suiteHEART® Software

cMRI Analysis Software

Instructions for Use

NeoSoft, LLC

NS-03-008-0001 Rev. 11

Revision History

Document Revision	Date of Issue	Description
1	27-August-2014	Initial release
2	18-September-2014	Minor updates
3	19-November-2014	Add Medical device directive
4	7-May-2015	Updated to release suiteHEART® Software 3.X
5	20-May-2015	Changed arrow key descriptions.
6	16-June-2015	Update screens.
7	28-July-2015	Update screens.
8	24-August-2015	Minor updates
9	25-September-2015	Minor updates
10	2-February-2016	Updated to release suiteHEART® Software 3.0.1
11	1-September-2016	Updated to release suiteHEART® Software 4.0

Manufacturer

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Medical device directive

This product conforms with the requirements of council directive 93/42/EEC concerning medical devices when it bears the following CE mark of Conformity:

CE
0086

European Representatives:

EC REP

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

CAUTION: ***United States federal law restricts this device to sale by, or on the order of, a physician.***

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Installation

Prerequisites

Prior to installation of the software, one set of the following prerequisites must be met:

Table 1: System Requirements

Minimum System Requirements (Non-4D Flow Systems)	Minimum System Requirements (4D Flow Systems)
Supported Operating Systems: • Windows 7 Professional or Enterprise with SP1 (64 bit version) • Windows 8.1 Professional or Enterprise (64 bit version) • Windows 10 Professional or Enterprise (64 bit version)	Supported Operating Systems: • Windows 7 Professional or Enterprise with SP1 (64 bit version) • Windows 8.1 Professional or Enterprise (64 bit version) • Windows 10 Professional or Enterprise (64 bit version)
Video card shall support 1920 x 1080 resolution or higher	Video card; 4GB RAM, minimum of 1664 CUDA Cores, support for OpenGL 4.0, support 1920 x 1080 resolution or higher
Monitor shall support 1920 x 1080 resolution or higher	Monitor shall support 1920 x 1080 resolution or higher
Anti-Virus software installed	Anti-Virus software installed
Minimum 8GB memory	Minimum 16GB memory
Available hard drive space minimum 5GB	Available hard drive space minimum 25GB
PDF viewer, Adobe Reader 11.0 or higher	PDF viewer, Adobe Reader 11.0 or higher
An open network port for DICOM transfer over network	An open network port for DICOM transfer over network
Static IP address (recommended)	Static IP address (recommended)
Java Runtime Environment (JRE) version 8 (update 60 or later)	Java Runtime Environment (JRE) version 8 (update 60 or later)
Solid-State hard drive	Solid-State hard drive
Intel® Core™ i7 processor	Intel® Core™ i7 processor
27" Monitor	27" Monitor

NOTE: suiteHEART® Software is not supported in Virtual Machine environments.

NOTE: suiteHEART® Software does not support scaling/zoom levels greater than 125%.

Installation

1. Double-click on the suiteHEART® Software windows application installer.

   NOTE: Installing the software on a machine could result in a Open File - Security Warning indicating that the publisher could not be verified. Click Yes when asked if you are sure you want to run the software.
2. Select the appropriate language for your installation and click **OK**.
3. In the "Welcome to suiteHEART® Software Setup Wizard window, click **Next**.
4. On the License Agreement Window, select "I accept the agreement" and click **Next**.
5. Browse to the directory in which to install the software or use the default directory (recommended). Click **Next**.
6. Click **Next** on the Ready to Install screen.
   A progress bar will display.
7. Click **Finish** to complete the installation.

Application Inactivity Setting

The suiteHEART® Software application will automatically close, save all analysis for the study and remove the associated lock file when the application has been inactive for 60 minutes. To change this setting do the following:

Navigate to the C:\Program Files\NeoSoft, LLC\suiteHEART\resources\properties\product.properties file and change the values of SHIDLE_TIMER to the desired time out. Note that the time is in seconds.

Licensing Schemes

suiteHEART® Software has 3 different licensing schemes. They are Evaluation, Unlimited and Per-Case Pack Limited.

1. Evaluation: This is a time limited license which does not allow the saving of analysis results or exam approval. Evaluation Version will be indicated on the report footer and splash screens. If the approval of an exam is attempted a message will appear stating: Evaluation version: Analysis state will not be saved.
2. Unlimited: No restrictions on analysis and is not case-limited.
3. Per-Case Pack Limited: The software will use the unique study instance id to identify the number of cases analyzed against the Per-Case Pack that has been purchased.

Once 100% of the Per-Case Pack has been used the software will indicate this condition by a pop-message prior to starting a new exam or an existing exam.

Per-Case Packs can be purchased in increments of 25, 50 and 100. Website: http://neosoftllc.com/ T: (262)522-6120 email: orders@neosoftmedical.com

Exams that have been counted once towards the Per-Case Pack limit can be re-opened and reviewed within the software and will not be counted against the Per-Case Pack limit.

Exams that are opened only for image viewing or if image manipulation tools are performed (Pan, Zoom, Window level, Rotate) will not be counted against the Per-Case Pack limit.

An exam is considered "consumed" or "counted" against the Per-Case Pack limit when any of the following actions are performed:

a.) Starting of any analysis mode by placing any ROI on an image.
b.) Creating a custom series.

c.) Report sign off.
d.) Export Cine DICOM.
e.) Export Report.
f.) DICOM Import.
g.) Switching function analysis types.

suiteHEART® Software has an expected useful service life of 7 years from its original release date.

Remote Connectivity

Remote connectivity allows suiteHEART®Software users remote access from computers not loaded with suiteHEART® Software. The remote user will have the ability to access the suiteHEART® Software system and have full functionality.

suiteHEART® remote connectivity needs to be installed/configured/supported by your Information Technology personnel.

Remote connectivity has been verified using the following platforms:

- TeamViewer (version 11)
- Citrix GoToMyPC (version 8.4)
- Windows Remote Desktop (Microsoft Windows 7/8/10 Professional/Enterprise)

NOTE: When using Windows Remote Desktop, screen resolution on the remote computer must be set to 1920x1080 or higher video display resolution.

The performance of the suiteHEART® Software via the remote connection cannot be guaranteed. Performance is dependent upon factors that are outside the scope of the suiteHEART® Software application. These factors include:

- Remote computer performance
- Internet download/upload speeds (Mbps)
- Network bandwidth speed (wired ethernet or wireless connection)

For more information on remote connectivity, refer to the suiteHEART® Software Addendum to Instructions for Use manual, NS-03-015-0006.

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Safety

Introduction

To assure efficient and safe use it is essential to read this safety section and all associated topics before attempting to use the software. It is important for you to read and understand the contents of this manual before attempting to use this product. You should periodically review the procedures and safety precautions.

The software is intended for use by trained and qualified personnel only.


CAUTION: Federal Law restricts this device to sale, distribution and use by or on the order of a physician.


CAUTION: This device is limited by Federal Law to investigational use for indications not in the Indications Statement.

The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level of seriousness. Hazard is defined as a source of potential injury to a person. Familiarize yourself with the terminology descriptions listed in the following table:

Table 1: Safety Terminology

Graphic	Definition
 DANGER:	Danger is used to identify conditions or actions for which a specific hazard is known to exist which will cause severe personal injury, death, or substantial property damage if the instructions are ignored.
 WARNING:	Warning is used to identify conditions or actions for which a specific hazard is known to exist which may cause severe personal injury, death, or substantial property damage if the instructions are ignored.
 CAUTION:	Caution is used to identify conditions or actions for which a potential hazard is known to exist that will or can cause minor personal injury or property damage if the instructions are ignored.

Indications for Use

suiteHEART® Software is an analytical software tool, which provides reproducible tools for the review and reporting of medical images. suiteHEART® Software can import medical images from a MR system and display them in a viewing area on the computer screen. The viewing area allows access to multiple studies and series of multi-slice, multi-phase images. Multi-phase sequences of images can be displayed in cine mode to facilitate visualization.

CAUTION: Data stored as a DICOM image that has been imported by an external PACS may not be compatible viewing for suiteHEART® Software.

A report input interface is also available. Measurement tools on the report interface make it possible to quickly and reliably fill out a complete clinical report of an imaging exam. Available tools include: point, distance, area, and volume measurement tools such as ejection fraction, cardiac output, end-diastolic volume, end-systolic volume, and volume flow measurements.

Semi-automatic tools are available for left ventricular contour detection, valve plane detection, vessel contour detection for flow analysis, signal intensity analysis for myocardium and infarct sizing measurement, and T2 star analysis.

The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians.

When interpreted by a trained physician these tools may be useful in supporting the determination of a diagnosis.

Intended Use

suiteHEART® Software is intended to assist trained clinical personnel in the qualification and quantification of cardiac function. The software provides the tools to adjust the parameters of the DICOM images and provides presentation states where the user can appreciate various MRI acquired images of the heart and vasculature over time. Additionally, the software provides tools for measuring linear distances, areas, and volumes that can be used to quantify cardiac function. Finally, the software provides the tools for volumetric flow measurements and the ability to calculate flow values.

Supported DICOM Image Formats

suiteHEART® Software supports the following DICOM format; MR and Enhanced MR. Refer to the suiteHEART® Software DICOM Conformance Statement manual for further detail on supported formats.

Safety Notices

WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

WARNING: Artifacts on an image can be misinterpreted, leading to misdiagnosis. Do not use images containing artifacts for diagnosis. Analysis should only be accomplished by a properly trained and qualified user.

WARNING: Diagnosis for the wrong patient could occur if images do not contain patient name or ID. Do not use images that do not contain patient name and ID for diagnosis. Visually confirm the patient information prior to analysis.

CAUTION: Using images upon which an image filter has been applied could result in altered results. The user must exercise discretion before analyzing pixel intensity corrected images. The software will display a warning message if loading images that have been filtered.

Equipment Hazards

CAUTION: Using equipment that is damaged or has been compromised can put the patient at risk by delaying diagnosis. Make sure that equipment is in proper working order.

CAUTION: Applications may run on equipment that includes one or more hard disk drives, which may hold medical data related to patients. In some countries, such equipment may be subject to regulations concerning the processing of personal data and free circulation of such data. Release of personal data may result in legal action depending on the applicable regulatory body. It is strongly recommended that access to patient files be protected. The user is responsible for understanding the laws regulating patient information.

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Getting Started

Launching and Exiting the Application

suiteHEART® Software is an application that can be used for analysis, review, and reporting of Cardiac MRI (Magnetic Resonance Imaging) studies. This manual provides a detailed explanation of the suiteHEART® Software user interface and the workflow for performing quantitative analysis on cardiac MR images.

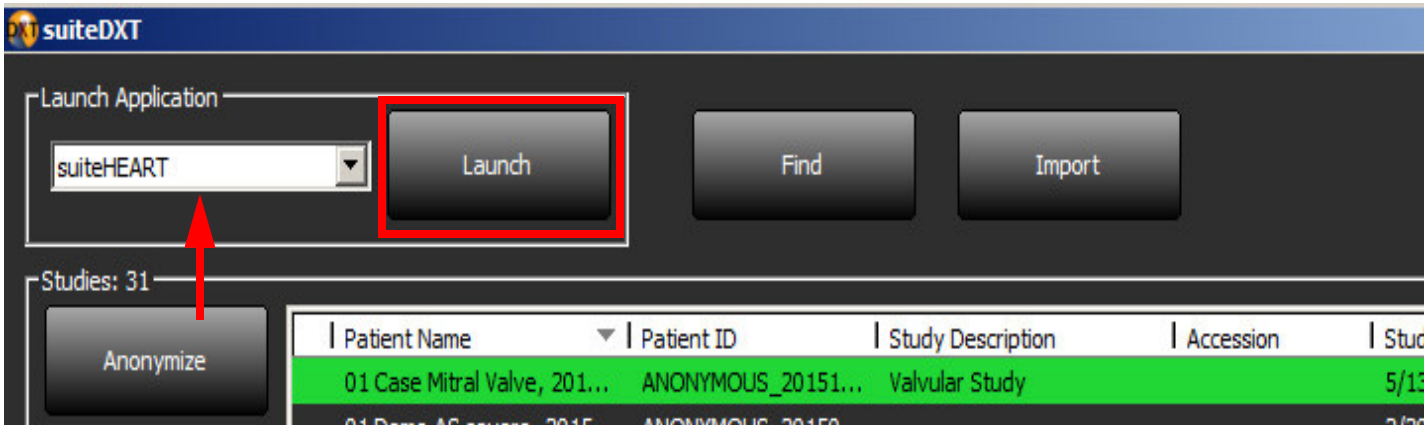
Launching suiteHEART® Software

1. Launch suiteDXT via the desktop shortcut.

   NOTE: Both suiteDXT and suiteHEART® Software applications must remain running (simultaneously) to facilitate the necessary file transfer(s) between the applications.

2. On the Main Screen go to the Launch Application drop-down menu and select suiteHEART® Software.

FIGURE 1. Launch Application



3. Select a study from the study list and do one of the following:
   - Select the Launch button.
   - Right mouse click and select “Launch using <selected application>.”
   - Double click on the study.

4. Exams containing images with pixel intensity filters applied will be listed in a message box prior to opening the exam.

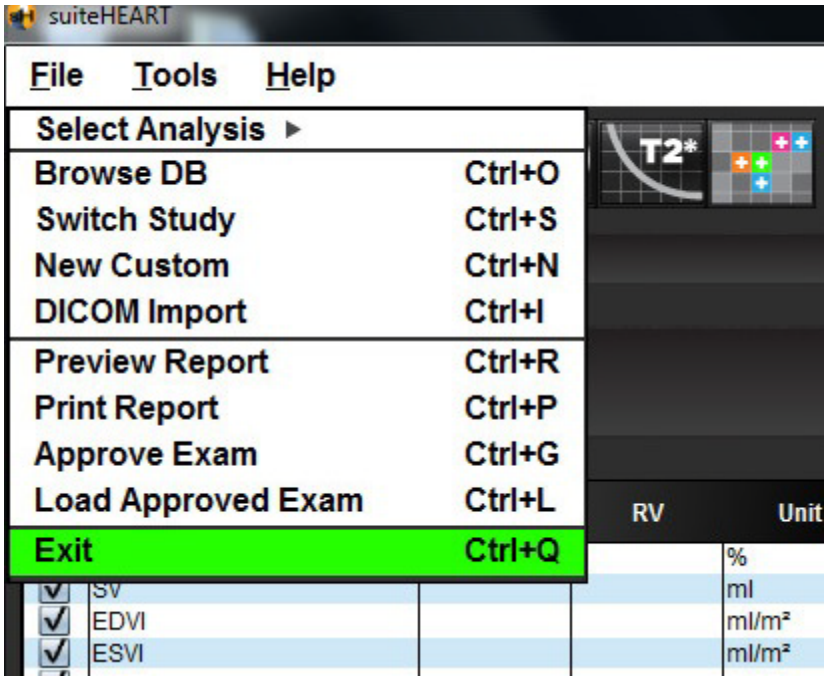
   NOTE: The screen resolution must be set to 1920x1080 or higher, otherwise the software will not launch.

WARNING: Using images with pixel intensity filters applied for analysis may cause inaccurate results.

Exiting suiteHEART® Software

To exit the application select **File > Exit**.

FIGURE 2. Close suiteHEART® Software



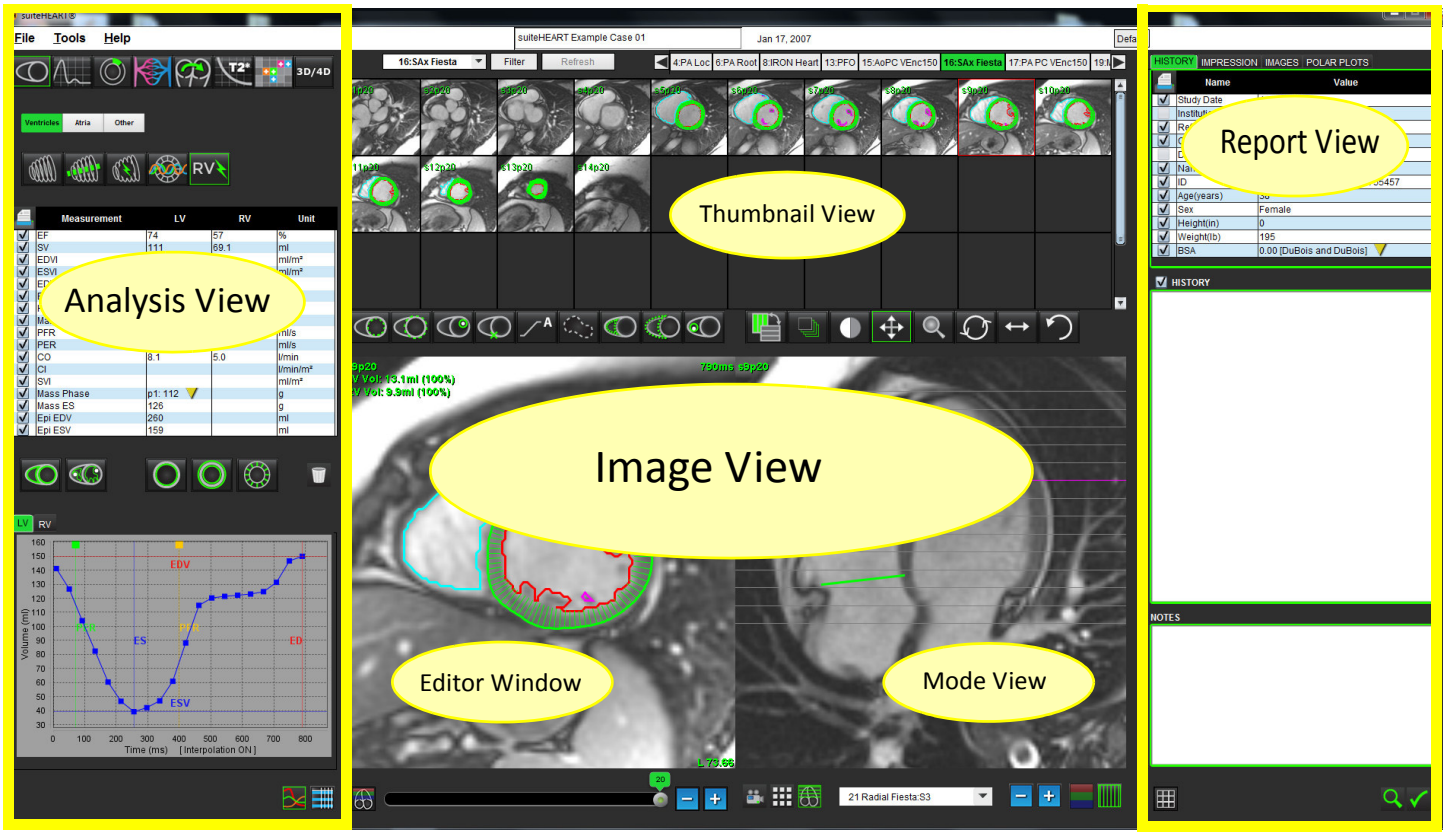
User Interface Overview

Overview

The suiteHEART® Software interface has three main panels as shown in Figure 1.

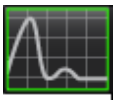
- Analysis View: Provides analysis tools for each analysis mode.
- Image View: Provides quick access for image analysis and review functions.
  - Comprised of thumbnail views, editor window, and mode view.
- Report View: Provides the tools used for structured reporting.

FIGURE 1. Three Main Panels: Analysis View, Image View, Report View



Analysis Modes

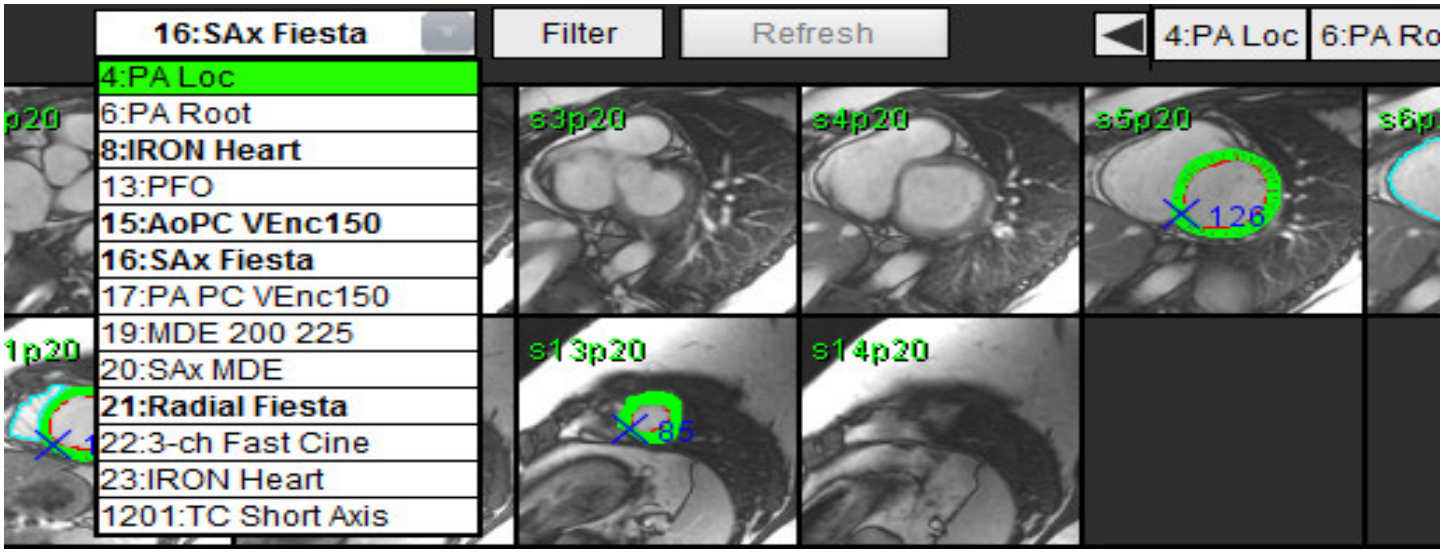
Table 1: Mode Buttons

							
Function Analysis	Flow Analysis	Myocardial Evaluation	Time Course Analysis	Patent Foramen Ovale Analysis	T2 Star Analysis	Custom Series	3D/4D Viewer

Series Navigation

To view images or change series within the selected study use the left and right arrow buttons at the top of the Image View. The series file pull-down menu, located to the left of the Filter button, can also be used to select the series. Series which have analysis or regions of interest present will be identified in bold text, as shown in Figure 2.

FIGURE 2. Series Navigation



Editor Window and Mode View

Performing a right mouse click on an image in the Image View will activate image manipulation tools.

Table 2: Image Manipulation Tools

	Window/Level Pan Zoom Rotate Flip Send to Report Scan Parameters Reset

File Menu Options

Select Analysis – Selects the analysis mode (Function, Flow, ME, Time Course, PFO, T2Star, T1 Mapping* Custom Series and 3D/4D)
BrowseDB – Opens local database
Switch Study – Lists available studies for quick access
New Custom – Creates a new custom series for viewing only
DICOM Import – Creates a new series for functional, myocardial evaluation and Time Course analysis
Preview Report – Preview of the formatted report
Print Report – Prints the report
Approve Exam – Approves and locks a final report with a signature
Load Approved Exam – Restores a previously opened report
Exit – Closes the application while saving current analysis results to a secondary capture (SCPT) series.

*T1 Mapping Analysis is an Investigational Device: Claims have not been evaluated by the FDA. Use pursuant to company instruction and research agreement. NeoSoft proprietary and confidential.

Tools Menu Options

Toggle Annotation – Toggles the display of the ROI annotation
Create Annotation >
- **Linear** – Provides measurement of a straight line distance
- **Crosshair** – Provides sampling of single pixel data
- **Region of Interest** – Provides area measurements
- **Label** – Provides image annotation

Preferences >
- **Edit Preferences** – Opens the preferences editor to set software and template preferences
- **Import Preferences** – Restores user preferences and macros
- **Export Preferences** – Exports all user preferences

Report Database
Export >
- **Export Report** – Generates a report based on current analysis and saves it as a secondary capture (SCPT) series.

Export Report to Excel – Generates Excel spreadsheet with analysis results.
Export Cine DICOM – Saves a DICOM cine of the currently selected series as a SCPT file.
Export Cine Files – Exports currently selected series images to any of the selected file formats. Available formats are: compressed QuickTime movie, JPEG, TIFF, PNG or uncompressed AVI movie.

Help Menu Options

Instructions for Use – suiteHEART® Software Instructions for Use
DICOM Conformance Statement – suiteHEART® Software DICOM Conformance Statement
About suiteHEART® – Version information about the application

Image View Controls

The Phase Slider Bar 

controls the cine phase selection.

The Image Step Icons 

allow for slice-to-slice navigation when the thumbnail view is in slice or phases.


Slice Classification: This button is only applicable for left ventricular Regional Analysis and Quantitative Myocardial Evaluation Analysis modes. Slice classification is only relevant to short axis images where quantitative polar plots are generated.

On your keyboard, the Left and Right Arrow Keys control navigation between slices and the Up and Down Arrow Keys control navigation between phases.

Mode Views

The mode view has three available formats:

Cine Mode

 - Cine: Controls the viewing of a cine image in a movie mode.

- Cine Mode Bar: Defines the start and end frame of the cine movie.

- Frames Per Second (FPS): Click on the arrow or enter a value in the text box to change the cine speed


- Play Icon: Located next to the cine mode bar

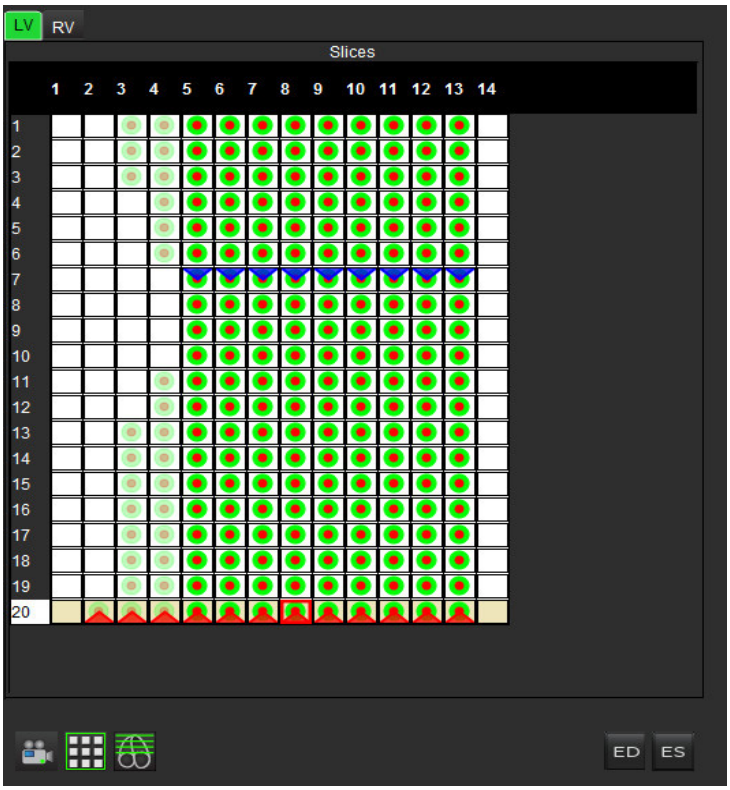

- Pause Icon: Located next to the cine mode bar

Matrix Mode


Matrix Mode Icon: Displays a grid of the images in slices/phases

The images selected for analysis are highlighted and the endocardial and epicardial contours are noted. Matrix mode may be used for phase navigation. The ED and ES buttons may be used to select the phases accordingly on the matrix. Matrix mode can also be used for slice selection. Clicking on a matrix entry results in the slice being loaded in the Image Editor.

FIGURE 3. Matrix Mode



Matrix Mode is used to assign the end-systolic and end-diastolic phases. This should be used when the heart rate changes during acquisition to allow an accurate measurement of end-systolic and end-diastolic volumes. Select the ES button and click on the cells in the matrix mode to set the specified slice / phase to end-systolic. Select the ED button and click on the cells in the matrix mode to set the specified slice / phase to end-diastolic. The volumes are re-calculated automatically as the end-systolic and end-diastolic image are selected.

Cross Reference Mode

Cross Reference mode displays the long axis view of an image when the short axis view is currently displayed in the image editor window. The long axis view is an orthogonal slice within an angle of 45 degrees and 95 degrees of the displayed image in the editor window. A drop-down menu of all the orthogonal slices available is provided, along with a button to toggle the display of the cross reference slice indicators. Use the minus and plus to navigate between slice locations.

FIGURE 4. Cross Reference Controls

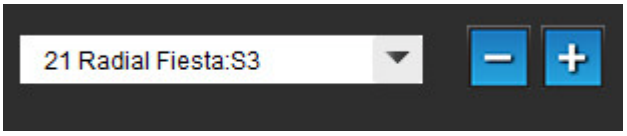


FIGURE 5. Cross Reference Mode Icon

Image Manipulation Tools

Table 3: Icons and Names

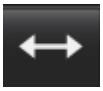
	Slice/Phase Review Toggle
	Window/Level – Select and use middle mouse button to make adjustment
	Pan – Select and use middle mouse button to make adjustment
	Zoom – Select and use middle mouse button to make adjustment
	Rotate – Select and use middle mouse button to make adjustment
	Flip Horizontal – Flips the image horizontally

Table 3: Icons and Names

	Scope All – Applies image manipulation to all slices
	Scope Current to End – Applies image manipulations from the current slice to the end slice
	Scope Current Only – Applies image manipulation to the current slice only
	Viewport Layout - Change viewer layout
	Compare Mode - Change to compare mode
	Review Mode - Change to review mode
	Show Cross Reference lines - Toggles cross reference lines on/off
	Colormap Overlay - Toggles slice classification colormap on/off
	Reset – Resets the W/L, Pan, Zoom and Rotate back to default, based on the scope setting
	Region of Interest – Provides area measurements
	Crosshair – Provides sampling of single pixel data
	Linear – Provides measurement of a straight line distance
	Label – Provides the addition of user annotation in the Editor window
	Refresh – Click button to update the Image View with newly networked images
	Filter – Sorts series by pulse sequence type according to analysis mode. Can be deselected by selecting ALL. Filters can be set under Preferences. The filter button will be green if a filter is in use.

Quick Keys

Table 4: Quick Keys

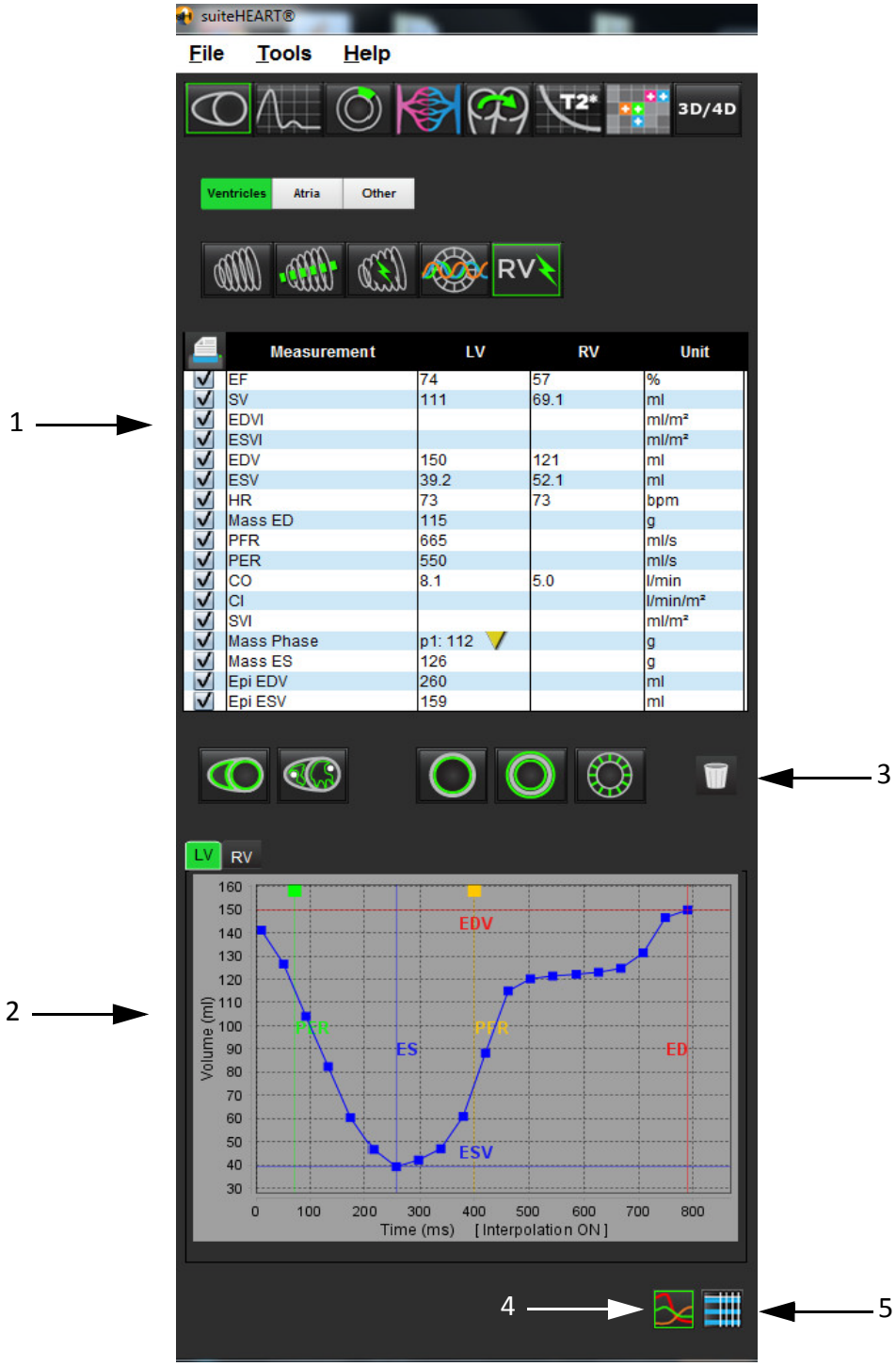
Function	Action
Image Zoom	Ctrl + Middle Mouse Button
Rotate Image	Ctrl + Shift + Middle Mouse Button
Image Pan	Shift + Middle Mouse Button
Window / Level	Middle Mouse Button
Toggle Annotation	Ctrl-T
Quit Application or Exit	Ctrl-Q
New Custom	Ctrl-N
Open Browse DB	Ctrl-O
Open Preview Report	Ctrl-R
Print Report	Ctrl-P
DICOM Import	Ctrl-I
Approve Exam	Ctrl-G
Load Approved Exam	Ctrl-L
Edit Preferences	Ctrl-E
Report Database	Ctrl-D
Switch Study	Ctrl-S
Function	Ctrl-1
Flow	Ctrl-2
Myocardial Evaluation	Ctrl-3
Time Course	Ctrl-4
PFO	Ctrl-5
T2 Star	Ctrl-6
T1 Mapping*	Ctrl-7
Custom Series	Ctrl-8
3D/4D	Ctrl-9
Navigate between Slices	Left & Right Arrow Keys
Navigate between Phases	Up & Down Arrow Keys
[	Reduce Nudge Tool Size
]	Increase Nudge Tool Size

*T1 Mapping Analysis is an Investigational Device: Claims have not been evaluated by the FDA. Use pursuant to company instruction and research agreement. NeoSoft proprietary and confidential.

Analysis View

The Analysis View is available for each analysis mode.

FIGURE 6. Analysis View Features

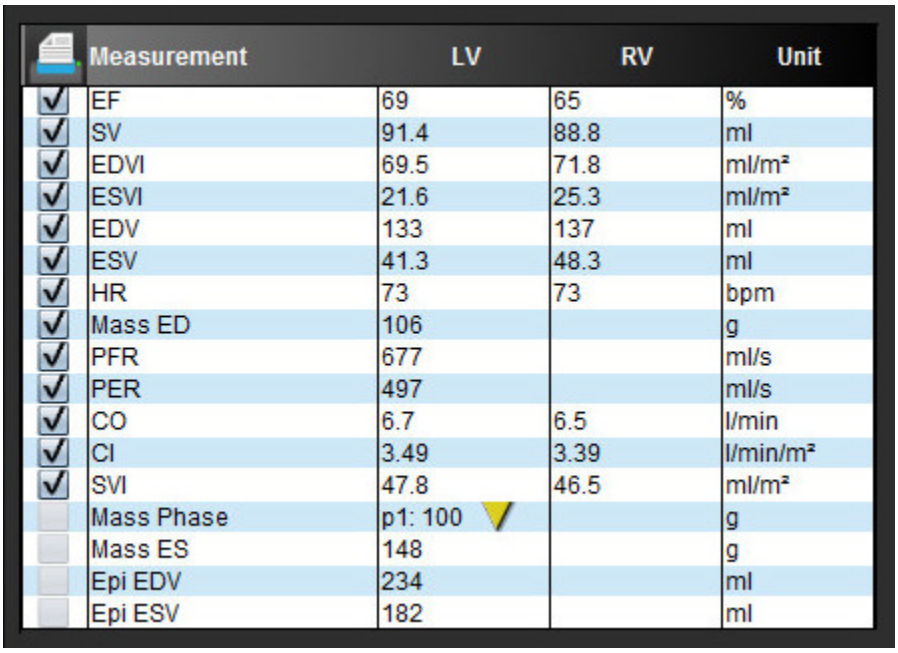


1. Measurement table, 2. Curve results, 3. Trashcan icon, 4. Graph icon, 5. Table icon

Analysis View Review

Measurement Table

FIGURE 7. Results Parameters: Select or deselect from inclusion on the report by clicking the box next to the parameter



Measurement	LV	RV	Unit
☑ EF	69	65	%
☑ SV	91.4	88.8	ml
☑ EDVI	69.5	71.8	ml/m²
☑ ESVI	21.6	25.3	ml/m²
☑ EDV	133	137	ml
☑ ESV	41.3	48.3	ml
☑ HR	73	73	bpm
☑ Mass ED	106		g
☑ PFR	677		ml/s
☑ PER	497		ml/s
☑ CO	6.7	6.5	l/min
☑ CI	3.49	3.39	l/min/m²
☑ SVI	47.8	46.5	ml/m²
☐ Mass Phase	p1: 100		g
☐ Mass ES	148		g
☐ Epi EDV	234		ml
☐ Epi ESV	182		ml

 - Trashcan Icon: Resets measurements performed by the Analysis View

Curve Results

Curve results can be displayed as a graph or in tabular format by clicking the desired icon located in the lower right hand corner of the Analysis View.

FIGURE 8. Graph (left) and Table (right) Icons: Displays curve results

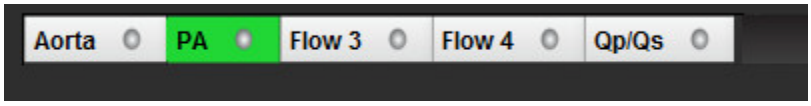

Table 5: Analysis Tools

 Left Ventricular Endocardial ROI
 Left Ventricular Epicardial ROI
 Right Ventricular Endocardial ROI
 Right Ventricular Epicardial ROI
 Left Ventricular Basal Line
 Right Ventricular Basal Line
 Right Ventricular Insertion Point
 Left Ventricular Papillary Muscle ROI
 Right Ventricular Papillary Muscle ROI
 Left Atrial ROI
 Right Atrial ROI
 Long Axis LV Endocardial ROI
 Long Axis LV Epicardial ROI
 Left Ventricular Septal ROI

Edit Tab Labels

Labels on tabs are editable if a dot resides on the tab beside the label.

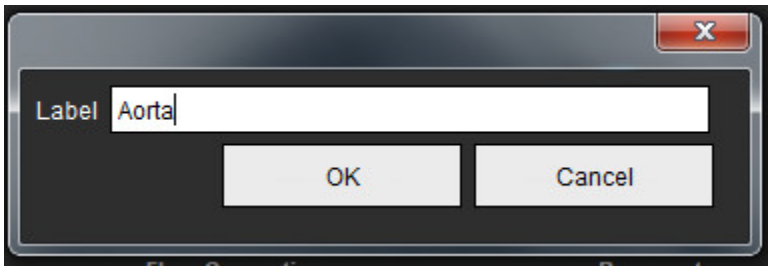
FIGURE 9. Flow Analysis Tabs Example



Edit Tab Procedure:

1. Select the dot on the tab.
2. Enter the new label name.

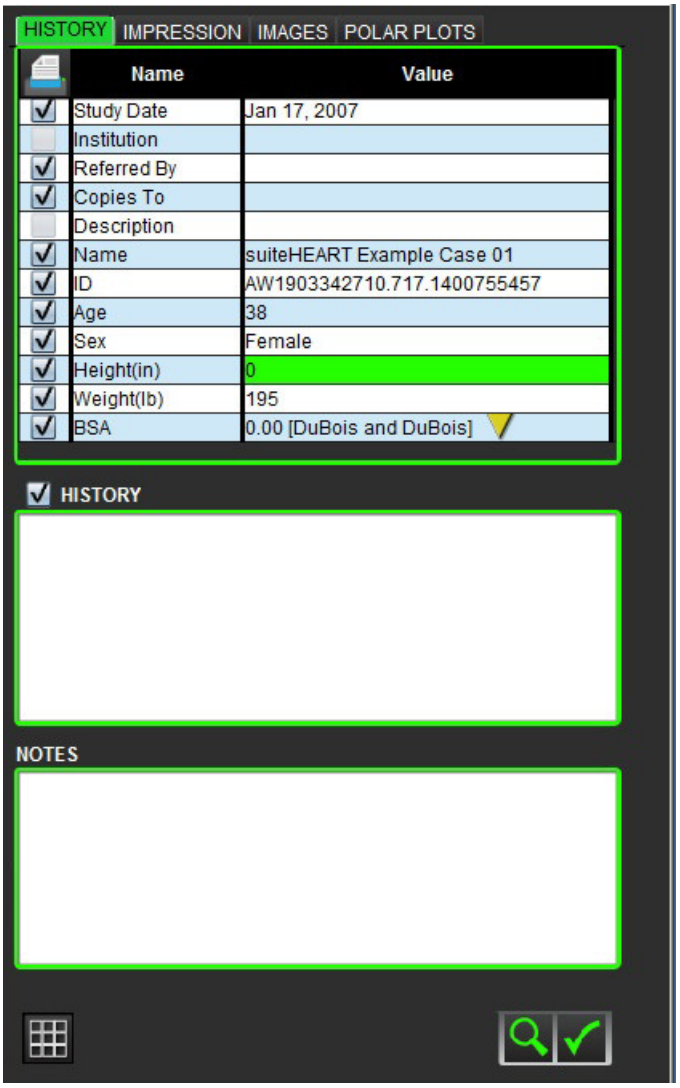
FIGURE 10. Edit Tab Label Pop-up Window



Report View

suiteHEART® Software has four report views for structured reporting. Refer to Structured Reporting on page 123 for more information.

FIGURE 11. Reporting Tabs



 - Preview Report: Used for previewing a report

 - Toggles between the review and analysis screens

 - Approve Exam: Used for report signature

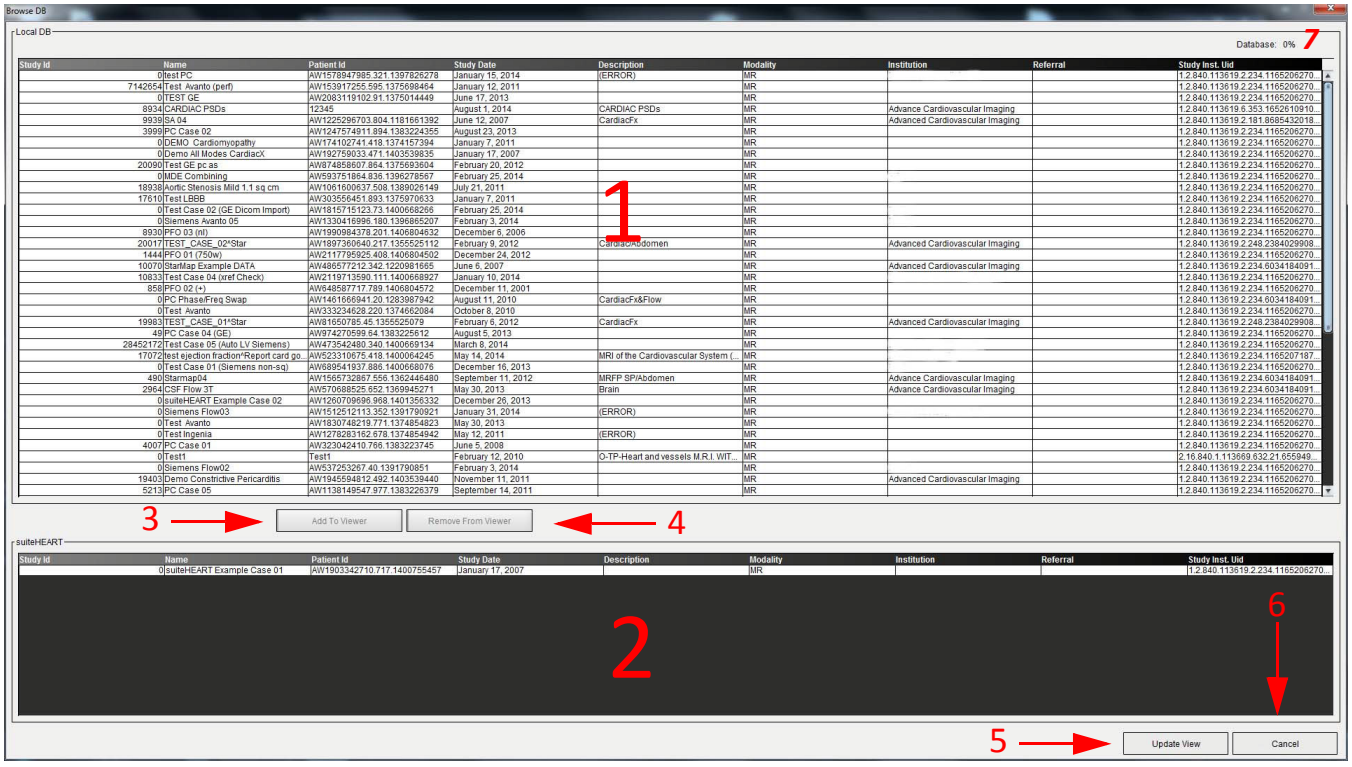
 - Toggles between the analysis and review screens

NOTE: ROI editing can be performed on the review screen.

Browse DB

The Browse DB window provides a view of the current contents of the local database. It features a view of exams in the local database and the controls that allow you to choose which exams to view or add to the switch study listing.

FIGURE 12. Browse DB Window



1. Local database listing, 2. suiteHEART® Software database viewer, 3. Add to Viewer button, 4. Remove from Viewer button, 5. Update View button, 6. Cancel button, 7. Database

Features of the Browse DB

The Browse DB always defaults to the local database.

1. **Local database listing** – displays the exams that are stored in the local database.
2. **suiteHEART® Software database viewer** – displays exams that are in the current suiteHEART® Software database.
3. **Add to Viewer** – Adds the selected exam from local database (shown in the top portion of the window) to the suiteHEART® Software database viewing area.
4. **Remove from Viewer** – Removes the exam from suiteHEART® Software database viewing area.
5. **Update View** – Closes the Browse Database window and bring the exams in the viewable listing area to the application viewer. Used to populate the switch studies window.
6. **Cancel** – Closes Browse Database window with no changes to the list.
7. **Database** – Displays available disk space on the Database directory.

Browse DB Procedure

Exams can be viewed by selecting them from the local database, adding them to the suiteHEART® Software database Viewer list and clicking **Update View**.

Add Exams to the suiteHEART® Software Switch Study List

1. Click **File** > **Browse DB**.
2. Locate the exam in the database viewer and click on the exam to highlight it.
3. Click **Add to Viewer**.
4. Click **Update View**.
5. The exam now appears in the suiteHEART® Software Switch Study List.

Remove Exams from the suiteHEART® Software Switch Study List

1. Click **File** > **Browse DB**.
2. Locate the exam and then click **Remove from Viewer**.
3. Click **Update Viewer**.

CAUTION: Do not delete the study currently opened in the suiteHEART® Software.

Exams must be loaded into suiteHEART® Software before they can be shown in the Viewer. See “Browse DB Procedure” to learn how to populate the Switch Study List.

Switch Studies within suiteHEART® Software

1. Click **File** > **Switch Study**.

   The Available Studies window is displayed with a list of all the exams that were previously loaded by the Browse DB procedure.

2. Select the exam.

   If you choose not to switch studies after opening the Switch Studies window, click anywhere outside of the window to return to the application.

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Defining Preferences

Selecting **Preferences** from the Tools menu on the suiteHEART® Software Interface menu bar displays three options:

- Edit Preferences
- Import Preferences
- Export Preferences

IMPORTANT: It is advisable to set up user preferences prior to analyzing the first case to be reported. Changes made to preferences do not take effect until a new exam is started.

Setting Preferences

The Edit Preferences feature allows for the customization of reporting features. The global settings include:

- Report Preferences
- Authorized Report Approvers
- Series Filter
- Miscellaneous
- Auto-save Preferences
- Export Preferences

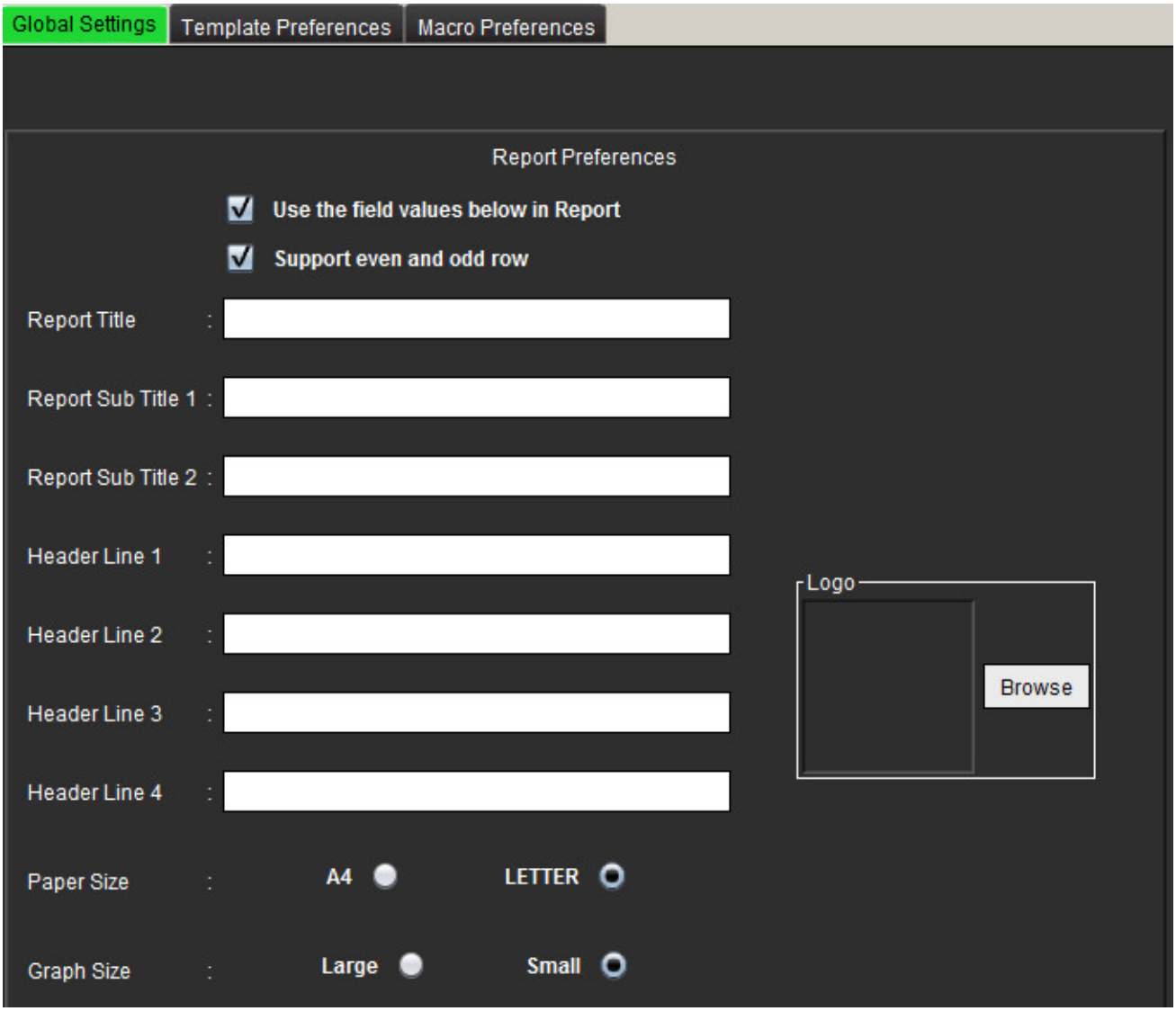
User defined result parameter ranges can be created under the Template Preference tab. Macros for structured reporting can be created under the Macro Preferences tab.

Global Settings

Report Preferences

Configures header information that appears on all reports.

FIGURE 1. Report Layout Tab



Report Preferences Procedure

1. From the Image View menu bar, select **Tools > Preferences > Edit Preferences**.
2. Select the **Global Settings** tab.
3. Place the cursor in the desired field of the **Report Preferences** panel and enter information.

   The titles, headers, and logo will appear on a report with the specified paper size. To omit this information from the report deselect the "Use the field values below in Report" checkbox. This will take effect for all patient reports that are printed.

   Checking “support even and odd row” will highlight the result rows on the report.
4. To insert a site logo into the report, prepare the file in a jpeg, png, or gif format and save to hard drive or CD-ROM. Select **Browse** under the Logo section and locate the file from the system browser window. Select the proper logo file and select **Open**.

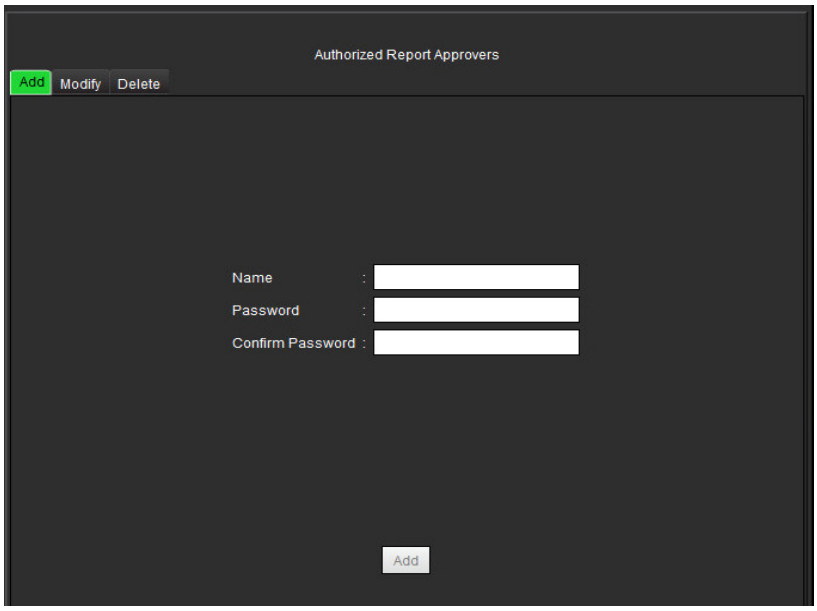
   The logo should now appear on the report preferences panel.

5. Select **Save and Exit** to store your entries and close Edit Preferences.
    - Select **Cancel** to exit the window without accepting any changes.
    - Select **Reset** to reset all values on the Global Settings tab without exiting the window.

Authorized Report Approvers

The application has a report approval feature that locks the final report. Once locked, the report cannot be modified. The credentials of the approvers are added, modified and deleted as described.

FIGURE 2. Authorized Report Approvers



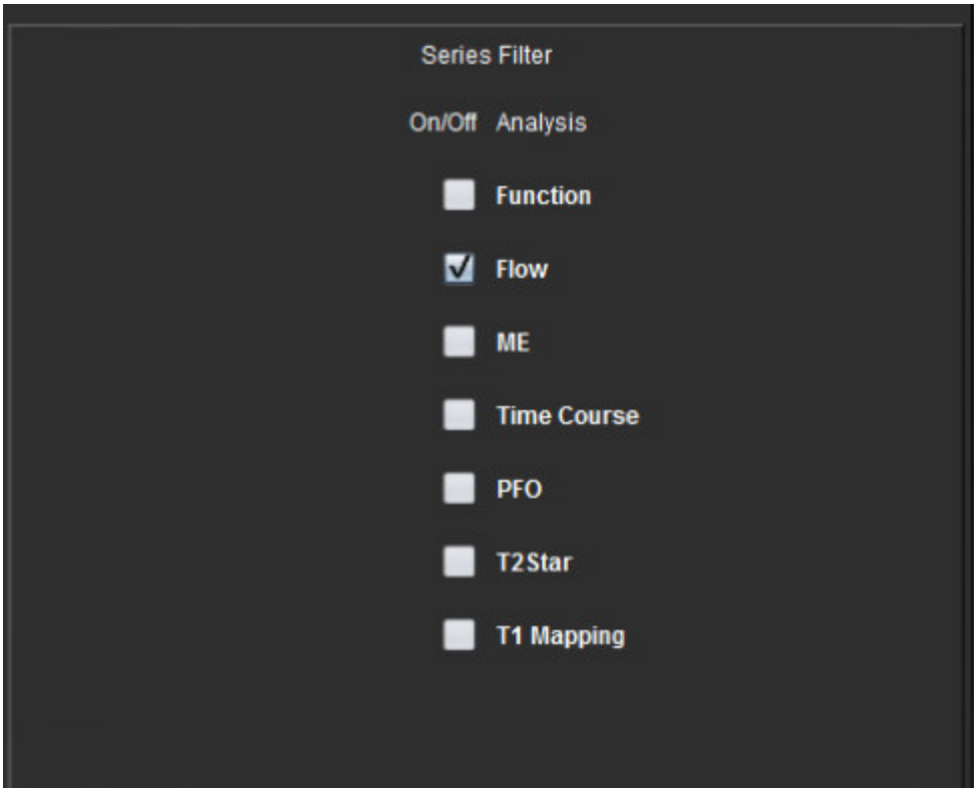
Manage Report Approvers Procedure

1. From the Image View menu bar, select **Tools > Preferences > Edit Preferences**.
2. Select the **Global Settings** tab and place the cursor in the **Authorized Report Approvers** panel.
3. Select the **Add** tab to add a user name to the authorized approvers list.
    - Enter the user name.
    - Enter the password twice.
    - Select **Add**.
4. Select the **Modify** tab to change the password of a user on the authorized approvers list.
    - Select the user to modify.
    - Enter the old password.
    - Enter the new password twice.
    - Select **Apply**.
5. Select the **Delete** tab to delete a user from the authorized approvers list.
    - Select the user(s) to delete.
    - Select **Delete**.

Series Filter

Based on analysis modes types, a series filter can be applied to expedite selection of the appropriate series for analysis. The filter preferences can also be selected during analysis by clicking the filter button on the main panel, above the thumbnail view.

FIGURE 3. Filter Preferences



Select Filter Preference

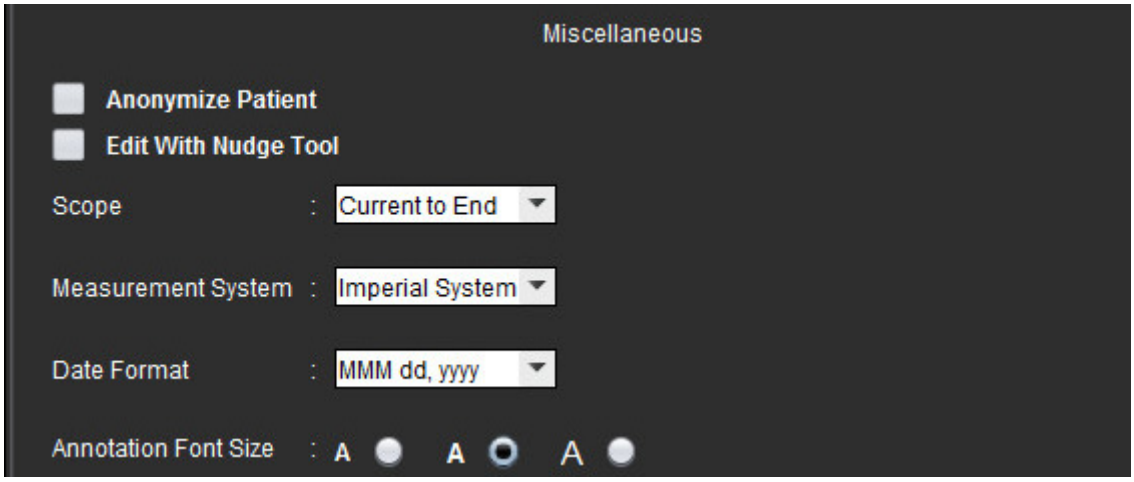
1. From the Image Viewer menu bar, select **Tools** > **Preferences** > **Edit Preference.**
2. Select Global Settings tab.
3. Click the appropriate on/off selection for each analysis type.
4. Select **Save and Exit** to store your entries and close Edit Preferences.
    - Select **Cancel** to exit the window without accepting any changes.
    - Select **Reset** to reset all values on the Global Settings tab without exiting the window.

NOTE: If a series filter has been applied and the required series is not present, a message will appear: “There are no series associated with the selected analysis type.” Clicking OK will disable the filter and display all of the series in the study.

Miscellaneous

The Miscellaneous panel allows you to anonymize the patient, set the default nudge tool setting, set the default Scope for editing, set the default measurement, date formats and annotation font size.

FIGURE 4. Miscellaneous Panel



Edit Miscellaneous Parameters Procedure

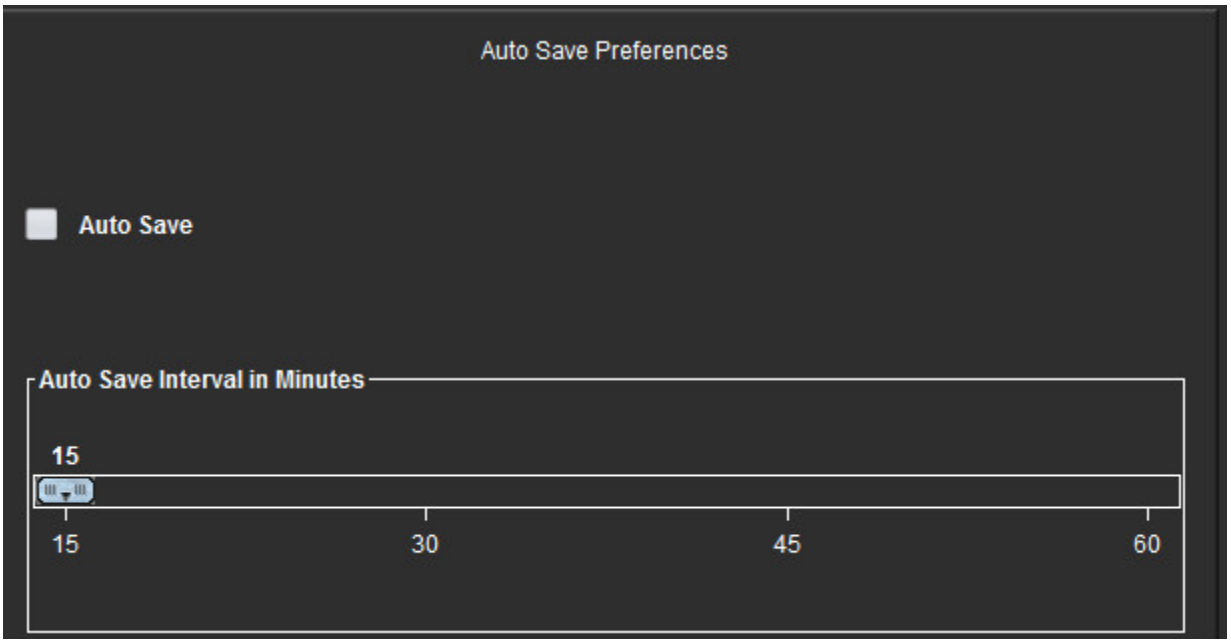
1. From the Image View menu bar, select **Tools > Preferences > Edit Preferences**.
2. Select the **Global Settings** tab and place the cursor in the **Miscellaneous** panel.
3. Check the **Anonymize Patient** check box to hide the patient name and id from the report.

   All patients' names will be displayed as "anonymous" and the ID will be blank. These changes will apply to the report and Image View.
4. Check the **Edit with Nudge Tool** check box to turn on the editing tool for all analysis sessions.
5. Select a default setting for **Scope**, the **Measurement System** and the **Date Format** from the pull-down menus.
6. Select **Annotation Font Size** by clicking on the radial button.
7. Select **Save and Exit** to store your entries and close Edit Preferences.
   - Select **Cancel** to exit the window without accepting any changes.
   - Select **Reset** to reset all values on the Global Settings tab without exiting the window.

Auto Save Preferences

The Auto Save Preferences panel sets the time interval in minutes for the system to automatically generate secondary capture files (SCPT) containing the current analysis. These SCPT files are saved along with the exam. Every time the auto save time interval is reached, a new secondary capture image is added to the series.

FIGURE 5. Auto Save Preferences Window



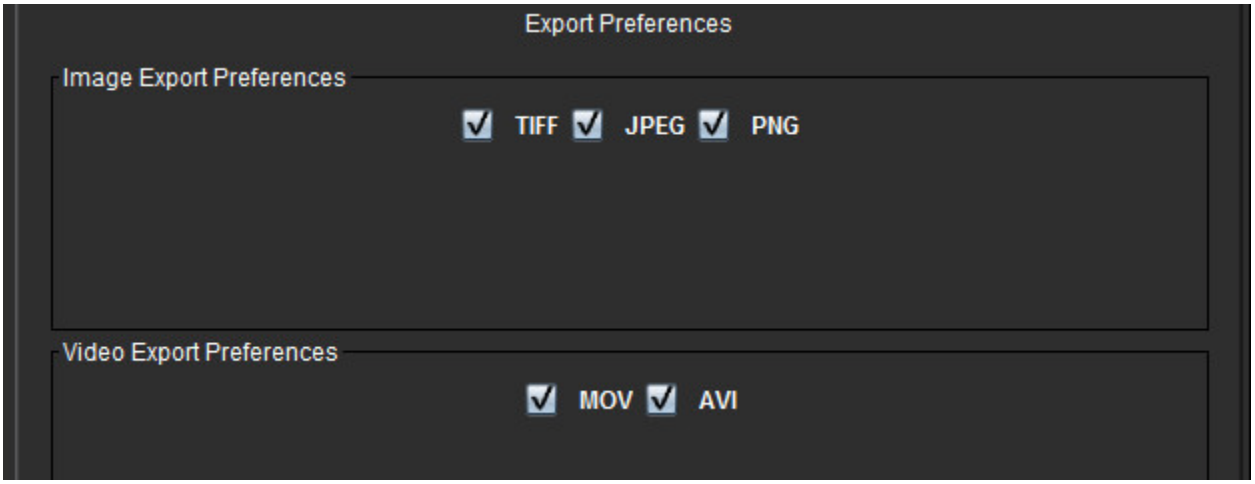
Edit Auto Save Preferences Procedure

1. From the Image View menu bar, select **Tools > Preferences > Edit Preferences**.
2. Select the **Global Settings** tab and place the cursor in the **Auto Save Preferences** panel.
3. Select the **Auto Save** check box to enable the auto save feature.
4. Drag the auto save interval marker to the desired time in minutes.
5. Select **Save and Exit** to store your entries and close Edit Preferences.
    - Select **Cancel** to exit the window without accepting any changes.
    - Select **Reset** to reset all values on the Global Settings tab without exiting the window.

Export Preferences

The Export Preferences panel allows you to select the image formats for exporting image and video data. The exporting feature allows you to create uncompressed AVI movies, compressed QuickTime movies, and JPEG, TIFF and PNG files of the image data.

FIGURE 6. Export Preferences Window



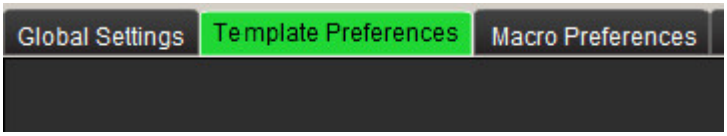
Export Preferences Procedure

1. From the Image View menu bar, select **Tools > Preferences > Edit Preferences**.
2. Select the **Global Settings** tab and place the cursor in the **Export Preferences** panel.
3. Select the appropriate image data types.
4. Select **Save and Exit** to store your entries and close Edit Preferences.
    - Select **Cancel** to exit the window without accepting any changes.
    - Select **Reset** to reset all values on the Global Settings tab without exiting the window.

Template Preferences

The application provides a tool to create user defined templates based on age, BSA, and weight that provide a structured workflow for measuring and reporting of specific quantitative parameters.

FIGURE 7. Template Preferences Tab



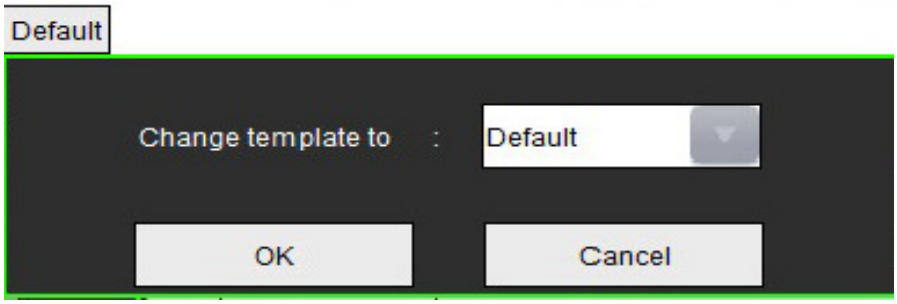
Considerations

Before starting analysis, the user defined template must be selected from the main interface. Click on the **Default** button at the upper right and select the template to be used. Changing the template after performing analysis will apply the preference range applied in the template.

NOTE: Imported studies with previous suiteHEART analysis may show the name of the template used for that study. That template may not be available in the current software.

It is recommended that if two systems are being used for analysis, create the template preference file on the first system and then import into the second system. Template preference files imported from a different system will overwrite the template preferences if they have already been created on that system.

FIGURE 8. Change Template



Create Template Procedure

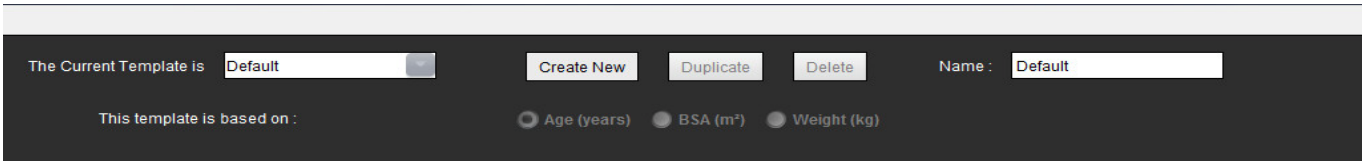
The following is a guide to creating a user defined template. It is up to the clinician's judgement to verify the validity of the parameter range utilized.

Create a Template

All new templates are created initially by duplicating a pre-existing template. The Default template will be used in the example since it is shipped with the product and always available. The default template is not editable. To create a user defined template perform the following:

1. Select **Tools > Preferences > Edit Preferences.**
2. Select the **Template Preferences** tab.
3. Click **Create New** button.
4. Select the preference range of either age, BSA, or weight.

FIGURE 9. Change Template Window



5. Type in a new name for the template.
   When a new name is entered, **The Current Template is** pull-down menu will update.
6. Enter range preferences for the desired parameters.
7. Select **Save and Exit**.
   - Select **Cancel** to exit the window without saving any changes.

Duplicate Template

1. Select **Tools > Preferences > Edit Preferences.**
2. Select the **Template Preferences** tab.
3. Select the template from **The Current Template is** pull-down menu.
4. Click the **Duplicate** button.

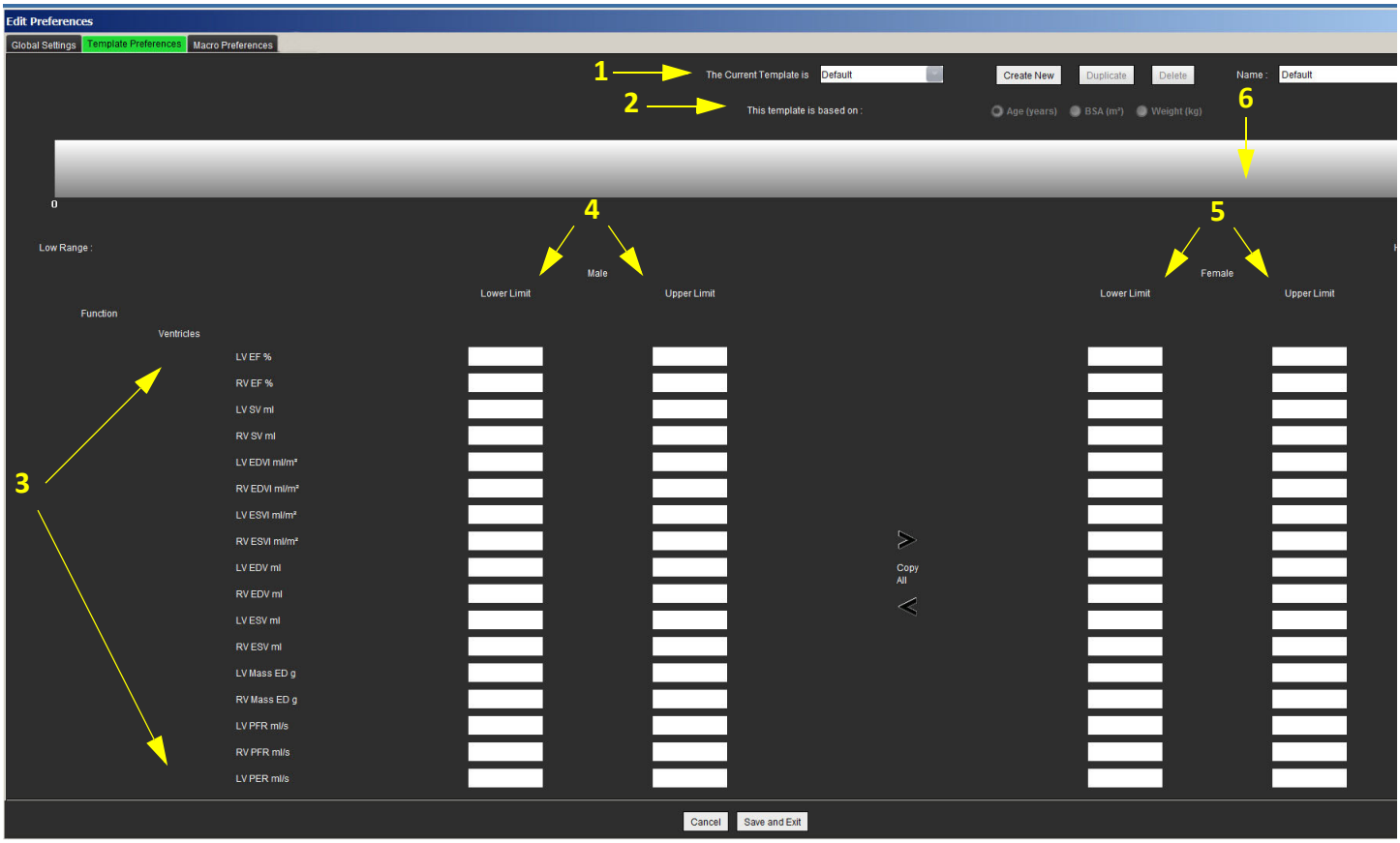
Delete a Template

1. Select **Tools > Preferences > Edit Preferences**.
2. Select the **Template Preferences** tab.
3. Select the template from **The Current Template is** pull-down menu.
4. Click the **Delete** button.

Edit the Preference Ranges

1. Select **Tools > Preferences > Edit Preferences.**
2. Select the **Template Preferences** tab.
3. Select a template other than default.

FIGURE 10. Template Preferences



1. Current template, 2. Category selection, 3. Parameter measurements per analysis, 4. Male upper and lower limits, 5. Female upper and lower limits 6. Range bar.

4. Select the desired template category. Selections are Age, BSA, and Weight.

   NOTE: The selected template will be the one applied to the session.

5. Left-click on the Range bar to activate.

   The bar turns green when active.

6. Right-click on the Range bar to create a range divider bar in the center of the Range bar.
    - The range divider bars can be dragged to adjust the location.
    - Multiple range divider bars can be created.
    - Range divider bars can be deleted by placing the cursor close to the bar and selecting **Delete Range** from the right mouse menu.
7. Enter the parameter range values for the selected category. Enter both the lower and upper limits. Differentiate between male and female values where necessary. Use the **Copy All** arrows to copy values between genders. Use the scroll bar to navigate to the measurements for all the analysis types.

WARNING: Values entered for parameter ranges are the sole responsibility of the user. Confirm all parameter ranges prior to analysis. Incorrect parameter values could lead to misdiagnosis.

8. Select **Save and Exit** to store your entries and close Preferences.
    - Select **Cancel** to exit the window without accepting any changes.

NOTE: For a template to be valid, parameter values must be entered as numerical numbers with both upper and lower values entered. If inconsistencies in the values are found, the following message will appear “Invalid normal range selected. Please correct and save again.” The parameter needing correction will be highlighted in red. Saving a blank template is not allowed and will cause the following message “Unable to Save Template(s)” to display.

NOTE: See Appendix A for more information.

Macro Preferences

Macros can significantly reduce the time spent reporting a cardiac MRI case. All macros are independent from templates. The macros’ streamlined user interface automates tasks, including the following:

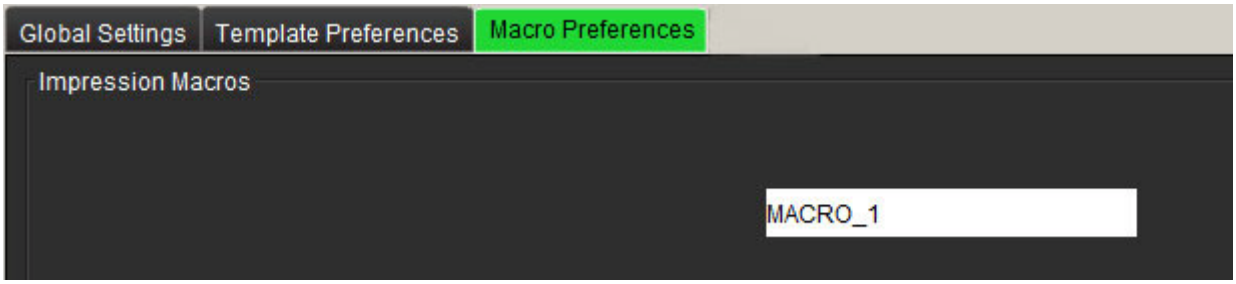
- Generate predefined clinical impressions and techniques that can be automatically inserted into the report.
- Automatically insert quantitative results from the analysis reporting windows.

Add an Impressions Macro

NOTE: Creating a History or Technique macro follows the same workflow as creating an Impression macro.

1. Select **Tools > Preferences > Edit Preferences.**
2. Select the **Macro Preferences** tab.
3. Select **Add Impressions Macro**. A new button appears in the Impression Macros panel.

FIGURE 11. Impression Macros Window



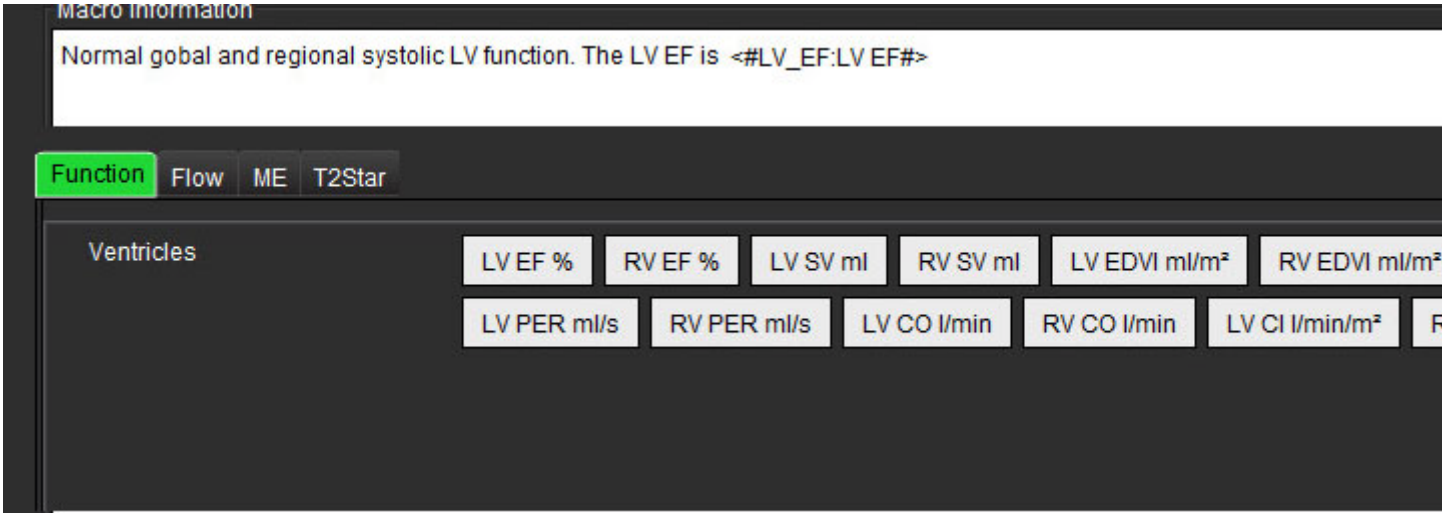
4. Place the cursor inside the new button field and edit the name as desired.

NOTE: The macro buttons created can be reordered. Click and drag the desired button to a new position within the list.

Enter the Macro Text

1. Place the cursor in the Macro Information text box and enter relevant text.
2. To enter a calculation, select any of the analysis tabs below and select the desired parameter button, which will be automatically entered into the macro information. In this example, the LV Ejection Fraction parameter was selected and entered at the end of the text.

FIGURE 12. Macro Information Window



3. Select **Save and Exit** to save your changes to the new macro and exit the Macro Editor.
   - Select **Cancel** to exit the Macro Editor without saving changes.

Execute a Macro

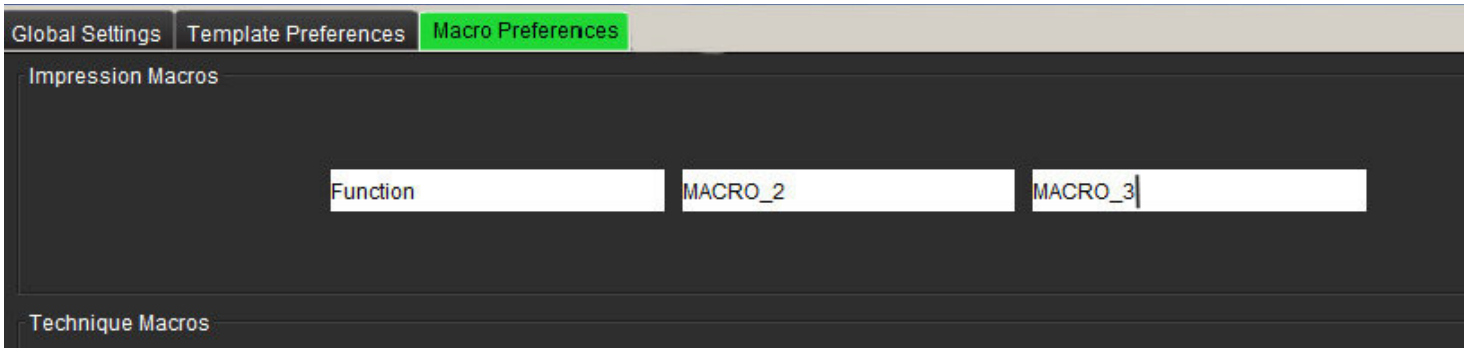
As a prerequisites to macro execution, analysis results must be generated prior to executing macros that involve numerical calculations. Technique and Impression macros can be created to automate report generation.

Delete a Macro

1. Select **Tools > Preferences > Edit Preferences.**
2. Select the **Macro Preferences** tab.
3. Select the macro from the list.

   In the example shown, the macro named MACRO_3 is selected for deletion.

FIGURE 13. Macro Selection List



4. Select **Remove Selected Macro(s)**.

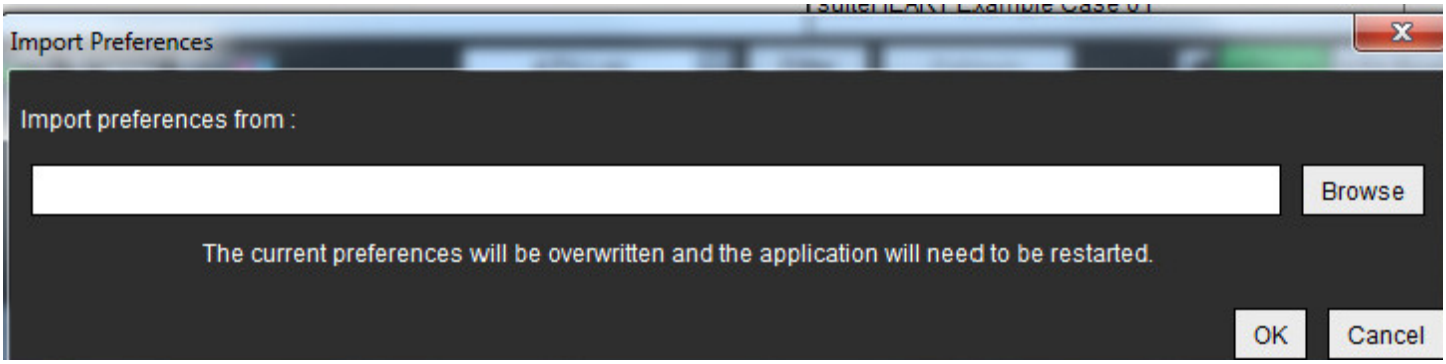
Import Preferences

Templates can be imported from the file system.

Import Preferences Procedure

1. Select **Tools > Preferences > Import Preferences.**

FIGURE 14. Import Preferences Window



2. Select the Browse button, select the location of the preference file and then select the Open button.
3. Select **OK** to perform the import procedure as defined.
   - Select **Cancel** to exit the window without importing the template

NOTE: Importing preferences from prior versions (3.0.1 or below) of suiteHEART® Software is not supported. Please contact NeoSoft Support at service@neosoftmedical.com for help with importing preferences from prior versions.

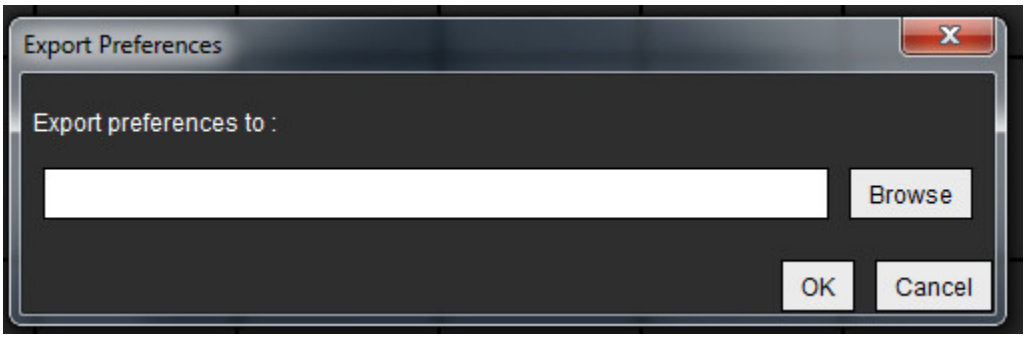
Export Preferences

Templates can be exported to the file system.

Export Preferences Procedure

1. Select **Tools > Preferences > Export Preferences**.

FIGURE 15. Export Preferences Window



2. Select **Browse**, select the folder in which to place the preference file and then select **Save**.
3. Select **OK** to perform the export procedure as defined.
    - Select **Cancel** to exit the window without exporting the template.

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Editing Contours

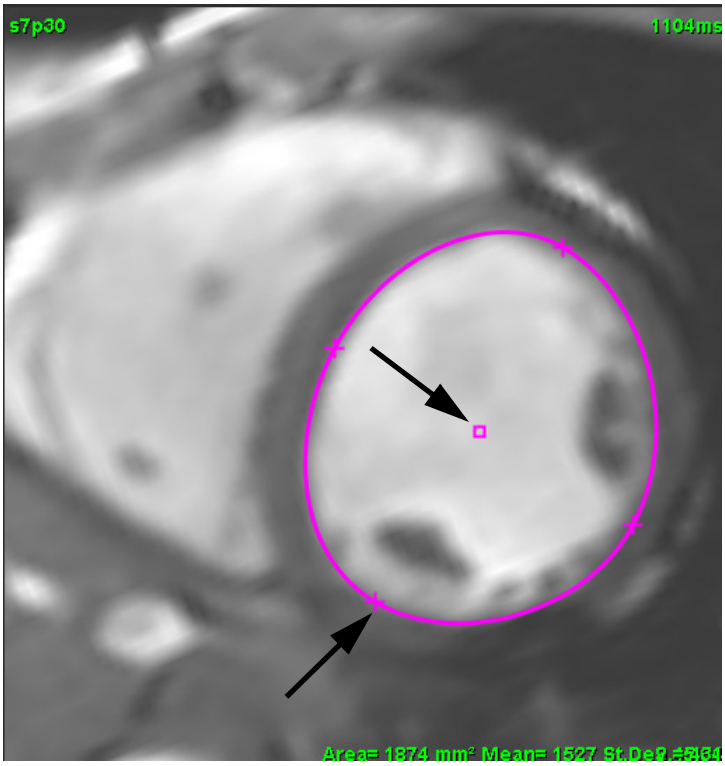
Editing contours, as described in this section, is available in all analysis modes. This feature is available in both the Editor Window and in Review Mode

Contour Edit Options

Conventional Editing

1. In the Editor Window, left mouse click on the contour. The contour will turn purple when selected.
2. Left mouse click and drag on the center of the contour to move it, as shown in Figure 1.
    - If the selected contour was created using the point spline method, the points are displayed for editing. Left mouse click and drag any of the points to adjust the contour size and shape as shown in Figure 1.
    - If the selected contour was created using the free-hand trace tool, left mouse click and hold to update the contour.

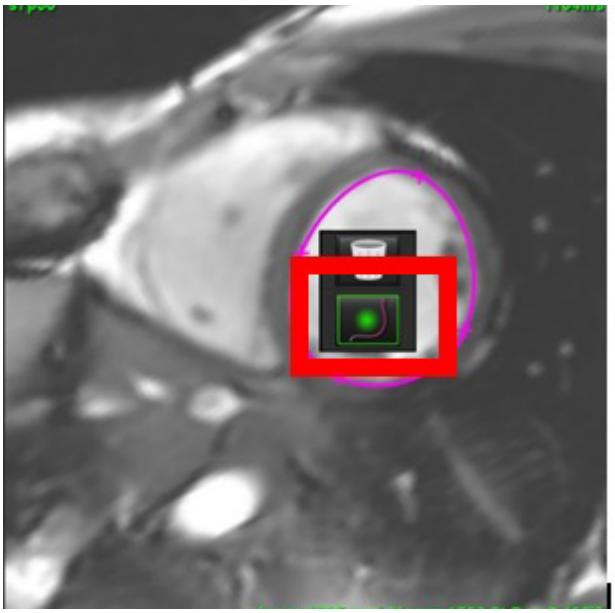
FIGURE 1. Conventional Contour Edit



Nudge Tool

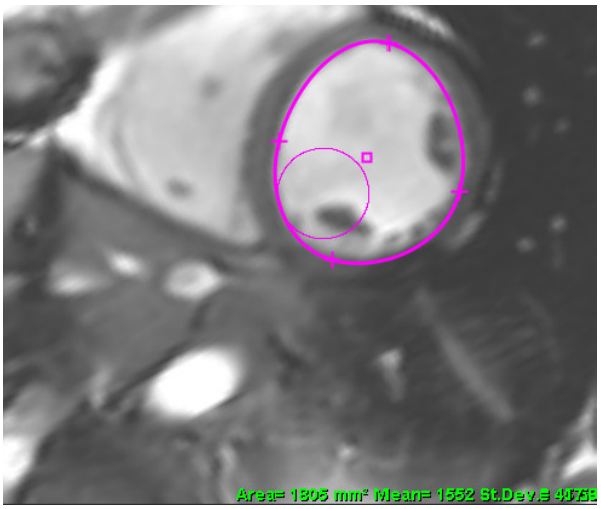
1. To activate the nudge tool, left mouse click on the contour to select it. Then right mouse click and select the nudge tool from the pop-up menu, as shown in Figure 2.
    - When the nudge tool is applied, the selected point spine ROI automatically becomes a free-hand ROI.

FIGURE 2. Nudge Tool Activation



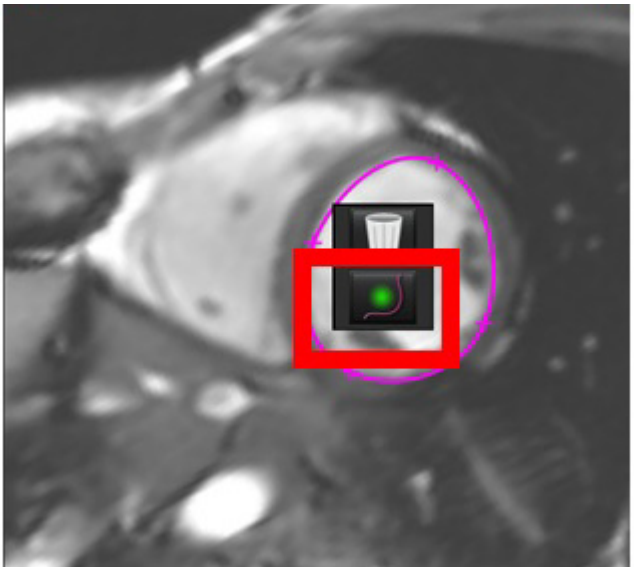
- The size of the nudge circle, as shown in Figure 3, defaults to the size that is an equal distance from the mouse point to the selected ROI.
- The size of the circle can be adjusted by using the mouse wheel or by pressing the bracket [ ] keys on the keyboard.

FIGURE 3. Nudge Tool



2. To deactivate the nudge tool, left mouse click on the contour, then right mouse click and select the nudge tool from the pop-up menu, as shown in Figure 4.

FIGURE 4. Nudge Tool Deactivation



NOTE: The on/off state of the nudge tool can be set in Preferences.

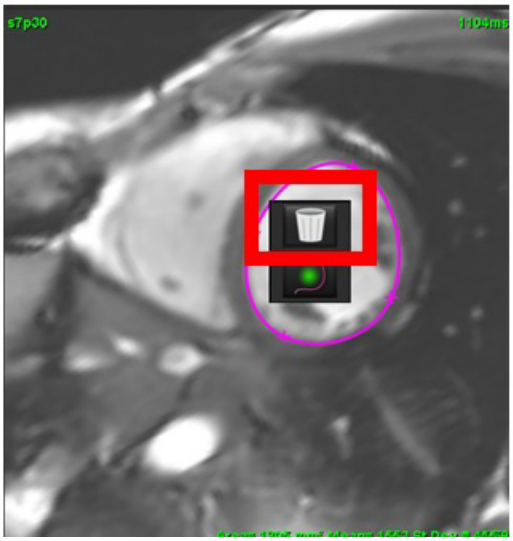
Delete a Contour

1. Left mouse click on the contour to select it and press the delete key on the keyboard.

or

2. Left mouse click on the contour to select it, then right mouse click and choose the trashcan from the pop-up menu, as shown in Figure 5.

FIGURE 5. Contour Deletion



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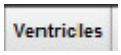
Function Analysis

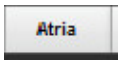
This section details the typical steps used for a cardiac function analysis. The sample workflows provide an overview of the steps used in the application to complete a cardiac function analysis. The procedures describe how to perform the following measurements:

WARNING: Incorrect scan plane may cause inaccurate analysis results. See Appendix B.

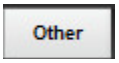
There are three categories for analysis:



- Includes volume and regional analysis for the left (LV) and right ventricles (RV)



- Includes volume analysis for the left (LA) and right atrium (RA).



- Includes pre-defined linear measurements and user defined measurements can be added.

Analysis Ventricles: Left Ventricular Function

Select the appropriate analysis type:

 Manual

 Fast

 Auto

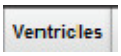
NOTE: Only one set of results are saved. If the method is changed, the prior analysis is deleted.

IMPORTANT: It is recommended that you are qualified in performing cardiac analysis, if the analysis results are to be used to reach a diagnosis.

WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

Manual LV Function Analysis Procedure

NOTE: It is recommended that the end-diastolic and end-systolic phases are used. Processing should begin on the end-diastolic phase. The analysis workflow is typically performed from the base to the apex.

1. Select  .
2. Select the appropriate short axis series from the Image View.
3. Click  .
4. Click  button for Volume measurements.
5. Locate the end-diastolic phase.

Define the Endocardium

1. Select  .
2. Trace the endocardial contour.
3. Proceed to the next slice using  or use <-- and --> or select the thumbnail.
4. Repeat steps 2 and 3 until the entire left ventricle is segmented.

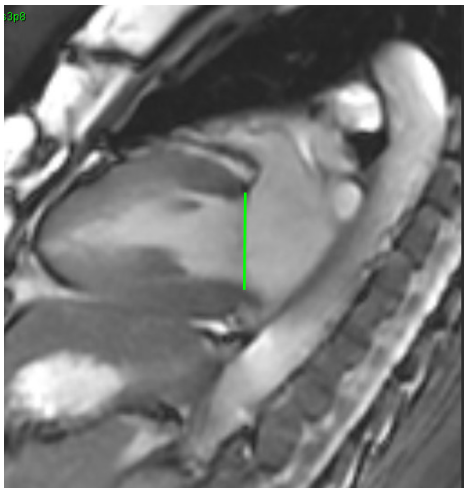
   The Endocardial contour tool will stay selected to expedite the segmenting of multiple slices.
5. Locate the end-systolic phase.
6. Repeat steps 2 and 3 on the end-systolic phase until the entire left ventricle is segmented.

   The results in the measurement table continually update after 3 contours have been drawn and as more volume measures are added.

NOTE: The software automatically defines the end-diastolic phase as the phase with the largest volume, and the end-systolic phase as the phase with the smallest volume. The end-diastolic and end-systolic phase assignments are updated during segmentation.

7. Review all results on the measurement table.
8. To ensure optimal basal segmentation, select a 2-chamber long axis view in the x-reference mode.
9. Select the LV basal line  .
10. Define the basal line as shown in Figure 1. Review the placement of the basal line on the appropriate end-systolic and end-diastolic phases by using the cine controls.

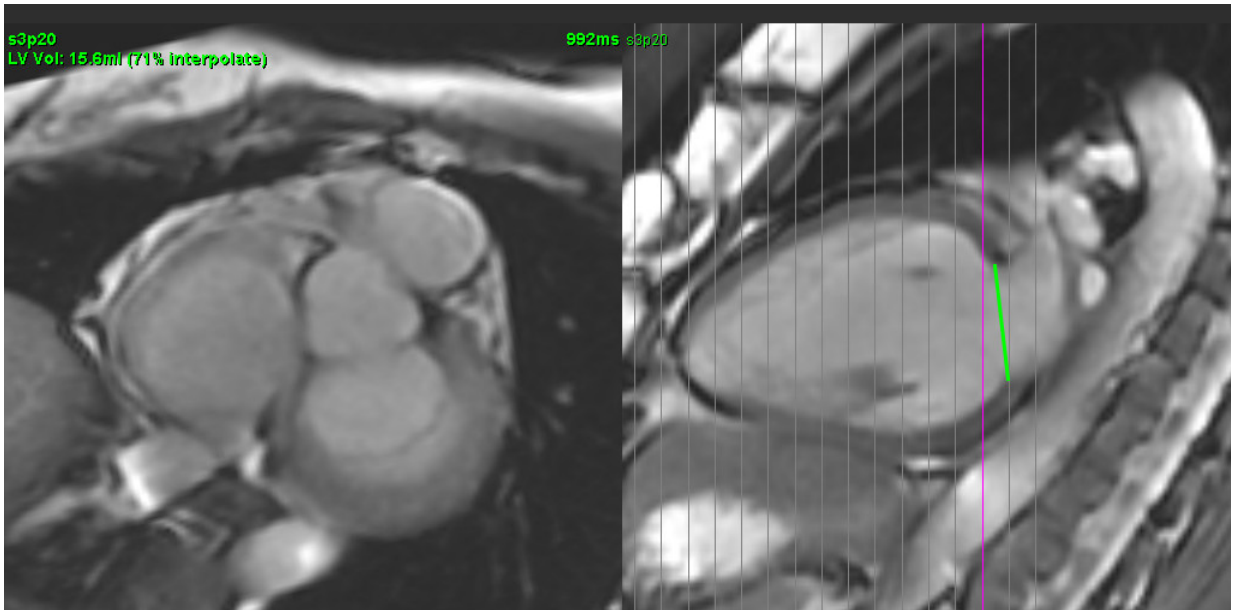
FIGURE 1. Basal Line



11. Review the updated calculation by reviewing the x-reference slices in relationship to the basal line.

As shown in Figure 2, the interpolated volume calculation is based upon the relationship of the basal line intersection with the slice (pink line) this volume is now included in the volume results. The actual region of interest will not be shown. Slices that have been interpolated will state the volume amount with the percentage of interpolation in left hand corner of the image as shown in Figure 2.

FIGURE 2. Volume Calculation



12. To reset the results back to the original manual inputs, perform a right mouse click hold directly on the basal line and select delete or left click and press the Delete key on the keyboard.

IMPORTANT: If the basal line is drawn before the Endocardial ROIs, the Endo/Epi ROIs shall be drawn starting from the LV apical slices towards the basal slices. This is important because the application sums the slice volumes to determine which side of the basal line is the LV. If Endo/Epi ROIs are drawn starting close to the basal slices or on LA slices, the software could misinterpret location of the LV. Check the volume contribution of each slice with an ROI.

Calculate Index Measurements

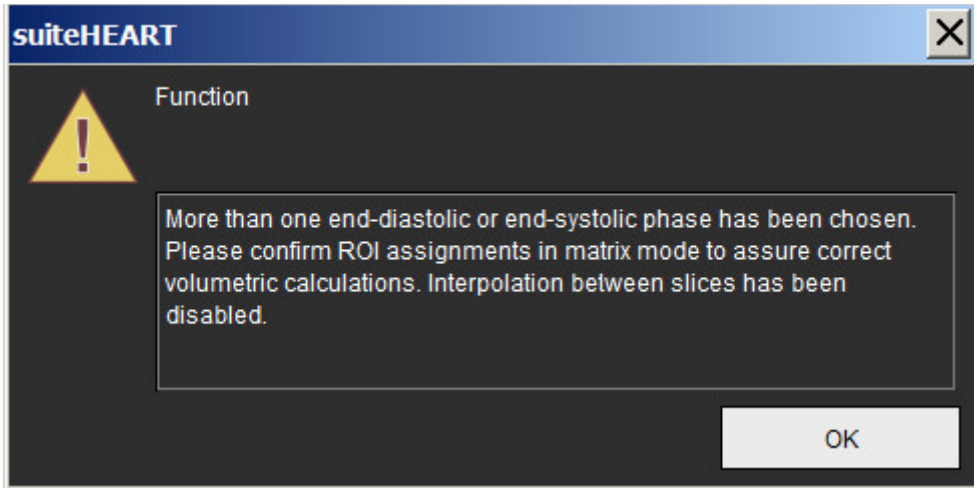
1. Select the **History tab** from Report View.
2. Enter patient **Height** and **Weight**.

   The end-diastolic volume index, end-systolic volume index, cardiac output index and stroke volume index measurements are calculated and added to the Measurement table.

NOTE: The BSA calculation method can be selected under the History tab located on the Report View.

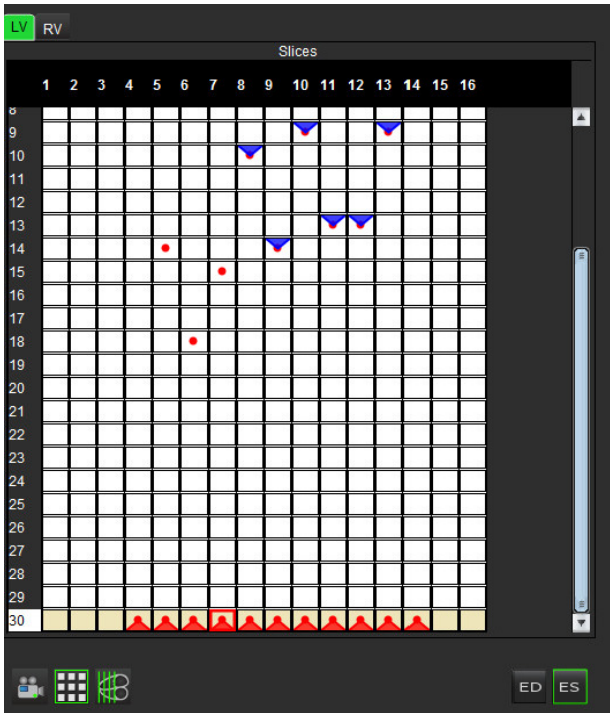
Reviewing End-Diastolic (ED) and End-Systolic (ES) Assignments

Upon completion of performing manual segmentation, review the matrix mode and confirm the end-diastolic or end-systolic assignments. If a different phase is selected for tracing, the software will automatically disable interpolation as the following user message will appear.



1. Select the Matrix mode  button.
2. The view port changes showing a matrix representing all of the slice locations and phases acquired. In Figure 3 all of the LV end-diastolic phases have been assigned as indicated by the red triangles. The blue triangles indicate assigned LV end-systolic phases. The red dots represent phases not yet assigned.

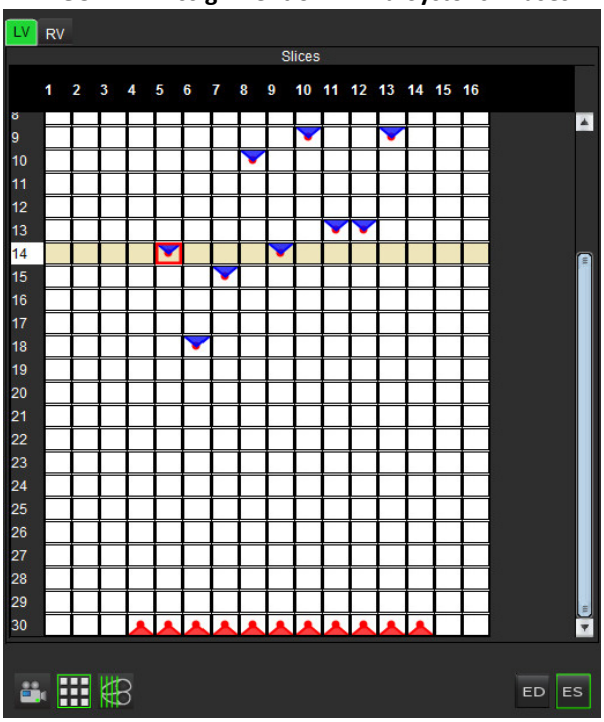
FIGURE 3. Slice Location and Acquired Phases Matrix



3. In this example, to assign the LV end-systolic phases click on the ES button and click on the appropriate phase that has a red dot. A blue triangle will appear after clicking on the matrix box. As shown in Figure 4 all of the end-diastolic and/or end-systolic assignments are now correct.

4. Repeat the above steps as needed for the RV. Click on the Tab for the RV.

FIGURE 4. Assignment of LV End-Systolic Phases



LV Myocardial Mass Procedure

1. Select the appropriate cardiac phase.
2. Select  for epicardium.
3. Trace the epicardial contour for the LV.
4. Proceed to the next slice using  or use <-- and --> or select the thumbnail.
5. Repeat steps 3 and 4 until the entire left ventricular epicardium is segmented.

   The LV Mass result is automatically updated as the epicardial contours are defined.

   The results in the measurement table continually update after 3 contours have been drawn.

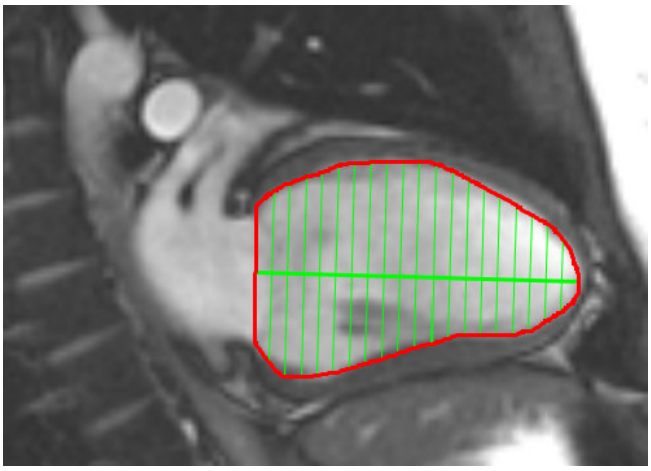
Fast LV Function Analysis Procedure

This method is performed on a long-axis series.

1. Select a long-axis series.
2. Select the end-diastolic phase.
3. Select the  button from the Function mode.
4. Click the  .
5. Trace the left ventricle endocardium. A center of rotation line is drawn automatically.
6. Adjust the center of rotation line so that it corresponds to the long axis of the left ventricle
7. If left ventricle mass is desired, trace the left ventricle epicardium by clicking  .
8. Repeat steps 4 - 6 for end systole.

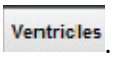
NOTE: When analyzing the LV, the correct position of the center line must run from the base to the apex.

FIGURE 5. Center of Rotation Line



The results are displayed on the Measurement table.

Auto LV Segmentation Procedure

1. Select the short axis series and adjust the window/level.
2. Click 

.
3. Click  to start auto segmentation.
4. Select the most apical slice of the end-systolic phase.

Start Auto LV Segmentation

1. Select  .
2. Deposit a point in the center of the blood pool on the apical slice and move the cursor out of the image editor window.

There are two methods for defining the range of segmentation: The first uses short axis images and the second uses long axis images.

Workflow 1: Short Axis Images

1. Select the most basal midventricular slice with a complete circumference of myocardium.
2. Select  .
3. Deposit a point in the center of the blood pool and move the cursor out of the image editor window.
4. Select **Propagate Contours** to begin segmentation.

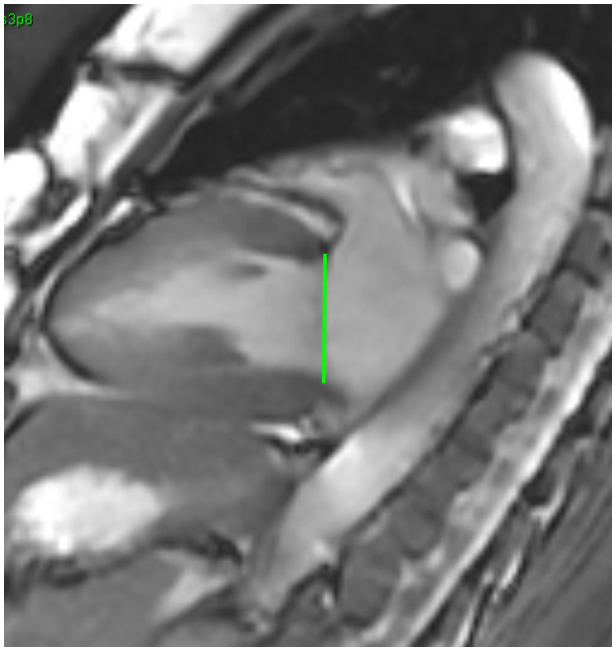
Workflow 2: Long-axis image

1. Select  .

   The **Cross-Ref** mode is automatically displayed.
2. Select a long-axis image from the Orthogonal Slice dropdown menu.
3. Deposit two points to define a line at the left ventricle base on the cross reference viewport.
4. Move the cursor out of the cross reference viewport

   A pop-up is displayed prompting the user to check the valve plane lines in all phases.
5. Verify the accuracy of the valve plane on each phase and make any necessary adjustments.
6. Select **Propagate Contours** to begin segmentation.

FIGURE 6. Basal Line



Review Accuracy

1. Play the short axis series in cine mode and review the accuracy of the contours.
2. Edit any contours that are inaccurate.

From the Analysis View select the desired type of contour to be displayed:

 - Smooth Endocardial Contour Only

 - Auto Contour including Papillary Muscles

 - Endocardial Contour Only

 - Epicardial and Endocardial Contour Only

 - Show Chords

CAUTION: The results are dependent upon the accurate and complete segmentation of the left and right ventricles. Misdiagnosis may occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

Editing multiple phases at a single slice location:

1. Select the slice location
2. Select 
3. Select the first phase of the range of phases to be edited.
4. Depress and hold the shift key and select the last phase of the range to be edited.

   The selected thumbnails will appear highlighted with a red border.
5. Edit the epicardial contour in the image editor window.
6. Deselect the contour by either clicking on the image away from the selected contour or move the cursor out of the editor window.

   The endocardial and epicardial contours in the range selected will be automatically updated.

NOTE: The volumetric values are automatically recalculated after any contours are edited.

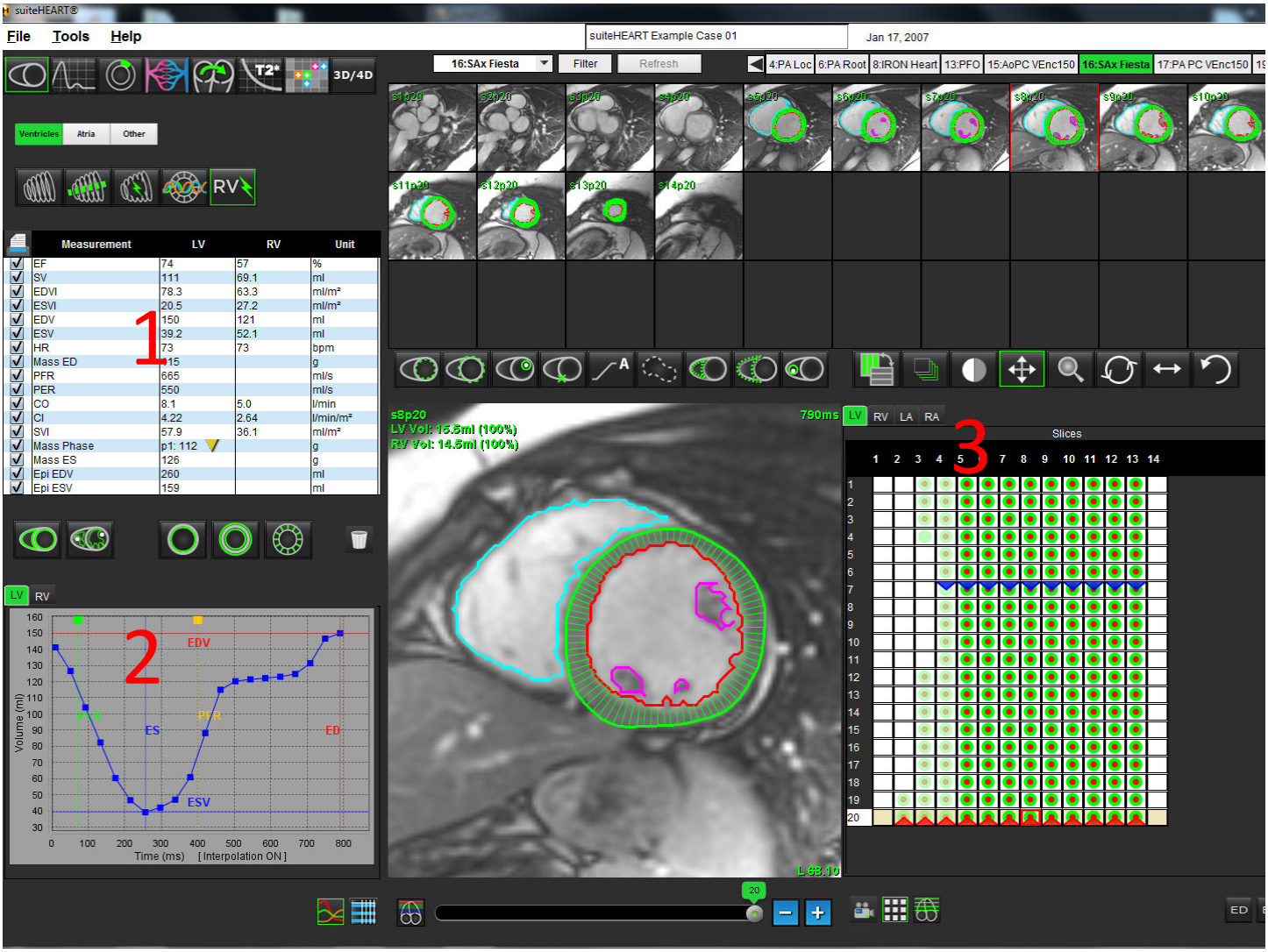
NOTE: When editing ROIs on studies restored from a previous software version (2.1.0 or below) where Auto function analysis was performed, endo or epi ROIs will need to be retraced.

LV Function Analysis Results

Volume Curve

The Auto LV function analysis includes generation of a left ventricular volume versus time curve as shown in Figure 7. This curve can be printed on the report. Markers with drag handles can be adjusted.

FIGURE 7. LV Auto-Segmentation Results



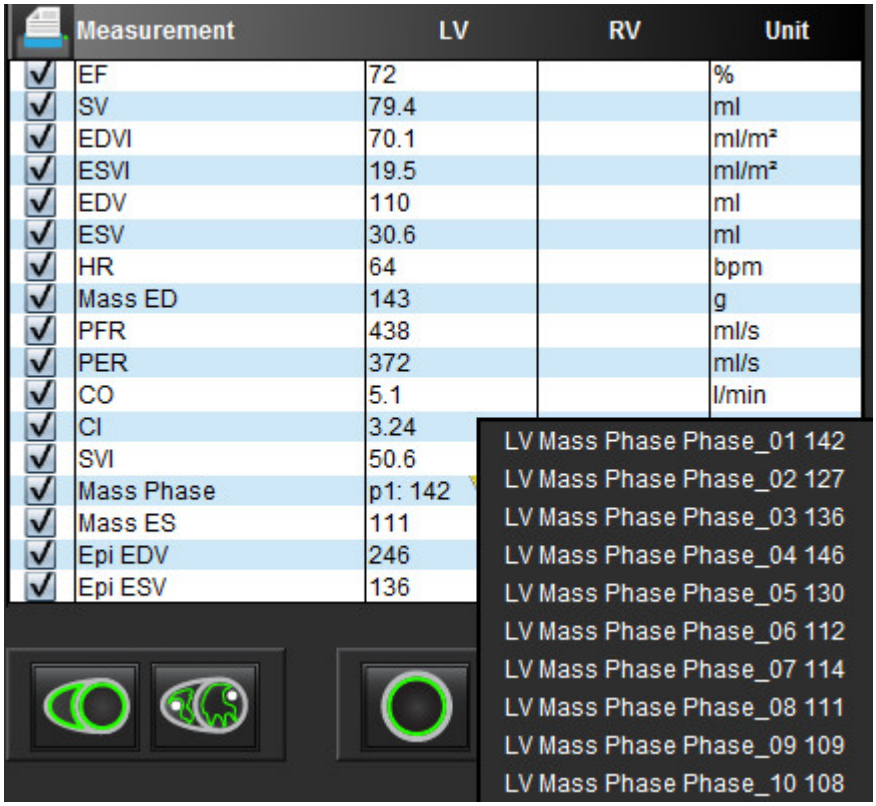
1. Volumetric measurements, 2. Volume curve, 3. Matrix mode

- The red cursor marks end-diastolic volume.
- The blue cursor marks end-systolic volume.
- The green cursor marks Peak Ejection Rate (PER) ml/sec. (Interactive Vertical Cursor).
- The yellow cursor marks Peak Filling Rate (PFR) ml/sec. (Interactive Vertical Cursor).

Volumetric results are displayed on the function analysis tab.

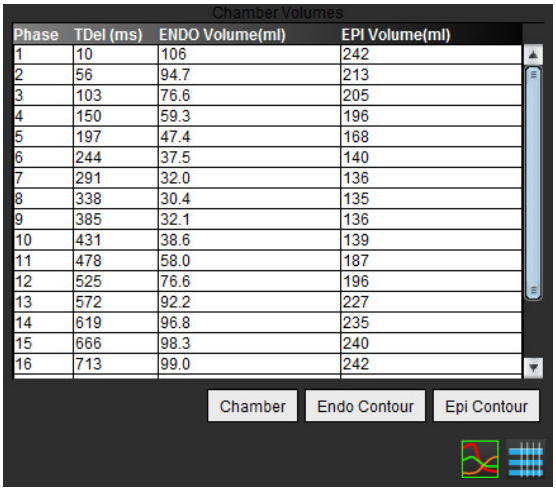
- To review the ventricular mass results, right-click on the inverted yellow triangle for either the LV or RV.
- Only the phase selected from the Measurement table is shown in the report.

FIGURE 8. Mass Phase Pull-down Menu



Chamber Volumes Table

FIGURE 9. Chamber Volume Table



Full LV Volumetric results are displayed in the Chamber Volumes table.

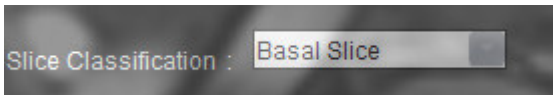
Regional Analysis

Regional Analysis calculates and allows you to examine wall motion, wall thickness, wall thickening and wall thickness over time in a specific slice.

1. Perform Auto LV segmentation (refer to page 52).

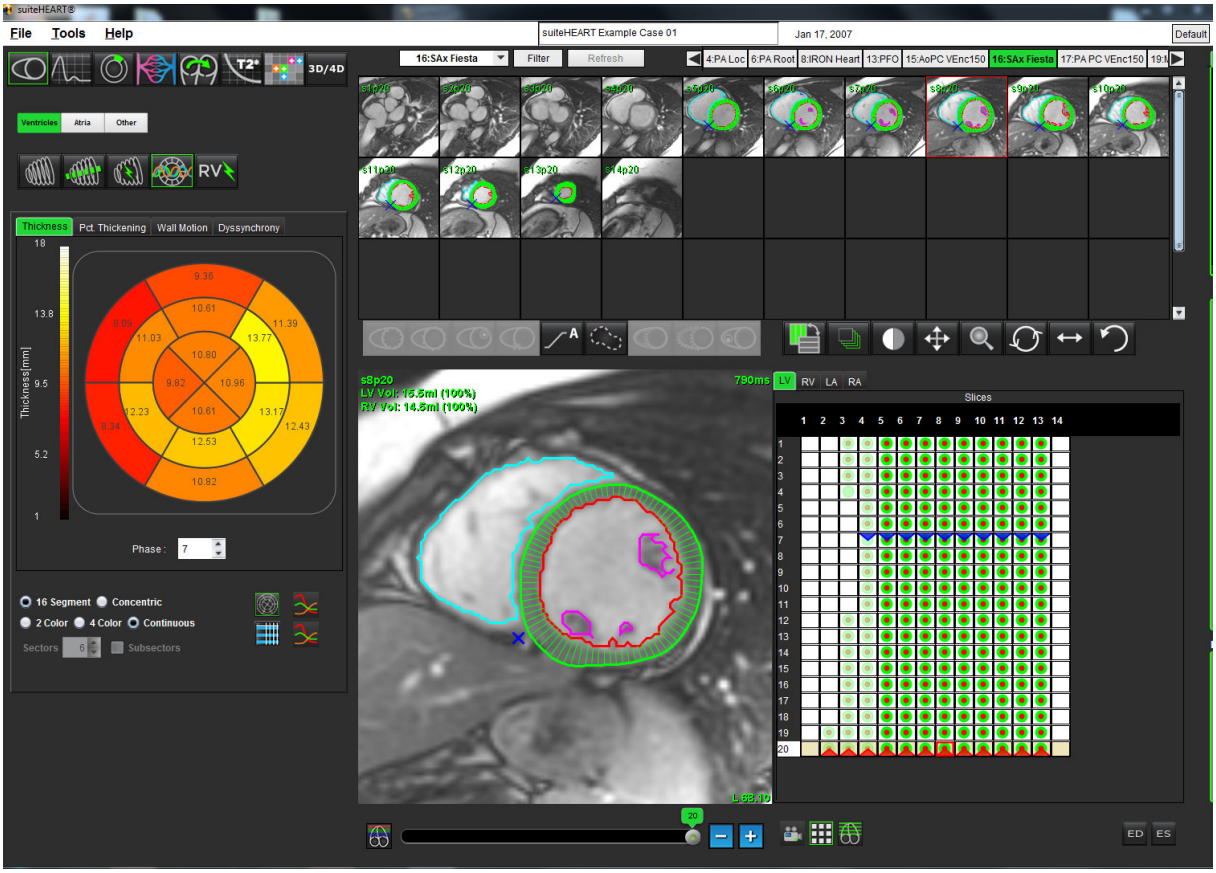
2. Click RV insertion point  , select an auto segmented slice and deposit the RV insertion point. Repeat for all of the auto segmented slices in the Left Ventricle.

3. Click the slice classification  and confirm basal, mid and apical classification.



4. Click Regional Analysis  . Thickness, Percent Thickening and Wall Motion will display in a plot graph or table formats.

FIGURE 10. Output of Regional Analysis



Dyssynchrony Analysis

Dyssynchrony is an extension of the Regional Analysis results allowing for the calculation of the Temporal Uniformity of Wall Thickness (TUWT) base upon circumferential information obtained from the Regional Analysis. Literature reference located in Table 1.

Dyssynchrony Analysis Procedure

1. Perform LV auto segmentation (see “Auto LV Segmentation Procedure” on page 52).
2. Select Regional Analysis  .
3. Select the Dyssynchrony tab.
4. The measurement table will show the results for each slice and the mean global result.
5. The global result calculation is optimal when only LV mid-ventricular slices are included. To remove a slice result from the Global result calculation, click directly on the box with the checkmark in the far right column (Figure 11).

FIGURE 11. Global Result Calculation

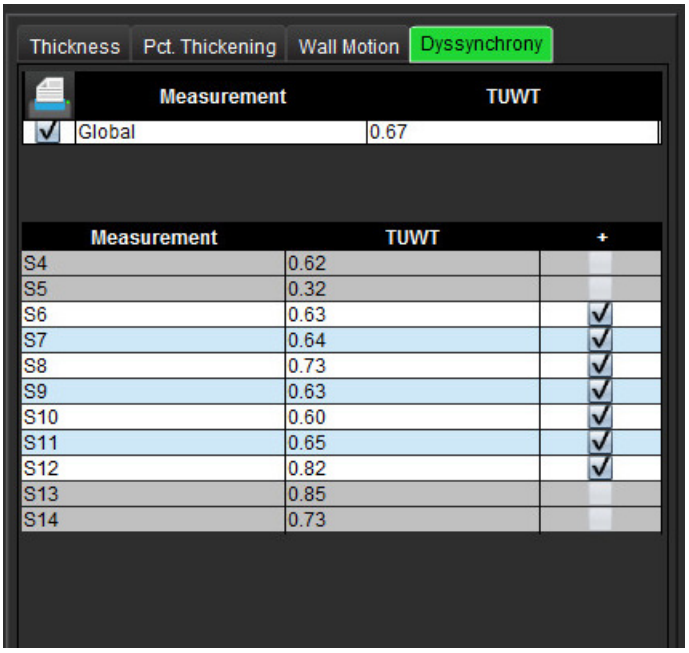


Table 1:

Result	Reference
Temporal Uniformity of Wall Thickness (TUWT)	*Bilchick et al, "Cardiac Magnetic Resonance Assessment of Dyssynchrony and Myocardial Scar Predicts Function Class Improvement Following Cardiac Resynchronization Therapy", JACC, Vol.1:No 5: 2008 p.561-8

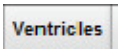
Analysis Ventricles: Right Ventricle Function

There are two methods of performing RV function analysis: manual and auto.

NOTE: LV auto segmentation must be completed prior to performing RV auto segmentation.

Manual RV Function Analysis Procedure

NOTE: It is recommended that the end-diastolic and end-systolic phases are used. Processing should begin on the end-diastolic phase. The analysis workflow is typically performed from the base to the apex.

1. Select the appropriate short axis series from the Image View.
2. Click 

.
3. Locate the end-diastolic phase.
4. Click the  button.

Define the Endocardium

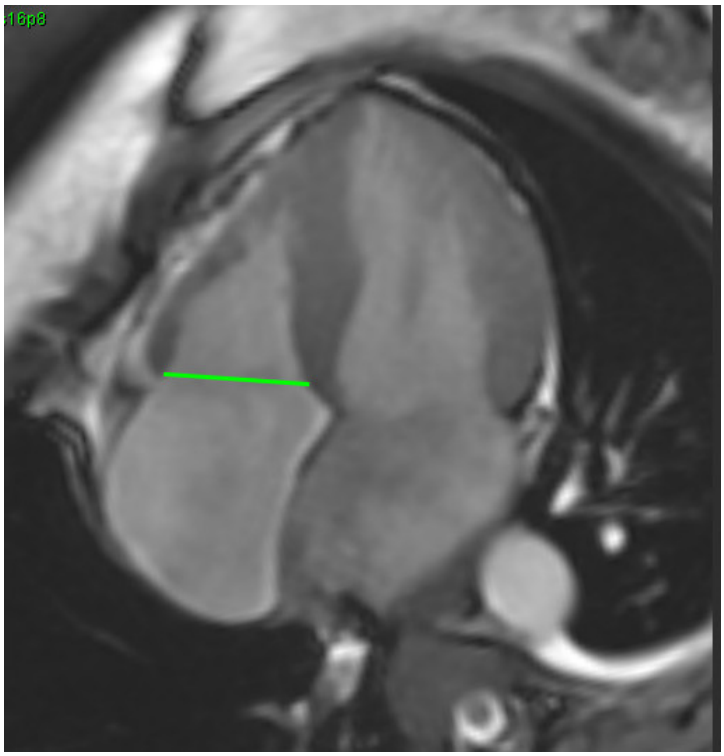
1. Select  .
2. Trace the endocardial contour.
3. Proceed to the next slice using  or use <-- and --> or click the thumbnail.
4. Repeat steps 2 and 3 until the entire right ventricle is segmented.

   The Endocardial contour tool will stay selected to expedite the segmenting of multiple slices.
5. Locate the end-systolic phase.
6. Repeat steps 2 and 3 on the end-systolic phase until the entire right ventricle is segmented.

   The values in the measurement table continually update after 3 contours have been drawn and as more volume measures are added.

   NOTE: The software automatically defines the end-diastolic phase as the phase with the largest volume, and the end-systolic phase as the phase with the smallest volume. The end-diastolic and end-systolic phase assignments are updated during segmentation.
7. Review all results on the measurement table.
8. To ensure optimal basal segmentation select a 4-chamber long axis view in the x-reference mode.
9. Select the RV basal line  button.
10. Define the basal line as shown in Figure 12. Review the placement of the basal line on the appropriate end-systolic and end-diastolic phases by using the cine controls.

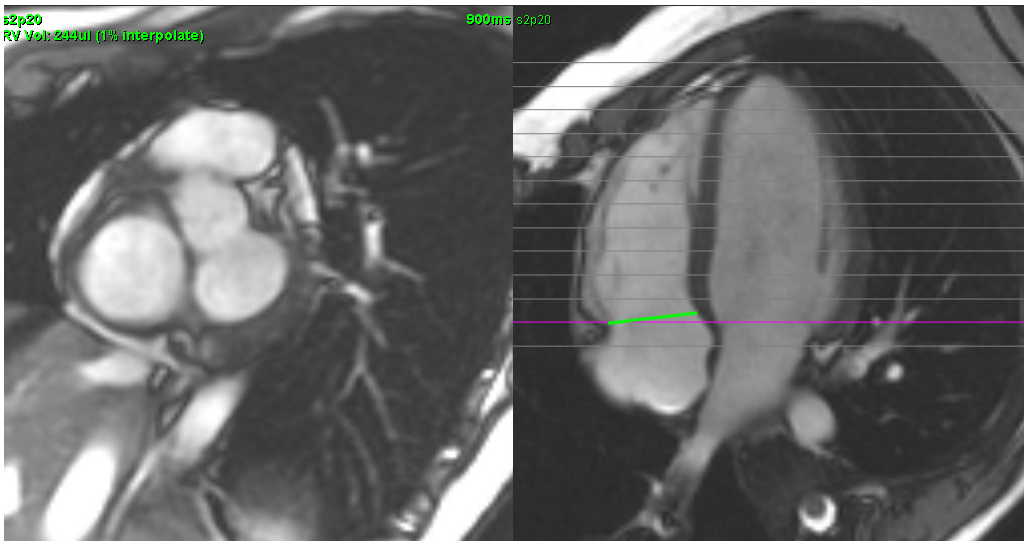
FIGURE 12. Basal Line Definition



11. Review the updated calculation by reviewing the x-reference slices in relationship to the basal line.

As shown in Figure 13 the interpolated volume calculation is based upon the relationship of the basal line intersection with the slice (pink line) this volume is now included in the volume results. The actual region of interest will not be shown. Slices that have been interpolated will state the volume amount with the percentage of interpolation in left hand corner of the image as shown in Figure 13.

FIGURE 13. Interpolated Volume Calculation



12. To reset the results back to the original manual inputs, perform a right mouse click hold directly on the basal line and select Delete; or left click and press the Delete key on the keyboard.

IMPORTANT: If the basal line is drawn before the Endocardial ROIs, the Endo/Epi ROIs shall be drawn starting from the apical slices towards the basal slices. This is important because the application sums the slice volumes to determine which side of the basal line is the RV. If Endo/Epi ROIs are drawn starting close to the basal slices or on RA slices, the software could misinterpret location of the RV. Check the volume contribution of each slice with an ROI.

Calculate Index Measurements

1. Select **History Tab.**
2. Enter patient **Height** and **Weight**.

   The end-diastolic volume index, end-systolic volume index, cardiac output index and stroke volume index measurements are calculated and added to the Measurement table.

NOTE: The BSA calculation method can be selected under the History tab located on the Report View.

RV Myocardial Mass Procedure

1. Select the appropriate cardiac phase.
2. Select  for RV epicardium.
3. Trace the epicardial contour for the RV.
4. Proceed to the next slice using  or use <-- and --> or click the thumbnail.
5. Repeat steps 3 and 4 until the entire right ventricular epicardium is segmented.
   - The RV Mass result is automatically updated as the epicardial contours are defined.
   - The results in the measurement table continually update after three contours have been drawn.

Auto RV Segmentation Procedure

1. Select the short axis series and adjust the window/level.
2. Click the **Auto**  .
3. Select the most apical slice of the end-systolic phase where the RV is visible.

Start Auto RV Segmentation

1. Select  .
2. Deposit a point in the center of the blood pool on the apical slice and move the cursor out of the image editor window.

There are two methods for defining the range of segmentation: The first uses short axis images and the second uses long axis images.

Workflow 1: Short Axis Images

1. Select the most basal midventricular slice with a complete circumference of myocardium.
2. Select  .
3. Deposit a point in the center of the blood pool and move the cursor out of the image editor window.
4. Select **Propagate Contours** to begin segmentation.

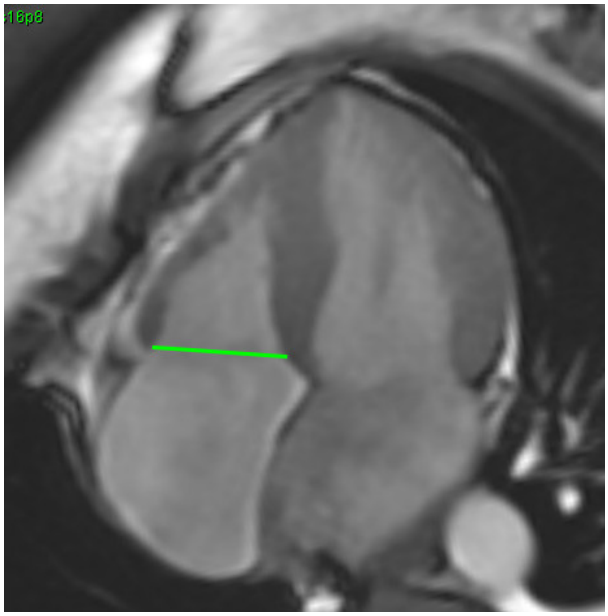
Workflow 2: Long Axis Images

1. Select  .

   The **Cross-Ref** mode is automatically displayed.
2. Select a long-axis image from the Orthogonal Slice drop-down menu.
3. Deposit two points to define a line at the right ventricle base on the cross reference viewport.
4. Move the cursor out of the cross reference viewport.

   A pop-up is displayed prompting you to check the valve plane lines in all phases.
5. Verify the accuracy of the valve plane on each phase and make any necessary adjustments.
6. Select **Propagate Contours** to begin segmentation.

FIGURE 14. Basal Line



Review Accuracy

1. Play the short axis series in cine mode and review the accuracy of the contours.
2. Edit any contours that are inaccurate.

CAUTION: The results are dependent upon the accurate and complete segmentation of the left ventricle. Misdiagnosis may occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

Editing Multiple Phases at a Single Slice Location

1. Select the slice location.
2. Select  .
3. Select the first phase of the range of phases to be edited.
4. Depress and hold the shift key and select the last phase of the range to be edited.

   The selected thumbnails will appear highlighted with a red border.
5. Edit the epicardial contour in the image editor window.
6. Deselect the contour by either clicking on the image away from the selected contour or move the cursor out of the editor window.

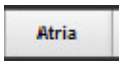
   The endocardial contours in the range selected will be automatically updated.

NOTE: The volumetric values are automatically recalculated after any contours are edited.

Analysis Atria: LA and RA

Manual LA and RA Function Analysis Procedure

1. Select the appropriate series from the Image View.

   NOTE: For optimal results, it is recommended to use a 4-chamber stack for analysis. The 4-chamber view better delineates the atrial anatomy.
2. Click 

button.
3. Select the  button
4. Locate the end-diastolic phase.

Define the Endocardium

1. Select  for LA Endocardium or  for RA Endocardium.
2. Trace the endocardial contour.
3. Proceed to the next slice using  or use <-- and --> or click thumbnail.
4. Repeat steps 2 and 3 until the entire atrium is segmented.
5. Locate the end-systolic phase.
6. Repeat steps 2 and 3 on the end-systolic phase until the entire atrium is segmented.

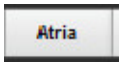
   The values in the measurement table continually update after 3 contours have been drawn and as more volume measures are added.

   NOTE: The software automatically defines the end-diastolic phase as the phase with the largest volume, and the end-systolic phase as the phase with the smallest volume. The end-diastolic and end-systolic phase assignments are updated during segmentation.
7. If a short axis view has been used, select the basal line button and define the appropriate base.

IMPORTANT: If the basal line is drawn before the Endocardial ROIs, the Endo ROIs shall be drawn starting from the slice furthest away from the basal slice moving towards the basal slice. This is important because the application sums the slice volumes to determine which side of the basal line is the ventricle (LA/RA). If Endo ROIs are drawn starting close to the basal slices or on LV/RV slices, the software could misinterpret location of the LA/RA. Check the volume contribution of each slice with an ROI.

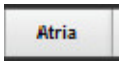
Fast LA or RA Function Analysis Procedure

This method is performed on a long-axis series.

1. Click the 

button.
2. Select a long-axis series.
3. Select the end-diastolic phase.
4. Select the  button.
5. Select  for LA Endocardium or  for RA Endocardium.
6. Trace the atrium endocardium. A center of rotation line is drawn automatically.
7. Adjust the center of rotation line so that it corresponds to the long axis of the atrium
8. Repeat steps 5-7 for end systole.

Atrial Dimensions and Area

1. Click the 

button.
2. Select the appropriate series.
3. To perform an atrial dimension measurement, click directly on the table in the column for either LA or RA and then deposit two points. See Figure 15.
4. To perform an atrial area measurement, click directly on the table in the column for either LA or RA and then draw an ROI. See Figure 15.

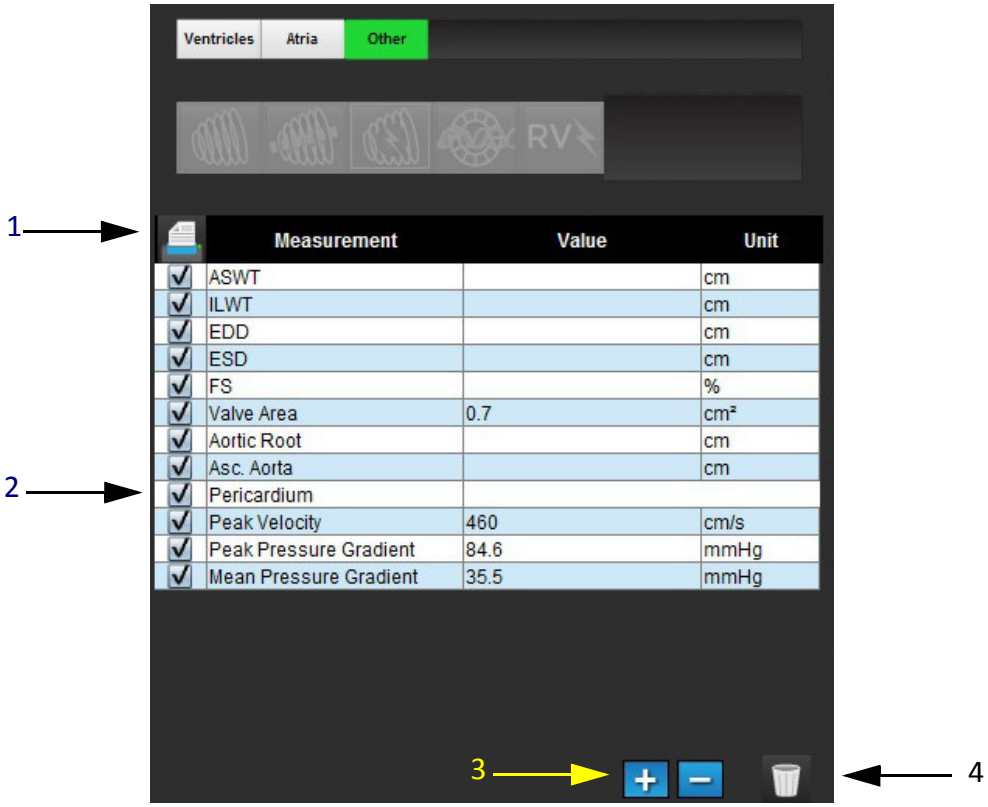
FIGURE 15. Atrial Measurement

Measurement	LA	RA	Unit
EF			%
EDVI			ml/m²
ESVI			ml/m²
EDV			ml
ESV			ml
Atrial Dimension			cm
Atrial Area			cm²

Linear Measurements

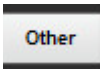
The application allows for the reporting of linear measurements. Tool tips are available by placing the cursor over the measurement listed on the table.

FIGURE 16. Linear Measurements



1. Print Option, 2. Type-in Field for Pericardium, 3. Add/Remove Custom Measurement, 4. Reset all Measurements

Linear Measurement Set-up

1. Select  .
2. Select the series.
3. Click 

button.
4. Locate the image with the anatomy to be measured.
5. Click the desired measurement from the Measurement table, which will turn the measurement green to indicate the selection is active.

CAUTION: Accurate placement of the line is critical to measurement results. Misdiagnosis may occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

6. To edit, click on annotation and when the color changes from green to purple it is active. Place the cursor over one of the endpoints and adjust the endpoint.

   The measure distance value updates accordingly in the Measurements table when you move the cursor outside of the Image Editor window.

   Place the cursor over the center marker to move the entire measure distance line to another location.

NOTE: To reset the measurement, select the measure distance line and access the right mouse menu and select Delete; or use the Delete key on the keyboard.

Reset Measurements

Select  to reset all measurements.

Add Custom Measurement

1. Select  .
2. Enter a unique label in the **Add Custom Measure pop-up window**.
3. Select the **measurement type** as either **Linear** or **Area**.
4. Select **OK**.

Remove Custom Measurement

1. Select the  .
2. Select the custom measurement(s) to be removed from list.
3. Select **Select**.

NOTE: Custom measurements created will be present for all future analysis until removed from the listing.

Valve Plane Analysis

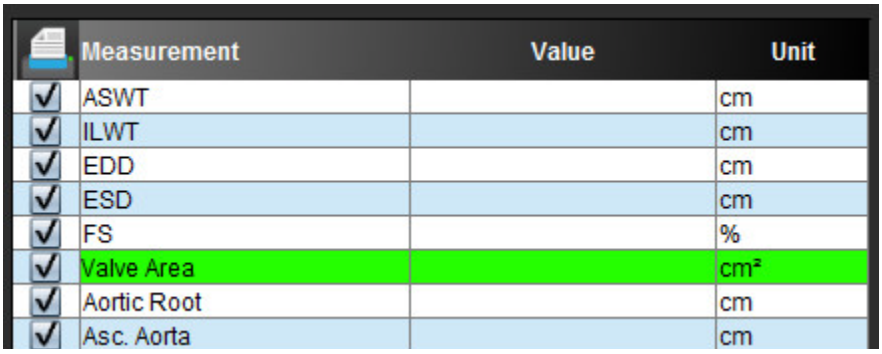
The valve plane analysis feature allows for the calculation of valve peak velocity, peak pressure gradient and mean pressure gradient for the valve.

Using the results from the LV auto segmentation, the pressure gradient is computed from the cardiac output, based on the frame-by-frame changes in left ventricular systolic volume.

Valve Plane Analysis Procedure

1. Perform LV auto segmentation (see page 52).
2. Select a series that demonstrates valve anatomy.
3. Select **Valve Area** from the measurement table Figure 17 and perform planimetry of the valve as shown in Figure 18.

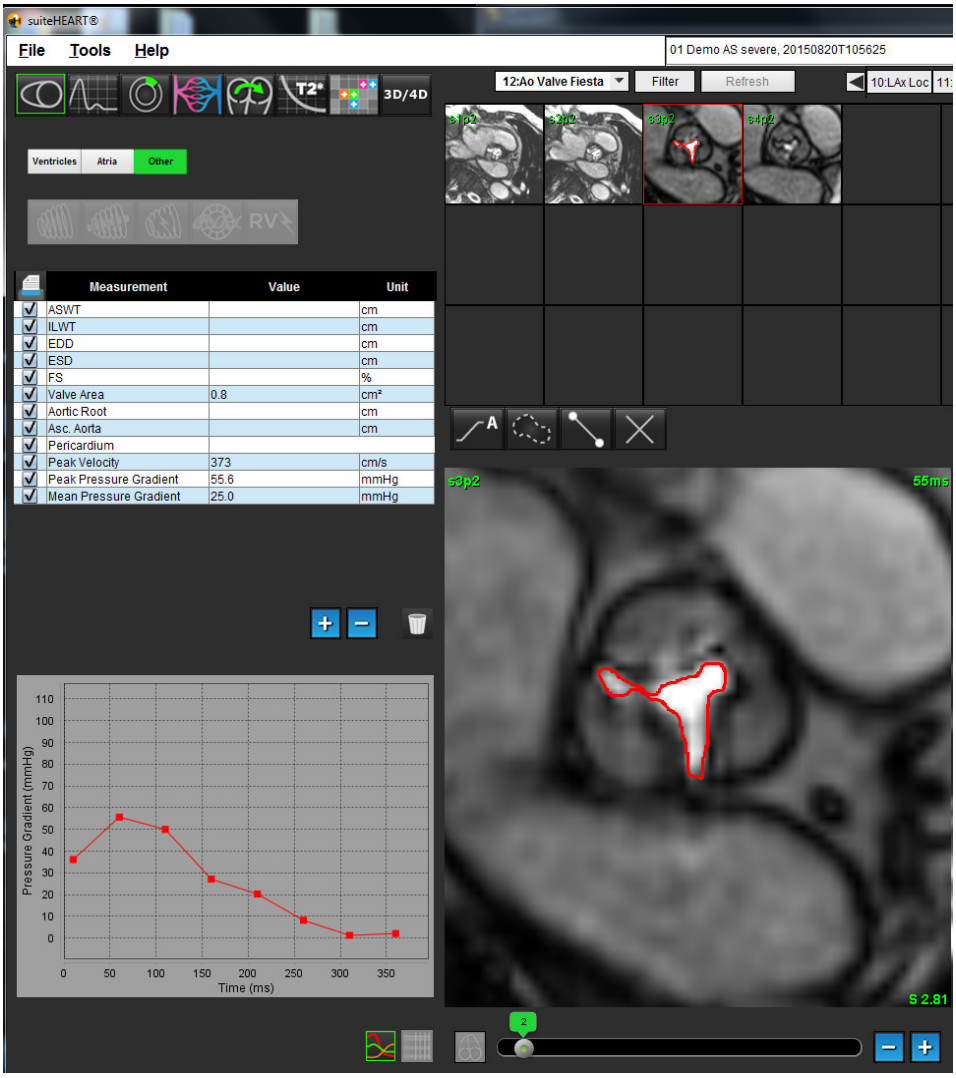
FIGURE 17. Valve Area



Measurement	Value	Unit
ASWT		cm
ILWT		cm
EDD		cm
ESD		cm
FS		%
Valve Area		cm^2
Aortic Root		cm
Asc. Aorta		cm

4. Upon completion of the ROI, the table will update with the results and present a graph showing the pressure gradient over time.
5. Click  to reset **all** measurements.

FIGURE 18. Valve Plane Analysis



IMPORTANT: It is recommended that you are qualified in performing cardiac analysis, if the analysis results are to be used to reach a diagnosis.

WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

NOTE: Peak Velocity, Peak Pressure Gradient, and Mean Pressure Gradient are not valid in patients with mitral regurgitation or a shunt.

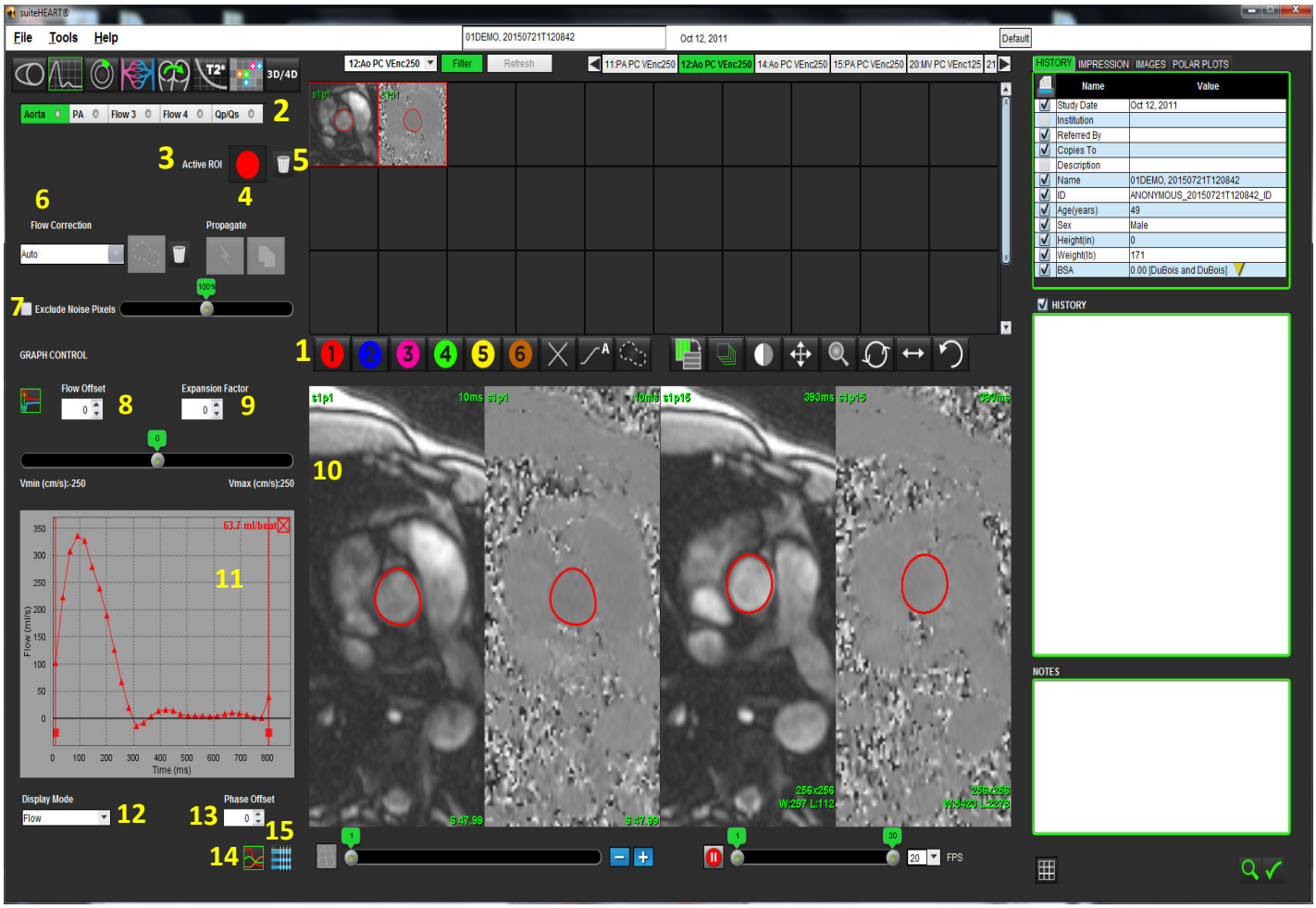
Flow Analysis

The Flow Analysis tool calculates flow and velocity information at various points in the cardiac cycle from 2D Phase Contrast (PC) images with through-plane flow encoding.

WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

Flow Window Components

FIGURE 1. Flow Window

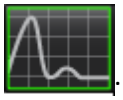


1. Flow Analysis ROIs, 2. Flow tabs, 3. Active ROI, 4. Propagate buttons, 5. ROI reset button, 6. Flow correction drop-down menu,
7. Exclude Noise Pixels, 8. Flow offset, 9. Expansion factor, 10. Venc slider bar, 11. Flow curve results, 12. Display mode, 13. Phase offset,
14. Switch to graph display, 15. Switch to summary table

NOTE: Flow Analysis displays the magnitude and phase images in a side-by-side image display. Other types of images acquired, at the same location, are not displayed and should be viewed in a separate DICOM viewer.

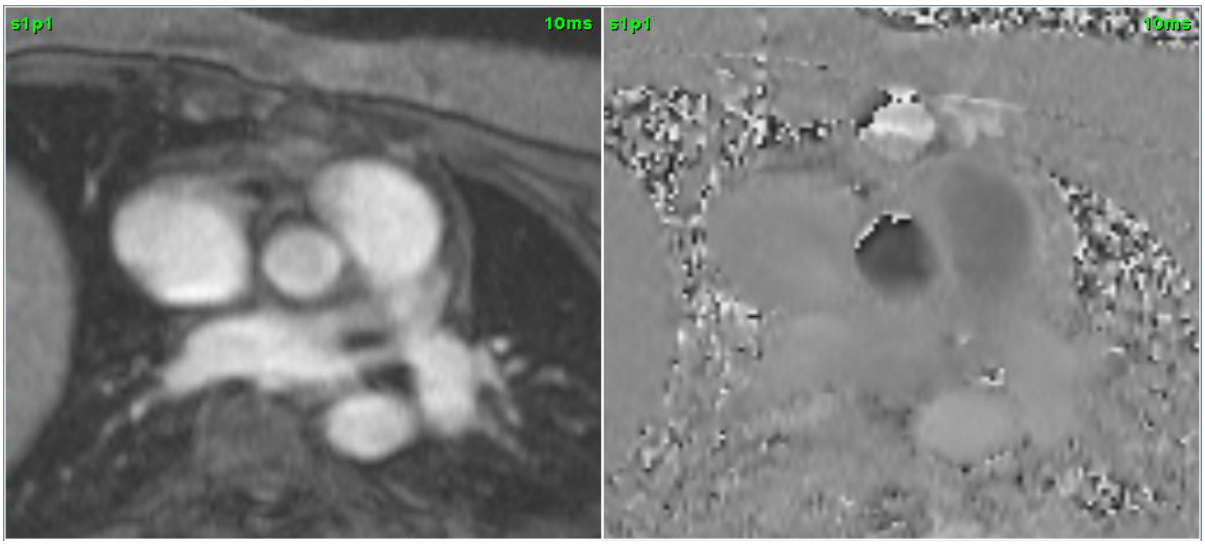
Flow Analysis Procedure

Generate a Flow Curve

1. Select **Flow Analysis Mode**  .
2. Select a phase contrast series.

   The magnitude image is displayed on the left, phase image is on the right.

FIGURE 2. Magnitude and Phase Images



3. Select a **Flow Tab**.

   There are five tabs available; one labeled aorta, one pulmonary artery (PA) and two user defined tabs with default labels of Flow 3 and Flow 4. The Qp/Qs tab allows for reporting of the Qp/Qs ratio.

4. Select  curve 1.

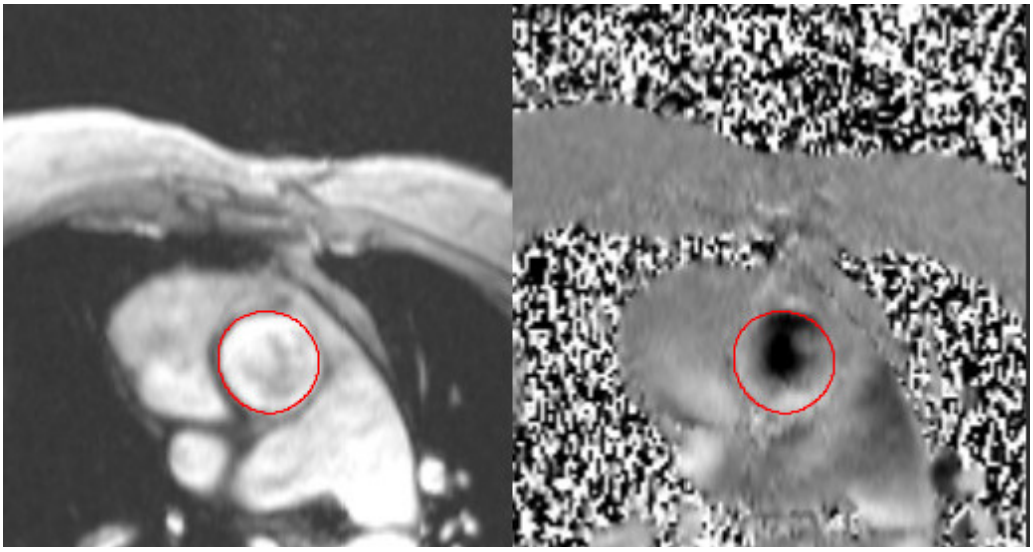
   Six ROIs are available, numbered 1 - 6. The color coding remains consistent across the analysis view, image viewports and graphs.

5. Create a contour around a vessel by depositing 4 points around the vessel of interest and double-clicking at the last point to close the ROI. Alternately, you can move the cursor out of the editor window to close the ROI.

   A manual trace of the vessel can also be performed.

   The contour is created on both the magnitude and phase images, as shown in Figure 3.

FIGURE 3. Flow ROIs



6. To perform automatic segmentation over all phases within the slice, select one of the propagation methods:

   - Choose  for automatic segmentation over all phases in the slice.

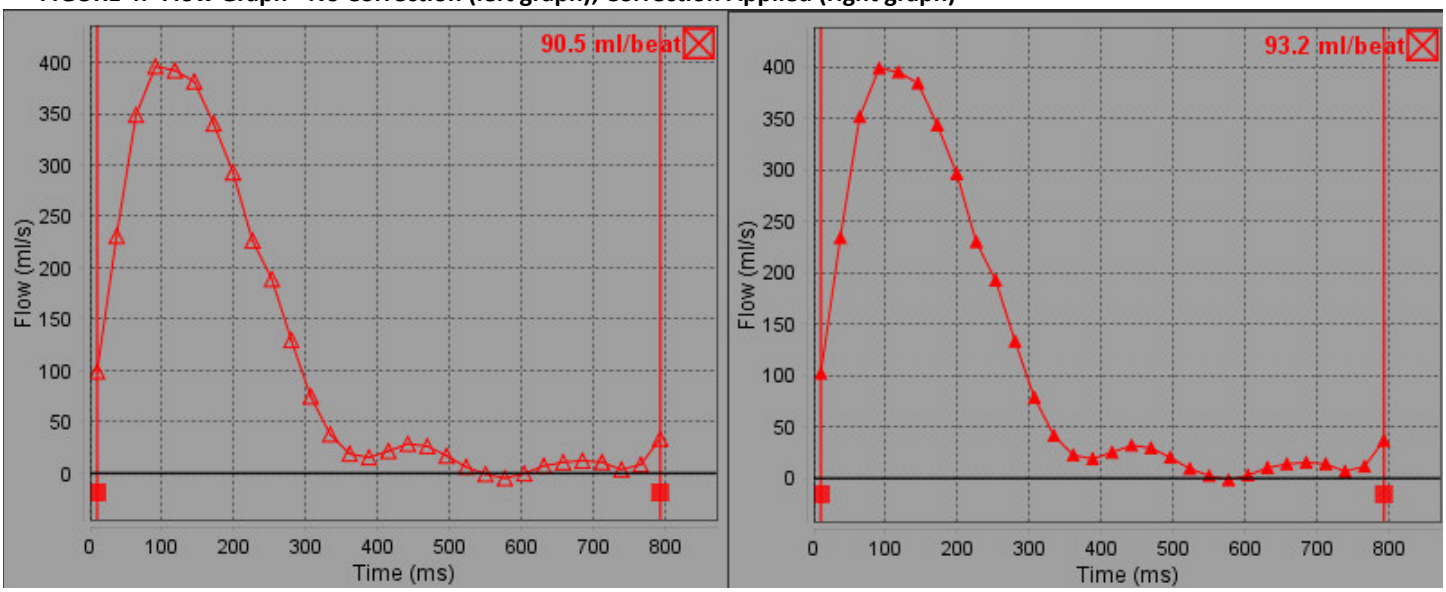
   or

   - Choose  to propagate the same contour over all phases in the slice. This is useful when analyzing small, stationary vessels.

7. Flow results are displayed on the graph and summary tables.
   - Click the check box beside the ml/beat rate to remove the associated curve from the graph. This does not change the calculations. It only removes the curve from the graph.

8. Select a Flow Correction option from the file pull-down.
   - Curves with a Flow Correction applied will have solid phase data points, as shown in Figure 4. Refer to “Flow Correction Options” on page 74.

FIGURE 4. Flow Graph - No Correction (left graph); Correction Applied (right graph)



9. Select  to invert the curve.

   NOTE: All flow curves generated are displayed in a positive direction. Inverted curves are indicated by the active invert button.

10. Select a Phase Offset to change the ordinate of the flow curve.
11. Select any point on the graph to locate the corresponding phase image.
12. Adjust the vertical cursor for the start and end points, as necessary.
13. Review the accuracy of the contours.

Flow Correction Options

There are three flow baseline corrections methods for 2D phase contrast. Flow curves that have a correction method applied will have solid phase data points.

NOTE: Phase contrast images that are used for analysis should not have image phase wrap. Phase wrap present in the image will cause inaccurate flow results.

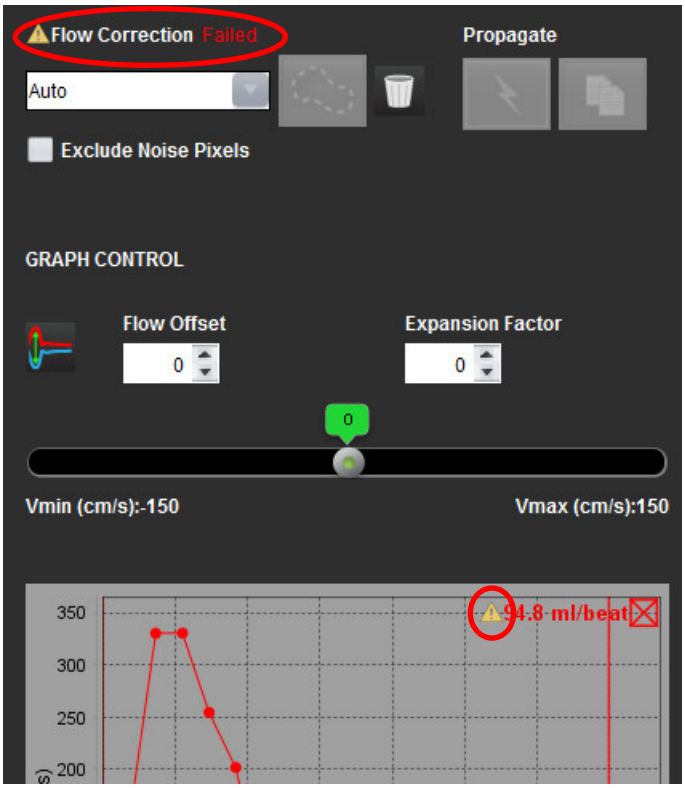
Auto Phase Error Correction

The Auto baseline phase error correction corrects for phase errors that occur during image acquisition by examining the phase error in distant stationary organs (e.g., chest wall, liver, etc.) and spatially fitting the data using linear or higher order interpolation.

NOTE: If a 2D magnitude and phase series is created by using the 3D/4D viewer, the application will create an uncorrected series and a second series to which phase error correction has been applied. Do not apply Auto from the flow correction pull-down to the series labeled “Corrected.”

1. Generate a flow curve using the appropriate phase contrast series.
2. Select **Auto** from the Flow Correction pull-down.
3. The correction will be applied with the updated results displayed directly on the flow graph.
4. Series which fail the fitting analysis will be indicated by a warning symbol, as shown in Figure 5.

FIGURE 5. Auto Flow Correction Failure



Phantom Correction

To improve the accuracy of phase contrast results and to correct for baseline phase shift errors, a phantom acquisition can be used to calculate this error.

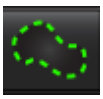
NOTE: The phantom correction series must have been acquired with the same scan prescription and parameters as the original phase contrast series. There must be signal from a stationary object filling the entire contour on the phantom series.

1. Generate a flow curve using the appropriate phase contrast series.
2. Select the corresponding phantom series from the Flow Correction pull-down.
3. The correction will be applied with the updated results displayed directly on the flow graph.

Background Contour Correction

This correction method can be considered for vessels that are surrounded by static tissue.

NOTE: For optimal correction the background contour must be placed in static tissue directly adjacent and surrounding the region of flow.

1. Generate a flow curve using the appropriate phase contrast series.
2. Select the **Background ROI** from the Flow Correction pull-down.
3. Click  to draw a contour.
4. The correction will be applied with the updated results displayed directly on the flow graph.

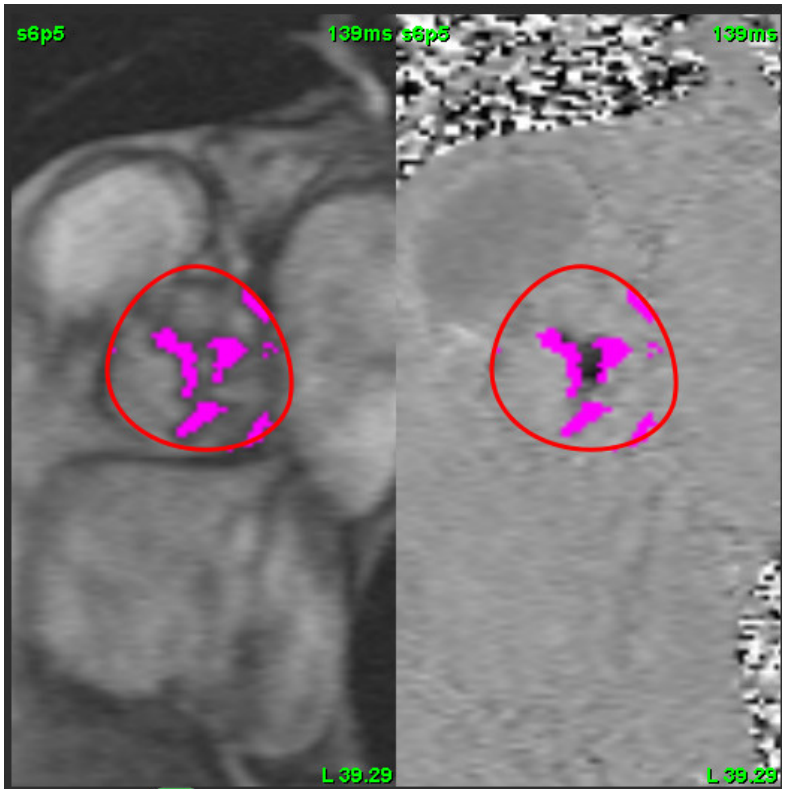
Flow Curve Options

Exclude Noise Pixels

This option identifies low intensity pixels (high fluctuation of velocities) if present within the ROI, identified by the pink overlay as shown in Figure 9 and excludes them from the flow calculation. Click the check box to apply this option. The percentage of noise pixels can be adjusted by the slider bar.

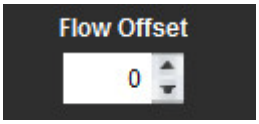
FIGURE 6. Noise Pixels

FIGURE 7. Noise Pixels Identified by Pink Overlay



Flow Offset

Flow offset changes the abscissa value of the flow curve which changes the baseline values of the flow result.

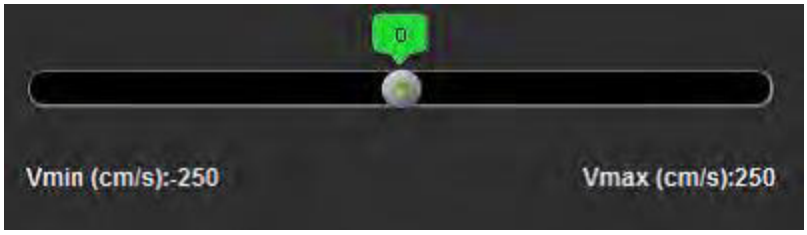


Expansion Factor

The expansion factor uniformly changes the radius of the segmented vessel by a specified pixel amount to include valid flow pixels.

Velocity Aliasing Correction

To correct for velocity aliasing, drag the slider bar control button to perform phase unwrapping. The effect of the change will be updated directly on the phase image and the results displayed directly on the flow graph.



Contour Editing

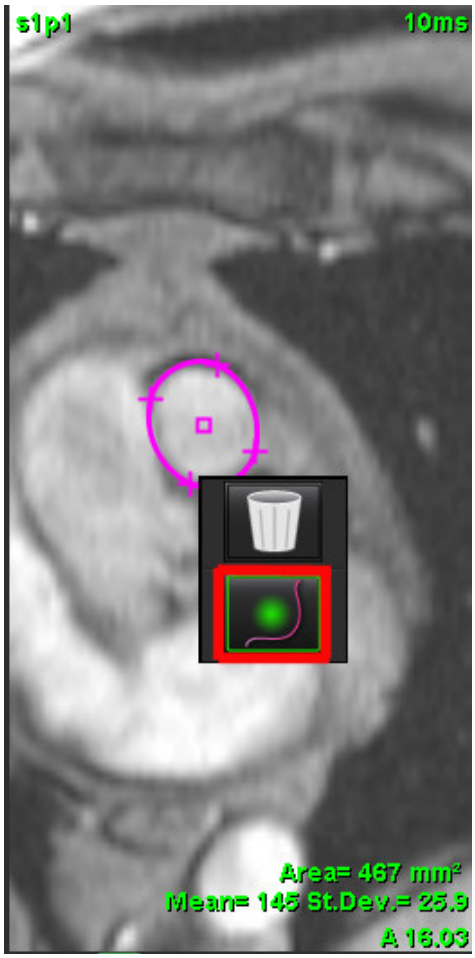
Contours can be edited one phase at a time or for a range of phases.

Editing a single phase

1. Select the desired phase to edit.
2. Click on the contour to activate it for editing.

   The contour will turn purple indicating it can be edited.
3. Edit the contour by moving the points for point spline contours or by drawing on the image with the left mouse button depressed for free hand or computer generated contours.
4. To activate the nudge tool, left mouse click on the contour to select it. Then right mouse click and select the nudge tool from the pop-up menu, as shown Figure 8. For more information, refer to "Editing Contours" on page 41.

FIGURE 8. Nudge Tool



Editing a range of phases

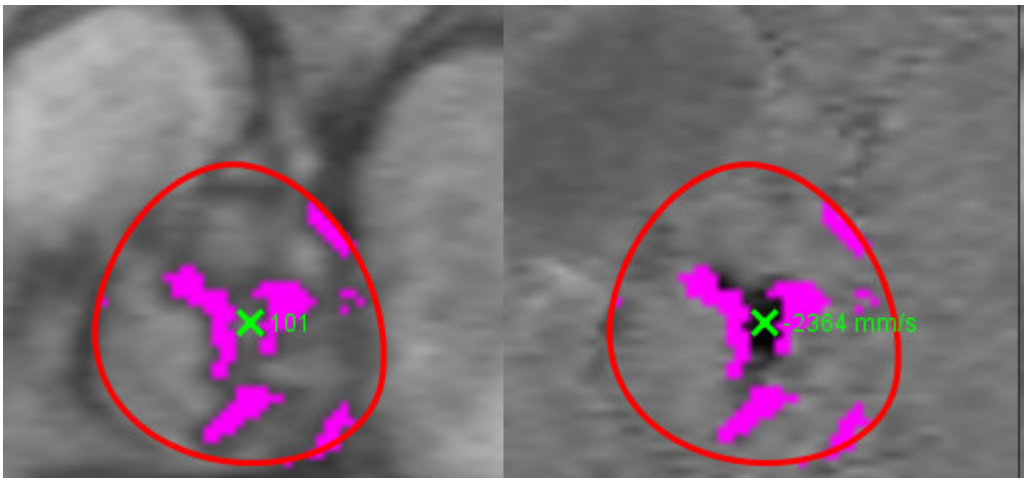
1. Select the desired slice.
2. Select  to display thumbnails of all the phases of a given slice.
3. Select the first phase of the range of phases to be edited.
4. Depress and hold the shift key and select the last phase of the range to be edited.
5. Edit the contour in the image editor window.
6. Deselect the contour by either clicking on the image away from the selected contour or by moving the cursor out of the editor window.

User Defined Peak Velocity

1. Select the appropriate phase of the cardiac cycle.
2. Use  to position the cursor on the phase image.

   The cursor is synchronized with both the magnitude and phase images. The velocity result appears in mm/s on the phase image next to the cursor.

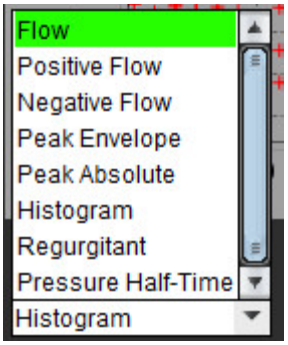
FIGURE 9. Pixel Flow Velocity



Display Modes

Select the desired **Display Mode** from the drop-down menu (Figure 10).

FIGURE 10. Display Mode Menu



Flow Display Mode Definitions:

Flow: This graph displays a plot that represents the flow volume of each phase in the entire cardiac cycle (default). Each point on the curve represents flow for that phase.

Positive: This graph displays the sum of the positive flow area over the cardiac cycle.

Negative: This graph displays the sum of the negative flow area over the cardiac cycle.

Peak Envelope: This graph displays a plot of peak positive and negative velocities for each phase of the cardiac cycle.

Peak Absolute: This graph displays a plot of absolute peak velocity for each phase.

Histogram: This graph displays a plot of the velocity of each pixel within each region of interest for every phase of the cardiac cycle.

Regurgitant: The Regurgitant Fraction (%) is the quotient of the negative flow divided by the total positive flow.

Pressure Half-Time (PHT): The time it takes for the peak transmitral pressure gradient to decrease by half.

Histogram Mode

Select histogram mode to display a plot of velocities per pixel.

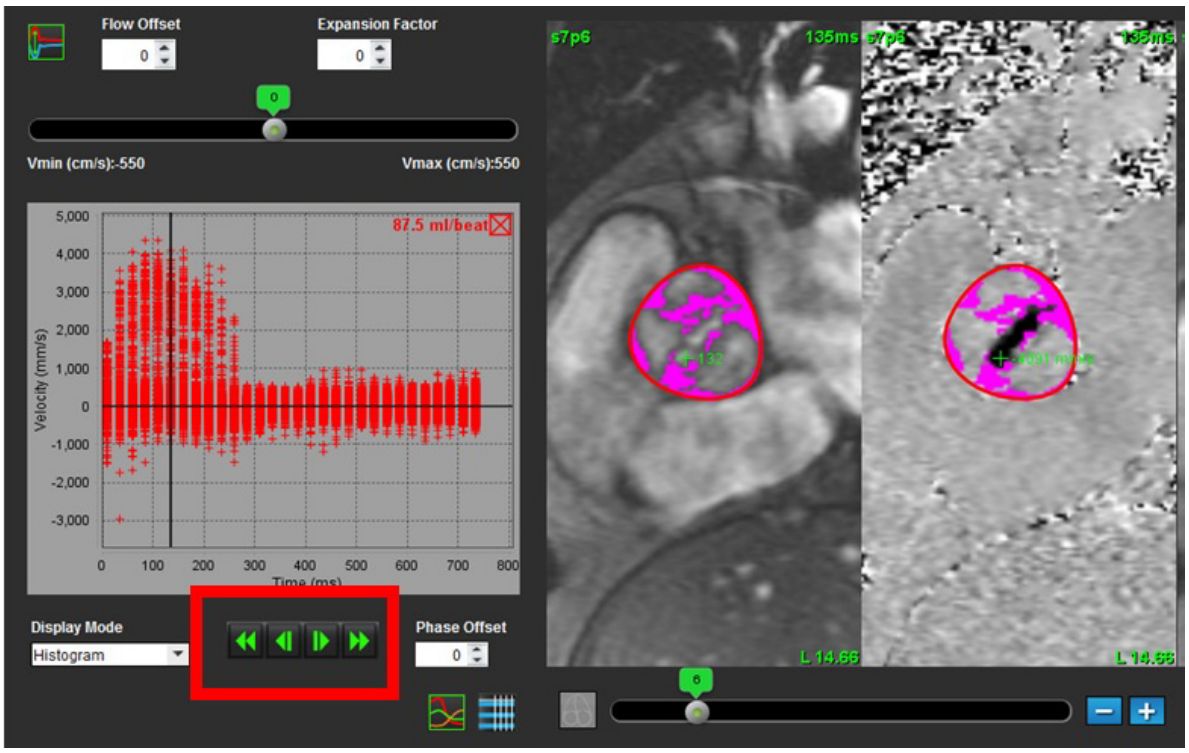
1. Generate a flow curve using the appropriate phase contrast series.
2. From the Display Mode pull-down menu, select **Histogram**.
3. Click directly on the graph to activate a cross hair cursor on the phase image, which indicates the corresponding location of that pixel.
4. Use the double arrow controls at the bottom of the graph to locate the highest or lowest velocity value, (Figure 11.)
5. Use the single arrow controls to increment discretely through the velocity values, as shown in Figure 11.

NOTE: The series locate functionality, when clicking directly on the flow curve, is disabled when in histogram mode. Switch to flow mode to enable the locate functionality.

NOTE: To ensure that the corresponding magnitude and phase image are displayed, work with one flow curve at a time, deselect the other histogram curves from the graph display.

NOTE: Studies analyzed using histogram mode with a previous version of suiteHEART® Software will need to be reanalyzed.

FIGURE 11. Histogram Mode

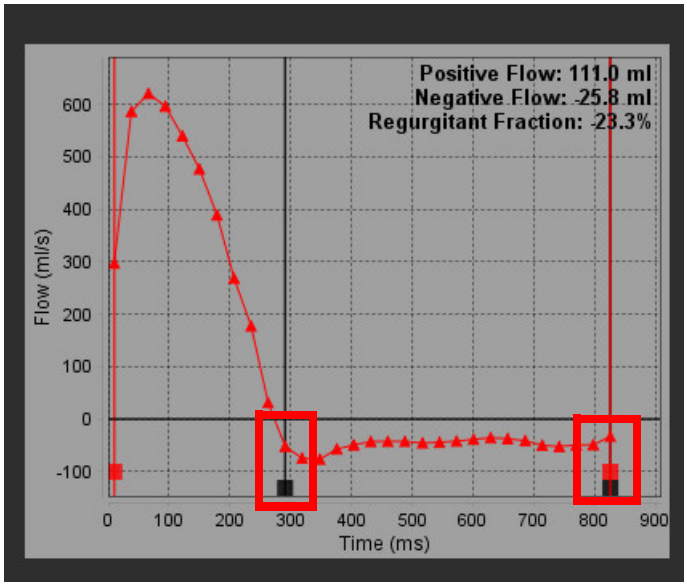


Regurgitant Mode

Select Regurgitant mode to calculate the negative flow and regurgitant fraction.

1. Generate a flow curve using the appropriate phase contrast series.
2. From the Display Mode pull-down select **Regurgitant**.
3. Click on the black vertical cursors and identify the start and end of the retrograde flow as shown in Figure 12.
   The results will then appear in the upper right hand corner of the flow graph display.

FIGURE 12. Regurgitant Results

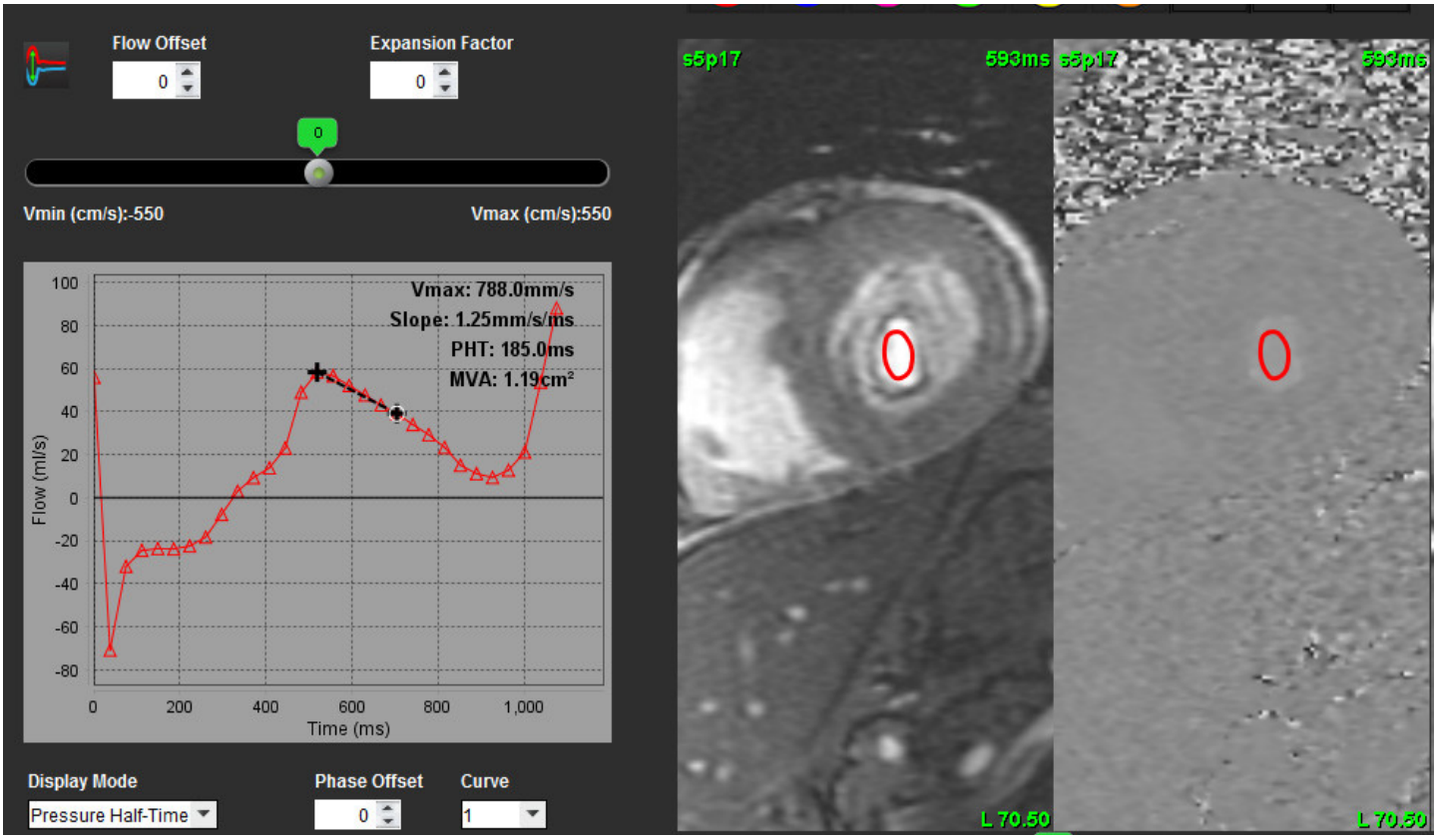


Pressure Half-Time

The Pressure Half-Time (PHT) can be obtained by measuring the deceleration slope of the E-wave on phase contrast images acquired of the mitral valve. This mode allows for the identification of slope of the graph to calculate the PHT and mitral valve area (MVA).

1. Generate a flow curve using the appropriate phase contrast series of the mitral valve.
2. For the ROI propagation use the copy paste option.
3. From the Display Mode pull-down menu, select **Pressure Half-Time**.
4. Click directly on the plot to identify the highest velocity of the deceleration portion of the curve.
5. Click an end point to calculate the slope of the curve as shown in Figure 13.

FIGURE 13. Pressure Half-Time Graph



NOTE: Mitral Valve area (MVA), Pressure Half-Time (PHT) results are not valid in patients with aortic insufficiency, cardiac shunt or decreased ventricular compliance.

NOTE: The series locate functionality, when clicking directly on the flow curve, is disabled when in PHT mode. Switch to flow mode to enable the locate functionality.

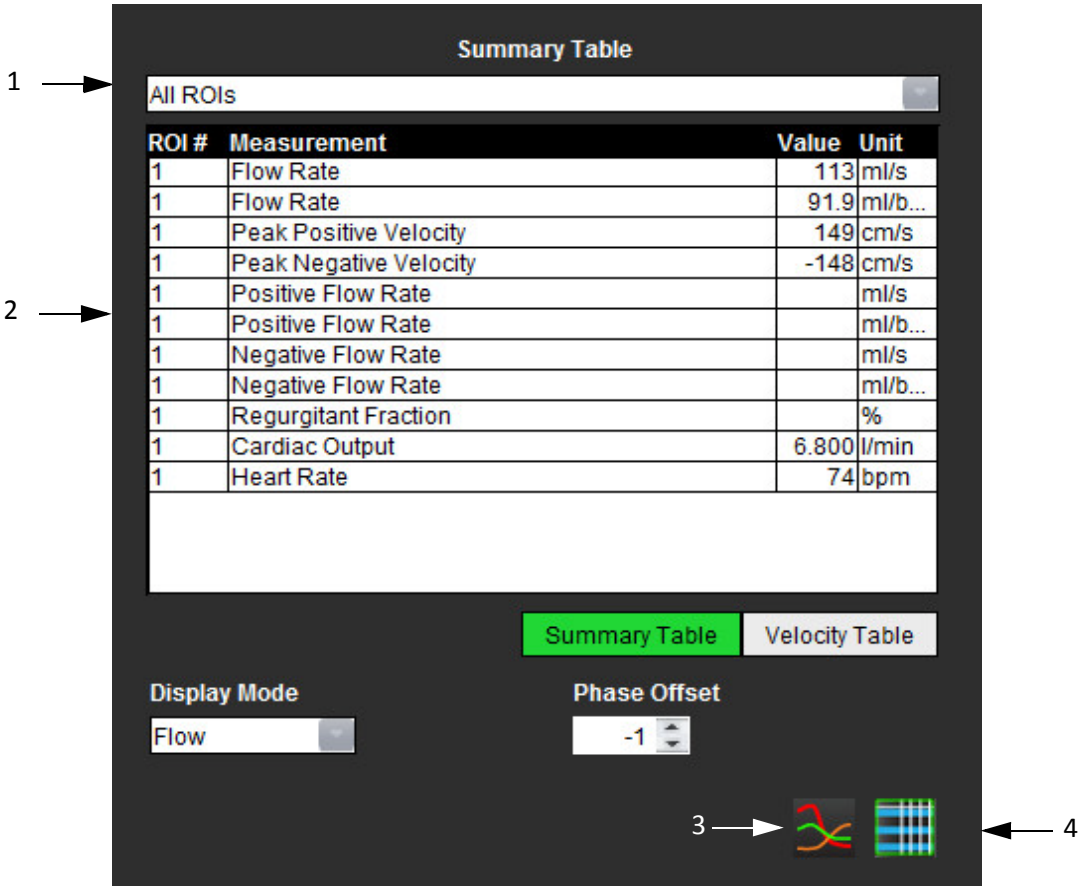
NOTE: To ensure that the corresponding magnitude and phase image are displayed, work with one flow curve at a time and deselect the other histogram curves from the graph display.

Reference:

http://www.csecho.ca/wp-content/themes/twentyelevencsecho/cardiomath/index.php?eqnHD=echo&eqnDisp=mvapht

Review Summary Tables

FIGURE 14. Summary Table



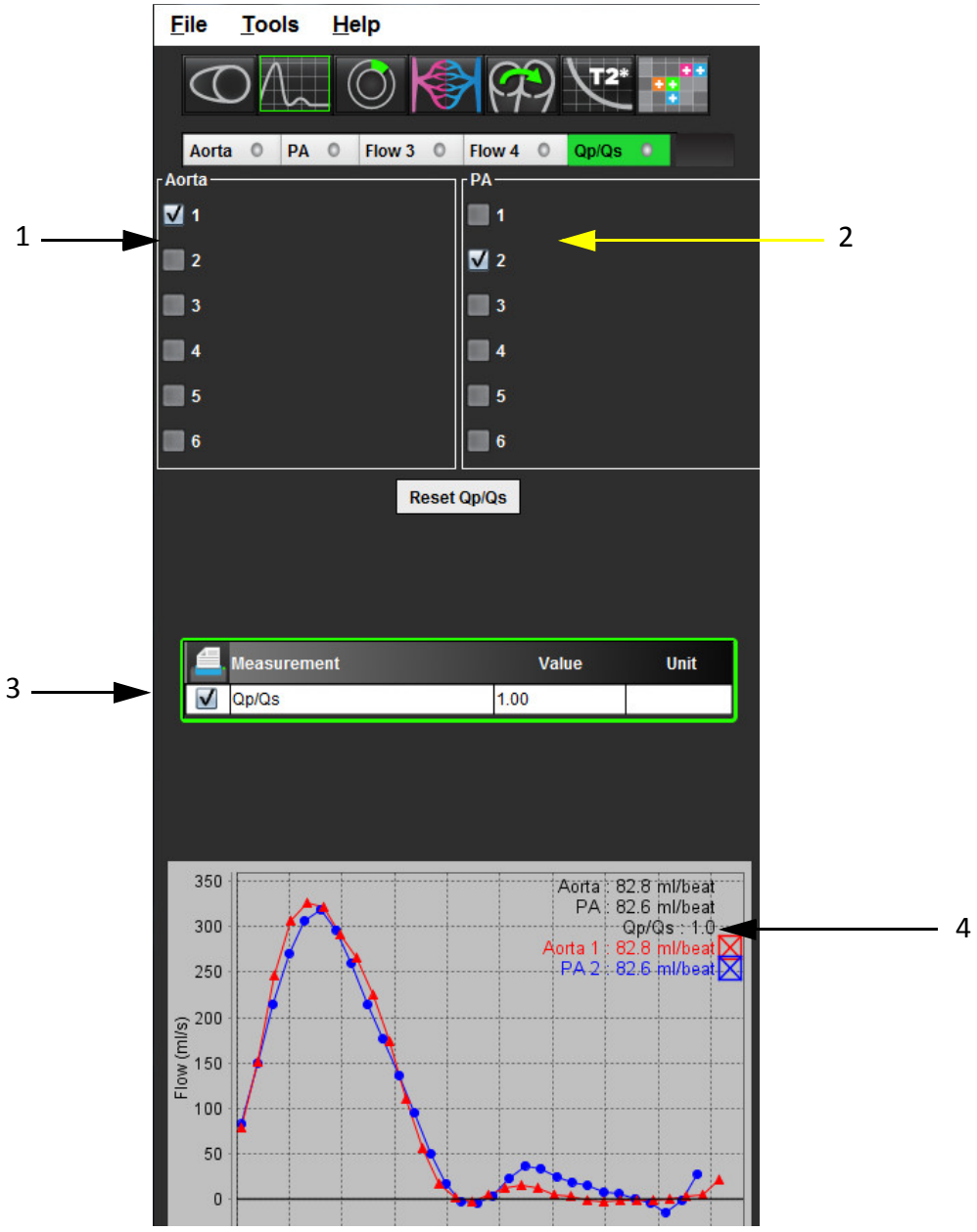
1. ROI drop-down menu, 2. Flow Results, 3.Graph icon, 4.Summary/Velocity Table icon.

1. Select **All ROIs** from the drop-down menu to include the values of all the curves in the tables.
2. Select  to view the summary table or velocity table.
3. Select  to toggle between summary and velocity table.
4. Select  to view the flow curves.

Qp/Qs Tab

The Qp/Qs reporting window differs from the layout of the vessel flow tabs reporting windows.

FIGURE 15. Qp/Qs Reporting Window



1. Aorta curve, 2. Pulmonary artery curve, 3. Qp/Qs measurement, 4. Flow curves

Calculate Qp/Qs

NOTE: Flow curves must be generated on the appropriate series for the aorta and pulmonary artery prior to Qp/Qs calculations.

1. Select at least one aorta curve.
2. Select at least one pulmonary artery curve.

   The Qp/Qs measurements are calculated automatically when both the aorta and pulmonary artery contours are selected. All contour selections affect the calculations. All the flow curves are displayed on the graph. Curves can be selected or deselected at any time.

   Deselecting the display of any curve on the graph does not affect the calculations.

   The system will average the values if more than one Aorta or PA is selected.
3. Select **Reset Qp/Qs** to reset the graph and all calculations on this tab, if desired.

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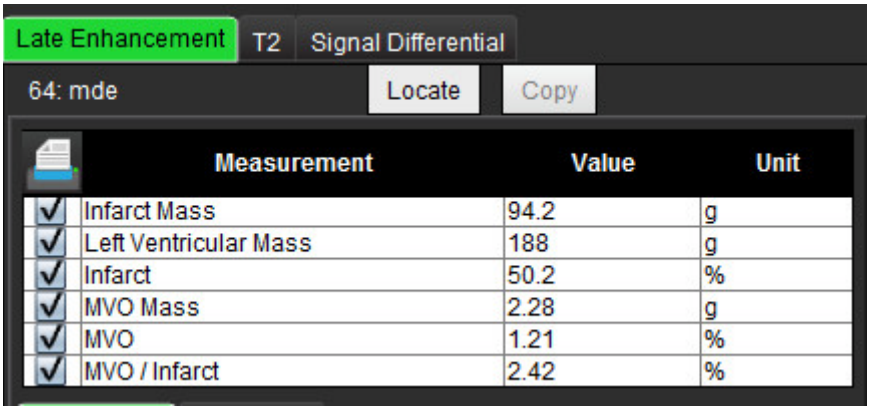
Myocardial Evaluation

The Myocardial Evaluation (ME) analysis tool aids in the quantitative determination of areas of different signal intensities within the myocardium.

There are three analysis tabs available:

- Late Enhancement - Determines myocardial segments of increased and low signal intensity.
- T2 - Determines myocardial segments of increased signal intensity from black-blood imaging techniques.
- Signal Differential - Displays the Salvage Mass results using both late enhancement and T2 analysis and the T2 signal intensity (SI) ratio.

FIGURE 1. Analysis Tabs

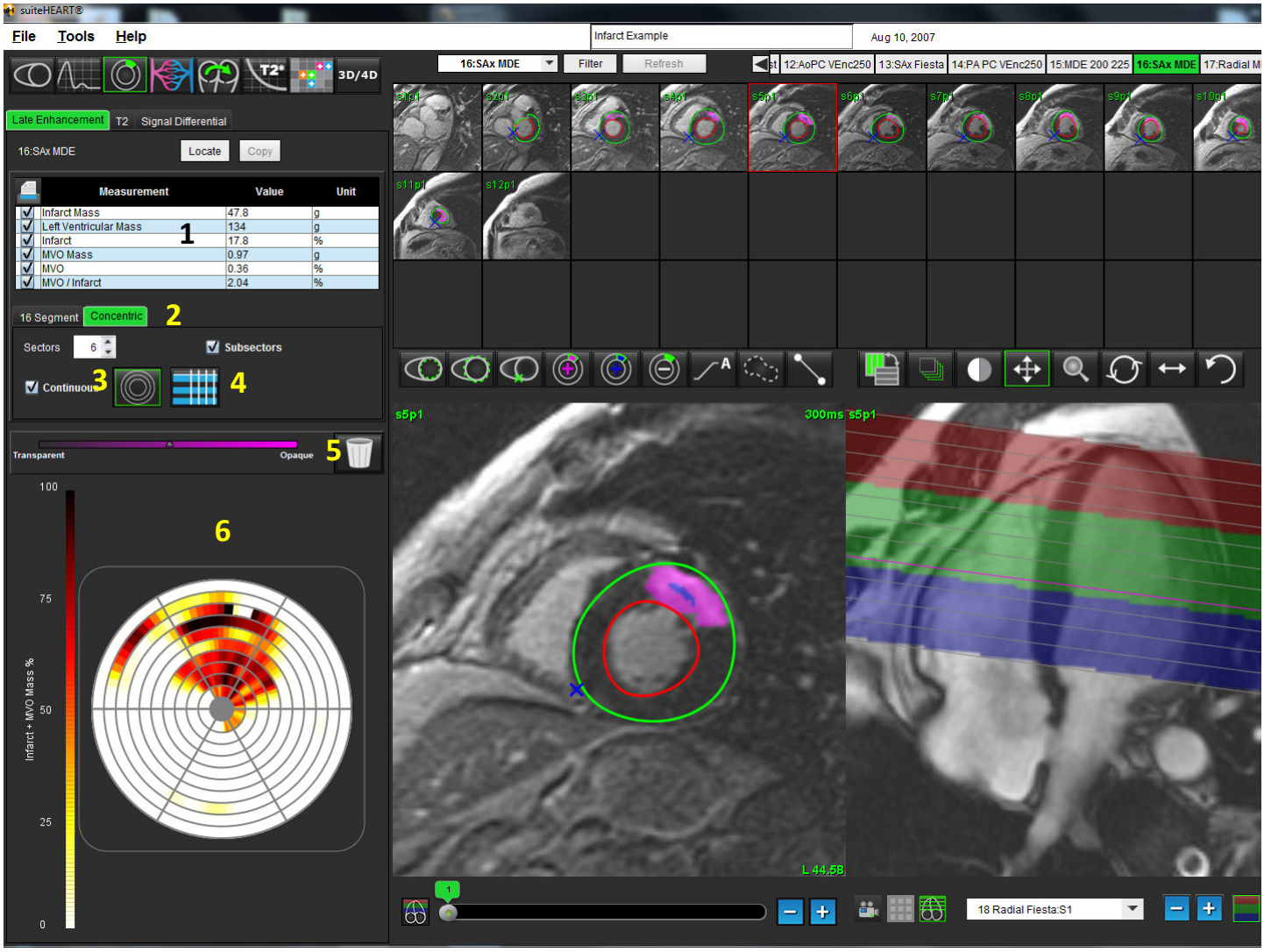


WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

Late Enhancement

1. Select  .
2. Select Late Enhancement tab.
3. Select the appropriate short axis series.

FIGURE 2. ME Quantitative Analysis Reporting Window



1. Result table, 2. Polar Plot type, 3. Polar Plot section, 4. Table section, 5.Reset, 6. Quantitative Polar Plot

4. Trace the LV endocardium on the most basal slice by selecting  .
5. Trace LV epicardium by selecting  .
6. Mark inferior RV insertion site with  .
7. Move the cursor outside of the editor window to complete the ROI.
8. Repeat steps 4 - 7 until the entire ventricle is segmented.
9. Click the Slice Classification  button to open the controls for adjusting the thresholding for each slice. Pixels are identified using a Full Width Half Max (FWHM) algorithm. Confirm the base, mid and apical classification.

Threshold Editing

1. To add high signal intensity regions select  .
2. To add low signal intensity regions select  .
3. To delete either signal intensity regions select  .

Polar Plot Display Formats

The ME analysis tool provides 2 polar plot formats: 16 Segment and Concentric

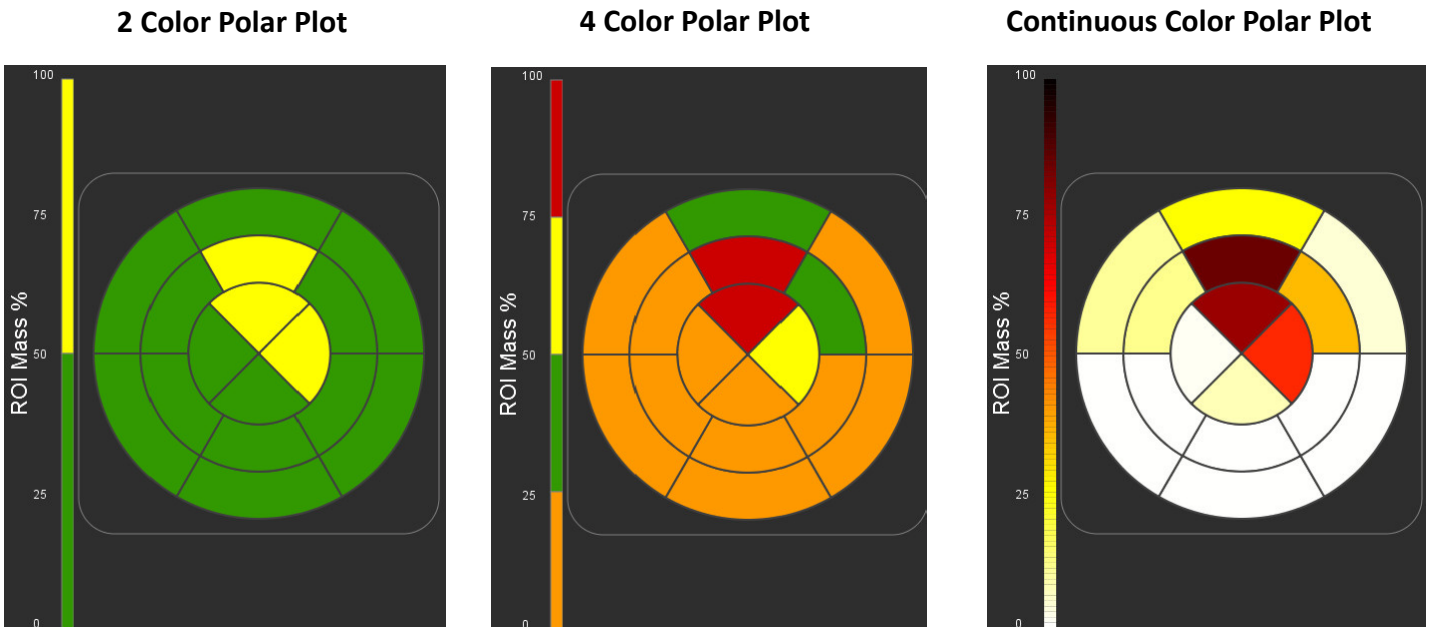
Option 1: 16-segment procedure

1. Select the **16 Segment** tab 

.
2. Select 2 Color, 4 Color, or Continuous.

   Color assignments can be defined by clicking on the color scale bar.

FIGURE 3. Polar Plots

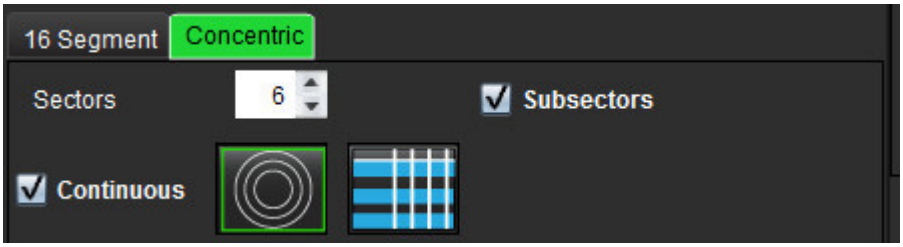


3. Select  to display the Polar Plot Summary Table.

Option 2: Slice by Slice format

1. Select the **Concentric** tab.

FIGURE 4. Concentric Tab



The Concentric tab provides the preferences that change the format of the Polar Plot to a slice-by-slice format, where each ring represents a slice. The number of rings is determined by the number of slices analyzed.

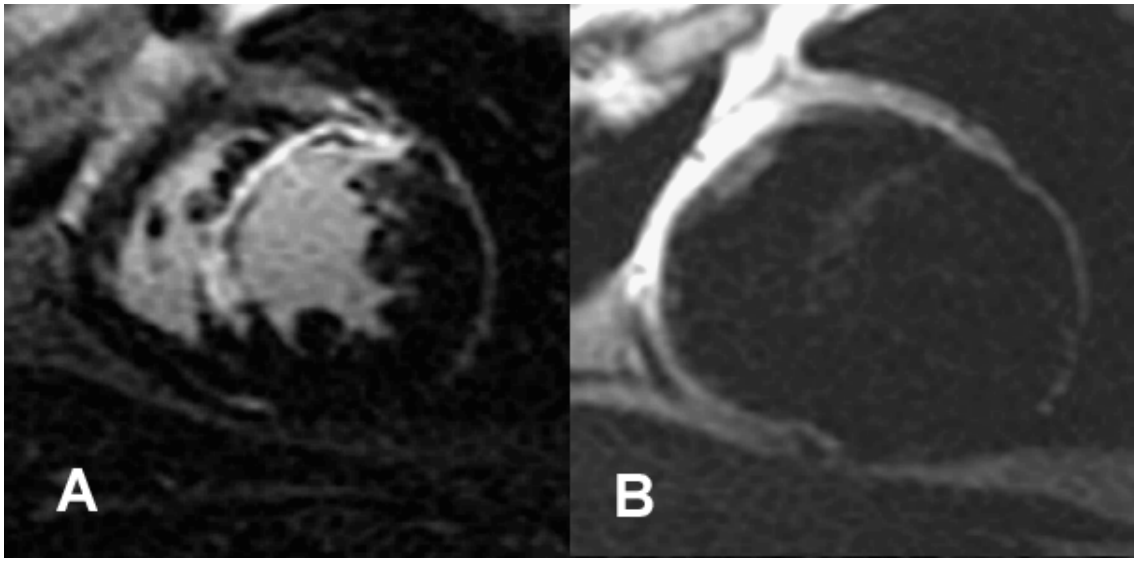
2. Select the number of sectors.
3. Check the subsectors to show the ROI mass percent changes within the sector.

   A smoothing function is applied when subsectors is selected.
4. Click the **Continuous** check box to change the Polar Plot to percent signal intensity and color code the values on a continuous spectrum from 0-100%.

Select  to reset the analysis.

NOTE: The semi-automatic thresholding for late enhancement analysis works optimally on high quality myocardial evaluation images as shown below (Image A). In images acquired without signal from the blood pool (Image B) or incorrect Inversion time, the threshold will need to be subjectively set by the user.

FIGURE 5. Myocardial Evaluation Images

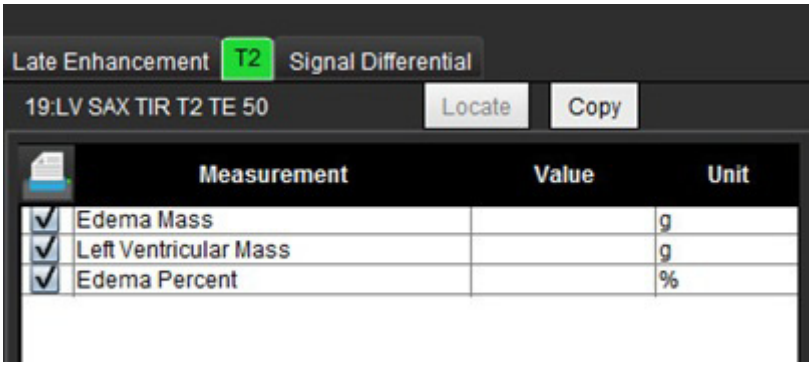


T2 Analysis

1. Select the T2 tab.
2. If the late enhancement series has been previously analyzed, the ROIs can be copied to the T2 series by clicking the copy button (see Figure 6).

NOTE: To copy ROIs it is required that the number of slices match for each series to get accurate results; if the number of slices does not match, the copy button will not be available. The DICOM import process can be used to create the appropriate series that contains the same number of slices.
Acquisition parameters, such as matrix and FOV, should be the same for each series for best results. After performing a copy, review the ROIs carefully on all of the slice locations and make appropriate edits.

FIGURE 6. Location of Copy Button



3. If there is no previous late enhancement analysis, the ROIs can be created manually.

4. Trace the LV endocardium on the most basal slice by selecting  .

5. Trace the LV epicardium by selecting  .

6. Mark the inferior RV insertion point by selecting  .

7. Move the cursor outside of the editor window to complete the ROI.

8. Repeat steps 4-7 until the entire ventricle is segmented.

9. To perform a 2 Standard deviation thresholding, select the Add Normal Region ROI  and place ROI in a normal segment. This ROI is copied to all of the images. Review each slice location and adjust the ROI as necessary.

   NOTE: When the skeletal muscle ROI and Normal ROI are provided, the software performs the following calculation:
   Normalized myocardial T2 SI = SI myocardium / SI skeletal muscle;
   Threshold calculation: Threshold = 2 * STD NORMAL + AVG NORMAL

10. Click the Slice Classification  button to open the controls for adjusting the threshold results. Confirm the base, mid and apical classifications.

11. To perform T2 Signal Intensity analysis, select the Add Skeletal muscle ROI  and place an ROI in the skeletal muscle. This ROI is copied to all of the images. Review each slice location and adjust the ROI as necessary.

12. The Locate button will update the viewer with the appropriate series used for the selected analysis.

    NOTE: Black-blood images may have insufficient flow suppression which could result in inaccurate signal intensity analysis and thresholding.

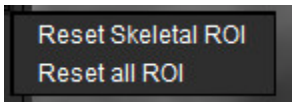
Threshold Editing

To add regions of high T2 signal intensity, select  .

To remove regions of high T2 signal intensity, select  .

Select  to reset the analysis as shown in Figure 7.

FIGURE 7. Reset ROI Menu



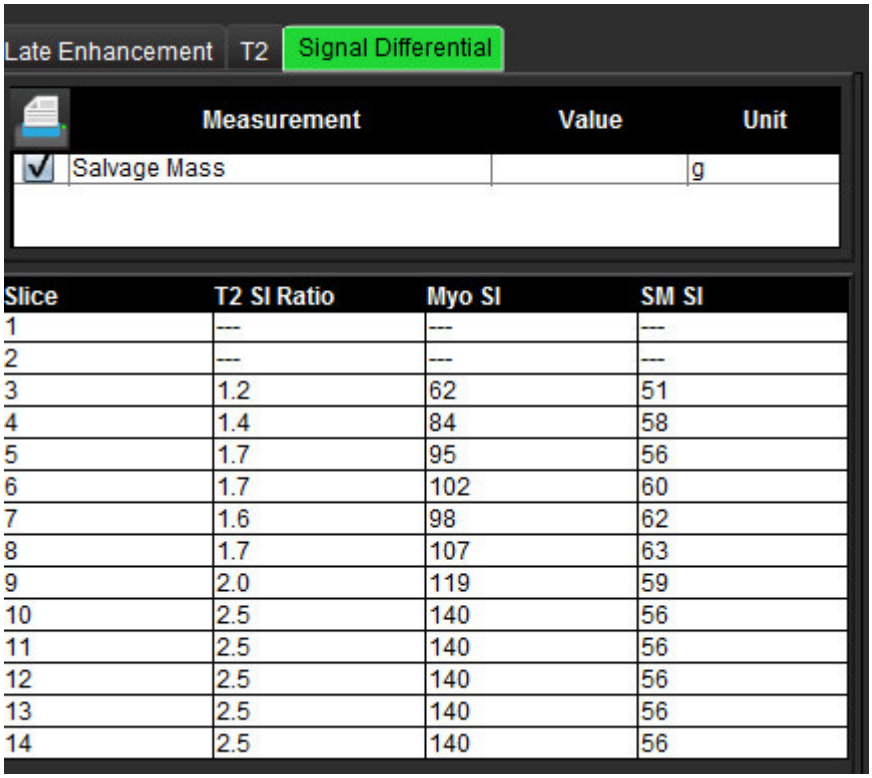
Signal Differential Results

Select the Signal Differential Tab

NOTE: Late enhancement and T2 analysis must be completed to obtain the Salvage Mass Results. The T2 analysis must be completed with the placement of the Skeletal muscle ROI for T2 Signal Intensity (SI) analysis.

NOTE: If the T2 (Edema) result is less than the Late Enhancement result (Infarct + MVO) the Salvage Mass result will be blank.

FIGURE 8. Signal Differential Tab



Slice	T2 SI Ratio	Myo SI	SM SI
1	---	---	---
2	---	---	---
3	1.2	62	51
4	1.4	84	58
5	1.7	95	56
6	1.7	102	60
7	1.6	98	62
8	1.7	107	63
9	2.0	119	59
10	2.5	140	56
11	2.5	140	56
12	2.5	140	56
13	2.5	140	56
14	2.5	140	56

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Time Course Analysis

The Time Course analysis tool allows the user to review and analyze myocardial time course images.

NOTE: Time Course results may not be accurate on images that are not surface coil intensity corrected.

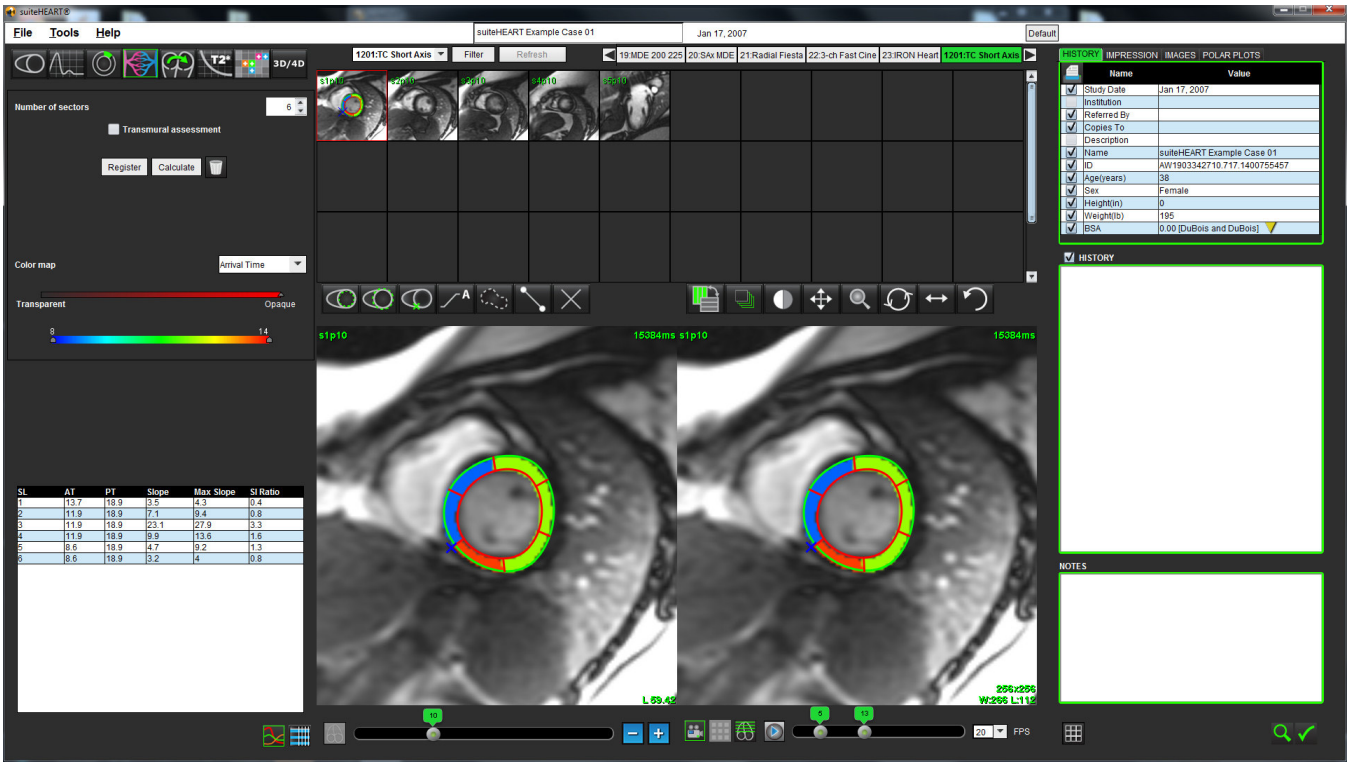
WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

Launch Time Course

Time Course Quantitative Procedure

1. Select  .
2. Select a myocardial time course series.

FIGURE 1. Time Course Analysis Window



Define Endocardial and Epicardial Contours

1. Select start and end phases using the cine window controls.

IMPORTANT: Be sure the phase selected on which to draw ROIs is included within the start and end range of phases.

2. Select  to draw the endocardial contour.

3. Select  to draw the epicardial contour.

4. Move the cursor out of the editing window.

5. Click **Register** to perform auto registration on all the images defined within the start and end phases.

Review the Image Registration

1. Click the  button.

2. Review the image registration in the thumbnails and adjust contours as needed. Press **Shift** + middle-click or select the pan tool to pan the images to correct registration. The scope of this pan/manual registration can be controlled by using the Scope selection.

Generate Curve and Color Map Overlay

1. Select the **Number of Sectors** from a range of 1 - 16.

   The sectors are numbered counter clockwise from the RV insertion point.

2. Click on the **transmural assessment check box** to create radial regions to distinguish between sub-epicardial and sub-endocardial values if desired.

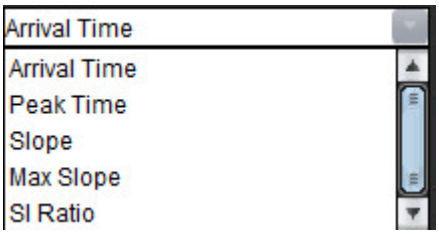
3. Define the RV insertion point by selecting  to deposit the cursor to mark the image.

4. Click **Calculate**.

A graph is generated that averages the signal intensity values versus time within each sector.

To change the results, select from the color map drop down menu.

FIGURE 2. Color Map Pull-down Menu

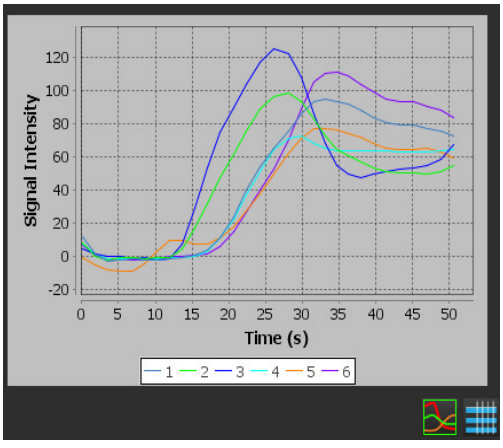


Review Results

1. Select **Chart icon** to review the Signal Intensity versus Time graph  .

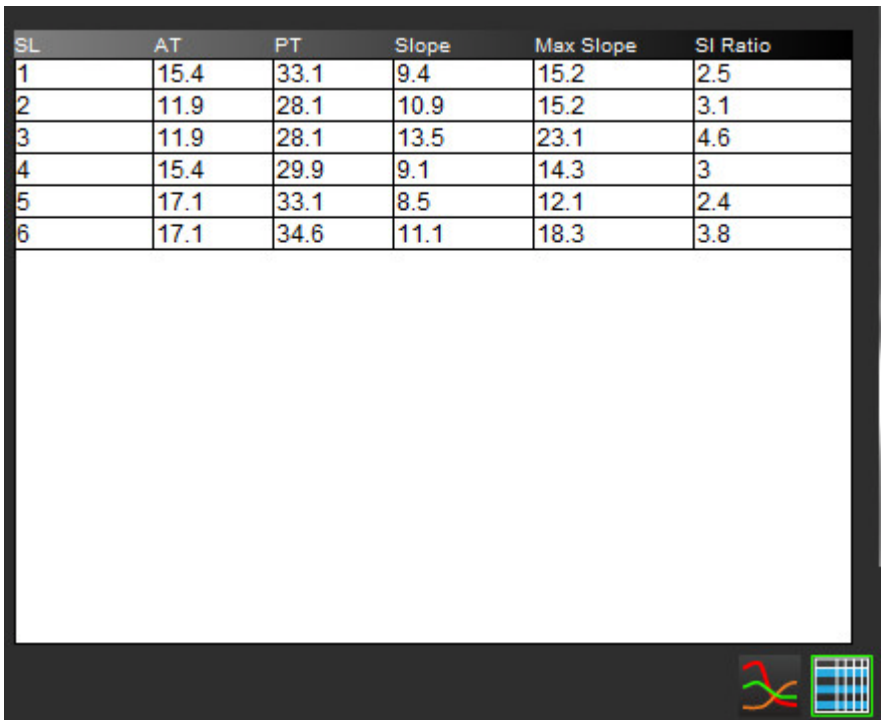
   A color code of the various sectors is provided below the graph. Placing the cursor directly on a colored segment on the image will highlight the corresponding graph for that segment.

FIGURE 3. Signal Intensity/Time Graph



2. Select **Table icon** to review the summary result table  .

FIGURE 4. Summary Result Table



SL	AT	PT	Slope	Max Slope	SI Ratio
1	15.4	33.1	9.4	15.2	2.5
2	11.9	28.1	10.9	15.2	3.1
3	11.9	28.1	13.5	23.1	4.6
4	15.4	29.9	9.1	14.3	3
5	17.1	33.1	8.5	12.1	2.4
6	17.1	34.6	11.1	18.3	3.8

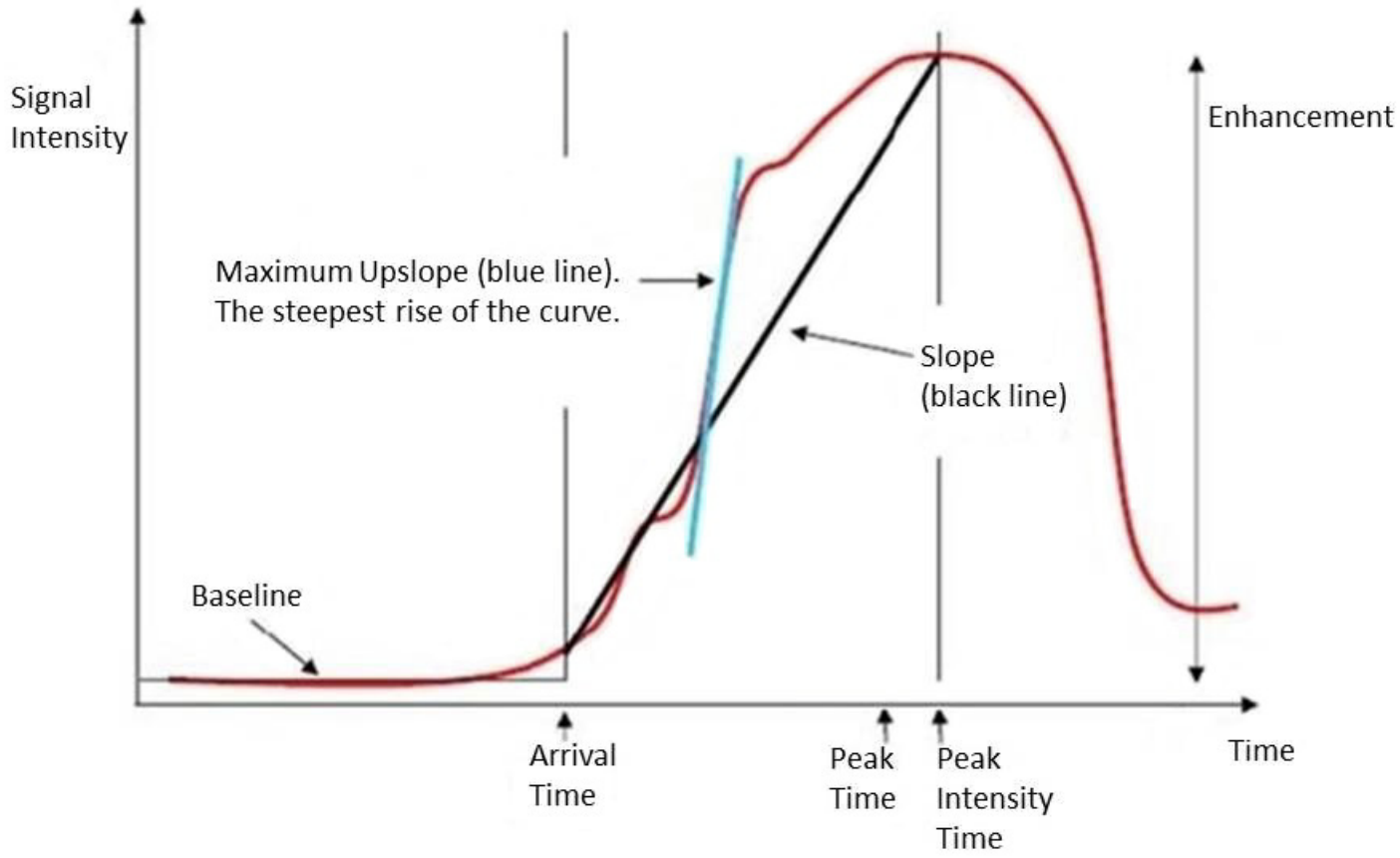
3. Placing the cursor directly on a colored segment on the image will highlight the corresponding result in green for that segment in the result table.

Graph and Contour Reset

Reset of the graph and contours can be performed at any point by clicking on  .

Time Course Curve

The Time Course Curve results are defined as follows:



Where:

slope	is the gradient difference of the arrival time and the peak time,
maximum upslope	is the highest gradient (rise) of the curve representing intensity over time,
signal intensity ratio	is calculated as follows: $\frac{\text{Intensity enhancement (peak signal - baseline signal)}}{\text{Baseline}}$
peak time	is time (in seconds) of which the signal intensity reaches 90% of the peak signal intensity
arrival time	time (in seconds) of which the signal intensity reaches 10% of the peak signal intensity

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Patent Foramen Ovale (PFO) Analysis

The PFO analysis tool allows the generation of signal versus time curves to demonstrate an early peak for the detection of a PFO.

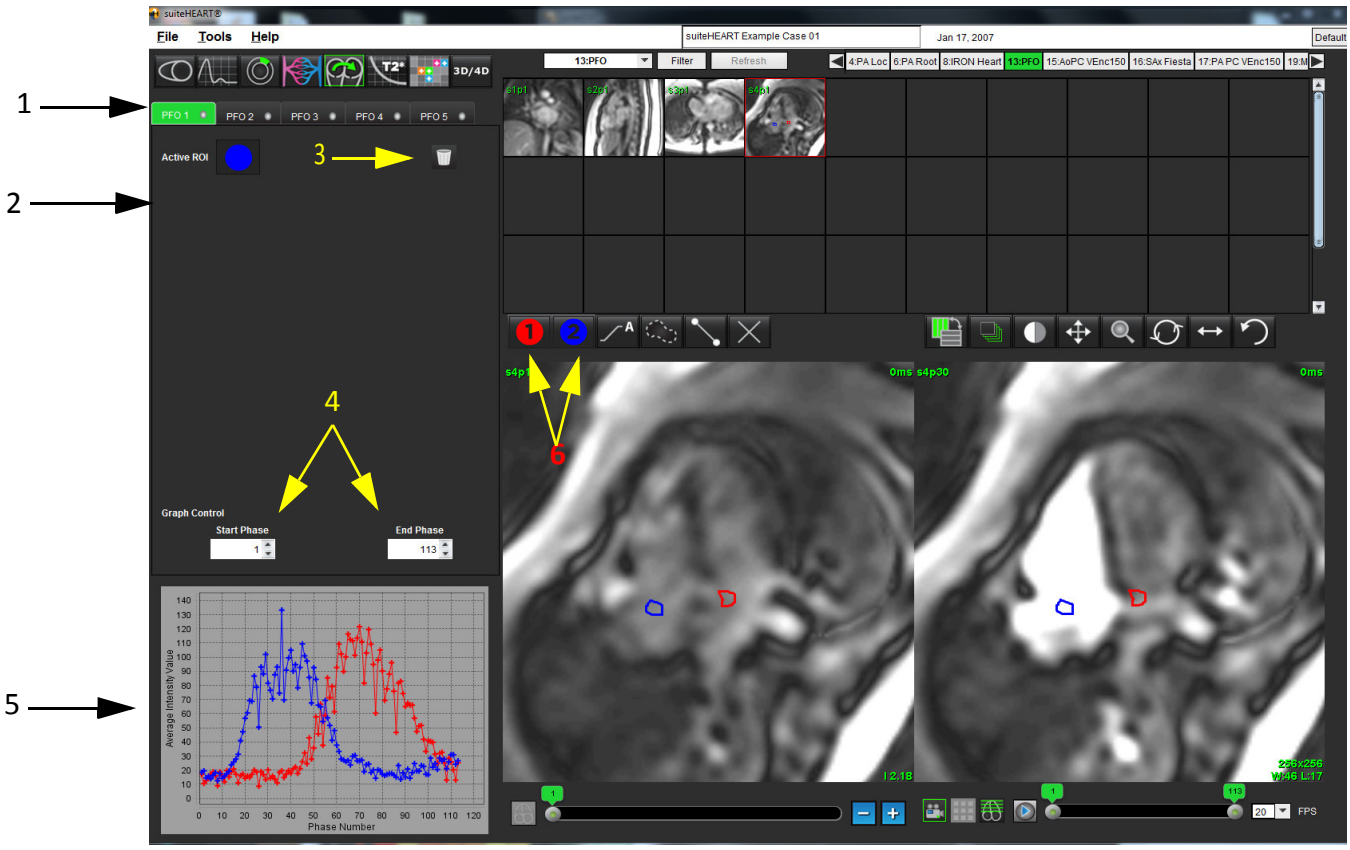
WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

Launch PFO

1. Select **PFO Analysis Mode**.

2. Select a realtime series.

FIGURE 1. PFO Analysis Window



1. PFO editable tabs, 2. Active ROIs, 3. Reset, 4. Start and End phase, 5. Signal Intensity vs Phase curve, 6. PFO Analysis icons

Select Atrial Anatomy

1. Select a PFO slice where the anatomy of the left atrium (LA) and right atrium (RA) can be appreciated.

Generate Left Atrial (LA) Intensity Curve

1. Draw the curve by selecting  .
2. Trace a contour on the LA in the Image Editor window.
3. Move the cursor out of the Image Editor window.
4. Generate LA intensity curve.

   The signal intensity curve for the LA is automatically generated.

Generate Right Atrial (RA) Intensity Curve

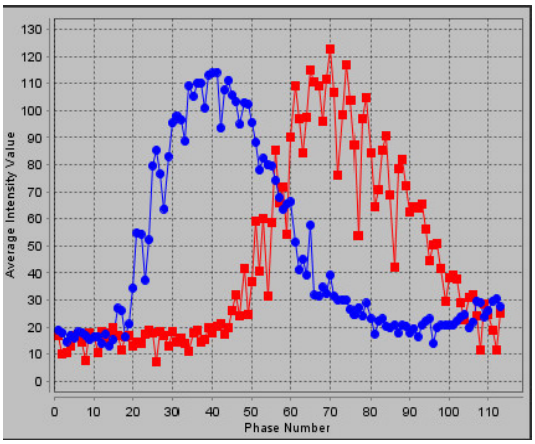
1. Generate the RA intensity curve following the same steps previously listed to generate the LA intensity curve while

using  .

The curves are overlayed and displayed in the curve results display window.

NOTE: If a ROI has been placed on phase 1, for example, and the start phase is changed, the user drawn ROI will still be present on the original image where the ROIs were placed.

FIGURE 2. PFO Curve Results



Review Curve Data and Select Phase Range

1. Review the curves in the report window and adjust the **Start Phase** and **End Phase**.
2. Use the up and down arrows to select the **Start Phase** and **End Phase** to set the phase range for curve display.

Adjusting the start and end phases affect the display of the PFO curves.

Clicking on a point on the graph updates the phase displayed in the Image Editor window.

FIGURE 3. Start and End Phase Selection Screen

NOTE: If there are two acquisitions in the same series, you can set the Start and End Phases for the first acquisition, draw the LA and RA ROIs (resulting in automatic generation of curves), and then repeat the process on another PFO tab for the second set of images. All PFO tab labels are editable.

Editing Contours

Editing multiple phases at a single slice location:

1. Select the slice location
2. Select 
3. Select the first phase of the range of phases to be edited.
4. Depress and hold the shift key and select the last phase of the range to be edited.

   The selected thumbnails will appear highlighted with a red border.
5. Edit the contour in the image editor window.
6. Deselect the contour by either clicking on the image away from the selected contour or move the cursor out of the editor window.

ROI editing can be controlled by setting the scope.

Select the proper scope function from the Image View.

 Scope All – Applies ROI edits to all phases.

 Scope Current to End – Applies ROI edits from the current phase to the end.

 Scope Current Only – Applies ROI edits to the current phase only.

Reset Graph and Contours

1. Optional: Click  to make the appropriate selection from the Reset PFO menu.

FIGURE 4. Reset PFO Curve Menu

Review Final Curve Results

A graph is generated from the contours showing pixel intensity versus time. Right mouse click on the graph  to send to the report.

T2Star

The T2Star analysis tool calculates the T2*values of tissue from a multi-echo fast gradient echo sequence.

The T2* curve is a graph of the signal intensity versus echo time using an exponential decay curve formula. The T2* fitting algorithm is based on Levenberg-Marquardt non-linear least square algorithm.

The calculation for the T2* decay curve is: $y = a * \exp(-TE/T2^*) + c$

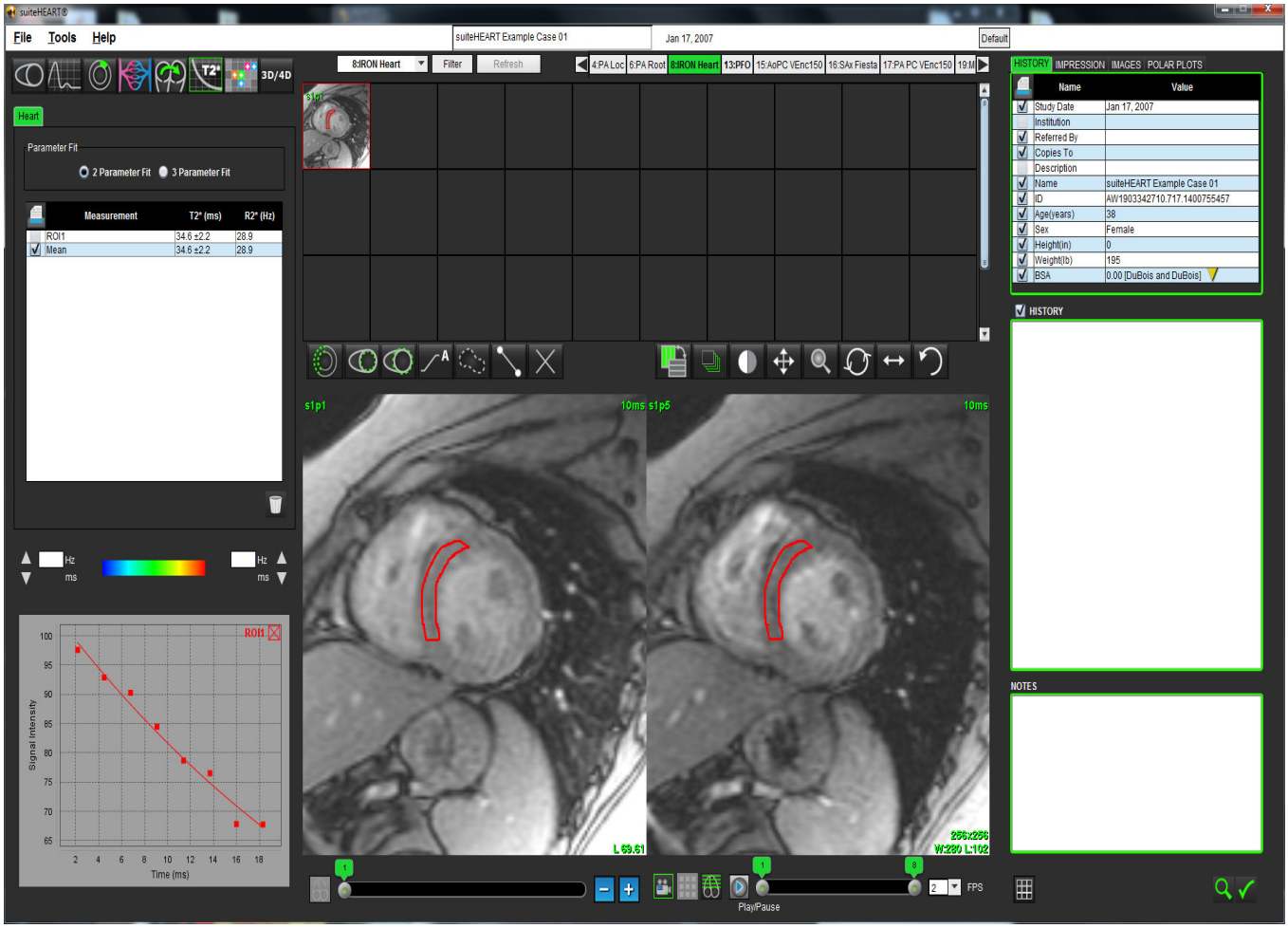
Where:

y	is the signal intensity at time TE
a	is the transverse magnetization at time 0 (zero)
TE	is the echo time
T2*	is the decay constant, and
c	is the background noise

WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created by a properly trained and qualified user.

Heart Analysis Procedure

FIGURE 1. T2Star Analysis View



1. Select  .
2. Select the appropriate series.
3. Select the short axis slice from the thumbnail panel.
4. Draw a contour that encompasses the interventricular septum using  .

   The T2* and R2* are calculated and are displayed in the result table.

Create Myocardial Colormap

1. Draw a contour the endocardial border using  .
2. Draw a contour of the epicardial border using  .

   The T2*/R2* colormap is overlayed on the image.
3. The R2* colormap value can be changed.

NOTE: The default range for 1.5T images is 5ms - 500ms for T2*. The default range for 3.0T images is 2.5ms - 1000ms for T2*.

4. Click  to toggle between a grey scale and a color map.
5. Click and drag up or down on arrows to adjust the dynamic color range for the color map.

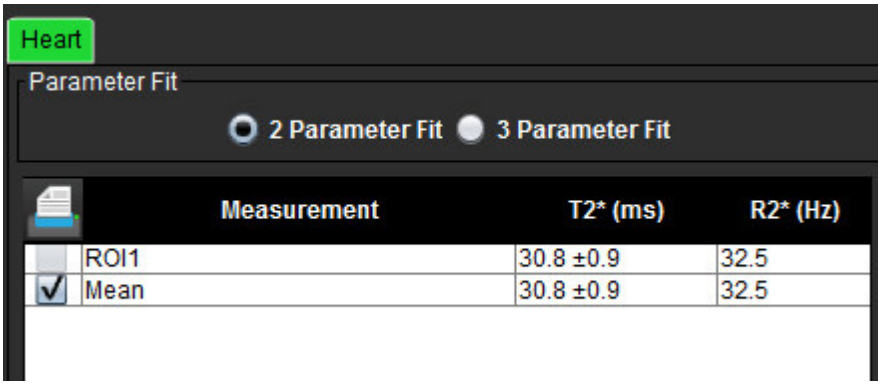
   The color overlay on the Image Editor changes dynamically.

   The Hz and ms values also change dynamically.
6. The T2* and R2* values can be determined by selecting the  and placing it over the color map overlay on the image.

Fitting Parameters

Select either the **2 Parameter** or **3 Parameter Fit** for the T2* decay curve.

FIGURE 2. Parameter Fit



The 2-parameter fit is widely accepted based on peer review literature [1]. In this model, the background noise, c, is calculated using a histogram-based algorithm and subtracted from the signal intensity, after which a non-linear fit is performed.

The 3-parameter fit is also available as referenced in peer review literature [2]. This model is a non-linear approach that works directly from the original input signal.

For both models, the initial T2Star value is estimated using a trial linear fitting.

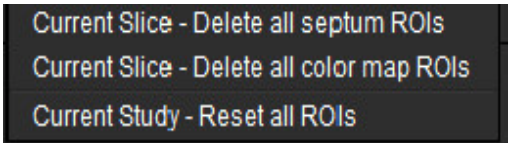
1. D.J Pennell, et al. “Cardiovascular T2-star (T2Star) magnetic resonance for the early diagnosis of myocardial iron overload,” Eur Heart J 2001; 22: 2171-2179.
2. Ghugre NR, et al. “Improved R2* Measurements in Myocardial Iron Overload,” Journal of Magnetic Resonance Imaging 2006; 23: 9-16.

Review the T2Star Results

1. Review the contour position on all of the images.
2. The table lists the individual T2*/R2* measurements and also calculates a mean value.

Click  to reset analysis as shown in Figure 3.

FIGURE 3. T2/R2 ROI Delete Choices



3. The option to print the results of each contour can be made by selecting the Printer setting for each value in the measurement table.

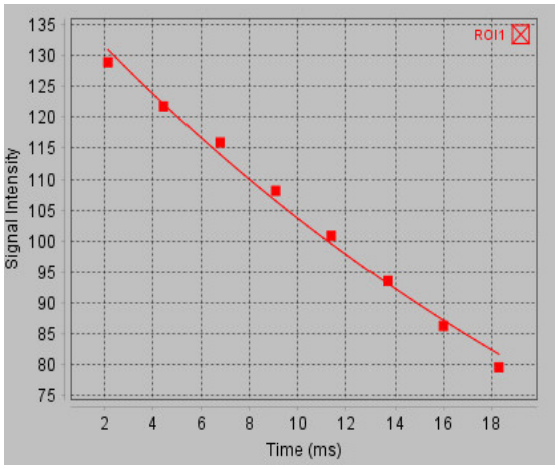
Review and Update the T2Star Curve

The T2* curve is a graph of the signal intensity versus echo time using an exponential decay formula. T2*/R2* values may be inaccurate if all images do not have adequate signal to noise ratio (ie. signal plateau to near zero).

To delete a single contour from an image

1. Select the contour and it turns purple.
2. Select Delete from the right-mouse menu or use the Delete key on the keyboard.
    - The contour is deleted and the associated point is removed from the graph.

FIGURE 4. T2Star Curve



WARNING: Review the results of the T2Star curve fit. A properly trained and qualified user should perform analysis and diagnosis.

R2*/T2* Conversions

Table 1:

Result	Unit	Conversion
R2*	Hz	R2*=1000/T2*
T2*	ms	T2*=1000/R2*

The factor of 1000 is used as the T2 and T2* are reported in units of milliseconds (ms) and R2 and R2* are Hertz (or s^{-1}).

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3D/4D Viewer

3D/4D viewer allows for the visualization of 3D and 4D Flow MRI images. It provides tools for reformatting and supports the creation of 2D phase contrast and 2D function images from 4D Flow MRI images that can be analyzed conventionally using suiteHEART® Software.

NOTE: A 3D series with isometric voxels and overlapping slices improves the quality of the reformatted images.

NOTE: The 4D Flow viewer is not available in a suiteHEART® Software multiuser environment (Citrix).

CAUTION: 3D or image reformats only provide additional supplemental information in the formulating of a diagnosis and should always be used in conjunction with conventional imaging techniques.

WARNING: Always correlate any 3D reformats with the original acquisition data.

WARNING: Window width and level (WW/WL) settings can affect the appearance of different pathologies and the ability to discern other anatomical structures. Incorrect WW/WL settings may cause the imaging data to not display. Different WW/WL settings may be needed to review all imaging data.

3D/4D Viewer Components

FIGURE 1. View Control Tools and Viewports

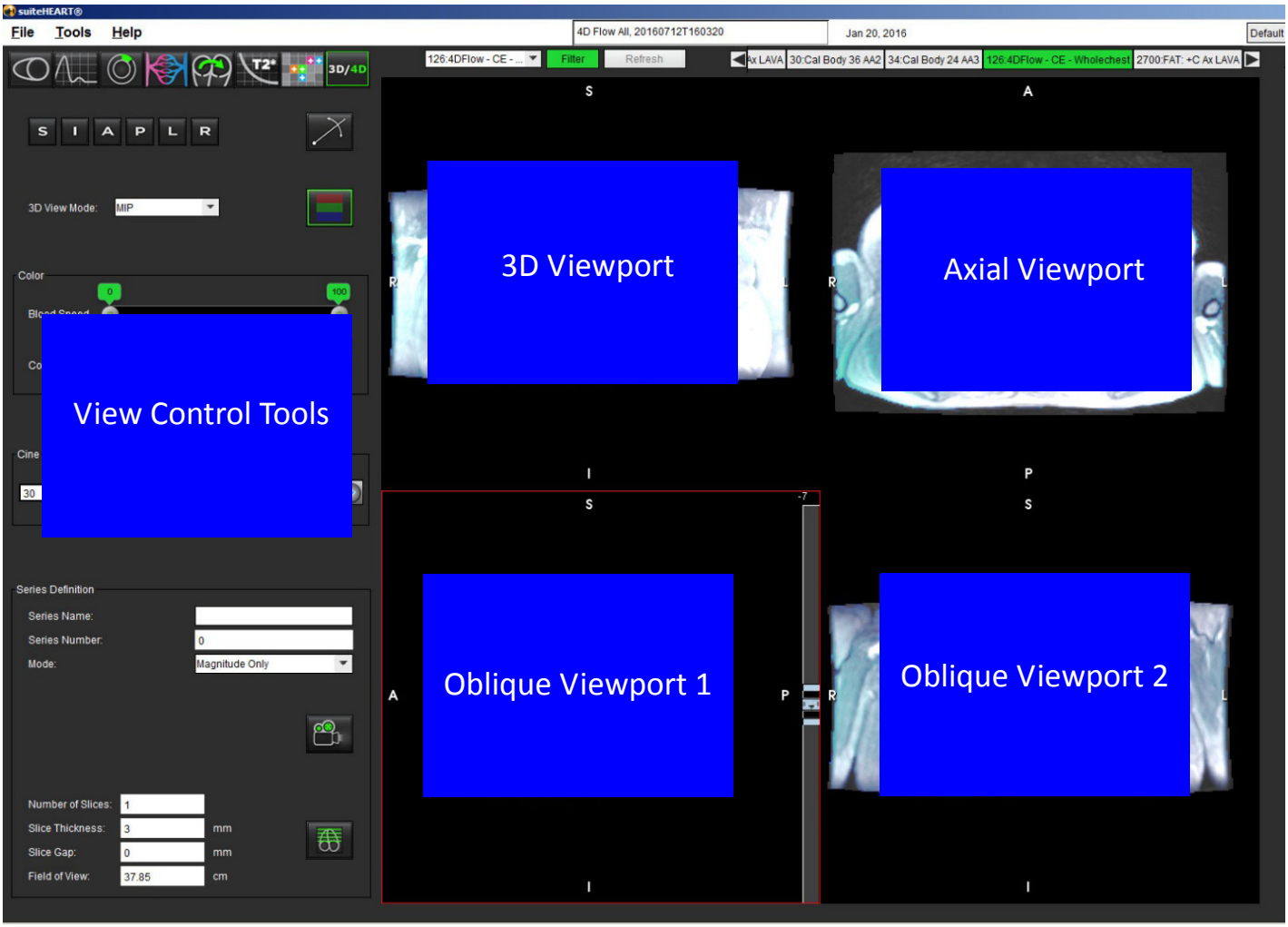


Table 1: View Control Tools

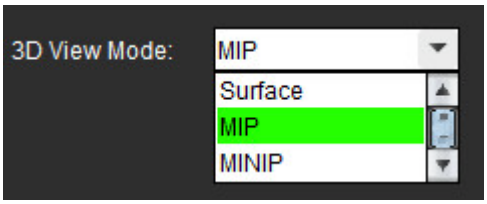
Tool	Description
	**Crosshair Cursor** - synchronizes navigation between all viewports.
	**Orientation Buttons** - change the image plane in the 3D and oblique viewports. S = Superior I = Inferior A = Anterior P = Posterior L = Left R = Right
	**Oblique Mode** - displays the plane of the oblique reformat and the perpendicular intersection to display desired anatomy.
	**3D View Mode** - provides image render modes in the 3D viewport Surface MIP = Maximum intensity projection (Default) MINIP = Minimum intensity projection
	**Color Overlay** - toggles the color overlay on/off. Available for 4D flow images only.
	**Blood Speed** - adjusts the assignment of the velocity encoding. Available for 4D Flow images only.
	**Color Opacity** - controls the color opacity on the image to improve the visualization underlying anatomy. Available for 4D flow images only.
	**Cine** - controls frames per second and defines start and end frame of the cine movie. Available for 3D time-resolved magnitude and 4D flow images only.

Table 1: View Control Tools

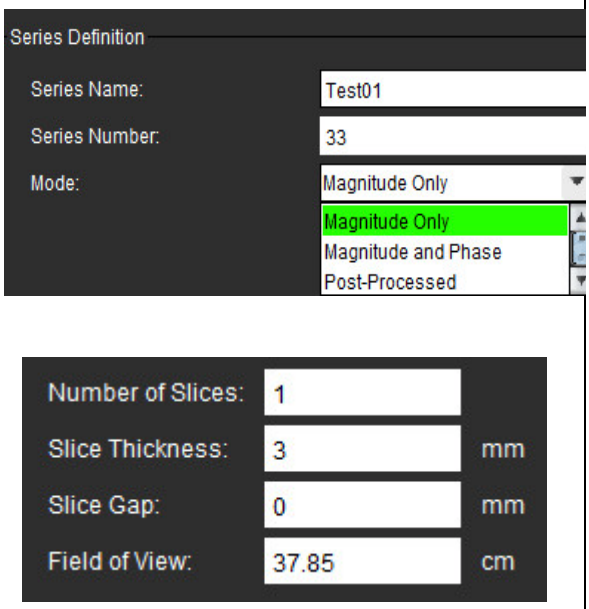
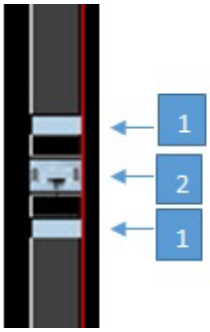
Tool	Description
	**Series Definition** - creates 2D conventional functional or a flow image series for analysis or post-processed MIP images. Use to enter the number of slices, slice thickness, gap and field of view. **Magnitude Only** - creates a single-slice or multi-slice multiphase magnitude series from the original images for use in function analysis. **Magnitude and Phase** - creates a single-slice or multi-slice multiphase magnitude with phase series from the original images for use in flow analysis. This option is only available when a 4D Flow series has been selected. (A duplicate series that is auto phase corrected is also created.) **Post-processed** - creates maximum intensity projection images from 3D images. When a 4D flow data is present single-slice or multi-slice multiphase series with color overlay will be created on the images for review purposes.
	**Save**- saves all image series types created by the series definition to the local database.
	**Rx Planning** - defines the desired scan plane axis created by series definition.
	**Paging and Thickening** - changes the thickness of the MIP image and pages through the image set. 1= click and drag either side buttons to change the thickness of the MIP image 2= click and drag the slider to page through the image set. Controls are found on the right hand side of the selected viewport.
	**3D Rotate** - tilts or rotates the images in the 3D viewport and/or oblique viewports 1 and 2. Left mouse click and drag directly in the viewport to tilt or rotate.
	**Flow Direction** - displays the perpendicular plane in oblique viewports 1 and 2. Left mouse click directly on the anatomy of interest to use this feature. Available for 4D flow images only.

Table 1: View Control Tools

Tool	Description
	**Window/Level** - available in all viewports.
	**Pan** - available in all viewports.
	**Zoom** - available in all viewports.
	**Rotate** - available for the 3D viewport, viewport 1 and viewport 2.
	**Reset** - available in all viewports.
	**Scan Parameters** - available in all viewports.

3D/4D Viewer Layout and Series Creation Outputs

Depending on the type of image series that are selected for reformatting, the image creation type is summarized in the table below.

Table 2: 3D/4D Layouts and Output

3D/4D Viewer Layout	3D Image Series Outputs	4D Flow Image Series Outputs
3D view (upper left viewport)	Post-Processed	Post-Processed
Axial (upper right viewport)	Magnitude Only Post-Processed (MIP)	Magnitude Only*, Magnitude and Phase*, and Post-Processed (color overlay)*
Oblique 1 (lower left viewport)	Magnitude Only Post-Processed (MIP)	Magnitude Only*, Magnitude and Phase*, and Post-Processed (color overlay)*
Oblique 2(lower right viewport)	Magnitude Only Post-Processed (MIP)	Magnitude Only*, Magnitude and Phase*, and Post-Processed (color overlay)*
***This series type can be used for conventional analysis in suiteHEART® Software**		
For each magnitude and phase series, a duplicate series that is auto phase corrected will be created.		

Sample Workflow: Create MIP Images from a 3D Image Series

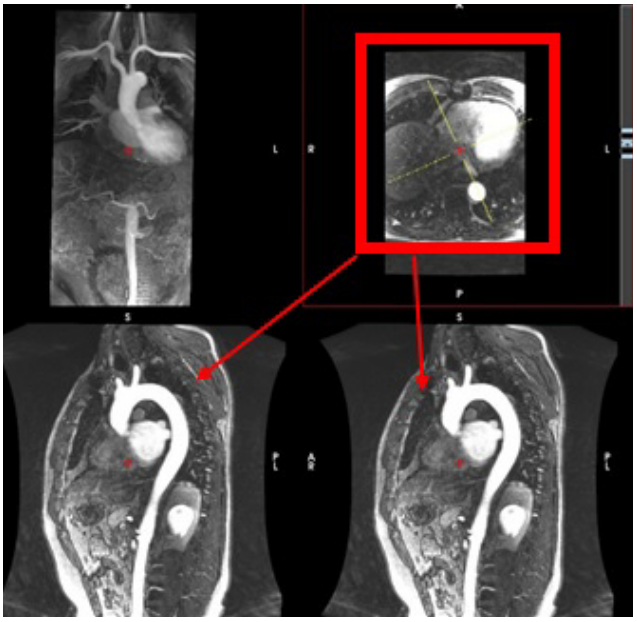
1. Select the appropriate study and launch suiteHEART® Software.
2. Select 

.
3. Select the appropriate 3D series from the series navigation pull-down. The image type selected will be indicated on the button, as shown in Figure 2.

FIGURE 2. Series Navigation

4. Select the  and click on the desired viewport. The active viewport will be highlighted in red. The yellow reformat lines will appear as shown in Figure 3.

FIGURE 3. Oblique Mode



5. Click on the solid yellow line, left mouse click and drag and tilt the line to display the desired anatomy.
   a.) Click on the desired viewport for saving.
   b.) Adjust the MIP thickness using the controls on the right hand side of the viewport.
   c.) Complete the series definition entries, as shown in Figure 4.
   d.) Click the save button to save the MIP image to the local database.

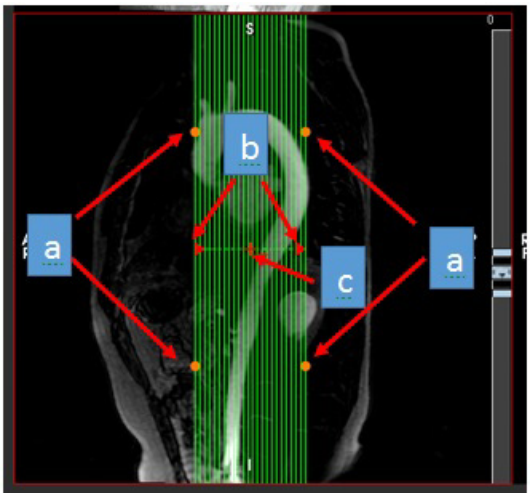
FIGURE 4. Series Definition

6. Create a stack of MIP images by selecting  .

NOTE: The maximum number of post-processed MIP images that can be created is 512.

7. Click on the viewport to be used as the reference image and define a stack of batch images, as shown in Figure 5.
    a.) Extend the range of the slice coverage.
    b.) Adjust the angle and arrows indicate slice direction.
    c.) Move the Rx.

FIGURE 5. Rx Planning



8. Enter the series definition options and click  to save the image stack to the local database.
9. To view the created series, switch to function analysis mode, select review mode and click refresh.

Example Workflow: Create 2D Series for Conventional Analysis

The creation of conventional 2D phase contrast and 2D functional images requires a 4D Flow series that has both time-resolved magnitude and flow conventions of R/L, A/P and S/I.

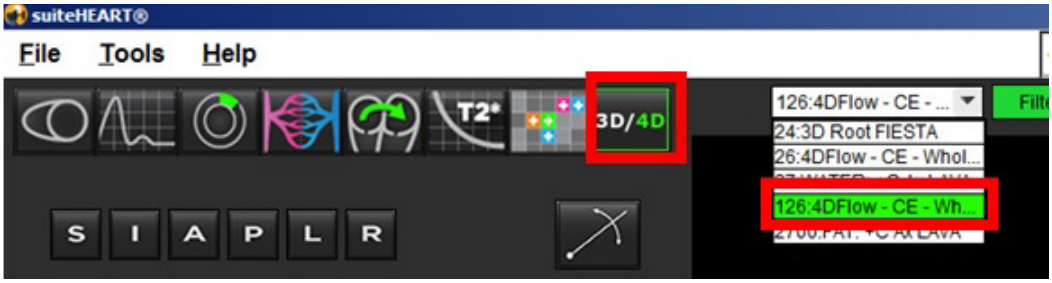
Series created as magnitude alone or magnitude and phase from 4D flow images are a valid 2D conventional series that can be used in function or flow analysis.

Series that are created as post-processed from 4D Flow will have a color flow overlay. If the appropriate scan plane is created the series can be used for function analysis.

1. Select the appropriate study and launch suiteHEART® Software.
2. Select 

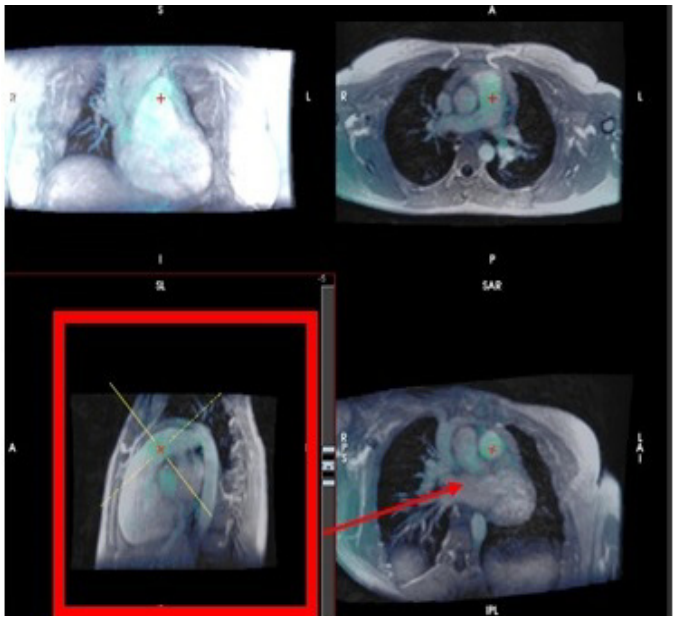
.
3. Select the appropriate 4D series from the series navigation pull-down, as shown in Figure 6. The image type selected will be indicated on the button, as shown in Figure 6.

FIGURE 6. Series Navigation



4. Select the  and click on the desired viewport. The active viewport will be highlighted in red. The yellow reformat lines will appear as shown in Figure 7.

FIGURE 7. Oblique Mode Reformat 4D



5. Click on the solid yellow line, left mouse click and drag and tilt the line to display the desired anatomy.
   a.) Click on the desired viewport for saving and select Magnitude and Phase mode to create a 2D phase contrast series or select Magnitude to create a functional series.
   b.) Adjust the slice thickness using the controls on the right hand side of the viewport.
   c.) Complete the series definition entries, as shown in Figure 8, and click the save button to save the series to the local database.

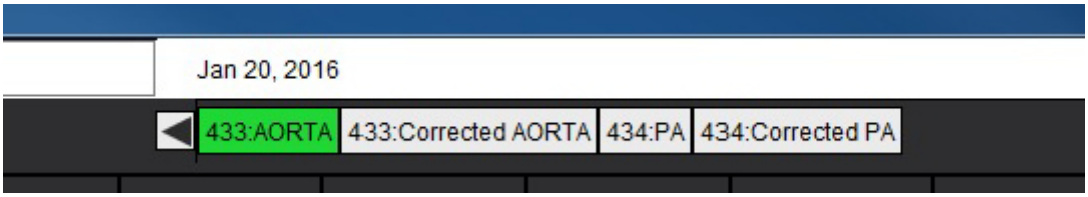
FIGURE 8. Series Definition and Save

6. To create a stack of multi-slice multiphase images select  .

NOTE: The maximum number of multiphase images that can be created is 32.

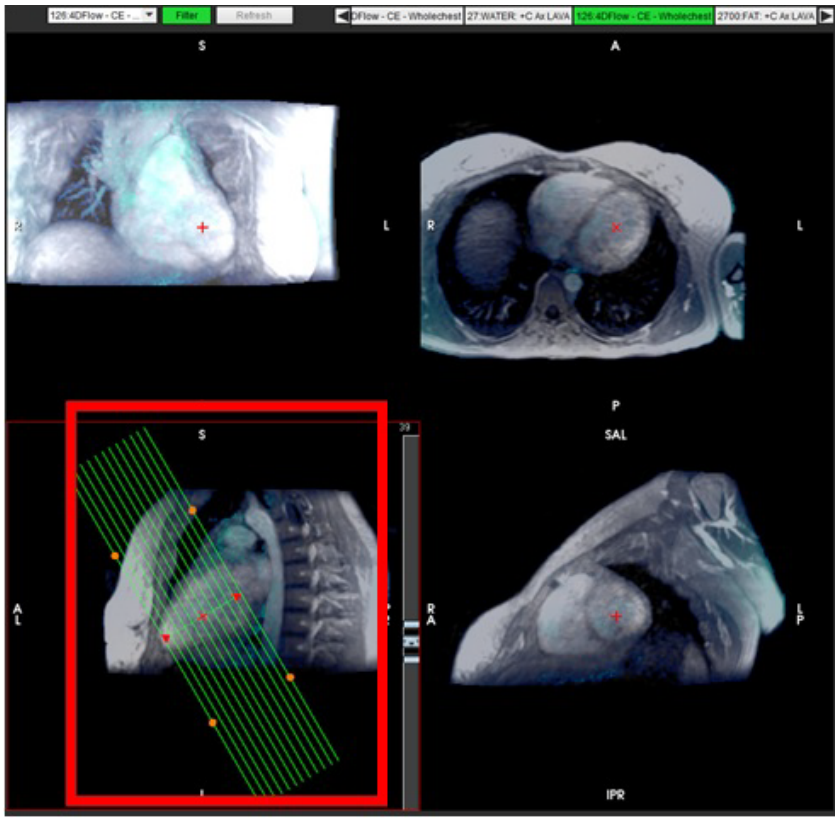
NOTE: If a 2D magnitude and phase series is created by using the 3D/4D viewer, the application will create a duplicate auto phase corrected series. The series will be labeled "corrected," as shown in Figure 9.

FIGURE 9. Duplicate Auto Phase Corrected Series Example



7. Click on the viewport to be used as the reference image and define a stack of batch images, as shown in Figure 10.

FIGURE 10. Rx Planning



8. Select the Series Definition options and click  to save the image stack to the local database.
9. To analyze the created series, switch to the appropriate analysis mode and click refresh.

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Structured Reporting

Define Report Content

The measurements and graphs that populate reports are taken from the results of the analysis modes. Each individual analysis result may be selected for inclusion in the report.

Predefined clinical impressions and techniques streamline custom reports. Refer to the Impression Tab section for procedural details on how to create clinical impressions and techniques. Report Preferences allows entering site information that will appear as titles and headers on the patient report.

Structured Report View

The Structured Report View is designed to aid in generating clinical reports. There are four tabs:

- History
- Impression
- Images
- Polar Plots

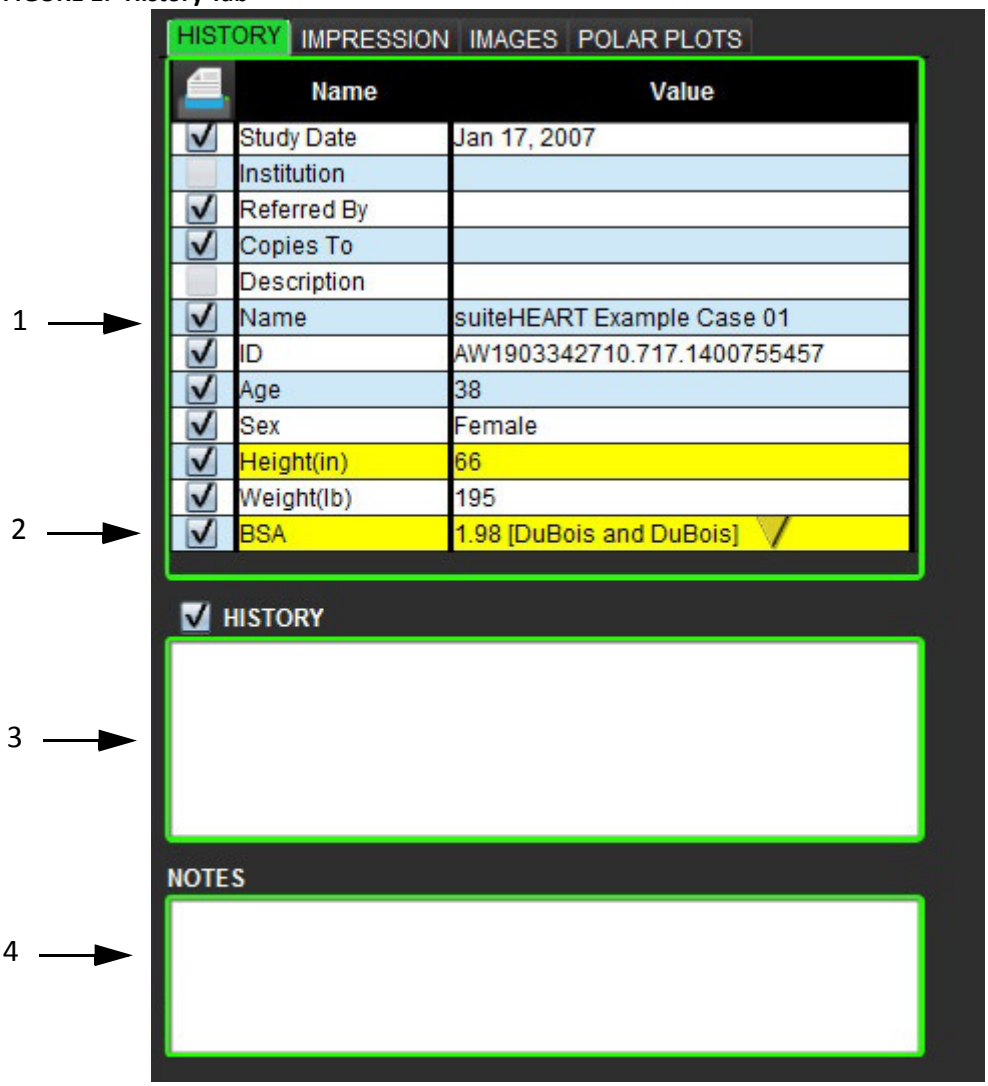
Each printable field is associated with a check box toggle button  . Click the check box to include or exclude the field from the report.

History Tab

The History tab contains patient information from the DICOM header. Editing information highlights the field in yellow.

NOTE: Edited patient information affects the report only. The DICOM header is left intact.

FIGURE 1. History Tab



1. DICOM Header Information, 2. BSA Selection, 3. Patient History, 4. Notes

The BSA calculation type can be selected by performing a right-mouse click on the inverted yellow triangle.

BSA Calculation Method	Formula
DuBois and DuBois	BSA (m2) = 0.20247 x Height(m)$^{0.725}$ x Weight(kg)$^{0.425}$
Mosteller	BSA (m2) = SQRT([Height(cm) x Weight(kg)]/3600) BSA (m2) = SQRT([Height(in) x Weight(lbs)]/3131)
Gehan and George	BSA (m2) = 0.0235 x Height(cm)$^{0.42246}$ x Weight(kg)$^{0.51456}$
Haycock	BSA (m2) = 0.024265 x Height(cm)$^{0.3964}$ x Weight(kg)$^{0.5378}$
Boyd	BSA (m2) = 0.0003207 x Height(cm)$^{0.3}$ x Weight(grams)($^{0.7285 - (0.0188 \times LOG(grams))}$)

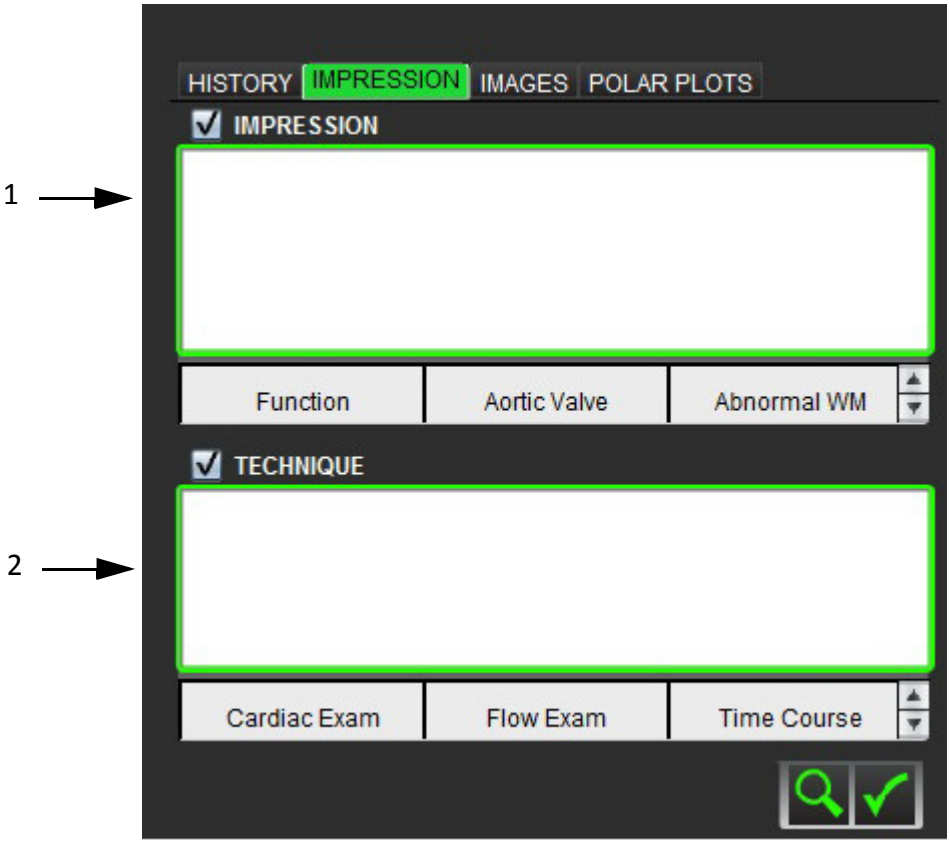
Reference: http://halls.md/formula-body-surface-area-bsa/

History and Notes Text Boxes

Enter any information relevant to the patient history in the History field or select the appropriate macro. The Notes panel displays the notes entered by the user during analysis, but will not be available for inclusion on the report.

Impression Tab

FIGURE 2. Impressions Tab



1. Impression, 2. Technique

Impression

Enter impression information by typing in the text box and/or click an impression macro button.

Predefined impression macros are located on buttons below the Impression panel.

NOTE: All appropriate analysis needs to be performed prior to generating result calculations with macros.

Technique

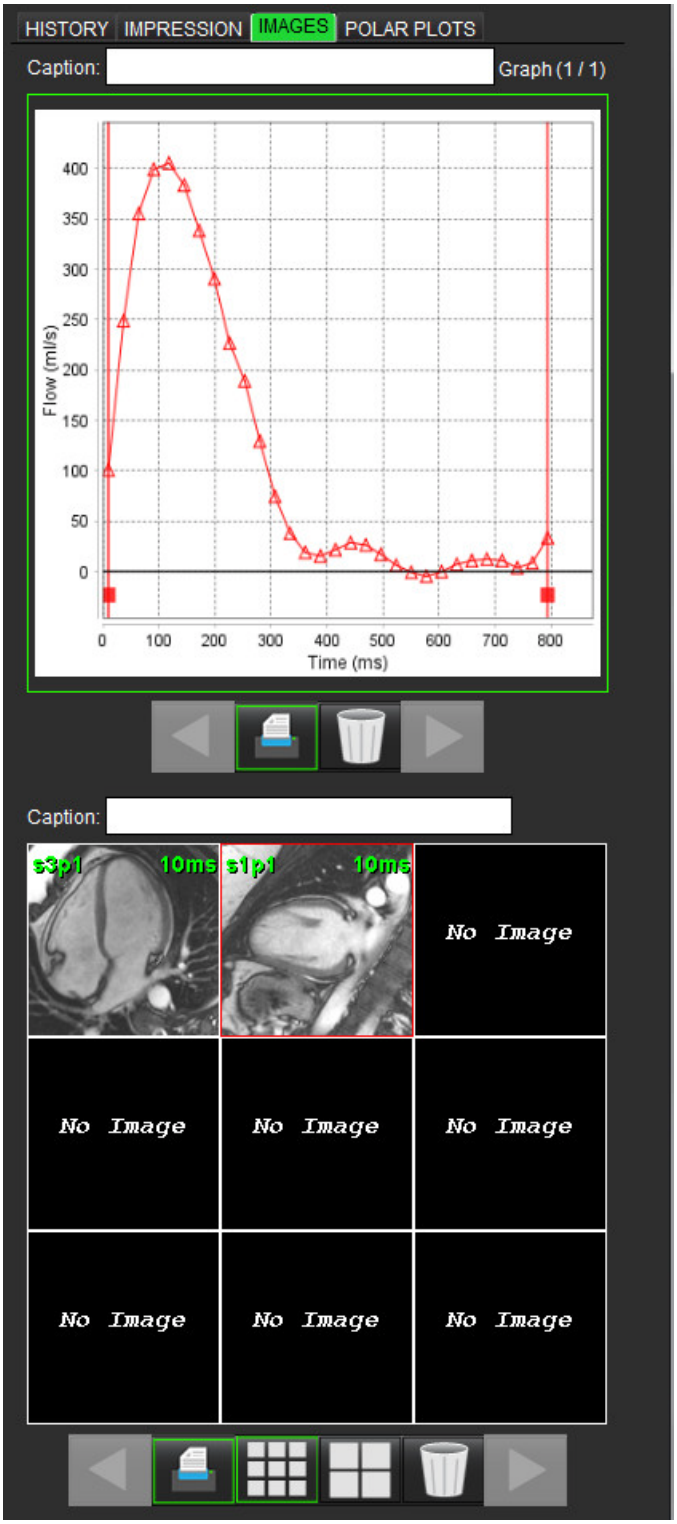
Enter technique information by typing in the text box and/or clicking a technique macro button.

Predefined technique macros are located on buttons below the Technique panel.

NOTE: All appropriate analysis needs to be performed prior to generating result calculations with macros.

Images Tab

FIGURE 3. Images Tab



1 →

2 →

1. Graphs/Tables, 2. Images for report

Review Graphs and Summary Tables for Report

The Graphs View panel contains all the graphs and summary table results that are included in the report during analysis.

1. Step through each graph and summary table using the  icons.
2. Click in the white text box to add a graph or summary table caption for the printed report.
3. When  is enabled, the graph or table will be included in the report.
4. Click on  to delete a graph or table.

Review the Images

The Image panel contains all the images that were sent to the Report during analysis.

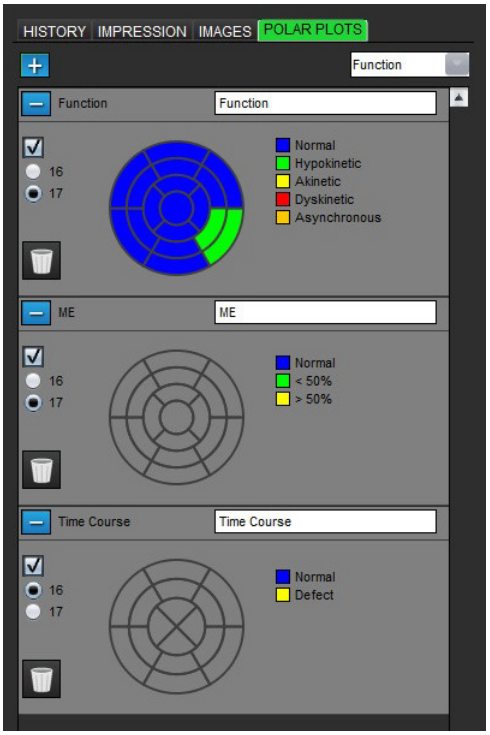
1. Step through each image using the  buttons.
2. Click in the white text box to add an image caption for the printed report.
3. Select the image size by choosing the small format  or large format  buttons.
4. Images in the image panel can be re-ordered by clicking and dragging the image into a different viewport.
5. Perform a right-mouse click directly on an image to access the image manipulation tools.
6. To locate the series from which the image originated, right-mouse click directly on the image and select the  locate button.
7. When  is enabled, the image will be included in the Report.
8. Delete an image by selecting  .

NOTE: If a study is opened which has been analyzed from a previous software version (2.1.0 or below), images previously added to the Report View cannot be manipulated using the image manipulation tools. Any new images added can be manipulated as expected.

Polar Plots Tab

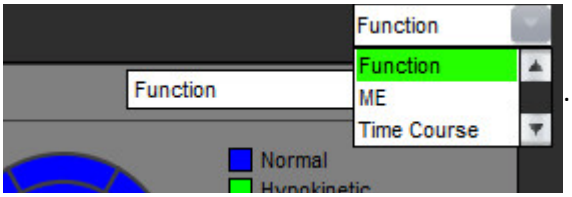
This table allows for the identification of functional, myocardial evaluation, and time course abnormalities qualitatively in a polar plot format. To change the color coding of the segments, right mouse click on the segment color legends to open the color palette.

FIGURE 4. Polar Plot Tab



Add Polar Plots to Report

To add additional polar plots to the report, click on the  and select the polar plot type from the file pull-down menu



.

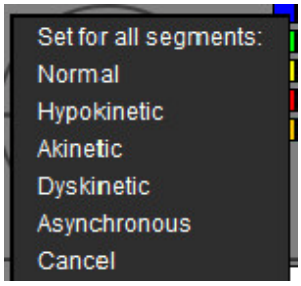
Selecting Colors per Segment

Click on the color box next to the desired terminology to describe the abnormality. The cursor changes to a paint brush. Then click on the segment directly on the polar plot to set the color.

Selecting Colors for All Segments

Right mouse click outside of the polar plot outline in the corners and make the desired selection from the list.

FIGURE 5. Selection for Function



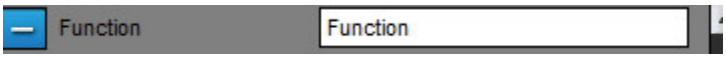
Selecting 16 or 17 Segment Plots

Select the appropriate radio button located on the left of the polar plot.

Editing the Title of the Polar Plot

Type title of each polar plot can be edited by clicking in the type-in field.

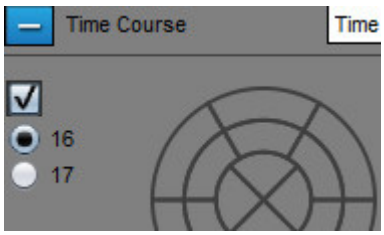
FIGURE 6. Edit Polar Plot Title Type-in Field



Removing a Polar Plot

Each plot can be removed from the tab by clicking the  button. To exclude the polar plot from the report, deselect the check box.

FIGURE 7. Exclude Polar Plot from Report



Select  to reset the polar plot back to default.

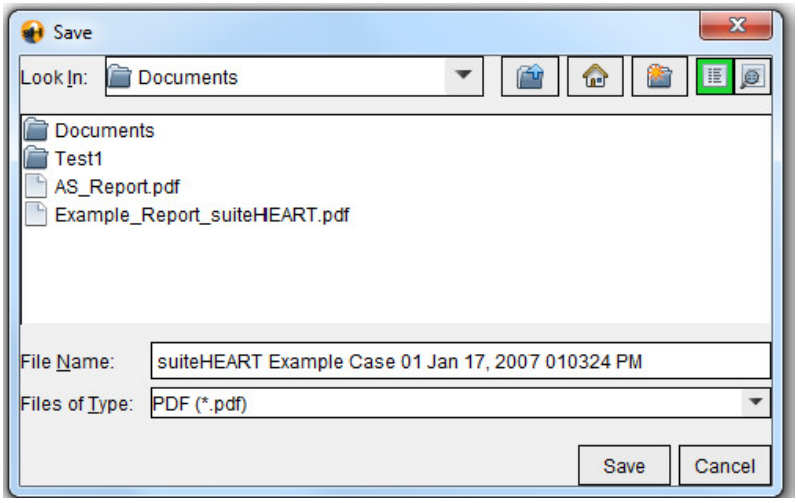
Preview the Report

1. Select **File > Preview Report** or select **Preview Report** from the Review window.
2. Review the report to ensure that all the desired analysis results and structured information is included.
3. Select  to save the report to the local hard drive.

   The Save pop-up window provides the tools to define the destination, name and report format options of the report.

IMPORTANT: Values shown in red are out of range, which will not be obvious if printing the report on a black and white printer.

FIGURE 8. Save Window



4. Select **Print** to print the report.

WARNING: The report should be inspected prior to approval and distribution to ensure that the content matches the analysis. Delayed or misdiagnosis may occur should the report contents be erroneous. Analysis and interpretation should be done by properly trained and qualified users.

Approve the Exam

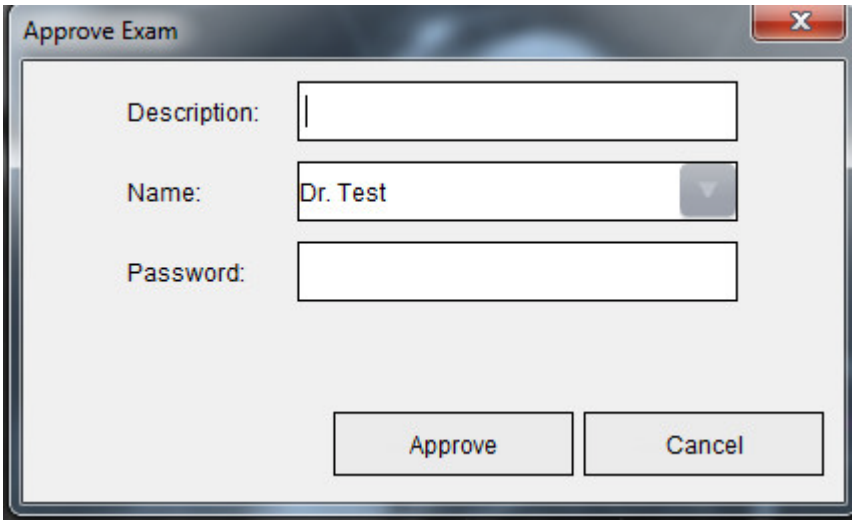
The application has a feature that approves and locks reports. The approved report is saved and can be viewed but it cannot be changed.

NOTE: Prerequisites: The user must be an authorized report signatory. See “Authorized Report Approvers” on page 29.

NOTE: The “Approved Exam” button and menu are not enabled until an action has been performed on an image.

1. Select **Approve Exam** or select **File > Approve Exam**.

FIGURE 9. Approve Exam Window



2. Enter a signature description if desired.
3. Select your user name from the Name pull-down menu.
4. Type in your password.
5. Click **Approve** to confirm and close the window. Click **Cancel** to close the window without completing the sign-off procedure.

   Using the description provided, a series is created.

NOTE: To return to analysis state, you must first approve the exam and then load the approved exam.

NOTE: When an approved exam has been performed the report will have the date and time stamp.

Export Options

The exporting feature is designed to create backups of the exams and the analysis results for future review. The exporting feature allows you to create uncompressed AVI movies, compressed QuickTime movies, and JPEG, TIFF and PNG files of the images. These files can be written to the file system.

Select **Tools > Export > Export Report**.

A secondary capture (SCPT) is created and is saved in the series listing.

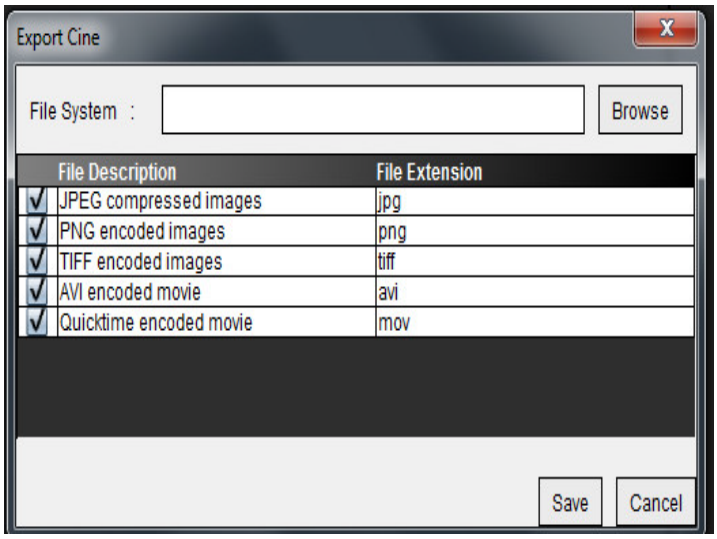
Select **Tools > Export > Export Cine DICOM**.

A secondary capture (SCPT) is created and is saved in the series listing.

Select **Tools > Export > Export Cine Files**.

The Save Cine popup window is displayed.

FIGURE 10. Save Cine Window



1. Select the file types to be exported.
2. Browse to the location in which to save the file(s).
3. Click **Save** to start the exporting process and close the window. The currently viewed series is the only file exported.

NOTE: When exporting data to AVI or MOV files, suiteHEART® Software sets the maximum frames-per-second rate to 20 frames-per-second regardless of the settings used for viewing within the application.

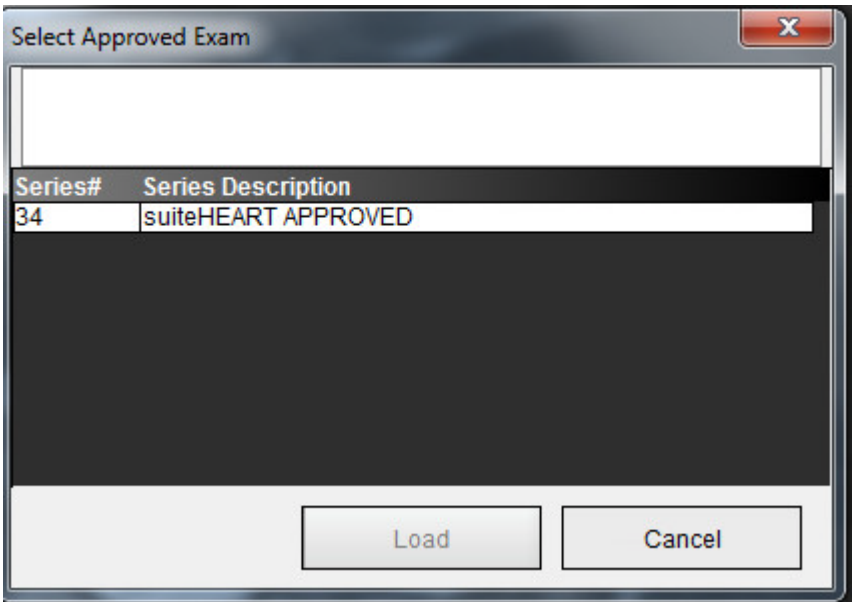
NOTE: If exporting a custom series with both multiphase and single-phase images as a .avi or .mov file, ensure that a viewport containing a multiphase image is selected prior to exporting.

Review an Approved Exam

1. Select **File > Load Approved Exam**.

   This displays the Select Approved Exam window. All the approved exams related to the exam are displayed in the list.

FIGURE 11. Approved Exam Selection Window



2. Select the series from the list.
3. Click **Load** to load and display the approved exam and it's accompanying analysis.
   - An approved exam can be viewed only.
   - A new exam can be generated from an approved exam by editing an approved report and saving those changes to a new exam. The new exam is saved as a secondary capture series.

NOTE: Loading an approved exam and analysis will overwrite the information in the current analysis session.

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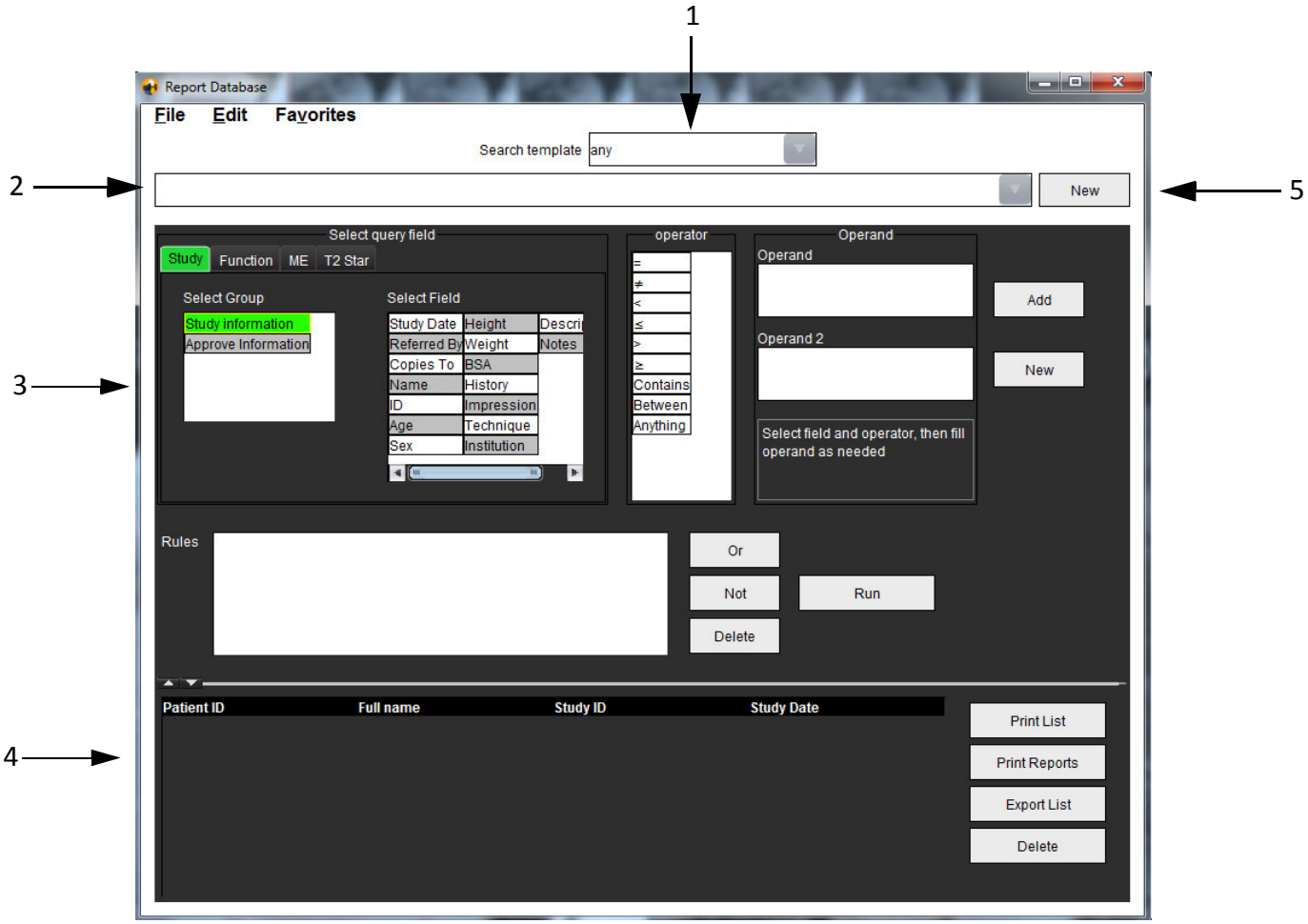
Report Database

The Report Database Tool allows you to perform a search on the contents of previously approved reports. A report is only entered into the report database after it has been approved.

FIGURE 1. Report Database Window



1. Search template drop-down menu, 2. History bar, 3. Create query fields, 4. Query results, 5. New button

Report Database Tool Procedure

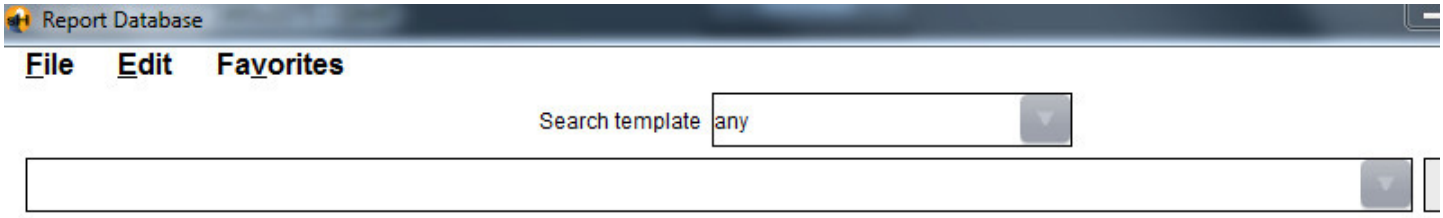
Open the Database Tools Window

1. Select **Tools > Report Database**.

Select Search Criteria

1. Select the correct template for the search from the Search template drop-down menu.
2. Select the search query from the History drop-down menu. The current query bar displays your selected values.

FIGURE 2. Search Template Menu



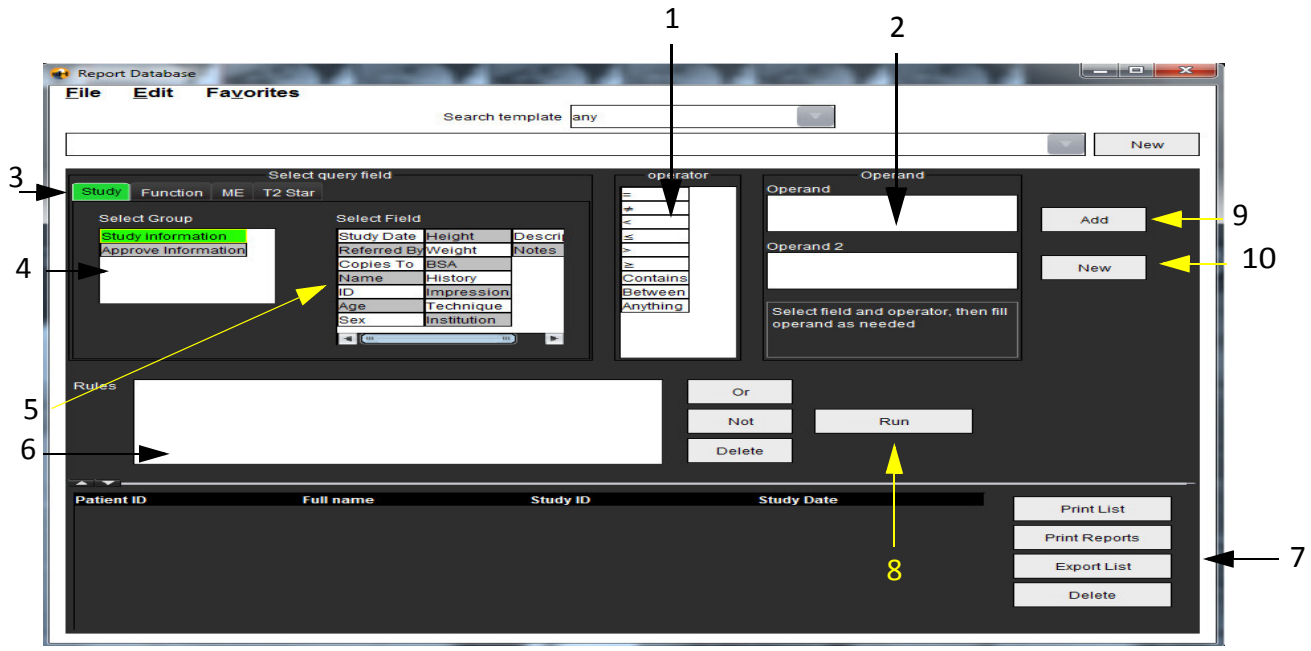
NOTE: If the desired query does not exist already, create a new query.

Create a Query

1. Select **New** to the right of the History bar.

   The create query panels are displayed in the Report Database window.

FIGURE 3. Create Query Panel



1. Query Operators, 2. Query Operands, 3. Query category tabs, 4. Query group, 5. Query fields, 6. Query rules,
7. Query options, 8. Run button, 9. Add button, 10. New button

2. Select the query category tab from Study, Function, ME and T2 Star. The query groups and fields update accordingly.
3. Select the query group.
4. Select the query field.

   NOTE: The Report Database cannot perform a search on custom measurements.
5. Select the operator to define the query search parameters.
6. Enter the operand(s) to provide values to the search parameters.
7. Select **Add** to display the query values in the **Rules** panel. Multiple queries can be executed during a single search operation. Repeat steps 1 through 7 for each additional rule.

   The **Not** button will negate a query value.

   The **Or** button will concatenate multiple queries while satisfying the search with only one of the queries. The **Or** function applies to the query rule above the selection.

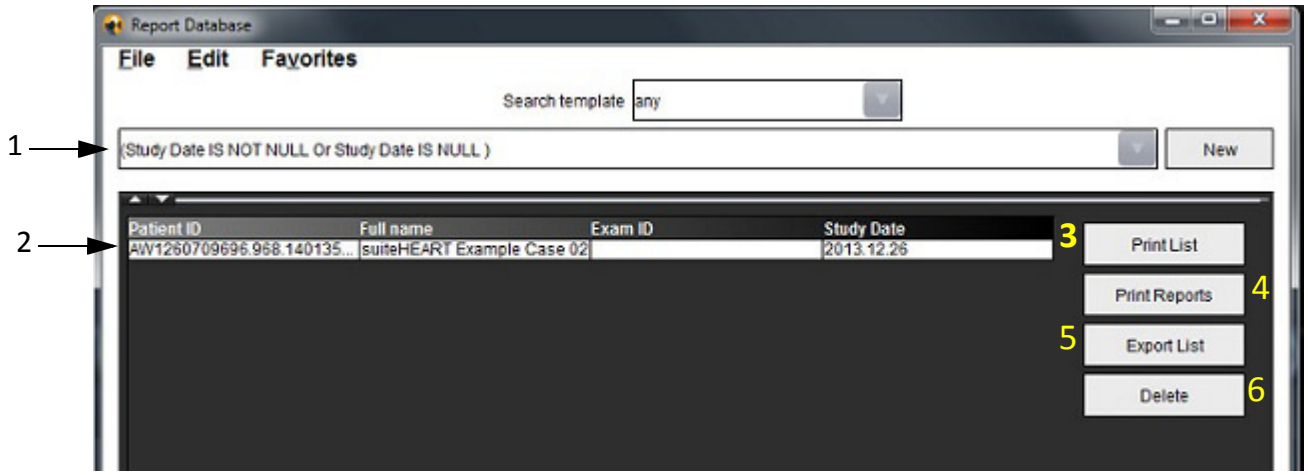
   The **Delete** button provides a means to select and delete a query rule.

Activate the Search

1. Select **Run** to search the database.

   The search results are displayed in the Query result area. The query values that satisfy the search are displayed in the right most column of the result window.

FIGURE 4. Query Result Window



1. History bar, 2. Query results, 3. Print list button, 4. Print reports button, 5. Export list button, 6. Delete button

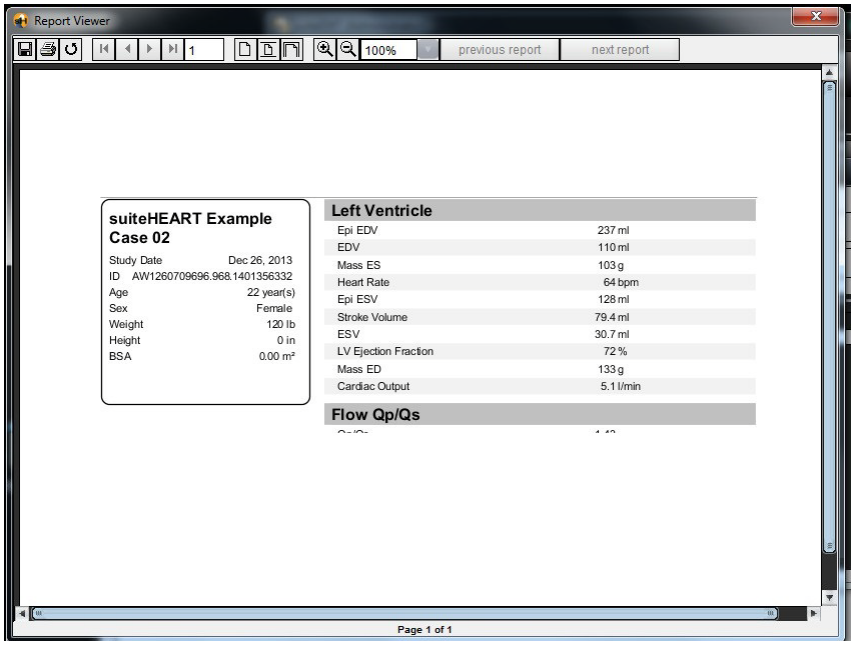
NOTE: New query results are only created based on a unique combination of exam ID, exam date, authorized signature and report template. If a duplicate of these fields is recognized, the old report is replaced by the new report.

View the Results

1. To view a report, double click an entry in the Query result area.

   A new window opens displaying the selected report. If more than one report is available, use **Next Report** and **Previous Report** to step through the reports. Click the close window marker  to close the Report Review window.

FIGURE 5. Report Window



2. Apply the Edit menu selection options to modify the result selections:

   Edit > Select All selects all search results.

   Edit > Clear Selection deselects all search results.

   Edit > Invert Selection toggles the selection state of each result.

   Edit > Clear History deletes record of previous queries.

3. Select **Print List** to send the query list to the printer.
4. Select **Print Reports** to send the selected reports to the printer.
5. Select **Export List** to save the list as an html file.
6. Select **Delete** to remove the selected report(s) from the report database

Save a Query

1. Select **Favorites > Add to Favorites**.
2. In the Add To Favorites text box, type in a label for the query and click **OK**.

FIGURE 6. Favorites Menu

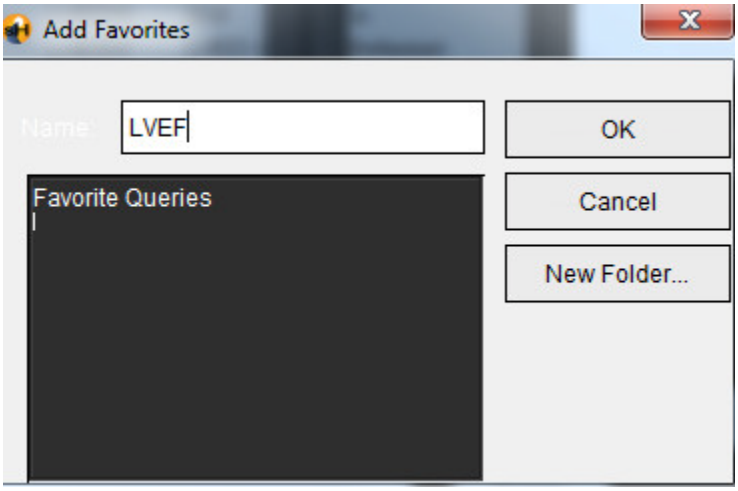
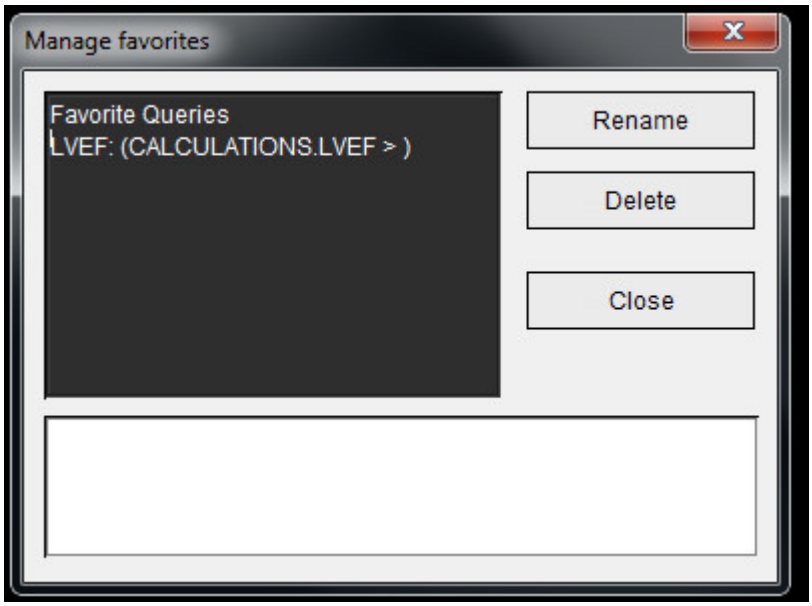


FIGURE 7. Favorites Pull-down

Delete a Favorite

1. Select **Favorites > Manage Favorites** from the Report Database window.

FIGURE 8. Manage Favorites Window



2. Select the favorite item.

   The entire query formula is displayed in the Result window.

3. Click **Delete**.

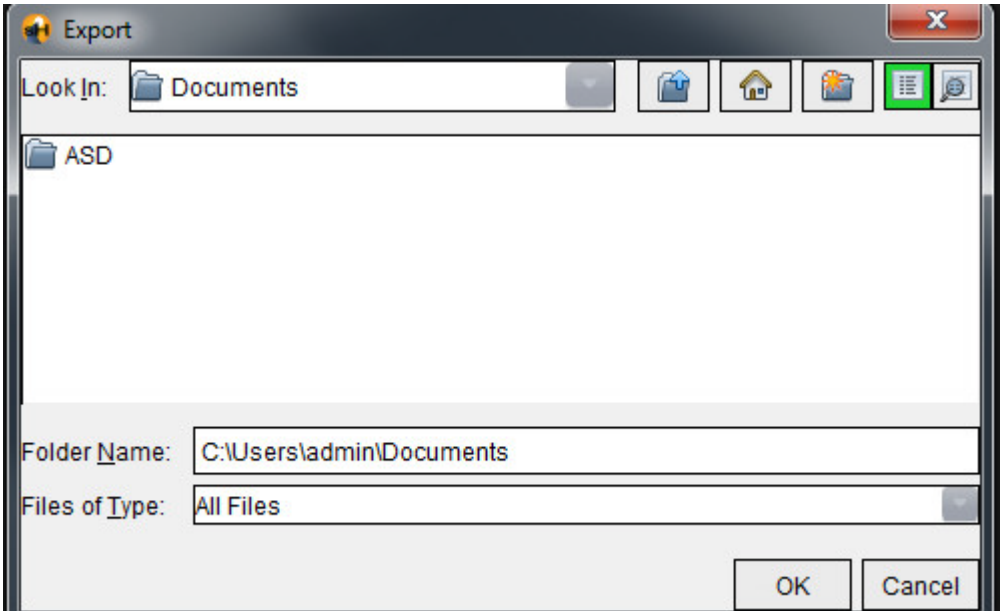
   A confirmation popup will verify your delete selection. Select **Yes**.

4. Select **Close**.

Export Search Results to an HTML File

1. Select **Export List** on the right hand side of the Report Database window.

FIGURE 9. Export Window



2. Select the directory to which to export the list.
3. Select **OK**.
    - A popup window inquires whether the reports should be included.
    - The listing and reports are exported to an HTML file.

Export the Database

As the database becomes larger it is advisable to archive the data.

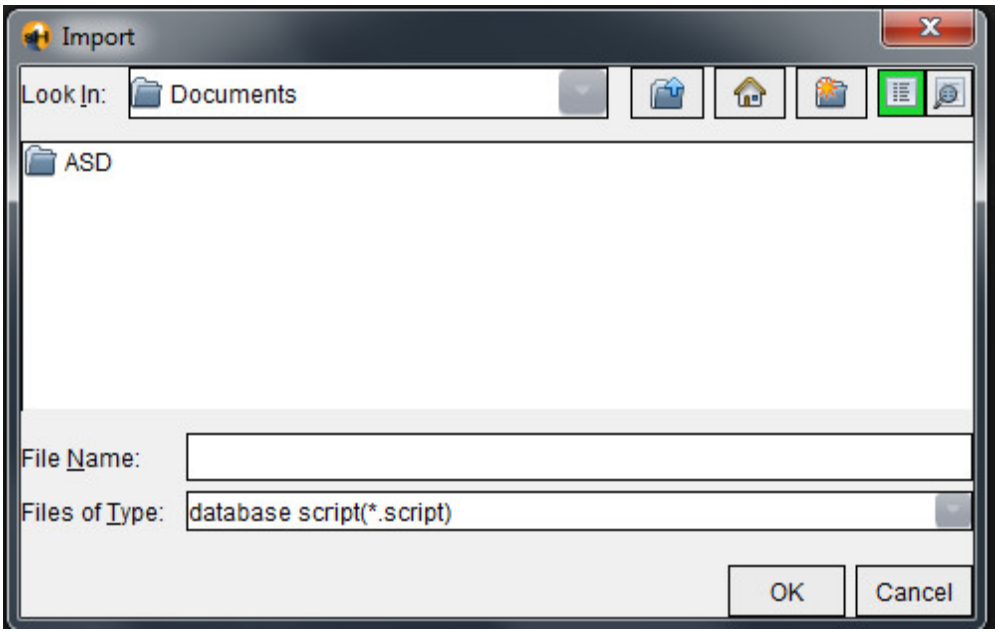
1. Select **File > Export** from the Report Database menu bar.
2. Select the directory to which to export the list.
3. Select **OK**. The database is exported to the external storage device.

Import a Database

The database can be imported from another PC to which it was exported.

1. Select **File > Import**.

FIGURE 10. Import Window



2. Select the directory from which to import the database.
3. The imported database is merged with the existing database.

Image Management Tools

Creating a Custom Series for Viewing Purposes

The application has a number of features designed to assist you in organizing and managing images.

The Custom Series editor is used to create a new custom series that contains images from other series within the same exam or from other exams for viewing purposes only.

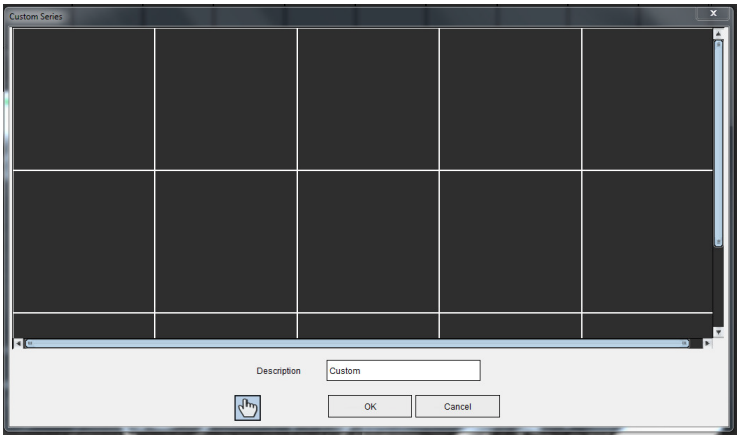
WARNING: Creation of a new series should be for viewing purposes only. Custom series can be created from different prescriptions, exams and patients which could lead to patient information mismatch and / or misdiagnosis. All analysis should be performed on the original series within the exam for correct results.

Create a Custom Series Procedure

NOTE: If a user has applied image manipulation tools on an image and then uses that image in a custom series, any image manipulation that has been performed is not retained by the custom series.

1. Select a series.
2. Select **File > New Custom**.
    - The Custom Series editor window appears.

FIGURE 1. Custom Series Editor Window



3. Select an image from the thumbnail images and drag it to a frame in the Custom Series editor window.
    - The hand icon is highlighted by default to enable the drag mode.
    - Image(s) from a different series within the exam can also be placed into the Custom Series editor window.
    - Image(s) within a series from a different exam can also be placed into the Custom Series editor window.

NOTE: If images from a different exam are added, the message “There is mixed patient data in this custom series.” will be displayed.

WARNING: User accepts responsibility for mixing series from different patient exams and should label the custom series accordingly. Series from different exams and patients could result in patient information mismatch and / or misdiagnosis. The user should be properly trained in cardiac analysis and should not interpret information directly from custom created series.

4. Enter a label in the Custom Series editor window.
   - Type a name in the **Description** field to be appended to the new series description.
5. To delete an image from the editor window, select the image and strike the Delete key.
6. Click **OK** to close the editor and create a new series.

   A progress marker is displayed while the database is updated with the new series.

View a Custom Series Procedure

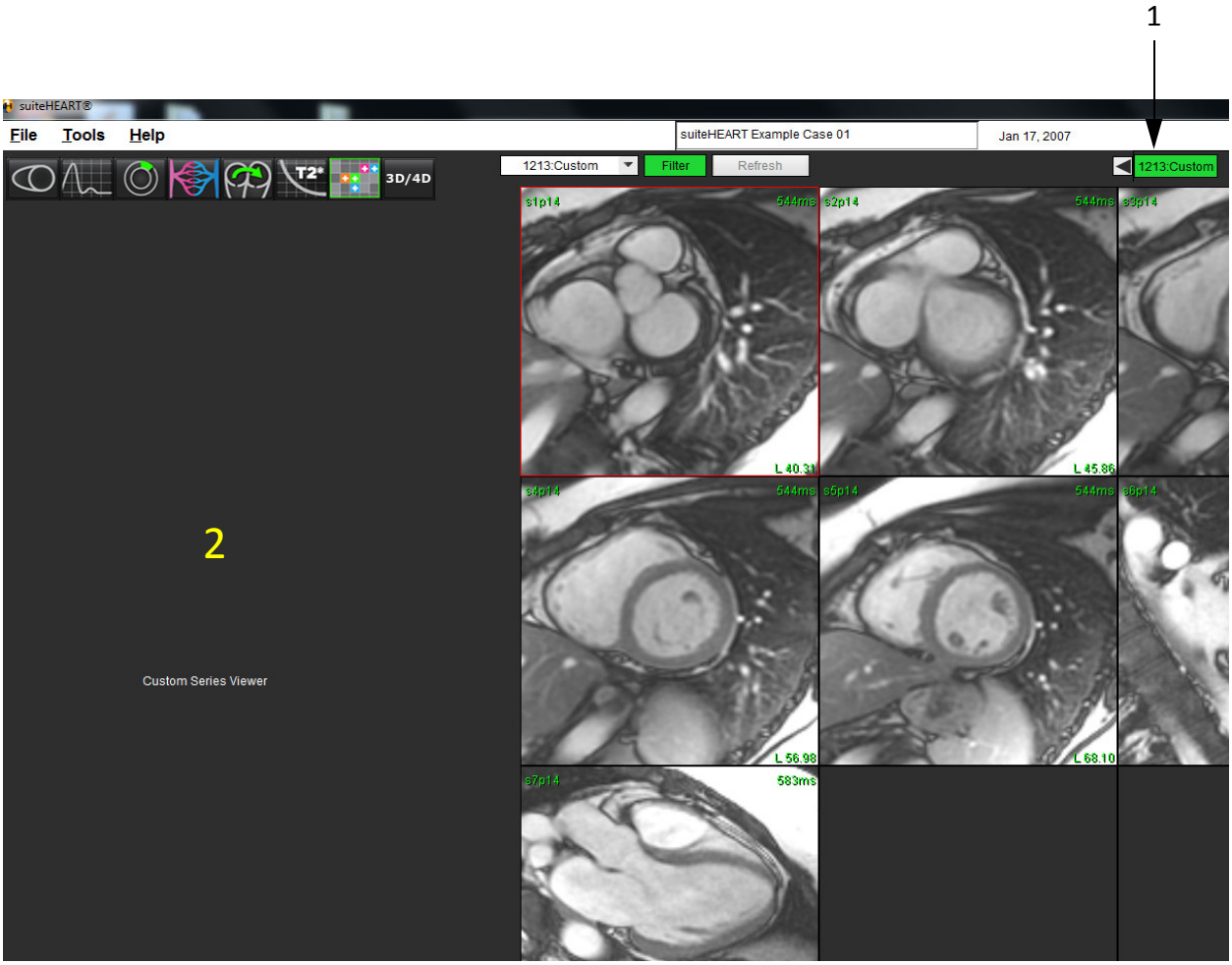
1. Select  **button.**

   The Custom Series Viewer is displayed with tabs for each custom series available within the current exam.
2. Select the series tab with the desired custom series.

   The custom series is available for viewing purposes only.

NOTE: A custom series can be deleted by clicking on each image viewport and selecting the delete key on the keyboard. If window leveling has been performed it will be reset upon deletion of an image.

FIGURE 2. Custom Series Viewer



1. Custom series tabs, 2. Blank analysis view window

DICOM Import Procedure

The DICOM import tool allows the user to create new DICOM series for analysis.

WARNING: Images that have been imported and localized by an external PACS may be ignored by suiteHEART® Software.

FIGURE 3. DICOM Import Tool

1. Series filter, 2. Series list, 3. Series / Slice panel, 4. New series panel, 5. Selected image information, 6. Save series

Create a DICOM Import Series

1. Select **File** > **DICOM Import**
2. Select the series from the series list to view the slices in the series slice panel
3. The series that appear in the series list can be filtered by typing into the **Description** text box and clicking **Apply**.

   Any series description containing the text in the Description text box will be shown in the Series list.

   NOTE: The series filter is case sensitive.
4. Select the image in the Series / Slice panel.

   The image information is shown in the Selected image information table.
5. Drag and drop images from the Series / Slice panel into the New Series panel.

   All phases for the selected slice are copied to the new series.

   The order of the slices in the new series panel reflect the order of images in the new series.

OR

6. Select a group of series by performing a Shift click or a Ctrl click for adding a single series. Perform a right mouse click to **Add to Series**.

NOTE: Each slice of the new series must have the same number of phases, be of the same acquisition prescription, and must be parallel.

7. Select the analysis type for the new series in the New series information panel.
8. Type the new series description into the in the New series information panel.
9. Select **Save** to write the new series to the currently loaded study.
    - Once a series is saved it cannot be modified.
    - The DICOM import tool is reset after saving a new series.

Click  to reset the DICOM import tool without saving a new series.

NOTE: The new series created with this tool are only reviewable within the suiteHEART application.

WARNING: The user is responsible for creating new series for analysis that contain the correct images for analysis. Incorrectly formed series may be analyzed but could produce inaccurate results. The user should be properly trained in cardiac analysis and must be aware of the slice location images copied into the new series. Do not delete original images that have been used for DICOM import.

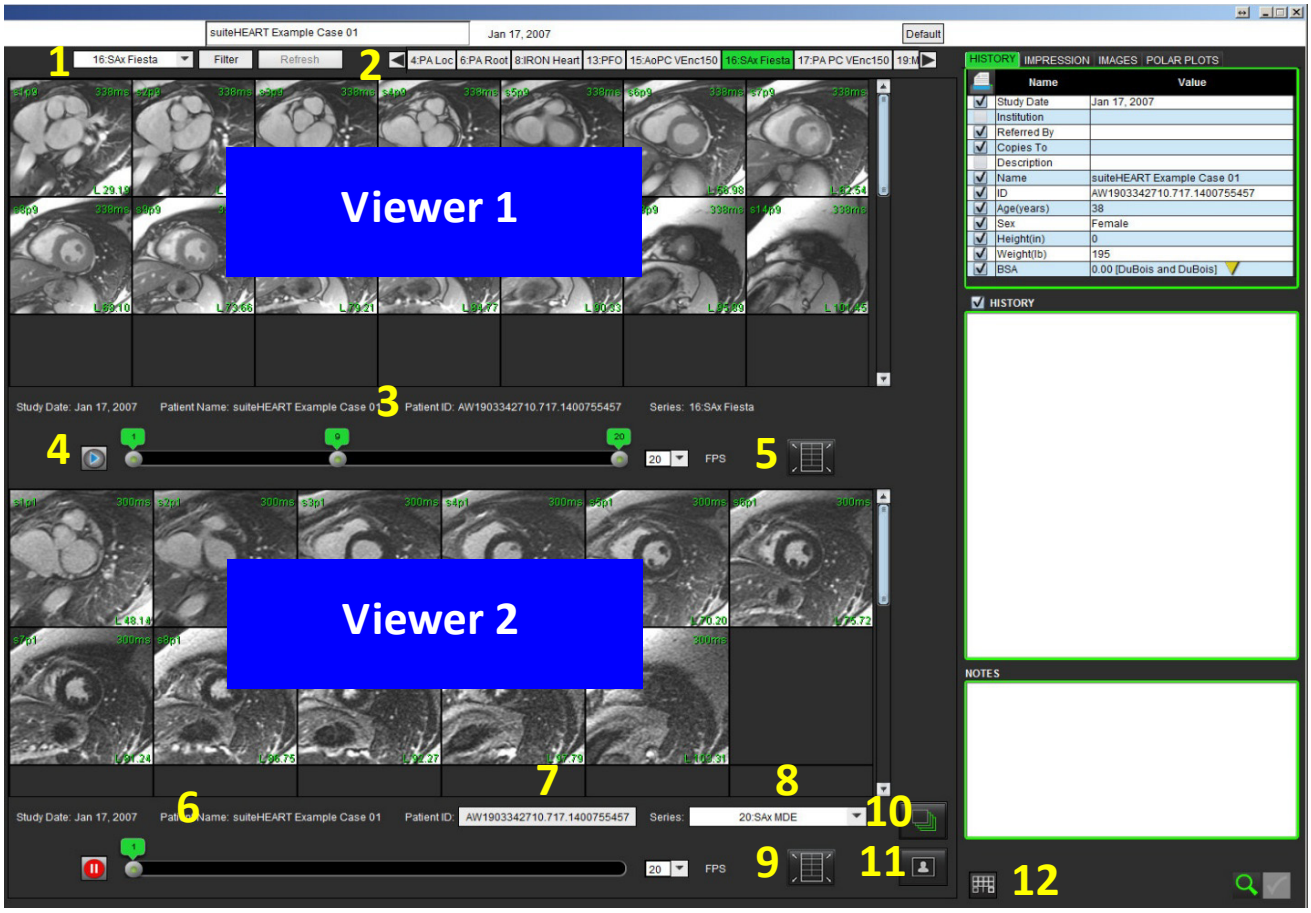
Compare Mode

Compare mode gives you the ability to review images/series from a current exam, or from a prior exam, simultaneously within the same interface.

NOTE: Editing of analysis types, Export DICOM Cine and Export Cine files is not available in compare mode.

WARNING: Prior to the review or comparison of exams or series within an exam, visually confirm all exam patient indicator information for both viewers.

FIGURE 4. Compare Mode Viewer



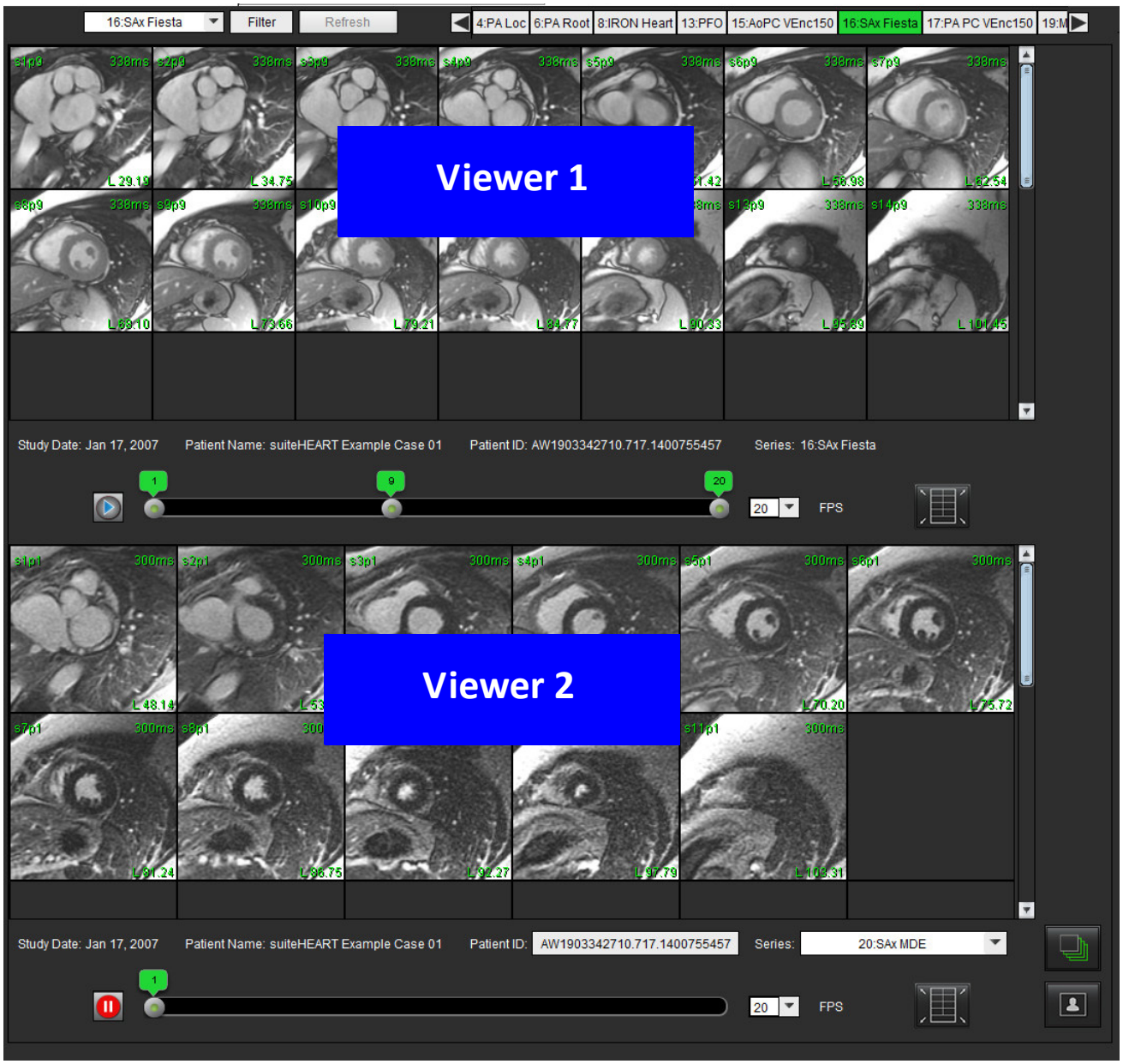
Viewer	Callout	Description
Viewer 1	1	Series pull-down
	2	Series selector
	3	Currently viewed patient exam indicator line
	4	Image controls
	5	Viewport layout selections
Viewer 2	6	Currently viewed patient exam indicator line
	7	Exam selector
	8	Series selector
	9	Viewport layout selections
Both Viewers	10	Change scope settings
	11	Toggle for Review Mode
	12	Toggle for Analysis Mode

Sample Workflow

1. Select  from the lower right side of the Report View Window.

2. Select  to split the interface into two viewers, as shown in Figure 5.

FIGURE 5. View in Compare Mode



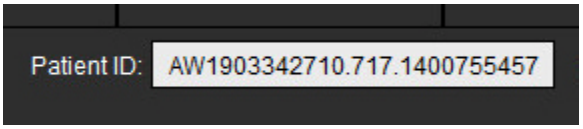
3. Change the series in Viewer 1 by using the series selection pull-down menu or right/ left arrows.
    - This upper viewer always displays the current study that has been previously launched.

4. In Viewer 2, use the series pull-down to choose a different series, within the same exam, to compare with that which is shown in Viewer 1.
    - When a viewport is selected in any viewer and if the slice is parallel such as a short axis series, the corresponding slice, based on slice location, will be highlighted.

FIGURE 6. Series Pull-down, Viewer 2

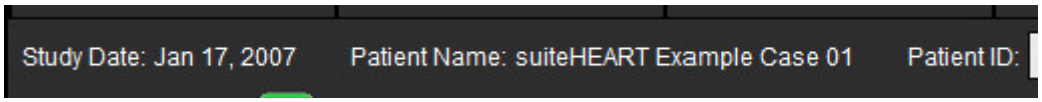
5. Use the exam selector, to compare a different exam in Viewer 2 to the current exam shown in Viewer 1.

FIGURE 7. Exam Selector, Viewer 2



6. Confirm proper exam selection by checking the exam indicator information for both viewers.

FIGURE 8. Exam Indicator Information



7. Performing a right mouse click on either viewer will open the image manipulation tools.
    - The scope selection applies to both viewers.

NOTE: Performing image locate from the Images tab will not be valid if the image is from a different study.

Appendix

Formulas and Technical Reference

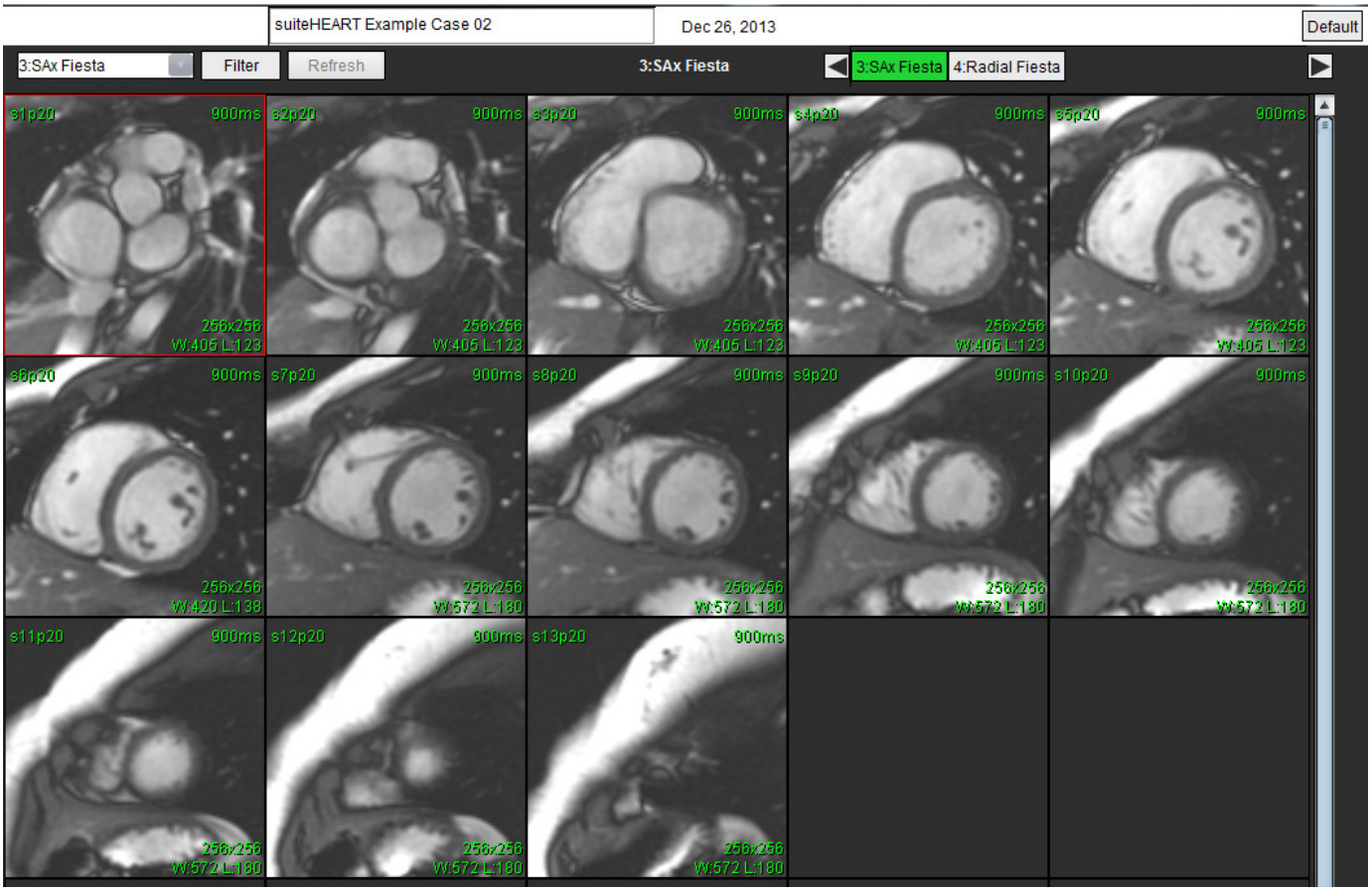
Appendix A - Reference Articles

Preference ranges, as described on page 35 of this manual, may be established from the following peer review literature references:

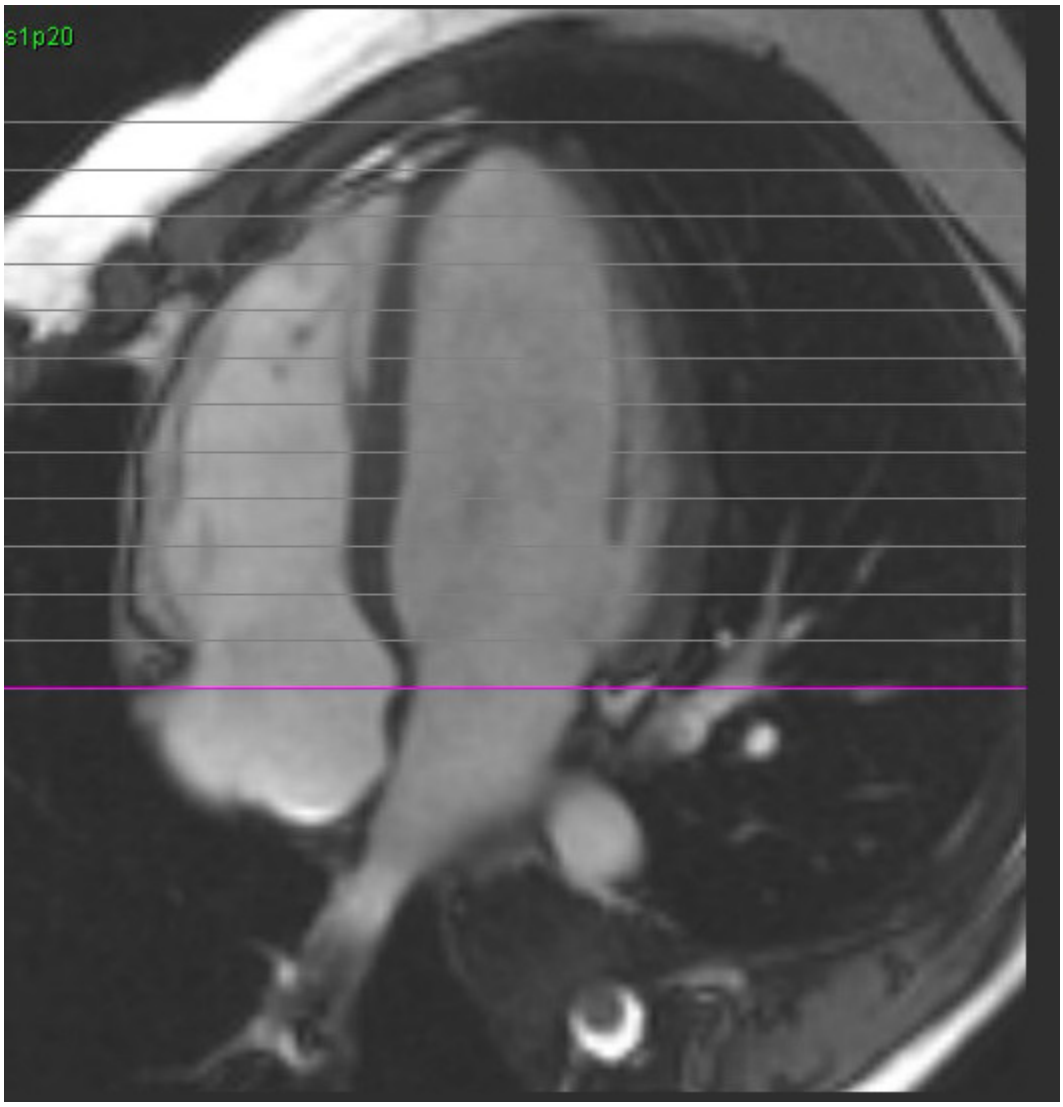
1. Maceira A.M. et al, "Normalized Left Ventricular Systolic and Diastolic Function by Steady State Free Precession Cardiovascular Magnetic Resonance." Journal of Cardiovascular Magnetic Resonance (2006) 8, 417-426.
2. Lorenz C. et al. “Normal Human Right and Left Ventricular Mass, Systolic Function, and Gender differences by Cine Magnetic Resonance Imaging.” Journal of Cardiovascular Magnetic Resonance 1(1), 7-21, 1999.
3. Sechtem, U. et al. “Regional left ventricular wall thickening by magnetic resonance imaging: evaluation in normal persons and patients with global and regional dysfunction.” Am. J. Cardiol. 1987 Jan 1;59(1):145-51.
4. Storey P, et al. “R2* Imaging of Transfusional Iron Burden at 3T and Comparison with 1.5T,” Journal of Magnetic Resonance Imaging 25:540–547 (2007)
5. D.J Pennell, et al. “Cardiovascular T2-star (T2Star) magnetic resonance for the early diagnosis of myocardial iron overload”, Eur Heart J 2001; 22: 2171-2179.

Appendix B - Functional Analysis Scan Plane Example

For accurate function results, analysis should be performed on a short axis view as shown in the first figure below.



Correct scan plane prescription for the acquisition of the short axis view. Slices should be prescribed perpendicular to the long axis of the left ventricle with at least 2 slices above the base and 1 slice after the apex included in the series.



Appendix C - Supported Manufacturers

suiteHEART® Software has been evaluated with cardiac MRI images from the following manufacturers listed in the table below.

Manufacturer	Scanner Type	Analysis Mode
GE Healthcare	Discovery MR750 Discovery MR750w Optima MR360 Optima MR450w Optima MR450 Signa HD Signa HDx Signa HDxt	All Analysis Modes
Philips Healthcare	Achieva Ingenia Intera Intera Achieva	Function, Myocardial Evaluation, Time Course, Flow
SIEMENS	Aera Avanto Espree Skyra Sonata Symphony Verio	Function, Myocardial Evaluation, Time Course, Flow

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