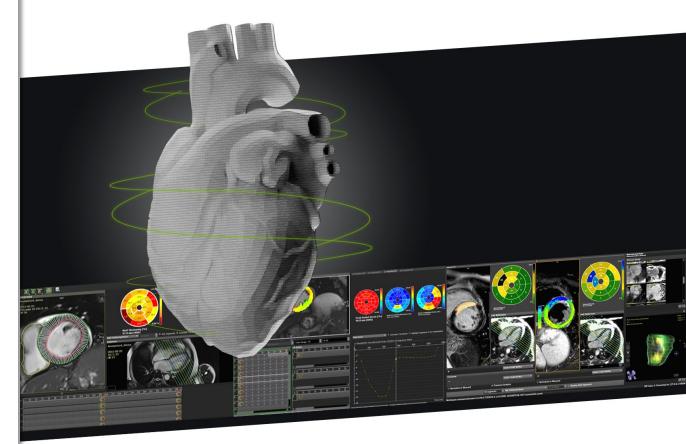


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cvi**42**

User Manual

April 2020

Regulatory Information

Manufactured by:



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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



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

UDI: 00882916000011



EU Authorized Representative Philipp Barckow Dipl. MedInf. Ravenweg 9 14163 Berlin Germany

European Office

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1.1 Regulatory Information

AGENCY	Authorized Representative	Approval/ Clearance Reference
Australia TGA ARTG	Market Access Australia Pty Lt PO Box 1019, WAHROONGA, NSW, 2076, Australia	177785
Brazil ANVISA	Olphi Assessoria e Consultoria Internacional Edificio West Tower Rua: Monte Alegre, 100 12 andar – sala 124 Sumarezinho – Ribeirao Preto Cep: 14051-260 - Brasil	094337/14-1
	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
South Korea KFDA*	DANY Trading Co Ltd B120 Penterium 282 Hakui-ro, Anyang-si, Gyeonggi-do Dongan-gu 431-810, Korea	14-1134
Singapore HAS	Pharmeng Technology PTE. LTD. 1 Fusionpolis Place, Galaxis, #03-20, Singapore 138522	MD17634993V
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

*cmr42 only

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.



3.1 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**
- 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 suchlesions.

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 and Perfusion modules are not available in the USA since 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
- 4.2 Customize Tools and Working Modules
- 4.3 Crash Reporter

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)
- 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 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

4.3 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:

😳 Cvi42 - Crash Reporter	\times
We apologize for the inconvenience.	
Cvi42 has quit unexpectedly.	
A Crash Report is being collected, which contains information useful for our team to address the issue. This data is collected locally within the facility, and will not be sent externally unless done so intentionally by the facility's Cvi42 server administrator.	
Please describe the events just prior to this dialog appearing:	
Accept	

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

Preferences		×
Appearance Viewer Series Overview Reporting Contours 4D Viewer Strain Image Database	Crash Reporter Options Crash Reporting Upload URL 127.0.0.1 Upload Port 8080	Í
Anonymization Network License Server Admin LDAP Admin Workflow Housekeeping Server-side Processing Crash Reporting	Note: Restart of CVI42 dient and server processes is required for Crash Reporting configuration changes to take place.	
	•	
Reset to Default Set as Defau	ult	OK Cancel

5 Viewing

- 5.1 View Ports Overview
- 5.2 Image Editing, Viewer Controls
- 5.3 Additional Viewing
 - 5.3.1 Floating Viewer

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

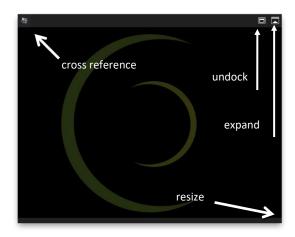
ICON	FUNCTION	MOUSE CLICKS	ALTERNATIVE
٢	Windowing	Push mouse wheel and drag Auto adjust: double-click MMB Holding shift-key+LMB and drag	Windowing pre-sets: keyboard keys 1-2-3-0 Windowing pre-sets: context menu Define your own pre-set via <i>Edit</i> in the context menu
Ś	Panning	Hold LMB down and pan	
n V	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
0	Navigation	Open on-screen navigation buttons	
e e e	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

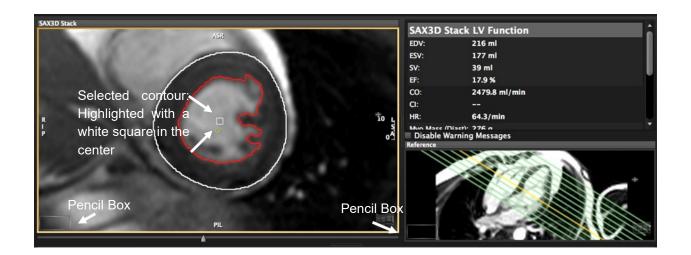
• Located underneath the thumbnail panel, is an additional detachable viewer that can be undocked and changed in size. It will stay on-screen even when switching to a different module.

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



Provides a cross reference

- 6.1 Manual Contouring
 - 6.1.2 Manual Contour Definition
 - 6.1.3 Using a Selected Drawing Mode (e.g. by setting points)
 - 6.1.4 Semiautomatic Contour Detection
 - 6.1.5 Automatic Contour Detection
 - 6.1.6 Contour Saving and Deleting

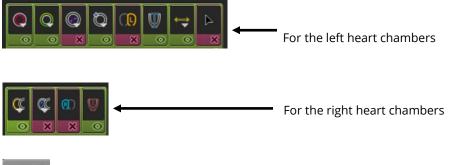


- Drawing tools are in the top toolbar or the on-screen pencil box
- Tooltip: All buttons show a brief description on mouse hover

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:





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 file system
- Reset Workspace: Deletes all drawn contours in the current patient study, and clears all frames
- Close Study

8 Patient Data

1/

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
- 9.2 Create a Report
- 9.3 Update the Report
- 9.4 Configure Export Options
- 9.5 Show/Hide Report Fields
- 9.6 Delete Report

9.1 Customize Logo and Header



Simply type your address and upload a logo

9.2 Create a Report

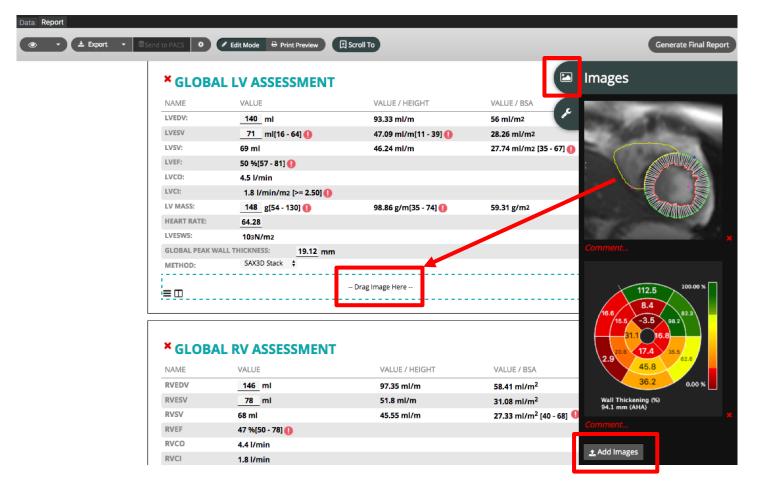
• Add to report will transfer analyses and measurements to the report module

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

Data Report				
● • 🕹 Export • 🗏 Sen	d to PACS 🔹 🗸 E	idit Mode 🔒 Print Preview 🗍 Scro	ПТО	
_			_	
		LV ASSESSMENT		
	NAME	VALUE	VALUE / HEIGHT	VALUE / BSA
	LVEDV:	140 ml	93.33 ml/m	56 ml/m2
	LVESV	71ml[16 - 64] 🊺	47.09 ml/m[11 - 39] 🅕	28.26 ml/m ²
	LVSV:	69 ml	46.24 ml/m	27.74 ml/m2 [35 - 67] 🌗
	LVEF:	50 %[57 - 81] 🅕		
	LVCO:	4.5 l/min		
	LVCI:	1.8 l/min/m2 [>= 2.50] 🌗		
	LV MASS:	148 g[54 - 130] 🌗	98.86 g/m[35 - 74] 🌗	59.31 g/m ²
	HEART RATE:	64.28		
	LVESWS:	103N/m2		
	GLOBAL PEAK WALL	THICKNESS: 19.12 mm		
	METHOD:	SAX3D Stack 💠		
	≡□	Di	ag Image Here	

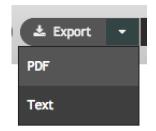
Images collected during the analysis are available in the Image tab and may be added by drag-and-drop into



- *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:

	Export Options			×
	Output Format:	PDF Text		
I	PDF, DICOM			
	Paper:	🔵 A4 📀 US Letter		
	Tissue Diagram:	 Include If Present Polarmaps 		
	Axial Coronary Anatomy:	Include If Present		
1	Text			
	Destination: Screen	File		-
			Save changes	Cancel

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

Acc #	EMPTY C	Custom Patient ID	D	HL7 Patient ID	O
Prior Names	EMPTY	Ethnicity	EMPTY O	Insurance Information	EMPTY O
Gender	Female	Blood Pressure	EMPTY / EMPTY ①	Birthdate	22 Mar 1972 (48 yrs)
Heart Rate	75.00	Height (Cm)	150.00	Weight (Kg)	150.00
BMI (kg/m ²)	66.67 🜑	BSA (m ²)	2.50 (Mosteller Formula)	Patient History	EMPTY
Risk Factors	EMPTY	Medications	EMPTY	Allergies	EMPTY
Clinical Situations	EMPTY	Staff	EMPTY O]	
STUDY In Progress		Study Date	17 Mar 2020		
Report Number Referring Physician	16	Study Date Modality	17 Mar 2020 MR 💽	Study Description	Cardiac MRI O
Report Number	16 C	Modality		Indication Name	÷ ••
Report Number Referring Physician Protocol Name	16 EMPTY Show Address	Modality	MR O	Indication Name	¢ ©
Report Number Referring Physician Protocol Name	16 EMPTY Show Address	Modality	MR O	Indication Name	÷ ••
Report Number Referring Physician Protocol Name SCANNER	16 EMPTY Show Address	Modality Modality Image Quality Model Sequences	MR O	Indication Name Study Indications Serial Number	÷ O
Report Number Referring Physician Protocol Name SCANNER Manufacturer	16 EMPTY Show Address Valve Dis SIEMENS SIEMENS Syngo MR B15	Modality Modality Image Quality Model Sequences	MR O	Indication Name Study Indications Serial Number	+ • • • • • • • • • • • • • • • • • • •
Report Number Referring Physician Protocol Name SCANNER Manufacturer Software Platform Field Strength STRESS INFORMAT	16 EMPTY Show Address Valve Dis SIEMENS SIEMENS Syngo MR B15 EMPTY	Modality Modality Model Model Sequences	MR OEMPTY O Avanto OEMPTY O	Indication Name Study Indications Serial Number	+ • • • • • • • • • • • • • • • • • • •
Report Number Referring Physician Protocol Name SCANNER Manufacturer Software Platform Field Strength	16 EMPTY Show Address Valve Dis SIEMENS Syngo MR B15 EMPTY	Modality Modality Image Quality Model Sequences	MR O	Indication Name Study Indications Serial Number	+ • • • • • • • • • • • • • • • • • • •

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

10.1 Series Overview

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

10.2 Series Composer

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

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.



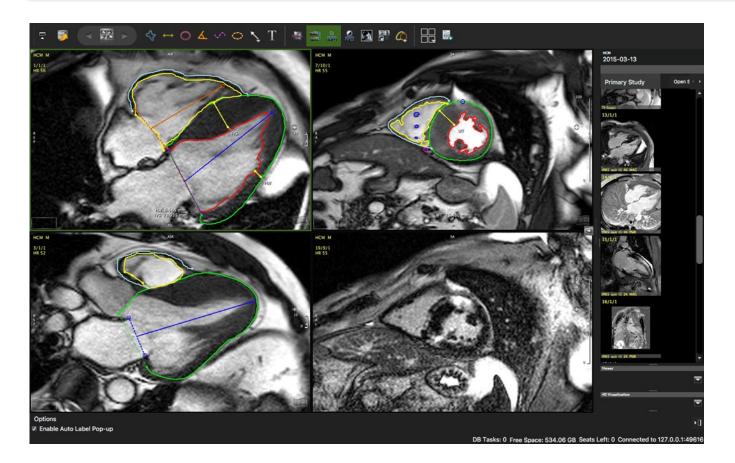
1. Drag a series to the Browser, choose slices or phases and drag them into the composer

- 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

11.1 Custom Measurements

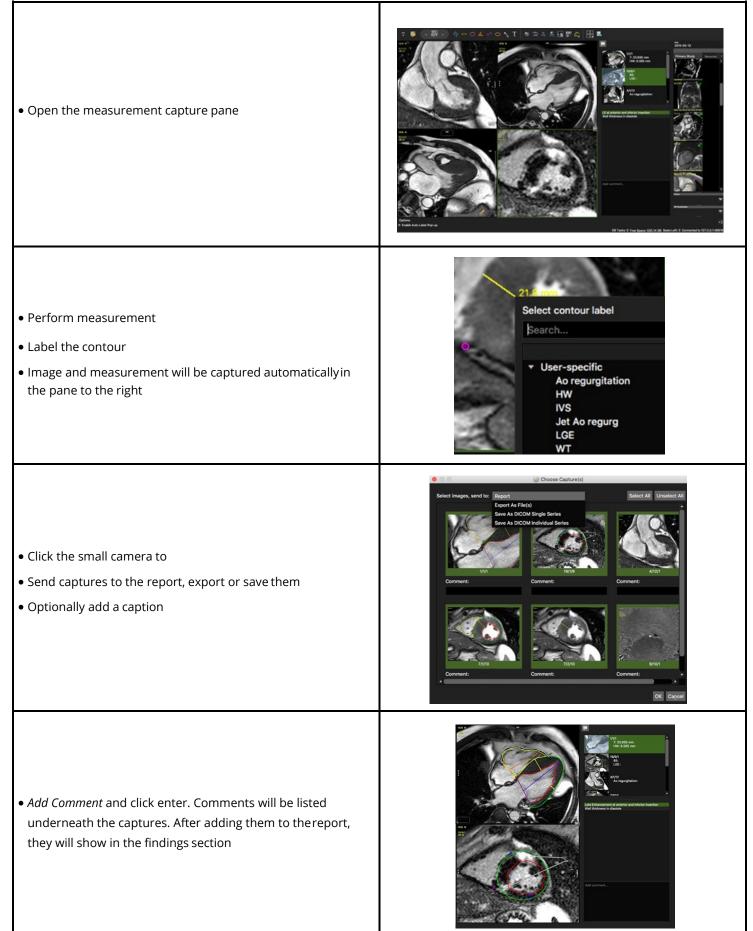
11.2 Compare Follow-up Scans



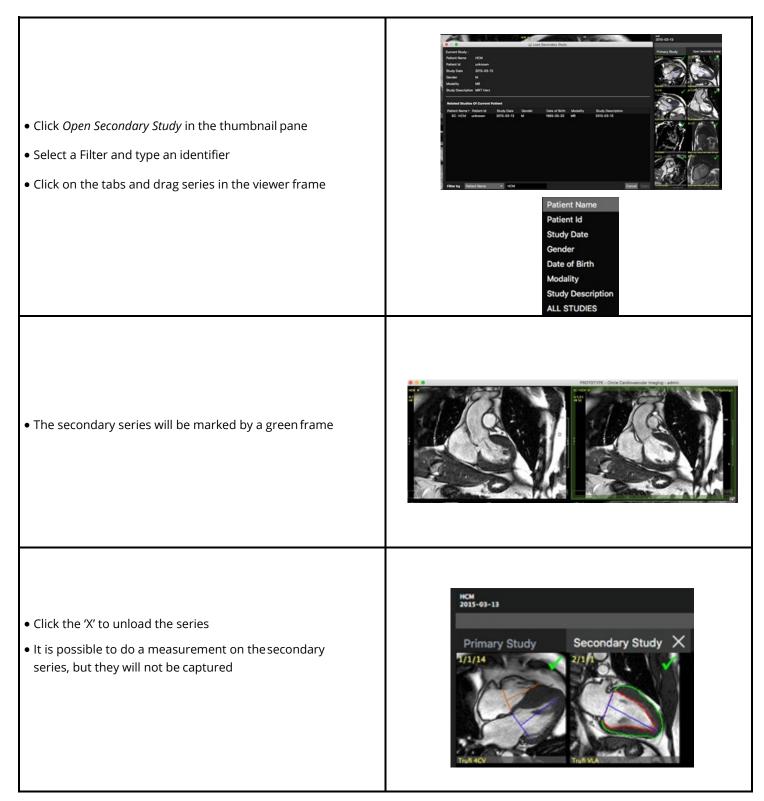
Intended use:

- 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

11.1 Custom Measurements



11.2 Compare Follow-up Scans



Intended use:

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

The MPR Module provides 2 tabs:





Free Form Navigation

Double Oblique

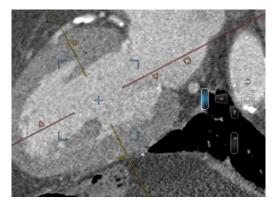
12.1 Double Oblique

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.



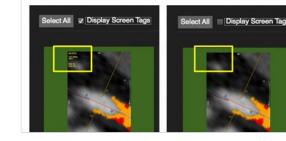
Click the icon in the top tool bar

- 2. To add images click Select All or select single images
- 3. Choose between displaying or hiding Screen Tags
- 4. Optionally enter a comment

1.

- 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

*.png
*.bmp
*.ico
*.jpeg
*.jpg
*.ppm
*.tif
*.tiff
*.xbm
*.xpm



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

4.

- 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
 - 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 the circle
- 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

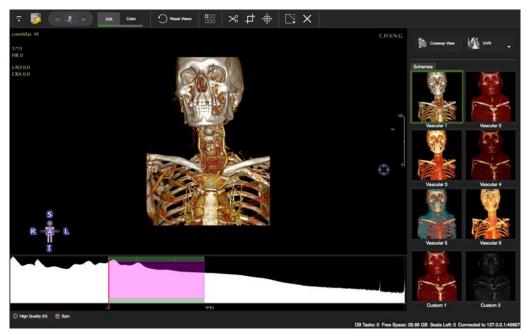
accelerate slice navigation by holding down the Ctrl/CMD key

13 4D Viewer

13.1	Edit
	13.1.1 Measurement Option
	13.1.2 Segmentation
	13.1.2.1 How to Do an Automatic Segmentation
	13.1.2.2 How to Use Clipping and Cropping
13.2	Color

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 <i>Region of Interest</i> Select one of four options 	
ROI-Heart: • The heart will be segmented automatically	
ROI - User defined: • Activate the Cutaway button (former View Clip)	Cutaway View
• 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	Keep (K) Add (F) Delete (D) Continue clicking on the button to expand clipping region.
• Turn off the grow button	i i i i i i i i i i i i i i i i i i i
• Optionally, add a background: Context Menu>Rendering>Background	Volume Ctrl+F1 MIP Ctrl+F2 Fluoro Ctrl+F3 Surface High Quality H Background B Set as 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)



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



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



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



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

14.1 Flow Quantification

14.1.1 How to Do a Flow Analysis

14.1.2 How to Do a Flow Correction

14.1.3 How to Display Flow Curves

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

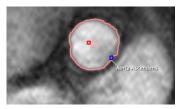
- Color-coded flow display with semiautomatic contour detection, synchronization and forwarding
- Automatic calculations of flow parameter
- Shunt assessment (Qp/Qs)

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. UDefine 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

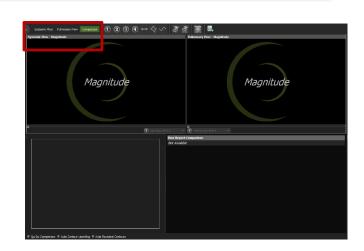


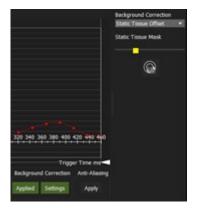
- 6. Scroll through phases to ensure the contours are correct
- 7. Add to Report: Flow assessments of different series have to beadded

individually to the report

14.1.2 How to Do a Flow Correction

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



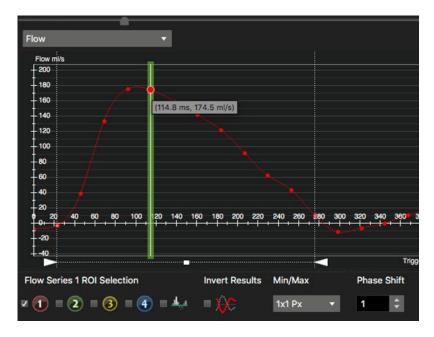


Background correction options:

• 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

- 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 (formerly Phase Unwrapping) has been moved from the Background Corrections Widget to the main interface. Anti-aliasing shall be applied as the last step of the flow analysis (after ROI1 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)

Flow Series 1	Flow Series 2	Comparison	
Measurement		Total	Inside Ruler
Total Forward Volum	ie:	27.52 ml	27.16 ml
Total Backward Volu	me:	-0.49 ml	-0.06 ml
Total Volume:		27.03 ml	26.31 ml
Regurgitation Fraction	on:	1.78 %	0.24 %
Vol/min:		2906.43 ml/min	
Vol/min (effective):		2854.72 ml/min	

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
	15.1.1 How to Do Bi-triplanar LV Function and Volume Analysis
	15.1.2 How to Do Automated Atrial Volumetry
15.2	Function Radial LAX Module
	15.2.1 How to Do LV Function with Multiple Radial Long Axis
	15.2.2 How to Create a Ventricular Volume/mass Curve
15.3	Function SAX Module
	15.3.1 Short 3D Interface
	15.3.1.1 Thumbnail Grid
15.4 Glo	bal LV function and volume analysis
	15.4.1.1 How to Do Fully Automatic LV/RV Segmentation
	15.4.1.2 How to Do a Mitral/tricuspid Valve Plane Correction
	15.4.1.3 How to Do Manual Phase Shifting Per Slice
	15.4.1.4 How to in/exclude Papillary Muscles
	15.4.1.5 How to Create and Display a Volume Curve
	15.4.1.6 How to Do a Regional Wall Motion Analysis
	15.4.1.7 How to Do Atrial Volumetry
	15.3.2.9.1 How to Do Atrial Volumetry in Short/Long Axis Orientation

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



WARNING: Bi/Triplanar

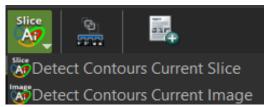
For the calculations, the diastolic and systolic phase are assumed to be in the same phase of the cardiac cycle in all three views. The volume calculation is done per phase. The smallest volume is assumed to be the systolic volume and the largest volume is assumed to be the diastolic volume. In case 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.

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 and option and activate it with LMB click.
- Check the contours and correct if necessary
- Add the analysis to report

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

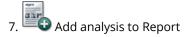


LAX LV Extent contour: Set two points in the mitral valve plane, and a third point in the apex to define the length of the ventricle. As soon as the apex point has been placed, the endocardial contour will be detected automatically. Correct if necessary

- 4. Draw an epicardial contour
- 5. Do the same for the end-systolic phase



Segment Myocardial Contours LAX in Slice: Optionally propagate endo- and epicardial contours for a myocardial segmentation in all phases



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.

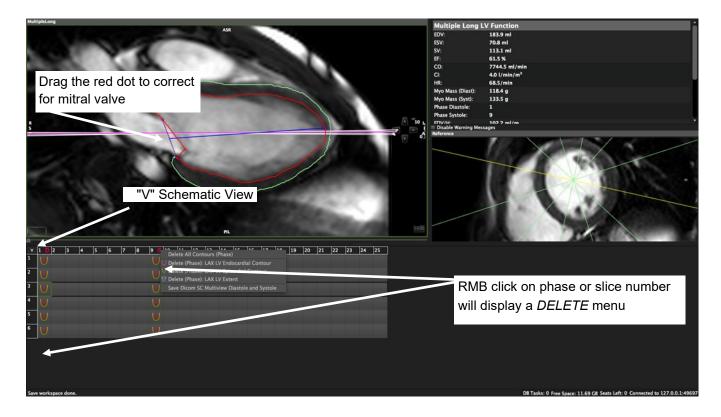
Depending on the shape of the left ventricle the method in use might not be suitable for all evaluations (e.g. severe regional wall motion abnormalities), it is the user's responsibility to verify the suitability of the selected method.

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.



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

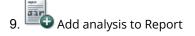
perpendicular short axis cine series (if available) will automatically be displayed in the reference window

- 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. W Define the extend of the left ventricle: Set 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



7. Optionally propagate the contour use the toolbar button *Segment Myocardial Contours LAX in Slice* button

8. Repeat for all slices



15.2.2 How to Create a Ventricular Volume/mass Curve

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



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

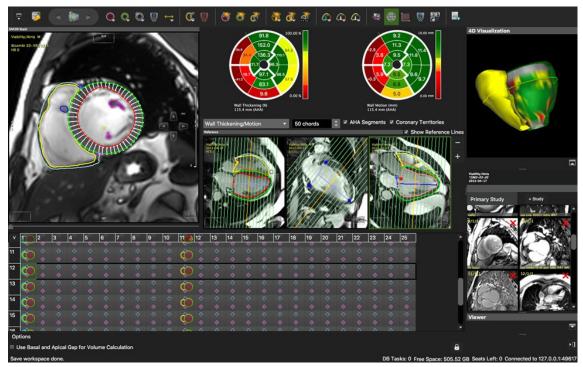


WARNING: SA 3D

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.

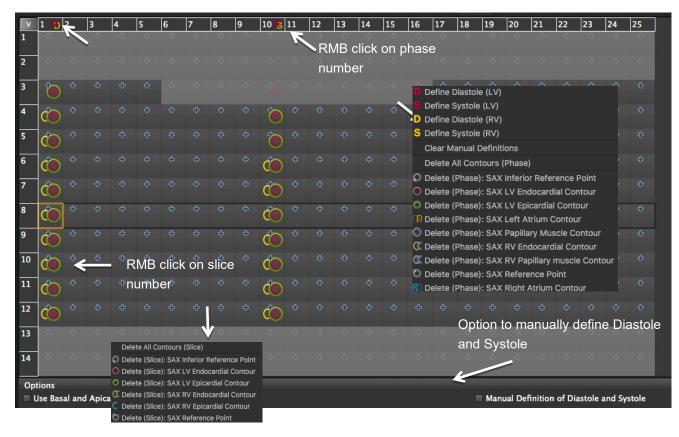
Calculations are performed based on the current state of contour definition and image selections. For every change in this state the calculations are updated immediately. It is the responsibility of the user to verify that the contours reflect the desired measurements before releasing final results.

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

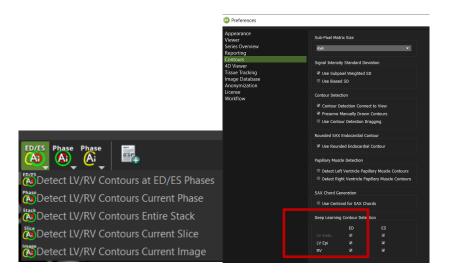
15.3.2 Global LV Function and Volume Analysis 15.3.2.1 How to Do Fully Automatic LV/RV Segmentation



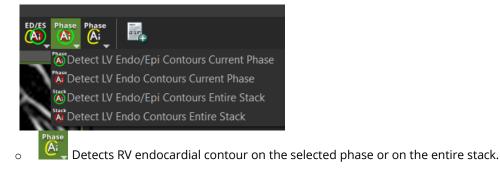
- There are three main AI icons
- Right-mouse clicking on each of the AI tools will open a dropdown menu with other AI contour detection options.
 - ED/ES

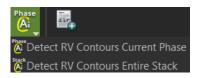
0

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)



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





0

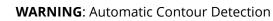
Whenever the LV epicardial contour is detected with an AI tool, the respective anterior and inferior insertion points of the RV will also be detected. If the detection runs on all slices of a selected phase or on the entire stack, the LV LAX extent will also be detected on the respective phase(s) of each LAX series loaded on the reference frame(s).

ED/ES

With a single click on the ED/ES tool (A), 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

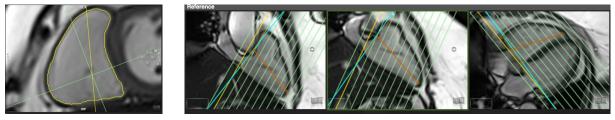


The expected input for the volume calculation in this module is a series containing parallel slice in the short axis direction.

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



з. 💐

. 💜 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:

		_							=		_									
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5	do								do							Un	lock	÷		c
	4P	÷	÷	÷	÷	÷	÷	÷	ΨΨ	÷	÷	÷	÷	÷	÷	÷	÷	+	÷	· -
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- 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. Construction 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*.



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 Rounded Endocardial Contour". Using automated edge detection, the software will apply a rounded contour, cutting offtrabecular structures

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



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 display frame.
- 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

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



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

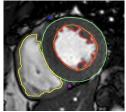
Note: The segmentation points don't have to be adjusted in the remaining images.

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)
- 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



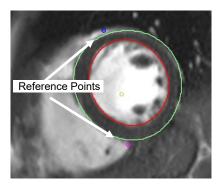
Rounded SAX Endocardial Contour

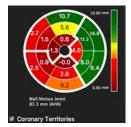
Use Rounded Endocardial Contour

Papillary Muscle Detection

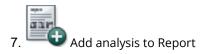
Detect Left Ventricle Papillary Muscle Contours

Detect Right Ventricle Papillary Muscle Contours





- 5. RMB click allows to export the polar map
- 6. Repeat for all slices you want to include in the analysis.



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.

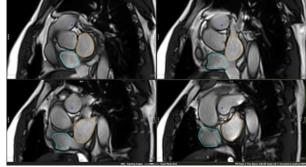
15.3.2.7 How to Do Atrial Volumetry

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

- The atrial volumes will be reported for LV systole and diastole and therefore require the definition for the LV end-systolic and enddiastolic phase.
- 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

16.1	Analysis of LGE and T2 Images
	16.1 How to Do Scar and Edema Analysis
	16.1.2 How to Do T2 Ratio Analysis
	16.1.3 How to Assess Microvascular Obstruction
	16.1.4 How to Do Greyzone Analysis
	16.1.5 How to Assess Salvaged Area at Risk
16.2	Early Enhancement Analysis
	16.2.1 How to Assess the Early Gd Enhancement Ratio
16.3	Regional LGE and T2 Analysis and Assessment of Transmurality
	16.3.1 How to Do Segmental Scar and Edema Analysis
	16.3.2 How to Assess Transmurality
	16.3.2.1 How to Display a Greyzone Polar Map
164	LGE AL Contour Detection

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

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



WWUse the *Exclude Enhancement* contour in case of e.g. artifacts



🥏 Quantify MVO (see below for more information)

Click on *Display Result* to view the analysis

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. We 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 lowsignal
- 3. EXAMPLE 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.

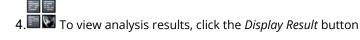


 \checkmark If you are not able to define endo and epicardial contours, use the Myocardial Contour tool

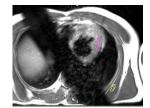


2. Provide a skeletal reference

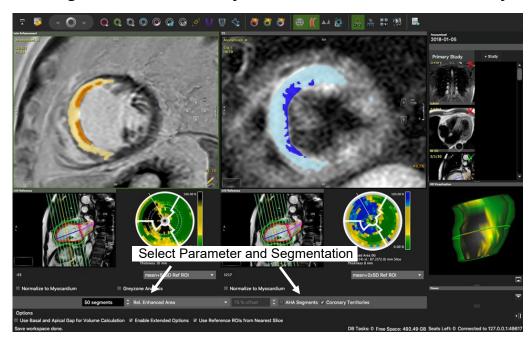
3.Repeat for all slices







16.3 Regional LGE and T2 Analysis and Assessment of Transmurality



Toggle Polar Map



16.3.1 How to Do Segmental Scar and Edema Analysis

- 1. Set Segmentation points
- 2. W 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

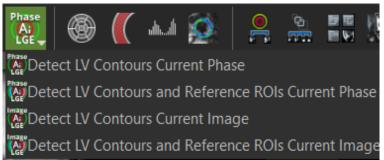
- 1. Repeat step 1-2
- 2. Select *Transmurality* from the drop-down menu at the bottom of the page
- 3. If you want to display a defined percentage, select *Transmurality Offset* and set the percentage with the arrowkeys

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

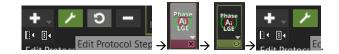
• There are four LGE AI options.



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

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

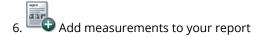
a

3. Dome 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

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



18 Tissue | T2 Mapping

18.1	T2 Measurements
	18.1.1 How to Do a T2 Analysis
	18.1.2 How to Apply a Motion Correction to T2 Series
18.2	Т2 Мар
	18.2.1 How to Analyze T2 Maps

Intended use:

T2 quantification and mapping for myocardial tissue characterization (edema)

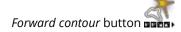
18.1 T2 Measurements

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

18.1.1 How to Do a T2 Analysis

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



- 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



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

- Click the registration button: The new series will be created and automatically loaded into the respectiveframes 4.
- 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. 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
- 3. Derive existing contours from the T2 measurement via context menu>Derive Contours Phase. Alternatively, draw new contours



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

19 Tissue | T1 Mapping

- 19.1 Module Layout
 19.2 T1 Analysis (native and post contrast)

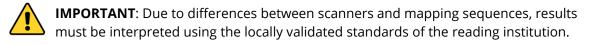
 19.2.1 How to Load Various Sequences
 19.2.2 How to Do Global or Regional T1 Analysis

 19.3 Motion Correction for ECV map generation

 19.3.1 How to Do Intensity Based Registration
 19.3.2 How to Do Feature Based Registration

 19.4 T1 Map Analysis

 19.4.1 T1* Maps
 19.4.2 How to Analyze the T1 Map
- 19.5 ECV and lambda quantification (λ)
 19.5.1 How to Do Segmental ECV and Lambda Quantification



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 R² 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. Select the correct sequence in the option menu

2. Load the sequence from the thumbnail panel. 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 TI information

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



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)

- For regional analysis, select one of the ROI contours. This contour can be forwarded via toolbar butto
- 3. Repeat for all slices
- 4. Global, regional T1 Relaxation times and R2-values will be shown in the result frame
- 5. The T₁ recovery curve will be presented in the frame below. RBM click in the graph opens a *Context Menu* offering dis- play options



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



🕮 🔁 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



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 postcontrast 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 preand post-contrast series
- 2. Select a reference image in the native series with the best contrast and enter the phase into Native RegistrationPhase
- 3. Click the registration button: Two new registered series will be Ecreated 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
- 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. To exclude zero values (non-signals) you can set an off-set by checking Exclude Zero Values for MapMeasurements

8. Add evaluations (images, values

19.5 ECV and Lambda Quantification (λ) 19.5.1 How to Do Segmental ECV and Lambda Quantification

Make sure you have contours, segmentation points and ablood-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* Enter the hematocrit for the ECV quantification

- 3. Add an ECV map
- 4. W 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

20.1	Multi View Compare Rest and Stress Perfusion
	20.1.1 How to Do a Visual Perfusion Analysis
20.2	Edit Contour, Semi-Quantitative Analysis
	20.2.1 How to Do Semi-Quantitative Perfusion Analysis
	20.2.2 Option Menu
	20.2.3 How to Analyze Perfusion Curves
20.3	Analysis, Segmental Analysis

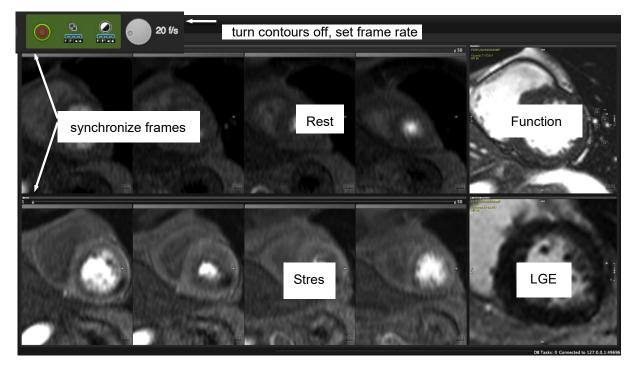
Intended use:

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

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
 - WW 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)
 - 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



3.

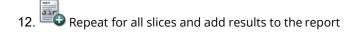
5.

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
- 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)

April 1st, 2020

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



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

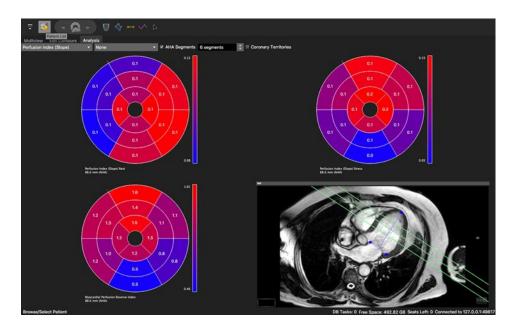
1. To switch to an enlarged view, go to the context menu and check Enlarged View



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. **W** 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 Vascular Module

21.1	Centerline page
	21.1.1 Main Page
	21.1.2 Vessel Lists
	21.1.3 Region Growing
	21.1.4 Edit the Centerline
21.2	Cross Section
	21.2.1 How to Do a Stenosis Assessment

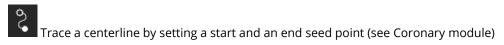
The module covers two topics:

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

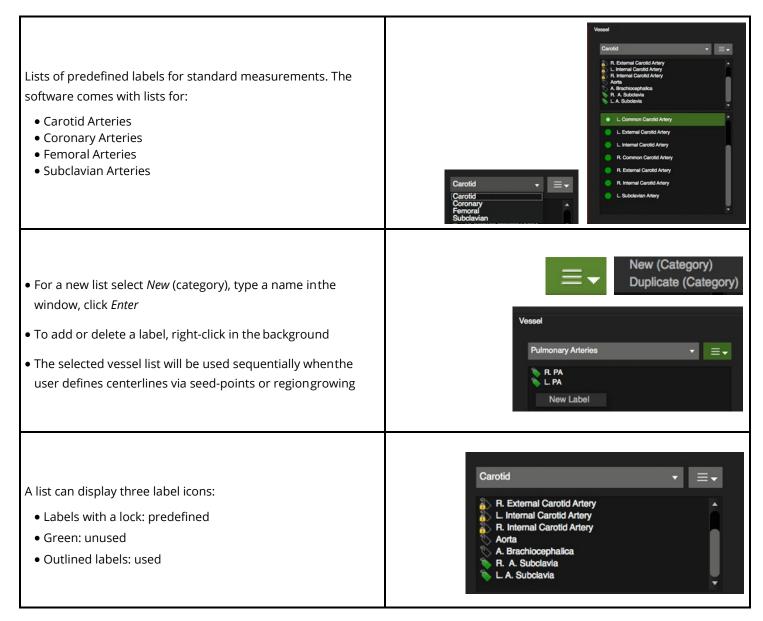


21.1 Centerline Page

21.1.1 Main Page

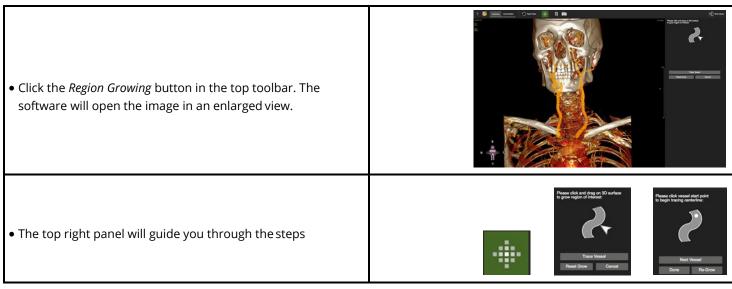


21.1.2 Vessel Lists



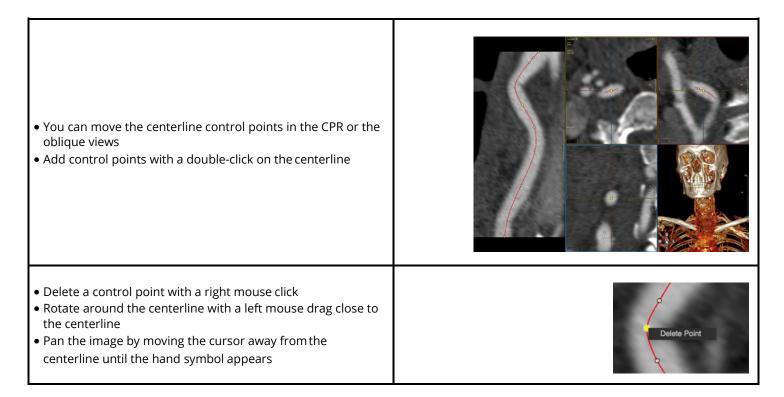
21.1.3 Region Growing

Trace a centerline via region growing.



 Grow the vessel by dragging on the 3D surface Click <i>Trace vessel</i>, to extract the vessel 'Alt' key allows to turn, 'Ctrl' (command Mac) allows topan the image In the segmented vessel, extract the centerline byplacing a start and an endpoint 'T' toggles the centerline on/off 	
 Click Next Vessel to proceed to the next vessel in yourlist Right-click to add or delete a centerline. The label will be updated to 'un-used' 	 R. Common Carotid Artery R. External Carotid Artery R. Internal Carotid Artery Delete New
• <i>Done</i> will go back to the Main page	

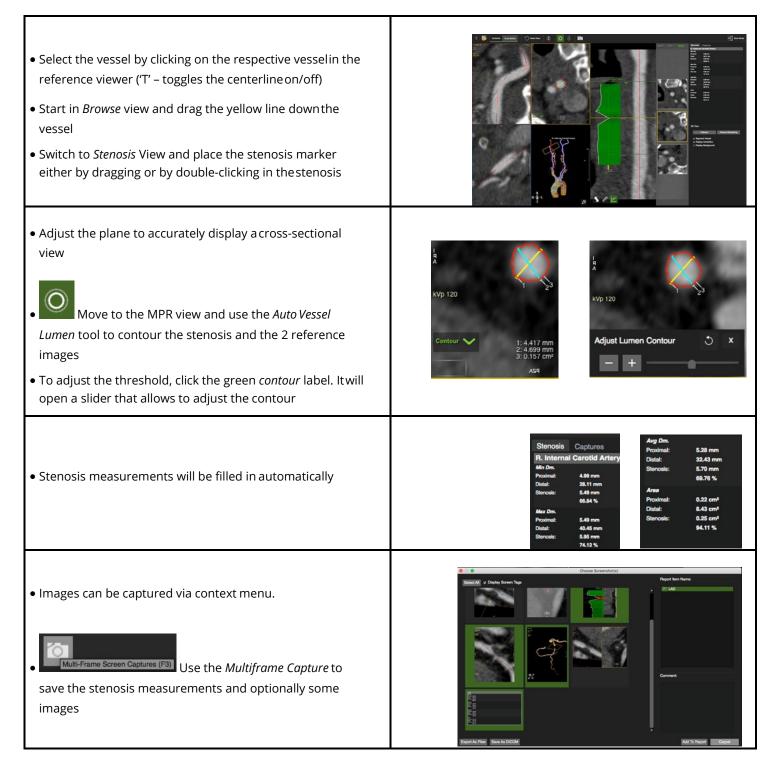
21.1.4 Edit the Centerline



21.2 Cross Section

Stenosis Assessment

21.2.1 How to Do a Stenosis Assessment



22 Strain

22.1	Auto Contour Detection Using Al
22.2	Strain Analysis
	22.2.1 How to Do LV 2D Strain Analysis in SAX
	22.2.2 How to Do LV 2D Strain Analysis in LAX
	22.2.3 How to Do 3D Strain Analysis
	22.2.4 How to Do RV Strain Analysis
22.3	Performance Check and Adjustments
22.4	4D LV Visualization
	22.4.1 How to View a Strain Cine Loop
22.5	Regional LV Analysis
	22.5.1 How to Display Polar Maps
	22.5.2 How to Evaluate a Single Segment
22.6	Diagrams for Strain, Displacement and Torsion
	22.6.1 How to Display Strain and Displacement Diagrams.

Intended use:

Assessment of myocardial deformation.

22.1 Auto Contour Detection Using AI

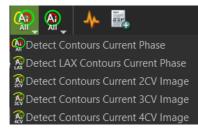
• There are two main AI icon tools, the left-hand tool will detect LV (endocardial and epicardial) and RV (endocardial) contours, and the righthand will detect LV contours only.



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

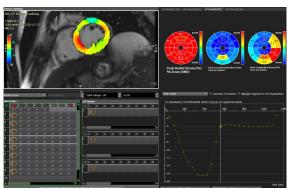


- "AI All" means that **cvi42** will detect the contours on the selected phase for all loaded series (SAX and LAX). If a SAX image is selected, it is possible to run the automatic contour detection on the selected phase of the SAX series only. Whenever the SAX contours are detected, the respective anterior 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:



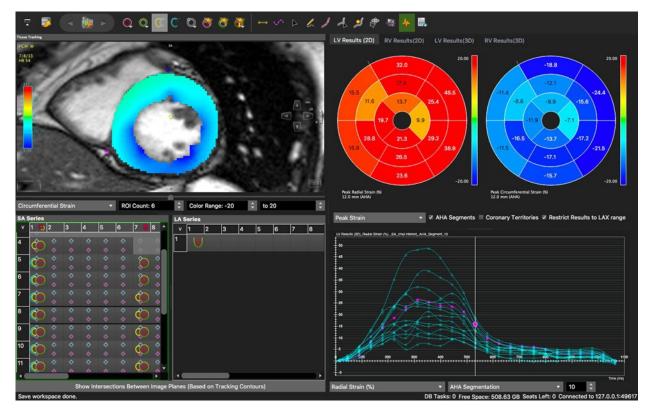




NOTE: Before running the strain analysis, the user must carefully check each contour on each image and correct them whenever necessary.

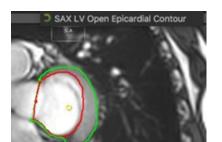
22.2 Strain Analysis

22.2.1 How to do LV 2D Strain Analysis in SAX



1. Load a short axis stack into the analysis frame

2. O O In a reference phase (most commonly end-diastole) define endo-April 1st, 2020



and epicardial contours for all slices that cover the left ventricle

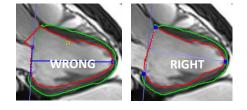
3. Use open contours for the base

For a regional analysis (polar maps):



set the anterior SAX reference points at the insertion of the right ventricle

- 5. Next, load a long axis series
- 6. For contour delineation, go to the same phase in which you drew your short axis contours
- 7. W Use the *LAX LV extend* contour to define the analysis range. Theland- mark for the basal points is the muscle and not the valve
- The endocardial contour will be drawn automatically. Correct if necessary.
 Vice versa, drawing an endocardial contour will automatically place a *LAX extend* contour.



9. W Define an epicardial contour

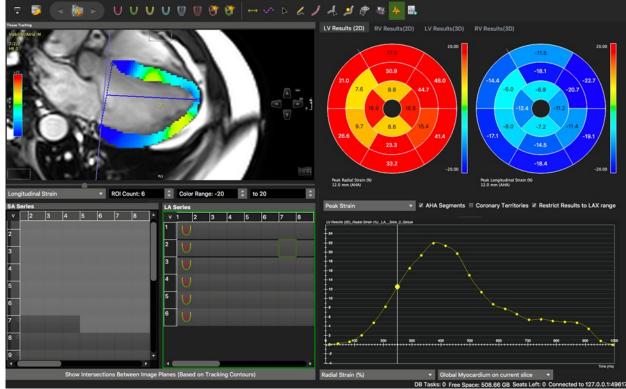
10. Check 'Restrict Results to LAX range"



11. Make sure you have selected the reference phase with the contours and *Perform Automatic Strain Analysis*.

12. Click the LV Results 2D tab above the polar maps

22.2.2 How to do LV 2D Strain Analysis in LAX



It is recommended to have at least 3 LAX slices in total and one mid-ventricular short axis slice for the generation of a polar map. 1. Load a radial long axis stack or sequentially load all radial long axis series into the viewer

2. W Place a Long Axis Extend Contour, which will trigger an endocardial contour in a reference phase or vice versa

3. U Define epicardial LAX contours 4.

4. For the generation of polar maps:

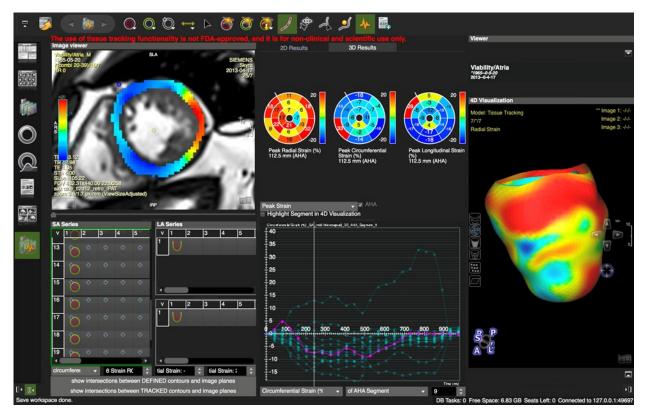
- Load a short axis slice
- Draw epicardial and endocardial contours in the SAX image

Place an anterior insertion point for the polar map segmentation

5. 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

22.2.3 How to do 3D Strain Analysis

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. O Define endo- and epicardial SAX contours in all slices that that cover the LV. Make sure not to include blood volume
 - We fine the anterior SAX reference point at the insertion of the right ventricle in a SAX
- 4. 🛡

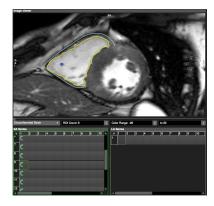
3

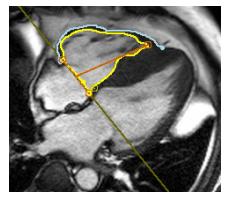
- ${m W}$ In long axis, setting the LV extend will trigger an endocardial contour detection and vice versa
- 5. Correct if needed. Pay attention to exclude papillary muscle
- 6. Select the reference phase by clicking on an image within that phase and click the *Perform Automatic Strain Analysis* button. 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

22.2.4 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 shortaxis.
- 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.

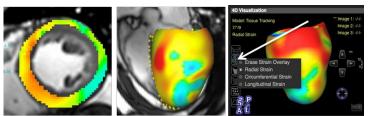
22.2 Performance Check and Adjustments

- 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*

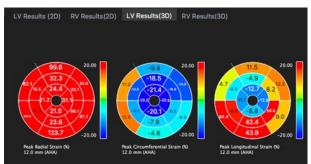
• Click the film icon or spacebar to run the movie. Cines are synchronized with the image viewer



2D Radial Strain

2D/3D Visualization

22.4 Regional LV Analysis 22.4.1 How to Display Polar Maps

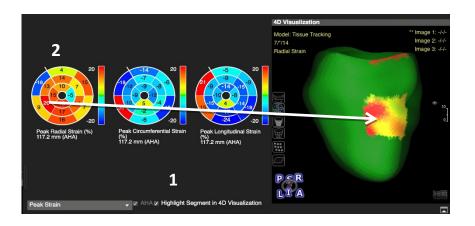


Polar maps display different values, which can be chosen from a drop-down menu.

- 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 thumbnailgrid
- 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 filmicon
- 3. The respective segment in the AHA segment will be highlighted automatically

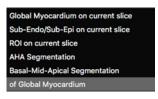


22.5 Diagrams for Strain, Displacement and Torsion 22.5.1 How to Display Strain and Displacement Diagrams

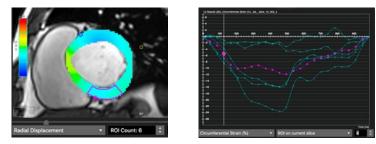
1. Start with selecting the region for which you would like to display the parameter:

• 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



23 Flow |4D

23.1	Data Cropping
23.2	Preprocessing
	23.2.1 How to Preview 4D Flow
	23.2.2 How to Do an Offset Correction and Phase Aliasing
23.3	Segmentation
	23.3.1 How to Segment a Vessel
	23.3.2 How to Extract a Centerline
23.4	Analysis
	23.4.1 How to Visualize Flow in 4D
	23.4.2 How to Do a Flow Measurements
	23.4.3 Ventricular Flow Analysis
	23.4.4 How to Do a Shunt Calculation Qp/Qs
23.5	Advanced 4D Flow Parameter Analysis
	23.5.1 How to Assess Wall Shear Stress
	23.5.2 How to Do Relative Pressure Mapping
	23.5.3 How to Calculate Pulse Wave Velocity
	23.5.4 How to Analyze Energy Loss

Intended Use:

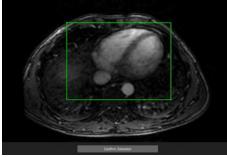
Preprocessing.

23.1 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)
- The static tissue mask is also defined inside of the bounding box, which means that the cropped region should include some static tissue areas, to estimate the fit with good accuracy. The user should select a bounding box with a symmetric and representative amount of static tissue.

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. 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.

Analysis of Smaller Vessels Confirm Selection		
Analysis of Smaller Vessels Confirm Selection		IRP
	Analysis of Smaller Vessels	Confirm Selection

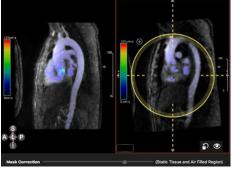
- 5. Confirm Selection
- 6. To change the selection, go to *Workspace*>*Reset Workspace*

23.2 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.

Mask Correction	tion Static Tissue and Vess (Threshold: 0.50)	
Offset Correction		Polynomial Degree: 1
Anti-Aliasing		Point-Click Anti-Aliasing
		Reset Correction(s)



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

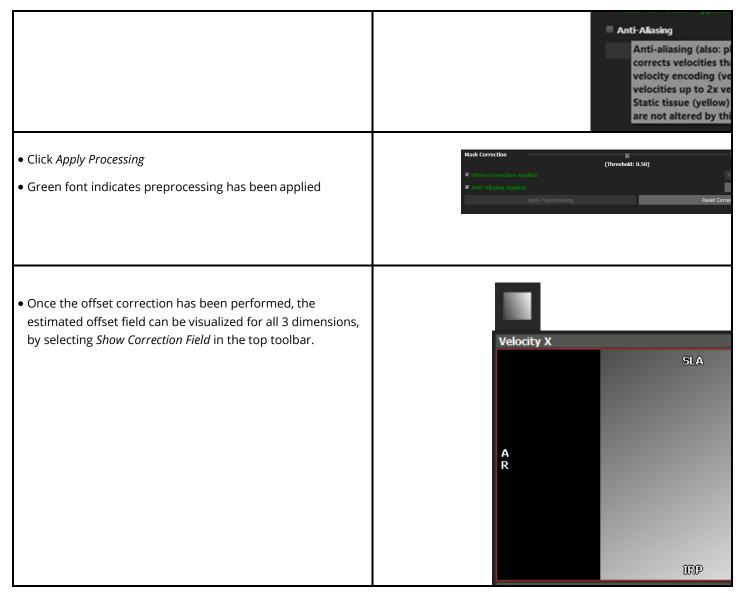
magnitude and velocity views (see MPR Viewer)

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.

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

• The software automatically defines a static tissue mask.	
 The user can use the suggested mask for OC or adjust it 	Mask Correction (Threshold: 0.50)
with the Mask Correction slider.	Offset Correction
 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. 	The static tissue mask (yellow) is an important parameter of the velocity offset correction. M that static tissue voxels are distributed evenly the whole image. Do not include voxels repre- vessels, noise (air) or spatial aliasing. A polynomial surface is fitted to the velocities tissue voxels and then subtracted from the wh image. This is based on the assumption that th flow in static tissue.
• Click on <i>Mask Overlay</i> to activate and deactivate the static- tissue (yellow) and air- filled (blue) mask overlays.	
• In case of aliasing, check 'Anti-Aliasing"	



23.3 Segmentation



Intended use:

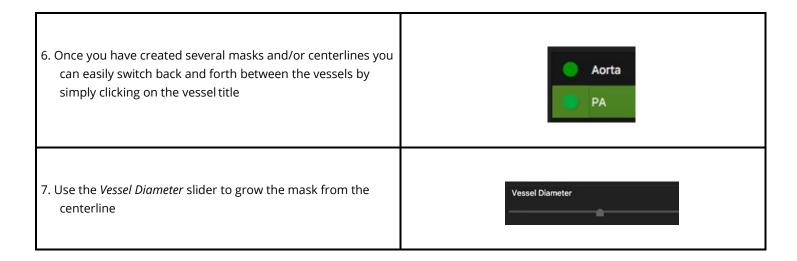
- Segmentation
- Centerline extraction

23.3.1 How to Segment a Vessel

 Show Magnitude Image toggles between magnitude and phase-contrast display. The magnitude allows you torun a cine in the background. 	Show Magnitude Image
2. Activate the <i>Display Mask Overlay</i> button.	
3. Use the <i>Mask Threshold</i> slider to adjust the segmentation.	Mask Threshold
 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 	LT Crop ≻ Cut Aorta PA Delete New Aorta Delete New

23.3.2 How to Extract a Centerline

1. Click Trace Centerline	2 Trace Vessel Centerline
 Set a start and an endpoint in the PC image 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.	



23.4 Analysis

Intended Use

- Flow visualizations
- Quantitative Flow analysis

23.4.1 How to Visualize Flow in 4D

1. Select a flow visualization from the top tool bar	() # 16 ~ %
2. Start the cine and adjust the frame rate	▷ 3/14 🕜 20 fps
• 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 <i>Set Pathline Color</i> from the context menu 2. To save and add a second plane, click <i>Add Measurement</i> 3. Position the free plane and set a color 4. Again, save the plane by clicking <i>Add Measurement</i> 5. Run cine to visualize the custom color-coded flow 	AND
• Pathline (Mask) Visualization : Display pathlines of particles emitted from all areas within thesegmented mask. Select phase and density of the pathlines	~5
• <i>Streamline Visualization</i> : 3D velocity fields at aspecific temporal phase. Change the density of the streamlines.	

23.4.2 How to do a Flow Measurement

1. Select a vessel from the list	Main PA Aorta
 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 > <i>Invert</i>. 	Flow D (caved)
The direction can be changed via context mend - 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 <i>Velocity</i> and <i>Vectors</i> 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	Flow
 A checkbox allows to deactivate automatic contour detection in both Analysis and Ventricular pages. 	✓ Auto Contouring
 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	n= 1 1040d 11 ← 1 → 1 ♥
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 <i>Point-Click</i> or <i>Thresholding</i> will be available by dragging the mouseon the top position tag	ASL
 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 	Net Flow Peak Vel. Regur. Measurement (ml/cycle) (cm/s) 00 Flow 3 98.98 120.00 2.50 Aorta Ascendens[Qs] 116.12 131.00 5.59 Flow 3 62.03 116.02 116.77 Aort Decendens 59.24 103.00 15.57 Flow 6 49.04 109.00 8.66
• To label a contour right-click on the plane in the PC MRA, or right-click on the flow measurement in the report, select <i>Rename</i> from the menu	Rename Hide Delete Measurement Set Pulmonary Flow Set System Flow

23.4.3 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.

23.4.4 How to do a Shunt Calculation Qp/Qs

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

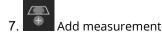
- 1. Segment the vessels (no centerline) and move to the analysis page
- 2. Place a plane in the aorta and in the pulmonary artery
- 3. Scroll through the phases and correct contours if necessary

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



Add measurement

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



23.5 Advanced 4D Flow Parameter Analysis

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

23.5.1 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



Add a measurement to the report

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

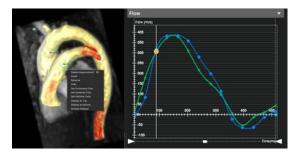
23.5.2 How to do Relative Pressure Mapping

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.

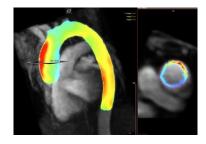


Activate the Pressure Visualization button

2. You will be given a reference and a free plane. Position them in your ROI.

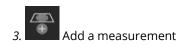


	Net Flow	Peak Vel.	Regur.
Measurement	(ml/cycle)	(cm/s)	(%)
Flow 7[Qp]	78.94	75.00	2.88
Flow 9[Qs]	81.40	132.00	7.04
Qp/Qs	0.969762		



Avg Axial WSS	Avg Cir WSS
(Pa)	(Pa)
0.22	0.13
0.08	0.18
	(Pa) 0.22



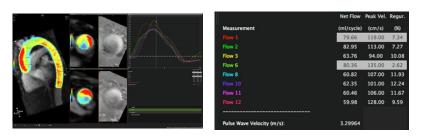


4. Pressure curves from the measurement and the free plane will be displayed in a graph. The relative pressure difference to thereference plane will be reported

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

23.5.3 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



23.5.4 How to Analyze Energy Loss

Note: Not for clinical use.

 Activate the button Define a region by placing 2 planes 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	Max Energy Loss Avg Energy Loss Region Name (mW) R.1 0.69 0.36 R.2 0.40 0.20 R.3 0.58 0.26

24 Coronary Module (Auto plaque)

24.1 Landmark Page 24.2 **Centerline Page** 24.2.1 How to Define a Centerline via Region Growing 24.2.2 Define a Centerline via Seed Points 24.2.3 Edit the Centerline 24.2.4 Save Options 24.2.5 3D View 24.3 **Cross Section** 24.3.1 How to Do a Stenosis Assessment 24.3.2 How to Use the Centerline Graph 24.3.3 Endoluminal View and a Fly Through 24.4 **Plaque Analysis**

24.4.1 How to Perform a Plaque Analysis

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.

24.1 Landmark Page

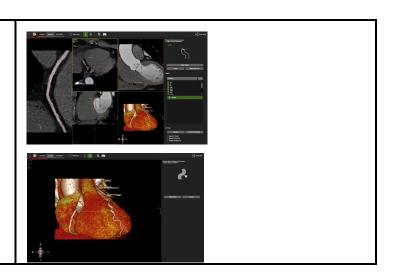
Placing a Landmark in the ascending aorta will support the centerline generation.



24.2 Centerline Page

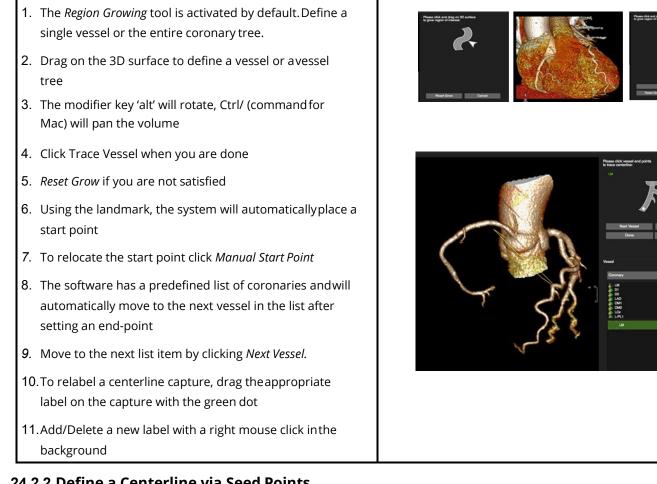
- Create a centerline via 3D-Region-Growing or setting seed points (start and end points)
- Using the landmark point, the system will automatically segment the heart
- The thresholding page will be the default, if you prefer to create a centerline by setting seed points, exit the page by clicking 3D-Region-Growing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

tool bar 👾

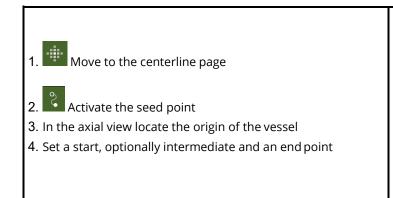


24.2.1 How to Define a Centerline via Region Growing

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



24.2.2 Define a Centerline via Seed Points





24.2.3 Edit the Centerline

- 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 mousedrag close to the centerline
- 3. Pan the image by moving the cursor away from the centerline until the hand symbol appears

24.2.4 Save Options

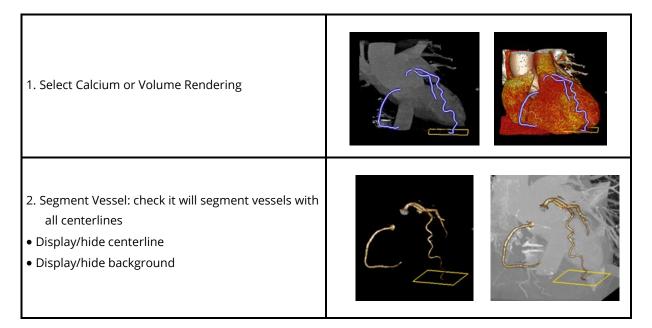
• Save rotational images



• Multi Frame Captures (See MPR Viewer)



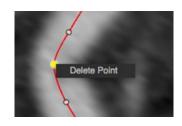
24.2.5 3D View

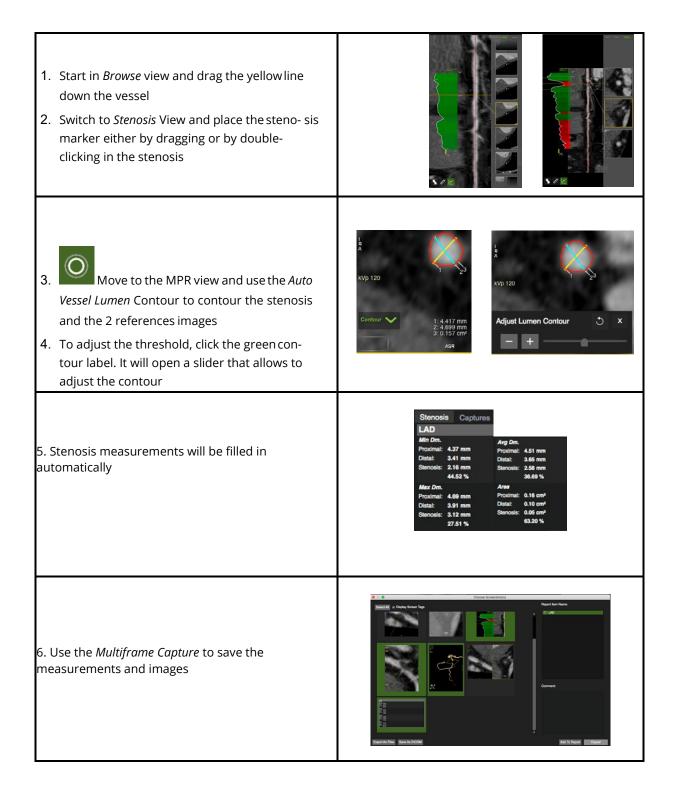


24.3 Cross Section

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

24.3.1 How to do a Stenosis Assessment





24.3.2 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:

E

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

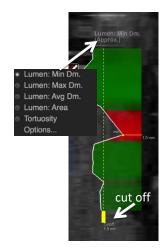
24.3.3 Endoluminal View and Fly Through



- In the reference viewer click the *Endoluminal* view
- 2. Drag the stenosis marker in the CPR viewer
- 3. Click the *Play* button, for a fly through animation
- 4. Export via Context Menu>Export>Export Video Immersion
- The context menu offers viewing, rendering, saving, export and more options

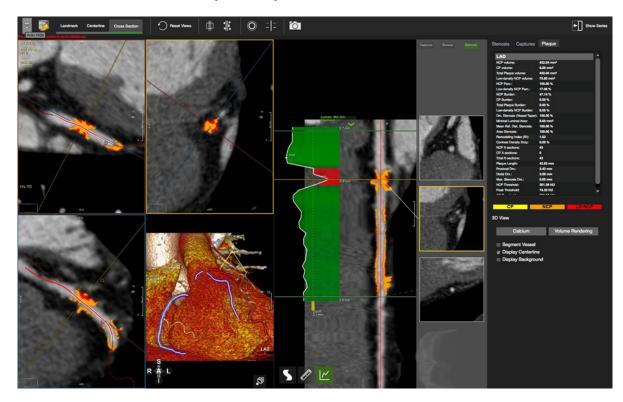
24.4 Plaque Analysis

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





24.4.1 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



Click on auto plaque

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



Select frames and add them to the report

25 Calcium Scoring

25.1 Toolbar

25.1.1 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.

25.1 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

25.1.1 How to do Calcium Scoring

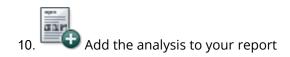
1. Open the on-screen navigation buttons or use your keyboard arrow keys to scroll through the slices

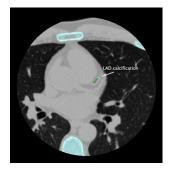


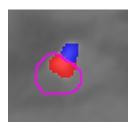
- Toggle the Overlay Display and scroll through the volume
- 3. When you have detected Ca, select the respective coronary ROI-button and simplyclick in the calcified area
- 4. To re-do the region selection, click again
- 5. To reset all region selections, use the *Reset Selection* button in the toolbar



- 6. When the format of the format o format oo the format oo the format oo the format oo
- 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







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

Artery	Volume mm ³	Mass mg	Score Agatston
	0.00	0.00	0.00
	75.44	27.55	100.59
	0.00	0.00	0.00
	54.44	19.51	72.59
Total	129.88	47.06	173.18
Ca Threshold:	130.00		
Ca Mass Calibr	ation Factor:	1.00	
Agatston S	core Classi	fication:	
Moderate Coronary Artery Calcification			

Nganskan Scane • 1600	95t
1400	
1200	
1000	
800	
600	
400	
200	500

26 Aortic Valve Module

26.1	Landmark page	
26.2	Annulus Page	
	26.2.1 Measurements	
	26.2.2 Reporting options	
	26.2.2.1 Capture Measurements and Images	
	26.2.2.2 Standard Report	
26.3	Aorta Fluoro Page	
26.4	Calcium Page	
	26.4.1 Control Feature	
	26.4.2 How to Detect Calcium	
26.5	Valve in Valve	

26.6 Apical Page

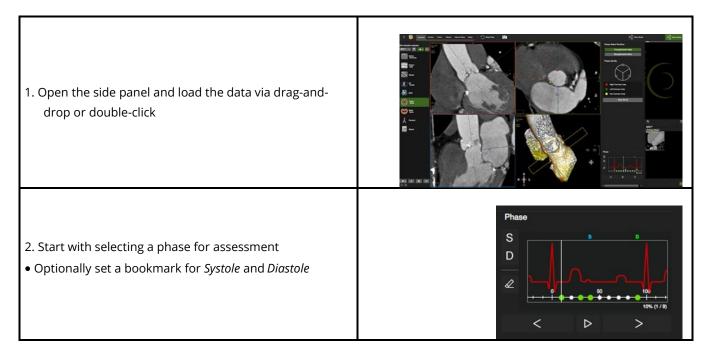
Intended Use

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

26.1 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.



3. Select Workflow: • Choose between a bi- or tricuspid valve	Please Select Workflow: Tricuspid Aortic Valve Bicuspid Aortic 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	Peak dentity
 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 	Ar the state The state is a state of the st

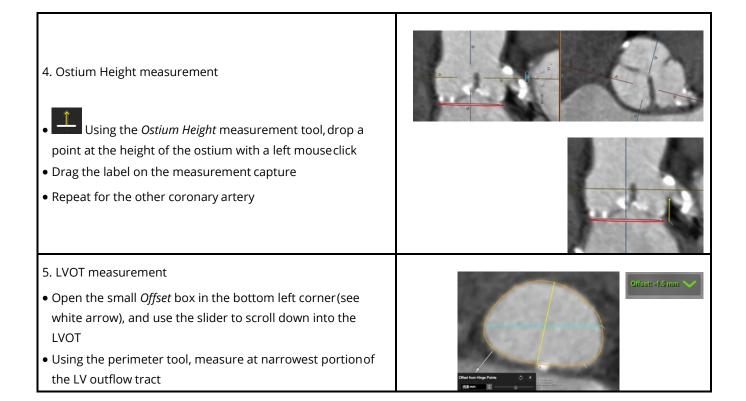
26.2 Annulus Page

26.2.1 Measurements

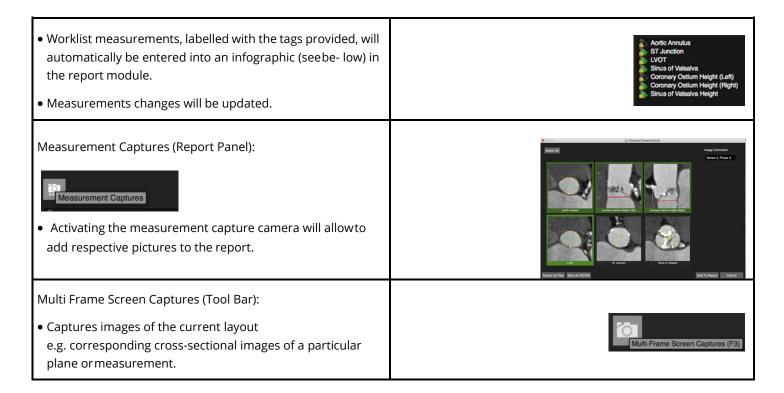
Aortic Annulus

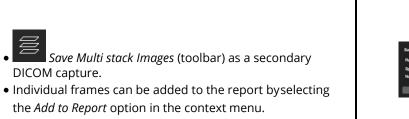
Г

 Use the <i>Perimeter</i> tool and set control points around the annulus. You can maximize the view witha spacebar-click, or by clicking in the top right corner of the view port To edit the perimeter, single-click on the control points. Single-click in the background to disengage The annulus will be the only measurement that isla- belled automatically 	
 Ancillary measurements: 'Reset View' button in the toolbar will take you back to the annulus plane 	Reset Views
• 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	$\bigcirc \longleftrightarrow \checkmark \uparrow \checkmark$
 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 	Actic Annulus S F Junction S



26.2.2 Reporting Options 26.2.2.1 Capture Measurements and Images

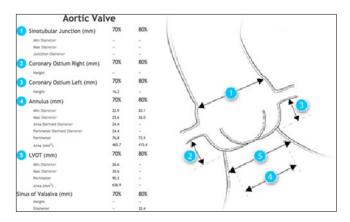




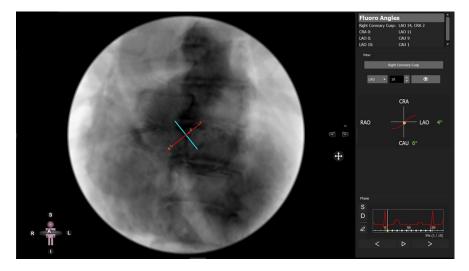
26.2.2.2 Standard Report

Upon opening the default report module:

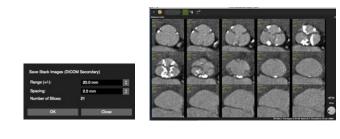
• Review the infographic and related measurements



26.3 Aorta Fluoro Page



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

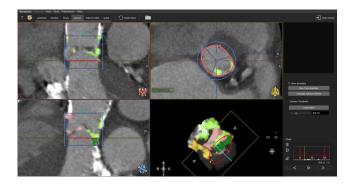




These angles can be used as suggested orientation for C-arm during the intervention, due to the fact that the conditions during the CT scan are not identical to those during the procedure, angles may vary.

26.4 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



26.4.1 Control Feature

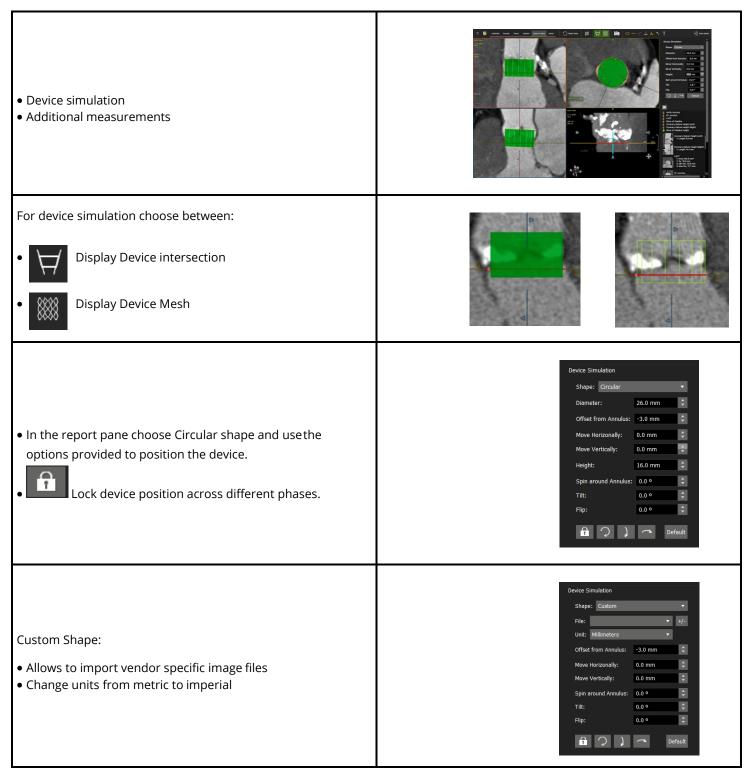
- 1. Mouse drag in the long axis will rotate around the valve center
- 2. Mouse drag in the short axis will scroll up/down the Aorta/LVOT
- 3. Press the Ctrl (command in Mac) key to pan the image in the view port

26.4.2 How to Detect Calcium

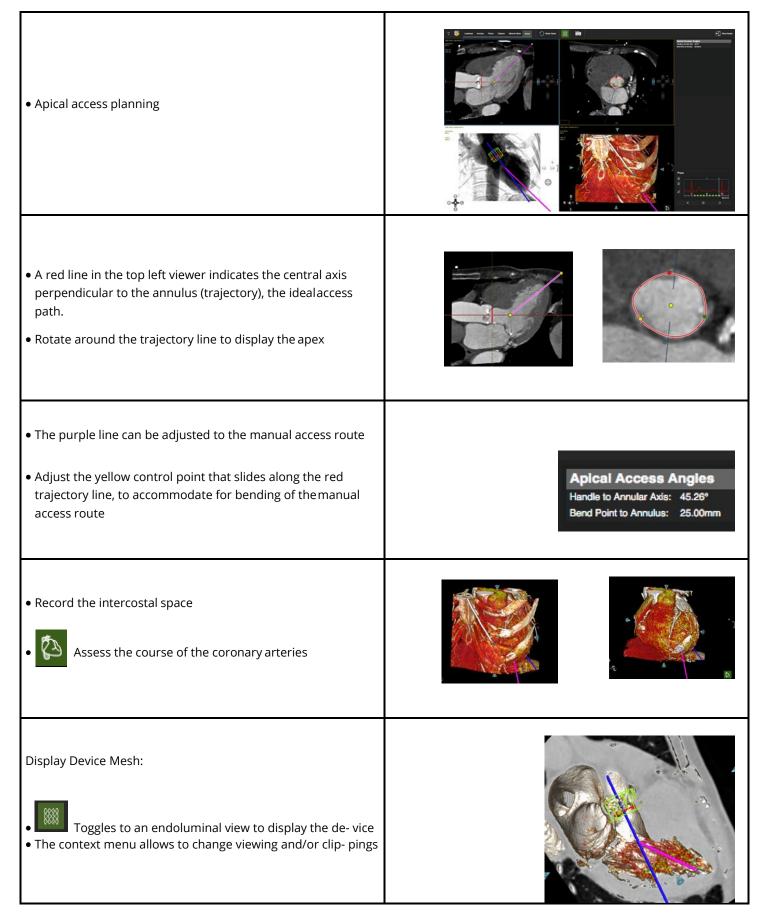
 In the valve view, scroll up to the sinus to displaythe commissures The calcium color corresponds to the nadir point colors. Adjust the center and move the arms of the cusp divider, so that the colors are properly assigned to a cusp 	
 Drag horizontal lines to increase or decrease height Drag control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

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	Fine Tune Boundary
6.	Using the <i>Auto Detect</i> 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)	Calcium Threshold:
7.	Alternatively, drag the slider to manually changethe threshold for HU	Auto Detect 485 HU
8. 9.	In the report pane click <i>Calculate Calcium Volume</i> for a calcium report Click on the camera to add the Calcium Volume and images to your report	Calcium VolumeAortic Valve Region Calcium:1213.5 mm³- Left Coronary Cusp:305.8 mm³- Right Coronary Cusp:387.0 mm³- Non-Coronary Cusp:520.7 mm³- Non-Coronary Cusp:520.7 mm³Upper LVOT Calcium:44.0 mm³- Below Left Coronary Cusp:0.0 mm³- Below Right Coronary Cusp:15.2 mm³

26.5 Valve in Valve



26.6 Apical Page

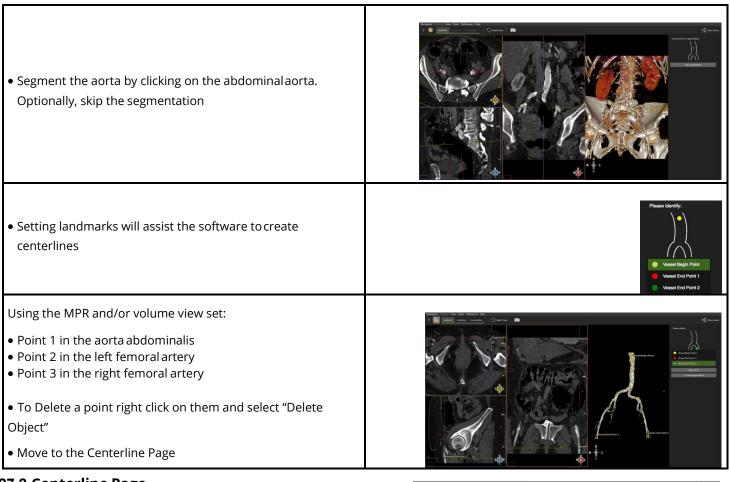


27 Femoral Module

- 27.1 Landmark Page
- 27.2 Centerline Page
 27.2.1 Edit the Centerline
 27.2.2 Assessment of the Puncture Site
 27.3 Cross Section
 27.3.1 Reporting

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

27.1 Landmark Page



27.2 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

27.2.1 Edit the Centerline

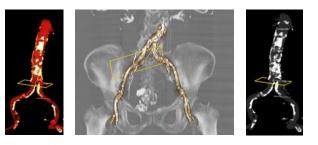
- Use the up/down arrow keys on the keyboard to navigate along the control points
- Add control points with a double-click on the centerline
- Delete a control point with a right mouse click on the point
- Rotate around the centerline with a left mouse drag close to the centerline
- Pan the image by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

27.2.2 Assessment of the Puncture Site

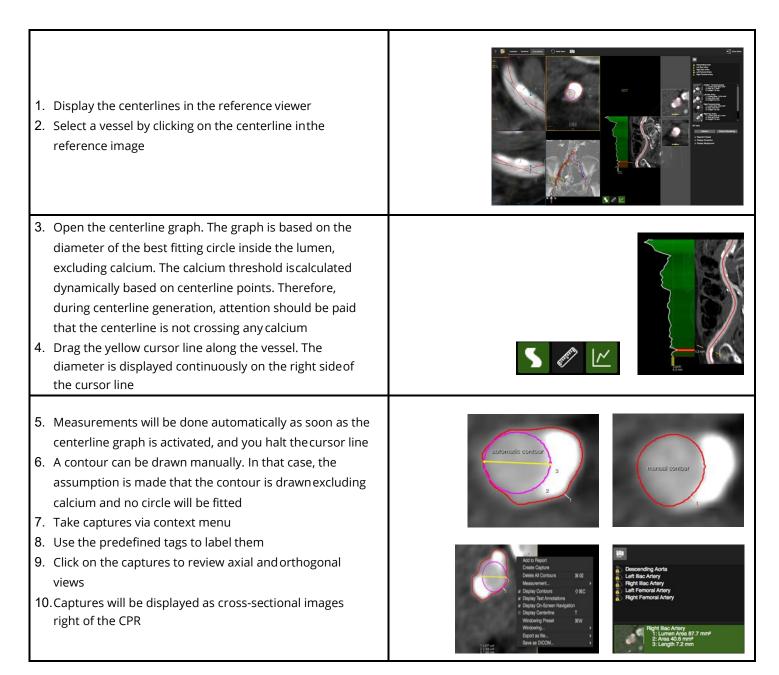
Use the 3D View menu in the right-hand panel to:



- 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



27.3 Cross Section



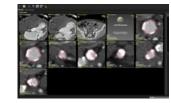
27.3.1 Reporting

Click the camera button in the reporting pane to:

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

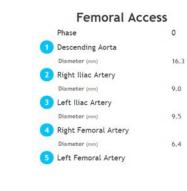
Measurements labeled as described in the previous step will end up automatically in the infographic of the report.





.png bmp bmp ico jpeg jpg pm ttif

*.tiff *.xbm *.xpm



28 Mitral Valve Module

28.1	Landmark page
28.2	Annulus Page
	28.2.1 How to Define the Mitral Annulus (MA) Plane
	28.2.2 Mitral Annular Calcification (MAC) Assessment
	28.2.3 How to Define the Mitral Annulus (MA) Plane - Advanced
	28.2.4 Guide Wire Simulation
28.3	Calcium Page
	28.3.1 Control Feature
	28.3.2 Three Chamber View
	28.3.3 Quantify the Calcium Load
28.4	LVOT Page
	28.4.1 LVOT Assessment
	28.4.2 Device Simulation
28.5	Fluoroscopy Page
	28.5.1 Optimal Viewing Curve
28.6	Apical Page

Intended Use

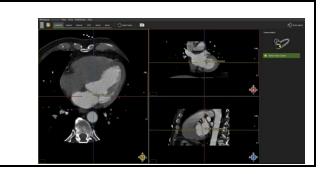
The Mitral Valve module offers a structured workflow for pre-procedural planning of transcatheter mitral valve replacement (TMVR).

28.1 Landmark Page

Set landmark for the assisted generation mitral valve plane

•	Click <i>Show Series</i> and load the series from the thumbnail pane.	
•	If the software detects contours or measurements, the module will open in the <i>Annulus</i> page. Phases with measurements can be identified by the green dots.	Phase S D 2 C C C C C C C C C C C C C C C C C C

- 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.

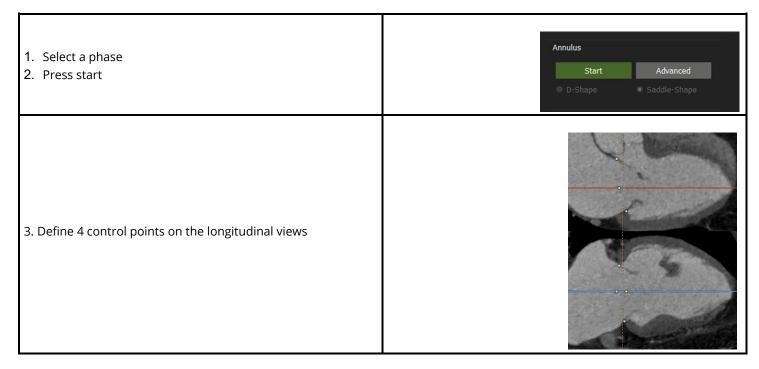


28.2 Annulus Page

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

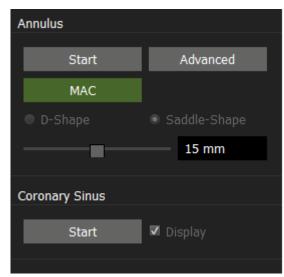
Note: When needed adjust the mitral valve center point and apex point.

28.2.1 How to Define the Mitral Annulus (MA) Plane

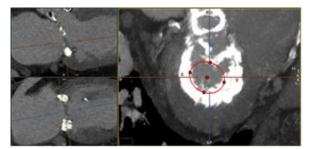


28.2.2 Mitral Annular Calcification (MAC) Assessment

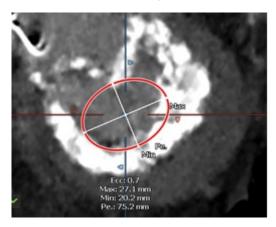
- Mitral annular calcification assessment.
 - \circ $\,$ $\,$ To asses a calcified Mitral Annuls, press the MAC button.



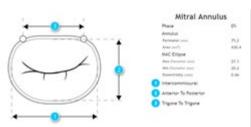
- The long axis views will be set to MPR mode, the short axis will be set to a slabbed MIP.
- Place the short axis in the center of the calcified mitral valve.
- Adjust the ellipse annotation in the short axis view by dragging the control points to their desired locations.



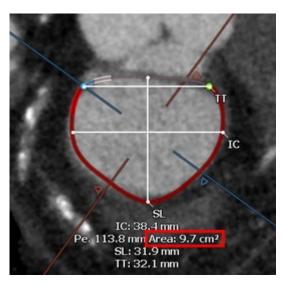
- o Click outside the ellipse, to finalize the measurement.
- o Min/max diameter, perimeter and eccentricity will be reported on screen.



• The report will be updated accordingly.



• Annulus area is now shown in the User interface.

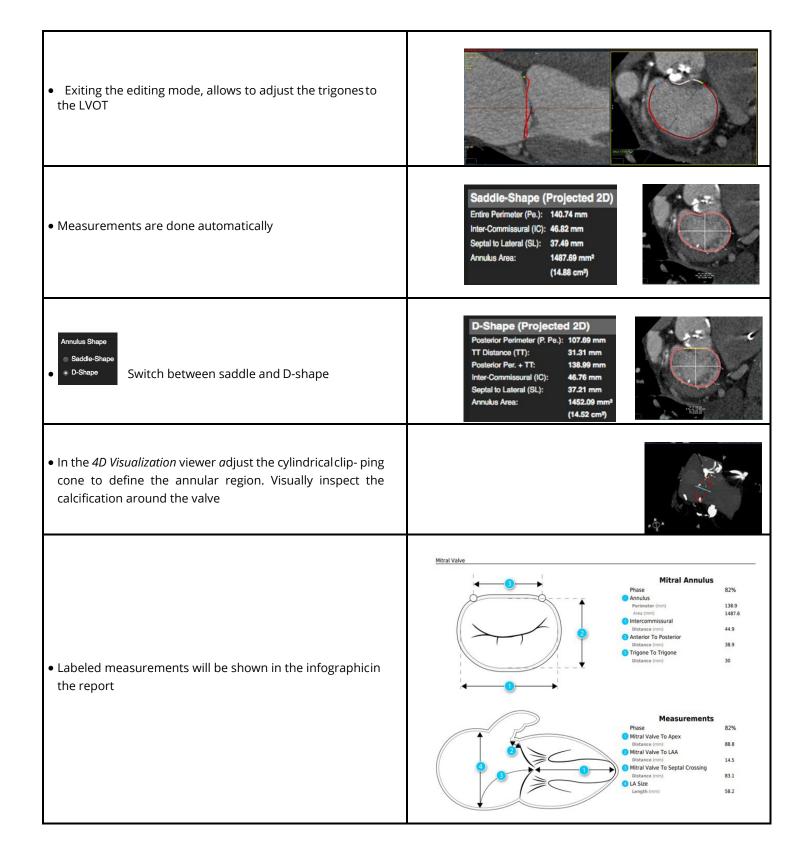


28.2.3 How to Define the Mitral Annulus (MA) Plane – Advanced

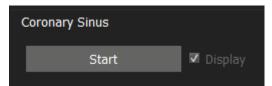
 Select a phase Start the workflow Press "advanced" 	Annulus Start Advanced D-Shape Saddle-Shape
 4. Define control points: The annular contour will be segmented within the 3D space by placing 16 seeding points at the insertion of the valve leaflet After each click, the software automatically rotates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

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

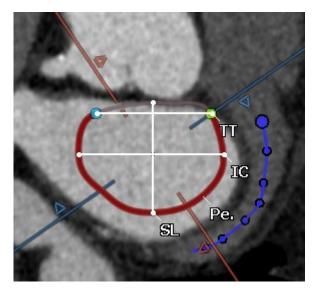
5. Edit the Annulus	
 Double-click to toggle control points on/off 	
• Drag to shift points	
• Left-click to add points	
Right-click to delete points	
• To redo the annulus, restart the annulus definition by	Pelete Point
clicking the bar again	
5 5	



28.2.4 Guide Wire Simulation

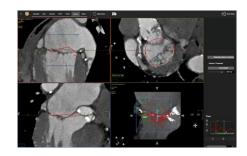


- 1. Press **Start** to begin defining the Coronary Sinus.
- 2. Scroll through the data set in the short-axis view or rotate around the horizontal axis in the long-axis view and click to add key points along the sinus.
- 3. Double-click on the last point to finish.



28.3 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

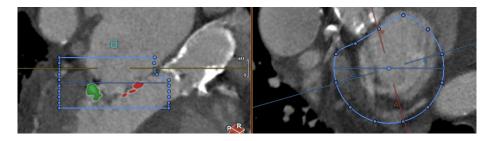


28.3.1 Control Feature

- 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

28.3.2 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

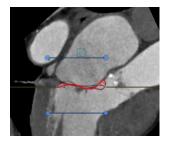


28.3.3 Quantify the Calcium Load

- 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

Calcium Volume Mitral Valve Region Calcium: 423.7 mm³ - Anterior Region: 218.0 mm³ - Posterior Region: 205.7 mm³





28.4 LVOT Page

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report.

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



28.4.1 LVOT Assessment

 Activate the Centerline Control Points Place points in the Aorta and the LVOT 	EXAMPLE TO A CONTRACT OF A CON
3. De-activate the centerline points and use the green bar to scroll along the centerline	References
 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 viewto SL direction with every phase change	View: <u>R</u> e-Align SL Direction (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 	Upper LVOT Med LVOT Med LVOT Med LVOT New Label

28.4.2 Device Simulation



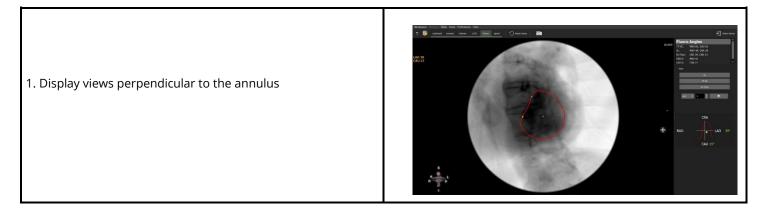
- Turn on the Device Mesh or Device Intersection buttons
- 2. Choose a shape from the drop-down list
- 3. Optionally import vendor specific device image files
- 4. Adjust the device position
- 5. Make additional measurements, e.g. neo-LVOT
- 6. Lock device position across different phases:

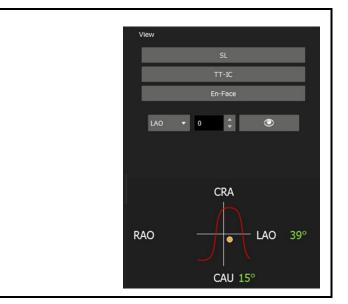
Device Simulation Annulus				
Shape:	Cylinder/Ellipse			
Conical				
bidifiete	Custom			
Diameter	r 2:	29.0 mm	Ŧ	
Offset fro	om Annulus:	12.0 mm	1	¢
Adjust al	ong IC	0.0 mm		¢
Adjust al	ong SL	0.0 mm		÷
Height:		15.0 mm	1	¢
Rotate a	round Annular	Trajectory	0.0 °	¢
Rotate al	long SL		0.0 °	¢
Rotate al	long IC		0.0 °	¢
1	5)	1	Def	ault

28.5 Fluoroscopy Page

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

28.5.1 Optimal Viewing Curve



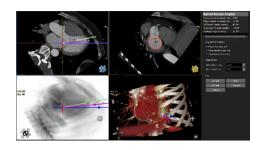


2. Use the pre-set buttons or drag the cursor line over the curve *t*

28.6 Apical Page

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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 intraprocedur	al cathotor angles	Apical Access Angles	
1. Displays initiapi ocedui	al catileter angles.	Manual Handle to Annular Axis: 23.56°	
		Target Handle to Annular Axis: 8.61°	
		Off Table (Target Handle): 34.54°	
		Transverse (Target Handle): -19.31°	
		Clocking (Target Handle): 19.29°	
		•	
		Long Axis View Rotation:	
2. Select the rotation ang		Annulus Axis (Blue Line)	
•	to mitral plane (blue line)	Manual Handle (Purple Line)	
Left ventricle axis (purple line)Delivery sheath axis (green line)		Target Handle (Green Line)	
		Target Handle:	
		Move along SL Line: 8.6 °	
3. Positions delivery shea	th.	Move along IC Line: -0.9 • 🗘	
		View	
		En-Face Apical	
		Off Table Transverse	
4. Buttons for default flue	proscopic and volume views.	Clocking	

5.	Switch between different visualization techniques.	Volume (Ribcage) Volume (Skin) Volume (Heart) Endoluminal
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.	Volume Sync Volume Sync Volume Sync Atrial View Vertrocalar view
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.	

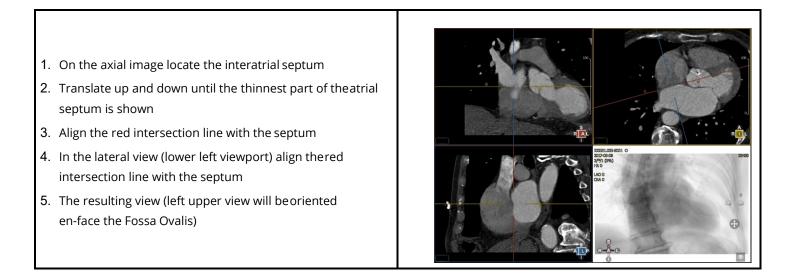
29.1 Contours page 29.1.1 Finding the Fossa Ovalis 29.1.2 Marking the Vena Cava Inferior and Superior and Other Structures

Intended Use

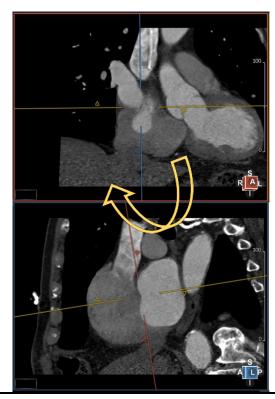
This module allows the user to gain a better understanding of the relationships of different parts of the anatomy and how they can appear on a fluoroscopic view during the actual trans septal interventions.

29.1 Contours Page

29.1.1 Finding 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

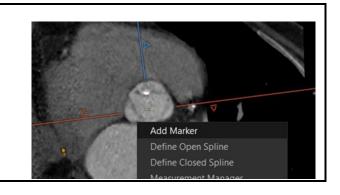


29.1.2 Marking the Vena Cava Inferior and Superior and Other Structures

 Reset views In the lateral viewport translate until the IVC is visible 	
 Place the crosshair on the IVC On the axial image, the IVC contour can be traced 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



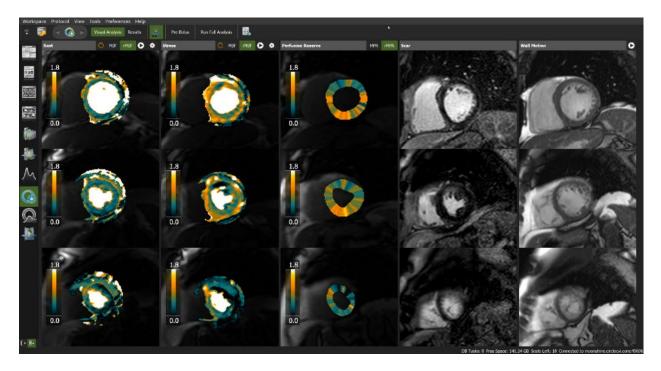
30 Perfusion | Quantitative

30.1	Analysis
	30.1.1 Workflow
30.2	Result Review
	30.2.1 Rest and Stress Pixel Maps
	30.2.2 SI Curves
	30.2.3 Polar Maps
30.3	Report

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.

30.1 Analysis



30.1.1 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 and run the cine
- Click on (MBF/remote MBF) to review the relative myocardial blood flow.

4. Map Review – Myocardial Perfusion Reserve (MPR)

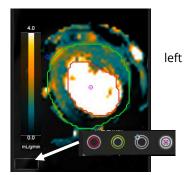
- Color-coded MPR (MBF stress/rest) segments will be displayed in the middle column.
- Click on rMPR (MPR/remote MPR) tab to review the relative myocardial perfusion

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.

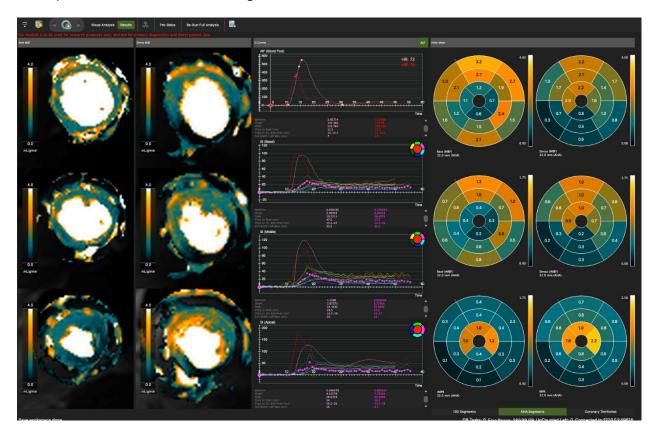
Note: Outliers (white pixel within the map) will be excluded automatically from the calculation of blood flow and is reflected in <u>the</u> maps.

- 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 bottom corner of the view frame.
- After contour correction re-run analysis.



30.2 Results Review

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

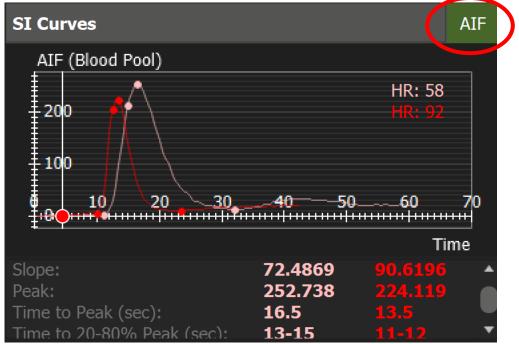


30.2.1 Rest and stress pixel maps

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

30.2.2 Signal Intensity Curves

AIF and Segmental Perfusion Curves





Hovering over a colored coded segment in the slice specific segment icon will display associated segment perfusion

curves.

1.

- 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

30.2.3 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.

30.3 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.

31 Technical Support

31.1 Technical Support

For technical questions please contact our team by phone or e-mail:

North America

Circle Cardiovascular Imaging Inc.

1100, 800 5th Avenue SW Calgary, Alberta, T2P 3T6

Canada

P: +1 403 338 1870

F: +1 403 338 1895

Europe

Circle Cardiovascular Imaging B.V.

Europe Support Phone: + 31 (800)265 8982

Report a problem:	support@circlecvi.com
Website:	www.circlecvi.com