to perform count-based calculations only. Note that if **Counts Only** is selected, no surfaces will be generated and limited information only will be available in the **Counts** page.

If the **RV Truncation** is off, no RV truncation will be performed. At any time, use the **Reset** button to reset the mask to its original (non dataset-specific) configuration. This will void all user changes.

The remaining page controls (**LV, RV, ED, ES, Blur, Smear, Gate, Mask, Frame, Zoom**, and **Rate**) perform the same function as they do in the **Slice** page.

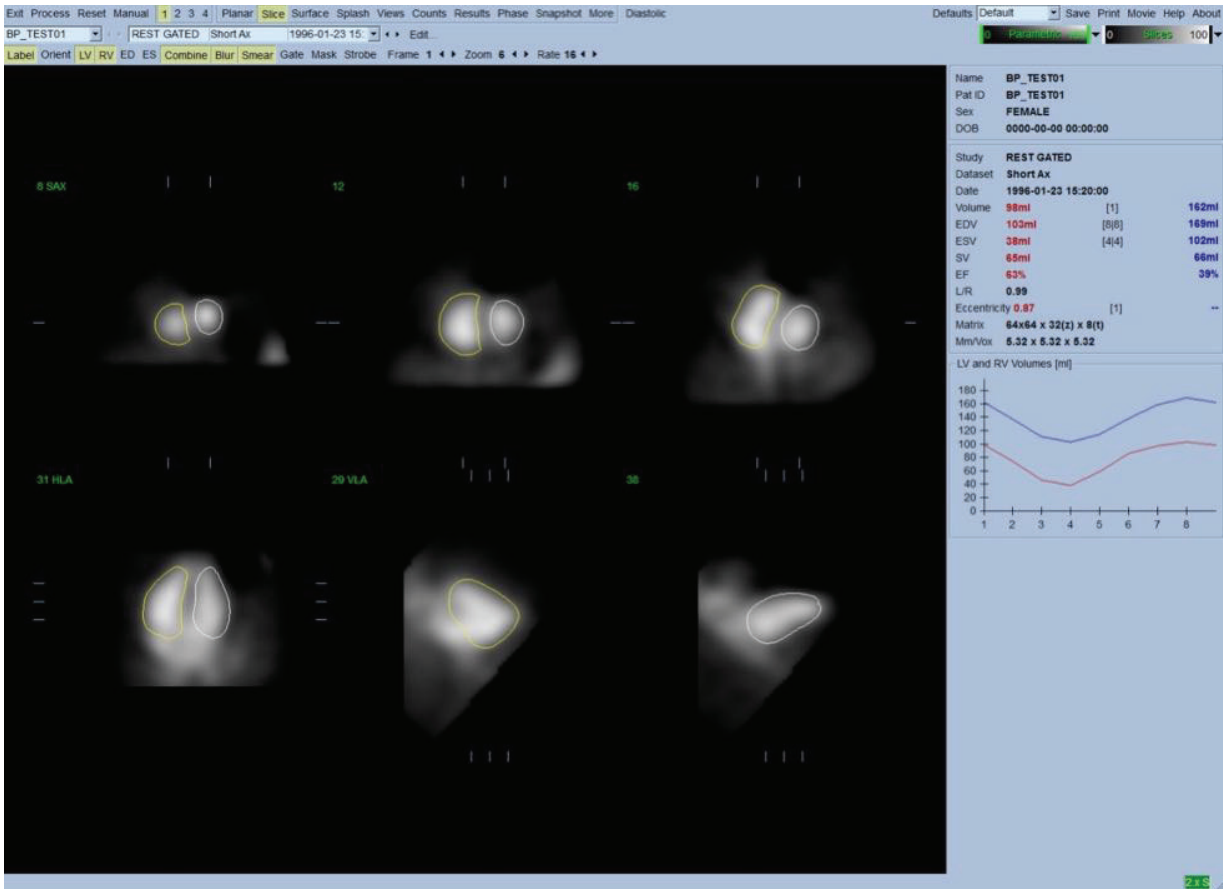
5.6 Reviewing Gated SPECT Blood Pool Images in the Slice Page

A first visual assessment of LV and RV function can be performed by left-clicking the **Gate** toggle to display a cine of the six slices while clicking the **LV** and **RV** toggles on and off. The cine speed can be adjusted by clicking the ◄► symbols on the right side of the **Rate** label. Moreover, a temporal and spatial smoothing filter can be applied to the images by clicking the **Blur** and **Smear** toggles, respectively. This is especially useful to reduce statistical noise in low-counts images for visual assessment, and it will not affect the quantitative results. Shown below is the **Slice** page set for review of gated images.

NOTE: The ***Blur*** and ***Smear*** functions only affect image display. The QBS algorithms operate on the original, unsmoothed data regardless of Blur and Smear settings.

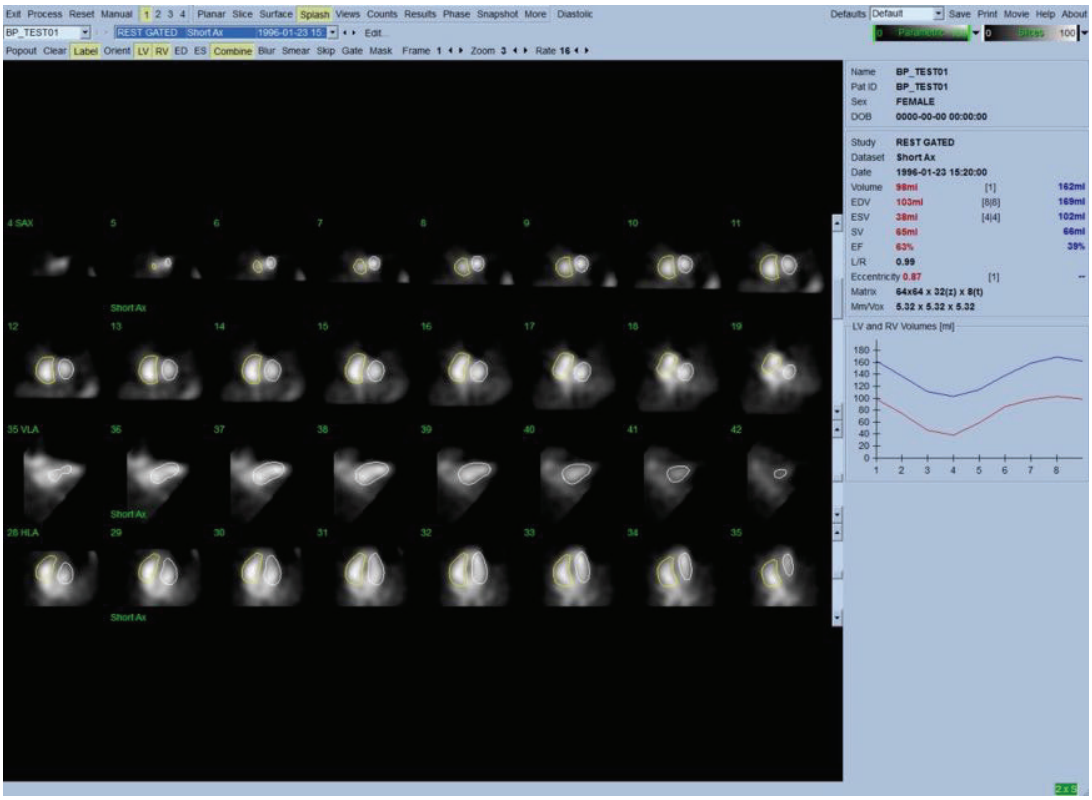
NOTE: At Cedars-Sinai Medical Center, a gray or thermal scale is typically used to visually assess wall motion.

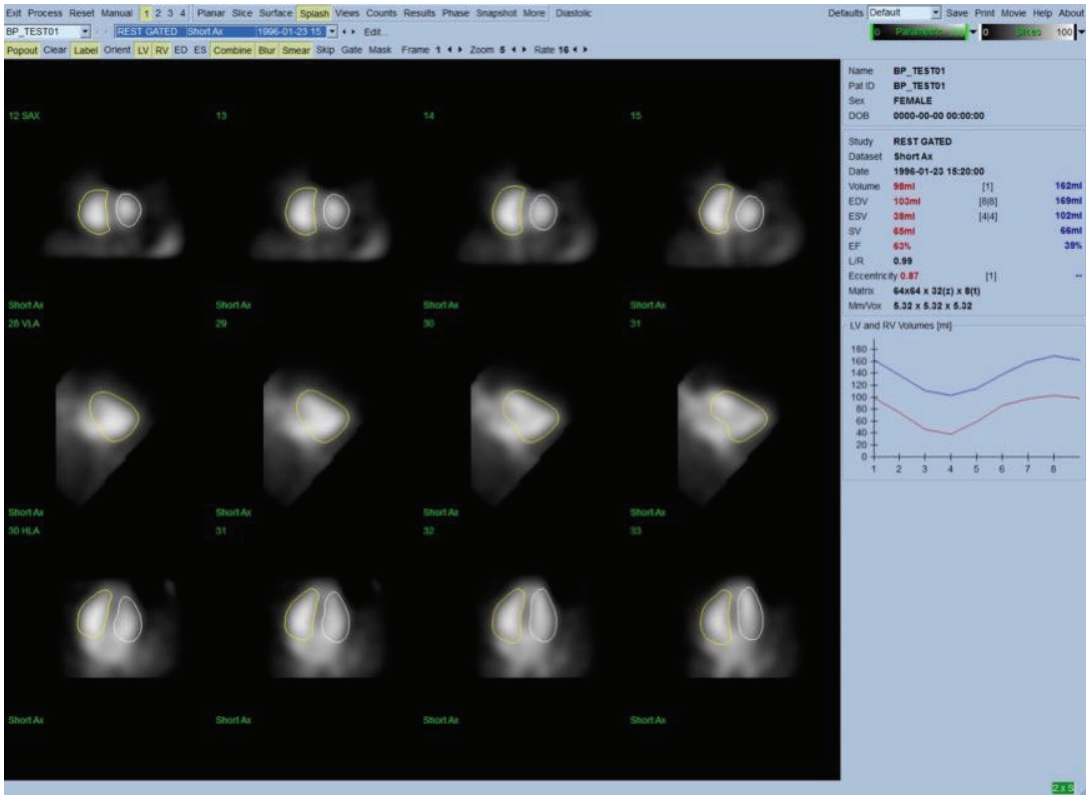
.



5.7 Reviewing Gated SPECT Blood Pool Images in the Splash Page

Clicking on the **Splash** page indicator will bring up the **Splash** page shown below, with all the available short images, which can be then gated simultaneously by left-clicking the **Gate** toggle. At times, a user may want to select images for closer inspection. This is accomplished by using the “popout” feature. This is performed by right-clicking on the desired images to select/deselect them (the corners of the selected items are highlighted in blue), then left-clicking on the **Popout** toggle shown on the bottom.

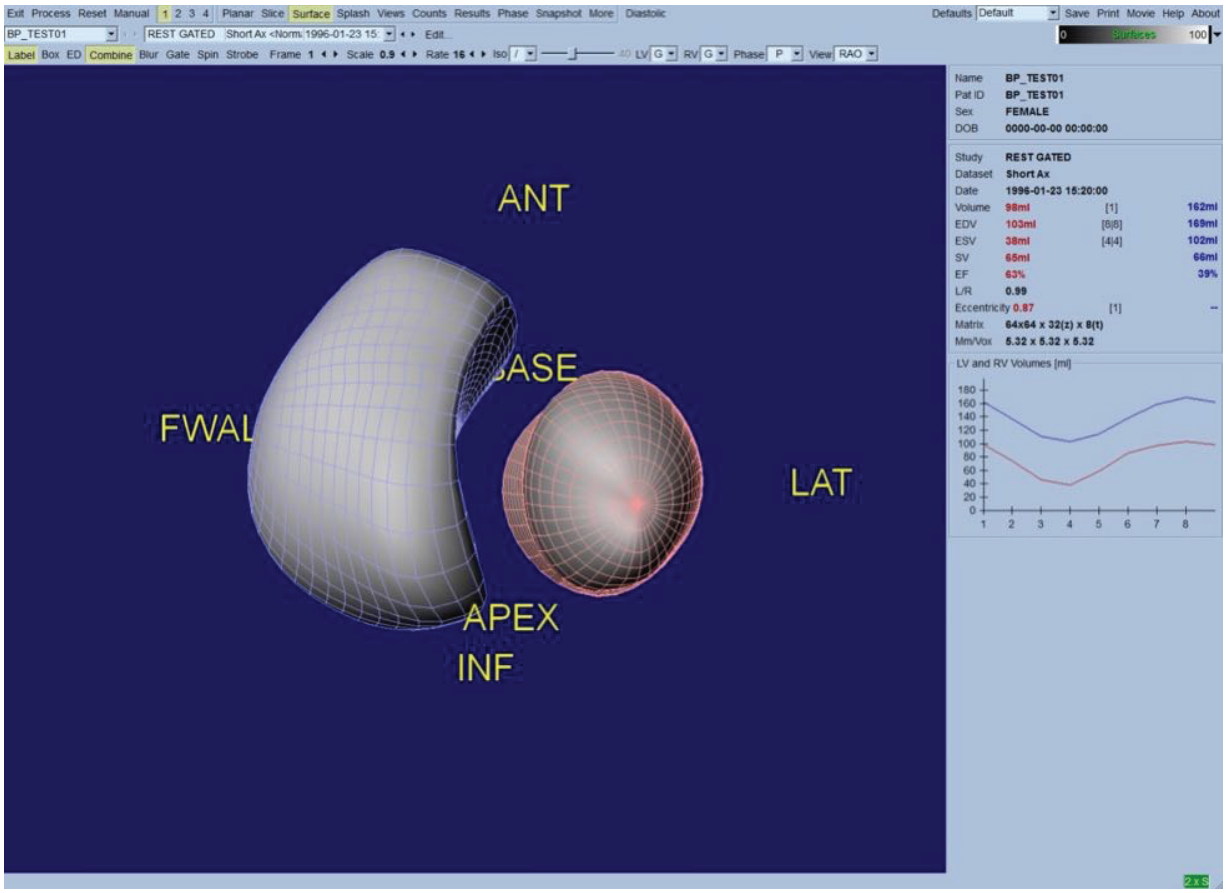




Splash page after Popout enabled

5.8 Reviewing Gated SPECT Blood Pool Images in the Surface Page

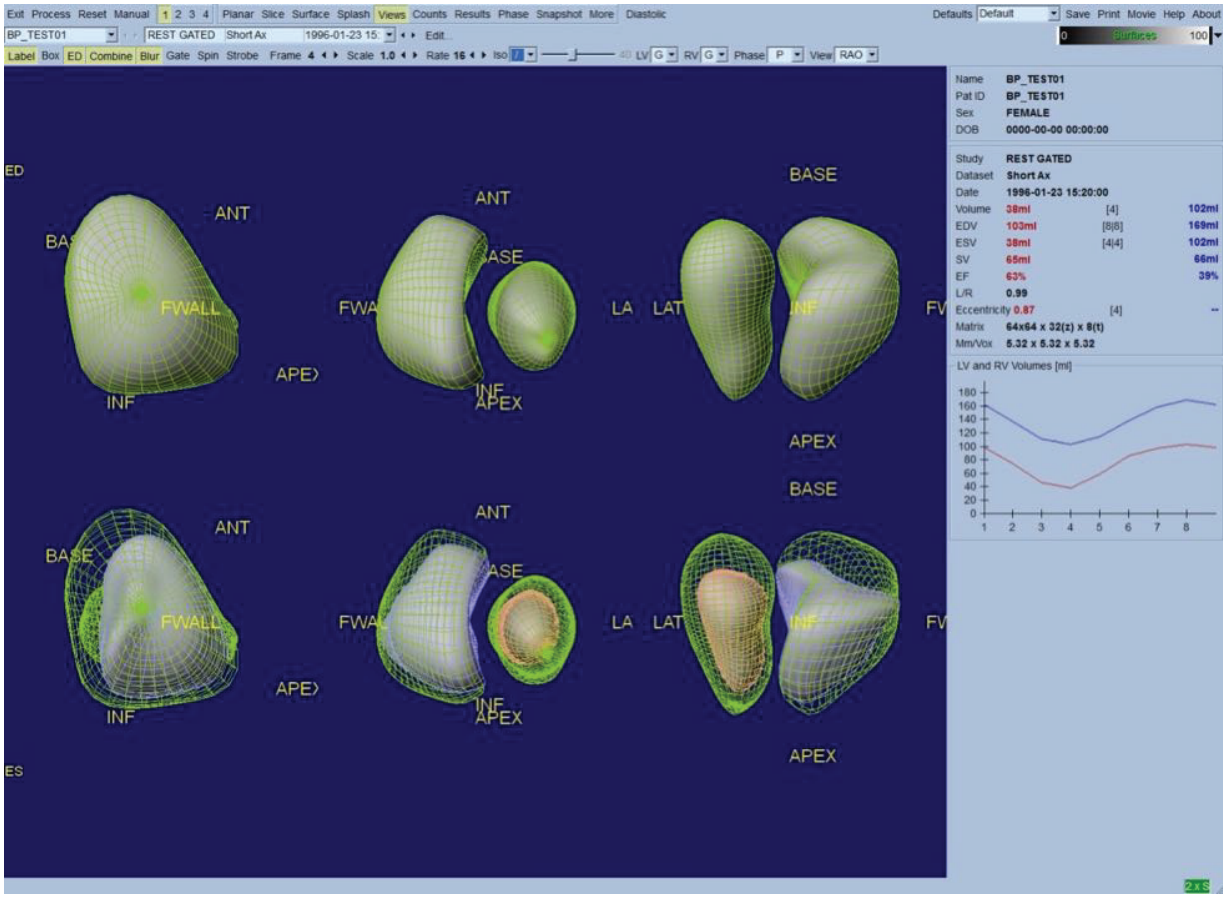
Clicking on the **Surface** page indicator will bring up the **Surface** page shown below; a parametric representation of the ventricles, consisting of green wireframe surfaces (ventricular ED endocardium) and shaded surfaces (ventricular endocardium). The **Gate** toggle allows the user to follow the 3D wall motion throughout the cardiac cycle, while clicking and dragging on the image will interactively and in real time position it to the observer's liking.



It is also possible to display an isosurface extracted from the counts data. This surface can potentially be used to visually assess wall motion as well, though no isosurface (at any level) gives the location of the endocardium. The user can then superimpose the calculated surfaces onto the isosurface display. The best way to do this is to display the LV and RV surfaces as wireframes (red and blue, respectively) along with the shaded isosurface. To minimize noise effects in the isosurface extraction, it is recommended to toggle on temporal smoothing by clicking the **Blur** toggle. Display characteristics can be set separately for the LV and RV using the appropriate option menus.

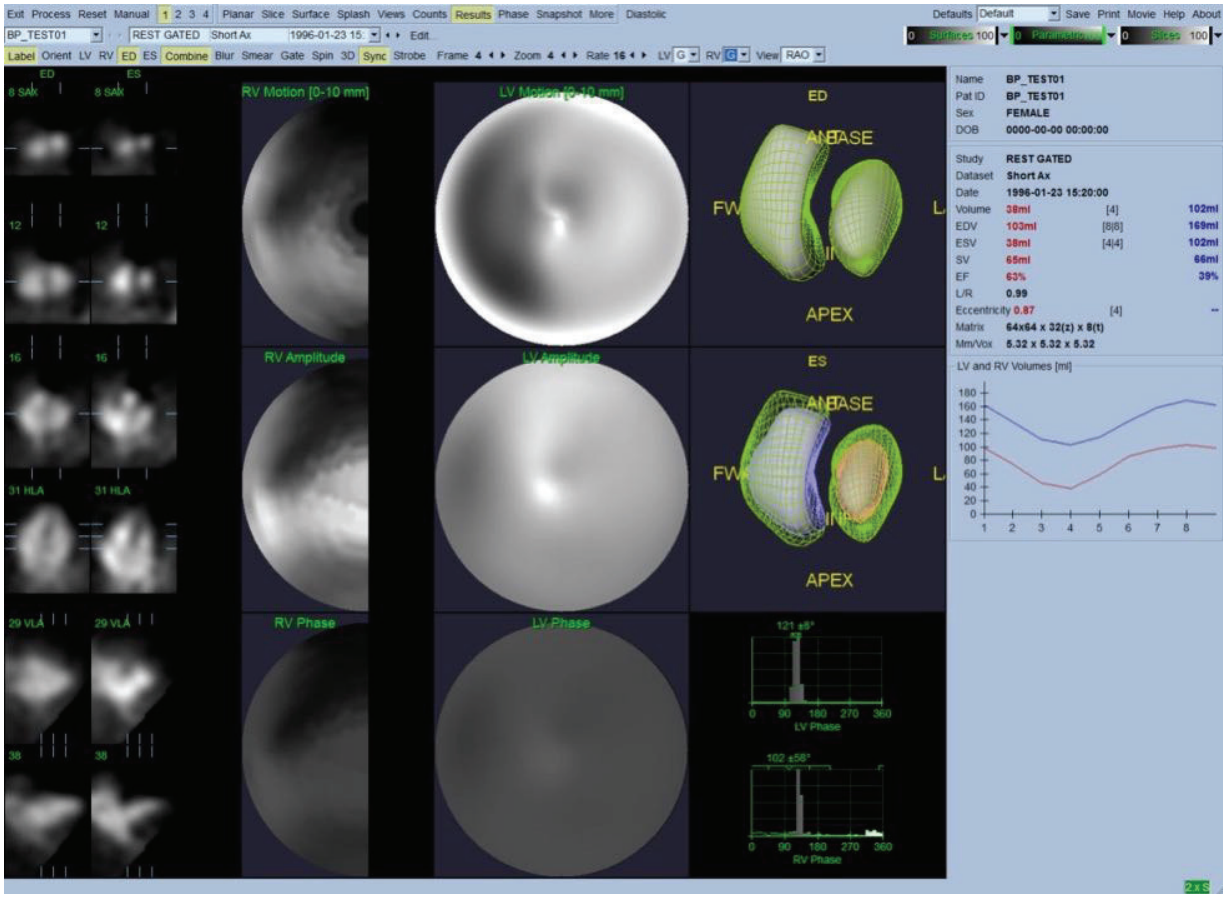
5.9 Reviewing Gated SPECT Blood Pool Images in the Views Page

Clicking on the **Views** page indicator will bring up the **Views** page with six 3D viewports shown below, very similar to that in the **Surface** page. In fact, the main purpose of this page is to allow full coverage of the LV and RV, albeit with smaller images compared to the one in the **Surface** page.



5.10 Putting it All Together: The Results Page

Clicking on the **Results** page indicator will bring up the **Results** page shown below, which aims at presenting, in synthetic format, all information related to the gated SPECT blood pool study in this patient. If a screen capture is taken of this page with the LV and RV contour toggles off, it would represent a good image to send the referring physician.



Results page

5.10.1 Assessing the Time-Volume Curve

A valid time-volume curve would be expected to have its minimum (end-systole) at frame 3 or 4, and its maximum (end-diastole) at frame 1, 7 or 8 of an 8-frame gated acquisition. For a 16-frame gated acquisition, the minimum (end-systole) would be expected to be at frame 7 or 8 and its maximum (end-diastole) at frame 1 or 16. If major deviations from this expected behavior occur, the prudent assumption is that gating or processing was unsuccessful and the study needs to be repeated. An example of a correct curve is shown above.

NOTE: In the time-volume curve graph, the volumetric value for interval 1 is also “appended” to the curve after interval 8 or 16, respectively, for 8-frame and 16-frame gated acquisitions.

5.10.2 Assessing the Polar Maps

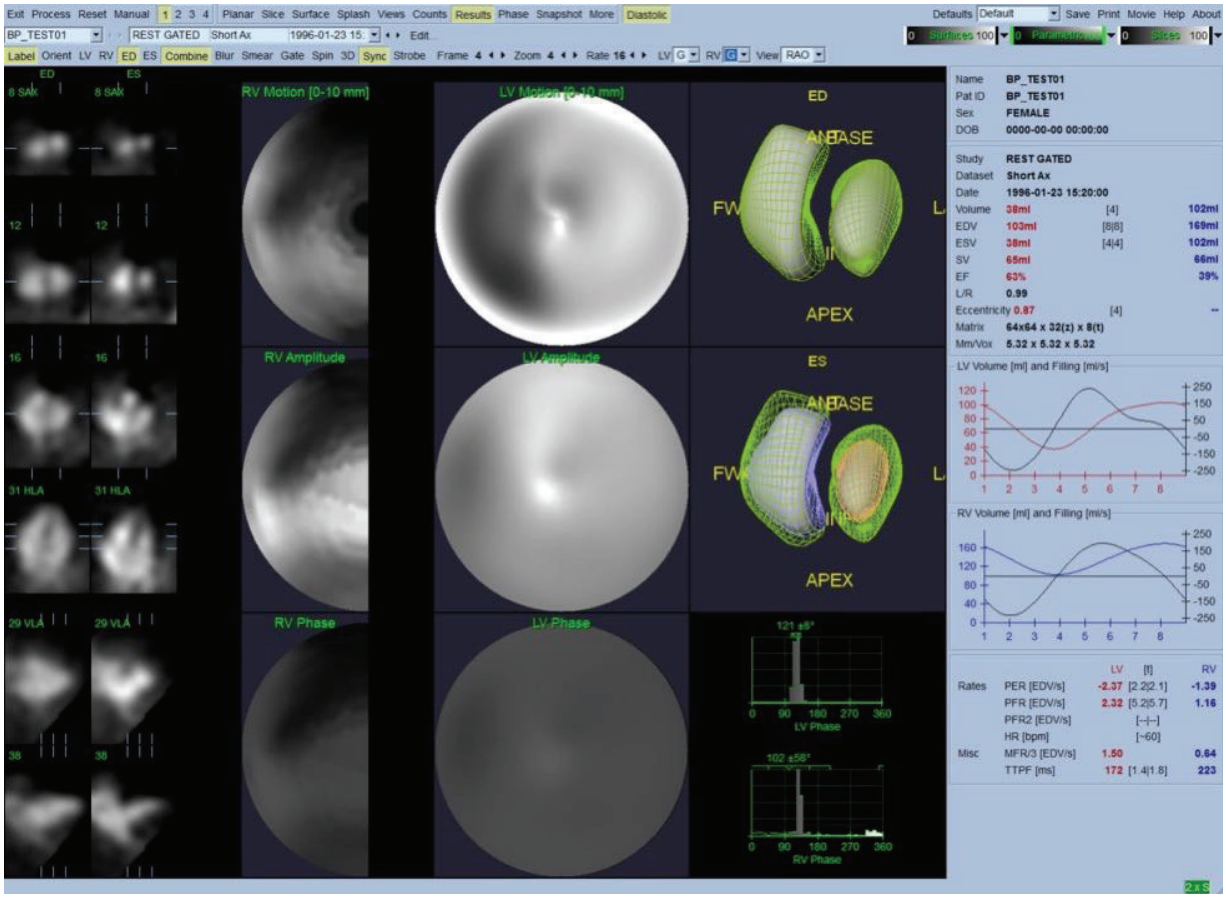
QBS provides two wall motion polar maps, one each for the LV and RV.

Mapping of the endocardial motion in the motion polar map follows a linear model from 0 mm to 10 mm. Motion greater than 10 mm is assumed to be = 10 mm (the scale "saturates" at 10 mm), while motion <0 mm (dyskinesia) is assumed to be = 0 mm. The parametric surfaces displayed on the Results page are not normalized to this 10 mm limit but to the maximum wall motion value instead. The FFH Amplitude polar maps and surfaces are not normalized in any way. The FFH Phase polar maps and surfaces are displayed in such a manner than angles between 0 and 360^{o} span the color stripe (negative angles wrap around to the 0-360 range, i.e., -20^{o} is displayed as 340^{o}). Note that paradoxical motion would appear to have a non-zero amplitude and a phase value opposed to normal areas (i.e., the color of the phase will correspond to a different portion of the parametric color stripe).

NOTE: It is well known that, even in normal patients, the septum typically moves less than the lateral wall (resulting in a “dark” area in the motion map).

5.10.3 Diastolic Function

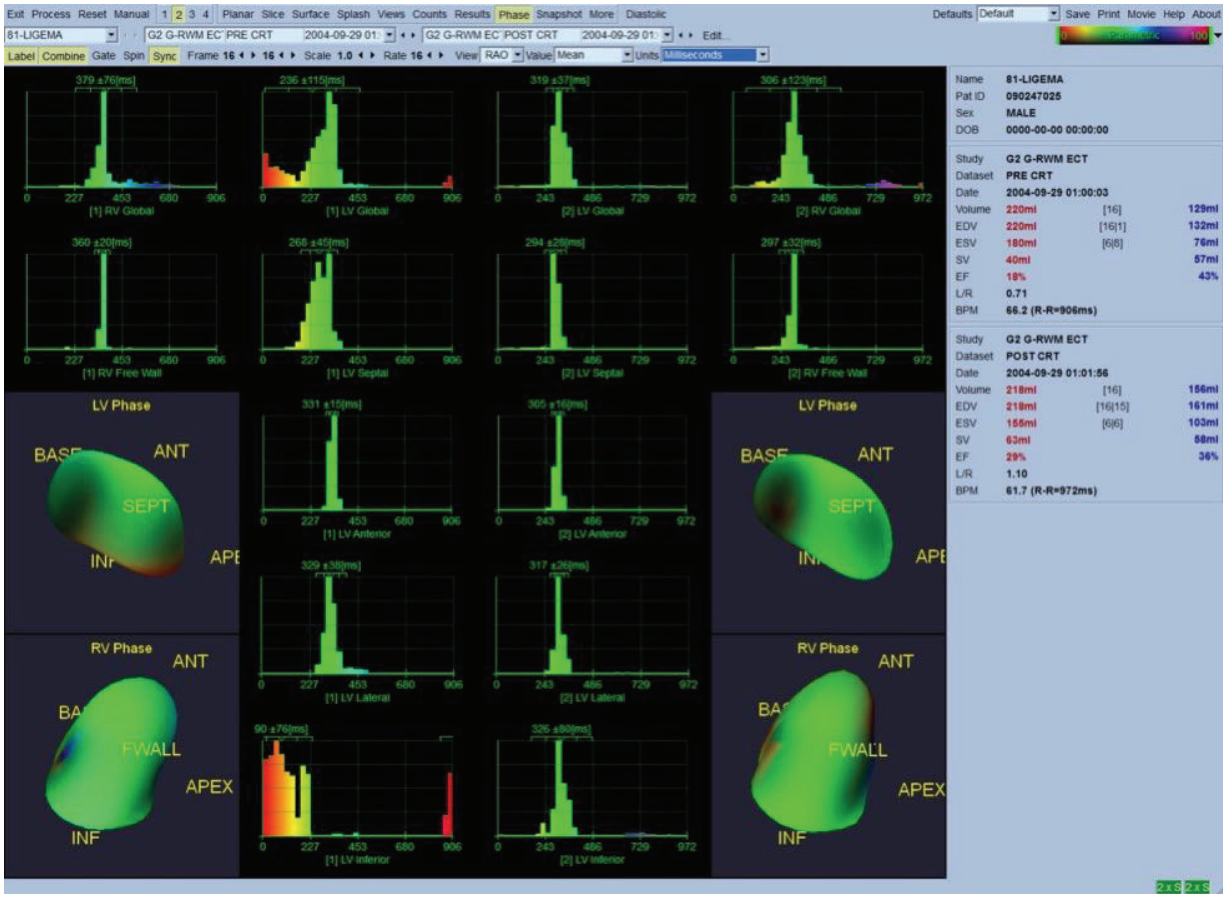
Clicking the **Diastolic** toggle replaces the LV and RV volumes curves with LV and RV volume and filling curves as well as computed diastolic parameters. The user may have to scroll down the Info box or maximize the QBS window to see all the computed parameters.



Diastolic results

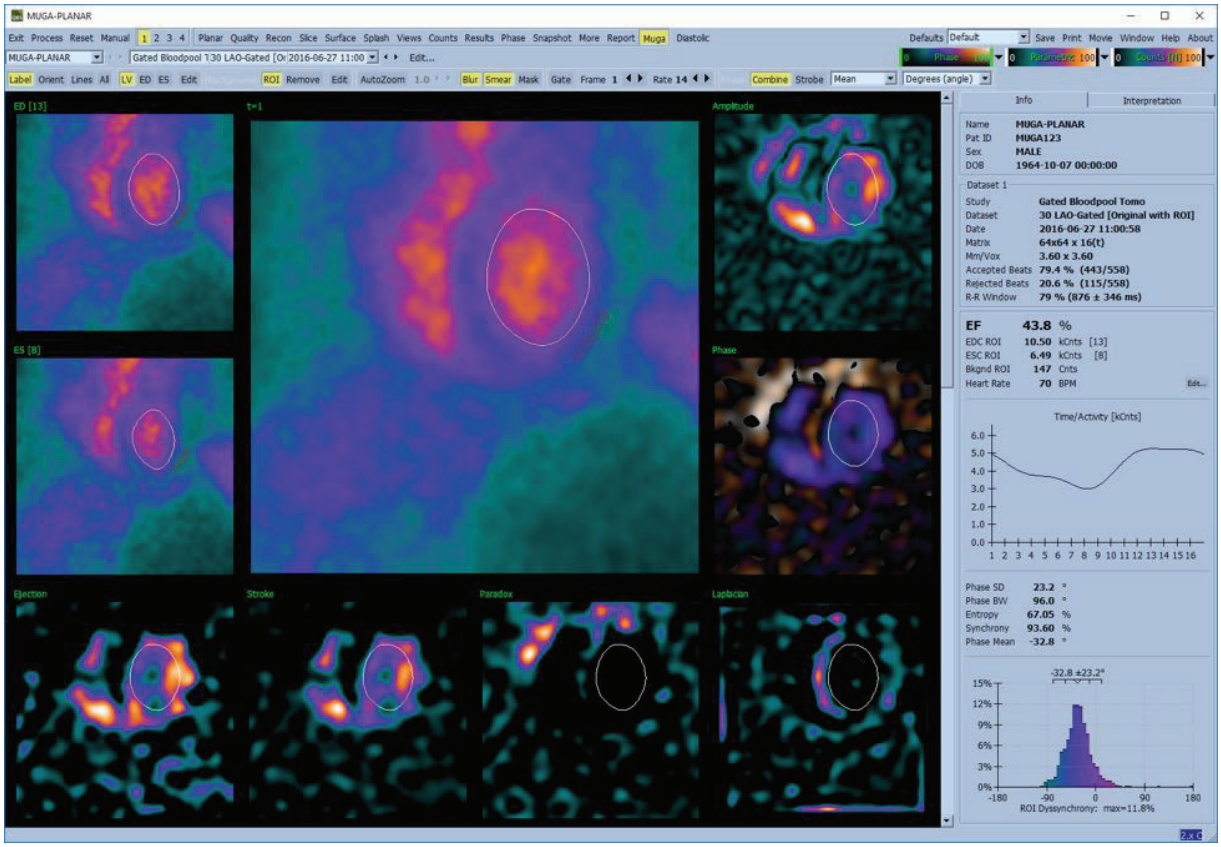
5.11 Phase Analysis

With the optional “PlusPack” component, QBS offers a phase analysis page with global and regional histograms and parametrically-mapped surfaces. Clicking the **Phase** page button brings up the phase analysis page. Detailed statistics and timing differences between regions can be found in the info box (right side of the application). The user may have to scroll down the Info box or maximize the QBS window to see all the computed parameters.


Exit Process Reset Manual 1 2 3 4 Planar Slice Surface Splash Views Counts Results Phase Snapshot More Diastolic
Defaults Default Save Print Movie Help About
81-LIGEMA G2 G-RWM EC PRE CRT 2004-09-29 01: G2 G-RWM EC POST CRT 2004-09-29 01: Edit...
Label Combine Gate Spin Sync Frame 16 16 Scale 1.0 Rate 16 View RAO Value Mean Units Milliseconds
379 ±76[ms]
[1] RV Global
236 ±115[ms]
[1] LV Global
319 ±37[ms]
[2] LV Global
306 ±123[ms]
[2] RV Global
360 ±20[ms]
[1] RV Free Wall
268 ±45[ms]
[1] LV Septal
294 ±28[ms]
[2] LV Septal
297 ±32[ms]
[2] RV Free Wall
LV Phase
BASE
ANT
SEPT
INF
APEX
331 ±15[ms]
[1] LV Anterior
305 ±16[ms]
[2] LV Anterior
329 ±38[ms]
[1] LV Lateral
317 ±26[ms]
[2] LV Lateral
RV Phase
FWALL
90 ±76[ms]
[1] LV Inferior
326 ±80[ms]
[2] LV Inferior
Name 81-LIGEMA
Pat ID 090247025
Sex MALE
DOB 0000-00-00 00:00:00
Study G2 G-RWM ECT
Dataset PRE CRT
Date 2004-09-29 01:00:03
Volume 220ml [16] 129ml
EDV 220ml [16|1] 132ml
ESV 180ml [6|8] 76ml
SV 40ml 57ml
EF 18% 43%
L/R 0.71
BPM 66.2 (R-R=906ms)
Study G2 G-RWM ECT
Dataset POST CRT
Date 2004-09-29 01:01:56
Volume 218ml [16] 156ml
EDV 218ml [16|15] 161ml
ESV 156ml [6|6] 103ml
SV 63ml 58ml
EF 29% 36%
L/R 1.10
BPM 61.7 (R-R=972ms)
2 x S 2 x S

5.12 Muga page

The muga (multi-gated acquisition) page is used for planar gated bloodpool datasets that contain 8 or 16 frames. It is used for both processing and reviewing quantitative results from muga scans. Additional details for the Muga page are described in the QBS reference guide.

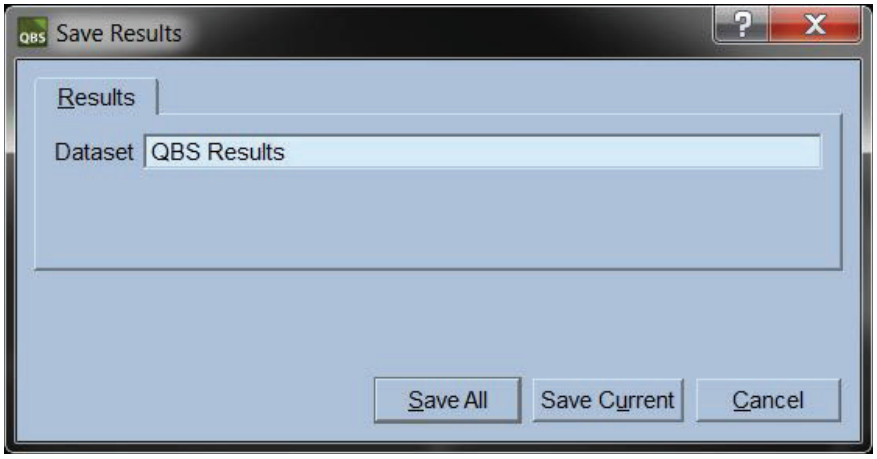


5.12.1 Pixel Size

QBS volume measurements can be hampered by incorrect listing of the pixel size in the image header (this is usually not a problem with the ejection fractions, which are derived from a ratio of volumes). Pixel size is usually automatically calculated by modern cameras, based on knowledge of field of view and zoom information. However, older cameras or "hybrid" systems (where one manufacturer's camera is interfaced to another manufacturer's computer) may not be set up to transfer pixel size information from the gantry, or may take a "standard" size (i.e., 1 cm) as default. In these cases, a correction factor should be manually calculated by imaging a known pattern (for example, two line sources separated by an exact distance), and counting the number of pixels between the lines' centroids in the reconstructed transaxial image.

5.13 Saving your Results

With completion of the processing and reviewing steps outlined above, the user has the option of saving the results to a results file. From the main tool bar click **Save** to display the ***Save Results*** dialog window as shown below.



There are two tab choices for saving, **Results** and **PowerPoint**. Selecting the **Results** tab (default) allows saving of processed results as a dataset within the patient study. The user gives the results dataset a name that will appear in the patient study dataset list upon exiting QBS. In some cases, there may be an additional option to select the format of the results file. This is to ensure some compatibility with older versions of the software. Note that all calculation results from the most recent version may not be available in older versions of the software.

Selecting the **PowerPoint** tab allows saving of results and application configuration information in a format that allows for fast and easy launching of case studies directly from a PowerPoint presentation.

The following actions are supported:

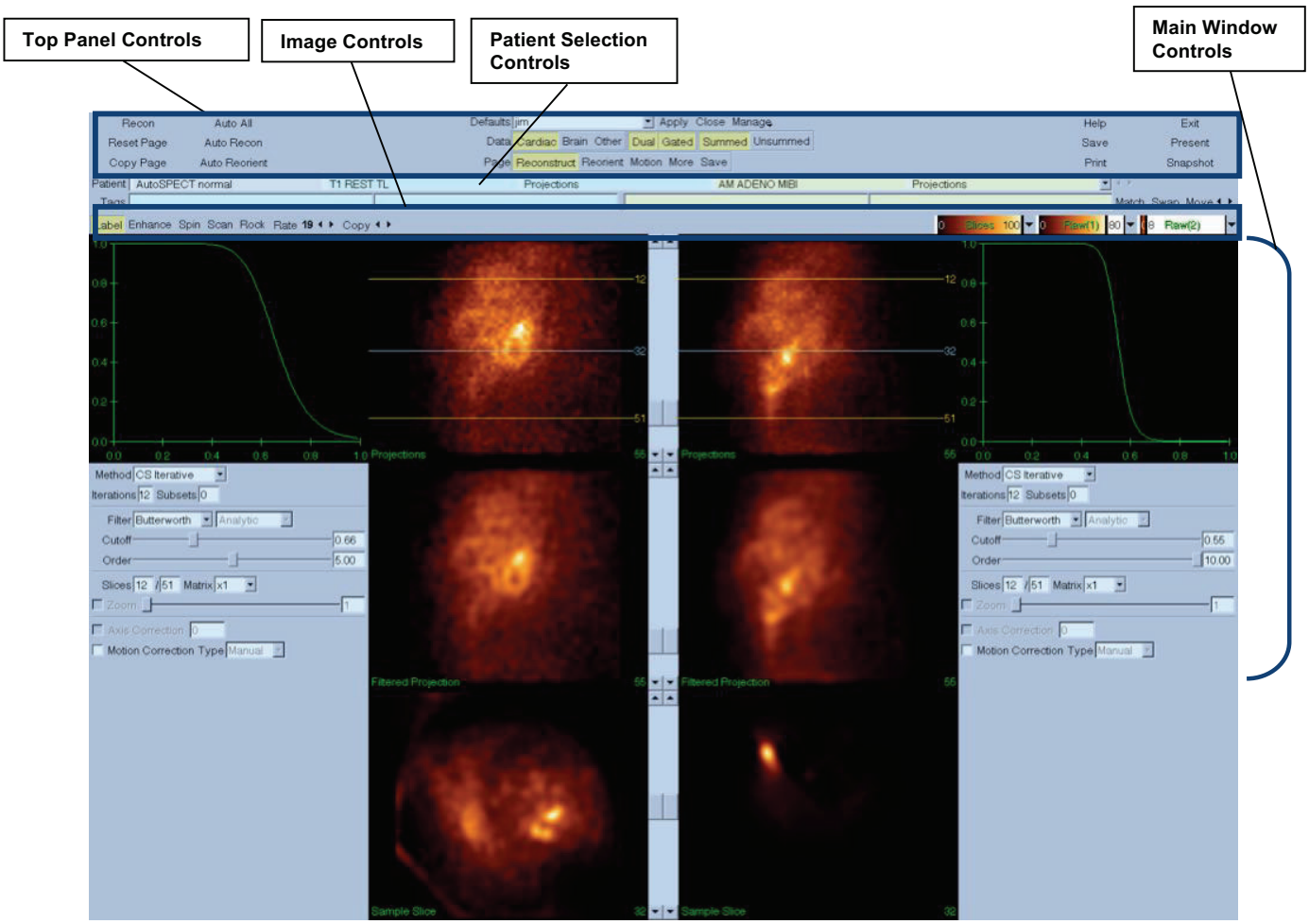
Action	Purpose
Save All	Saves results for all selected studies
Save Current	Saves results for the currently displayed study.
Cancel	Exits the dialog without saving results. The user may also exit the dialog by clicking the "X" in the upper right-hand corner of the dialog window.

6 AutoRecon Application (Automated Reconstruction)

AutoRecon is an optional application for the automatic and manual reconstruction, reorientation and motion correction of Cardiac, Brain, other (liver, bone, etc) SPECT and gated SPECT datasets. The amount of automation and processing options provided by AutoRecon depends upon the type of dataset selected. AutoRecon applies validated rules to reconstructing and reorienting projection images, and reduces the number of decisions required when processing studies.

6.1 Launching AutoRecon

Launching AutoRecon in its standard configuration will bring up the Reconstruct page with the selected dataset(s) loaded as shown in the figure below.



6.1.1 Top Panel Controls

The AutoRecon top panel controls allow you to perform application functions such as selecting defaults files, saving files, or formatting images. You can access most of these controls regardless of the currently displayed AutoRecon window. A brief description of some of the buttons contained in this panel is shown below.

- **Recon** - Clicking it will manually reconstruct the currently displayed dataset(s). To manually process a dataset, define the reconstruction limits, verify and adjust the main window controls as desired and then click the **Recon** button. AutoRecon does not automatically advance to the Reorient window when using the **Recon** button. If Motion Correction type is set to **Auto**, the Motion window will be displayed after reconstruction of the dataset(s) has commenced.
- **Reset Page** - Clicking it will restore the processed dataset(s) and viewport settings to their initial values. It also removes any processed dataset(s) that have not been saved.
- **Copy Page** - Clicking it will copy the processing settings from one set of viewports to all other objects loaded in memory.
- **Auto All** - **Auto All** is only available for cardiac dataset(s). Using this option will automatically determine the reconstruction limits, reconstruct and reorient cardiac dataset(s). **Auto All** generates the transverse slices, proceeds automatically to the Reconstruct window, and automatically reorients the ventricular volume. If Motion Correction type is set to **Auto**, the Motion window will be displayed after reconstruction has commenced using the motion corrected dataset(s).
- **Auto Recon** - This option automatically determines the reconstruction limits and reconstructs the cardiac dataset(s). **Auto Recon** automatically generates the transverse slices, but does not proceed to the Reorient window. If Motion Correction type is set to **Auto**, the Motion window will be displayed after reconstruction has commenced using the motion corrected dataset(s).
- **Auto Reorient** - Clicking it will automatically reorient cardiac dataset(s). If you have not reconstructed the dataset(s), **Auto Reorient** will reconstruct and then reorient the datasets. If Motion Correction type is set to **Auto**, the Motion window will be displayed after reconstruction has commenced using the motion corrected dataset(s).
- **Defaults** - The Defaults field displays the name of the currently selected default settings.

6.2 Workflow

Typical processing sequence for Cardiac datasets in AutoRecon might be as follows:

1) **Load desired dataset(s)** from the patient browser and click AutoRecon button.

2) From the Reconstruct Page, **click Auto All to automatically reconstruct and reorient** the unprocessed SPECT or gated SPECT cardiac datasets, Auto Recon to automatically generate the cardiac SPECT or gated SPECT transverse dataset, Auto Reorient to automatically reorient the cardiac SPECT or gated SPECT transverse datasets.

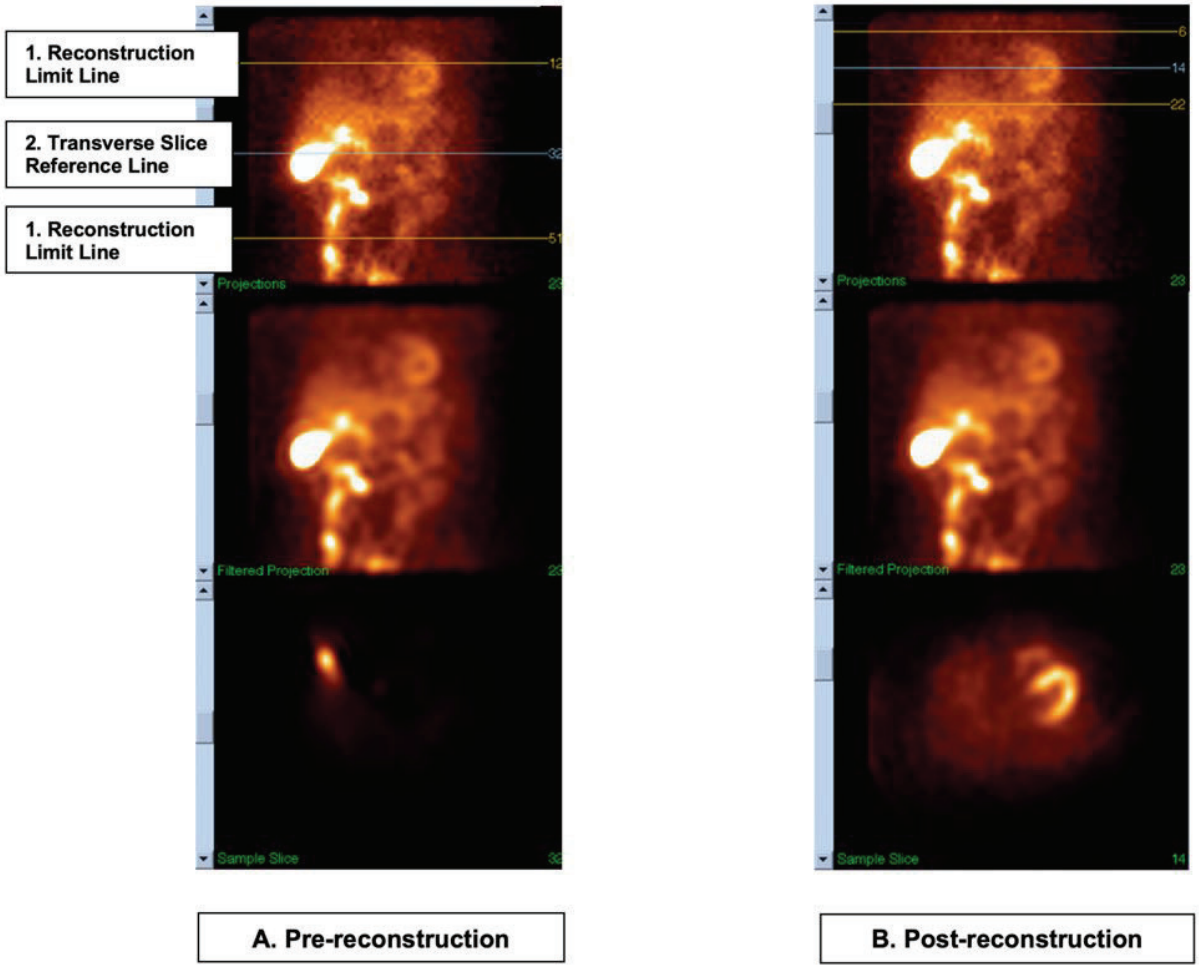
NOTE: If you have not reconstructed the transverse dataset, Auto Reorient will automatically reconstruct the dataset prior to reorienting the dataset. AutoRecon will automatically proceed to the Reorient window if Auto All or Auto Reorient options were selected.

3) **Evaluate the images** to ensure no further manipulation is necessary by checking the following pages:

a) Reconstruct page

i) The reconstruction limits should completely enclose the left ventricle and be symmetrically placed above and below the left ventricle less than 5 pixels from the ventricle.
ii) The reconstruction limits should not clip the left ventricle.

NOTE: If the reconstruction limits are not properly determined, you can manually process the cardiac dataset(s). Press the left mouse button and drag the reconstruction limit lines close to the ventricle, and then left click the **Recon** button. If motion correction type is set to **Auto,** the Motion window is displayed after reconstruction.



Legend

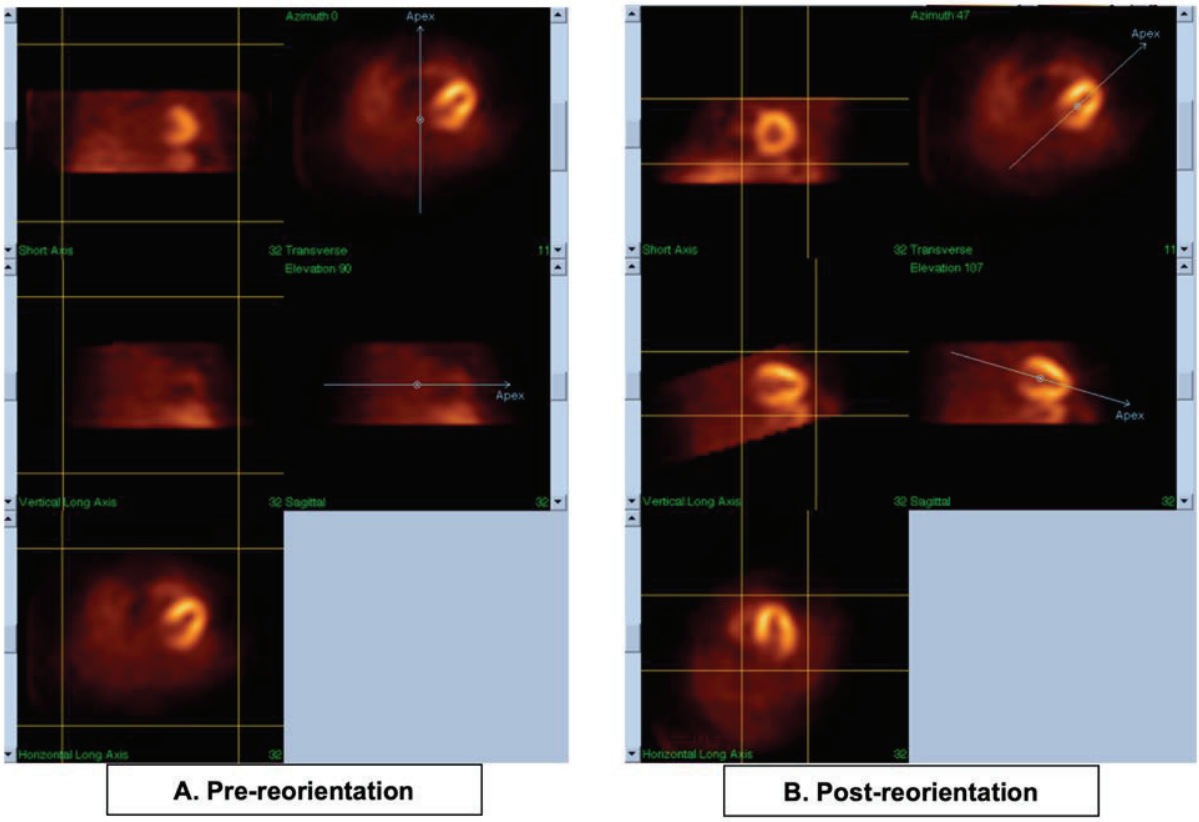
A. Pre-reconstruction
B. Post-reconstruction
1. Reconstruction limit line
2. Transverse slice reference line

b) Reorient page

i) The reoriented left ventricle should be visible in the Short Axis, Vertical Long Axis, and Horizontal Long Axis viewports.
ii) Verify placement and orientation of the Azimuth line in the Transverse viewport.
iii) Verify placement and orientation of the Elevation line in the Sagittal viewport.

NOTE: If necessary, manually reorient the ventricle. Left click and drag the circle on the Azimuth or Elevation reference line to the center of the ventricle. Left click and drag the ends of the Azimuth or Elevation reference line in the direction that you want to orient the ventricle. Left click and drag the dataset

reference lines so that they are close to the ventricle but not clipping the ventricle.



A. Pre-reorientation **B. Post-reorientation**

Legend

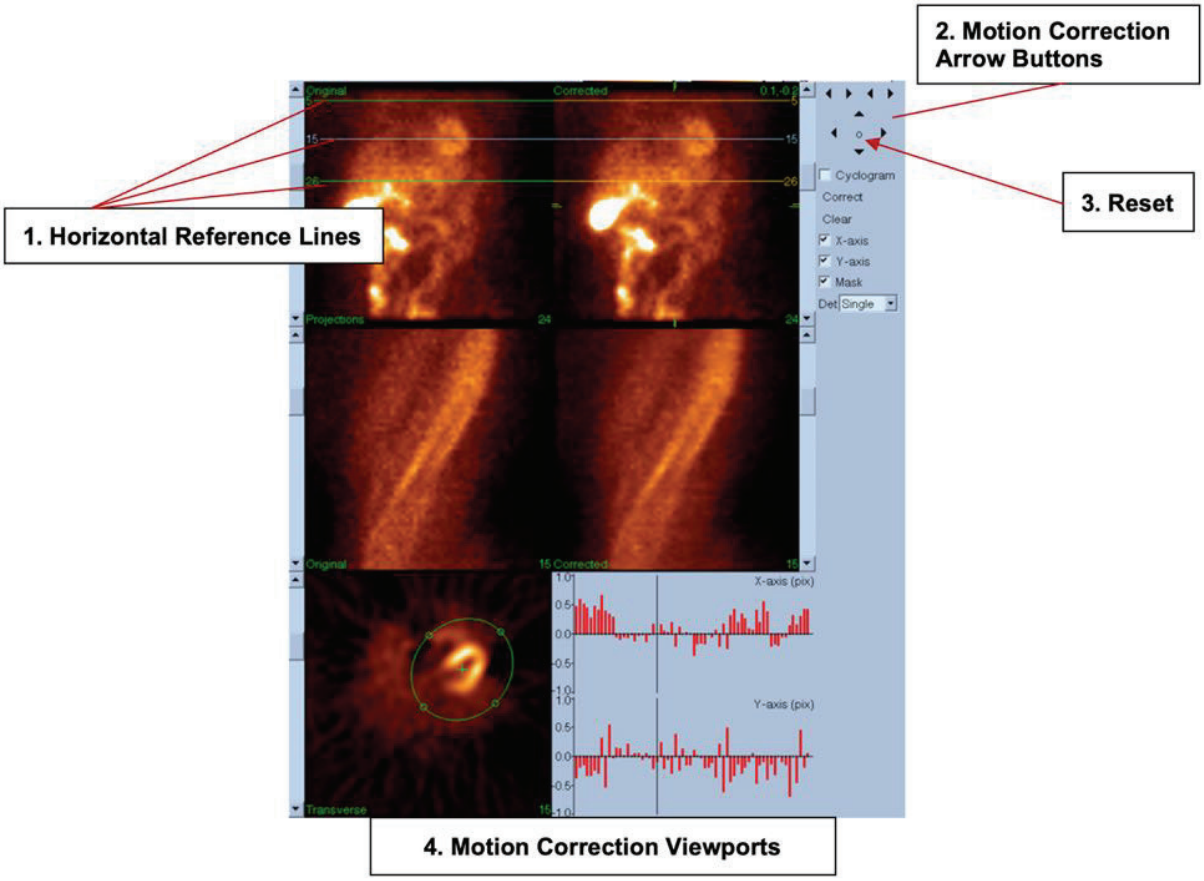
A. Pre-reorientation
B. Post-reorientation

c) Motion page

i) The Motion page houses the MoCo (Cedars-Sinai Motion Correction) application, which is used for automatic and manual correction of SPECT acquisition motion artifacts. Datasets will be automatically corrected for motion artifacts if the motion correction type is set to Auto on the Reconstruction page.

ii) Verify that any motion artifact has been accurately corrected for.

NOTE: To manually correct for motion, step through each slice in the reference viewport, move the image in each slice as needed to align the images using the motion correction clickers. Change the motion correction type to **Manual** on the Reconstruct page to reconstruct the study with the manually motion corrected dataset(s).



Legend

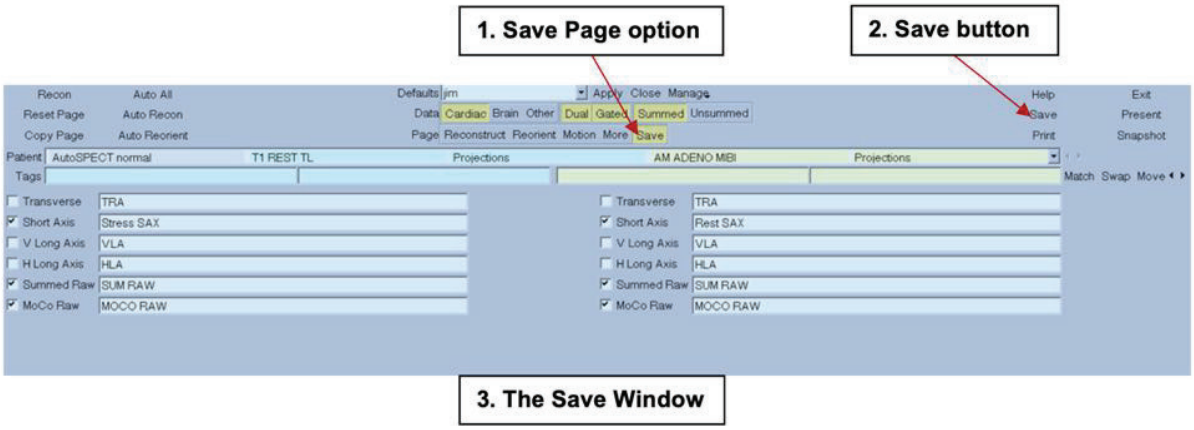
1. Horizontal reference lines
2. Motion correction arrow buttons
3. Reset
4. Motion correction viewports

d) Save Page

i) Enable the toggle boxes for each dataset that you want to save and verify that the View IDs are correct.

ii) Left click on the **Save** button to save the datasets.

CAUTION: Do not confuse the Save Page option with the **Save** button in the far right side of the Top Panel Controls. The **Save** button saves all of the datasets without allowing you to change the save parameters**.**



Legend

1. Save page option
2. Save button
3. The Save window

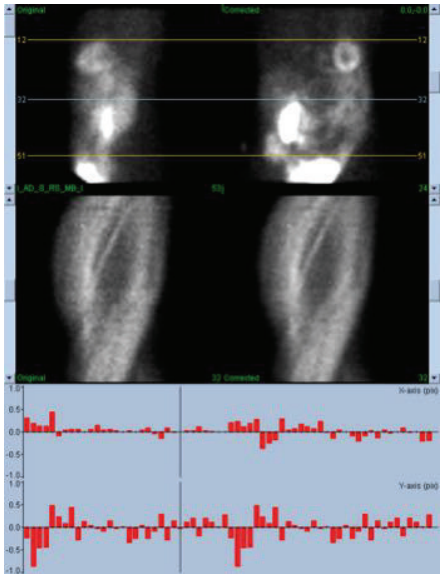
5) Left click on the **Exit** button to **exit AutoRecon**.

7 MoCo Application (Motion Correction)

MoCo is constructed from the following components:

Viewport Display	Images and results display
Color Control	Selects current color scale and intensity mapping.
Dataset Selector	Selects the currently displayed dataset.
Viewport Control	Controls display of viewports
MoCo Control	Controls automatic and manual motion correction processing and validation.

7.1 Viewport Display



The interface, which does not include externally accessible exit or save functionality as it is intended primarily to be embedded in a containing application, is constructed from the following components:

Original Projection Viewport	Displays a single projection from the uncorrected dataset. The current projection is selected by its corresponding scrollbar; horizontal motion reference lines are moved by dragging.
Corrected Projection Viewport	Displays a single projection from the corrected dataset. The current projection is selected by its corresponding scrollbar; horizontal motion reference lines are moved by dragging. The motion correction x and y axis offsets are also displayed.
Original Sinogram Viewport	Displays a single sinogram from the uncorrected dataset. The current sinogram is selected by dragging the sinogram reference line in the corresponding projection viewport.

Corrected Sinogram Viewport	Displays a single sinogram from the corrected dataset. The current sinogram is selected by dragging the sinogram reference line in the corresponding projection viewport.
X-axis Motion Graph	Displays the current x-axis motion correction offsets.
Y-axis Motion Graph	Displays the current y-axis motion correction offsets.
Motion Cursor	Manually selects the x and y axis motion correction offsets. Also selects the current projections for the Original and Corrected Projection Viewports.

7.2 Color Control

Two color scales exist: ***Raw*** controls most images which include the projections, sinograms and cyclogram displays. ***Slices*** controls the single slice displays, which is only available when Mask or Cyclogram is selected.

The Color Control is used to select the current color scale and intensity mapping. The color scale is selected by clicking on the color scale option menu and choosing from the ensuing list of available color scales. The intensity mapping is set using two parameters, the lower and upper levels, either of which can range from 0 to 100 percent. They together specify that portion of a dataset's dynamic range that is to be mapped onto the full color scale.

The lower and upper levels of the intensity mapping, represented with the lower and upper level bars, can be set through the color scale viewport, which supports the following interactions:

- Left drag either level bar to move it.
- Left drag any other point on the viewport to move both level bars simultaneously.
- Middle click or drag any point on the viewport to move the closer level bar to that point.
- Double left click anywhere in the viewport to reset the level bars to 0 and 100.

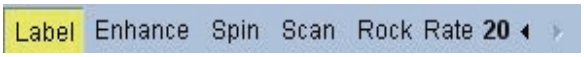
The following features are also provided through the option menu:

Reset	Resets lower and upper levels.
Invert	Toggles the sense of the lower and upper levels.
Step	Toggles color scale discretization.
Gamma	Toggles display of color scale gamma control.
Expand	Toggles dynamic range expansion of lower and upper levels.
Normalize	Toggles automatic dataset normalization based on segmentation results.

7.3 Dataset Selector

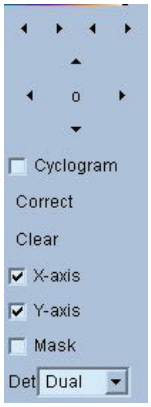
At start up the application is passed a list of one or more datasets as input. The dataset selector selects from this list the current dataset, i.e. the dataset to be viewed. It allows the user to page through the datasets by clicking the arrow buttons. In addition, the user can jump directly to a dataset by clicking on the dataset option menu; this pops up a list of available datasets from which the desired dataset can be selected.

7.4 Viewport Control



Label	Enables viewport labeling including slice and projection numbers and motion reference lines.
Enhance	Applies a spatial filter designed to enhance motion artifact visibility to the original and corrected projection sequences.
Spin	Toggles projection cine.
Scan	Toggles the sinogram cine.
Rock	Toggles bi-directional projection cine for sub 360° acquisitions (with spin also enabled).
Rate	Selects the cine and scan speeds.

7.5 MoCo Control



The MoCo Control is used to control automatic and manual motion correction processing and validation. The following controls are available:

Cyclogram	Enables cyclogram display mode. When enabled the sinogram viewports are replaced with their corresponding cyclogram viewports. A cyclogram is constructed by compositing the set of vertical strips defined by the intersection of each projection in the projection sequence with a plane constrained to be perpendicular to the projection and to the transverse plane and further constrained to intersect a user specified point in the transverse plane. A cyclogram accentuates horizontal (x-axis) motion artifacts in a manner analogous to a sinogram's accentuation of vertical (y-axis) motion.
Correct	Initiate automatic or semi-automatic motion correction.
Clear	Reset all motion correction offsets to zero.
X-axis	Enable x-axis motion correction.
Y-axis	Enable y-axis motion correction.
Mask	Enable masking mode. When enabled an additional transverse slice viewport is enabled allowing the user to define a transverse volume delimited by an ellipse and lower and upper slice bounds upon which the motion correction algorithm should focus its efforts.
Det	Selects the number detector heads, permitting differing constraints to be used by the motion correction algorithm based on the camera geometry.

8 Troubleshooting

Symptom: I receive a "database connection failed" error message when launching QPS or QGS
Resolution:

1. Verify that ARG Server has been correctly installed.
2. Verify that the ARG Server is reachable over the network (try "ping [argserver]" from the command prompt, where argserver is the IP address of the arg server)

Symptom: I can't push images to CSImport from my camera.
Resolution:

1. Verify that both systems have been configured correctly; consult the connectivity section of CSImport configuration, and the camera vendor's user manual.
2. Verify that the windows firewall has an exception for the Cedars-Sinai DICOM Store
3. Verify that the "pushing" workstation is able to reach the CSImport station (try "ping [csimport_ip]" from the command prompt on the camera's workstation, where csimport_ip is the IP address of the CSImport machine)

Symptom: In QGS+QPS or QPET I receive "multiple matches" when opening a dataset
Resolution:

1. Verify that the necessary matching fields (e.g. patient sex) are getting populated. If they are not, they will show up in yellow in the dataset editor window. If fields are not correctly populated this could indicate an error with the DICOM data. Contact the camera manufacturer for more information.
2. Note the sex, isotope, and acquisition state for the dataset.
3. Open the Database page, select "List..." verify that there is only 1 active database for sex/isotope/acquisition state combination. If more than one active databases are present, open the database which should not be selected, turn off "allow automatic selection" and save.

Document Index

Blur, 50, 51, 81, 84
Constrain, 49
Counts, 74
CSImport, 12
Data
  Importing, 28
Device Description, 9, 15, 22
Diastolic Function, 87
DICOM
  Push, 35
  Query/Retrieve, 34
Extent, 62
FFH Amplitude, 74
FTP, 34
Fusion, 11
Gate, 51
Mask, 48
MoCo, 12, 99
Movie, 43
Page
  Manual, 48, 77
  More, 63
  QBS Results, 85
  QGS Results, 60
  QPS Results, 59
  Raw, 42, 44, 74
  Slice, 44, 50, 75, 81
  Splash, 51, 82
  Surface, 56, 84
  Views, 85
Parametric, 74
Phase Analysis, 63, 88
Philips Odyssey, 33
Philips Pegasys, 33
Polar Maps, 62
Popout, 52, 82
PowerPoint, 71, 91
Process, 44, 48, 75
Purpose of Device, 9
QBS, 10, 72
QGS, 10
QPS, 9
Results
  Saving, 70, 91
Rock, 75
SDS, 54
Setup, 24
Severity, 62
Smear, 50, 51, 81
SMS, 54
Spin, 74
SRS, 54
SSS, 54
STS, 54
Vessels, 60
Visual Score, 53, 60
volume curve, 61
Voxel, 63
Walls, 60

1 Instructions for Use (IFU) for CarimasCE

This is the Instruction for Use for CarimasCE. This first section contains the information you should know before starting to use the program, as well as the information you need to get started with it. Before performing any analysis, you must at least read the Warnings and Notices for Safety section.

CarimasCE Version (UDI-PI): 1.3.9.2501170 **Release date: 17.1.2025**
UDI-DI: 06438270000002
IFU revision date: 18.02.2025

CE
0537

1.1 Introduction

Summary

CarimasCE is a software that aids clinical work by providing a workflow for PET radiowater analysis.

Currently there are limited data in using [15O] H2O myocardial PET perfusion imaging in patients with heart failure or reduced left ventricular pump function. There are no contraindications and it is not expected that the [15O] H2O PET analysis would be biased in these patients but the perfusion reference values are not well established. Therefore, currently CarimasCE analysis of [15O] H2O PET are recommended to be used only in patients with suspected or known coronary artery diseases but with preserved left ventricular function.

The results of imaging are used, together with symptoms, clinical information, biomarkers, and other anatomical imaging results to set the diagnosis of ischemic heart diseases and estimate the prognosis of the patient. The perfusion imaging is only one source of information for clinical decision making.

Carimas needs to be able to locate the positions of apex and base of the left ventricle, as well as centre of right ventricle for the segmentation algorithm. Therefore, appropriate experience and training for such definitions must be obtained before analysis.

CarimasCE is a medical device as defined in the European Union Medical Devices Regulation (MDR).

Intended User

CarimasCE is intended to be used by trained physicians and researchers in a department that utilizes O15-H2O in myocardial PET imaging.

Clinical Benefits

CarimasCE is used for accurate detection and confirmation of diagnosis of suspected coronary artery disease.

Intended Use

6.1.11

CarimasCE is a software application that is intended to display blood flow in the left ventricle muscle of the heart by using dynamic PET images acquired with O15-H2O tracer. The blood flow information is used in adult patients and provides information that aids a clinical expert in making a diagnosis.

System and environment requirements

System and environment requirements are detailed in the Installation Guide

Reporting malfunctions and dangerous incidents

All serious incidents encountered while operating the software must be reported to the software manufacturer and to the competent authority of the Member State where the user and/or patient is established.

Contact Information

The wellbeing services county of Southwest Finland / Turku PET Centre
Kiinamyllynkatu 4-8
20520 Turku
FINLAND

Email address: support.software@tyks.fi
Web address: https://carimas.fi/carimasce/

1.2 Getting Started

Installation

To install the program, follow the steps in the Installation Guide. Note that the installation may require administrator privileges on your system.

Starting the program

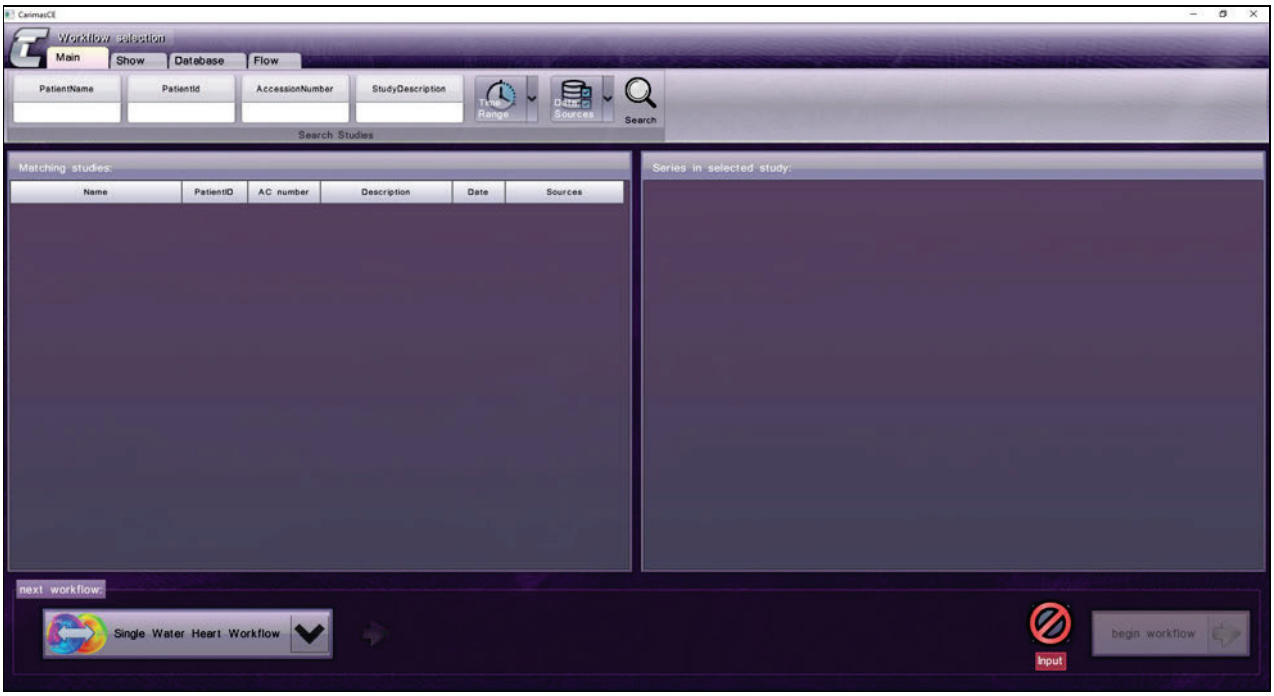
To start the CarimasCE program, open the Windows Start Menu on your workstation. Under the "CarimasCE" entry, you will find a link to this User's Guide, a link to the CarimasCE website and the CarimasCE program icon that launches the application.

User interface

The CarimasCE display has two main areas: a display area that takes up most of of the bottom part of the screen, and a toolbar area at the top of the screen.

The toolbar area contains the buttons for the various tools needed during the analysis. The buttons are grouped under various tabs, shown in the top of the toolbar. The contents of the toolbar changes when you move through the analysis.

The display area content displays one or more views, with different content in each stage of the heart analysis workflow. When the CarimasCE application is launched, the display area shows the Study selection view, and the workflow and image selection buttons.



WARNING

To view important information about the program, click the "About" button in the "Show" tab of the toolbar. Verify that the program version number is the same as the version number in the first page of this guide.

Tip

Some steps may be performed in multiple ways. These notes contain information on any additional tools that may help you in the analysis.

Next

When you are ready, move on to the Starting the Analysis section of this guide.

1.3 Symbols, Abbreviations and Warnings

Symbols and warnings in this manual

Warnings in this manual are displayed as follows:

> **WARNING**
> Pay special attention to these warnings in this manual. They contain notes for any actions or unexpected situations with potentially significant effect on the analysis results.

Warnings within the program

CarimasCE displays in-program warning messages when situations with increased risk status are detected. Usually this means that the action or used data could influence the analysis in an undesired way. The content of these warnings is also inserted to the analysis final report.

> **WARNING**
> Carefully read the contents of all warning messages displayed in the program and make necessary adjustements before continuing with the analysis.

The warning symbols used within the program are as follows:

Symbol	Name	Explanation
	Warning	Displayed when there is a possibility the used data or user action could influence the analysis in an undesired way.
	Error	Displayed if the program encounters an error it can recover from.
	Fatal Error	Displayed if the program encounters an error it cannot recover from.

Symbols within the program

This section shows the symbols used within the program and their explanations:

Symbol	Name	Explanation
	Valid Input	This symbol means that the workflow input in the relevant slot is valid for beginning the workflow. Displayed only during Workflow selection.
	Input Missing	This symbol means that the relevant input for the workflow is not defined or the input image is invalid. Displayed only during Workflow selection.
	No Thumbnail	This symbol means that the Thumbnail of a series cannot be displayed. Note that the thumbnail is only calculated if the series is imported to CarimasCE's local data. Displayed only during Workflow selection.
	About	Displays the About box, showing important information about the program and the manufacturer. Accessible from everywhere in the program.
	Log Window	Displays the Log window, showing information related to the execution of the program.
	Time Range	Displays options for defining a time range criteria for a search.
	Data Sources	Displays options for what data sources to use as the target of a search.

	Search	Executes a search with the defined criteria.
	Manage Local Data	Opens the Local Data manager, where you can e.g. export and remove studies.
	Import From Disk	Displays information about importing data to CarimasCE from the local disk.
	Add PACS	Options for configuring a new PACS connection.
	Remove PACS	Options for removing PACS connections from the program.
	Edit PACS	Options for editing the settings of existing PACS connections.
	Clear Inputs	Clears all user-defined workflow inputs.
	Import	Shows that a series can be imported to CarimasCE. Clicking this symbol will import the series to CarimasCE's local data.
	Imported	Shows that the series is already present in CarimasCE's local data.
	Previous Step	Returns to the previous workflow step.
	Next Step	Proceeds to the next workflow step.
	General Tool	Automatically uses the mouse tool that is relevant to the item closest to the cursor.
	Move Tool	Restricts the mouse to moving the image around in the window.
	Zoom Tool	Restricts the mouse to zooming in and out of the image.
	Cut Line Tool	Restricts the mouse to moving the Cut Lines.
	Break Workflow	Quits the workflow and returns to Study and Workflow Selection.
	Image Verification Step	Moves to the Image Verification step of the workflow.
	Heart Location Step	Moves to the Heart Location step of the workflow.

	Segmentation Step	Moves to the Segmentation step of the workflow.
	Quality Control Step	Moves to the Quality Control step of the workflow.
	Report Step	Moves to the Report step of the workflow.
	Locator Tool	Restricts the mouse to defining the left ventricular Base/Apex and the heart LV/RV centre point Locators.
	Reset Locator	Resets the Locators to the default position.
	Restrict to Input Function	Restricts segmentation editing to the Input Function.
	Restrict to whole LV	Restricts segmentation editing to the whole left ventricular.
	Restrict to LV Inner Wall	Restricts segmentation editing to the inner wall of the left ventricular mesh.
	Restrict to LV Outer Wall	Restricts segmentation editing to the outer wall of the left ventricular mesh.
	Smooth Mesh	Smooths the selected mesh.
	Enlarge Mesh	Makes the selected mesh larger.
	Shrink Mesh	Makes the selected mesh smaller.
	Thicken Mesh	Makes the left ventricular mesh thicker by shrinking/enlargening the selected mesh.
	Thin Mesh	Makes the left ventricular mesh thinner by shrinking/enlargening the selected mesh.
	Reset Mesh	Resets the whole mesh into a state without any automatic wall findings.
	Save as Bitmap	Saves the workflow report as a bitmap image to the local disk.

Abbreviations used in the program

LV
Left Ventricle

RV
Right Ventricle

F

Myocardial blood flow

PTF
Perfusable Tissue Fraction

VL
Arterial blood volume

MASE
Mean Absolute Scaled Error

DF
Diff Frame

TAC
Time Activity Curve

VOI
Volume Of Interest

PACS
Picture Archiving and Communication System

WARNING MESSAGES AND THEIR EXPLANATIONS

This section expands upon the warning messages displayed by the system

Warning Message	Explanation
The selection contains [NUMBER] items that are not yet exported and the deletion will remove the results for good!	There are such studies checked that contain data created in Carimas and stored only in the local system. If the items are removed from the local system, the data will be gone for good. You can avoid this message by exporting the created data to some external storage. Most easy way to locate the non exported data is to look at the 'No Export' -column in Data Management. The item count informed in this box is the number of non exported series (every completed analysis flow results and possible other data, like parametric images).
The selection contains [NUMBER] items that have no analysis done at all yet!	This message is shown, if you are removing an item that was imported into local system but no analysis has been done for it yet. If the data was accidently imported, you can ignore this message and remove it, but normally the data is imported by someone for running analysis on it. All removed data is backed up if only this message is shown and no data will be removed for good if proceeded.
Failed to delete the item!	This is general message that is shown if you are trying to remove single report under some study and the attempt failed for some reason. The application log may contain more detailed information about the error.
Failed to delete [NUMBER] items!	This is general error message shown if the deletion failed somehow. This is the summary message showing the total failure count of all items selected for removing. A more detailed reason for each failure might be stated in other message boxes or in the application log.
The used disk space has reached the defined warning limit. Do you want to open the size management dialog?	The system administrator has defined some warning limit for disk space of the local system and exceeding it causes this warning when the disk space is running low. This message will appear every time when the program is started until some data is removed from the local dataase or more disk space is allocated.
You are deleting a non-exported analysis report from the local data. The analysis results will be permanently lost. Do you want to proceed?	Message that is shown when you are removing single Carimas analysis report that has not been exported yet. If it is removed, the data will be gone for good. You can avoid this message by exporting the report to some external storage by selecting the study containing the report and running 'Export'.
Total [NUMBER] items will be removed permanently, are you sure?	This message is shown if you are removing only items having the analysis workflow already done and all data created in Carimas has already been exported to external storage. Therefore all the removed data can be restored if needed.
The analysis report will be deleted from the local data, do you want to proceed?	Message that is shown when you are deleting single analysis report from the study that is already exported into some external location and thus you will not lose the only copy of the data.

All the series will be recursively searched from folder '[PATH]' and imported into local data. Do you want to proceed?	This message is always shown to user before some importing is started from some root folder. This is for avoiding unintended importing tasks, for example from accidental drag & drops.
No suitable items found from given folder	This message is shown if the user has defined some import root folder and the program has scanned it trough and no supported series were found. See the DICOM conformance statement for more information about supported images.
There were failures in importing process. [NUMBER] of total [NUMBER] series failed to import!	This message is shown as a summary of the number of errors encountered when a local folder was chosen for import and the system has searched recursively all the studies under that location. More detailed errors might be found in the application log.
Conflicting Study Information	This message is shown if the imported data contains conflicting header information with some already existing data, for example there is already a patient with same PatientID, but with a different name, or there is already the same AC number, but under a totally different patient. In these cases the user must check the reason for this conflict and correct the header fields somehow before importing.
Saving the report failed!	Message that is shown when the report saving process fails for any reason, for example if there is no writing rights to local data storage. The application log may contain a more detailed message about the error.
Current report is not saved! Results will be lost if you exit now!	Message that is shown when the analysis has been done up to the Report Step and the user is trying to close the program before saving the results.
You are moving away from the report phase and you have not yet saved the report. Do you want to proceed?	This message is shown when you have reached the reporting phase and go back to a previous Step without saving. This means that any modifications to the analysis will cause the current results to be overwritten and thus lost for good.
The current analysis data will be lost if exited now	This message is show to the user, if they try to exit from program in middle of the analysis (before the Report Step). If exited, the information of the analysis will be lost.
Searches from PACS with empty search fields are disabled because of possible overwhelming response count	Carimas does not allow running searches without any terms or restrictions on PACS systems, because that would ask the PACS systems to gather all their data as response which would in many cases cause excessive network traffic and heavy workload to servers. The empty search can still be run (getting all items) if only the local data of Carimas is chosen as a source.
Series importing failed!	This message is shown when the user has tried to import data from a PACS, but the importing failed for some reason. There might be a better message in the application log telling what went wrong. Usually there are some errors in the DICOM device pairing.
Cannot use this image for this input slot because: [MESSAGE]	This message is shown, if the selected workflow does not accept the chosen image series as its input. A more detailed reason is shown in the [MESSAGE].
The datasource '[SOURCE]' will be removed (disconnected) permanently from the database. Do you want to proceed?	This confirmation message is always presented to the user before external data sources are removed from the system. All the reports that were exported to this source before are still assumed to be exported (Carimas knows that they exist externally although the source is no longer connected into Carimas).
Ping failed!	This message is shown, if the target PACS did not answer to a DICOM ping query. That indicates that there is some problem in the physical connection or the DICOM pairing. Run the normal OS ping to ensure that the issue is in the connection, and if not, the problem is likely in DICOM pairing information. It might also be that the PACS in question does not support this ping feature.
Cannot parse hostname [HOSTNAME] value: [VALUE]	This message is shown if some new PACS setting contains some information that cannot be parsed. Normally the user has typed some illegal characters in the box, or entered some illegal value, for example negative number to the port property. The changes are not saved before the value is changed to expected form.

Error saving server: [REASON_MSG] please check the text fields	This message is shown if some new PACS setting contains some information that cannot be parsed. Normally the user has typed some illegal characters in the box, or entered some illegal value, for example negative number to the port property. The changes are not saved before the value is changed to expected form.

The following are "Active Status Warnings", meaning they do not prevent the analysis but they are something the user must take into account. Some of them, like for example 'SmaGlo', can be rectified by the user during the analysis and will no longer be displayed if the user has taken the necessary steps. The warning codes for any remaining ones that have not been rectified will be displayed in the final Report.

Warning Message	Explanation
The current left ventricle muscle segmentation is smaller than 10 voxels and that may cause error from noise	This message is shown if the LV muscle region is exceptionally small and might thus contain lots of noise. To avoid this message you must make the LV muscle region larger with 'Larger' and 'Thicker' -tools. This is an active status warning and is shown in the report with code: 'SmaGlo'
The current left ventricle cavity segmentation (LV input) is smaller than 10 voxels and that may cause error from noise	This message is shown if the LV cavity region is exceptionally small and might thus contain lots of noise. To avoid this message you must make the LV cavity region larger with 'Larger' and 'Thicker' -tools This is an active status warning and is shown in the report with code: 'SmaInp'
The heart axis might be misaligned. Please check that the heart axis is in the center of the cavity and the end point is not drawn too far	The axis position has an effect on the polarmap values and therefore the system will show this warning if it detects that the axis might be far from the optimal position and may cause distortion of the polarmap. If the axis is drawn too close to the heart wall, the wall close to the axis will appear smaller in the polarmap than the region far from the axis. The program is calculating the area of each polarmap segment in the real mm space and shows this warning, if some area differs by at least 50% of the area of some other segment. This is an active status warning and is shown in the report with code: 'DistAx'
The selected image has so few frames that the model might not give meaningful results	This warning is shown if the image is reconstructed so that there are too few frames for the model to work optimally. If you see this message, it might indicate that wrong image series is selected accidentally or that the image reconstruction is non-optimal. This message is shown if the image has less than 5 frames. This is an active status warning and is shown in the report with code: 'FewFram'
The current image series header claims that the image tracer is not O15 that is expected by the water model	The model used by CarimasCE expects the image data to be O15 tracer and if created properly the image header should have this information. If the information is missing from the header, this message is shown to inform the user they might have accidentally picked the wrong image series from the series list. If you know that the image is actually valid, you can proceed with the analysis. The settings of the device or the image should perhaps be adjusted so that this value is included in the header. This is an active status warning and is shown in the report with code: 'NoO15'
The current image series header claims that the image is not decay corrected. The water model expects the data to be decay corrected	If the decay correction is done correctly to the image, the image header should contain proper fields containing the information. If these fields are not found, this warning is shown indicating that user might have picked the wrong image series from the list, or that some of the preprocessing steps are missing from the image. If the image has no decay correction, the water model used will not show correct values. Because O15 tracer halflife is quite small, the decay might have significant effect to results if not removed. If you know that your images are properly corrected into injection time, you can proceed with the analysis. The settings of the device that created the images or the image itself should perhaps be adjusted to include all required decay correction header values. This is an active status warning and is shown in the report with code: 'Decay'

Image orientation is possibly incorrect (may lead to upside down polar maps). Please check that the image orientation matches with the direction arrows	The image header should contain all the information to show the image pixels in correct orientation (which side is left, which side head, etc...) Based on this information Carimas will align the image so that front, head and left of the image points to same direction on screen. The screens in Carimas indicate the dimensions that Carimas assumes the image pixels to be. Therefore when the long axis is drawn by the user, the axis should always point towards the same direction: Patients Front, Feet and Left. If this axis is pointing somewhere else, like that head would go towards feet or that right ventricle would be on left side, this warning is shown to user indicating that: 1) the axis might be incorrectly drawn 2) The image is for some reason loaded to incorrect orientation 3) The Image might be mirrored (the hardest case to notice) 4) The patient might actually have so unique a physiology that the heart axis direction does not fall on the usual range. If you see this message, you should compare the image physiology to the direction arrows shown in the screens. Is the image head going towards head arrow, is the right ventricle really on right side. If the image data is mirrored, the polarmap pixels will be upside down compared to reality, which might be difficult to notice. This is an active status warning and is shown in the report with code: 'ExOri'
You have tried the segmentation with only a single diff frame selection and it is recommended to try with more scenarios	In order to see and segment the heart LV muscle, the dynamic image must be processed somehow. In Carimas this is done by selecting one of the frames as a Diff Frame (DF) and producing the image pixels as: SUM(DF+1 to LAST) - SUM(1 to DF). This simple method reveals the LV muscle, but on the other hand can produce many good looking (but different) wall locations with different frame selections. Therefore user should check many different frame selections to find the best one and estimate where the real heart wall is most likely located. If the user has only used the default selection and is going further in the analysis, this warning will be shown to the user. To avoid this message, check multiple diff frame selections. This is an active status warning and is shown in the report with code: 'OneDiff'
The image defines unit that is not convertible into the expected unit of kBq/ml	This message is shown, if the image unit (from the image header) is not something convertible to the expected kBq/ml. Examples of convertible units are Bq/ml or MBq/ml. This message indicates that the selected image series might not be the correct one, or that some part of the reconstruction process is missing (for example if the units are counts). If the image is correct, the analysis can be done with the only effect being that the displayed TACs will have nonstandard units. This is an active status warning and is shown in the report with code: 'NoBqMl'

1.4 Values, Units, Accuracy and Precision

WARNING

CarimasCE produces several values during the analysis. The myocardial flow (F) parameter is the only clinically significant value; the other values and model parameters are provided to make the analysis easier to perform and for quality control purposes.

Accuracy of the Myocardial Flow Estimation

Both the intraobserver and interobserver variability in measuring the myocardial flow has been shown to be within 10 %. In literature, 15-20% difference is typically estimated as clinically significant. Typical diagnostic cut-off value in literature is 2.3 ml/g/min.

CarimasCE presents the flow parameter with two significant digits, in ml/g/min.

See the publication list at the end of this guide for details.

Units and Precision

The following table contains the units and precision of values presented by CarimasCE.

Value	Unit	Accuracy
MousePos/Slice position	mm	integer value/one millimeter
F	ml/(g*min)	one decimal place
PTF	ml/ml	one decimal place
VL	ml/ml	one decimal place
MASE	-	one decimal place

1.5 Shutting down CarimasCE

There are no special steps that need to be taken in order to shut down CarimasCE.

Tip

Note, that if you close CarimasCE before you have finished the analysis and saved the report, all results will be lost.

WARNING

CarimasCE should never be closed while the import process is ongoing. This may result in broken images or other undesirable behaviour.

1.6 Sources of Error in the CarimasCE Analysis

The segmentation of left ventricular myocardium and cavity is based on the visualized image, and that is dependent on selection of frame that defines the diff images used for segmentation.

The segmentation near the septum need special attention because of near right ventricle (RV) region that should be avoided in segmentation because it can cause distortion to result curves

The cardiac axis orientation may be also incorrect. These errors are detectable by careful consideration of the different metrics provided in the Report and Quality Control steps of the CarimasCE analysis, and can be avoided by with experience and consultation of more experienced users. These mistakes do not typically lead to wrong diagnosis but the ischemic regions may be incorrectly located.

Verification of the quality control step results

Before proceeding to the Report Step, carefully review the displayed data to verify the quality of the segmentation and the suitability of the data.

Inspect the polarmaps to get a quick visual overview. Make sure the myocardial flow (F) values are within the expected range; a very high value may indicate a bad model fit in the segment. A high arterial blood volume (VL) in a segment may indicate that the VOI is drawn to include parts of the ventricle cavity. A very low perfusable tissue fraction may indicate, that the VOI is drawn outside the myocardial wall at the segment location.

Select each segment in turn, by selecting it from a polarmap. The time activity curves should be inspected, making sure that the input function TAC shape is as expected, and that the modelled segmental TAC is reasonable, relative to the data points. Poorly fitting data is an indicator of poor segmentation or bad data quality.

Pay attention especially to segments that stand out from the others. Higher, or lower, values may reflect poor segmentation, and not an actual anomaly in the image data. As a rule of thumb, any segment with a notably higher or lower value in any parameter merits a closer look. If needed, return to the Segmentation Step to ensure the correct placement of the myocardial VOI, and adjust as needed. The modeling is automatically recalculated, if the segmentation is modified.

WARNING

Pay special attention to the areas near the septum. The VOIs should not include any portion of the right ventricle (RV) region.

When you are satisfied that the segmentation quality is sufficient, proceed to the Report Step.

Known Issues

For any known issues related to the usage of CarimasCE, please visit our website: https://carimas.fi/carimasce/.

2 Working with data

In order to run the analysis workflows the series data needs to be imported to CarimasCE. This section explains how to connect CarimasCE to external sources and import new data to the program, how to manage and export previously handled data, as well as how to view existing reports within the program.

2.1 Connecting to external sources

By default, CarimasCE is not connected to any external sources like PACS. You will need to connect CarimasCE to any external data source that you wish to use. These connections are made and managed through the Database tab of the toolbar.

> **Tip**
> Many PACS servers only allow access for known devices. Consult with your system administrator if you are unable to connect despite having input the correct settings.

PACS controls

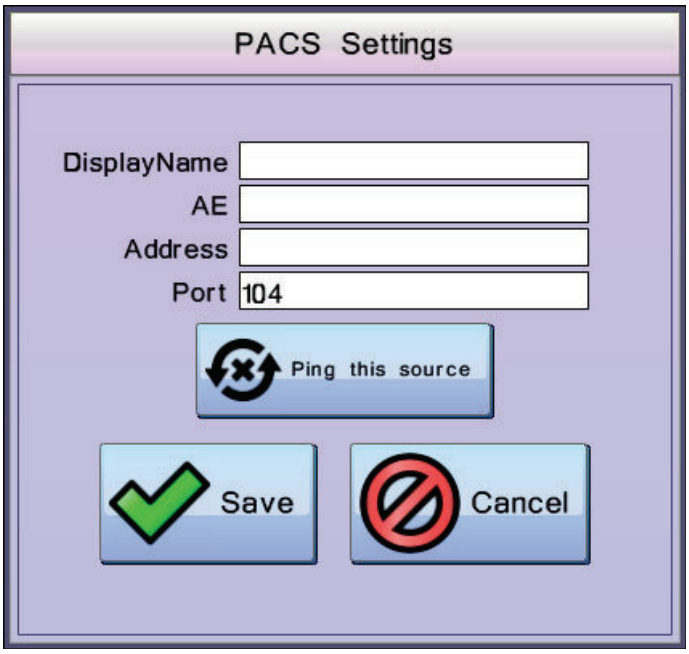
A new PACS connection can be established by clicking the "Add PACS" button. This opens the "PACS Settings" dialog window, where you need to insert relevant details for connecting to a PACS: The Display name, AE title, Address, and Port.

You can remove PACS connections by clicking the "Remove Sources" button. This will list all external sources connected to CarimasCE, and clicking any of them will give a prompt to remove them from the program.

You can modify the settings of existing PACS connections by clicking the "PACS Settings" button. This will list all external sources connected to CarimasCE, and clicking any of the items in the list will open the "PACS Settings" dialog window for modifying its settings.

PACS Settings Dialog

When adding or modifying PACS settings a separate window will open:



In this window you will need to define the settings of the PACS you are attempting to connect to. The fields are as follows:

1. **DisplayName:** The name you want the PACS to be displayed as in CarimasCE. This field is only to help you identify this PACS within the program and has no impact on the connection itself.
2. **AE:** The AE or "Application Entity" title of the PACS. This is an identifier specific to the PACS you wish to connect to.
3. **Address:** The network address of the PACS. For example *pacs.example.org*
4. **Port:** The port through which the PACS accepts incoming connections. Well known ports for DICOM connections are 104 and 11112, but other ports are also possible.

If modifying existing PACS settings, simply edit the prior values in the fields and click save when done.

> **Tip**
> Click "Ping this source" to test if the PACS can be reached with your settings before saving.

2.2 Importing and Exporting

Tip

Importing from and exporting to PACS requires connecting CarimasCE to the PACS of your choice. See Connecting to external sources for detailed information on setting up the connection.

Importing studies to CarimasCE

There are two ways of importing series data to CarimasCE:

From the local filesystem

Import any suitable series data from the filesystem by dragging and dropping it in the CarimasCE program window. You can drag-and-drop folder(s) containing multiple series to CarimasCE to import all of them. More information can be read in-program by clicking the "Import" button in the Database tab.

From PACS

Importing from PACS is done by first using the searching tools to find the study containing the series you wish to import. When you've found the study, click it to expand the included series. Finally, click the import button on the right side of any series you wish to import.

Working with the search, studies, and series in CarimasCE is described with more detail in Starting an Analysis Workflow.

Exporting studies and reports

Studies and reports saved in CarimasCE local data can be exported to external sources (PACS) connected to the program.

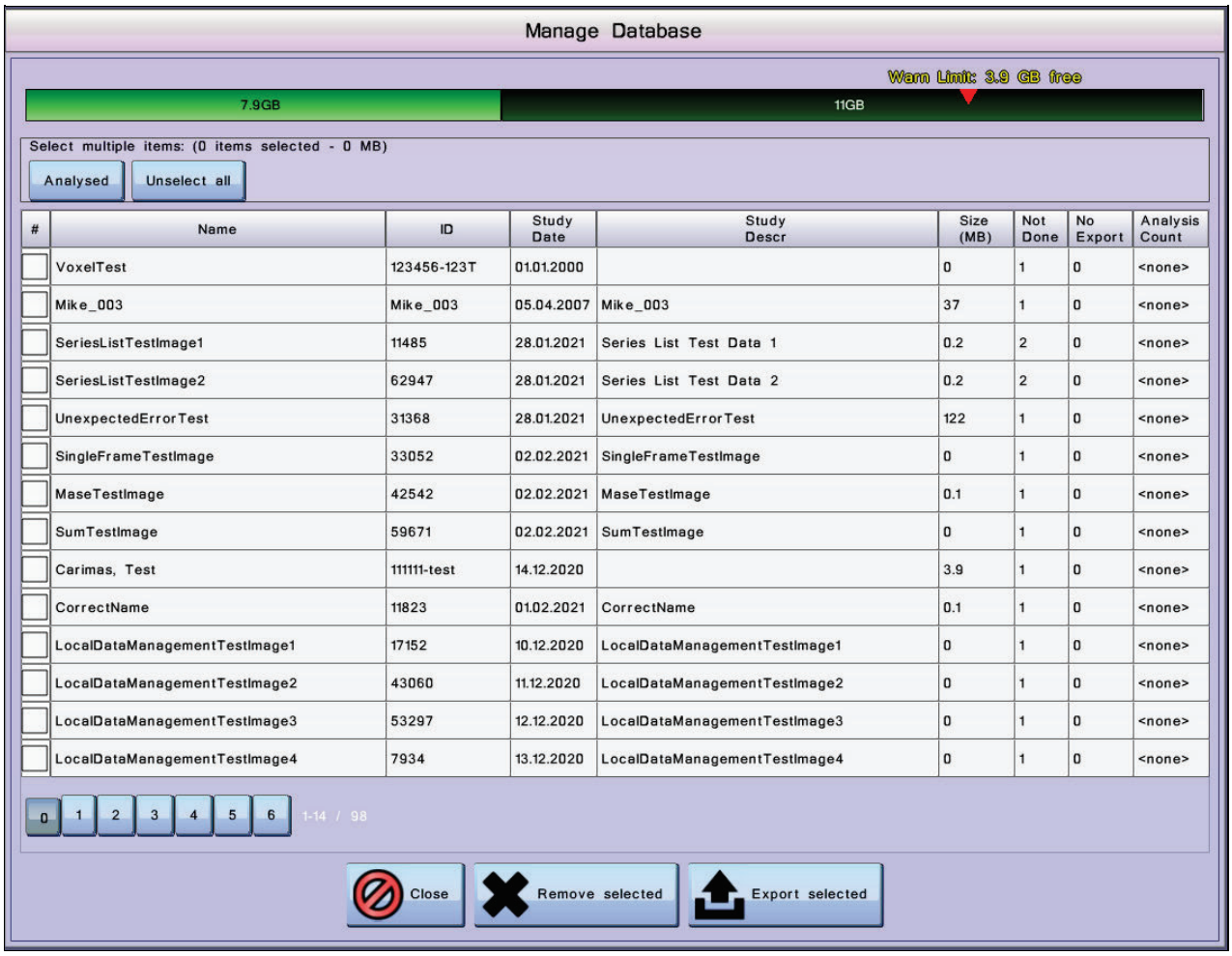
Exporting is done through the Database Management window, which can be accessed by clicking the "Manage" icon in the Database tab of the toolbar. Select any series (with reports) you wish to export and click the Export selected button on the bottom of the window. This will open a list of all external sources connected to CarimasCE. Select one of the locations to begin the export process.

Tip

Note: This exports ALL reports under a selected study. If you wish to export only a single report, see Report Viewer.

2.3 Managing storage space

The storage space used by CarimasCE can be managed by clicking the "Manage" button in the toolbar in the Database tab. This will open the "Manage Database" window containing tools for managing the data stored in the filesystem by CarimasCE:



The controls visible in this window are explained in detail below.

The Disk space bar

The Disk space indicator bar summarizes essential information related to CarimasCE's disk usage. As visible in the image above, the bar has three separate sections. The leftmost section (light green) shows the disk space used by the studies and reports currently in the Local Data. When studies are selected, the middle section (yellow) shows the amount of disk space that they take. Finally, the rightmost section (dark green) shows the amount of free space left until the storage limit set for CarimasCE is reached.

The light green section grows in size as you import more data into CarimasCE.

The small red triangle on the top of the bar is the "Warn Limit". When used disk space exceeds this limit, CarimasCE will display a warning and automatically suggest opening the Data Management window upon startup. You can set this limit by dragging the red triangle with the mouse.

Item list

The Item list displays the data items saved in CarimasCE at the series level. The columns contain relevant information for identifying the series at a glance and determining if it should be removed or not. The column headers correspond to the following information:

- Name: PatientName
- ID: PatientID
- Study Date: Date of the study
- Study Descr: Study description of the parent study to the item
- Size (MB): Disk space used by the item in megabytes

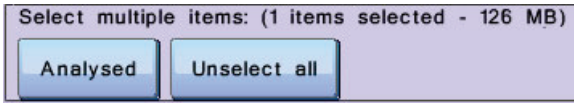
- Not Done: how many series for which no analysis has been performed does the study contain
- No Export: how many analyses that have not been exported have been performed for the study
- Analysis count: how many analyses have been performed in total for the study

Additional pages are generated to the list if all the items would not otherwise fit in view. The current page can be changed by clicking the page numbers at the bottom of the list. Note that no buttons are displayed if all the items fit on one page.

The list can also be sorted by any of the aforementioned properties by clicking on the corresponding column header. There are two modes of sorting, ascending and descending, and they can be toggled between by clicking the column header. The sorting applies to all results among all pages in the list.

A checkbox in the very left side of each item shows if the item has been selected. The checkboxes can be clicked to select an item, and clicked again to unselect it. Removing and exporting actions are applied to selected items only as described below in Removing and Exporting items.

Item autoselection tools



The autoselection buttons allow for selecting all items in the list that match the criteria specified in the button, or in case of the "Unselect all" button deselecting them. The text above the buttons shows how many individual items have been selected and how much total disk space they occupy.

Removing and Exporting items

The bottom of the window contains three action buttons. "Close" simply closes the window, returning to the Workflow selection screen. "Remove selected" removes all selected items from the CarimasCE local data. "Export selected" opens a list of external (PACS) locations configured in the program, and clicking one of the locations exports all series and reports of the selected study to the chosen location.

Removing items only removes them from the local disk. No data in external locations is affected.

WARNING

Removing data from CarimasCE that is not exported to or already present in external sources can cause that data to be lost permanently.

2.4 Viewing Reports within CarimasCE

Reports created with CarimasCE can be viewed from the workflow selection screen by selecting a study, the clicking the R-button on the desired series.

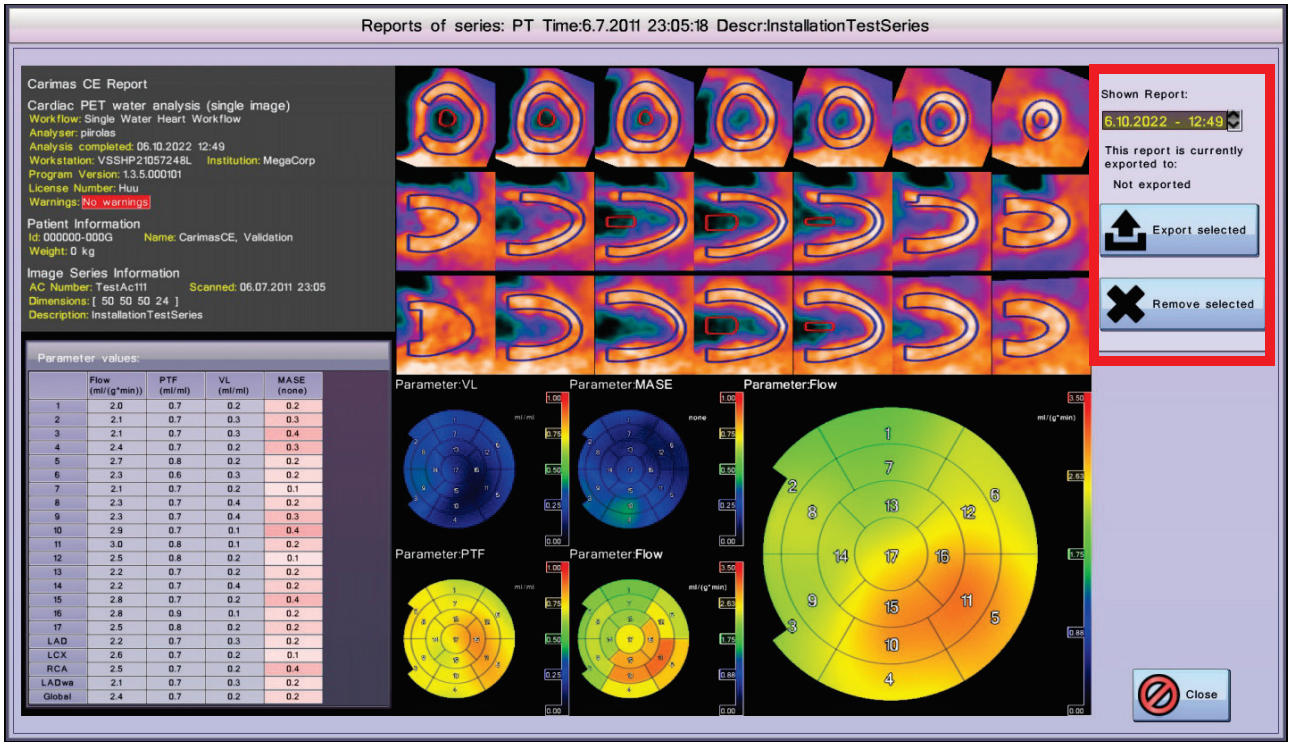
Tip

The report viewer button is only active if a report for the series is present on the disk.

This opens a new window with the latest report displayed by default. If there are multiple reports for the chosen series, they can be viewed through the "Shown Report" drop-down menu. The currently displayed report can be be exported to a configured PACS via the "Export Selected" button or removed from the local disk via the "Remove Selected" button.

Tip

From the "Export Selected" -button, it is also possible to export the modelling parameters of the report to the clipboard as text.

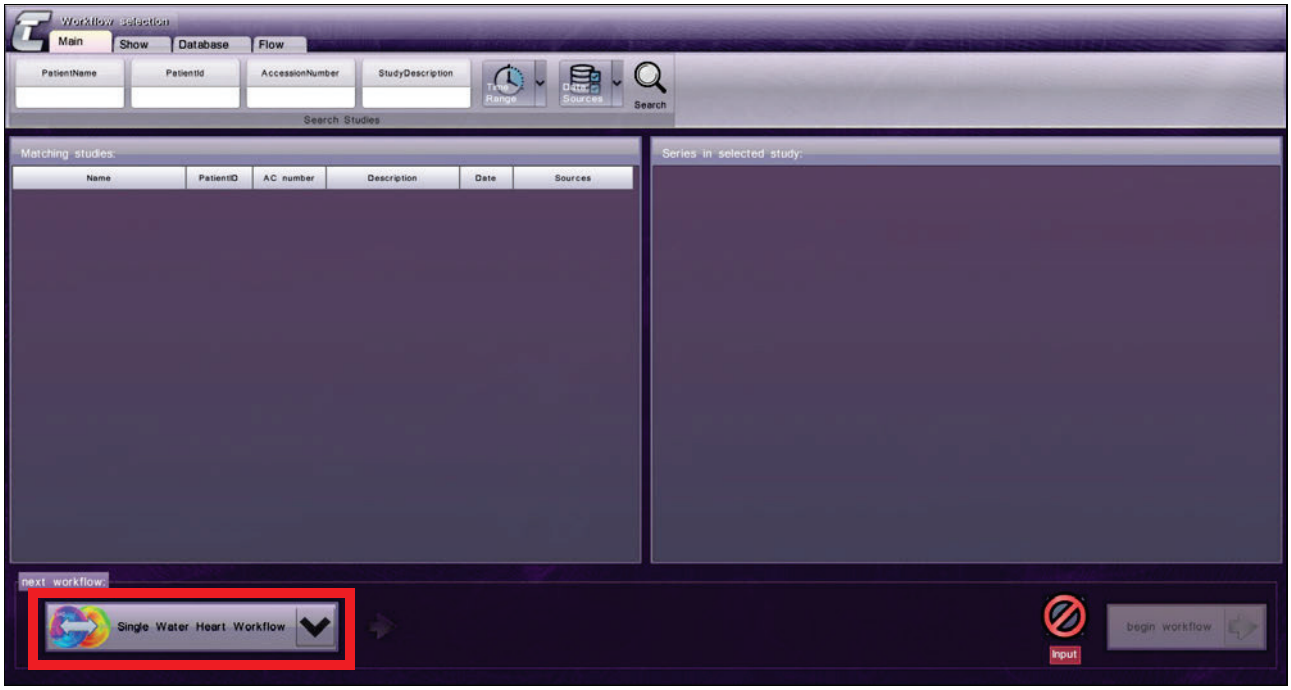


3 Starting an Analysis Workflow

The use of CarimasCE is determined by "Workflows". They are a series of steps that you take, assisted with the program, that lead from specific input to the analysis results. This page is a quick walkthrough on selecting a workflow and its inputs.

Selecting the Workflow

First, it's advisable to select the analysis workflow you wish to run. This is done by clicking the button under the "Next workflow" text at the bottom left of the program, highlighted with a red border in the image below:

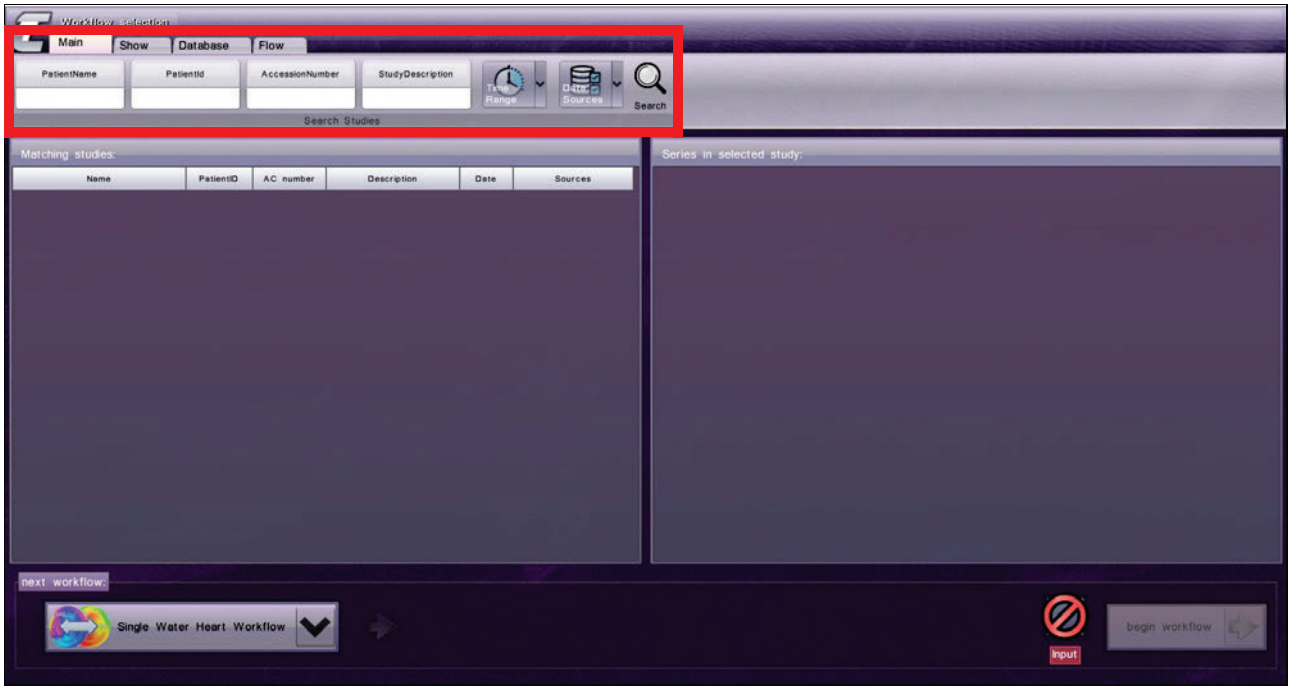


Clicking the button will display all available workflows in your installation of CarimasCE.

> **Tip**
> This version of CarimasCE currently only includes the Single Water Heart Workflow, which is selected by default.

Search for suitable Studies

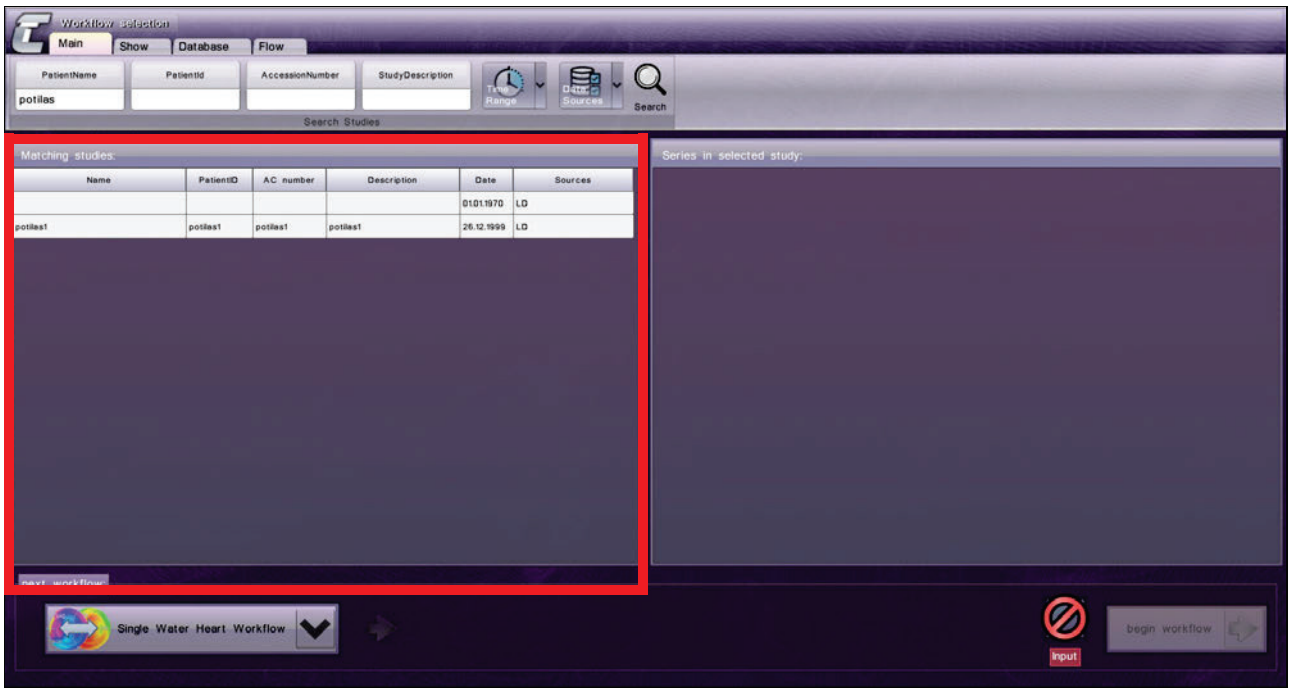
Next, use the Search controls under the Main tab of the toolbar to search for suitable Studies.



Any connected PACS and the CarimasCE's Local Data can be searched for studies. See Searching for more in-depth explanation of the Search functionality.

Select the Study from the Search results

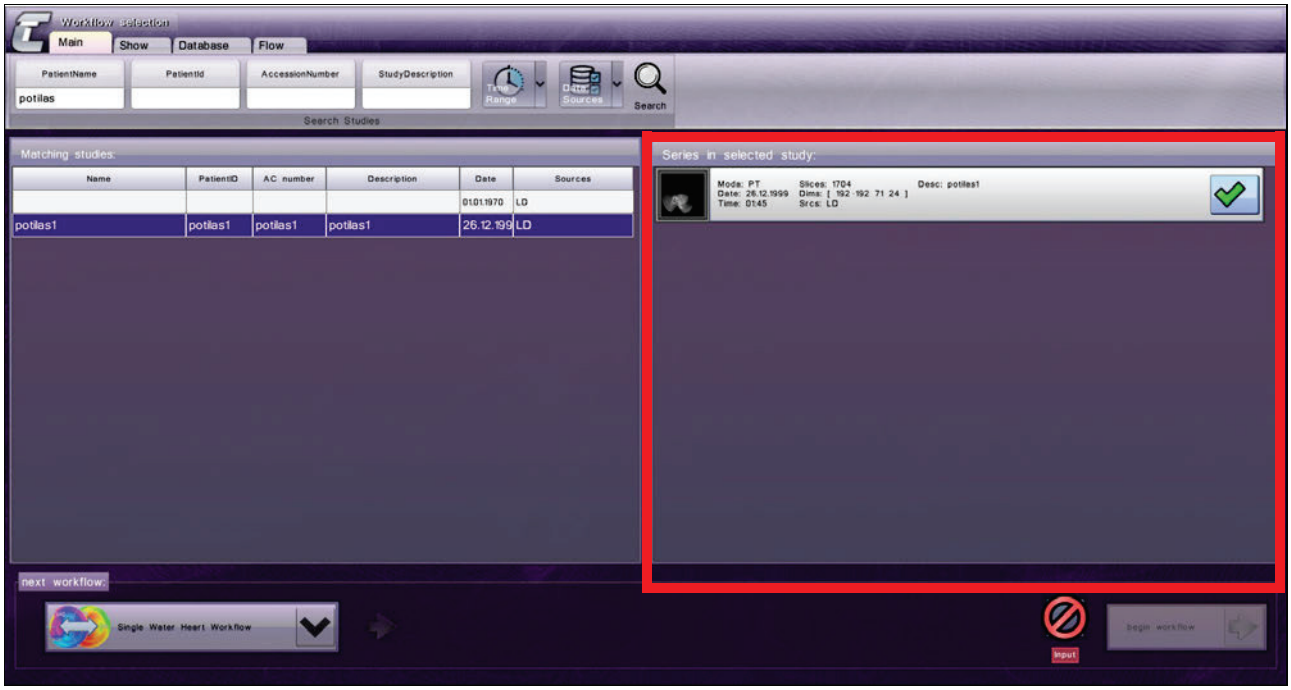
After a successful search the results will appear in the "Matching studies" list below the Search controls.



Select the desired study from the Matching studies list by clicking it with the left mouse button. This causes the row to become highlighted. Now all Series contained in that study will appear in the "Series in selected study" window to the right:

Select series to use as the Workflow Input

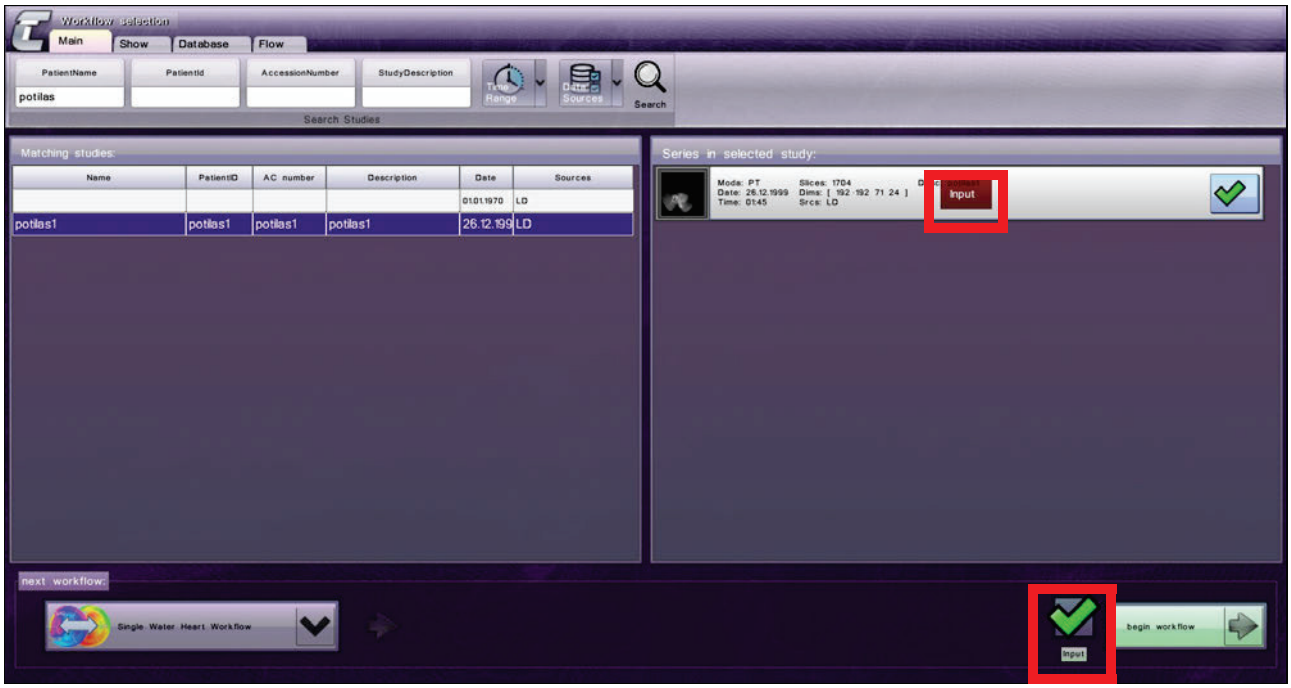
As mentioned above, all series in the selected study will appear in the "Series in selected study" window:



Mouseovering a series in this list will cause the "To Input" button to appear above it:

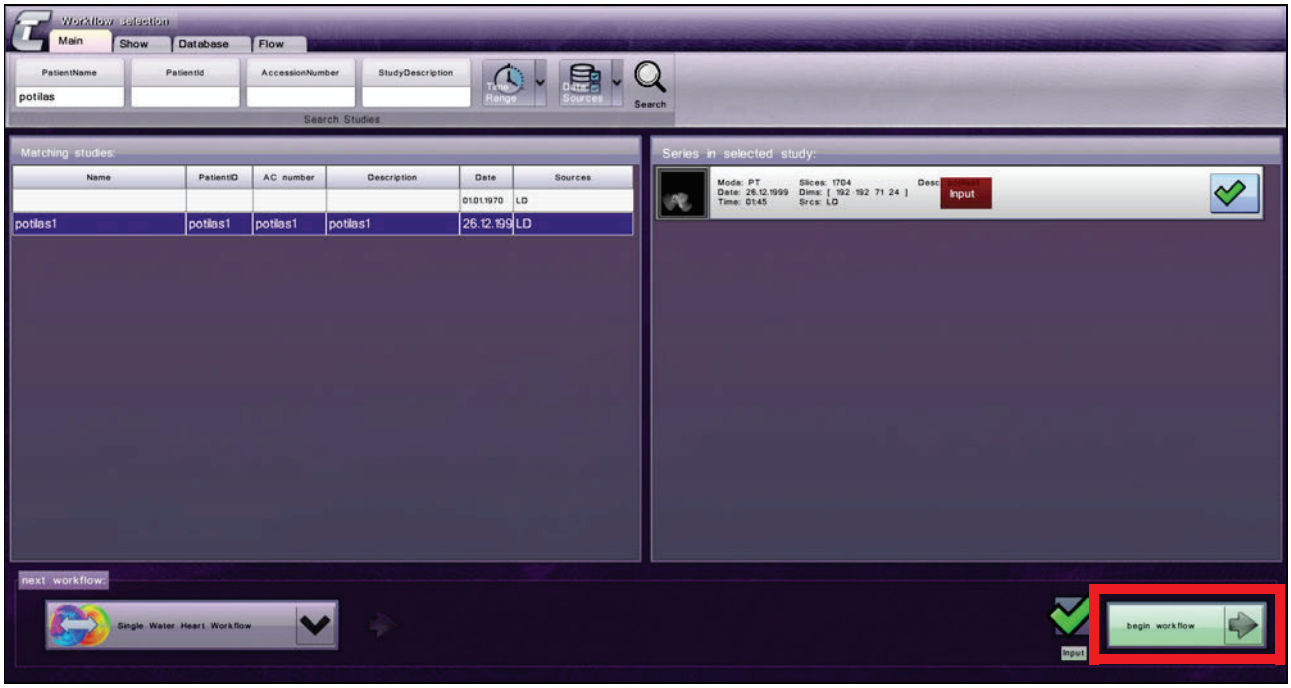
Clicking the button will select that series as the input(s) of the workflow. The input status will be displayed on the series itself, as

well as in the workflow's Input slot at the bottom of the window:



Begin the Workflow

When the inputs for the workflow are in place, the "Begin workflow" button will light up:



Next

Click the "Begin workflow" button to start the Workflow.

3.1 Searching

The series you wish to insert to the workflow first have to be located with the searching tool. You can search from CarimasCE local data or any PACS you have connected to the program. Select the "Main" toolbar tab from the top of the window. This will change the toolbar contents to display all search related controls:

Text criteria

Anything you type in the first five fields will be used as criteria for the search. Partial matches are supported for all of the fields, e.g. searching for PatientName "John" will also list "John Smith" as the result.

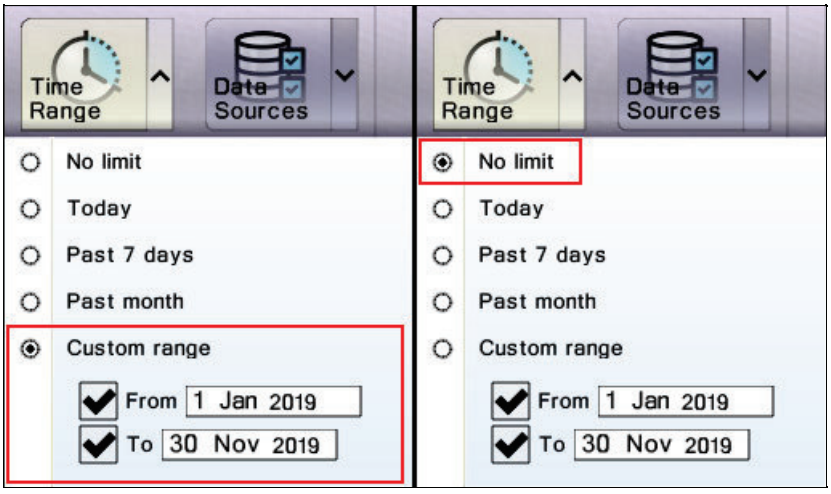
Tip
Only the beginning is matched, so if the Patient's Name is recorded as "Smith Jane", searching with "Jane" will yield no results.

Tip
If you are searching from a PACS, then at least one search term has to be entered. If you are only searching from the Local Data, then you can leave the fields blank in order to get all the studies currently hosted on the local system.

Time criteria

You can set criteria for the timing of the data. Click the "Time Range" button to open a menu containing several pre-set conditions to choose from, as well as the possibility to define a completely custom time range. Click the radio button next to the time range option you wish to use in the search.

If you wish to use the "Custom range" option, define the start and/or end date of the range to your liking. Return the radio button to "No limit" if you do not wish to use Time Range options.



Data sources

You can limit the search to one or more of the sources connected to CarimasCE. Clicking the "Data Sources" button will list all sources known to the program, with a checkbox next to each source. Checking the box next to a source will include that source as the search target.

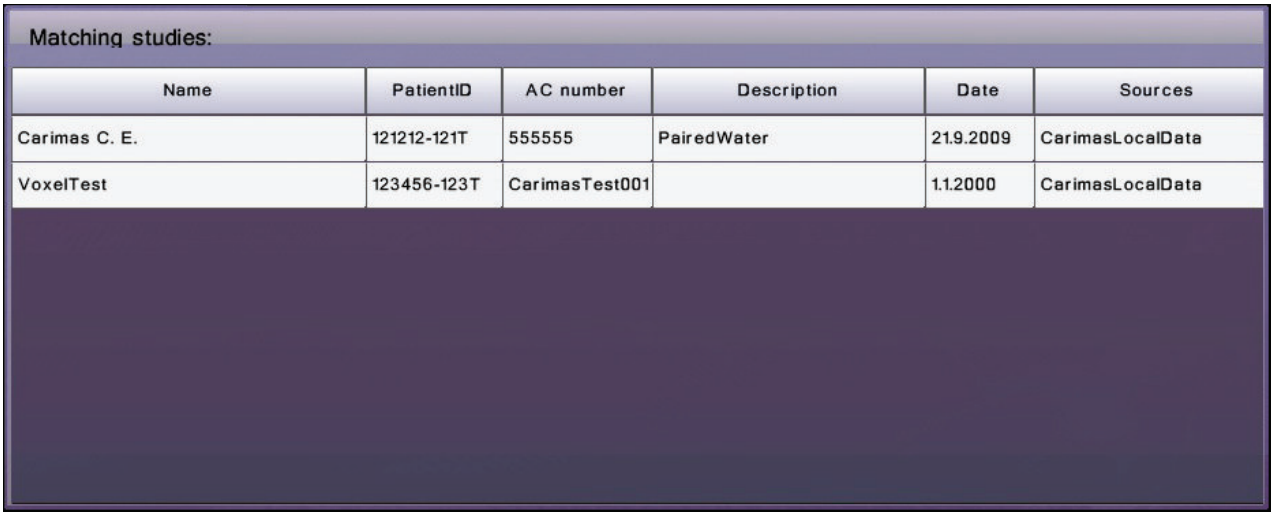
Tip
If you wish to search only from the local data, e.g the data stored in the disk by CarimasCE, check "CarimasLocalData" as the only data source. Reversely, if you would like to search only from external sources, make sure that "CarimasLocalData" is not checked as a data source.

Executing the search

Finally, the "Search" button executes the search with all the criteria defined in the previous controls. The results will appear in the Study List window in the main part of the program.

3.2 Study list

After a successful search the results are listed in the Study List window below the toolbar. Each study will comprise its own row in the list, with the relevant information visible separated into different columns.



Result pages

If all the results do not fit in the window more pages will be created. The current page can be changed by clicking the page numbers at the bottom of the list.

No page number buttons are displayed if all results fit on one page.

Sorting the list

The list can be sorted by the values of any column by clicking the column header. On the first click of the header the sorted will be applied in ascending order, and on the second click in descending order, with further clicks toggling between these modes. The active sorting mode is visible from the small arrow under the column header:

Note: If there are several pages, the sorting is applied to items in all of them.

Viewing the series in a study

Click a study row in the list to select it. This will display all its series in the Series List window on the right side of the program.

Tip

CarimasCE installation includes a sample PET heart study that can be used for training and experimentation. You can find it in the local data under the patient name "Carimas C. E."

3.3 Series List

Upon selecting a study in Study List its included series become visible in the Series List comprising the right half of the program main window ("Series in selected study"). Each series is listed as their own item containing a thumbnail of the image data, relevant series information, and controls used for importing and using the series as a workflow input.

WARNING

Series that are not in the CarimasCE local data (i.e. series that are only located in an external source such as PACS) will not display thumbnails or dimensions information. The series has to be imported to local data for this information to become visible.

Importing and Import Status

All series must be imported to CarimasCE before they can be used in a workflow. It is also possible to import series that you do not immediately plan to use for future.

The import status of a series (whether it is saved in CarimasCE's local data or not) can be viewed at a glance from the right side of the item. There are two indicators:

If the item is not in CarimasCE's local data, an import icon will be shown on the right side of the series item. Clicking this icon will import the series to local data.

However, if the item is already in CarimasCE's local data, a green checkmark icon will be shown instead to signify the series is already saved to the program.

WARNING

Importing series to CarimasCE uses local disk space. If you need to free space, use the Local Data Manager to remove series you no longer need.

Using a series as a Workflow Input

A series can be selected as the workflow input by mouseovering it and pressing the "To Input" button:

Selecting a valid workflow input will change the "Input" slot at the bottom of the program to a green checkmark signifying that a series is ready to be used in the workflow. A red "Input" tag is also attached to the series currently designated as the input:

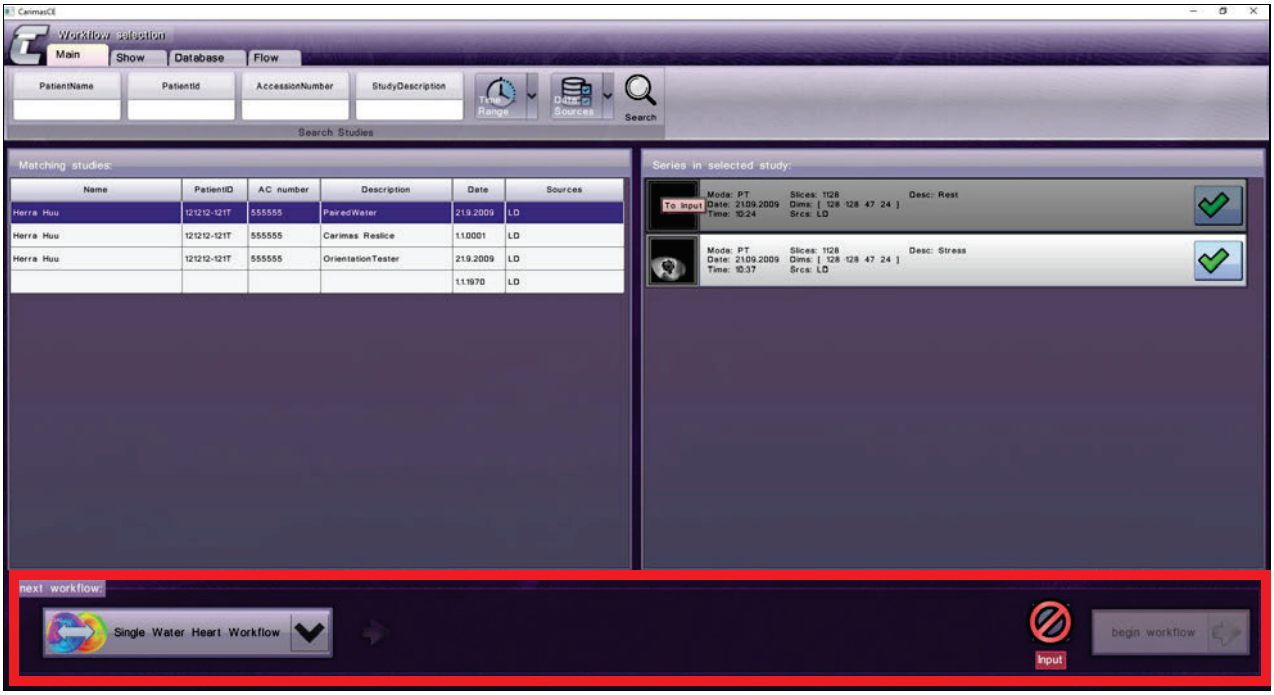
See Workflow Controls for additional information on Input slots and starting the workflow.

Tip

Should you forget which series is set as the workflow input, the green checkmark in the "Input" slot can be mouseovered to see relevant information about the currently selected input.

3.4 Workflow Controls

This section explains how to select an analysis workflow, assign and view the state of its inputs, and how to begin the selected workflow.



The main workflow controls are visible when you start CarimasCE, and are hilighted with a red border in the image above. All these controls are explained in detail below:

The workflow selection button

Clicking this button will open an additional menu where you can select between all analysis workflows available in the program.

WARNING

Note that only the Single Water Heart Workflow is available in this version of CarimasCE.

Input Slots

The Input Slot shows the input status of the selected workflow, i.e. what (if any) image series have been assigned to the selected analysis workflow. A slot has two different states:

Missing or incorrect input is signified by the red blocked icon. This is the default state of all Input Slots, as no inputs are assigned when the program starts. If any slots have this icon the analysis workflow cannot be begun.

Correct input is signified by the green checkmark. This symbol means that the input in the relevant slot is valid. When all available slots display this icon the analysis workflow can be begun.
The Single Water Analysis Workflow only takes one input.

Tip

The green checkmark in the Input Slot can be mouseovered to see relevant information about the currently selected input.

Assigning inputs

Inputs are assigned through the Series List after a suitable study has been found. Mouseover the series you wish to assign as the input and press the "To Input" button that appears. See Series List - Using a series as a Workflow Input for more details on assigning a workflow input.

Begin workflow button

Once the analysis workflow has been selected, and all its required inputs have been assigned valid image series, the "Begin workflow" button will light up.

Next

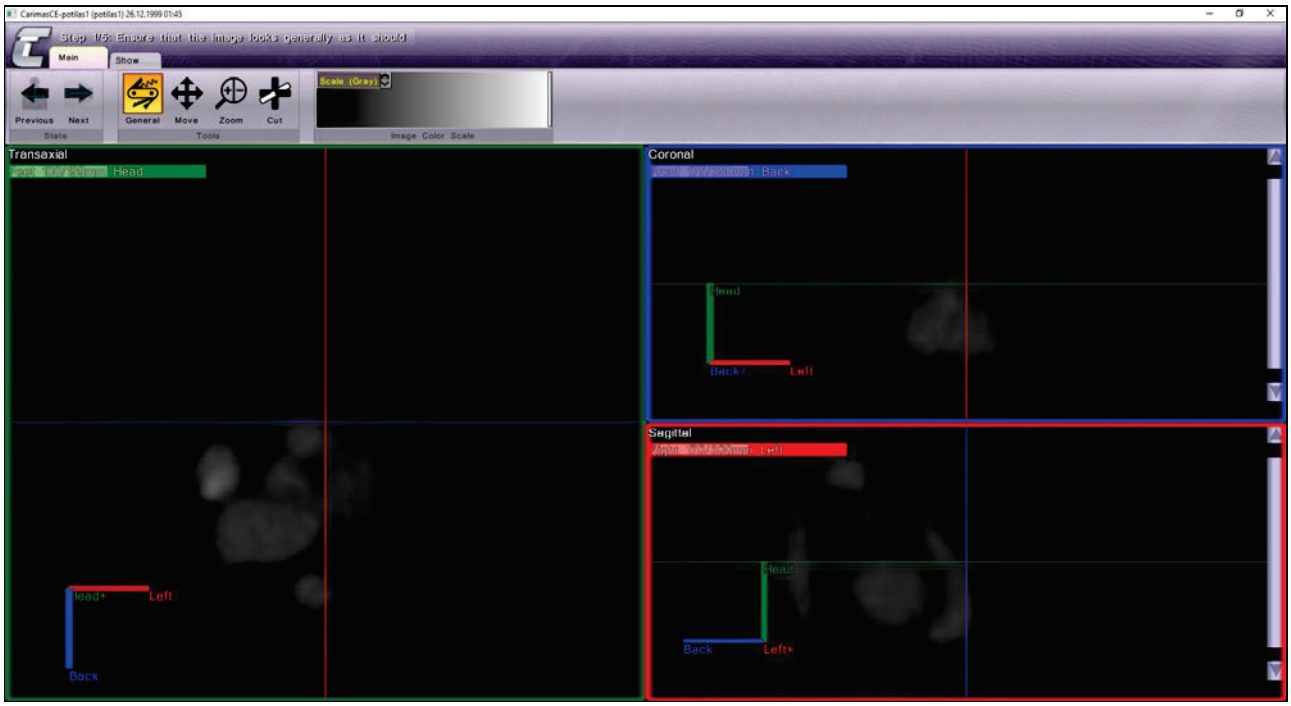
Pressing the "Begin workflow" button will start the selected workflow with the defined inputs.

4 Step 1: Image verification

> **Tip**
> This section is a quick walkthrough of the Step 1 functionality. See the subchapters for more detailed explanations.

When the workflow is started the first step you will see is the image verification step.

The greatest portion of the screen is occupied by the Image Windows: The green-bordered window visualizes images from the transaxial plane, the red-bordered window from the sagittal plane, and the blue-bordered window from the coronal plane. Above the images, at the top of the interface, are the tools you might need during this step.



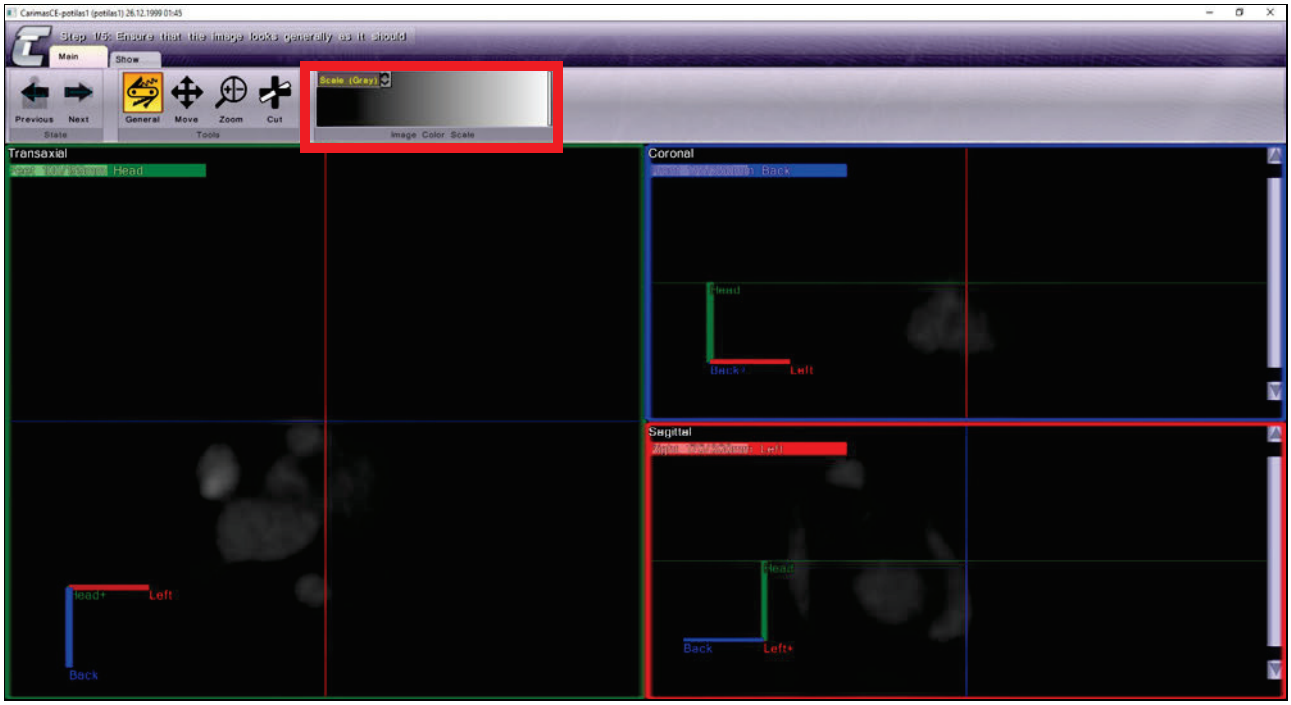
The purpose of this step is to to check that the base image appears valid and properly oriented. The image presented in this Step is a Sum Image, in later steps the images presented are Diff Images.

This is done in practice by adjusting the Color Scale, comparing the image orientation data and the visualizations in the Image Windows, and ensuring you're viewing the optimal slices from each anatomical plane by using the Tools available in this step.

1. Choose and Adjust the Color Scale

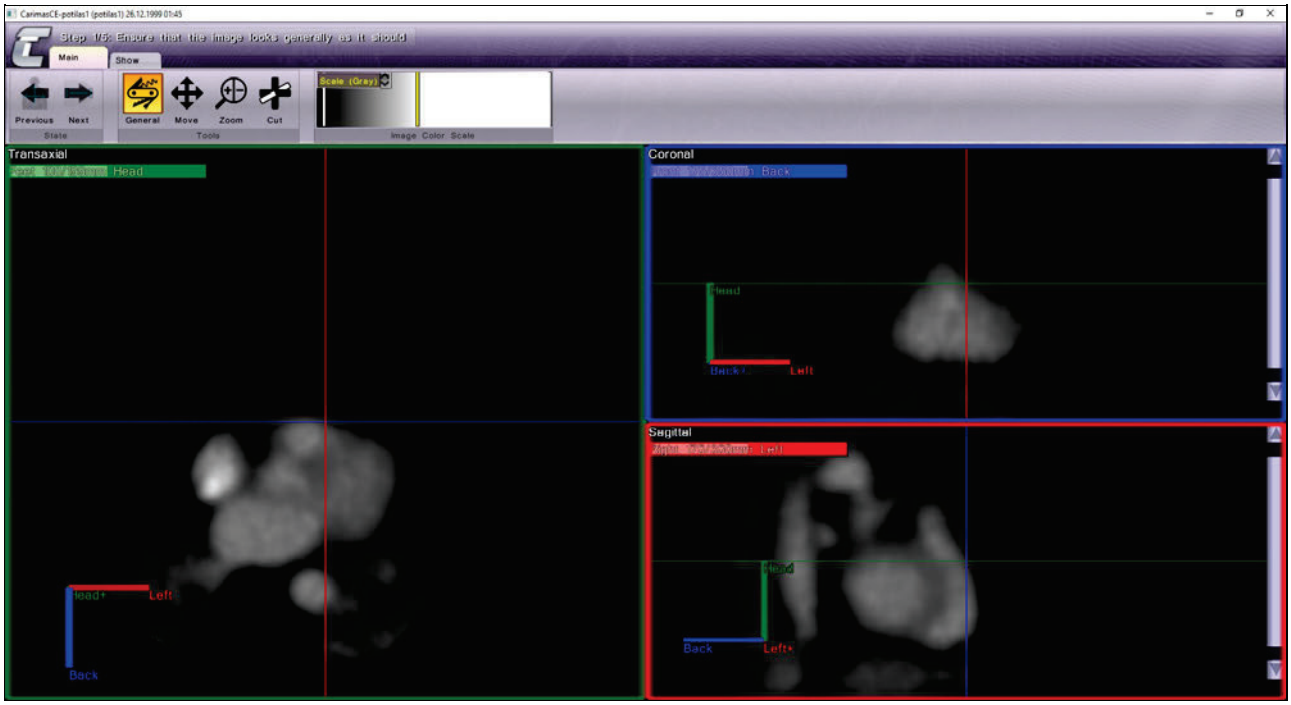
> **Tip**
> Any adjustments made in this step do not affect later steps, but the same principles apply.

First, it is recommended that you adjust the color scale of image to one that best helps you determine the correctness of the image. This is done with the Image Color Scale tool, highlighted with red in the image below:



Select your preferred color scale by clicking the name on the color scale tool ("Grey" by default). This example uses the "Grey" scale.

Finally, adjust the bars at both ends of the scale to get the desired result.



WARNING

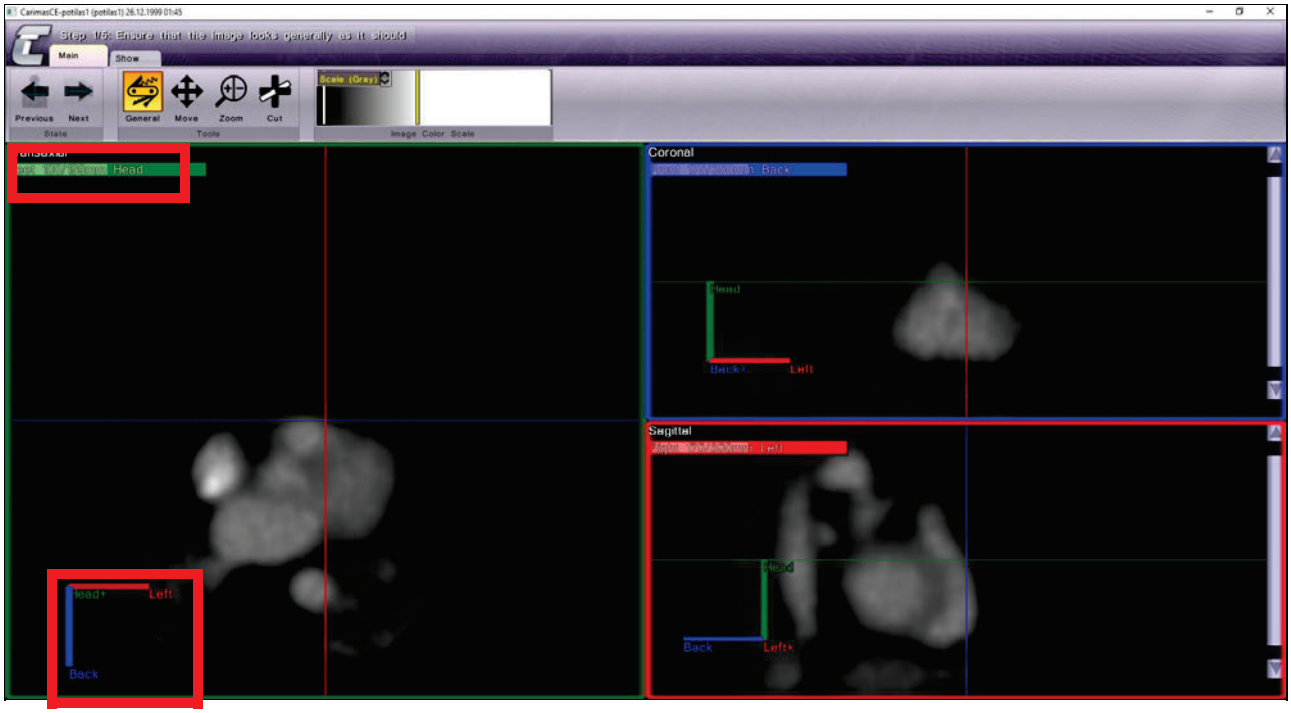
Colors in CarimasCE are only used to aid in viewing the images. The color scales, and their start and end points can be changed at will. As such, a color or hue in itself does not hold any inherent meaning.

WARNING

The image above is an example of using the Image Color Scale tool, and does not represent the desired result for your input image. Experiment with the tool to find the configuration that works best for your situation.

2. Check that the image appears valid

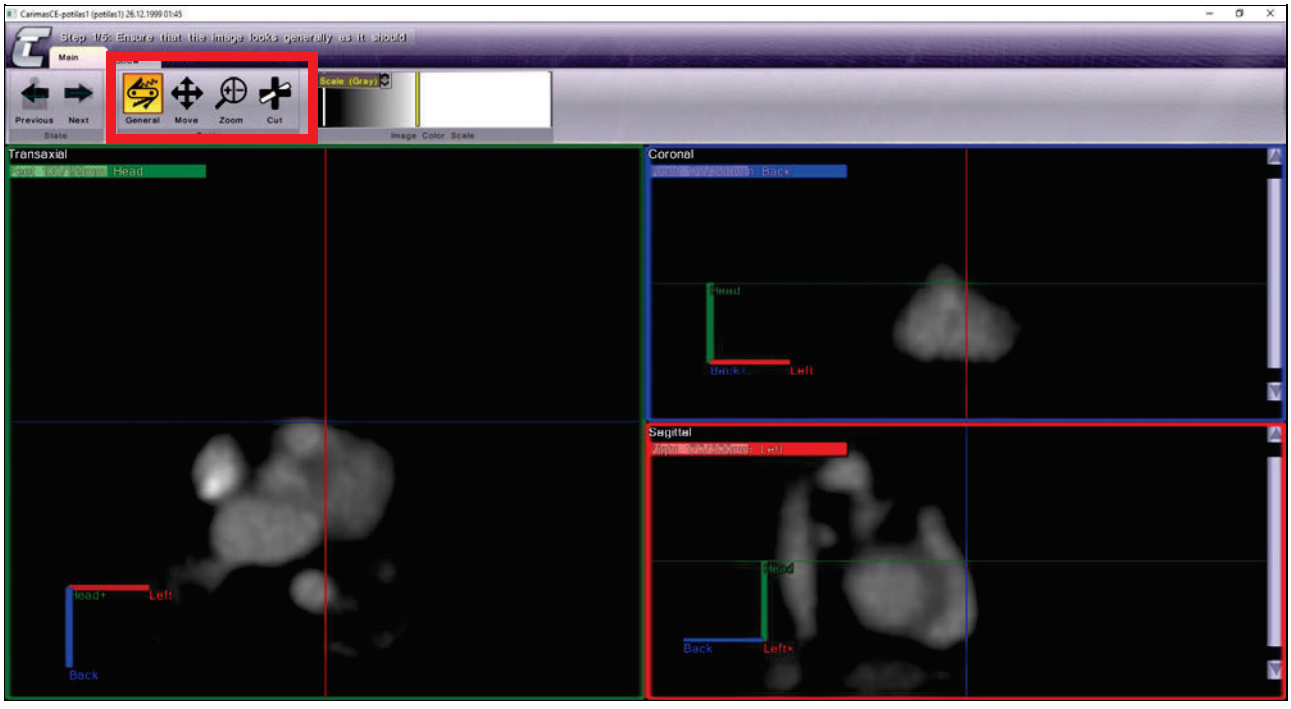
The image is visualized as 3 two-dimensional images, one on each of the three anatomical planes. Each of these windows includes the Depth Slider (top left) and the Orientation Guide (bottom left), highlighted with red boders in the image below:



1. Scroll through the image slices in each window. Verify with the help of the Depth Slider that the visual change truly happens to the direction displayed in the slider.
2. Use the Orientation Guide to verify that the patient image in each window truly matches the directions displayed by the Guide arrows.

3. Use the available Tools to check the image visualization

The tools are also available to help check that the image is of high enough quality to facilitate an analysis.



For this step, the "General" tool contains all necessary functions. You should adjust the slice in each window until you have an optimal view from all the angles:

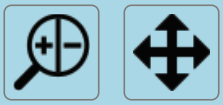
- Drag the Cut Lines inside a window with the left mouse button held down to influence the displayed slices in the other windows.
- Click a point in the image with the left mouse button to instantly move the Cut Point (intersection of the Cut Lines) to that point, influencing the displayed slice in the respective windows. It is often optimal to set the cut point as close to the centre of the

heart as possible.

- Drag the Depth Slider with the left mouse button held down, or scroll with the mousewheel, to change the slices in the current window.
- Hold down and drag with the right and middle mouse buttons to zoom and pan the image.

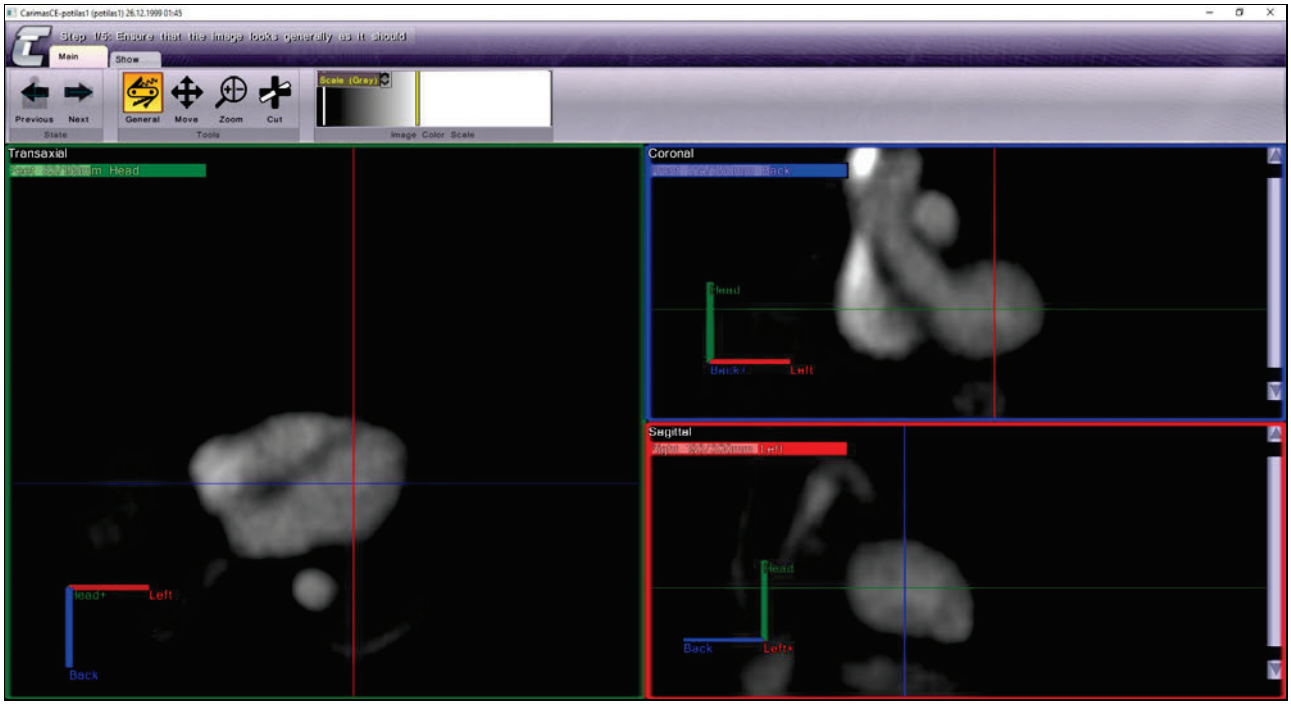
Tip

If you wish to use the left mouse button for zooming or panning instead of moving the Cut Lines, select the respective tool from the toolbar.



Tip

The only change here that affects the next step is the chosen Cut Point. It can be benificial for the next step, so you should consider changing it. See below:

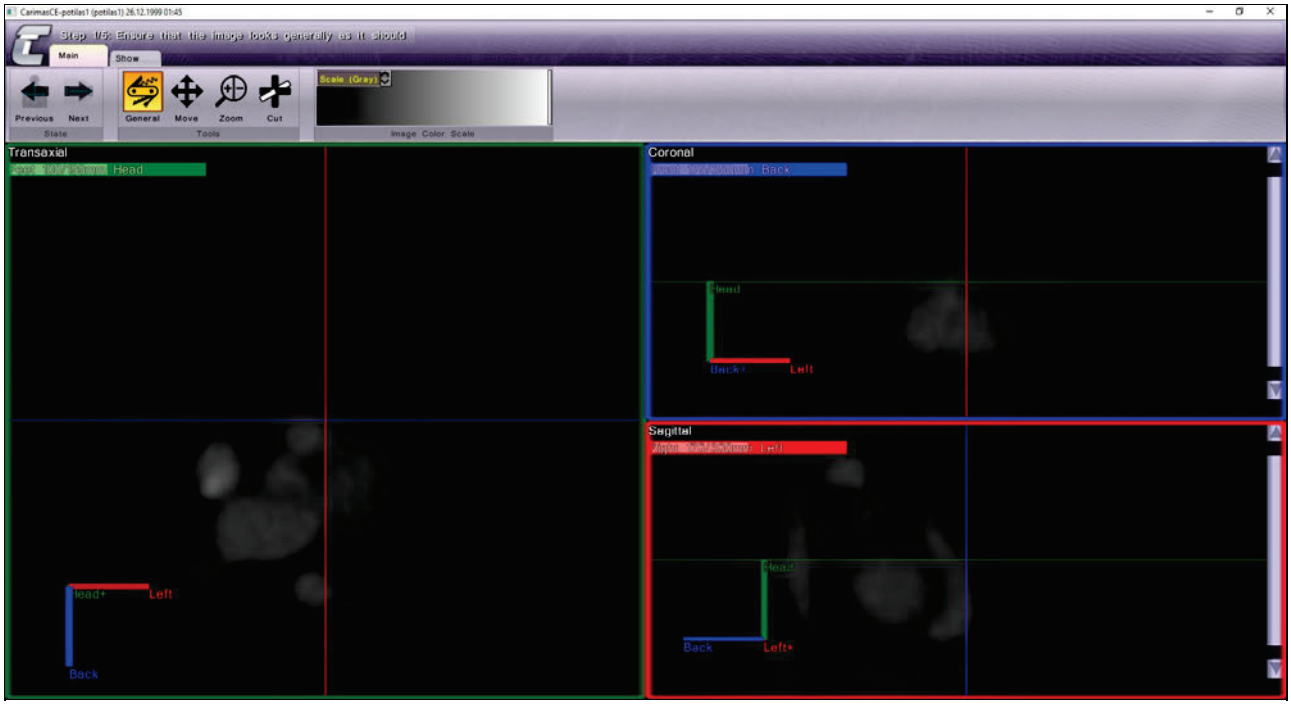


Next

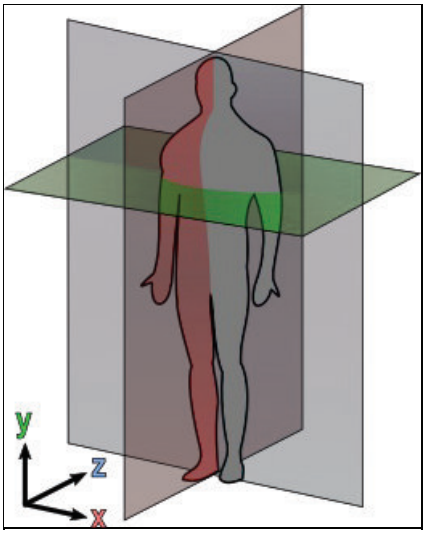
After you have checked the image validity and adjusted the settings to your liking, it's time to proceed to Heart Location step by clicking the Next arrow.

4.1 2D Image Window

In CarimasCE, three-dimensional images are visualized using tree two-dimensional images. These images are displayed in the 2D Image Windows as follows:



Each of the 2D Image windows represents one of the main three anatomical planes, i.e. the transaxial, coronal, and sagittal plane.



1. The large window on the left (with a green border) visualizes images from the Transaxial plane. Thus the displayed image (or "slice") in the window represents the green square in the guide image to the right of this paragraph. When a different slice is shown, the square "moves" along the y-axis, i.e. head to toes. The viewing direction is from the feet of the patient towards the head.

2. The window on the top right (with a blue border) visualizes images from the Coronal plane. Each image represents a blue square. When a different slice is shown, the square "moves" along the z-axis, i.e. front to back.

3. The window on the bottom right (with a red border) visualizes images from the Sagittal plane. Each image represents a red square. When a different slice is shown, the square "moves" along the x-axis, i.e. left to right..

WARNING

In CarimasCE the images are visualized by the**radiological convention**: The patient orientation is as if they were facing the viewer, meaning the patient's left and right are flipped (i.e. your right is the patient's left).

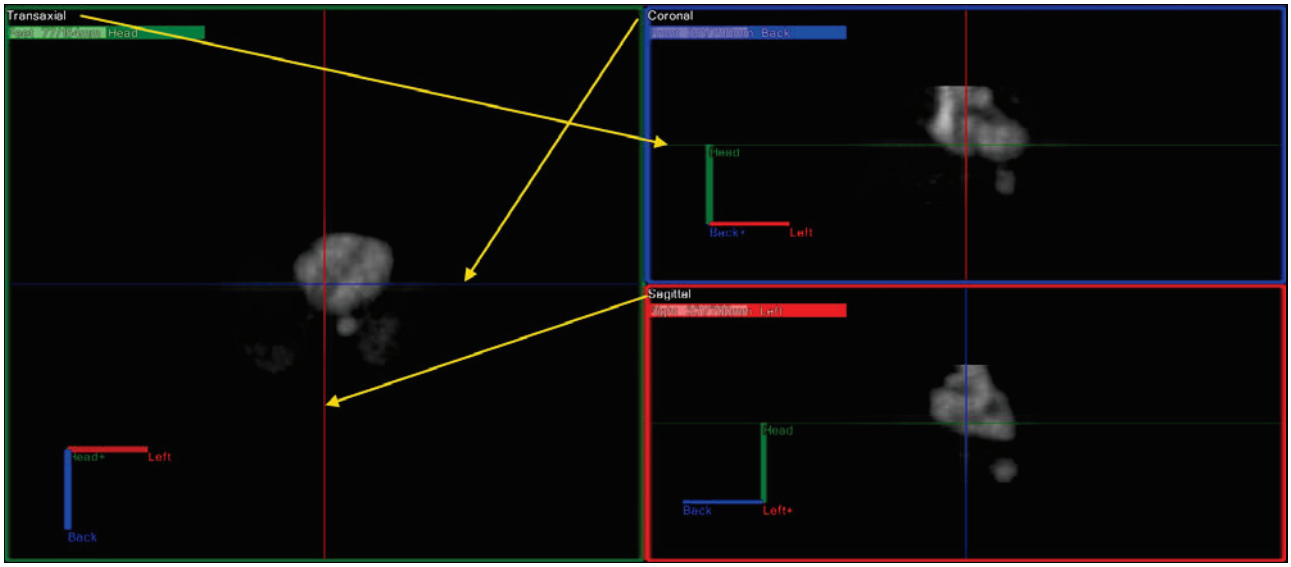
2D Image Window Components

Each window includes shared components that provide additional information about the visualization and the orientation of the patient.

Cut Lines

As stated previously, each window visualizes slices from one of the three anatomical planes. The position of a slice in one image window is visualized in the other windows with the help of lines that share the color of their plane: The Cut Lines.

In the image below, the yellow arrows represent this relation between the Cut Lines in the Transaxial image window and the other windows.



In the above image, the Transaxial window contains two Cut Lines: Blue and red. The blue line shows the location of the current Coronal slice (blue window border), and the red line shows the location of the current Sagittal slice (red window border) in relation to the transaxial image.

Note: Although not marked by yellow arrows in the above image, the aforementioned holds true for all windows. A 2D Image Window will always contain Cut Lines representing slices of the other two planes.

The Cut Lines can be moved with the Cut tool by selecting it from the Toolbar. Holding down the left mouse button over a Cut line and dragging will move the line, updating its position in the other windows. With the Cut tool, you can also click on any point of the image to immediately move the Cut lines to intersect there.

Tip

In Step 1 of the workflow, you can also use the General tool instead of the Cut tool to the same effect.

Slice Depth Slider

Each 2D Image Window also contains information about the currently viewed slice and all slices on that plane. This information is visible in the Slice Depth Slider in the top left corner of the window.

- The numbers in the middle of the bar represent the ordinal number of the currently displayed slice and the total amount of slices.
- The text towards the left and right ends of the bar represents the opposite ends of the plane in relation to the patient (e.g. "Feet" and "Head" in the image above).
- The brighter color bar under the text is a representation of the current slice. In the image above, the bright green bar grows to the right as slices closer to the Head of the patient are displayed, and shrinks to the left as slices closer to Feet of the patient are displayed.

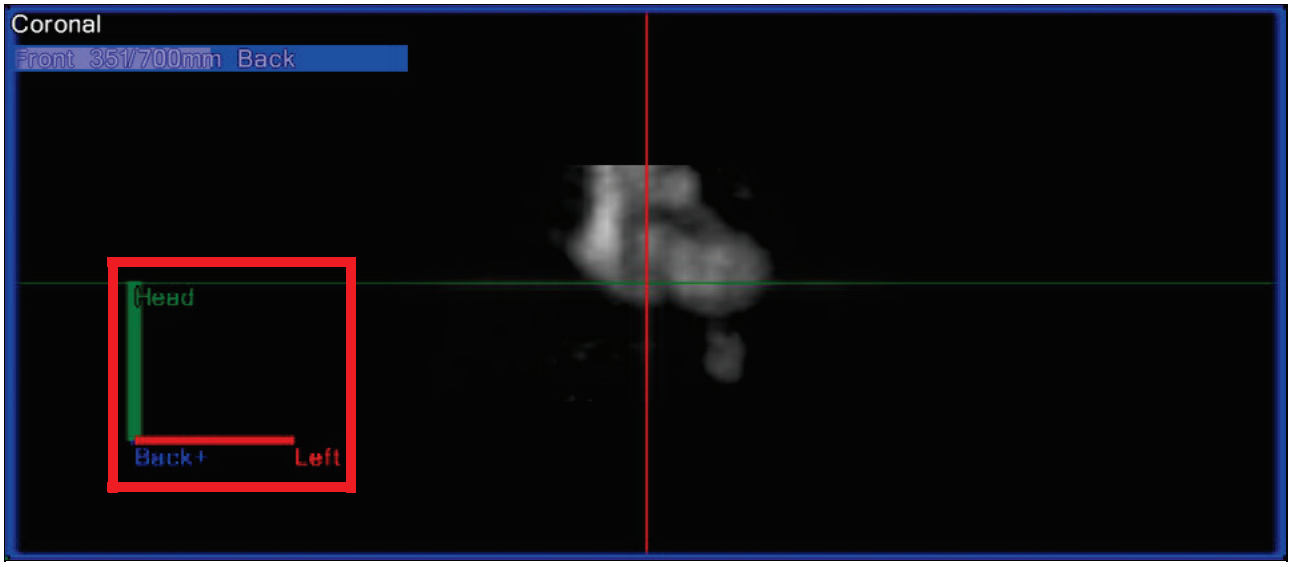
Clicking and dragging (left or right) with the left mouse button on the slider will change the currently displayed slice.

Tip

Alternatively, hover the mouse over an image window and scroll with the mouse wheel to change the displayed slice in that window.

Orientation Guide

To help with verifying the orientation of the patient in any 2D image, the lower left corner of each 2D Image Window contains the Orientation Guide (highlighted with a red frame in the image below):



The Orientation Guide contains three arrows that point to the following directions:

- Head (green) - The head of the patient.
- Back (blue) - The back of the patient, i.e. the direction the patient is facing.
- Left (red) - The left side of the patient.

Depending on the anatomical plane, one of the directions might not be discernible from the image. In this case the arrow for the direction goes "straight through the image" and only the name of the direction is visible. A plus sign next to the direction means the arrow is pointing away from the viewer and a minus denotes pointing towards.

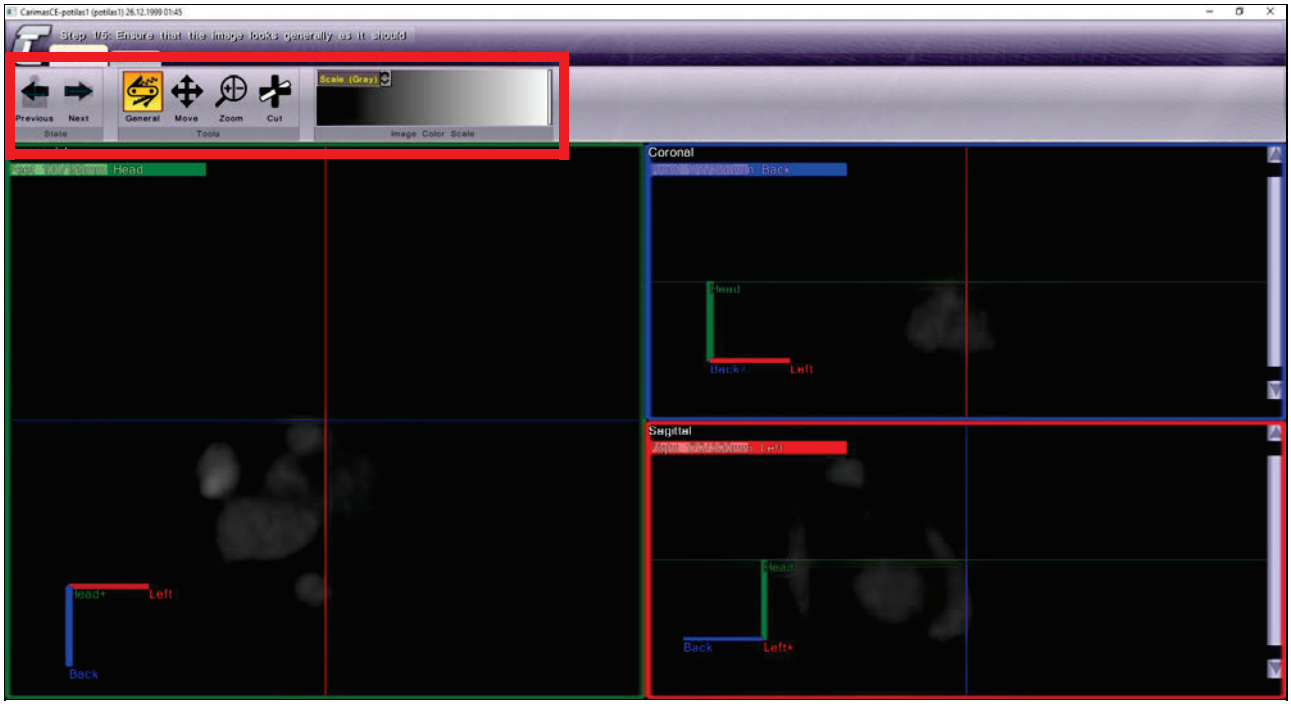
Example: In the image above, the image slice is on the Coronal plane, and the directional arrows for the Head and Left of the patient are visible. The arrow pointing to the Back of the patient is perpendicular to the Coronal plane and thus cannot be visualized, so only the name of the direction is shown at the origin point of the arrows.

WARNING

If the orientation of the visible image and the directional arrows do not seem to match, it is possible that the input image data is wrong or corrupted in a way that cannot be detected by CarimasCE. This kind of input should be discarded, as proceeding could lead to unreliable results.

4.2 The Toolbar in Step 1

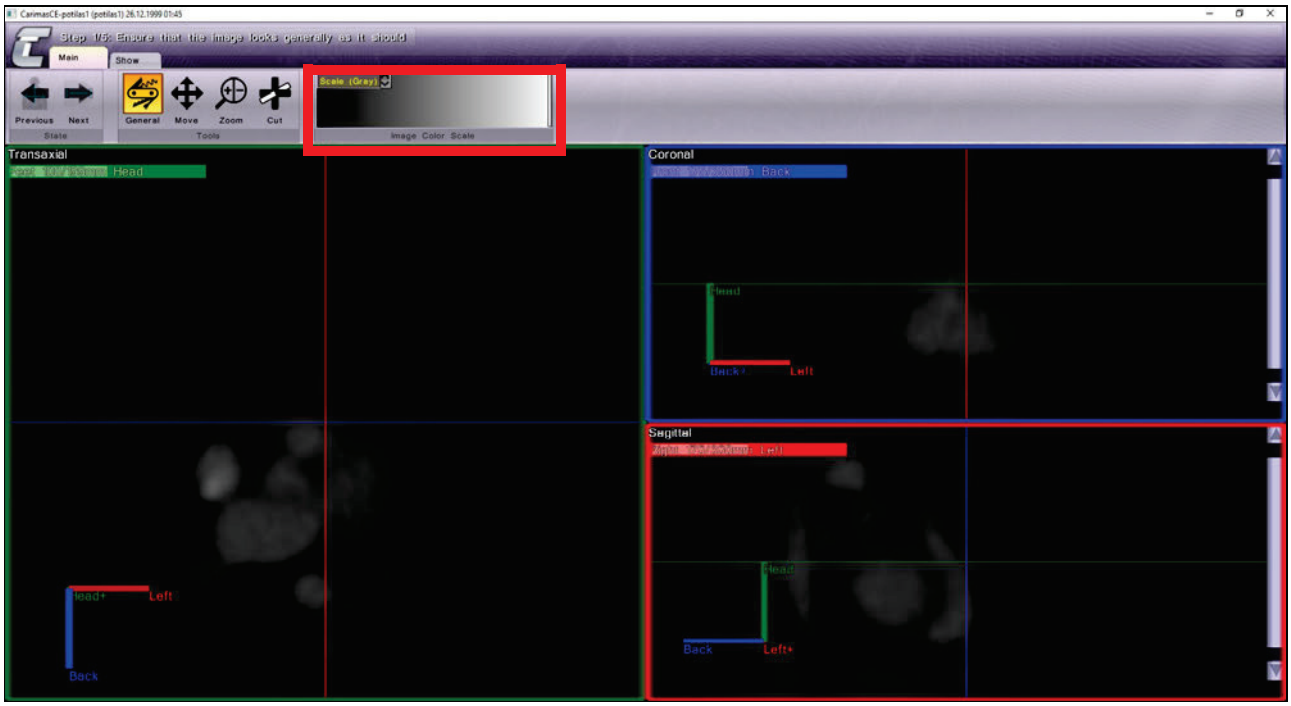
This section explains the tools available during the first step of the Single Water workflow. The different tools can be selected from the toolbar at the top of the program.



See the subchapters to this section for detailed explanations.

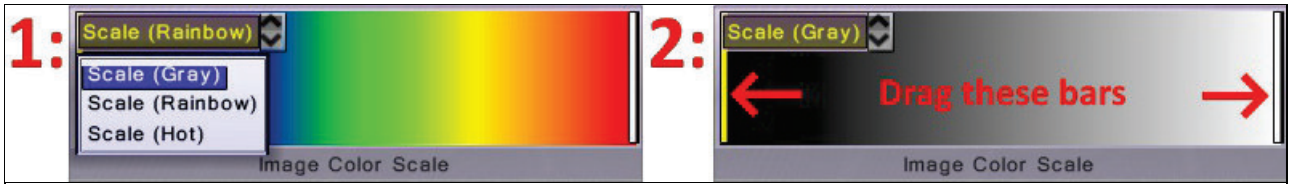
4.2.1 Color Scales

The Color Scales dictate how the image data is mapped into visible colors. Adjusting this is done through the Image Color Scale tool, which is typically located in the Main section of the toolbar:



The color scale can be selected by clicking the name on the Image Color Scale tool ("Rainbow" in the image below) and selecting one of the color scales in the menu that opens. CarimasCE comes with three pre-installed scales: Gray, Hot, and Rainbow, of which the Gray Scale is selected by default.

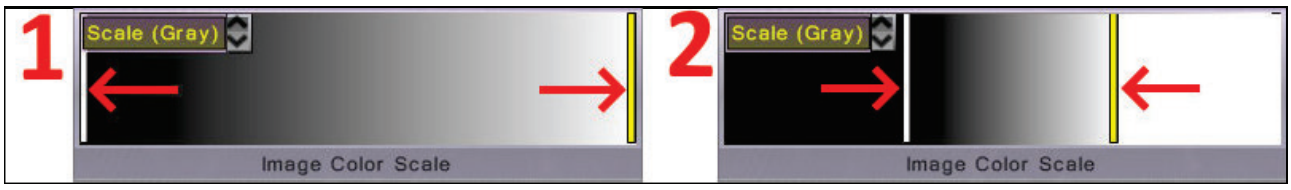
The scale can be switched by clicking the name (1) and choosing a new one from the dropdown list:



The left and right ends of the Color Scale tool represent the minimum and maximum values in the input image. The upright bars on either end of the scale (2. in the image above) define the start and end values when the image is visualized. The bars can be dragged with the left mouse button held down to define a different start or end value, causing change in how different regions of the image are shown.

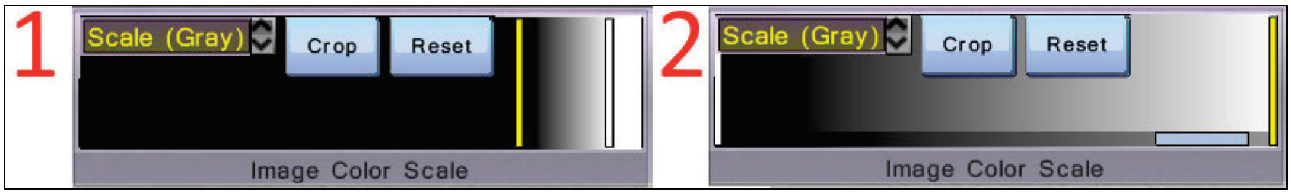
Any values below the defined start value for the visualization (left bar) will be shown as the minimum value of the scale. Likewise, any values above the defined end value for the visualization (right bar) will be shown as the maximum value of the scale. The values in between are visualized as a range between these values, dictated by the selected color scale.

This is best exemplified in the image below: After moving the bars, everything to the left of the start bar is black and everything to the right of the end bar is white. Notice how the Gray scale has been shrunk in between these bars.

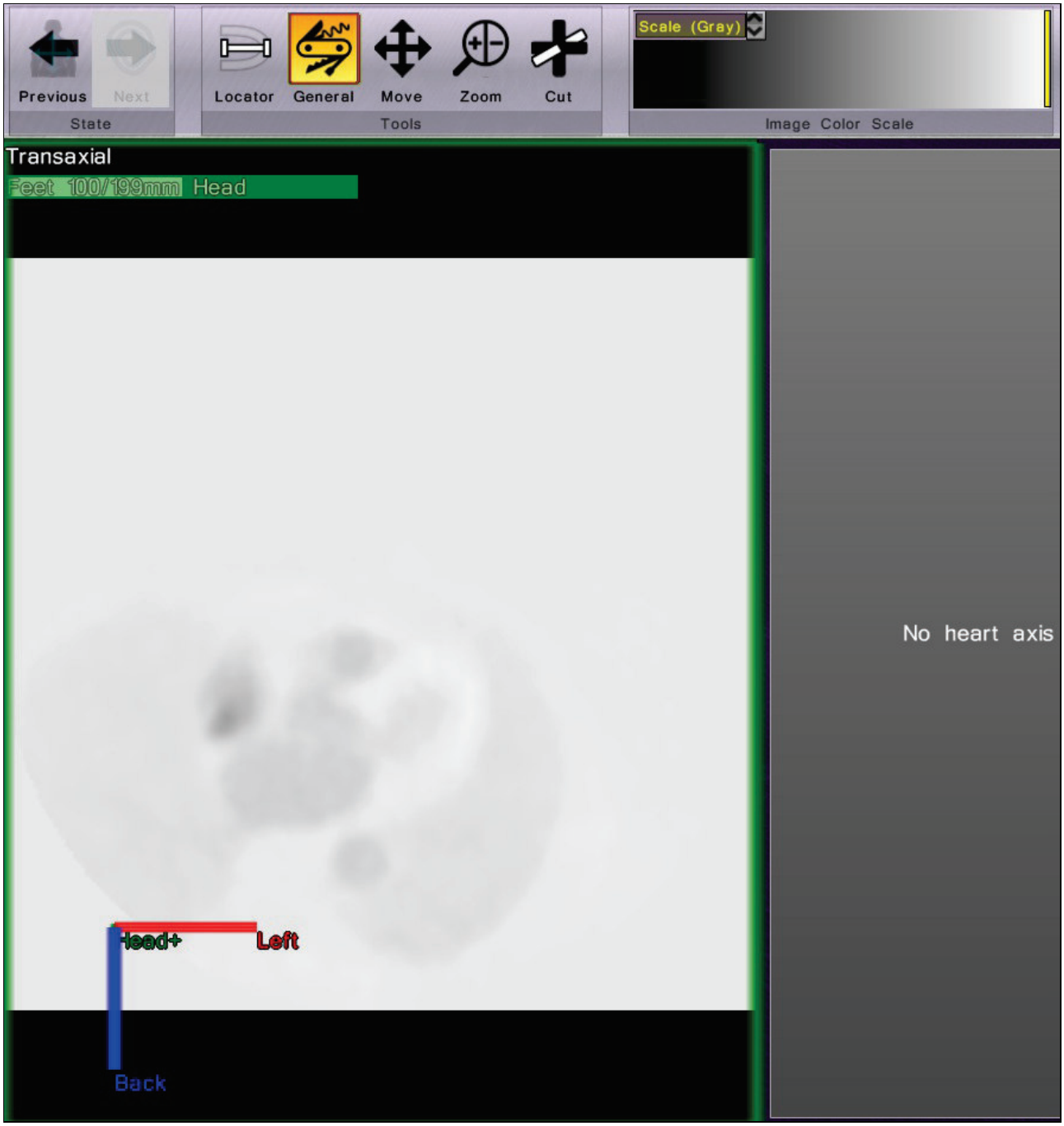


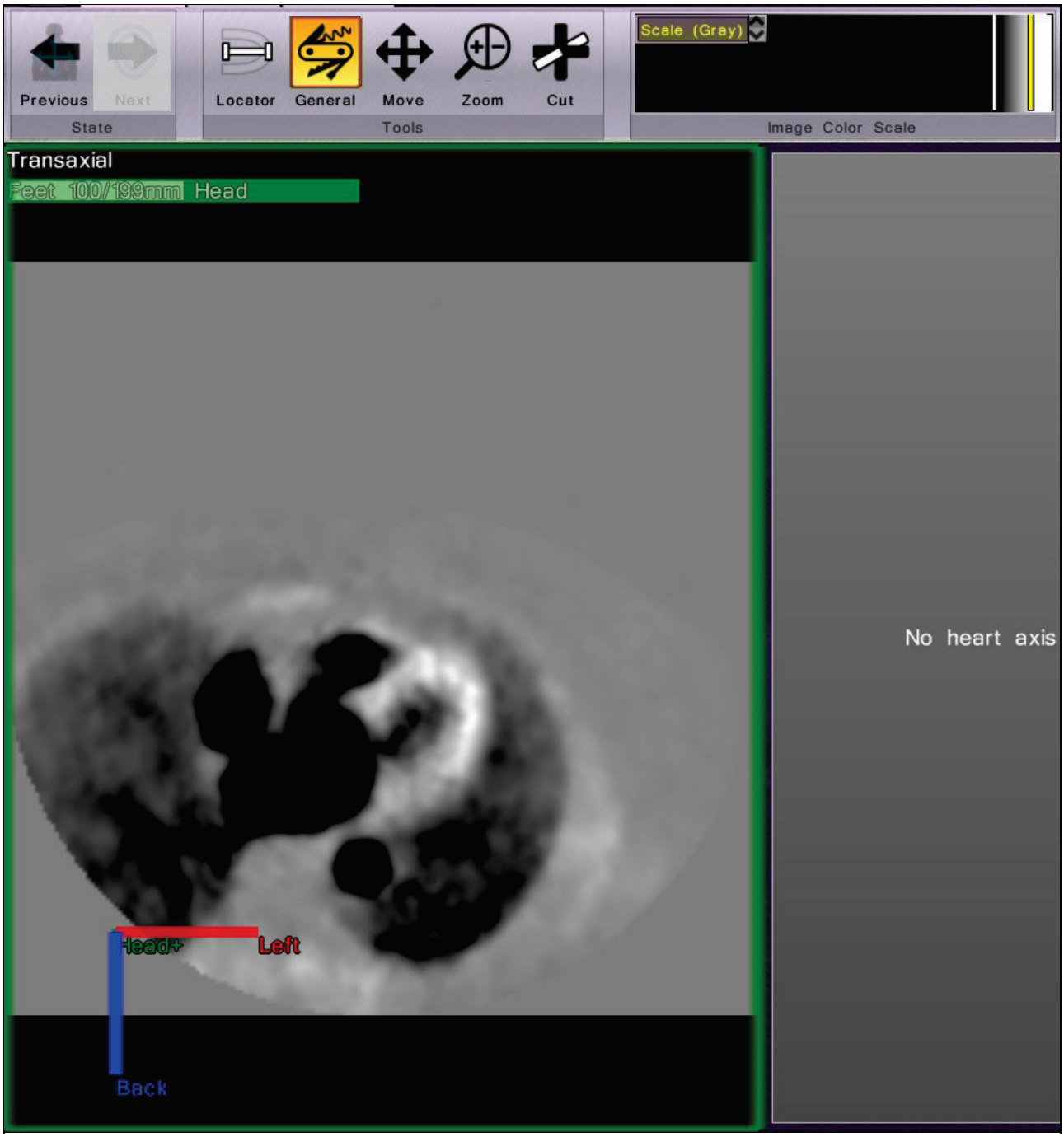
Besides the colors in the Image Color Scale tool itself, the colors of the images below will also immediately adjust to the selected scale and any adjustments. Thus it is a good idea to adjust the ends of the color scale while looking at the image to ensure you get the best results.

A Crop Tool was added to the Color Scale in CarimasCE version 1.3.8. Clicking on the "Crop" button will "zoom in" on the selected range and allow you to fine-tune your selection. The location and size of the cropped selection in relation to the original uncropped scale is shown as a blue bar at the bottom of the color scale. You can crop the scale further by moving the end bars and clicking on the "Crop" button again. You can also extend the cropped selection by dragging and dropping the end bars away from each other, that is, outside the Color Scale window. The scale can be reset completely by clicking the "Reset" button.



Often the most useful case for adjusting the Color Scale is when viewing the Diff Images, and below is an example of this. In the first image the Scale is in its default state and in the next, the Scale minimum and maximum has been adjusted thus showing the muscle wall much more clearly:


Previous
Next
State
Locator
General
Move
Zoom
Cut
Tools
Scale (Gray)
Image Color Scale
Transaxial
Feet 100/199mm Head
Head+
Left
Back
No heart axis



WARNING

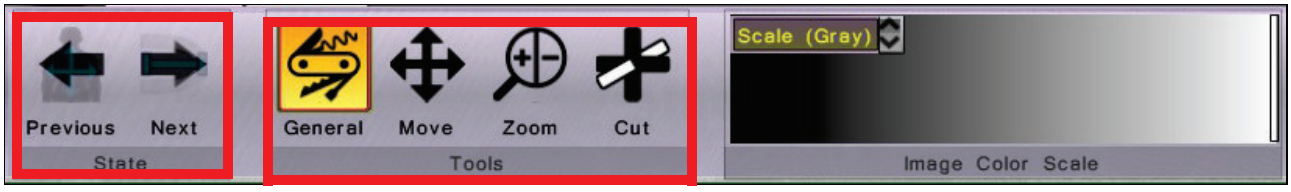
Colors in CarimasCE are only used to aid in viewing the images. As discussed above, the color scales and their start and end points can be changed at will. As such, a color or hue in itself does not hold any inherent meaning.

WARNING

The images in this section are examples of using the Image Color Scale tool, and do not represent the desired result for your input image. Experiment with the tool to find the configuration that works best for your situation.

4.2.2 General Controls in Step 1

The general controls are found in the Main tab of the toolbar.



The "Previous" button returns to the previous step, i.e. Study and Workflow Selection.

The "Next" button moves to the workflow Step 2: Heart Location. There are no requirements for moving to Step 2, but you should check that the image is properly oriented and that it is of sufficient quality overall.

General Tool

The "General" tool usually takes the role of the most important tool in any workflow step. In this step it functions identically to the Cut tool. In normal use, it is possible to complete this step with only this tool selected, granted that you use the right and middle mouse shortcuts for panning and zooming.

See below for more information on the other tools.

Panning the Image

The image visualizations in the workflow can be panned using the "Move" tool. While the tool is active, holding down the left mouse button and dragging moves (pans) the images respective to the direction the mouse is dragged to.

Tip

You can pan the image regardless of the selected tool by holding down and dragging with the middle mouse button *(clicking the wheel)*.

Zooming the Image

You can zoom in and out of the images by using the "Zoom" tool. While the tool is active, holding down the left mouse button and dragging zooms the image: Dragging up will zoom in while dragging down will zoom out.

Tip

You can zoom the image regardless of the selected tool by holding down and dragging with the right mouse button.

Moving the Cut Lines

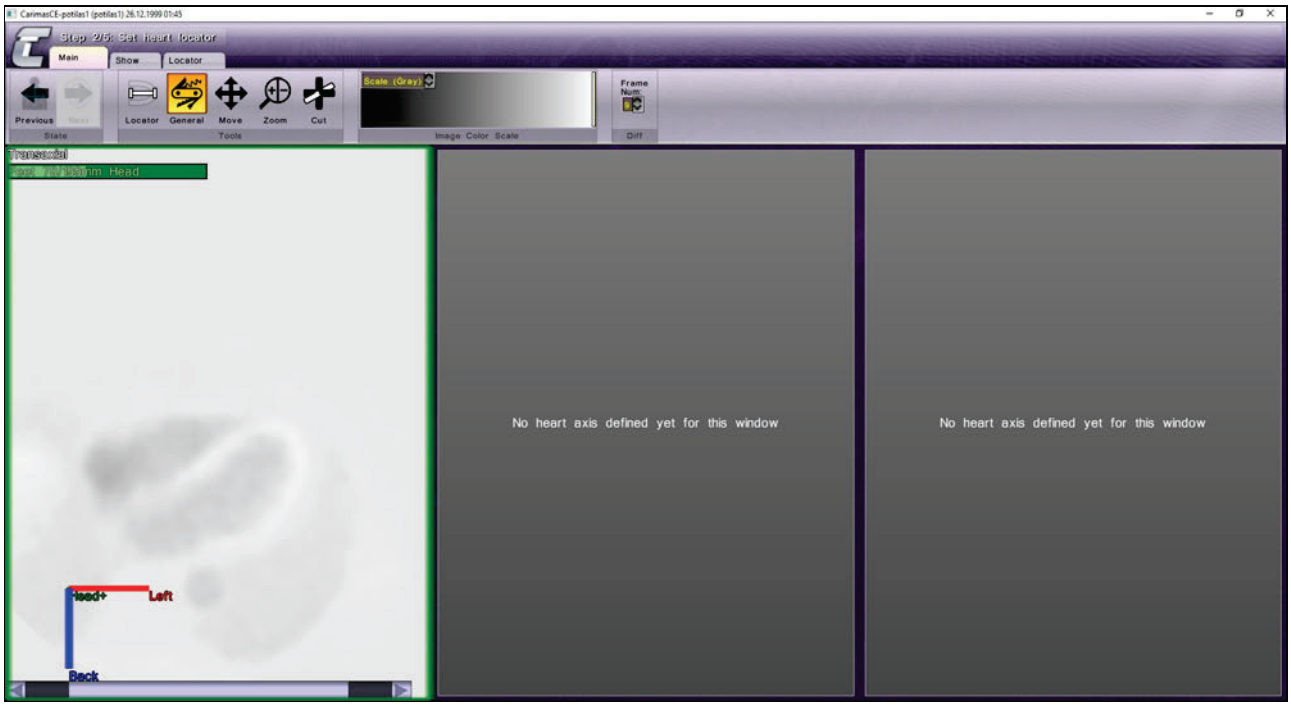
You can move the Cut Lines in any window with the "Cut" tool, which is signified by the Cut Lines becoming more pronounced when the tool is selected. Bring your mouse over a cut line and drag it with the left mouse button held down to move it. Dragging from where the lines intersect will move both lines at the same time.

You can also click at any point in the image that is not already occupied by a Cut Line to instantly move the Cut Lines in that window to intersect at the point.

See 2D Image Window for more information on Cut Lines.

5 Step 2: Heart Location

After the orientation checking step you will enter the Heart Location step. You will need to define the heart position before moving to the next step. The program shows three windows side by side, of which only the leftmost window contains an image in the beginning:

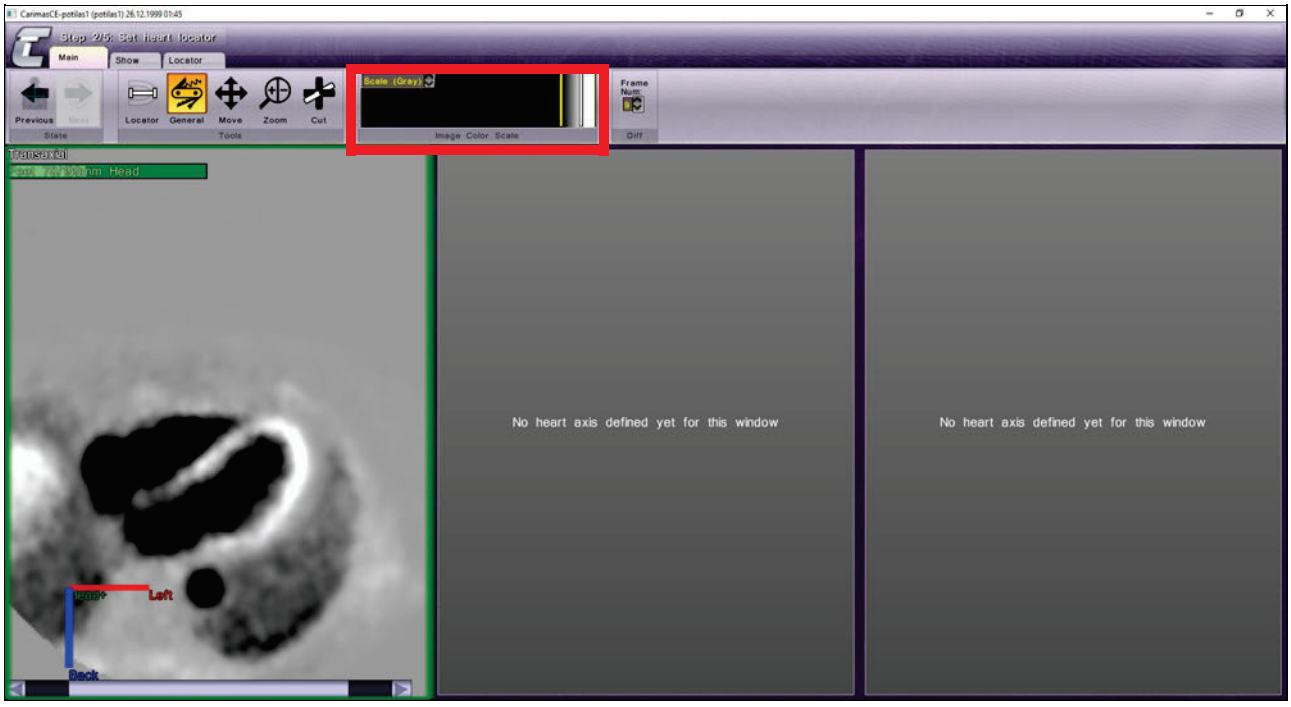


Adjust the settings to make the LV optimally visible

The dynamic image is visualized as a Diff Image to help accentuate the left ventricle (LV) muscle. The first adjustment you should do is to try different Diff frames to make the LV muscle as visible as possible. The Diff frame can be changed with the "Frame" tool in the Toolbar. See Diff image for more information.

The cut position remains the same as what was defined in the previous step. Thus it is often optimal to define the cut centre point as close to the heart centre as possible in the previous step. If the depth slice position is not inside the LV, it can be adjusted by scrolling with the mouse wheel over the image or by dragging the slice slider. The end result should look similar to the image above.

After adjusting the color scale end points the LV muscle should be much more visible:



Tip

You can return to the previous step by pressing the "Previous" arrow in the Toolbar.

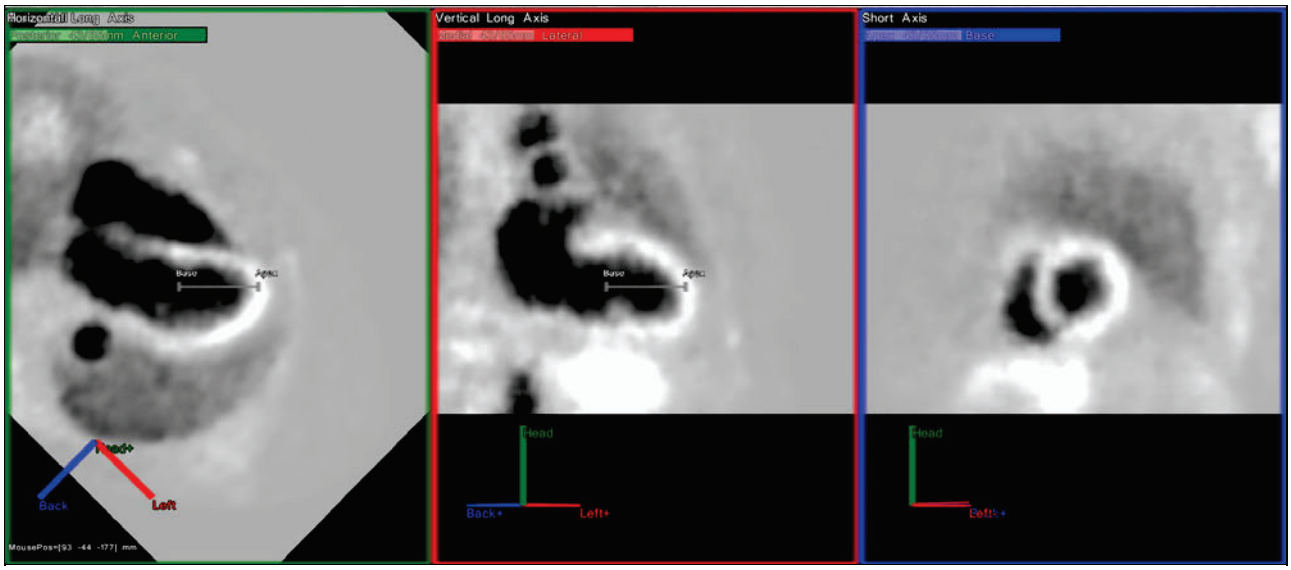
WARNING

Several Diff Frames should be tested in the analysis. CarimasCE will display a warning message if only one DF option is used in the analysis. This warning is also included in the final report.

Drawing the Long Axis

When you deem the LV wall to be sufficiently visible, you can begin defining the location of the heart. First you will need to draw the Long Axis that will define the Base and Apex of the heart. The Long Axis is drawn by holding down the left mouse button at the Base area of the LV, dragging the mouse towards the Apex, and then releasing the mouse button. This will define the Long Axis, with the starting point as the Base and the ending point as the Apex.

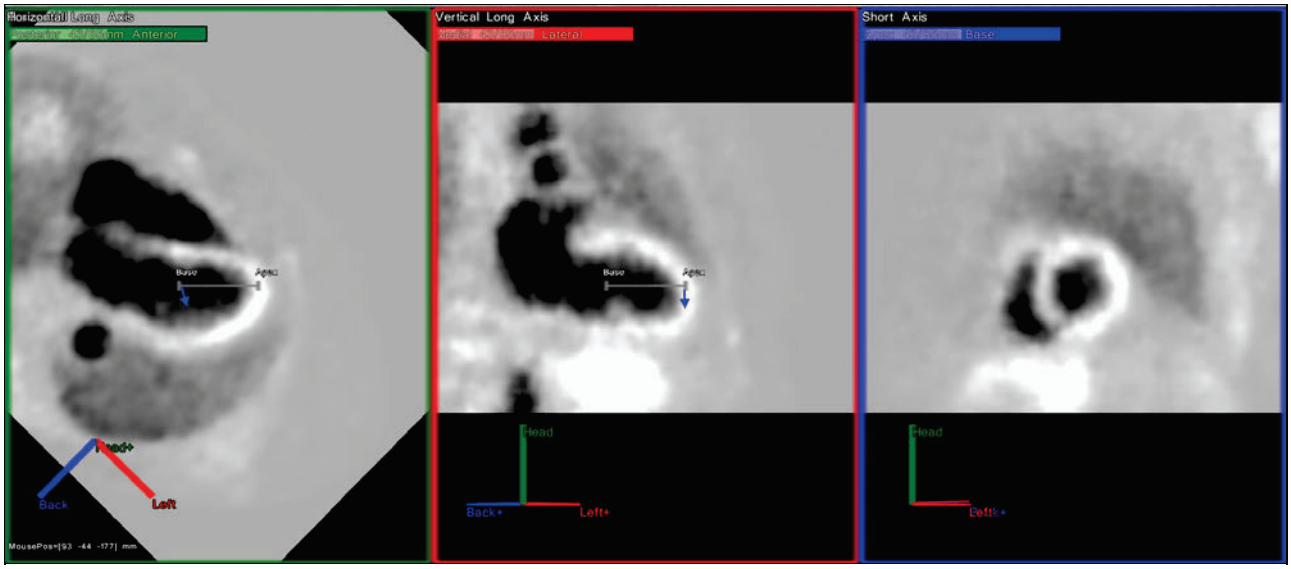
After the Long Axis has been first defined, the two empty windows become active and also the image in the first window changes significantly. The outcome should look similar to the following image:



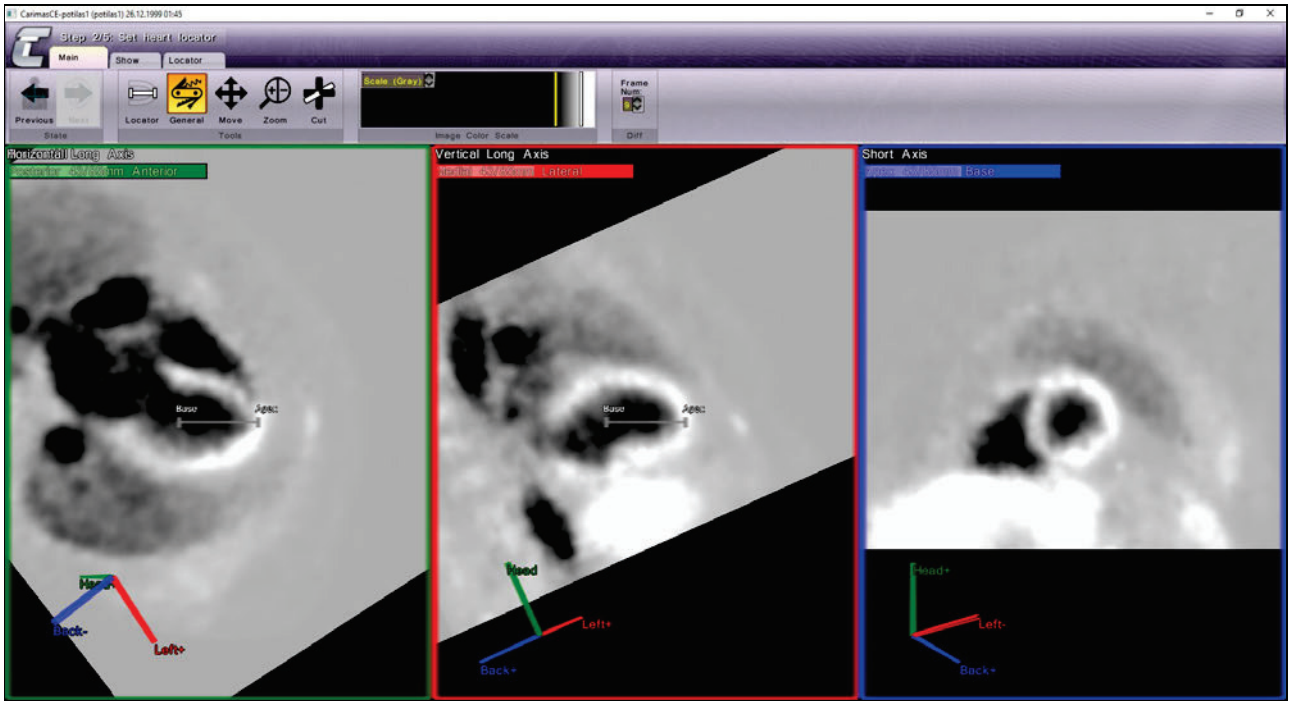
The first window automatically zooms and transforms so that the drawn axis is always horizontal and fully perpendicular to the window. The viewpoints of the windows are as follows:

1. The first window views the patient from the head towards the feet. Thus the depth of the Base and Apex points will always be at the same distance from the viewer.
2. The second window is otherwise similar to the first, but the view is from the side of the patient.
3. The third window views the axis from behind, so the axis is essentially just a dot in the centre of the window.

With the automatic window realignment it should be quite simple to adjust the base and apex points of the Long Axis in the first two screens so that the axis follows the centre of the LV cavity. This can be done by dragging either the Base or Apex end of the axis with the left mouse button. The small arrows in the following image demonstrate how each point could be adjusted in our example:

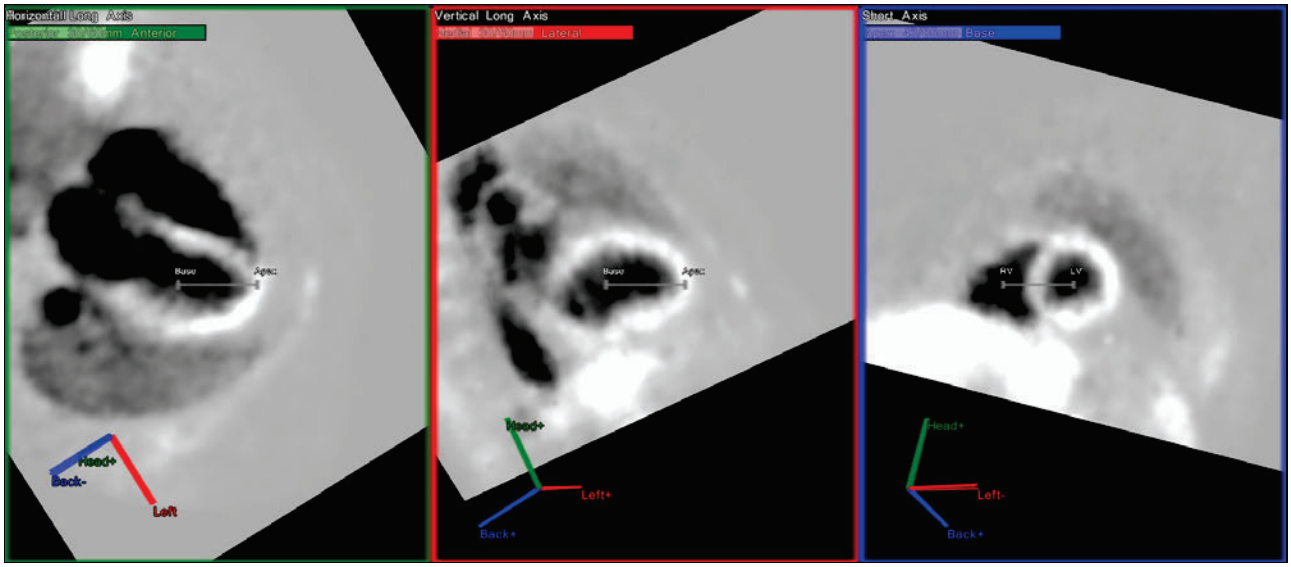


After these suggested adjustments the screens will again realign themselves perpendicular to the axis. These points can also be adjusted in the next step. The result looks like this:



The next task is to define the right ventricle (RV) centre point in the third, rightmost window. It might be necessary to adjust the Diff frame in order to optimally locate the RV.

After you have located the RV centre point, it can be defined in the program simply by clicking that point in the window with the left mouse button. This automatically places the Short Axis, with one end as the the RV centre point and the other end as the LV centre point:



The third window automatically aligns itself so that the LV and RV centre points are completely horizontal. The viewpoint remains from behind the patient, so RV will be on the left side of the window. The two other windows will also readjust: The viewpoint of the first window will now be directly above the heart due to the defined RV point. A similar modification will also happen in the second window, resulting in all three windows now being perpendicular to each other.

Both axes (in all three windows) can be adjusted by dragging their end points with the left mouse button. Readjust the axes until the heart location is correctly defined.

The whole step can be reset from the Locator-tab (this removes all drawn axes).

Next

After the RV point has been defined it's possible to proceed to the next step: Segmentation. However, you should continue making adjustments until you are satisfied with the result, and then proceed by clicking the Next arrow.

5.1 Diff Image

There are several potential ways to visualize a dynamic image. In water heart analysis a fast and effective way is to use the so called Diff Image. This is how CarimasCE visualizes the heart in Step 2 of the workflow and further. The Diff Image is calculated by defining one of the frames as the Diff Frame (DF) and then calculating a new visualized image with the following operation for every pixel:

Result Intensity = Sum(DF+1 to LastFrame) minus sum(FirstFrame to DF)

> **Tip**
> Note, that the Diff Frame indexing of a N-frame image is done from 0 to N-1.

After this operation, low pixel values mean regions where the intensities are high before the DF but fade to smaller intensity after the DF. Respectively, high values are regions with low intensity before the DF and high intensity after the DF. Because the intensity travels in right ventricle, left ventricle (LV) and the LV muscle at different times, selecting the correct DF is crucial for optimizing the visibility of the LV for segmentation.

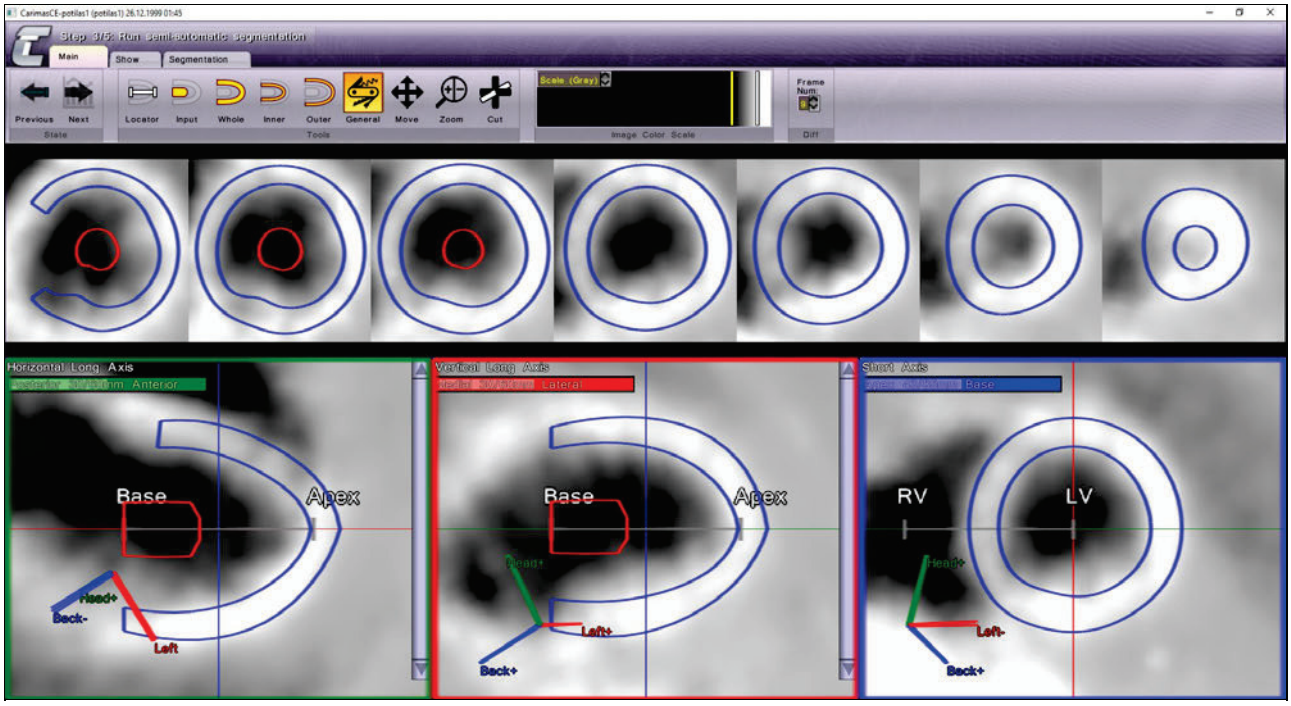
In Carimas the DF is by default set to be at 1/3 of the frame count, which normally gives a reasonable starting point. The user should still always try the different DF options, and see how they affect the segmentation. It is normal for several DF values to give a good segmentation end results. Thus it is necessary to understand that selecting a lower DF usually results in smaller LV ROI. The user should observe how much the heart ROI changes between different 'good' DF values and probably not select boundary case, but a result in the middle.

> **WARNING**
> Several Diff Frames should be tested in the analysis. CarimasCE will display a warning message if only one DF option is used in the analysis. This warning is also included in the final report.

The Diff Frame (DF) can be changed with the Diff Frame selection tool in the Toolbar.

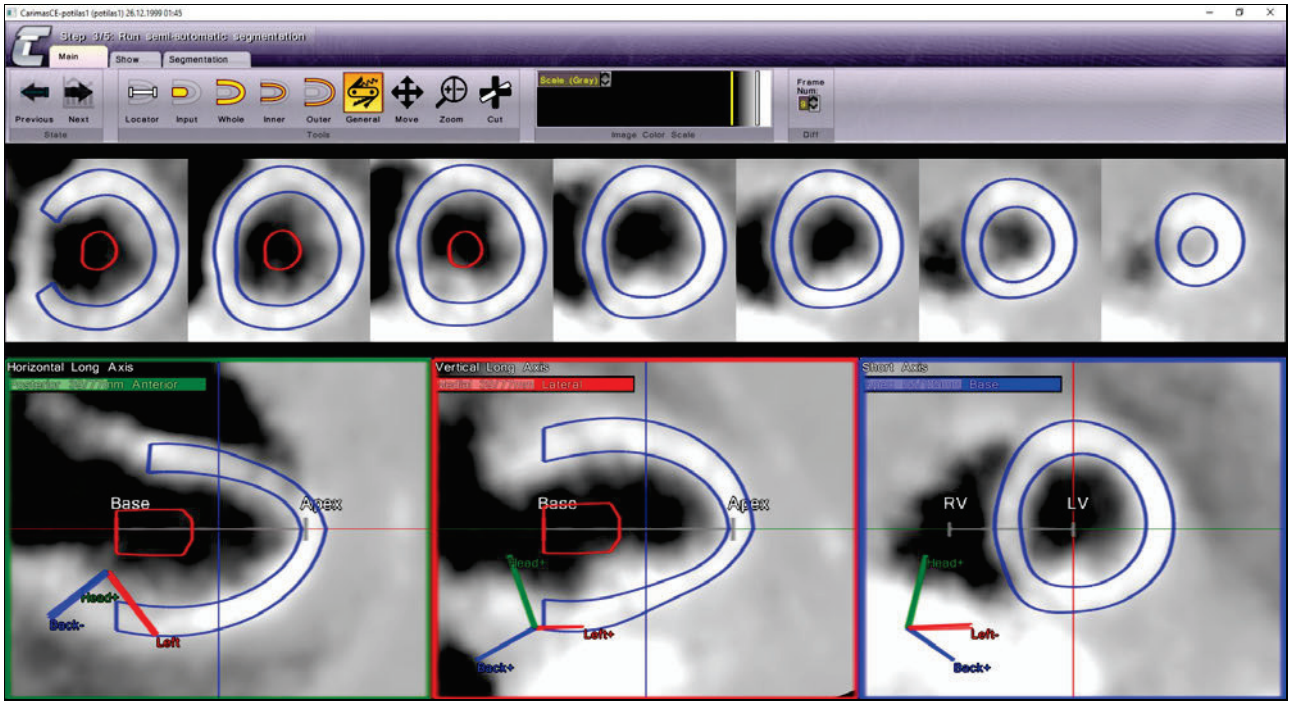
6 Step 3: Segmentation

When the Heart Location step is finished, Carimas will automatically calculate the segmentation of the Left Ventricle (LV) based on the previously defined axis. If the axes were drawn correctly and there are no oddities in the image, the automatic segmentation should be fairly good:



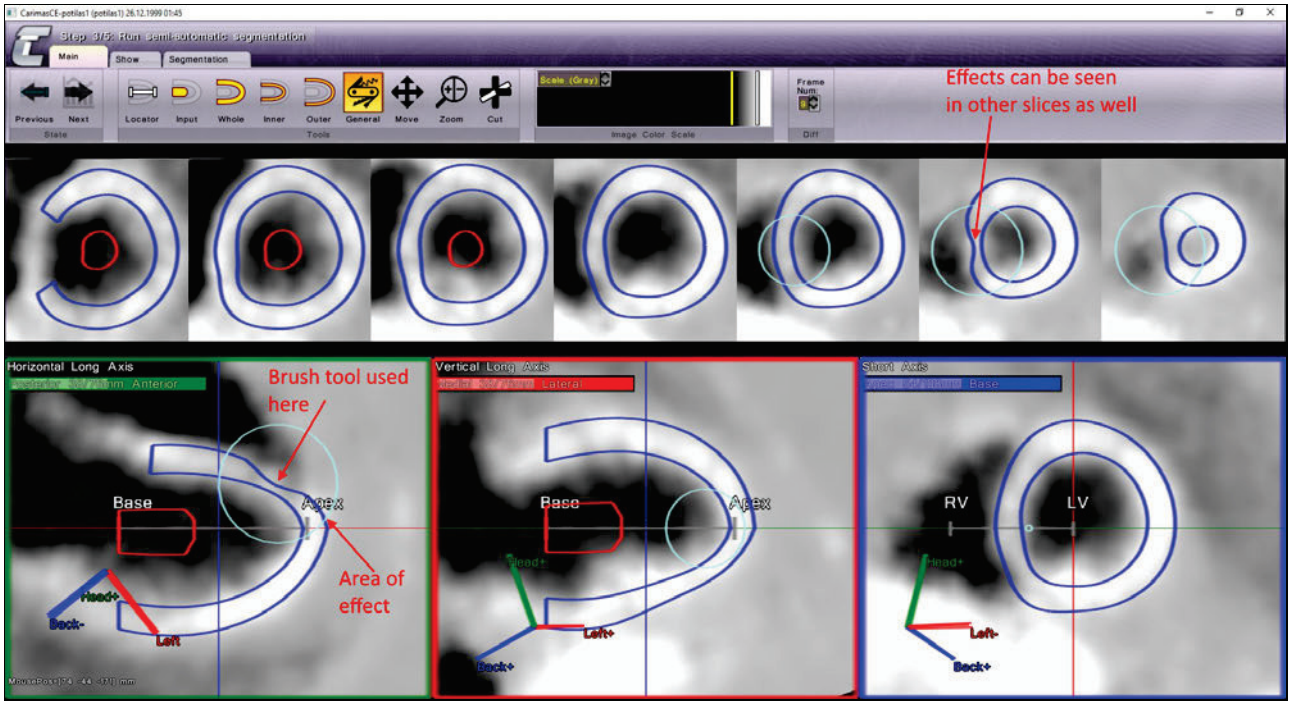
Next we will use a badly drawn axis for the purposes of demonstration. The base has been drawn too close to the LV muscle wall, so the automatic segmentation failed partially:

The axes can be adjusted by clicking & dragging as before. The nearby slices should be looked at as well by scrolling with the mouse wheel or by clicking (and dragging) the slice indicators to make sure the segmentation is good. After each adjustment the segmentation is re-calculated:

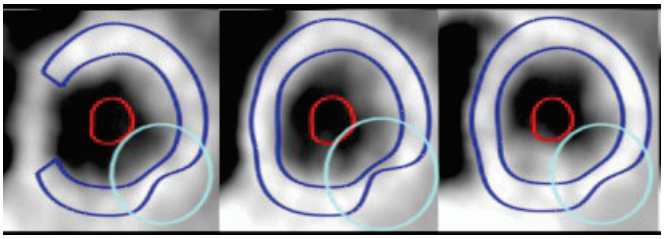


When editing the segmentation, the tool can affect the whole segmentation (general) or only a specific part.

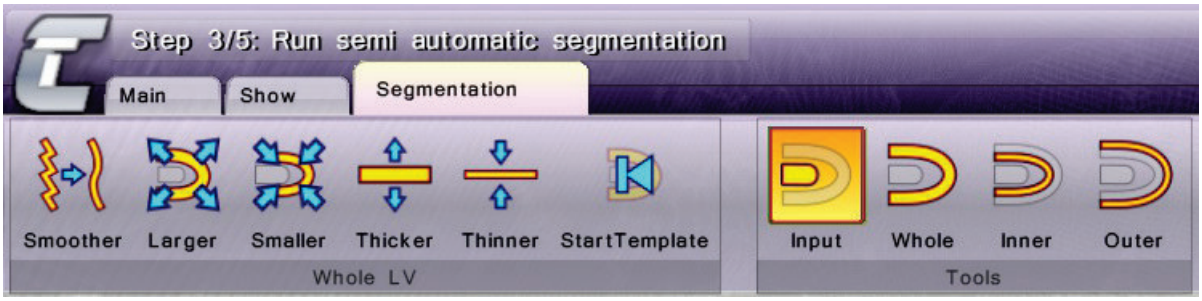
The segmentation can also be fine tuned with the brush tool (shown as the grey circle when the General Tool is selected) by clicking & dragging in any of the Axis or the Slice windows.



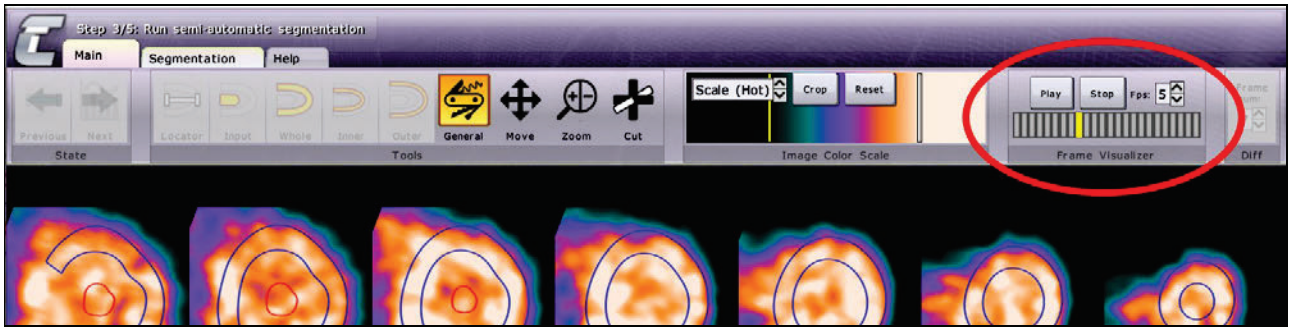
The brush can be used in the Slice Views as well.



The segmentation can also be altered with the Tools in the Segmentation-tab. The Tools alter which specific part of the segmentation is affected when the Whole LV controls are used. StartTemplate works only with Whole/Inner/Outer tools.



For detecting possible movement of the patient during the scan, the software provides player -tool, visualizing the pixel activities as function of time. The tool activates when the "Play" -button is pressed and the image activities are played from the beginning of the scan to its end. The player will loop, until it is stopped from the "Stop" -button. The visualization of the player does not affect to the defined segmentation, which can be used as reference for detecting, if the heart muscle gets outside of the segmentation at some time phase. The software does not provide tools for correcting the image movement.



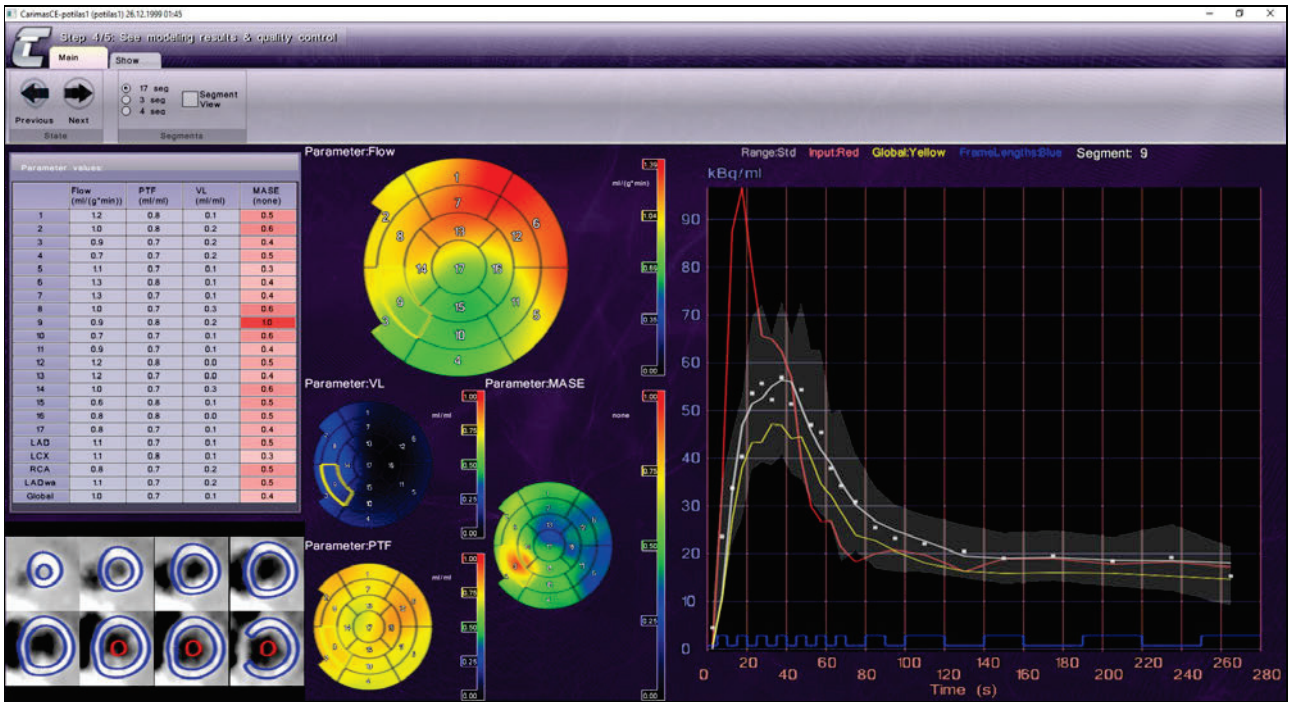
Tip

You can also visualize different time phases by dragging the time indicator with mouse (when the player is on)

When the segmentation is ready, it's time to press the next step arrow again, which will lead us to Quality Control step.

7 Step 4: Quality Control

After the Segmentation Step you will enter to the Quality Control Step. The water modeling will be executed when you enter the step and the results are displayed in numeric form, polarmaps and graphs. A segmentation overview is also displayed. You should verify the results and determine the quality of the segmentation, and return to the previous steps to adjust if necessary.



Modeling Results Table

On the left side of the screen is a table with the numerical modeling results, for each polarmap segment. For each segment, four parameters are listed:

- Myocardial blood flow (F)
- Perfusable tissue fraction (PTF)
- Arterial blood volume (VL)
- Mean absolute scaled error (MASE)

The first three values are the fitted parameters from the model. The last (MASE) is a measure of the quality of the model fit to the data. The values shown are calculated from the segmental mean time activity curves (TACs).

Result Polarmaps

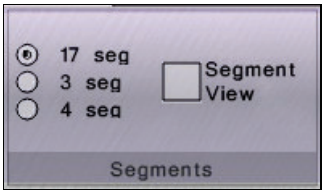
Each of the parameters is also displayed in polarmap form. Each polarmap shows the modelled values within the polarmap, overlaid with the polarmap segment grid. Selecting a segment, from any of the polarmaps, with a mouse click highlights the selected segment and displays the segmental TACs in the TAC display. Clicking outside the polarmaps highlights the entire polarmap and selects the global mean TACs for the TAC display.

Polarmap Segment Modes

The polarmaps are displayed in one of the three modes:

- 17 Segment mode (the default mode)
- 4 Segment mode
- 3 Segment mode

You can change the segment mode from the Segments toolbar. The segment mode changes the polarmap segment grid overlaid on the polarmaps, allowing you to view and select segments from the different segmentation modes.



In addition to the segment mode, you can select, or unselect, the Segment View. While the Segment View is selected, the polarmap

segments are shown with a uniform color of the segment's mean value. If the Segment View is unselected, the parameter variance within the polarmaps is shown in more detail.

Note that the numerical values shown in the table or the segmental mean TACs are not affected by the changes in the polarmap segment modes. These modes are only used for polarmap visualization.

Time Activity Curve Display

The right side of the display shows the segmental mean TACs of the currently selected segment, or the global mean TACs, if no segment is selected.

For each segment, five curves are displayd:

- Modelled segmental mean, in solid white line
- Segmental mean data points, in white dots
- Input function, in solid red line
- Myocardial mean, in solid yellow line
- The frame times and lengths, in solid blue line

In addition, a one standard deviation range of the segmental mean data is shown as a grey range around the data points.

Segmentation Overview

At the bottom left, the segmentation overview displays a series of eight image planes, displaying the location of the myocardial VOI along the long axis from apex to base.

Verification of the Results

Before proceeding to the Report Step, carefully review the displayed data to verify the quality of the segmentation and the suitability of the data.

Inspect the polarmaps to get a quick visual overview. Make sure the myocardial flow (F) values are within the expected range; a very high value may indicate a bad model fit in the segment. A high arterial blood volume (VL) in a segment may indicate that the VOI is drawn to include parts of the ventricle cavity. A very low perfusable tissue fraction may indicate, that the VOI is drawn outside the myocardial wall at the segment location.

Select each segment in turn, by selecting it from a polarmap. The time activity curves should be inspected, making sure that the input function TAC shape is as expected, and that the modelled segmental TAC is reasonable, relative to the data points. Poorly fitting data is an indicator of poor segmentation or bad data quality.

Pay attention especially to segments that stand out from the others. Higher, or lower, values may reflect poor segmentation, and not an actual anomaly in the image data. As a rule of thumb, any segment with a notably higher or lower value in any parameter merits a closer look. If needed, return to the Segmentation Step to ensure the correct placement of the myocardial VOI, and adjust as needed. The modeling is automatically recalculated, if the segmentation is modified.

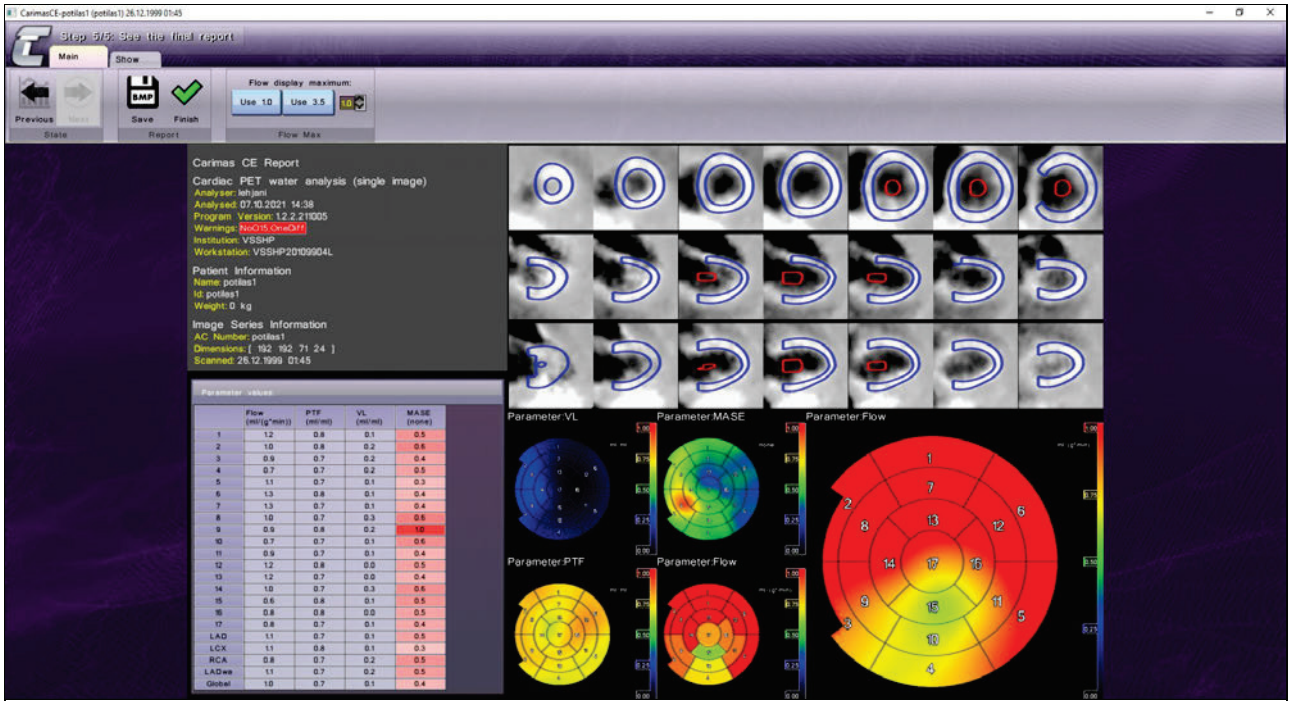
WARNING

Pay special attention to the areas near the septum. The VOIs should not include any portion of the right ventricle (RV) region.

When you are satisfied that the segmentation quality is sufficient, proceed to the Report Step.

8 Step 5: Report

After the Quality Control Step the final analysis report is generated. The Report step displays the report page and allows you to save the report to the Carimas database.



Report Content

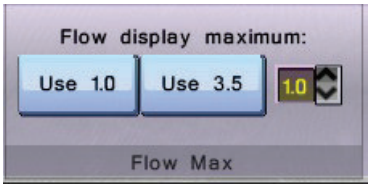
The report contains the result table and the parametric polarmaps from the Quality Control Step, a study panel, and a segmentation overview.

In the study panel, the current analysis workstation, date and your login name is displayed, in addition to patient and study information. If CarimasCE detected any anomalies during the analysis, these are displayed in red alongside other analysis information.

The segmentation overview displays a series of image planes along the long and short axis.

All unresolved warnings will also be displayed on the report, see Symbols, Abbreviations and Warnings for more information.

Flow Parameter Scale



To increase the readability of the Flow polarmap, you may change the polarmap scale from the toolbar. Select one of the available scales:

- Use 1.0: 0-1 ml/g*min, for low flow values, such as rest studies
- Use 3.5: 0-3.5 ml/g*min, for high flow values, such as stress studies
- Manually from the drop-down menu. As the previous ones but the maximum can be chosen from a list of options.

Saving the Results

Once you have reviewed the report information, you may save the Report by selecting the "Save" button from the toolbar. The report is now attached to the study in the CarimasCE database, and may be exported later from the Database Management.

The analysis is now complete. Select "Finish" from the toolbar to return to the workflow selection screen.

9 Administrator's Guide

This portion of the IFU contains the relevant information on how to:

Install CarimasCE
Verify the installation of CarimasCE
Check the system, audit and error logs
Uninstall CarimasCE and remove all locally stored data

9.1 Installation Guide

System Requirements

Operating system

CarimasCE requires a 64 bit Windows operating system with .NET Core 2.0 installed.

Memory

CarimasCE requires at least 8 GB of installed memory on the workstation.

Graphics processing unit

A GPU with OpenGL 3.0 support is required.

Display

A display with resolution of 1920*1080 is required. The display must be calibrated such that every pixel is displayed as a perfect square.

WARNING

The colors displayed by the program may appear different depending on the monitor used and the color scale settings applied within the program. For comparison between analysis results, use only numeric outputs of the program.

Environment requirements

Workstation login

CarimasCE should only be used on workstations that are accessed by password protected personal user accounts (such as through AD). This helps prevent unauthorized access and the logged-in username is also stored by CarimasCE to the analysis report.

IT-network safety

CarimasCE should only be used in a safe and protected internal IT-network to prevent unauthorized access and to facilitate safe transfers to and from a PACS, since the connection is not secure.

Tip

If you need to change the configuration of CarimasCE due to a change in the IT-network, please re-install the program.

WARNING

It is the sole responsibility of the organization using CarimasCE to provide an environment that is secure and protected against the unauthorized access of personal patient information.

WARNING

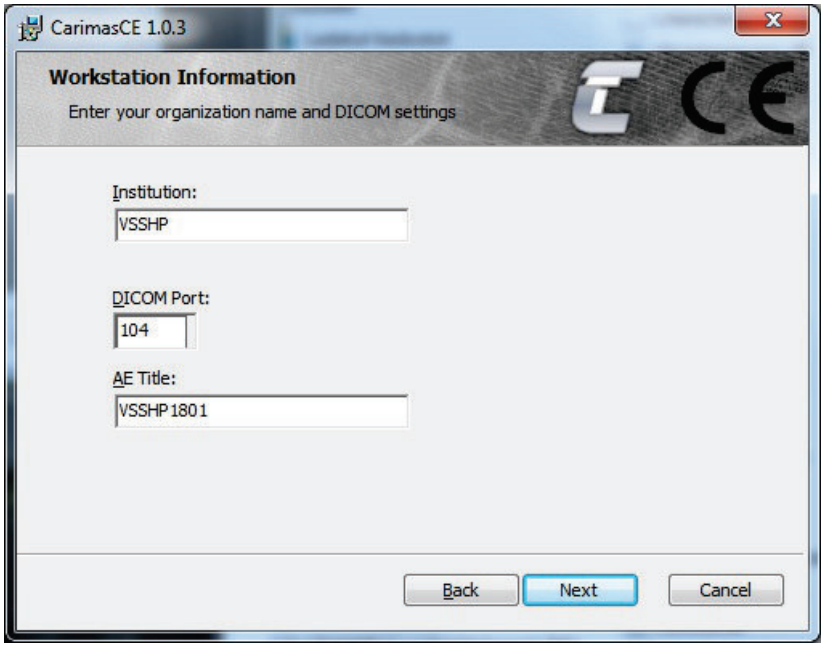
The locally stored data in CarimasCE is not encrypted. If non-anonymized patient data is stored it is recommended that Bitlocker or similar type of technology is used to encrypt the whole hard drive to help prevent non-authorized access.

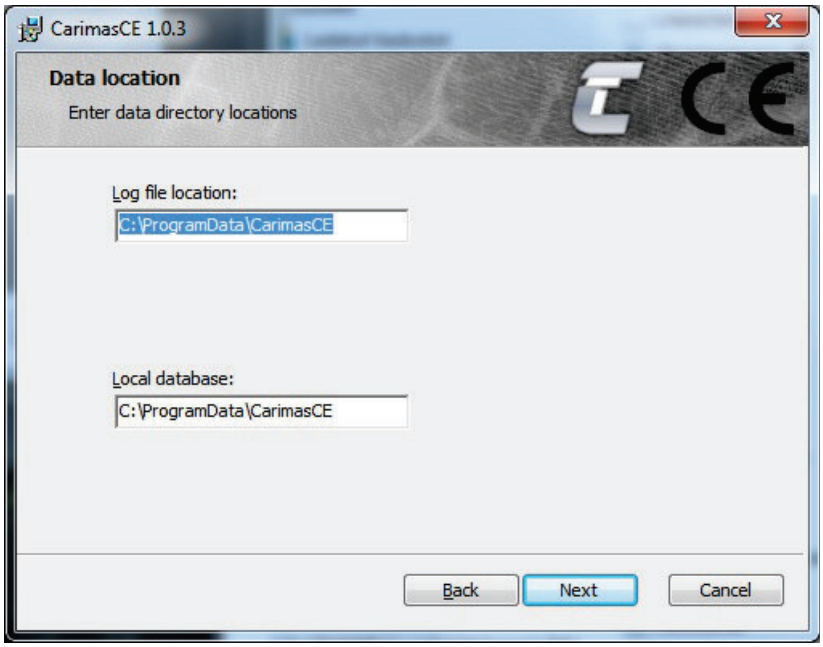
Installing CarimasCE

Running the installer

CarimasCE installation package should include an executable MSI-file, CarimasCEInstaller_<version>.msi. To install CarimasCE to your Windows workstation, double-click on the installer to start the setup process. Running the installer requires Administrator privileges on the workstation.

The installer will ask you to accept the licensing terms of the program, and then enter the information detailed below.





Workstation information

Enter the information for your Institution, and for PACS connections also the local DICOM port and AE Title for the workstation.

Log file location

Enter the location where system, audit and error logs are recorded.

Local database

CarimasCE requires local storage space for PET images analyzed and the analysis result reports. Enter a directory with sufficient storage space. At minimum, one gigabyte of available storage space is recommended.

Enter the full path of the data directory. The default directory is in the ProgramData directory of the workstation.

> **Tip**
>
> You may manage the storage space available to CarimasCE later. Refer to the User's Guide for details.

DICOM settings for CarimasCE

To be able to connect to external DICOM devices, servers and workstations, CarimasCE requires an identifier, or "Application Entity Title". Enter the application entity title used by your workstation, and a port used for incoming connections.

Many DICOM services allow access only for known devices. Contact your system administrator to find out the required AE-title and port settings.

Tip

A well known port for DICOM connections is the port 104. Port 11112 is also commonly used.

WARNING

Make sure that the port and AE title are not used by other programs or devices.

Tip

CarimasCE complies with the DICOM standard. For more information to help determining if your PACS is compatible with CarimasCE, refer to the provided CarimasCE Dicom Conformance statement.

Tip

After installing CarimasCE, it may be validated using the following guide.

9.2 Installation Validation Guide

This guide details the instructions on how to verify that the installed version of CarimasCE is working correctly.

Provided Materials

There should be a zip file provided with the installation media containing the following:

- CarimasCETestPacs.exe
- CarimasCEValidation.png

Validation Procedure

The validation can be done in the following way:

1. Start CarimasCE and configure a PACS connection with the following parameters: AE=CARIMASTEST, address=localhost, port=11112
2. Start 'CarimasCETestPacs.exe'
3. Import the image with Patient Name 'CarimasCE, Validation' from the PACS configured in Step 1
4. Use CarimasCE to analyse the imported image
5. Open the CarimasCEValidation.png image and compare the analysis results to it
6. Export the analysis report.

CarimasCE works properly, if:

- There were no errors when running the program or conducting the analysis
- The image could be imported from the configured PACS
- The analysis report could be exported to the configured PACS
- The resulting Flow parameter values were within 10% of the provided reference values

WARNING

The analysis portion of the validation should be performed by an intended user as defined on the General Information page.

Log Types and Location

CarimasCE keeps three separate logs based on the content logged:

1. Application Log: Program events and communication between different parts of the program.
2. Error Log: Any program errors during use.
3. Audit Log: Important events in which sensitive patient data might have been accessed.

The logs are stored in the folder chosen at program installation.

9.4 Removal Guide

You can remove the CarimasCE program normally from Windows' Add/Remove Programs.

WARNING

This will not remove the Local Data or the Log folders. These need to be deleted by hand and can be located in the folder(s) chosen when the program was installed.

10 References and Publications

Mathematical Model Validation

Iida H, Rhodes CG, de Silva R, Yamamoto Y, Araujo LI, Maseri A, Jones T. Myocardial tissue fraction - correction for partial volume effects and measure of tissue viability. J Nucl Med 1991; 32:2169-2175. PMID: 1941156.

Iida H, Rhodes CG, de Silva R, Araujo LI, Bloomfield P, Lammertsma AA, Jones T. Use of the left ventricular time-activity curve as a noninvasive input function in dynamic oxygen-15-water positron emission tomography. J Nucl Med 1992; 33:1669-1677. PMID: 1517842.

Reproducibility and Performance

Harms, H. J., Nesterov, S. V., Han, C., Danad, I., Leonora, R., Raijmakers, P. G., … Knaapen, P. (2014). Comparison of clinical non-commercial tools for automated quantification of myocardial blood flow using oxygen-15-labelled water PET/CT. European Heart Journal Cardiovascular Imaging, 15(4), 431–441. http://doi.org/10.1093/ehjci/jet177

Nesterov, S. V, Han, C., Mäki, M., Kajander, S., Naum, A. G., Helenius, H., … Knuuti, J. (2009). Myocardial perfusion quantitation with 15O-labelled water PET: high reproducibility of the new cardiac analysis software (Carimas). European Journal of Nuclear Medicine and Molecular Imaging, 36(10), 1594–602. http://doi.org/10.1007/s00259-009-1143-8

Nesterov, S.V., Knuuti, J.M., Myocardial Blood Flow Quantification in PET: Can we Agree on Values? (2016). Proceedings in European Journal of Nuclear Medicine and Molecular Imaging, 43(S1), 1–734. http://doi.org/10.1007/s00259-016-3484-4

AlJaroudi, W. A., & Hage, F. G. (2014). Review of cardiovascular imaging in The Journal of Nuclear Cardiology in 2014: Part 1 of 2: Positron emission tomography, computed tomography, and neuronal imaging. Journal of Nuclear Cardiology. http://doi.org/10.1007/s12350-014-0045-8

Diagnostic Performance

Kajander, S. A., Joutsiniemi, E., Saraste, M., Pietilä, M., Ukkonen, H., Saraste, A., … Knuuti, J. (2011). Clinical value of absolute quantification of myocardial perfusion with 15O-water in coronary artery disease. Circulation: Cardiovascular Imaging, 4(6), 678–684. http://doi.org/10.1161/CIRCIMAGING.110.960732

Joutsiniemi, E., Saraste, A., Pietilä, M., Mäki, M., Kajander, S., Ukkonen, H., … Knuuti, J. (2014). Absolute flow or myocardial flow reserve for the detection of significant coronary artery disease? European Heart Journal Cardiovascular Imaging, 15(6), 659–665. http://doi.org/10.1093/ehjci/jet274

Stuijfzand, W. J., Uusitalo, V., Kero, T., Danad, I., Rijnierse, M. T., Saraste, A., … Knaapen, P. (2014). Relative flow reserve derived from quantitative perfusion imaging may not outperform stress myocardial blood flow for identification of hemodynamically significant coronary artery disease. Circulation: Cardiovascular Imaging, 8(1), 1–10. http://doi.org/10.1161/CIRCIMAGING.114.002400

Kajander, S., Joutsiniemi, E., Saraste, M., Pietilä, M., Ukkonen, H., Saraste, A., … Knuuti, J. (2010). Cardiac positron emission tomography/computed tomography imaging accurately detects anatomically and functionally significant coronary artery disease. Circulation, 122(6), 603–613. http://doi.org/10.1161/CIRCULATIONAHA.109.915009

Hacker, M. (2011). Absolute quantification of myocardial perfusion a method proves its mettle. Circulation: Cardiovascular Imaging, 4(6), 607–609. http://doi.org/10.1161/CIRCIMAGING.111.969550

Danad, I., Raijmakers, P. G., Appelman, Y. E., Harms, H. J., de Haan, S., van den Oever, M. L. P., … Knaapen, P. (2013). Hybrid Imaging Using Quantitative H215O PET and CT-Based Coronary Angiography for the Detection of Coronary Artery Disease. Journal of Nuclear Medicine, 54(1), 55–63. http://doi.org/10.2967/jnumed.112.104687

Thomassen, A., Petersen, H., Diederichsen, A. C. P., Mickley, H., Jensen, L. O., Johansen, A., … Høilund-Carlsen, P. F. (2013). Hybrid CT angiography and quantitative 15O-water PET for assessment of coronary artery disease: Comparison with quantitative coronary angiography. European Journal of Nuclear Medicine and Molecular Imaging, 40(12), 1894–1904. http://doi.org/10.1007/s00259-013-2519-3

Danad, I., Uusitalo, V., Kero, T., Saraste, A., Raijmakers, P. G., Lammertsma, A. A., … Knuuti, J. (2014). Quantitative assessment of myocardial perfusion in the detection of significant coronary artery disease: Cutoff values and diagnostic accuracy of quantitative [15O]H2O PET imaging. Journal of the American College of Cardiology, 64(14), 1464–1475. http://doi.org/10.1016/j.jacc.2014.05.069

Danad I, Raijmakers PG, Driessen RS, Leipsic J, Raju R, Naoum C, Knuuti J, Mäki M, Underwood RS, Min JK, Elmore K, Stuijfzand WJ, van Royen N, Tulevski II, Somsen AG, Huisman MC, van Lingen AA, Heymans MW, van de Ven PM, van Kuijk C, Lammertsma AA, van Rossum AC, Knaapen P. Comparison of Coronary CT Angiography, SPECT, PET, and Hybrid Imaging for Diagnosis of Ischemic Heart Disease Determined by Fractional Flow Reserve. JAMA Cardiol. 2017 Oct 1;2(10):1100-1107. doi: 10.1001/jamacardio.2017.2471.

Driessen RS, Danad I, Stuijfzand WJ, Raijmakers PG, Schumacher SP, van Diemen PA, Leipsic JA, Knuuti J, Underwood SR, van de Ven PM, van Rossum AC, Taylor CA,Knaapen P. Comparison of Coronary Computed Tomography Angiography, Fractional Flow Reserve, and Perfusion Imaging for Ischemia Diagnosis. J Am CollCardiol. 2019 Jan 22;73(2):161-173. doi: 10.1016/j.jacc.2018.10.056.

van Diemen PA, Driessen RS, Kooistra RA, Stuijfzand WJ, Raijmakers PG, Boellaard R, Schumacher SP, Bom MJ, Everaars H, de Winter RW, van de Ven PM, Reiber JH, Min JK, Leipsic JA, Knuuti J, Underwood RS, van Rossum AC, Danad I, Knaapen P. Comparison Between the Performance of Quantitative Flow Ratio and Perfusion Imaging for Diagnosing Myocardial Ischemia. JACC Cardiovasc Imaging. 2020 Sep;13(9):1976-1985. doi: 10.1016/j.jcmg.2020.02.012. Epub 2020 Apr 15.

van Diemen PA, Driessen RS, Stuijfzand WJ, Raijmakers PG, Schumacher SP, Bom MJ, Everaars H, Min JK, Leipsic JA, Knuuti J, Underwood SR, van de Ven PM, van Rossum AC, Danad I, Knaapen P. Data on the impact of scan quality on the diagnostic performance of CCTA, SPECT, and PET for diagnosing myocardialschemia defined by fractional flow reserve on a per vessel level. Data Brief. 2019 Sep 28;27:104584. doi: 10.1016/j.dib.2019.104584.

Thomassen, A., Braad, P. E., Pedersen, K. T., Petersen, H., Johansen, A., Diederichsen, A. C. P., Mickley, H., Jensen, L. O., Knuuti, J., Gerke, O., & Høilund-Carlsen, P. F. (2018). 15-O-water myocardial flow reserve PET and CT angiography by full hybrid PET/CT as a potential alternative to invasive angiography. International Journal of Cardiovascular Imaging, 34(12), 2011–2022. https://doi.org/10.1007/s10554-018-1420-3

Anagnostopoulos CD, Siogkas PK, Liga R, Benetos G, Maaniitty T, Sakellarios AI, Koutagiar I, Karakitsios I, Papafaklis MI, Berti V, Sciagrà R, Scholte AJHA, Michalis LK, Gaemperli O, Kaufmann PA, Pelosi G, Parodi O, Knuuti J, Fotiadis DI, Neglia D. Characterization of functionally significant coronary artery disease by a coronary computed tomography angiography-based index: a comparison with positron emission tomography. Eur Heart J Cardiovasc Imaging. 2019 Aug 1;20(8):897-905. doi: 10.1093/ehjci/jey199. PMID: 30629151.

Kajander, S. A., Joutsiniemi, E., Saraste, M., Pietilä, M., Ukkonen, H., Saraste, A., … Knuuti, J. (2011). Clinical value of absolute quantification of myocardial perfusion with 15O-water in coronary artery disease. Circulation: Cardiovascular Imaging, 4(6), 678–684. http://doi.org/10.1161/CIRCIMAGING.110.960732

Joutsiniemi, E., Saraste, A., Pietilä, M., Mäki, M., Kajander, S., Ukkonen, H., … Knuuti, J. (2014). Absolute flow or myocardial flow reserve for the detection of significant coronary artery disease? European Heart Journal Cardiovascular Imaging, 15(6), 659–665. http://doi.org/10.1093/ehjci/jet274

Schindler, T. H., Schelbert, H. R., Quercioli, A., & Dilsizian, V. (2010). Cardiac PET imaging for the detection and monitoring of coronary artery disease and microvascular health. JACC: Cardiovascular Imaging, 3(6), 623–640. http://doi.org/10.1016/j.jcmg.2010.04.007

Schindler, T. H. (2015). Positron-Emitting Myocardial Blood Flow Tracers and Clinical Potential. Progress in Cardiovascular Diseases, 57(6), 588–606. http://doi.org/10.1016/j.pcad.2015.01.001

Saraste, A., Kajander, S., Han, C., Nesterov, S. V, & Knuuti, J. (2012). PET: Is myocardial flow quantification a clinical reality? Journal of Nuclear Cardiology?: Official Publication of the American Society of Nuclear Cardiology, 19(5), 1044–59. http://doi.org/10.1007/s12350-012-9588-8

Bom MJ, van Diemen PA, Driessen RS, Everaars H, Schumacher SP, Wijmenga JT, Raijmakers PG, van de Ven PM, Lammertsma AA, van Rossum AC, Knuuti J, Danad I, Knaapen P. Prognostic value of [15O]H2O positron emission tomography-derived global and regional myocardial perfusion. Eur Heart J Cardiovasc Imaging. 2020 Jul 1;21(7):777-786. doi: 10.1093/ehjci/jez258. PMID: 31620792.

Maaniitty T, Stenström I, Bax JJ, Uusitalo V, Ukkonen H, Kajander S, Mäki M, Saraste A, Knuuti J. Prognostic Value of Coronary CT Angiography With Selective PET Perfusion Imaging in Coronary Artery Disease. JACC Cardiovasc Imaging. 2017 Nov;10(11):1361-1370. doi: 10.1016/j.jcmg.2016.10.025. Epub 2017 May 17. PMID: 28528146.

Harjulahti E, Maaniitty T, Nammas W, Stenström I, Biancari F, Bax JJ, Knuuti J, Saraste A. Global and segmental absolute stress myocardial blood flow in prediction of cardiac events: [15-O] water positron emission tomography study. Eur J Nucl Med Mol Imaging. 2020 Nov 11. doi: 10.1007/s00259-020-05093-2. Epub ahead of print. PMID: 33174090.

Stenström I, Maaniitty T, Uusitalo V, Ukkonen H, Kajander S, Mäki M, Nammas W, Bax JJ, Knuuti J, Saraste A. Absolute Stress Myocardial Blood Flow After Coronary CT Angiography Guides Referral to Invasive Angiography. JACC Cardiovasc Imaging. 2019 Nov;12(11 Pt 1):2266-2267. doi: 10.1016/j.jcmg.2019.08.002. Epub 2019 Sep 18. PMID: 31542538.

Maaniitty T, Jaakkola S, Saraste A, Knuuti J. Hybrid coronary computed tomography angiography and positron emission tomography myocardial perfusion imaging in evaluation of recurrent symptoms after coronary artery bypass grafting. Eur Heart J Cardiovasc Imaging. 2019 Nov 1;20(11):1298-1304. doi: 10.1093/ehjci/jey160. PMID: 30388202.