cvi42®

Version 5.13

User Manual

circle CARDIOVASCULAR IMAGING

cvi42

User Manual

February 2021

Regulatory Information

Manufactured by:

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bsi. ISO 13485:2016 Medical Device Quality Management

FM 539204

Canada

cvi42: Health Canada device license number**:** 93385

United States of America
The following 510K clearances applicable for this product: K082628, K111373, K141480

European Union

CE 2797

cvi42 is qualified as a class IIa medical device. It complies with the requirements of the European Medical Device Directive 93/42/EEC

UDI: 00882916000011

EC REP

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European Office

Circle Cardiovascular Imaging B.V.

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1 Regulatory

1.1 Regulatory Information

AGENCY	Authorized Representative	Approval/ Clearance Reference
Australia TGA ARTG	KD&A Pty Ltd 286 Flinders Street , Adelaide, SA, 5000 Australia	177785
Brazil ANVISA	Edifício Times Square Av. Presidente Vargas, 2121 11º andar - sala 1103 Jardim América - Ribeirão Preto - SP ZIP: 14020-260 - Brazil	81118639002
China CFDA	Shanghai (Viacert) Product Technology Service Ltd. Shanghai Chong Ming County Pu Zhen Zhen Pu Zhen Nan Lu 300-4-101, Shanghai, China	NIMR 20172705228
Japan MHLW	ENTORRES 2F 1-82 3 Edobashi Tsu City. Mie Japan	BG30200090 227ADBZX00153000 227ADBZX00157000
South Korea KFDA	DANY Trading Co Ltd B120 Penterium 282 Hakui-ro, Anyang-si, Gyeonggi-do Dongan-gu 431-810, Korea	KCL-BBAA-8279
Singapore HSA	Pharmeng Technology PTE. LTD. 1 Fusionpolis Place, Galaxis, #03-20, Singapore 138522	DE0019287
Taiwan FDA	Yi-An International Ltd, 11F-5 N0. 91 Hua-Yin Street, Datong District, Taipei, Taiwan, 10351	DHA05603258904/MF010798
Malaysia MDA	Biod Medica SDN. BHD. N-12-16, First Subang Mall Jalan SS15/4G Subang Jaya, 47500 Selangor Darul Eshan, Malaysia	GB7605919-32314
Argentina ANMAT	Medes Argentina Gorriti 6046, OFF 202 Buenos Aires, C141BKN, AR	256-36
Thailand FDA	Tilleke & Gibbins, Supalai Grand Tower, 26th Floor, 1011 Rama 3 Road, Chongnonsi, Yannawa, Bangkok 10120, Thailand	CAN 6304061
United Arab Emirates MOHAP	Lifetastic FZ LLC Dubai Science Park PO Box 75344 Dubai-UAE	DRCLAS-2019-002545

2 Measurement Accuracy

2.1 Measurement Accuracy

All the measurements in the software application are direct transfer of the original DICOM data acquired as a result of image acquisition process. The expected error for the on-screen measurements will be limited to sub pixel matrix size, which divides up each pixel of the input image into a set of sub pixels, i.e.

Depending on the original pixel dimensions and the number of sub pixels used, the accuracy of our measurements will be limited to each sub pixel dimension.

For example, given an original CT or MR image with an isotropic pixel dimension of 0.4 mm and a sub pixel matrix size of 4 x 4, the length (min/max/average diameter) accuracy will be limited to ±0.05 mm. The accuracy for area and volume will be dependent on the size and complexity of shape, in addition to the sub pixel matrix size. For example, a 4-pixel diameter circle with isotropic pixel dimension of 0.4 mm and 1 x 1 sub pixel matrix will have an accuracy of ±0.96 mm2.

3 Basic Components and Indication for Use

3.1 Intended Use

cvi42 is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) images and cardiovascular computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format.

It enables:

- Importing cardiac MR & CT Images in DICOM format.
- Supporting clinical diagnostics by qualitative analysis of cardiac MR & CT images using display functionality such as panning, windowing, zooming, navigation through series/slices and phases, 3D reconstruction of images including multiplanar reconstructions of the images.
- Supporting clinical diagnostics by quantitative measurement of the heart and adjacent vessels in cardiac MR & CT images*, specifically signal intensity, distance, area, volume and mass.
- Supporting clinical diagnostics by using area and volume measurements for measuring LV function and derived parameters cardiac output and cardiac index in long axis and short axis cardiac MR & CT images.
- Flow quantifications based on velocity encoded cardiac MR images including 4D flow analysis
- Tissue characterization of cardiac MR Images**
- Perfusion analysis of cardiac MR Images**
- Strain analysis of cardiac MR images **
- Supporting clinical diagnostics of cardiac CT images including quantitative measurements of calcified plaques in the coronary arteries (calcium scoring), specifically Agatston and volume and mass calcium scores, evaluation of heart structures including coronaries, femoral, aortic and mitral values.
- Evaluating CT and MR images of blood vessels. Combining digital image processing and visualization tools such as multiplanar reconstruction (MPR), thin/thick maximum intensity projection (MIP), inverted MIP thin/thick, volume rendering technique (VRT), curved planner reformation (CPR), processing tools such as bone removal (based on both single energy and dual energy) table removal and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics) and key images). The software package is designed to support the physician in conforming the presence or absence of physician identified lesion in blood vessels and evaluation, documentation and follow up of any such lesions.

cvi42 shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR or CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. **cvi42** is a software application that can be used as a stand-alone product or in a networked environment.

The target population for **cvi42** is not restricted, however the image acquisition by a cardiac magnetic resonance scanner may limit the use of the software for certain sectors of the general public.

cvi42 shall not be used to view or analyze images of any part of the body except the cardiac images acquired from a cardiovascular magnetic resonance or computed tomography scanner.

WARNING: The Tissue Characterization, Strain and Perfusion modules are not available for clinical use in the USA. The FDA does not approve the use of contrast agents for cardiac MR procedures.

WARNING: Quantitative analysis is dependent on the quality and correctness of the image source data.

WARNING: Software may slow down when other software applications are being run on the same machine.

4 Customization

4.1 How to Define A Protocol

The definition of protocols allows for setting up a workflow according to standardized image acquisition protocols.

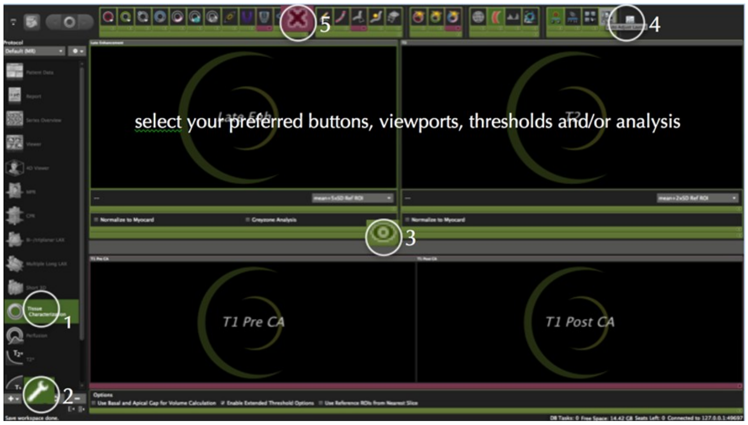
1. Open the drop-down menu next to Protocol selection
2. Choose *New* and type in the protocol name. Hitting the *return* key will enter the new name and clear the list
3. Go to *Add* and select your modules
4. Rearrange modules via drag-and-drop
5. Rename a module with a double LMB click on the name (e.g. change "Tissue Characterization" into "Infarct")
6. Delete a module with the *Delete* button (bottom right)
7. Automate protocol selection: If you are using standardized image acquisition protocols, you can link your **cvi42** protocol to the scanning protocol. Open a standard e.g. AMI sequence, set up a post-processing protocol, open the menu and choose "typical". The next time you open an AMI sequence that exact protocol with all the defined pre-sets will pop up
8. Reset typical studies. This removes all recorded study characteristics for the respective protocol and allows to start selecting typical studies from scratch
9. Save the protocol by clicking on the floppy-disk next to the protocol name
10. The protocol can be “Set to Default” in the dropdown menu.

4.2 CMR Essentials and CMR Advanced Protocols

The tools displayed by default on the modules of the CMR Essentials protocol were reduced to the essential ones, typically used in the clinical workflows. The user can always add or remove tools to the modules and save the changes to the protocol. Click on the “Edit Protocol Step”, make the desired changes, click again on ”Edit Protocol Step” to exit editing mode, and save the changes by clicking on ”Save Current Protocol”.

The first time a user saves changes to the global/system-wide CMR Essentials or CMR Advanced protocols, a new user-specific CMR Essentials or CMR Advanced is created and named as follows: CMR Essentials [username] or CMR Advanced [username].

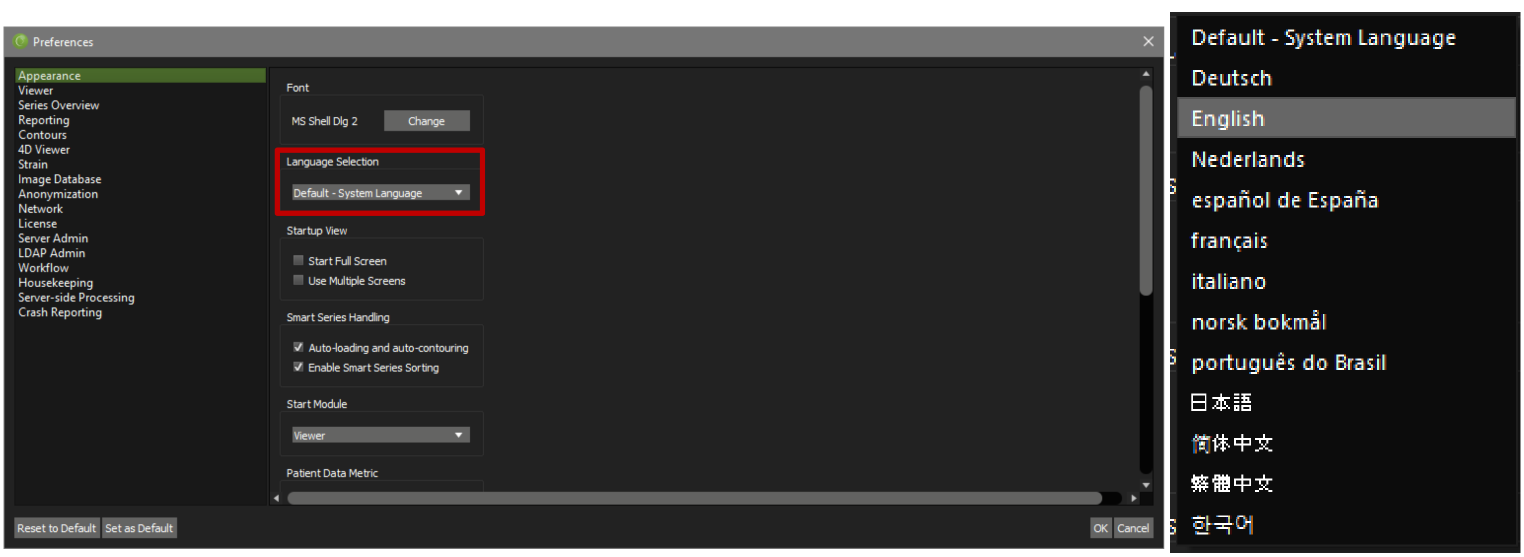
4.3 Customize Tools and Working Modules



1. In the protocol list, select the module you would like to customize
2. Click on the wrench (bottom left)
3. Everything highlighted in green can be turned on or off. Click the small circular *off* button in the right lower corner of the frame. They will be hidden in all your protocols
4. De-activated functionality is highlighted by a purple frame
5. To reactivate click on the X
6. To return to default click 
7. Save your selection by clicking the wrench again

4.4 Configuring Client Language

From a specified list, each user can select their preferred language for the cvi**42** client user interface.



To configure the language the user interface:

1. Click Preferences -> Appearance.
2. Select the Language Selection dropdown list and select the desired langauge.
3. Click OK to save the language preference.

4. A warning message will be displayed , indicating that the cvi**42** client must be restart in order for the language settings to applied. Click OK.

> **IMPORTANT**: To apply the language settings the cvi**42** client must be restarted.

5. Restart the cvi**42** client. Once restarted the cvi**42** client login screen will be displayed in the users preferred language.

> **IMPORTANT**: If no language has been configured the cvi**42** user interface will be displayed in the OS Regional Language.

4.5 Configuring Smart Series Handling

Each user can enable/disable the Smart Series Handling functionality. Smart Series Handling is used to automate some workflow steps in order to speed up analysis. This feature will identify each series in the selected study, auto-load the appropriate series into the proper module frames, and in some cases, identify and segment contours.

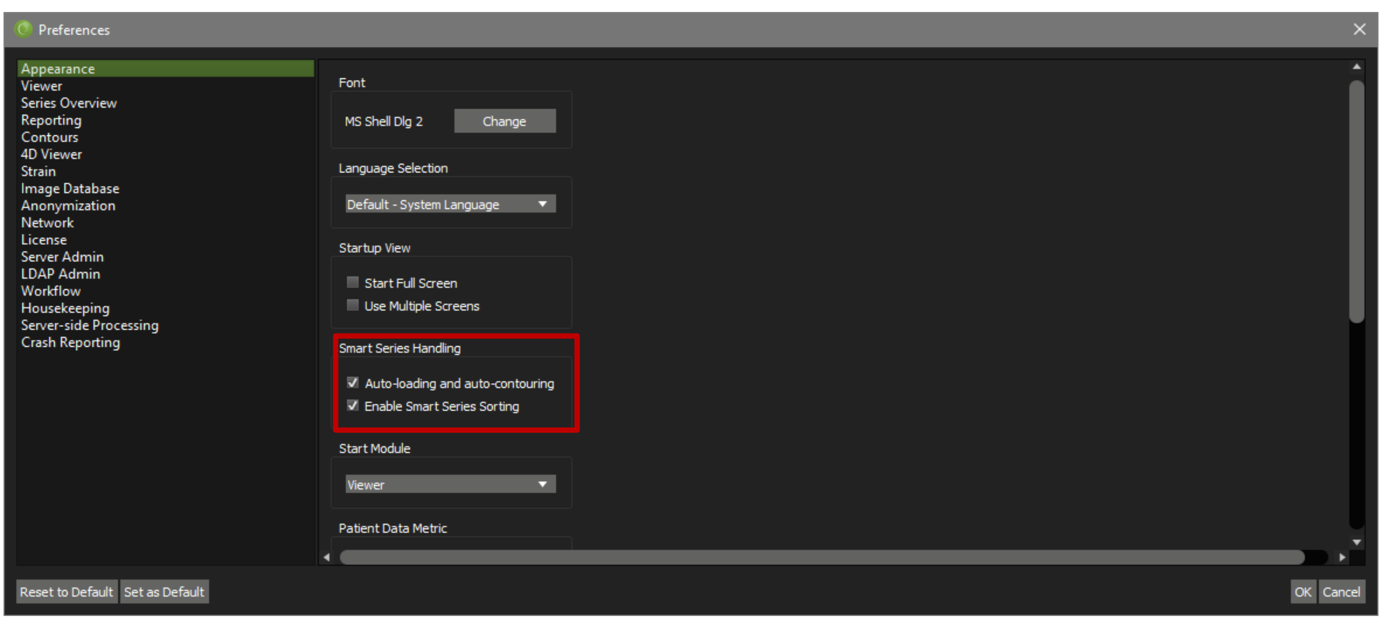
If Auto-loading and auto-contouring is enabled, the auto-classified series will be auto-loaded into the following modules:

- Function|SAX Module
- Function|Biplanar LAX Module
- Function|Radial LAX Module
- Strain
- Tissue: Signal Intensity

Additionally the auto-loaded series will be auto-contoured on Function|SAX Module

Smart Series Sorting is used to identify appropriate series that can be loaded into the current Module, and mark suitable series in the Series Thumbnails overview with a green checkmark. Series that are unsuitable are marked with red crosses.

To configure Smart Series Handling:



1. Click Preferences -> Appearance.

2. In the Smart Series Handling section there are two options: 1) Auto Load Series in Modules and 2) Enable Smart Series Sorting
3. Add checkmarks for the desired feature(s) to be enabled.
4. Click OK to save the configuration.

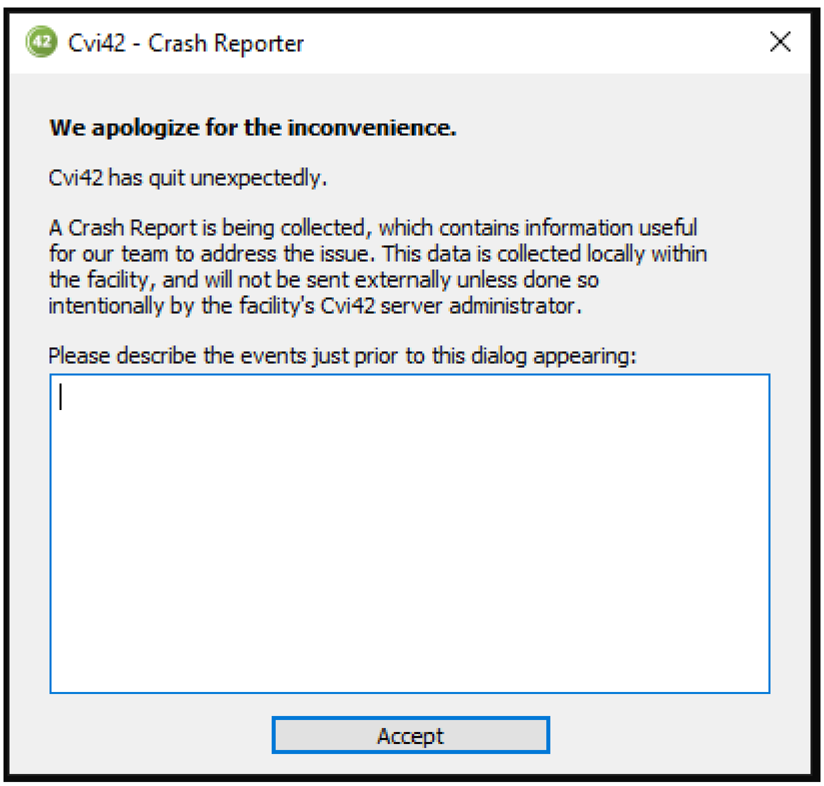
> **IMPORTANT**: By default Auto Load series in Modules is enabled and Smart Series Sorting is disabled.

4.6 Crash Reporter

The Crash Reporter is a feature designed to capture crash reports and other relevant details from software applications, as well as the machines running them. This information is used to improve software quality by understanding the nature of any unexpected problems that might occur during deployment.

This system is currently available for Windows only.

When a software crash occurs on a **cvi42** Client instance, the following dialog should appear:



> **IMPORTANT**: All data collected remains within the local network between the cvi42 Client machines and the cvi42 Server.

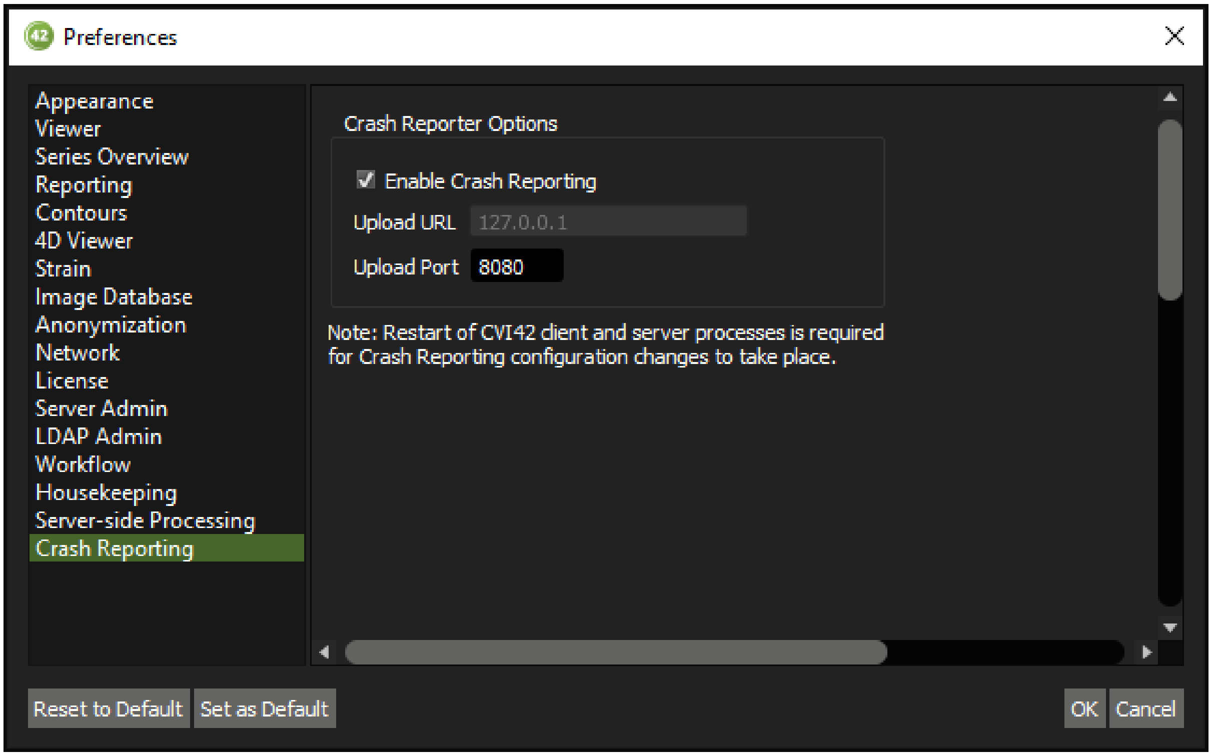
As an administrator, the Crash Reporter system can be enabled as follows:

1. Click Preferences -> Config, (Or press F12).

2. Click the Crash Reporting tab.
3. Check the Enable Crash Reporting checkbox.
4. Select a dedicated Upload Port that will always be available on the Server machine (0-65535).

> **IMPORTANT**: Ensure that a firewall on the Server machine is not blocking this port, otherwise Crash Reports will not be collected.

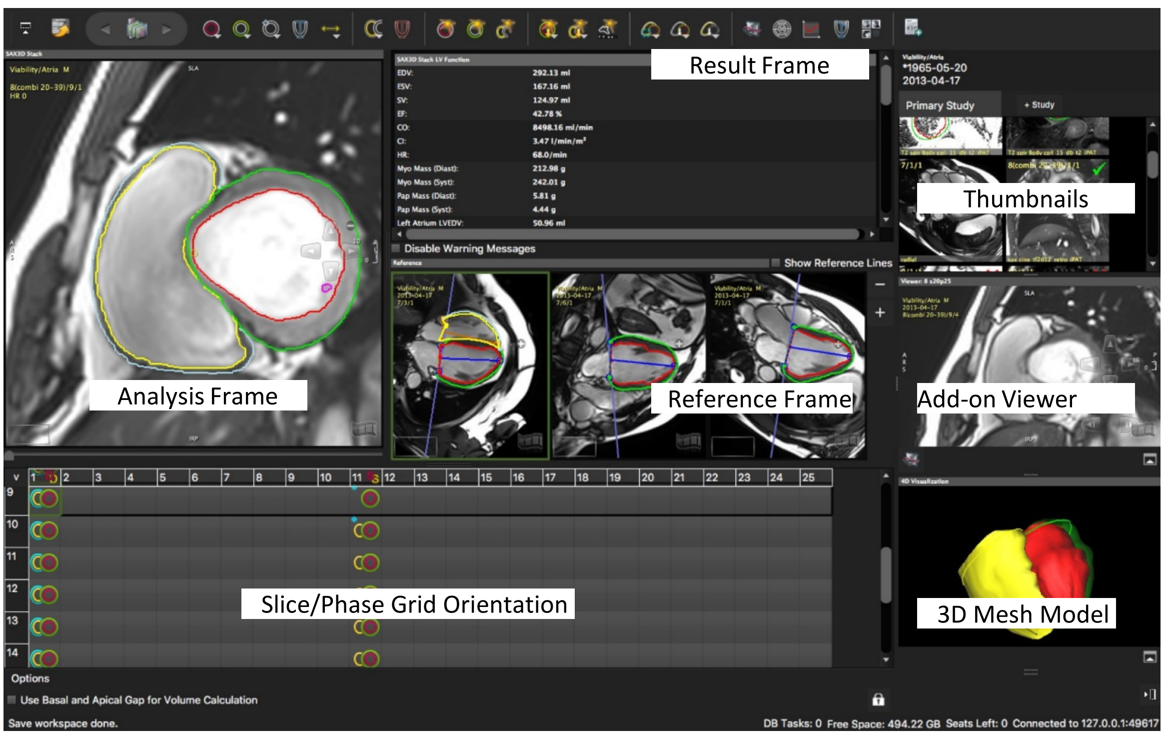
5. Restart all instances of CVI42 Server and CVI42 Client.



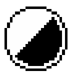
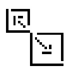
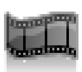
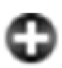
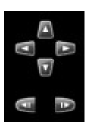
5 Viewing

5.1 View Ports - Overview

Each module provides viewer frames for image post-processing.
The frames are tagged and prepared for specific image sets (e.g. T2-weighted images)

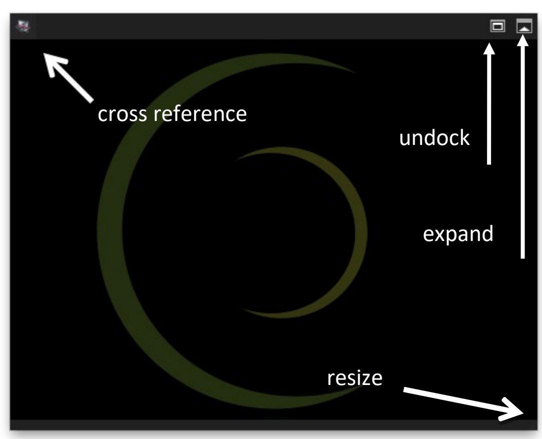


5.2 Image Editing, Viewer Controls

ICON	FUNCTION	MOUSE CLICKS	ALTERNATIVE
	**Windowing**	Push mouse wheel and drag Auto adjust: double-click MMB Holding shift-key+LMB and drag	Windowing pre-sets: keyboard keys 1-2-3-0 Windowing pre-sets: context menu Define your own pre-set via *Edit* in the context menu
	**Panning**	Hold LMB down and pan	
	**Zooming**	Scroll mouse wheel	Move cursor to the right frame border until symbol appears; LMB drag up/down Context menu: Image/Auto adjust Zoom
	**Cine mode**		Spacebar
	**Navigation**	Open on-screen navigation buttons	
	**Scroll through phases/slices and series**	Hold the shift-key and scroll the mouse wheel	Keyboard arrow keys Customize your mouse wheel: Preferences/Viewer/Mouse Wheel function

5.3 Additional Viewer

5.3.1 Floating Viewer

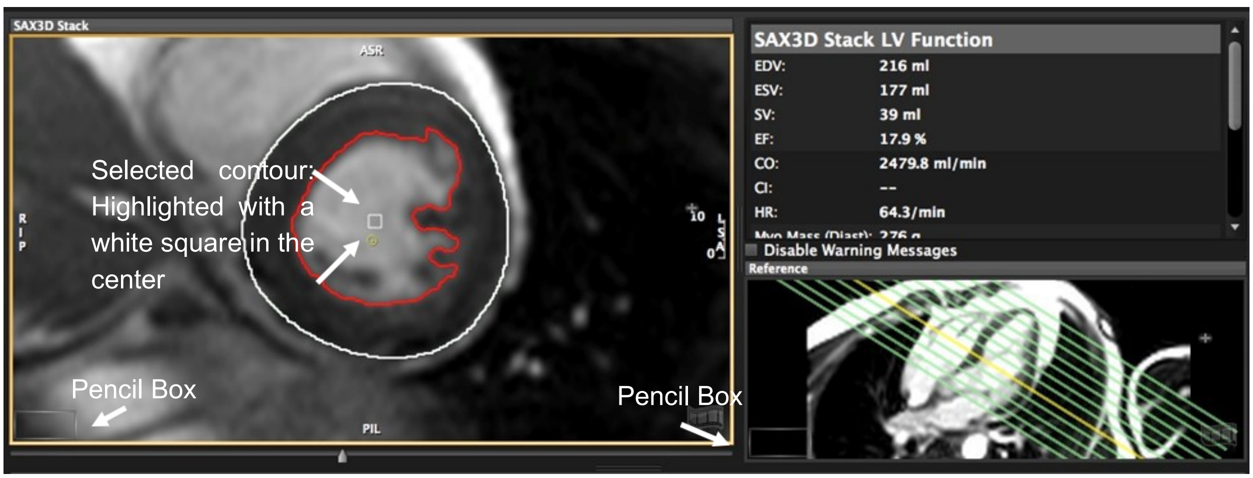


- Located underneath the thumbnail panel, is an additional detachable viewer that can be undocked and changed in size. It will stay on-screen even when switching to a different module.

- Expand/Collapse Viewer: Select an image via drag-and-drop from the thumbnail panel

- Provides a cross reference

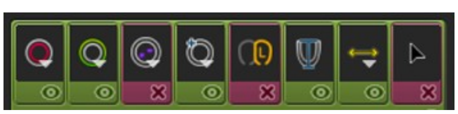
6 Contour Drawing, Labeling and Measurement Tools



- Drawing tools are in the top toolbar or the on-screen pencil box
- Tooltip: All buttons show a brief description on mouse hover

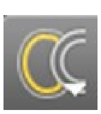
6.1 Manual Contouring

Some tools are hidden by default (as shown below in pink - See Chapter 2) The toolbar is sorted into tool-sets:



For the left heart chambers

For the right heart chambers

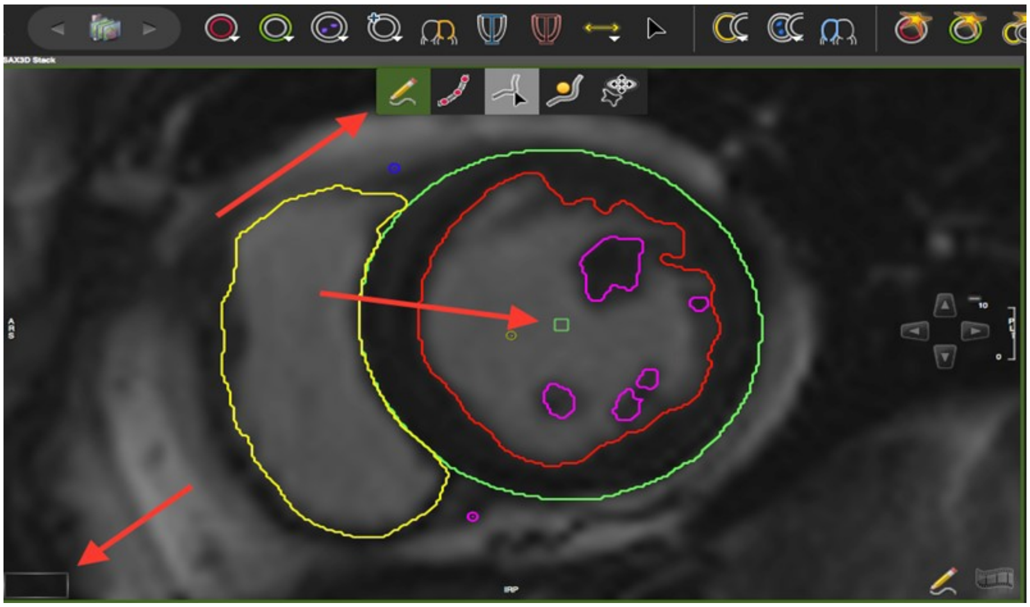


Buttons with a small white triangle indicate that there are more options provided:
Click and hold the LMB for displaying more options
To select, drag the cursor to the desired function and release the mouse button

6.1.2 Manual Contour Definition

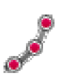
1. Select a tool with a LMB click
2. To draw, click and hold the left mouse button
3. To switch to another tool, simply click on the new tool
4. To drop the tool, double click LMB anywhere within the frame or click ESC
5. The mouse cursor will display the tool that is active

6.1.3 Using a Selected Drawing Mode (e.g. by setting points)



1.  Select a contour (e.g. endocardial)
2. Open the pop-up menu and select the drawing mode:

Freehand: default



Click-Draw-Contour: sets a series of points for edge definition

Threshold segmentation: allows to define borders by dragging with the LMB downwards and sideways until you have found the threshold that best defines your border

Nudge Contour: allows to drag part of the contour in a defined direction

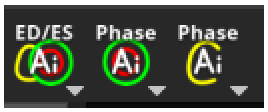
Push Contour: Shape the contour by pushing the circle

3. Switch back to the freehand mode
4. The selected drawing mode is displayed on the lower right corner of the frame

6.1.4 Semiautomatic Contour Detection

1. Target your area of analysis (LV or RV) by centering the small yellow circle (target point) in the respective chamber cavity. Therefore, drag the image and not the yellow point.
2. Click the button once to apply a contour detection
3. Click and hold to adjust

6.1.5 Automatic Contour Detection



For automatic contouring based on deep learning please refer to the respective modules.

6.1.6 Contour Saving and Deleting

Contour Saving

- Contours are saved automatically

Contour Deletion

- Delete or backspace key
- Context menu
- Shortcut keys (listed in the context menu)

Note: A warning message will be displayed in the results frame (and the exported reports), if:

- Only one phase has been evaluated
- The number of evaluated slices differ between systole and diastole
- Less than 3 slices are used for calculations

At the readers' discretion, warning messages can be turned off. They will re-appear after contour alteration.

WARNING: Automatic Contour Detection
The automatic contour detection provides an initial assumption of contour definitions. It is the responsibility of the user to verify and correct the results.

7 Workspaces

7.1 Workspace Menu

By default, drawn contours are automatically saved and will be reloaded when the patient study is reopened. In addition, the user has the option to:

- *Load Workspace*: Loads a workspace that has been previously stored in a location other than the default location. ("Save Workspace As" option)
- *Save Workspace*: Saves a newly created or updated workspace in the default location
- *Save Workspace As*: Saves the workspace to a different location
- *Load Workspace DICOM*: Loads a workspace that has been previously created as a DICOM Secondary Capture
- *Save Workspace DICOM*: Saves the current workspace as a DICOM Secondary Capture and appends it as an image to the series
- *Import Workspace*: Imports a workspace from a local filesystem
- *Export Workspace*: Exports a workspace from a local filesystem
- *Reset Workspace*: Deletes all drawn contours in the current patient study, and clears all frames
- *Close Study*

8 Patient Data Module

WARNING: Patient Data
The displayed study/patient data is initially derived from the DICOM information if available. Note that editing these values affect the calculations of all modules. It is the responsibility of the user to verify the data before releasing final results.

Note: To change from metric to imperial units go to *Preferences>Appearance>Patient Data Metric*

8.1 Edit Patient Data

1. Edit patient related data necessary for calculation, documentation and reporting
2. Enter patient related comments
3. Create a *Case Review Presentation*: Select your image for review via context menu, Add Current Series to Case Review or ⌘R.
4. Present Your Case Review: Go to *Overview* and select *Case Review* in the Filter

Note: The software retrieves the heart rate from the first image of a series. A heart rate over 250 bpm will not be displayed. The value remains at 250 bpm.

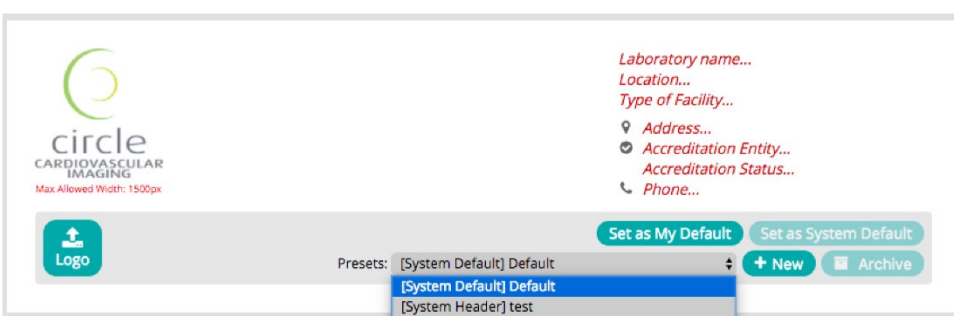
9 Report Module

9.1 Customize Logo and Header

To create the first header, simply type your address and upload a logo. This header will be set for all reports. To support multiple headers, or to select a banner logo, Click on "+New".

- Select system (admin only) or User specific header.
- Enter a "Preset Name" for the header.
- Select Logo or Custom header (I.e. for a banner style header).
- Check "Set as My Default" to set a default.
- Save.

The saved header will now be available for reports. Preset headers can be selected using the first drop down "Presets".



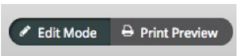
Only users with the system admin role can add system headers.

Users with reporting permissions can create their own headers.

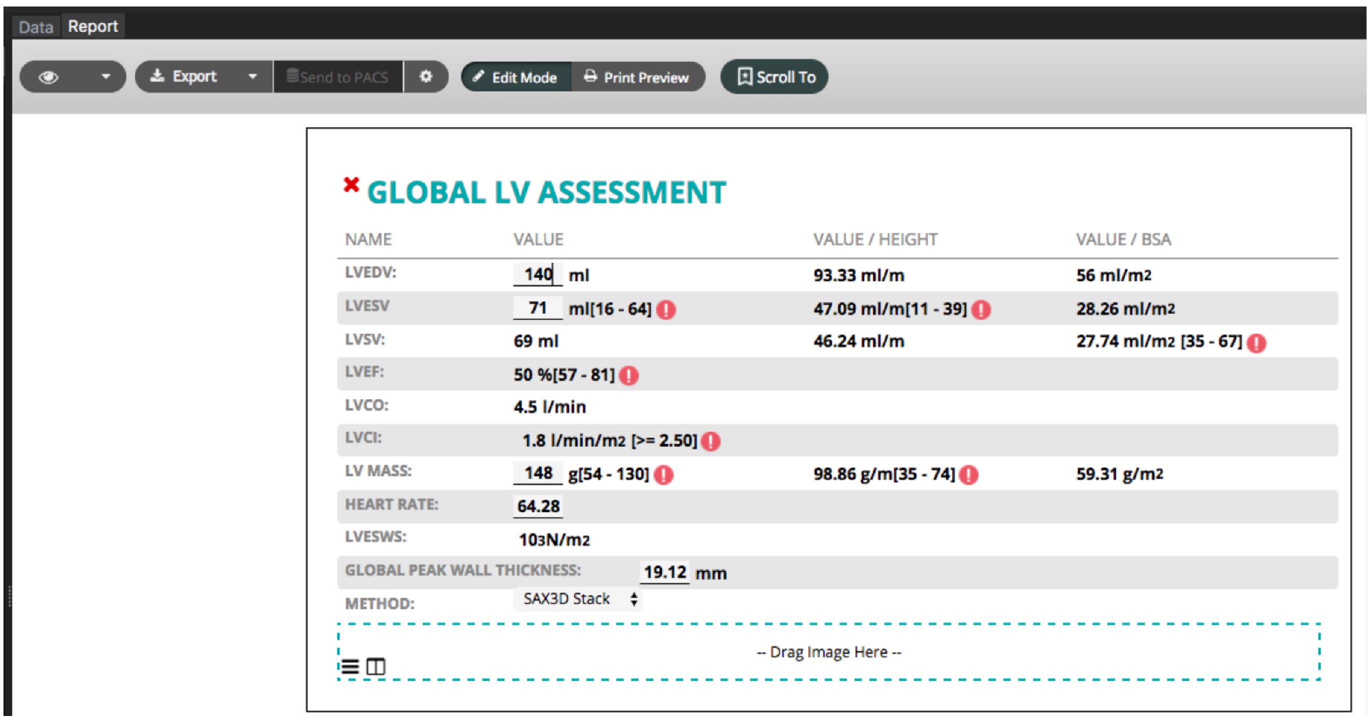
User specific headers cannot be shared with other users.

A user can select that their own header is used as a default over the system default

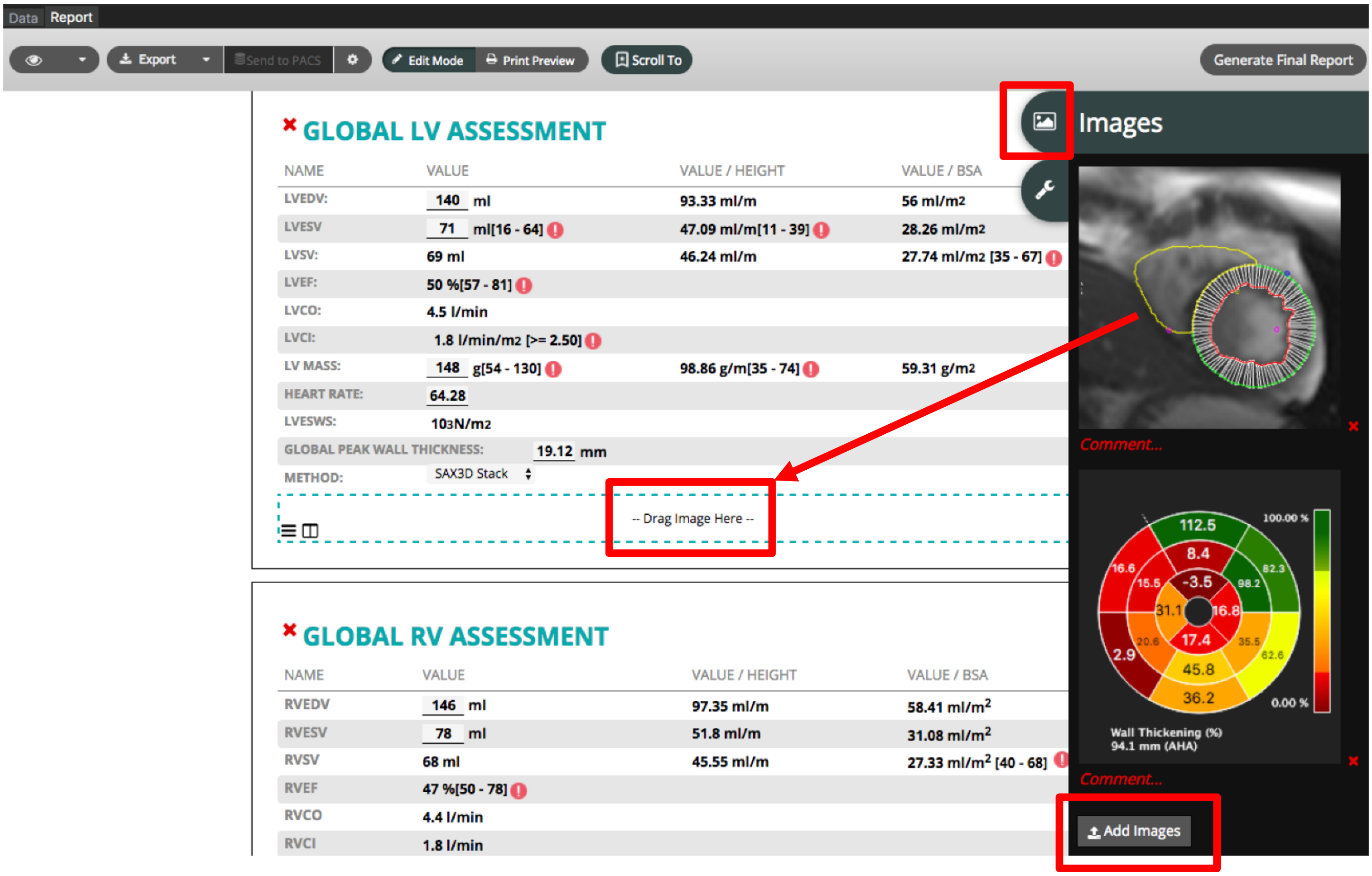
9.2 Create a Report

- *Add to report* will transfer analyses and measurements to the report module
- 

The report will open in *edit mode* initially, *print preview* mode can be toggled on/off but editing is not possible in this mode.
- If gender and birthdate are present, normal values will be classified




Images collected during the analysis are available in the Image tab and may be added by drag-and-drop into designated "—Drag Image Here—"areas

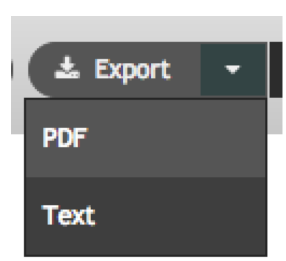


- *Add Images*: Additional images (e.g. polar maps), can be exported to the desktop and imported into the image pane via the *Add Images* at the bottom of the image pane
- Image captions can be edited from within the image pane, or inline in the report, by clicking on the text directly below the image
- Deleting an image from the report section will return the image to the Image pane

1. Review the report, add findings and write the summary

2. Generate a final report. Once a report has been finalized, a .pdf of this report is stored in settings pane, under History

3. Once the report is done go to *Export* and select the output format. The selected output format will be remembered for future reports



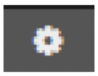
9.3 Update the Report

- Update before finalization, after contour corrections or recalculations: In the module click *Add to Report.* The report should automatically update, it might take a few seconds.

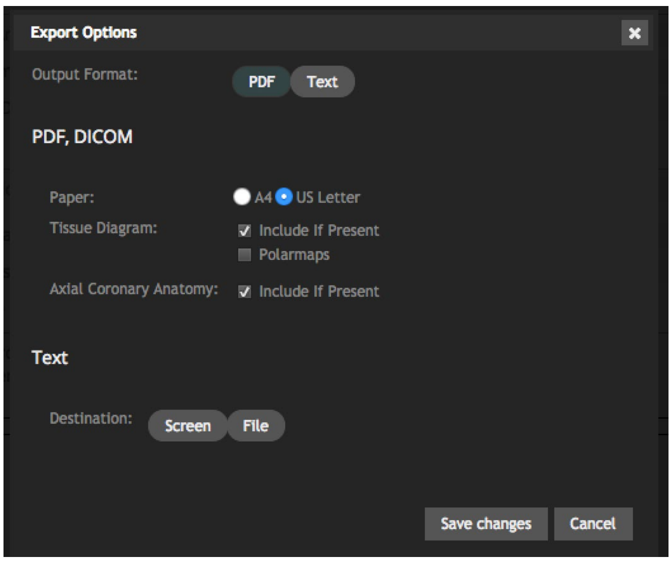
- Update after finalizing the report: Do the same as above and click create addendum.

Note: Any finalized reports or addendums will have a pdf stored under settings pane, *History*.

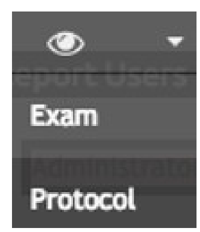
9.4 Configure Export Options



Click the configuration button (gear icon) to set your Export Preferences:



9.5 Show/Hide Report Fields

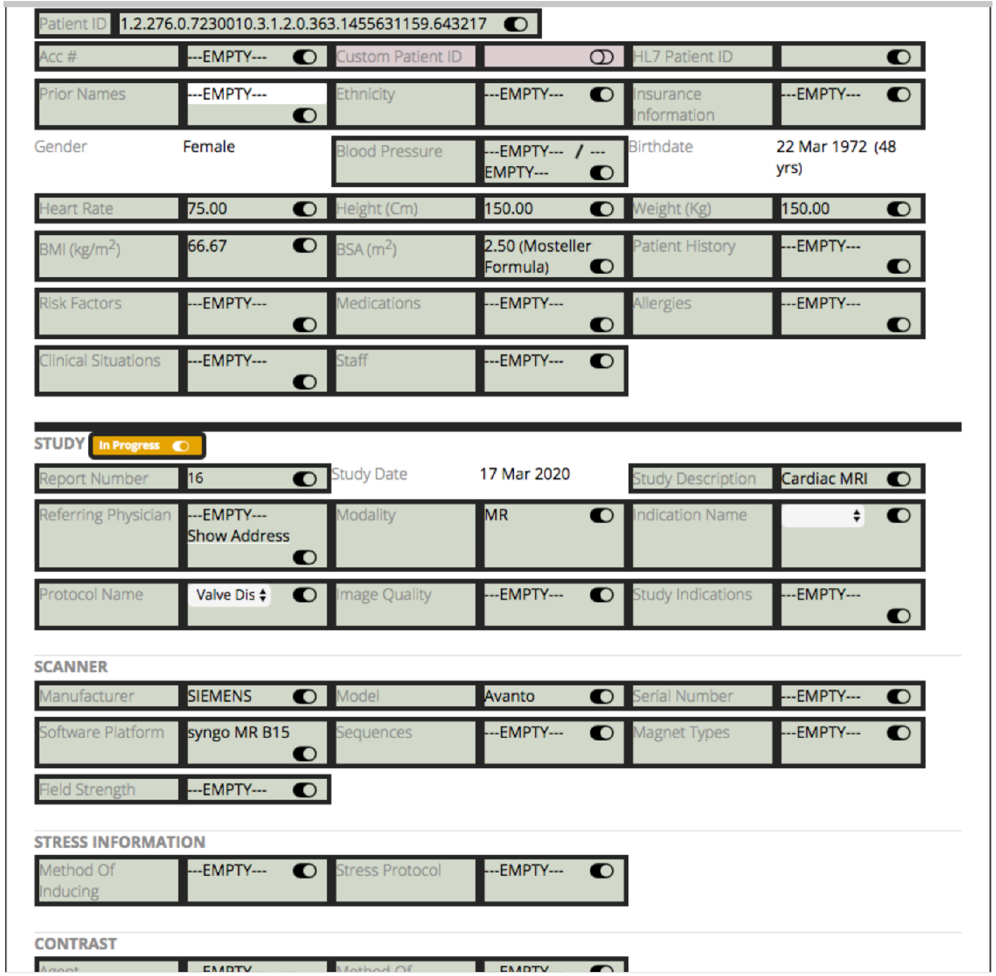


From the drop-down, select what you would like to edit:

- *Exam*: allows to hide sections for the current report (Note that this is the only mode available to non-administrative users and will be used by default)

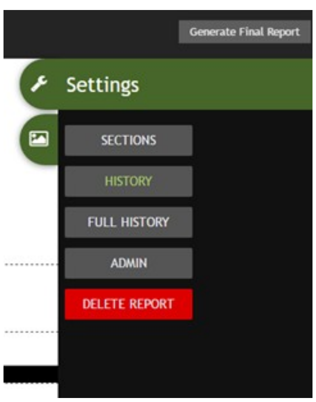
- *Protocol:* available to administrators, this mode will save the selection to the current protocol

1. Click the eye icon and toggle the field-visibility switch to hide/show report fields. Fields highlighted in red will be hidden from the onscreen and printed/exported reports. Fields highlighted in beige will be visible
2. Click the eye icon again to return to report editing mode



9.6 Delete Report

To start with a new report, use the delete report option and the software will create a new report.



10 Series Overview

Intended use:

- Get a quick, in-depth overview of sequences and images
- Choosing image/ series for evaluation
- Series Composer sub-unit allows for recomposing studies

If Smart Series Sorting is enabled, cvi**42** will identify appropriate series that can be loaded into the current module. Suitable series are marked in the Series Thumbnails overview with green checkmarks. Series that are deteremined to be unsuitable are marked with red crosses and cannot be loaded into the current module.

10.1 Series Overview

Use *PgUp/PgDown* to navigate to the next/previous series in slideshow mode

10.1.1 How to Open a Series in One of the Analysis Mode

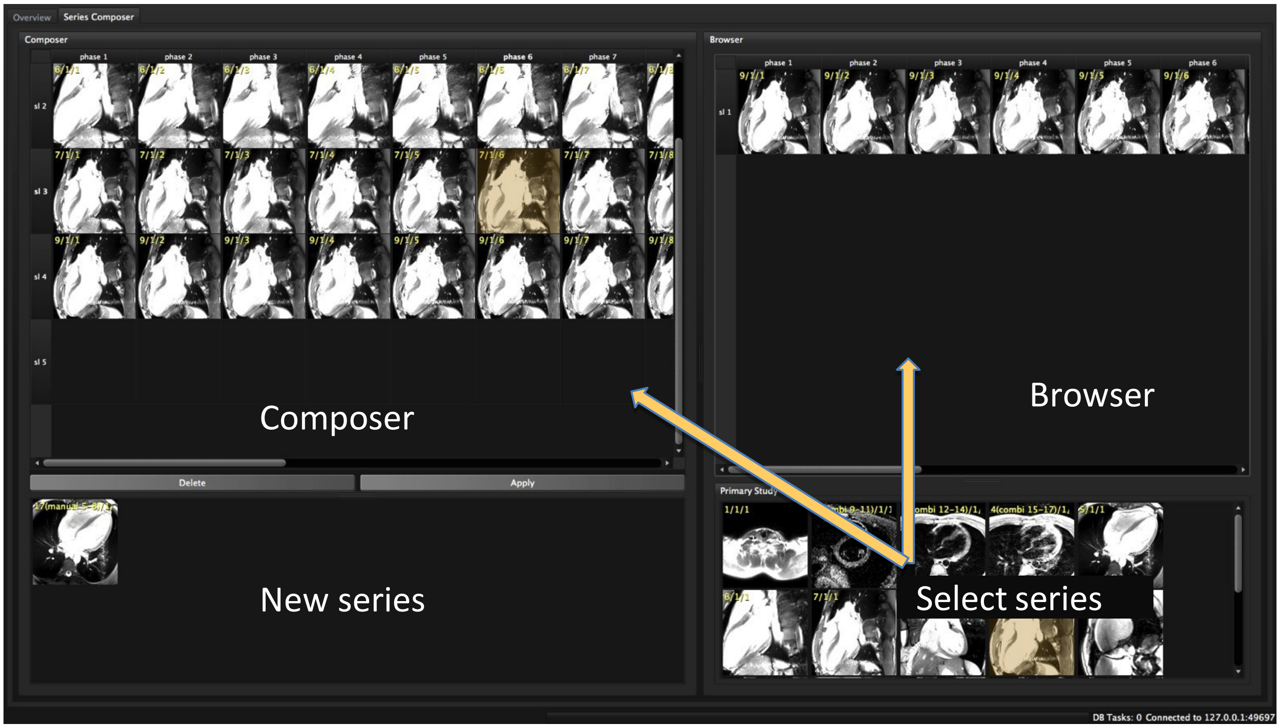
1. Drag and drop it into one of the modules in the module pane

or

2. Open the context menu with a right mouse button (RMB) click and select the module from here

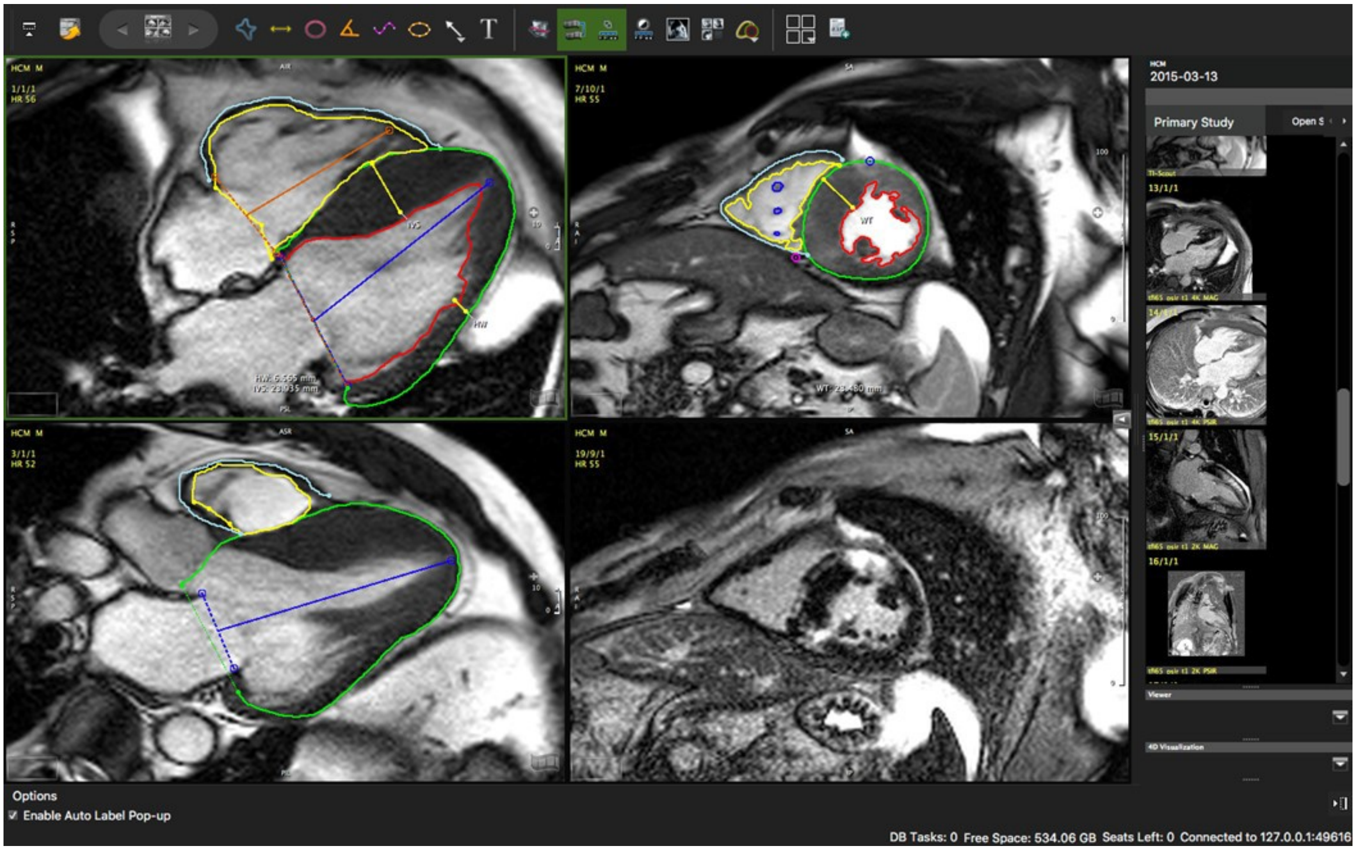
10.2 Series Composer

The Series composer allows to generate new manually composed series.



1. Drag a series to the *Browser*, choose slices or phases and drag them into the composer
2. A complete series can be dragged directly to the composer
3. For sequence information (e.g. trigger time or slice location) hover over an image
4. In the *Composer* select the phase/slice or series and use the context menu to remove, insert or sortimages
5. Click *Apply* to assemble the newly composed series and name it. The lower window provides a showcase for newly composed series
6. A newly composed series will automatically be appended to the list of series. Manually composed series can be identified by their tag (e.g. 28 (manual 9/1/1)
7. Rename and remove manual series from the study with RMB on the manual series in the thumbnail preview pane.

11 Study Viewer Module



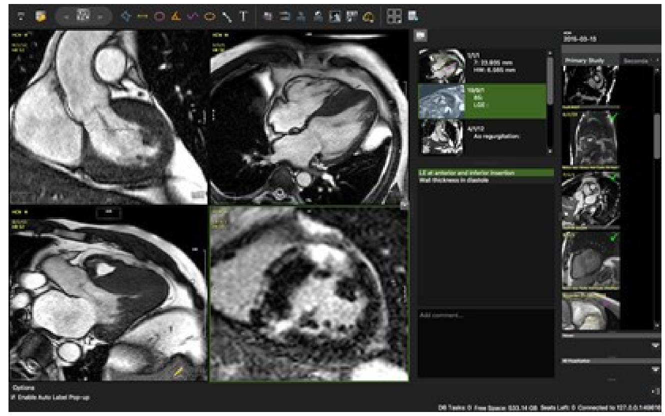
Intended use:

- View and compare multiple sequences next to each other
- View and compare multiple scans of one patient next to each other
- Perform and automatically capture measurements
- Add contour labels and annotations
- Add comments/findings that will be pushed to the report *Findings* section

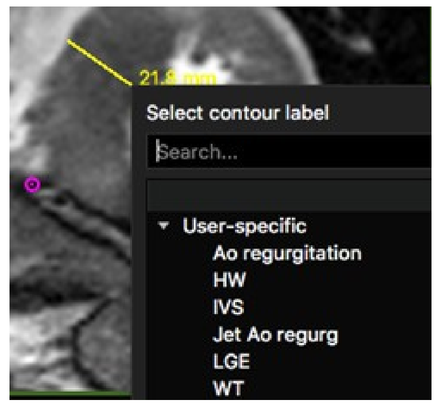
When using the Study Viewer Module, if "Auto Load Series in Module" is enabled, cvi**42** will auto-load an appropriate SAX CINE series into the first viewer frame and appropriate LAX CINE series will be auto-loaded into the subsequent frames.

11.1 Custom Measurements

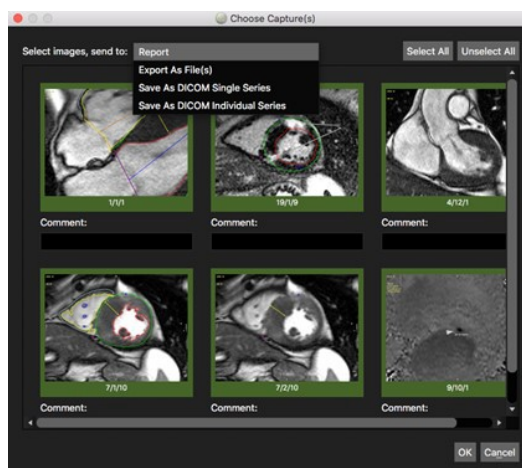
- Open the measurement capture pane



- Perform measurement
- Label the contour
- Image and measurement will be captured automatically in the pane to the right



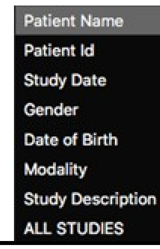
- Click the small camera to
- Send captures to the report, export or save them
- Optionally add a caption



- *Add Comment* and click enter. Comments will be listed underneath the captures. After adding them to the report, they will show in the findings section

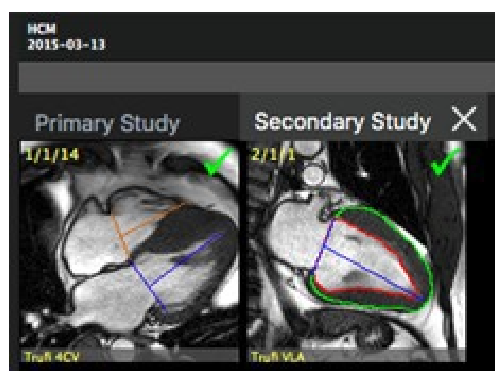
11.2 Compare Follow-up Scans

- Click *Open Secondary Study* in the thumbnail pane
- Select a Filter and type an identifier
- Click on the tabs and drag series in the viewer frame



- The secondary series will be marked by a green frame

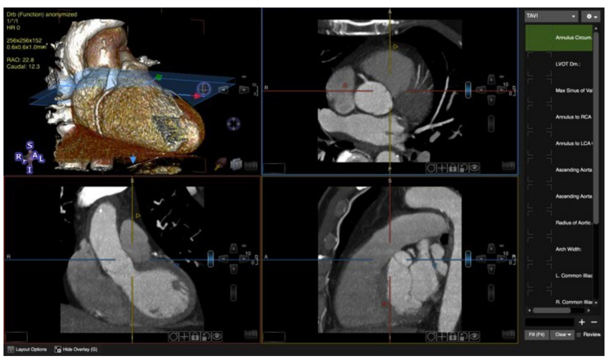
- Click the 'X' to unload the series
- It is possible to do a measurement on the secondary series, but they will not be captured



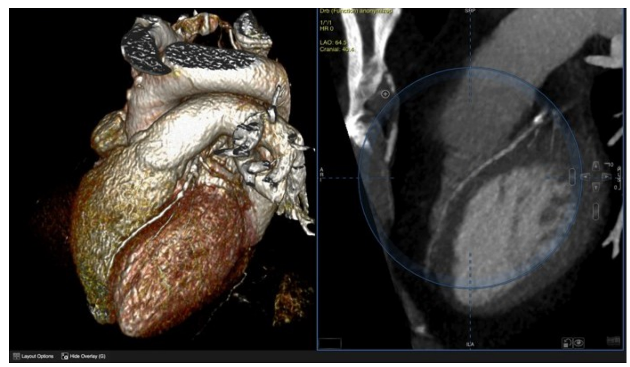
12 Multiplanar Reformatting

Intended use:
Reconstruct a slice in any position and orientation through the 3D Volume.

The MPR Module provides 2 tabs:



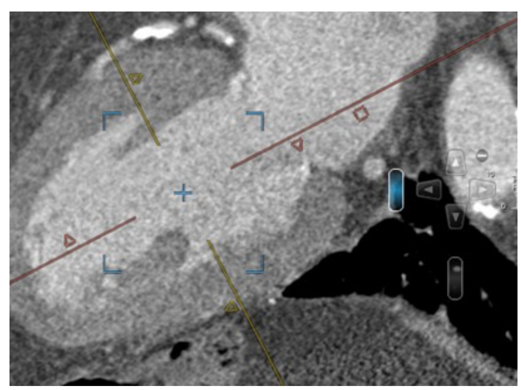
Double Oblique



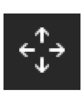
Free Form Navigation

12. 1 Double Oblique

12.1.1 Navigation



By default, a mouse drag in the view port slices through the volume. Alternatively, click the arrow keys.

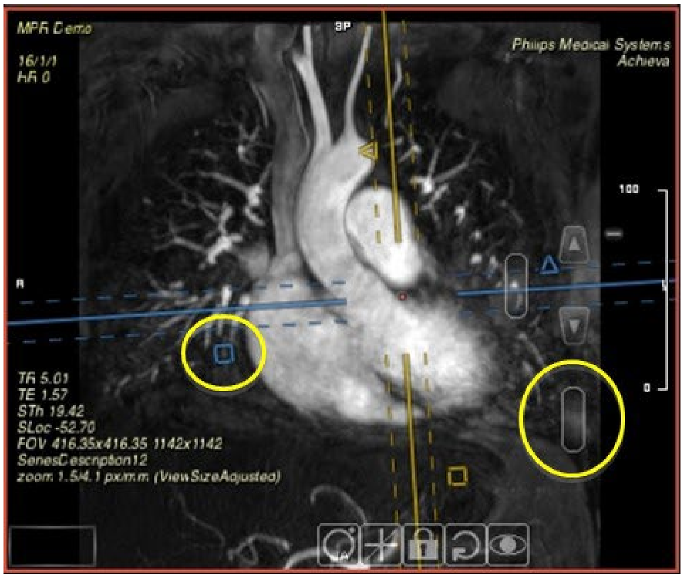
 Use the toolbar button to toggle between panning and slice navigation. Alternatively press the Ctrl (command) key to switch to panning.

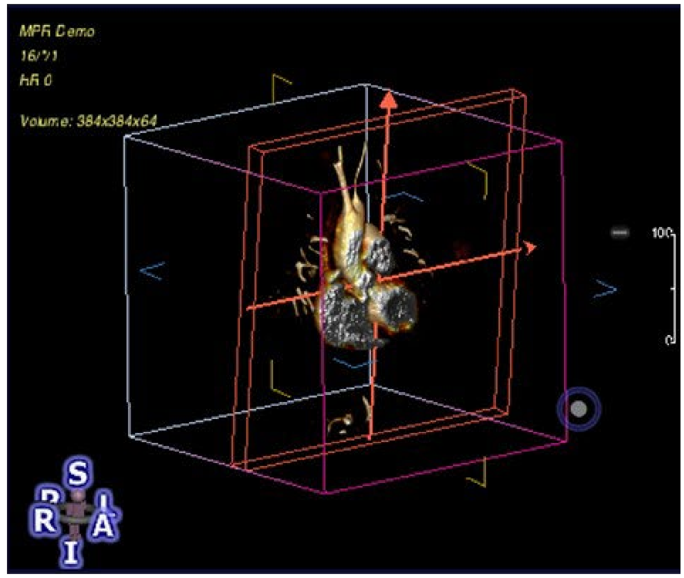
12.1.1.1 Crosshair Navigation

- Two color-coded orthogonal crosshairs within a viewport correspond to the frame with the same color
- Drag the center of the crosshairs to reposition the MPR center. Alternatively, click in a region of interest within the Reference Viewer
- Dragging a crosshair on a triangle will rotate around the MPR center, the lines will always stay orthogonal to each other
- Dragging a crosshair close to the center allows to rotate, and close to the end allows to move it in a vertical/horizontal direction.
- This behaviour will be indicated by icons when hovering over the line
- To move the crosshairs individually, open the context menu and select *Rotate Individual Plane*
- Dragging on a square will adjust the slab thickness

12.1.1.2 Adjust the Slab-Thickness

- A square **icon** next to the crosshairs allows to change the slab thickness by dragging the square
- Another option to change the slab thickness is the **slab-thickness scroll bar** (see screenshot): Dragging the scroll bar with
- LMB increases/decreases the slab thickness using the smallest amount of data increment available for the loaded volume

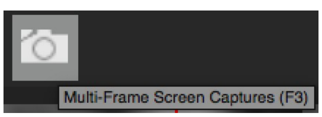




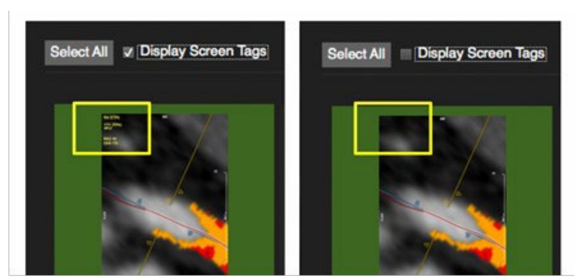
12.1.2 Reporting and Saving of Image Captures and Measurements

12.1.2.1 How to use Multi-Frame Screen Capture (top toolbar)

Add single or multiple images of the current layout to your report.



1. Click the icon in the top tool bar
2. To add images click *Select All* or select single images
3. Choose between displaying or hiding Screen Tags
4. Optionally enter a comment
5. Other options are *Export As Files* and *Save As DICOM*
6. Finally, click the *Add to Report* button
7. Images will show up in the report



12.1.2.2 How to Save Measurement Captures

Add captures to the report.

1. As soon as you have done a measurement the capture will show up in the panel as *Untitled*
2. Drag a label on the capture
3.  Click the small camera in the panel to add the capture to the report
4. The captures are part of the workspace and can be reviewed by clicking on the capture
5. Labels will be “auto” saved alongside with the current workflow protocol per user

12.2 Navigation Tab

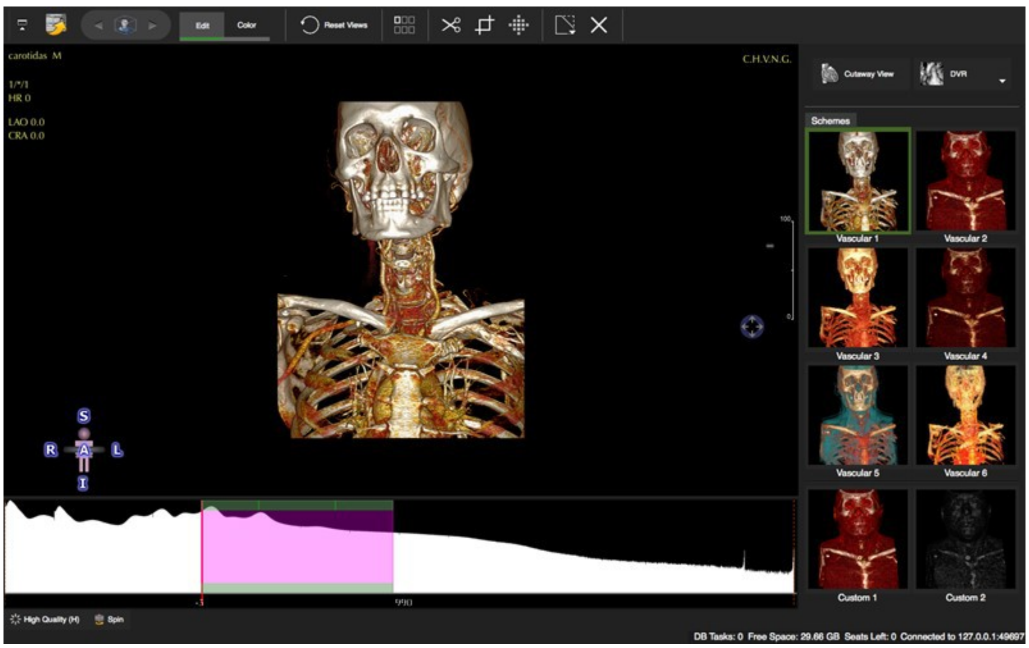
1. Select the MPR viewer Frame and click the *Navigation* sub-module button
2. Move the MPR center by clicking in your ROI
3. Slice Navigation: left mouse drag or by dragging the slice navigation slider
4.  Toggle on *Rotate Image* to freely rotate with a mouse drag within the circle
5. When in *Slice Navigation*, you can still freely navigate initiating your mouse drag in the shaded area, of thecircle
6. Hold the center of rotation during free-form navigation: Click the "+" at around 11 o'clock or use the modifier key"Shift"
7. When your mouse wheel is set to *Slice Navigation* (Preference->Viewer->Mouse Wheel Function) it is possible to

accelerate slice navigation by holding down the Ctrl/CMD key

13 4D Viewer

This viewer is designed to analyze 3D and 4D data such as MR and CT (**cvi42** only) angiography. The *4D*

Viewer module provides 2 sub-modules: *Edit* and *Color*



13.1 Edit

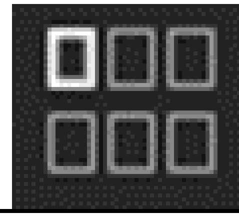
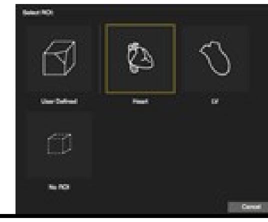
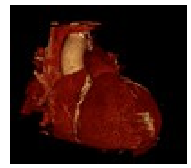
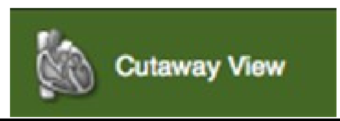
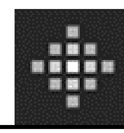
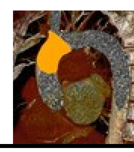
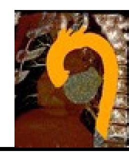
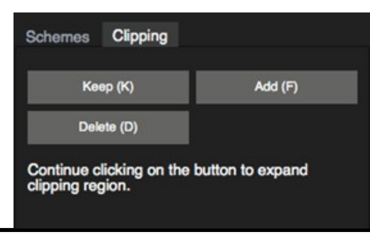
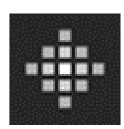
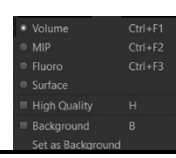
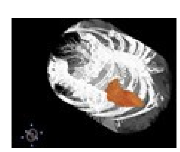
- Drag a 3D, 4D or stacked 2D image data set into the viewer frame.
- The right-side panel offers different rendering options as well as a *Cutaway View*, to scroll through a volume in this view press Ctrl+Alt and drag the LMB.

13.1.1 Measurement Option

- *Measurement* is an option that can be found in the context menu.
- It allows to set a marker which will indicate the position within the volume that can be viewed across pages and modules. Marker points are automatically saved to a workspace

13.1.2 Segmentation

13.1.2.1 How to Do an Automatic Segmentation

• Select the *Region of Interest* • Select one of four options	 
ROI-Heart: • The heart will be segmented automatically	
ROI - User defined: • Activate the Cutaway button (former View Clip)	
• Activate the 3D Region Grow Clip	
• Point the cursor in the middle of your ROI and drag	 
• When you are done, go to the clipping pane and click Keep	
• Turn off the grow button	 
• Optionally, add a background: Context Menu>Rendering>Background	 
ROI-LV: • Repeat steps 1-6	 

• No Region of Interest • Will display the original volume	

13.1.2.2 How to Use Clipping and Cropping

1. Select the tool from the tool bar and select a drawing mode from the tool pop-up menu (default=freehand)

2.  *Cut: Drag the mouse cursor to encircle structures you would like to remove*

3.  *Crop:* Drag the mouse cursor to encircle things you would like to keep

4.  *Grow*: Move the cursor over the region of interest. A black dot will indicate the software has detected a structure that can be segmented. A red square will appear over a structure that has already been segmented. Dragging the cursor downwards will define the region of interest according to the SI threshold. Dragging the cursor sideways will increase the threshold, taking more SI into account.

5. To rotate  or pan  the volume while in clipping mode, move the mouse over the icons and drag

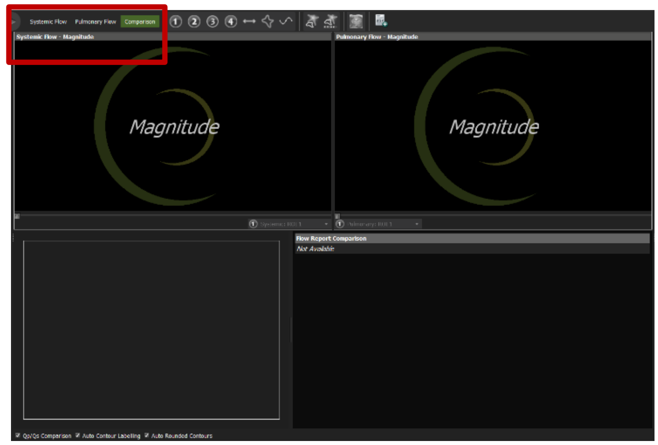
13.2 Color

- **Ambient** Light: simulates surrounding light
- **Diffuse** Light: light that reflects into all directions
- **Specular** Light: simulates the light reflection on the surface depending on the vantage point
- **Shininess**: increases the highlights

Color Schemes: cvi42 provides 6 predefined color schemes (vascular 1-6) and 2 custom schemes

14 Flow|2D

Flow analysis (Only through plane velocity encoding) Intended use:

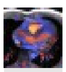


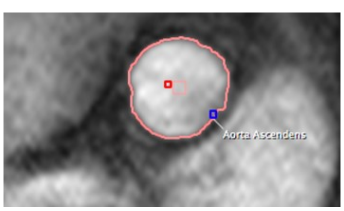
- Color-coded flow display with semiautomatic contour detection, synchronization and forwarding
- Automatic calculations of flow parameter
- Shunt assessment (Qp/Qs)

The *Flow1/Systemic Flow*, *Flow2/Pulmonary Flow* and *Comparison* tabs are located at the top of the module

14.1 Flow Quantification

14.1.1 How to Do a Flow Analysis

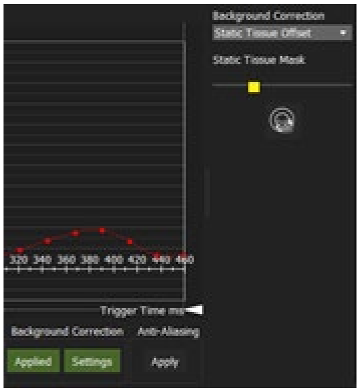
1.  For color encoding click on the *Toggle Flow Overlay* button
2. To reduce noise, the threshold color overlay can be adjusted;
3. Define the vessel border
4. Label the contour
5.  Forward the contour. The automatic contour detection will grow the contour towards the vessel borders based on the information from all phases. It also forwards the contours to all phases



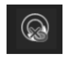
6. Scroll through phases to ensure the contours are correct
7. *Add to Report*: Flow assessments of different series have to beadded individually to the report

14.1.2 How to Do a Flow Correction

When clicking on "Apply" in the Background Correction options, a static tissue mask offset correction is automatically applied. The "Settings" are automatically displayed, so that the user can check and edit the correction that has been applied. Click again on "Settings" to hide the settings panel.



Background correction options:

• Offset Correction: Define Static Tissue mask (yellow) with the slider. Manually exclude regions that should not be part of the static tissue mask, e.g. spatial aliasing, using the "Erase Mask" tool 

• Phantom Correction: Drag the phantom image in the box

• Background Correction (BC): Click on BC, draw and forward (use context menu command) a ROI in an area with no flow

Anti-aliasing shall be applied as the last step of the flow analysis (after ROI drawing and correction, and after background corrections).

14.1.3 How to Display Flow Curves

1. Use the color-coded checkbox to toggle flow curves on/off
2. Invert Results in case of wrong encoding directions
3. Shift the curve on the time axis for better viewing
4. Adjust the triangles on the bottom of the graph to calculate flow within a set time range (inside ruler)
5. Hover over a data point to view the numbers
6. A right mouse click in the graph opens a context menu, that offers several display options and an option to export the flow curves
7.  Add to report. Flow assessments of different series have to be added individually to the report

15 LV/RV Function Modules

15.1 Function|Biplanar LAX Module

Intended use:

- LV function analysis biplanar in 2CV and 4CV or triplanar by adding a short axis view
- Atrial volumetry in one or 2 planes
- Cardiac valve displacement (MAPSE/TAPSE assessment, longitudinal atrial and ventricular function)

WARNING: Longitudinal atrial and ventricular function are not for clinical use.

WARNING: Bi/Triplanar
For the calculations, the diastolic and systolic phase are assumed to be in the same phase of the cardiac cycle in all three views. The volume calculation is done per phase. The smallest volume is assumed to be the systolic volume and the largest volume is assumed to be the diastolic volume. In case a volume can be calculated for one phase only, ESV and EDV will be displayed as equal and no calculations will be performed for derived parameters such as ejection fraction.

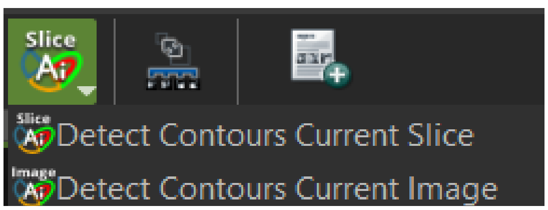
Endocardial contours must always be on the inside of the epicardial contour, does not check for that.

Calculations in **cvi42** are performed based on the current state of contour definition and image selection. For every change the calculations are updated immediately. It is the responsibility of the user to decide whether the stage of contour definitions reflects the intended measurement task.

When using the Function|Biplanar LAX Module, if "Auto Load Series in Module" is enabled, cvi**42** will auto-load an appropriate 2CV LAX CINE series into the first viewer frame and appropriate 4CV LAX CINE series into the subsequent frame.

15.1.1 How to do Biplanar LAX Automatic Contour Detection

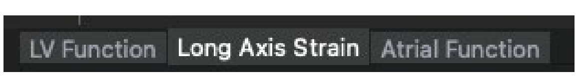
- There are two AI options. The first one will detect LV, LA and RA contours on all phases of the selected 2CV and 4CV slices, and the second one will do the same for the selected image (phase) only.



- Right-mouse clicking on the AI tool will open a dropdown menu with the available AI options.
- Choose an option and activate it with LMB click.
- Check the contours and correct if necessary
- Add the analysis to report

The on-screen report is split into 3 tabs:

- LV Function
- Long Axis Strain
- Atrial Function



The LV function contains all quantitative LV function data, including MAPSE (2CV, 4CV) and TAPSE (4CV) measurements.

LV Function

Biplanar LV Function

not available

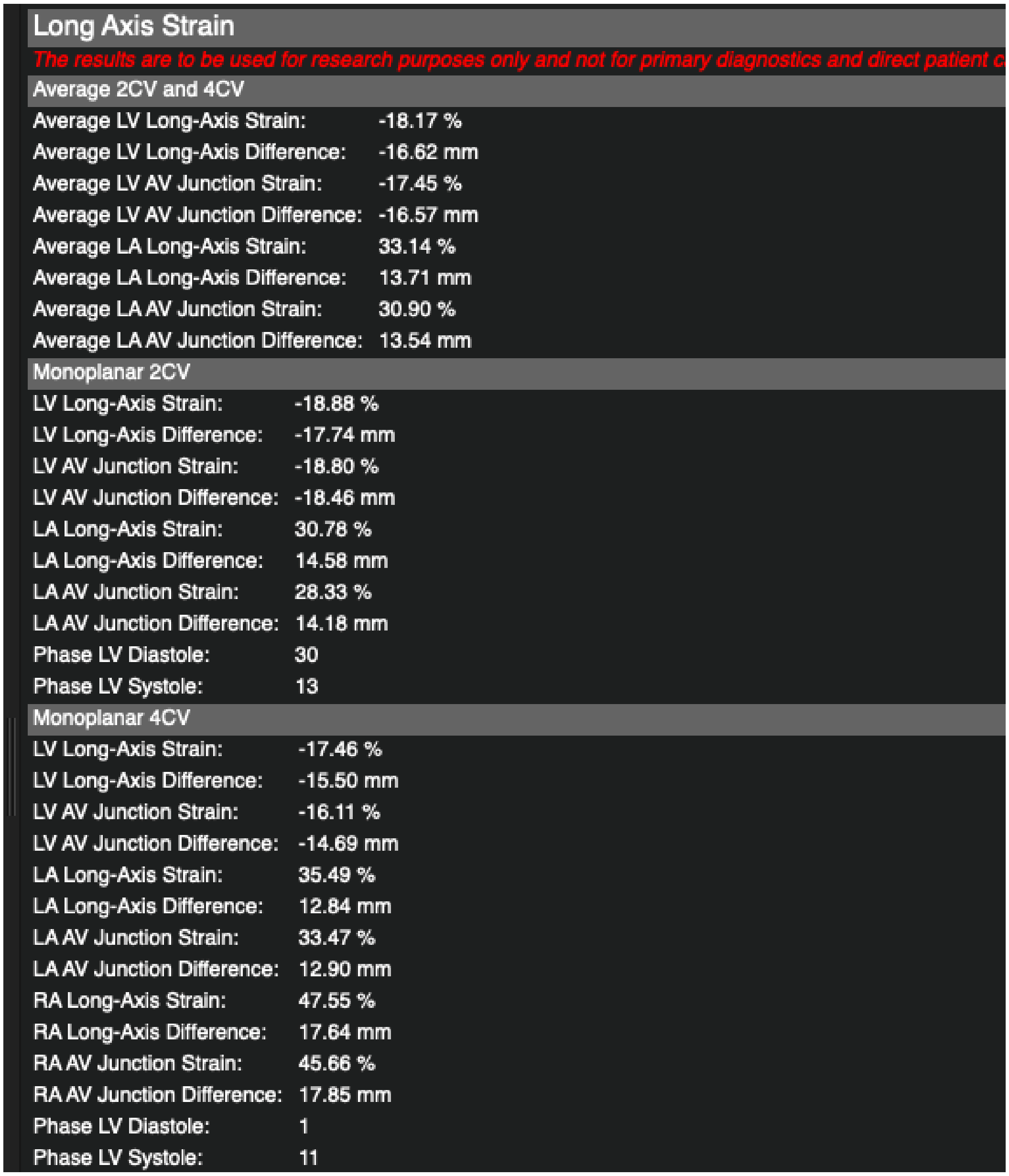
Monoplanar 2CV LV Function

EDV:	**226.06 ml**
ESV:	**88.44 ml**
SV:	**137.62 ml**
EF:	**60.88 %**
CO:	**7.43 l/min**
CI:	**4.03 l/min/m²**
HR:	**54.00 /min**
Myo Mass (Diast):	**299.84 g**
Myo Mass (Syst):	**329.47 g**
Phase LV Diastole:	**24**
Phase LV Systole:	**10**
EDV/H:	**129.18 ml/m**
EDV/BSA:	**122.55 ml/m²**
ESV/H:	**50.54 ml/m**
ESV/BSA:	**47.94 ml/m²**
SV/H:	**78.64 ml/m**
SV/BSA:	**74.61 ml/m²**
Myo Mass/H (Diast):	**171.34 g/m**
Myo Mass/BSA (Diast):	**162.55 g/m²**
Myo Mass/H (Syst):	**188.27 g/m**
Myo Mass/BSA (Syst):	**178.61 g/m²**
MAPSE Inferior:	**16.02 mm**
MAPSE Anterior:	**7.20 mm**

The Atrial Function page includes all atrial function data, with the introduction of EF and indexed values

Atrial Function	
Biplanar LA Function	
not available	
Monoplanar 2CV LA Function	
Left Atrium Vol at LVED:	**92.62 ml (25.08 cm²)**
Left Atrium Vol at LVES:	**155.97 ml (35.77 cm²)**
Phase LV Diastole:	**24**
Phase LV Systole:	**10**
Left Atrium Vol at LVED/H:	**52.92 ml/m**
Left Atrium Vol at LVED/BSA:	**50.21 ml/m²**
Left Atrium Vol at LVES/H:	**89.13 ml/m**
Left Atrium Vol at LVES/BSA:	**84.55 ml/m²**
Min LA Vol:	**92.62 ml (25.084 cm²)**
Phase Min LA Vol:	**24**
Max LA Vol:	**159.76 ml (36.260 cm²)**
Phase Max LA Vol:	**9**
Min LA Vol/H:	**52.92 ml/m**
Min LA Vol/BSA:	**50.21 ml/m²**
Max LA Vol/H:	**91.29 ml/m**
Max LA Vol/BSA:	**86.61 ml/m²**
LA EF:	**42.03 %**

The long axis strain tab contains strain related data as summarised below. Note: this is not for clinical use and results are sent only to scientific data.



Long Axis Strain

The results are to be used for research purposes only and not for primary diagnostics and direct patient c

Average 2CV and 4CV	
Average LV Long-Axis Strain:	-18.17 %
Average LV Long-Axis Difference:	-16.62 mm
Average LV AV Junction Strain:	-17.45 %
Average LV AV Junction Difference:	-16.57 mm
Average LA Long-Axis Strain:	33.14 %
Average LA Long-Axis Difference:	13.71 mm
Average LA AV Junction Strain:	30.90 %
Average LA AV Junction Difference:	13.54 mm
Monoplanar 2CV	
LV Long-Axis Strain:	-18.88 %
LV Long-Axis Difference:	-17.74 mm
LV AV Junction Strain:	-18.80 %
LV AV Junction Difference:	-18.46 mm
LA Long-Axis Strain:	30.78 %
LA Long-Axis Difference:	14.58 mm
LA AV Junction Strain:	28.33 %
LA AV Junction Difference:	14.18 mm
Phase LV Diastole:	30
Phase LV Systole:	13
Monoplanar 4CV	
LV Long-Axis Strain:	-17.46 %
LV Long-Axis Difference:	-15.50 mm
LV AV Junction Strain:	-16.11 %
LV AV Junction Difference:	-14.69 mm
LA Long-Axis Strain:	35.49 %
LA Long-Axis Difference:	12.84 mm
LA AV Junction Strain:	33.47 %
LA AV Junction Difference:	12.90 mm
RA Long-Axis Strain:	47.55 %
RA Long-Axis Difference:	17.64 mm
RA AV Junction Strain:	45.66 %
RA AV Junction Difference:	17.85 mm
Phase LV Diastole:	1
Phase LV Systole:	11

15.1.2 How to Do manual Biplanar LV Function and Volume Analysis

1. Drag and drop the series (2CV, 4CV) from the thumbnail panel into their respective frames and adjust viewer properties
2. Select the end-diastolic phase
3.  *LAX LV Extent* contour: Set two points in the mitral valve plane, and a third point in the apex to define the length of the ventricle. As soon as the apex point has been placed, the endocardial contour will be detected automatically. Correct if necessary
4. Draw an epicardial contour
5. Do the same for the end-systolic phase
6.  *Segment Myocardial Contours LAX in Slice*: Optionally propagate endo- and epicardial contours for a myocardial segmentation in all phases

7.  Add analysis to Report

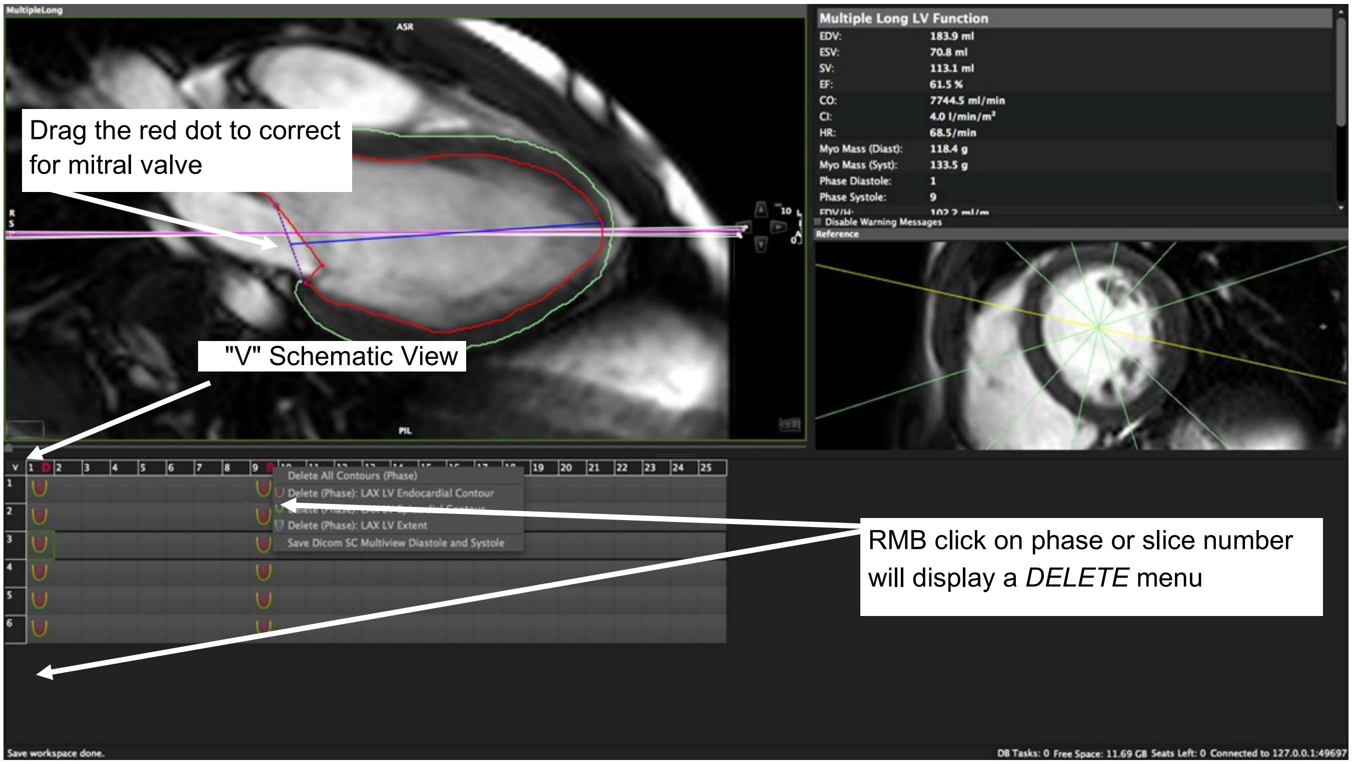
15.2 Multiple Long LAX Module

Intended use:

LV function volume and mass analysis.

WARNING: Multiple Long
The input for multiple long calculations requires a multi-slice series with long axis slices that are acquired along a central rotation axis. **cvi42** checks for the presence of these requirements, although it allows some
variance to avoid small aberrations being rejected from the analysis. It is the responsibility of the user to verify the cutting line of the slices and decide whether the variance in the rotation axis is acceptable.
Depending on the shape of the left ventricle the method in use might not be suitable for all evaluations (e.g. severe regional wall motion abnormalities), it is the user's responsibility to verify the suitability of the selected method.
Endocardial contours must always be within (i.e. on the luminal side of) the epicardial contour, c **cvi42** does not check for that.
The volume calculation is performed for every phase. The smallest volume is assumed to be the systolic volume and the largest volume is assumed to be the diastolic volume. If the volume can only be calculated for one phase, ESV and EDV will be displayed as equal and no further calculations are done.
Missing contours are interpolated, if possible.
Calculations are performed based on the current state of contour definition and image selections. For every change in this state the calculations are updated immediately. It is the responsibility of the user to verify that the contours reflect the desired measurements before releasing final results.

When using the Function|Radial LAX Module, if "Auto Load Series in Module" is enabled, cvi**42** will auto-load an appropriate multiple Long LAX CINE series into the first viewer frame and appropriate SAX CINE series into the reference frame.

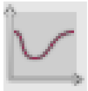


15.2.1 How to Do LV Function with Multiple Radial Long Axis

1. Drag the radial long axis series from the thumbnail panel into the respective frame and adjust viewer properties. A perpendicular short axis cine series (if available) will automatically be displayed in the reference window
2. Clicking on the “V” in the left top corner switches to a schematic view to help you find the right slice and phase
3. Visually select diastole and systole
4.  Define the extend of the left ventricle: *S*et two points defining the mitral valve plane and a third point in the apex to define the length of the ventricle, the endocardial contour will be detected automatically. Correct endocardial contour
5. Adjust the valve plane by dragging the red dot
6. Draw an epicardial contour  manually or  semiautomatic
7.  Optionally propagate the contour use the toolbar button *Segment Myocardial Contours LAX in Slice* button
8. Repeat for all slices
9.  Add analysis to Report

15.2.2 How to Create a Ventricular Volume/mass Curve

1. Define endocardial and epicardial contours in all phases and slices

2.  Click LV volume curve

Peak Ejection and Filling Rate and Peak Wall Thickness can be found in the scientific report (Report Module)

15.3 Short 3D Module

Intended use:

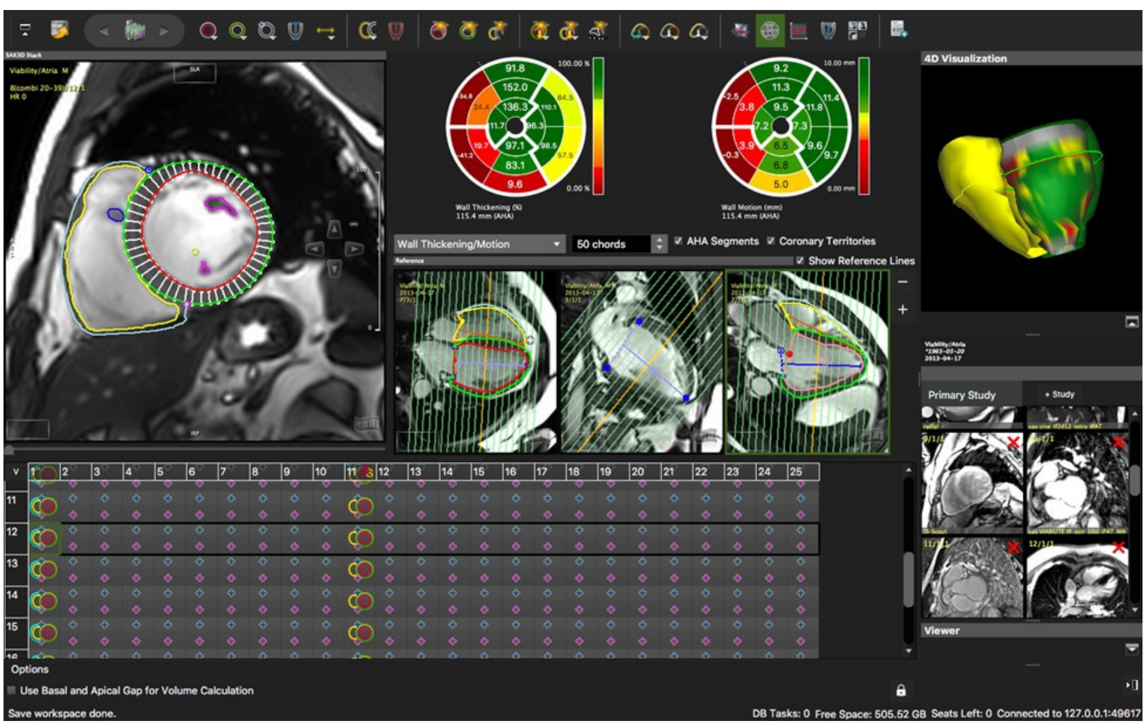
Using the disc-summation technique this module can analyze a stack of parallel images in long, short or axial orientations:

- Global and regional LV function and volume analysis
- Global RV function analysis
- Atrial volumetry

> **WARNING**: SA 3D
> The volume calculation is done for phases. The smallest volume is assumed to be in systole and the largest volume is assumed to represent diastole. In case a volume can only be calculated in one phase, ESV and EDV will be displayed as equal and no further calculations are done.
> Missing contours are interpolated, if possible.
> Calculations are performed based on the current state of contour definition and image selections. For every change in this state the calculations are updated immediately. It is the responsibility of the user to verify that the contours reflect the desired measurements before releasing final results.

When using the Function|SAX Module, if “Auto Load Series in Module” is enabled, cvi**42** will auto-load an appropriate SAX CINE stack into the first frame, a 4CV LAX CINE series into the first reference frame, a 3CV LAX CINE series into the second reference frame, and a 2CV LAX CINE series ito the third reference frame. cvi**42** will also generate contours at the end-diastolic and end-systolic phases (ED/ES) of the CINE series as per the contours preferences.

15.3.1 Short 3D Interface



15.3.1.1 Thumbnail Grid

The thumbnail grid represents images of all slices and phases that are contained in a parallel stack. Optionally, the display can be changed to a schematic view click the **V**.

RMB click on phase number:

- 'V' toggles between image and contour view
- Right mouse click on a phase or slice number opens a context menu

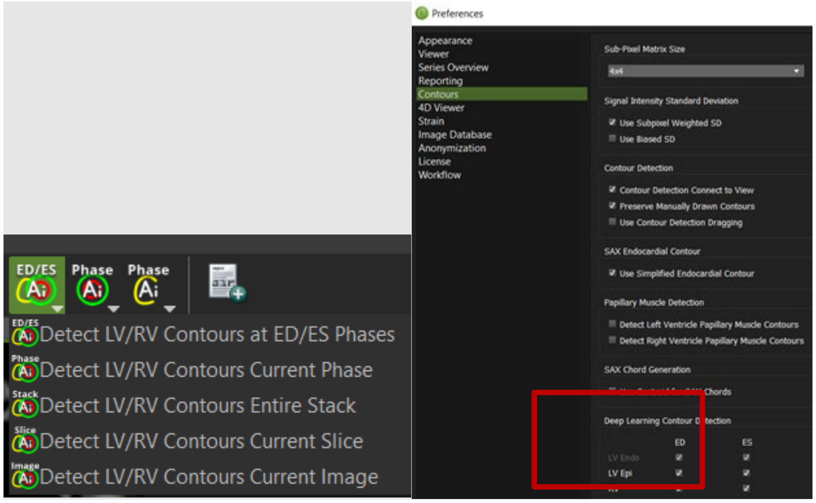
15.3.2 Global LV Function and Volume Analysis

15.3.2.1 How to Do Fully Automatic LV/RV Segmentation

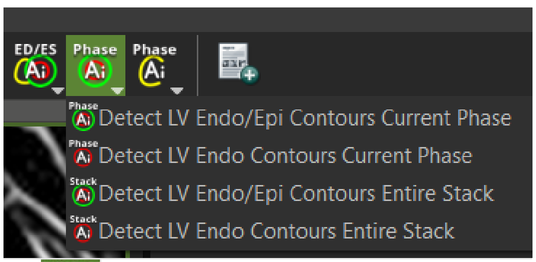
- There are three main AI icons 

- Right-mouse clicking on each of the AI tools will open a dropdown menu with other AI contour detection options.
  - 

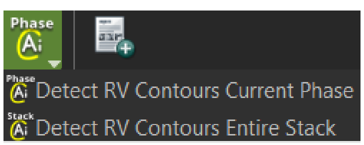
 Detects LV (endocardial and epicardial) and RV (endocardial) contours on the selected image, phase, slice, entire stack, or at end-diastolic and end-systolic phases (ED/ES). The LV and RV contours that are detected with the option ED/ES can be customized in "Preferences→Config→Contours→Deep Learning Contour Detection" (all options are checked by default)



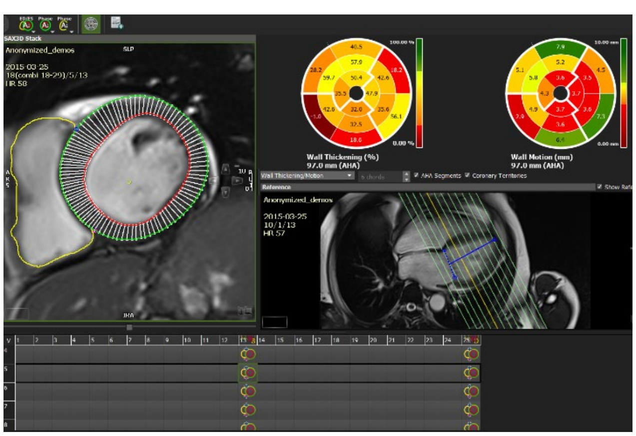
-  Detects LV endocardial and epicardial contours on the selected phase or on the entire stack.



-  Detects RV endocardial contour on the selected phase or on the entire stack.



- Whenever the LV epicardial contour is detected with an AI tool, the respective anterior and inferior insertion points of the RV will also be detected. If the detection runs on all slices of a selected phase or on the entire stack, the LV LAX extent will also be detected on the respective phase(s) of each LAX series loaded on the reference frame(s).
- With a single click on the ED/ES tool , the user obtains the onscreen report (EDV, ESV, EF, SV, etc..) and the Wall Thickening/Motion and Thickness polar maps:



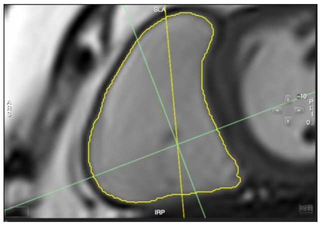
1. Select the AI tool of your choice as detailed above
2. Once contours have been detected, move the mouse in the analysis frame and click 'm' for a multiview display
3. Review the segmentation in all slices
4. Correct where needed
5. Click Add to Report

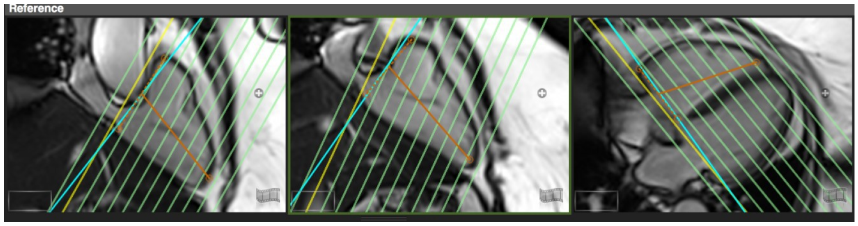
WARNING: Automatic Contour Detection
The expected input for the volume calculation in this module is a series containing parallel slice in the short axis direction.
Endocardial contours must always be inside the epicardial contour. **cvi42** does not check for that. In case of missing contours in one slice linear interpolation is done if possible.
Module calculations in **cvi42** are in generally done based on the current state of contour definition and image selections. For every change in this state, the calculations are updated immediately. It is the responsibility of the user to decide whether the stage of contour definitions reflects the desired measurement task before releasing final results.

15.3.2.2 How to Do a Mitral/Tricuspid Valve Plane Correction

1. Visually identify the most basal slice of the left ventricle and/or the outflow tract

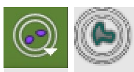
2.  Activate the *Valve plane correction* button to open additional reference windows





3.  Using the *Cross-Reference* display, define the plane in two orthogonal orientations

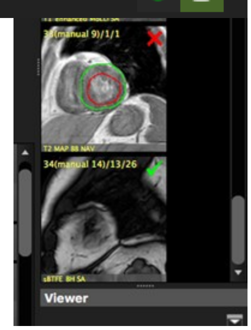
4. The correction will be calculated automatically

5.  Use the *Exclude Area Contour* tool to exclude atrial volume in mitral plane

15.3.2.3 How to Do Manual Phase Shifting Per Slice

In case of mis-triggered slices:

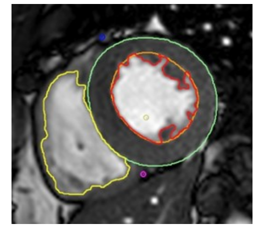
1. Click the lock
2. In the slice, grab the box with correct diastolic phase and shift it into the red box
3. Delete any existing contours that are outside diastolic and/or systolic phase
4. Delineate the myocardium for the newly defined systole and diastole
5. Click the lock again
6. The phase shift will be remembered and is stored in the workspace



7.  Only if you want to run the ML based automatic contour detection after phase shifting, you have to save the shifted series. This will create a manually composed series.
8. Load the new series and run the ML contour detection

15.3.2.4 How to in/exclude Papillary Muscles

By default, the automatic contour detection will include papillary muscles in mass calculations and exclude them from the lumen. This can be changed in the *Preferences.*

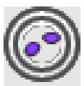


1.  To exclude papillary muscle in the current image, use the Exclude Papillary tool

2. To exclude them when using an automated contour detection method, go to the *Preferences/Contour:*


3. Check *"Use Simplified Endocardial Contour".* Using automated edge detection, the software will apply a simplified contour, cutting offtrabecular structures

4. De-select Detect *papillary muscle contours* to turn off the detectionof papillaries within the LV lumen (pink contour)

5.  Include papillary muscles in the current image: *SA papillary muscle contour tool*

15.3.2.5 How to Create and Display a Volume Curve

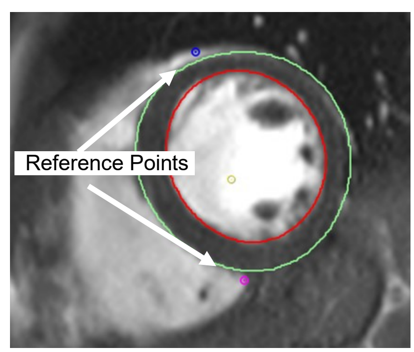
Define endocardial and epicardial contours in all phases.

-  A click on the volume curve button will display a graph next to the study displayframe.
- Peak Ejection Rate and Filling Rate and Peak wall thickness will be reported in the Scientific Report(Report Module)

15.3.2.6 How to Do a Regional Wall Motion Analysis

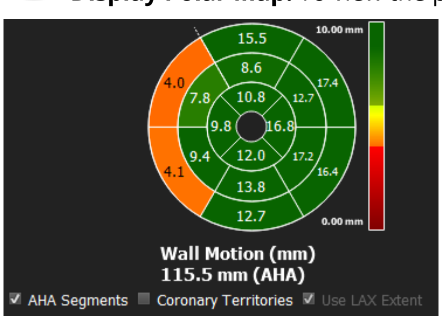
1.  Define the analysis range: Define length of anatomical long axis using the *LA LV Extent Contour* button. (see above)

2.  Define reference points for the segmentation: In the analysis window select a mid-ventricular slice and set the points at the anterior and inferior insertion of the RV



Note: The segmentation points don't have to be adjusted in the remaining images.

 **Display Polar Map:** To view the polar maps click the *View Regional Function* button



- Chords: Range between 2 and 100 chords. (segments will be counted clockwise)

- For non-AHA polar maps, there is the option to specify whether the LV LAX extent contour is used to define the spatial limits of the polar map representation. If "Use LAX extent" is turned off, the first and last slice in the LAX extent will define the spatial limits of the polar maps. When adding the polar map to the report, the LAX reference image, containing the LV LAX extent and SAX reference lines, will be attached to the report image. If "Use LAX extent" is turned on, the basal and apical points of the LAX extent will define the spatial limits of the polar map representation.
- AHA segmentation: Volumes per AHA segment will be reported in the Scientific Report

3. From the menu select wall thickening/motion or wall thickness (Diastole/Systole).

The chords in the analysis image reflect the wall thickness measurements (not the segment border)

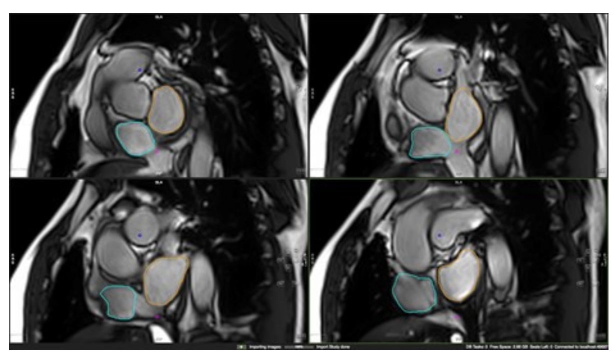
4.  Add analysis to Report. Max. diastolic wall thickness will be reported in the scientific report
5. RMB click allows to export the polar map
6. Repeat for all slices you want to include in the analysis.
7.  Add analysis to Report

Note: Make sure to always use the same technique, either in or exclude papillaries and/or delineate trabecle. Left and right SV should match. Follow-up results done with a different contouring technique can mimic deterioration.

15.3.2.7 How to Do Atrial Volumetry

By default, the atrial contour buttons are hidden. In the protocol pane go to the wrench to edit the interface and activate the buttons.

15.3.2.9.1 How to Do Atrial Volumetry in Short or Long Axis Orientation



1. The atrial volumes will be reported for LV systole and diastole and therefore require the definition for the LV end-systolic and end-diastolic phase.
2. Drag a stack of parallel images, long or short axis, into the analysis frame. If there is no LV analysis applicable, you can manually define the phases. Please refer to the chapter "Manual Definition of Systole and/or Diastole for LV and/or RV"
3. Click on the *SAX Left Atrium Contour* tool to trace the border of the left atrium
4. Use the *SAX right Atrium Contour* tool for the right atrium
5. The software will report ESV, and EDV for the right and left atrium

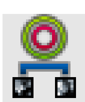
16 Tissue|Signal Intensity

cvi42 provides four adjustable viewer frames for determining various tissue characteristics by CMR methods.

When using the Tissue|Signal Intensity Module, if "Auto Load Series in Module" is enabled, cvi**42** will auto-load an appropriate Late Gadolinium Enhancement (LGE) series into the first frame and a LAX LGE series into the reference frame. If no LAX LGE series is available, cvi**42** will auto-load a LAX CINE series into the reference frame.

16.1 Analysis of LGE and T2 Images

16.1.1 How to Do Scar and Edema Analysis

1. Drag and drop series into the frames marked "Late Enhancement" and "T2" respectively.
2. Derive existing contours via *Context Menu/Contours/Derive Cardiac Contours*. If no contours are present, draw endocardial and epicardial contours for each slice.
3.  *Synchronize Contours*: Provided that T2 and LGE images have the same slice location, contours will automatically be copied to the other frame
4.  *Segment Reference ROIs*: Automatically detect a reference ROI. The blue contour will depict the remote myocardium and the pink contour a reference ROI for FWHM algorithm in the enhanced area
5.  Toggle the *Overlay Display* to display a color overlay for scar and edema
6.  Use the *Exclude Enhancement* contour in case of e.g. artifacts
7.  Quantify MVO (see below for more information)

8. Click on *Display Result* to view the analysis

9. Add measurements to report by clicking the *Add to Report* button

16.1.2 How to Do T2 Ratio Analysis

1. Select the *Skeletal Muscle* contour tool and draw a contour within skeletal muscle in every slice. The percentage as well as the SI ratio will be reported on the right bottom corner of the frame
2. Activate the T2 Ratio Overlay
3. Repeat for all slices

16.1.3 How to Assess Microvascular Obstruction

1. To quantify a 'No Reflow Area' (depicting MVO - micro vascular obstruction), use the *No Reflow Contour* button
2. Roughly draw a contour around the region with low signal
3. Click on *Display Result* to view the analysis

16.1.4 How to Do Greyzone Analysis

1. Check the box Greyzone Analysis
2. Select a threshold

16.1.5 How to Assess Salvaged Area at Risk

Using the results of LGE and T2 segmentation, calculation will be done automatically by subtracting scar from edema volumes.

You will find the quantified area at risk in the result pane (click on the *Display Result* button).

Note: It will **not** be calculated in case

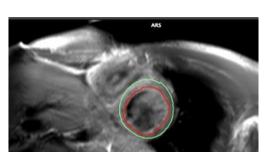
- slice locations are not matching
- number of slices are not matching
- there is a difference of myocardial volumes > 10%

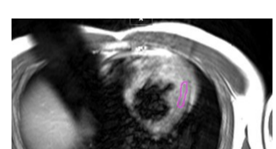
16.2 Early Enhancement

16.2.1 How to Assess the Early Gd Enhancement Ratio

Draw endocardial and epicardial contours in T1 pre and post contrast images.

1. If you are not able to define endo and epicardial contours, use the *Myocardial Contour* tool
2. Define a skeletal reference



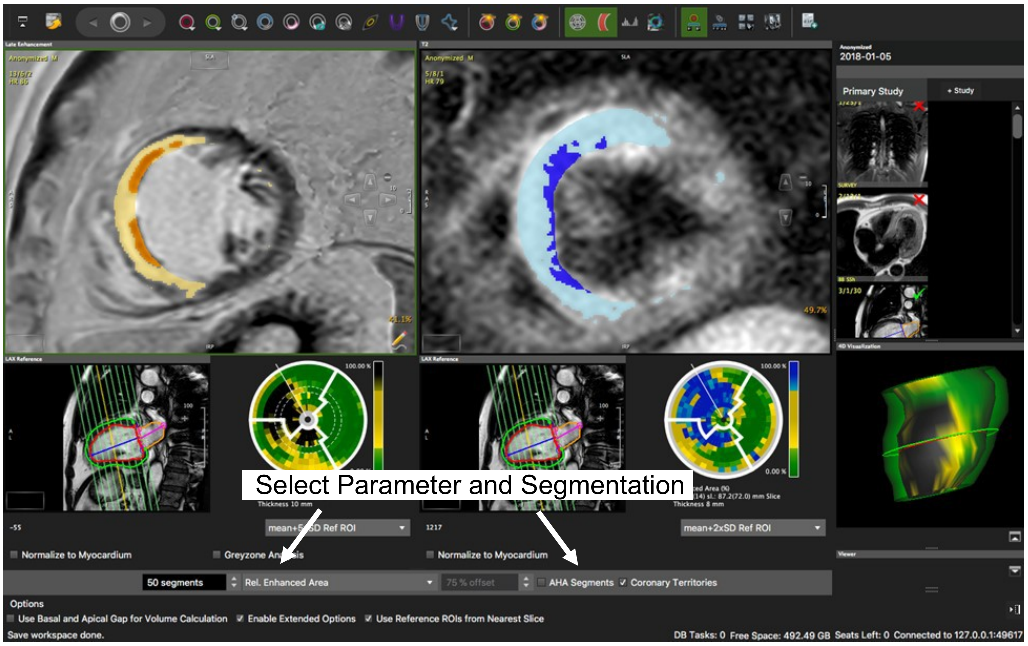


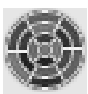
3. Repeat for all slices

4.  To view analysis results, click the *Display Result* button

5.  Add measurements to report using the *Add to Report* button

16.3 Regional LGE and T2 Analysis and Assessment of Transmurality



Toggle Polar Map  button

16.3.1 How to Do Segmental Scar and Edema Analysis

1.  Set Segmentation points
2.  Define length of anatomical long axis using the *LAX Extent* contour button: Set 3 points, where the first two define the base, and the third point is set in the apex.
3. Select Parameter from drop-down menu

For the *Enhanced Area* you have the option between custom and AHA segmentation.

16.3.2 How to Assess Transmurality

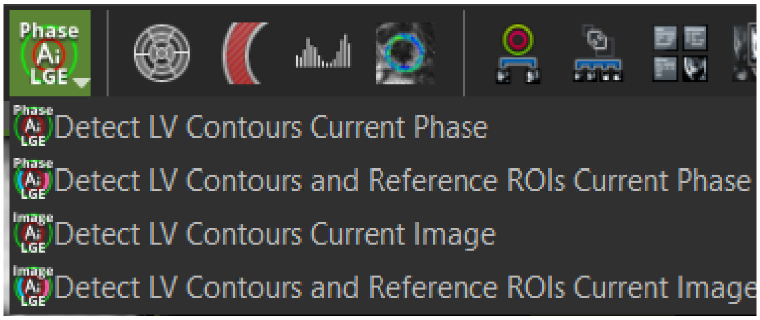
1. Repeat step 1-2
2. Select *Transmurality* from the drop-down menu at the bottom of the page
3. If you want to display a defined percentage, select *Transmurality Offset* and set the percentage with the arrow keys

16.3.2.1 How to Display a Greyzone Polar Map

1. Repeat steps 1-2
2. Select *Relative Greyzone* from the menu (make sure you have defined a threshold for the greyzone and activated the analysis option)

16.4 LGE AI Contour Detection

- There are four LGE AI options.



- Detects LV endocardial and epicardial contours, anterior and inferior RV insertion on all slices of the selected phase. A LV LAX series will be automatically loaded into the reference frame and the respective LAX extent will be detected. This can be checked by activating the polar map visualization.

- Detects LV endocardial and epicardial contours, anterior and inferior RV insertion points and references of remote and enhanced myocardium on all slices of the selected phase. A LV LAX series will be automatically loaded into the reference frame and the respective LAX extent will be detected. This can be checked by activating the polar map visualization. With a single click, the user obtains the LV LGE quantification and respective polar maps.

- Detects LV endocardial and epicardial contours, anterior and inferior RV insertion points on the selected image.

- Detects LV endocardial and epicardial contours, anterior and inferior RV insertion points and references of remote and enhanced myocardium on the selected image.

NOTE: This is the first version of the LGE AI automatic contour detection function, and the accuracy is very dependent of a high image quality. The user must check carefully each contour on each image and correct them whenever necessary. By default, the tool is not shown in the interface. To activate it, the user must click on "Edit Protocol Step", activate the tool and save it to the protocol in use:

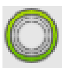
17 Tissue|T2* Mapping

17.1 How to Do T2* Analysis

Intended use:

T2* quantification and mapping for myocardial tissue characterization (iron, hemorrhage, thrombus)

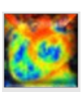
17.1 How to Do T2* Analysis

1.   For global T2* times, draw an endocardial and an epicardial contour for the assessment of global T2* values

2.  Draw a ROI contour in the septal wall for regional T2* values

3.  Forward contours to other images within the series or via context menu *Forward Contour*

T2* values will immediately be displayed, as well as the absolute iron content (1.5 Tesla only)
T2* decay curves will immediately be displayed, choose a fitting algorithm (nonlinear=default) and a fitting correction method from the option menu

4.  Toggle color map on

5.  Create DICOM grayscale map. In addition to the grayscale map a R2 map will be created. You will find both maps combined in one series. They will be appended to your thumbnails

6.  Add measurements to your report

18 Tissue|T2 Mapping

Intended use:

T2 quantification and mapping for myocardial tissue characterization (edema)

18.1 T2 Measurements

The module consists of two pages:

- T2 Measurements: that allow for the assessment of T2 times
- T2 Map: and the analysis of a T2 map

In order to exclude any extra map attached to the raw data, it is possible to skip the last 1 or 2 phases of the series for T2 calculations.

18.1.1 How to Do a T2 Analysis

1. Segment the myocardium for global T2 values. Forward the contours via context menu

2. Select one of the ROI contours for the assessment of a specific region of interest. The ROI can be forwarded with the *Forward contour* button

- Global and regional T2 times will be calculated immediately
- The decay curve will be displayed. A right mouse click in the graph allows to change the display or to export the graph. In the option menu choose a fitting algorithm and a fitting correction method

3. Add calculations to your report

Note: Automate DICOM map generation by checking the box for *Create map upon loading.* Save this step to your protocol. The next time a T1 sequence will be loaded, the map will be generated automatically

18.1.2 How to Apply a Motion Correction to T2 Series

1. Make sure you have endo- and epicardial contours in all images.

2.  Set the Segmentation point

3. Select the image with the best contrast and enter the phase that you would like to use for the registration

4.  Click the registration button: The new series will be created and automatically loaded into the respective frames

5. If you decide to use a different phase for registration, reload the original series and repeat steps 1-4

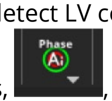
Note: The registration works for points that are on or inside the contours; the image outside of the contours may appear warped or distorted after registration. This is expected, and users should not use any outer regions for analysis

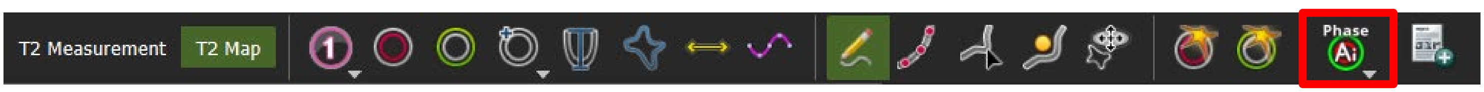
18.2 T2 Map

18.2.1 How to Analyze T2 Maps

1. Drag and drop the map from the thumbnail panel into the respective window

2. Draw, derive, or automatically detect LV contours for a segmental analysis

   2.1 AI based contouring tools, , are supported for LV Endo/Epi contours and the RV insertion points on T2 maps.



2.2 The user can derive LV contours from the Cine SAX stack, provided the SAX stack has previously been contoured.

3.  Drag a long axis reference into the reference window and define the extent of the left ventricle: Set 3 points, the first two define the base, the third defines the apex and thereby the extent of the LV

4.  Add analysis to the report. The values can be found in the scientific report

19 Tissue|T1 Mapping

IMPORTANT: Due to differences between scanners and mapping sequences, results must be interpreted using the locally validated standards of the reading institution.

Intended use:

T1 quantification and mapping for myocardial tissue characterization (fibrosis, edema, tissue infiltration).

19.1 Module Layout

Analysis options are organized in pages:

- *T1 Native:* T1 values and recovery curve for global and/or regional myocardium
- *T1 CA*: s.a. post contrast
- *T1 Map Native*: T1 and R^2 maps and a segmental polar map display (1-100 or AHA)
- *T1 CA*: s.a. post contrast
- ECV/λ: Polar maps and global/per slice ECV and partition coefficient (λ) quantification

19.2 T1 Analysis (native and post contrast)

19.2.1 How to Load Various Sequences

1. Load the sequence from the thumbnail panel
2. Select the correct sequence in the T1 options menu
3. In the T1 options menu of the T1 calculation tab it is possible to skip the last 1 or the last 2 phases of the series for T1 calculations, to exclude any extra map attached to the raw data.

4. In the DICOM header the TI time can be encoded in the field for the Trigger Time. To address this, from he option menu, check the box for Use Trigger Time as Inversion Time If the series is rejected, it could have been due to one of the following reasons:

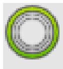
- The last image of the series is a scanner generated map (Siemens). **Solution:** In the option menu, check the box for *Skip Last Slice Image*

- In the DICOM header the TI time is encoded in the field for the Trigger Time (Philips). **Solution:** In the option menu, check the box for *Use Trigger Time as Inversion Time*
- During anonymization the information for TI has been stripped and you get a warning message "TI times are equal."

Solution: Go to the patient list module and in the *Extended view* check if the information for the TI can be found under either *TI* or *Image Comments* (Siemens). If possible, try to re-anonymize the data, preserving the TIinformation

Note: Some recent **Siemens** sequences use a correction or scaling factor for the calculation of T1 times. You will find the scaling factor in your Siemens documentation. Enter the factor in the option menu. Alternatively, use Siemens-generated maps.

19.2.2 How to Do Global or Regional T1 Analysis

1.   For global T1 values, draw endocardial and an epicardial contours. Forward the contours via context menu *Forward All Contours Slice (*short-cut*:* ⌘E/Ctrl E)

2.  For regional analysis, select one of the ROI contours. This contour can be forwarded via toolbar button 
3. Repeat for all slices
4. Global, regional T_1 Relaxation times and R^2-values will be shown in the result frame
5. The T_1 recovery curve will be presented in the frame below. RBM click in the graph opens a *Context Menu* offering dis- play options

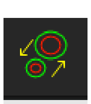
6.  Create DICOM map
7. Automate DICOM map generation: In the option menu, check the box for *Create map upon loading* and save this step to your protocol
8. For the post-contrast series, contours can be derived via context menu: *Derive Contours>Derive Contours Cardiac Phase,* will derive previously drawn contours for all slices

9.  Add evaluation (images, values and graph) to the report

19.3 Motion Correction for ECV Map Generation

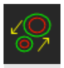
- *Intensity-based* registration is to be used with already motion corrected images and will register between pre- and post-contrast series
- Feature-based registration registers all images (pre- and post-contrast) to a selected image in the native series. Therefore, it is required to have contours in both the pre- and post-contrast series as well as in all slices
- Go to the respective pages and select the motion correction of your choice

19.3.1 How to Do Intensity Based Registration

1. Identify motion corrected series in the thumbnail panel
2. Drag the series into the respective pages: T1 Native/T1 CA
3. Choose a phase with good contrast between endo- and epicardial contour as well as between surrounding tissues in both the native and post contrast series. Avoid images with bright intensities in the outer regions (areas of fat, air regions, etc.)
4. In the *Registration Options* enter the phase number:
5. *Native Registration Phase*: Image in the native series to be the reference image
6. *CA Registration:* Image in the post contrast series, to be registered with the reference image
7.  Click the registration button
8. The registration registers the CA Series to the Native Series
9. To re-register, reload the initial series and repeat steps 1-6

19.3.2 How to Do Feature Based Registration

This registration can be used on motion and non-motion corrected series. It registers every phase in both the native and post-contrast series to a chosen reference image in the native series.

1. Make sure you have accurately drawn the endo- and epicardial contours, as well as a segmentation point in all images, in pre- and post-contrast series
2. Select a reference image in the native series with the best contrast and enter the phase into *Native Registration Phase*
3.  Click the registration button: Two new registered series will be created and automatically loaded into the respective frames. Contours of the reference phase will be forwarded to all registered images
4. If you decide to use a different phase for registration, reload the original series and repeat steps 1-4

Note: The registration works for points that are on or inside the contours; the image outside of the contours may appear warped or distorted after registration. This is expected, and users should not use any outer regions for analysis

19.4 T1 Map Analysis

Either create map in **cvi42** or load a map that has been created by the scanner software.

19.4.1 T1* Maps

- T1* maps may offer a more accurate estimation of blood pool T1
- T1* maps will be automatically extracted of Molli, shMolli and Molli Oxford sequences

19.4.2 How to Analyze the T1 Map

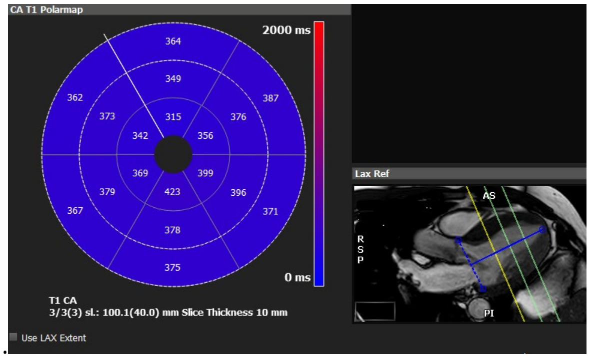
1. Drag the map from the thumbnail panel to the analysis window
2. Draw or derive contours for a segmental analysis

    2.1 AI based contouring tools, 

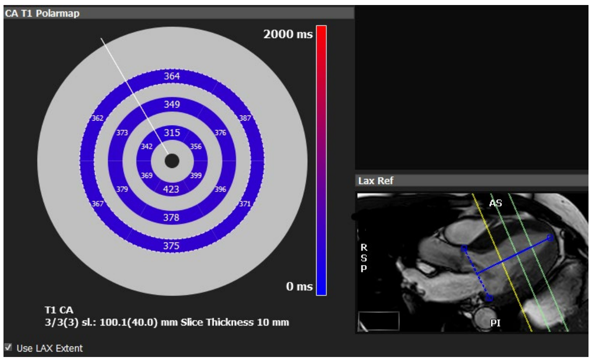
, are supported for LV Endo/Epi contours and the RV insertion points on T1 Native maps.

    On all frames, the user can derive LV contours from the Cine SAX stack, provided the SAX stack has previously been contoured.

3. For a color-coded display, select a color map from the drop-down menu or create your own LUT
4. For a segmental polar map display, place an anterior and inferior *SAX Reference* point
5. Define the left ventricular extent in the reference window
6. In the polar map frame, the number of segments per ring can be customized or you can switch to a 16- segment AHA model
7. For non-AHA polar maps, there is the option to specify whether the LV length (LV LAX extent contour) is used to define the spatial limits of the polar map representation. If "Use LAX extent" is turned off, the first and last slice in the LAX extent will define the spatial limits of the polar maps. When adding the polar map to the report, the LAX reference image, containing the LV LAX extent and SAX reference lines, will be attached to the report image



If "Use LAX extent" is turned on, the basal and apical points of the LAX extent will define the spatial limits of the polar map representation.



8. In the *T1 Options* Apply and endo and epicardial offset to make sure that only LV myocardial tissue in included in the quantification

9.  Add evaluations (images, values

19.5 ECV and Lambda Quantification (λ)

19.5.1 How to Do Segmental ECV and Lambda Quantification

1. Make sure you have contours, segmentation points and a blood-pool contour  in all slices in both *T1 map Native* and *T1Map* CA. The blood pool contour can be drawn either in the *T1 or the T1* map*

2. Enter the hematocrit for the ECV quantification

3.  Add an ECV map

4.  For a polar map display, make sure you have defined the Long Axis Extent in the reference frame of the *T1 Map Native and T1 Map CA* page

5. Add evaluation (images, values and graph) to the report 

20 Perfusion|Semi-quantitative

Intended use:

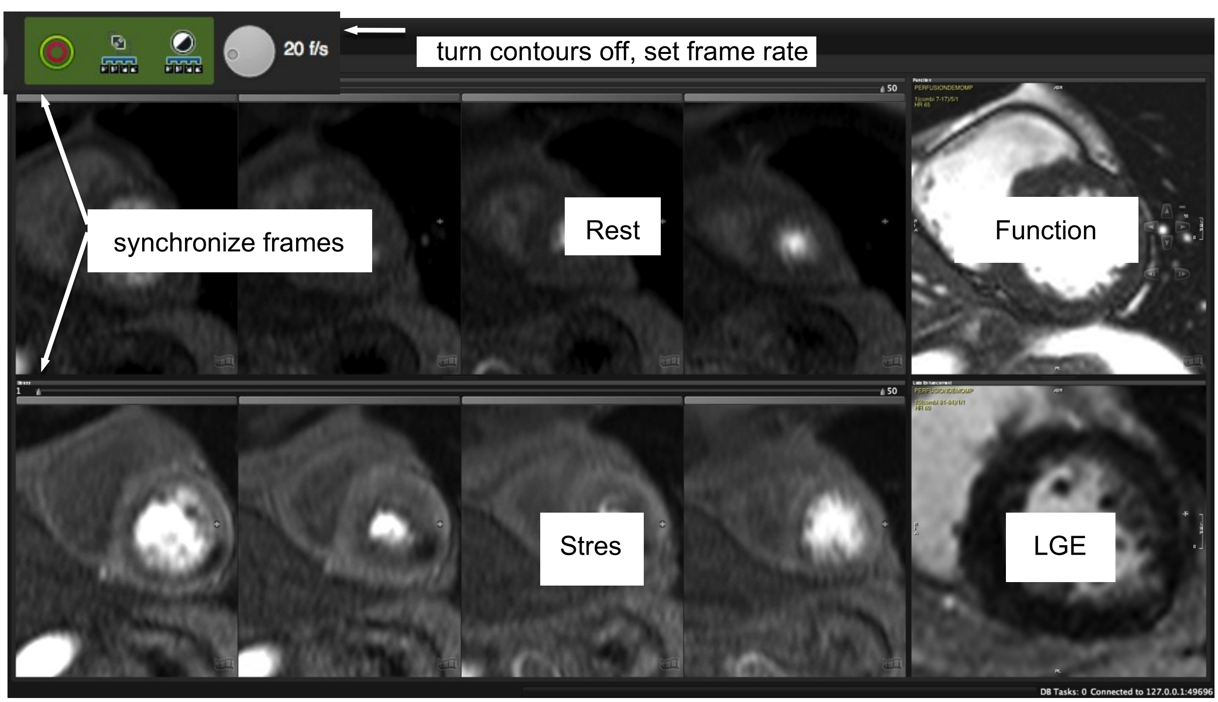
Visual and semi-quantitative assessment of myocardial perfusion

The Perfusion module consists of 3 pages:

- *Multi View*: Compare rest and stress perfusion with scar images and wall motion kinetics
- *Edit Contour*: Semi-quantitative analysis
- *Analysis*: Polar Maps

WARNING: Perfusion|Semi-quantitative
Perfusion analysis should not be done on GE dual-bolus or pre-bolus sequences. For more information please contact GEHC.

20.1 Multi View Compare Rest and Stress Perfusion

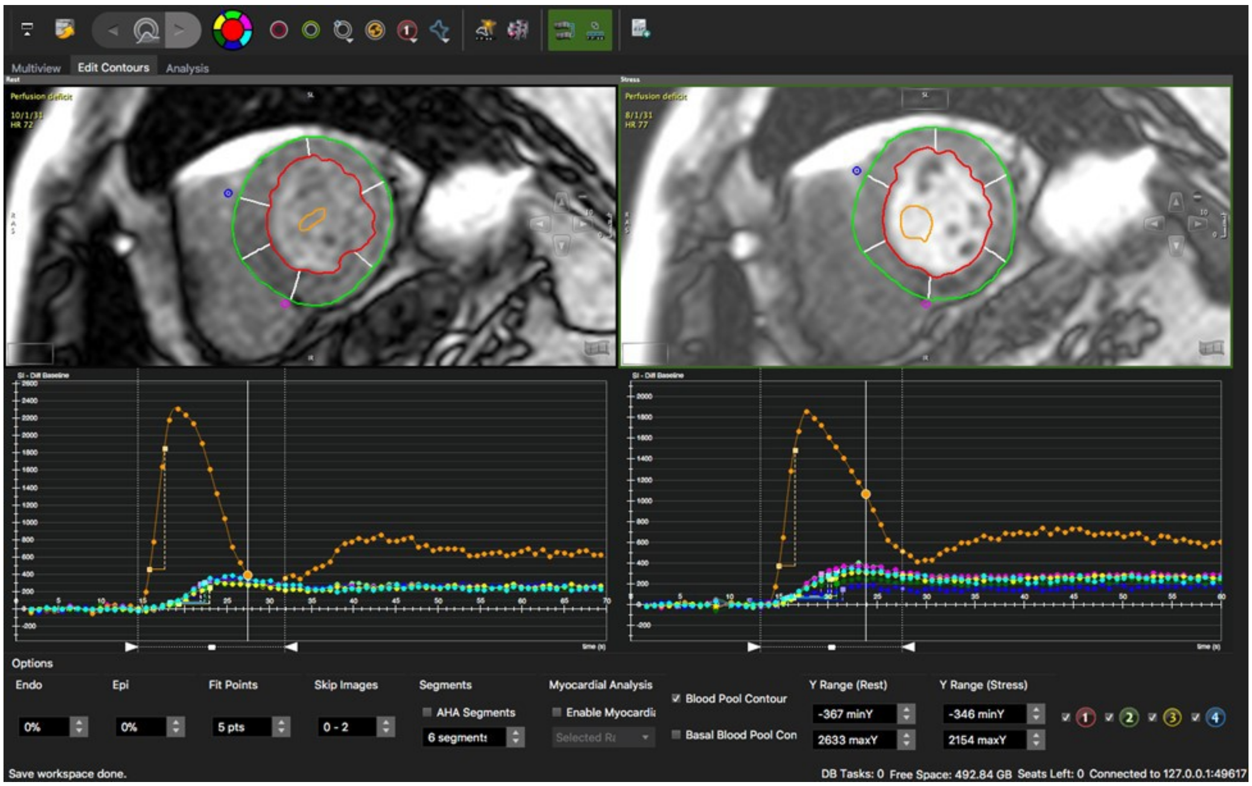


20.1.1 How to Do a Visual Perfusion Analysis

1. Adjust window and zoom for rest and stress series
2. To set the frame rate use the wheel in the toolbar
3. Turn existing contours off (toolbar button)
4. Synchronize the frames for rest and stress by using the slider
5. If applicable, drag Late Enhancement and Function images into their respective frames for comparison
6. Add the *Floating Viewer* for more viewing options

20.2 Edit Contour, Semi-Quantitative Analysis

20.2.1 How to Do Semi-Quantitative Perfusion Analysis



1. Drag the appropriate series in the *Rest* and *Stress* frame and adjust viewer properties
2. Select a phase with good contrast and draw endo- and epicardial contours
3.  Draw a *Blood Pool* contour, (input function) in the brightest, most homogeneous area of the blood pool
4. Check *Use Bloodpool Contour* in the *Options* (underneath the graph)
5.  Set the anterior and inferior segmentation reference points at the insertion of the RV to the epicardial border of the LV
6.  Contour Propagation: Forward all contours, including blood pool contour and segmentation point to the remaining phases

7.  Check and adjust contours for each phase within the analysis range. Use the align contour button to correct for breathing motion
8. Choose between AHA or custom segmentation
9. Define the analysis range (contrast inflow during first pass) by moving the left and right slider at the bottom of the graph. Alternatively, set start and end frame via context menu. This will also limit the frames in the 'Multi View' to the defined range
10. Apply baseline correction via context menu (right-click in the graph)
11. For a special region of interest, there are 4 additional contours in the top tool bar. To view the curve, check the respective ROI in the *Option* menu

12.  Repeat for all slices and add results to the report

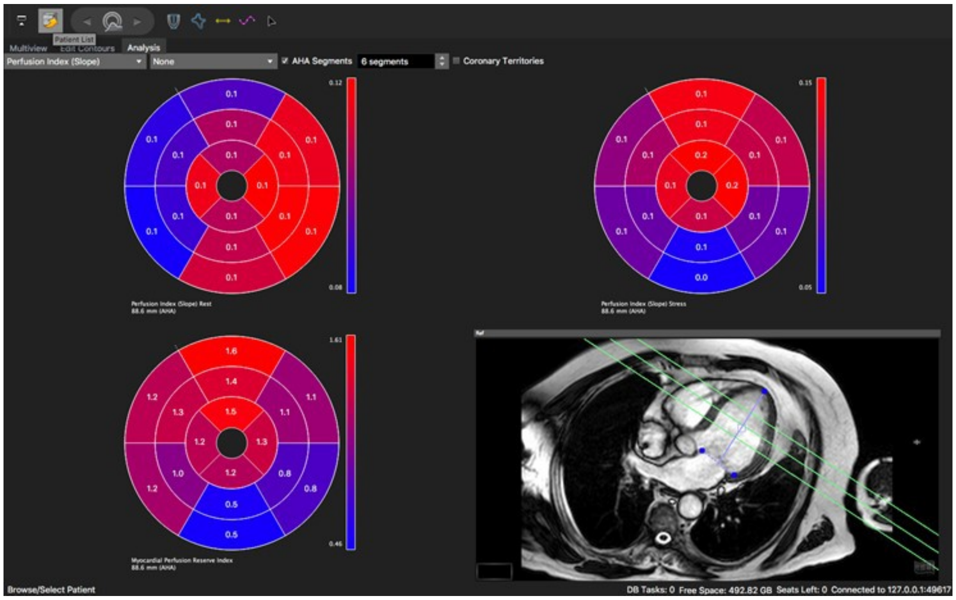
20.2.2 Option Menu

- *Endo/Epi:* Exclude sub-endocardial and/or sub-epicardial layers
- *Fit points* Choose the number of points that will define the slope
- *Skip Images:* you can exclude images from the from baseline
- *Segments:* Choose between custom segments (up to 100) or AHA segmentation
- *Myocardial Analysis:* Analyze different layers
- *Blood Pool contour:* Checked, it requires to define a blood pool contour
- *Basal Blood Pool Contour:* The software only uses the most basal blood pool contour
- Check a box to view the perfusion curve of a drawn ROI

20.2.3 How to Analyze Perfusion Curves

1. To switch to an enlarged view, go to the context menu and check *Enlarged View*
2.  Move the mouse cursor over the icon to view the curve of the respective segment
3. Display semi-quantitative parameter such as *upslope* or *time to max*. from the context menu
4. Optionally apply a baseline correction
5. *Exit the Enlarged View* via context menu (uncheck)

20.3 Analysis, Segmental Analysis



How to do a regional perfusion analysis:

1. Define length of anatomical long axis using the *LAX LV Extent Contour* button 2.

Select a parameter from the drop-down list

3. Apply a baseline correction

21 Perfusion|Quantitative

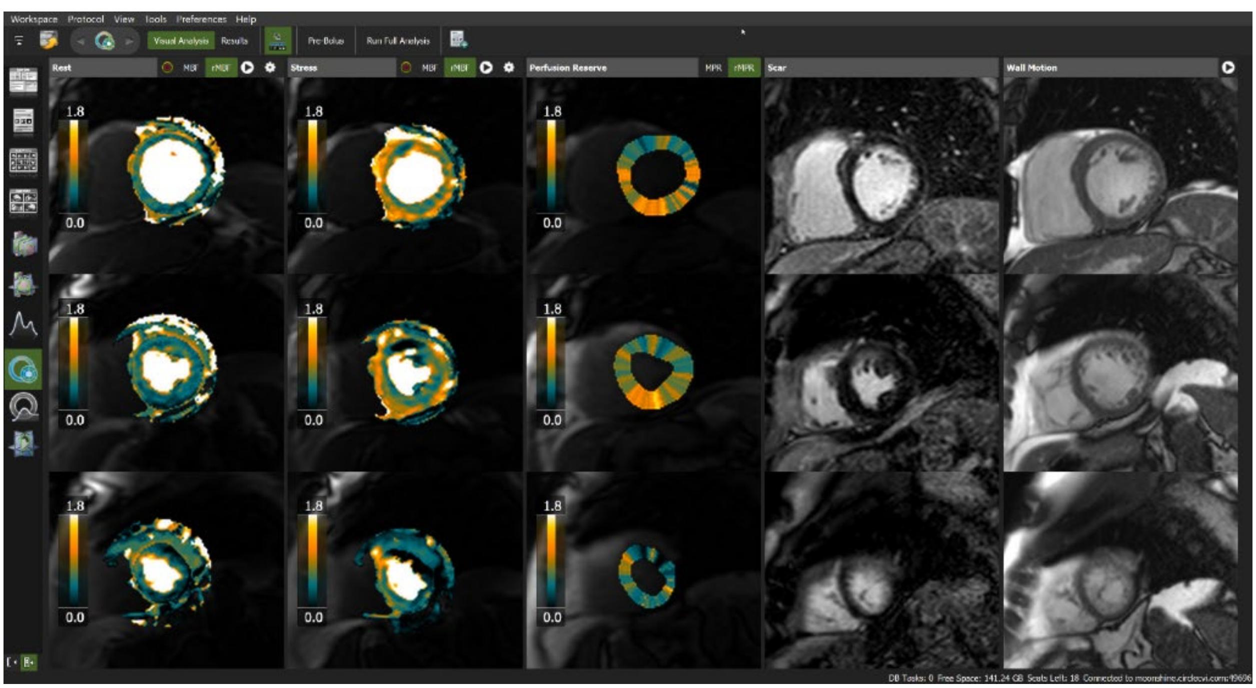
Intended Use

This module allows for quantitative analysis of myocardial blood flow for the detection of coronary artery disease and microvascular dysfunction as well as rapid generation of pixel-wise myocardial blood flow maps for visual depiction of ischemia.

WARNING: Perfusion|Quantitative
Perfusion analysis should not be done on GE dual-bolus or pre-bolus sequences. For more information please contact GEHC.

WARNING: Perfusion|Quantitative
Analysis of Enhanced DICOM datasets is not supported in the Quantitative Perfusion module.

21.1 Analysis



20.1.1 Workflow

The software supports the following techniques

- Dual bolus, single sequence.
- Pre-bolus, single sequence.
- Single bolus, dual sequence.

1. Adjust settings for the protocol in use

Pre-bolus injection scheme:
Before loading any series in the analysis frame, click <Pre-Bolus>, enter the volume of the big bolus and select the contrast agent used.
(Otherwise, start on step 2.)

2. Load series

From the thumbnail panel, select the following series via double-click in the order below, or drag and drop.

- Short axis perfusion rest series into <Rest> column.
- Short axis perfusion stress series into the <Stress> column.
- Optionally, load LGE and function images in <Scar> and <Wall Motion> columns for reference.
- If prompted, select the correct AIF from the thumbnail panel, and drag it into the AIF selector.

- Click <Run Full Analysis>.

If needed, the HR can be manually entered (next to the AIF selector). Otherwise, the HR will be automatically calculated during the analysis. The HR in use will be displayed on the AIF graphs in the Results page.

3. Map Review – Myocardial Blood Flow

- MBF-pixel-maps are automatically overlaid on rest and stress perfusion images.
- To visually assess the first pass perfusion, click MBF and run the cine .
- Click on rMBF (MBF/remote MBF) to review the relative myocardial blood flow.

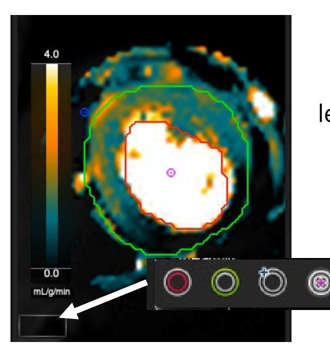
4. Map Review – Myocardial Perfusion Reserve (MPR)

- Color-coded MPR (MBF stress/rest) segments will be displayed in the middle column.
- Click on rMPR (MPR/remote MPR) tab to review the relative myocardial perfusion

5. Review Segmentation

Contrary to MBF maps, the calculation of MPR and polar maps rely on accurate delineation of the myocardium. Prior to interpretation, the user should verify endo- and epicardial contours.

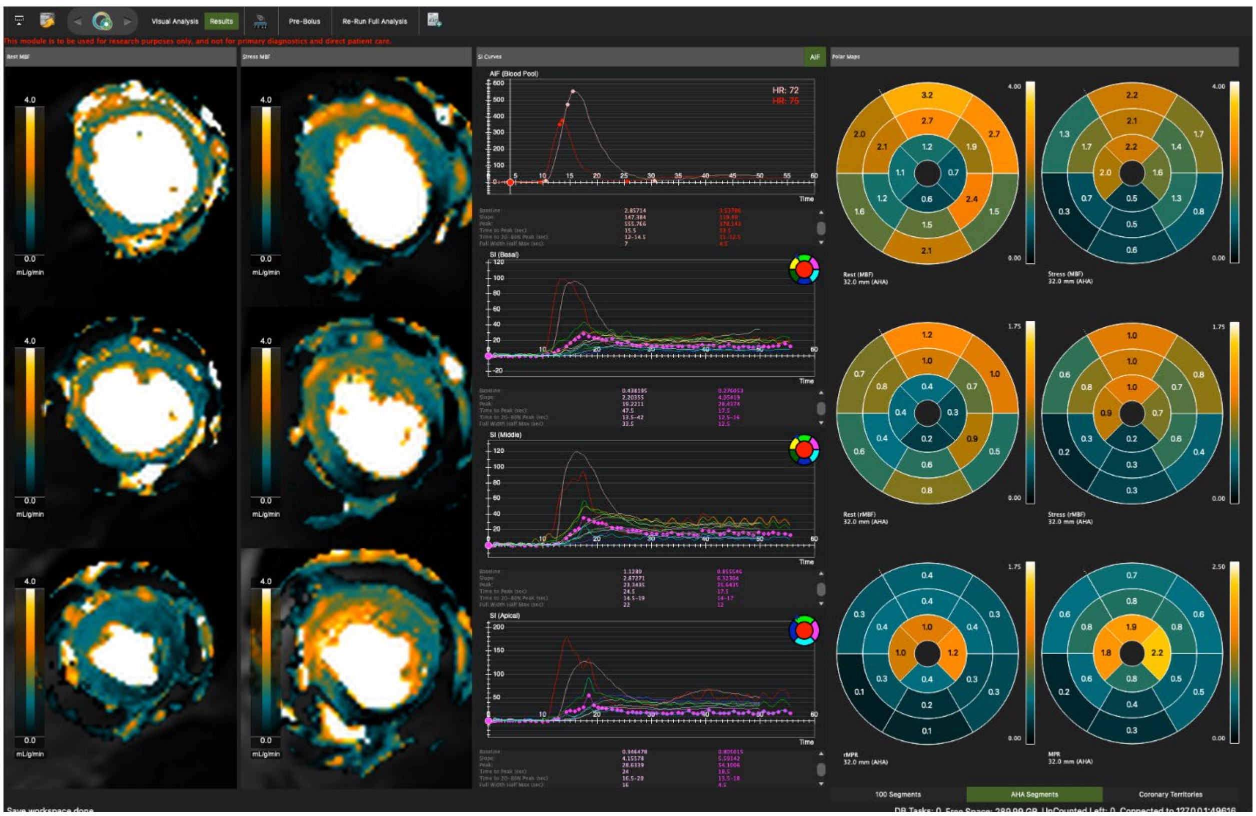
Note: Outliers (white pixel within the map) will be excluded automatically from the calculation of blood flow and is reflected in the maps.



- Click on the contour icon in the header bar and optionally toggle MBF maps on/off.
- Correct contours if needed: Contour correction tools will be provided in the shadow box in the left bottom corner of the view frame.
- After contour correction re-run analysis.

21.2 Results Review

The <Result> tab provides for review of the following:

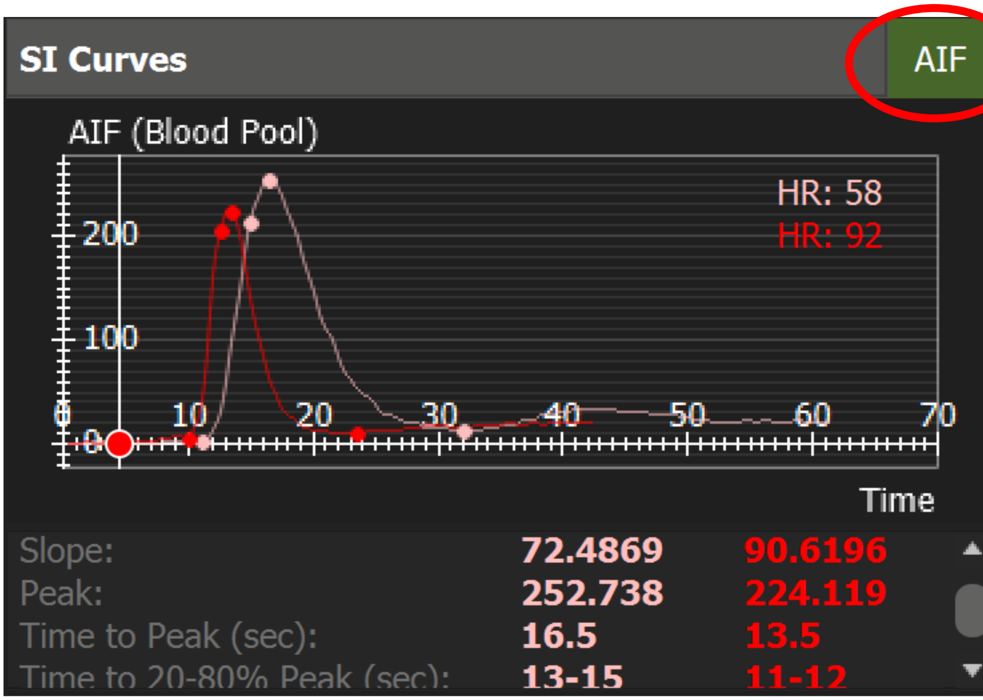


20.1.2 Rest and stress pixel maps

Rest MBF: Myocardial Blood Flow at baseline.
Stress MBF: Blood Flow during vasodilation.

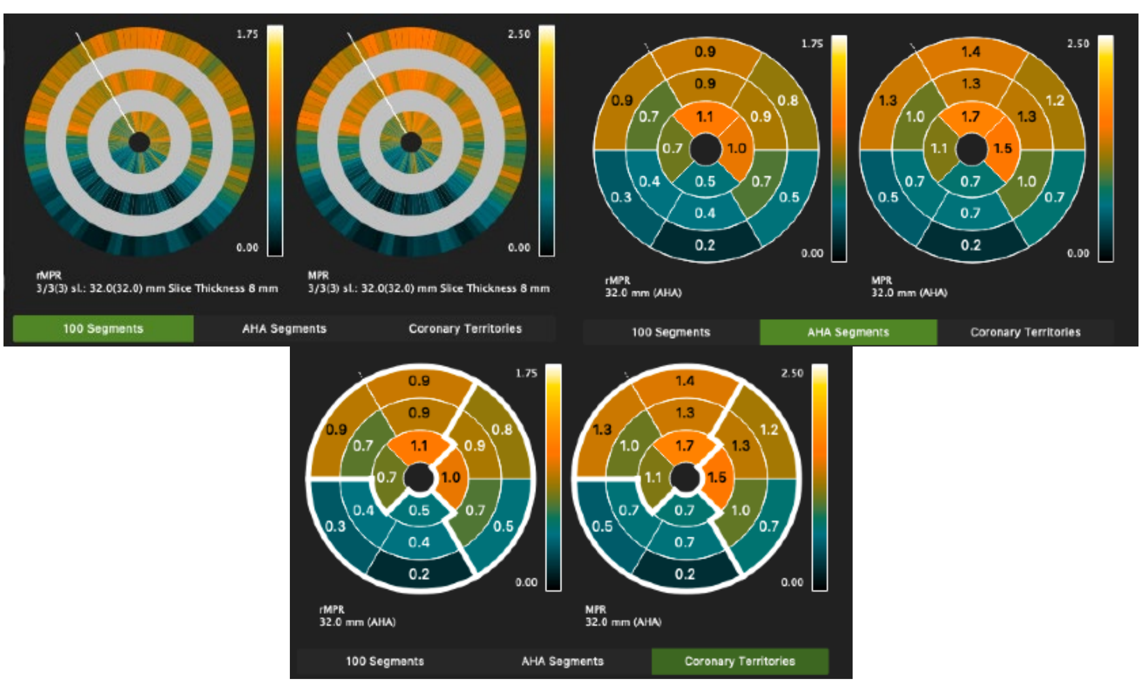
20.1.3 Signal Intensity Curves

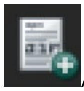
AIF and Segmental Perfusion Curves



1.  Hovering over a colored coded segment in the slice specific segment icon will display associated segment perfusion curves.
2. Clicking the segment in the icon will hide the curve.
3. Click and hold a data-point to display the associated values.
4. Review Perfusion parameters:
   - Baseline
   - Slope
   - Peak
   - Time to Peak
   - Time to 20 to 80 % of peak value
   - Full Width Half Max

20.1.4 Polar maps:



1. Review polar maps, checking the various segmentation options (100 Segments, AHA, Coronary Territories).
2. Add Results to the report – Polar maps will appear in the Clinical Data Report and integrated report.

21.3 Report

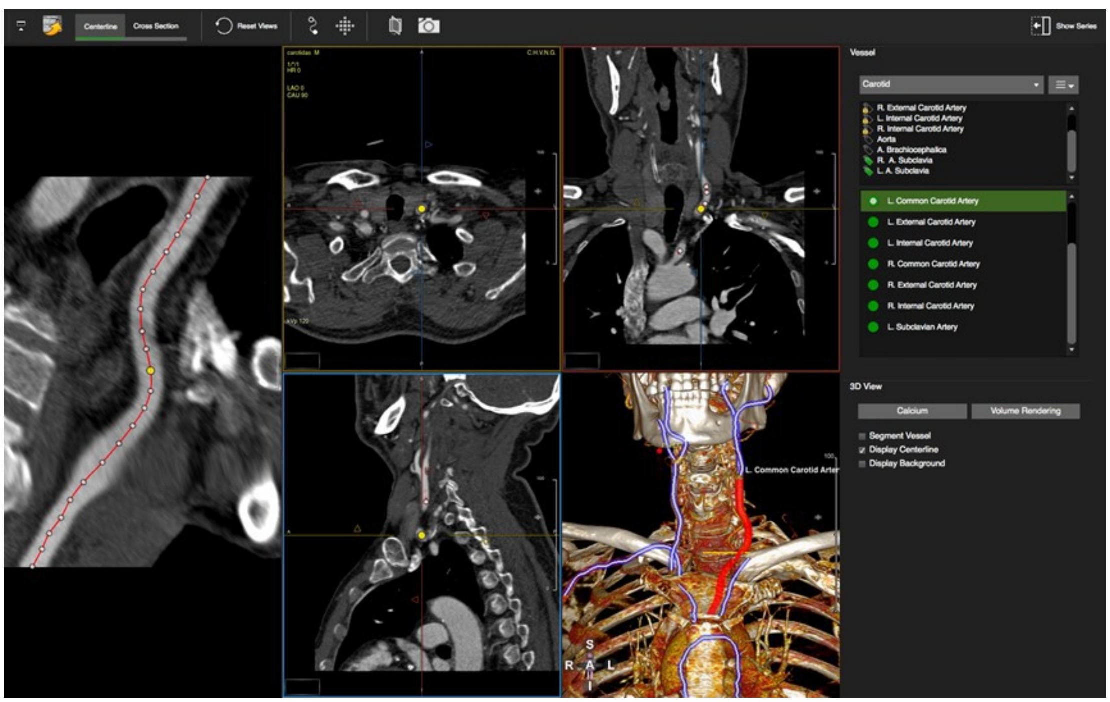
The following will be exported to the clinical Report:

- Rest and Stress MBF and rMBF values, separated by coronary territories.
- Rest and Stress MPR and rMPR values, separated by coronary territories.
- Blood pool AIF SI graph.
- Rest and Stress MBF maps.
- AHA polar maps for coronary territories.
- For more detailed reporting, please see the scientific report.

22 Vascular Module

The module covers two topics:

- Centerline: Centerline extraction of any vessel using orthogonal MPR views
- Cross Sections: Visual and quantitative assessment



22.1 Centerline Page

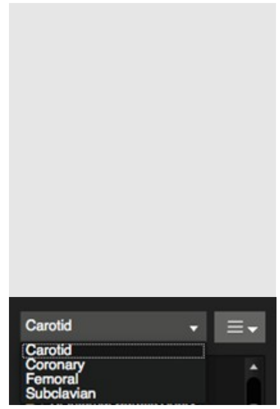
22.1.1 Main Page

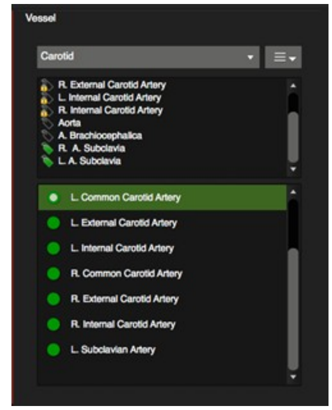
 Trace a centerline by setting a start and an end seed point (see Coronary module)

22.1.2 Vessel Lists

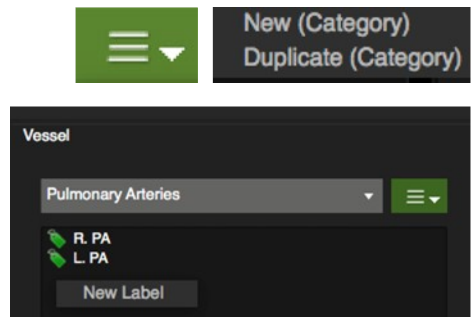
Lists of predefined labels for standard measurements. The software comes with lists for:

- Carotid Arteries
- Coronary Arteries
- Femoral Arteries
- Subclavian Arteries



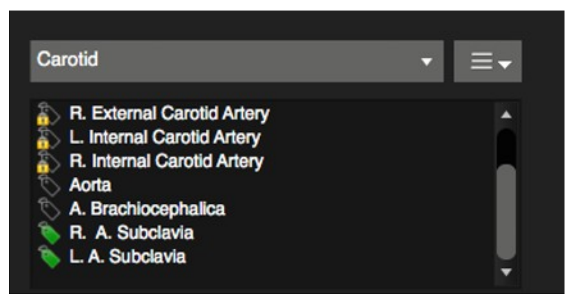


- For a new list select *New* (category), type a name in the window, click *Enter*
- To add or delete a label, right-click in the background
- The selected vessel list will be used sequentially when the user defines centerlines via seed-points or region growing



A list can display three label icons:

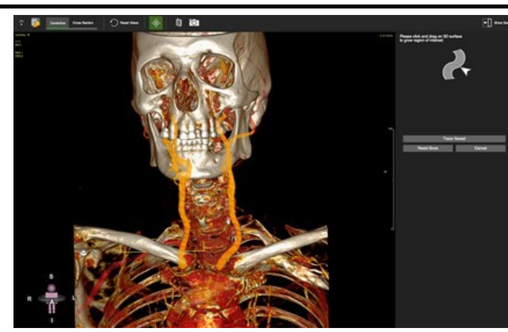
- Labels with a lock: predefined
- Green: unused
- Outlined labels: used



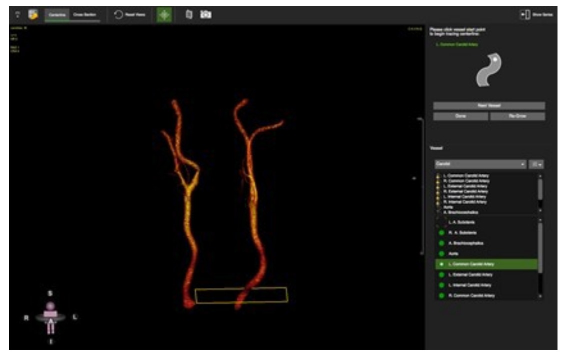
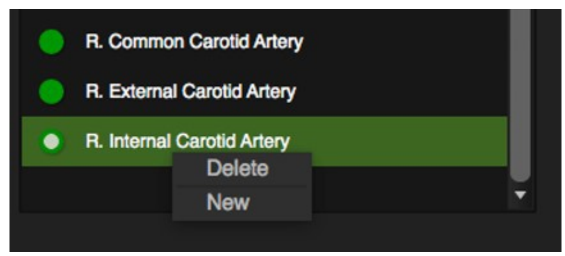
22.1.3 Region Growing

Trace a centerline via region growing.

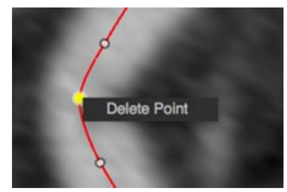
- Click the *Region Growing* button in the top toolbar. The software will open the image in an enlarged view.



• The top right panel will guide you through the steps	

• Grow the vessel by dragging on the 3D surface • Click *Trace vessel*, to extract the vessel • 'Alt' key allows to turn, 'Ctrl' (command Mac) allows to pan the image • In the segmented vessel, extract the centerline by placing a start and an endpoint • 'T' toggles the centerline on/off	
• Click Next Vessel to proceed to the next vessel in your list • Right-click to add or delete a centerline. The label will be updated to 'un-used'	
• *Done* will go back to the Main page	

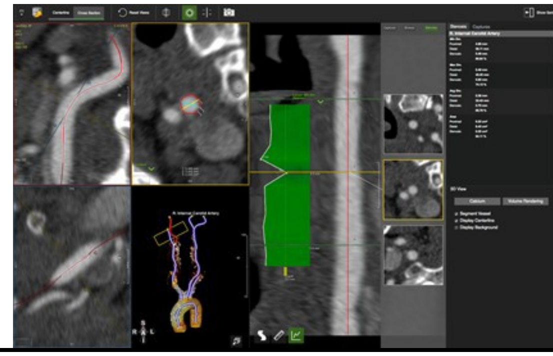
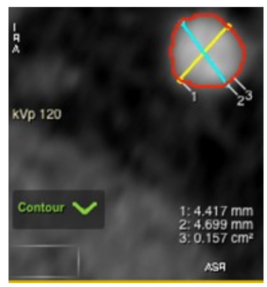
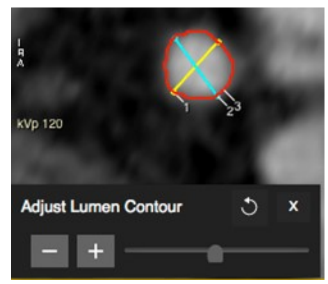
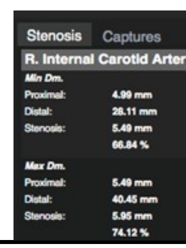
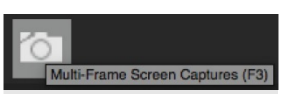
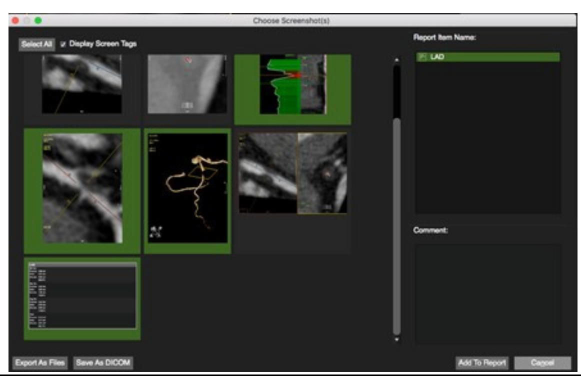
22.1.4 Edit the Centerline

• You can move the centerline control points in the CPR or the oblique views • Add control points with a double-click on the centerline	
• Delete a control point with a right mouse click • Rotate around the centerline with a left mouse drag close to the centerline • Pan the image by moving the cursor away from the centerline until the hand symbol appears	

22.2 Cross Section

Stenosis Assessment

22.2.1 How to Do a Stenosis Assessment

• Select the vessel by clicking on the respective vessel in the reference viewer ('T' – toggles the centerline on/off) • Start in *Browse* view and drag the yellow line down the vessel • Switch to *Stenosis* View and place the stenosis marker either by dragging or by double-clicking in the stenosis	
• Adjust the plane to accurately display a cross-sectional view •  Move to the MPR view and use the *Auto Vessel Lumen* tool to contour the stenosis and the 2 reference images • To adjust the threshold, click the green *contour* label. It will open a slider that allows to adjust the contour	 
• Stenosis measurements will be filled in automatically	 
• Images can be captured via context menu. •  Use the *Multiframe Capture* to save the stenosis measurements and optionally some images	

23 Strain

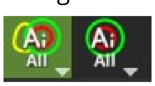
Intended use:

Assessment of myocardial deformation.

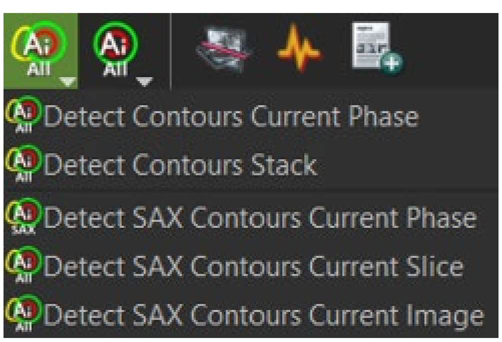
When using the Strain Analysis Module, if "Auto Load Series in Module" is enabled, cvi**42** will identify and auto-load appropriate SAX and LAX series.

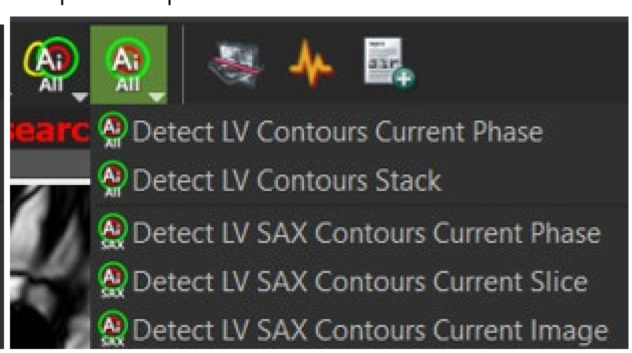
23.1 Auto Contour Detection Using AI

- There are two main AI icon tools, the left-hand tool will detect LV (endocardial and epicardial) and RV (endocardial) contours, and the righthand will detect LV contours only.

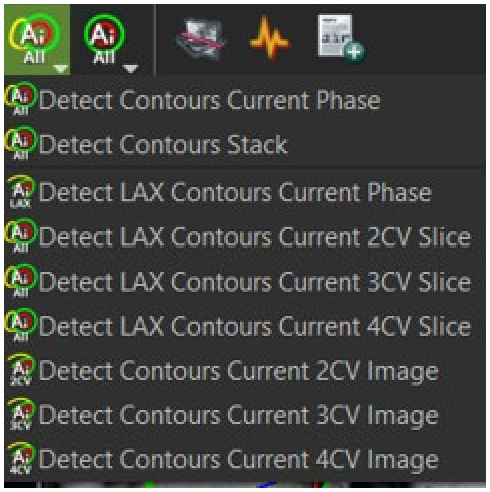


- Right-mouse clicking on each of the AI tools will open a dropdown menu with other AI contour detection options.

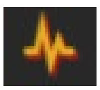


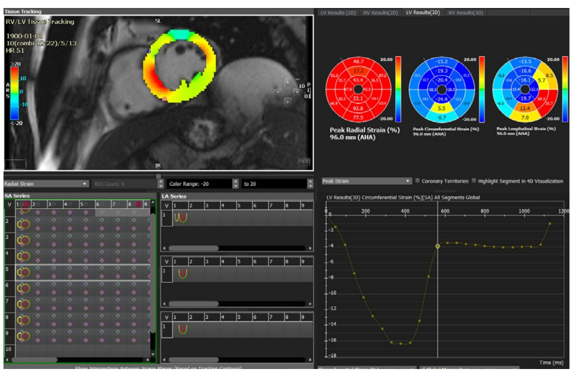


- "AI All" means that **cvi42** will detect the contours on the selected phase for all loaded series (SAX and LAX). If a SAX image is selected, it is possible to run the automatic contour detection on the selected phase of the SAX series only. Whenever the SAX contours are detected, the respective anterior and inferior RV insertion points will also be automatically detected.
- If a LAX image is selected, it is possible to run the automatic contour detection on the selected phase of all LAX series only. If the automatic classification of the LAX series in 2CV, 3CV or 4CV fails, it is possible to select the detection of a specific LAX series, by clicking on the LAX image and selecting the right option from the dropdown menu.



- With two clicks the user can run obtain a complete LV strain analysis:

 →  :



NOTE: Before running the strain analysis, the user must carefully check each contour on each image and correct them whenever necessary.

23.2 Strain Analysis

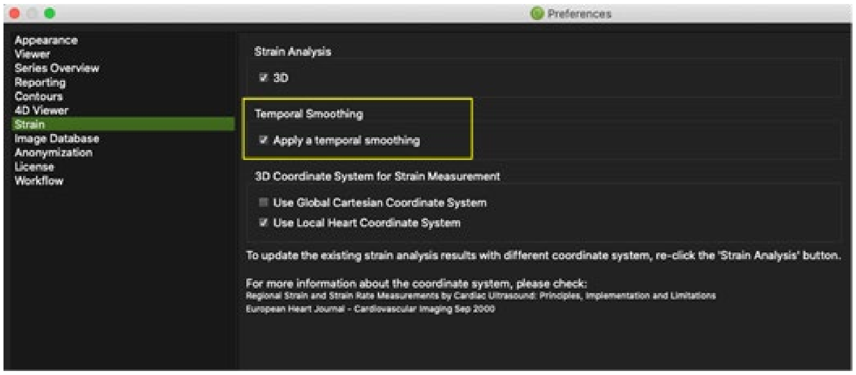
23.2.1 How to do LV 2D Strain Analysis

Load a short axis stack and long axis series into the analysis frame

Contouring the Reference Phases

- Visually select end-systolic and end-diastolic phase. Alternatively, check in the function module which phase has been identified as diastole and systole based on minimum and maximum volume. Make a note of the phase number.
- Zoom in as far as possible and window properly.
- Display an image in end-diastole.
- Go to the AI button  and make sure it is set to <Detect LV Contour in Current Phase>. This will segment LV in the end-diastolic phase in all series simultaneously.

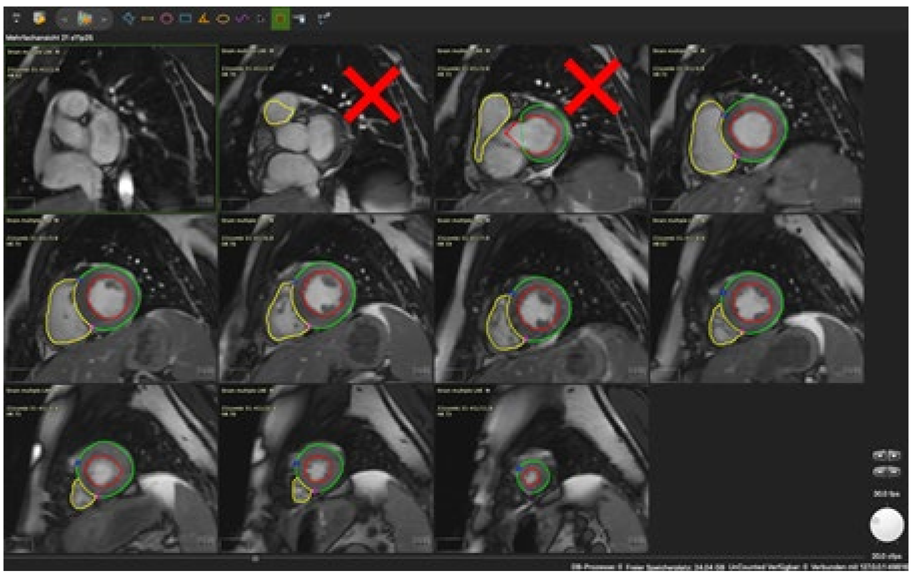
- For better tracking performance we recommend to additionally contour the systolic phase, which will serve the system as a guidance. Make sure you have activated the preference <Apply Temporal Smoothing>



- Repeat step 5 for systole.

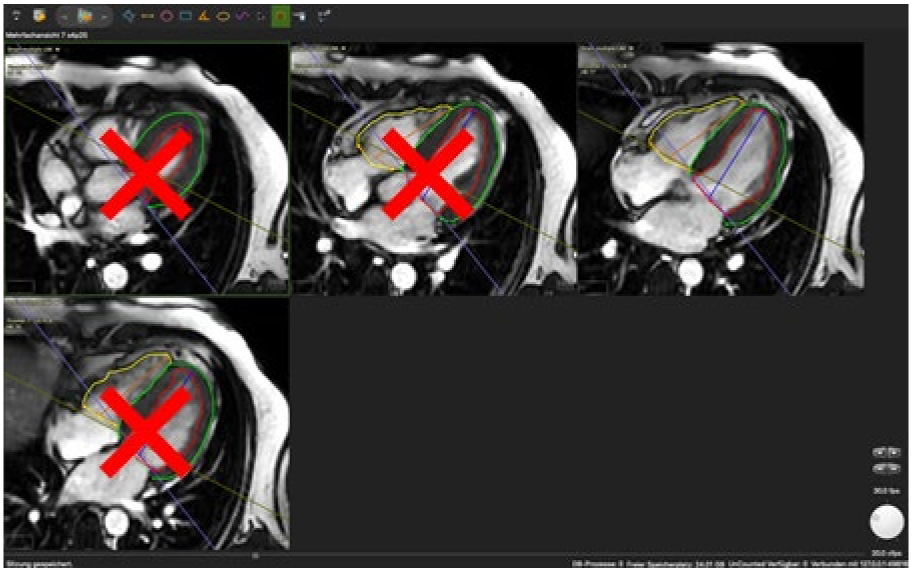
Contour Check

Short Axis

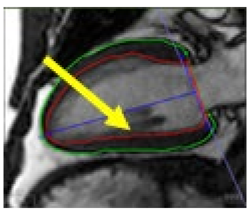


- In short axis go to <multiview> and click through the phases. Delete contours in phases where the LVOT comes into view or where the apex moves out of the plane.
- Zoom in and carefully check your borders. Ensure contours are placed in the myocardium avoiding chemical shift artefact or pericardium. Trabecle and Papillary muscles have to be excluded.

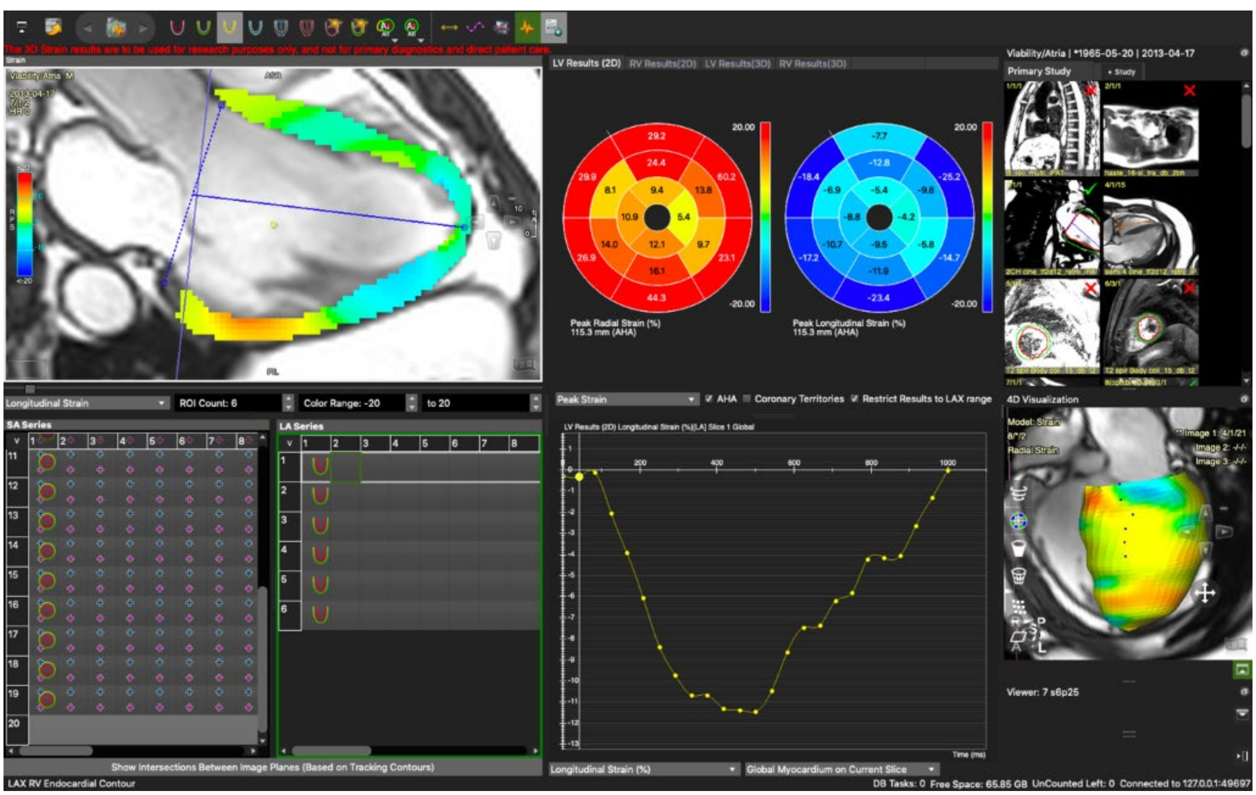
Long axis

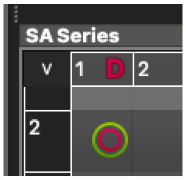


- Verify that contours in end-diastole and end-systole have to be in the same phase as in the short axis!
- In case of multiple parallel long axis slices, only contour the slice that cuts through the true apex (see above). Otherwise, the other slices will falsify the mean global strain values.
- Papillary muscles have to be cut off. Play the cine or slowly move through the phases to identify papillary muscle in systole.



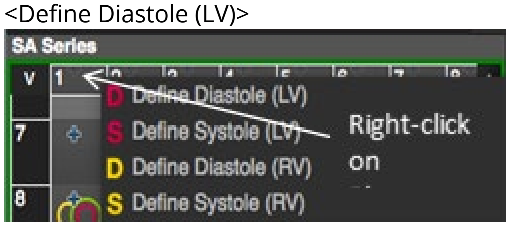
Perform Strain Analysis



- Make sure an image in end-diastole with the contours is selected in the viewport.
- 

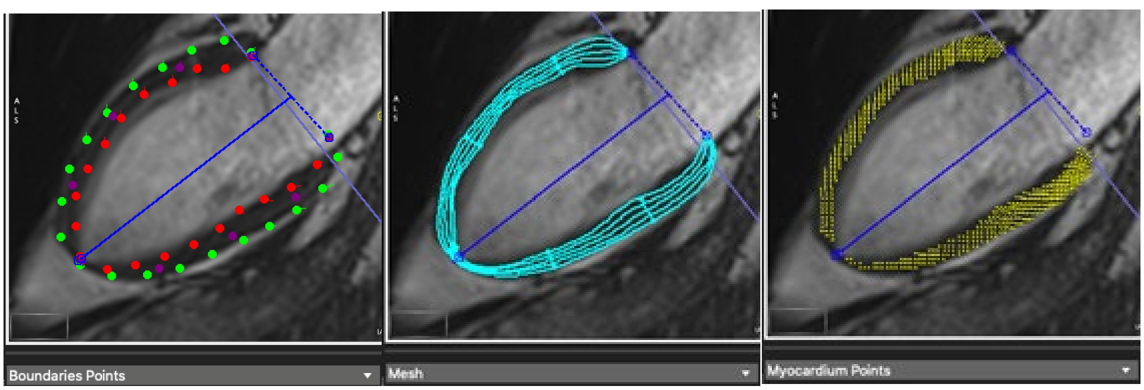
- Click the <Perform Automatic Strain Analysis> button. 
- Strain will be calculated with reference to diastole.
- Based on the tracked borders, the system runs a volume calculation in the background and might now identify a different phase as diastole or systole.

If you have deleted basal slices this is not reliable, and you should manually re-set the label: Right-click on the phase number and select <Define Diastole (LV)>

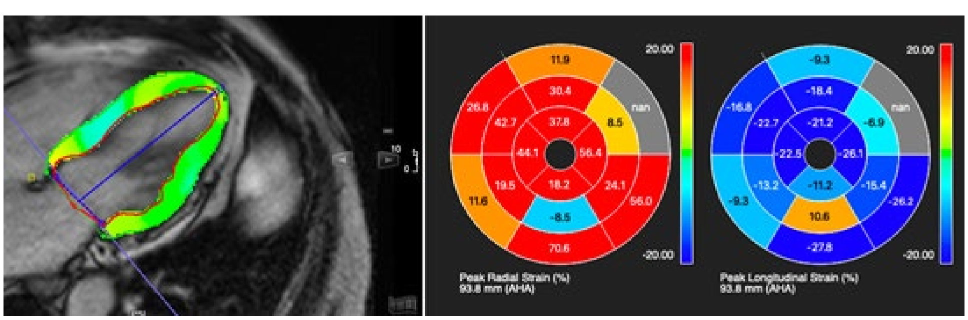


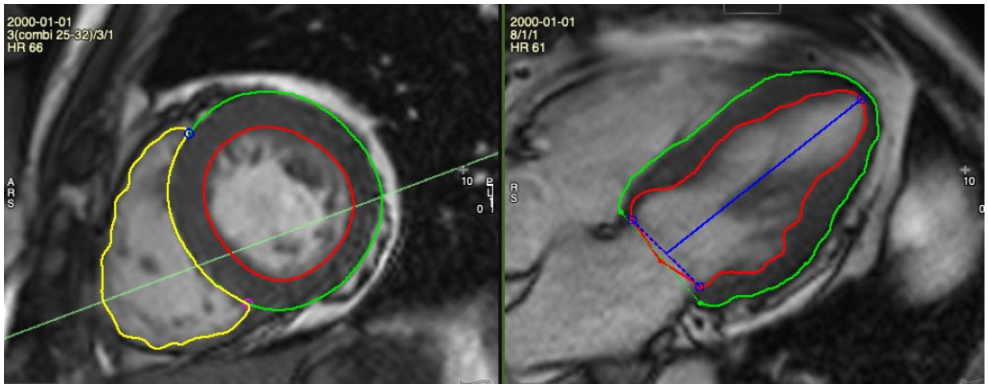
Tracking Quality Assurance

- Set Image Overlay to <Boundary points>, run the series, and check location, displacement, direction and vector length.
- <Mesh> visualizes the deformation of the centrelines,



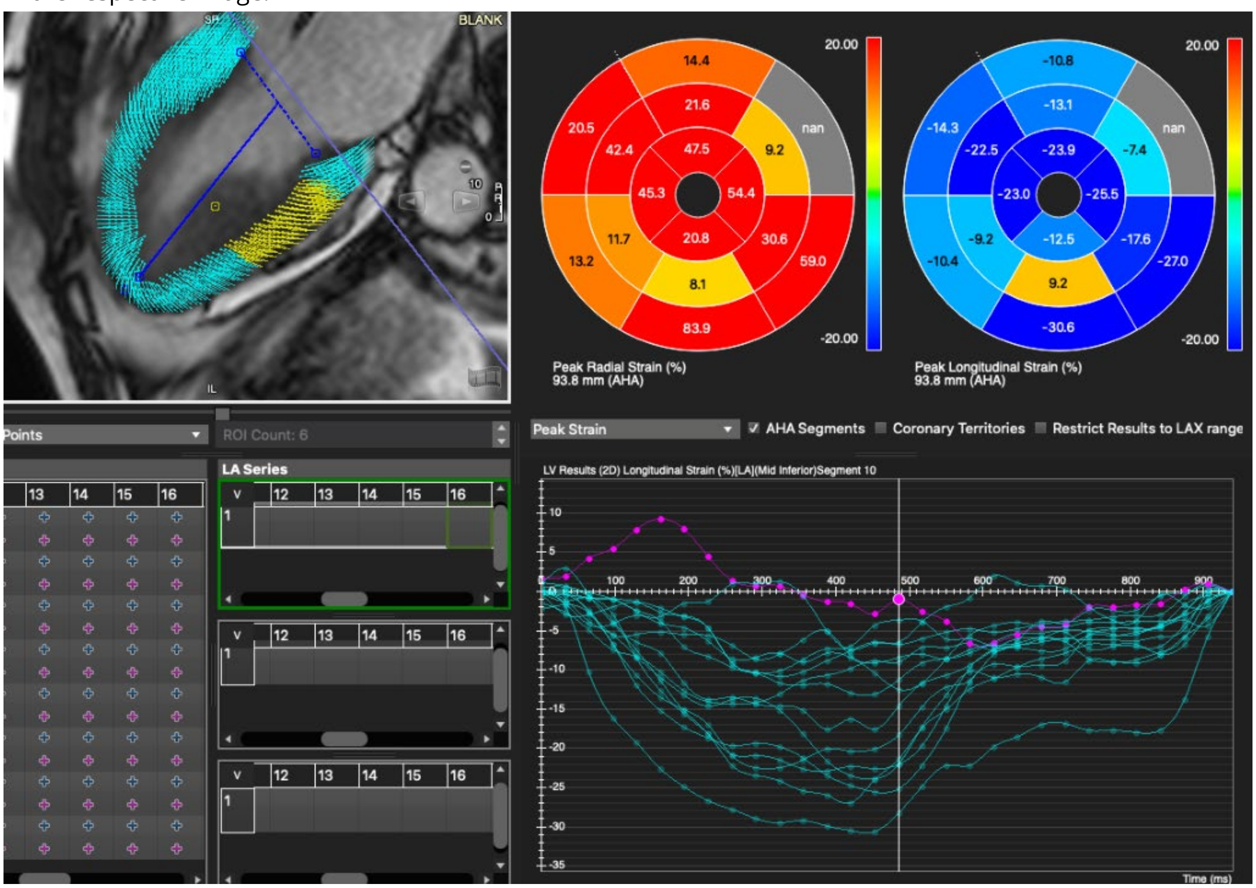
- In long axis, check the tracking of the blue T-Line, which is indicative of tracking quality
- In short axis, check the tracking of the anterior insertion point.
- Check polar maps: Below an example where the basal, antero-lateral segment displays a grey segment (non-analysable), indicative insufficient coverage due to bad planning





The short axis reference of the respective 4CV reveals that the slice is off-axis.

- Setting the overlay to myocardial points and click on segment in the polar map. The segment will be highlighted in yellow in the respective image.



Options to enhance the tracking

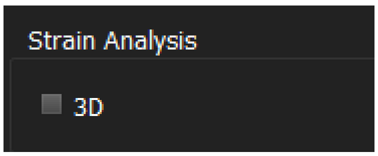
- Set the overlay to boundary points.
- Add contours where the tracking starts to deviate. Only correct the contour that is affected and keep to the boundary points where you had good tracking.
- Go back to the end-diastolic phase and re-run the strain analysis.

Saving

- Click the Add to Report button.
- Save workspace DICOM.

23.2.2 How to do 3D Strain Analysis

Check the 3D strain option in the Strain preferences

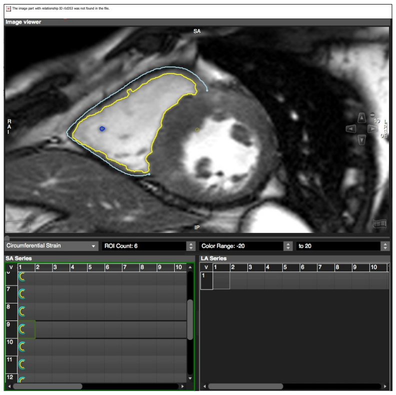


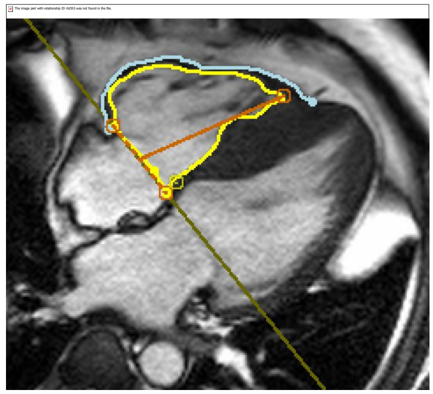
It is recommended to have at least 3 short and long axis slices and 25 phases.

1. Sequentially load short and long axis (either a stack or 3 different radial cines) in the analysis frame
2.  Define endo- and epicardial SAX contours in all slices that that cover the LV. Make sure not to include blood volume
3.  Define the anterior *SAX reference point* at the insertion of the right ventricle in a SAX
4.  In long axis, setting the *LV extend* will trigger an endocardial contour detection and vice versa
5. Correct if needed. Pay attention to exclude papillary muscle
6.  Select the reference phase by clicking on an image within that phase and click the *Perform Automatic Strain Analysis* button. Strain will be automatically computed in all slices, that contain endo- and epicardial contours
7. Click the *3D LV Results* tab above the polar maps
8. The software will generate polar maps, strain curves and a 4D contour model based on the tracking results

23.2.3 How to do RV Strain Analysis

1. Load a short and/or long axis stack into the analysis frame
2. In a reference phase, define RV endo- and epicardial contours in all slices that cover the RV





3. For a segmental analysis:

- Load an orthogonal slice of the RV with the same number of phases
- Endo- and epicardial contours have to be drawn consistently in the same phase for long and short axis.
- Add an anterior and inferior insertion point

4. For 3D RV analysis it is recommended to load at least 3 additional orthogonal slices

5.  Select the reference phase and click the *Perform Automatic Strain Analysis* button. Strain will be automatically computed in all slices, that contain endo- and epicardial contours.

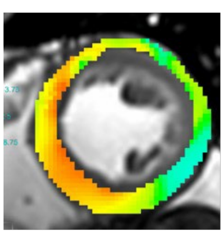
22.2 Performance Check and Adjustments

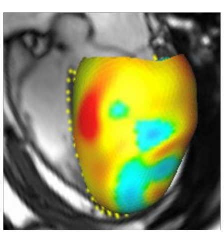
- Use the overlays to check the performance of myocardial tracking
- To review the parts of the myocardium that have been included into the strain analysis, based on the Restrict to LAX extend, select the Myocardial Points
- If you are not satisfied with the strain borders visible in the overlay, try to re-adjust contours or draw contours in a different phase, then re-run the strain analysis

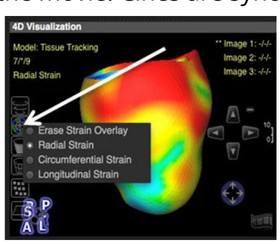
22.3 4D LV Visualization

22.3.1 How to View a Strain Cine Loop

- After the strain analysis, you can view a cine loop of radial/longitudinal or circumferential strain in the *4DVisualization Viewer*
- Click the film icon or spacebar to run the movie. Cines are synchronized with the image viewer



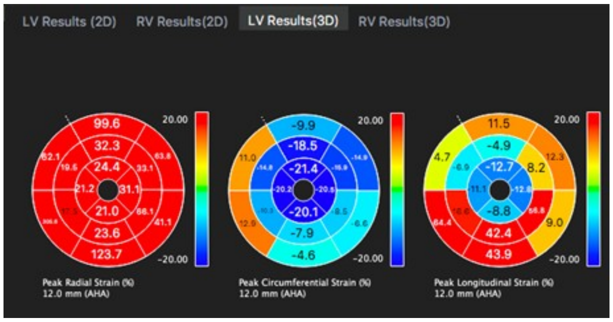




2D Radial Strain *2D/3D Visualization*

22.4 Regional LV Analysis

22.4.1 How to Display Polar Maps

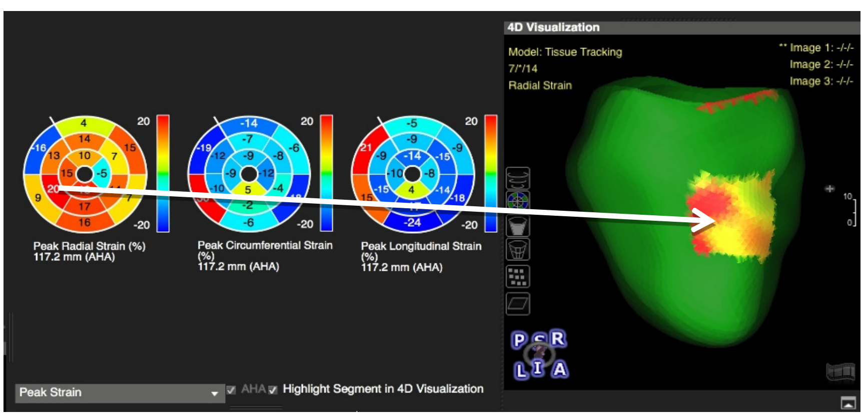


Polar maps display different values, which can be chosen from a drop-down menu.

- To view polar maps for the different strain analyses, click the *2D or 3D Results* tab
- A click on the polar map will automatically synchronize curves, image viewer and 4D viewer to display the selected strain, e.g. circumferential strain
- 2D results can be viewed for a 16-segment model or a defined number (between 6 and 24) of ROIs. To set the number of ROIs per slice, use the drop-down menu located underneath the analysis frame.
- Adjust the color map for minimum and maximum strain using the menu located underneath the LAX thumbnail grid
- The drop-down menu will offer different results

22.4.2 How to Evaluate a Single Segment

1. To view a specific segment in the 4D viewer check the box for *Highlight Segment in 4D Visualization*
2. Double-click a segment in the polar map and view the strain of the selected segment in 4D by clicking the film icon
3. The respective segment in the AHA segment will be highlighted automatically



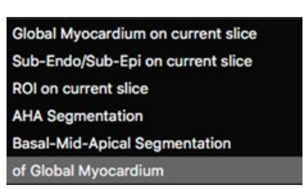
22.5 Diagrams for Strain, Displacement and Torsion

22.5.1 How to Display Strain and Displacement Diagrams

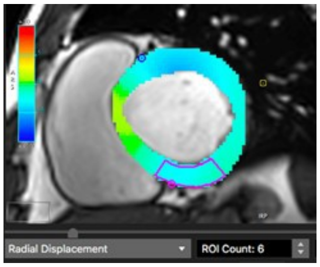
1. Start with selecting the region for which you would like to display the parameter:

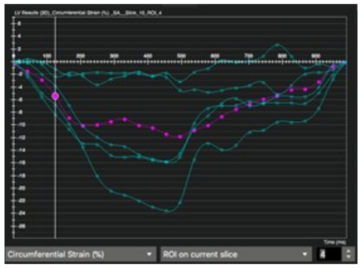
- *ROI on current slice*

- The number of ROIs can be in-/decreased (minimum is 6, maximum 24) using the menu located underneath analysis viewer



2. Use the up/down arrows next to *ROI on current slice* to highlight the respective ROI





Torsion:

- If not defined, the software uses the most basal and apical slice to calculate torsion
- To select different slices for the torsion calculation: Right-click on the slice number in the thumbnail grid and select B/A

24 Flow|4D

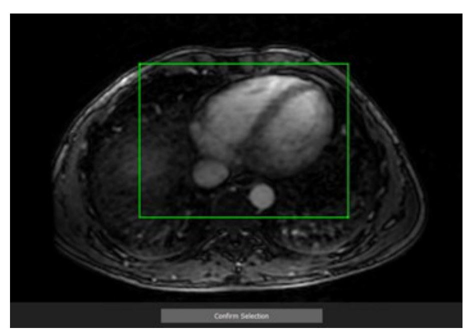
Intended Use:

Preprocessing.

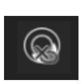
24.1 Data Cropping

1. Load the 4D flow study from the thumbnail pane into the module via double-click or drag-and-drop

- The cropping tool can be used to better define the field of interest and improve performance for big studies (acquisitions with more than 3000 slices)



Note: Once the bounding box is fixed, all the further analysis will be done within the bounding box. If the bounding box is deleted or modified before saving workspace, all the measurements will be changed.

2. Select the box by clicking the green line
3. Grab the green dots at the left top and right bottom corner of the box and drag to confine the region of interest
4. Use the "Erase Mask" tool  to manually exclude regions that should not be part of the static tissue mask, e.g. spatial aliasing or regions of high flow inside of the green bounding box. The static tissue mask is not restricted to the bounding box.
5. part of the static tissue mask, e.g. spatial aliasing or regions of high flow inside of

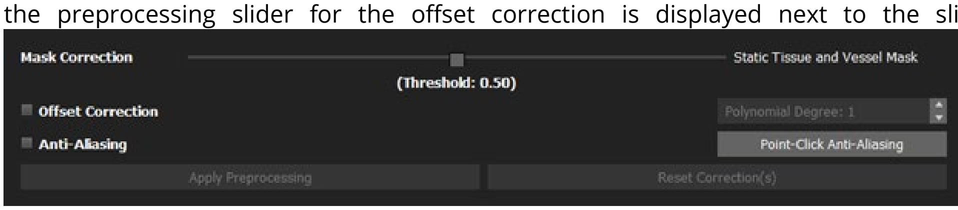
the green bounding box.

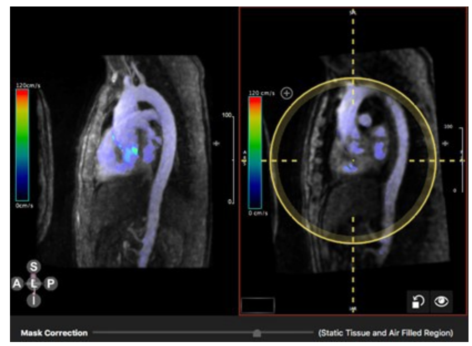
6. A checkbox in the ROI selection page allows the user to adjust the 4D analysis, more specifically the PcMRA segmentation, to small sized vessels. If unchecked, the analysis is optimized for (big) cardiovascular vessels. The option is saved to the workspace. Reset workspace will not change the checked status of the checkbox.

7. *Confirm Selection*
8. To change the selection, go to *Workspace>Reset Workspace*

24.2 Preprocessing

- When a user loads a study into the Preprocessing Page, the static tissue and vessel mask will be automatically identified, but the Offset Correction (OC) won't be automatically applied. The user can use the suggested mask for OC or adjust it with the slider. The static tissue mask shall be distributed evenly across the images. The used/selected threshold value of the preprocessing slider for the offset correction is displayed next to the slider.





1. Run the cine and scroll through the slices. The left central View port displays the time averaged MRA. The right MPR Viewer allows for navigation in any plane and direction with synchronized magnitude and velocity views (see MPR Viewer)

2. Adjust the color bar: LMB click on the bar will open a dialog.

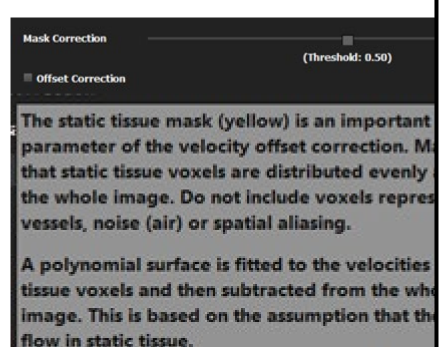
Note: Structures on preview page are independent from the structures on the segmentation page.

24.2.1 How to apply an Offset Correction (OC) and Phase Anti Aliasing

<table>
<tr><td>

- The software automatically defines a static tissue mask.
- The user can use the suggested mask for OC or adjust it with the Mask Correction slider.
- Make sure that there are no unwanted regions included in the mask. Having flow or noise included in the static tissue can have a severely negative influence on the result.
- The static Tissue mask will be used for Offset Correction.

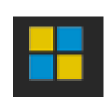
</td><td>



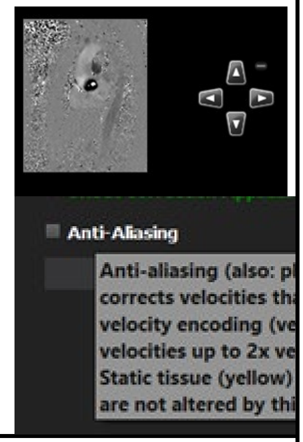
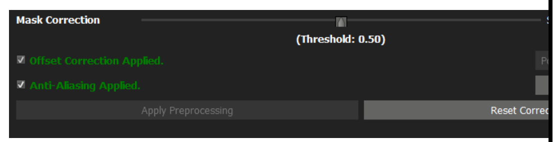
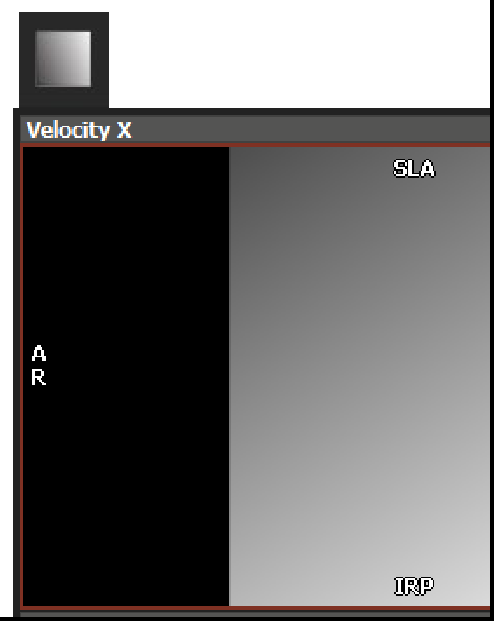
</td></tr>
<tr><td>

- Click on *Mask Overlay* to activate and deactivate the static-tissue (yellow) and air- filled (blue) mask overlays.

</td><td>



</td></tr>
</table>

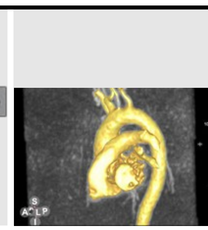
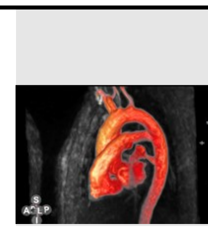
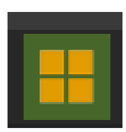
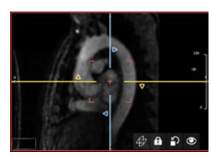
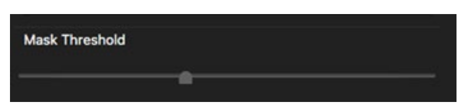
• In case of aliasing, check 'Anti-Aliasing"	
• Click *Apply Processing* • Green font indicates preprocessing has been applied	
• Once the offset correction has been performed, the estimated offset field can be visualized for all 3 dimensions, by selecting *Show Correction Field* in the top toolbar.	

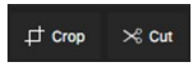
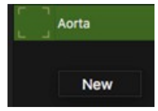
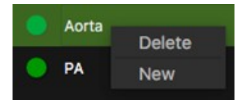
24.3 Segmentation

Intended use:

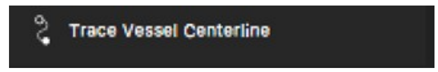
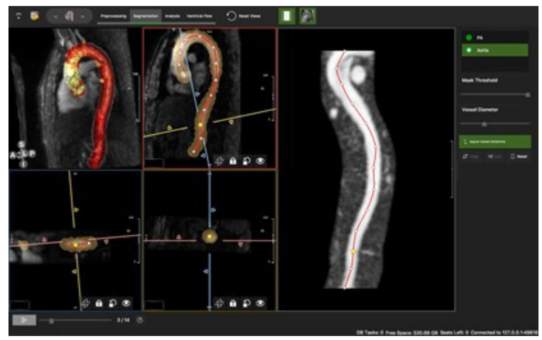
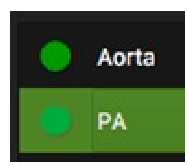
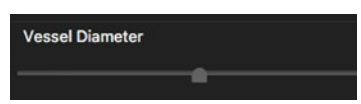
- Segmentation
- Centerline extraction

24.3.1 How to Segment a Vessel

1. *Show Magnitude Image* toggles between magnitude and phase-contrast display. The magnitude allows you to run a cine in the background.	  
2. Activate the *Display Mask Overlay* button.	  
3. Use the *Mask Threshold* slider to adjust the segmentation.	

4. Use cut and crop to refine the MRA segmentation in the PC MRA • Define one or several masks with, or without creatinga centerline • Right-click to add a new or delete structure • Double-click on a title to rename • Right-click on the existing vessels to delete	   

24.3.2 How to Extract a Centerline

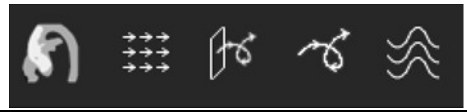
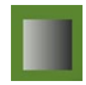
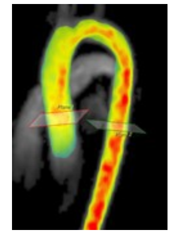
1. Click *Trace Centerline*	
2. Set a start and an endpoint in the PC image 3. Select if you are about to trace a small or large vessel (coronaries are small, everything larger is classified as large). 4. Adjust the control points in any view port 5. Rotate around the centerline with a left mouse dragnext to the line in the CPR view. **Note:** Only the spline and control points within the slab range is visible.	
6. Once you have created several masks and/or centerlines you can easily switch back and forth between the vessels by simply clicking on the vessel title	
7. Use the *Vessel Diameter* slider to grow the mask from the centerline	

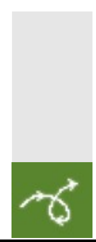
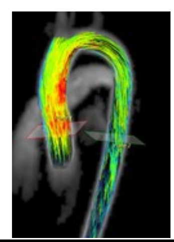
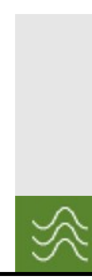
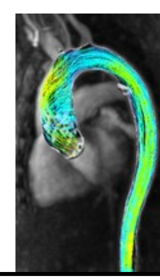
24.4 Analysis

Intended Use

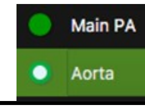
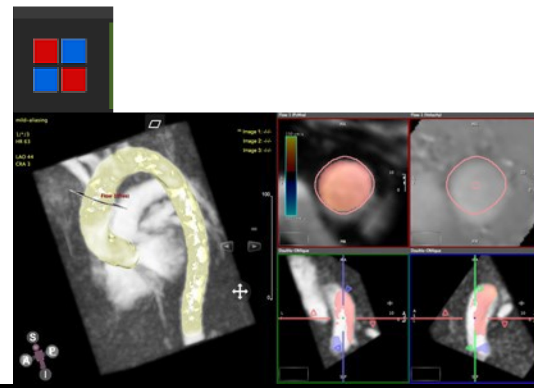
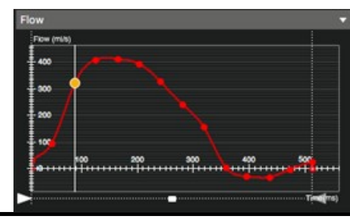
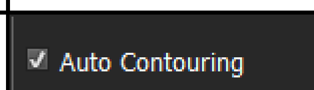
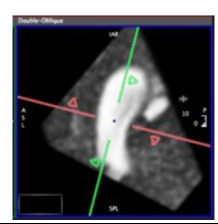
- Flow visualizations
- Quantitative Flow analysis

24.4.1 How to Visualize Flow in 4D

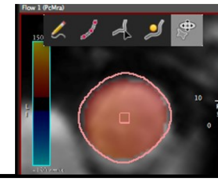
1. Select a flow visualization from the top tool bar	
2. Start the cine and adjust the frame rate	
• Velocity Visualization	 

• ***Vector Visualization:*** Displays speed and direction. Change the density of the vectors between 1-20 lines/ml	
• ***Pathline (Planes) Visualization***: Evolution of 3D blood flow over one or more heartbeats. **Note:** User needs to check accuracy of contours before observing the particle tracing. • **Pathline density** can be adjusted via slider heartbeats. Requires a centerline. • **Pathline of a specific phase**: By default, pathlines are emitted continuously. Use the slider on the bottom of the page to scroll through the phases to identify the onset of e.g. a jet.	
• **Pathline color**: Illustrate complex flow dynamics in congenital heart disease. **Note:** Single color map mode does not indicate velocities. *1.* Click on the flow plane and select *Set Pathline Color* from the context menu *2.* To save and add a second plane, click *Add Measurement* 3. Position the free plane and set a color *4.* Again, save the plane by clicking *Add Measurement* 5. Run cine to visualize the custom color-coded flow	
• ***Pathline (Mask) Visualization***: Display pathlines of particles emitted from all areas within the segmented mask. Select phase and density of the pathlines	 
• ***Streamline Visualization**:* 3D velocity fields at a specific temporal phase. Change the density of the streamlines.	 

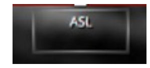
24.4.2 How to do a Flow Measurement

1. Select a vessel from the list	
2. Place a plane in your ROI. Planes will follow a center- line, if present. (toggle on/off the centerline display with short-cut key 'T') **Note:** The flow direction of the plane is indicated by an arrow. The direction can be changed via context menu > *Invert.*	
• Magnitude and Velocity images will be displayed next to the MRA. • Maximize the view: Space-bar-click on a view-port • Optionally, activate a **color-**coded flow overlay to the cross-sectional images • *Velocity* and *Vectors* can be displayed color-coded in cross-sectional views	
• A **contour** will be drawn and propagated automatically, and a flow curve will be displayed instantaneously	
• A checkbox allows to deactivate automatic contour detection in both Analysis and Ventricular pages. • If auto contouring is disabled, the user has to draw the contour manually and it will only be smoothed to remove sharp edges but not made circular as before. • The user can round the contour with ctrl + L. If auto contouring is on, it will behave as before. In both cases the contour will propagated to other phase images automatically	
3. **Adjust** the double oblique views to accurately display cross-sectional images	

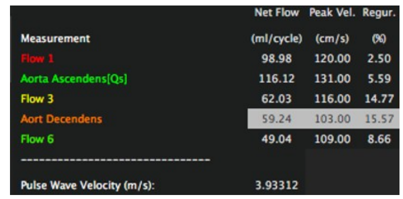
4. Run a cine to check for correct edge detection
5. Single-click the contour to adjust it. **Note:** The modified contour is only forwarded to the end of the cycle.



- Different contouring modes, such as *Point-Click* or *Thresholding* will be available by dragging the mouse on the top position tag



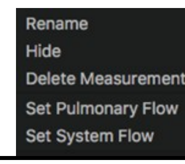
-  Add a measurement triggers the flow calculation: Net, peak and regurgitant flow will be calculated automatically.
- As soon as there are more than 2 planes, pulse wave velocity will be calculated.
- Note: Regurgitation fraction can only be calculated if the dataset covers the full cardiac cycle



Measurement	Net Flow (ml/cycle)	Peak Vel. (cm/s)	Regur. (%)
Flow 1	98.98	120.00	2.50
Aorta Ascendens[Qs]	116.12	131.00	5.59
Flow 3	62.03	116.00	14.77
Aort Decendens	59.24	103.00	15.57
Flow 6	49.04	109.00	8.66

Pulse Wave Velocity (m/s):	3.93312		

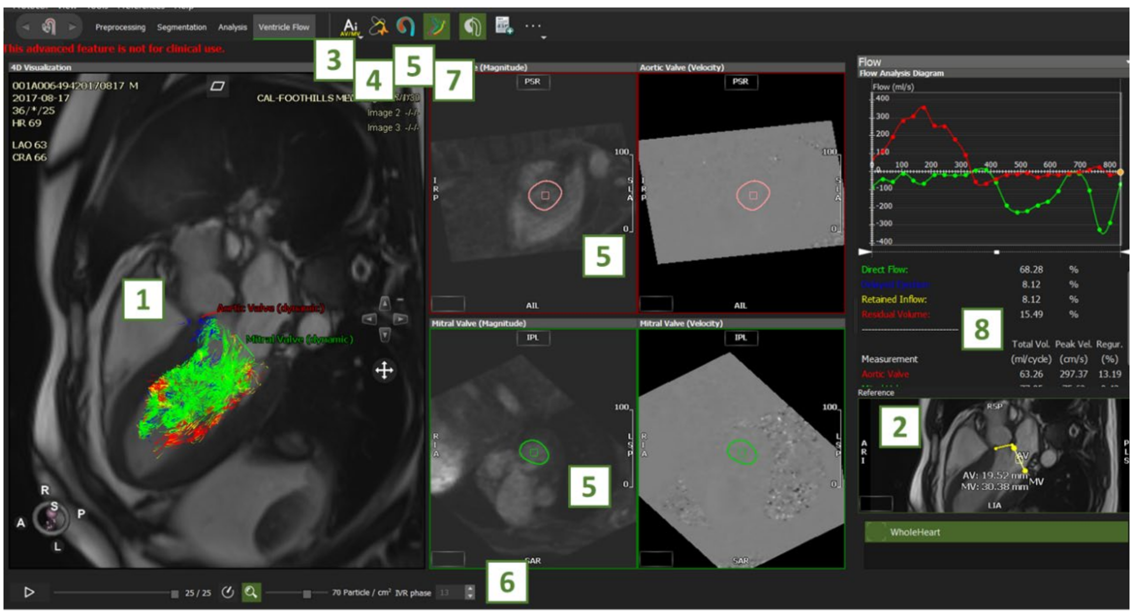
- To **label** a contour right-click on the plane in the PC MRA, or right-click on the flow measurement in the report, select *Rename* from the menu



24.4.3 Ventricular Flow Analysis

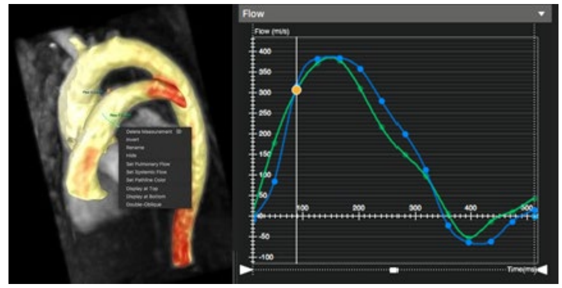
In order to calculate the LV functional flow components (Direct Flow, Delayed Ejection, Retained Inflow, Residual Volume (%)) the AV and the MV contours must be defined on each phase of the 4D Flow series. This can be done manually or semi-automatically. For semi-automatic analysis, the LAX cine SFFP series from the study can be used as reference for AV and MV tracking. Therefore:

1. Start by checking the alignment of the LAX series and the 4D Flow volume, by loading the LAX cine into the 4D Visualization frame. If there is significant misalignment, the LAX series should not be used for the tracking of the valves.
2. Drag a LAX cine SFFP series in the LAX reference frame, preferably a 3CV to track both the AV and the MV.
3. Click on the AiAV/MV line detection tool, check the valve lines on each phase of the LAX series and correct if necessary. It is also possible to draw the AV/MV lines manually and label them as “AV” and “MV”, at least on ED and ES phases. The valve locations will be interpolated in such cases. However, adding correct valve locations on more phases will provide higher accuracy of the valve tracking. The contour forwarding action may also be used from the context menu.
4. Click on the Valve Tracking tool. This will use the LAX contours information to find the dynamic AV and MV planes position in the 4D PCMRA.
5. Check and correct the AV/MV contours on each phase of the 4D Flow series. Select and right-mouse click (RMC) on the plane on the 4D Visualization. Selecting the Double-Oblique View, helps to check and correct the respective valve plane on each phase. The Flow Visualization can be used for better identification of the valves’ planes.
6. Define the Isovolumetric Relaxation Phase (IVR).
7. Run the Ventricular Flow Analysis.
8. The onscreen report will return the LV Functional Flow Components, and these can also be visualized on the 4D PCMRA. The AV/MV Net Flow, Peak Velocity and Regurgitation Fraction will also be reported.



> ⚠ **NOTE**: Other LAX series, e.g. 2CV, can be loaded in the reference frame to track the valves. If a 2CV is loaded after a 3CV, and steps 3) and 4) are repeated, the software will “retrack” the MV from the 2CV and will keep the AV information from the 3CV.

24.4.4 How to do a Shunt Calculation Qp/Qs



Other than in 2D Flow, planes must be set in the same structure.

1. Segment the vessels (no centerline) and move to the analysis page
2. Place a plane in the aorta and in the pulmonary artery
3. Scroll through the phases and correct contours if necessary

4. Open the context menu by clicking on the respective plane, e.g. in the ascending Aorta and select *Set Systemic Flow*

	Net Flow	Peak Vel.	Regur.
Measurement	(ml/cycle)	(cm/s)	(%)
Flow 7[Qp]	78.94	75.00	2.88
Flow 9[Qs]	81.40	132.00	7.04
Qp/Qs	0.969762		

5.  Add measurement

6. Place a second plane in the Pulmonary artery and select *Set Pulmonary Flow*

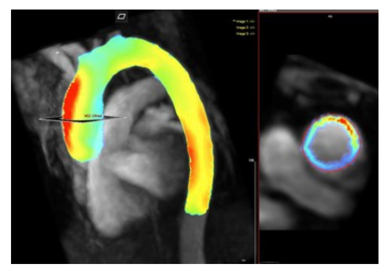
7.  Add measurement

24.5 Advanced 4D Flow Parameter Analysis

Note: A separate advanced license needs to be installed in order to use the ventricular flow analysis.

24.5.1 How to Assess Wall Shear Stress

cvi42 automatically calculates axial and circumferential wall shear stress as soon as a plane is set, and a contour is defined (*Flow* menu).



1.  To visualize 3D wall shear stress, activate the button in the top tool bar and run the cine
2. The stress curve will be updated as you drag the plane along the centerline

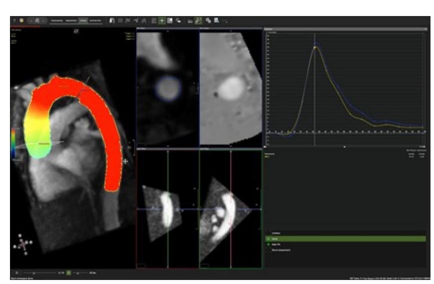
3.  Add a measurement to the report

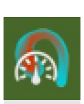
	Avg Axial WSS	Avg Cir WSS
Measurement	(Pa)	(Pa)
Flow 3	0.22	0.13
Flow 4	0.08	0.18

4. WSS components will be calculated automatically and the curvesand their respective measurements can be selected from the *Flow* Menu

24.5.2 How to do Relative Pressure Mapping

The software will compute a relative pressure field, giving the pressure difference between any two points. This will be translated into a colored pressure map.



1.  Activate the Pressure Visualization button
2. You will be given a reference and a free plane. Position them in your ROI.

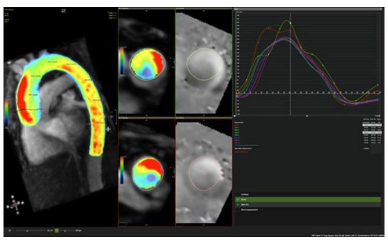
3.  Add a measurement

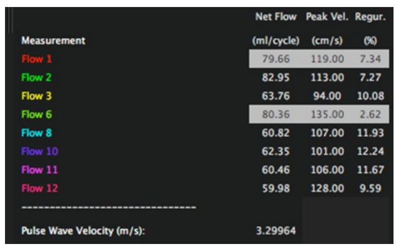
4. Pressure curves from the measurement and the free plane will be displayed in a graph. The relative pressure difference to thereference plane will be reported

Measurement	Max Pressure (mmHg)	Avg Pressure (mmHg)
RPM 2	26.47	8.95

24.5.3 How to Calculate Pulse Wave Velocity

1. Pulse wave velocity (PWV) is a biomarker directly related to vessel stiffness that has the potential to provide information on early atherosclerotic disease burden
2. Pulse wave velocity calculation requires a centerline for the vessel structure with at least two flow measurement planes
3. Once two measurements have been provided (The limit is 12 planes) the system automatically calculates and reports PWV

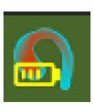
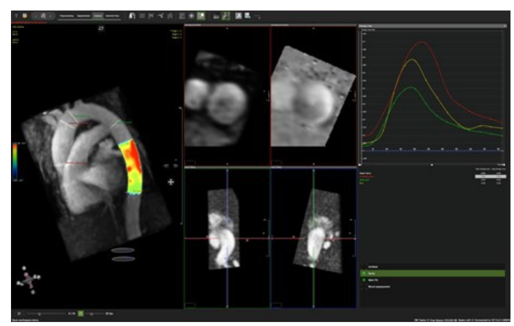




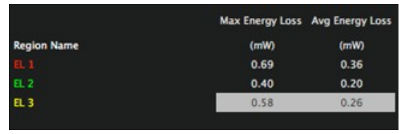
Measurement	Net Flow (ml/cycle)	Peak Vel. (cm/s)	Regur. (%)
Flow 1	79.66	119.00	7.34
Flow 2	82.95	113.00	7.27
Flow 3	63.76	94.00	10.08
Flow 6	80.36	135.00	2.62
Flow 8	60.82	107.00	11.93
Flow 10	62.35	101.00	12.24
Flow 11	60.46	106.00	11.67
Flow 12	59.98	128.00	9.59
Pulse Wave Velocity (m/s):	3.29964		

24.5.4 How to Analyze Energy Loss

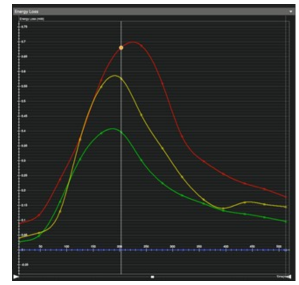
Note: Not for clinical use.

1.  Activate the button 2. Define a region by placing 2 planes 3. Add a measurement	
4. Hovering over the plane will display the color overlay 5. Label the region by either right-clicking on the variable in the report or the plane. Choose a description from the menu if present	

6. Maximum and average energy loss over time will be reported and the curves per region (limited to 6) are displayed



Region Name	Max Energy Loss (mW)	Avg Energy Loss (mW)
EL 1	0.69	0.36
EL 2	0.40	0.20
EL 3	0.58	0.26



25 Coronary Module (Auto plaque)

The Coronary Module includes the following pages:

- Landmark: aids the coronary segmentation
- Centerline: Create a centerline for CPR
- Cross Section: Evaluation

Auto-plaque assessment requires a separate license.

25.1 Landmark Page

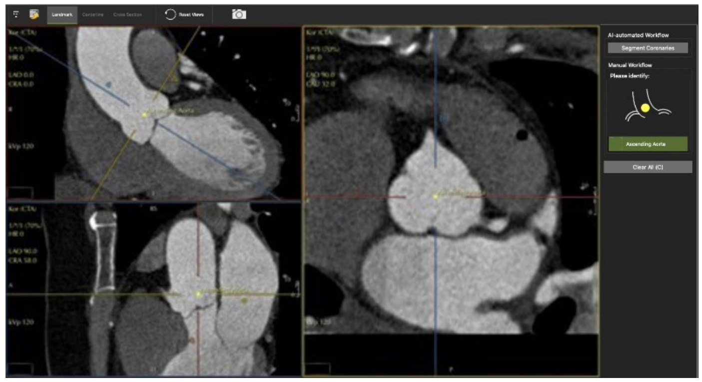
The Landmark Page allows the user to either use an automated workflow to segment and label the major coronary arteries, or a manual workflow to identify various vessel centerlines, starting with identifying the aorta.

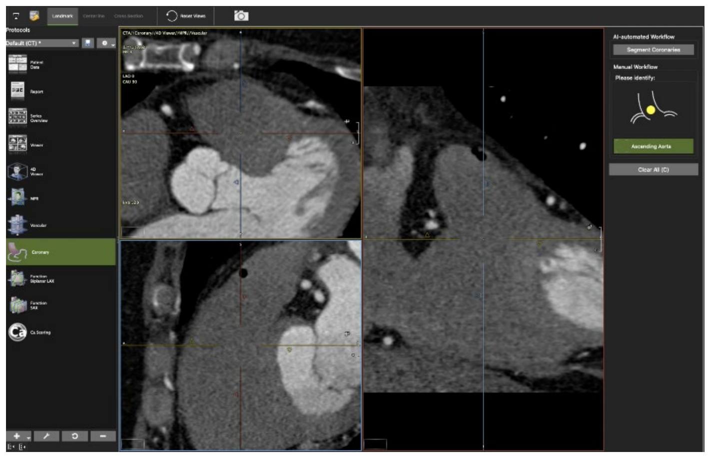
25.1.1 Automated Workflow

- To segment and label the three major coronary arteries, press “Segment Coronaries”. Additional arteries or branches can be segmented on the centerline page using the seed point method described below

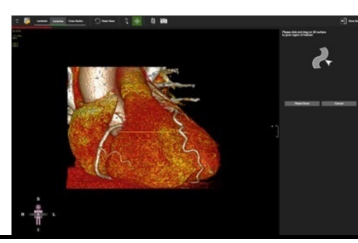
25.1.2 Manual Workflow

- Placing a Landmark in the ascending aorta will support the centerline generation.





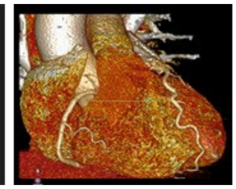
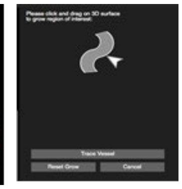
25.2 Centerline Page

• Create a centerline via 3D-Region-Growing or setting seed points (start and end points) • Using the landmark point, the system will automatically segment the heart • The thresholding page will be the default, if you prefer to create a centerline by setting seed points, exit the page by clicking 3D-Region-Growing in the tool bar 	 

25.2.1 How to Define a Centerline via Region Growing

The Grow Region Interface provides a guide diagram to indicate the next user action.

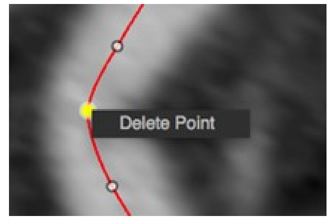
1. The *Region Growing* tool is activated by default. Define a single vessel or the entire coronary tree.
2. Drag on the 3D surface to define a vessel or a vessel tree
3. The modifier key 'alt' will rotate, Ctrl/ (command for Mac) will pan the volume
4. Click Trace Vessel when you are done
5. *Reset Grow* if you are not satisfied
6. Using the landmark, the system will automatically place a start point
7. To relocate the start point click *Manual Start Point*
8. The software has a predefined list of coronaries and will automatically move to the next vessel in the list after setting an end-point
9. Move to the next list item by clicking *Next Vessel.*
10. To relabel a centerline capture, drag the appropriate label on the capture with the green dot
11. Add/Delete a new label with a right mouse click in the background

25.2.2 Define a Centerline via Seed Points

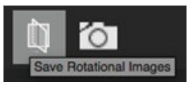
1. Move to the centerline page
2. Activate the seed point
3. In the axial view locate the origin of the vessel
4. Set a start, optionally intermediate and an end point

25.2.3 Edit the Centerline

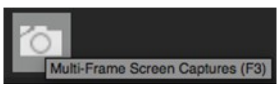
1. Shift, add (single left-click), delete (right-click) control points in the CPR or the oblique views 2. Rotate around the centerline with a left mouse drag close to the centerline 3. Pan the image by moving the cursor away from the centerline until the hand symbol appears	

25.2.4 Save Options

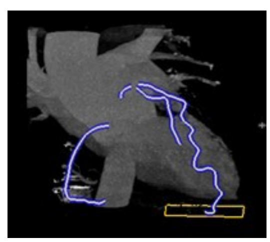
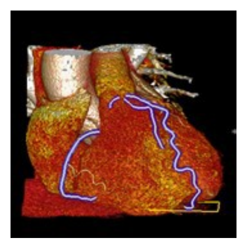
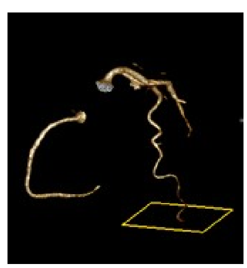
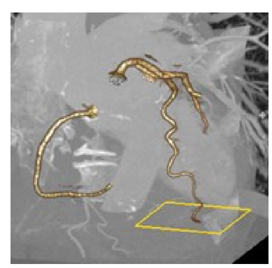
- Save rotational images



- Multi Frame Captures (See MPR Viewer)



25.2.5 3D View

1. Select Calcium or Volume Rendering	 
2. Segment Vessel: check it will segment vessels with all centerlines • Display/hide centerline • Display/hide background	 

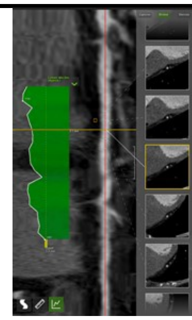
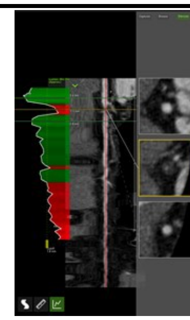
25.3 Cross Section

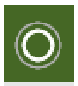
The page is designed to visually and quantitatively assess the vessels with existing centerlines.

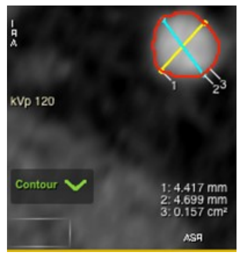
25.3.1 How to do a Stenosis Assessment

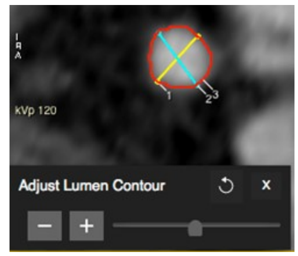
<table>
<tr>
<td>

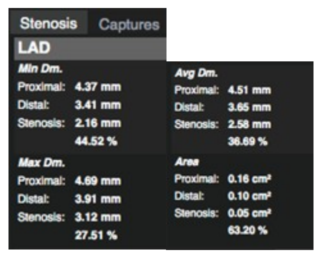
1. Start in *Browse* view and drag the yellow line down the vessel
2. Switch to *Stenosis* View and place the steno- sis marker either by dragging or by double- clicking in the stenosis

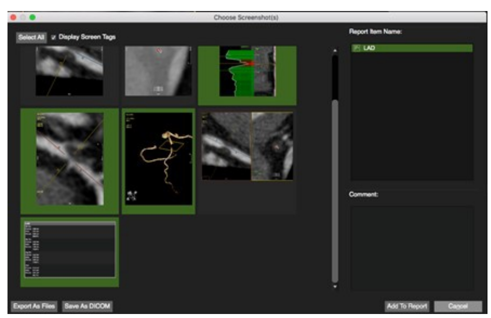
</td>
<td>


</td>
</tr>
<tr>
<td>

3.  Move to the MPR view and use the *Auto Vessel Lumen* Contour to contour the stenosis and the 2 references images
4. To adjust the threshold, click the green con- tour label. It will open a slider that allows to adjust the contour

</td>
<td>


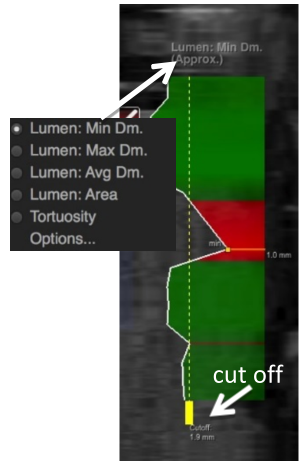


</td>
</tr>
<tr>
<td>
5. Stenosis measurements will be filled in automatically
</td>
<td>


</td>
</tr>
<tr>
<td>
6. Use the *Multiframe Capture* to save the measurements and images
</td>
<td>


</td>
</tr>
</table>

25.3.2 How to Use the Centerline Graph



Centerline Graph displays min./max./average lumen diameter, lumen area and tortuosity. It will automatically detect the minimum and maximum point along the centerline graphs.

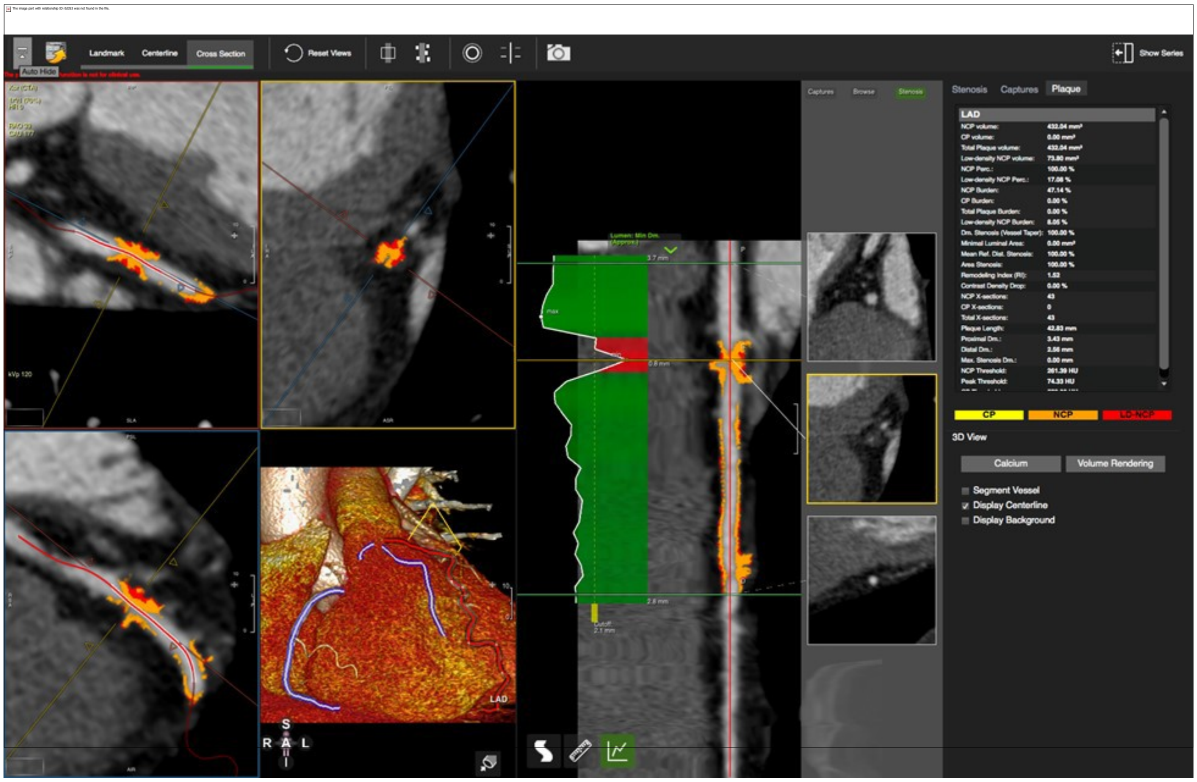
Options:
- *Lumen* menu, offering display options
- Cut off: Drag the yellow handle to set a cut off
-  The ruler measures a custom defined distance

- The context menu offers viewing, rendering, saving, export and more options

25.4 Plaque Analysis


WARNING: Auto-Plaque
The use of the Auto-Plaque is not FDA approved and is for non-clinical, scientific use only.

25.4.1 How to Perform Plaque Analysis

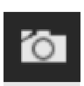


1. Load the study into the Vessel module

2.  Define a *Lesion* range by dragging the shaded area over the lesion

3.  Click on auto plaque

- The plaque will be color-coded, and your report is available in the *Plaque* tab of the reporting panel

4.  Select frames and add them to the report

26 Calcium Scoring

26.1 Toolbar

26.1.1 How to Do Calcium Scoring

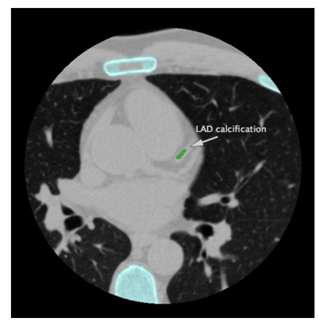
Calcium Scoring is a method to quantify the plaque load of the coronary arteries.

Post processing for Calcium Scoring requires the detection of calcium and assignment to a coronary.

26.1 Toolbar

- The toolbar provides 4 buttons to identify Calcium in the different coronary arteries
- Ca Mass calibration factor: Using a phantom with calcium inserts of known mass allows for determination of a calibration factor for different MDCT scan protocols

26.1.1 How to do Calcium Scoring

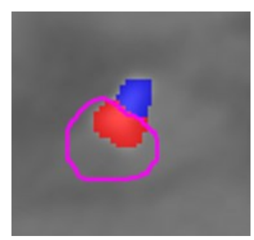


1. Open the on-screen navigation buttons or use your keyboard arrow keys to scroll through the slices

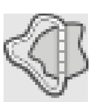
2.  Toggle the Overlay Display and scroll through the volume

3. When you have detected Ca, select the respective coronary ROI-button and simply click in the calcified area

4. To re-do the region selection, click again



5.  To reset all region selections, use the *Reset Selection* button in the toolbar

6.  To assign calcification to two different coronaries:

7. Split the lesion with the Ca Scoring Selection Contour
8. Select the first matching ROI (e.g. LM) and click into the respective section
9. Then, select the second ROI (e.g. LAD) and click into the other part of the lesion

10.  Add the analysis to your report

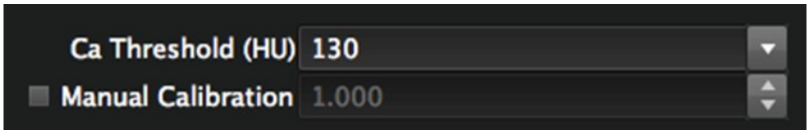
Threshold

- Set the Threshold (default 130) (on the bottom of the reporting panel, underneath the Percentiles)

Calibration Factor

- The Calibration Factor will be retrieved from the DICOM header or can be entered manually

(Calibration Factors are specific to scanner, protocol and patient weight)

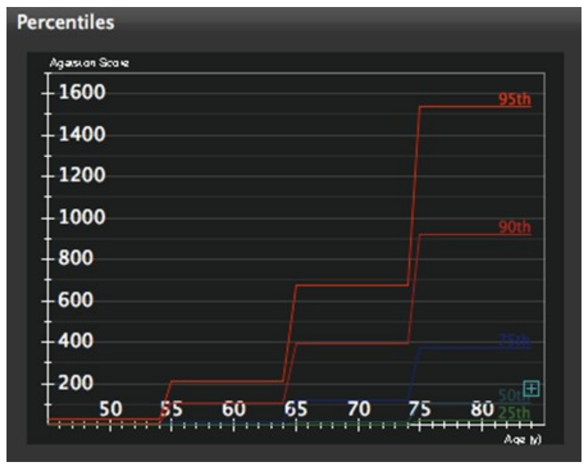


Agatston Classification

- Volume, Mass and Agatston Score and Agatston Classification determined automatically

Percentiles

- To determine the Percentiles of the patients Agaston Score per coronary, select the ethnic group



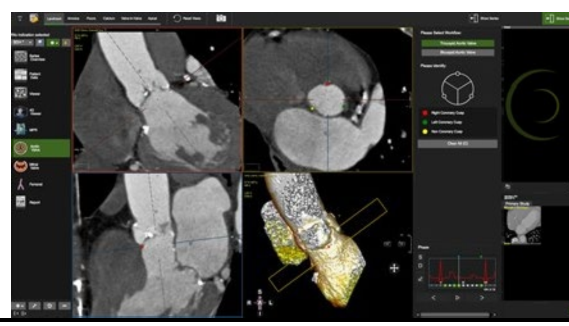
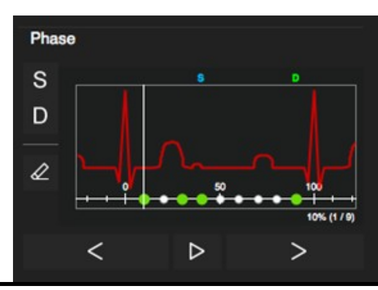
27 Aortic Valve Module

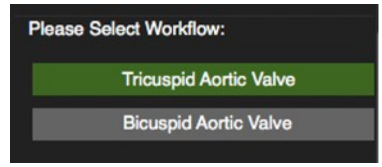
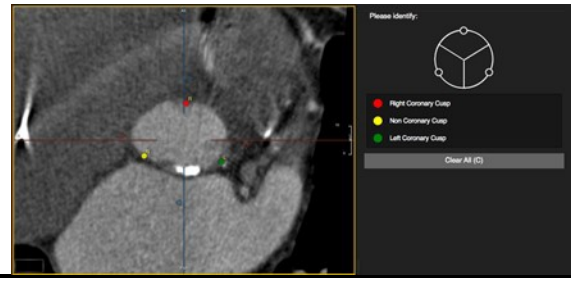
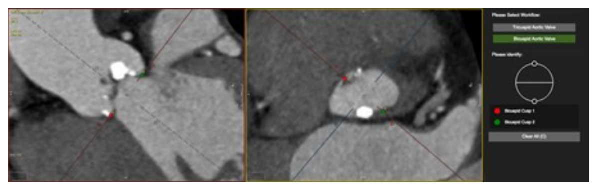
Intended Use

cvi42 – The Aortic Valve module offers a structured workflow for pre-procedural planning of trans catheter aortic valve re-placement.

27.1 Landmark page

Landmarks will define the annulus plane.
If measurements already exist, the module will skip the landmark page and will open the Annulus page.

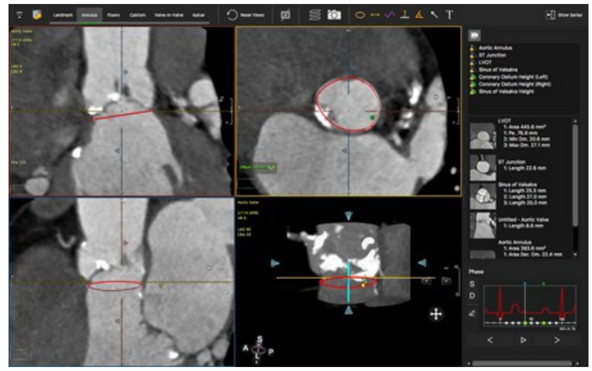
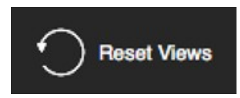
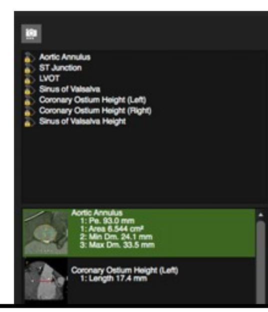
1. Open the side panel and load the data via drag-and-drop or double-click	
2. Start with selecting a phase for assessment • Optionally set a bookmark for *Systole* and *Diastole*	

3. Select Workflow: • Choose between a bi- or tricuspid valve	
4. Identify the cusps (tricuspid) In random order, place three points at the hinge ofthe right, left and non-coronary cusp. The software will identify and label the cusp points	
5. Identify the cusps (bicuspid) • Clicking on one of the hinge point markers will automatically rotate the red crosshair to display the point in the respectively color-coded orthogonal viewer frame • Modifier key '*M*' hides the cross-reference lines If necessary, the marker can be adjusted with a mouse drag in either frame	

27.2 Annulus Page

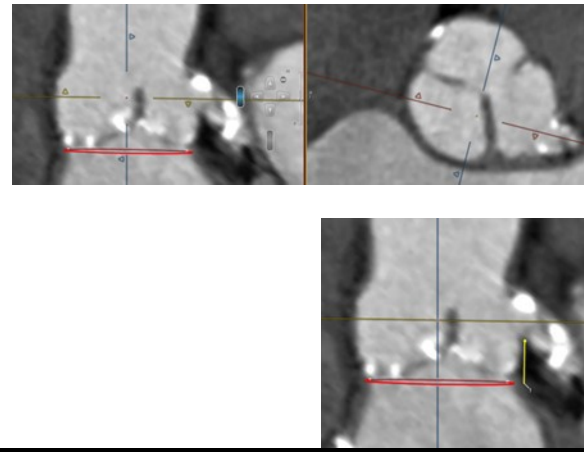
27.2.1 Measurements

Aortic Annulus

1.  Use the *Perimeter* tool and set control points around the annulus. You can maximize the view with a spacebar-click, or by clicking in the top right corner of the view port 2. To edit the perimeter, single-click on the control points. Single-click in the background to disengage 3. The annulus will be the only measurement that is labelled automatically	
Ancillary measurements: • 'Reset View' button in the toolbar will take you back to the annulus plane	
• Tools are in the top tool bar and the pencil box in the left bottom corner of the viewer frame. Measurements can be done in any viewer frame	
• Measurements and images are captured automatically • Drag the appropriate label from the predefined list on the capture • To review a measurement, simply click on the capture • Right-click to delete the capture. Alternatively, use the delete key	

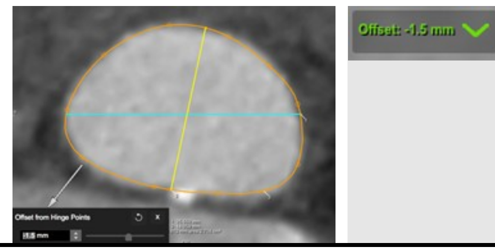
4. Ostium Height measurement

-  Using the *Ostium Height* measurement tool, drop a point at the height of the ostium with a left mouse click
- Drag the label on the measurement capture
- Repeat for the other coronary artery



5. LVOT measurement

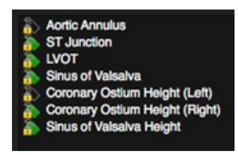
- Open the small *Offset* box in the bottom left corner (see white arrow), and use the slider to scroll down into the LVOT
- Using the perimeter tool, measure at narrowest portion of the LV outflow tract



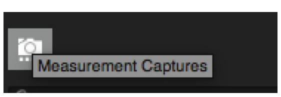
27.2.2 Reporting Options

27.2.2.1 Capture Measurements and Images

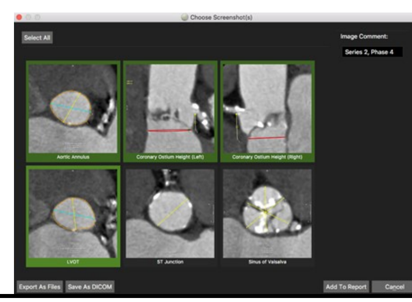
- Worklist measurements, labelled with the tags provided, will automatically be entered into an infographic (see be- low) in the report module.
- Measurements changes will be updated.



Measurement Captures (Report Panel):

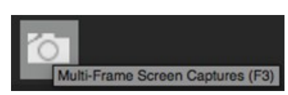


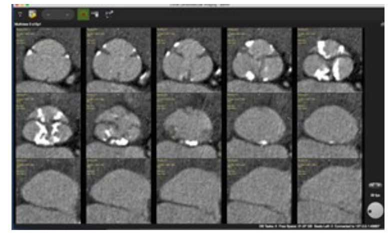
- Activating the measurement capture camera will allow to add respective pictures to the report.



Multi Frame Screen Captures (Tool Bar):

- Captures images of the current layout e.g. corresponding cross-sectional images of a particular plane or measurement.

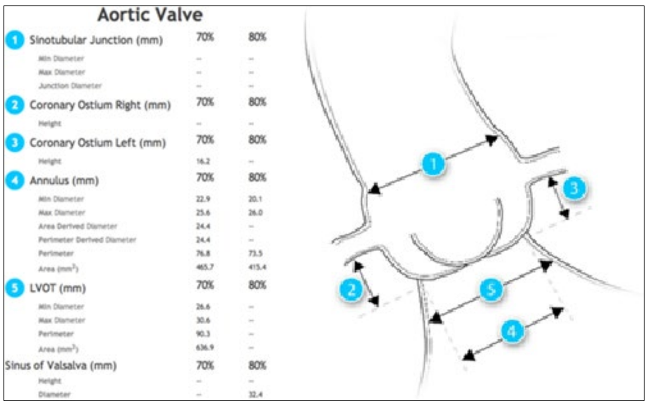


•  *Save Multi stack Images* (toolbar) as a secondary DICOM capture. • Individual frames can be added to the report byselecting the *Add to Report* option in the context menu.	 

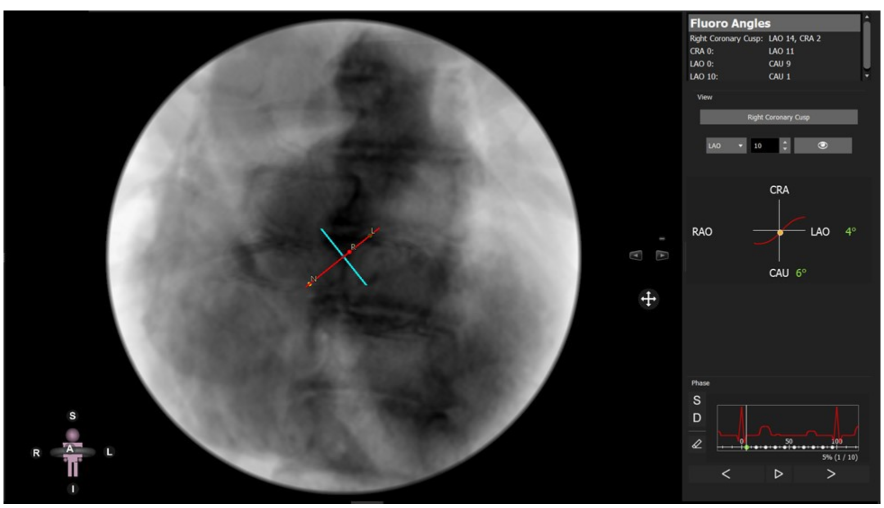
27.2.2.2 Standard Report

Upon opening the default report module:

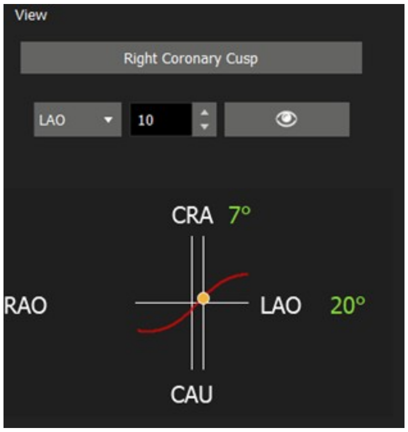
- Review the infographic and related measurements



27.3 Aorta Fluoro Page

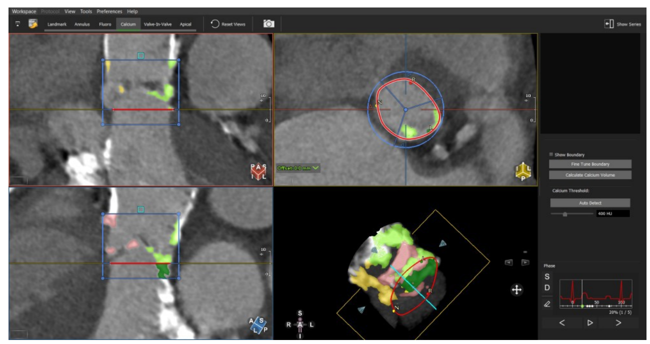


Each point on the “s-curve” will return an angio angle perpendicular to the aortic valve plane.



These angles can be used as suggested orientation for C-arm during the intervention, due to the fact that the conditions during the CT scan are not identical to those during the procedure, angles may vary.

27.4 Calcium Page

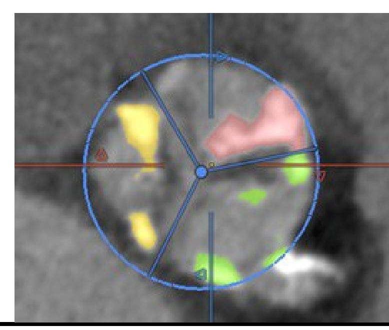
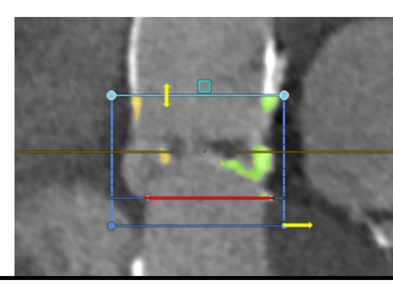


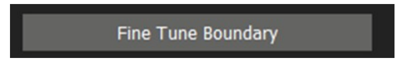
- 3 MPR and a 3D Viewer
- Auto detect or manually adjust the calcium threshold
- Cusp specific color-coded calcium overlay
- Calcium volume report per cusp, in aorta and LVOT

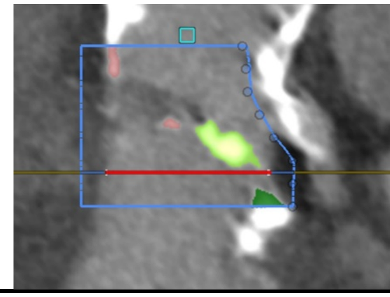
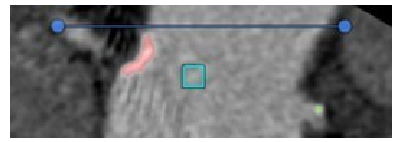
27.4.1 Control Feature

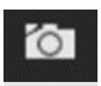
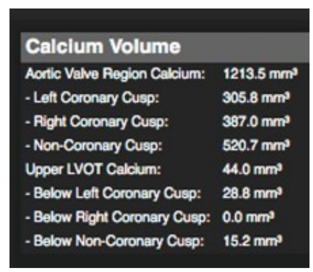
1. Mouse drag in the long axis will rotate around the valve center
2. Mouse drag in the short axis will scroll up/down the Aorta/LVOT
3. Press the Ctrl (command in Mac) key to pan the image in the view port

27.4.2 How to Detect Calcium

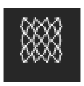
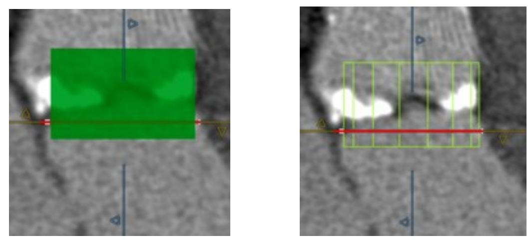
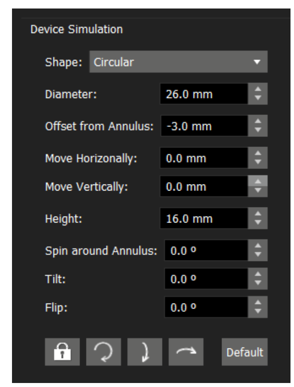
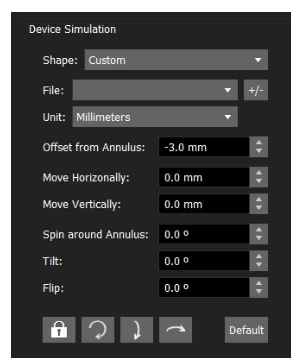
1. In the valve view, scroll up to the sinus to displaythe commissures 2. The calcium color corresponds to the nadir point colors. Adjust the center and move the arms of the cusp divider, so that the colors are properly assigned to a cusp	
3. Drag horizontal lines to increase or decrease height 4. Drag control points to increase or decrease width	

<table>
<tr>
<td>5. Use the fine tune option to include or exclude certain structures, e.g. to exclude the coronaries. Once the fine tune option is enabled drag the control points in the short and long axis views</td>
<td>

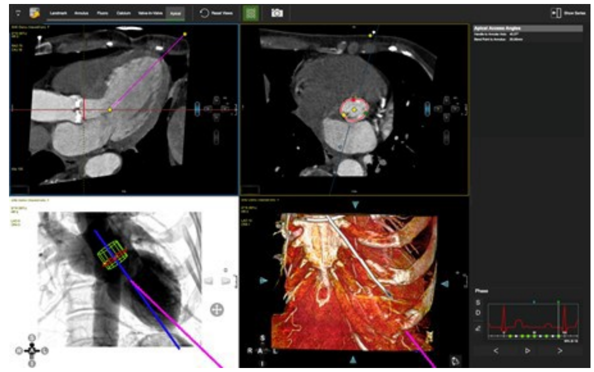
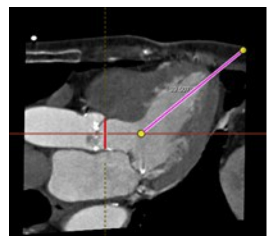
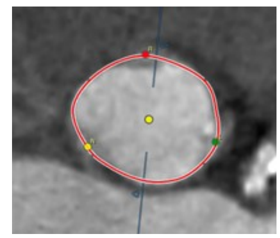
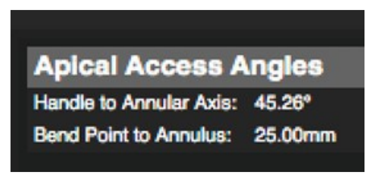
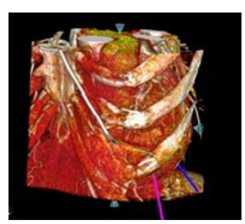
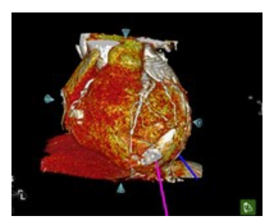
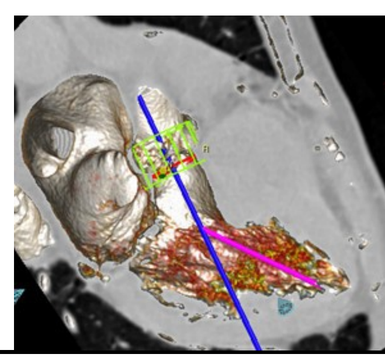
</td>
</tr>
<tr>
<td>6. Using the Auto Detect button, the software will automatically place a sample area (blue square) above the annulus in the log axis view. From that sample, a threshold will be determined to auto detect calcium. (According to the formula: average HU + 4.0 *standard deviation)
7. Alternatively, drag the slider to manually change the threshold for HU</td>
<td>

</td>
</tr>
<tr>
<td>8. In the report pane click Calculate Calcium Volume for a calcium report
9.  Click on the camera to add the Calcium Volume and images to your report</td>
<td>
<table>
<tr><th colspan="2">Calcium Volume</th></tr>
<tr><td>Aortic Valve Region Calcium:</td><td>1213.5 mm³</td></tr>
<tr><td>- Left Coronary Cusp:</td><td>305.8 mm³</td></tr>
<tr><td>- Right Coronary Cusp:</td><td>387.0 mm³</td></tr>
<tr><td>- Non-Coronary Cusp:</td><td>520.7 mm³</td></tr>
<tr><td>Upper LVOT Calcium:</td><td>44.0 mm³</td></tr>
<tr><td>- Below Left Coronary Cusp:</td><td>28.8 mm³</td></tr>
<tr><td>- Below Right Coronary Cusp:</td><td>0.0 mm³</td></tr>
<tr><td>- Below Non-Coronary Cusp:</td><td>15.2 mm³</td></tr>
</table></td>
</tr>
</table>

27.5 Valve in Valve

• Device simulation • Additional measurements	
For device simulation choose between: •  Display Device intersection •  Display Device Mesh	
• In the report pane choose Circular shape and usethe options provided to position the device. •  Lock device position across different phases.	
Custom Shape: • Allows to import vendor specific image files • Change units from metric to imperial	

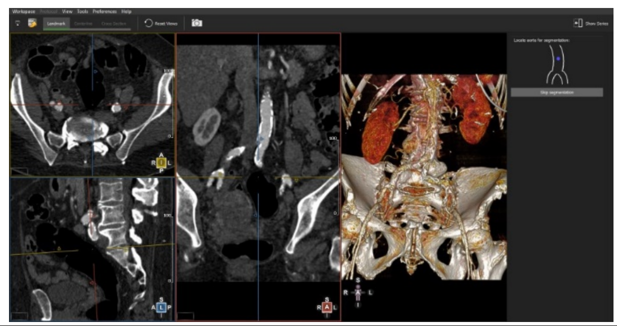
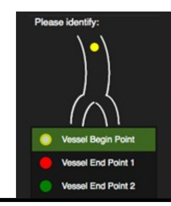
27.6 Apical Page

• Apical access planning	
• A red line in the top left viewer indicates the central axis perpendicular to the annulus (trajectory), the ideal access path. • Rotate around the trajectory line to display the apex	 
• The purple line can be adjusted to the manual access route • Adjust the yellow control point that slides along the red trajectory line, to accommodate for bending of the manual access route	
• Record the intercostal space  • Assess the course of the coronary arteries	 
Display Device Mesh: • Toggles to an endoluminal view to display the de- vice • The context menu allows to change viewing and/or clip- pings	

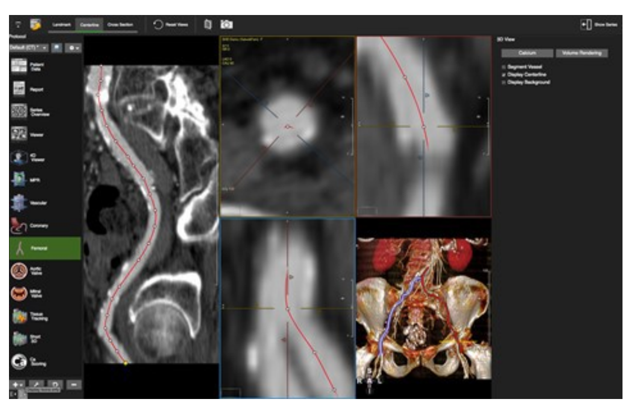
28 Femoral Module

The Femoral Module allows to assess the access for cardiac interventions.

28.1 Landmark Page

• Segment the aorta by clicking on the abdominal aorta. Optionally, skip the segmentation	
• Setting landmarks will assist the software to create centerlines	
Using the MPR and/or volume view set: • Point 1 in the aorta abdominalis • Point 2 in the left femoral artery • Point 3 in the right femoral artery • To Delete a point right click on them and select “Delete Object” • Move to the Centerline Page	

28.2 Centerline Page



• Edit centerline control points

• Assess the calcium load

Based on the landmarks a centerline is generated automatically.

• ‘T’ toggles the centerline on/off

• Select the vessel simply by clicking on the vessel of interest in the reference viewer

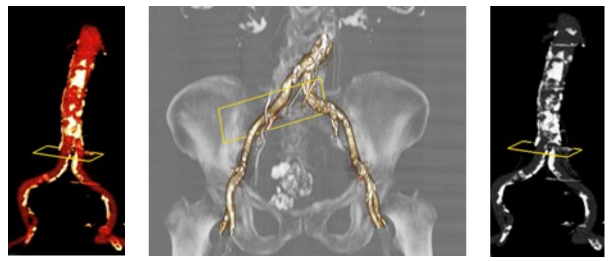
- Make sure the centerline is not crossing calcium.

The software will dynamically calculate a calcium threshold for automatic vessel lumen assessment based on the centerline points

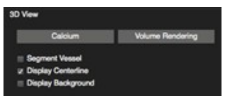
28.2.1 Edit the Centerline

- Use the up/down arrow keys on the keyboard to navigate along the control points
- Add control points with a double-click on the centerline
- Delete a control point with a right mouse click on the point
- Rotate around the centerline with a left mouse drag close to the centerline
- Pan the image by moving the cursor away from the centerline until the hand symbol appears

28.2.2 Assessment of the Puncture Site

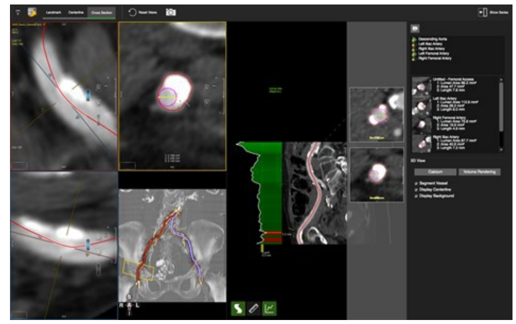
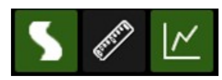
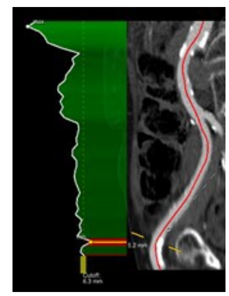
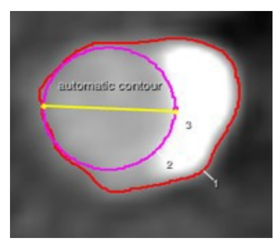
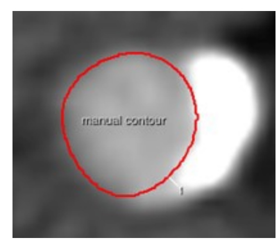
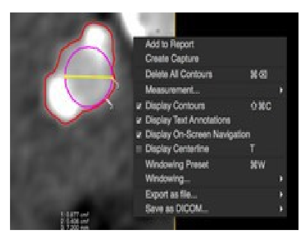
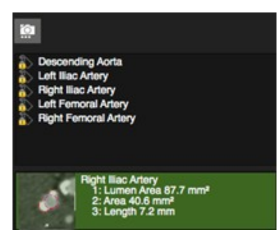


Use the *3D View* menu in the right-hand panel to:



- Hide the centerline
- Segment the vessels
- Add a background to visualize the femur heads
- Assess Calcium by switching to a *Calcium* View
- Enlarge the view by clicking the space bar key

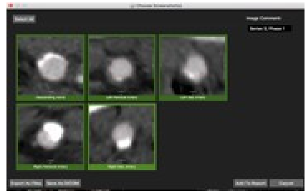
28.3 Cross Section

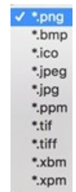
1. Display the centerlines in the reference viewer 2. Select a vessel by clicking on the centerline in the reference image	
3. Open the centerline graph. The graph is based on the diameter of the best fitting circle inside the lumen, excluding calcium. The calcium threshold is calculated dynamically based on centerline points. Therefore, during centerline generation, attention should be paid that the centerline is not crossing any calcium 4. Drag the yellow cursor line along the vessel. The diameter is displayed continuously on the right side of the cursor line	 
5. Measurements will be done automatically as soon as the centerline graph is activated, and you halt the cursor line 6. A contour can be drawn manually. In that case, the assumption is made that the contour is drawn excluding calcium and no circle will be fitted 7. Take captures via context menu 8. Use the predefined tags to label them 9. Click on the captures to review axial and orthogonal views 10. Captures will be displayed as cross-sectional images right of the CPR	   

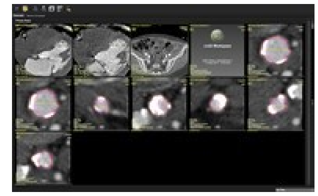
28.3.1 Reporting

Click the camera button in the reporting pane to:

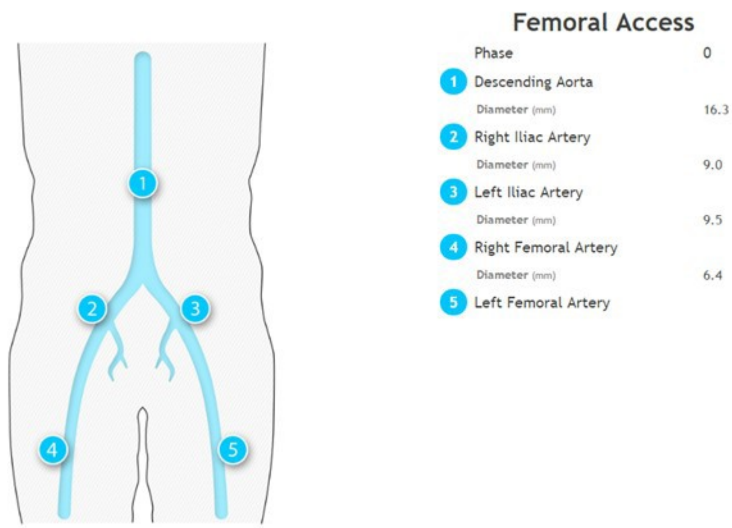
- Add images to the report
- Export them in different formats
- Save the in DICOM format







Measurements labeled as described in the previous step will end up automatically in the infographic of the report.



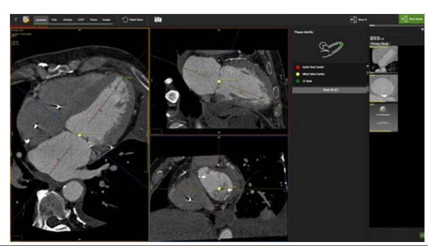
29 Mitral Valve Module

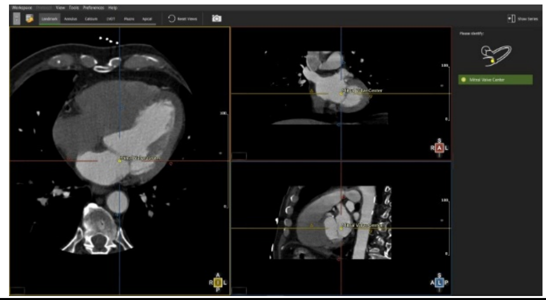
Intended Use

The *Mitral Valve* module offers a structured workflow for pre-procedural planning of transcatheter mitral valve replacement (TMVR).

29.1 Landmark Page

Set landmark for the assisted generation mitral valve plane

• Click *Show Series* and load the series from the thumbnail pane.	
• If the software detects contours or measurements, the module will open in the *Annulus* page. Phases with measurements can be identified by the green dots.	

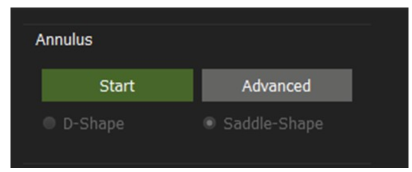
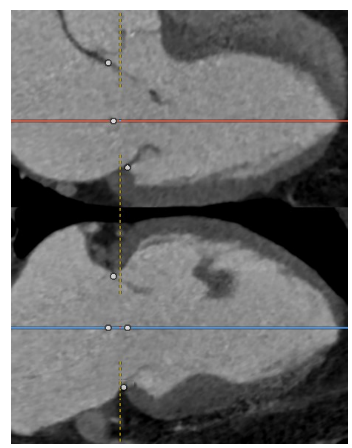
• The Aortic Root center will be detected automatically. • Slice through the images by dragging the mouse in the axial image, to display the mitral valve center. Click to set the second landmark. • The LV Apex will be placed automatically. • Use the crosshairs and swing around the apex to check for correct positioning. Simply drag the points to reposition.	

29.2 Annulus Page

Definition and automated measurement of the valve plane for saddle and D-shaped annulus.

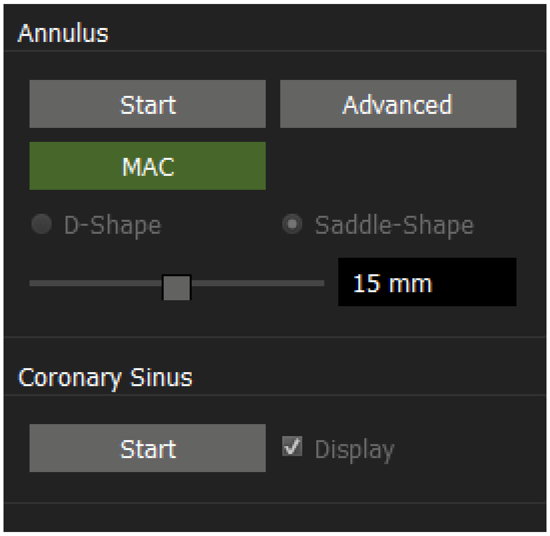
Note: When needed adjust the mitral valve center point and apex point.

29.2.1 How to Define the Mitral Annulus (MA) Plane

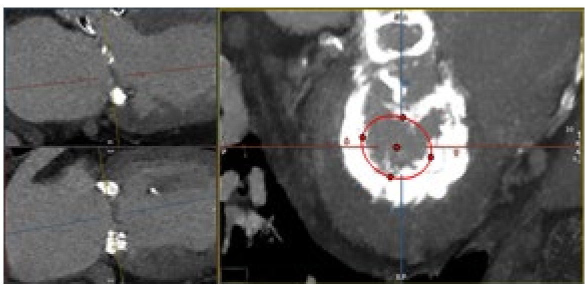
1. Select a phase 2. Press start	
3. Define 4 control points on the longitudinal views	

29.2.2 Mitral Annular Calcification (MAC) Assessment

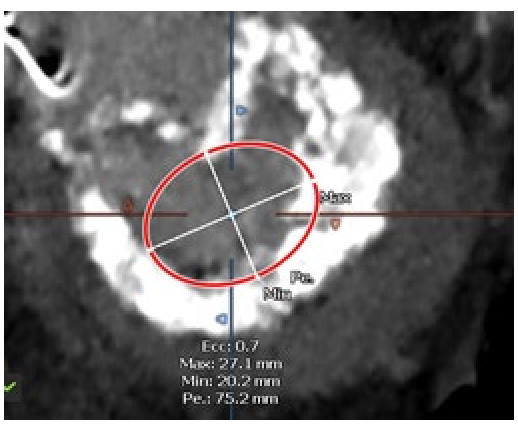
- Mitral annular calcification assessment.
  - To asses a calcified Mitral Annuls, press the MAC button.



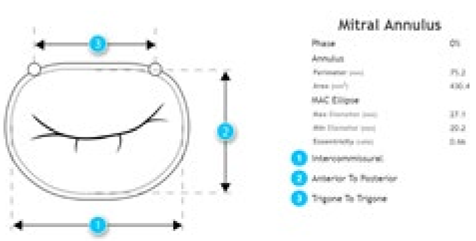
- The long axis views will be set to MPR mode, the short axis will be set to a slabbed MIP.
- Place the short axis in the center of the calcified mitral valve.
- Adjust the ellipse annotation in the short axis view by dragging the control points to their desired locations.



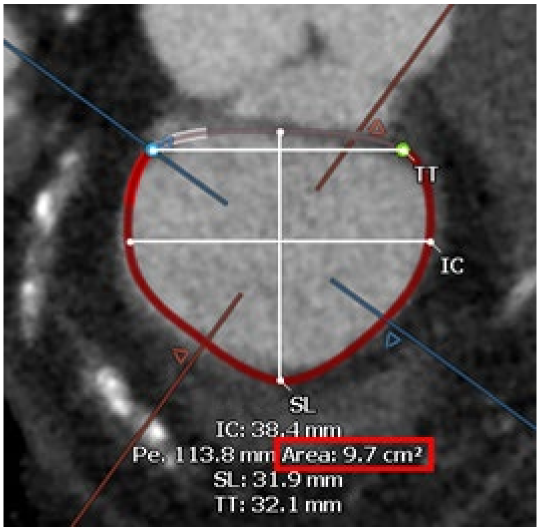
- Click outside the ellipse, to finalize the measurement.
- Min/max diameter, perimeter and eccentricity will be reported on screen.



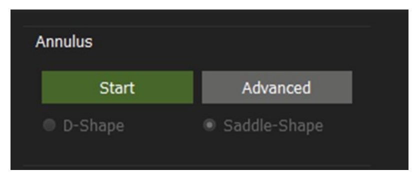
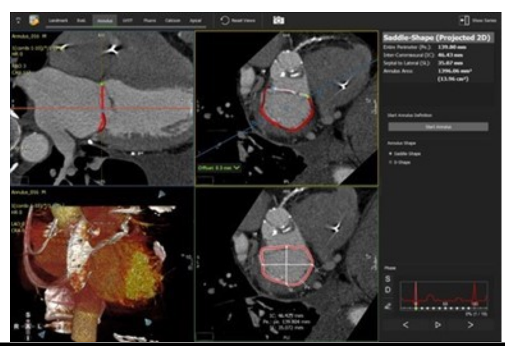
- The report will be updated accordingly.



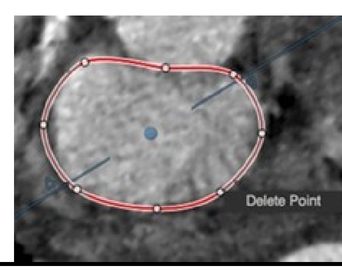
- Annulus area is now shown in the User interface.



29.2.3 How to Define the Mitral Annulus (MA) Plane – Advanced

1. Select a phase 2. Start the workflow 3. Press "advanced"	
4. Define control points: • The annular contour will be segmented within the 3D space by placing 16 seeding points at the insertion of the valve leaflet • After each click, the software automatically rotates around the red trajectory line by 22.5° • The short axis view is synchronized, displaying the plane that intersects trajectory line and last defined control point • After 16 clicks, the entire circumference of the annulus will be identified and is shown in all 4 viewports	

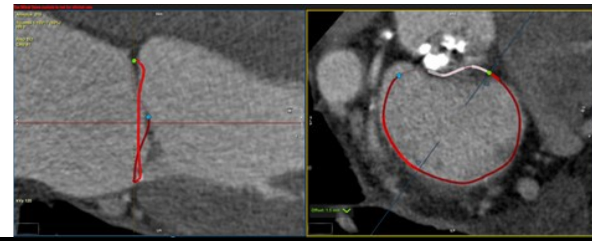
Note: Both the regular and the advanced Annulus can be edited

5. Edit the Annulus • Double-click to toggle control points on/off • Drag to shift points • Left-click to add points • Right-click to delete points • To redo the annulus, restart the annulus definition by clicking the bar again	

<table>
<tr><td>

• Exiting the editing mode, allows to adjust the trigones to the LVOT

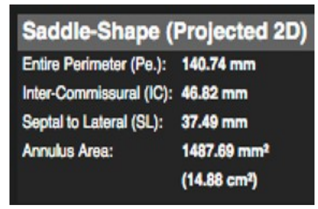
</td><td>

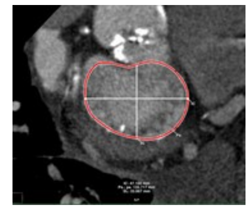


</td></tr>
<tr><td>

• Measurements are done automatically

</td><td>





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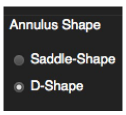
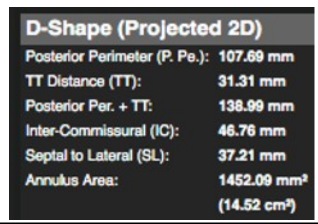
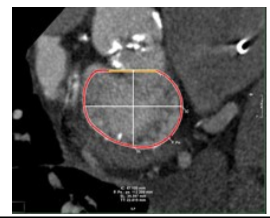


• Switch between saddle and D-shape

</td><td>

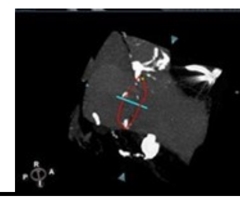




</td></tr>
<tr><td>

• In the *4D Visualization* viewer *a*djust the cylindrical clip- ping cone to define the annular region. Visually inspect the calcification around the valve

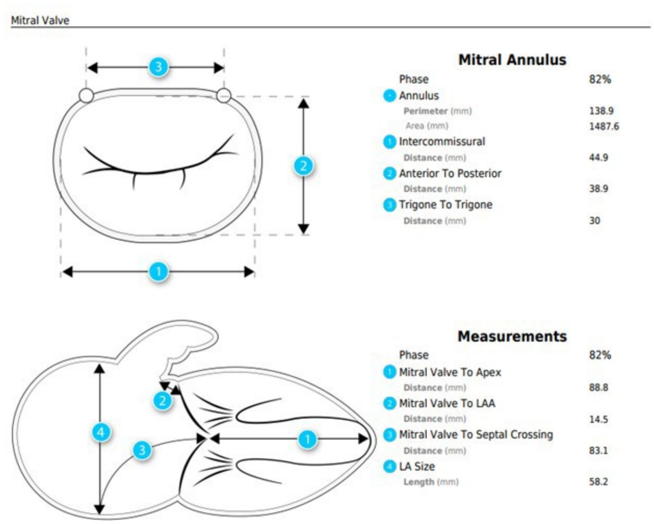
</td><td>



</td></tr>
<tr><td>

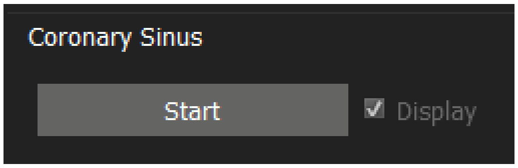
• Labeled measurements will be shown in the infographic in the report

</td><td>

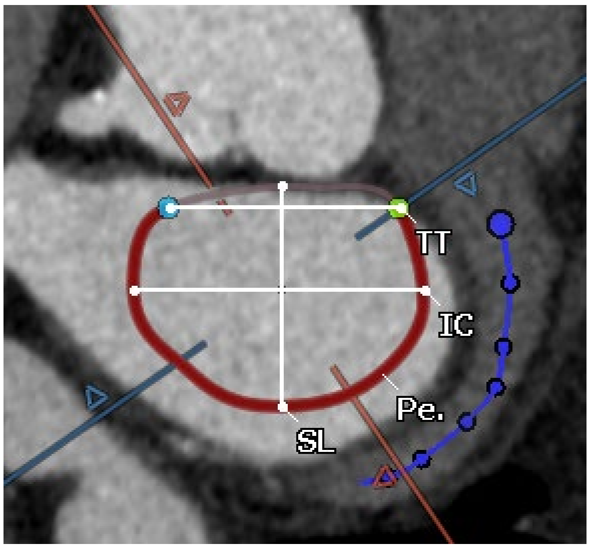


</td></tr>
</table>

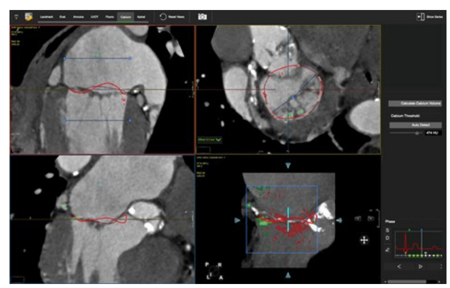
29.2.4 Guide Wire Simulation



1. Press **Start** to begin defining the Coronary Sinus.
2. Scroll through the data set in the short-axis view or rotate around the horizontal axis in the long-axis view and click to add key points along the sinus.
3. Double-click on the last point to finish.



29.3 Calcium Page

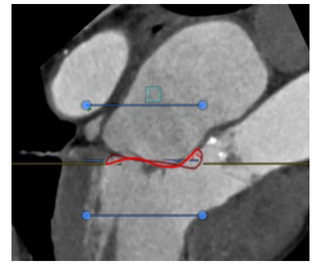


- Auto detect or manually adjust the calcium threshold
- Calcium will be displayed in a color-coded calcium overlay
- Calcium volume will be reported per leaflet

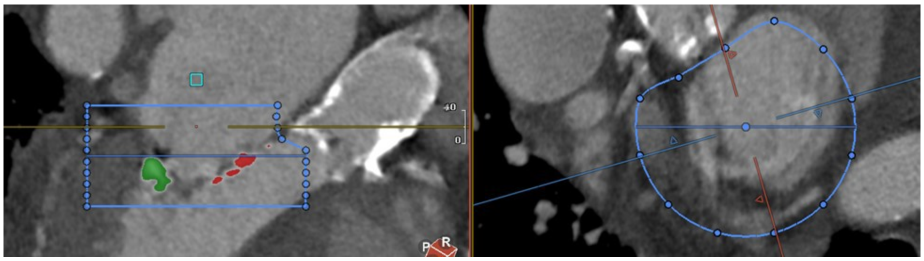
29.3.1 Control Feature

- Mouse drag in the long axis will rotate around the valve center
- Mouse drag in the short axis will scroll up/down along the trajectory line
- Press the Ctrl (command in Mac) key to pan the image in the view port

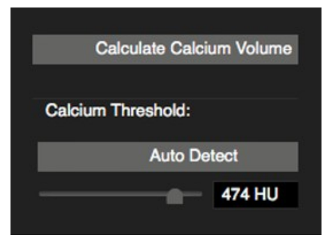
29.3.2 Three Chamber View



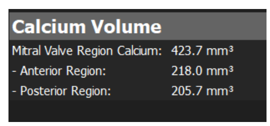
- The area of interest (cylinder) can be in- or decreased by dragging the blue lines up/down or left/right in the long axis viewer (top left).
- The small square in the atrium on top of the line indicates the sample used to calculate the calcium threshold
- Use the fine tune button to include or exclude certain areas



29.3.3 Quantify the Calcium Load



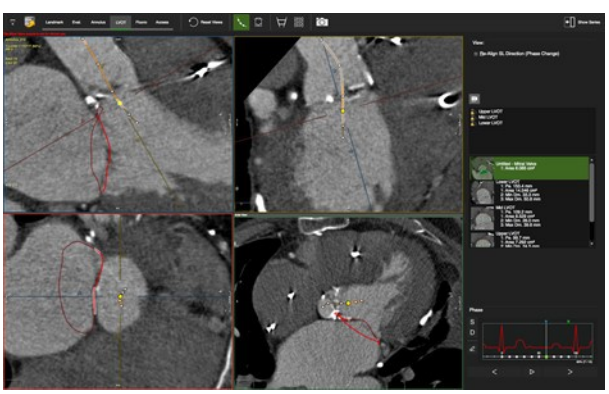
- In the report pane click *Calculate Calcium Volume* for a calcium report
- You can customize the calcium threshold. Click calculateCalcium Volume again



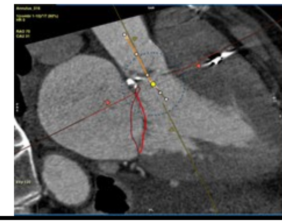
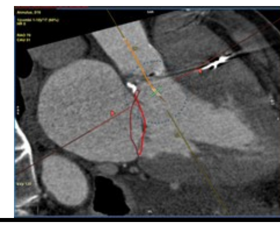
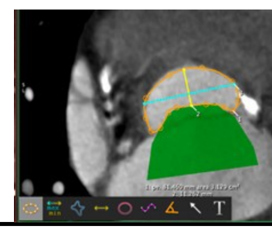
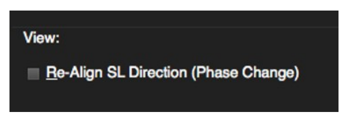
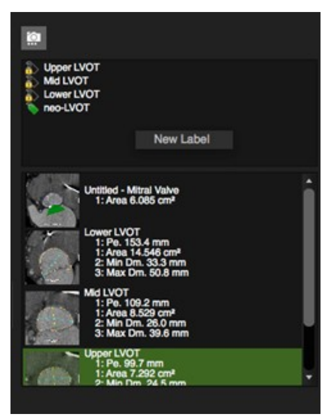
-  Click on the camera to add the calcium Volume and imagesto your report.

29.4 LVOT Page

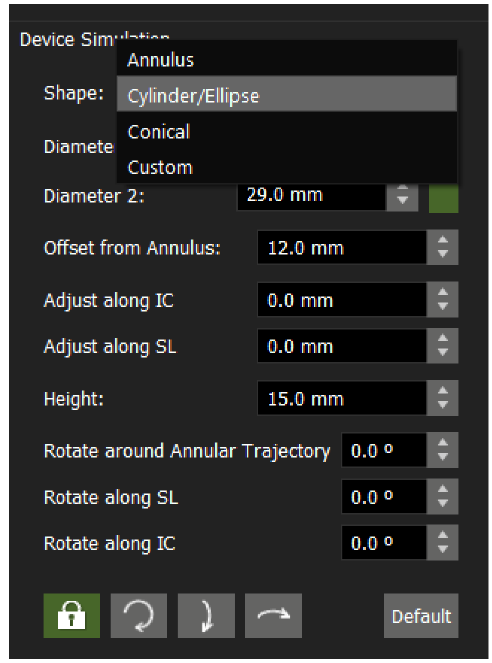
- Assessment of the LVOT
- Device simulation
- Planimetric measurement of LVOT and neo-LVOT



29.4.1 LVOT Assessment

1.  Activate the Centerline Control Points 2. Place points in the Aorta and the LVOT	
3. De-activate the centerline points and use the green bar to scroll along the centerline	
4. Using the measurement tools provided in the tool box (white box in the lower left corner), measure the upper-, mid-, and lower LVOT	
5. Use the phase diagram to inspect the LVOT in different phases. Optionally, realign the view to SL direction with every phase change	
6. Label the measurements by dragging the predefined tags on the capture 7. Right-click next to the labels, to add a new label 8. For review, simply click on a capture	

29.4.2 Device Simulation

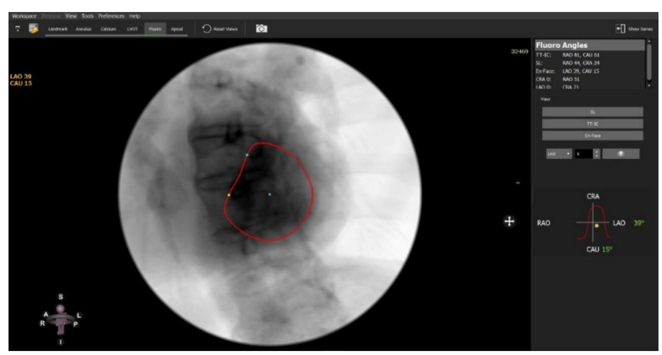


1.  Turn on the Device Mesh or Device Intersection buttons
2. Choose a shape from the drop-down list
3. Optionally import vendor specific device image files
4. Adjust the device position
5. Make additional measurements, e.g. neo-LVOT
6. Lock device position across different phases:

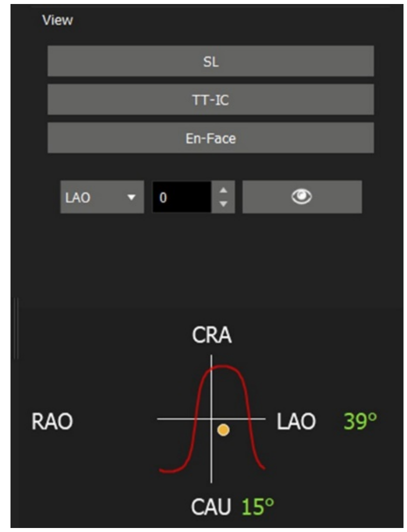
29.5 Fluoroscopy Page

- Display images along the optimal viewing curve
- Capture C-arm angles

29.5.1 Optimal Viewing Curve

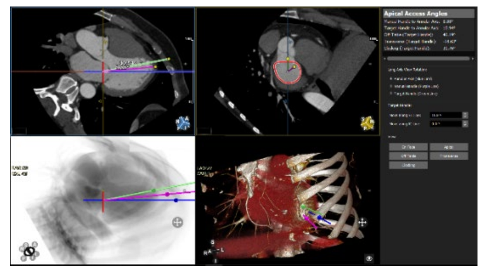
1. Display views perpendicular to the annulus	

2. Use the pre-set buttons or drag the cursor line over the curve
t

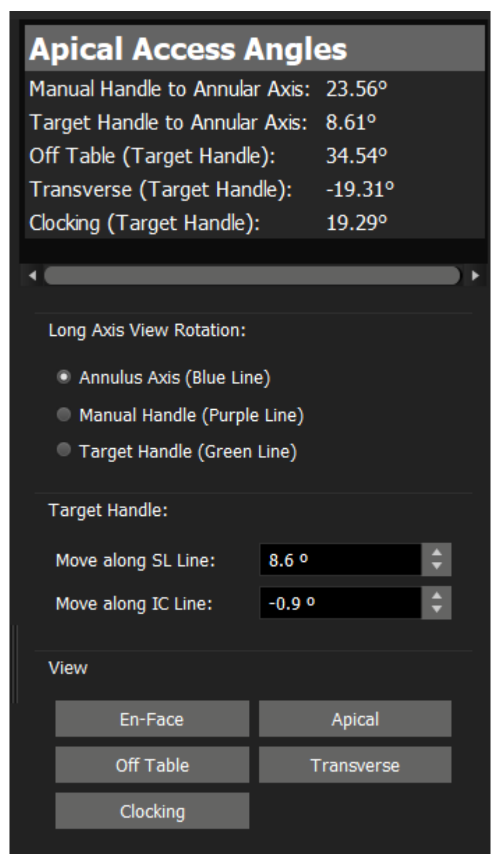


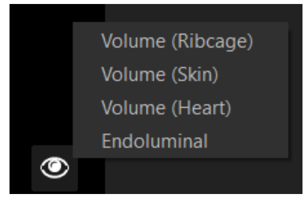
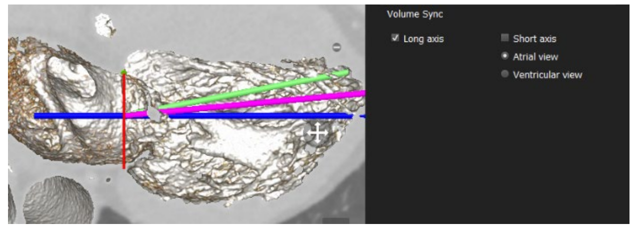
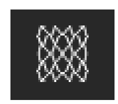
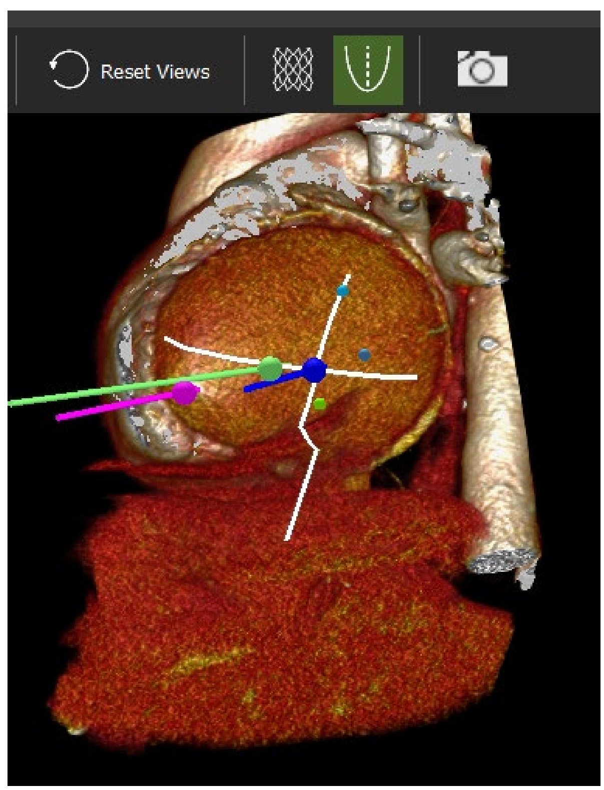
29.6 Apical Page

Assessment of trans apical approach to the mitral structure. Visualization of angles, catheter path, relationship to ribcage,
pericardial structures, papillary muscles, and mitral apparatus.



1. Displays intraprocedural catheter angles.
2. Select the rotation angles:
   - Perpendicular axis to mitral plane (blue line)
   - Left ventricle axis (purple line)
   - Delivery sheath axis (green line)
3. Positions delivery sheath.
4. Buttons for default fluoroscopic and volume views.



5. Switch between different visualization techniques.	
6. When the endoluminal view is active, select the “Volume Sync” options to synchronize the endoluminal view with the long or the short axis MPR.	
7. Toggle virtual valve on or off	
8. When “Volume(heart)” is selected, use the IC/SL projection button to project the IC and SL lines on the surface of the heart.	

30 Trans-Septal Module

Intended Use

This module allows the user to gain a better understanding of the relationships of different parts of the anatomy and how they can appear on a fluoroscopic view during the actual trans septal interventions.

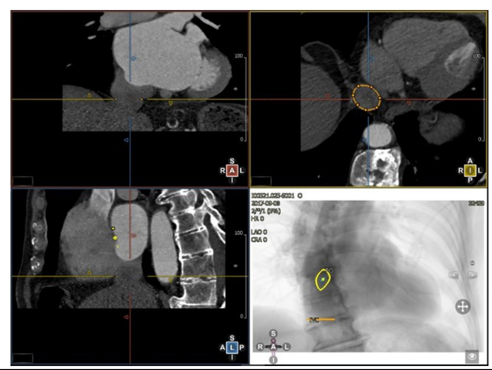
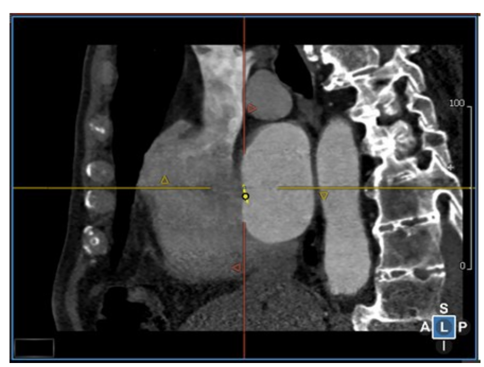
30.1 Contours Page

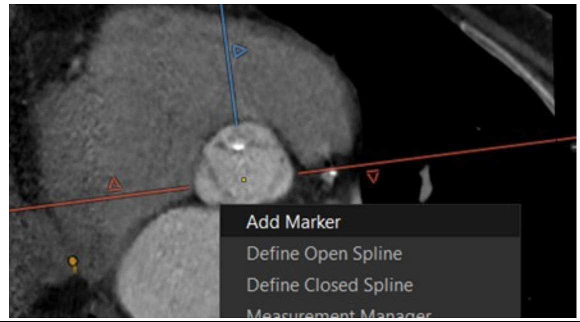
30.1.1 Finding the Fossa Ovalis

1. On the axial image locate the interatrial septum 2. Translate up and down until the thinnest part of theatrial septum is shown 3. Align the red intersection line with the septum 4. In the lateral view (lower left viewport) align thered intersection line with the septum 5. The resulting view (left upper view will beoriented en-face the Fossa Ovalis)	

6. In the en-face view rotate the intersection lines to verify in the orthogonal views that the center of the crosshair is in the middle of the Fossa 7. Click the Fossa Ovalis button and then click on the center of the crosshair in the en-face view to mark the Fossa 8. When needed, resize the annotation that indicates the Fossa	

30.1.2 Marking the Vena Cava Inferior and Superior and Other Structures

1. Reset views 2. In the lateral viewport translate until the IVC is visible	
3. Place the crosshair on the IVC 4. On the axial image, the IVC contour can be traced 5. Do the same for the SVC	
6. Use the catheter feature to draw a spline to indicate the catheter path or use the automatic option for an automated suggestion.	

7. Use markers to identify other anatomical markers, like the aorta In case the Mitral annulus has been detected in the Mitral workflow, the annotation will be transferred to the septal crossing workflow	

31 Technical Support

Technical Support

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