

suiteHEART™

Instructions for Use

NeoSoft, LLC



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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

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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:



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

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Installation

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“Licensing Schemes” on page 2

Prerequisites

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

- Supported Operating Systems:
 - Windows 7 Professional or Enterprise with SP1 (64 bit version)
 - Windows 8.1 Professional or Enterprise (64 bit version)
- Video card and monitor shall support 1920 x 1080 resolution.
- Anti-Virus software installed.
- Minimum 4GB memory.
- Available hard drive space minimum 5GB.
- PDF viewer, Adobe Reader 11.0 or higher.
- An open network port for DICOM transfer over network.
- Static IP address (recommended).
- Java Runtime Environment (JRE) version 7 (update 40 or later).

NOTE: suiteHEART is not supported in Remote Desktop or Virtual Machine environments.

Installation

1. Double-click on the suiteHEART 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. Click **Next** on the Wizard.
4. In the “Welcome to suiteHEART Setup Wizard window, 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.

Licensing Schemes

suiteHEART 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 70% of the Per-Case Pack has been used the software will indicate this condition by a pop-up message prior to starting an analysis with a new exam or an existing exam.

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 version 2.1.0 has an expected useful service life of 7 years from its original release date.

Safety

“Indications for Use” on page 4

“Intended Use” on page 4

“Safety Notices” on page 5

“Equipment Hazards” on page 5

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 <u>will</u> 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 <u>may</u> 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 <u>can</u> cause minor personal injury or property damage if the instructions are ignored.

Indications for Use

suiteHEART is an analytical software tool, which provides reproducible tools for the review and reporting of medical images. suiteHEART 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.



WARNING: Data stored as a DICOM image that has been imported by an external PACS may be ignored by suiteHEART.

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 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 supports the following DICOM format; MR and Enhanced MR. Refer to the suiteHEART 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” on page 7

“Launching suiteHEART” on page 7

“Exiting suiteHEART” on page 8

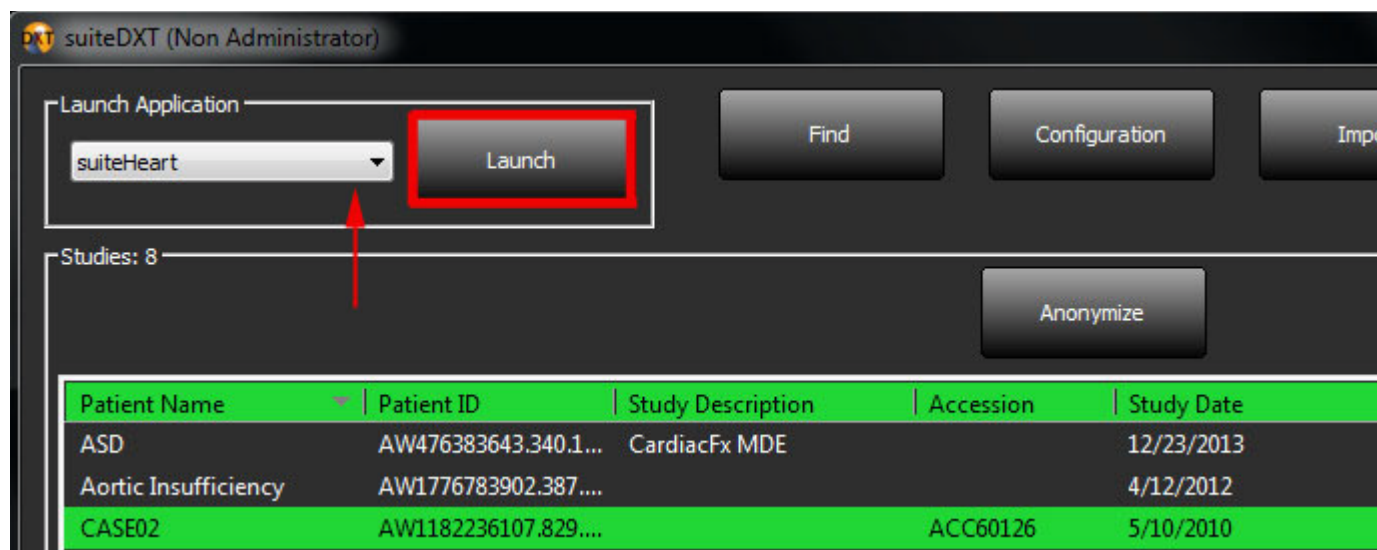
Launching and Exiting the Application

suiteHEART is a software 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 user interface and the workflow for performing quantitative analysis on cardiac MR images.

Launching suiteHEART

1. Launch suiteDXT via the desktop shortcut.
2. On the Main Screen go to the Launch Application drop-down menu and select suiteHEART.

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.

- Exams containing images with pixel intensity filters applied will be listed in a message box prior to opening the exam. To load the filtered images, click Select All > Continue.

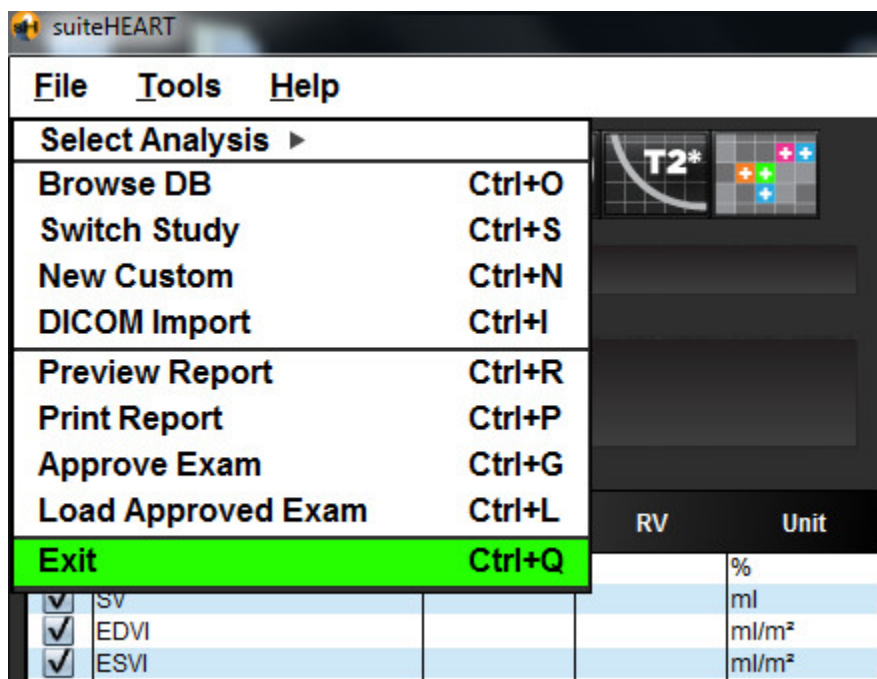


WARNING: Using images with pixel intensity filters applied for analysis may cause inaccurate results.

Exiting suiteHEART

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

FIGURE 2. Quit suiteHEART



User Interface Overview

Overview on page 9

Analysis Modes on page 10

Editor Window and Mode View on page 11

Mode Views on page 12

Quick Keys for Image Manipulation on page 16

Analysis Panel on page 17

Edit Tab Labels on page 19

Reporting Tabs on page 21

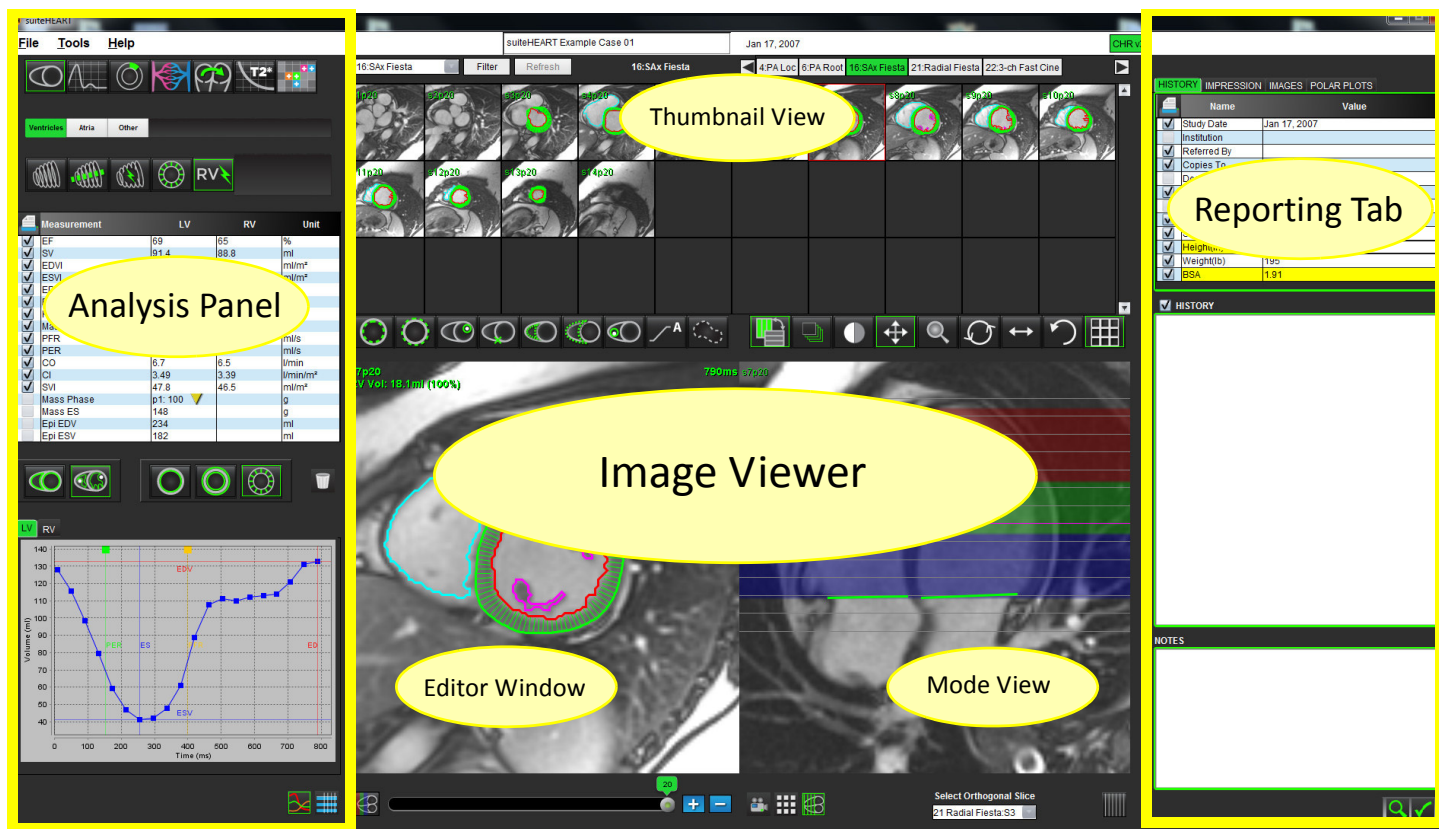
Browse DB on page 22

Overview

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

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

FIGURE 1. Three Main Panels: Analysis Panel, Image Viewer, Reporting Tab



Analysis Modes

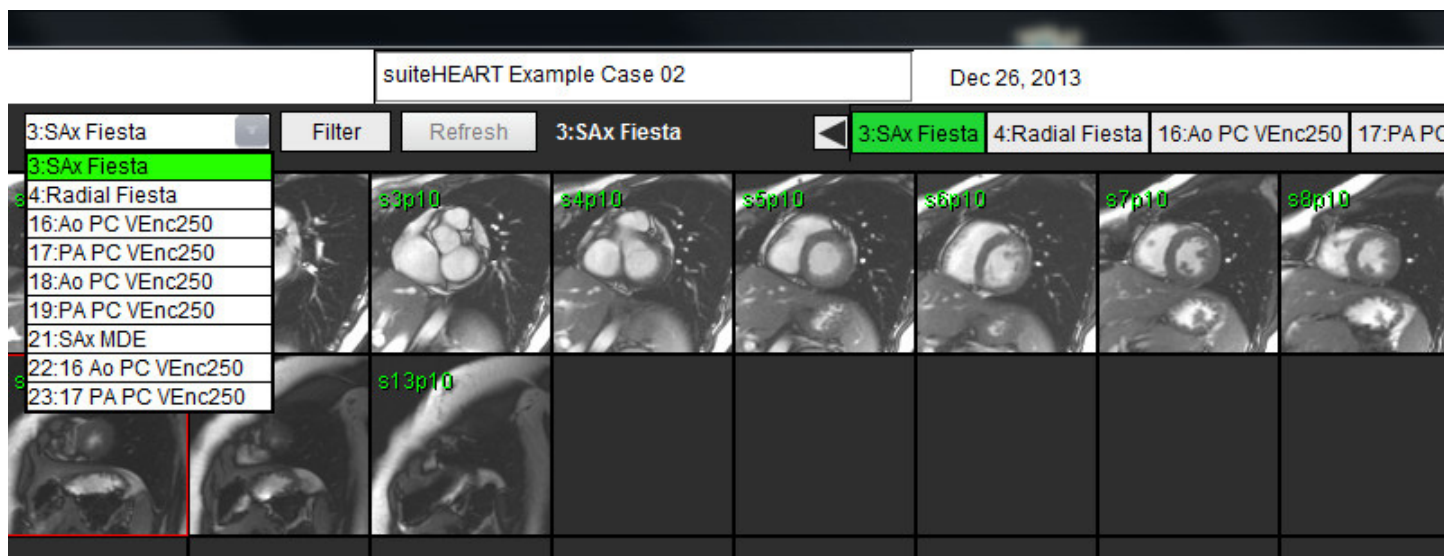
Table 1: Icons and Names

Function Analysis	Flow Analysis	Myocardial Evaluation	Time Course Analysis	Patent Foramen Ovale Analysis	T2 Star Analysis	Custom Series

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 Viewer. The series file pull-down menu, located to the left of the Filter button, can also be used to select the series, 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 Viewer will activate image manipulation tools.

Table 2: Icons and Names

	Window/Level
	Pan
	Zoom
	Rotate
	Send to Report
	Scan Parameters

File Menu Options

Select Analysis – Selects the analysis mode (Function, Flow, ME, Time Course, PFO, T2Star, and Custom Series)

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 and myocardial evaluation modes
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.

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
Freehand ROI – Provides area measurements
Label – Provides the addition of used annotation in the Editor Window

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

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

Operator Document – suiteHEART Operator Manual
DICOM Conformance Statement – suiteHEART DICOM Conformance Statement
About suiteHEART – Version information about the application

Mode Views

Image Viewer 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 Tool: Allows for the definition of basal, mid ventricular, apical slices for regional analysis

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

Cine Mode

The mode view has three available formats:



- 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 to select the cine speed



- Play Icon: Located directly on the image



- Pause Icon: Located directly on the image

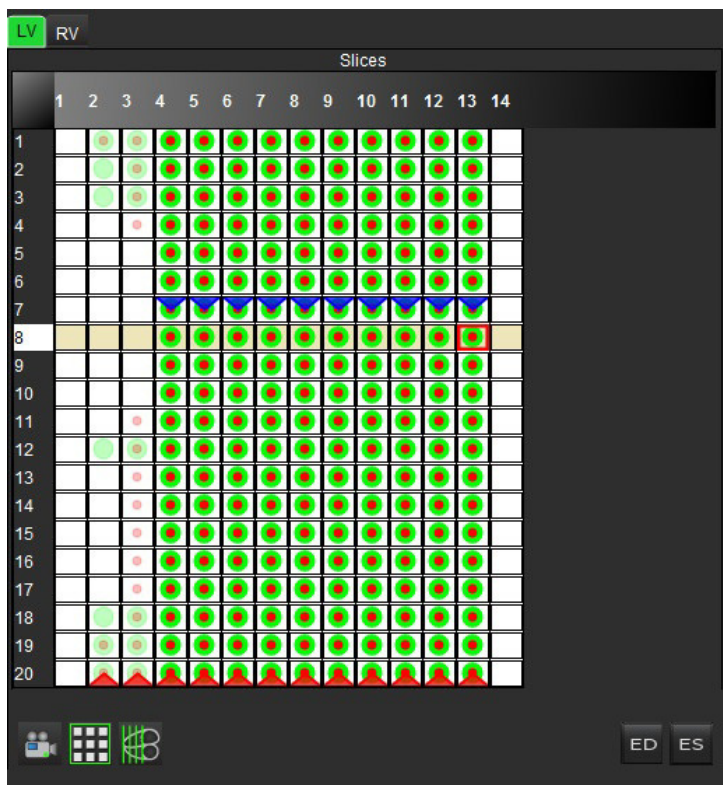
Matrix Mode



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 Controls are used to adjust the end systolic and end diastolic phases within the matrix mode. 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 displayed in the multi-view 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.



- Cross Reference Controls

FIGURE 4. Cross Reference Mode Icon



Image Manipulation Tools

Table 3: Icons and Names

















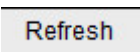
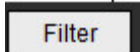
	Slice/Phase Review Toggle
	Window/Level – Select and use middle mouse button to make adjustment
	Pan – Select and use middle mouse button to make adjustment
	Zoom – Select and use middle mouse button to make adjustment
	Rotate – Select and use middle mouse button to make adjustment
	Flip Horizontal – Flips the image horizontally
	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
	Toggles between the analysis and review screens
	Toggles between the review and analysis screens
	Reset – Resets the W/L, Pan, Zoom and Rotate back to default, based on the scope setting
	Freehand ROI – Provides area measurements

Table 3: Icons and Names

	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 viewer with newly networked images
	Filter – Sorts series by pulse sequence type according to analysis mode. Can be deselected by selecting ALL

Quick Keys for Image Manipulation

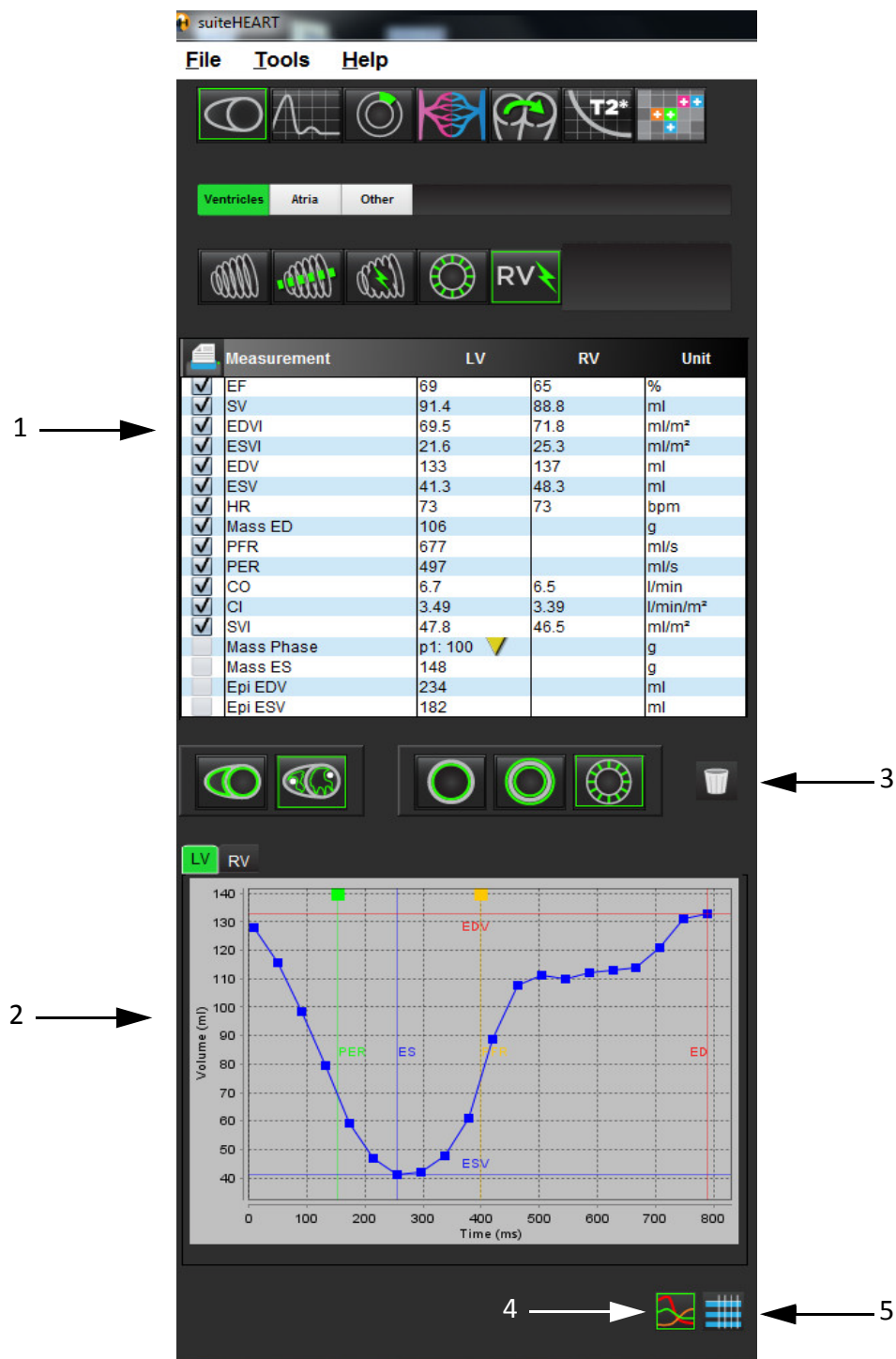
Table 4: Quick Keys

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 Reporting Interface	Ctrl-R
Print Report	Ctrl-P

Analysis Panel

The Analysis Panel is available for each analysis mode.

FIGURE 5. Analysis Panel Features





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

Analysis Panel Functions

Measurement Table

FIGURE 6. Results Parameters: Select or deselect from inclusion on the report by clicking the box next to the parameter

	Measurement	LV	RV	Unit
<input checked="" type="checkbox"/>	EF	69	65	%
<input checked="" type="checkbox"/>	SV	91.4	88.8	ml
<input checked="" type="checkbox"/>	EDVI	69.5	71.8	ml/m ²
<input checked="" type="checkbox"/>	ESVI	21.6	25.3	ml/m ²
<input checked="" type="checkbox"/>	EDV	133	137	ml
<input checked="" type="checkbox"/>	ESV	41.3	48.3	ml
<input checked="" type="checkbox"/>	HR	73	73	bpm
<input checked="" type="checkbox"/>	Mass ED	106		g
<input checked="" type="checkbox"/>	PFR	677		ml/s
<input checked="" type="checkbox"/>	PER	497		ml/s
<input checked="" type="checkbox"/>	CO	6.7	6.5	l/min
<input checked="" type="checkbox"/>	CI	3.49	3.39	l/min/m ²
<input checked="" type="checkbox"/>	SVI	47.8	46.5	ml/m ²
<input type="checkbox"/>	Mass Phase	p1: 100 		g
<input type="checkbox"/>	Mass ES	148		g
<input type="checkbox"/>	Epi EDV	234		ml
<input type="checkbox"/>	Epi ESV	182		ml



- Trashcan Icon: Resets measurements performed by the Analysis Panel

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 Panel.

FIGURE 7. Graph (left) and Table (right) Icons: Displays curve results



Table 5: Analysis Icons















	Left Ventricular Endocardial ROI
	Left Ventricular Epicardial ROI

Table 5: Analysis Icons

	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.

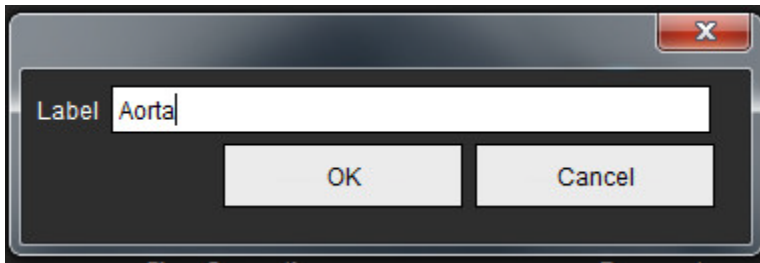
FIGURE 8. Flow Analysis Tabs Example



Edit Tab Procedure:

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

FIGURE 9. Edit Tab Label Pop-up Window



Reporting Tabs

suiteHEART has four reporting tabs for structured reporting. Refer to Structured Reporting on page 85 for more information.



FIGURE 10. Reporting Tabs

HISTORYIMPRESSIONIMAGESPOLAR PLOTS

	Name	Value
<input checked="" type="checkbox"/>	Study Date	Jan 17, 2007
<input type="checkbox"/>	Institution	
<input checked="" type="checkbox"/>	Referred By	
<input checked="" type="checkbox"/>	Copies To	
<input type="checkbox"/>	Description	
<input checked="" type="checkbox"/>	Name	suiteHEART Example Case 01
<input type="checkbox"/>	ID	AW1903342710.717.1400755457
<input checked="" type="checkbox"/>	Age	38
<input checked="" type="checkbox"/>	Sex	Female
<input checked="" type="checkbox"/>	Height(in)	63
<input checked="" type="checkbox"/>	Weight(lb)	195
<input checked="" type="checkbox"/>	BSA	1.91

☒ HISTORY

NOTES





- Review Report: Used for previewing a report

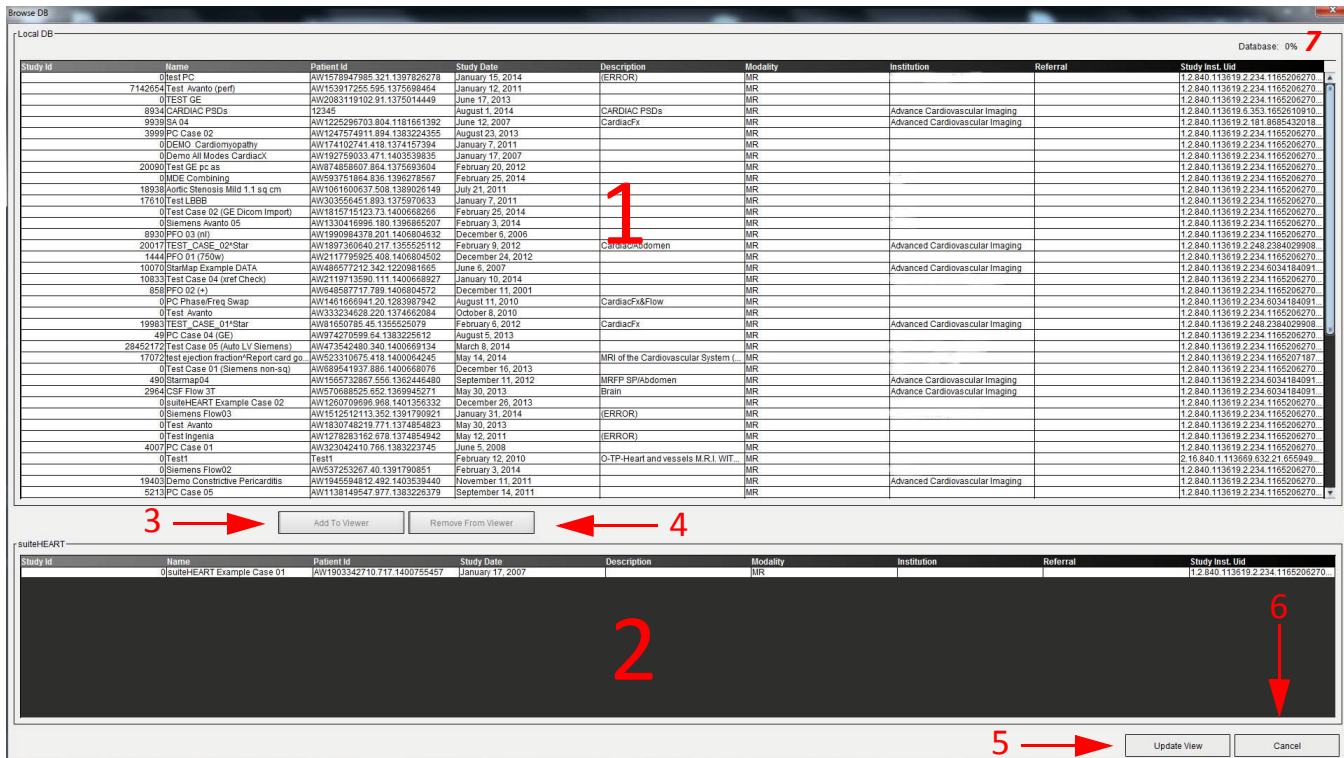


- Signoff: Used for report signature

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 11. Browse DB Window



1. Local database listing, 2. suiteHEART 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 database viewer** – displays exams that are in the current suiteHEART database.
3. **Add to Viewer** – Adds the selected exam from local database (shown in the top portion of the window) to the suiteHEART database viewing area.
4. **Remove from Viewer** – Removes the exam from suiteHEART 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 database Viewer list and clicking **Update View**.

Add Exams to the suiteHEART 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 Switch Study List.

Remove Exams from the suiteHEART Switch Study List

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

NOTE: Exams can only be deleted from the suiteDXT Main screen.

Switch Study Procedure

Exams must be loaded into suiteHEART 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

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

“Edit Preferences” on page 25

“System Preferences” on page 25

“Template Preferences” on page 30

“Macro Preferences” on page 33

“T2Star Preferences” on page 35

“Import Preferences” on page 35

“Export Preferences” on page 36

Selecting **Preferences** from the Tools menu on the suiteHEART 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.

Edit Preferences

The Edit Preferences feature offers tools to modify system preferences and create range preference templates. The system preferences include:

- Report Preferences
- Authorized Report Approvers
- Auto-save Preferences
- Export Preferences

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

System Preferences

Report Preferences

Configures the information that appears on all reports.

FIGURE 1. Report Layout Tab

The screenshot shows the 'Report Preferences' dialog box. At the top, there are four tabs: 'System Preferences' (highlighted in green), 'Template Preferences', 'Macro Preferences', and 'T2Star'. The 'Report Preferences' section contains the following elements:

- Two checked checkboxes: 'Use the field values below in Report' and 'Support even and odd row'.
- Seven text input fields labeled: 'Report Title', 'Report Sub Title 1', 'Report Sub Title 2', 'Header Line 1', 'Header Line 2', 'Header Line 3', and 'Header Line 4'.
- A 'Paper Size' section with two radio buttons: 'A4' (selected) and 'LETTER'.
- A 'Logo' section with a large empty box and a 'Browse' button.

Report Preferences Procedure

1. From the Image Viewer menu bar, select **Tools > Preferences > Edit Preferences**.
2. Select the **System Preferences** 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.
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**.

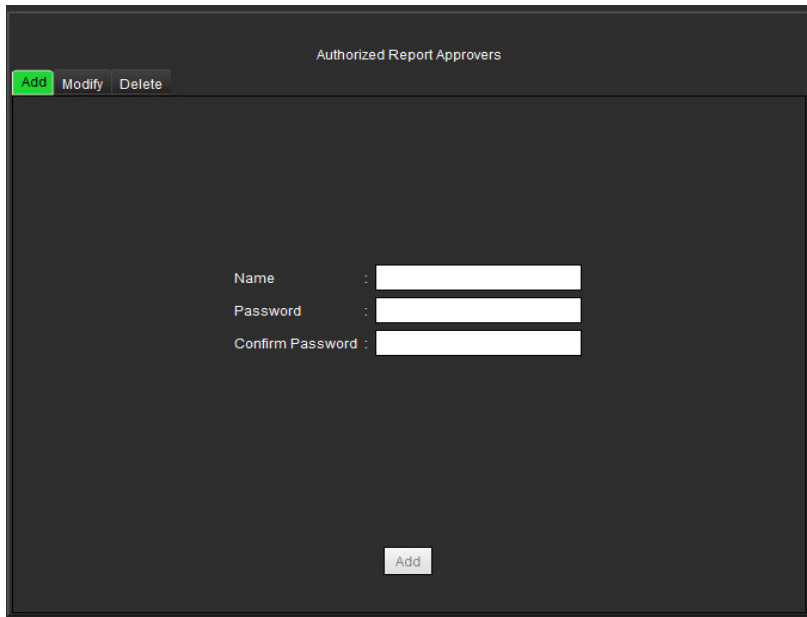
The logo should now appear on the report preferences panel.
5. Select **Save and Exit** to store your entries and close Edit Preferences.
 - Select **Cancel** to exit the window without accepting any changes.
 - Select **Reset** to reset all values on the System Preferences tab without exiting the window.

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.

Prerequisites – All tasks on each analysis report window are completed and ready for signature lock.

FIGURE 2. Authorized Report Approvers



Authorized Report Approvers

Add Modify Delete

Name :

Password :

Confirm Password :

Add

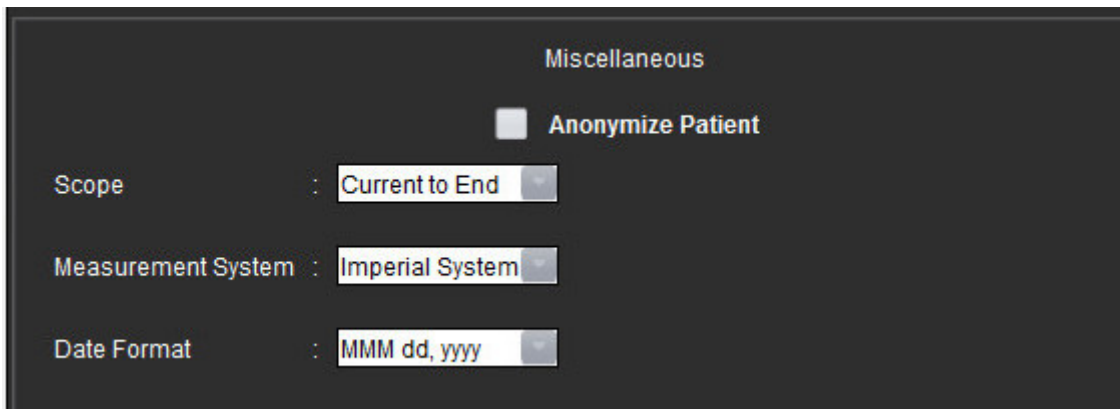
Manage Report Approvers Procedure

1. From the Image Viewer menu bar, select **Tools > Preferences > Edit Preferences**.
2. Select the **System Preferences** 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**.

Miscellaneous

The Miscellaneous panel allows you to anonymize the patient, set the default Scope for editing and set the default measurement and date formats.

FIGURE 3. Miscellaneous Panel



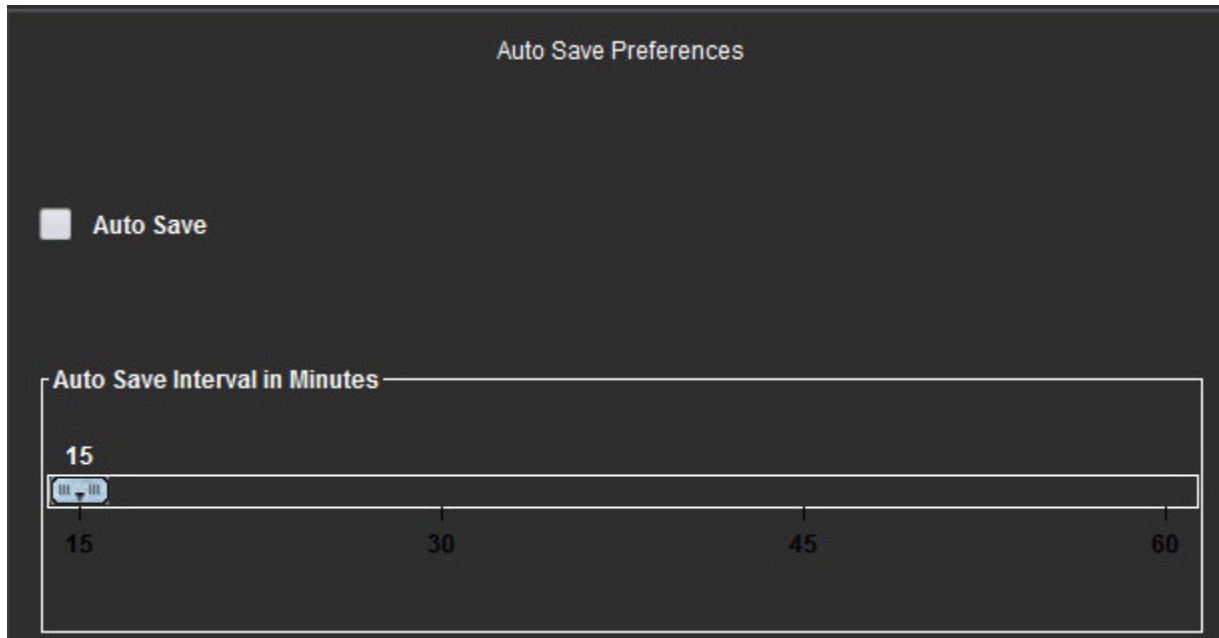
Edit Miscellaneous Parameters Procedure

1. From the Image Viewer menu bar, select **Tools > Preferences > Edit Preferences**.
2. Select the **System Preferences** 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 Viewer.
4. Select a default setting for **Scope**, the **Measurement System** and the **Date Format** from the pull-down menus.
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 System Preferences 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 4. Auto Save Preferences Window



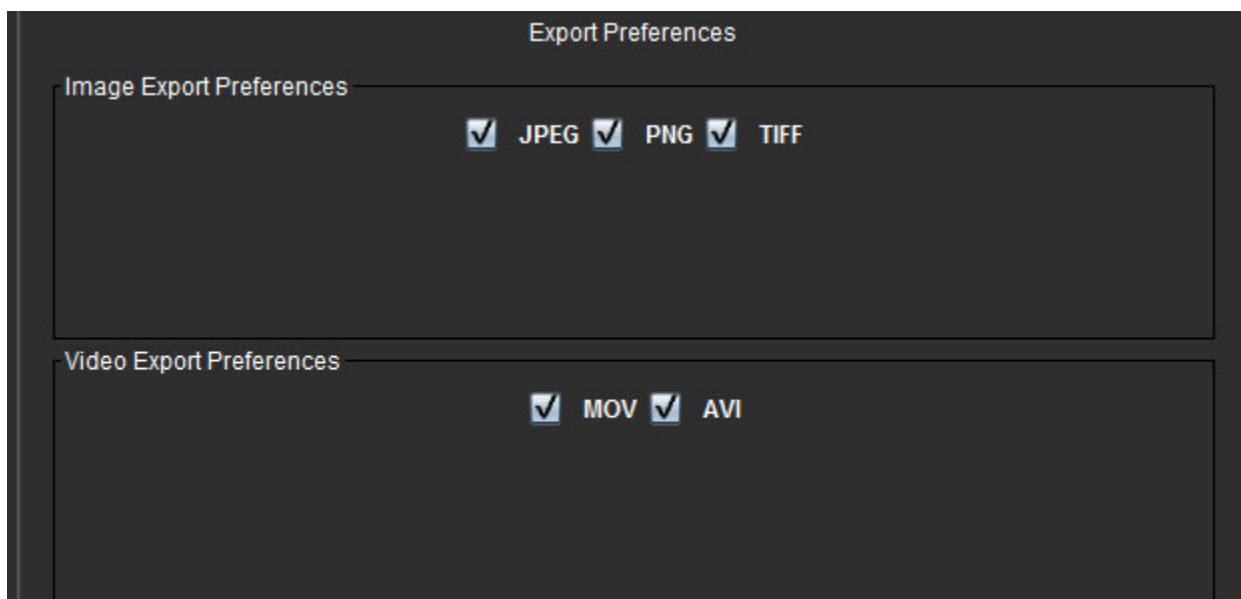
Edit Auto Save Preferences Procedure

1. From the Image Viewer menu bar, select **Tools > Preferences > Edit Preferences**.
2. Select the **System Preferences** 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 System Preferences 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 5. Export Preferences Window



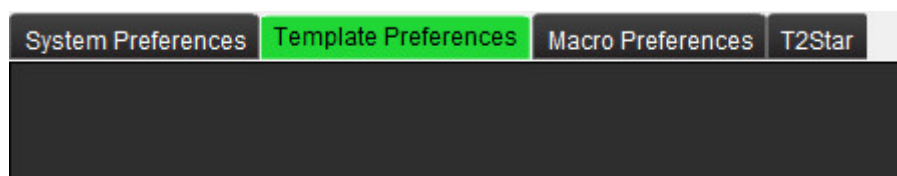
Export Preferences Procedure

1. From the Image Viewer menu bar, select **Tools > Preferences > Edit Preferences**.
2. Select the **System Preferences** 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 System Preferences 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.

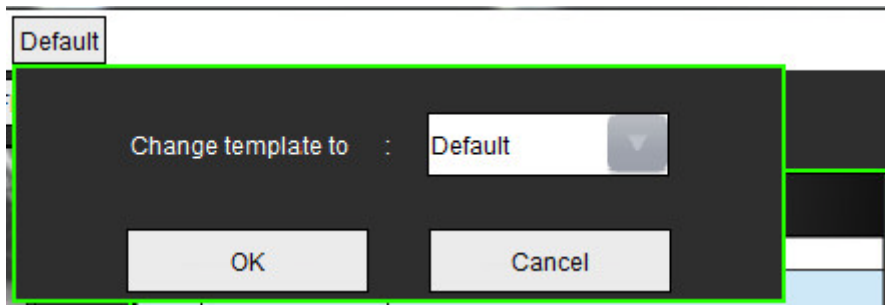
FIGURE 6. Template Preferences Tab



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.

FIGURE 7. Change Template



Create Template Procedure

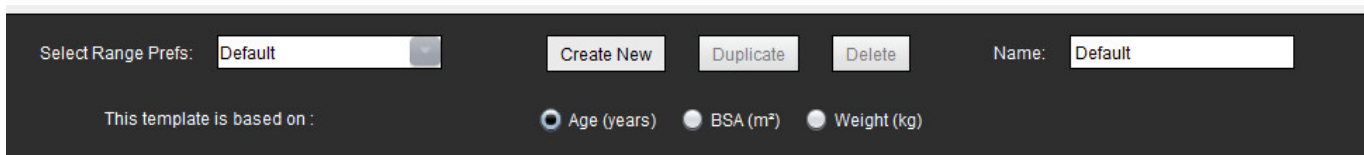
The following is a guide to creating a user defined template. It is up to the clinician's judgement to verify the validity of the parameter range utilized.

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 8. 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 End**.
 - 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 Select Range Prefs pull-down menu.

Delete a Template

1. Select **Tools > Preferences > Edit Preferences**.
2. Select the **Template Preferences** tab.
3. Select the template from the Select Range Preferences 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 9. 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.
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** markers to copy values between genders. Use the scroll bar to navigate to the measurements for all the analysis types.
 8. Select **Save and Exit** to store your entries and close Preferences.
 - Select **Cancel** to exit the window without accepting any changes.

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:

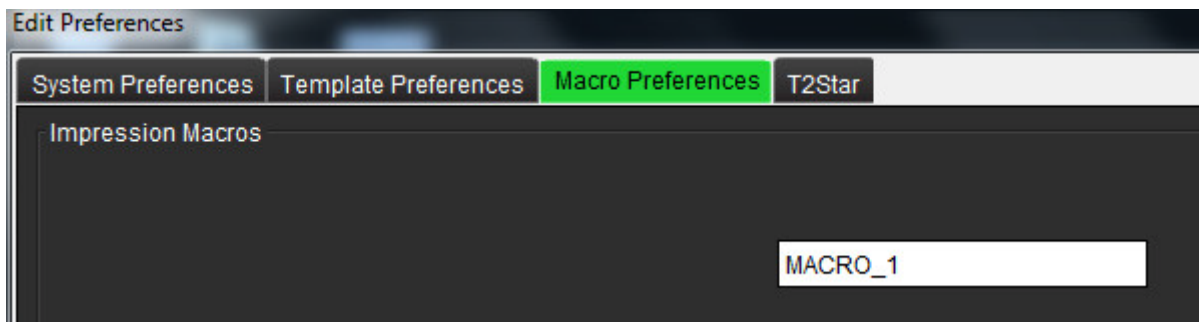
- Generate predefined clinical impressions and techniques that can be automatically inserted into the report.
- Automatically insert quantitative results from the analysis reporting windows.

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 10. Impression Macros Window

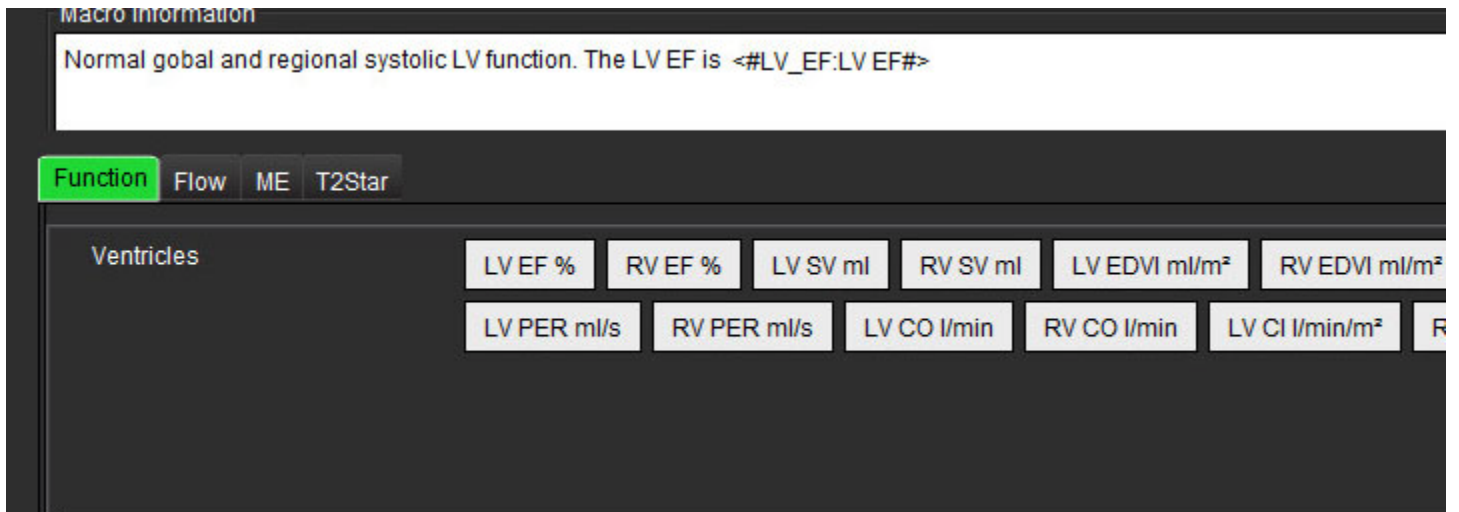


4. Place the cursor inside the new button field and edit the name as desired.

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 11. 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

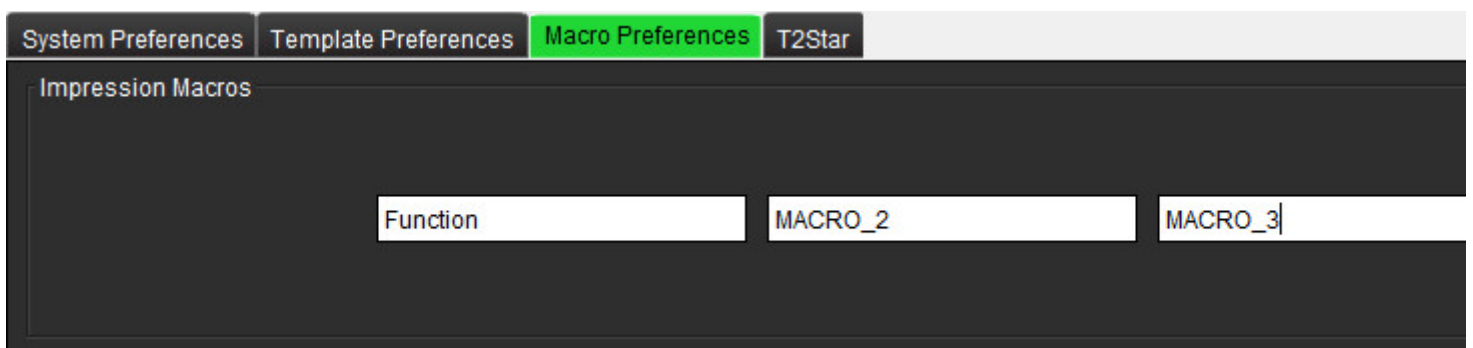
As a prerequisites to macro execution, analysis results must be generated prior to executing macros that involve numerical calculations. Technique and Impression macros can be created to automate report generation.

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.

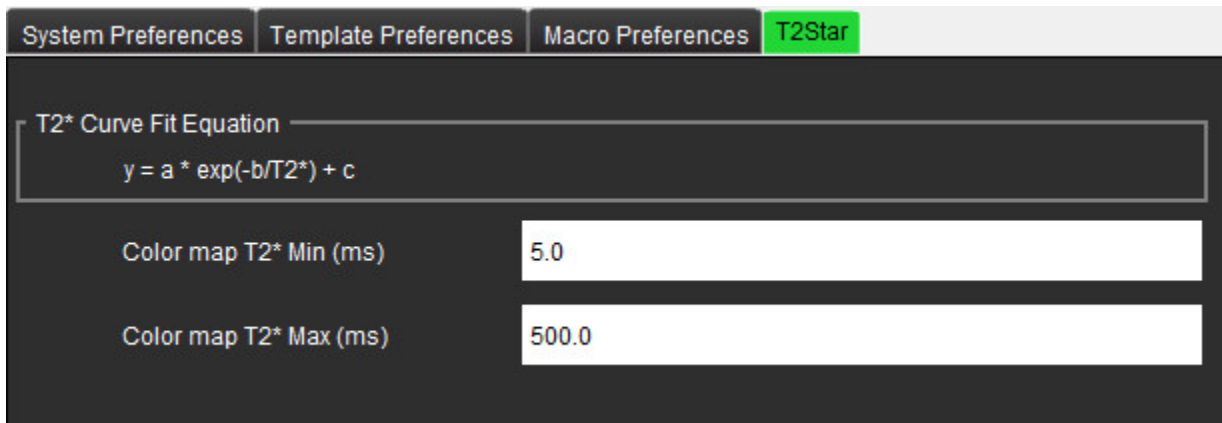
FIGURE 12. Macro Selection List



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

T2Star Preferences

FIGURE 13. T2Star Preferences



System Preferences | Template Preferences | Macro Preferences | **T2Star**

T2* Curve Fit Equation

$$y = a * \exp(-b/T2^*) + c$$

Color map T2* Min (ms) 5.0

Color map T2* Max (ms) 500.0

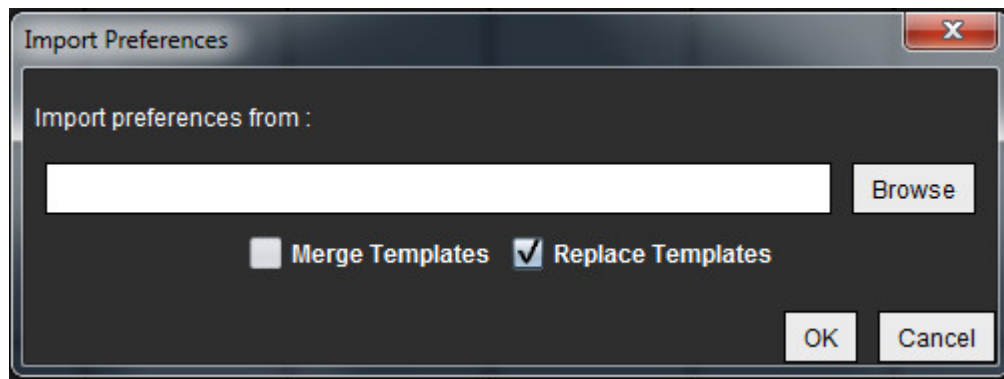
Import Preferences

Templates can be imported from the file system.

Import Preferences Procedure

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

FIGURE 14. Import Preferences Window



Import Preferences

Import preferences from :

Browse

☐ Merge Templates ☒ Replace Templates

OK Cancel

2. Select the Browse button, select the location of the preference file and then select the Open button.
3. Select the duplicate template name strategy and either merge the templates or replace the template on the system with the backup copy.
 - Merge Templates combines the contents of the two templates with the same name.
4. Select **OK** to perform the import procedure as defined.
 - Select **Cancel** to exit the window without importing the template

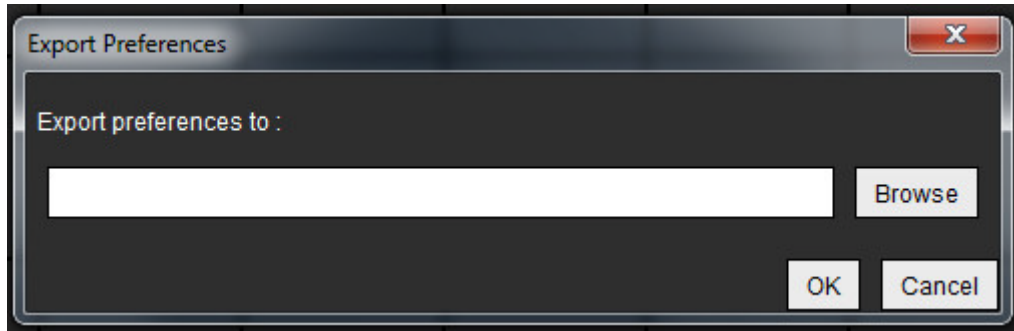
Export Preferences

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.

Function Analysis

“Analysis Ventricles: Left Ventricular Function” on page 37

“Analysis Ventricles: Right Ventricle Function” on page 47

“Analysis Atria: LA and RA” on page 50

“Linear Measurements” on page 52

“Valve Plane Analysis” on page 54

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:

Overview of Function Analysis Panel

There are three categories for analysis:

Ventricles

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




Atria

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

Other

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

Analysis Ventricles: Left Ventricular Function

There are three methods of performing a LV function analysis: Manual , Fast , and Auto .

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


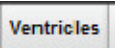

IMPORTANT: It is recommended that you are qualified in performing cardiac analysis. If the analysis results are to be used to reach a diagnosis.





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 Viewer.
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.
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 Endocardial contour tool will stay selected to expedite the segmenting of multiple slices.

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. Draw the basal line.

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 Reporting tabs.
2. Enter patient **Height** and **Weight**.

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

Define the Epicardium

1. Locate the end diastolic phase.



2. Select

3. Trace the epicardial contour.



4. Proceed to the next slice using or use <-- and --> or select the thumbnail.

5. Repeat steps 3 and 4 until the entire left ventricle epicardium is segmented.

The Epicardial contour tool will stay selected to expedite the segmenting of multiple slices.

The Left Ventricular Mass measurement is automatically updated as the epicardial contours are defined.

6. Locate end systolic phase.

7. Repeat steps 3 and 4 on the end systolic phase until the entire left ventricle is segmented.

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

Edit a Volume Measurement

FIGURE 1. LV Manual Segmentation






1. Cross-Reference mode, 2. Editor Window, 3. Review contours from base through apex

NOTE: When using the measurement editor, the contours for both endocardium and epicardium are displayed to make the editing process easier. Upon returning to the Report Window the volume contribution will be recalculated.

1. Perform a left mouse click on the contour from the Image Editor Window.
The contour turns purple when selected. Drag on the center of the ROI to move it.
 - If the selected contour was created using the point spline method, the points are displayed for editing. Click and drag any of the point to adjust the contour size and shape.
 - If the selected contour was created with free-hand trace, update the contour on the image with the left mouse button depressed.
2. Left mouse click on the contour, it will turn purple. **Perform a right mouse click and hold on the selected ROI and a pop-up option to Delete appears.**

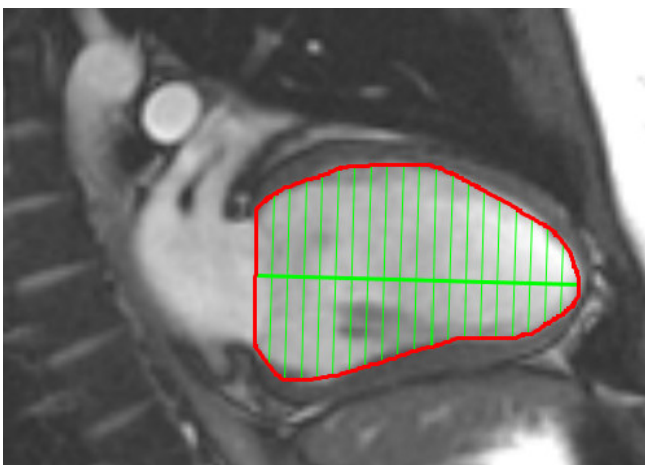
Fast LV Function Analysis Procedure

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.

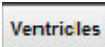

NOTE: When analyzing the LV, the correct position of the center line must run from the base to the apex.

FIGURE 2. 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 the  button.
3. Click  button from Volume measurements.
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.

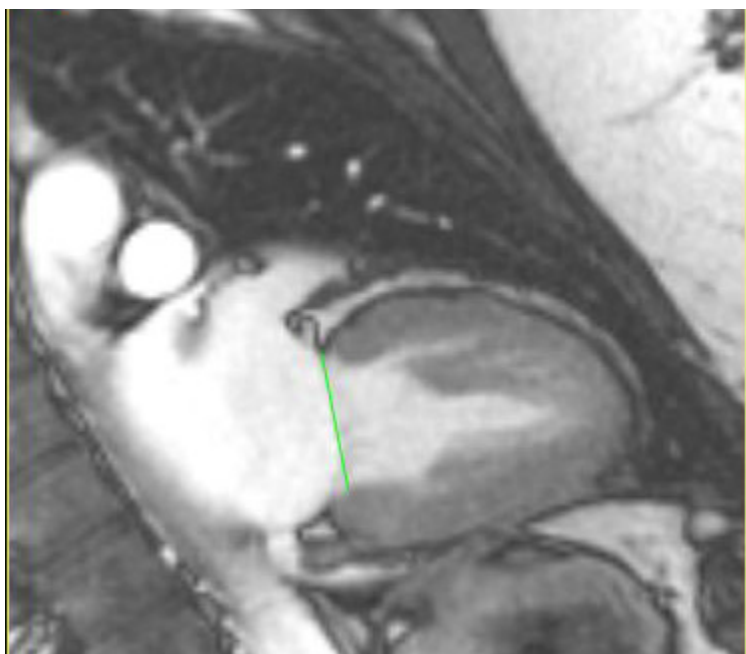
Workflow 2: Long-axis image

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 3. Basal Reference Line



Review Accuracy

1. Play the short axis series in cine mode and review the accuracy of the contours.

From the Analysis Panel 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

2. Edit any contours that are inaccurate.



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.

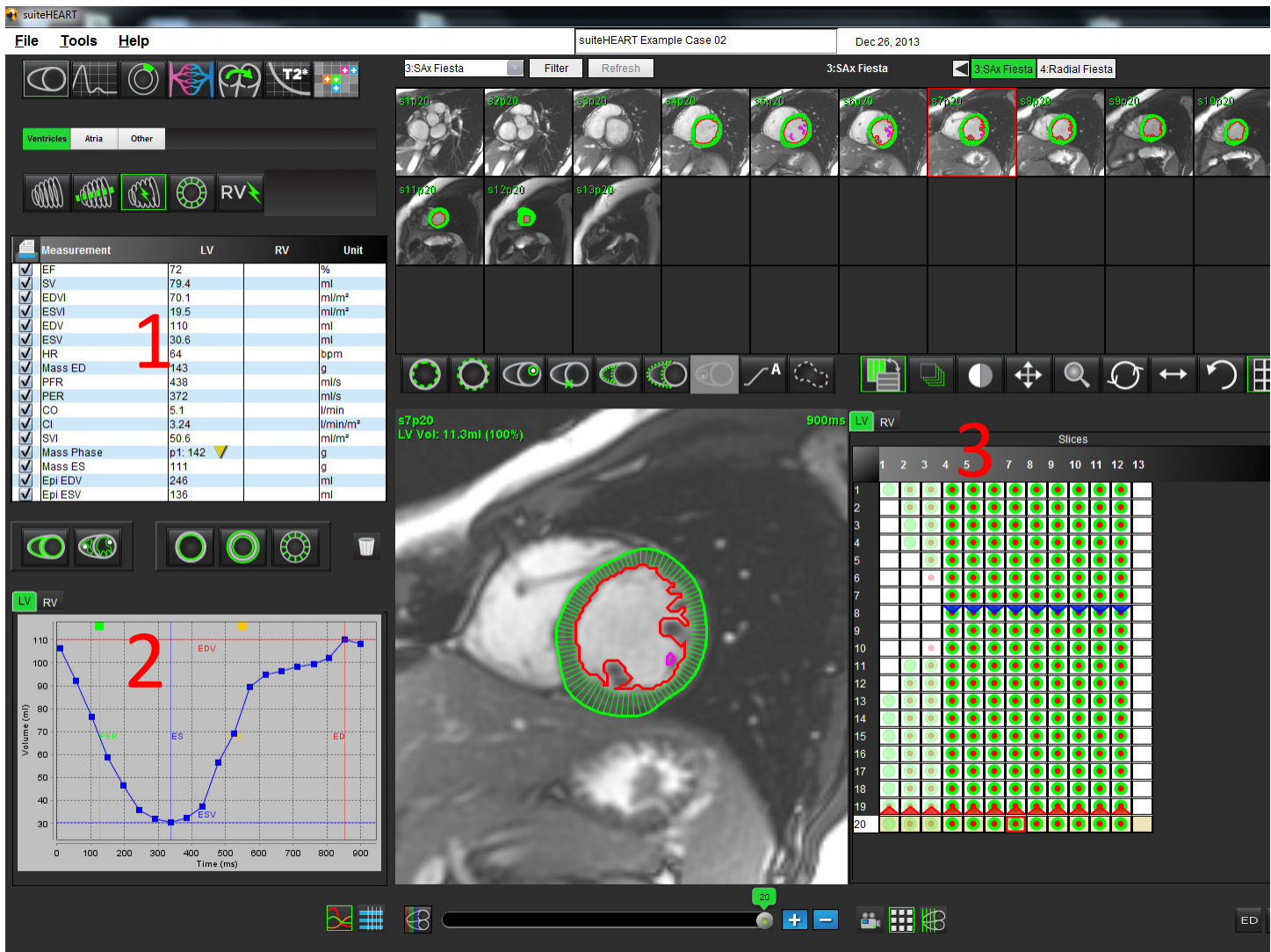
NOTE: The volumetric values are automatically recalculated after any contours are edited.

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 4. This curve can be printed on the report. All markers with drag handles can be adjusted.

FIGURE 4. LV Auto-Segmentation Results



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

- 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 5. Mass Phase Pull-down Menu

	Measurement	LV	RV	Unit
<input checked="" type="checkbox"/>	EF	72		%
<input checked="" type="checkbox"/>	SV	79.4		ml
<input checked="" type="checkbox"/>	EDVI	70.1		ml/m ²
<input checked="" type="checkbox"/>	ESVI	19.5		ml/m ²
<input checked="" type="checkbox"/>	EDV	110		ml
<input checked="" type="checkbox"/>	ESV	30.6		ml
<input checked="" type="checkbox"/>	HR	64		bpm
<input checked="" type="checkbox"/>	Mass ED	143		g
<input checked="" type="checkbox"/>	PFR	438		ml/s
<input checked="" type="checkbox"/>	PER	372		ml/s
<input checked="" type="checkbox"/>	CO	5.1		l/min
<input checked="" type="checkbox"/>	CI	3.24		
<input checked="" type="checkbox"/>	SVI	50.6		
<input checked="" type="checkbox"/>	Mass Phase	p1: 142		
<input checked="" type="checkbox"/>	Mass ES	111		
<input checked="" type="checkbox"/>	Epi EDV	246		
<input checked="" type="checkbox"/>	Epi ESV	136		

LV Mass Phase Phase_01 142

LV Mass Phase Phase_02 127

LV Mass Phase Phase_03 136

LV Mass Phase Phase_04 146

LV Mass Phase Phase_05 130

LV Mass Phase Phase_06 112

LV Mass Phase Phase_07 114

LV Mass Phase Phase_08 111

LV Mass Phase Phase_09 109

LV Mass Phase Phase_10 108

Chamber Volumes Table

FIGURE 6. Chamber Volume Table

Chamber Volumes			
Phase	TDel (ms)	ENDO Volume(ml)	EPI Volume(ml)
1	10	106	242
2	56	94.7	213
3	103	76.6	205
4	150	59.3	196
5	197	47.4	168
6	244	37.5	140
7	291	32.0	136
8	338	30.4	135
9	385	32.1	136
10	431	38.6	139
11	478	58.0	187
12	525	76.6	196
13	572	92.2	227
14	619	96.8	235
15	666	98.3	240
16	713	99.0	242

Chamber Endo Contour Epi Contour

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 41).



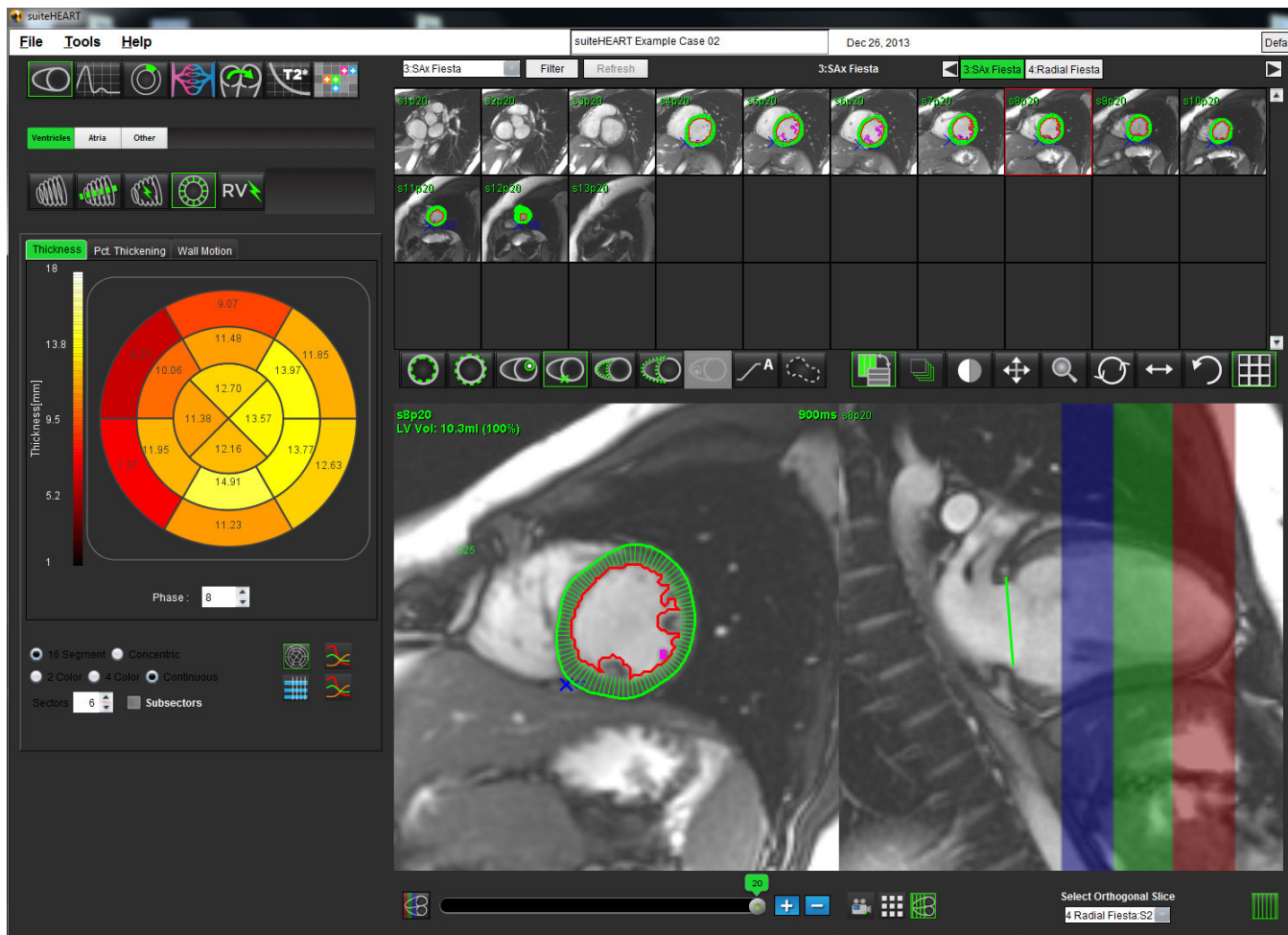
2. Click the RV insertion point button, select an auto segmented slice and deposit the RV insertion point. Repeat for all of the auto segmented slices in the Left Ventricle.

3. Confirm the slice classification for all of the segmented slices in the Left Ventricle and adjust as necessary.



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

FIGURE 7. Output of Regional Analysis



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.

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.

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.

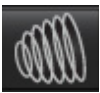
The endocardial contours in the range selected will be automatically updated.

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

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 Viewer.
2. Click the  .
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. Draw the basal line.

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 and cardiac output index measurements are calculated and added to the Measurement table.

Define the Epicardium

1. Locate the end diastolic phase.



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

- The Right Ventricular Mass measurement is automatically updated as the epicardial contours are defined.

Editing a right ventricle contour follows the same procedures as editing a left ventricle manual freehand contour.

6. Locate the end systolic phase.
7. Repeat steps 3 and 4 on the end systolic phase until the entire left ventricle is segmented.

Analysis Atria: LA and RA

Manual LA and RA Function Analysis Procedure



1. Select the appropriate short axis series from the Image Viewer.

2. Click the  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.

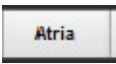



NOTE: The software automatically defines the end diastolic phase as the phase with the largest volume, and the end systolic phase as the phase with the smallest volume. The end diastolic and end systolic phase assignments are updated during segmentation.

7. Draw the basal line.

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- 6 for end systole.

NOTE: Fast segmentation of the LA and RA does not allow for the determination of the myocardial mass.

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 8. 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. Select **Delete**.

Reset Measurements




Select  to reset all measurements.

To delete a single measurement, click directly on the measurement which will turn purple, then select the delete key on the keyboard.


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 41).
2. Select a series that demonstrates valve anatomy.
3. Select **Valve Area** from the measurement table and perform planimetry of the valve as shown in Figure 9.

FIGURE 9. Valve Area

	Measurement	Value	Unit
<input checked="" type="checkbox"/>	ASWT		cm
<input checked="" type="checkbox"/>	ILWT		cm
<input checked="" type="checkbox"/>	EDD		cm
<input checked="" type="checkbox"/>	ESD		cm
<input checked="" type="checkbox"/>	FS		%
<input checked="" type="checkbox"/>	Valve Area		cm ²
<input checked="" type="checkbox"/>	Aortic Root		cm
<input checked="" type="checkbox"/>	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.




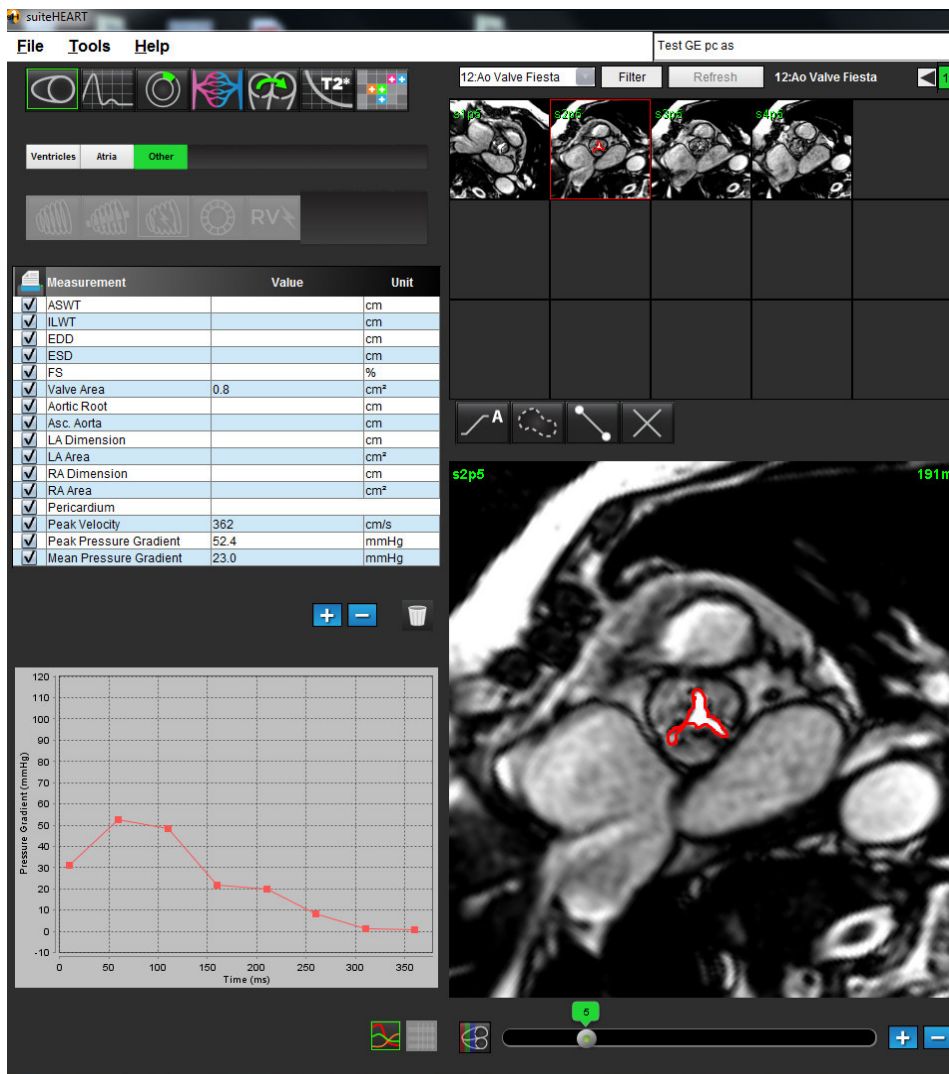
5. Click  to reset all measurements.

FIGURE 10. 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.

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Flow Analysis

“Flow Window Components” on page 58

“Flow Analysis Procedure” on page 59

“Review and Editing of the Auto Segmentation Results” on page 62

“Qp/Qs Tab” on page 66

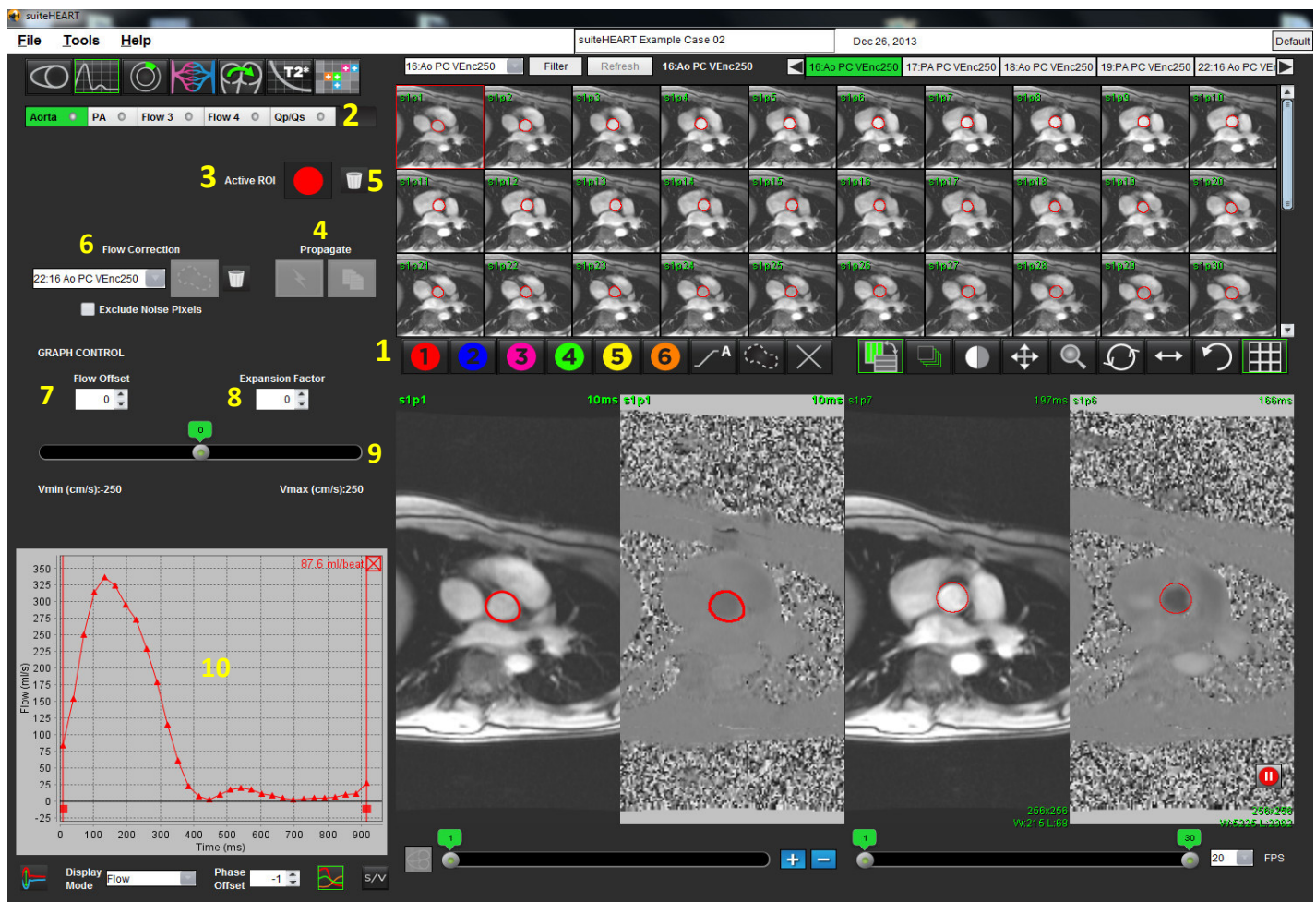
The Flow Analysis tool calculates flow and velocity information at various points in the cardiac cycle from Cine Phase Contrast (PC) images with through plane flow encoding.



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. Flow offset, 8. Expansion factor, 9. Venc slider bar, 10. Flow curve results

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.

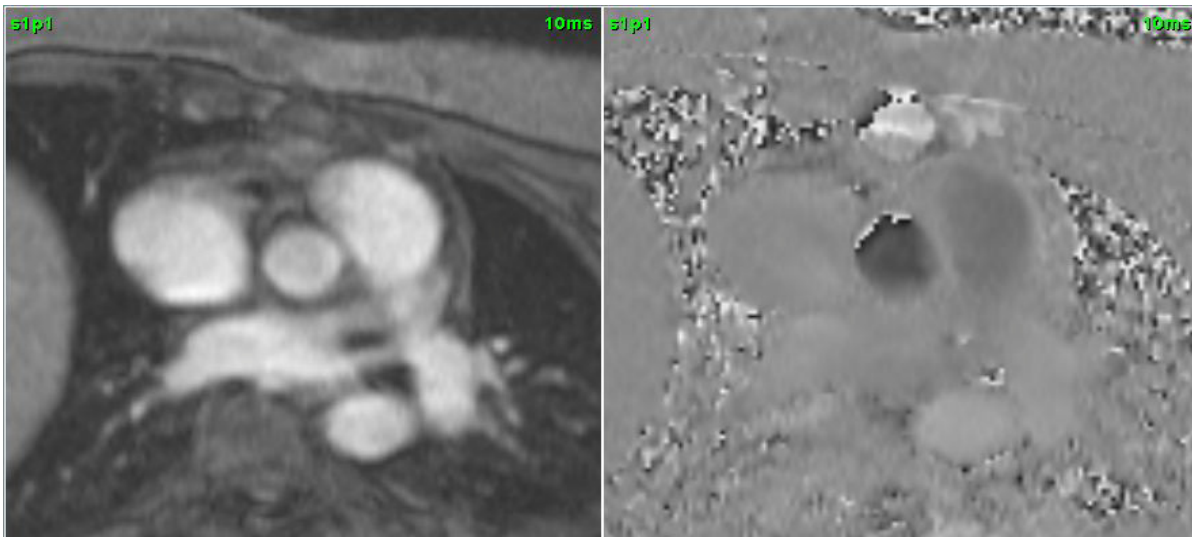
Flow Analysis Procedure

Select the Series and Image

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

The magnitude image is displayed on the left, while the flow image is on the right.

FIGURE 2. Magnitude and Flow Images



Generate Contour for Curve 1


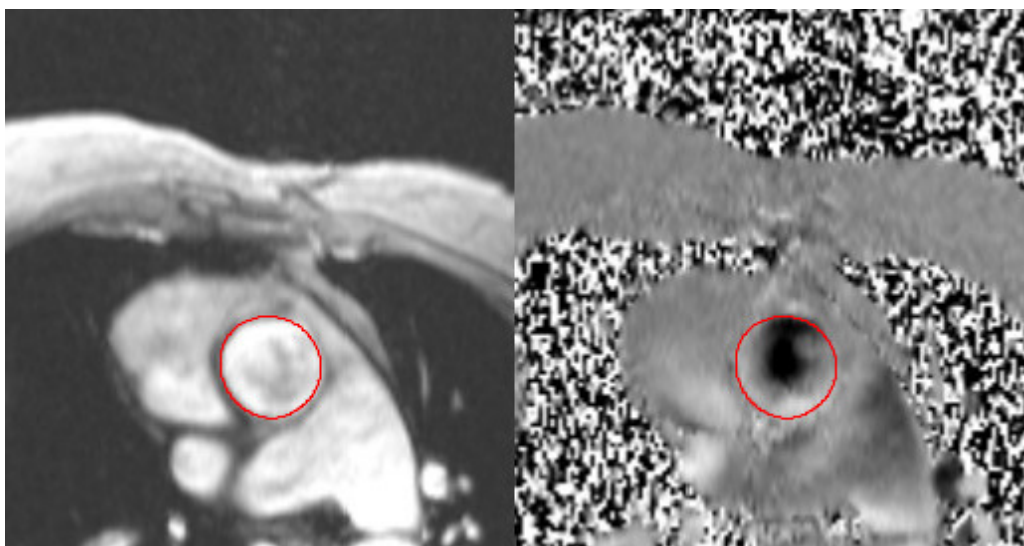
1. Select a vessel **Flow Tab**.
Five flow tabs are available, including the aorta, pulmonary artery (PA), two user defined vessels with default labels Flow 3 and Flow 4, and Qp/Qs.
2. Select .
3. Draw a contour around a vessel either by depositing 4 points around the vessel of interest and double-clicking at the last point to close the ROI or perform a manual trace around the vessel.
4. Move the cursor out of the Image Editor window.
The contour is applied to both the magnitude and phase images.

FIGURE 3. Flow ROIs



Generate Auto Segmentation

1. Perform automatic segmentation over all phases in the slice by doing one of the following:



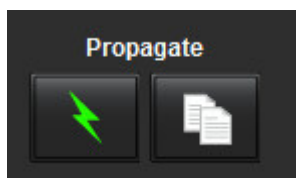
- Click  for automatic segmentation over all phases in the slice.
- Click  to propagate the same contour over all phases in the slice. This is useful when analyzing small, stationary vessels.

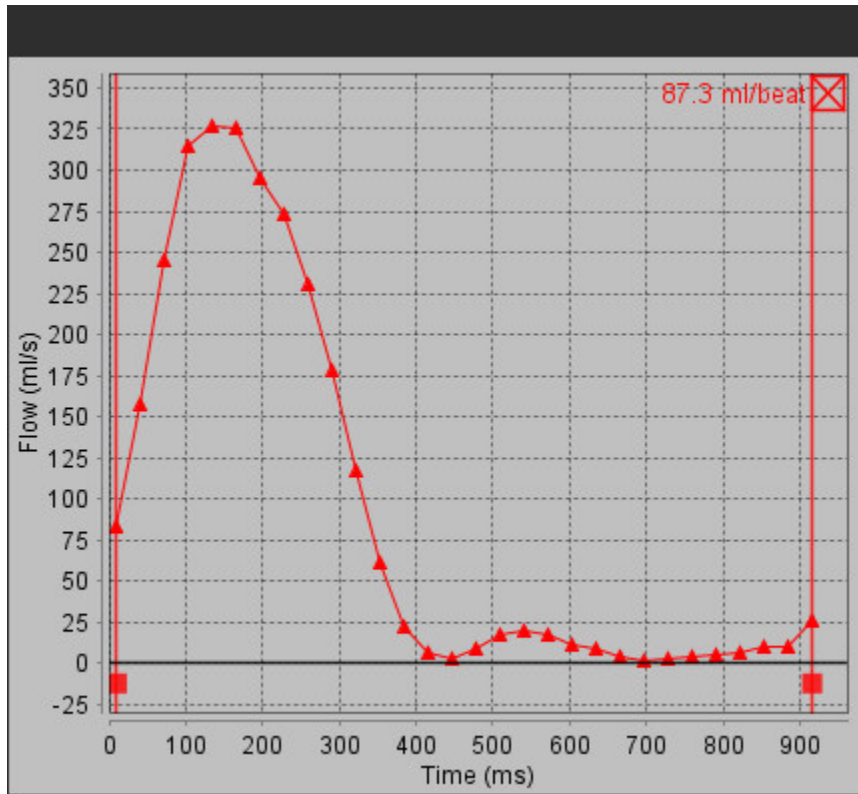
FIGURE 4. Propagate Buttons




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 display of the curve from the graph.

FIGURE 5. Flow Graph



2. Select  to invert the display of the graph.
3. Select a Phase Offset to change the ordinate of the flow curve.
4. Select any point on the graph to locate the desired phase.

Baseline Flow Correction

There are two methods for flow correction. The first uses a flow correction series and the second uses a contour on the flow series.

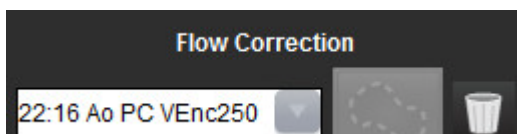
Flow correction series method

Select the appropriate flow correction series from the dropdown menu.

The flow correction series flow values will be subtracted from the vessel flow values.

NOTE: The flow correction series must have been acquired with the same scan prescription as the flow series. There must be MR signal from a stationary object filling the entire contour on the flow corrected series.

FIGURE 6. Flow Correction Menu and Icons



Background contour method

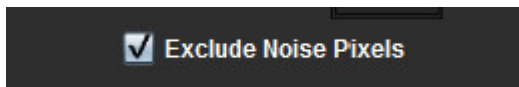
Select **Background ROI** from the **Flow Correction** drop-down menu and click  to draw the contour.

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

Review and Editing of the Auto Segmentation Results

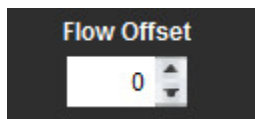
1. To exclude noise pixels click the box. The option identifies low intensity pixels (high fluctuation of velocities) within the ROI and excludes them from the flow calculation.

FIGURE 7. Noise Pixels



2. Adjust the **Flow Offset** to change the baseline of the flow values by adding a constant value to all flow values.

FIGURE 8. Flow Offset Menu



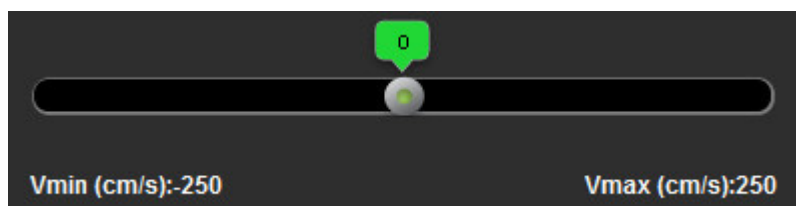
3. Adjust the **Expansion Factor** to uniformly change the radius of the segmented vessel by a specified pixel amount.

FIGURE 9. Expansion Factor Menu



4. Move the Venc slider bar to change the range of velocity values attributed to the gray values in the phase images.
This can correct for velocity aliasing.

FIGURE 10. Venc Slider Bar



5. Move the vertical bars on the graph to limit the time range for flow calculations.
All calculations are adjusted to reflect the new start and end points.
6. Once the segmentation is completed, review the accuracy of the contours on both the phase and magnitude images.

Editing the Contours

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.

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

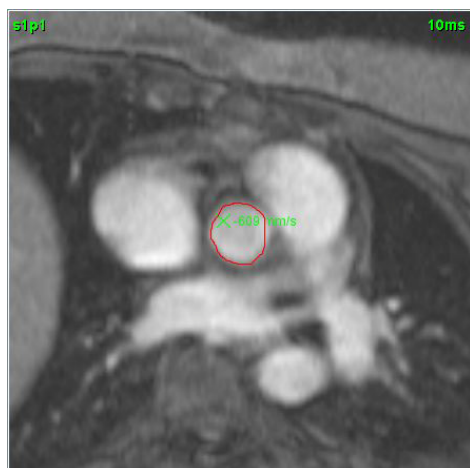
1. Select the appropriate phase of the cardiac cycle.



2. Use  to position the cursor on the flow image.

The results are displayed next to the cursor in mm/s.

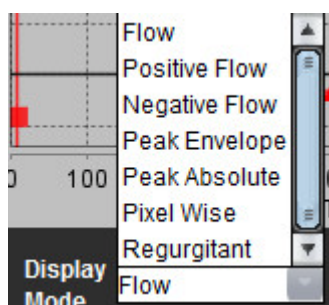
FIGURE 11. Flow Velocity Data



Display Modes

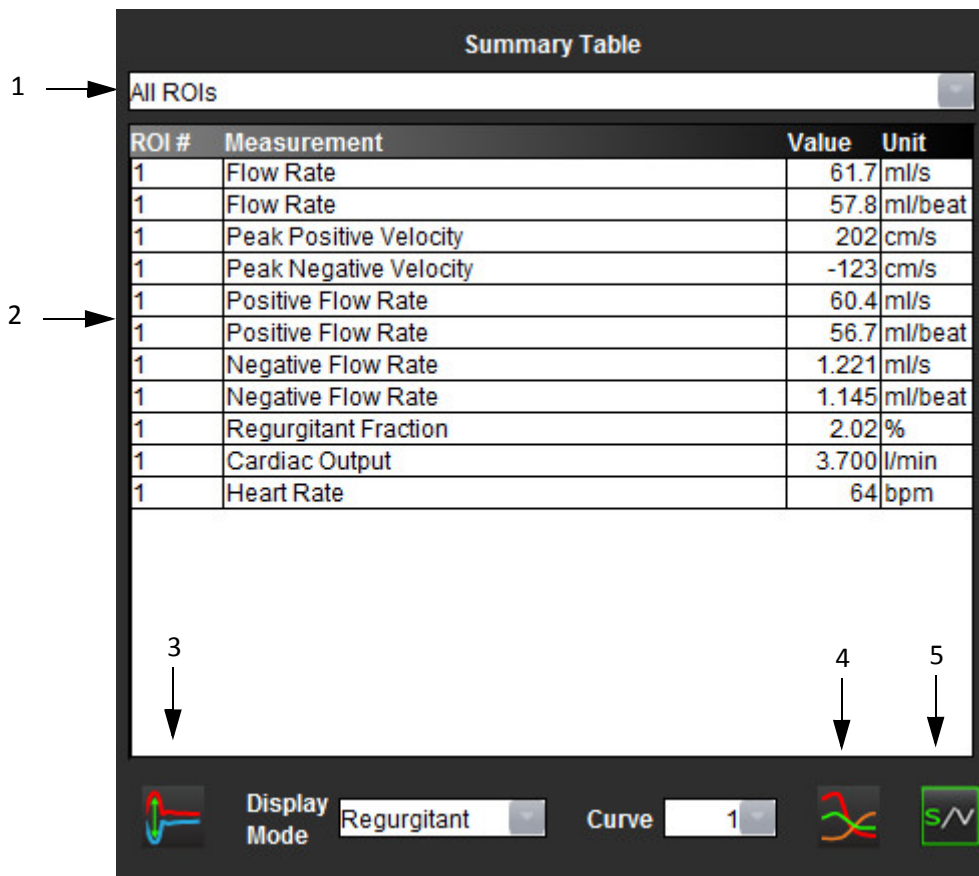
1. Select the desired **Display Mode** from the drop-down menu.
Curves defining each ROI are overlaid in the curve display window.

FIGURE 12. Display Mode Menu




Review Summary Tables


FIGURE 13. Summary Table



1. ROI drop-down menu, 2. Flow Results, 3. Invert icon, 4. Graph icon, 5. Summary/Velocity Toggle Table icon.

1. Select **All ROIs** from the drop-down menu to include the values of all the curves in the tables.

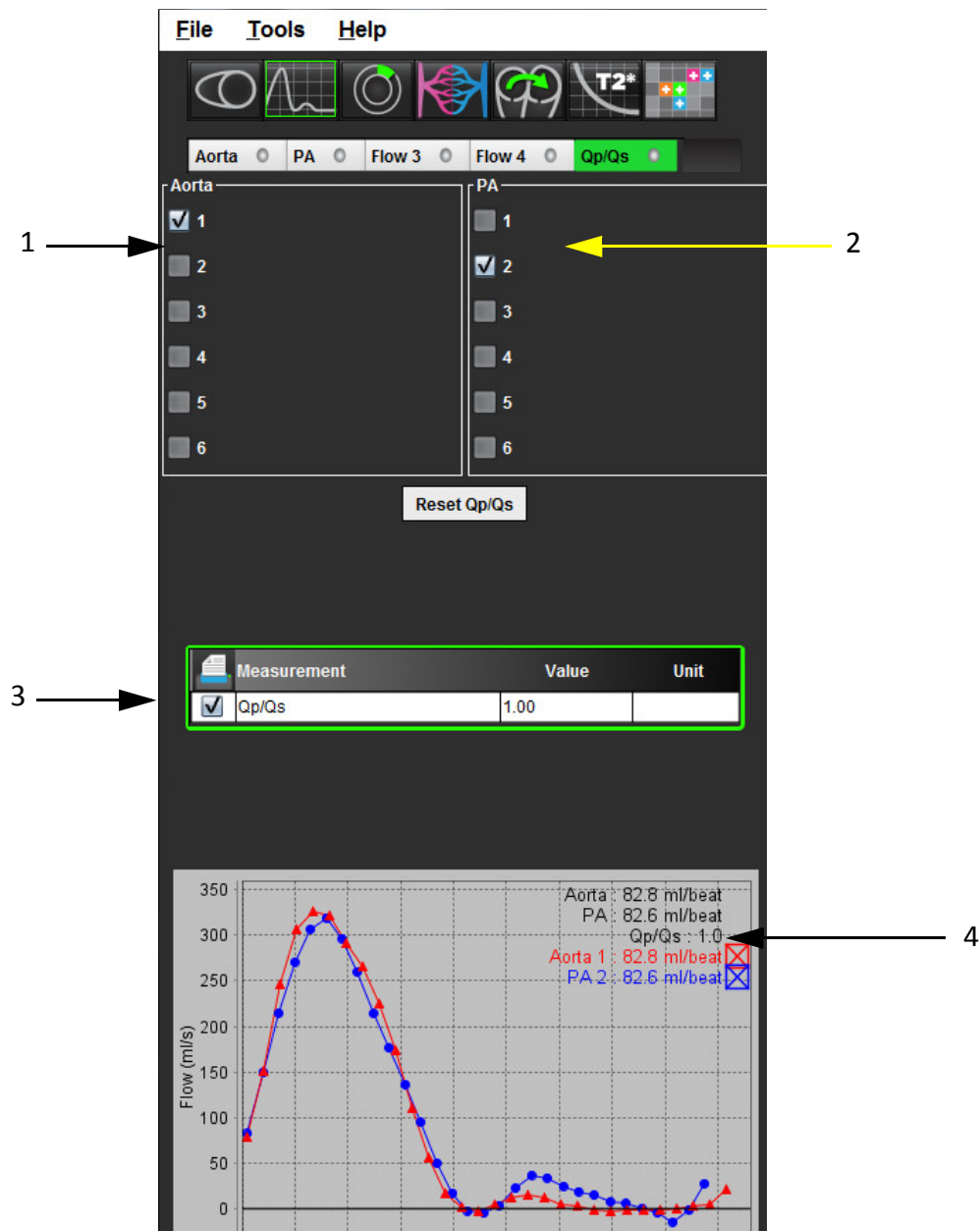
2. Select  toggle button to view the summary table or velocity table.

3. 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 14. Qp/Qs Reporting Window



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

Calculate Qp/Qs

NOTE: Curves must be generated 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.

The aorta curves are designated with triangle markers and the pulmonary artery curves are designated with circle markers.

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

“ME Quantitative Analysis Procedure” on page 70

“Polar Plot Display Formats” on page 71

The Myocardial Evaluation (ME) analysis tool allows for the quantitative determination of areas of increased signal intensity within the myocardium.



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.

ME Quantitative Analysis Procedure


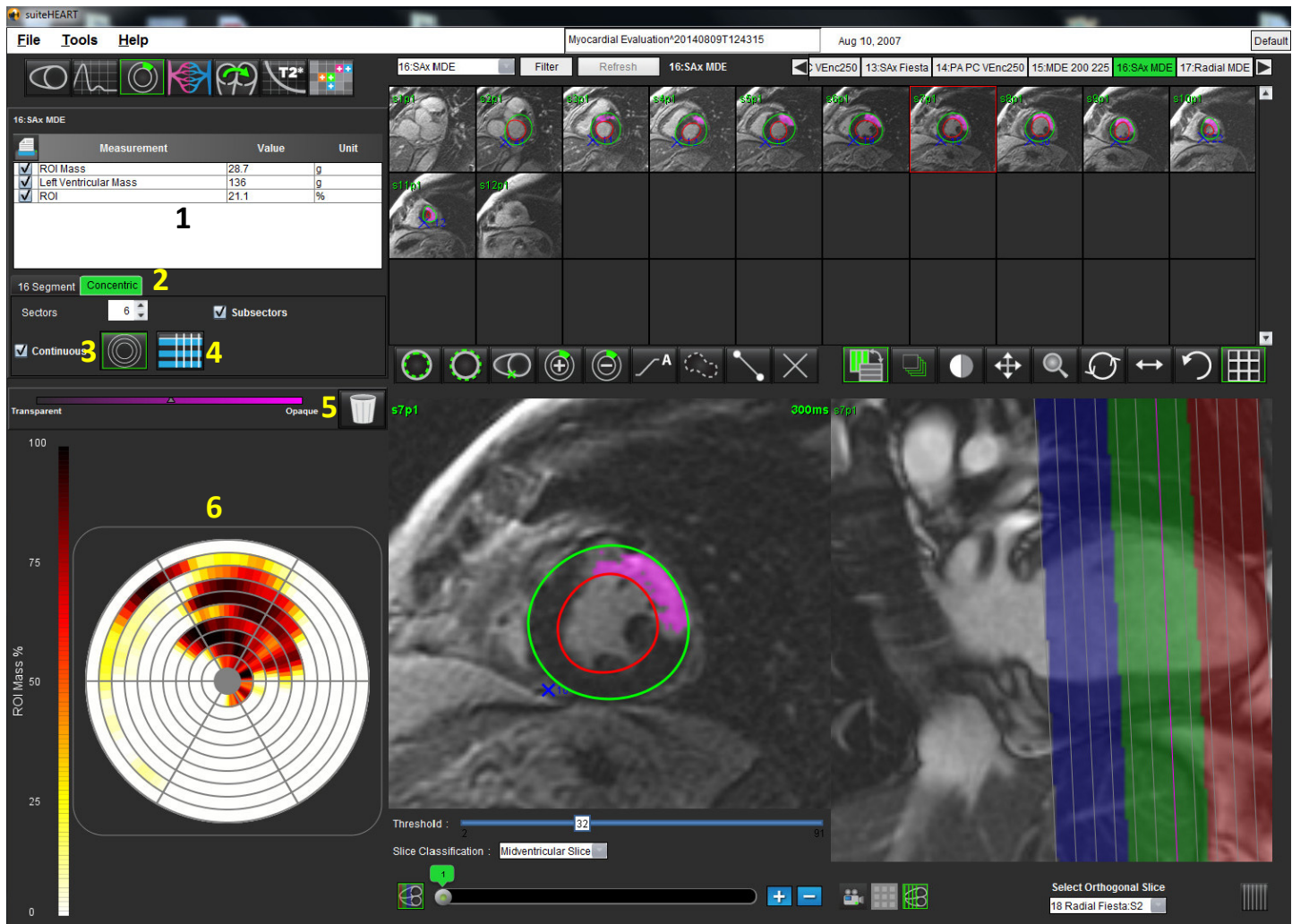



1. Select  mode icon.
2. Select a myocardial evaluation short axis series.

FIGURE 1. ME Quantitative Analysis Reporting Window



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

1. Trace the LV endocardium on the most basal slice by selecting .
2. Trace LV epicardium by selecting .
3. Mark inferior RV insertion site with .

4. Move the cursor outside of the editor window.
5. Adjust the slider to manually change the threshold for identifying areas of abnormally high signal intensity.
6. Classify the slice by choosing a value from the **Slice Classification** drop down menu.
7. Repeat steps 1 - 6 until the entire myocardium is segmented.

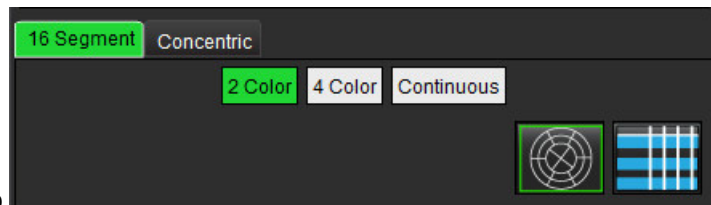
Threshold Editing

To add signal intensity regions select . To delete 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

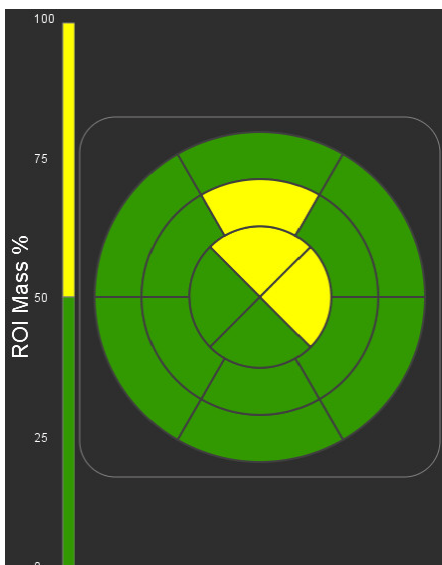


1. Select the **16 Segment** tab
2. Select 2 Color, 4 Color, or Continuous.

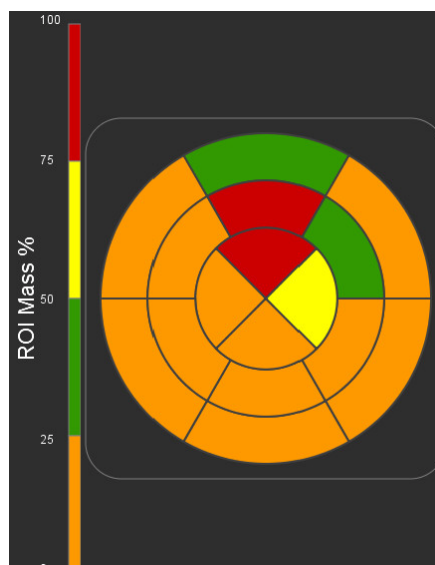
Color assignments can be defined by clicking on the color scale bar.

FIGURE 2. Polar Plots

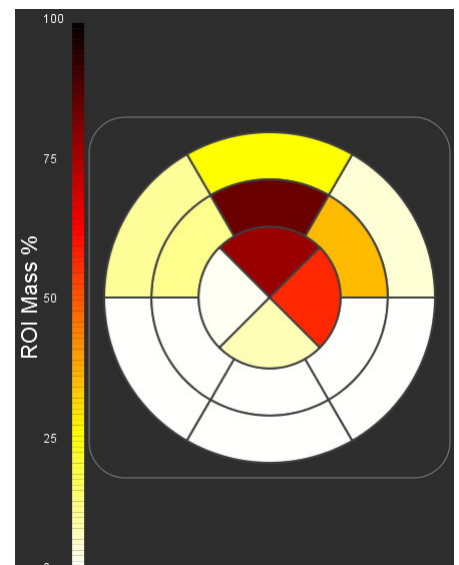
2 Color Polar Plot




4 Color Polar Plot



Continuous Color Polar Plot

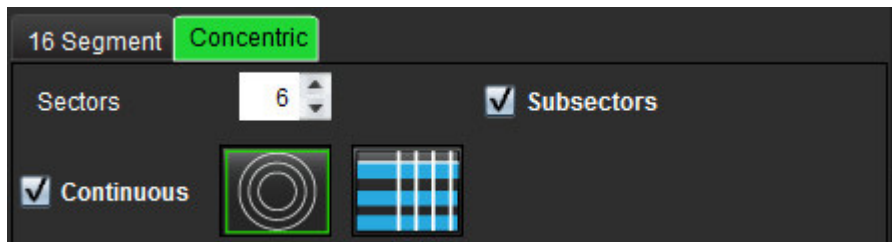


3. Select  to display the Polar Plot Summary Table.

Option 2: Slice by Slice format

1. Select the **Concentric** tab.


FIGURE 3. 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%.

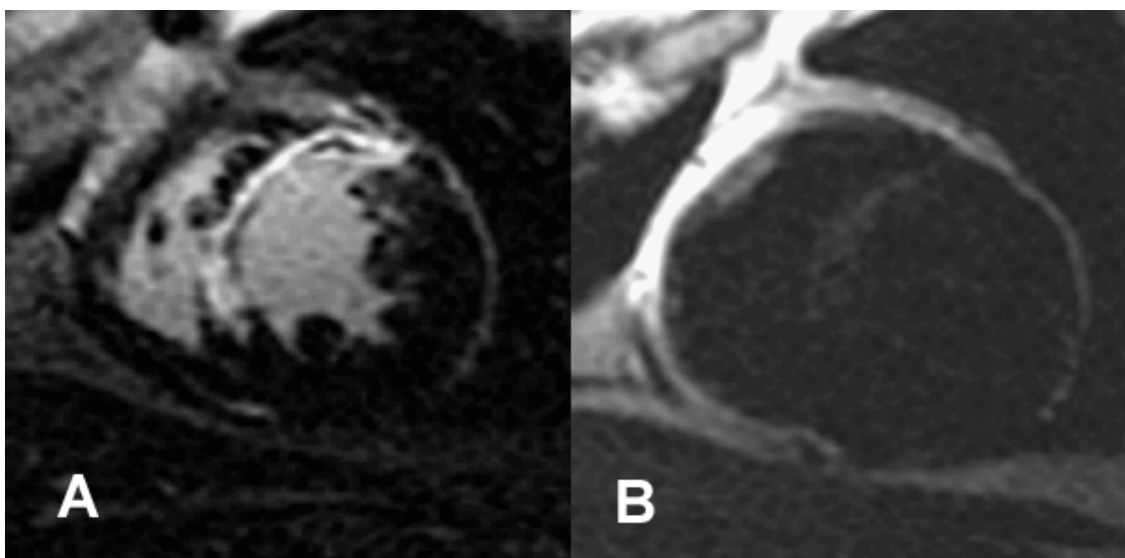


Select  to reset the color mapping of the segments.

Consideration

The automatic thresholding 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 4. Myocardial Evaluation Images



Time Course Analysis

“Launch Time Course” on page 73

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

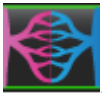
NOTE: Time Course results may not be accurate on images that are not surface coil intensity corrected.



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.

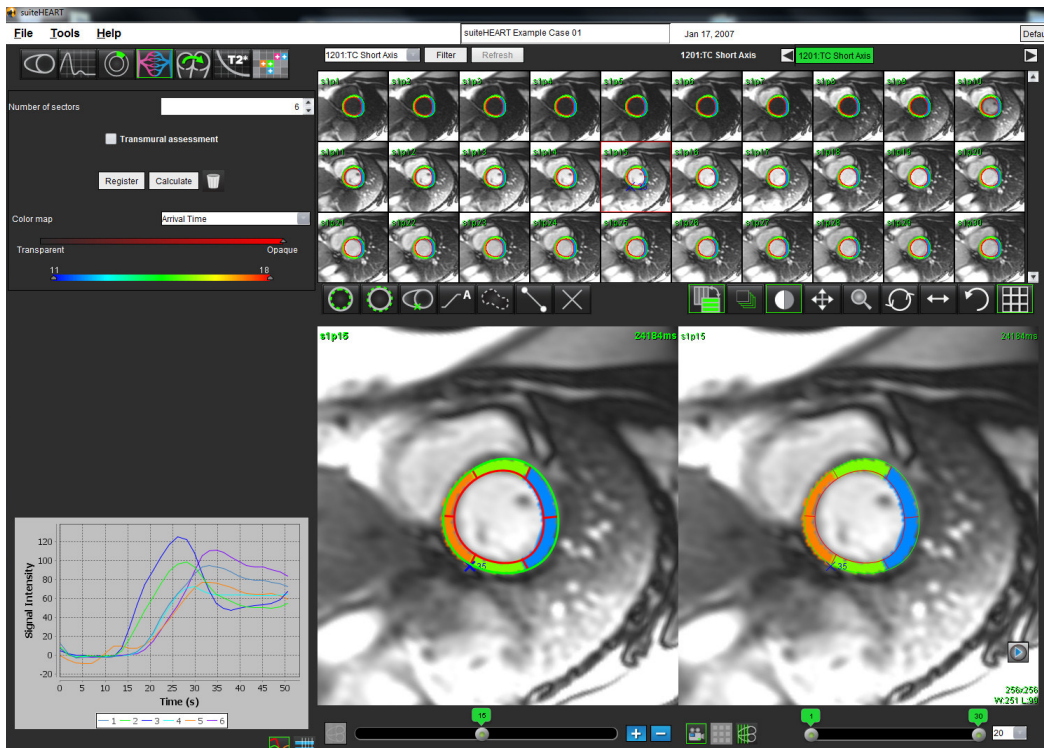
Launch Time Course

Time Course Quantitative Procedure



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



FIGURE 1. Time Course Quantitative 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 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.

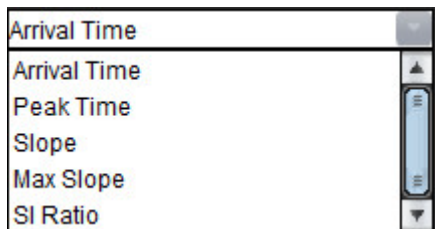


3. Define the RV insertion point by selecting  to deposit the cursor to mark the image.
4. Click **Calculate**.

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

To change the type of analysis select from the color map drop down menu.

FIGURE 2. Color Map Pull-down Menu

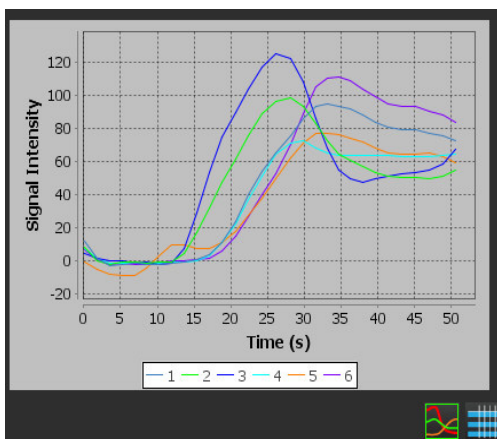


Review Results

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

A color code of the various sectors is provided below the graph.

FIGURE 3. Signal Intensity/Time Graph



NOTE: See appendix D for more information about this topic.



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



Patent Foramen Ovale (PFO) Analysis

“Launch PFO” on page 77

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.

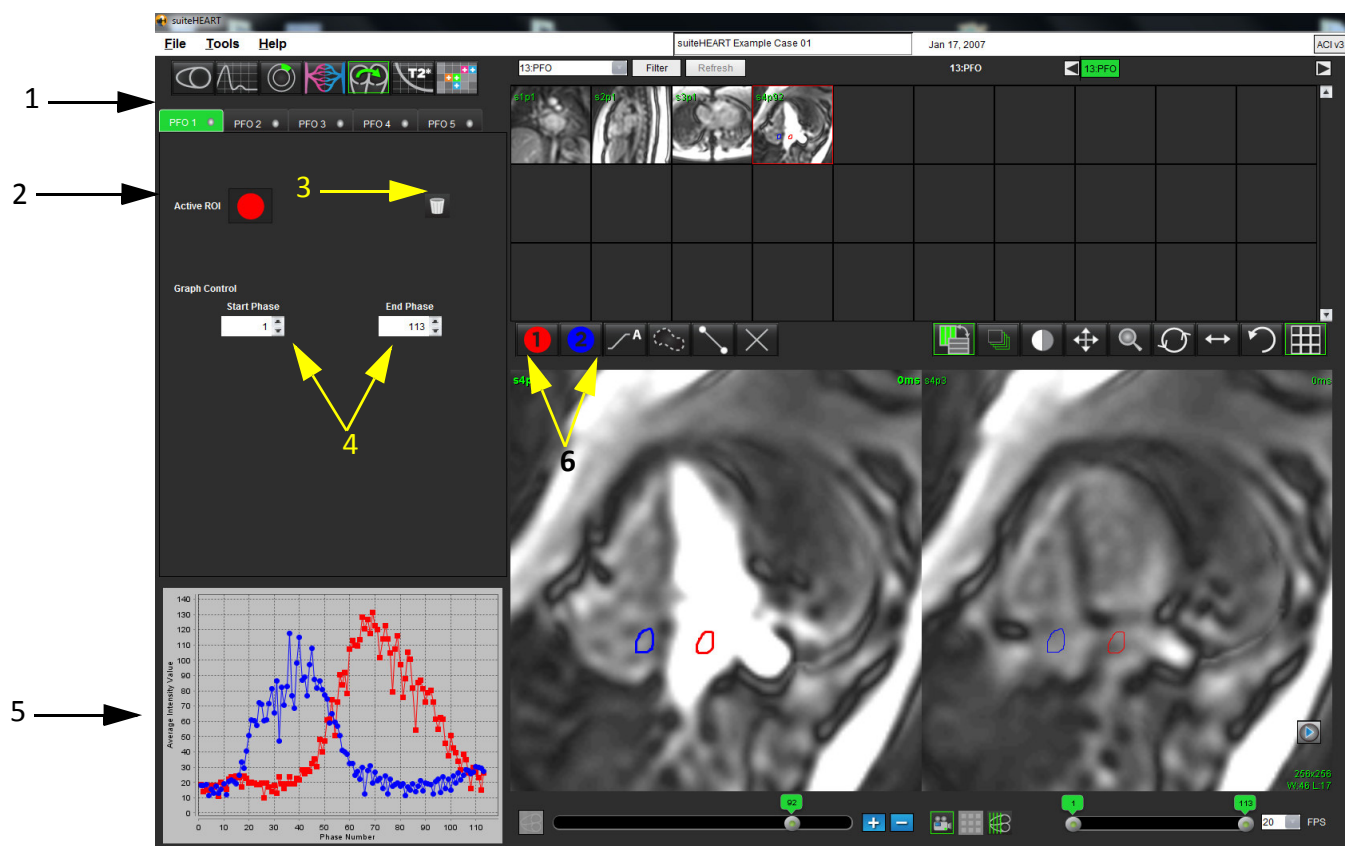
Launch PFO

1. Select **PFO Analysis Mode**.



2. Select a realtime series.

FIGURE 1. PFO Report 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 Phase Range

1. Use the up and down arrows to select the **Start Phase** and **End Phase** to set the phase range for curve generation.
2. The ROI should be drawn on a phase that is in between the selected Start and End phases.

FIGURE 2. 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.

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.

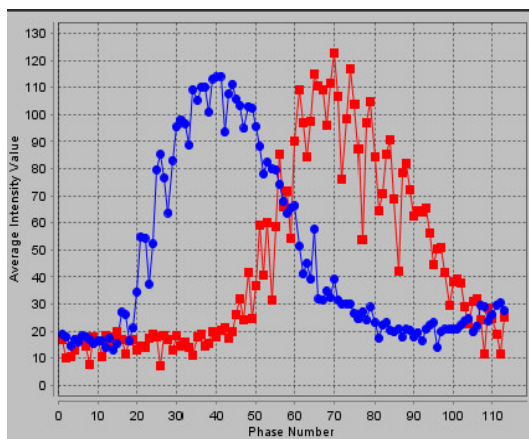
The signal intensity curve for the LA is automatically generated.

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 overlaid and displayed in the curve results display window.

FIGURE 3. PFO Curve Results



View Curve Data

1. Review the curve results in the report window and adjust as needed.
Adjusting the start and end phases affect the display of the PFO curves.
Selecting points on the graph updates the phase displayed in the Image Editor window.

2. Click  beside the active contours to reset the currently selected contour and the related curve.

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.

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

“Heart Analysis Procedure” on page 81

The T2Star analysis tool quantifies the T2Star of tissue from a multi echo fast gradient echo sequence.

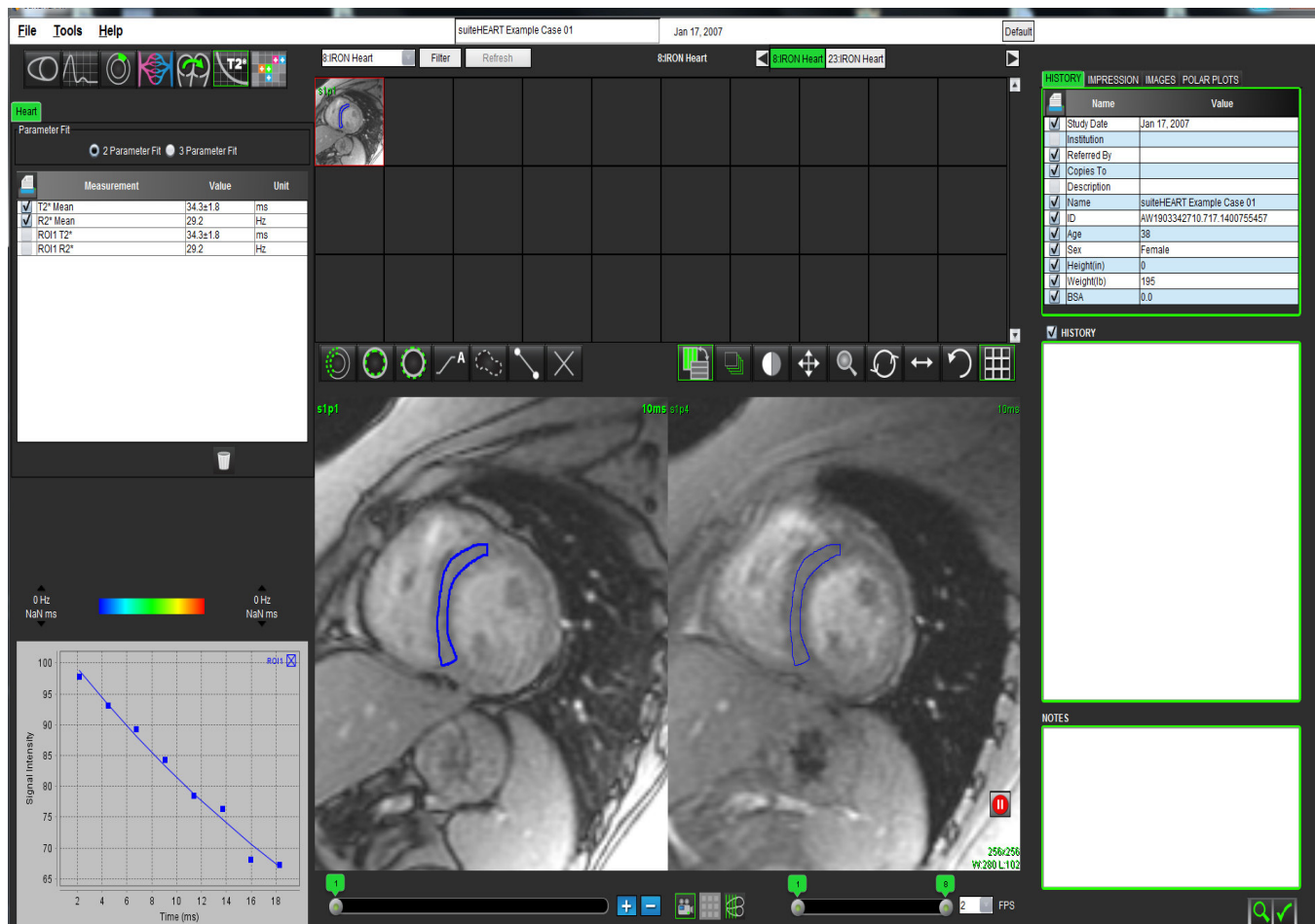


WARNING: The application assists in the analysis of the images only and does not automatically produce quantifiable results. The use and placement of quantitative measurements is at the discretion of the user. Misdiagnosis can occur if measurements are inaccurate. Measurements should only be created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

NOTE: See appendix B and C for more information about this topic.

Heart Analysis Procedure

FIGURE 1. T2Star Analysis Panel



Select Images



1. Select .
2. Select a series.
3. Select the short axis slice from the thumbnail panel.



4. Draw a contour that encompasses the inter-ventricular 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 T2Star/R2Star color map is overlaid on the image.


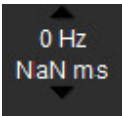
Choose Fitting Parameters


Select either the **2 Parameter** or **3 Parameter Fit** for the T2Star decay curve.

FIGURE 2. Parameter Fit

Heart			
Parameter Fit			
<input type="radio"/> 2 Parameter Fit <input checked="" type="radio"/> 3 Parameter Fit			
	Measurement	Value	Unit
<input checked="" type="checkbox"/>	T2* Mean	34.7±2.1	ms
<input checked="" type="checkbox"/>	R2* Mean	28.8	Hz
<input type="checkbox"/>	ROI1 T2*	34.7±2.1	ms
<input type="checkbox"/>	ROI1 R2*	28.8	Hz

Adjust the Myocardium Colormap

1. Click  to toggle between a grey scale and a color map.
2. Click and drag up or down on  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.
3. The T2Star and R2Star values can be determined by selecting the  and placing it over the color map overlay on the image.

Review the T2Star Results

1. Review the contour position on all of the images.
2. The table lists the individual T2Star/R2Star measurements and also calculates a mean value.


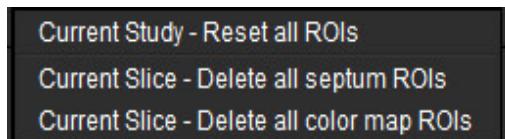
Click  to reset analysis as show in Figure 3.

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

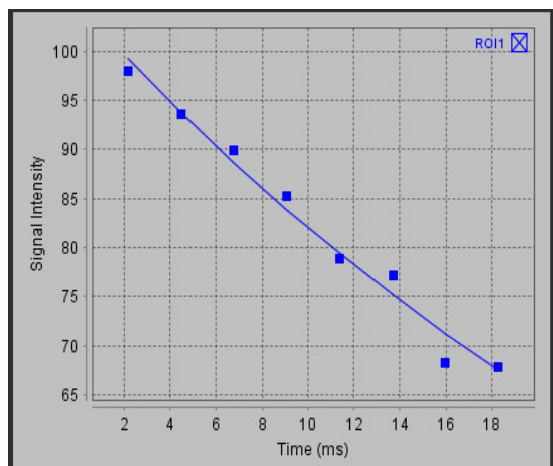
NOTE: See appendix B for more information about this topic.

The T2Star curve is a graph of the signal intensity versus echo time using an exponential decay formula. T2Star/R2Star 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.
 - 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.

Structured Reporting

“Define Report Content” on page 85

“Structured Reporting Tabs” on page 85

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 Reporting Tabs

The Structured Reporting Tabs are 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

The screenshot shows a software interface with a dark background. At the top, there are four tabs: 'HISTORY' (highlighted in green), 'IMPRESSION', 'IMAGES', and 'POLAR PLOTS'. Below the tabs is a table with two columns: 'Name' and 'Value'. The table contains the following data:

	Name	Value
<input checked="" type="checkbox"/>	Study Date	Dec 26, 2013
<input type="checkbox"/>	Institution	
<input checked="" type="checkbox"/>	Referred By	
<input checked="" type="checkbox"/>	Copies To	
<input type="checkbox"/>	Description	
<input checked="" type="checkbox"/>	Name	suiteHEART Example Case 02
<input checked="" type="checkbox"/>	ID	AW1260709696.968.1401356332
<input checked="" type="checkbox"/>	Age	22
<input checked="" type="checkbox"/>	Sex	Female
<input checked="" type="checkbox"/>	Height(in)	64
<input checked="" type="checkbox"/>	Weight(lb)	120
<input checked="" type="checkbox"/>	BSA	1.57

Below the table is a section labeled 'HISTORY' with a checked checkbox. Underneath this is a large, empty white rectangular box. At the bottom of the interface is a section labeled 'NOTES' with another empty white rectangular box. Three numbered callouts with arrows point to these sections: '1' points to the table, '2' points to the History text box, and '3' points to the Notes text box.

1. DICOM Header Information, 2. Patient History, 3. Notes

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

The screenshot shows a software interface with a dark background. At the top, there are four tabs: 'HISTORY', 'IMPRESSION' (highlighted in green), 'IMAGES', and 'POLAR PLOTS'. Below the tabs, there are two main sections. The first section is labeled 'IMPRESSION' with a checked checkbox. It contains a large white text box, which is pointed to by a green arrow labeled '1'. Below this text box are three buttons: 'Function', 'Aortic Valve', and 'Abnormal WM'. The second section is labeled 'TECHNIQUE' with a checked checkbox. It contains a large white text box, which is pointed to by a green arrow labeled '2'. Below this text box are three buttons: 'Cardiac Exam', 'Flow Exam', and 'Time Course'. At the bottom right of the interface, there are two green icons: a magnifying glass and a checkmark.

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

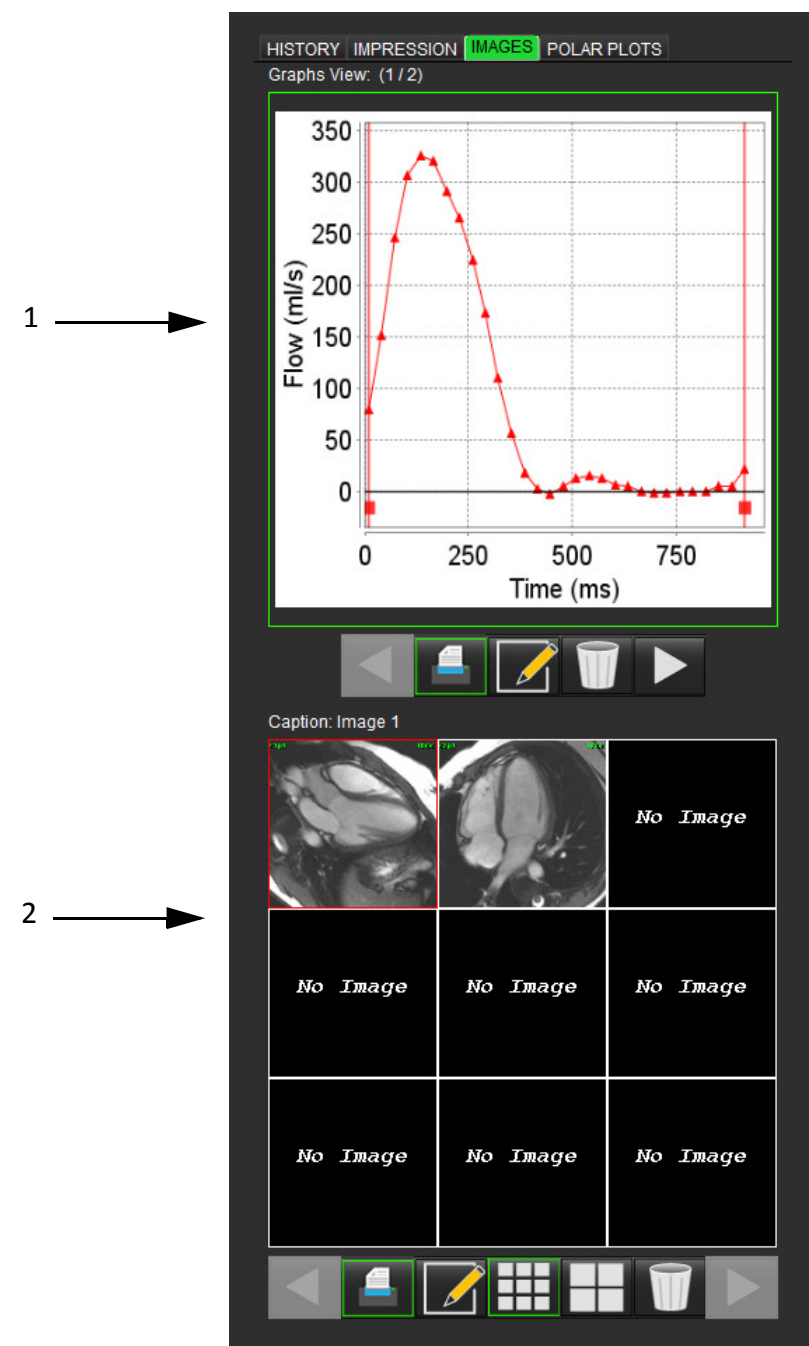
Enter technique information by typing in the text box and/or clicking a technique macro button.

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. Graphs, 2. Images

Review Graphs and Summary Tables for Report


The Graphs View panel contains all the graphs and summary table results that were copied to the report during analysis.


1. Step through each graph and summary table using the  icons.



2. Click  to edit the graph or summary table captions for the printed report.


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  icons.

2. Select  to edit the image caption for the printed report.

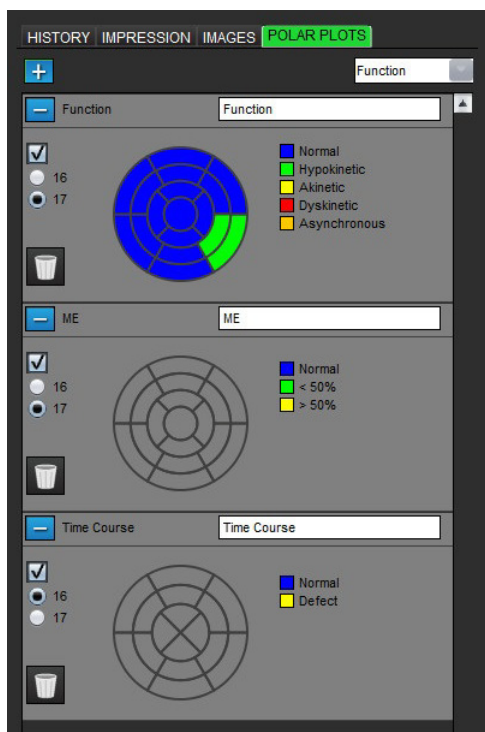
3. Select the image size by choosing the small format  or large format  buttons.

4. Delete an image by selecting .

Polar Plots Tab

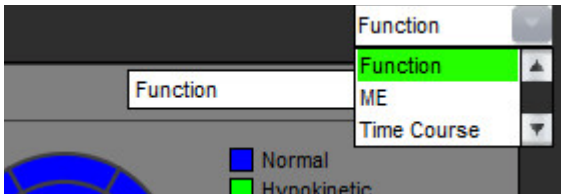
This table allows for the identification of functional, myocardial evaluation, and time course abnormalities qualitatively in a polar plot format. To change the color coding of the segments, right mouse click on the segment color legends to open the color palette.

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



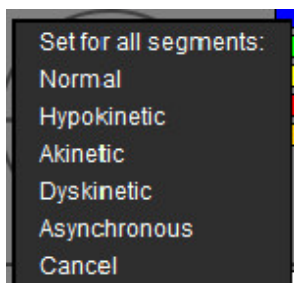
Selecting Colors per Segment

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



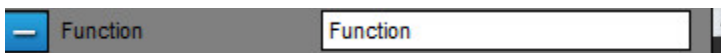
Selecting 16 or 17 Segment Plots

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


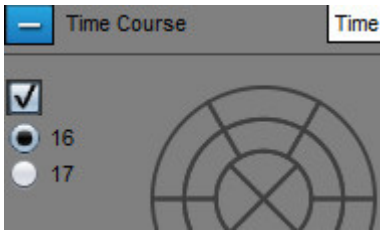


Each plot can be removed from the tab by clicking the  button. To exclude the polar plot from the report, deselect the check box.

FIGURE 7. Exclude Polar Plot from Report



Select  to reset the polar plot back to default.

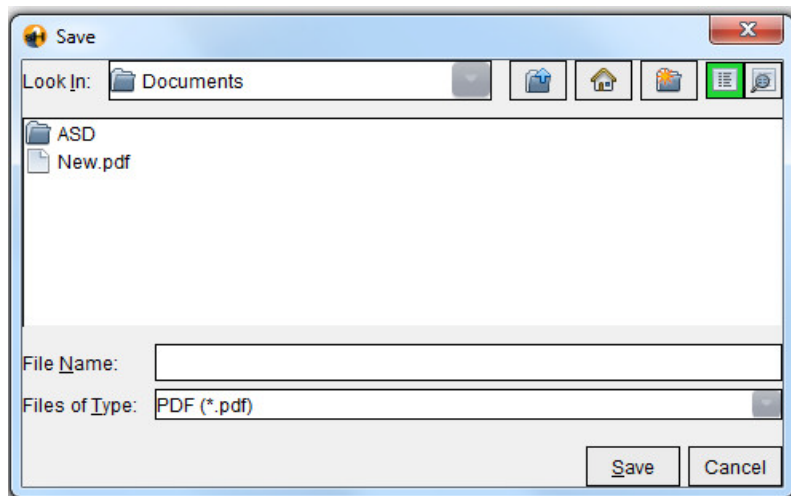
Preview the Report

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.

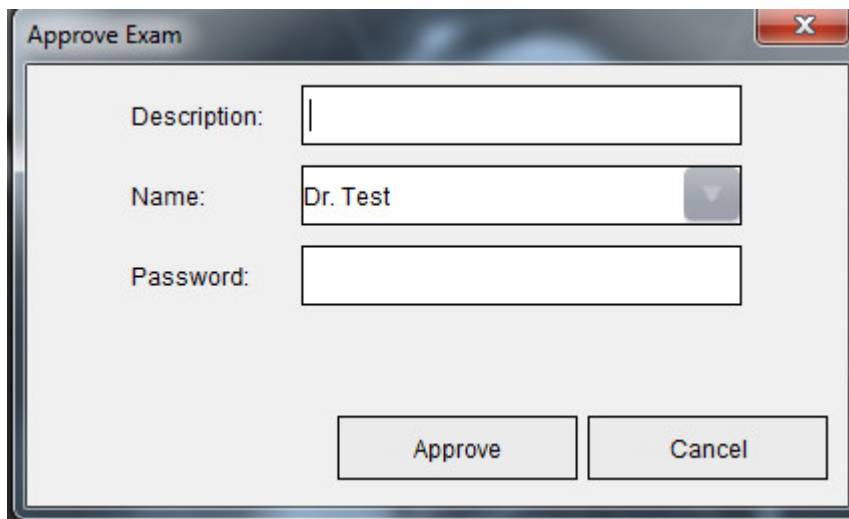
Approve the Exam

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 27.

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

FIGURE 9. Approve Exam Window

The image shows a software dialog box titled "Approve Exam" with a standard Windows-style title bar (minimize, maximize, close buttons). Inside the dialog, there are three input fields: "Description:" followed by a text box, "Name:" followed by a pull-down menu showing "Dr. Test", and "Password:" followed by a text box. At the bottom of the dialog, there are two buttons: "Approve" and "Cancel".

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.

Export Options

The exporting feature is designed to create backups of the exams and the analysis results for future review on suiteHEART. 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.

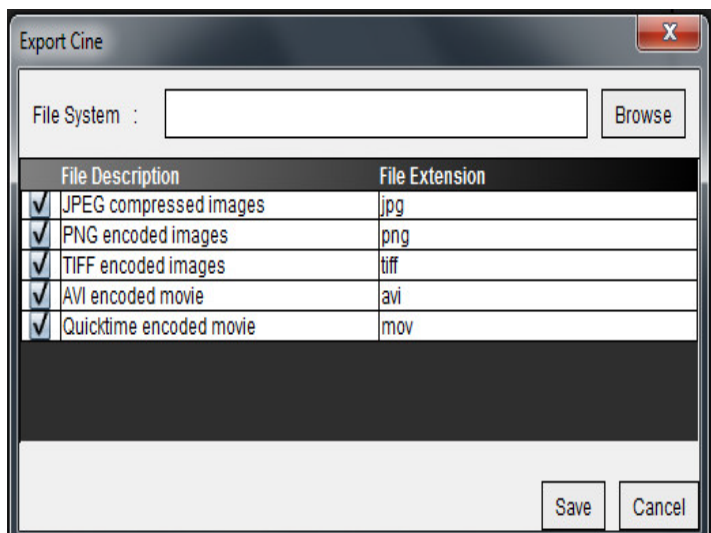
Select **Tools > Export > Export Cine DICOM**.

A secondary capture (SCPT) is created and is saved as part of the study.

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

The Save Cine popup window is displayed.

FIGURE 10. Save Cine Window



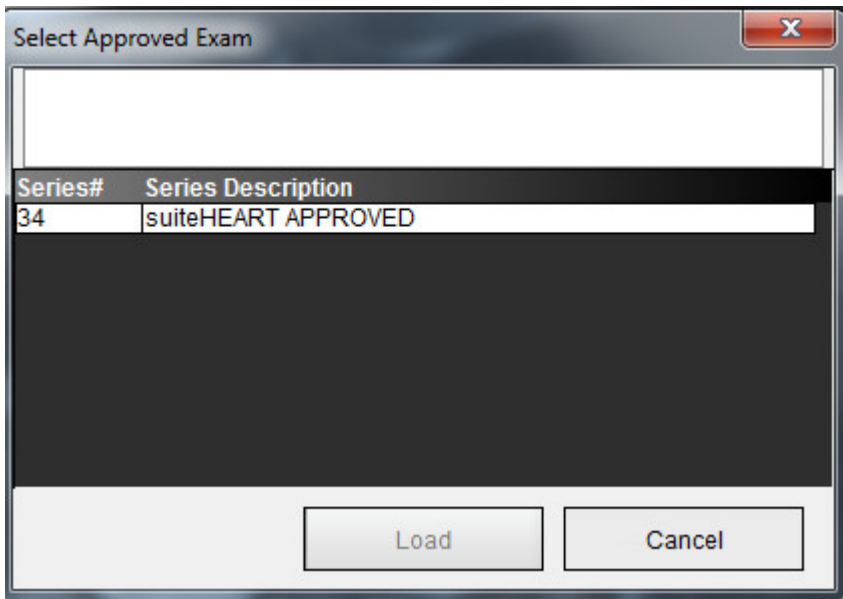
1. Select the file types to be exported.
2. Browse to the location in which to save the file(s).
3. Click **Save** to start the exporting process and close the window. The currently viewed series is the only file exported.

Review an Approved Report

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

This displays the Select Approved Exam window. All the series 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 report and it's accompanying analysis.
 - An approved report can be viewed only.
 - A new report can be generated from an approved report by editing an approved report and saving those changes to a new report. The new report is saved as a secondary capture series.

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

Report Database

“Report Database Tool Procedure” on page 96

“Delete a Favorite” on page 100

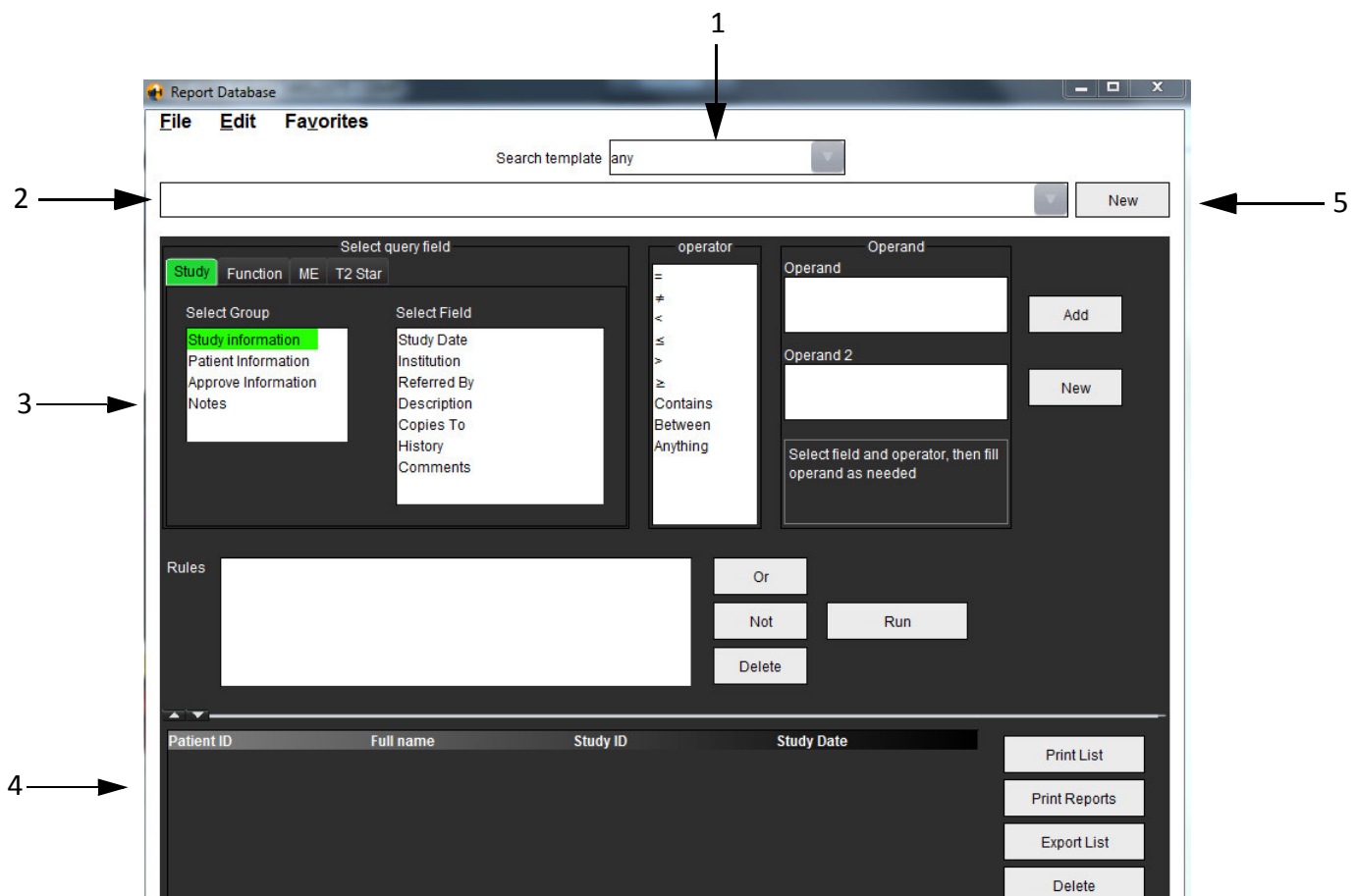
“Export Search Results to an HTML File” on page 101

“Export the Database” on page 101

“Import a Database” on page 102

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

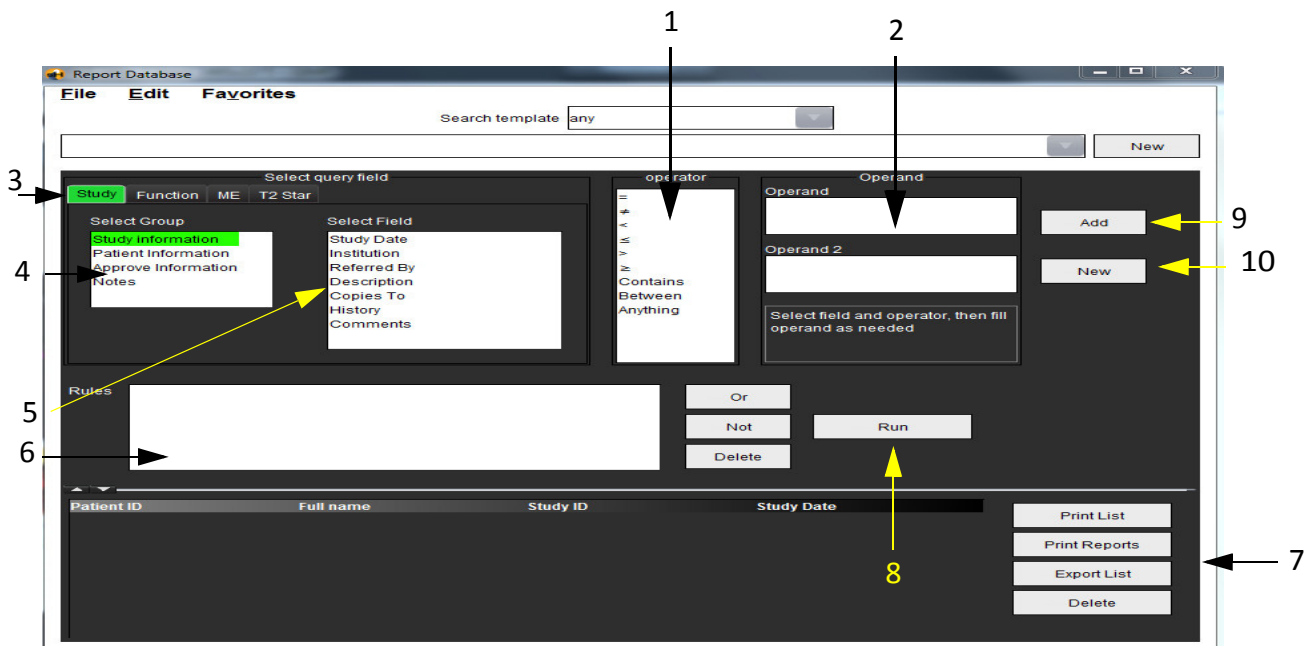


NOTE: If the desired query does not exist already, create a new query.

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 manipulation controls, 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.

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.

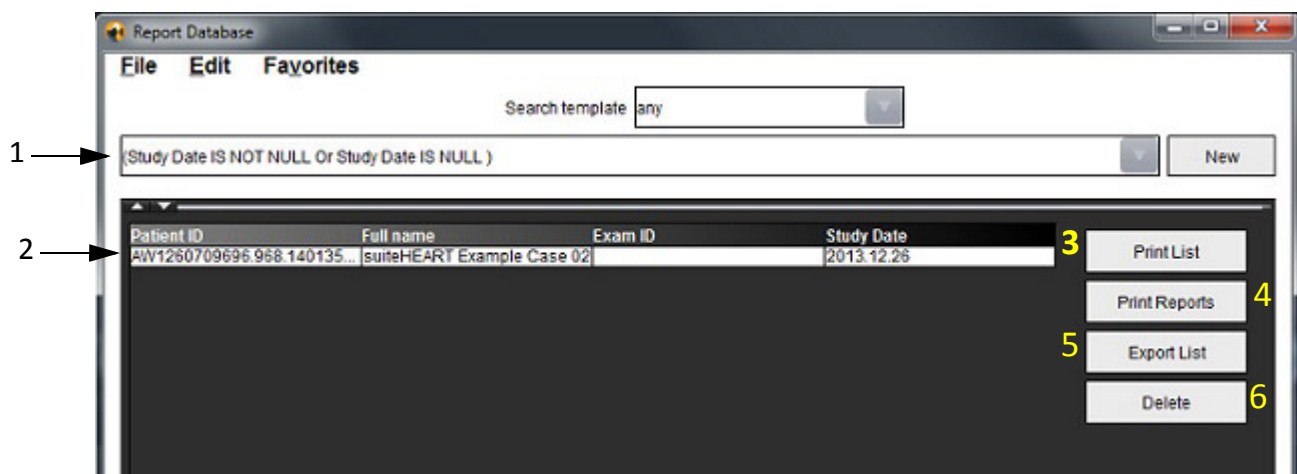
The **Delete** button provides a means to select and delete a query rule.

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. In this example, all reports with a heart rate > 70 bpm are displayed.

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.

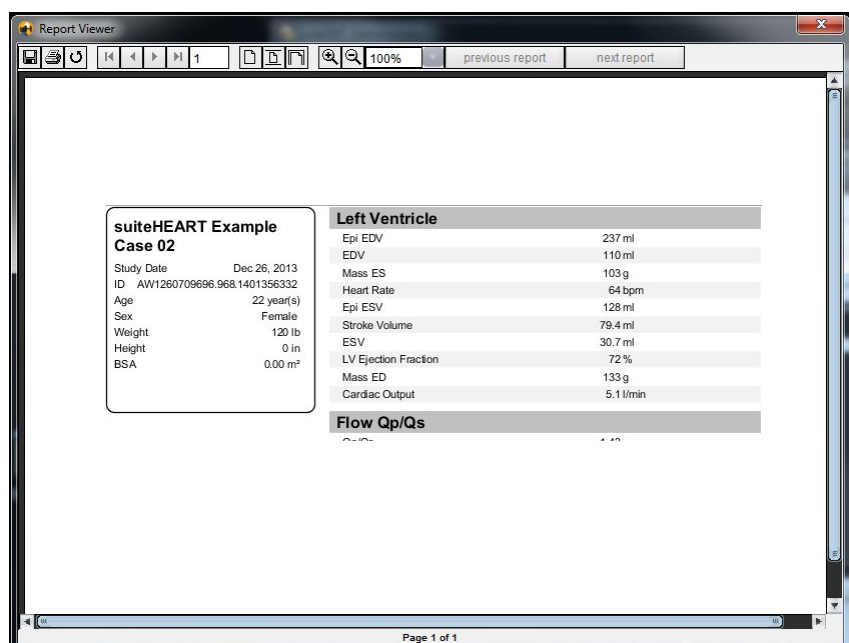
View the Results

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. Double-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 **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

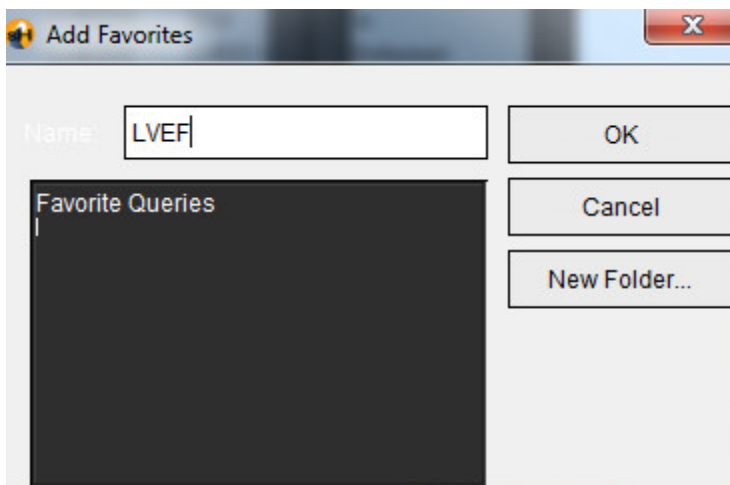


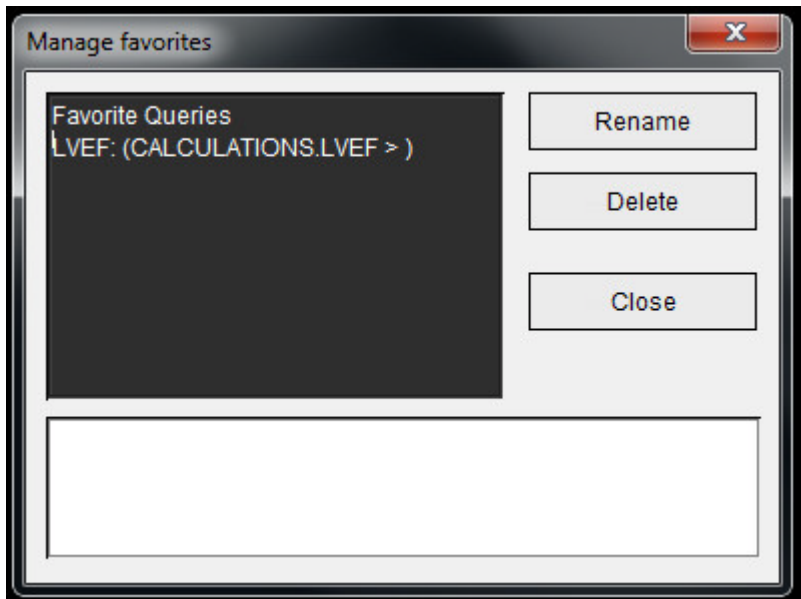
FIGURE 7. Favorites Pull-down



Delete a Favorite

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

FIGURE 8. Manage Favorites Window

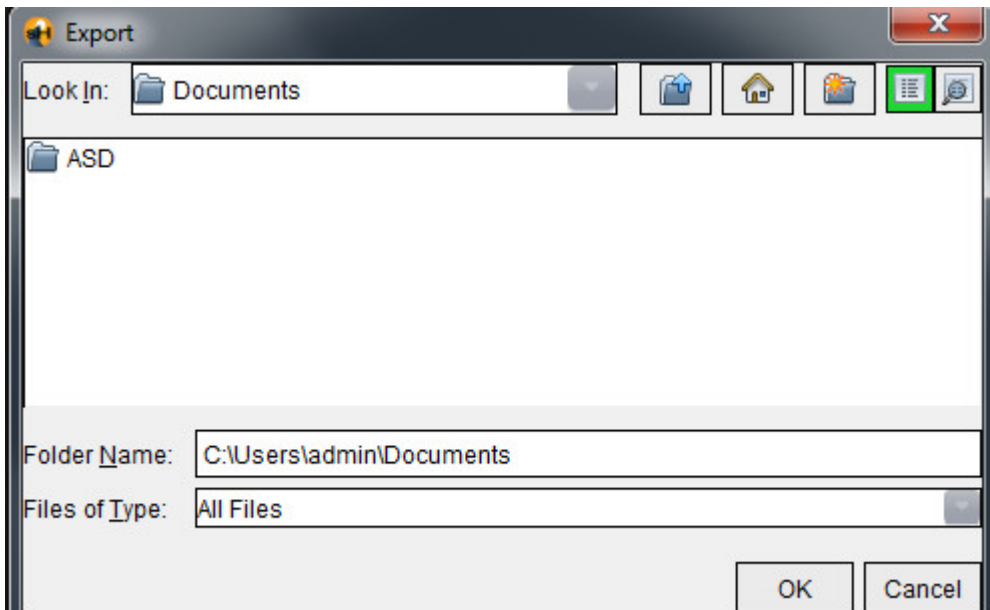


2. Select the favorite item.
The entire query formula is displayed in the Result window.
3. Click **Delete**.
A confirmation popup will verify your delete selection. Select **Yes**.
4. Select **Close**.

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.

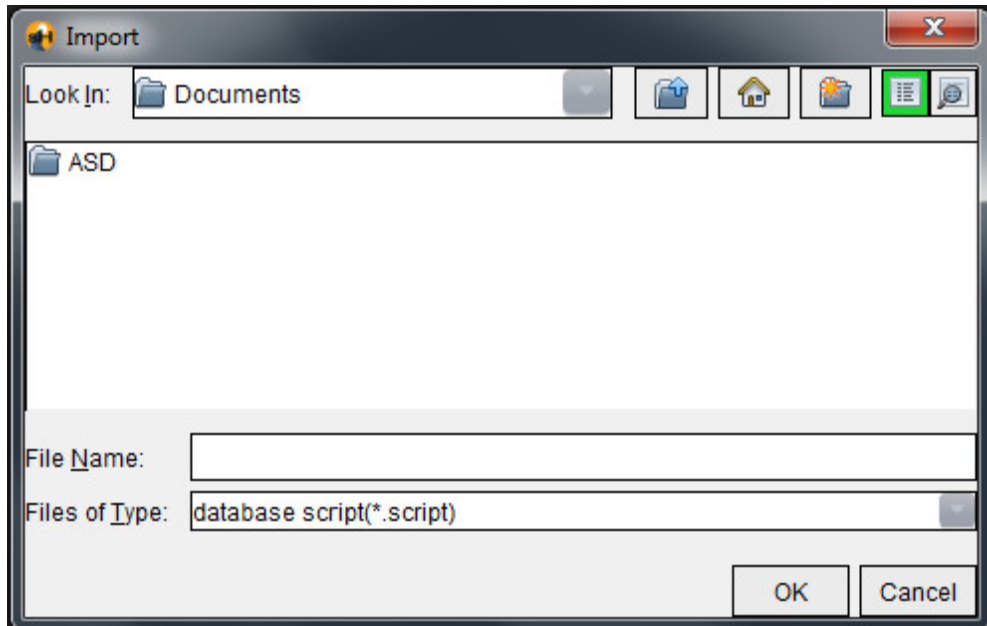
1. Select **File > Export** from the Report Database menu bar.
2. Select the directory to which to export the list.
3. Select **OK**. The database is exported to the external storage device.

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” on page 103

“DICOM Import Procedure” on page 105

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.

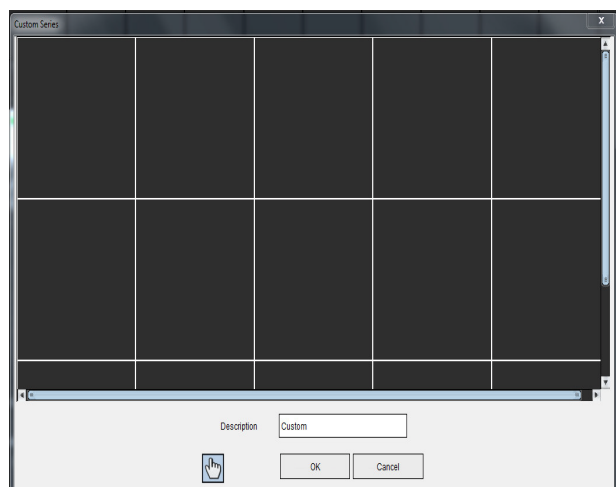


WARNING: Creation of a new series should be for viewing purposes only. Custom series can be created from different prescriptions, exams and patients which could lead to patient information mismatch and / or misdiagnosis. All analysis should be performed on the original series within the exam for correct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

Create a Custom Series Procedure

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.



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



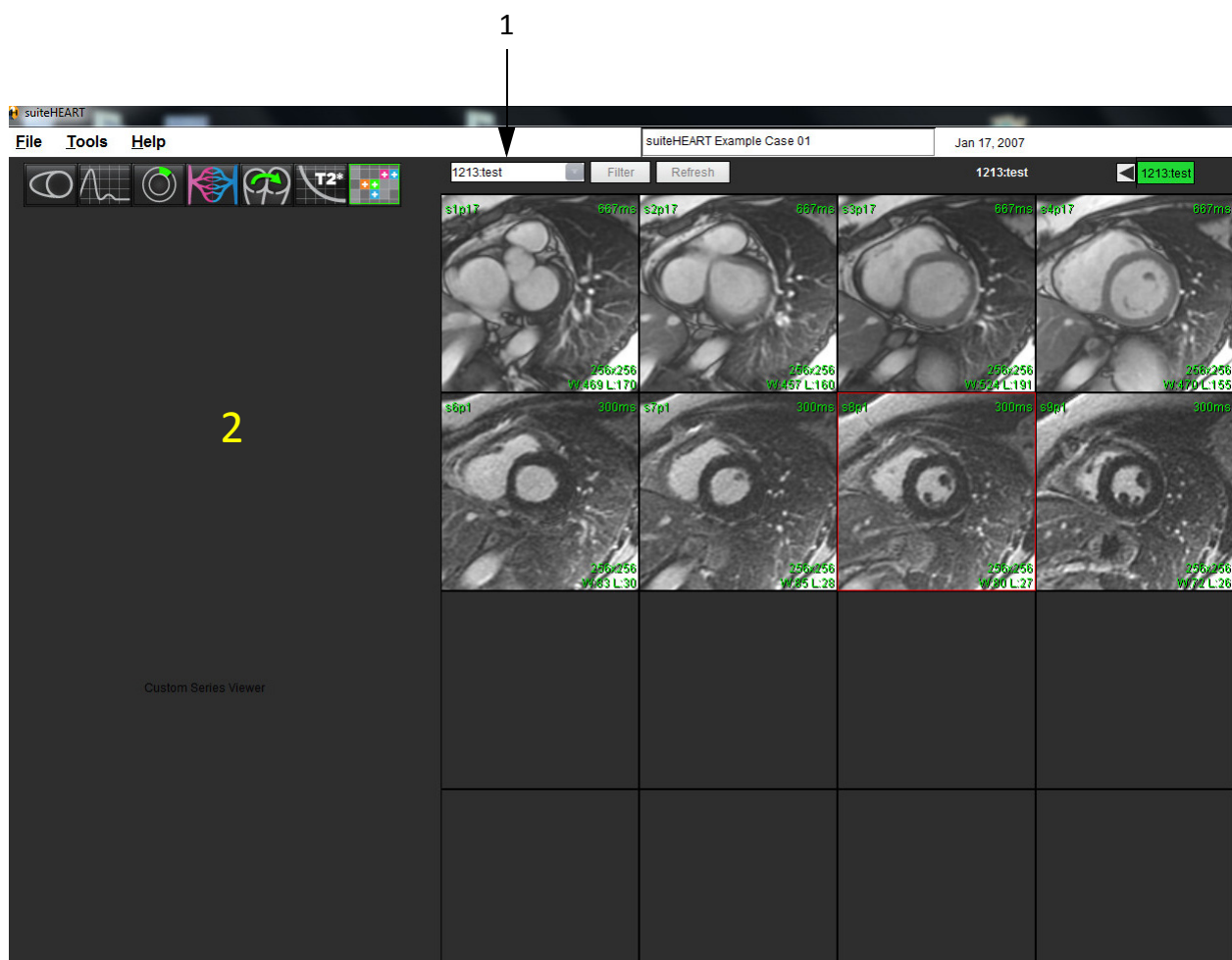
1. Select **button**.

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.

FIGURE 2. Custom Series Viewer



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

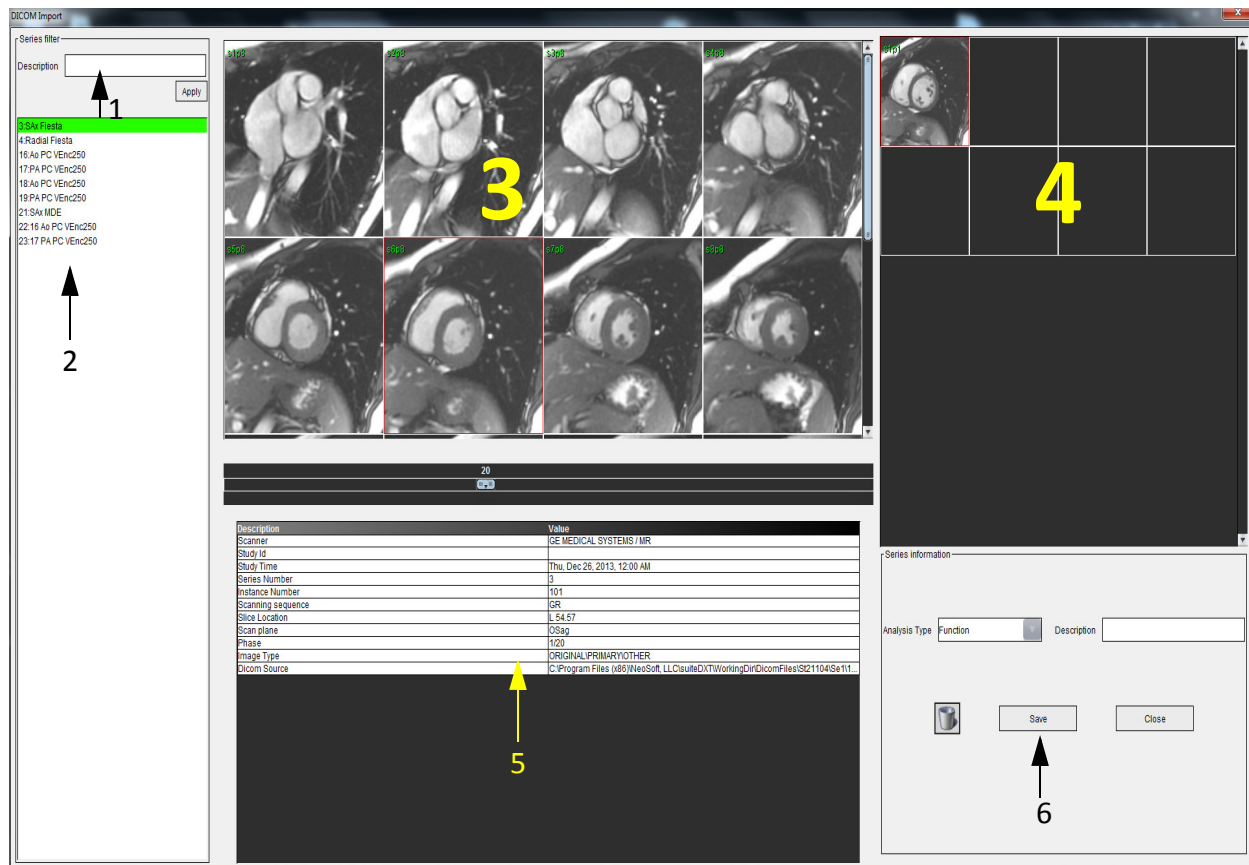
DICOM Import Procedure

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.

FIGURE 3. DICOM Import Tool



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

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.

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

6. Select the analysis type for the new series in the New series information panel.
7. Type the new series description into the in the New series information panel.
8. Select Save to write the new series to the DICOM database.
 - 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.

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Appendix

"Appendix A - Reference Articles" on page 109

"Appendix B - T2Star Calculation" on page 110

"Appendix C - R2Star/T2Star Conversions" on page 110

"Appendix D - Time Course Curve" on page 111

"Appendix E - Formula References" on page 112

"Appendix F - Functional Analysis Scan Plane Example" on page 112

"Appendix G - Supported Manufacturers" on page 114

Formulas and Technical Reference

Appendix A - Reference Articles

Preference ranges, as described on page 32 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 - T2Star Calculation

The T2Star curve is a graph of the signal intensity versus echo time using an exponential decay curve formula. The T2Star fitting algorithm is based on Levenberg-Marquardt non-linear least square algorithm.

The calculation for the T2Star 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
T2Star	is the decay constant, and
c	is the background noise

The range of T2Star is dependent on the signal decay of the target tissue; curve fitting requires echo points having signal that contributes to the T2Star decay.

The 2-parameter fit as described on page 82 of this manual, is widely accepted based on peer review literature [6]. 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, as described on page 82 of this manual, is also available as referenced in peer review literature [7]. This model is a non-linear approach that works directly on the original input signal.

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

6. 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.
7. Ghugre NR, et al. "Improved R2* Measurements in Myocardial Iron Overload," Journal of Magnetic Resonance Imaging 2006; 23: 9-16.

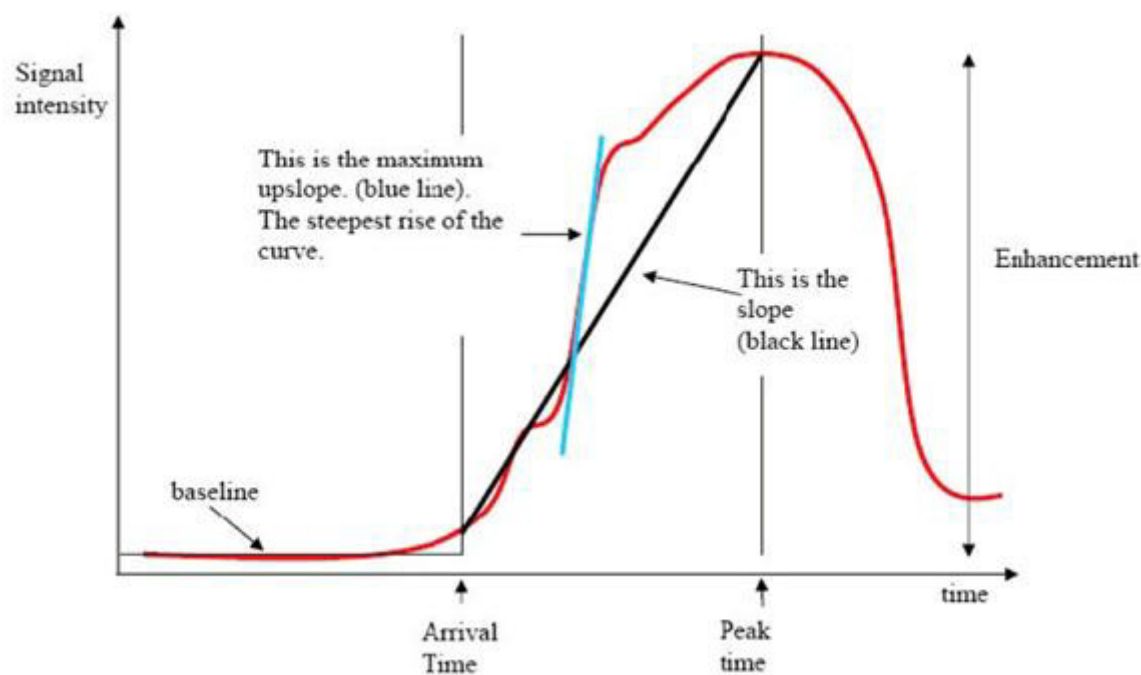
Appendix C - R2Star/T2Star Conversions

R2* value is the reciprocal of T2* value. The formula is: $R2^* = 1000/T2^*$

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}).

Appendix D - Time Course Curve

The Time Course Curve is expressed 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: <div>Intensity enhancement (peak signal - baseline signal) Baseline</div>
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

Appendix E - Formula References

BSA Formula:

DuBois and DuBois Formula [Ref: <http://www.halls.md/body-surface-area/refs.htm>]

$$BSA \text{ in M2 (Sq. Metre)} = 0.007184 \times (\text{Height in cm})^{0.725} \times (\text{Weight in kilos})^{0.425}$$

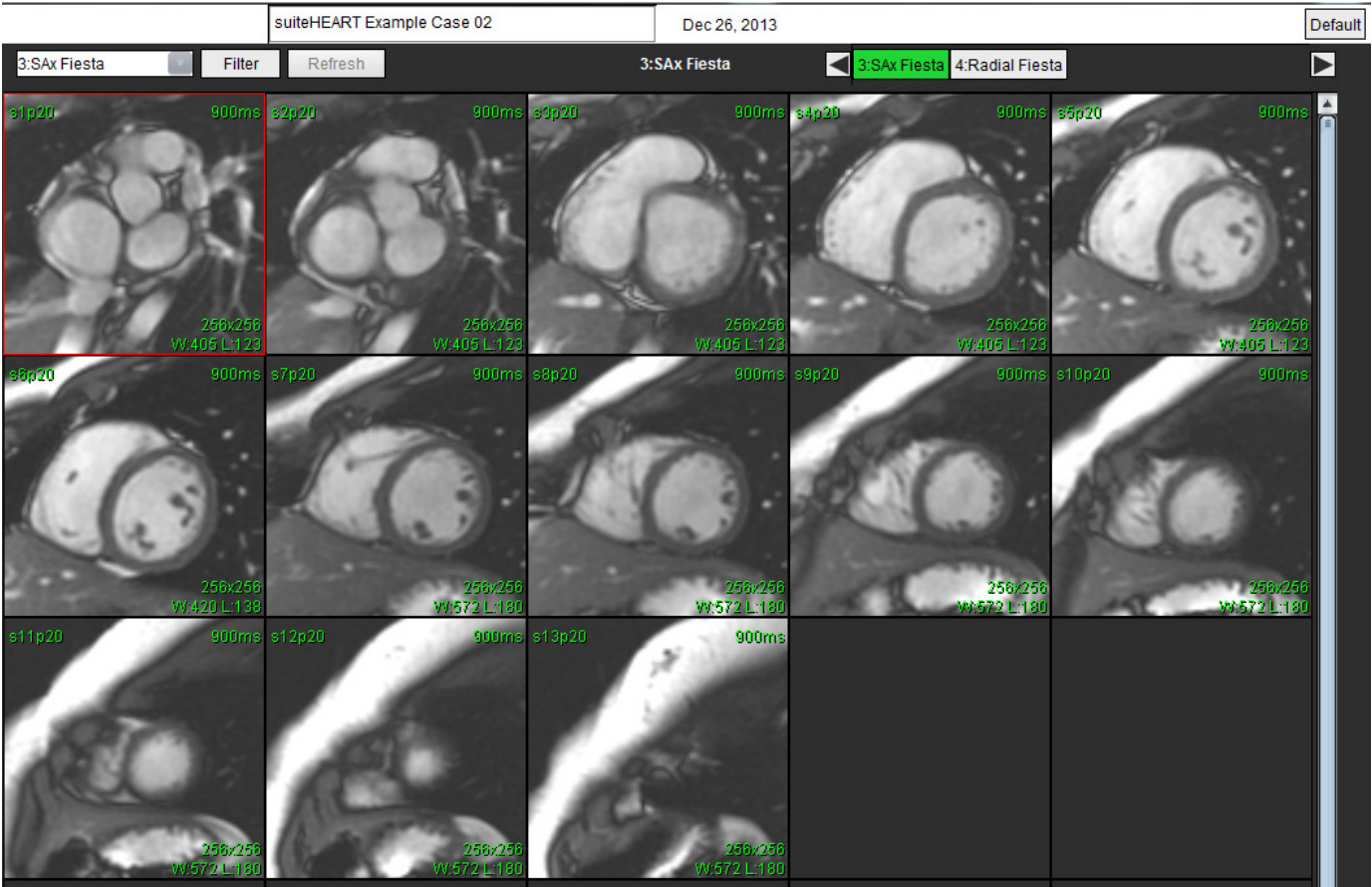
Valve Plane Analysis:

Valve Plane Analysis uses the area and volume flow measurements to derive the pressure gradient based on simplified Bernoulli's equation.

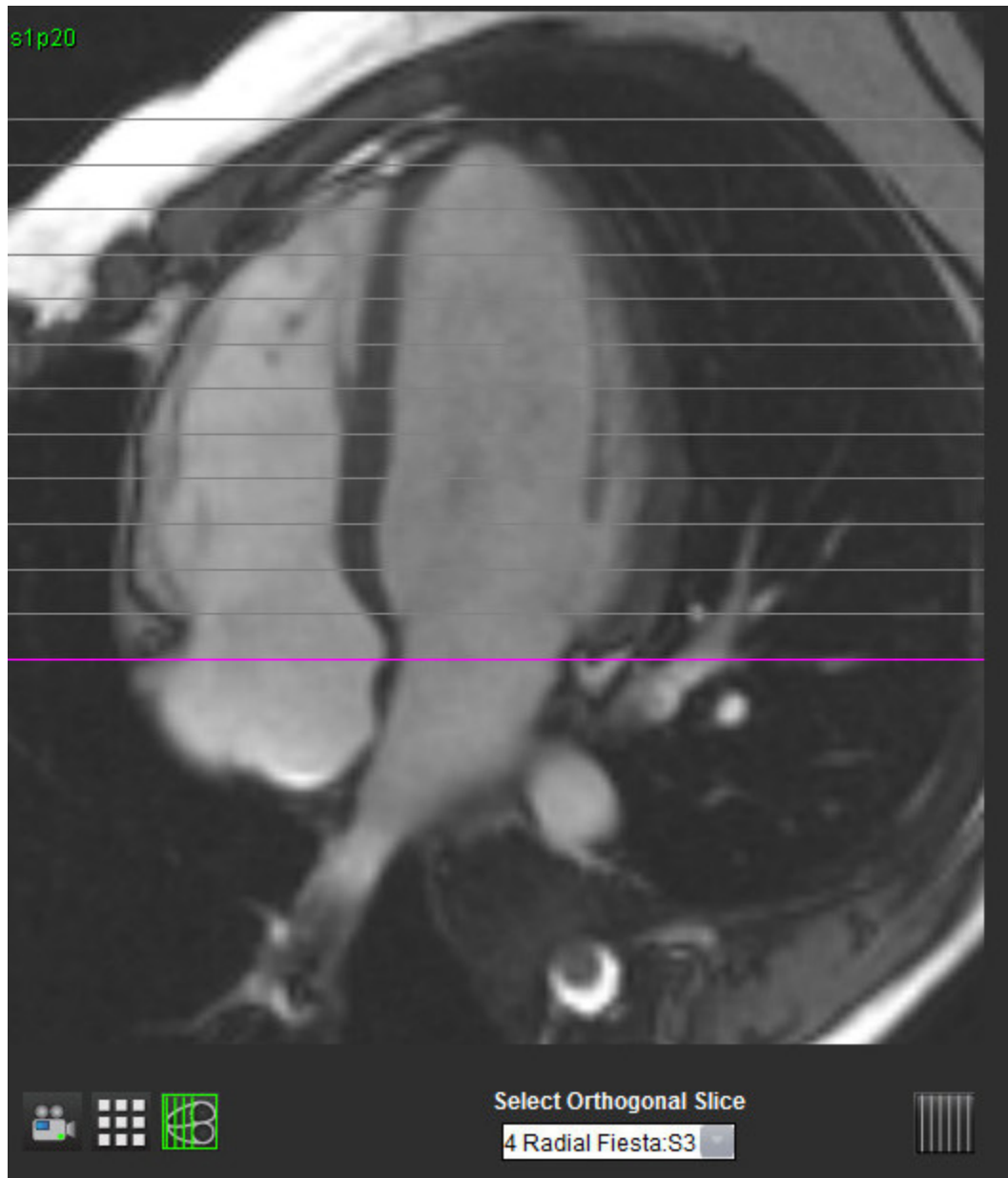
For practical use in Doppler echocardiography the Bernoulli formula has been simplified to: $p_1 - p_2 = 4V^2$

Appendix F - 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 G - Supported Manufacturers

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

Table 1: Supported Manufacturers

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, Flow
SIEMENS	Aera Avanto Espree Skyra Sonata Symphony Verio	Function, Myocardial Evaluation, Flow

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