suiteHEART® Software

cMRI Analysis Software

Instructions for Use

NeoSoft, LLC

Revision History

Rev	Date	Description of Change	Safety Related Update (Yes/No)
1	23APR2019	Updated for the 5.0.0 product release. Previous manual NS-03-008-0001, Rev 15	No
2	30NOV2019	Updated for the 5.0.1 product release.	No
3	23NOV2020	Updated for the 5.0.2 product release.	No
4	11JAN2021	Added Malaysian authorized representative.	No
5	14JUNE2021	Added MD symbol, EU importer reference, incident reporting information.	No

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The Instructions for Use for this device are provided electronically in Portable Document Format, (.pdf). A pdf viewer is required to view the Instructions for Use. A paper copy of the Instructions for Use can be provided upon request, at no cost, within 7 calendar days, by emailing service@neosoftmedical.com.

Instructions for Use may be accessed in the following ways:

1. After launching the application, click "Help" or "About" from the main screen. Select the "Instructions for Use" option. The Instructions for Use will open in a pdf viewer.
2. If the original installation package received from NeoSoft is available, open the zip file and navigate to the "Documentation" folder, then the "Instructions for Use" folder and double click on the Instructions for Use.pdf in your language, denoted by EN - English, FR - French, DE - German, EL - Greek, IT - Italian, LT - Lithuanian, ES - Spanish, SV - Swedish, TR - Turkish, RO - Romanian, NL - Dutch, PT-PT - Portuguese, HU - Hungarian.
3. Navigate to the folder where the application is installed. Locate the "Documentation" folder, open the "Instructions for Use" folder and double click on the Instructions for Use.pdf in your language, denoted by EN - English, FR - French, DE - German, EL - Greek, IT - Italian, LT - Lithuanian, ES - Spanish, SV - Swedish, TR - Turkish, RO - Romanian, NL - Dutch, PT-PT - Portuguese, HU - Hungarian.
4. Electronic copies of Instructions for Use are also available at www.neosoftllc.com/neosoft/product_manuals/ for at least 15 years from last date of manufacture.

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:

$$C\mathcal{E}$$
2797

This product is a Medical Device: **MD**

European Representatives:
EMERGO EUROPE
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EC | REP

EU Importer:

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Health Canada device license number: 99490

Malaysian Medical Device Registration Number: GB10979720-50888

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⚠️

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

Any serious incident that has occurred in relation to this device should be reported to NeoSoft and the competent authority of your Member State.

Table of Contents

Safety

Introduction

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

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

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

⚠️

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

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

Table 1: Safety Terminology

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

Indications for Use

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

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 mea-

surement tools such as ejection fraction, cardiac output, end-diastolic volume, end-systolic volume, and volume flow measurements.

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

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

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

Intended Use

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

Supported DICOM Image Formats

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

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

Safety Notices

⚠️ WARNING: The application assists in the analysis of the images only and does not automatically produce a clinical interpretation of the 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.

Getting Started

Launching and Exiting the Application

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

Launching suiteHEART® Software

1. Launch suiteDXT via the desktop shortcut.

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

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

   FIGURE 1. Launch Application
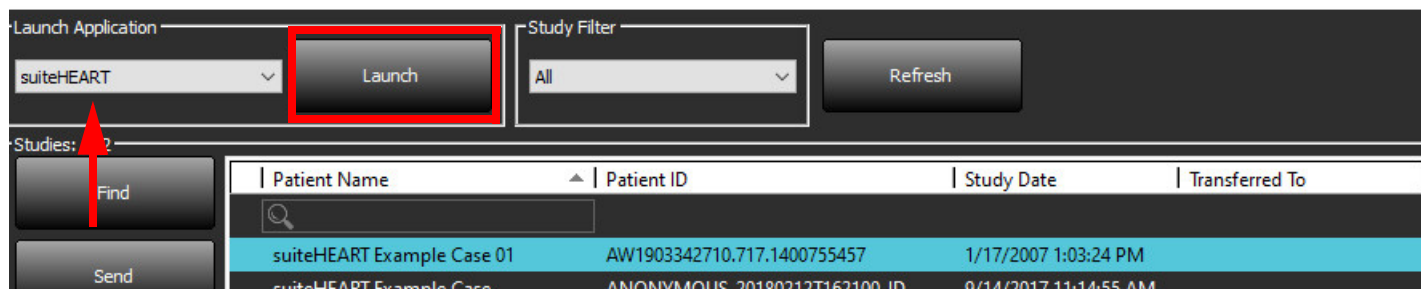
3. Select a study from the study list and do one of the following:
   - Select Launch.
   - Double click on the study.

4. Select a group of studies and select Launch.

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

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

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

Exiting suiteHEART® Software

To exit the application select **File > Exit** or click on the X in the upper right corner of the interface.

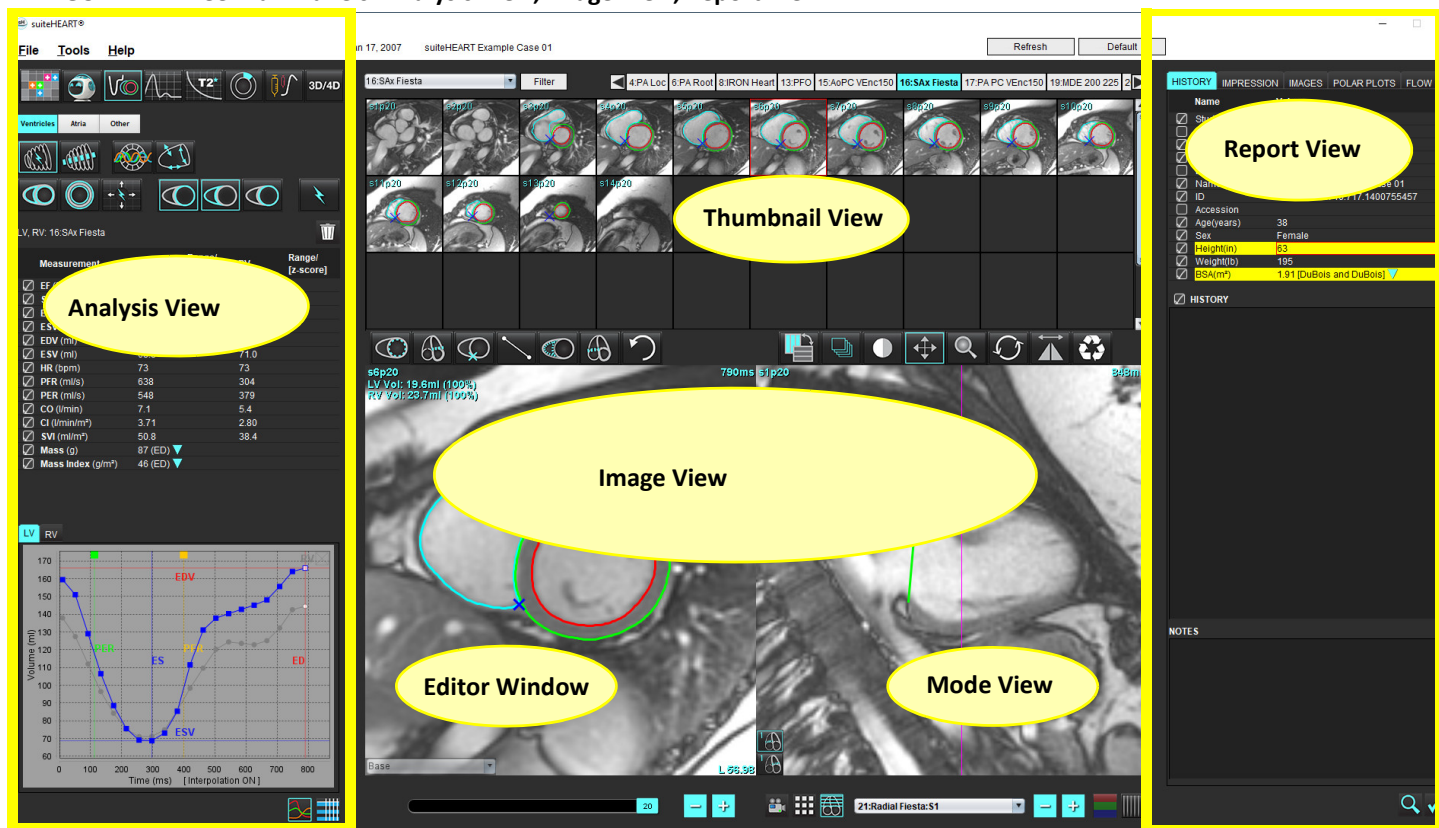**FIGURE 2. Close suiteHEART® Software**

User Interface Overview

Overview

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

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

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

Analysis/Viewer Modes

Table 1: Analysis Modes

Function Analysis	Flow Analysis	Myocardial Evaluation	T1 Mapping	T2 Mapping	Myocardial Perfusion Analysis	T2 Star Analysis

NOTE: Patent Foramen Ovale (PFO) Analysis can be selected from the file pull-down menu or by using Ctrl 5 on the keyboard.

Table 2: Viewer Modes

Viewer	Virtual Fellow®	3D/4D Flow Viewer

Series Navigation

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

FIGURE 2. Series Navigation
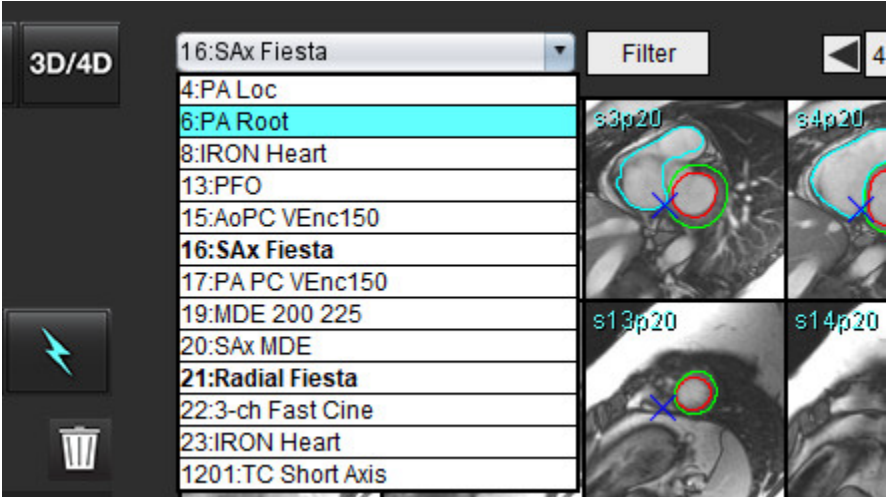
Editor Window and Mode View

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

Table 3: Image Manipulation Tools

◑	Window/Level
✛	Pan
🔍	Zoom
↻	Rotate
◭	Flip
📊	Send to Report
▤	Scan Parameters
♻	Reset

File Menu Options

    Select Analysis – Selects the analysis mode (Function, Flow, Myocardial Evaluation, Myocardial Perfusion, PFO, T2Star, T1 Mapping, T2 Mapping, 3D/4D Flow Viewer and DENSE*)
    BrowseDB – Opens local database
    Switch Study – Lists available studies for quick access
    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.

*Requires Research Agreement

Tools Menu Options

    Preferences >
        Edit – Opens the preferences editor to set software and template preferences
        Import – Restores user preferences and macros
        Export – Exports all user preferences
    Export >
        Report to DICOM – Generates a report based on current analysis and saves it as a secondary capture (SCPT) series.
        Report to Excel – Generates Excel spreadsheet with analysis results.
        Report to XML – Exports report as an XML file.
        Images to DICOM – Saves a DICOM cine of the currently selected series as a SCPT file.
        Report to... – Exports results to a third party reporting system.
        Images to JPEG, AVI, etc. – Exports currently selected series images to any of the selected file formats. Available formats are: compressed QuickTime movie, JPEG, TIFF, GIF, PNG or uncompressed AVI movie.
        Data to Matlab – Exports a Mat-file in binary form. (Available by license only)
        Strain Data to Matlab – Exports a Mat-file in binary form. (Strain Analysis requires a research agreement)

Report Database – Opens database search interface
Toggle Annotation – Toggles the display of the ROI annotation
Toggle Line Thickness – Toggles line thickness of annotations.
Toggle Cross Reference Lines – Toggles cross reference lines on images.
Toggle FOV – Toggles the field of view
Invert Window/Level – Inverts the window/level view

Help Menu Options

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

Image View Controls

The Phase Slider Bar controls the cine phase selection.

The Image Step Icons allow for slice-to-slice navigation when the thumbnail view is in slice or phases.

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

NOTE: The x (slice) and y (phase) axis can be swapped. Refer to . If swapped the application should be restarted.

Mode Views

The mode view has three available formats:

Cine Mode

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

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

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

 - Play Icon: Located next to the cine mode bar

 - Pause Icon: Located next to the cine mode bar

Matrix Mode

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

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

The matrix mode supports the deletion of contours on a slice location within a row or column which can be performed by selecting the slice number or phase number and performing a right mouse click and selecting the trashcan. Contours from a single phase, group of phases or slices can also be performed by directly selecting the desired phase and slice locations on the matrix and performing a right mouse click and selecting the trashcan.

> **NOTE:** The x (slice) and y (phase) axis can be swapped. Refer to . If the preference is changed the application should be restarted.

FIGURE 3. Matrix Mode
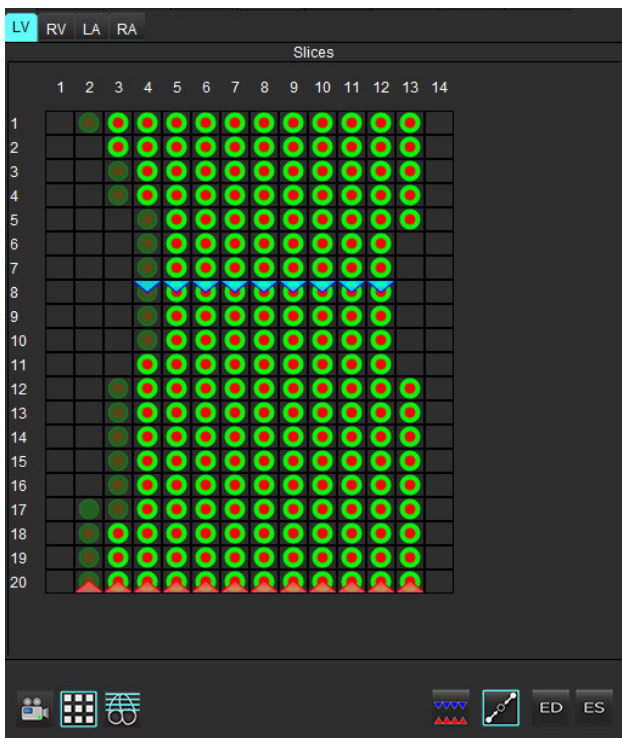
Matrix Mode is used to review and assign the end-systolic and end-diastolic phases. It can be used in the single ED/ES mode when the heart rate changes during acquisition to allow an accurate measurement of end-systolic and end-diastolic volumes. Select the ES button and click on the cells in the matrix mode to set the specified slice / phase to end-systolic. Select the ED button and click on the cells in the matrix mode to set the specified slice / phase to end-diastolic. The volumes are re-calculated automatically as the end-systolic and end-diastolic image are selected.

Cross Reference Mode

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

FIGURE 4. Cross Reference Controls

FIGURE 5. Cross Reference Mode Icon

Image Manipulation Tools
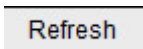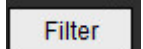
Table 4: Tool Descriptions

	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

Table 4: Tool Descriptions

	Scope Current to End – Applies image manipulations from the current slice to the end slice
	Scope Current Only – Applies image manipulation to the current slice only
	Viewport Layout - Change viewer layout
	Compare Mode - Change to compare mode
	Review Mode - Change to review mode
	Show Cross Reference lines - Toggles cross reference lines on/off
	Colormap Overlay - Toggles slice classification colormap on/off
	Reset – Resets the W/L, Pan, Zoom and Rotate back to default, based on the scope setting
	Region of Interest – Provides area and circumference measurements
	Crosshair – Provides sampling of single pixel data
	Linear – Provides measurement of a straight line distance
	Label – Provides the addition of user annotation in the Editor window
	Angle – Provides angle measurement

Table 4: Tool Descriptions

	Find Feature – Cross reference tool that automatically identifies and displays images that contain the same location
	Undo – Undo functionality available for ROI editing
Refresh	Refresh – Click button to update the Image View with newly networked images
Filter	Filter – Sorts series by pulse sequence type according to analysis mode. Can be deselected by selecting ALL. Filters can be set under Preferences. The filter button will be green if a filter is in use.

Quick Keys

Table 5: 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	Alt + Middle Mouse Button
Cine Play/Pause	Spacebar
Reselect all images for viewing	Ctrl+A
Report Database	Ctrl+D
Edit	Ctrl+E
Toggle Field of View (FOV)	Ctrl+F
Approve Exam	Ctrl+G
Invert Window/Level	Ctrl+I
Thick Line Annotation	Ctrl+L
Open Browse DB	Ctrl+O
Print Report	Ctrl+P
Quit Application or Exit	Ctrl+Q
Open Preview Report	Ctrl+R
Switch Study	Ctrl+S
Toggle Annotation	Ctrl+T
Toggle Cross-Reference Lines	Ctrl+X
Undo	Ctrl+Z
DENSE	Ctrl+0

Table 5: Quick Keys

Function	Action
Function	Ctrl+1
Flow	Ctrl+2
Myocardial Evaluation	Ctrl+3
Myocardial Perfusion	Ctrl+4
PFO	Ctrl+5
T2Star	Ctrl+6
T1 Mapping	Ctrl+7
T2 Mapping	Ctrl+8
3D/4D Flow Viewer	Ctrl+9
Navigate between Slices*	Left & Right Arrow Keys
Navigate between Phases*	Up & Down Arrow Keys
Navigate Virtual Fellow® Slice	Z & A key for next & previous slice
ROI Editing Tools	
Copy ROI	Ctrl+C
Paste ROI	Ctrl+V
Smooth ROI	Ctrl+S
Shift ROI horizontally	W & S Keys
Shift ROI vertically	A & D Keys
Generate a point spline corner	Alt + Left Mouse Button
Delete a point (point spline)	DELETE + Cursor on a point
3D/4D Flow Viewer Editing Tools	
3D Rotate	Ctrl + Alt + Middle Mouse Button
Image Zoom	Ctrl + Middle Mouse Button
Window/Level	Alt + Middle Mouse Button

*The active setting will depend on what is chosen in Preferences.

Analysis View

The Analysis View is available for each analysis mode.

FIGURE 6. Analysis View Features
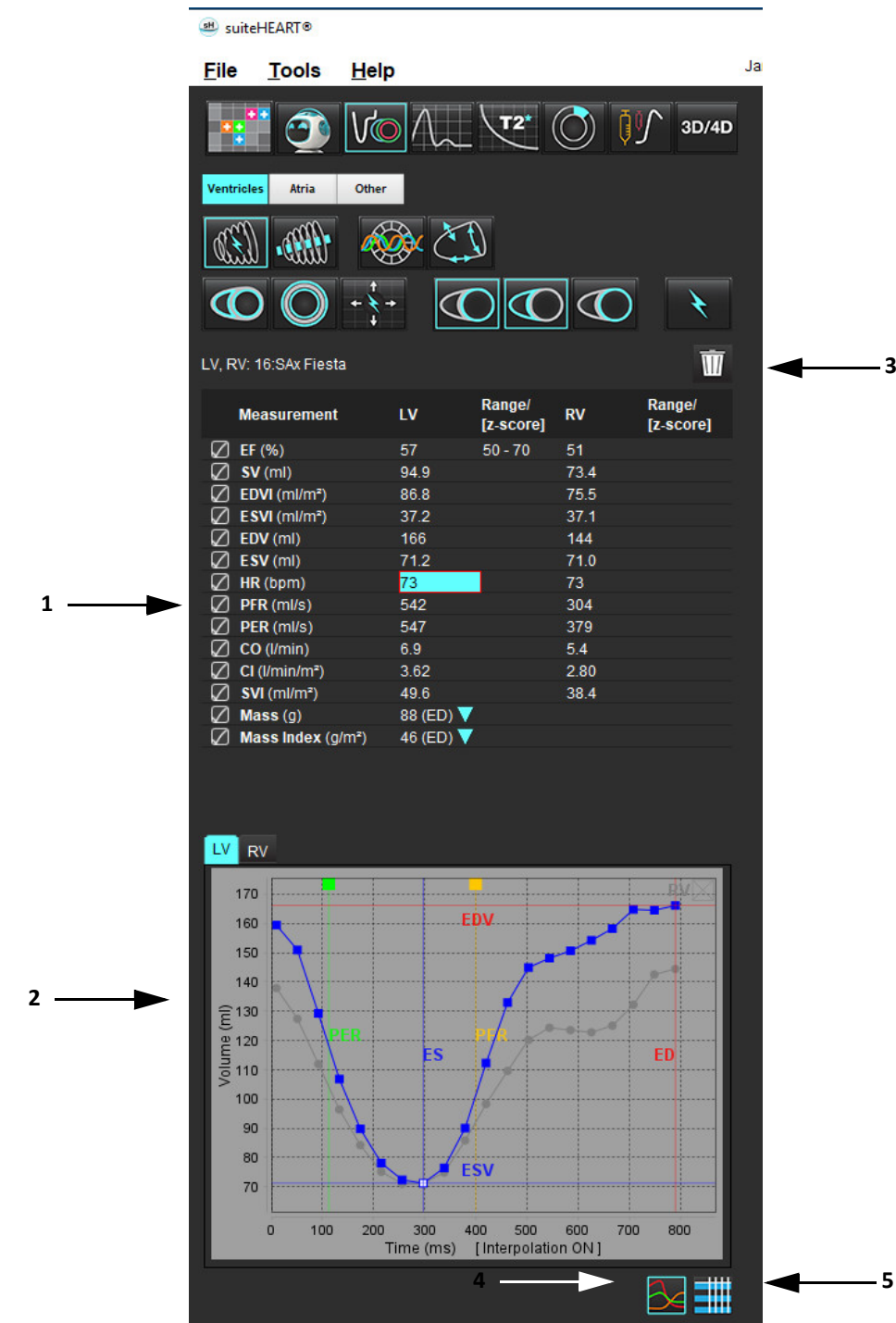
1. Result table, 2. Graph display 3. Delete, 4. Graphs, 5. Tables

Analysis View Review

Result Table

The measurement results can be reordered and configured in preferences (refer to Print Tab on page 43). The measurement table can be reordered by selecting a row and dragging to a new position. The order of the table will always default to the order in preference for all new studies. Select or deselect a measurement from inclusion on the report by clicking the box next to the measurement.

FIGURE 7. Result Table

	Measurement	LV	Range/ [z-score]	RV	Range/ [z-score]
☑	EF (%)	57	50 - 70	51	
☑	SV (ml)	94.9		73.4	
☑	EDVI (ml/m²)	86.8		75.5	
☑	ESVI (ml/m²)	37.2		37.1	
☑	EDV (ml)	166		144	
☑	ESV (ml)	71.2		71.0	
☑	HR (bpm)	73		73	
☑	PFR (ml/s)	542		304	
☑	PER (ml/s)	547		379	
☑	CO (l/min)	6.9		5.4	
☑	CI (l/min/m²)	3.62		2.80	
☑	SVI (ml/m²)	49.6		38.4	
☑	Mass (g)	88 (ED) ▼			
☑	Mass Index (g/m²)	46 (ED) ▼			

NOTE: Click directly on the table in the column to enter or edit the heartrate.

Graph and Table Results

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

FIGURE 8. Graph (left) and Table (right)

Table 6: Analysis Tools

Tool	Tool
Left Ventricular Endocardial ROI	Left Ventricular Local ROI
Left Ventricular Epicardial ROI	Left Ventricular Blood Pool ROI
Right Ventricular Endocardial ROI	
Right Ventricular Epicardial ROI	
Mitral Valve Annulus	
Tricuspid Valve Annulus	
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	

Report View

suiteHEART® Software has four report views for structured reporting. Refer to Structured Reporting on page 162 for more information.

FIGURE 9. Reporting Tabs

 - Preview Report: Used for previewing a report

 - Approve Exam: Used for report signature

Browse DB

The Browse DB window provides a view of the current studies in the local database. There are controls that allow you to choose which studies to view or add to the switch study listing.

FIGURE 10. Browse DB
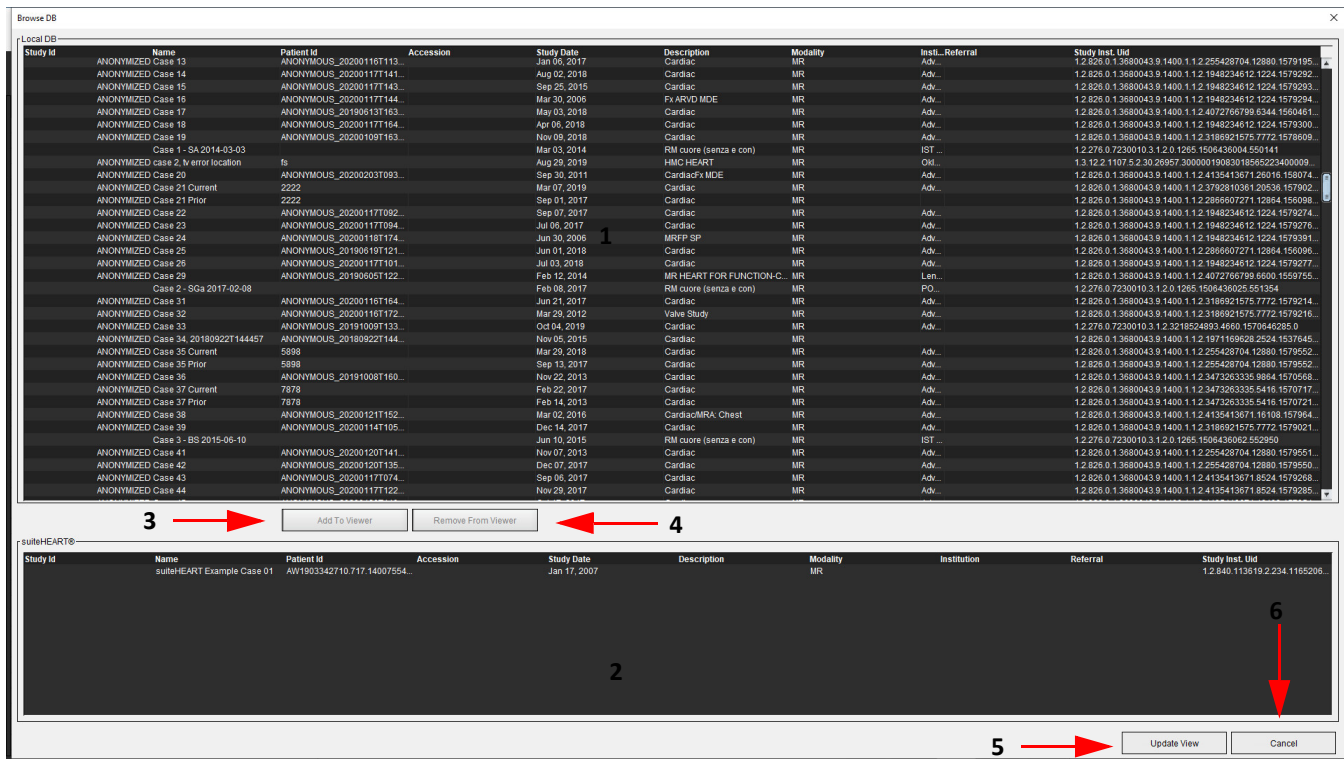
1. Local database listing, 2. suiteHEART® Software database viewer, 3. Add to Viewer button, 4. Remove from Viewer, 5. Update View, 6. Cancel

Features of the Browse DB

The Browse DB always defaults to the local database.

1. Local database listing – displays the exams that are stored in the local database.

2. suiteHEART® Software database viewer – displays exams that are in the current suiteHEART® Software database.

3. Add to Viewer – Adds the selected exam from local database (shown in the top portion of the window) to the suiteHEART® Software database viewing area.

4. Remove from Viewer – Removes the exam from suiteHEART® Software database viewing area.

5. Update View – Closes the Browse Database window and bring the exams in the viewable listing area to the application viewer. Used to populate the switch studies window.

6. Cancel – Closes Browse Database window with no changes to the list.

Browse DB Procedure

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

Add Studies to the suiteHEART® Software Switch Study List

1.   Click **File > Browse DB**.

2.   Locate the study in the database viewer and click on the exam to highlight it.

3.   Click **Add to Viewer**.

4.   Click **Update View**.

5.   The study now appears in the suiteHEART® Software Switch Study List.

Remove Exams from the suiteHEART® Software Switch Study List

1.   Click **File > Browse DB**.

2.   Locate the study and then click **Remove from Viewer**.

3.   Click **Update Viewer**.

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

Studies must be loaded into suiteHEART® Software before they can be shown in the Viewer. See to learn how to populate the Switch Study List.

Switch Studies within suiteHEART® Software

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

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

2.   Select the study.

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

Image Management Tools

Viewer

The viewer allows for the quick review of the study with cross referencing. The viewer interface displays the listing of the series that have been acquired for the selected study with each series displayed in a viewport. New series types can be created for analysis and review within the viewer interface. User defined viewing protocols for routine acquired series can also be created to expedite study review.

> **NOTE:** Image exporting can only be performed in the analysis modes.

FIGURE 1. Viewer
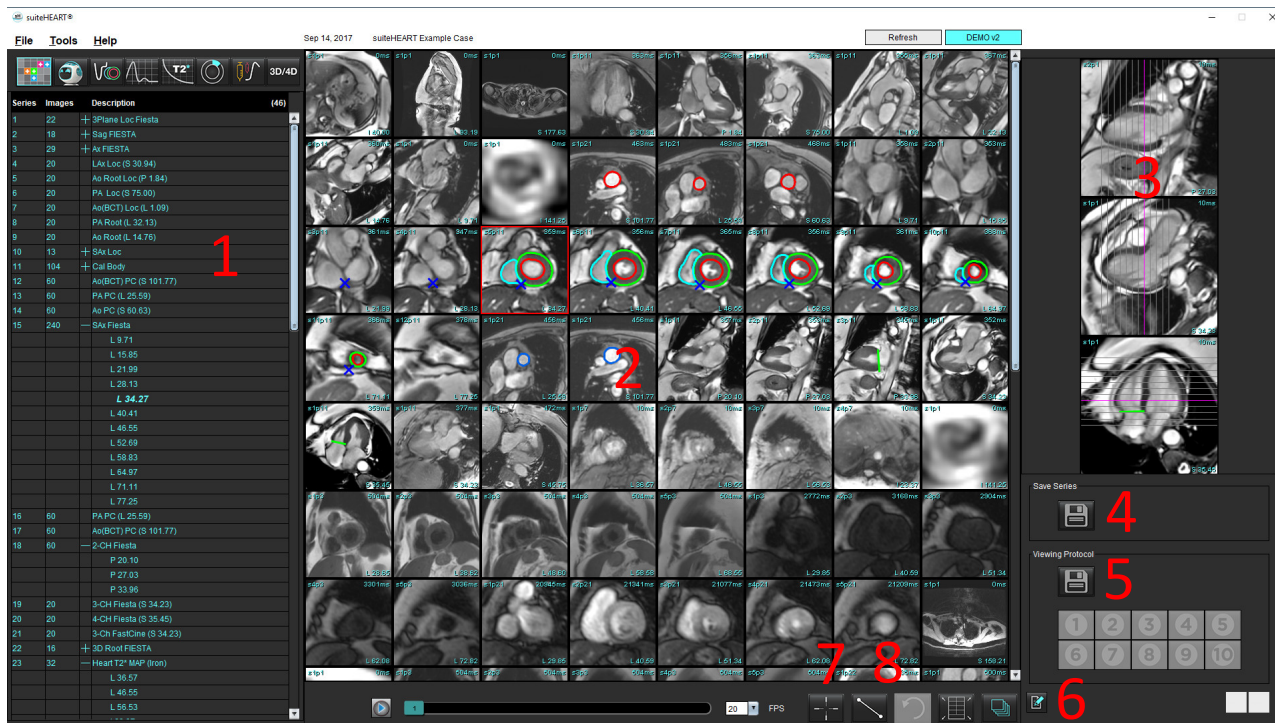
1. Study series listing, 2. Series/Slice viewport, 3. Cross Reference, 4. Save series, 5. Viewing Protocols, 6. Switch to Report tabs, 7. Find Feature, 8. Measurement Tools

Image/Series Navigation

Click on a series and use Page Up or Page Down on the keyboard to navigate through slice locations within the series.

Navigate to the next series by pressing the right arrow key on the keyboard and the left arrow for the previous series.

When navigating to a multi-phase series they are displayed in an auto layout, whereas a single-phase series will be displayed in a 1x1 layout.

Find Feature*

1. Select to use the cross reference tool.

   The purple cursor is the primary cursor that can be positioned on the image.

2. Press the Ctrl key and select the cross reference tool to activate the primary cursor. All close slice locations are automatically displayed.

   The main view will then be populated with only those slices where the secondary green cursor was calculated as close to the primary purple cursor.

   NOTE: The green secondary cross annotations appear on viewports containing **non-parallel** images and at points that are calculated to be within 10mm 3D distance of the primary cursor.

   NOTE: The green secondary cross annotations appear on viewports containing **parallel** images and at points that are calculated to be within 5mm 3D distance of the primary purple cursor.

Quick Key

Function	Action
Reselect all images for viewing	Ctrl+A

Viewer Functionality

Create a New Series

The viewer allows for the creation of series types that can be used for Function, Myocardial Evaluation, Myocardial Perfusion, T2Star, T1 Mapping, T2 Mapping analysis for review only (custom). Series that are created will be added to the series listing for that study and are available for viewing and analysis within the suiteHEART® Software application.

> NOTE: For a series to be valid for analysis, each slice location must have the same number of phases, same acquisition parameters and scan plane prescription.

⚠️

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 locations copied into the new series. Do not delete original images that have been used for DICOM import.

1. Select the desired series or slice locations from the series listing.
2. Select a group of series or slice locations by performing a Shift click or a Ctrl click for adding a single series or slice location.
3. Clicking and dragging allows for the ordering of the images within the viewports.
4. To delete an image from a viewport, select the viewport and press the Delete key on the keyboard.
5. Select 💾 from the Save Series pane Figure 2.

FIGURE 2. Save Series Pane

6. Type in a series name for the application Series description.
7. Select the appropriate series application type from the pull-down menu (Figure 3). If **Custom** is selected, images with different scan planes and sequence types can be saved as a series.

FIGURE 3. Save New Series
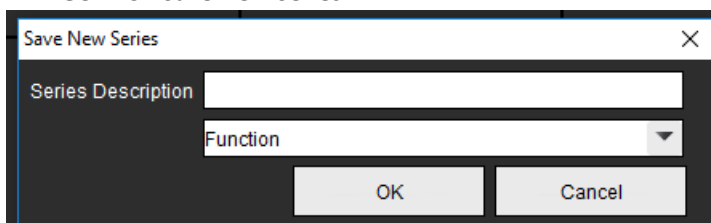
Create a Viewing Protocol

Expedite the review process by creating a Viewing Protocol which saves a user defined viewport layout based upon the series label.

NOTE: Viewing Protocols require that the series labels are the same for each study. If series labels have been changed the images will not appear in the viewport.
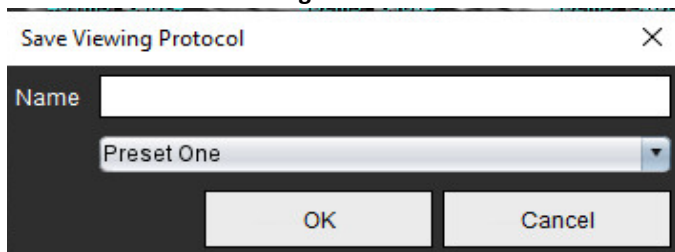
WARNING: The user is responsible for creating Viewing Protocols used for review that contain the correct series types. If the series labels are changed in a study the Viewing Protocol needs to be resaved. Always review the series listing to confirm the correct series types are used for review.

1. Select the desired series or slice locations from the series listing.
2. Select a group of series or slice locations by performing a Shift click or a Ctrl click for adding a single series or a slice location.
3. Clicking and dragging allows for the ordering of the images within the viewports.
4. To delete an image from a viewport, select the viewport and press the Delete key on the keyboard.
5. Select from the Viewing Protocol pane.
6. Type in a label name and select a preset number from the pull-down menu (Figure 4).
7. Click OK to save.

FIGURE 4. Save Viewing Protocol

Accessing Reporting View Tabs

To access the reporting view tabs, click .

To return back to viewer functionality, click .

Compare Mode

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

> **NOTE:** Images sent to a report in compare mode will be in bitmap format. No image manipulations will be possible on these images.

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

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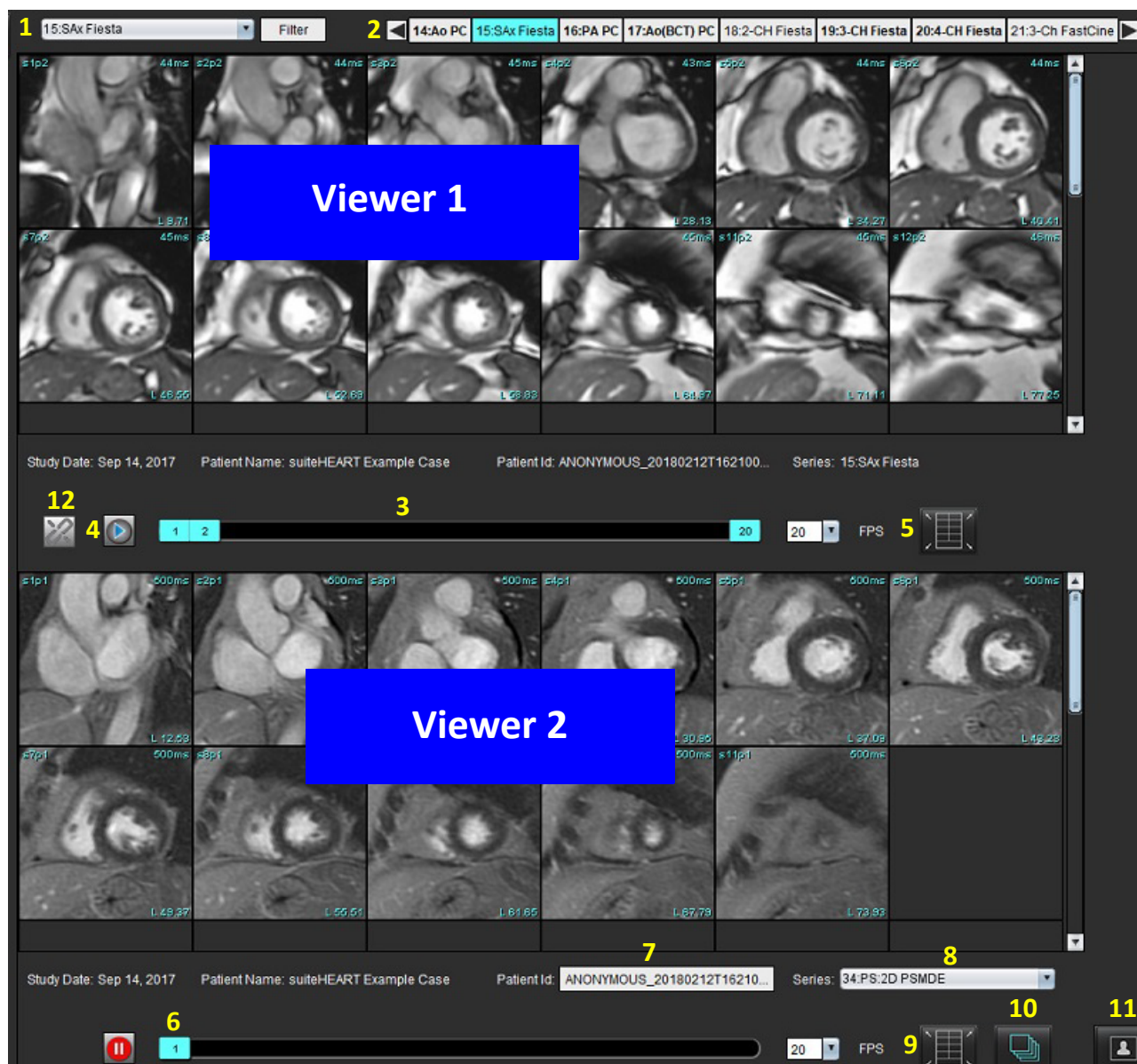
Viewer	Callout	Description
Viewer 1	1	Series pull-down
	2	Series selector
	3	Currently viewed patient exam indicator line
	4	Image controls
	5	Viewport layout selections
Viewer 2	6	Currently viewed patient exam indicator line
	7	Exam selector
	8	Series selector
	9	Viewport layout selections
Both Viewers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

Sample Workflow

1. Double click on the editor window on any analysis mode.

2. Select [icon] to split the interface into two viewers, as shown in Figure 6.

   FIGURE 6. View in Compare Mode
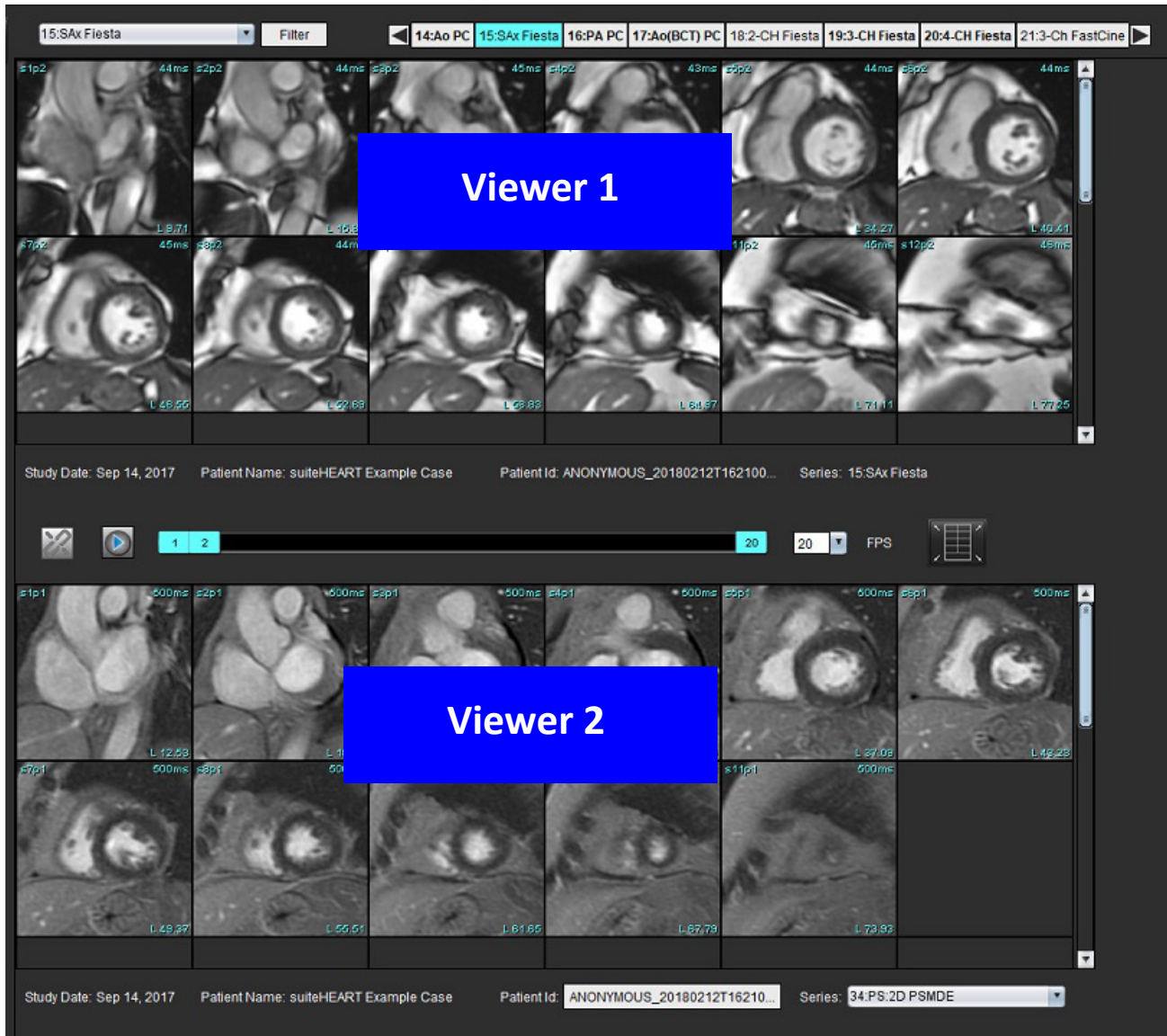
3. Change the series in Viewer 1 by using the series selection pull-down menu or right/ left arrows.
   - This upper viewer always displays the current study that has been previously launched.

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

FIGURE 7. Series Pull-down, Viewer 2

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

FIGURE 8. Exam Selector, Viewer 2
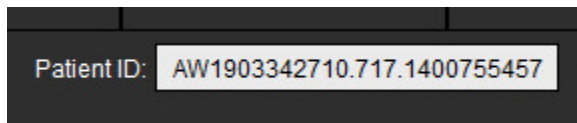
6. Confirm proper exam selection by checking the exam indicator information for both viewers.

FIGURE 9. Exam Indicator Information
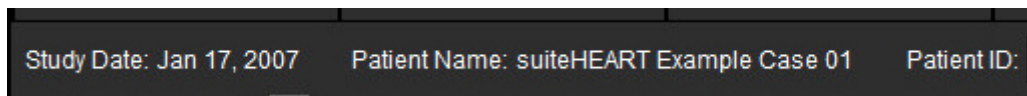
7. Performing a right mouse click on either viewer will open the image manipulation tools.
   • The scope selection applies to both viewers.

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

   NOTE: If a cine series is selected in both viewers and both series have the same number of phases, click the to sync the cine views.

Defining Preferences

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

- Edit
- Import
- Export

IMPORTANT: It is advisable to set up user preferences prior to analyzing the first case to be reported. For changes in preferences to take effect, close the current exam and then close and re-launch suiteDXT.

Setting Preferences

Preferences can be customized for the following features under the Global tab.

- Report
- Authorized Report Approvers
- General
- Flow
- Idle Timer
- Function
- Virtual Fellow®
- Myocardial Evaluation
- Series Filter
- Export (Image/Video)

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

Global Tab

Selecting Reset in the upper left corner of the tab will clear all user selections.

Report

Configures header information that appears on all reports.

FIGURE 1. Report Preferences

Selections for Report Preferences

1. From the Image View menu bar, select **Tools > Preferences > Edit**.

2. Select the **Global** tab.

3. Place the cursor in the desired field of the **Report** panel and enter information.

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

   Checking "support even and odd row" will highlight the result rows on the interface and on the report.

4. To insert a site logo into the report, prepare the file in a jpeg, png, or gif format and save to hard drive or CD-ROM. Select **Browse** under the Logo section and locate the file from the system browser window. Select the proper logo file and select **Open**.
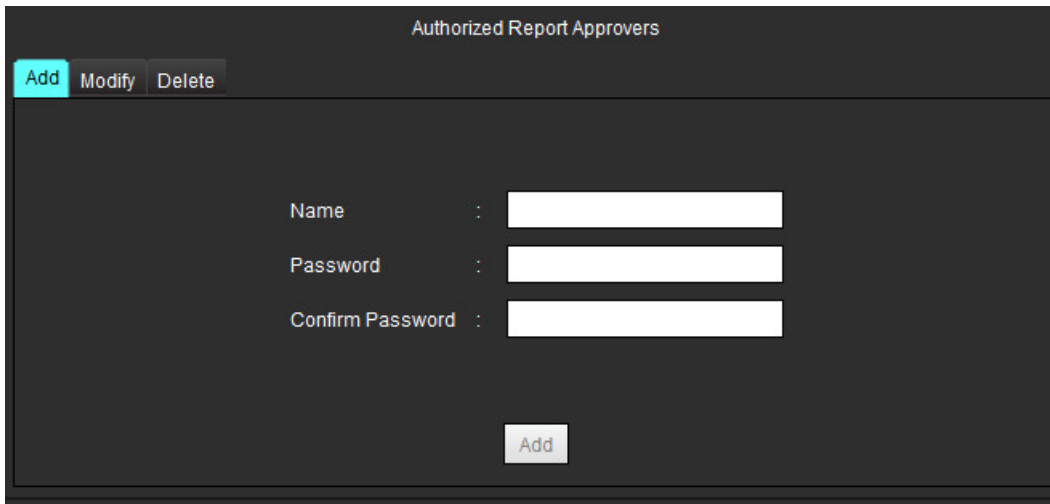
   The logo should now appear on the report preferences panel.

5. Right mouse click on the **Exam File Name** to configure the export report file name (for approved exams only).

6. Select **Save and Exit**.

   Select **Cancel** to exit without saving or accepting any changes.

Authorized Report Approvers

The application has a report approval feature that locks the final report. Once approved, the report cannot be modified. The credentials of the approvers are added, modified and deleted as described.
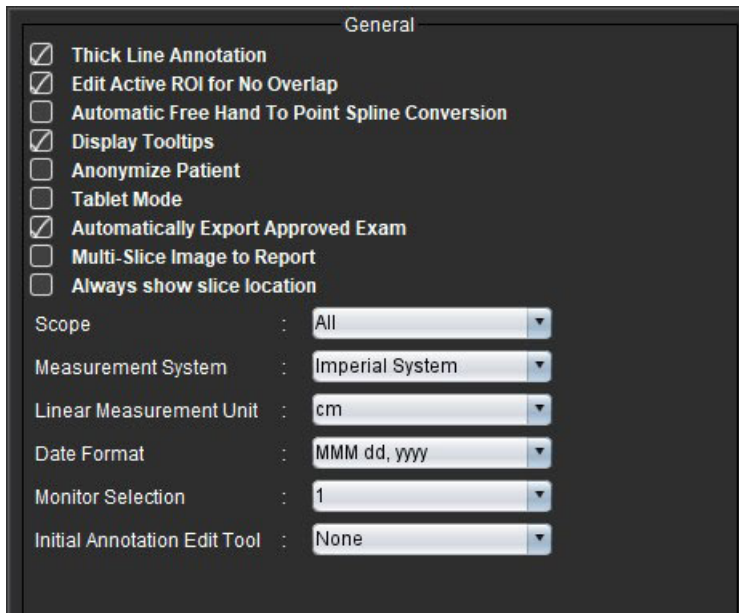
FIGURE 2. Authorized Report Approvers

Manage Report Approvers

1. From the Image View menu bar, select **Tools > Preferences > Edit**.

2. Select the **Global** 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**.

6. Select **Save and Exit**.

    • Select **Cancel** to exit without saving or accepting any changes.

General

FIGURE 3. General Preferences

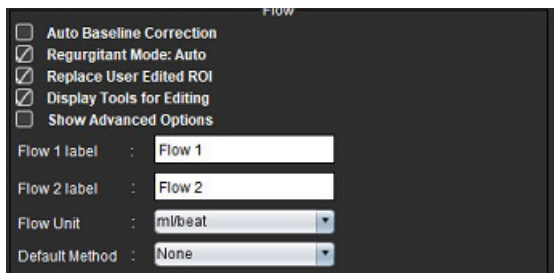### Selections for General Preferences

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

2. Select **Global** tab.

3. Check the **Thick Line Annotation** check box to show annotation as thick lines.

4. Check **Edit Active ROI** for no overlap to disable overlap.

    When "Edit Active ROI for No Overlap" is checked the ROIs that are not currently selected are dominant and when it is unchecked the ROI that is being edited is dominant.

5. Check **Automatic Free Hand to Point Spline Conversion** to automatically convert a free hand ROI to point spline.

6. Check the **Display Tooltips** to show interface tooltips.

7. Check the **Anonymize Patient** check box to hide the patient name and id from the report.

    All patients' names will be displayed as "anonymous" and the ID will be blank. These changes will apply to the report and Image View.

8. Check **Tablet Mode** to use the application on a tablet device.

9. Check **Automatically Export Approved Exam** to export the report as a DICOM file upon approval.

10. Check **Multi-Slice Image to Report** to add a right mouse click option to add a group of multi-frame short axis images.

11. Check **Always show slice location** to display the slice location annotation in the viewport.

12. Set the **Scope** selection for image manipulation from the file pull-down menu.

13. Set the **Measurement System**, either Imperial or Metric from the file pull-down menu.

14. Set the **Date Format** from the file pull-down menu.

15. Set the **Monitor Selection** from the file pull-down menu if a dual monitor is used.

16. Set the **Initial Annotation Editing Mod**e from the file pull-down menu. Selections include None, Nudge Tool or Pull Tool.

Flow

FIGURE 4. Flow Preferences

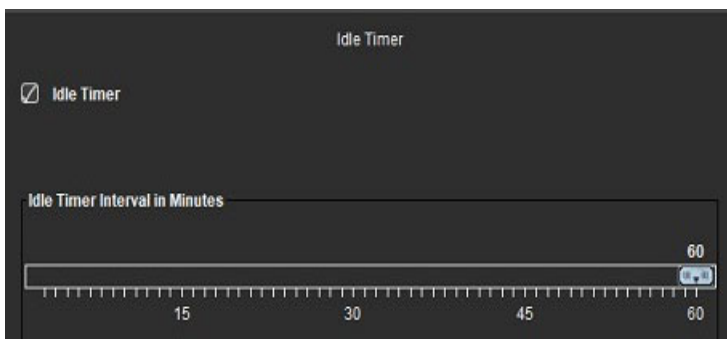### Selections for Flow Preferences

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

2. Select **Global** tab.

3. Check the **Auto Baseline Correction** check box to automatically perform auto phase error correction for 2D and 4D phase contrast.

4. Check **Regurgitant Mode: Auto** to automatically calculate the net negative flow (below x axis).

5. Check **Replace User Edited ROI**, will replace user edited ROIs if propagation is performed.

6. Check **Display Tools for Editing** to show editing tools directly on the image viewport.

7. Check **Show Advanced Options** to access Positive, Negative, Peak Envelope and Peak Absolute results.

8. Define category labels for **Flow 1** or **Flow 2** by typing in a new label. These labels will appear as tool tips on the flow interface.

9. Select the proper **Flow Unit** of either ml/beat or l/min from the file pull-down.

10. Select the **Default Method** for persistence of the calculation method for the Integrated Flow panel

11. Select **Save and Exit**.

    Select **Cancel** to exit without saving or accepting any changes.

Idle Timer

The Idle Timer panel sets the time interval in minutes for the application to close after a set period of inactivity.

FIGURE 5. Idle Timer Settings

Selections for Idle Timer

1. From the Image View menu bar, select **Tools > Preferences > Edit**.

2. Select the **Global** tab and place the cursor in the **Idle Timer** panel.

3. Select the Idle Timer check box to enable the idle timer feature.

4. Drag the idle timer interval marker to the desired time in minutes.

5. Select **Save and Exit** to store your selections.

    Select **Cancel** to exit without saving or accepting any changes.

Function

FIGURE 6. Function Preferences
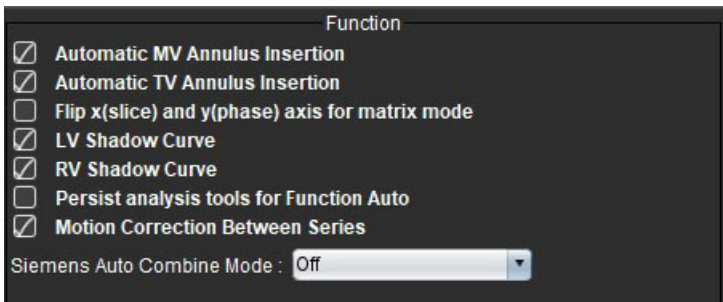
1. From the Image Viewer menu bar, select **Tools > Preferences > Edit**.

2. Select **Global** tab.

3. For automatic basal line placement for function analysis check either **Automatic MV** or **TV Annulus Line Insertion**.

4. Check **Flip x(slice) and y(phase) axis for matrix mode** to swap the axis.

5. Check either **Enable LV** or **RV Shadow Curve** to display both curves.

6. Check **Persist analysis tools for Function Auto** for performing editing when using Auto Segmentation.

7. Check **Motion Correction Between Slices** to access this feature in Function Analysis, refer to Motion Correction Between Series on page 68.

8. Select Newest, Oldest, or Prompt for the **Siemens Auto Combine Mode** from the file pull-down menu.

9. Select **Save and Exit** to store your selections.

    Select **Cancel** to exit without saving or accepting any changes.

Virtual Fellow®

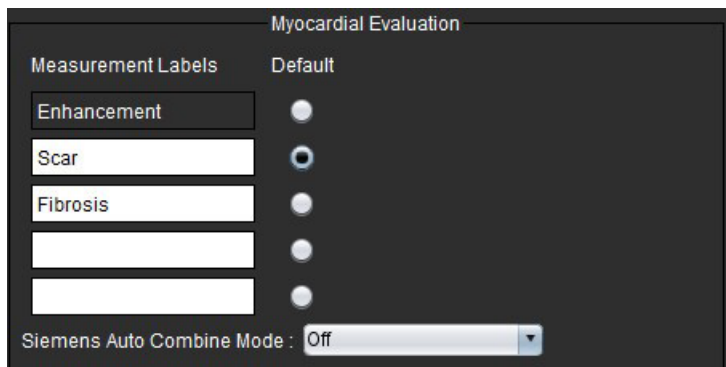**FIGURE 7. Virtual Fellow® Preferences**

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

2.   Select **Global** tab.

3.   Check **Open study in Virtual Fellow®** to directly open the study with the Virtual Fellow® application.

4.   Select **Save and Exit**.

Select **Cancel** to exit without saving or accepting any changes.

Myocardial Evaluation

FIGURE 8. Myocardial Evaluation Preferences

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

2.   Select **Global tab**.

3.   To define measurement labels refer to Define Result Measurement Labels on page 111.

4.   Select Newest, Oldest or Prompt for the **Siemens Auto Combine Mode** from the file pull-down menu.

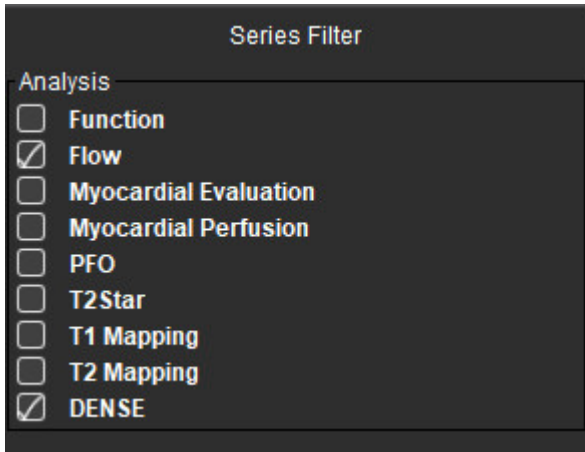   **NOTE:**   If the series label is "null" the series will be ignored.

5.   Select **Save and Exit**.

Select **Cancel** to exit without saving or accepting any changes.

Series Filter

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

FIGURE 9. Filter Preferences


Setting Filter Preferences

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

2. Select **Global** tab.

3. Click the appropriate on/off selection for each analysis type.

4. Select **Save and Exit**.

    - Select **Cancel** to exit without saving or accepting any changes.

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

Export (Image/Video)

The Export 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, GIF, JPEG, TIFF and PNG files of the image data.

FIGURE 10. Image/Video Export Preferences
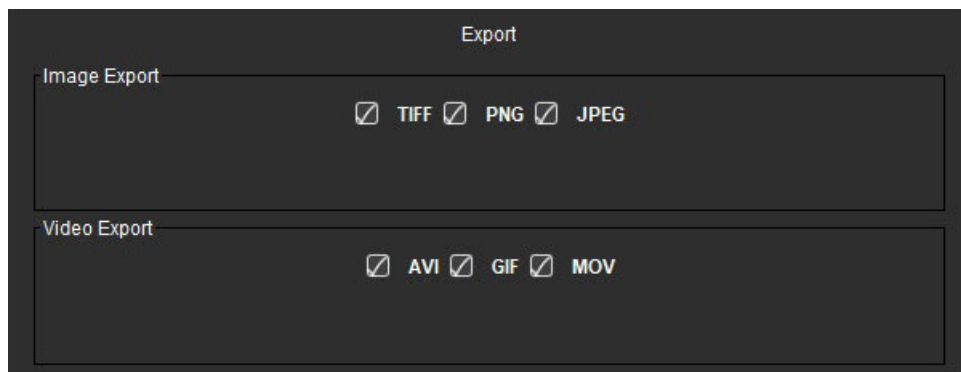
Export Selections

1. From the Image View menu bar, select **Tools > Preferences > Edit**.
2. Select the **Global** tab and place the cursor in the **Export** panel.
3. Select the appropriate image data types.
4. Select **Save and Exit** to save the selections.
   Select **Cancel** to exit the without saving or accepting any changes.

Template Preferences

The application provides a tool to crate templates based upon user defined normal ranges specified by age and gender. The calculation and reporting of z-scores is supported based on a user defined model. Refer to the recommended references.
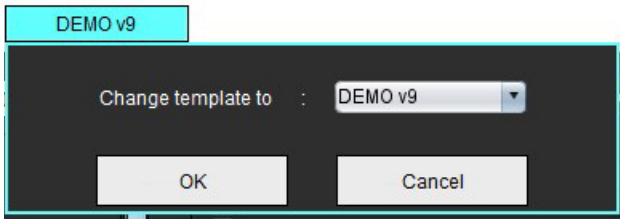
FIGURE 11. Template Tab

Considerations

Before starting analysis, the user defined template must be selected from the main interface. Click on **Default** at the upper right and select the template to be used. Changing the template after performing analysis will apply the normal range and/or Z-score defined in the template.

FIGURE 12. Change Template

> **NOTE:** Imported studies with previous suiteHEART analysis may show the name of the template used for that study. That template may not be available for other studies.

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

Create a Template

WARNING: The validity of the values entered for normal ranges and Z-scores parameters are the sole responsibility of the user. Confirm all entries prior to analysis. Incorrect values could lead to misdiagnosis.

All new templates are created initially by duplicating the default template. The default template is not editable.

1. Select **Tools > Preferences > Edit.**

2. Select the **Template** tab.

3. Click **Create New** or to duplicate a template click **Duplicate**.

    Age is the default.

FIGURE 13. Create Template Selections

4. Type in a new name for the template.

    When a new name is entered, **The Current Template is** pull-down menu will update.

FIGURE 14. Example Template Tab - Short Axis Function is Shown

1. Current template, 2. Age range bar, 3. Result parameters per analysis type, 4. Male Z-score BSA limits, 5. Male upper and lower limits, 6. Male Z-score parameters, 7. Female Z-score BSA limits, 8. Female upper and lower limits, 9. Female Z-score parameters

5.　Select the desired application analysis type for which to create a template.

6.　If age ranges are to be used, right click on the Age Range Bar to create an age range divider.

　　The age range divider bars can be dragged and adjusted for the desired age range.
　　Multiple age range divider bars can be created.
　　Age 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 normal range values for the appropriate analysis mode, as well as both the lower and upper limits.

8.　Differentiate between male and female values if necessary. Use the Copy All arrows to copy values between genders. Use the scroll bar to navigate to the complete measurements listing for that analysis type.

9.　If z-scores are to be calculated, values for both **a**, **b**, and **SD** as well as the **BSA Limits** must be entered by the user.

The reporting priority is outline in the table below. Depending on the condition either the normal range or the calculated z-score on the measurement result tables will be shown.

Reported/Calculated	Condition
z-score Calculated	If z-score parameters have been entered and the BSA is within limits
Normal Range Reported	If the z-score and normal range are entered and the BSA is out of limits
Normal Range Reported	Only if a normal range as been entered
Neither Normal Range or z-score Calculated	If the z-score parameters are entered. No normal range entered and BSA is out of limits
Neither Normal Range or z-score Calculated	Nether z-score parameters or a normal range has been entered

⚠️

WARNING: The validity of the values entered for normal ranges and Z-scores parameters are the sole responsibility of the user. Confirm all entries prior to analysis. Incorrect values could lead to misdiagnosis.

10. Select **Save and Exit** to save all entries.

    - Select **Cancel** to exit without saving or accepting any changes.

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

NOTE: Normal ranges entered for the Flow tab apply to both 2D and 4D flow analysis results.

Recommended References

Buechel EV, Kaiser T, Jackson C, Schmitz A, Kellenberger CJ. Normal right- and left ventricular volumes and myocardial mass in children measured by steady state free precession cardiovascular magnetic resonance. J Cardiovasc Magn Reson. 2009 Jun 21;11(1):19. doi: 10.1186/1532-429X-11-19. PMID: 19545393; PMCID: PMC2718870.

Kawel-Boehm N, Maceira A, Valsangiacomo-Buechel ER, Vogel-Claussen J, Turkbey EB, Williams R, Plein S, Tee M, Eng J, Bluemke DA. Normal values for cardiovascular magnetic resonance in adults and children. J Cardiovasc Magn Reson. 2015 Apr 18;17(1):29. doi: 10.1186/s12968-015-0111-7. PMID: 25928314; PMCID: PMC4403942.

Maceira AM, Prasad SK, Khan M, Pennell DJ. Normalized left ventricular systolic and diastolic function by steady state free precession cardiovascular magnetic resonance. J Cardiovasc Magn Reson. 2006;8(3):417-26. doi: 10.1080/10976640600572889. PMID: 16755827.

Maceira AM, Prasad SK, Khan M, Pennell DJ. Reference right ventricular systolic and diastolic function normalized to age, gender and body surface area from steady-state free precession cardiovascular magnetic resonance. Eur Heart J. 2006 Dec;27(23):2879-88. doi: 10.1093/eurheartj/ehl336. Epub 2006 Nov 6. PMID: 17088316.

Delete a Template

1. Select **Tools > Preferences > Edit**.

2. Select the **Template** tab.

3. Select the template from **The Current Template is** pull-down menu.

4. Click **Delete**.

Macro Tab

Customized reporting macros can be created which can automatically populate with calculated values. Macros are independent from templates, as created macros are available to all users.

Macros can be created for the following reporting sections:

- History
- Impression
- Technique

Add an Impressions Macro

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

1. Select **Tools > Preferences > Edit**.

2. Select the **Macro** tab.

3. Select **Add Impressions Macro**.

   A new text field appears in the Impression Macros panel.

   FIGURE 15. Impression Macros Window
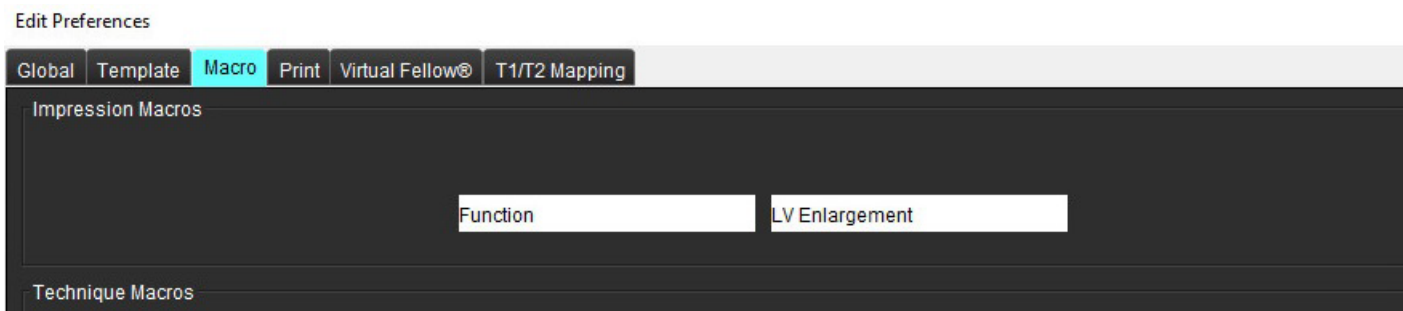
4. Place the cursor inside the new text field and edit the name as desired.

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

Enter Macro Text

1. Place the cursor in the Macro Information text box and enter relevant text.

2. To enter a parameter result, 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 16. Macro Information

Macro Information

Normal global and regional systolic biventricular function.
The LV EF is <#LV_EF:SA LV EF#> . The RV EF is <#RV_EF:SA RV EF#> .
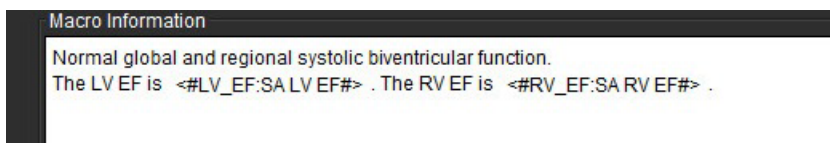
FIGURE 17. Macro Parameter Result Selections

| Function | Flow | Myocardial Evaluation | T2Star | T1 Mapping | T2 Mapping |

Ventricles | SA LV EF % | SA RV EF % | SA LV SV ml
SA RV PFR ml/s | SA LV PER ml/s | SA RV
LV Mass Index ES g/m² | RV Mass Index ED
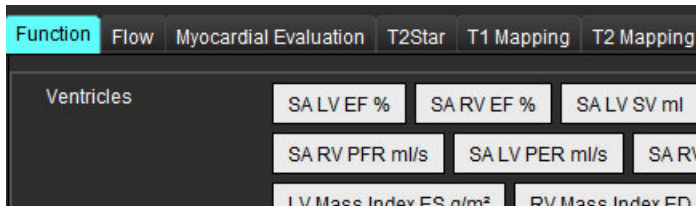
3.   Select **Save and Exit**.

        Select **Cancel** to exit without saving or accepting any changes.

Execute a Macro

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

Delete a Macro

1.   Select **Tools > Preferences > Edit**.

2.   Select the **Macro** tab.

3.   Select the macro from the list.

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

FIGURE 18. Macro Selection List

| Global | Template | Macro | Print | Virtual Fellow® | T1/T2 Mapping |

Impression Macros

Function | LV Enlargement

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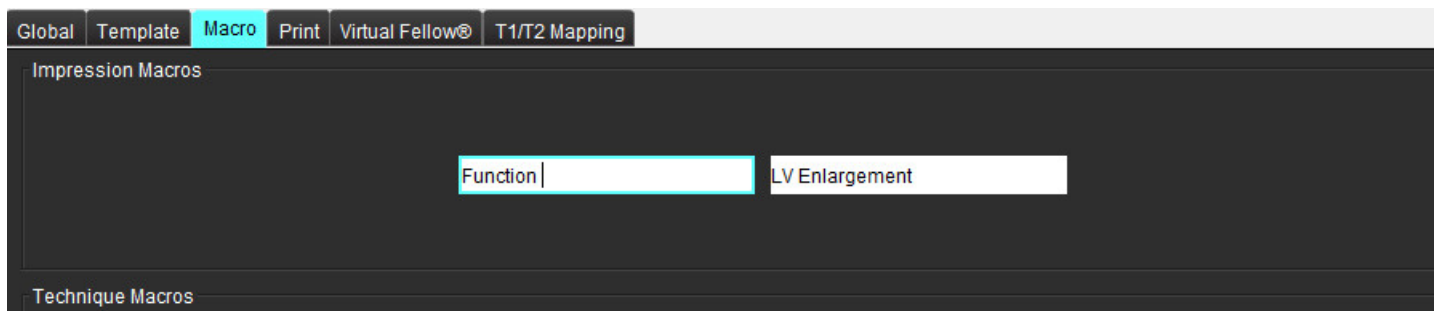
4.   Select **Remove Selected Macro(s)**.

Print Tab

Calculated results from each analysis mode can be configured for inclusion and ordered on the report under the **Print** tab.

FIGURE 19. Print Preferences
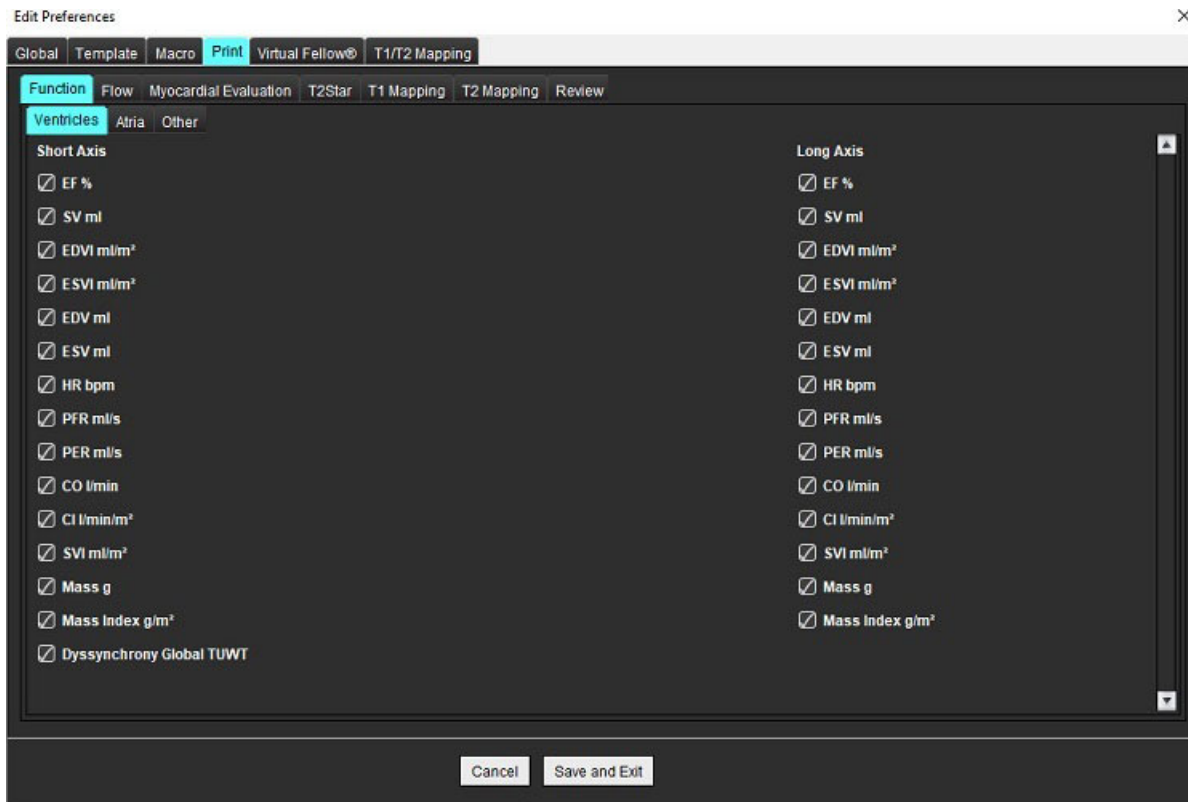
1. From the Image View menu, select **Tools** > **Preferences** > **Print**.

2. Select the appropriate analysis tab and check the desired result to be included on the report.

3. The order of the results as they are listed on the report can be changed by clicking directly on a result and dragging to a new position on the list.

4. Repeat for each analysis mode tab.

5. Select **Save and Exit**.

   Select **Cancel** to exit without saving or accepting any changes.

   NOTE: If print selections are made directly on the application interface they will not be saved with the template.

   NOTE: If the order of the results are changed directly on the interface, the change will not be saved with the template.

Virtual Fellow® Tab

FIGURE 20. Virtual Fellow® Preferences
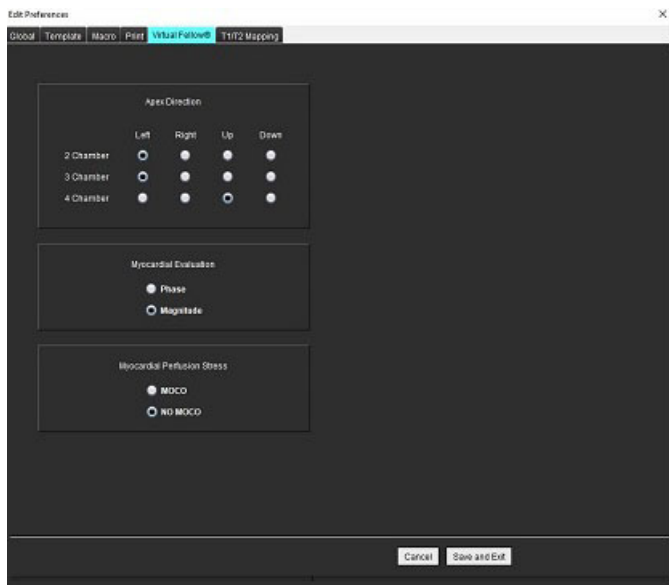
1.   Select **Tools > Preferences > Edit**.

2.   Select the **Virtual Fellow®** tab.

3.   Select the Apical Direction for the long axis views

4.   Select the series for display of either **Phase** or **Magnitude** for Myocardial Evaluation.

5.   Select the **MOCO** or the **NO MOCO** series for display for myocardial perfusion.

6.   Select **Save and Exit**.
        Select **Cancel** to exit without saving or accepting any changes.

T1/T2 Mapping Tab

FIGURE 21. T1/T2 Mapping Preferences

1. Select **Tools > Preferences > Edit**.

2. Select the **T1/T2 Mapping** tab.

3. Select **MOLLI** or **Saturation Recovery** for the Sequence type for T1 Mapping.

4. Select the default **Color Map** from the file pull-down menu and the color map range for either T1 or T2 Mapping.

5. To automatically display the color map select the default **Overlay** for either **T1**, **ECV** or **T2**.

6. To create a valid series for analysis select the correct option for the vendor type under the **Auto Compose Series for Analysis**.

7. Select **Save and Exit**.

   Select **Cancel** to exit without saving or accepting any changes.

Import Preferences

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

    FIGURE 22. Import Preferences
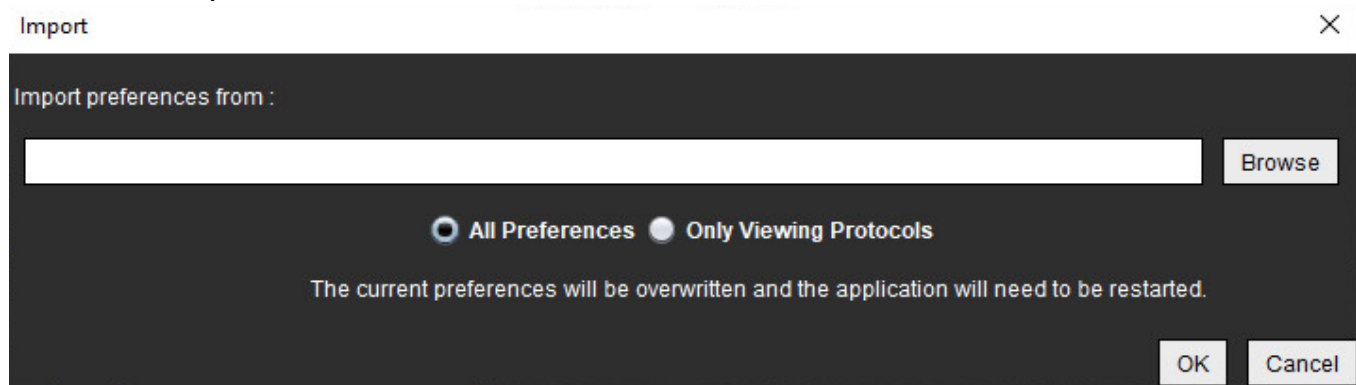
2. Select the Browse button, select the location of the preference file and then select the Open button.

3. To import viewing protocols, select the radio button for **Only Viewing Protocols**.

4. Select **OK** to perform the import procedure as defined.

    Select **Cancel** to exit without importing.

    NOTE: Importing preferences from prior versions (4.0.4 or below) of suiteHEART® Software is not supported. Please contact NeoSoft Support at service@neosoftmedical.com for help with importing preferences from prior versions.

Export Preferences

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

    FIGURE 23. Export Preferences
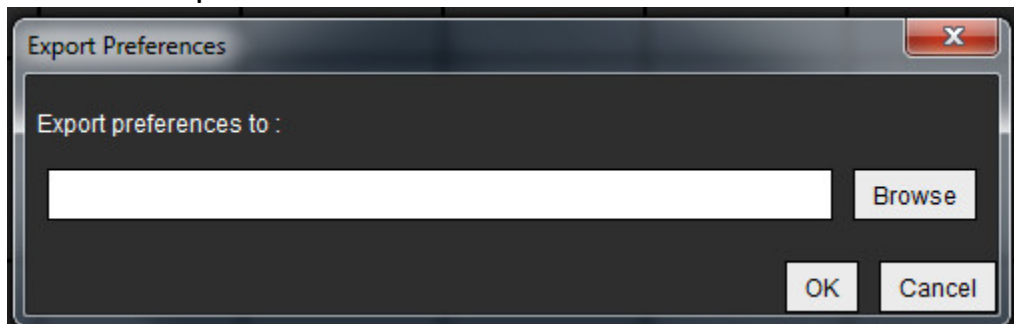
2. Select **Browse**, select the folder in which to place the preference file and then select **Save**.

3. Select **OK**.

    Select **Cancel** to exit without exporting.

Virtual Fellow®

Virtual Fellow® is an image viewing standardized feature for cardiac MR studies. The feature improves visualization work-flow making it easier for clinicians to review cardiac MR studies. The feature automatically applies image manipulation tools such as window level, zooming, panning and rotation. Current and prior cardiac MR studies can be easily reviewed with the Virtual Fellow® feature.

> **NOTE:** To enable the Virtual Fellow® feature with preprocessing, refer to the suiteDXT Instructions for Use NS-03-039-0008.

> **NOTE:** The patient ID should match for both the current and prior exam to be viewed in Virtual Fellow®.

> **NOTE:** Editing of analysis results cannot be performed in Virtual Fellow®, select the appropriate analysis mode to perform editing.

⚠️

WARNING: The user is responsible for confirming the correct image selection for the viewing protocols created by the Virtual Fellow®. Images identified incorrectly for current/prior viewing protocols can be selected manually. The user should be properly trained in cardiac imaging techniques to ensure that the appropriate images are reviewed. To review all images acquired for the study use the Viewer mode found in Image Management Tools on page 21.

⚠️

WARNING: Prior to the review or comparison of studies, visually confirm all exam patient indicator information at the top of the interface. #1 indicates the current study, #2 indicates the prior study.

⚠️

WARNING: Image manipulation such as WW/WL, pan, zoom, rotate, and flip performed by Virtual Fellow® can affect the appearance of different pathologies and the discerning of other anatomical structures. Review each viewing protocol and perform the appropriate adjustments.

Preprocessing with Virtual Fellow®

```
┌─────────────────────────────┐
│                             │
│     Series Identification   │
│                             │
└─────────────────────────────┘
               │
               ▼
┌─────────────────────────────┐
│      Auto Segmentation      │
│    (of identified series)   │
└─────────────────────────────┘
               │
               ▼
┌─────────────────────────────┐
│ Automatic Valve Annulus Detection │
│         (if enabled)        │
└─────────────────────────────┘
               │
               ▼
┌─────────────────────────────┐
│ Virtual Fellow® - View Optimization │
│         (if enabled)        │
└─────────────────────────────┘
               │
               ▼
┌─────────────────────────────┐
│          Complete           │
│                             │
└─────────────────────────────┘
```
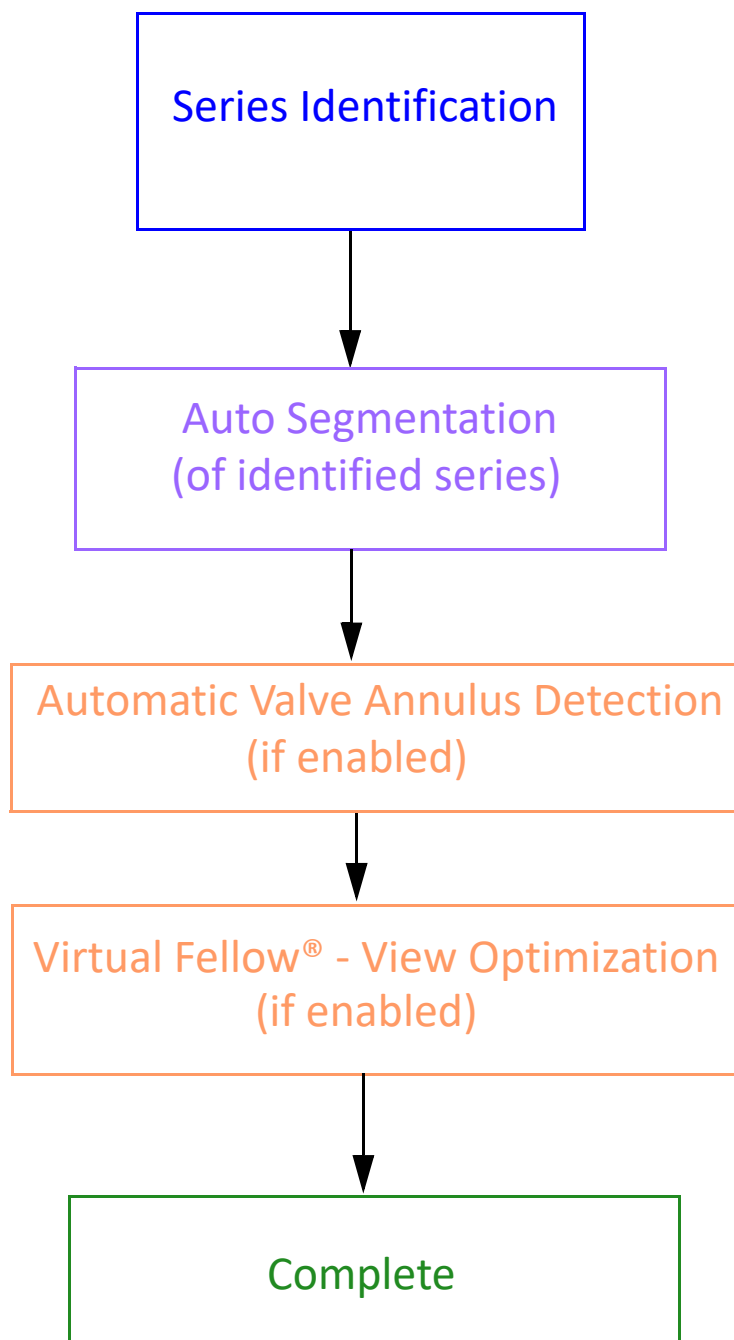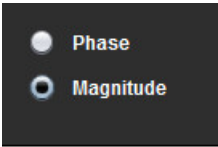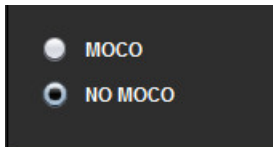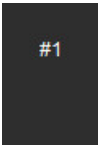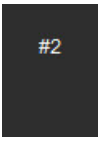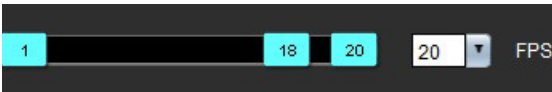
Virtual Fellow® Interface
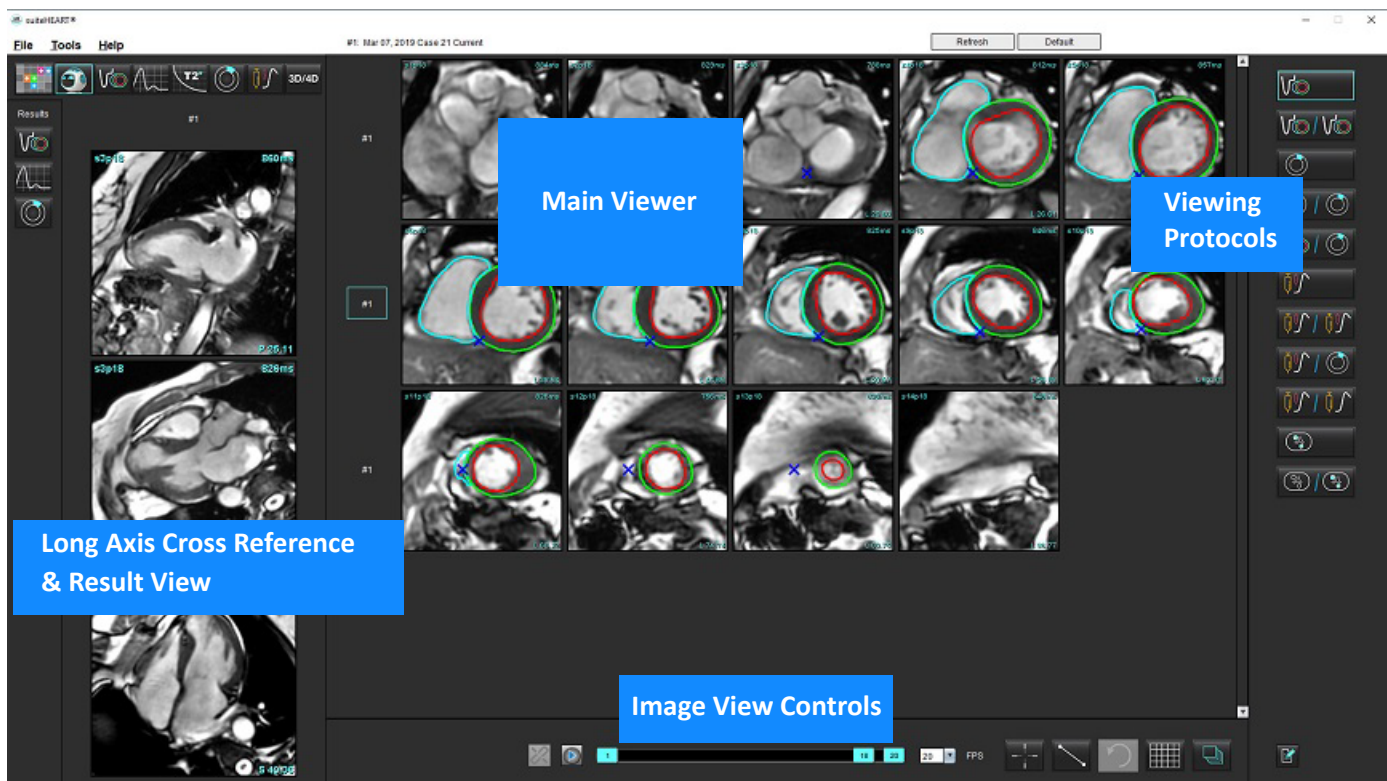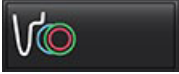
Virtual Fellow® Selections

Selection	Description
	Virtual Fellow®
	Display Function results
	Display Flow results
	Display Myocardial Evaluation results

Selection	Description
	Link Toggle used to perform WW/WL, pan, rotate, and flip on both current and the prior series.
	Unlink Toggle used to perform WW/WL, pan, rotate, and flip on a single series. Note: Zoom is always applied to both current and prior series.
Phase Magnitude	Phase is used to view phase sensitive late enhancement. Magnitude is used to view magnitude late enhancement.
MOCO NO MOCO	MOCO is used to view motion correction Myocardial Perfusion series. NO MOCO is used to view Myocardial Perfusion series with no motion correction.
#1	#1 is the indicator for the series displayed for the current study. Left mouse click directly on #1 to change the series.
#2	#2 is the indicator for the series displayed for the prior study series. Left mouse click directly on #2 to change the series.
1 18 20 20 ▼ FPS	Cine controls are used to play, pause, select the frames per second, and define the start and end frames of the cine movie.
	Cross reference tool that automatically identifies and displays images that contain the same location. For information on using this feature refer to Find Feature* on page 22.
	Measurement tools.
	Undo generic measurement edits.

Selection	Description
	Viewport layout options*: 1x1, 1x2, 4x4 and 5x4. *Dependant on selected protocol.
	Scope has the same function as described in Image Manipulation Tools on page 11.
Keyboard Arrow Left	Used to advance the slice location when in a current/prior viewing protocol.
Keyboard Arrow Right	Used to reverse the slice location when in a current/prior viewing protocol.

Viewing Protocols

	Series Type
	Short axis cine function series.
	Current short axis cine function with prior.
	Myocardial Evaluation.
	Current Myocardial Evaluation with prior.
	Short axis cine function with Myocardial Evaluation.
	Myocardial Perfusion series Stress.
	Current Myocardial Perfusion Stress series with prior.
	Current Myocardial Perfusion Stress with Myocardial Evaluation.

	Series Type
	Myocardial Perfusion Stress/Rest series.
	T1 axial series.
	SSFP with T1 axial series.

Keyboard Shortcuts

Function	Keyboard Action
Scroll forward on long axis views if yellow corner indicator is present.	Z
Scroll backward on long axis views if yellow corner indicator is present.	A

User Selection of a Series for Viewing Protocols

Viewing protocols are configured to view images from the current study or from the current and prior study. If the images displayed are not the expected images to be reviewed, reselect the appropriate series by performing a left mouse click directly over the number notation (#1 for current study or #2 for prior study) on the Virtual Fellow® interface as shown in Figure 1. The series listing for the current study (#1) will be displayed, select the appropriate series.

FIGURE 1. Virtual Fellow® Interface
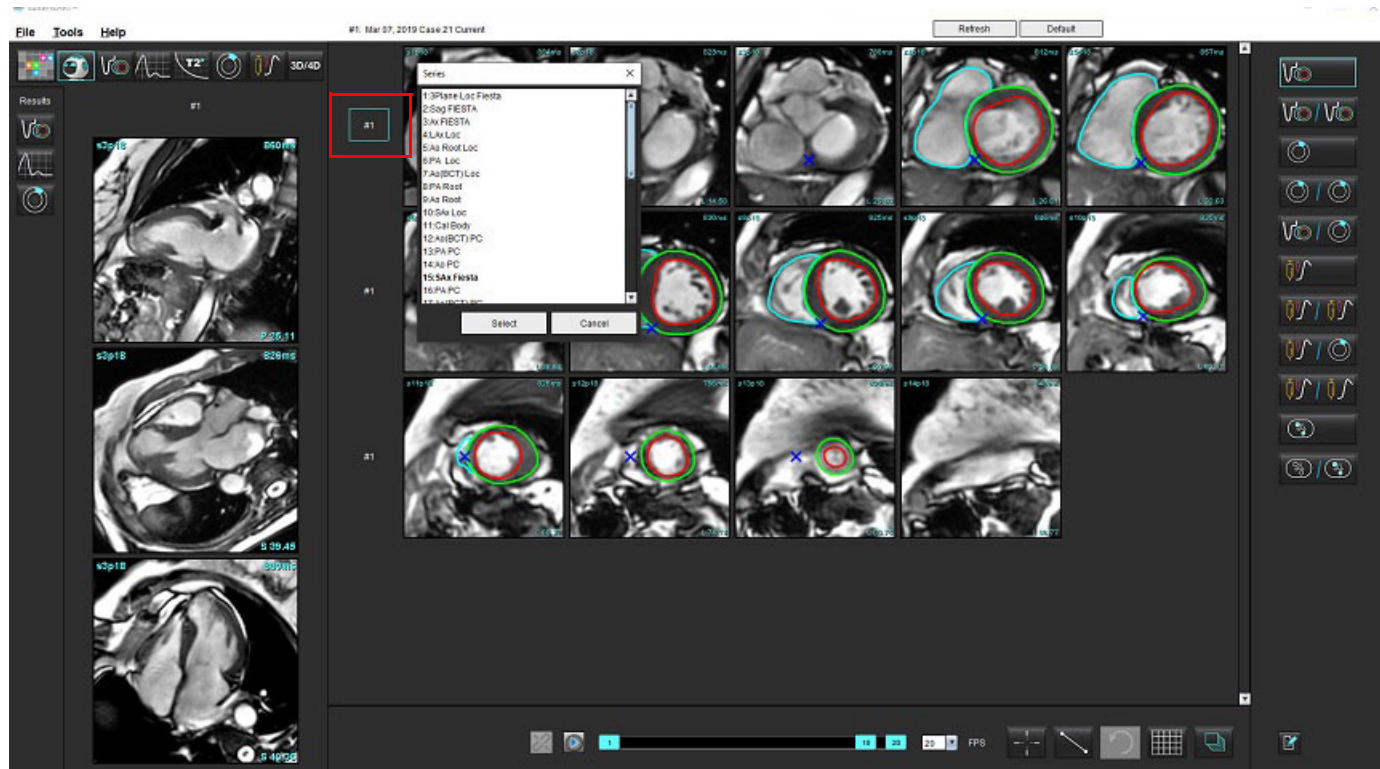
User Selection of a Series for Long Axis Cross Reference Viewports

If images displayed are not the expected views, the appropriate series can be selected by directly clicking on a long axis viewport and then selecting the image from the file pull-down menu, as shown in Figure below.

> **NOTE:** If the keyboard selections of **Z** or **A** are used the user selected image will no longer be present in the viewport.

> **NOTE:** To set the desired apical direction from the Image Viewer menu, select Tools > Preferences > Edit and select the Virtual Fellow® tab.
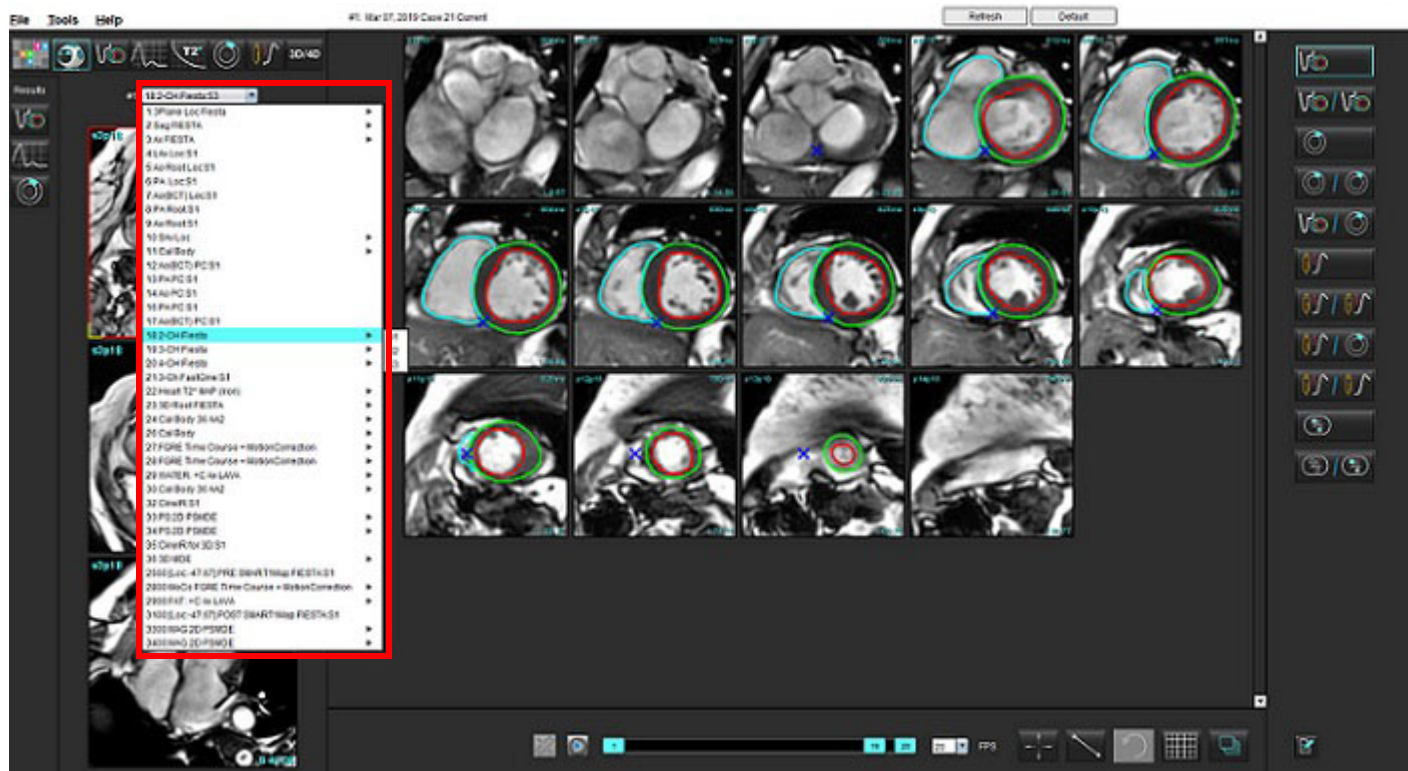
Editing Contours

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

Conventional Editing

1. In the Editor Window, left mouse click on the contour. The contour will turn purple when selected.

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

FIGURE 1. Conventional Contour Edit
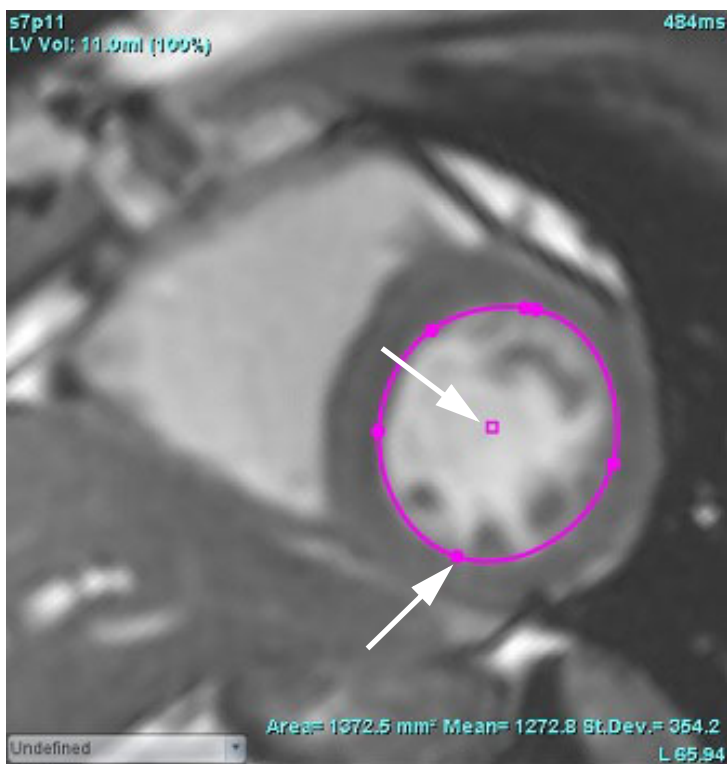
Nudge Tool

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

FIGURE 2. Nudge Tool Activation
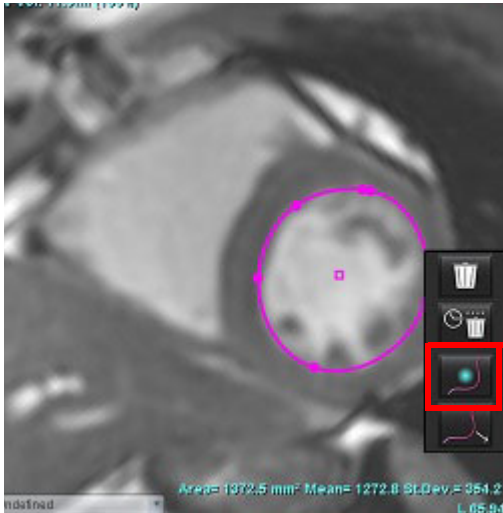
2. The cursor will appear as a square. Position the cursor away from the ROI and press and hold the left mouse button. The nudge tool will appear, as shown in Figure 3.

    NOTE: The size of the nudge circle defaults to the size that is an equal distance from the mouse point to the selected ROI. Reposition the cursor to change the size.

FIGURE 3. Nudge Tool
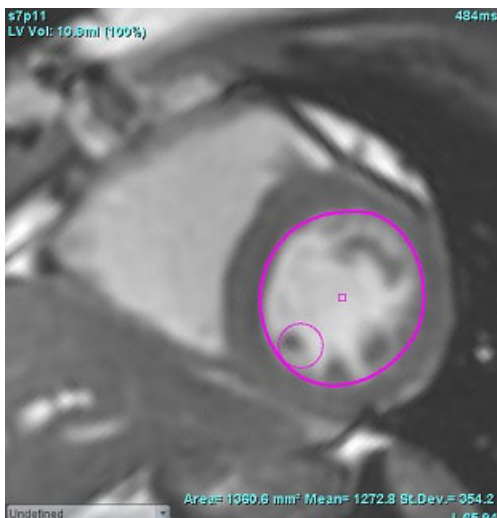
3. To deactivate the nudge tool, left mouse click on the contour, then right mouse click and select the nudge tool from the pop-up menu, as shown in Figure 4.

FIGURE 4. Nudge Tool Deactivation

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

Contour Pull Tool

1. To activate the pull tool, left mouse click on the contour to select it. Then right mouse click and select the pull-tool from the pop-up menu, as shown in Figure 5. It allows for the adjusting of a contour segment by dragging portions of the contour to make small adjustments.

FIGURE 5. Pull Tool Activation

2. Left click directly on the segment of the contour to be edited. The length of the black dashed segment can be controlled by the middle mouse scroll-wheel. The position of the mouse cursor from the black dashed line will control the change of the edit for that segment of the contour.

FIGURE 6. Pull Tool

3. To deactivate the pull tool, left mouse click on the contour, then right mouse click and select the nudge tool from the pop-up menu, as shown in Figure 7.

FIGURE 7. Pull Tool Deactivation
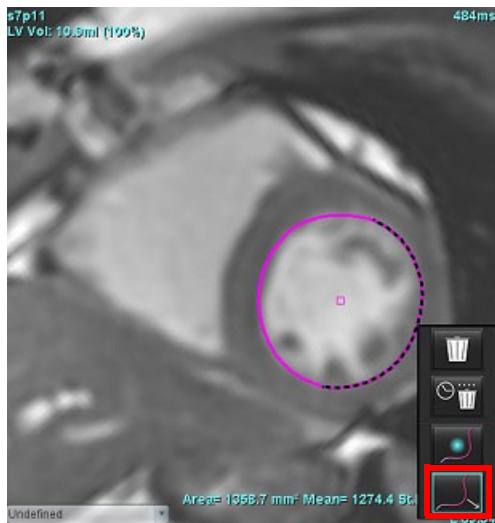
Delete a Contour

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

or

2. Left mouse click on the contour to select it, then right mouse click and choose either ![trash icon] to delete a single contour or ![clock trash icon] to delete contours from all phases or all time points, as shown in Figure 8.

FIGURE 8. Contour Deletion

Function Analysis

The user is responsible for the accurate and complete placement (and correct assignment) of all regions of interest (ROIs), including those generated or modified by the auto segmentation algorithms. The quantitative values generated by the software depend on the accurate and complete placement (and correct assignment) of these regions of interest.

The study preprocessing feature allows for the preprocessing of function analysis. Refer to the suiteDXT Instructions for Use NS-03-039-0008.

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 quantitative 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: Follow preprocessing the user is responsible for assessing the accuracy of the entire analysis and making any necessary corrections. A comprehensive review should include:

- ROI placement/identification
- ED/ES assignments
- MV/TV annulus placement
- RV insertion location

⚠️

WARNING: The application assists in the analysis of the images only and does not automatically produce a clinical interpretation of the 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: Incorrect scan plane may cause inaccurate analysis results. See Appendix B.

   NOTE: Retrospective 2D series created from 4D Flow may require manual segmentation.

There are three categories for analysis:

Ventricles - Includes volume analysis for the left ventricle (LV) and right ventricle (RV)
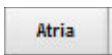
Atria - Includes volume analysis for the left (LA) and right atrium (RA).
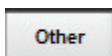
Other - Includes pre-defined linear measurements and user defined measurements that can be added.

Ventricles

Select the analysis type:

Short Axis	Long Axis

Click to delete contours.

> **NOTE:** Matrix mode can be used for the deletion of contours.

Calculate Index Measurements

1. Select History Tab.

2. Enter patient Height and Weight.

   The end-diastolic volume index, end-systolic volume index, mass end-diastolic index, mass end-systolic index, mass index phase, cardiac output index and stroke volume index measurements are calculated on the Measurement table.

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

Auto LV & RV Segmentation

The auto segmentation feature calculates standard parameters of cardiac function without anatomical input. After segmentations results are generated, ROI types can be selected or deselected for viewing. Segmentation editing can also be performed from user input.

> **NOTE:** If the LV and RV buttons in Function Short Axis are both deselected or if the chamber selection button in Long Axis is deselected, the Start Auto Propagation button will be disabled.

To start LV & RV segmentation perform the following:

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

2. Click **Ventricles** .

3. Click for auto segmentation.

4. Make the appropriate selections from the segmentation tool bar, as shown in Figure 1.

5. Select to start auto segmentation.

FIGURE 1. Segmentation Toolbar
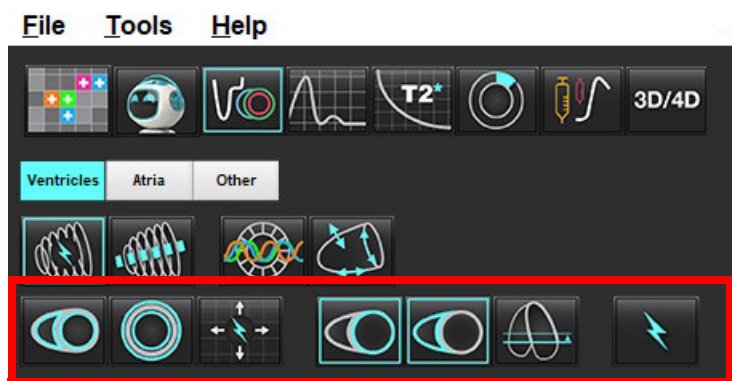
Table 1: Auto Segmentation Contour Types

Smooth Mode – Includes the papillary muscles in the ventricular volume.	Rough Mode – Excludes the papillary muscles from the ventricular volume.	Show endocardial and epicardial contours.	Show endocardial contours.	Show chords.	Rough LV, Smooth RV.	Smooth LV, Rough RV

Table 2: Auto Segmentation Propagation* Types

Propagate all slices all phases or show all slices all phases	Propagate all slices; single phase	Propagate all phases; single slice	Propagate showing contours for ED/ES phases only
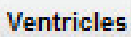
*Propagation functionality will be swapped when the preference is checked for flip x(slice) and y(phase) axis for matrix mode.

Table 3: Ventricular Selection

Left Ventricle - Generate segmentation or display	Right Ventricle - Generate segmentation or display

Perform Auto Segmentation for All Slices and All Phases

This option is required for the generation of regional analysis, dyssynchrony and valve plane analysis results.

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

2. Click **Ventricles** .

3. Click for auto segmentation.

4. From the segmentation bar select either smooth or rough mode .

5. To generate myocardial mass results, select .

6. Select for all phases and all slices.

7. Select either or or both.

   NOTE: For optimal RV segmentation, select both the epicardial and endocardial traces.

8. Select to start auto segmentation.

   NOTE: The Start Auto Propagation button will be disabled if the LV and RV selections are both deselected.

Review Segmentation Accuracy/Editing

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

2. Edit any contours that are inaccurate.

   The phase assignments for ED and ES are locked. To reassign ED or ES, click on either the ED or ES buttons and select the phase number directly on the matrix. Locked phases are indicated by a lighter triangle color.

3. Review placement of RV insertion point on each slice. Correct the RV insertion point for the basal slices.

4. Review matrix mode and confirm ED and ES assignments.

   NOTE: Contour editing is supported for smooth mode. Perform a contour edit and select start auto segmentation.

Perform Auto Segmentation for All Slices in a Single Phase

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

2. Click **Ventricles** .

3. Click ![icon] .

4. From the segmentation bar select either smooth ![icon] or rough mode ![icon] .

5. To generate myocardial mass results, select ![icon] .

6. Review the short axis images and select the end-diastolic phase.

7. Select either ![icon] or ![icon] or both.

8. Select ![icon] for all slices in a single phase.

9. Select ![icon] to start auto segmentation.

10. Review the short axis images and select the end-systolic phase.

11. Select ![icon] to start auto segmentation.
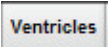
   NOTE: The Start Auto Propagation button will be disabled if the LV and RV selections are both deselected.

Review Segmentation Accuracy/Editing

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

2. Edit any contours that are inaccurate.

3. Review matrix mode and confirm ED and ES assignments.

4. Review all results on the measurement table.

Manual LV and 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 .

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

3. Click .

4. Click button for Volume measurements.

5. Locate the end-diastolic phase.

Define the Endocardium

1. Select for LV or for RV.

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 and/or 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 left and/or right ventricle is segmented.

> **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.

Review Segmentation Accuracy/Editing

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

2. Edit any contours that are inaccurate.

3. Review matrix mode and confirm ED and ES assignments.

4. Review all results on the measurement table.

Manual LV and RV Myocardial Mass Procedure

1. Select the appropriate cardiac phase.

2. Select for LV epicardium or for RV epicardium.

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 and/or right ventricular epicardium is segmented.

   The mass results are automatically updated as the epicardial contours are defined.

Review Segmentation Accuracy/Editing

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

2. Edit any contours that are inaccurate.

3. Review matrix mode and confirm ED and ES assignments.

4. Review all results on the measurement table.

Basal Interpolation

To perform segmentation interpolation for the basal slices, identify either the mitral or tricuspid valve annulus on a long axis view.

> **NOTE:** Automatic insertion of the valve annulus for the LV and RV can be set in preferences. Select T**ools > Preferences > Edit.** Select **Automatic MV or TV Annulus Insertion** under Function.

1. For LV basal interpolation, select a 2-Chamber view in the cross-reference mode.

2. Select .

3. Define the MV annulus, as shown in Figure 2. Review the placement of the line on the appropriate end-systolic and end-diastolic phases using the cine controls.

> **NOTE:** Multi-plane basal interpolation is supported. For example, the MV annulus can be identified on 2-chamber and a 4-chamber views; fit is done between the two planes.

> **NOTE:** Locate the series of either the MV or TV annulus placement by clicking or located in the lower left on the viewport.

FIGURE 2. MV Annulus
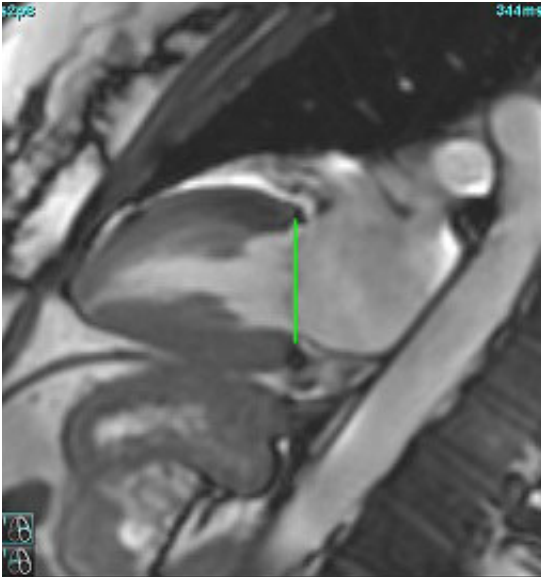
4.   Review the updated calculation by reviewing the cross-reference slices in relationship to the line.

As shown in Figure 3, the interpolated volume calculation is based upon the relationship of the line intersection with the slice (pink line) this volume is now included in the volume results. The actual region of interest will not be shown. Slices that have been interpolated will state the volume amount with the percentage of interpolation in left hand corner of the image, as shown in Figure 3.

FIGURE 3. Volume Calculation
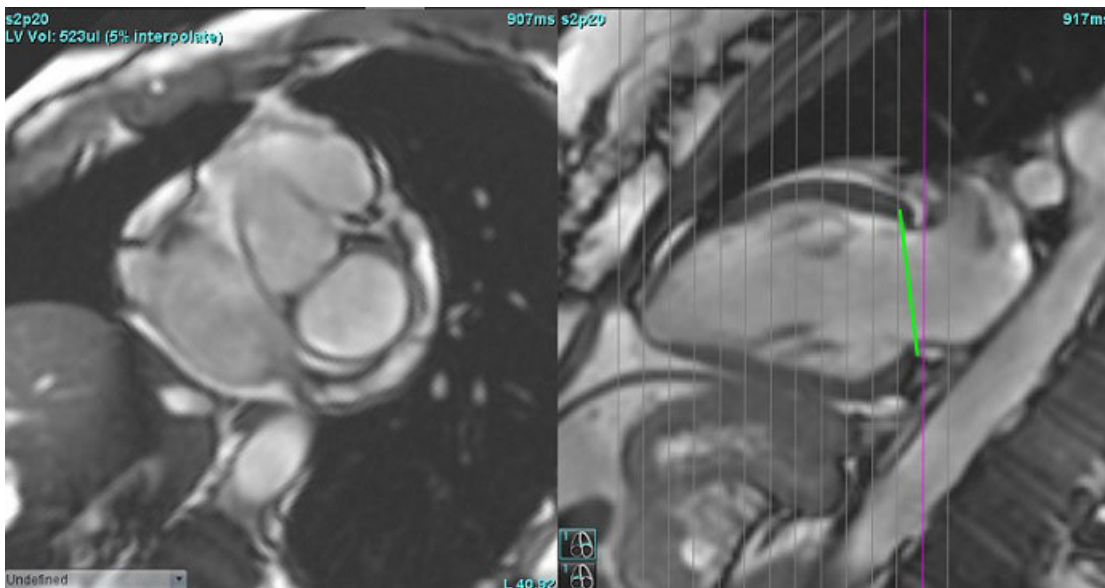
5.   For RV basal interpolation, select a 4-Chamber view in the cross-reference mode.

6.   Select .

7.   Define the TV annulus, as shown in Figure 4. Review the placement of the line on the appropriate end-systolic and end-diastolic phases using the cine control.

FIGURE 4. TV Annulus
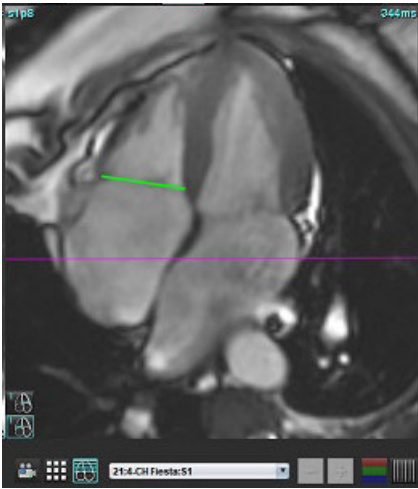
8.   Review the updated calculations by reviewing the cross-reference slices in relationship to the line and review the ED and ES assignments in matrix mode.

9.   To reset the result back to the original value, right mouse click and hold directly on the line to select delete or left mouse click on the line and use the delete key on the keyboard.

Review Accuracy

1.   Play the long axis series in cine mode and review the placement of the line.

2.   Adjust the line placement as needed.

3.   If automatic insertion has been performed, check for proper series selection and line placement. If not properly placed perform a right mouse click on the line and delete.

Motion Correction Between Series

Motion Correction Between Series compensates for cardiac translation that may occur between the acquisition of long axis images and short axis images. Errors in chamber volumes can occur if annular planes are derived from long axis images that do not spatially register with short axis images that contain the endocardial contours used for volumetric analysis. The error may occur if the short and long axis images are acquired in different stages of the respiratory cycle or if the patient changes position (i.e. translates) between the acquisition of the long and short axis images. When **Motion Correction Between Series** is selected, the end-diastolic center of the atrioventricular valve plane is defined by the most basal end-diastolic ventricular endocardial contour. The angulation of the annulus valve plane and the relative position of its center on other cardiac phases are determined by the angulation of the annulus lines and the relative position of the annulus centers as defined on the long axis images.

   NOTE: To access the feature in Function Analysis mode. Select **Tools > Preferences > Edit**. Select **Motion Correction Between Slices** under Function.

1.   Perform LV and RV auto segmentation for all phases all slices.

2.   Perform the Basal Interpolation for the LV and RV.

3.   Select .

4. Agreement can be confirmed when the dashed line appears superimposed over the MV annulus line placement, as shown in Figure 5 (left).

FIGURE 5. Confirmed Agreement (left) Cardiac Translation (right)
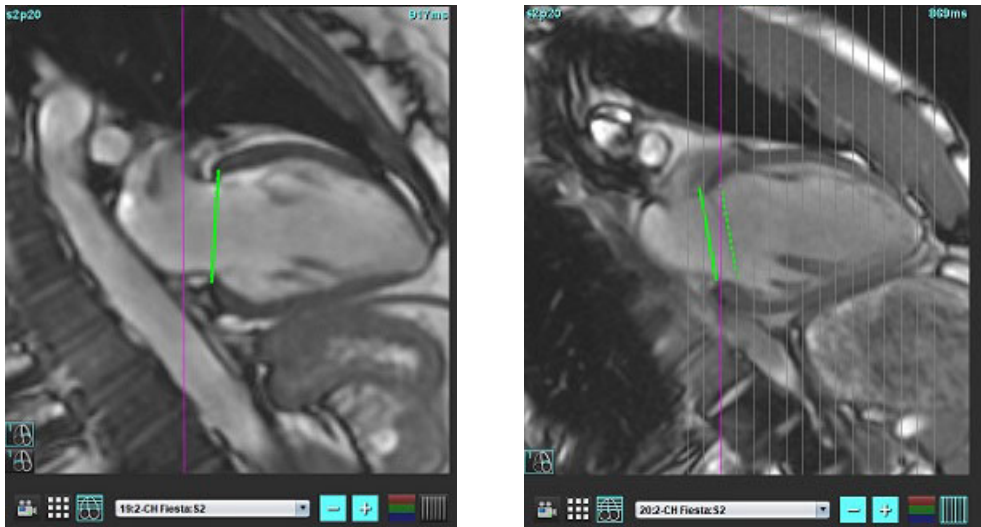
5. Figure 5 (right) shows a gap between the solid and dashed annulus lines.

6. The solid line represents the annulus plane drawn on the long axis image. The dashed line represents the translated annulus plane based on the location of the most basal endocardial contour.

   NOTE: It is the responsibility of the user to determine the reason for the gap between the solid and dashed line, and to correct the analysis if necessary. Possible reasons for a gap include:
   - The most basal endocardial contour on the short axis image is not drawn on the correct slice. If not corrected, the software will incorrectly compensate for translation.
   - The annulus line does not represent the position of the annulus. If not corrected, the software will incorrectly compensate for translation.
   - Cardiac translation between the long axis acquisition and the short axis acquisition.

   If the most basal endocardial contour is drawn on the correct slice and the annulus line is drawn correctly on the long axis image, then the gap between the solid and dashed line represents true cardiac translation and the software will correct for that translation.

7. Review the translation if the RV segmentation has been performed and the TV annulus has been placed.

Interpolation Functionality

When performing function analysis for either the LV or the RV the interpolation functionality is turned "off."

Interpolation functionality can be applied for the following conditions:

- If the same cardiac phase is traced across slices for either end-systole or end-diastole and a slice has been skipped the interpolation can be enabled by selecting interpolation "On" as shown in Figure 6.
- If the same cardiac phase is traced across slices for either end-systole or end-diastole and/or a slice has been skipped the basal interpolation can be applied automatically.

FIGURE 6. Interpolation

Interpolation OFF   Interpolation ON
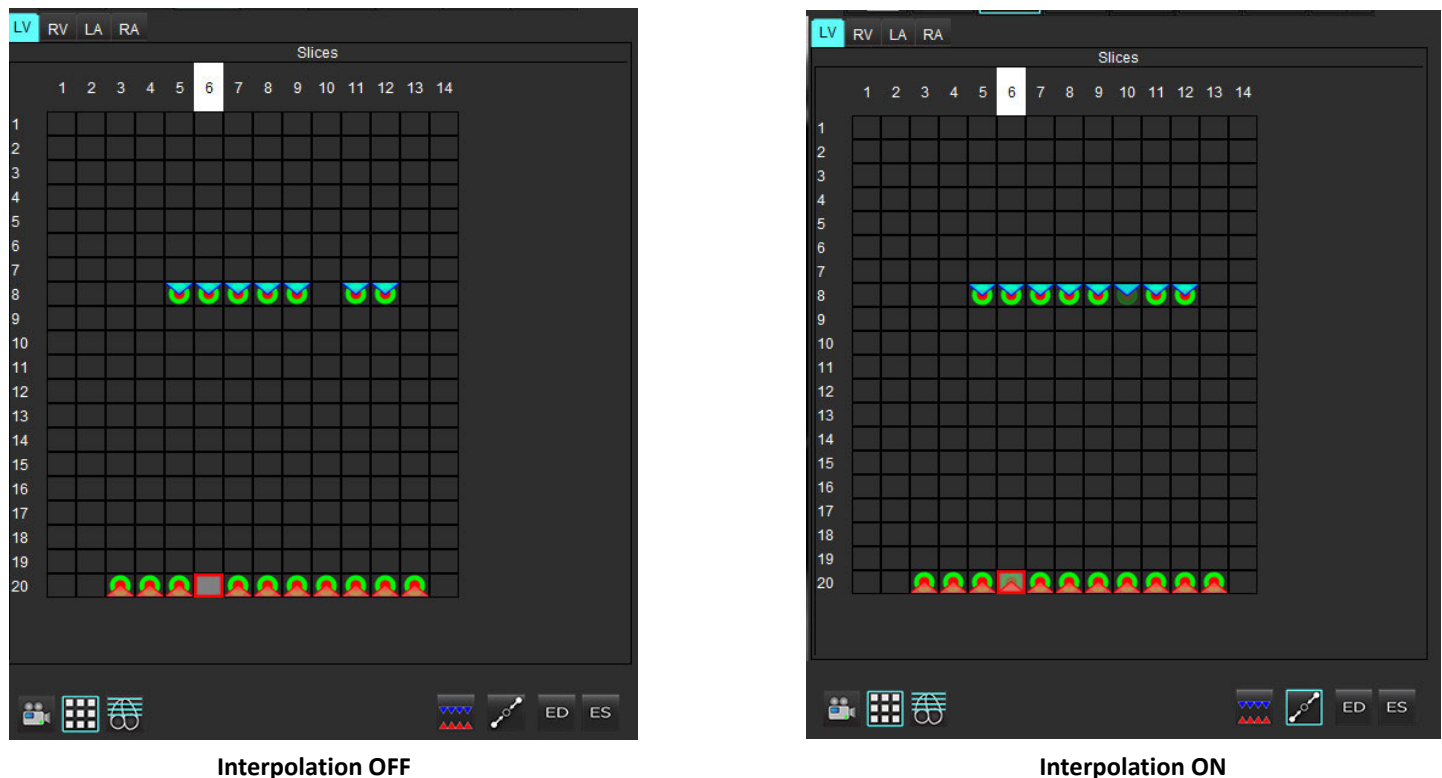
Reviewing End-Diastolic (ED) and End-Systolic (ES) Assignments

Upon completion of performing segmentation, review the matrix mode and confirm the end-diastolic or end-systolic assignments.

NOTE: For any ventricular volume analysis type if the End-Diastolic (ED) or End-Systolic (ES) traces are performed manually on a different phase the following message will appear.

FIGURE 7. ROI Assignment Message
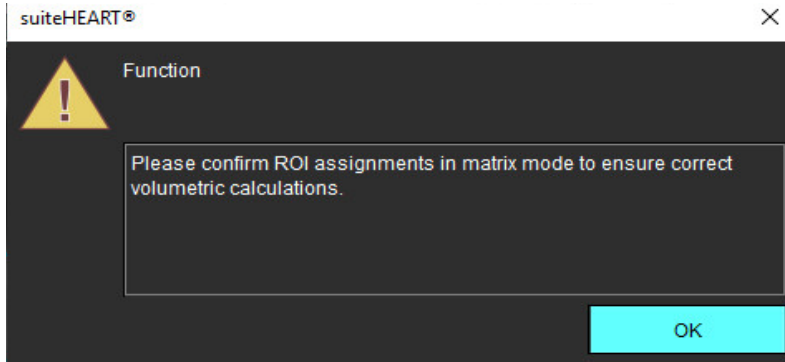
1. Select the Matrix mode ⊞ button.

2. Select Slice-by-Slice ED/ES mode

   The view port changes showing a matrix representing all of the slice locations and phases acquired. In Figure 8 all of the LV end-diastolic phases have been assigned as indicated by the red triangles. The blue triangles indicate assigned LV end-systolic phases. The red dots represent phases not yet assigned.

FIGURE 8. Assignment of LV End-Diastolic Phases
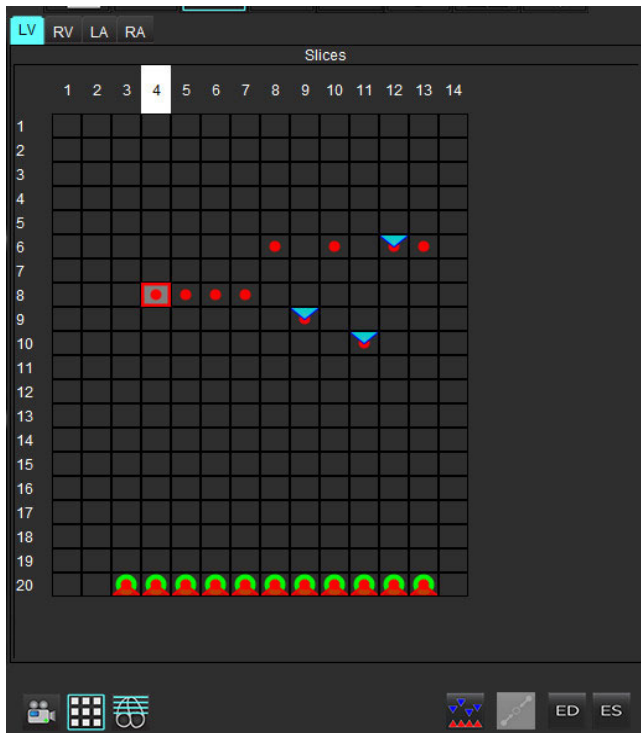
FIGURE 9. Assignment of LV End-Systolic Phases
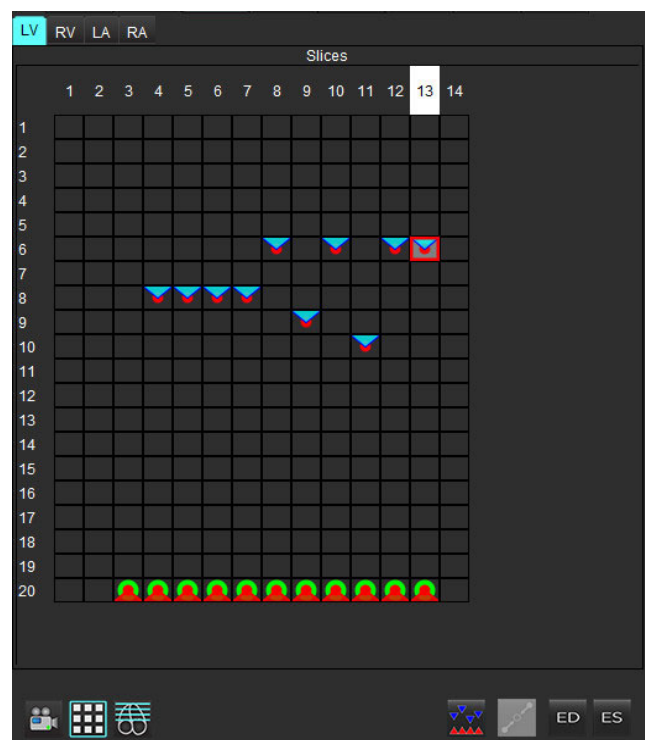
3. In this example, to assign the LV end-systolic phases click on the **ES** button and click on the appropriate phase that has a red dot. A blue triangle will appear after clicking on the matrix box. As shown in Figure 9, all of the end-diastolic and/or end-systolic assignments are now correct.

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

Volume Method Determination

The volume method determination for ED and ES is based upon the selection of the toggle button for global and slice-by-slice.

Table 4: Volume Method Determination Toggle Button

Global ED/ES		When global is selected, the combined volume is based upon the ED and ES assignments based upon the same phase.
Slice-by-slice ED/ES		When slice-by-slice is selected, the combined volume is based upon the largest and smallest volume per phase for each slice. Must select Propagate All Slices, All Phases mode to activate.

Ventricular Function Analysis Results

Volume Curve

When auto segmentation is performed for all phases and all slices for either the LV or RV, a ventricular volume versus time curve is generated, as shown in Figure 10. This curve can be included on the report. Markers with drag handles can be adjusted.

FIGURE 10. Ventricular Auto-Segmentation Results
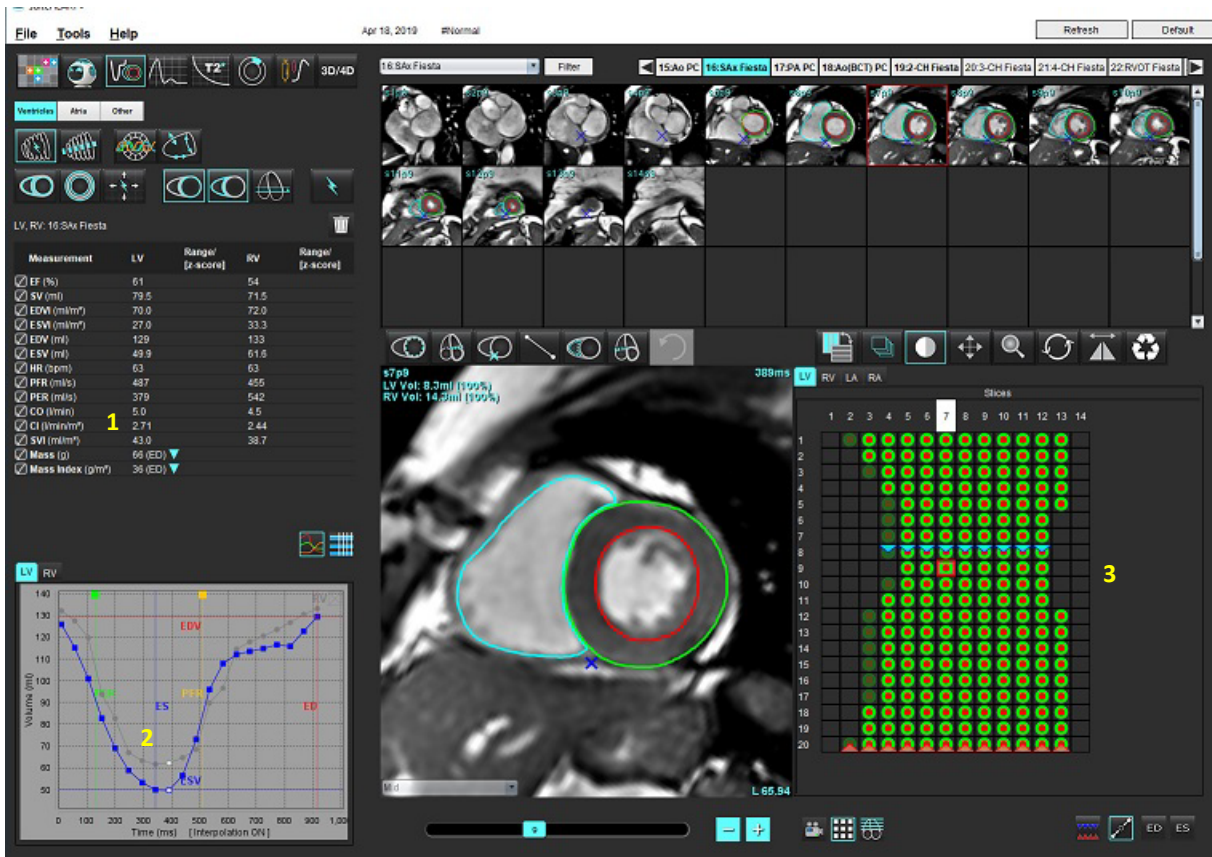
1. Volumetric results, 2. Volume curve, 3. Matrix mode

- The red cursor marks end-diastolic volume.
- The blue cursor marks end-systolic volume.
- The green cursor marks Peak Ejection Rate (PER) ml/sec. (Interactive Vertical Cursor).
- The yellow cursor marks Peak Filling Rate (PFR) ml/sec. (Interactive Vertical Cursor).
- Corresponding image phase selection is indicated by the white marker on the volume curve.

Volumetric results are displayed on the measurement table.

- To review the ventricular mass results or mass index, left-click on the inverted triangle for either the LV or RV.
- Only the phase selected from the table is shown in the report. The default is ED.

FIGURE 11. Mass Results

Measurement	LV	Range/[z-score]	RV	Range/[z-score]
☑ EF (%)	61		54	
☑ SV (ml)	79.5		71.5	
☑ EDVI (ml/m²)	70.0		72.0	
☑ ESVI (ml/m²)	27.0		33.3	
☑ EDV (ml)	129		133	
☑ ESV (ml)	49.9		61.6	
☑ HR (bpm)	63		63	
☑ PFR (ml/s)	487		455	
☑ PER (ml/s)	379		542	
☑ CO (l/min)	5.0		4.5	
☑ CI (l/min/m²)	2.71		2.44	
☑ SVI (ml/m²)	43.0		38.7	
☑ Mass (g)	66 (ED) ▼			
☑ Mass Index (g/m²)	36 (ED) ▼			

66 (ED)
66 (ES)
66 (p1)
67 (p2)
68 (p3)
68 (p4)
70 (p5)
66 (p6)

LV RV

FIGURE 12. Chamber Volume Table

LV RV

Chamber Volumes

Phase	TDel (ms)	ENDO Volume(ml)	EPI Volume(ml)
1	10	126	189
2	57	115	179
3	105	101	166
4	153	82.8	148
5	200	69.0	136
6	248	58.8	122
7	296	53.2	116
8	343	49.9	113
9	391	49.7	112
10	439	56.4	119
11	487	73.1	135
12	534	95.9	160
13	582	108	171

Chamber Endo Contour Epi Contour

LV and RV Volumetric values are displayed in the Chamber Volume table.

Left Ventricular Regional Analysis

LV Regional Analysis allows for the review of wall motion, wall thickness, wall thickening and wall thickness results.

> **NOTE:** If the LV and RV buttons in Function Short Axis are both deselected or if the chamber selection button in Long Axis is deselected, the Start Auto Propagation button will be disabled.

1. Perform Auto LV segmentation for all slices in all phases (refer to page 63).

2. Review the placement of the RV insertion point on each slice and adjust the RV insertion point for the basal slices.

3. To add an RV insertion point to a slice location, click RV insertion point , select an auto segmented slice and deposit the RV insertion point.

4. Confirm basal, mid and apical classification.

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

FIGURE 13. Regional Analysis
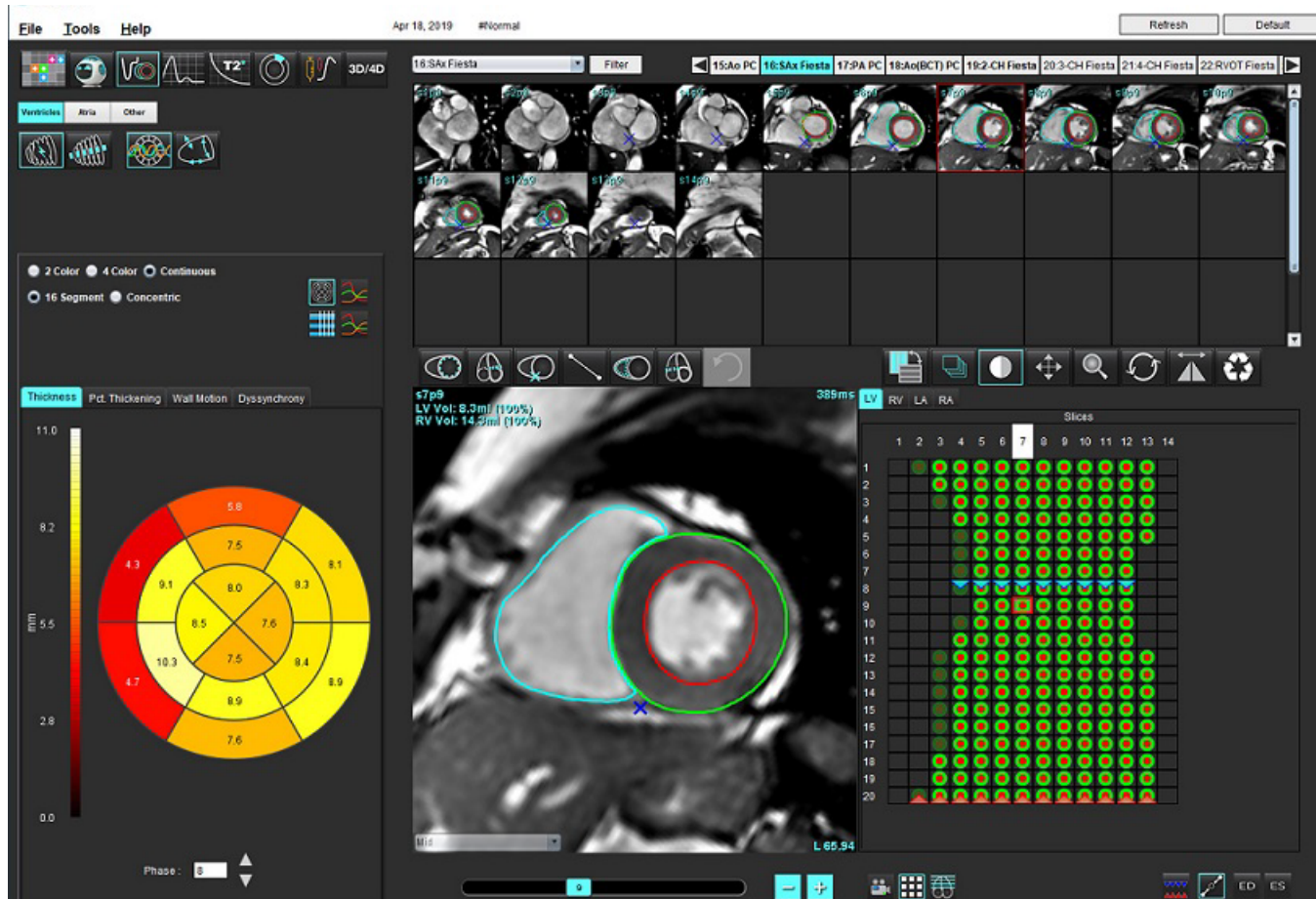
Dyssynchrony Analysis

Dyssynchrony is an extension of the Regional Analysis results allowing for the calculation of the Temporal Uniformity of Wall Thickness (TUWT) base upon circumferential information obtained from the Regional Analysis. Literature reference located in Table 5.

Dyssynchrony Analysis Procedure

1. Perform LV auto segmentation (See Perform Auto Segmentation for All Slices and All Phases on page 63.).

2. Select Regional Analysis .

3. Select the Dyssynchrony tab.

4. The measurement table will show the results for each slice and the mean global result.

5. The global result calculation is optimal when only LV mid-ventricular slices are included. To remove a slice result from the global result calculation, click directly on the box with the checkmark in the far right column (Figure 14).

FIGURE 14. Global Result Calculation

Table 5:

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

Fast LV Function Analysis Procedure

1. Select .

2. Select a long-axis series.

3. Select .

4. Select the to propagate all slices, all phases.

5. Click .

   NOTE: The Start Auto Propagation button will be disabled if the long axis view selection is deselected.

6. Review all traces. Adjust centerline so it corresponds to the long axis of the left ventricle from base to apex.

7. Manual tracing can be performed. Click to trace the left ventricle endocardium for both end-diastole and end-systole.

8. For the calculation of left ventricular mass, trace the left ventricular epicardium .

FIGURE 15. Centerline Placement
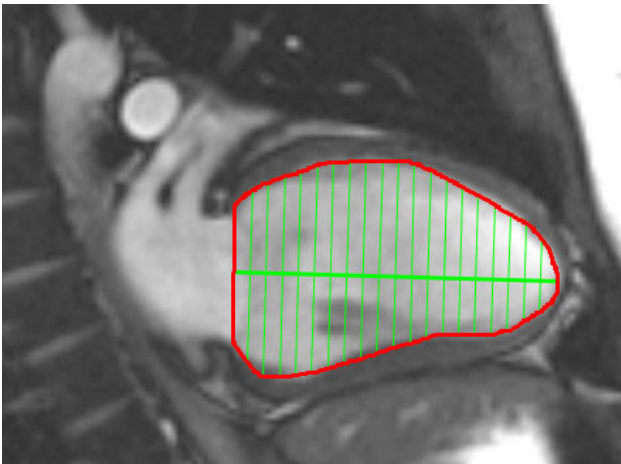
The results are displayed on the Measurement table.

Atria

Manual LA and RA Function Analysis Procedure

1. Select the appropriate series from the Image View.

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

2. Click [Atria] .

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.

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

7. If a short axis view has been used, identify the MV and/or TV annulus.

Fast LA or RA Function Analysis Procedure

This method is performed on a long-axis series.

1. Click [Atria].

2. Select a long-axis series.

3. Select the end-diastolic phase.

4. Select the [icon] button.

5. Select [icon] for LA Endocardium or [icon] for RA Endocardium.

6. Trace the atrium endocardium. A center of rotation line is drawn automatically.

7. Adjust the center of rotation line so that it corresponds to the long axis of the atrium

8. Repeat steps 5-7 for end-systole.

Atrial Dimensions and Area

1. Click [Atria].

2. Select the appropriate series.

3. To perform an atrial dimension measurement, click directly on the table in the column for either LA or RA and then deposit two points. See Figure 16.

4. To perform an atrial area measurement, click directly on the table in the column for either LA or RA and then draw an ROI. See Figure 16.

FIGURE 16. Atrial Measurement

Measurement	LA	Range/ [z-score]	RA	Range/ [z-score]
☑ EF (%)				
☑ EDVI (ml/m²)				
☑ ESVI (ml/m²)				
☑ EDV (ml)				
☑ ESV (ml)				
☑ Dimension (cm)				
☑ Area (cm²)				

Default Measurements

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

FIGURE 17. Default Measurements
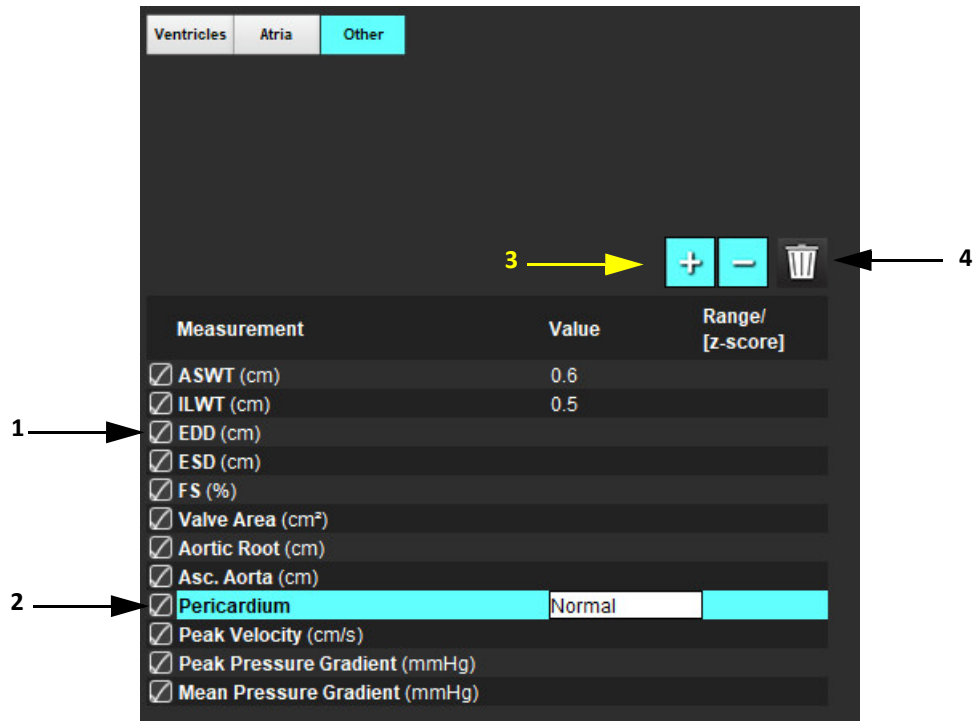
1. Include on Report, 2. Type-in Field for Pericardium, 3. Add/Remove Custom Measurement, 4. Delete all Measurements

Perform a Measurement

1.   Select [image].

2.   Select the series.

3.   Click [Other] button.

4.   Locate the image with the anatomy to be measured.

5.   Click the desired measurement, which will highlight 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 to purple it is active. Place the cursor over one of the endpoints and adjust the endpoint.

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

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

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

Delete Measurements

Click 🗑 to delete all measurements.

Add Custom Measurement

1. Select ➕.

2. Enter a unique label in the Add Custom Measure pop-up window.

3. Select the measurement type as either Linear or Area.

4. Select OK.

Remove Custom Measurement

1. Select the ➖.

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

3. Choose Select.

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

Valve Plane Analysis
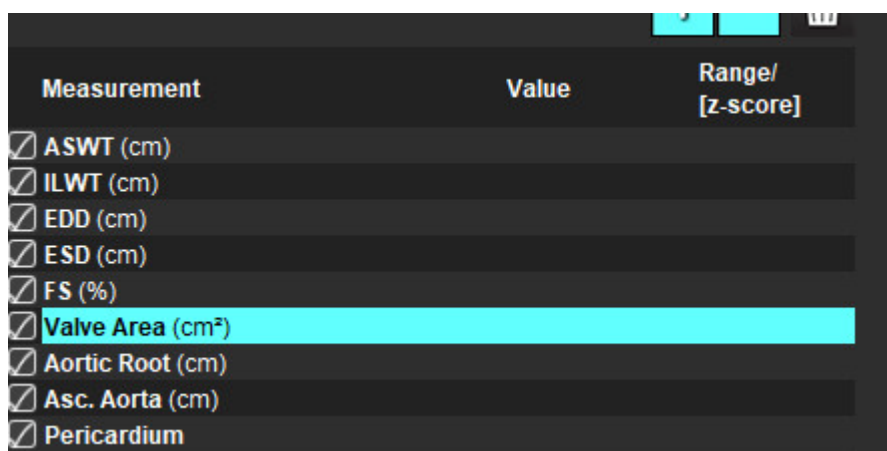
The valve plane analysis feature allows for the calculation of valve peak velocity, peak pressure gradient and mean pressure gradient for the valve.[1]

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 on all slices in all phases (see).

2. Select a series that demonstrates valve anatomy.

3. Select Valve Area from the measurement table (Figure 18) and perform planimetry of the valve, as shown in Figure 19.

   FIGURE 18. Valve Area

4. Upon completion of the ROI, the table will update with the results and present a graph showing the pressure gradient over time.

Click to delete all measurements.

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1. Wolff, Steven D., M.D., Ph.D. Noninvasive methods for determining the pressure gradient across a heart valve without using velocity data at the valve orifice. U.S. Patent 9,585,568, March 7, 2017.

FIGURE 19. Valve Plane Analysis

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

NOTE: The results of Peak Velocity, Peak Pressure Gradient, and Mean Pressure Gradient obtained by Value Plane Analysis are not valid in patients with mitral regurgitation or a shunt.

Flow Analysis

The Flow Analysis mode supports both 2D and 4D Flow acquisitions. Both manual and fully automatic segmentation with the quantification of flow volume, velocity, regurgitant volume, pressure gradient, pressure half-time, and Qp/Qs are supported. Based on user method selection(s), automatic calculation of aortic, mitral, pulmonic, and tricuspid regurgitation can be obtained. Accurate flow results depend on images being acquired using the correct scan plane, the appropriate acquisition parameters, and through-plane flow encoding.

NOTE: Auto segmentation may be less accurate in cases where image quality is poor. In those cases, the user is responsible for editing the contours or performing manual segmentation.

NOTE: If both 2D phase contrast and inline 4D Flow analysis has been performed, all results will be available in Flow Analysis Mode.

The Preprocessing feature supports the identification of vessel types for 2D phase contrast as listed in Table 1. Refer to the suiteDXT Instructions for Use NS-03-039-0008.

WARNING: Following preprocessing, the user is responsible for assessing the accuracy of the entire analysis and making any necessary corrections. A comprehensive review should include:

- ROI placement
- Correct vessel identification for each category
- Baseline correction

WARNING: The user is responsible for the accurate placement and correct category assignment of all regions of interest (ROIs), including those generated or modified by the auto segmentation algorithms. The quantitative values generated by the software depend on the accurate placement and correct vessel category assignment of all regions of interest.

WARNING: The application assists in the analysis of the images only and does not automatically produce a clinical interpretation of the 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.

FIGURE 1. Flow Analysis Interface Overview
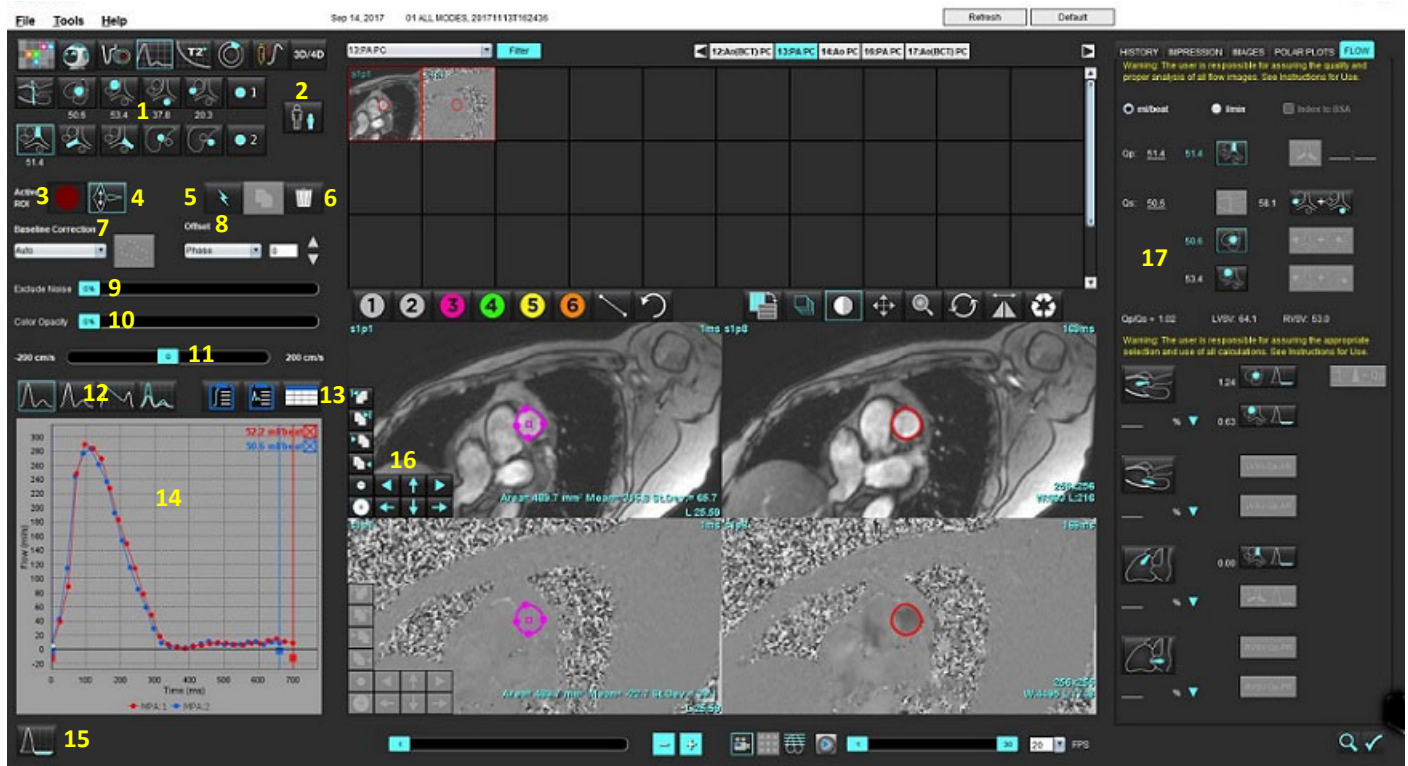
1. Vessel Categories, 2. Adult/Pediatric Selection, 3. Active ROI selection, 4. Invert Graph, 5. Propagate selections, 6. Delete options, 7. Baseline, correction drop- down menu 8. Offset: Phase, Dilation, Flow, 9. Exclude Noise Pixels, 10. Color Opacity Control, 11. Aliasing Correction, 12. Curve Mode Selections, 13. Result table selections, 14. Curve Result/Display, 15. Regurgitant Mode, 16. Editing tools, 17. Integrated Analysis

NOTE: Flow Analysis displays the magnitude and phase images in a side-by-side image display. Other image types acquired at the same scan location are not displayed and should be reviewed in the Viewer.

NOTE: The heart rate can be obtained by hovering over the flow result on the curve display.

Flow Analysis Using Auto Segmentation

If preprocessing has been completed, based on the 2D phase contrast series present in the study, the segmentation will be performed automatically on the 2D phase contrast series and assigned to the appropriate vessel category (Table 1). Auto segmentation does not require an initial ROI to be placed on the vessel just select the appropriate vessel category and the proper series displaying that vessel. If preprocessing is not performed It is important to select the appropriate category that correlates to the vessel anatomy that has been acquired.

WARNING: The user is responsible for the accurate placement and correct category assignment of all regions of interest (ROIs), including those generated by preprocessing.

NOTE: If there are more than six vessels acquired for phase contrast per tab, the Preprocessing feature will only keep the six most recent results.

NOTE: The net flow result will be displayed under each vessel category. If there is more than one flow measurement in a vessel category the average result will be shown. To hide this value, select **Tools > Preferences > Edit** and set the flow unit to **NONE** under Flow.

Table 1: Vessel Categories

Vessel Category	Tool Tip	Label
	LVOT	Left Ventricular Outflow Tract (Pediatric)
	pAAo	Proximal Ascending Aorta
	mAAo	Mid Ascending Aorta
	pDAo	Proximal Descending Aorta (Pediatric)
	SVC	Superior Vena Cava (Pediatric)
	MPA	Main Pulmonary Artery
	RPA	Right Pulmonary Artery (Pediatric)

Table 1: Vessel Categories

Vessel Category	Tool Tip	Label
	LPA	Left Pulmonary Artery (Pediatric)
	IVC	Inferior Vena Cava (Pediatric)
	dDAo	Distal Descending Aorta (Pediatric)
	Flow 1, Flow 2	User defined categories. Right click and enter a new label for the category. The label will appear as a tool-tip.

Perform Auto or Manual Segmentation

(Example of Proximal Ascending Aorta Segmentation)

1. Select either Adult or Pediatric .

2. Select the category.

3. Select the appropriate phase contrast series that demonstrates the proximal ascending aorta, as shown in Figure 2.

FIGURE 2. Proximal Ascending Aorta

4. Select the Active ROI color, as shown in Figure 3.

FIGURE 3. Active ROI Selection

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

5. Select .

6. Review the segmentation on the vessel. Confirm that the correct vessel was segmented.

    If the incorrect vessel is segmented perform manual segmentation.

7. To perform manual segmentation select .

8. Create a contour around a vessel by depositing 4 points around the vessel of interest, move the cursor out of the editor window to close the ROI.

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

    or

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

9. To edit, click on a contour, perform the edit and click . Refer to Contour Editing on page 89.

10. Flow results are displayed on the graph and results tables. Click the check box beside the flow result to remove the associated curve from the graph.

11. Select a Baseline Correction option from the file pull-down.

    Curves with a Baseline Correction applied will have solid phase data points, as shown in Figure 8. Refer to Baseline Correction Options on page 92.

FIGURE 4. Flow Graph - No Correction (left graph); Correction Applied (right graph)
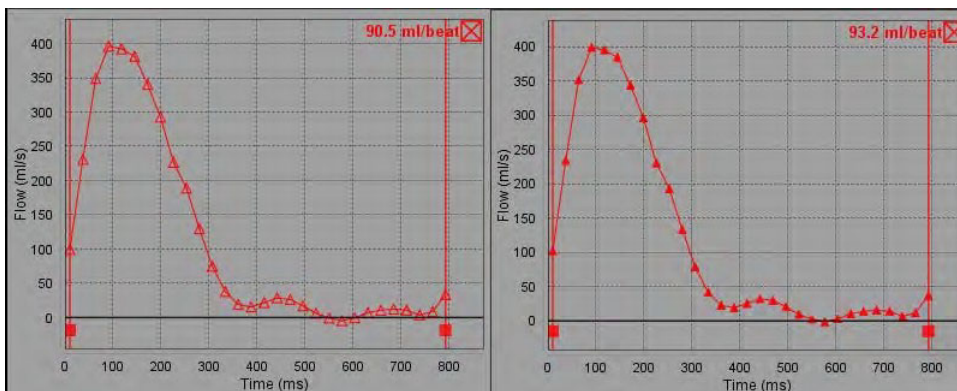
All flow curves generated are displayed in a positive direction. Inverted curves are indicated by .

Vessel Category Move

Upon review, if a completed flow result is not in the correct vessel category it can be moved to the appropriate category.

Left click on the contour, right click and release; then cursor over the vessel type and select the appropriate flow category as shown in Figure 5. (Pediatric categories are shown.) The flow result will now be shown in that category.

FIGURE 5. Vessel Category Move Selection
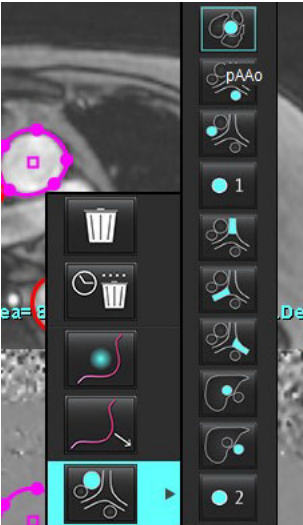
Contour Editing

1. Select the desired phase to edit.

2. Left click on the contour to activate it for editing.
   The contour will turn purple indicating it can be edited.

3. If displayed, edit the contour by moving the points for point spline contours.

4. Perform a free hand edit by clicking and tracing.

5. Left mouse click on the contour to select, then right mouse click to use tools, as described in Table 2.

6. Use the viewport editing tools as described in Table 3.

Table 2: Right Mouse Click Options

Tool	Description
	Delete a single ROI on current phase
	Delete all ROIs on all phases

Table 2: Right Mouse Click Options

Tool	Description
	Nudge Tool selection
	Pull tool selection
Current vessel category will be shown.	Move flow results to a different category

Edit a Range of Phases

1.   Select the desired slice.

2.   Select to display thumbnails of all the phases of a given slice location.

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.

Table 3: Viewport Editing Tools

Tool	Description
	Copy edit to end of phases
	Copy edit to start of phases
	Copy ROI from previous phase
	Copy ROI to next phase
	Decrease ROI size

Table 3: Viewport Editing Tools

Tool	Description
	Expand ROI size
	Navigate to Previous and Next Phase
	Shift ROI right or left
	Shift ROI up or down

Baseline Correction Options

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

> **NOTE:** Phase contrast images that are used for analysis should not have image phase wrap. Phase wrap present in the image will invalidate the auto baseline correction.

Auto Baseline Correction

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

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

1. Generate a flow curve using the appropriate phase contrast series.

2. Select Auto from the Baseline Correction pull-down.

> **NOTE:** Auto baseline correction will be automatically applied if **Auto Baseline Correction** is selected in Preferences.

3. The correction will be applied with the updated results displayed directly on the flow graph.

4. Series which fail the fitting analysis will be indicated by a warning symbol, as shown in Figure 6.

FIGURE 6. Baseline Correction Failure
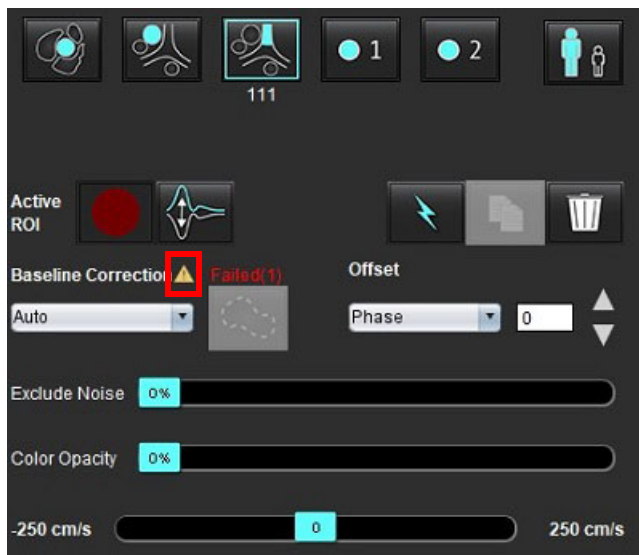
Failure Types:

1 – Wrap in the Image
2 – Noise in the Image
3 - Image is invalid

> **NOTE:** Phase wrap present in the image will cause inaccurate flow results, as shown in Figure 7. 2D Cine Phase Contrast images that are used for flow analysis should not have image phase wrap, as shown in Figure 8.

FIGURE 7. Example Images Showing Phase Wrap (White Arrows)

FIGURE 8. Example Images with No Phase Wrap
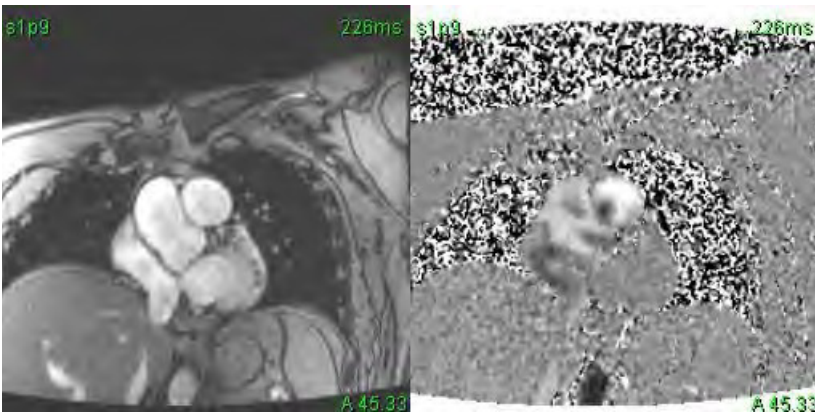
Phantom Correction

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

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

1. Generate a flow curve using the appropriate phase contrast series.

2. Select the corresponding phantom series from the Baseline Correction pull-down.

3. The correction will be applied with the updated results displayed directly on the flow graph.

Background Contour Correction

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

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

1. Generate a flow curve using the appropriate phase contrast series.

2. Select the Background ROI from the Baseline Correction pull-down.

3. Click to draw a contour.

4. The correction will be applied with the updated results displayed directly on the flow graph.

Flow Tools

Offset Options

The file pull-down has 3 options: Phase, Flow, Dilation

Table 4:

Selection	Description
Phase	Changes the ordinate of the flow curve.
Flow	Changes the abscissa value of the flow curve which changes the baseline values of the flow result.
Dilation	Uniformly changes the radius of the segmented vessel for all phases by a specified pixel amount to include valid flow pixels.

Exclude Noise Pixels

This option identifies low intensity pixels (high fluctuation of velocities) if present within the ROI, identified by the pink overlay as shown in Figure 10 and excludes them from the flow calculation. The percentage of noise pixels can be adjusted by the slider bar.

FIGURE 9. Noise Pixels

FIGURE 10. Noise Pixels Identified by Pink Overlay
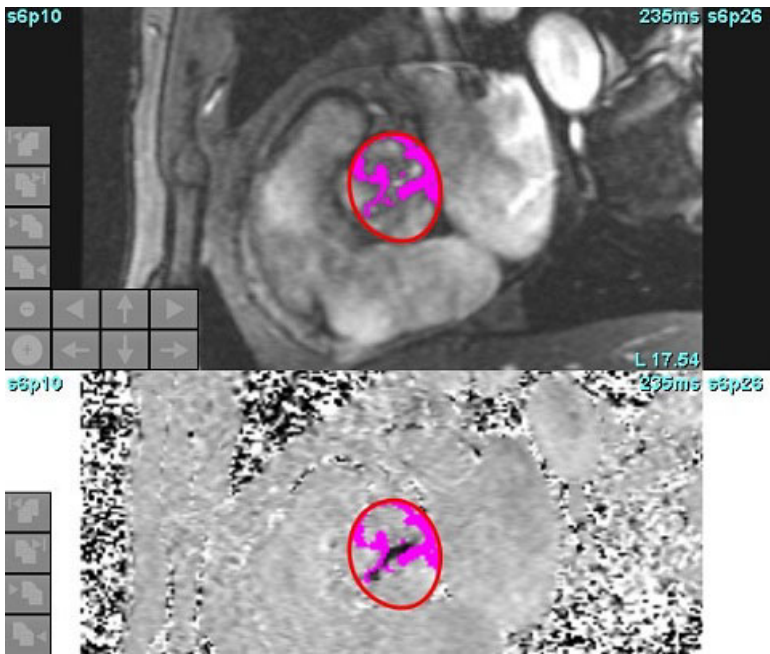
Color Overlay

To display a red/blue color overlay representing velocities on the magnitude image click and drag the color opacity slider bar. Adjust the velocity range by setting the blue or red markers as shown in Figure 11.

FIGURE 11. Color Overlay Controls
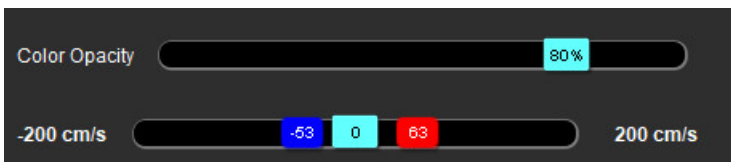
Velocity Aliasing Correction

To correct for velocity aliasing, drag the slider bar control marker to perform phase unwrapping. The effect of the change will be updated directly on the phase image and flow graph will update. Aliasing correction can be performed without a ROI present on the image. If a more than one slice location is present in the series changing the setting will affect all slice locations. To change a single slice location use the Ctrl or Alt key on the keyboard when changing the slider bar control.

User Defined Peak Velocity

1. Select the appropriate phase of the cardiac cycle.

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

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

FIGURE 12. Pixel Flow Velocity
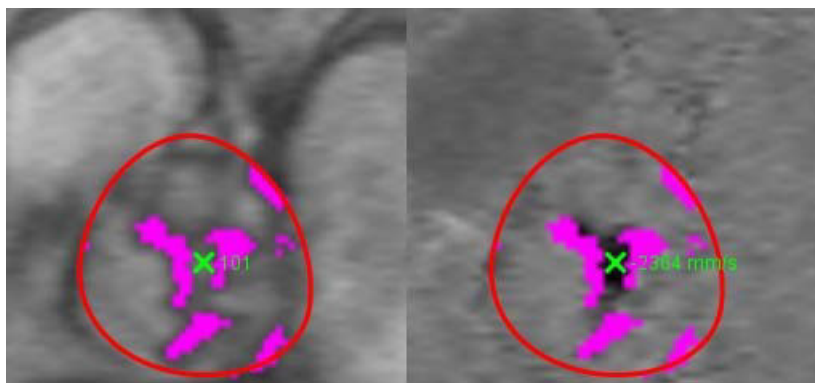
Curve Mode Selections

Table 5:

Selection	Mode	Description
	Flow	Curve represents the flow volume of each phase in the entire cardiac cycle (default). Each point on the curve represents flow for that phase. Net flow result is displayed.
	Histogram	Displays a plot of the velocity of each pixel within each region of interest for every phase of the cardiac cycle. Peak and mean pressure gradient results are displayed.
	Pressure Half-Time (PHT)	The time it takes for the peak transmitral pressure gradient to decrease by half. Allows for the identification of slope of the graph to calculate the PHT and mitral valve area (MVA).
	Compare	Allows for the display of curves from two different categories.
	Regurgitant	Calculates the net negative flow (below x-axis).

Table 5:

Selection	Mode	Description
	Positive*	Displays the sum of the positive flow area over the cardiac cycle.
	Negative*	Displays the sum of the negative flow area over the cardiac cycle.
	Peak Envelope*	Displays a plot of peak positive and negative velocities for each phase of the cardiac cycle.
	Peak Absolute*	Displays a plot of absolute peak velocity for each phase

*These selections are only available if the preference is selected. Select **Tools > Preferences > Edit**. Select **Show Advanced Options** under Flow.

Histogram Mode

Select histogram mode to display a plot of velocities per pixel and the calculation of the peak and mean pressure gradient.

1. Generate a flow curve using the appropriate phase contrast series.

2. Select .

3. Click directly on the graph to activate a cross hair cursor on the phase image, which indicates the corresponding location of that pixel.

4. Use the double arrow controls at the bottom of the graph to locate the highest or lowest velocity value, (Figure 13).

5. Use the single arrow controls to increment discretely through the velocity values, as shown in Figure 13.

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

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

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

FIGURE 13. Histogram Mode
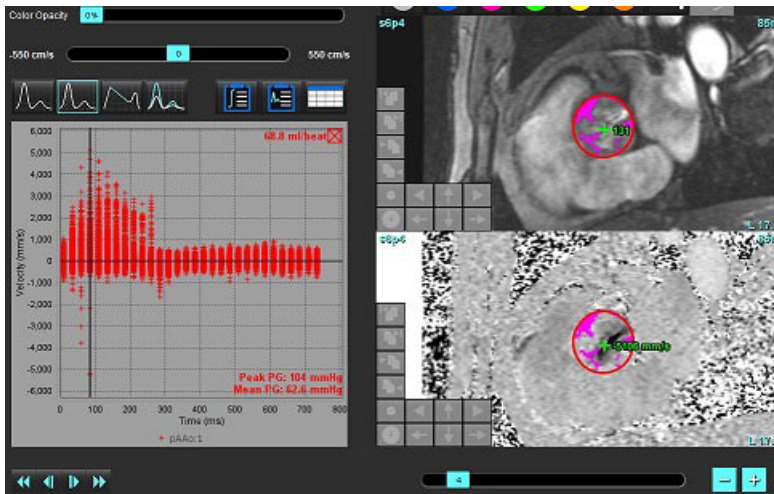
Pressure Half-Time

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

1. Generate a flow curve using the appropriate phase contrast series of the mitral valve.

2. For the ROI propagation use the copy paste option.

3. Select .

4. Click directly on the plot to identify the highest velocity of the deceleration portion of the curve.

5. Click an end point to calculate the slope of the curve as shown in Figure 14.

6. To reset the calculation, place the cursor over an end point, right mouse click and select the trash can.

FIGURE 14. Pressure Half-Time Results
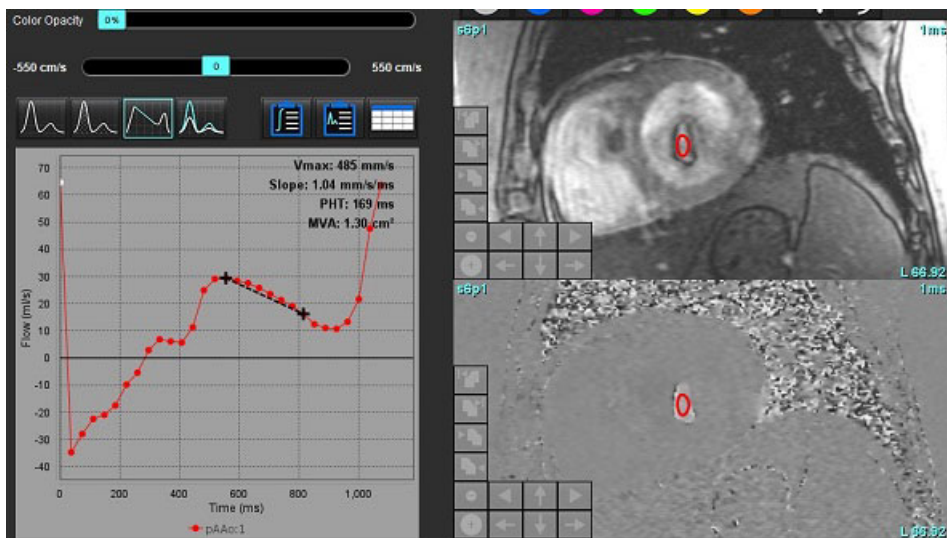
NOTE: Mitral Valve area (MVA), Pressure Half-Time (PHT) results are not valid in patients with aortic insufficiency, cardiac shunt or decreased ventricular compliance.

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

Reference:

http://www.csecho.ca/mdmath/?tag=mvaph

View Flow Results

Select one of the following options to review flow results in a table format.

Table 6: Result Table Options

Selection	Label	Description
	Integrated Analysis	Displays the analysis results from the flow panel. Includes results for aortic, mitral, pulmonic, and tricuspid regurgitation and Qp/Qs. Refer to Integrated Analysis on page 102.
	Flow Analysis	Summary of results per flow curve.
	Data Table	Lists detailed flow parameters for each phase per flow curve.

Change Category Label for Flow1, Flow2

Only the labels for the categories of Flow 1 or Flow 2 can be changed.

FIGURE 15. Flow 1, Flow 2
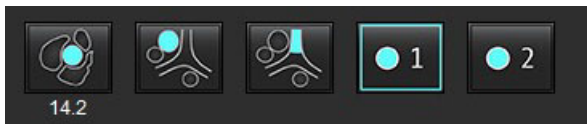
Change Label

1. Right mouse click on either Flow 1 or Flow 2 (Figure 15).

2. Enter the new label name (Figure 16).

3. The new labels will appear as tool tips.

   NOTE: The curve legend label will be assigned the same label.

FIGURE 16. Edit Category Label

| Label | Flow 1 |
| OK | Cancel |
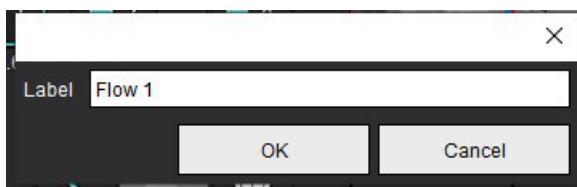
NOTE: Changing the flow category labels changes the flow header label for the report.

Edit Curve Legends

1. Right mouse click on Flow 1:1 on the bottom of the flow graph (Figure 17).

    NOTE: If the category label has been changed then that label will be shown.

FIGURE 17. Edit Curve Legends
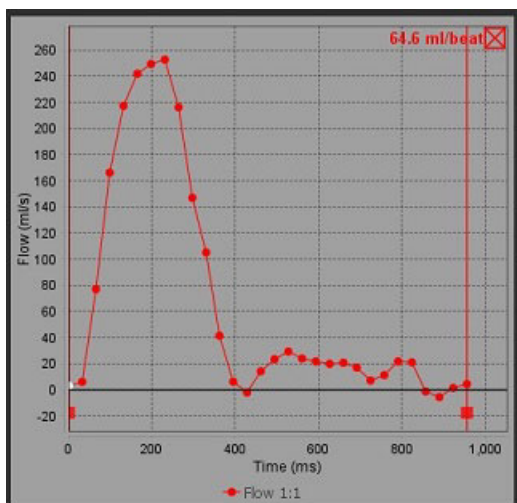
2. Enter the new label name.

FIGURE 18. Change Flow Curve Legends Label

| Label | Flow 1: |
| OK | Cancel |
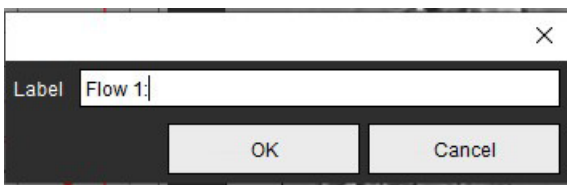
NOTE: The new flow curve legends will be saved with the current template.

Integrated Analysis

Based on a user selected method, Integrated Analysis calculates Qp, Qs, Qp/Qs, aortic, mitral, pulmonic, and tricuspid regurgitant volumes and regurgitant fractions (RF%).

⚠️

WARNING: The user is responsible for selecting the method for determining Qp, Qs, and aortic, mitral, pulmonic, and tricuspid regurgitant volumes and regurgitant fractions.

⚠️

WARNING: Some or all methods may not be appropriate, depending on patient pathology. The user is responsible for determining, which if any method is valid for interpretation.

⚠️

WARNING: The user is responsible for the accurate placement and correct category assignment of all regions of interest (ROIs), including those generated by preprocessing.

NOTE: The user can set the default calculation method for Integrated Analysis by selecting Tools > Preferences > Edit. From the file pull-down menu. Default Method selections are: None, All, or Last.

Integrated Analysis Overview (Adult is shown)
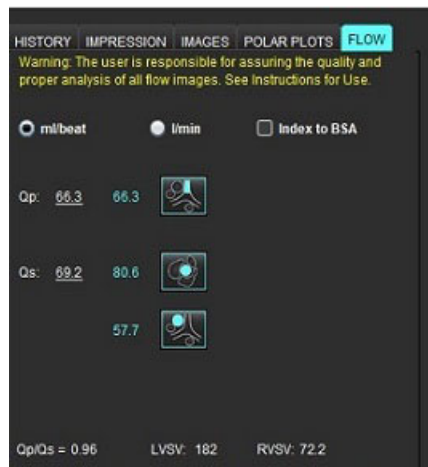
- ml/beat or l/min unit selection
- Index to BSA selection (height and weight must be entered on History tab)

Selections for Qp and Qs
- Qp: Displays the flow values from the MPA category
- Qs: Displays the flow values from either the pAAo or mAAo categories
- Qp/Qs result
- LV and RV stroke volume results displayed from the short axis function analysis

Underlined Qp or Qs values can be manually entered. To reset, delete the value and press enter on the keyboard.

Calculation method can be selected for the following:
- 1- Aortic regurgitation and RF%
- 2- Mitral regurgitation and RF%
- 3- Pulmonic regurgitation and RF%
- 4-Tricuspid regurgitation and RF%

Underlined regurgitant values can be manually entered. To reset, delete the value and press enter on the keyboard.

Table 7: Qp/Qs Selections

> **NOTE:**   If a vessel category has more than one measurement the average will be used.

> **NOTE:** For Qp or Qs, the value can be obtained from a single or a combination of the selections described in the table.

Result	Selection	Description
Qp		Flow result from the MPA category.
Qp (Pediatric)		Flow result from LPA + RPA
Qs		Flow result from the pAAo or mAAO category. Select both vessel types to average the Qs result.
Qs		Flow result from the LVOT category.
Qs (Pediatric)		Flow result SVC + pDAo
Qs (Pediatric)		Flow result SVC + IVC
Qs (Pediatric)		Flow result SVC + dDAo
Qp/Qs=		Result is based upon the above selections.

Calculate Qp/Qs

1.   To use the Integrated Analysis feature, select FLOW from the Reporting Tabs as shown in Figure 19.

   FIGURE 19. Reporting Tabs

2.   Prior to using the Integrated Analysis, confirm all vessel assignments and accurate contours in all categories.
   • If the vessel segmented is in the incorrect category perform a right mouse click and move to the correct category.

- If the vessel segmented is the incorrect vessel for that category, delete the Active ROI and click ![icon].

- If after using auto segmentation and the vessel is not identified correctly perform manual segmentation. Refer to Perform Auto or Manual Segmentation on page 87.

![warning icon] WARNING: The user is responsible for the accurate placement and correct category assignment of all regions of interest (ROIs), including those generated by preprocessing.

3. For Qp select ![icon].

4. For Qs select ![icon] or ![icon] or both vessels categories (the values from the two categories will be averaged).

5. The Qp/Qs result will be calculated as shown in Figure 20.

FIGURE 20. Qp/Qs Results (Adult shown)
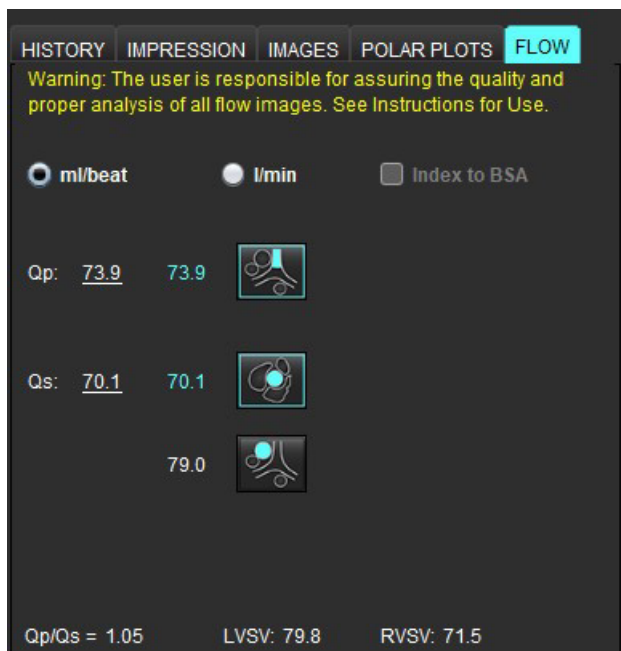
Table 8: Calculation Methods for Regurgitant Volume

Selection	Valve Type	Method Description
	Aortic	Direct from Flow Curve (Proximal)
	Aortic	Direct from Flow Curve (Mid)
	Aortic (Pediatric)	LVOT positive flow rate - Qp
LVSV-Qs-AR	Mitral	Indirect (LVSV used is obtained from short axis functions results)
LVSV-Qp-AR	Mitral	Indirect (LVSV value used is obtained from short axis functions results)
	Pulmonic	Direct from flow curve (MPA)
	Pulmonic (Pediatric)	Direct from flow curve LPA + RPA negative flow
RVSV-Qp-PR	Tricuspid	Indirect (RVSV used is obtained from short axis functions results)
RVSV-Qs-PR	Tricuspid	Indirect (RVSV used is obtained from short axis functions results)

Calculate Regurgitant Volume and Regurgitant Fraction (RF%)

1. To use the Integrated Analysis feature, select FLOW from the Reporting Tabs as shown in Figure 21.

   FIGURE 21. Reporting Tabs
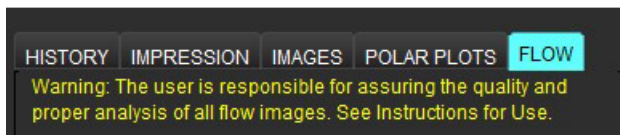
2. Prior to using the Integrated Analysis, confirm all vessel assignments and accurate contours in all categories.
   - If the vessel segmented is in the incorrect category perform a right mouse click and move to the correct category.
   - If the vessel segmented is the incorrect vessel for that category, delete the Active ROI and click .
   - If after using auto segmentation and the vessel is not identified correctly perform manual segmentation. Refer to Perform Auto or Manual Segmentation on page 87.

WARNING: The user is responsible for the accurate placement and correct category assignment of all regions of interest (ROIs), including those generated by preprocessing.

3. Select the calculation mode. Shown in Figure 22 the aortic regurgitation and regurgitant fraction is calculated by selecting and the pulmonic regurgitation and regurgitant fraction is calculated by selecting .

FIGURE 22. Method Selections for Aortic and Pulmonic (Adult Shown)
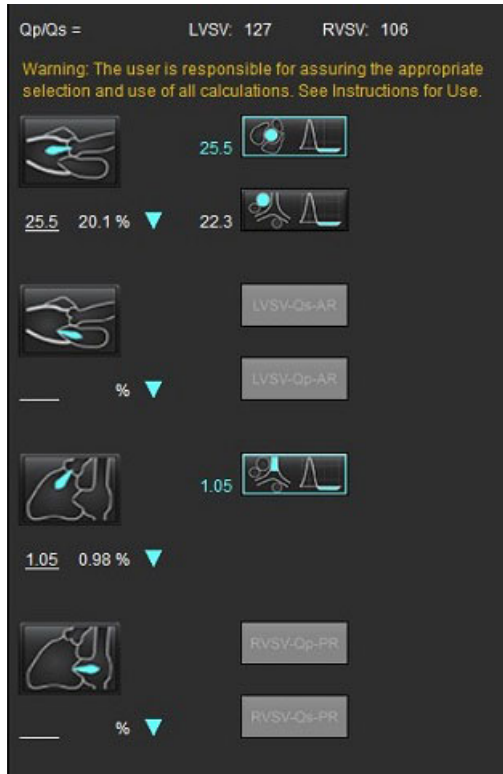
4. The regurgitant volume and RF% is calculated as shown in Figure 22. The denominator value used is the LVSV for aortic and mitral the RVSV for tricuspid and pulmonic. To enter a different value left click on the triangle and type in a new value into the field. To reset to the original value just clear the field and press enter on the keyboard, as shown in Figure 23.

NOTE: If the LVSV and RVSV are not available the RF% will not be automatically calculated.

FIGURE 23. RF Denominator

5. If more than one calculation method is selected the values are averaged for the regurgitant volume result.

6. For the calculation of mitral regurgitation and RF% there needs to be a Qp, Qs and an aortic regurgitation method selected, as shown in Figure 24.

7. For the calculation of tricuspid regurgitation and RF% there needs to be a Qp, Qs and a pulmonic regurgitation method selected, as shown in Figure 24.

8. Any result that is negative is considered an invalid result and will be indicated by a yellow triangle as shown in Figure 24.

FIGURE 24. Method Selections (Adult Shown)

Integrated Analysis Results Review

To review all results select .

NOTE: The selection of the flow units are at the top of the Integrated Analysis panel, select ml/beat or l/min.

NOTE: The results can be index to BSA by selecting the Index to BSA at the top of the Integrated Analysis panel. Both height and weight must be entered in the History tab.

FIGURE 25. Integrated Results

Measurement	Value
☑ Qp (ml/beat)	60.0
☑ Qs (ml/beat)	71.4
☑ Qp/Qs	0.84
☑ Aortic Regurgitant Volume (ml/beat)	0.70
☑ Aortic Regurgitant Fraction (%)	0.97
☑ Mitral Regurgitant Volume (ml/beat)	-0.17
☑ Mitral Regurgitant Fraction (%)	-0.23
☑ Pulmonic Regurgitant Volume (ml/beat)	1.02
☑ Pulmonic Regurgitant Fraction (%)	0.67
☑ Tricuspid Regurgitant Volume (ml/beat)	92.3
☑ Tricuspid Regurgitant Fraction (%)	60.2

Myocardial Evaluation

The user is responsible for the accurate and complete placement of all regions of interest (ROIs), including those generated or modified by the auto segmentation algorithms. The quantitative values generated by the software depend on the accurate and complete placement of these regions of interest and applied thresholding.

The study Preprocessing feature allows for the preprocessing of Late Enhancement. Refer to the suiteDXT Instructions for Use NS-03-039-0008.

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

There are four analysis tabs available:

- **Late Enhancement** - Determines myocardial segments of increased and low signal intensity.
- **T2** - Determines myocardial segments of increased signal intensity from black-blood imaging techniques.
- **Signal Differential** - Displays the Salvage Mass results using both Late Enhancement and T2 analysis and the T2 signal intensity (SI) ratio.
- **Early Enhancement** - Determines the ratio of the signal intensity of the myocardium and the percent of absolute myocardial enhancement from T1 weighted images.

WARNING: Following preprocessing, the user is responsible for assessing the accuracy of the entire analysis and making any necessary corrections. A comprehensive review should include:

- ROI placement/identification
- RV insertion location
- Signal intensity threshold

WARNING: The application assists in the analysis of the images only and does not automatically produce a clinical interpretation of the 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.

Analysis Tabs

Define Result Measurement Labels

The result measurement labels can be user defined; the default label is Enhancement.

1. Select Tools >Preferences >Edit.

2. Type in additional labels in the blank fields, as shown in Figure 1.

3. Select the default label.
   > This label will be used for all new analysis.

4. Click Save and Exit.

FIGURE 1. Define Labels
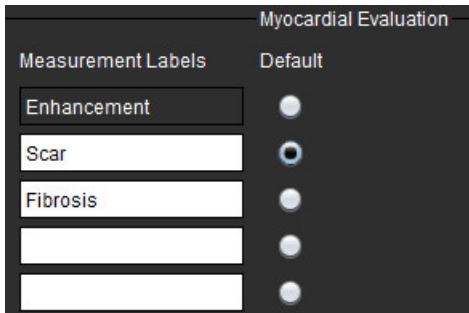
To change the label on the measurement table, left click on the arrow to select a new label.

FIGURE 2. ME Measurement Labels
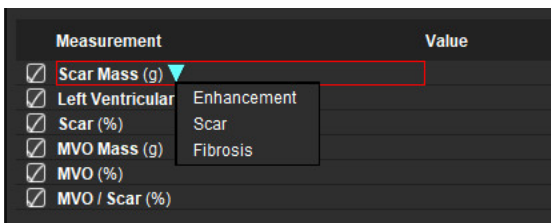
Late Enhancement Analysis Procedure

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

4. Select [icon] to perform Auto Segmentation.

5. Review all endocardial and epicardial traces, RV insertion point and the thresholding on each slice. Edit thresholding as necessary.

FIGURE 3. Myocardial Evaluation Analysis
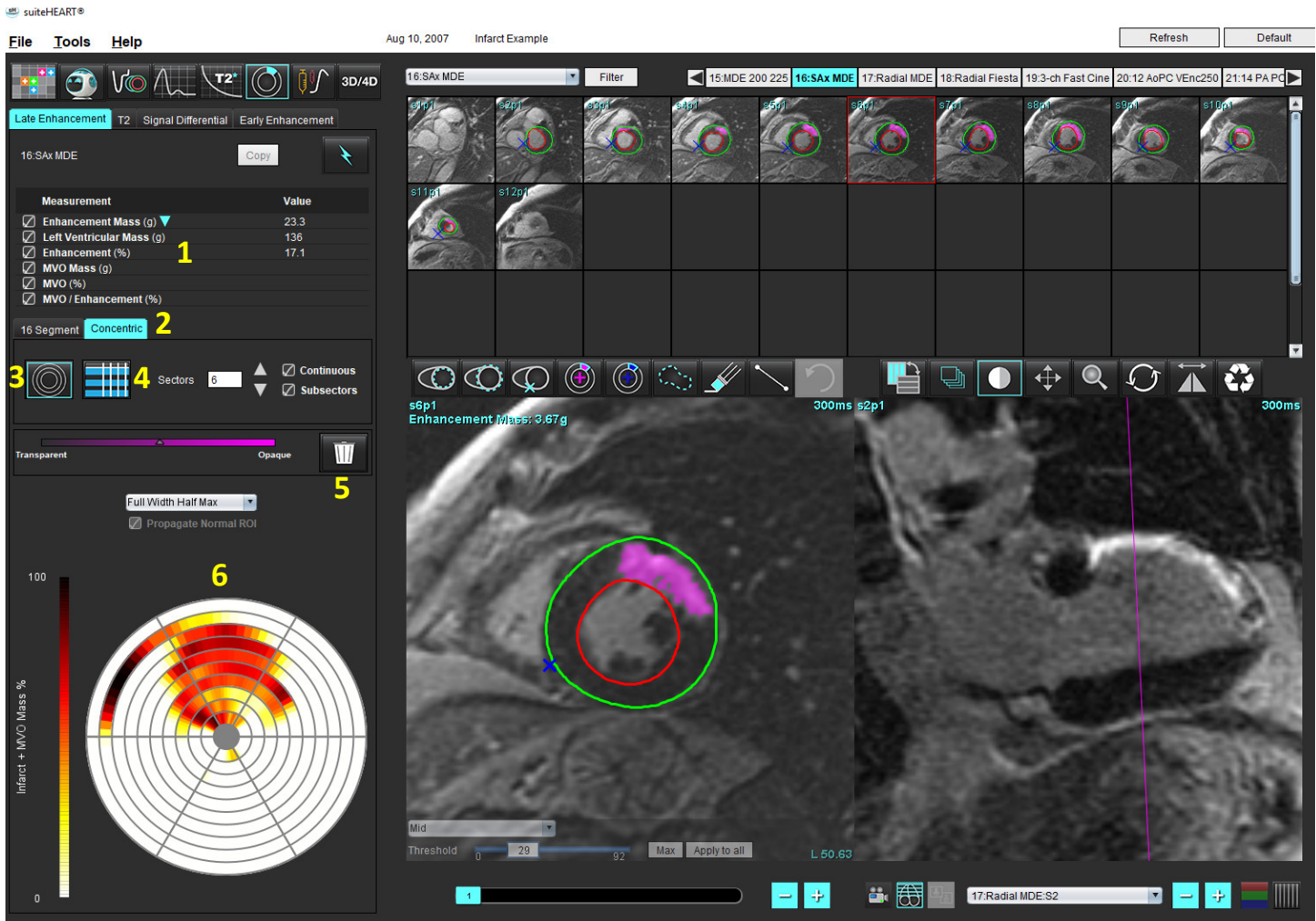
1. Result table, 2. Polar Plot Selection, 3. Polar Plot Display, 4. Result Table Display, 5.Delete, 6. Polar Plot
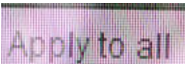
6. To perform manual segmentation, trace the LV endocardium on the most basal slice by selecting .

7. Trace LV epicardium by selecting .

8. Place the inferior RV insertion point by selecting .

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

10. Repeat steps 6 - 9 until the entire ventricle is segmented.

11. Confirm the base, mid and apical classification.

Threshold Selection

1. Select the appropriate threshold algorithm from the file pull-down menu (Figure).
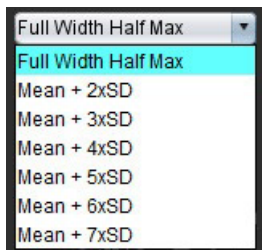
2. If required, click to maximize the threshold value for that slice. Click to apply that value to all slices. Use the slider bar to adjust the threshold algorithm for each slice, if needed.

3. For mean +2 to +7 SD results, place a normal ROI in a normal myocardium segment. This ROI is copied to all slices if the Propagate Normal ROI is checked.

Threshold Editing

1. To add high signal intensity regions select .

2. To add low signal intensity regions select .

3. To delete either signal intensity regions select small eraser tool or large eraser tool.

Polar Plot Display Formats

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

Option 1: 16 Segment polar plot
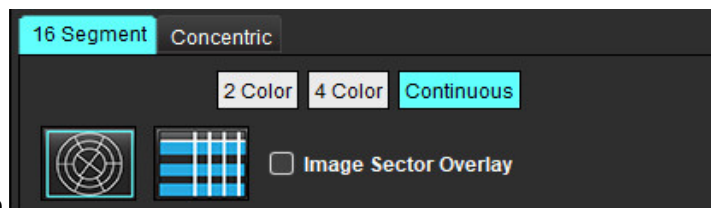
1. Select the **16 Segment** tab .

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

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

   To change the percent values, click and drag directly on the color divider.

FIGURE 5. Polar Plots

2 Color Polar Plot	4 Color Polar Plot	Continuous Color Polar Plot
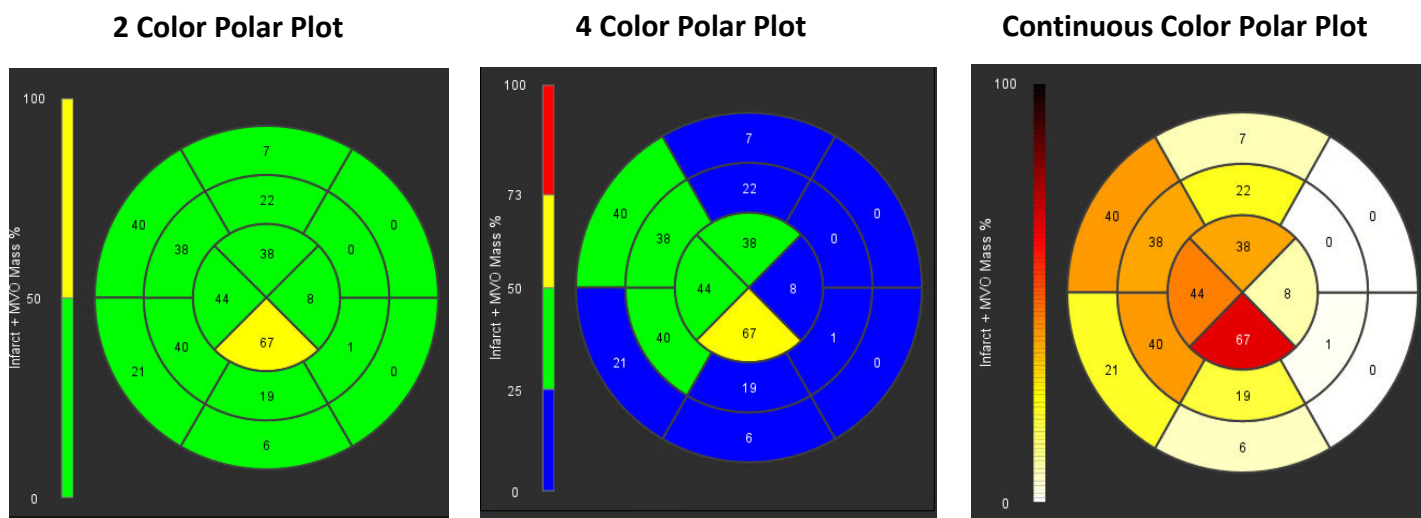
3. Select ▦ to display the Polar Plot Summary Table.

Option 2: Slice-by-Slice format

1. Select the **Concentric** tab.

FIGURE 6. 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%.

Click 🗑 to delete contours.

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

FIGURE 7. Myocardial Late Enhancement Images
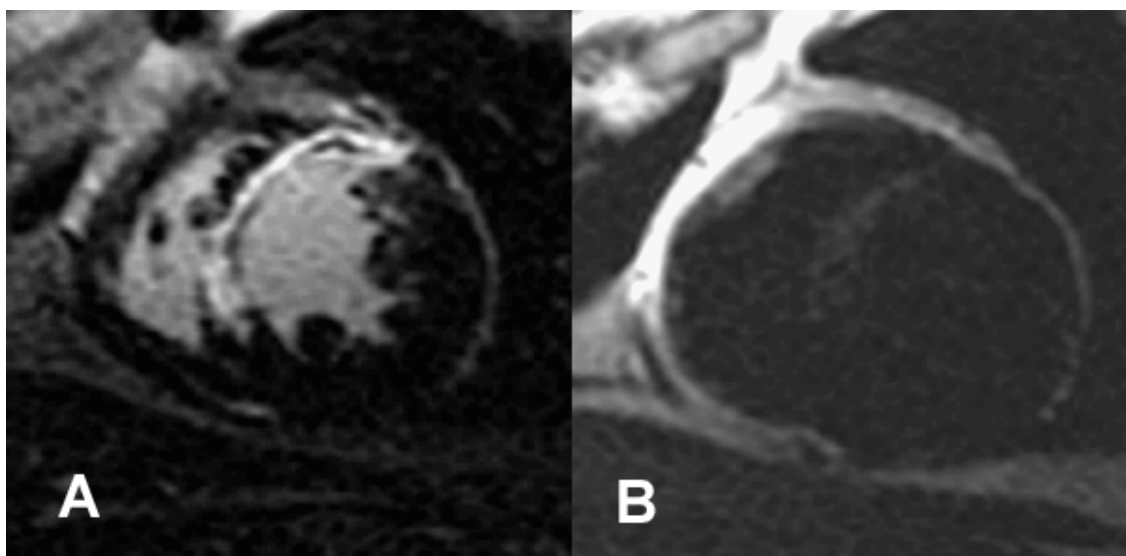
T2 Analysis

1. Select the T2 tab.

2. If the Late Enhancement series has been previously analyzed, the ROIs can be copied to the T2 series by selecting copy (see Figure 8).

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

FIGURE 8. Copy Button
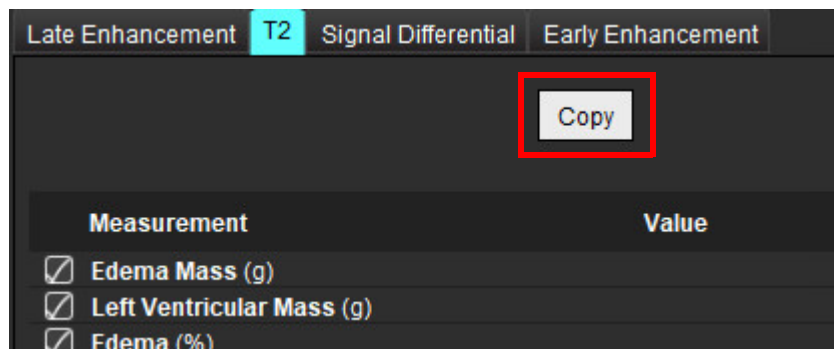
3. If there is no previous Late Enhancement analysis, the ROIs can be created manually.

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

5. Trace the LV epicardium by selecting .

6. Mark the inferior RV insertion point by selecting .

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

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

9. To perform a 2 Standard deviation thresholding, select the Add Normal ROI and place an ROI in a normal myocardium segment. This ROI is copied to all slices if the Propagate Normal ROI is checked. Review each slice location and adjust the ROI as necessary.

    NOTE: When the skeletal muscle ROI and Normal ROI are provided, the software performs the following calculation:

    Normalized myocardial T2 SI = SI myocardium / SI skeletal muscle;

    Threshold calculation: Threshold = 2 * STD NORMAL + AVG NORMAL

10. Select the first basal slice and use the slice classification pull-down to select Base. Confirm the classifications for the remaining slices. Use the slider bar to adjust the threshold algorithm for each slice, if needed.

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

    NOTE: Black-blood images may have insufficient flow suppression which could result in inaccurate signal intensity analysis and thresholding. Insufficient flow suppression can result in high signal intensity which may be confused with myocardial edema. Low signal intensity artifacts can cause a false low result.

Editing

To add regions of high T2 signal intensity, select .

To remove regions of high T2 signal intensity, select small eraser tool or large eraser tool.

Click to delete contours.

Combined Analysis

Late Enhancement and T2

The combined analysis mode allows for side-by-side analysis with editing tools for Late Enhancement and T2 (Edema) images.

> **NOTE:** To enable the combined analysis mode, the analysis of a short axis Late Enhancement series must be completed first using the Late Enhancement tab. T2 (Edema) images must be present in the same study.

1. Select ⬤.

2. Select an appropriate study with both Late Enhancement and T2 (edema) images. Complete the analysis procedure for Late Enhancement.

> **NOTE:** Review the thresholding for each short axis slice on the Late Enhancement tab prior to selecting combined analysis mode.
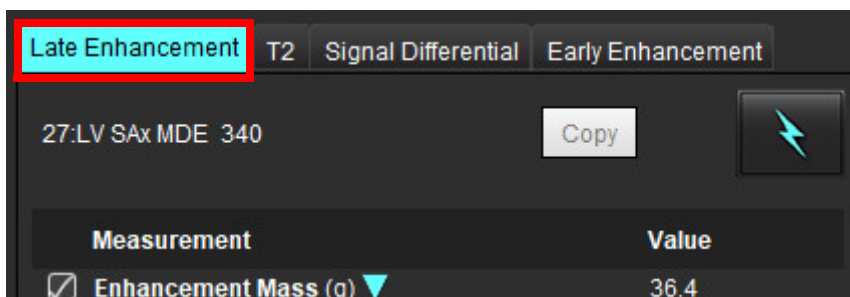
3. Select the T2 tab and complete the analysis procedure for the T2 series.
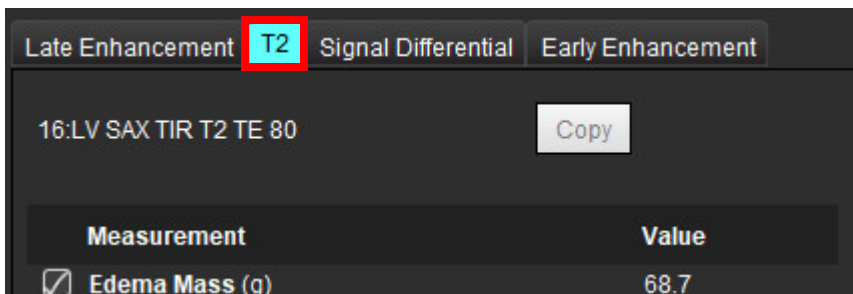
4. Select ![icon] to start combined analysis, as shown in Figure 9.

FIGURE 9. Combined Analysis Mode
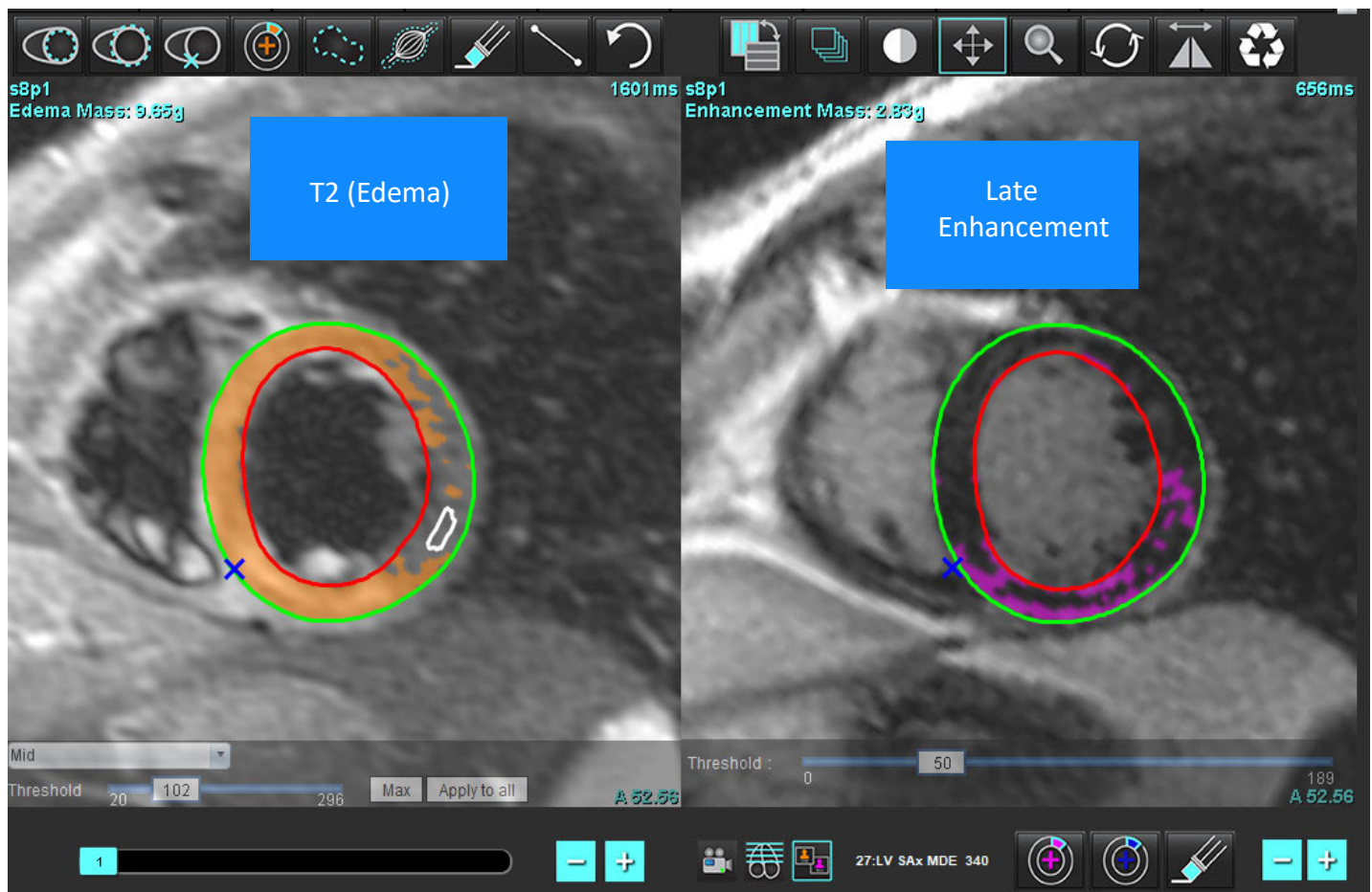
5. Upon selection, the previously analyzed Late Enhancement series will appear in the mode view window. This window then becomes an editor window for the Late Enhancement images.

6. For editing of the Late Enhancement images, use the editing tools located below the image viewport as shown in Figure 10.

    NOTE: Confirm all updates to the results directly on the Late Enhancement tab.

    NOTE: If the LV endocardium or LV epicardium ROIs are deleted, go back to the Late Enhancement tab to retrace.

FIGURE 10. Late Enhancement Editing Tools
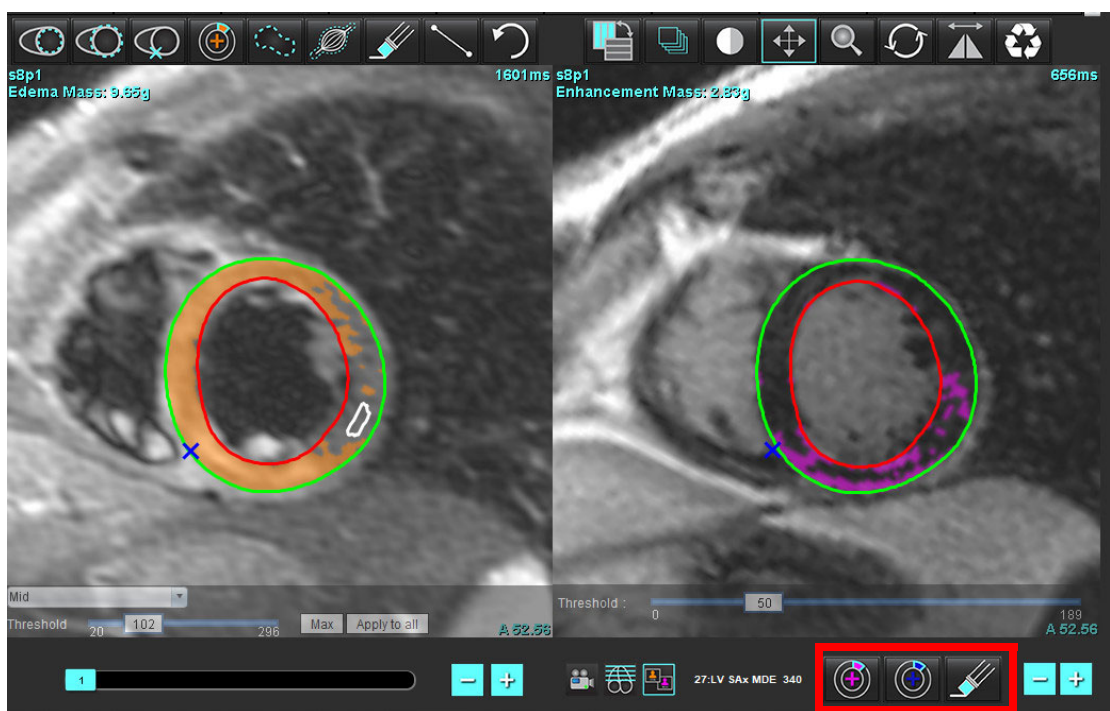
7. For editing of the T2 (Edema) series on the left, use the editing tools located above the image viewport, as shown in Figure 11.

FIGURE 11. T2 (Edema) Analysis Tools
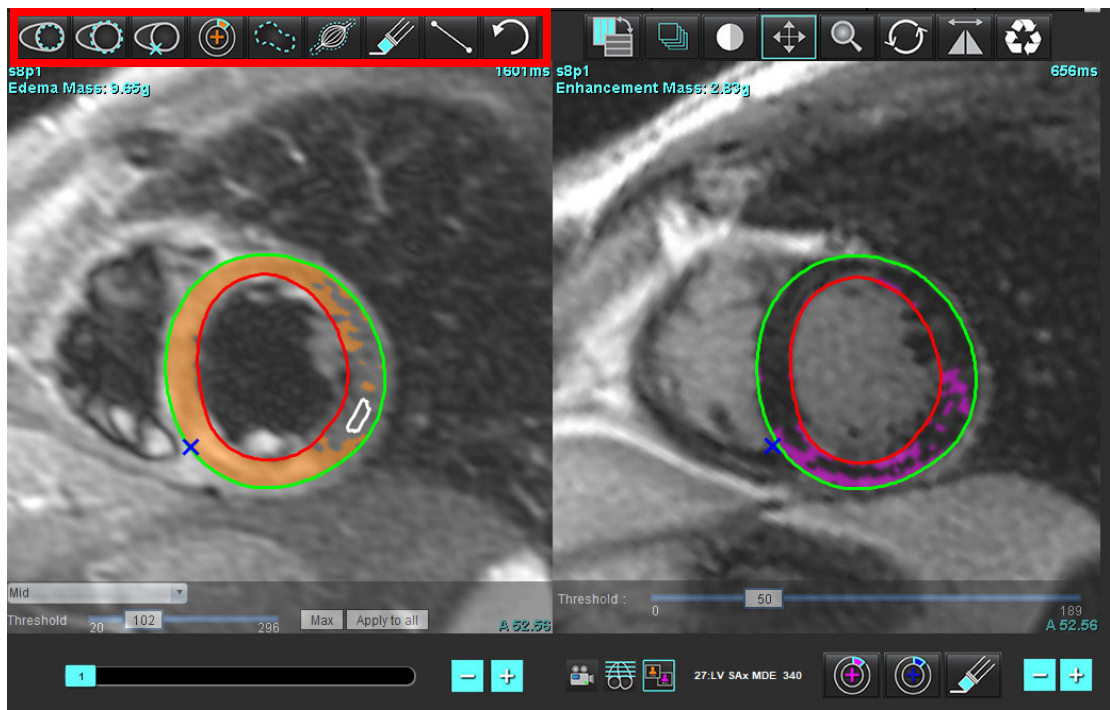
8. Use the minus and plus buttons to navigate to a different slice level for the Late Enhancement series, as shown in Figure 12.
    • Slice location information is located in the lower righthand corner of each viewport.

    NOTE: The slice location displayed for the Late Enhancement is determined by the slice location in the T2 (Edema) editor window. Use the minus/plus buttons to override this selection.

FIGURE 12. Slice Navigation Controls Late Enhancement
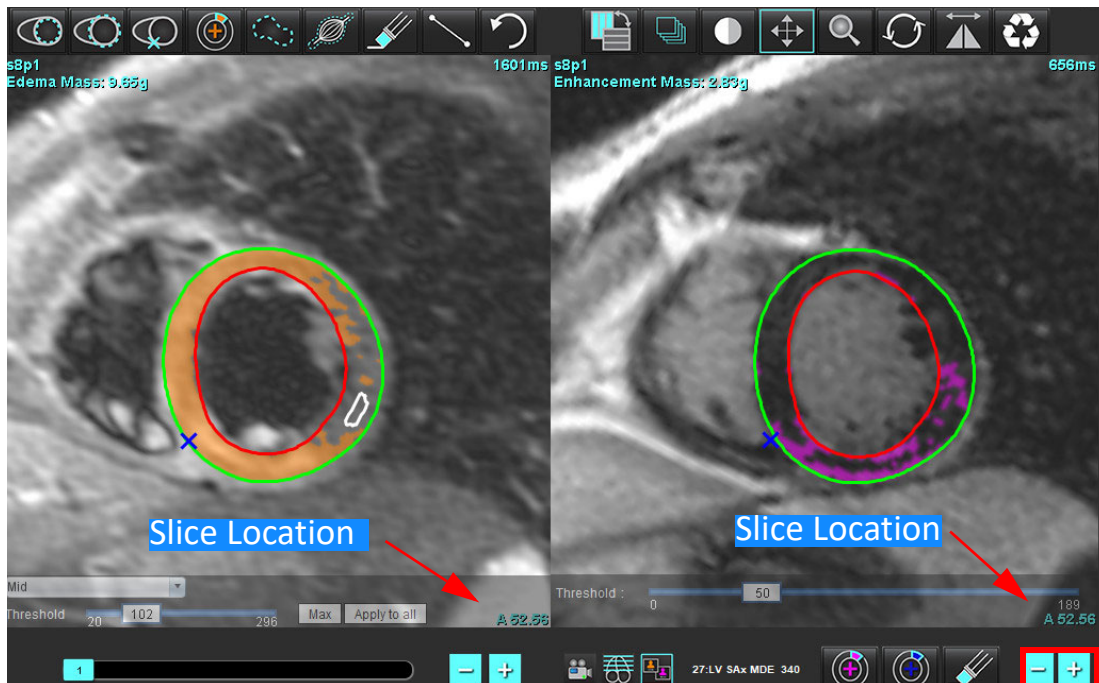
9. Use the minus and plus buttons located below the T2 (edema) editor viewport to navigate to a different slice level for both the Late Enhancement and T2 (Edema) series, as shown in Figure 13.

    NOTE: In combined analysis mode the plus and minus buttons on the left link slice navigation for both viewports.

FIGURE 13. Combined Slice Navigation Controls
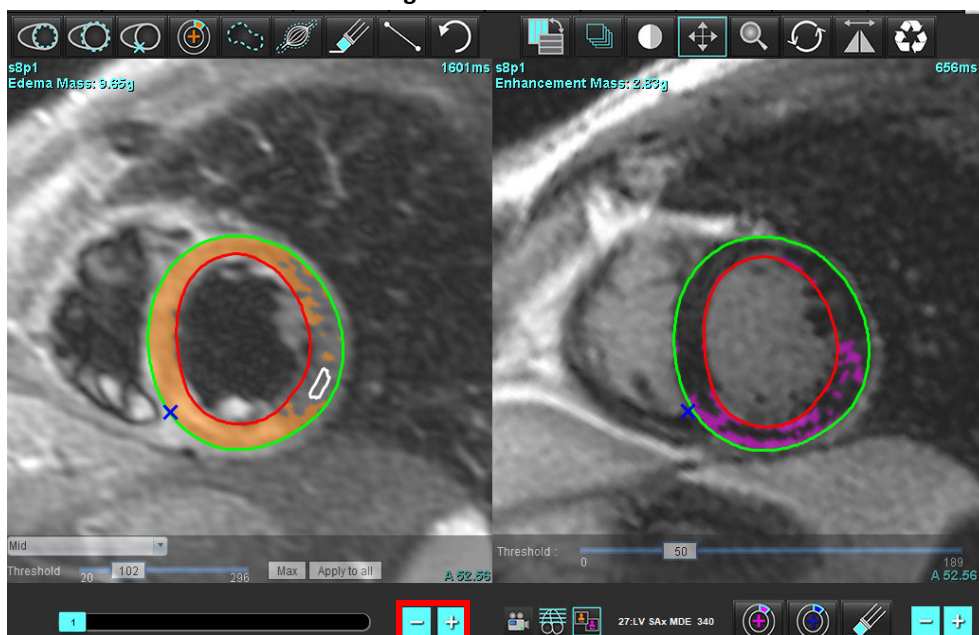
Signal Differential Results

Select the Signal Differential Tab

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

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

FIGURE 14. Signal Differential Tab

Measurement	Value
☑ Salvage Mass (g)	36.0

Slice	T2 SI Ratio	Myo SI	SM SI
1	---	---	---
2	1.4	113	78
3	1.3	132	103
4	1.0	145	145
5	1.5	153	101
6	1.2	134	114
7	1.1	138	125
8	1.4	209	144
9	1.1	198	186
10	1.1	209	183
11	1.3	238	181
12	1.4	259	190

Early Enhancement Analysis

Images required for the analysis is a short axis stack using a gated spin echo T1 sequence, Pre- and Post Enhancement. The analysis allows for the manual segmentation of the epicardium and endocardium on the initial series with a copy function. A local ROI can be used to analyze regions in the myocardium.

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

1. Select the Early Enhancement Tab.

2. Select the appropriate short axis T1 weighted series.
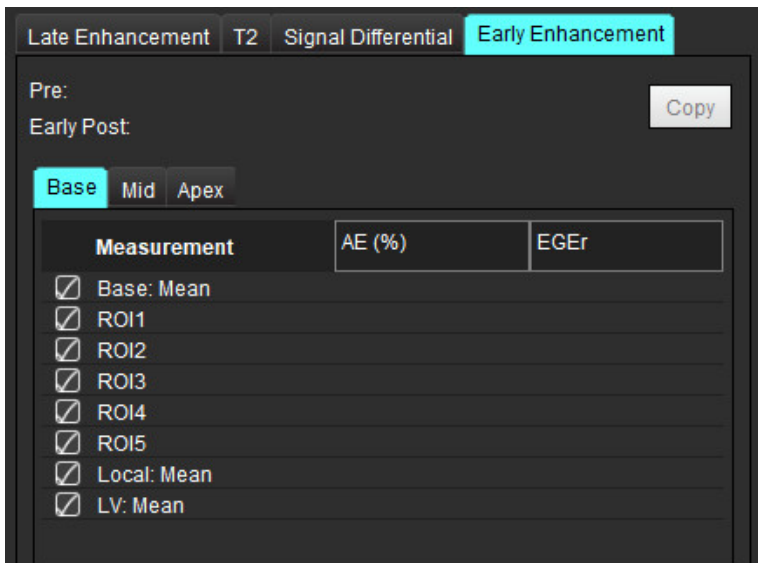
3. Trace the LV endocardium on the most basal slice by selecting .

4. Trace the LV epicardium by selecting .

5. Mark the inferior RV insertion point by selecting .

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

7. Repeat steps 3-6 until the entire ventricle is segmented.

8. Add an ROI in the skeletal muscle by selecting .

9. Select a basal slice location. Click the Slice Classification pull-down menu and select Base.

10. Confirm the base, mid and apical classifications for each slice.

11. To analyze a specific myocardial region, select and trace an ROI in the myocardium.

FIGURE 15. Slice Classification and Series Type Selection
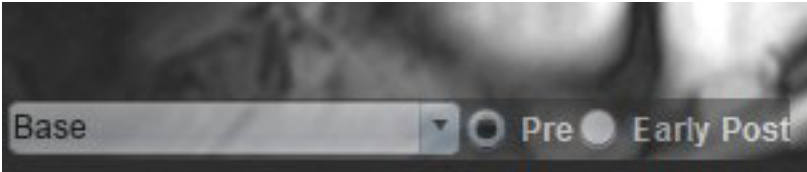
12. Select the series type of Pre.

> If the Early Post series was segmented first, select Early Post.

13. Select the appropriate short axis T1 weighted Early Post series type.

> If the Early Post series was segmented first, select the Pre series.

14. Select Copy.

15. Review all endocardial and epicardial traces, RV insertion and skeletal muscle placements and edit as necessary.

16. ROIs can only be copied when all ROIs and RV insertion, slice classification, series type (steps 3-12) have been completed on the selected series.

   NOTE: If an Endocardial or Epicardial trace is deleted use the Undo.

   NOTE: The skeletal ROI can be adjusted on each slice location. If deleted, the analysis will need to be redone.

17. Click and select **ALL: Early Enhancement** to remove all analysis.

   NOTE: To copy ROIs it is required that the number of slices match for each series to get accurate results; if the number of slices does not match, the copy button will not be available. The DICOM import process can be used to create the appropriate series that contains the same number of slices.

   NOTE: Acquisition parameters, such as matrix and FOV should be the same for each series for best results. After performing a copy, review the ROIs carefully on all of the slice locations and make appropriate edits.

Local ROI Tool

1. Select the appropriate Pre-enhancement short axis T1 weighted series.

2. Trace a local ROI in the specific myocardium region by selecting .

3. Add an ROI in the skeletal muscle by selecting .

4. Select the proper slice classification and the series type as shown in Figure 16.

FIGURE 16. Slice Classification and Series Type Selection

5. Select the appropriate short axis T1 weighted Early Post series type.

6. Select Copy.

7. Click and select **ALL: Early Enhancement** to remove all analysis.

Myocardial Evaluation References

Abdel-Aty H, Boyé P, Zagrosek A, Wassmuth R, Kumar A, Messroghli D, Bock P, Dietz R, Friedrich MG, Schulz-Menger J. Diagnostic performance of cardiovascular magnetic resonance in patients with suspected acute myocarditis: comparison of different approaches. J Am Coll Cardiol. 2005 Jun 7;45(11):1815-22. doi: 10.1016/j.jacc.2004.11.069. PMID: 15936612.

Amado LC, Gerber BL, Gupta SN, Rettmann DW, Szarf G, Schock R, Nasir K, Kraitchman DL, Lima JA. Accurate and objective infarct sizing by contrast-enhanced magnetic resonance imaging in a canine myocardial infarction model. J Am Coll Cardiol. 2004 Dec 21;44(12):2383-9. doi: 10.1016/j.jacc.2004.09.020. PMID: 15607402.

Berry C, Kellman P, Mancini C, Chen MY, Bandettini WP, Lowrey T, Hsu LY, Aletras AH, Arai AE. Magnetic resonance imaging delineates the ischemic area at risk and myocardial salvage in patients with acute myocardial infarction. Circ Cardiovasc Imaging. 2010 Sep;3(5):527-35. doi: 10.1161/CIRCIMAGING.109.900761. Epub 2010 Jul 14. PMID: 20631034; PMCID: PMC2966468.

Ferreira VM, Schulz-Menger J, Holmvang G, et al. Cardiovascular Magnetic Resonance in Nonischemic Myocardial Inflammation: Expert Recommendations. J Am Coll Cardiol. 2018;72(24):3158-3176. doi:10.1016/j.jacc.2018.09.072.

Galea N, Francone M, Fiorelli A, Noce V, Giannetta E, Chimenti C, Frustaci A, Catalano C, Carbone I. Early myocardial gadolinium enhancement in patients with myocarditis: Validation of "Lake Louise consensus" criteria using a single bolus of 0.1mmol/Kg of a high relaxivity gadolinium-based contrast agent. Eur J Radiol. 2017 Oct;95:89-95. doi: 10.1016/j.ejrad.2017.07.008. Epub 2017 Jul 27. PMID: 28987703.

T1 Mapping Analysis

This feature allows for the signal quantification of the longitudinal spin-lattice relaxation time (T1). The application supports T1 analysis for both Native (non-enhanced) and Post enhancement images and the calculation of the extracellular volume fraction (ECV).

Required Images: Inversion or saturation recovery images with varying inversion times (TI) or inline maps. Series that have motion corrected applied are recommended for analysis. Representative slice locations for the left ventricular base, mid and apex are recommended.

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: The user is responsible for the accurate placement of all regions of interest (ROIs), including those generated by auto segmentation.

NOTE: To set the T1 Mapping preferences, Select **Tools > Preferences > Edit**. Select the T1/T2 Mapping tab.

NOTE: It is recommended to set the **Auto Compose Series for Analysis** in preferences for your scanner type. The analysis requires that all slice locations are present in the series. Select **Tools > Preferences > Edit**. Select the T1/T2 Mapping tab.
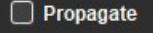
FIGURE 1. T1 Mapping Interface
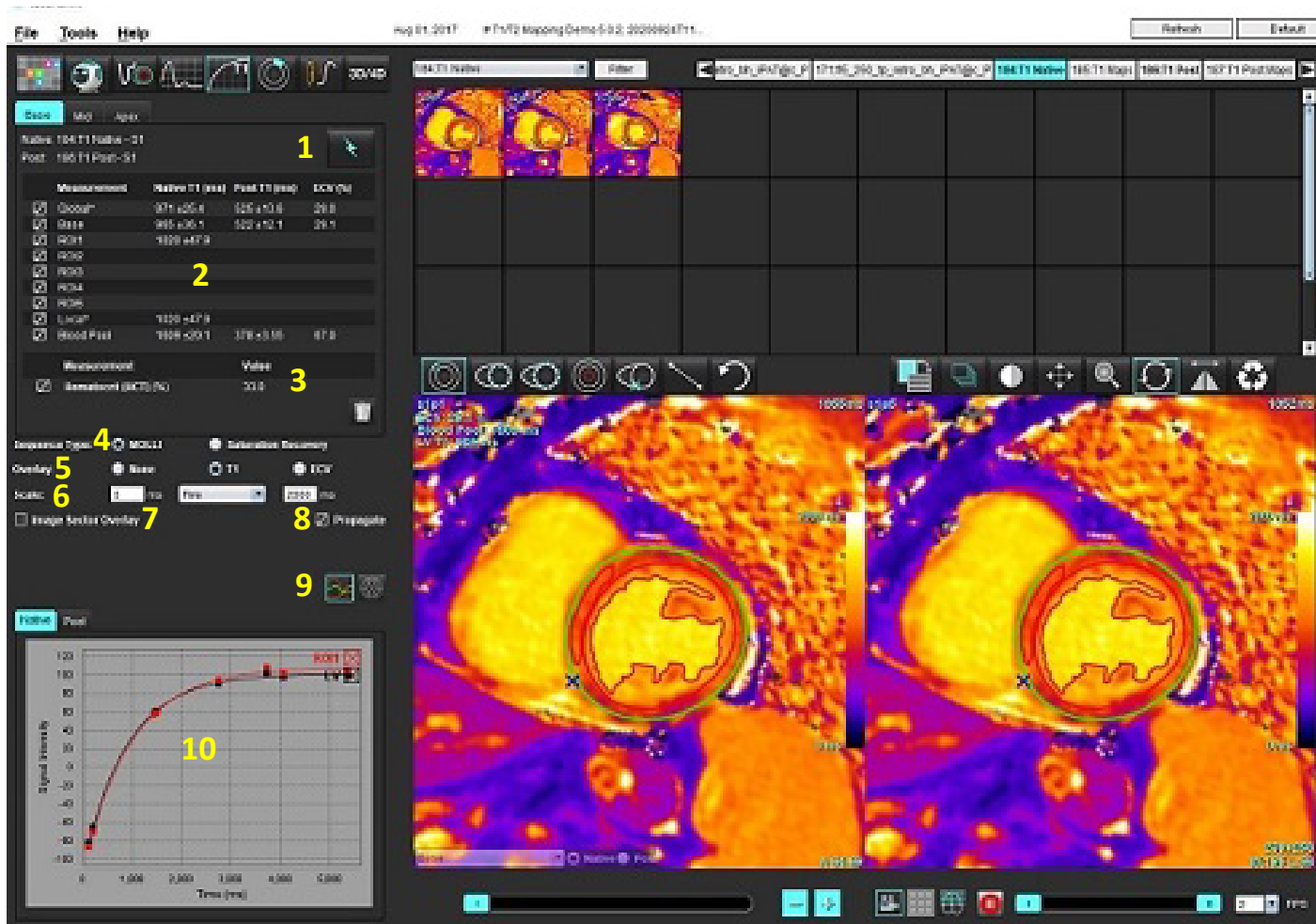
1. Auto Segmentation, 2. T1 Results, 3. Hematocrit entry, 4. Sequence Type selection, 5. Colormap overlay selections, 6. Colormap options,
7. Display sector overlay, 8. Editing propagation, 9. Curve or 16-Segment Polar plot, 10. T1 Curves

Perform Analysis

1.   Select [T1 icon].

2.   Select the appropriate T1 Mapping series.

3.   The color map will be displayed automatically if the preference for overlay has been selected.

4.   To select a different color scale use the file-pull down menu.

5.   To create a Global T1 result select [icon].

6.   Review all endocardial and epicardial traces, RV insertion point and blood pool placement.

7.   Edit any inaccurate contours.

8. To edit a single inversion time click off the ☐ Propagate .

9. Confirm slice classification for each slice location and series type.
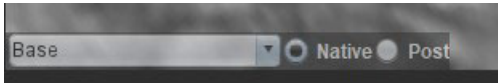
> **NOTE:** If a stack of short axis images are segmented the T1 result for the Base, Mid or Apex and the 16-segment polar plot sectors will be averaged based upon the slice classification. The blood pool T1 result will not be averaged.

10. To calculate the ECV perform auto segmentation on both the Native and Post Series.

11. Review all endocardial and epicardial traces, RV insertion point and blood pool placement on both series.

12. To measure a segment of the myocardium select .

> **NOTE:** If a local ROI is used to calculate the ECV there must be a local ROI and a blood pool ROI for both Native and Post.

> **NOTE:** Up to five Local ROI measurements can be created on an image for Base, Mid and Apex.

13. Select to place a blood pool ROI, if needed.

14. Enter the Hematocrit (HCT) value.

15. The ECV result (%) will be displayed in the result table.

16. Manual segmentation can be performed.

- Trace the LV endocardium by selecting .

- Trace the LV epicardium by selecting .

- Mark the RV insertion point by selecting .

- If the ECV is to be calculated place the blood pool ROI by selecting .

- Confirm slice classification for each slice location and series type.

Reference: Wong. et al,. "Association Between Extracellular Matrix Expansion Quantified by Cardiovascular Magnetic Resonance and Short-Term Mortality." Circulation (2012):126:1206-1216.

16-Segment Polar Map

NOTE: ECV Polar Plot requires that the ECV analysis is completed.

1. Complete the Global T1 analysis for Base, Mid and Apex tabs.

2. Confirm the RV insertion point for each slice location.

3. Confirm the correct slice classification and series type.

4. Select the 16 Segment Polar Plot .

5. Select to show the sector overlay directly on the image.

6. Select Graphs to return to the T1 curves.

T1 Result Values Format

Result	DICOM Images		Map Images
Global	mean +/- std		mean +/- std
Base/Mid/Apex	value +/- error		mean +/- std
Local ROIs	value +/- error		mean +/- std
Local	mean +/- std		mean +/- std
Blood Pool	value +/- error		mean +/- std

Delete Contours

Click ![trash icon] on the interface to delete **ALL** contours on the series selected.

Left mouse click on a contour followed by a right mouse click to delete a single contour or select ![clock trash icon] to delete contours on all time points.

Review the T1 Curves

1. The curve fitting results show the signal behavior from the image data. In cases of image artifacts due to misregistration, breathing artifacts or arrhythmias the curve fit may not be optimal.

2. A signal intensity point can be eliminated from the calculation by clicking directly on the point on the graph and selecting the contour on the image, which turns purple.

3. Select delete from the right mouse (click and hold) or select the keyboard delete.
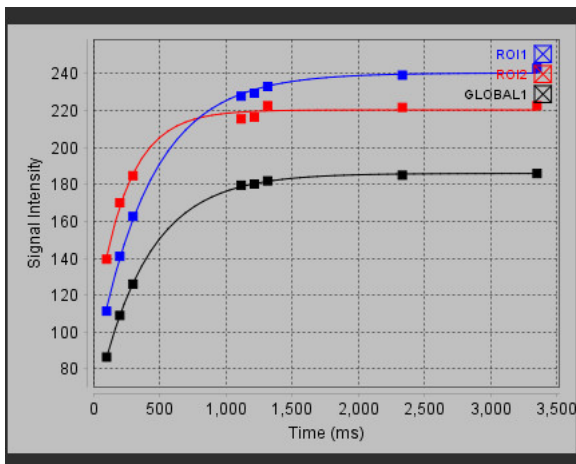
WARNING: The results of the T1 curve fit should be reviewed by a properly trained and qualified user.

Result	Equation Reference	Fit Type
T1 Look-Locker (MOLLI)	y=A-B exp(-t/T1*)	Nonlinear curve fitting using a Levenberg-Marquardt algorithm*

Reference: *Messroghli D. R. et al,. "Modified Look-Locker Inversion Recovery (MOLLI) for High Resolution T1 Mapping of the Heart." Magnetic Resonance in Medicine (2004) 52: 141-146.

T2 Mapping Analysis

This feature allows for the signal quantification of the T2 relaxation time. T2 mapping is a tissue characterization technique.

Required Images: T2 preparation sequence with a steady-state free precession readout with varying echo times (TE) or inline maps. Representative slice locations for the left ventricular base, mid and apex are recommended.

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

There are 2 fitting correction methods a 2-parameter fit where 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 uses a non-linear approach.

NOTE: Severe image wrap can cause the noise calculation to fail for the 2-parameter fit. It is important to analyze images that do not have phase wrap.

⚠️

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: The user is responsible for the accurate placement of all regions of interest (ROIs), including those generated by auto segmentation.

NOTE: To set the T2 Mapping preferences, Select **Tools > Preferences > Edit**. Select the T1/T2 Mapping tab.

NOTE: It is recommended to set the **Auto Compose Series for Analysis** in preferences for your scanner type. The analysis requires that all slice locations are present in the series. Select **Tools > Preferences > Edit**. Select the T1/T2 Mapping tab.

FIGURE 1. T2 Mapping Interface
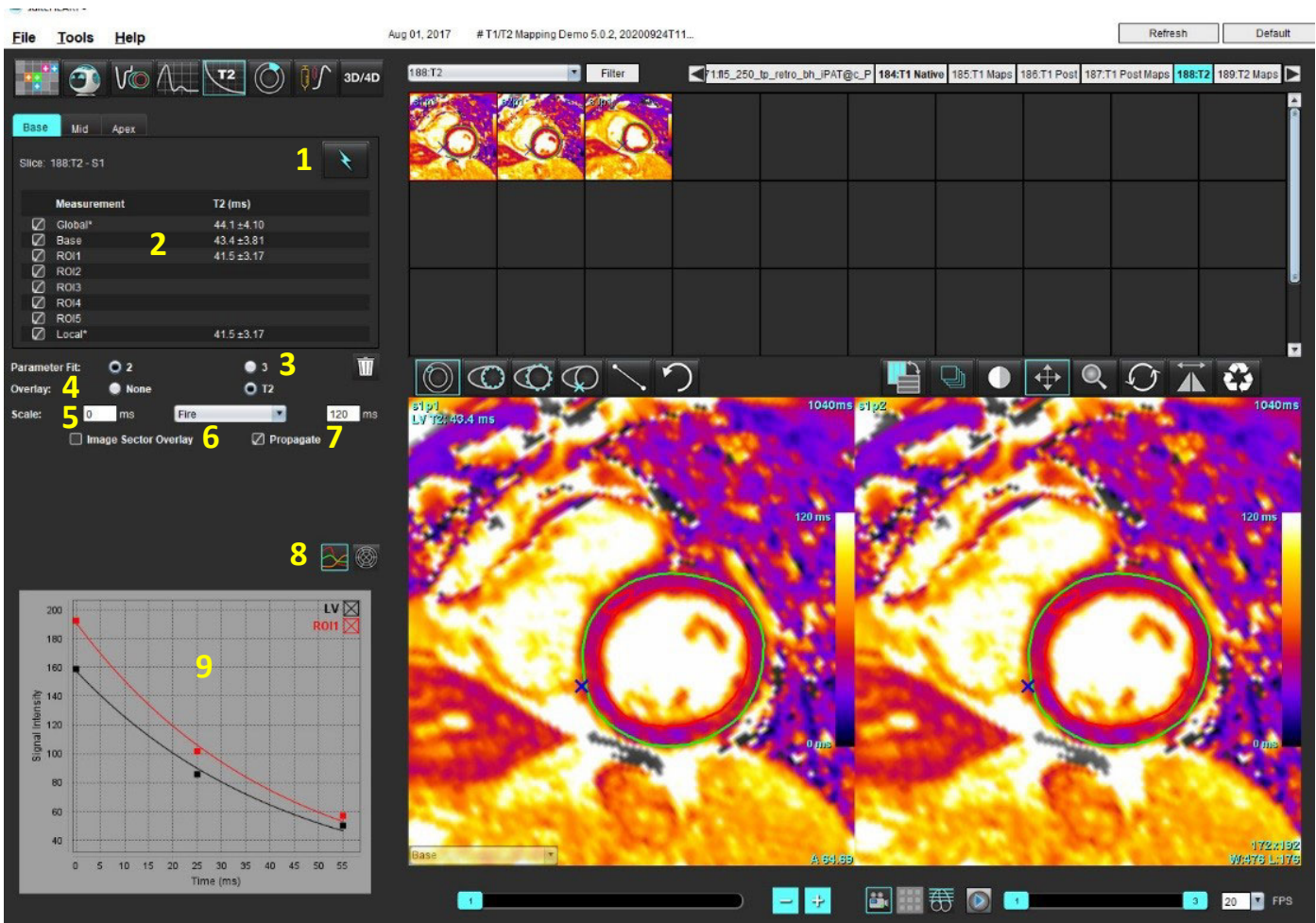
1. Auto Segmentation, 2. T2 Results, 3. Parameter fit selection 4. Colormap overlay selections, 5. Colormap options 6. Display sector overlay, 7. Editing propagation, 8. Curve or 16-Segment Polar plot, 9. T2 Curves

Perform Analysis

1. Select ![T2 icon].

2. Select the appropriate T2 Mapping series.

3. For the fitting correction select either a 2-Parameter or a 3-Parameter Fit.

4. Set the overlay preference to automatically display the color map, if desired.

5. Use the file-pull down menu to select a different color scale.

6. Create a Global T2 result by selecting ![lightning icon].

7. Review all endocardial and epicardial traces and the RV insertion point.

8.   Edit any inaccurate contours.

9.   To edit a single echo time click off the [Propagate] .

10.   Confirm slice classification for each slice location and series type.

Base

>   **NOTE:**   If a stack of short axis images are segmented the T2 result for the Base, Mid or Apex and the 16-segment polar
>   plot sectors will be averaged based upon the slice classification.

11.   To measure a segment of the myocardium select [icon] .

>   **NOTE:** Up to five Local ROI measurements can be created on an image for Base, Mid and Apex.

12.   Manual segmentation can be performed.

- Trace the LV endocardium by selecting [icon] .

- Trace the LV epicardium by selecting [icon] .

- Mark the RV insertion point by selecting [icon] .

- Confirm slice classification for each slice location.

16-Segment Polar Map

1.   Complete the Global T2 analysis for Base, Mid and Apex.

2.   Confirm the RV insertion point for each slice location.

3.   Confirm the correct slice classification.

4.   Select the 16 Segment Polar Plot [icon] .

5. Select ![Image Sector Overlay] to show the sector overlay directly on the image.
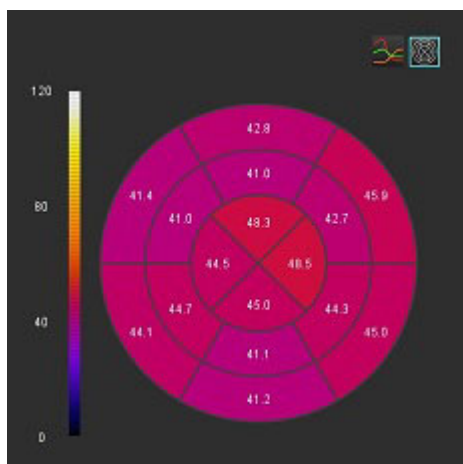
6. Select Graphs ![icon] to return to the T2 curves.

T2 Result Values Format

Result	DICOM Images		Map Images
Global	mean +/- std		mean +/- std
Base/Mid/Apex	value +/- error		mean +/- std
Local ROIs	value +/- error		mean +/- std
Local	mean +/- std		mean +/- std

Delete Contours

Click ![trash icon] on the interface to delete **ALL** contours on the series selected.

Left mouse click on a contour followed by a right mouse click to delete a single contour or select ![icon] to delete contours on all time points.

Review the T2 Curves

1. The curve fitting results show the signal behavior from the image data. In cases of image artifacts due to wrap, misregistration, breathing artifacts or arrhythmias the curve fit may not be optimal.

2. A signal intensity point can be eliminated from the calculation by clicking directly on the point on the graph and selecting the contour on the image, which turns purple.

3. Select delete from the right mouse (click and hold) or select the keyboard delete.

![warning icon]

WARNING: The results of the T2 curve fit should be reviewed by a properly trained and qualified user.
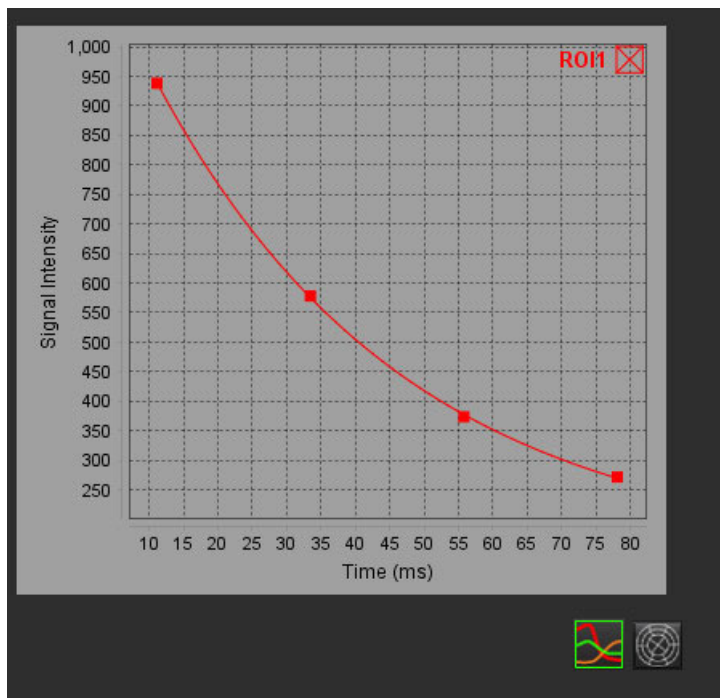
Myocardial Perfusion

The Myocardial Perfusion analysis mode allows the user to review and analyze myocardial perfusion images.

> **NOTE:** Semi-quantitative analysis is supported. If a dual sequence series is available a shading correction feature can be applied.

⚠️ CAUTION: Parameters of upslope and relative upslope may not be accurate on images that shading correction has not been performed.

⚠️ WARNING: The application assists in the analysis of the images only and does not automatically produce a clinical interpretation of the 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.

FIGURE 1. Myocardial Perfusion Analysis Interface
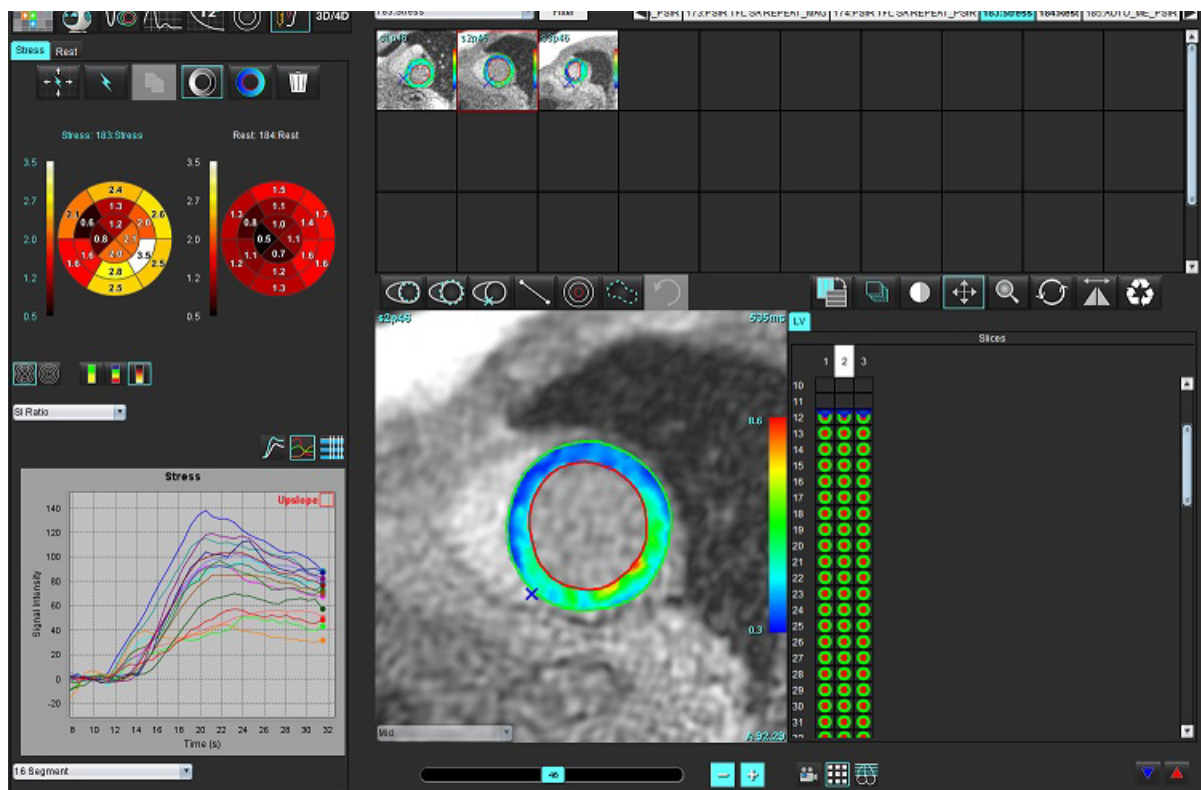
Table 1: Analysis Tools

	Propagate all slices, all phases.
	Propagate all phases, single slice.
	Perform auto-segmentation.
	Recalculate analysis after edit. (Only if auto segmentation has been performed.)
	Copy / paste contours over all phases.
	Recalculate analysis after edit. (Only if copy / paste has been performed.)
	Shading correction applied, only available for a dual sequence series.
	Display Segment color overlay.
	Display no overlay.
	Display pixel-wise color overlay for calculated parameter.
	Graph display.
	Display graphs of stress and rest.
	Display parameter results table.
	16 Segment or Concentric Polar Plot selection.
	2-Color, 4-Color or Continuous Polar Plot color selection.
	Concentric Polar Plot Selections.

Perform Myocardial Perfusion Analysis

1. Select .

2. Select the tab for either Stress or Rest.
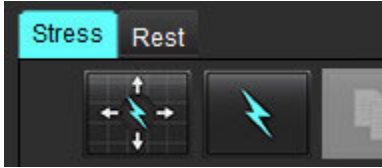
3. Select the myocardial perfusion series.

4. Select to perform Auto Segmentation and analysis calculation.

5. Review all endocardial and epicardial traces, RV insertion point on each slice and edit as necessary.

6. Confirm the base, mid and apical classification.

7. To perform manual segmentation, select to draw the endocardial contour on a single slice or all slices.

8. Select to draw the epicardial contour on a single slice or all slices.

9. Select to copy / paste the contours to all phases.

10. Place the inferior RV insertion point by selecting .

11. Review all endocardial and epicardial traces, RV insertion point on each slice and edit as necessary.

12. Confirm the base, mid and apical classification.

13. To choose the start and end phases select .

14. Click to assign the start phase, then click directly on the cell in the matrix.

15. Click to assign the end phase, then click directly on the cell in the matrix.

Contour Editing

When an edit is performed the analysis must be recalculated. The edit warning symbol will appear. Click [icon] to perform the recalculation.

Review Results: 16 Segment Polar Plot

1. Select to review the calculated parameters from the file pull-down menu. See Figure 2.

    Placing the cursor over a segment on the polar plot will highlight the corresponding graph for that segment.

FIGURE 2. Calculated Parameters Pull-down Menu
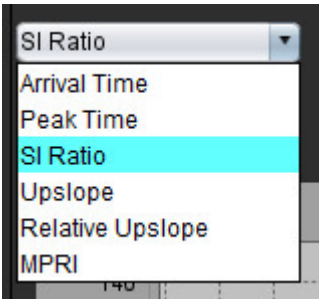
Review Graph/Table Results

1. Select to review graph results from the file pull-down menu, Figure 3, located on the lower left under the graph display.

2. Click [icon] to display the graphs.

    When displaying the segment color overlay on the image, placing the cursor directly on a colored segment will highlight the corresponding graph for that segment.

3. Click [icon] to display the parameter results.

FIGURE 3. Graph Results
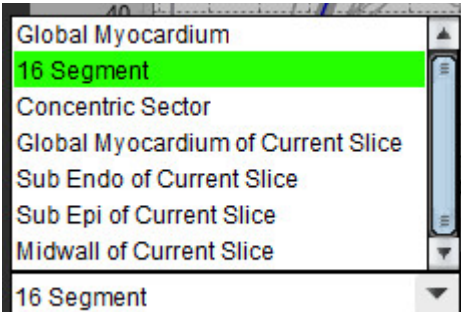
Calculate Relative Upslope (RU) and Reserve Index (RI)

1. Select and place an ROI in the blood pool at the basal slice level.

2. To delete the blood pool ROI right mouse click and select

    NOTE: For the calculation of the reserved index, both Stress and Rest analysis must be present.

CAUTION: Myocardial Perfusion result parameters of upslope and relative upslope may not be accurate on images that shading correction has not been performed.

Definition of Parameters Calculated from the Myocardial Perfusion Curve
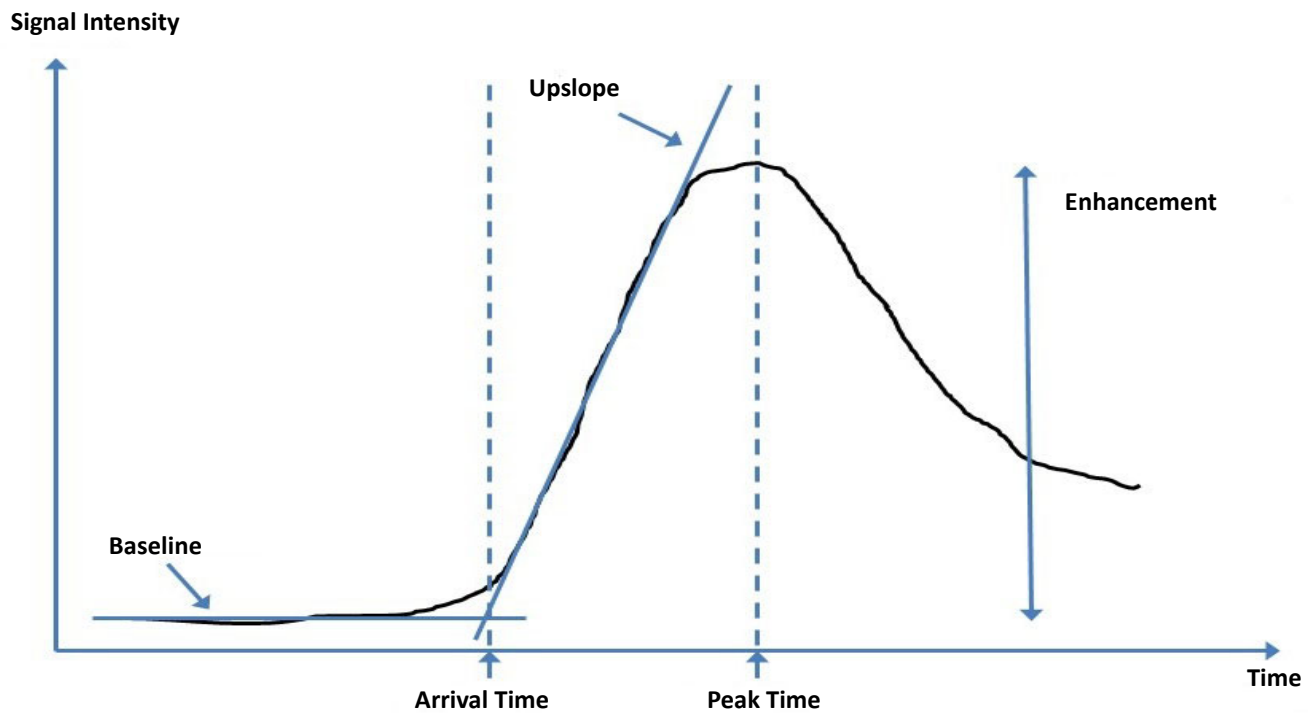
Arrival Time	time (in seconds) of the intersection of the baseline and upslope
Peak Time	time (in seconds) of which the signal intensity reaches maximum
SI Ratio	SI(peak time - baseline)/ baseline
Upslope	The upslope is calculated by the weighted linear fitting using points between arrival time and peak time
Relative Upslope	RU = myocardial upslope / blood pool upslope
Reserve Index	The myocardial reserve index (RU) is defined as: RI = RU STRESS / RU REST

Patent Foramen Ovale (PFO) Analysis

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

WARNING: The application assists in the analysis of the images only and does not automatically produce a clinical interpretation of the 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 **File > Select Analysis > PFO**.

2. Select a realtime series.

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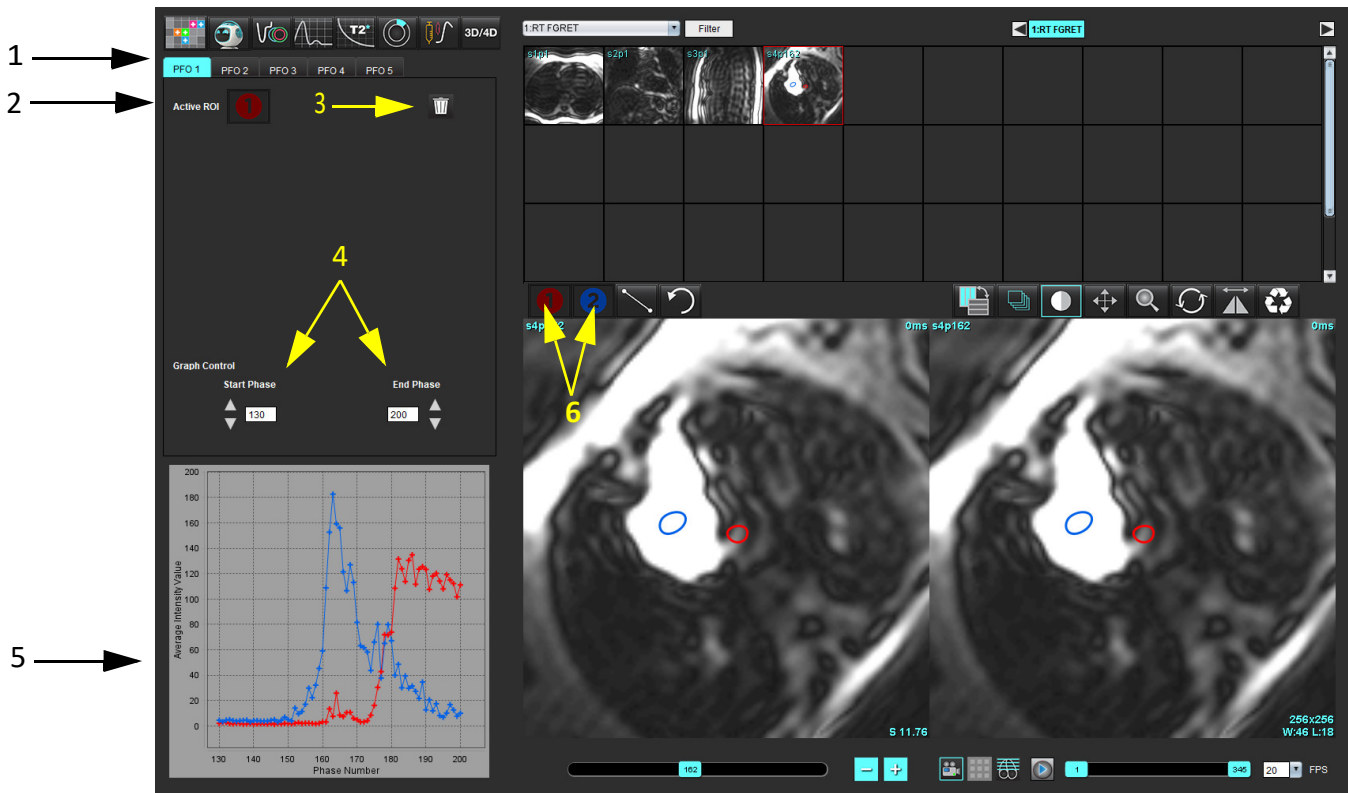
1. PFO editable tabs, 2. Active ROIs, 3. Delete, 4. Start and End phase, 5. Signal Intensity vs Phase curve, 6. PFO Analysis icons

Select Atrial Anatomy

Select an image 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 [1].

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 [2].

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

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

FIGURE 2. PFO Curve Results
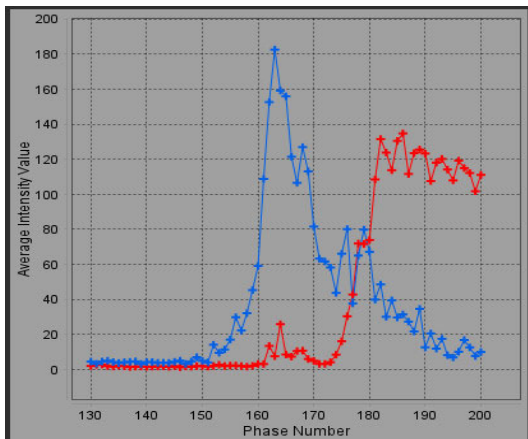
Review Curve Data and Select Phase Range

1. Review the curves in the report window and adjust the **Start Phase** and **End Phase**.

2. Use the up and down arrows to select the **Start Phase** and **End Phase** to set the phase range for curve display.

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

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

FIGURE 3. Start and End Phase Selection Screen

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

Editing Contours

Editing multiple phases at a single slice location:

1. Select the slice location

2. Select

3. Select the first phase of the range of phases to be edited.

4. Depress and hold the shift key and select the last phase of the range to be edited.
    The selected thumbnails will appear highlighted with a red border.

5. Edit the contour in the image editor window.
6. Deselect the contour by either clicking on the image away from the selected contour or move the cursor out of the editor window.

ROI editing can be controlled by setting the scope.

Select the proper scope function from the Image View.

 Scope All – Applies ROI edits to all phases.

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

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

Delete Contours

Click to delete **ALL** contours.

Left mouse click on an image followed by a right mouse click select to delete contours on all time points.

Review Final Curve Results

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

T2Star

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

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

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

 Where:

Table 1:

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

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

Heart Analysis Procedure

FIGURE 1. T2Star Analysis Interface
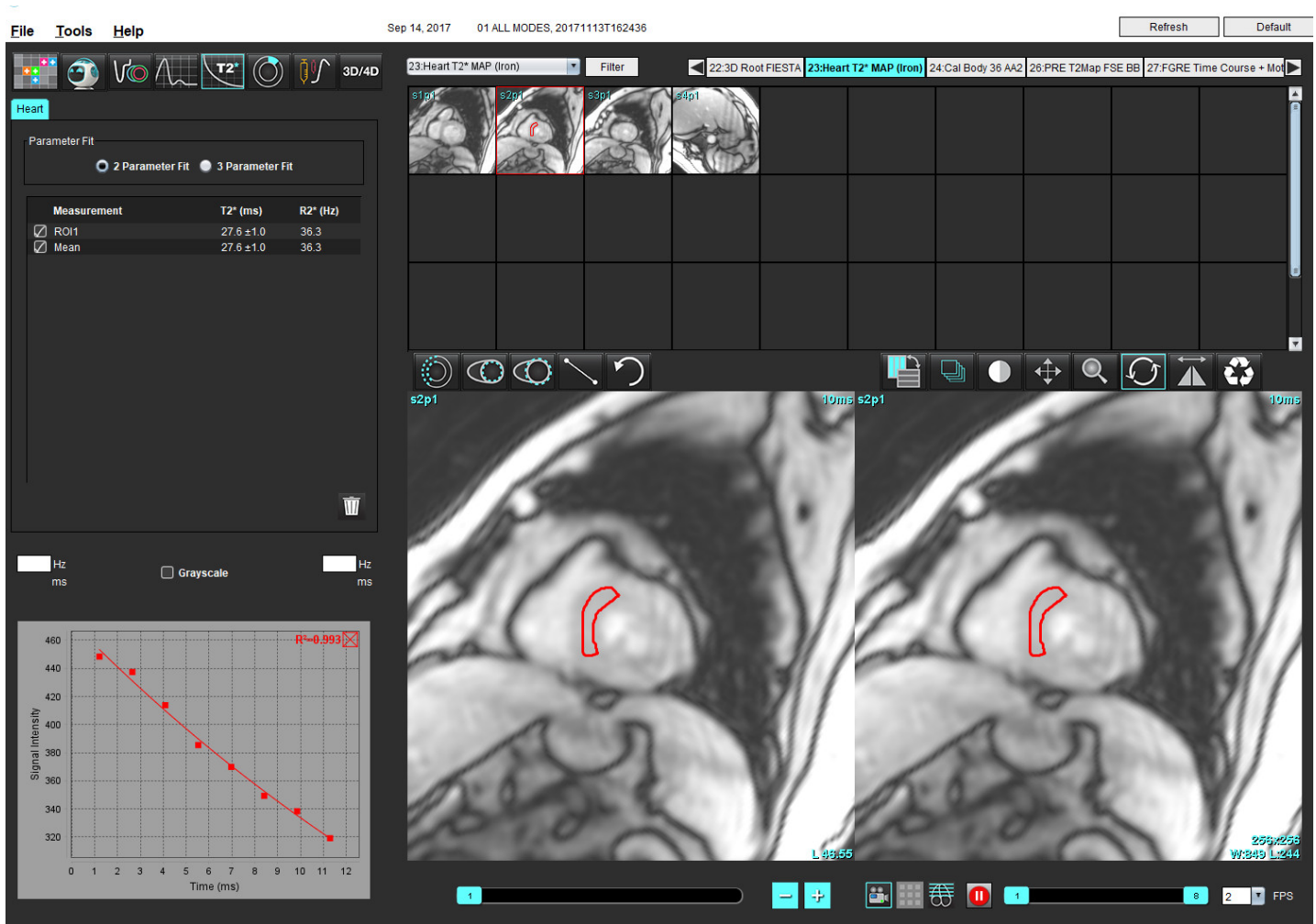
1. Select .

2. Select the appropriate series.

3. Select the short axis slice from the thumbnail panel.

4. Draw a contour that encompasses the interventricular septum using .

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

    The R2 value is calculated and displayed on the graph.

Create Myocardial Colormap

1. Draw a contour the endocardial border using .

2. Draw a contour of the epicardial border using .

    The T2*/R2* colormap is overlayed on the image.

3. The R2* colormap value can be changed.

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

4. Click and drag up or down on arrows to adjust the dynamic color range for the color map.

    The color overlay on the Image Editor changes dynamically.

    The Hz and ms values also change dynamically.

5. The T2* and R2* values can be determined by selecting the and placing it over the color map overlay on the image.

Fitting Parameters

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

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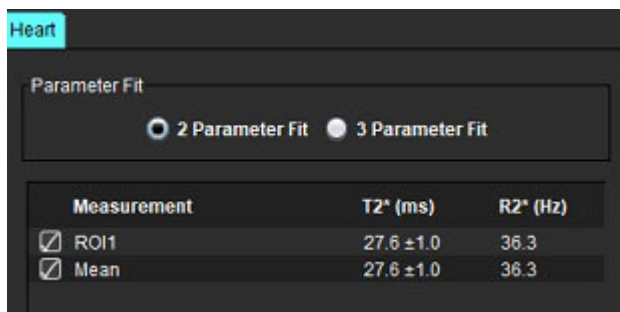
The 2-parameter fit is widely accepted based on peer review literature [1]. In this model, the background noise, c, is calculated using a histogram-based algorithm and subtracted from the signal intensity, after which a non-linear fit is performed.

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

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

1. D.J Pennell, et al. "Cardiovascular T2-star (T2Star) magnetic resonance for the early diagnosis of myocardial iron overload," Eur Heart J 2001; 22: 2171-2179.

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

Review the T2Star Results

1. Review the contour position on all of the images.

2. The table lists the individual T2*/R2* measurements and also calculates a mean value.

   NOTE: The T2* curve is a graph of the signal intensity versus echo time using an exponential decay curve formula. On occasion, it may be necessary to remove later echo points from the decay curve for a better curve fit. This may occur in extreme cases of iron overload when the signal intensity can be very low.

To delete a single contour from an image

1. Left mouse click to select the contour, which turns purple.

2. Right-mouse to select the trash can or use the Delete key on the keyboard to remove a contour.
   • The contour is deleted and the curve fit is recalculated.

   FIGURE 3. T2Star Curve
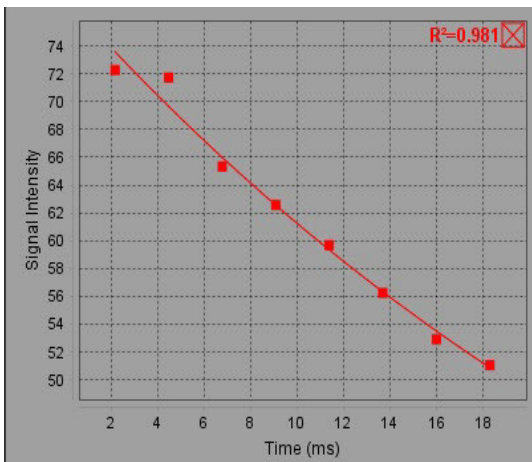
WARNING: The results of the T2Star curve fit should be reviewed by a properly trained and qualified user.

Table 2: R2*/T2* Conversions

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

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

3D/4D Flow Viewer

Provides interactive oblique reformatting of 3D and 4D flow images. Tools are available to create 2D phase contrast and 2D function images from 4D that can be analyzed. Inline flow analysis can be performed.

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

> **NOTE:** The 3D/4D Flow Viewer shall display a 4D series only if 4D is licensed.

> **NOTE:** If both 2D phase contrast and inline 4D flow analysis have been performed all results will be available in Flow Analysis Mode.

⚠️

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

⚠️

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

⚠️

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

3D/4D Flow Viewer Interface Components

FIGURE 1. Display Control Tools and Viewports
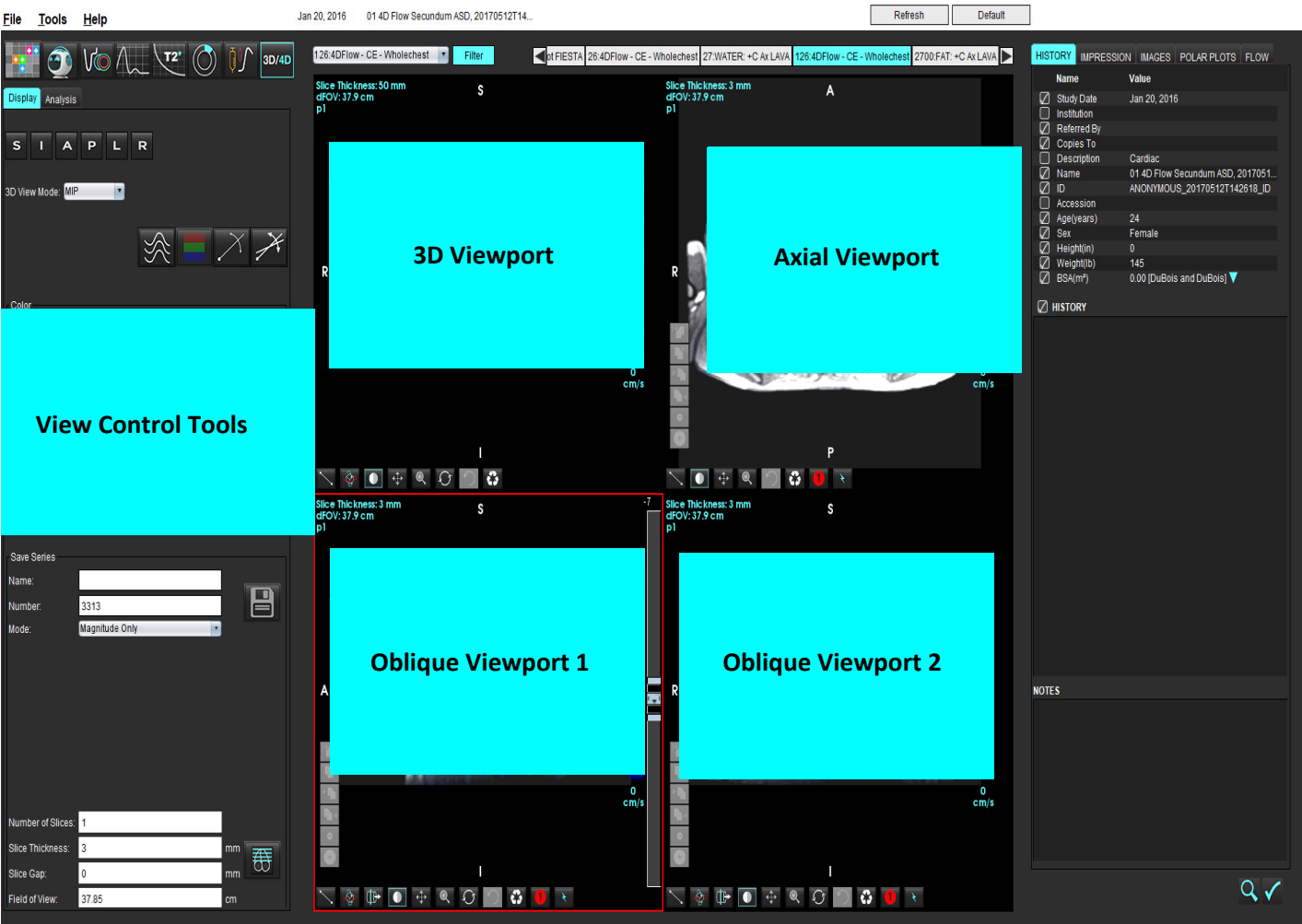
Table 1: View Control Tools
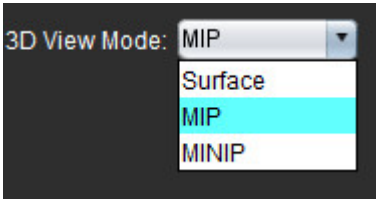
Tool	Description
	Crosshair Cursor - synchronizes navigation between all viewports.
	Orientation Buttons - change the image plane in the 3D and oblique viewports. **S = Superior** **I = Inferior** **A = Anterior** **P = Posterior** **L = Left** **R = Right**
	Oblique Mode - displays the plane of the oblique reformat and the perpendicular intersection to display desired anatomy.
	Double Oblique Mode - displays three oblique planes defined by three adjustable color axis - blue, yellow, green. Adjust any axis to update the two other oblique planes.
	3D View Mode - provides image render modes in the 3D viewport Surface MIP = Maximum intensity projection (Default) MINIP = Minimum intensity projection
	Streamlines- Visualize 3D velocity fields at a specific temporal phase.
	Color Overlay - toggles the color overlay on/off. Available for 4D flow images only.
	Phase - toggles the image display of magnitude and phase.

Table 1: View Control Tools
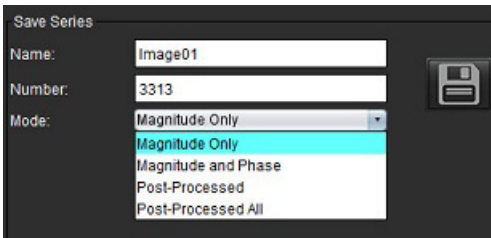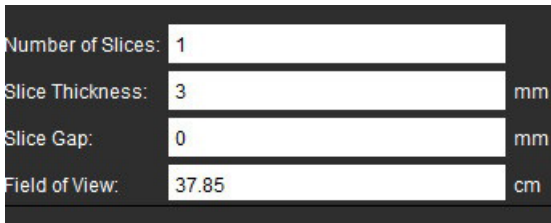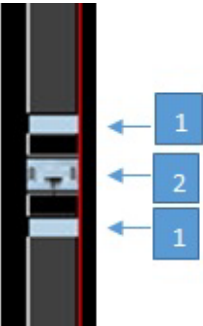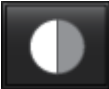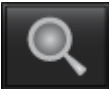
Tool	Description
Speed Range (cm/s) [0 _____ 164]	**Speed Range** - adjusts the color assignment of the direction of flow. Available for 4D Flow images only. The Speed Range color bar legend is displayed on the right hand side of each viewport. The value is an estimate.
Color Opacity [_____]	**Opacity** - controls the color opacity on the image to improve the visualization underlying anatomy. Available for 4D flow images only.
30 ▼ FPS [1 _____ 20] ▶	**Cine** - controls frames per second and defines start and end frame of the cine movie. Available for 3D time-resolved magnitude and 4D flow images only. Use space bar on keyboard to play or pause cine.
Save Series — Name: Image01 — Number: 3313 — Mode: Magnitude Only ▼ — Magnitude Only / Magnitude and Phase / Post-Processed / Post-Processed All — 💾 — Number of Slices: 1 — Slice Thickness: 3 mm — Slice Gap: 0 mm — Field of View: 37.85 cm	**Save Series** - creates 2D conventional functional or a flow image series for analysis or post-processed MIP images. Use to enter the number of slices, slice thickness, gap and field of view. These parameters are annotated in the upper left of each viewport. Use Ctrl + T to toggle on/off. **Magnitude Only** - creates a single-slice or multi-slice multiphase magnitude series from the original images for use in function analysis. **Magnitude and Phase** - creates a single-slice or multi-slice multiphase magnitude with phase series from the original images for use in flow analysis. This option is only available when a 4D Flow series has been selected. (A duplicate series that is auto phase corrected is also created.) **Post-Processed** - creates maximum intensity projection images from 3D images. When a 4D flow data is present single-slice or multi-slice multiphase series with color overlay will be created on the images for review purposes. **Post-Processed All** - Saves all formatted images from each viewport.
💾	**Save**- saves all image series types created by the series definition to the local database.
(icon)	**Rx Planning** - defines the desired scan plane axis created by series definition.

Table 1: View Control Tools

Tool	Description
	Paging and Thickening - changes the thickness of the MIP image and pages through the image set. 1= click and drag either side buttons to change the thickness of the MIP image 2= click and drag the slider to page through the image set. Controls are found on the right hand side of the selected viewport.
	Linear - Provided measurement of a straight line distance. Click directly on the measurement then right mouse to perform Delete, Locate, or Label.
	3D Rotate - tilts or rotates the images in the 3D viewport and/or oblique viewports 1 and 2. Left mouse click and drag directly in the viewport to tilt or rotate.
	Flow Direction - displays the perpendicular plane in oblique viewports 1 and 2. Left mouse click directly on the anatomy of interest to use this feature. Available for 4D flow images only.
	Window/Level - available in all viewports.
	Pan - available in all viewports.
	Zoom - available in all viewports.
	Rotate - available for the 3D viewport, viewport 1 and viewport 2.

Table 1: View Control Tools

Tool	Description
	Reset - available in all viewports.
	Scan Parameters - available in all viewports.

Table 2: Quick Key

Function	Action
Target Cursor	Press Shift key and move the crosshair cursor to the desired anatomy.

3D/4D Flow Viewer Layout and Series Creation Outputs

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

Table 3: 3D/4D Flow Viewer Layouts and Output

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

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

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

2. Select **3D/4D**.

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

FIGURE 2. Series Navigation
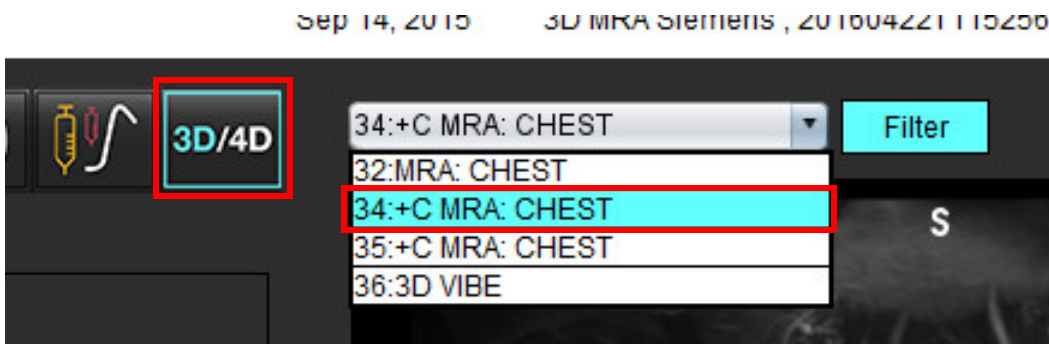
4. Select ✕ and click on the desired viewport. The active viewport will be highlighted in red. Reformat lines will appear as shown in Figure 3.

FIGURE 3. Double Oblique Mode

5. Click on the solid line, left mouse click and drag and tilt the line to display the desired anatomy.

   a.) Click on the desired viewport for saving.
   b.) Adjust the MIP thickness using the controls on the right hand side of the viewport.
   c.) Complete the series definition entries, as shown in Figure 4.
   d.) Click the save button to save the MIP image to the local database.

FIGURE 4. Series Definition

6.   Create a stack of MIP images by selecting .

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

7.   Click on the viewport to be used as the reference image and define a stack of batch images, as shown inFigure 5.

>   a.)   Extend the range of the slice coverage.
>   b.)   Adjust the angle and arrows indicate slice direction.
>   c.)   Move the Rx.

FIGURE 5. Rx Planning
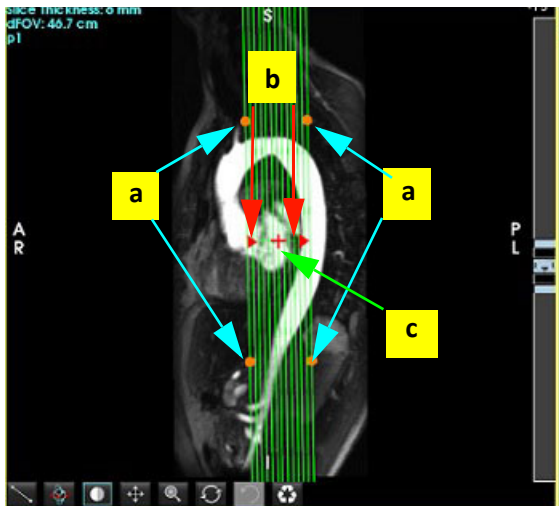
8.   Enter the series definition options and click to save the image stack to the local database.

9.   To view the created series, switch to function analysis mode, select review mode and click refresh.

Example Workflow: Create 2D Series for Analysis

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

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

Series that are created as post-processed from 4D Flow will have a color flow overlay.

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

2. Select **3D/4D**.

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

    FIGURE 6. Series Navigation
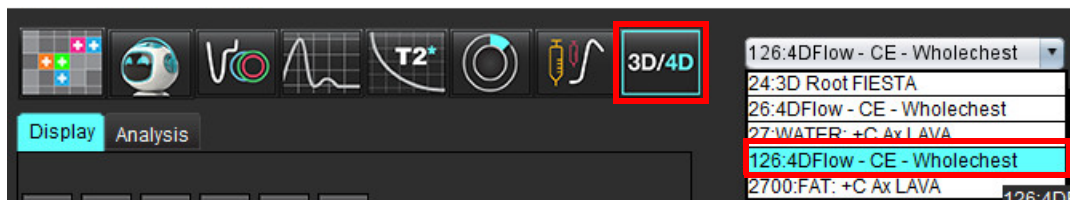
4. Select and click on the desired viewport. The active viewport will be highlighted in red. The yellow reformat lines will appear as shown in Figure 7.

    FIGURE 7. Oblique Mode Reformat 4D
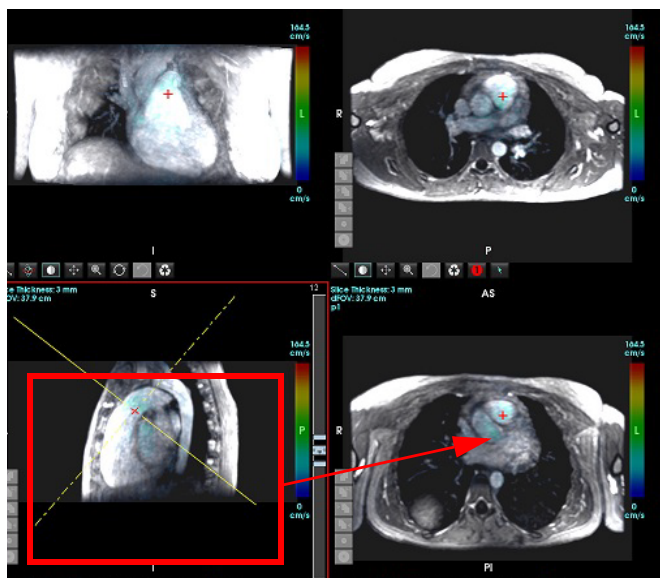
5. Click on the solid yellow line, left mouse click and drag and tilt the line to display the desired anatomy.
    a.) Click on the desired viewport for saving and select Magnitude and Phase mode to create a 2D phase contrast series or select Magnitude to create a functional series.
    b.) Adjust the slice thickness using the controls on the right hand side of the viewport.
    c.) Complete the series definition entries, as shown in Figure 8, and click the save button to save the series to the local database.

FIGURE 8. Series Definition and Save

2. Click Save

1. Select Magnitude and Phase

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

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

   NOTE: When saving magnitude and phase series, the second series will have auto baseline correction applied. The series will be labeled "corrected" as shown in Figure 9.

FIGURE 9. Auto Phase Offset Error Corrected Series Example

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

FIGURE 10. Rx Planning
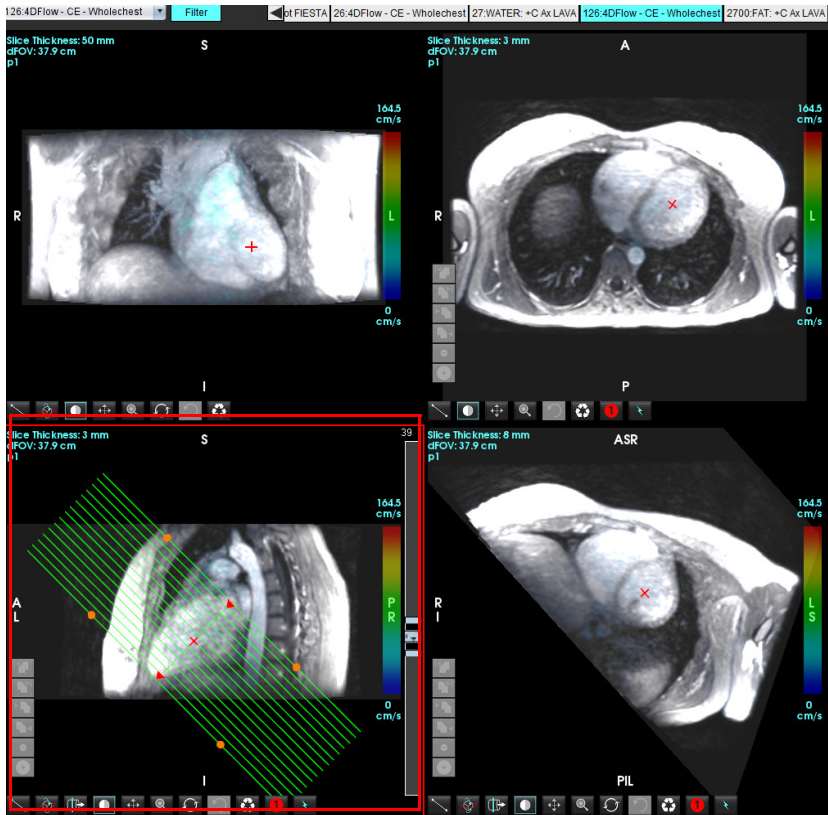
8. Select the Series Definition options and click to save the image stack to the local database.

9. To analyze the created series, switch to the appropriate analysis mode and click refresh.

Example Workflow: Create a Flow Measurement

For detailed information on the flow analysis interface tools, see Flow Analysis on page 84.

1. Select the **Analysis Tab**.
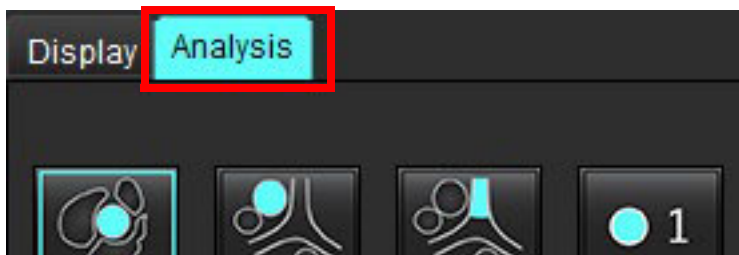
2. Localize the vessel of interest. Only aortic or pulmonary anatomy is supported for the auto segmentation as shown.

   Click the to generate a flow curve.

FIGURE 11. Aortic and Pulmonic Vessels Example
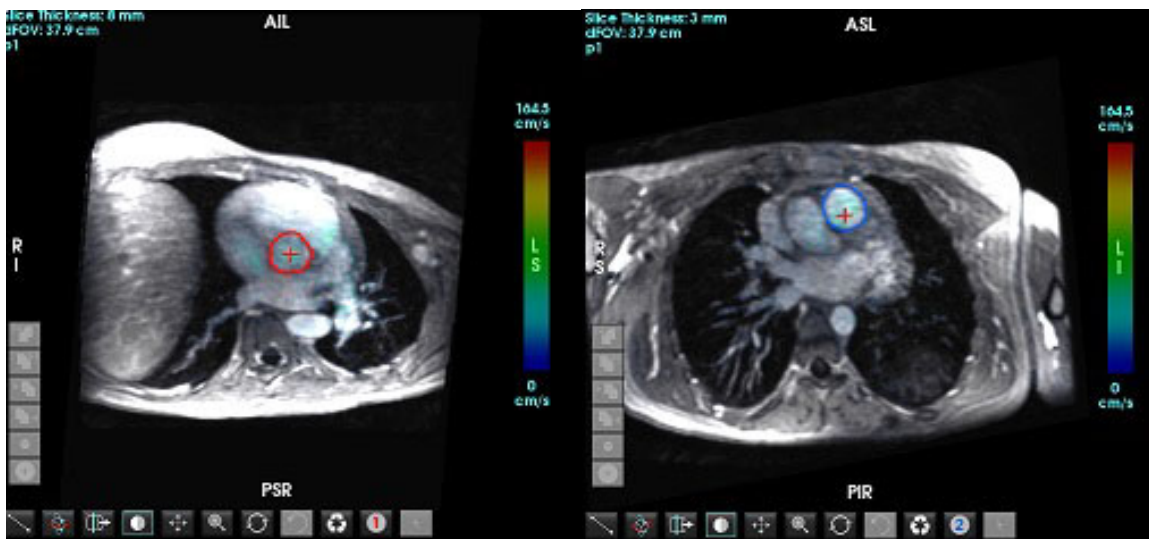
⚠️ WARNING: The user is responsible for the accurate placement and correct category assignments of all regions of interest (ROIs), including those generated by preprocessing.

3. For manual segmentation, localize the vessel of interest and click on the 🔴**1** as shown in Figure 12.

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

4. Create a contour around a vessel by depositing 4 points around the vessel of interest.

5. Click ⚡ for segmentation over all phases.

FIGURE 12. Manual ROI Placement
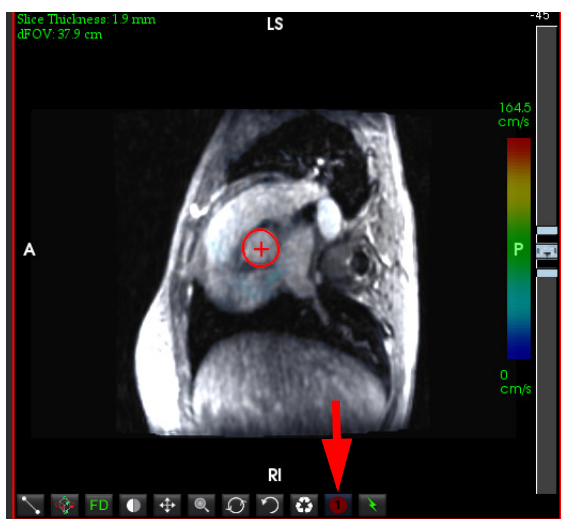
Perform Velocity Aliasing Correction

To correct for velocity aliasing, drag the slider bar control button to perform phase unwrapping. The effect of the change will be updated directly on the phase image and the results displayed directly on the flow graph. To check each of the three velocity-encoded images along the three orthogonal (x,y,z) directions select from the pull-down menu as shown in Figure 13.

FIGURE 13.

Structured Reporting

Define Report Content

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

Predefined clinical impressions and techniques streamline custom reports. Refer to the Impression Tab on page 164 section for procedural details on how to create clinical impressions and techniques. Report Preferences allows entering site information that will appear in the headers on the report.

Structured Report View

The Structured Report View is designed to aid in generating clinical reports. There are four tabs:
- History
- Impression
- Images
- Polar Plots

Each parameter is associated with a check box toggle . Click the check box to include or exclude the parameter in the report.

> **NOTE:** Print selections can be configured on the Print Preference tab under Tools > Preferences > Edit Print.

History Tab

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

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

FIGURE 1. History Tab

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

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

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

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

History and Notes Text Boxes

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

Impression Tab

FIGURE 2. Impressions Tab

1. Impression, 2. Technique

Impression

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

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

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

Technique

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

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

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

Images Tab

FIGURE 3. Images Tab
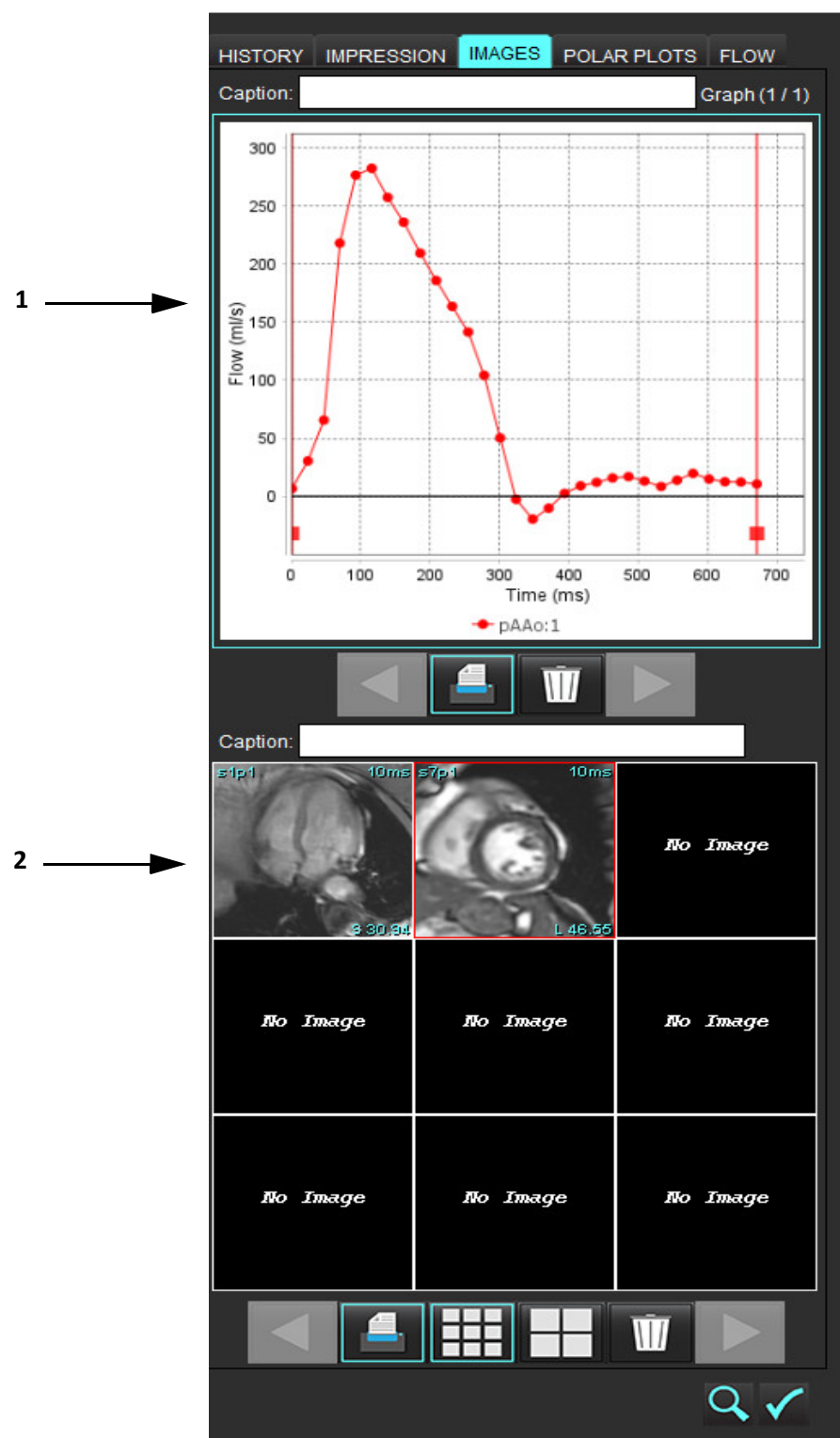
1. Graphs/Tables, 2. Images for report

Review Graphs and Summary Tables for Report

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

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

2. Click in the white text box to add a graph or summary table caption for the printed report.

3. When 📄 is enabled, the graph or table will be included in the report.

4. Click on 🗑 to delete a graph or table.

Review the Images

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

> **NOTE:** Multi-slice images can be sent to the report. From the Image Viewer menu bar select **Tools > Preferences > Edit**.
>
> Check the option **Multi-slice Images to Report**. In review mode, right mouse click select ▦⁺ ; cine mode must be paused.

1. Step through each image using the ◀ ▶ buttons.

2. Click in the white text box to add an image caption for the printed report.

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

4. Images in the image panel can be re-ordered by clicking and dragging the image into a different viewport.

5. Perform a right-mouse click directly on an image to access the image manipulation tools.

6. To locate the series from which the image originated, right-mouse click directly on the image and select the 🗺 locate button.

7. When 📄 is enabled, the image will be included in the Report.

8. Delete an image by selecting 🗑 .

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

Polar Plots Tab

This table allows for the identification of functional, myocardial evaluation, and myocardial perfusion 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
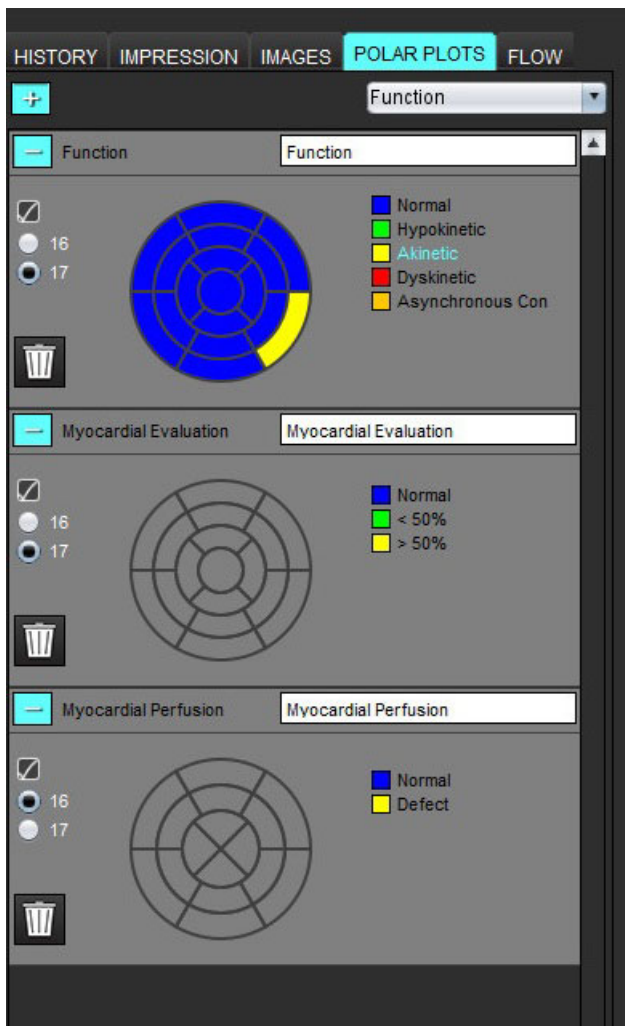
Add Polar Plots to Report

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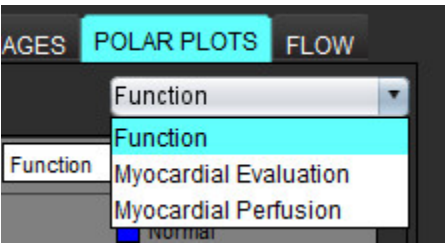
Selecting Colors per Segment

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
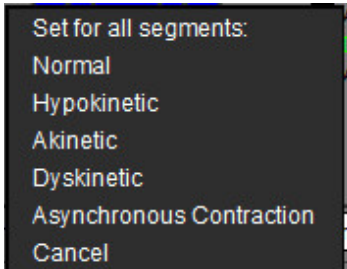
Selecting 16 or 17 Segment Plots

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
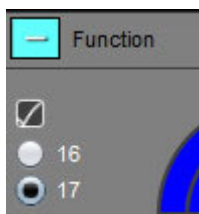
Select to reset the polar plot back to default.

Preview the Report

1. Select File > Preview Report or select from the lower right.

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.

    NOTE: The report file name can be configured in Preferences. See Selections for Report Preferences on page 30.

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
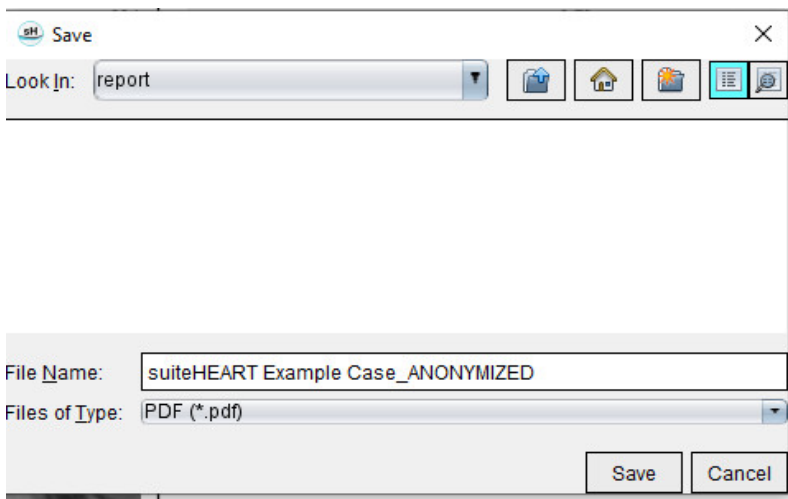
4. Select Print to print the report.

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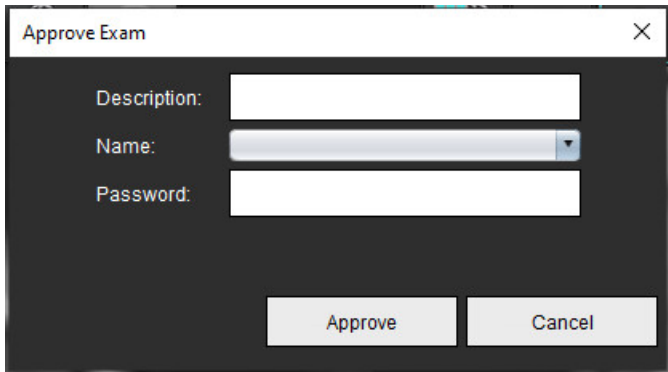
The application has a feature that approves and locks reports. The approved report is saved and can be viewed but it cannot be changed.

NOTE: Prerequisites: The user must be an authorized report signatory. See Authorized Report Approvers on page 31.

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

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

    FIGURE 9. **Approve Exam Window**

2. Enter a signature description if desired.

3. Select your user name from the Name pull-down menu.

4. Type in your password.

5. Click Approve to confirm and close the window. Click Cancel to close the window without completing the sign-off procedure.

    Using the description provided, a series is created.

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

Export Options

1. Select **Tools > Export > Report to DICOM**.

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

2. Select **Tools > Export > Report to Excel**.

   Exports report as an Excel file.

3. Select **Tools > Export > Report to XML**.

   Exports report as an XML file.

4. Select **Tools > Export > Images to DICOM**.

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

5. Select **Tools > Export > Report to...**

   Exports results to third party reporting system.

6. Select **Tools > Export > Images to JPEG, AVI, etc.**

   The Save Cine popup window is displayed.

7. Select **Tools > Export > Data to Matlab** (license only)**.**

   Exports a Mat-file in binary form.

FIGURE 10. Save Cine Window
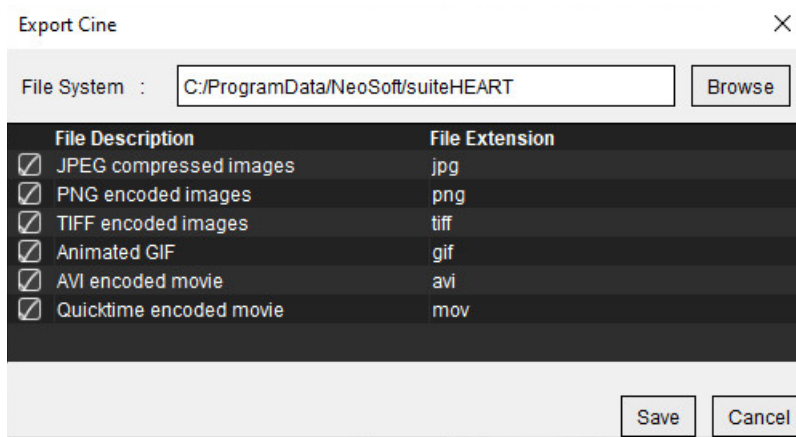
1. Select the file types to be exported.

2. Browse to the location in which to save the file(s).

3. Click Save to start the exporting process and close the window. The currently viewed series is the only file exported.

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

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

Review an Approved Exam

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

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

    FIGURE 11.   Approved Exam Selection Window
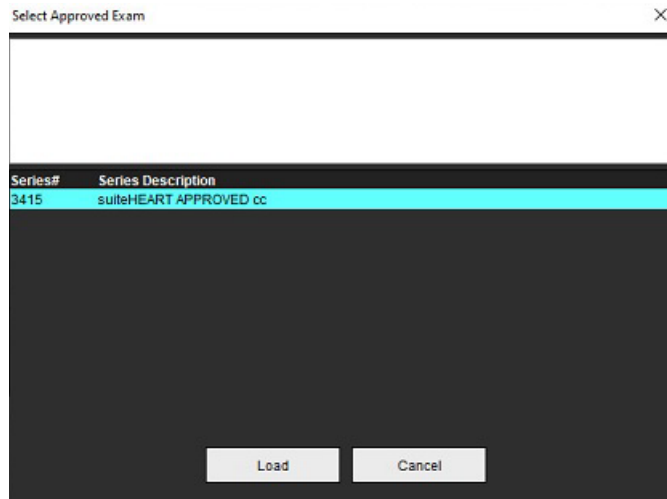
2. Select the series from the list.

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

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

    NOTE: When restoring exams that have been analyzed with prior versions of suiteHEART® Software, and if a "Load Approved Exam" has been performed, the report will not have the name of the approver or the date and time stamp. **It is recommended to review all analysis and confirm all results prior to reissuing the report.**

Report Database

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

Report Database Tool Procedure

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

Select Search Criteria

2. Select the correct template for the search from the Search template drop-down menu.

3. Select the search query from the History drop-down menu. The current query bar displays your selected values.

FIGURE 1. Search Options

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, as shown in Figure 1.

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

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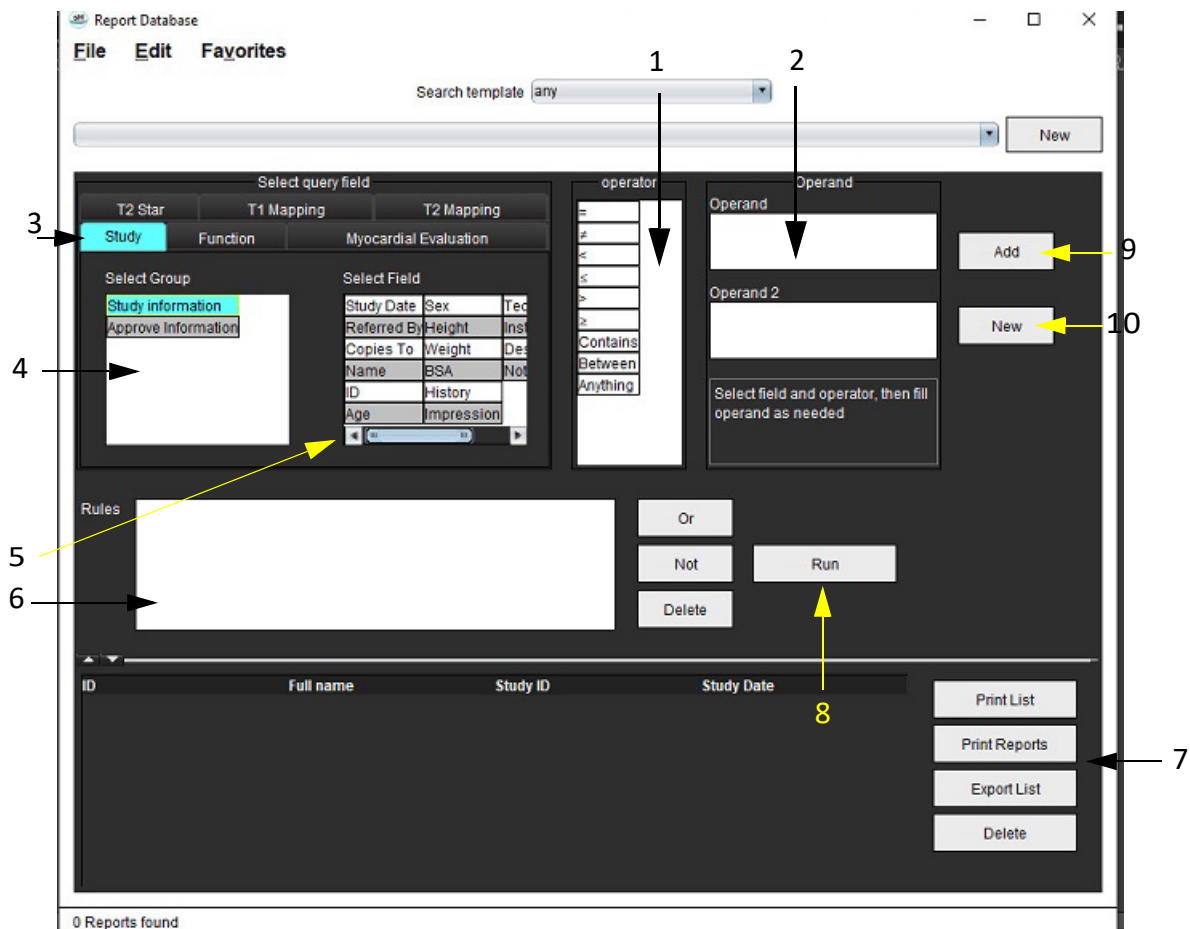
1. Query Operators, 2. Query Operands, 3. Query analysis tabs, 4. Query group, 5. Query fields, 6. Query rules, 7. Query options, 8. Run button, 9. Add query button, 10. New query button

2. Select the query category tab from Study, Function, ME, T2 Star, T1 Mapping and T2 Mapping. The query groups and fields update accordingly.

3. Select the query group.

4. Select the query field.

   NOTE: The Report Database cannot perform a search on custom measurements.

5. Select the operator to define the query search parameters.

6. Enter the operand(s) to provide values to the search parameters.

7. Select **Add** to display the query values in the **Rules** panel. Multiple queries can be executed during a single search operation. Repeat steps 1 through 7 for each additional rule.

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

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

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

Activate the Search

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

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

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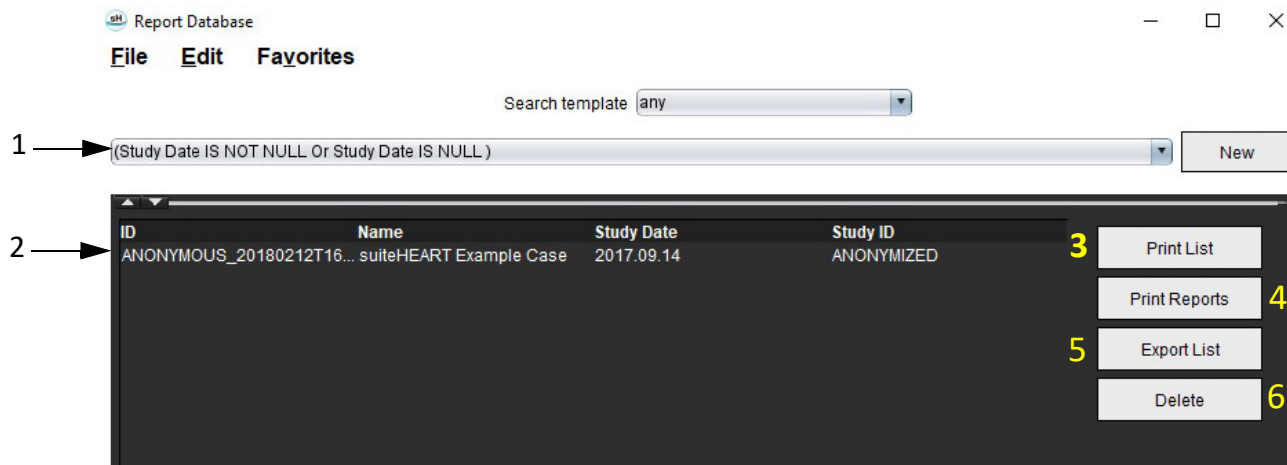
1. History bar, 2. Query results, 3. Print list button, 4. Print reports button, 5. Export list button, 6. Delete button

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

View the Results

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

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

FIGURE 4. Report Viewer
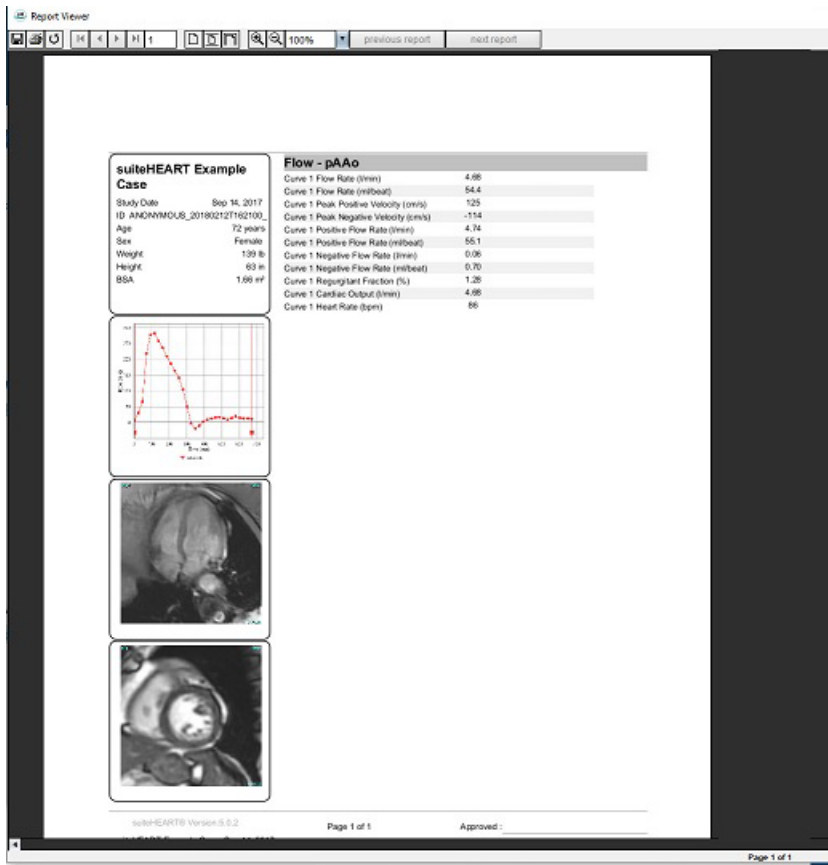
2. Apply the Edit menu selection options to modify the result selections:

>   **Edit > Select All** selects all search results.

>   **Edit > Clear Selection** deselects all search results.

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

>   **Edit > Clear History** deletes record of previous queries.

3. Select **Print List** to send the query list to the printer.

4. Select **Print Reports** to send the selected reports to the printer.

5. Select **Export List** to save the list as an html file.

6. Select **Delete** to remove the selected report(s) from the report database

Save a Query

1. Select **Favorites > Add to Favorites**.

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

FIGURE 5. Favorites Menu
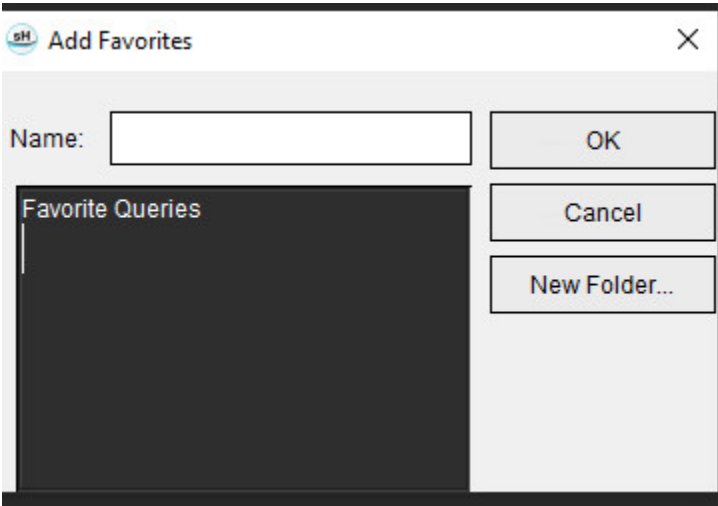
FIGURE 6. Favorites Pull-down

Delete a Favorite

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

   FIGURE 7. Manage Favorites Window
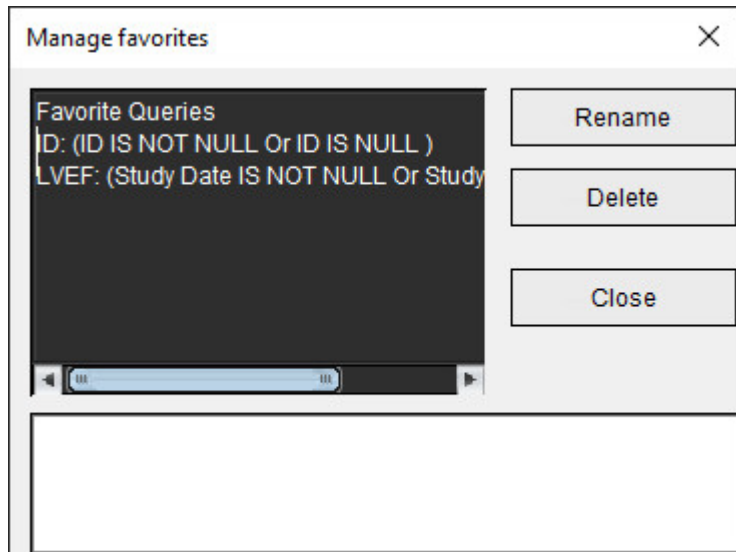
2. Select the favorite item.

   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 8. Export Window
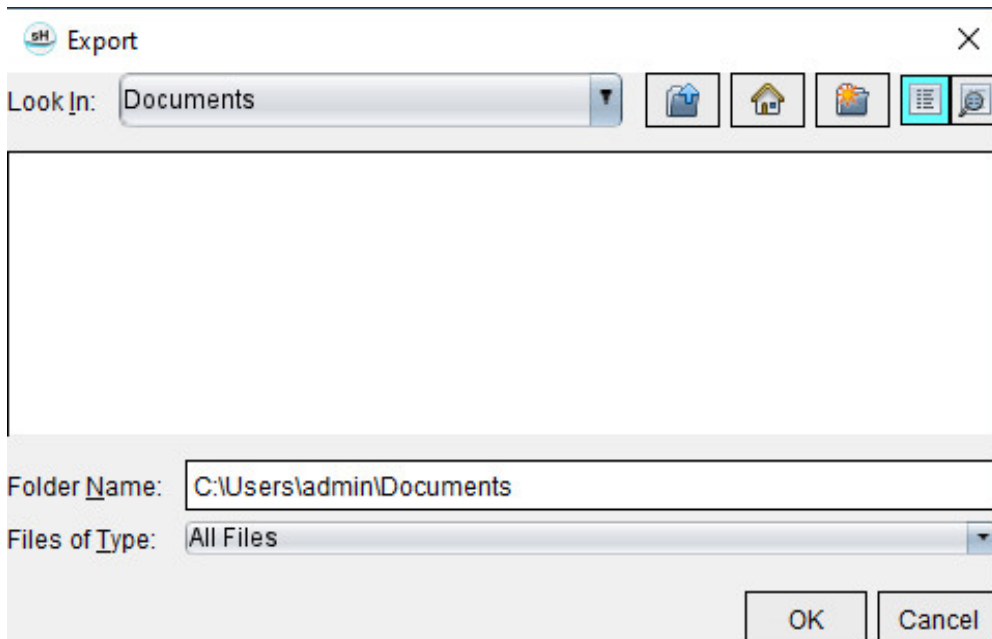
2. Select the directory to which to export the list.

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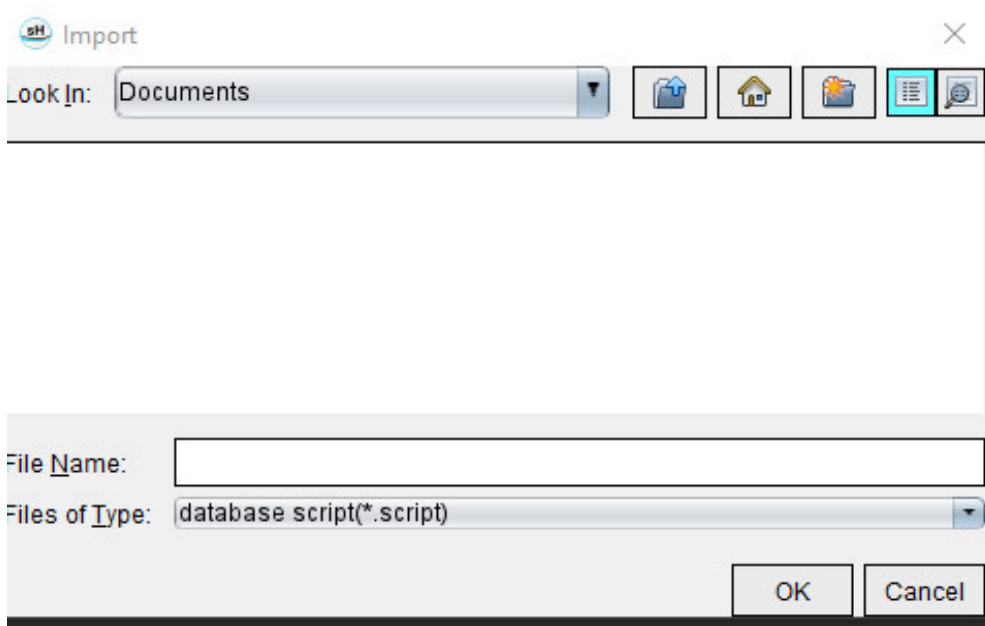
2. Select the directory from which to import the database.
3. The imported database is merged with the existing database.

Tablet Mode

suiteHEART® Software is supported on tablets with a 64-bit processor running on Windows 10 Professional or Windows 10 Enterprise operating system. Review the following section for using suiteHEART® Software on a tablet device.

Enable Tablet Mode
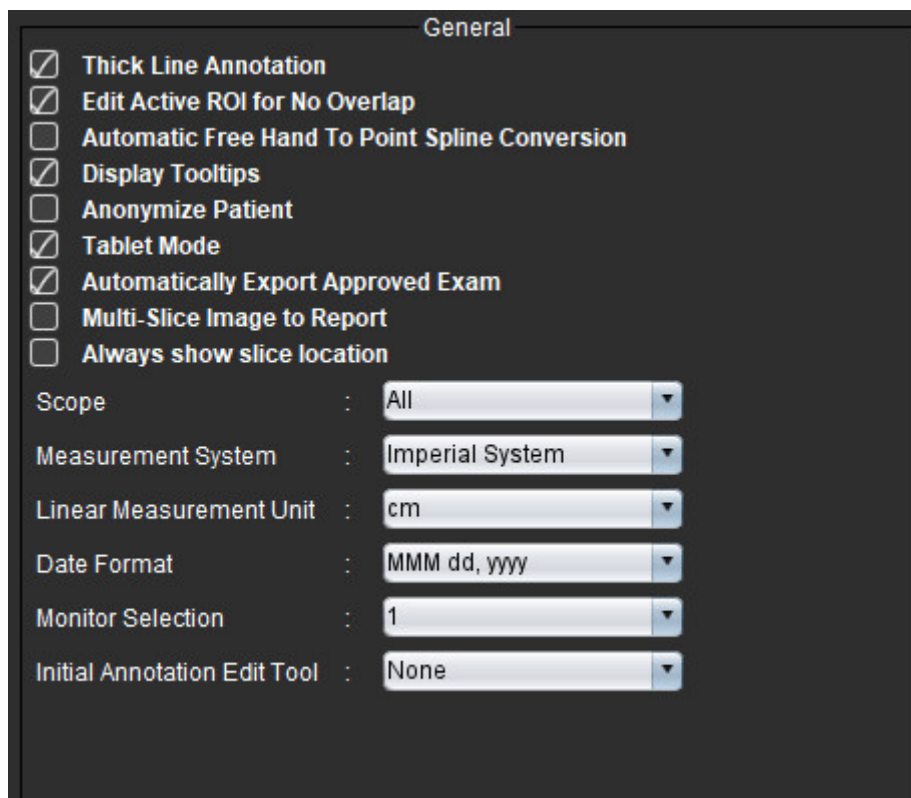
1. From the Image View menu bar, select **Tools > Preferences > Edit**.

2. Select the **Global** tab.

3. Check the **Tablet Mode** check box under General.

4. On the Report View a keyboard icon will be active, as shown in Figure 1.

FIGURE 1. Keyboard Toggle
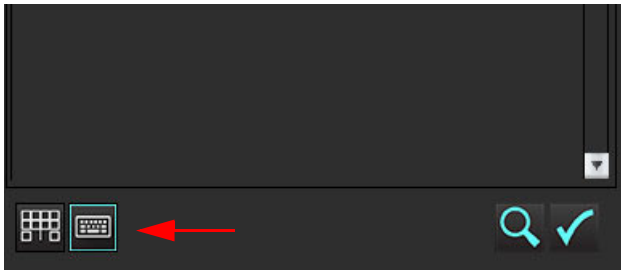
5. When a text field is used, a virtual keyboard will appear.

 The virtual keyboard can be moved on the interface.

6. When a selection is made on a non-text area, the keyboard will close.

7. To manually activate the virtual keyboard, click . To close, click .

Image Manipulation Tools

To use the image manipulation tools on a tablet, press using a stylus or, if a mouse is connected, left mouse click and drag on the tool.

To reorder images on the images tab, right mouse click, select the drop hand icon .

Appendix

Appendix A - Reference Articles

Normal ranges, as described on Template Preferences on page 37 of this manual, may be established from the following peer review literature references:

1. Kawel-Boehm et al, "Normal Values for Cardiovascular Magnetic Resonance in Adults and Children." Journal of Cardiovascular Magnetic Resonance (2015) 17:29

2. 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.

3. 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.

4. 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.

5. 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)

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.

Appendix B - Functional Analysis Scan Plane Example

For accurate function results, analysis should be performed on a short axis view as shown in the first figure below.
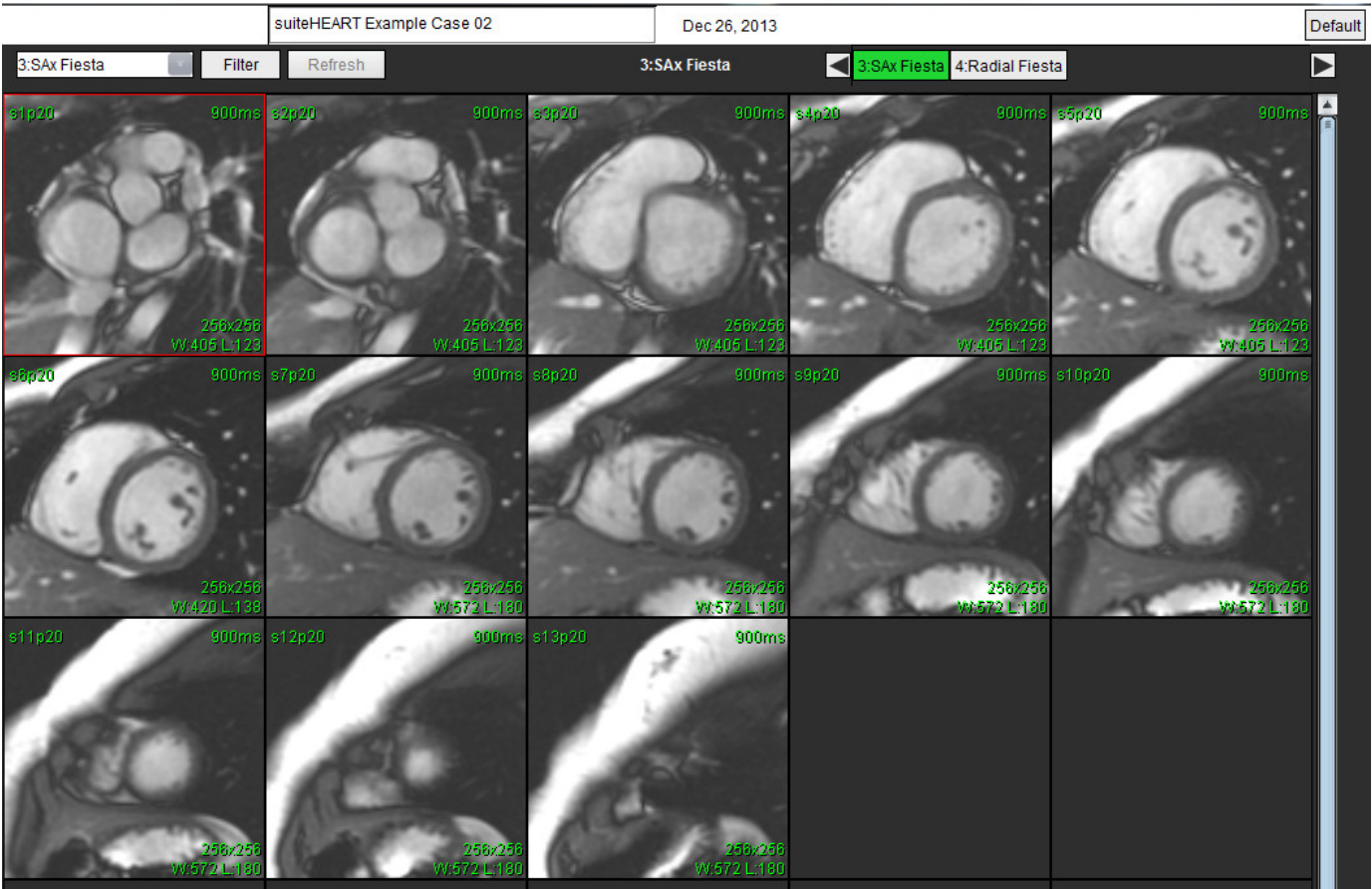
Correct scan plane prescription for the acquisition of the short axis view. Slices should be prescribed perpendicular to the long axis of the left ventricle with at least 2 slices above the base and 1 slice after the apex included in the series.

Index

D

E

F

Q

R

S

T