cvi42®

Version 5.17

User Manual

circle
CARDIOVASCULAR
IMAGING

cvi**42**

User Manual

April 2023

Regulatory Information

Manufactured by:

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EU SRN: CA-MF-000011835

bsi
ISO 13485
Quality
Management for
Medical Devices
CERTIFIED
FM 539204

Canada

Health Canada device license number**:** 93385

United States of America
The following 510K clearances applicable for this product: K082628, K111373, K141480, K213998

Importer (UK)
Circle Cardiovascular Imaging UK Ltd.
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Importer (EU)
Circle Cardiovascular Imaging B.V.
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European Union

CE
2797

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

UDI-DI: 00882916000011

EC	REP

EU Authorized Representative
QDossier B.V.
Julianastraat 11,
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CAUTION: US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx Only

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1 Regulatory

1.1 Regulatory Information

AGENCY	Authorized Representative	Approval / Clearance Reference
Argentina ANMAT	LEXEL S.R.L. Luis Saenz Peña 1937 CP1135 CABA, Argentina	256-36
Australia TGA ARTG	KD&A Pty Ltd 286 Flinders Street Adelaide SA, 5000 Australia	177785
Brazil ANVISA	OPTME IMPORTAÇÃO E EXPORTAÇÃO DE PRODUTOS LTDA – ME Edifício Times Square Av. Presidente Vargas, 2121 11° andar - sala 1103 Jardim América - Ribeirão Preto - SP ZIP: 14020-260 - Brazil	81118639002
Chile ISP	INSUMEDICAL SPA. Importer Address: Oficina 108. Las Condes, Santiago- Chile	N° ANDID / 2283/2021
China NMPA	Shanghai (Viacert) Product Technology Service Ltd. Shanghai Chong Ming County Pu Zhen Zhen Pu Zhen Nan Lu 300-4-101, Shanghai, China	NIMR 20172215228
Colombia INVIMA	Colmediks Carrera 25 756 050002 Medellín Antioquia - Colombia	2020DM-0022618
India CDSCO	Taevas Life Sciences Private Limited H.No: 2-3/AC/83, Aparna County, Behind Mathrusri Nagar Miyapur, Hyderabad-500049, India	CIRCLE-CAN/I/MD/004549
Indonesia MoH	PT TRITRA PRIMA INDONESIA Central Park Cikarang Blok A1 No. 02, Desa/Kelurahan Karangraharja, Kec. Cikarang Utara, Kab. Bekasi, Provinsi Jawa Barat Kode Pos: 17530	KEMENKES RI AKL 21501220230
Japan MHLW	ENTORRES 2F 1-82 3 Edobashi Tsu City. Mie Japan	BG30200090 227ADBZX00153000 227ADBZX00157000
Malaysia MDA	Biod Medica SDN. BHD. N-12-16, First Subang Mall Jalan SS15/4G Subang Jaya, 47500 Selangor Darul Eshan, Malaysia	GB7605919-32314
Singapore HSA	Pharmeng Technology PTE. LTD. 1 Fusionpolis Place, Galaxis, #03-20, Singapore 138522	DE0019287

South Korea KFDA	DYNAPEX A-2406-2, 606, Seobusaet-gil, Geumcheon-gu, Seoul, Korea	KCL-BBAAE-12474
Saudi Arabia FDA	Hatem I Alshedwy Commercial Est P.O.Box # 4596 Makkah 21955 – KSA	ARL-2022-MD-0238 MDMA GHTF-2020-1711
Taiwan FDA	Yi-An International Ltd, 11F-5 N0. 91 Hua-Yin Street, Datong District, Taipei, Taiwan, 10351	DHA05603258904/MF010798
Thailand FDA	Tilleke & Gibbins, Supalai Grand Tower, 26th Floor, 1011 Rama 3 Road, Chongnonsi, Yannawa, Bangkok 10120, Thailand	CAN 6304061
United Arab Emirates MOHAP	Lifetastic FZ LLC Dubai Science Park PO Box 75344 Dubai-UAE	DRCLAS-2022-005511

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 mm^2.

3 Basic Components and Indication for Use

3.1 Intended Use

cvi42 is intended to be used for viewing, post-processing, qualitative 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 2D and 4D flow analysis.
- Tissue characterization of cardiac MR Images.**
- Perfusion analysis of cardiac MR Images.**
- Strain analysis of cardiac MR images.**
- Supporting clinical diagnostics of cardiac CT images including quantitative measurements of calcified plaques in the coronary arteries (calcium scoring), specifically Agatston and volume and mass calcium scores, evaluation of heart structures including coronaries, femoral, aortic and mitral values.
- Evaluating CT and MR images of blood vessels. Combining digital image processing and visualization tools such as multiplanar reconstruction (MPR), thin/thick maximum intensity projection (MIP), inverted MIP thin/thick, volume rendering technique (VRT), curved planner reformation (CPR), processing tools such as bone removal (based on both single energy and dual energy) table removal and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics) and key images). The software package is designed to support the physician in conforming the presence or absence of physician identified lesion in blood vessels and evaluation, documentation and follow up of any such lesions.

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

The target population for **cvi42** is not restricted, however **cvi42**'s semi-automated machine learning algorithms are intended for an adult population. Further, 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: *Quantitative analysis is dependent on the quality and correctness of the image source data.

WARNING: **The Tissue, Strain and Perfusion modules are not available for clinical use in the USA. These modules are to be used for research purposes only, and not for primary diagnostics and direct patient care.

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

4 Customization

4.1 How to Define a Protocol

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

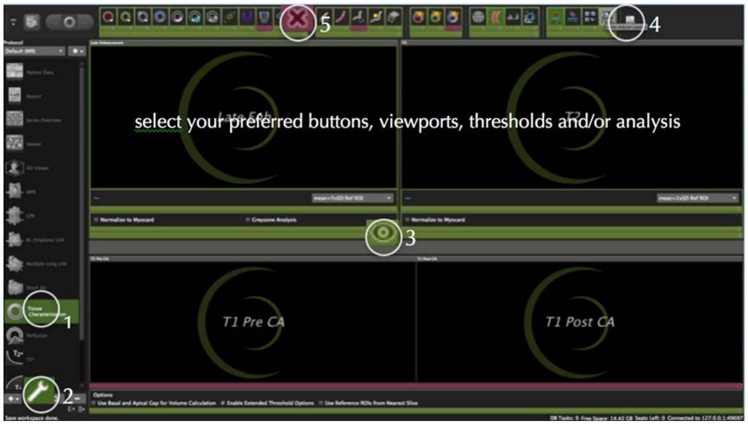
1. Open the drop-down menu next to *Protocol* selection ⚙▾.
2. Choose *New* and type in the protocol name. Hitting the *Return* key will enter the new name and clear the list.
3. Go to *Add* and select your modules.
4. Rearrange modules via drag-and-drop.
5. Rename a module with a double LMB click on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

4.2 CMR Essentials and CMR Advanced Protocols

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

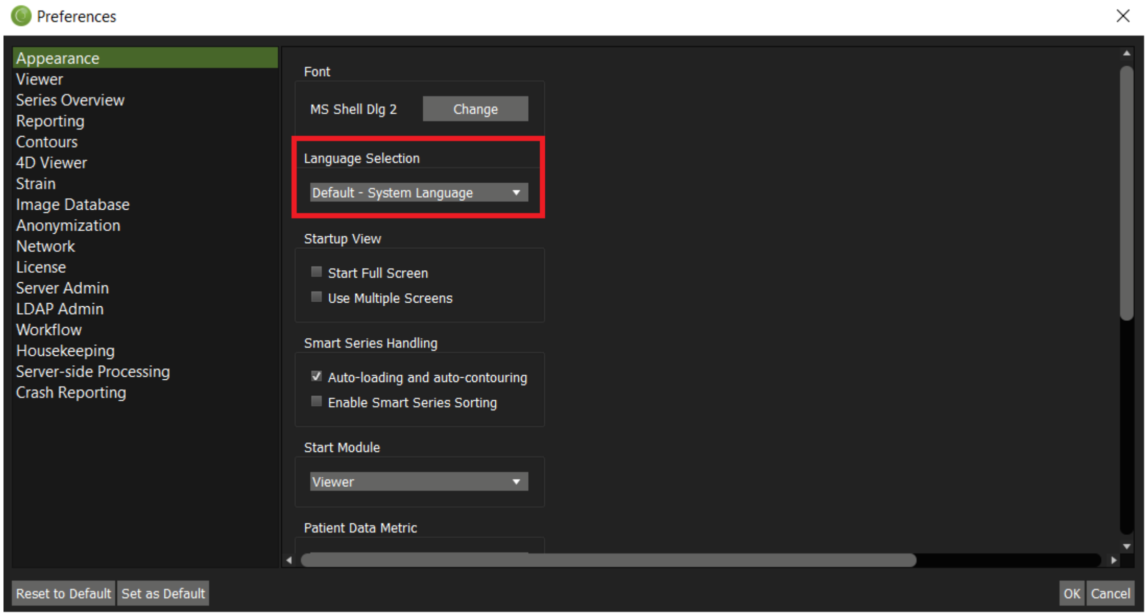
The first time a user saves changes to the global/system-wide *CMR Essentials* or *CMR Advanced* protocols, a new user-specific *CMR Essentials* or *CMR Advanced* is created and named as follows: *CMR Essentials* [username] or *CMR Advanced* [username].

4.3 Customize Tools and Working Modules


select your preferred buttons, viewports, thresholds and/or analysis

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

4.4 Configuring Client Language


Preferences

Font: MS Shell Dlg 2

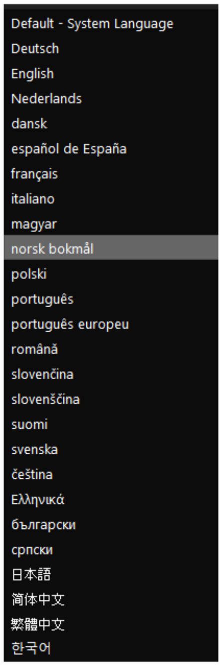
Language Selection: Default - System Language

Startup View:
☐ Start Full Screen
☐ Use Multiple Screens

Smart Series Handling:
☑ Auto-loading and auto-contouring
☐ Enable Smart Series Sorting

Start Module: Viewer

Patient Data Metric



From a specified list, each user can select their preferred language for the **cvi42** client user interface.

To configure the language the user interface:

1. Click *Preferences* -> *Appearance*.
2. Select the *Language Selection* dropdown list and select the desired language.
3. Click *OK* to save the language preference.
4. A warning message will be displayed, indicating that the **cvi42** client must be restarted in order for the language settings to applied. Click *OK*.

> ⚠ **IMPORTANT**: To apply the language settings the **cvi42** client must be restarted.

5. Restart the **cvi42** client. Once restarted the **cvi42** client login screen will be displayed in the users preferred language.

> ⚠ **IMPORTANT**: If no language has been configured the **cvi42** user interface will be displayed in the OS Regional Language.

4.5 Configuring Smart Series Handling

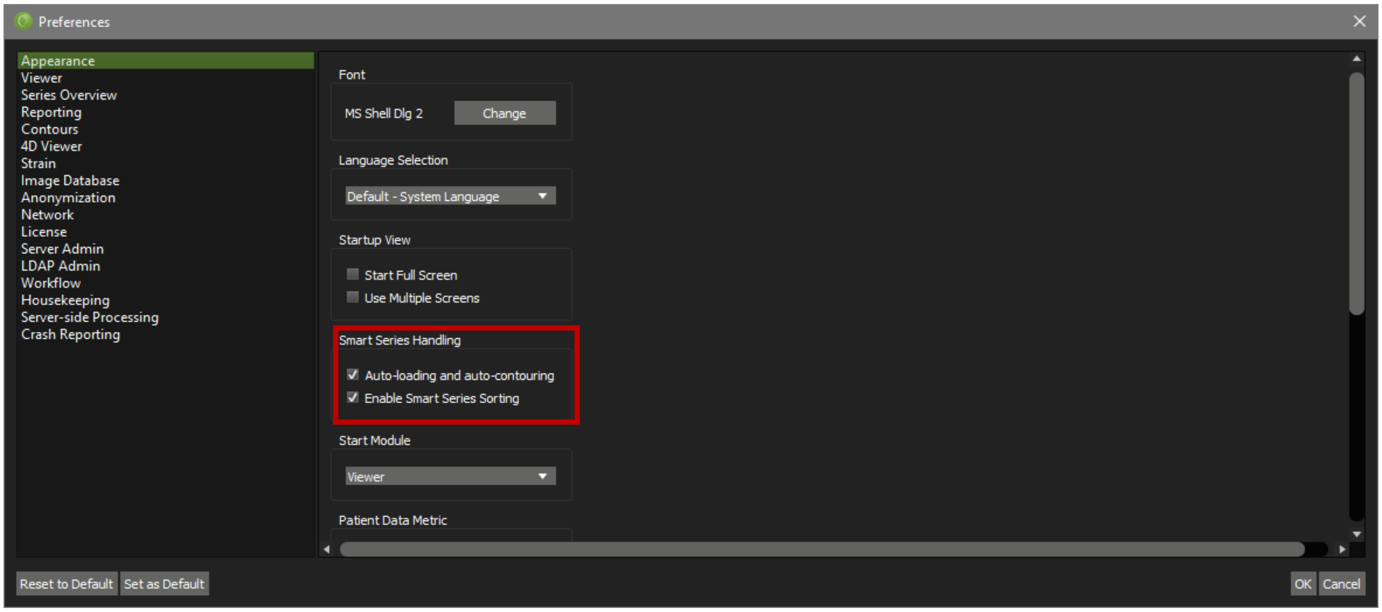
Each user can enable/disable the *Smart Series Handling* functionality. *Smart Series Handling* is used to automate some workflow steps to speed up analysis. This feature will identify each series in the selected study, auto-load the appropriate series into the proper module frames, and in some cases,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

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

- Function|SAX
- Function|Biplanar LAX
- Function|Radial LAX
- Strain
- Tissue| Signal Intensity
- Tissue|T1 Mapping
- Tissue|T2 Mapping
- Flow|2D
- Additionally, the auto-loaded series will be auto-contoured on Function|SAX, Tissue|T1 Mapping, Tissue|T2 Mapping and Flow|2Dmodules.

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

To configure *Smart Series Handling*:



Font
MS Shell Dlg 2

Language Selection
Default - System Language

Startup View
☐ Start Full Screen
☐ Use Multiple Screens

Smart Series Handling
☑ Auto-loading and auto-contouring
☑ Enable Smart Series Sorting

Start Module
Viewer

Patient Data Metric

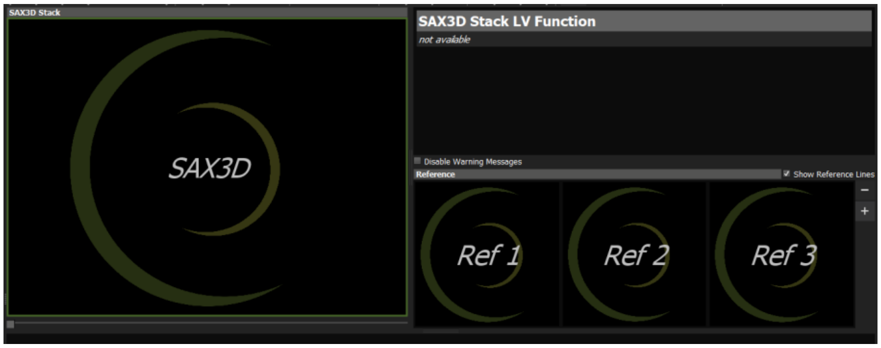
1. Click *Preferences* -> *Appearance*.
2. In the *Smart Series Handling* section there are two options: 1) *Auto-loading and auto-contouring* and 2) *Enable Smart Series Sorting*.
3. Add checkmarks for the desired feature(s) to be enabled.
4. Click *OK* to save the configuration.

⚠ **IMPORTANT**: By default *Auto-loading and auto-contouring* is enabled and *Smart Series Sorting* is disabled.

5 Viewing

5.1 View Ports - Overview

Each module provides viewer frames for image post-processing.
The frames are tagged and prepared for specific image sets (e.g. SAX3D or Ref1).

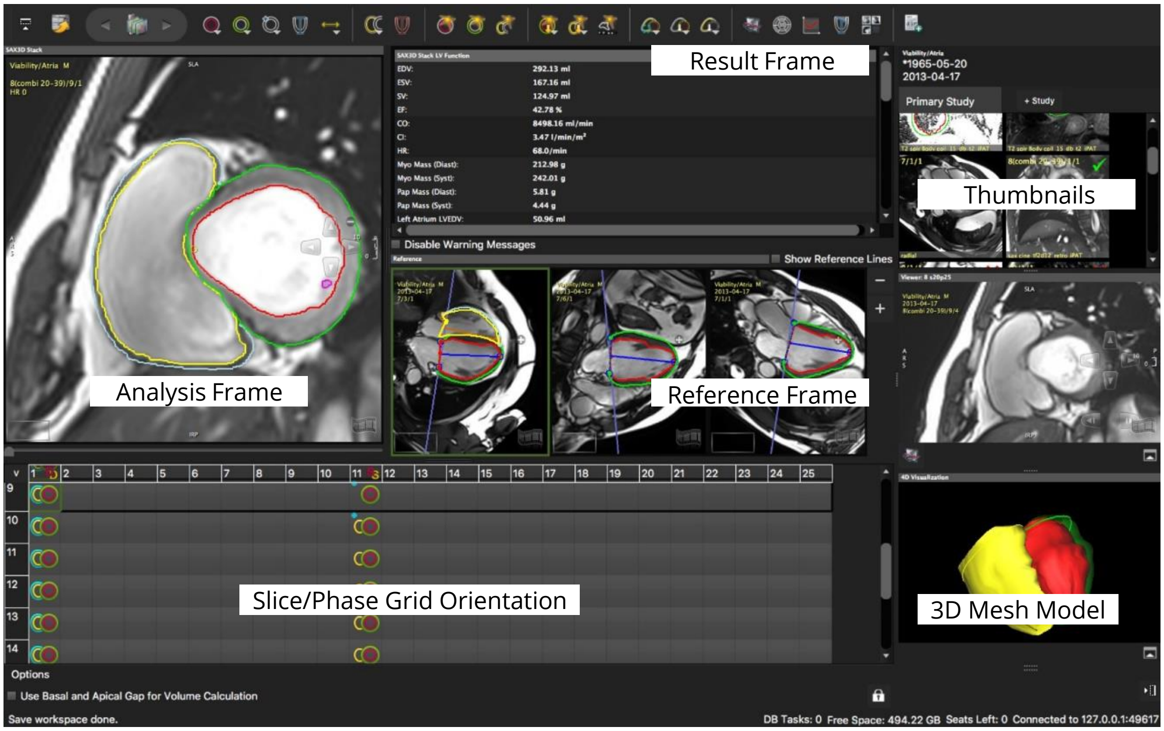


SAX3D Stack LV Function

not available

☐ Disable Warning Messages

☑ Show Reference Lines



SAX3D Stack LV Function

EDV:	292.13 ml
ESV:	167.16 ml
SV:	124.97 ml
EF:	42.78 %
CO:	8498.16 ml/min
CI:	3.47 l/min/m²
HR:	68.0/min
Myo Mass (Diast):	212.98 g
Myo Mass (Syst):	242.01 g
Pap Mass (Diast):	5.81 g
Pap Mass (Syst):	4.44 g
Left Atrium LVEDV:	50.96 ml

☐ Disable Warning Messages

☐ Show Reference Lines

Options

☐ Use Basal and Apical Gap for Volume Calculation

Save workspace done.

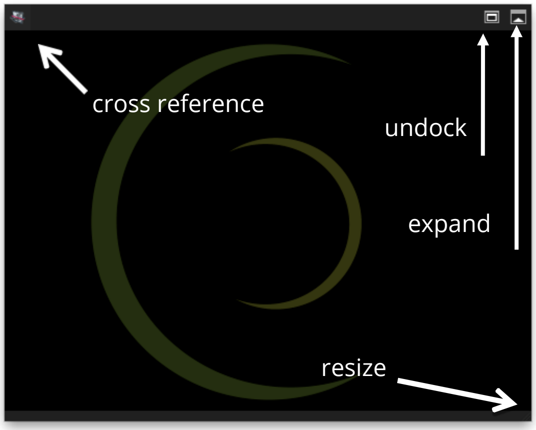
DB Tasks: 0 Free Space: 494.22 GB Seats Left: 0 Connected to 127.0.0.1:49617

5.2 Image Editing, Viewer Controls

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

5.3 Additional Viewer

5.3.1 Floating Viewer

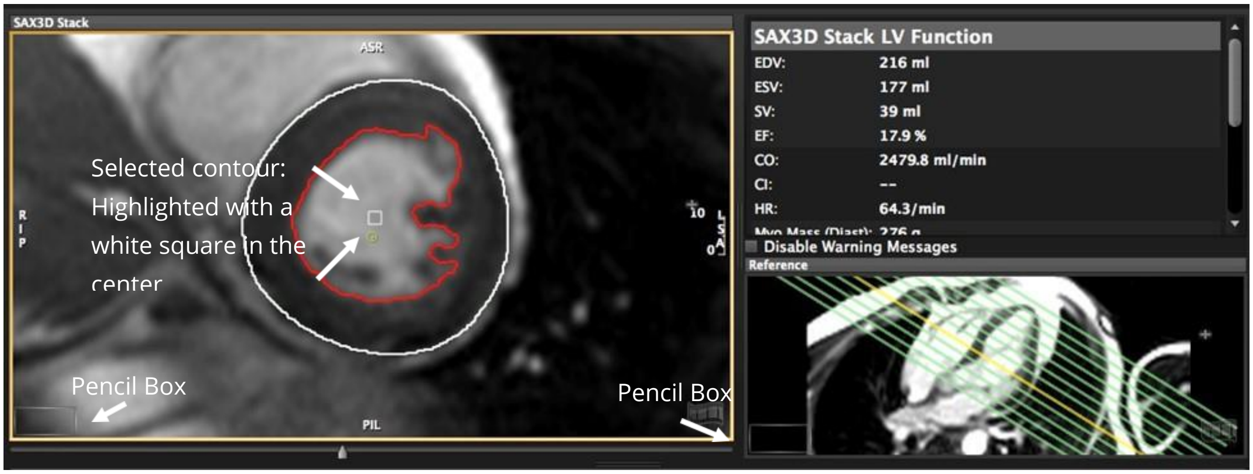


- Located underneath the thumbnail panel, is an additional detachable viewer that can be undocked and changed in size.
- It will stay on-screen even when switching to a different module.

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

- Provides a cross reference.

6 Contour Drawing, Labeling and Measurement Tools



Selected contour: Highlighted with a white square in the center

Pencil Box

Pencil Box

SAX3D Stack LV Function

EDV:	216 ml
ESV:	177 ml
SV:	39 ml
EF:	17.9 %
CO:	2479.8 ml/min
CI:	--
HR:	64.3/min
Myo Mass (Diast):	276 g

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

6.1 Manual Contouring

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

For the left heart chambers.

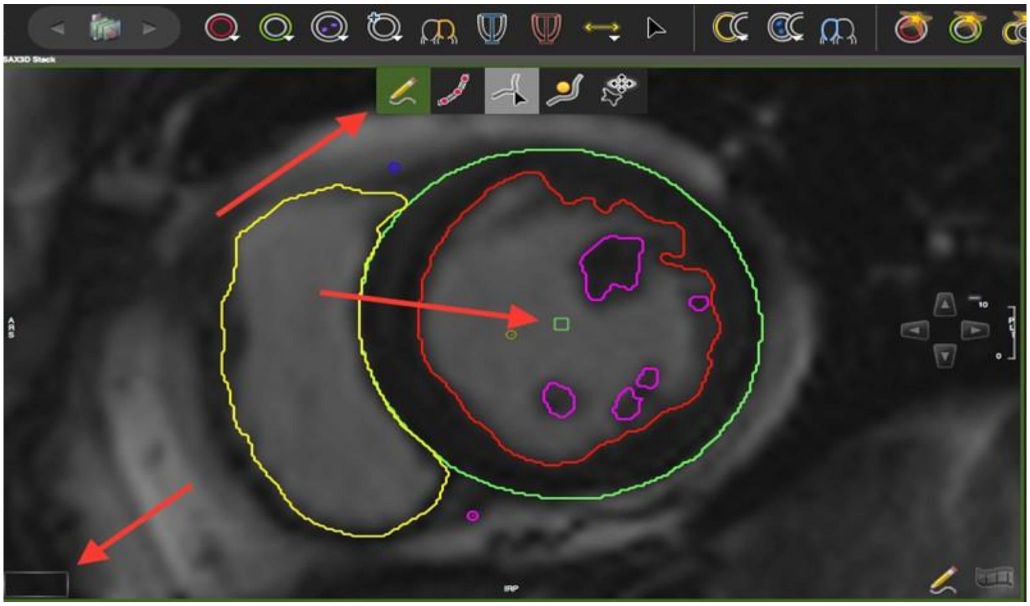
For the right heart chambers.

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

6.1.1 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.

6.1.2 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.

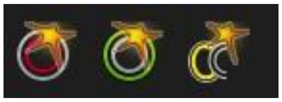
   Threshold segmentation: Allows to define borders by dragging with the LMB downwards and sideways until you have found the threshold that best defines your border.

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

   Push Contour: Shape the contour by pushing the circle.

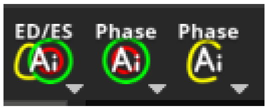
3. Switch back to the freehand mode.
4. The selected drawing mode is displayed on the lower right corner of the frame.

6.1.3 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.

6.1.4 Automatic Contour Detection



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

6.1.5 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 differs 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 file system.
- *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.

  If the preference *Auto-loading and auto-contouring* is enabled, upon resetting the workspace, the system will run the auto-loading and the auto-contouring.
- *Close Study*.

8 Patient Data Module

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

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

8.1 Edit Patient Data

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

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

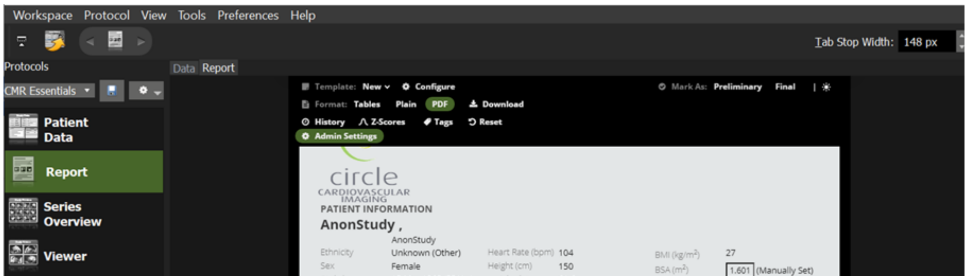
9 Report Module

9.1 Report Configuration

To configure reporting, open the *Report* module and on the top left select *Report*.

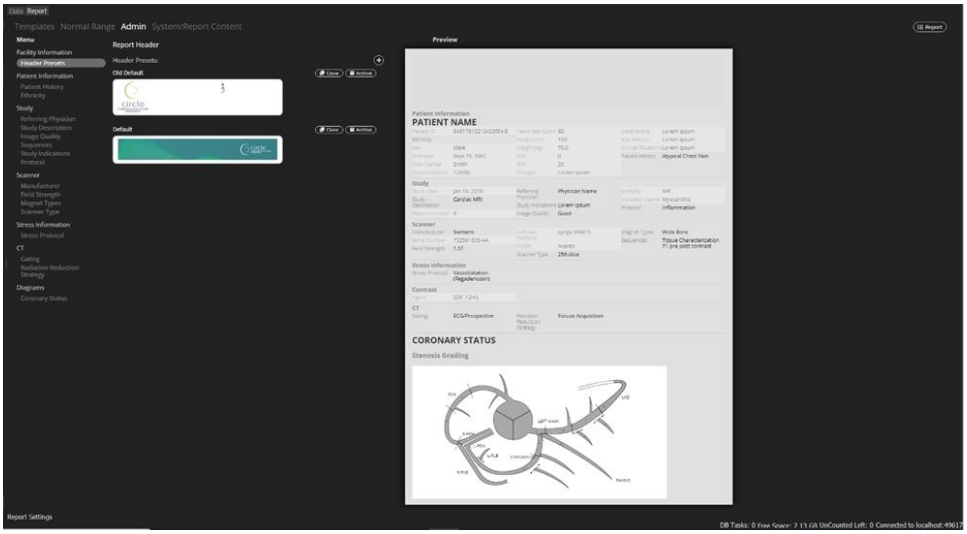
Hover the mouse on the top of the *Report Preview*, to display the *Report* Menu.

Click on *Admin Settings*, to open the *Report Configuration* section.



The following options can be selected:

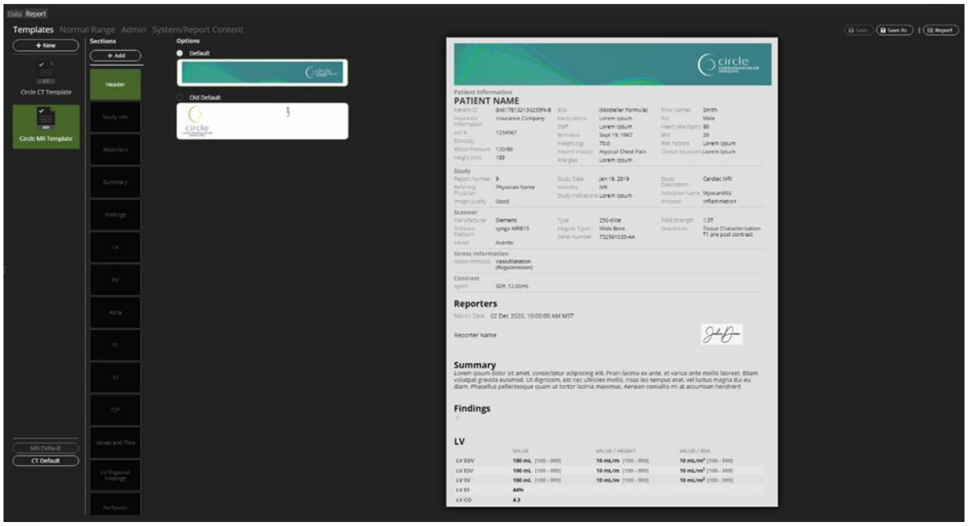
- **Report Templates**: Allows a user to create/edit report templates.
- **Normal Ranges**: Set normal ranges for various clinical parameters.
- **Report Admin**: Configure drop down/text options used in report.
- **System**: Allows to configure report language.



For details on each option see below.

9.1.1 Report Templates

Report templates provide configuration for custom reports, by allowing the user to select which sections to be included, section order, data fields, and images to be displayed, as well as standardized text for findings.



The list of available templates is located in the left column, template details in the middle, and a report mockup on the right.

1. Click on a template to review.
2. Two templates are included by default: Circle MR Template and Circle CT Template. These templates cannot be overwritten or deleted. Changes to these templates may be saved to a new template using the *Save As* button.
3. To create a new template, click on + *New* and name the template.

9.1.1.1 Editing Templates

- **Add Sections:** click on + *Add* and drag the desired section from the pop up, into the correct position in the *Sections* column.
- **Delete Sections:** from the template, click and hold on the section name, the + *Add* button will change to a trash can. Drag the section unto the trash can.
- **Edit data within a section:** Click on the section. Data and image options will appear if applicable. Set check boxes as desired.

Note: *some sections do not have configuration options yet*

Create custom findings text: Select Auto Text findings options as desired. Once selected these statements can be moved to either the top or bottom of findings section using the mock up.

Note: *auto text populates according to the interactive diagrams included in the LV Regional Findings and/or Coronary Status sections.*

To add custom findings statements, type directly into the bullet point(s) in the report mockup *findings* section.

To add quantitative values, and/or their associated normal ranges and classification (e.g. normal, increased, decreased) click and drag the values into the desired location in the findings text.

Note: *The cursor will change to a hand for values that can be moved to findings. The cursor will indicate in the mockup where that value will be placed.*

9.1.1.2 Default Templates

cvi42 will automatically apply a template based on modality. The default template for each modality will be indicated with either *MR* or *CT* at the bottom of the template icon.

To set/change the default, click on the desired template, and then click *MR Default* and/or *CT default* at the bottom of the column.

Note: *A single template can be assigned as the default for both MR and CT.*

9.1.2 Normal/Reference Ranges

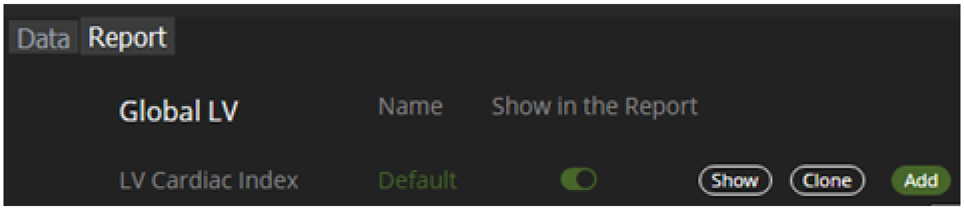
Normal ranges can be defined for most **cvi42** quantification parameters. Click on *Normal Ranges* page, to review, edit or create normal ranges.

Default normal ranges are provided. These values are not editable, however they can be cloned, and edits made there. The default values provided are based on the existing literature as follows:

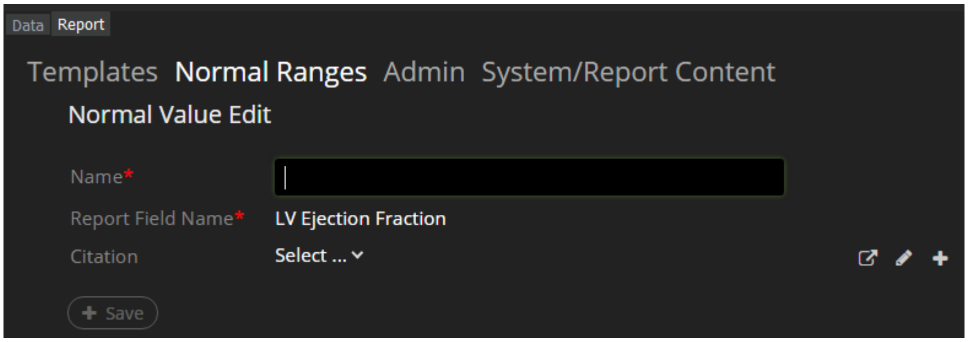
- *Normal human left and right ventricular and left atrial dimensions using steady state free precession magnetic resonance imaging Hudsmith LE, Petersen SE, Francis JM, Robson MD, Neubauer S. J Cardiovasc Magn Reson PubMed. 2005. 7:775-782.*
- *Height-Indexed Data from Normal human left and right ventricular and left atrial dimensions using steady state free precession magnetic resonance imaging. Hudsmith LE, Petersen SE, Francis JM, Robson MD, Neubauer S. Letter. 2006.*
- *Cardiovascular Magnetic Resonance in Myocarditis: A JACC White Paper. Friedrich MG, Sechtem U, Schulz-Menger J, Holmvang G, Alakija P, Cooper LT, White JA, Abdel-Aty H, Gutberlet M, Prasad S, Aletras A, Laissy JP, Paterson I, Filipchuk NG, Kumar A, Pauschinger M, Liu P. J Am Coll Cardiol PubMed. 2009. 53(17):1475-1487.*

⚠ **WARNING**: Normal Ranges are dependent on the acquisition, analysis, and reporting protocols used, and it is the responsibility of each institution to ensure the appropriate normal ranges are used.

1. Enabled normal ranges will be applied to all reports.
2. To enable a normal range, toggle the switch in the *Show in the Report* column.

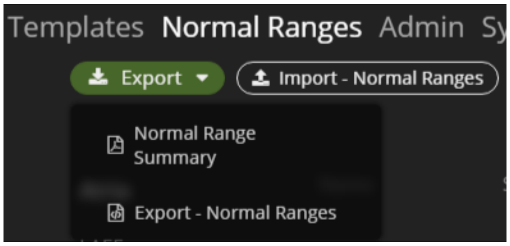


3. To add a new normal range, click on *Add*. Provide a name and citation details (click on +). Click *save*.



Report Field Name*: LV Ejection Fraction

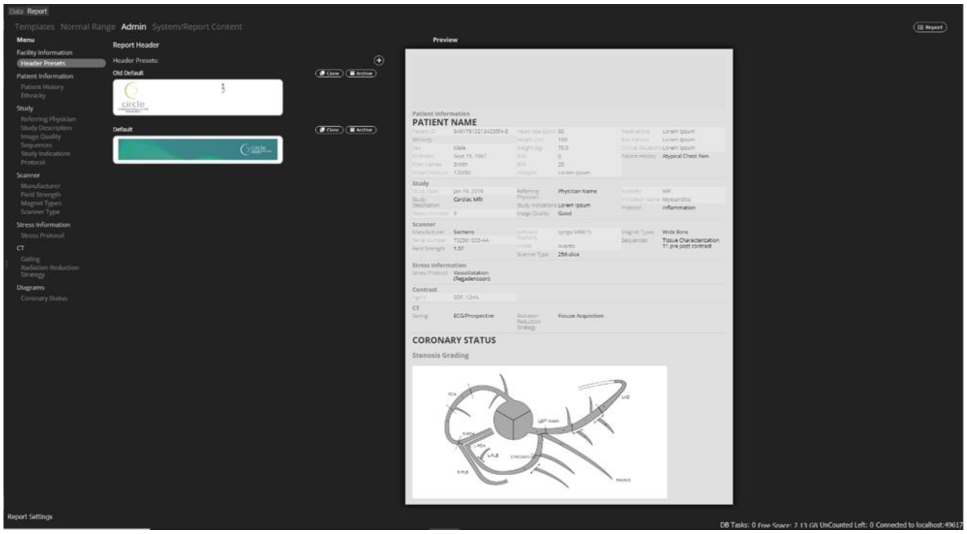
4. Enter *Normal Range* limits/details.
   - Ensure the *normal* value lines are checked
   - Ensure each entry line is saved
5. To delete a line, press the red *x*.
6. Normal ranges can be exported as a PDF or imported/exported using JSON files.
   - For export, click on the dropdown and select:
   - *Normal Range Summary* (PDF)
   - *Export – Normal ranges* (JSON)



To import normal ranges, click on *Import – Normal Ranges* and select the JSON file to import.

9.1.3 Admin

The report *Admin* page is used to configure headers, drop down fields, and the coronary diagram.
The different fields that can be configured are listed in the left column, details of the selected item in the middle column, and a mockup on the right.



9.1.3.1 Headers

- Header pre-sets allow for different report headers to be configured.
- To create a new header, click +.
- To edit an existing header, click *Edit*.
- To copy an existing header, click the *Clone* button.

There are two types of headers: logo or banner. Logo type headers provides fields for entering facility details in text and uploading of a logo image (max width 1500 px). Banner type headers allows for a header image to be uploaded (minimum 800px, recommended size 1200px).

9.1.3.2 Drop Down Lists

The majority of report field options provide configuration for drop down lists.

- To configure drop down lists, click on the desired field, and the field details will appear.
- To add new items, click on the + icon.
- To filter the list, start typing in the *search* field.
- To change view between 1 and 2 columns click on the *One Column*/*Two column* button.
- To edit or archive existing items, click on the item, then the pencil or trash can icon, respectively.

9.1.3.3 Sequences, Indications and Protocols

1. The sequences, study indication and protocol fields can be used independently, or a relationship between them can be established such that selecting the indication in the report, will auto-populate the protocol and sequences fields.
2. The sequences field is configured the same as a drop down.
3. Study Indications are lists of indications, grouped by “disease cluster”.
4. To create a disease cluster, click the + icon.
5. Enter the Disease Cluster name, and then click + to add Indication(s).
6. Multiple indications can be added at once.
7. Click Save.

8. To edit disease cluster/indication, click on *Edit* next to the Disease Cluster Name.
9. Protocols can be used as a drop down on its own, or to create the relationships between indications and sequences.

To create a protocol, click on the + icon.

- Enter the protocol name and select the related sequences and indication.
- Click *Save*.

Coronary Status

Coronary Status is used to configure the interactive coronary status diagram text and colours.

To add options, click *Add New* under the relevant details section.

- Enter text details and colour and save changes.
- To delete, click *x*.

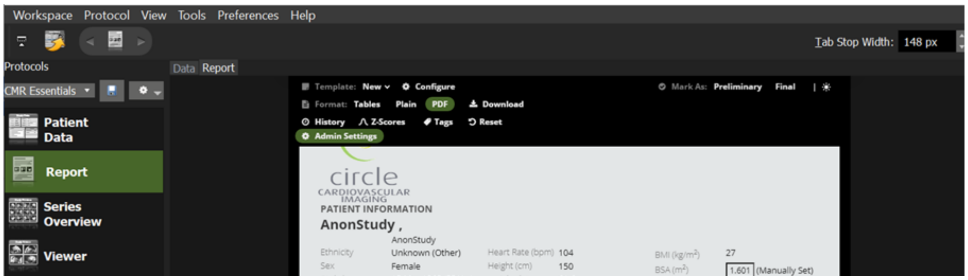
There is no edit function for these options.

9.2 Report Menu

The users will be able to interact with the report depending on their permissions (see Installation and Configuration Guide for details on assigning permissions). To view the report, users require “View reports” permission. To edit an in progress report and to create the preliminary report, users require “Preliminary reporter” permission. To edit a report in “preliminary” status and create the final report, as well as create and generate addendums, users require "Finalizing reporter” permission.

You can access the report by opening the Report module and on the top left selecting *Report*.

Hover the mouse on the top of the *Report Preview*, to display the Report status and options.



Tab Stop Width: 148 px

PATIENT INFORMATION

AnonStudy ,

AnonStudy

Ethnicity Unknown (Other)

Sex Female

Heart Rate (bpm) 104

Height (cm) 150

BMI (kg/m²) 27

BSA (m²) 1.601 (Manually Set)

9.2.1 Reset

To reset the report (i.e., delete all current data and reapply the default template), click on *Reset*. Only users with *Reset reports* permission can perform this action, password re-entry is required to confirm the action.

9.2.2 Light Mode/Dark Mode

Reports will load using the default template for the study modality. The top status bar will show the template name, report status, and light/dark mode.

9.2.3 Report Status

To change the status of the report, click on the desired status (i.e. preliminary or final). The current report Status will be displayed on the Study List.

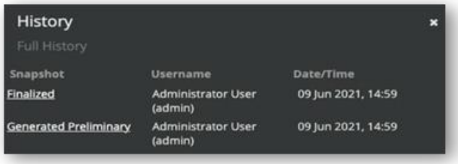
Note: *These options will only appear if the user has the associated permissions.*

9.2.4 Report History

On changing the status of the report, a PDF will be generated and available for viewing in *History*.

In the History pop up, you may select between *Full History* and *History* which will show report updates, and each status PDF respectively.

On finalising a report, a DICOM secondary capture of the report will be created.



History

Full History

Snapshot	Username	Date/Time
Finalized	Administrator User (admin)	09 Jun 2021, 14:59
Generated Preliminary	Administrator User (admin)	09 Jun 2021, 14:59

Full History

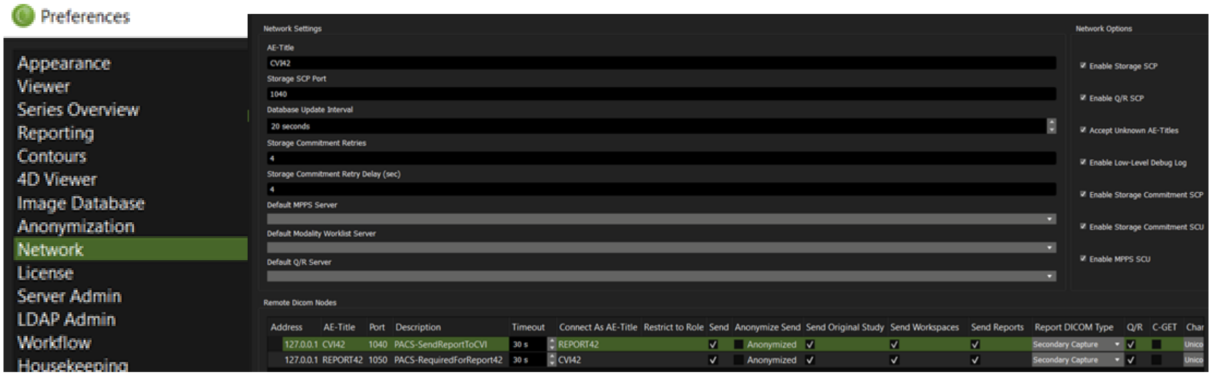
History

Date/Time	Username	Action
09 Jun 2021, 14:17:07	Administrator User (admin)	Imported Exam: Not Read
09 Jun 2021, 14:53:50	Administrator User (admin)	Imported Exam: In Progress
09 Jun 2021, 14:57:21	Administrator User (admin)	Imported Exam: In Progress
09 Jun 2021, 14:58:55	Administrator User (admin)	Changed Report State: Preliminary Report
09 Jun 2021, 14:59:47	Administrator User (admin)	Changed Report State: Final Report

9.2.5 Report DICOM SC or Encapsulated PDF Export

On finalizing a report, a DICOM secondary capture of the report can be saved to the study in the **cvi42** Server or can be sent to a PACS as a DICOM Encapsulated PDF. Therefore, you need to establish a DICOM connection between the Report and the **cvi42** Server and/or the PACS.

To establish a connection with the **cvi42** Server, go to the **cvi42** *Preferences*, select *Network*, and setup the two DICOM connections as shown on the image below (you need admin permissions to configure it):



Network Settings

AE-Title: CVI42
Storage SCP Port: 1040
Database Update Interval: 20 seconds
Storage Commitment Retries: 4
Storage Commitment Retry Delay (sec): 4
Default MPPS Server
Default Modality Worklist Server
Default Q/R Server

Network Options

☑ Enable Storage SCP
☑ Enable Q/R SCP
☑ Accept Unknown AE-Titles
☑ Enable Low-Level Debug Log
☑ Enable Storage Commitment SCP
☑ Enable Storage Commitment SCU
☑ Enable MPPS SCU

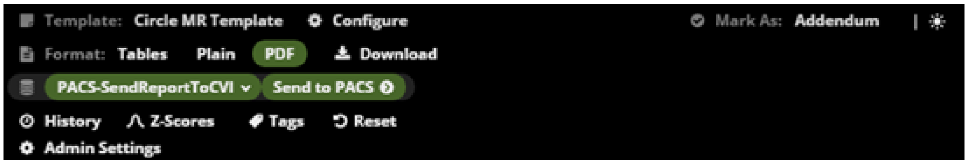
Remote Dicom Nodes

Address	AE-Title	Port	Description	Timeout	Connect As AE-Title	Restrict to Role	Send	Anonymize Send	Send Original Study	Send Workspaces	Send Reports	Report DICOM Type	Q/R	C-GET	Char
127.0.0.1	CVI42	1040	PACS-SendReportToCVI	30 s	REPORT42		✓	☐ Anonymized	✓	✓	✓	Secondary Capture	✓	☐	Unico
127.0.0.1	REPORT42	1050	PACS-RequiredForReport42	30 s	CVI42		✓	☐ Anonymized	✓	✓	✓	Secondary Capture	✓	☐	Unico

Note: cvi42 Client currently does not support the "Encapsulated PDF" Report DICOM Type.

You can also configure a DICOM connection to an external DICOM Node (e.g., hospital PACS) and configure it to send the reports as DICOM Encapsulated PDFs.

In the Report, hover over the top-menu bar to see the new DICOM connection. If the report has a final or an addendum status, then the DICOM connection options will be enabled, and you can send the DICOM Report to the PACS.

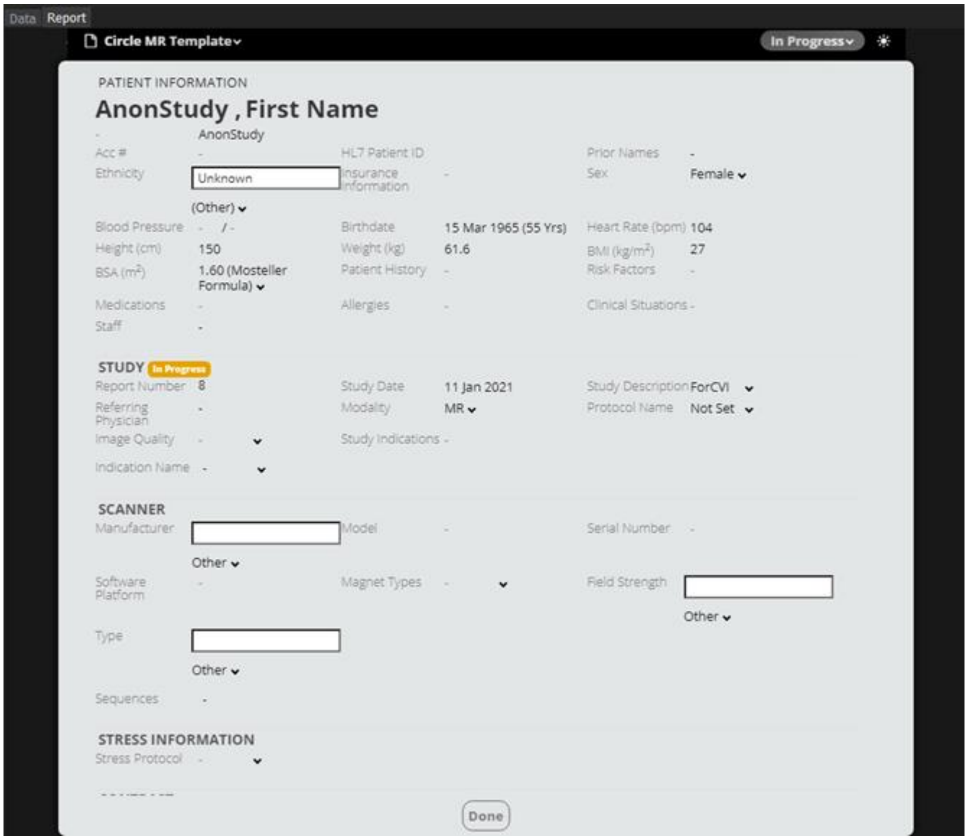


9.3 Create a Report

The report will open in print preview mode.

1. When you open the report of a study for the first time, the default template will be applied. This can be changed on the report Menu, at the top of the report preview, under *Templates*.

2. To add the measurements and results from a **cvi42** module to the report module, click on *Add to report*, on the top right of the toolbar of each module.
3. If a section in the report does not contain any data, then it will not be displayed in the report.
4. If a section is not part of the selected template and you send data from that section to the report, you will not see the results in the report. You have to add that section to the template in the *Templates* configuration page.
5. To make changes to the fields in a specific section of the report, click on the respective section to open the edit mode, make the necessary changes. Click on *Done*, to save the changes and close the edit mode. As an example, to add the patient height to the report, click on the *Patient Information* section.



PATIENT INFORMATION

AnonStudy , First Name

-	AnonStudy				
Acc #	-	HL7 Patient ID		Prior Names	-
Ethnicity	Unknown (Other)	Insurance Information	-	Sex	Female
Blood Pressure	- / -	Birthdate	15 Mar 1965 (55 Yrs)	Heart Rate (bpm)	104
Height (cm)	150	Weight (kg)	61.6	BMI (kg/m²)	27
BSA (m²)	1.60 (Mosteller Formula)	Patient History	-	Risk Factors	-
Medications	-	Allergies	-	Clinical Situations	-
Staff	-				

STUDY In Progress

Report Number	8	Study Date	11 Jan 2021	Study Description	ForCVI
Referring Physician	-	Modality	MR	Protocol Name	Not Set
Image Quality	-	Study Indications	-		
Indication Name	-				

SCANNER

Manufacturer	Other	Model	-	Serial Number	-
Software Platform	-	Magnet Types	-	Field Strength	Other
Type	Other				
Sequences	-				

STRESS INFORMATION

Stress Protocol	-

6. If gender, birthdate. height and weight are present as per the defined normal ranges, then the results will be classified accordingly.
7. Images collected during the analysis are available in the edit mode of each section.

8. To add an image to a section, click on that section to open the edit mode and drag-and-drop into the designated *Drag Image Here* areas. Click on *Done*, to save the changes and close the edit mode.
    - To import additional images from your desktop to the report, click on the *Images* section at the bottom of the report, drag-and-drop the image from the desktop into the designated *Drag Image Here* area.
    - Image captions can be edited in the edit mode by clicking on the text directly below the image.
    - Deleting an image from the report section will return the image to the Image section of the edit mode.
9. Images collected during the analysis are available in the edit mode of each section.
10. To add an image to a section, click on that section to open the edit mode and drag-and-drop into the designated *Drag Image Here* areas. Click on *Done*, to save the changes and close the edit mode.
    - To import additional images from your desktop to the report, click on the *Images* section at the bottom of the report, drag-and-drop the image from the desktop into the designated *Drag Image Here* area.
    - Image captions can be edited in the edit mode by clicking on the text directly below the image.
    - Deleting an image from the report section will return the image to the *Image* section of the edit mode.
11. Once all the data has been added to the report, review and/or add findings and write the summary.
12. To generate a final report, click on *Final* on the Report Menu pane, at the top right of the report preview. A PDF of this report is stored under *History* in the Report Menu pane.

Once the report is completed, go to the Report Menu pane, chose the download format and select *Download* and/or send it to **cvi42** Server and/or PACS.

9.4 Update a Report

Update before finalization, after contour corrections or recalculations: In the module click *Add to Report*. The report should automatically update, which might take a few seconds. If it does not automatically update, close and re-open the study.

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*.

9.5 Delete a report

To start with a new report, use the reset report option on the top menu bar and the software will create a new empty report.

10 Series Overview

Module overview:

- 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

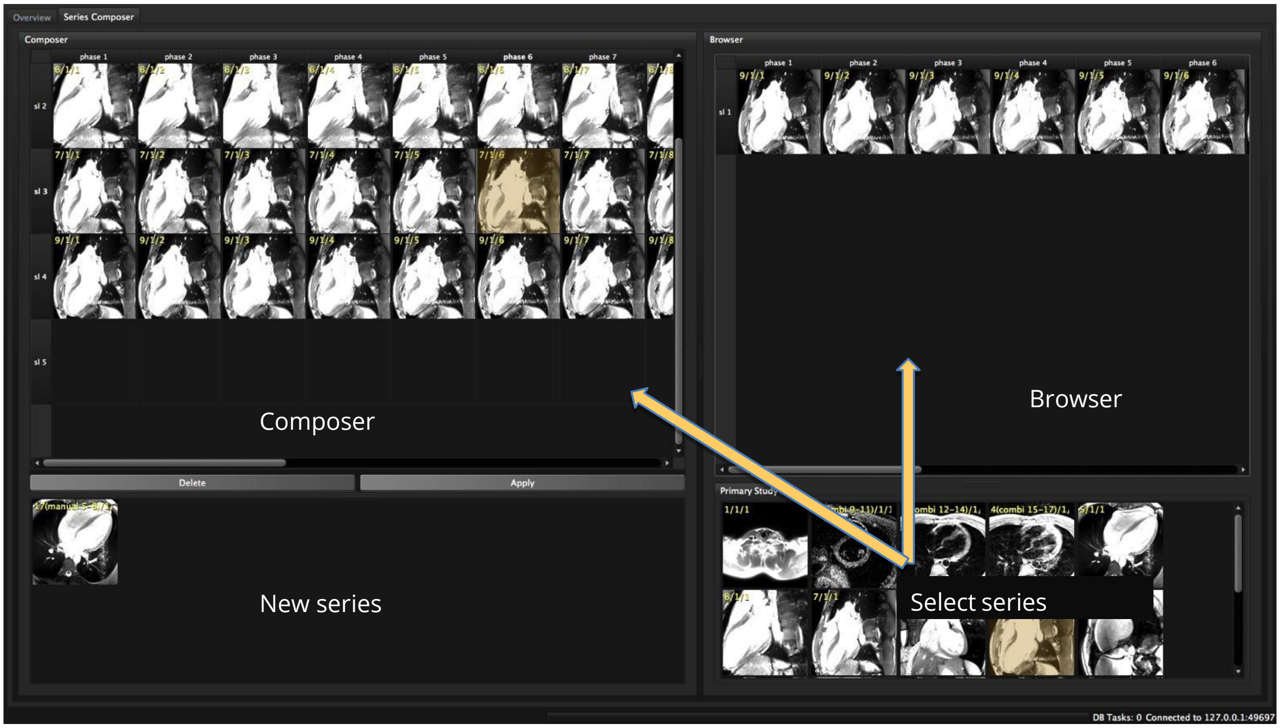
1. Drag and drop it into one of the modules in the module pane.

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.

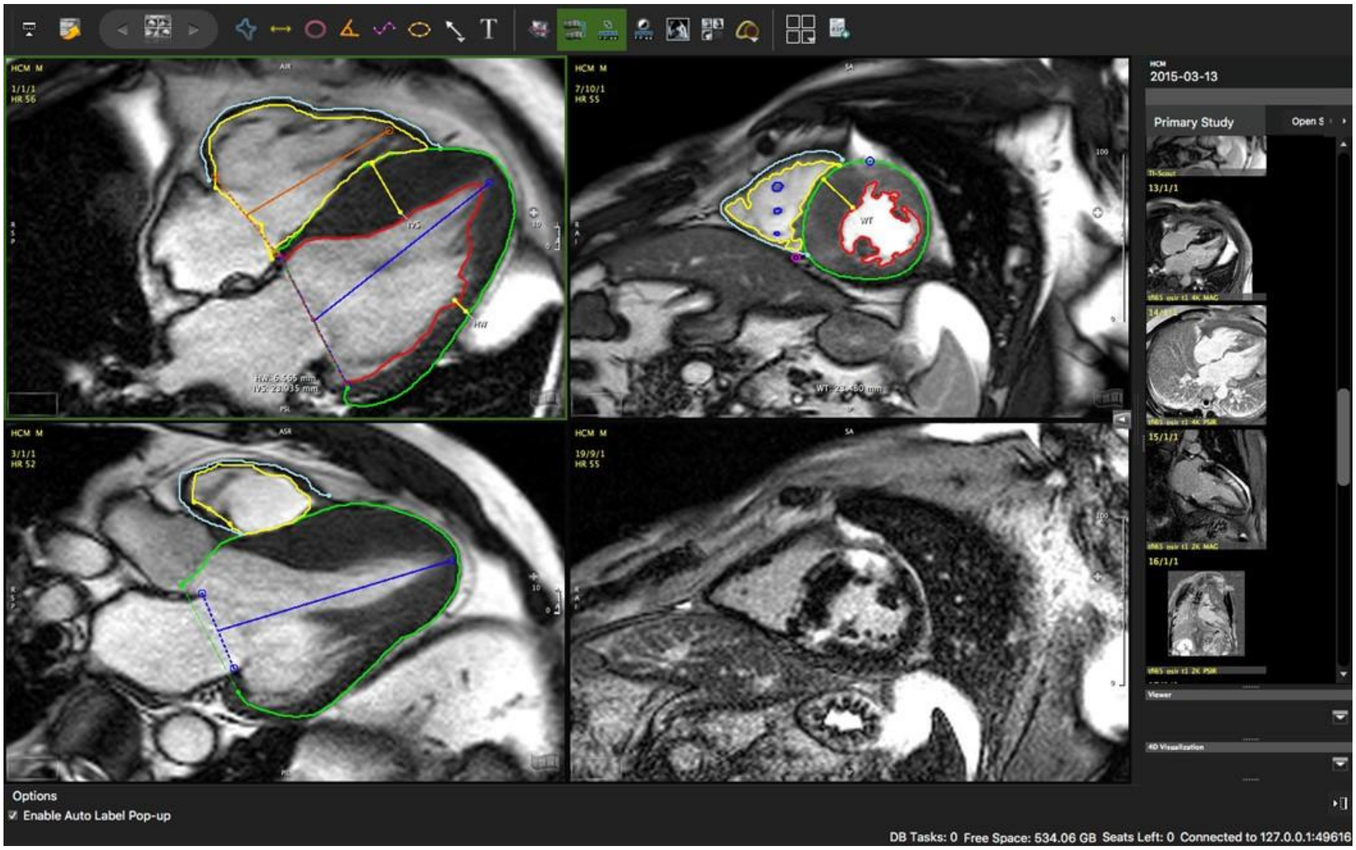


1. Drag a series to the *Browser*, choose slices or phases and drag them into the composer.
2. A complete series can be dragged directly to the composer.
3. For sequence information (e.g. trigger time or slice location) hover over an image.
4. In the *Composer* select the phase/slice or series and use the context menu to remove, insert or sort images.
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



☑ Enable Auto Label Pop-up

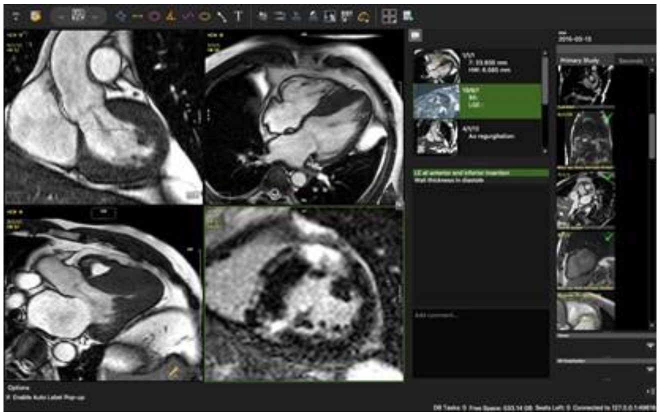
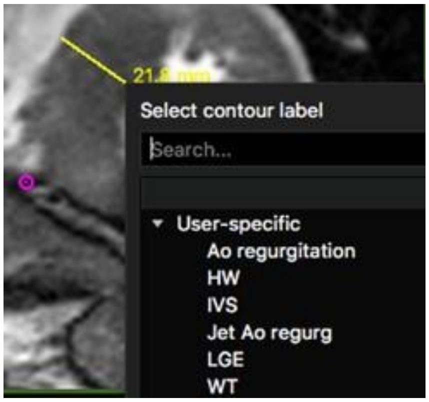
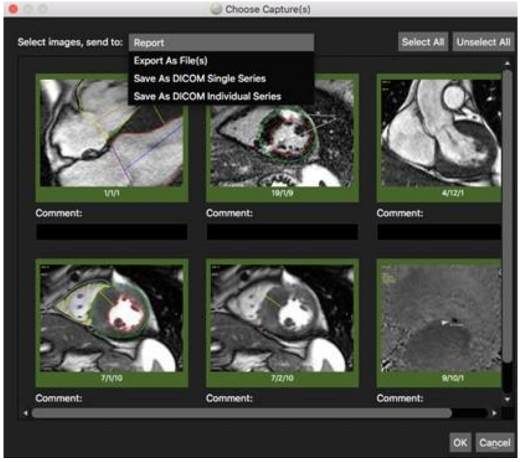
DB Tasks: 0 Free Space: 534.06 GB Seats Left: 0 Connected to 127.0.0.1:49616

Module overview:

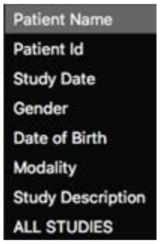
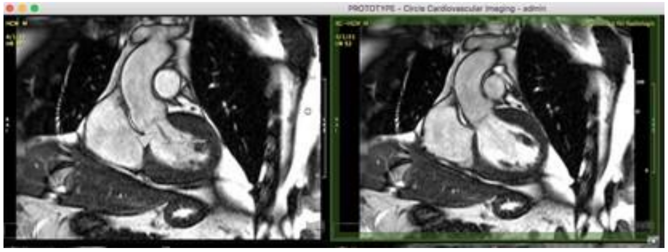
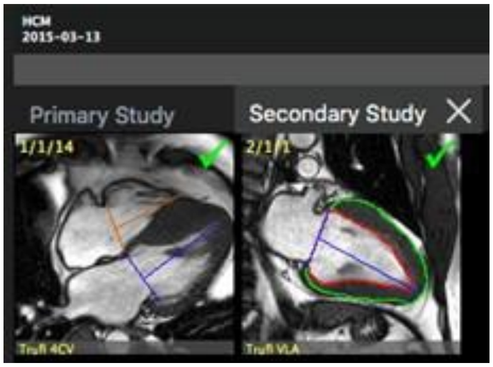
- View and compare multiple sequences next to each other.
- View and compare multiple scans of one patient next to each other.
- Perform and automatically capture measurements.
- Add contour labels and annotations.
- Add comments/findings that will be pushed to the report *Findings* section.

When using the Study Viewer Module, if the preference *Auto-loading and auto-contouring* is enabled, **cvi42** will auto-load an appropriate SAX CINE series into the first viewer frame and appropriate LAX CINE series will be auto-loaded into the subsequent frames.

11.1 Custom Measurements

• Open the measurement capture pane.	
• Perform measurement. • Label the contour. • Image and measurement will be captured automatically in the pane to the right.	
• Click the small camera to send captures to the report, Export or save them. • Optionally add a caption.	
• *Add Comment* and click enter. Comments will be listed underneath the captures. After adding them to the report, they will show in the findings section.	 Late Enhancement at anterior and inferior insertion Wall thickness in diastole

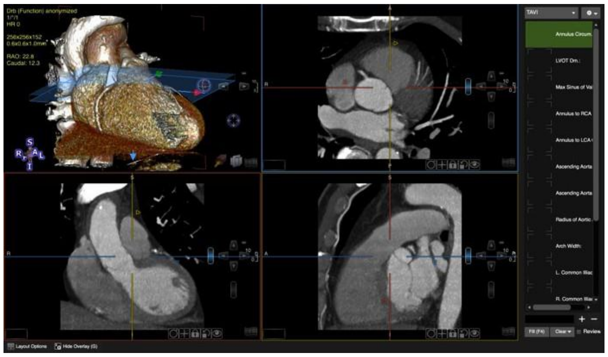
11.2 Compare Follow-up Scans

- Click *Open Secondary Study* in the thumbnail pane. - Select a Filter and type an identifier. - Click on the tabs and drag series in the viewer frame.	 Load Secondary Study Current Study : Patient Name HCM Patient Id unknown Study Date 2015-03-13 Gender M Modality MR Study Description MRT Herz Related Studies Of Current Patient Patient Name Patient Id Study Date Gender Date of Birth Modality Study Description BC -HCM unknown 2015-03-13 M 1965-05-20 MR 2015-03-13 Filter by Patient Name HCM 
- The secondary series will be marked by a green frame.	
- Click the 'X' to unload the series. - It is possible to do a measurement on the secondary series, but they will not be captured.	

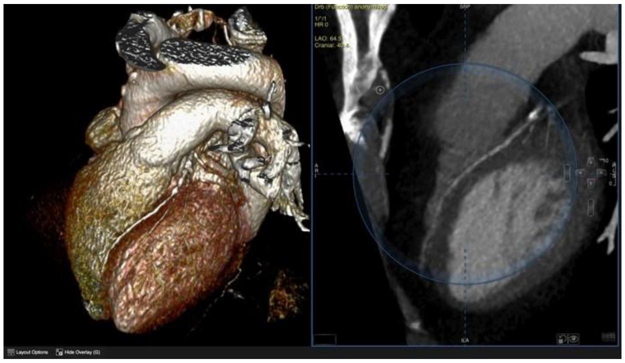
12 Multiplanar Reformatting

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

The MPR Module provides 2 tabs:



Double Oblique



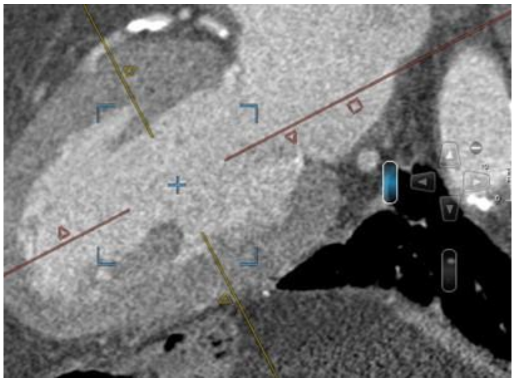
Free Form Navigation

12.1 Double Oblique

12.1.1 Navigation

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

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



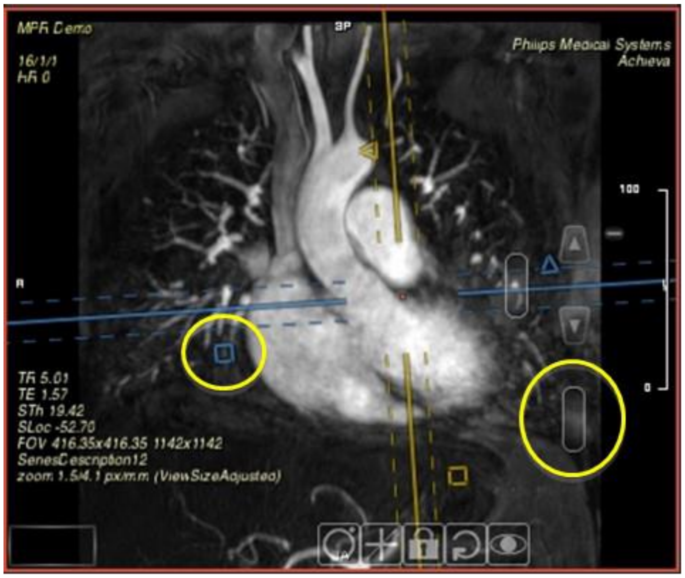
12.1.1.1 Crosshair Navigation

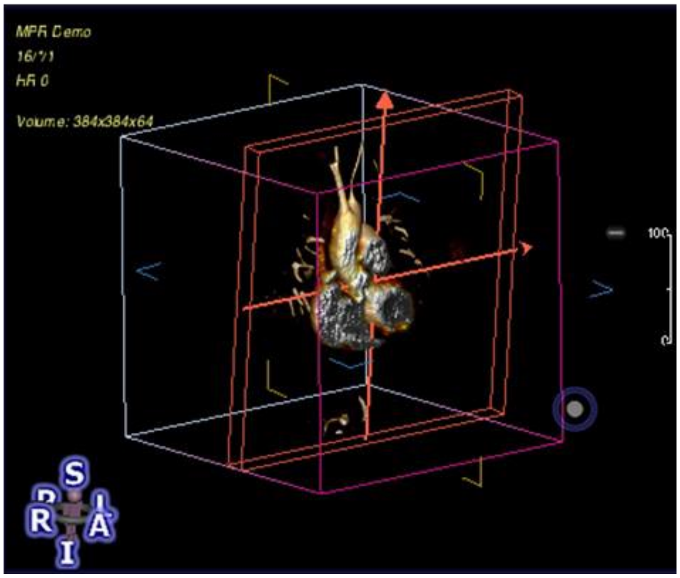
- Two color-coded orthogonal crosshairs within a viewport correspond to the frame with the same color.
- Drag the center of the crosshairs to reposition the MPR center. Alternatively, click in a region of interest within the Reference Viewer.
- Dragging a crosshair on a triangle will rotate around the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

- To move the crosshairs individually, open the context menu and select *Rotate Individual Plane*.
- Dragging on a square will adjust the slab thickness.

12.1.1.2 Adjust the Slab-Thickness

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

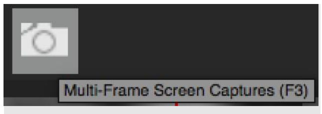




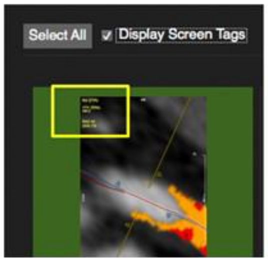
12.1.2 Reporting and Saving of Image Captures and Measurements

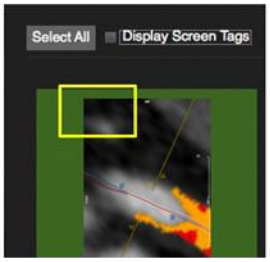
12.1.2.1 How to use Multi-Frame Screen Capture (top toolbar)

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

1. 

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





12.1.2.2 How to Save Measurement Captures

Add captures to the report.

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

Untitled
1: Min Dm. 31.8 mm
2: Max Dm. 33.9 mm
3: Area 8.418 cm²

STJ
1: Min Dm. 26.9 mm
2: Max Dm. 30.3 mm
3: Area 6.251 cm²

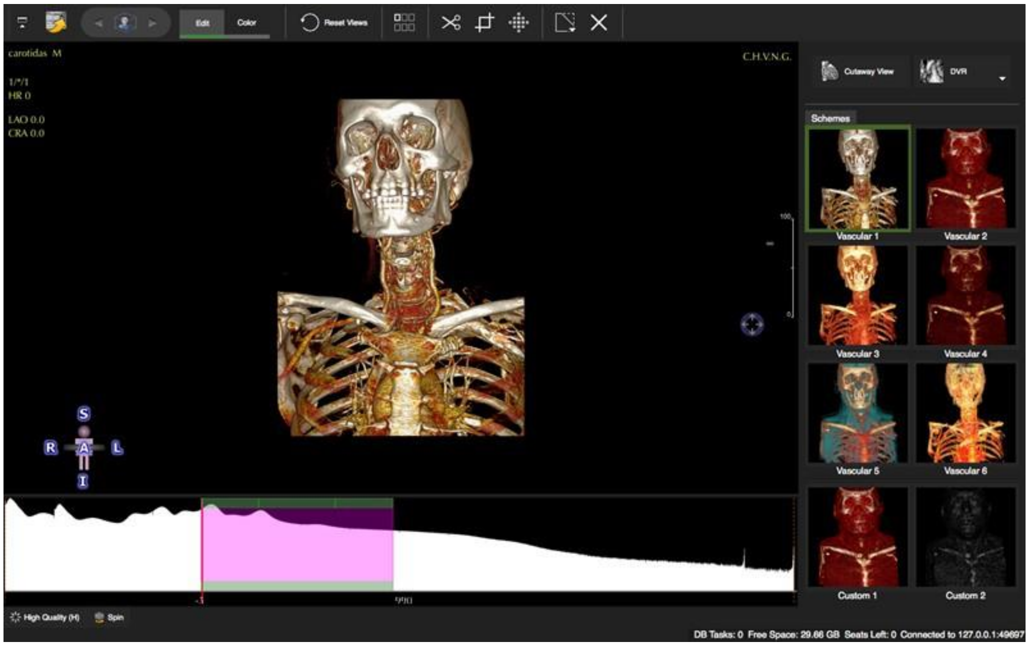
Sinus
1: Length 30.8 mm
2: Length 30.6 mm
3: Length 29.8 mm

12.2 Navigation Tab

1. Select the MPR viewer Frame and click the *Navigation* sub-module button.
2. Move the MPR center by clicking in your ROI.
3. *Slice Navigation*: left mouse drag or by dragging the slice navigation slider.
4. Toggle on *Rotate Image* to freely rotate with a mouse drag within the circle.
5. When in *Slice Navigation*, you can still freely navigate initiating your mouse drag in the shaded area, of 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

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*.



DB Tasks: 0 Free Space: 29.66 GB Seats Left: 0 Connected to 127.0.0.1:49697

13.1 Edit

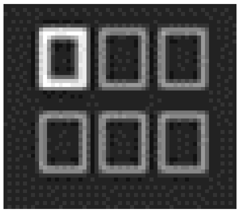
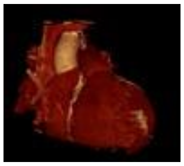
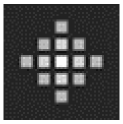
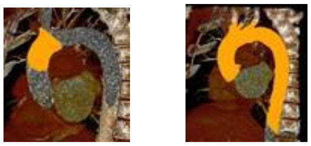
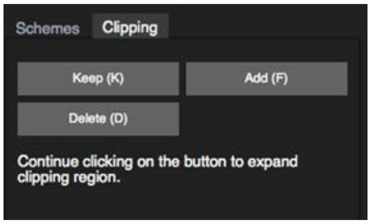
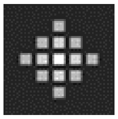
- Drag a 3D, 4D or stacked 2D image data set into the viewer frame.
- The right-side panel offers different rendering options as well as a *Cutaway View*, to scroll through a volume in this view press *Ctrl+Alt* and drag the LMB.

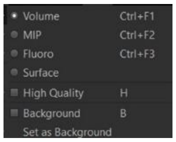
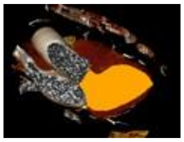
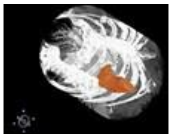
13.1.1 Measurement Option

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

13.1.2 Segmentation

13.1.2.1 How to Do an Automatic Segmentation

• Select the *Region of Interest*. • Select one of four options.	 
ROI-Heart: • The heart will be segmented automatically.	
ROI - User defined: • Activate the *Cutaway* button (former *View Clip*).	
• Activate the 3D Region Grow Clip.	
• Point the cursor in the middle of your ROI and drag.	
• When you are done, go to the clipping pane and click *Keep*.	 Continue clicking on the button to expand clipping region.
• Turn off the grow button.	 

• Optionally, add a background: *Context Menu* > *Rendering* > *Background*.	 
ROI-LV: • Repeat steps 1-6.	 
• No Region of Interest. • Will display the original volume.	

13.1.2.2 How to Use Clipping and Cropping

1. Select the tool from the tool bar and select a drawing mode from the tool pop-up menu (default=freehand).
2. *Cut:* Drag the mouse cursor to encircle structures you would like to remove.
3. *Crop:* Drag the mouse cursor to encircle things you would like to keep.
4. *Grow*: Move the cursor over the region of interest. A black dot will indicate the software has detected a structure that can be segmented. A red square will appear over a structure that has already been segmented. Dragging the cursor downwards will define the region of interest according to the SI threshold. Dragging the cursor sideways will increase the threshold, taking more SI into account.
5. To rotate or pan the volume while in clipping mode, move the mouse over the icons and drag.

13.2 Color

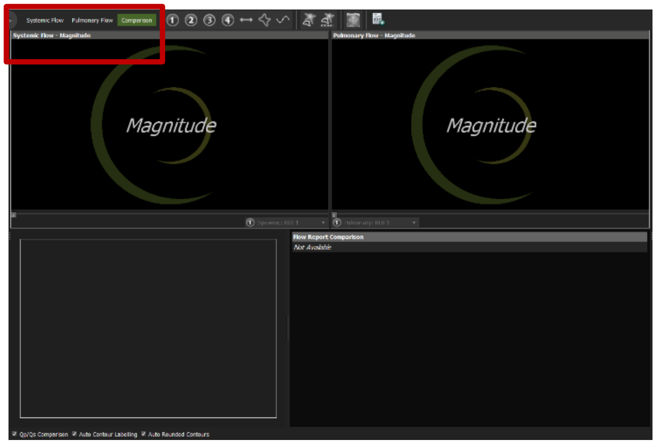
- **Ambient** Light: simulates surrounding light.
- **Diffuse** Light: light that reflects into all directions.
- **Specular** Light: simulates the light reflection on the surface depending on the vantage point.
- **Shininess**: increases the highlights.

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

14 Flow|2D

2D Flow) Module overview:

- Quantification and visualization of vessels blood flow and derived parameters
- Shunt assessment (Qp/Qs)
- Automatic and semiautomatic contour detection, contour synchronization and forwarding
- Color-coded flow display
- Automatic calculations of flow parameter (for through plane velocity encoding series only)



14.1 Flow Quantification

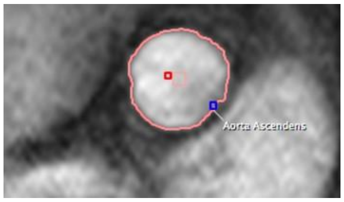
If the preference *Auto-loading and auto-contouring* is enabled, **cvi42** will auto-load and auto-contour an appropriate Aorta PC series into the first tab (Flow Series 1 or Systemic Flow) and will auto-load and auto-contour an appropriate Pulmonary Artery (PA) PC series into the second tab (Flow Series 2 or Pulmonary Flow). Upon loading the Aorta series, **cvi42** will also auto-load a 3CV cine series into the Floating Viewer and will display a cross-reference line, showing the location of the auto-loaded Aorta series.

The user shall review the automated results and correct them if necessary.
The *Flow Series 1/Systemic Flow*, *Flow Series 2/Pulmonary Flow* and *Comparison* tabs are located at the top of the module.

14.1.1 How to Do a Flow Analysis

1. Load a 2D Flow series into one of the viewports (Phase or Magnitude).
2. For color encoded flow display click on the *Toggle Flow Overlay* button.
3. To reduce noise, the threshold color overlay can be adjusted.Use the Ai Aorta or the Ai Pulmonary Artery contour tools to automatically segment the Aorta or the Pulmonary Artery on all phases of the current slice or on a specific phase/image of the loaded series. Slice Ai Ao Image Ai PA
4. Alternatively, use the Aorta or the Pulmonary contour tools to manually segment the Aorta or the Pulmonary Artery on all phases or on a specific phase. Ao PA
5. Use ROI 1, 2, 3, or 4 to manually define a vessel border on a specific phase. ①
6. Label the contour.

7. 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.



8. Scroll through phases to ensure the contours are correct.

14.1.2 How to Do a Flow Correction

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

Background correction options:

- Offset Correction: Define Static Tissue mask (yellow) with the slider. Manually exclude regions that should not be part of the static tissue mask, e.g. spatial aliasing, using the *Erase Mask* tool .
- Phantom Correction: Drag the phantom image in the box.
- Background Correction (BC): Click on BC, draw and forward (use context menu command) a ROI in an area with no flow.

If **cvi42** detects a GE PC series with inline background correction, it will disable the **cvi42** background correction options, to avoid that users apply a correction on the already corrected data.

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

14.1.3 How to Display Flow Curves

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

15 Function Modules

15.1 Function|Biplanar LAX Module

Module overview:

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

⚠ **WARNING**: The Long Axis Strain results are to be used for research purposes only, and not for primary diagnostics and direct patient care.

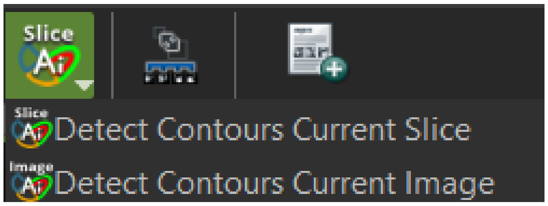
WARNING: Function|Biplanar LAX
For the calculations, the diastolic and systolic phase are assumed to be in the same phase of the cardiac cycle in all three views. The volume calculation is done per phase. The smallest volume is assumed to be the systolic volume and the largest volume is assumed to be 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.

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

When using the Function|Biplanar LAX Module, if the preference *Auto-loading and auto-contouring* is enabled, **cvi42** will auto-load an appropriate 2CV LAX CINE series into the first viewer frame and appropriate 4CV LAX CINE series into the subsequent frame. The user shall review the automated results and correct them if necessary.

15.1.1 How to do Biplanar LAX Automatic Contour Detection

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

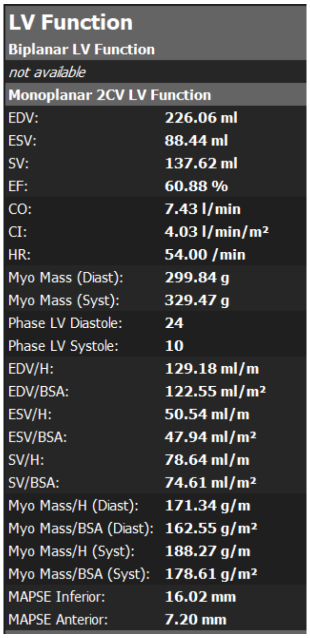


- Right-mouse clicking on the AI tool will open a dropdown menu with the available AI options.
- Choose an option and activate it with LMB click.
- Check the contours and correct if necessary.
- Add the analysis to report.

The on-screen report is split into 3 tabs:

- LV Function
- Long Axis Strain
- Atrial Function

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



LV Function

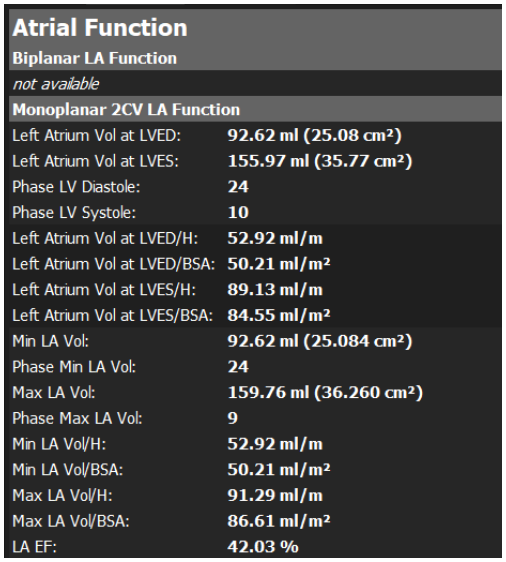
Biplanar LV Function

not available

Monoplanar 2CV LV Function

EDV:	**226.06 ml**
ESV:	**88.44 ml**
SV:	**137.62 ml**
EF:	**60.88 %**
CO:	**7.43 l/min**
CI:	**4.03 l/min/m^2**
HR:	**54.00 /min**
Myo Mass (Diast):	**299.84 g**
Myo Mass (Syst):	**329.47 g**
Phase LV Diastole:	**24**
Phase LV Systole:	**10**
EDV/H:	**129.18 ml/m**
EDV/BSA:	**122.55 ml/m^2**
ESV/H:	**50.54 ml/m**
ESV/BSA:	**47.94 ml/m^2**
SV/H:	**78.64 ml/m**
SV/BSA:	**74.61 ml/m^2**
Myo Mass/H (Diast):	**171.34 g/m**
Myo Mass/BSA (Diast):	**162.55 g/m^2**
Myo Mass/H (Syst):	**188.27 g/m**
Myo Mass/BSA (Syst):	**178.61 g/m^2**
MAPSE Inferior:	**16.02 mm**
MAPSE Anterior:	**7.20 mm**

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



Atrial Function

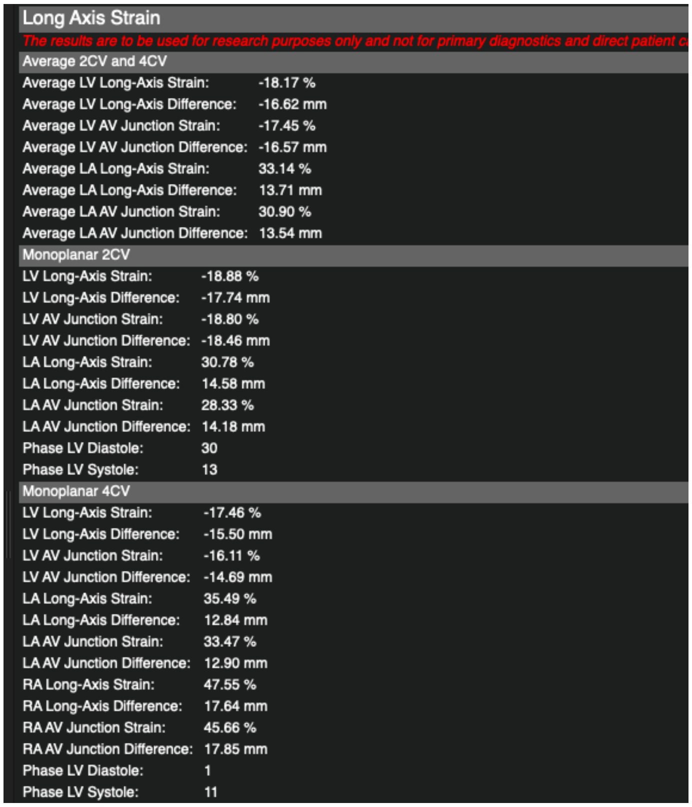
Biplanar LA Function

not available

Monoplanar 2CV LA Function

Left Atrium Vol at LVED:	**92.62 ml (25.08 cm^2)**
Left Atrium Vol at LVES:	**155.97 ml (35.77 cm^2)**
Phase LV Diastole:	**24**
Phase LV Systole:	**10**
Left Atrium Vol at LVED/H:	**52.92 ml/m**
Left Atrium Vol at LVED/BSA:	**50.21 ml/m^2**
Left Atrium Vol at LVES/H:	**89.13 ml/m**
Left Atrium Vol at LVES/BSA:	**84.55 ml/m^2**
Min LA Vol:	**92.62 ml (25.084 cm^2)**
Phase Min LA Vol:	**24**
Max LA Vol:	**159.76 ml (36.260 cm^2)**
Phase Max LA Vol:	**9**
Min LA Vol/H:	**52.92 ml/m**
Min LA Vol/BSA:	**50.21 ml/m^2**
Max LA Vol/H:	**91.29 ml/m**
Max LA Vol/BSA:	**86.61 ml/m^2**
LA EF:	**42.03 %**

The *Long Axis Strain* tab contains strain related data as summarized below. Note: this is not for clinical use and results are sent only to scientific data.



Long Axis Strain

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

Average 2CV and 4CV
Average LV Long-Axis Strain: -18.17 %
Average LV Long-Axis Difference: -16.62 mm
Average LV AV Junction Strain: -17.45 %
Average LV AV Junction Difference: -16.57 mm
Average LA Long-Axis Strain: 33.14 %
Average LA Long-Axis Difference: 13.71 mm
Average LA AV Junction Strain: 30.90 %
Average LA AV Junction Difference: 13.54 mm

Monoplanar 2CV
LV Long-Axis Strain: -18.88 %
LV Long-Axis Difference: -17.74 mm
LV AV Junction Strain: -18.80 %
LV AV Junction Difference: -18.46 mm
LA Long-Axis Strain: 30.78 %
LA Long-Axis Difference: 14.58 mm
LA AV Junction Strain: 28.33 %
LA AV Junction Difference: 14.18 mm
Phase LV Diastole: 30
Phase LV Systole: 13

Monoplanar 4CV
LV Long-Axis Strain: -17.46 %
LV Long-Axis Difference: -15.50 mm
LV AV Junction Strain: -16.11 %
LV AV Junction Difference: -14.69 mm
LA Long-Axis Strain: 35.49 %
LA Long-Axis Difference: 12.84 mm
LA AV Junction Strain: 33.47 %
LA AV Junction Difference: 12.90 mm
RA Long-Axis Strain: 47.55 %
RA Long-Axis Difference: 17.64 mm
RA AV Junction Strain: 45.66 %
RA AV Junction Difference: 17.85 mm
Phase LV Diastole: 1
Phase LV Systole: 11

15.1.2 How to Do manual Biplanar LV Function Analysis

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

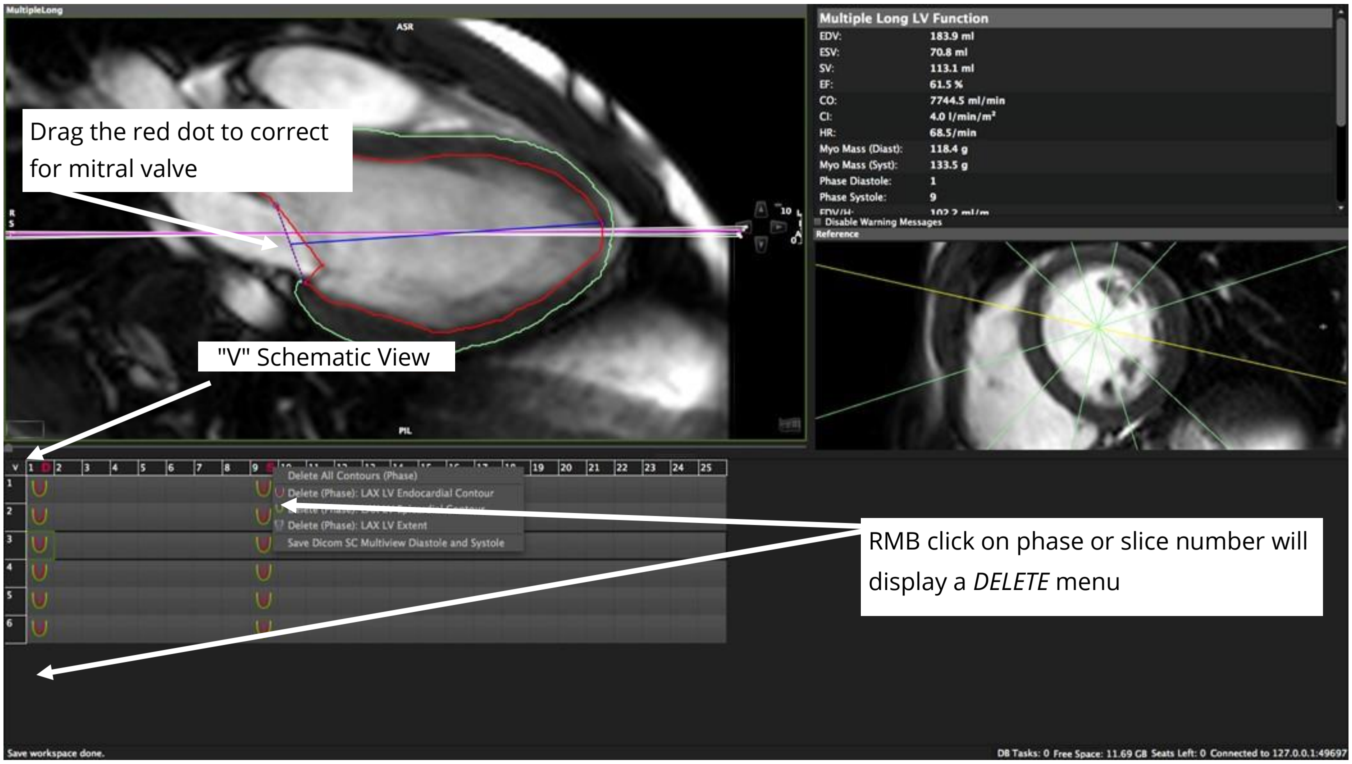
15.2 Function|Radial LAX Module

Module overview:

LV function volume and mass analysis.

WARNING: Function|Radial LAX
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.
The volume calculation is performed for every phase. The smallest volume is assumed to be the systolic volume and the largest volume is assumed to be the diastolic volume. If the volume can only be calculated for one phase, ESV and EDV will be displayed as equal and no further calculations are done.
Missing contours are interpolated, if possible.
Calculations are performed based on the current state of contour definition and image selections. For every change in this state the calculations are updated immediately. It is the responsibility of the user to verify that the contours reflect the desired measurements before releasing final results.

When using the FunctionRadial LAX Module, if *Auto Load Series in Module* is enabled, **cvi42** will auto-load an appropriate multiple Long LAX CINE series into the first viewer frame and appropriate SAX CINE series into the reference frame.



Multiple Long LV Function

EDV:	183.9 ml
ESV:	70.8 ml
SV:	113.1 ml
EF:	61.5 %
CO:	7744.5 ml/min
CI:	4.0 l/min/m²
HR:	68.5/min
Myo Mass (Diast):	118.4 g
Myo Mass (Syst):	133.5 g
Phase Diastole:	1
Phase Systole:	9

Drag the red dot to correct for mitral valve

"V" Schematic View

RMB click on phase or slice number will display a *DELETE* menu

15.2.1 How to Assess LV Function with Multiple Radial LAX

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

15.2.2 How to Create a Ventricular Volume/mass Curve

1. Define endocardial and epicardial contours in all phases and slices.
2. Click LV volume curve.

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

15.3 Function|SAX Module

Module overview:

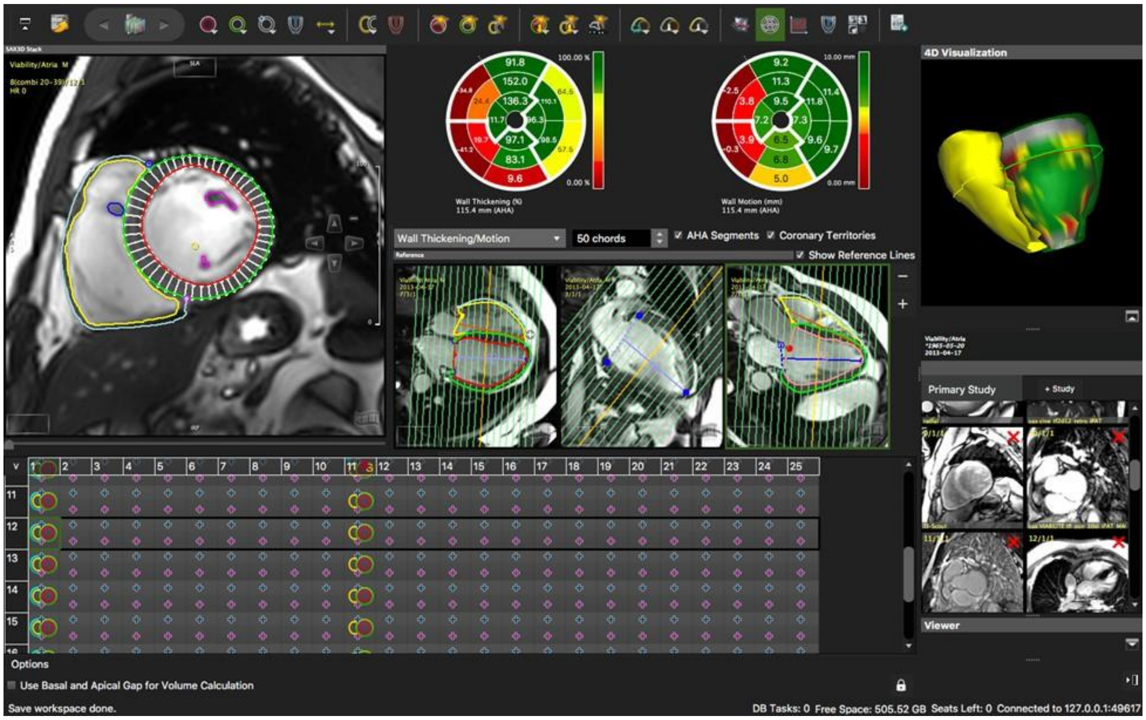
Using the disc-summation technique this module can analyze a stack of parallel images in long, short or axial orientations:

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

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

When using the Function|SAX Module, if *Auto Load Series in Module* is enabled, **cvi42** will auto-load an appropriate SAX CINE stack into the first frame, a 4CV LAX CINE series into the first reference frame, a 3CV LAX CINE series into the second reference frame, and a 2CV LAX CINE series into the third reference frame. **cvi42** will also generate contours at the end-diastolic and end-systolic phases (ED/ES) of the CINE series as per the contours preferences. The user shall review the automated results and correct them if necessary.

15.3.1 Function|SAX Interface



Wall Thickening/Motion ▾ | 50 chords | ☑ AHA Segments | ☑ Coronary Territories

☑ Show Reference Lines

Options

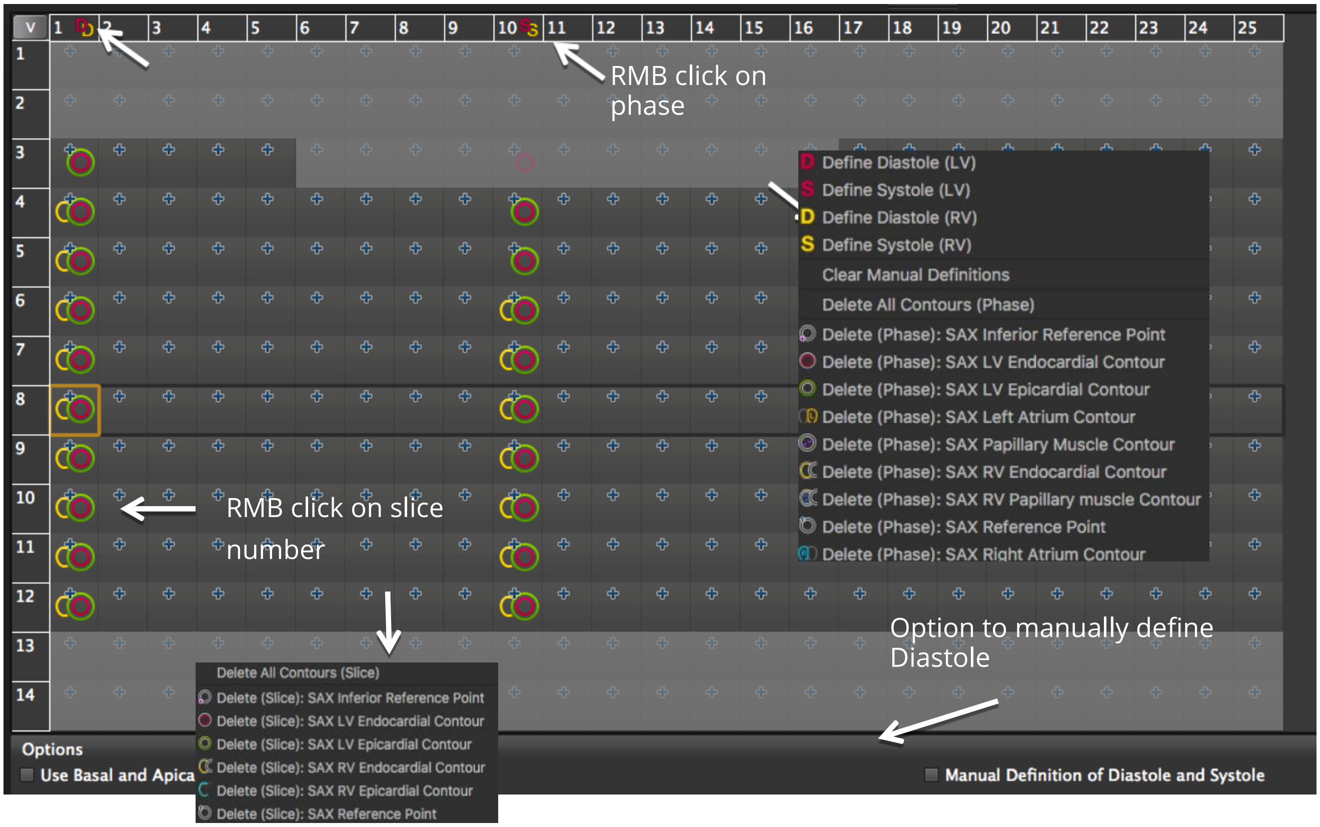
☐ Use Basal and Apical Gap for Volume Calculation

Save workspace done.

DB Tasks: 0 Free Space: 505.52 GB Seats Left: 0 Connected to 127.0.0.1:49617

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

RMB click on slice number

Option to manually define Diastole

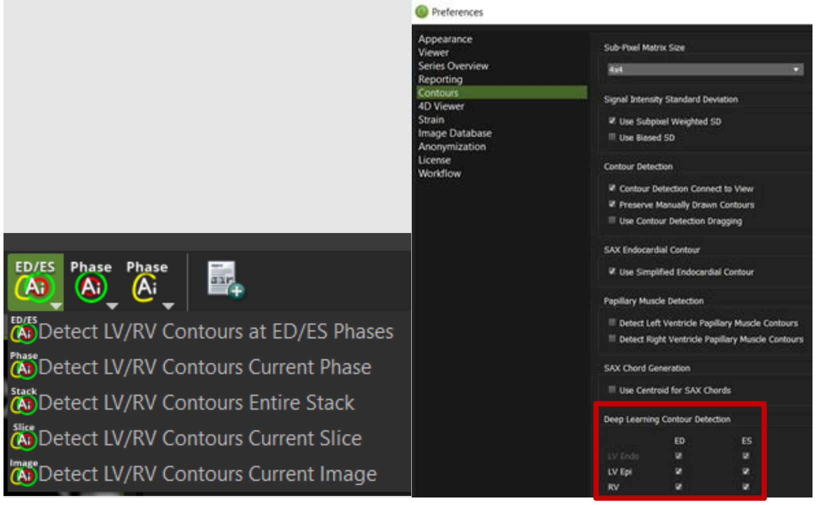
RMB click on phase number:

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

15.4 Global LV Function and Volume Analysis

15.4.1 How to Do Fully Automatic LV/RV Segmentation

- There are three main AI icons .
- Right-mouse clicking on each of the AI tools will open a dropdown menu with other AI contour detection options.
    - Detects LV (endocardial and epicardial) and RV (endocardial) contours on the selected image, phase, slice, entire stack, or at end-diastolic and end-systolic phases (ED/ES). The LV and RV contours that are detected with the option ED/ES can be customized in *Preferences → Config → Contours → Deep Learning Contour Detection* (all options are checked by default).



Sub-Pixel Matrix Size: 4x4

Signal Intensity Standard Deviation
☑ Use Subpixel Weighted SD
☐ Use Biased SD

Contour Detection
☑ Contour Detection Connect to View
☑ Preserve Manually Drawn Contours
☐ Use Contour Detection Dragging

SAX Endocardial Contour
☑ Use Simplified Endocardial Contour

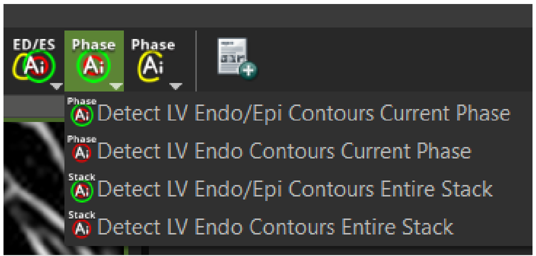
Papillary Muscle Detection
☐ Detect Left Ventricle Papillary Muscle Contours
☐ Detect Right Ventricle Papillary Muscle Contours

SAX Chord Generation
☐ Use Centroid for SAX Chords

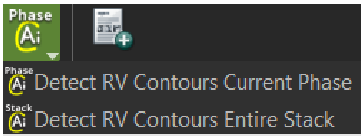
Deep Learning Contour Detection

	ED	ES
LV Endo	☑	☑
LV Epi	☑	☑
RV	☑	☑

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

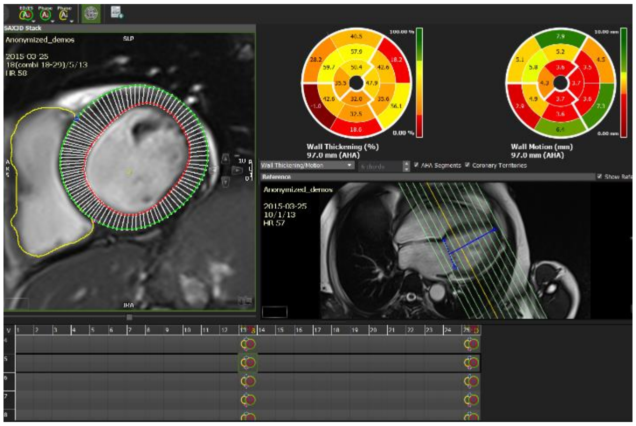


- - Detects RV endocardial contour on the selected phase or on the entire stack.



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

- With a single click on the ED/ES tool, the user obtains the onscreen report (EDV, ESV, EF, SV, etc..) and the Wall Thickening/Motion and Thickness polar maps:



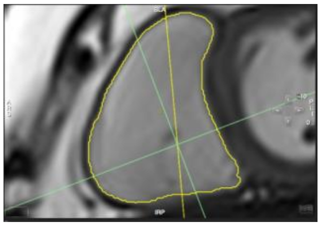
1. Select the AI tool of your choice as detailed above.
2. Once contours have been detected, move the mouse in the analysis frame and click 'm' for a multiview display.
3. Review the segmentation in all slices.
4. Correct where needed.
5. Click Add to Report.

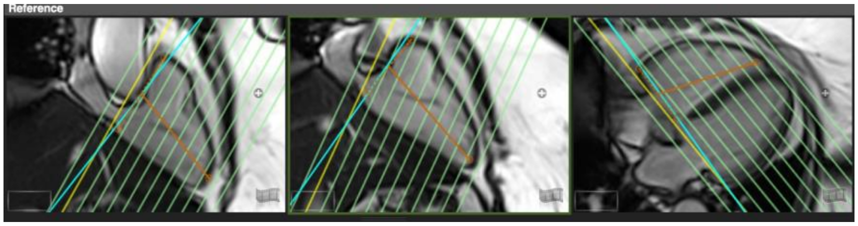
WARNING: Automatic Contour Detection
The expected input for the volume calculation in this module is a series containing parallel slice in the short axis direction.
Endocardial contours must always be inside the epicardial contour. **cvi42** does not check for that. In case of missing contours in one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

15.4.2 How to Do a Mitral/Tricuspid Valve Plane Correction

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

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





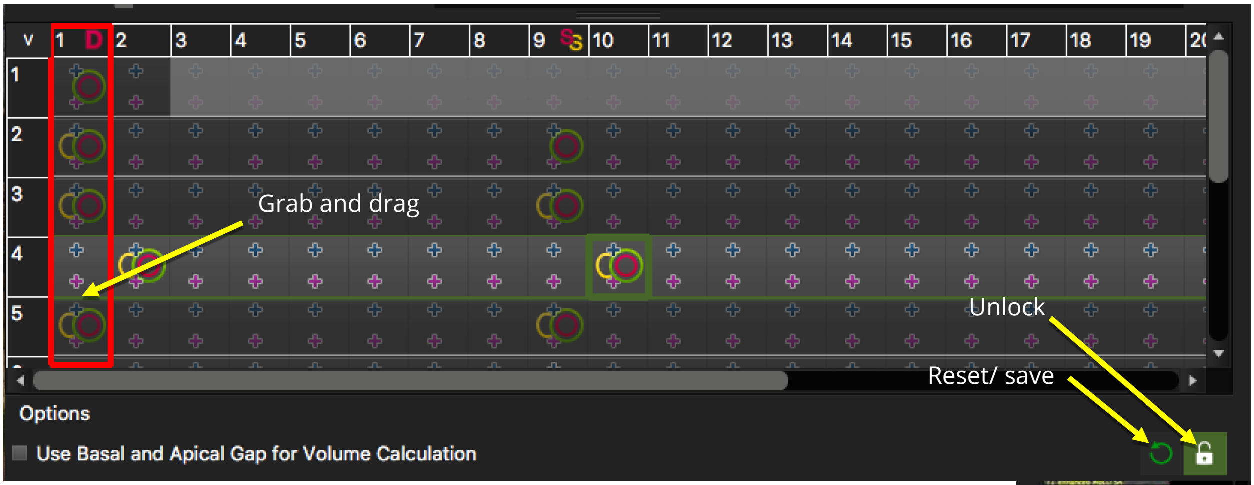
3. Using the *Cross-Reference* display, define the plane in two orthogonal orientations.

4. The correction will be calculated automatically.

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

15.4.3 How to Do Manual Phase Shifting Per Slice

In case of mis-triggered slices:



☐ Use Basal and Apical Gap for Volume Calculation

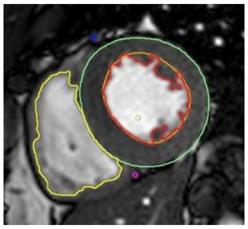
1. Click the lock.
2. In the slice, grab the box with correct diastolic phase and shift it into the red box.
3. Delete any existing contours that are outside diastolic and/or systolic phase.
4. Delineate the myocardium for the newly defined systole and diastole.
5. Click the lock again.
6. The phase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

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

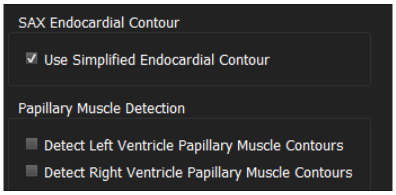
8. Load the new series and run the ML contour detection.

15.4.4 How to in/exclude Papillary Muscles

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



1. To exclude papillary muscle in the current image, use the Exclude Papillary tool.
2. To exclude them when using an automated contour detection method, go to the *Preferences/Contour*:



SAX Endocardial Contour

☑ Use Simplified Endocardial Contour

Papillary Muscle Detection

☐ Detect Left Ventricle Papillary Muscle Contours
☐ Detect Right Ventricle Papillary Muscle Contours

3. Check *Use Simplified Endocardial Contour.* Using automated edge detection, the software will apply a simplified contour, cutting offtrabecular structures.
4. De-select *Detect papillary muscle contours* to turn off the detection of papillaries within the LV lumen (pink contour).
5. Include papillary muscles in the current image: *SA papillary muscle contour tool*.

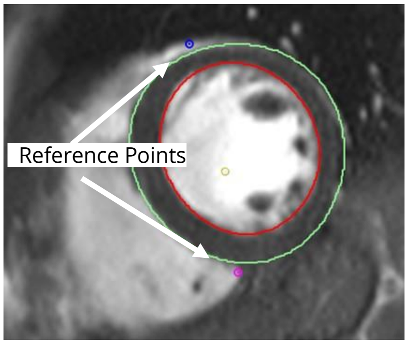
15.4.5 How to Create and Display a Volume Curve

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).

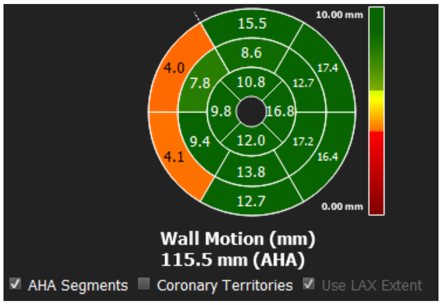
15.4.6 How to Do a Regional Wall Motion Analysis

1. Define the analysis range: Define length of anatomical long axis using the *LA LV Extent Contour* button. (see above).
2. Define reference points for the segmentation: In the analysis window select a mid-ventricular slice and set the points at the anterior and inferior insertion of the RV.



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

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



Wall Motion (mm)
115.5 mm (AHA)

☑ AHA Segments ☐ Coronary Territories ☑ Use LAX Extent

- *Chords*: Range between 2 and 100 chords. (segments will be counted clockwise).
- For non-AHA polar maps, there is the option to specify whether the LV LAX extent contour is used to define the spatial limits of the polar map representation. If *Use LAX extent* is turned off, the first and last slice in the LAX extent will define the spatial limits of the polar maps. When adding the polar map to the report, the LAX reference image, containing the LV LAX extent and SAX reference lines, will be attached to the report image. If *Use LAX extent* is turned on, the basal and apical points of the LAX extent will define the spatial limits of the polar map representation.
- AHA segmentation: Volumes per AHA segment will be reported in the Scientific Report.

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

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

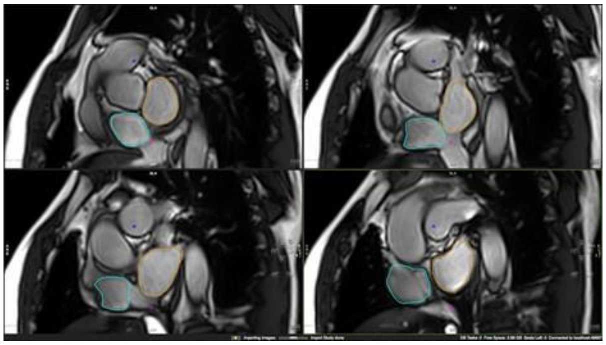
4. Add analysis to Report. Max. diastolic wall thickness will be reported in the scientific report.
5. Right-mouse Button click allows to export the polar map.
6. Repeat for all slices you want to include in the analysis.
7. Add analysis to Report.

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

15.4.7 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.

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



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

16 Tissue|Signal Intensity

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

When using the Tissue|Signal Intensity Module, if *Auto Load Series in Module* is enabled, **cvi42** will auto-load an appropriate Late Gadolinium Enhancement (LGE) series into the first frame and a LAX LGE series into the reference frame. If no LAX LGE series is available, **cvi42** will auto-load a LAX CINE series into the reference frame.

16.1 Analysis of LGE and T2 Images

16.1.1 How to Do Scar and Edema Analysis

1. Drag and drop series into the frames marked *Late Enhancement* and *T2* respectively.
2. Derive existing contours via *Context Menu/Contours/Derive Cardiac Contours*. If no contours are present, draw endocardial and epicardial contours for each slice.
3. *Synchronize Contours*: Provided that T2 and LGE images have the same slice location, contours will automatically be copied to the other frame.
4. *Segment Reference ROIs*: Automatically detect a reference ROI. The blue contour will depict the remote myocardium and the pink contour a reference ROI for FWHM algorithm in the enhanced area.

5. Toggle the *Overlay Display* to display a color overlay for scar and edema.
6. Use the *Exclude Enhancement* contour in case of e.g. artifacts.
7. Quantify MVO (see below for more information).
8. Click on *Display Result* to view the analysis.
9. Add measurements to report by clicking the *Add to Report* button.

16.1.2 How to Do T2 Ratio Analysis

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

16.1.3 How to Assess Microvascular Obstruction

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

16.1.4 How to Do Greyzone Analysis

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

16.1.5 How to Assess Salvaged Area at Risk

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

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

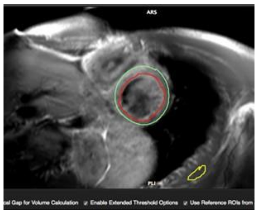
Note: It will **not** be calculated in case.

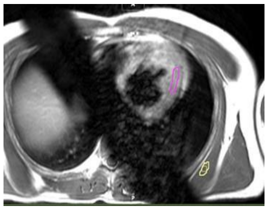
- slice locations are not matching.
- number of slices are not matching.
- there is a difference of myocardial volumes > 10%.

16.2 Early Enhancement

16.2.1 How to Assess the Early Gd Enhancement Ratio

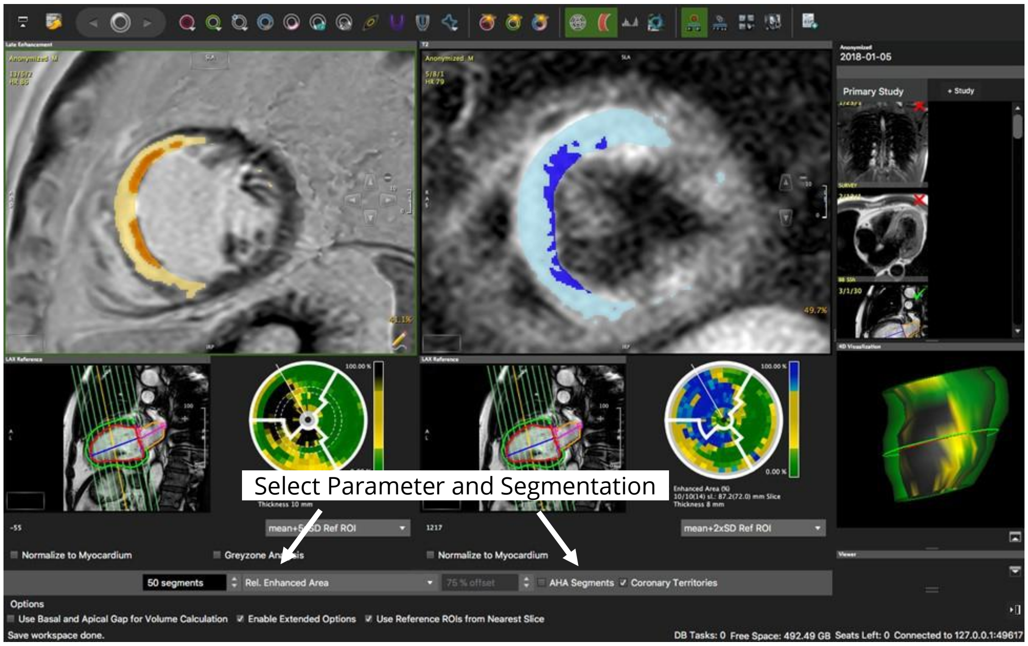
Draw endocardial and epicardial contours in T1 pre and post contrast images.





1. If you are not able to define endo and epicardial contours, use the *Myocardial Contour* tool.
2. Define a skeletal reference.
3. Repeat for all slices.
4. To view analysis results, click the *Display Result* button.
5. Add measurements to report using the *Add to Report* button.

16.3 Regional LGE and T2 Analysis and Assessment of Transmurality



Select Parameter and Segmentation

mean+5xSD Ref ROI ▾ mean+2xSD Ref ROI ▾

☐ Normalize to Myocardium ☐ Greyzone Analysis ☐ Normalize to Myocardium

50 segments Rel. Enhanced Area ▾ 75 % offset ☐ AHA Segments ☑ Coronary Territories

Options
☐ Use Basal and Apical Gap for Volume Calculation ☑ Enable Extended Options ☑ Use Reference ROIs from Nearest Slice

Save workspace done.

DB Tasks: 0 Free Space: 492.49 GB Seats Left: 0 Connected to 127.0.0.1:49617

Toggle Polar Map button.

16.3.1 How to Do Segmental Scar and Edema Analysis

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

3. Select *Parameter* from drop-down menu.

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

16.3.2 How to Assess Transmurality

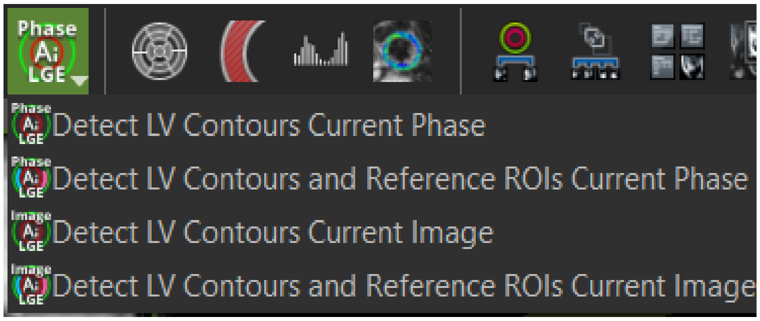
1. Repeat step 1-2.
2. Select *Transmurality* from the drop-down menu at the bottom of the page.
3. If you want to display a defined percentage, select *Transmurality Offset* and set the percentage with the arrow keys.

16.3.2.1 How to Display a Greyzone Polar Map

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

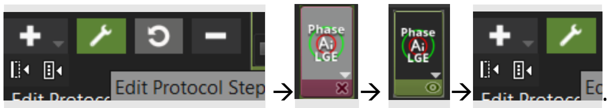
16.4 LGE AI Contour Detection

- There are four LGE AI options.



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

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



17 Tissue|T2* Mapping

17.1 How to Do T2* Analysis

Module overview:
T2* quantification and mapping for myocardial tissue characterization (iron, hemorrhage, thrombus).

17.1 How to Do T2* Analysis

1. Draw an endocardial and an epicardial contour for the assessment of global T2* values.
2. Draw a ROI contour in the septal wall for regional/septal T2* values.
3. Forward contours to other images within the series or via context menu *Forward Contour*. T2* decay curves will immediately be displayed, using a non-linear fitting algorithm.
4. Choose a correction method from the T2* options. The T2* values will be displayed, as well as the absolute iron concentrations (1.5 Tesla ***only***).
5. Toggle color map on.
6. 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.
7. Add measurements to your report.

18 Tissue|T2 Mapping

Module overview:

T2 quantification and mapping for myocardial tissue characterization (edema). The module consists of two pages:

- T2 Measurement: allows for the assessment of T2 raw data, motion correction and map generation.
- T2 Map: allows for regional and global T2 map quantification.
- If the preference *Auto-loading and auto-contouring* is enabled, **cvi42** will auto-load an appropriate T2 raw series in the T2 Measurements tab, a quality control map into the R2/Error Map frame and it will also auto-load and auto-contour a T2 Map in the T2 Map tab. **cvi42** will also auto-load a LAX series in the LAX Reference frame. The user shall review the automated results and correct them if necessary.

18.1 T2 Measurements

18.1.1 How to Do T2 Measurements

1. Draw an endocardial and an epicardial contour for the assessment of global T2 values.
2. Draw a ROI contour for regional T2 values.
3. Forward contours to other images within the series or via context menu *Forward Contour.* T2 decay curves will immediately be displayed.
4. Choose a fitting option from the T2 options.
5. In order to exclude any extra map attached to the raw data, in the T2 options, it is possible to skip the last 1 or last 2 phase images of the series for T2 calculations.
6. Add calculations to your report.

18.1.2 How to Apply Motion Correction to T2 Series

1. Make sure you have endo- and epicardial contours in all images.
2. Set the *Segmentation* point.
3. Select the image with the best contrast and enter the phase that you would like to use for the registration.
4. Click the *Registration* button: The new series will be created and automatically loaded into the respective frames.
5. If you decide to use a different phase for registration, reload the original series and repeat steps 1-4.

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

18.1.3 How to create a T2 map

1. Review the T2 Options.
2. To generate the T2 Map, click "Create DICOM T2 map" option .

Any existing contours on the T2 raw series will be copied to the generated T2 map. The generated map will auto-load into the T2 Map page. To automate DICOM map generation, from the T2 Options, check the box for Create T2 Map upon Loading and save this step to your protocol.

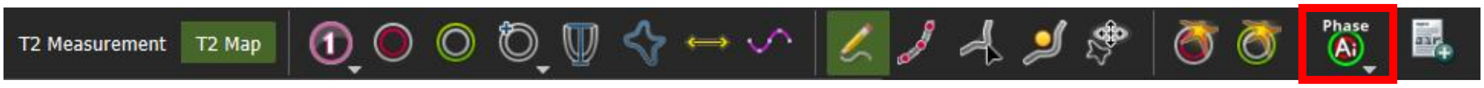
18.2 T2 Map

18.2.1 How to Analyze T2 Maps

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

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

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



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

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

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

19 Tissue|T1 Mapping

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

Module overview:

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

19.1 Module Layout

The module consists of two pages:

- T1 Calculation: allows for the assessment of native and post-contrast T1 raw data, motion correction and map generation.
- T1 Map: allows for regional and global native and post-contrast T1, ECV and lambda map quantification.
- If the preference *Auto-loading and auto-contouring* is enabled, **cvi42** will auto-load native and post-CA T1 raw series and respective quality control maps in the T1 Calculations tab and it will also auto-load and auto-contour native and post-CA T1 maps in the T1 Map tab. **cvi42** will also auto-load a LAX series in the LAX Reference frame. The user shall review the automated results and correct them if necessary.

19.2 T1 Analysis (native and post contrast)

1. Load a series from the thumbnail panel.
2. Select the correct sequence in the T1 options menu.
3. In the T1 options menu of the T1 calculation tab it is possible to skip the last 1 or the last 2 phase images of the series for T1 calculations, to exclude any extra map attached to the raw data.
4. In the DICOM header the T1 time may be encoded in the Trigger Time DICOM tag. To address this, from the T1 options menu, select the check box for Use Trigger Time as Inversion Time. If the series is rejected, it could have been due to one of the following reasons:
    - During anonymization the information for T1 has been stripped and you get a warning message "T1 times are equal." **Solution:** Go to the patient list module and in the *Extended view* check if the information for the T1 can be found under either *T1* or *Image Comments* (Siemens). If possible, try to re-anonymize the data, preserving the T1 information.

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

19.2.1 How to Do Global or ROI Analysis

1. For global T1 values, draw endocardial and an epicardial contours. Forward the contours via context menu.

   Forward All Contours Slice (short-cut*: ⌘E/Ctrl E*).

2. For regional analysis, select one of the ROI contours. This contour can be forwarded via toolbar button.
3. Repeat for all slices.

   Global and ROI l T_1 Relaxation times and R^2-values will be shown in the result frame. The T_1 recovery curve is also calculated and displayed. RBM click in the graph opens a *Context Menu* offering saving options.

4. 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.
5. Add evaluation (images, values and graph) to the report.

19.3 Motion Correction for ECV Map Generation

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

19.3.1 How to Do Intensity Based Registration

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

19.3.2 How to Do Feature Based Registration

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

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

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

19.3.3 How to create a T1 map

1. In the T1 Calculation tab, review the T1 Options.
2. To generate a T1 Map, click on “Create DICOM T1 map” option .

Any existing contours on the T1 raw series will be copied to the generated T1 map. The generated map will auto-load into the T1 Map page. To automate DICOM map generation, from the *T1 Options*, check the box for *Create T1 Map upon Loading* and save this step to your protocol.

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

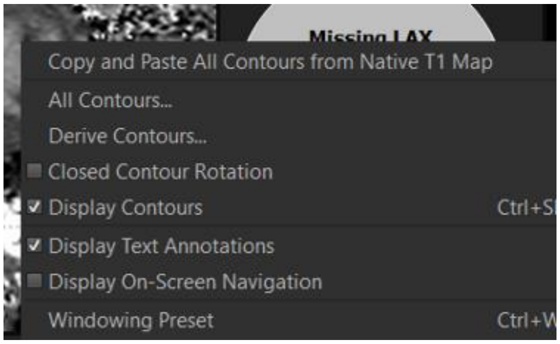
- T1* maps may offer a more accurate estimation of blood pool T1.
- T1* maps will be automatically extracted of Molli, shMolli and Molli Oxford sequences.

19.4.2 How to Analyze the T1 Map

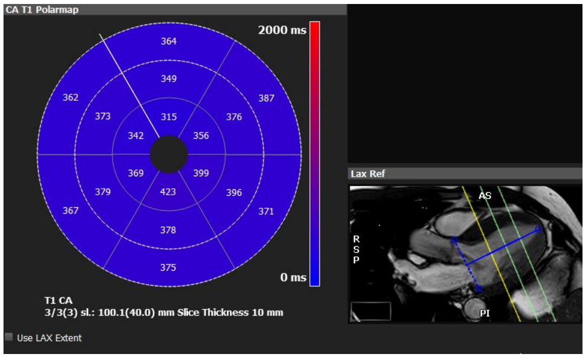
1. Drag the map from the thumbnail panel to the analysis window.
2. Draw or derive endocardial and epicardial contours.
   2.1 AI based contouring tools, , are supported for LV Endo/Epi contours and the RV insertion points on native and post-CA maps.

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

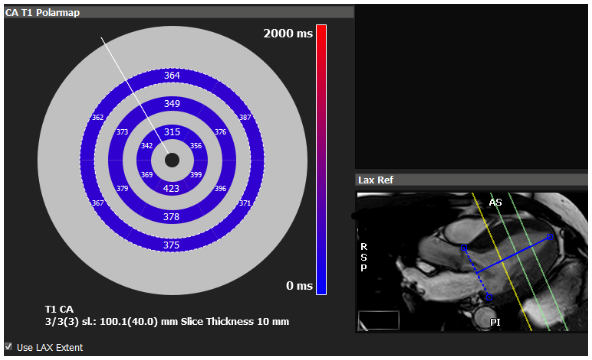
It is possible to derive all contours from the native T1 map to the post-CA T1 map, by selecting the first option on the top of the Context Menu on the post-CA T1 Map frame (Copy and Paste All Contours from Native T1 Map):
For a color-coded display, select a color map from the drop-down menu or create your own LUT.



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



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



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

8. Add evaluations to the report.

19.5 ECV and Lambda Quantification (λ)

19.5.1 How to Do Segmental ECV and Lambda Quantification

1. Make sure you have contours, segmentation points and a blood-pool contour in all slices in both *T1 Map Native* and *T1 Map* CA. The blood pool contour can be drawn either in the *T1 or the T1* Map.* You can easily copy contours from the native T1 Map to the post contrast T1 Map for all slices/phases, by using the context menu option “Copy and Paste All Contours from Native T1 Map” option.
2. Enter the hematocrit for the ECV quantification.
3. Create an ECV map.
4. For a polar map display, make sure you have defined the Long Axis Extent in the reference frame of the *T1 Map Native and T1 Map CA* page.
5. Add evaluation to the report.

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

20 Perfusion|Semi-quantitative

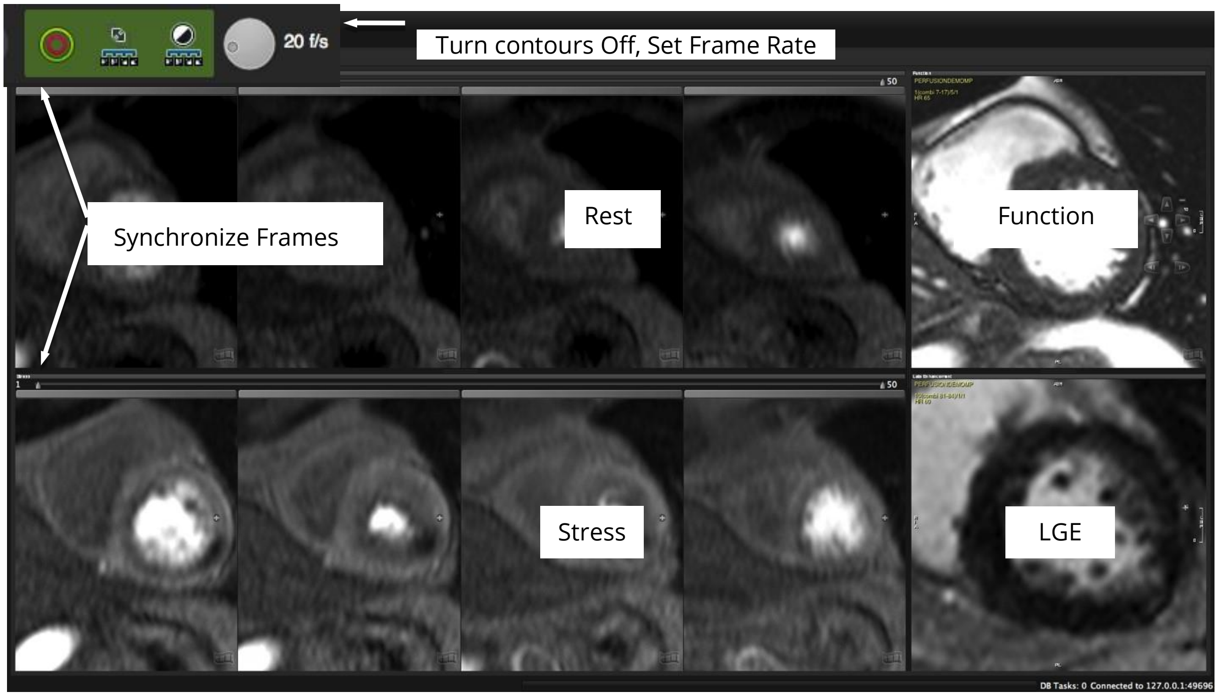
Module overview:

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

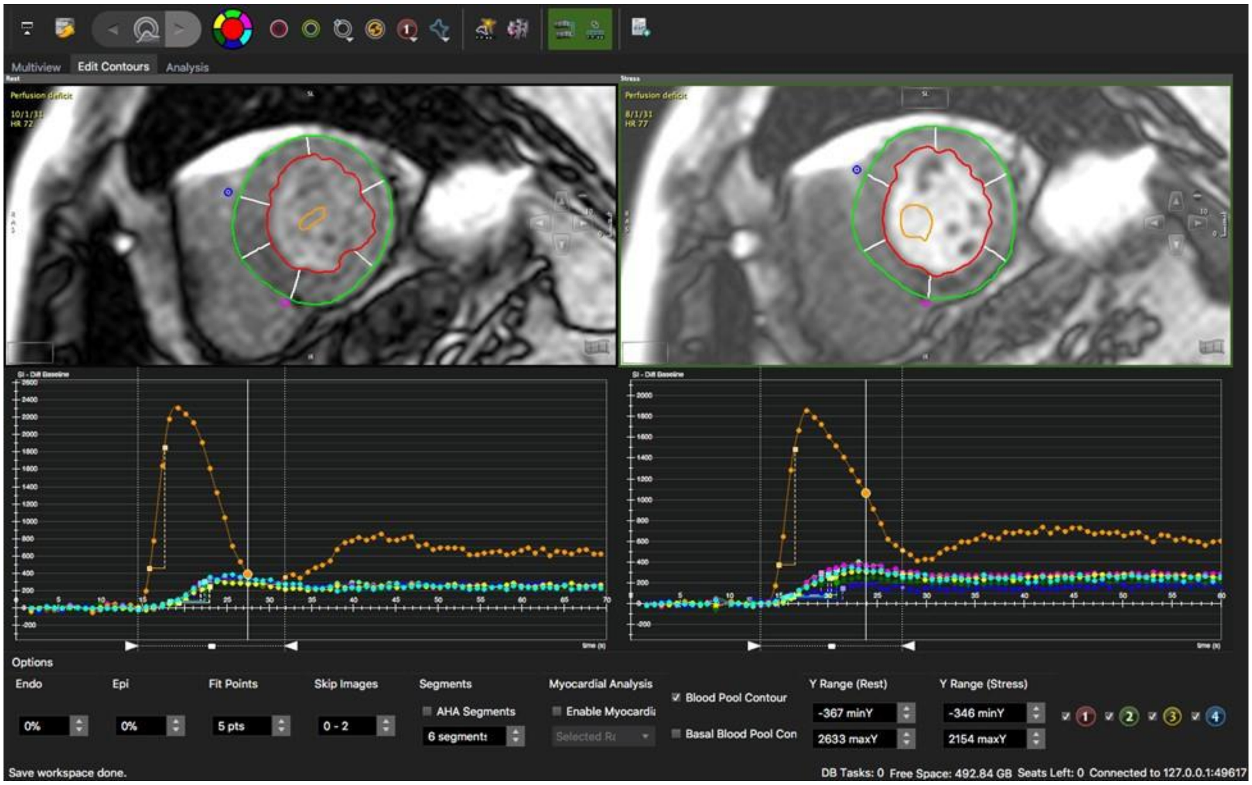


20.1.1 How to Do a Visual Perfusion Analysis

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



Options

Endo: 0%
Epi: 0%
Fit Points: 5 pts
Skip Images: 0 - 2
Segments: ☐ AHA Segments, 6 segments
Myocardial Analysis: ☐ Enable Myocardi
☑ Blood Pool Contour
☐ Basal Blood Pool Con
Y Range (Rest): -367 minY, 2633 maxY
Y Range (Stress): -346 minY, 2154 maxY
☑ ① ☑ ② ☑ ③ ☑ ④

Save workspace done.
DB Tasks: 0 Free Space: 492.84 GB Seats Left: 0 Connected to 127.0.0.1:49617

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

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

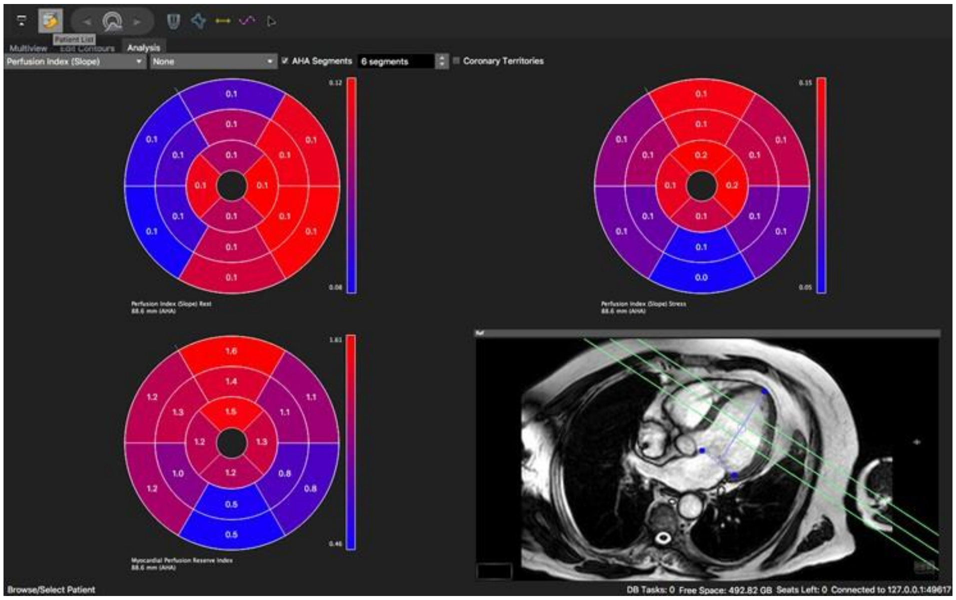
20.2.2 Option Menu

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

20.2.3 How to Analyze Perfusion Curves

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

20.3 Analysis, Segmental Analysis



How to do a regional perfusion analysis:

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

2. Select a parameter from the drop-down list.

3. Apply a baseline correction.

21 Perfusion|Quantitative

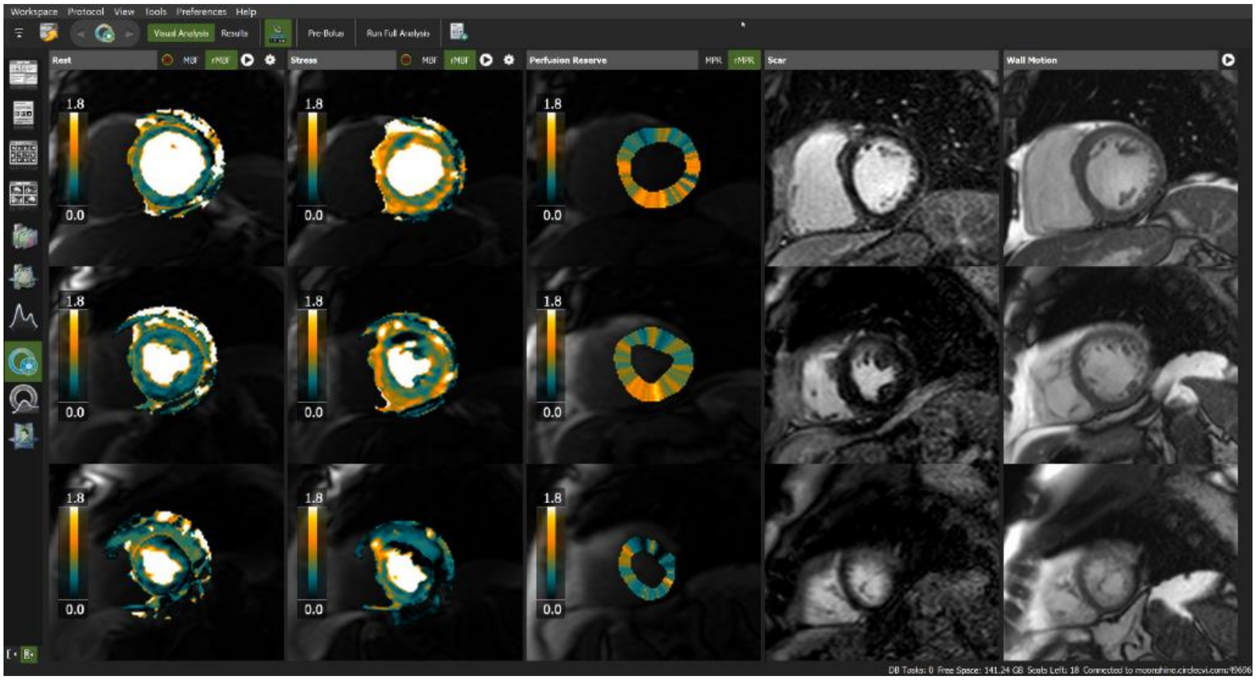
Module overview:

This module allows for quantitative analysis of myocardial blood flow from perfusion images.

⚠ **WARNING**: The Perfusion|Quantitative module is to be used for research purposes only, and not for primary diagnostics and direct patient care.

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

21.1 Analysis 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.).

Big Bolus Volume: 10 ml Gadovist

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.
- The rest and stress AIF series will be autoloaded into the respective frames

If the system did not auto-load the correct AIF series,select the correct AIF from the thumbnail panel, and drag it into the AIF frame.

☐ 2RR HR: — PD: — AIF:
☐ 2RR HR: — PD: — AIF:

- Optionally, load LGE and function images in <Scar> and <Wall Motion> columns for reference.
- Click <Run Full Analysis>.

Contrary to MBF maps, the calculation of MPR and polar maps rely on accurate delineation of the myocardium. Prior to interpretation, the user mustverify the LV and RV endocardial contours on the AIF series and the LV endo- and epicardial contours and the RV endocardial contours in the myocardial perfusion series.

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

- Click on the contour icon ◎ in the header bar to display the contours and optionally toggle MBF maps on/off.
- Correct contours if needed: Contour correction tools will be provided in the shadow box in the left bottom corner of the view frame.
- Go to the Results tab before rerunning the Analysi.

21.2 Results Review

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

- Contours
- HR
- PD image number
- AIF curve
- MBF pixelmaps
- Segmental myocardial semi-QP results

This module is to be used for research purposes only, and not for primary diagnostics and direct patient care.

AIF (Blood Pool):

	Rest	Stress
Baseline:	0.595882	0.565386
Slope:	123.15	139.454

SI (Basal):

	Rest	Stress
Baseline:	0.535483	0.545455
Slope:	3.98771	8.42872

SI (Middle):

	Rest	Stress
Baseline:	0.335367	1.63077
Slope:	6.01479	8.98613

SI (Apical):

	Rest	Stress
Baseline:	0.303371	1.99065
Slope:	3.06344	3.64462

21.2.1 Contours

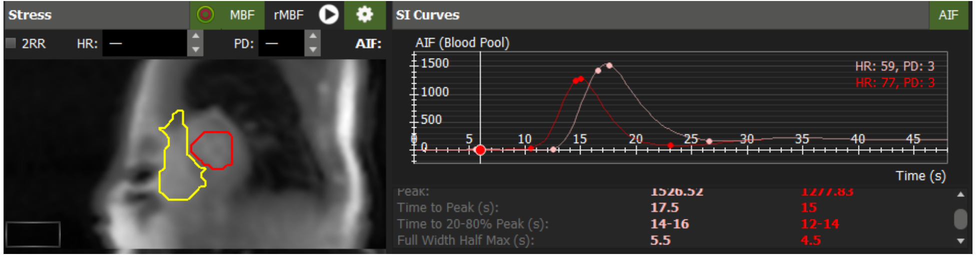
Contrary to MBF maps, the calculation of MPR and polar maps rely on accurate delineation of the myocardium. Prior to interpretation, the user must verify the LV and RV endocardial contours on the AIF series and the LV endo- and epicardial contours and the RV endocardial contours in the myocardial perfusion series.

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

- To visually assess the first pass perfusion, deactivate the MBF overlay, by clicking on MBF and run the cine ▶.
- Click on the contour icon ◎ in the header bar to display the contours and optionally toggle MBF maps on/off.
- Correct contours if needed: Contour correction tools will be provided in the shadow box in the left bottom corner of the view frame.

21.2.2 HR and PD image numbers

The detected HR and PD image numbers will be displayed on the AIF graph. If needed, correct them by clicking on the gear tool.



Peak:	1526.52	1277.83
Time to Peak (s):	17.5	15
Time to 20-80% Peak (s):	14-16	12-14
Full Width Half Max (s):	5.5	4.5

If the user enters a HR value, this will be used to synthetize new timestamps (which won't be read from the DICOM tags anymore).

After editing contours, HR or PD values, the user has to re-run the analysis Run Full Analysis.

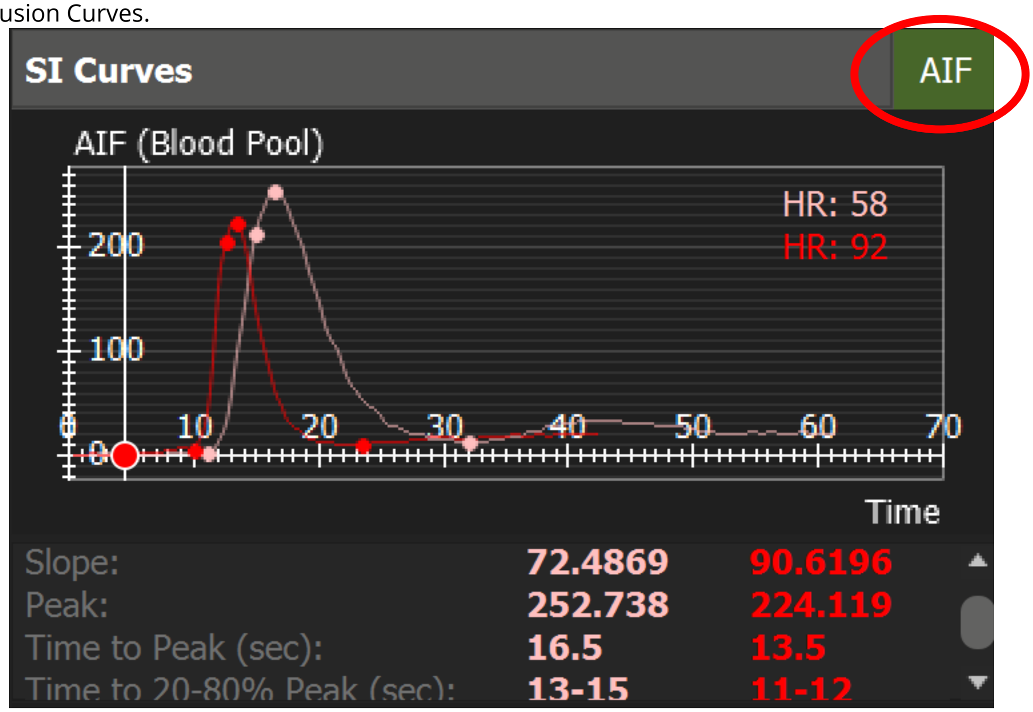
21.2.3 Rest and stress pixel maps and Myocardial Perfusion Reserve (MPR) review

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

- MBF-pixel-maps are automatically overlaid on rest and stress perfusion images.
- To visually assess the first pass perfusion, deactivate the MBF overlay, by clicking on MBF and run the cine ▶.
- Click on rMBF (remote MBF) to review the relative myocardial blood flow.
- Color-coded MPR (MBF stress/ MBF rest) segments will be displayed in the middle column.
- Click on rMPR (remote MPR) tab to review the relative myocardial perfusion reserve results.

21.2.4 Signal Intensity Curves

AIF and Segmental Perfusion Curves.

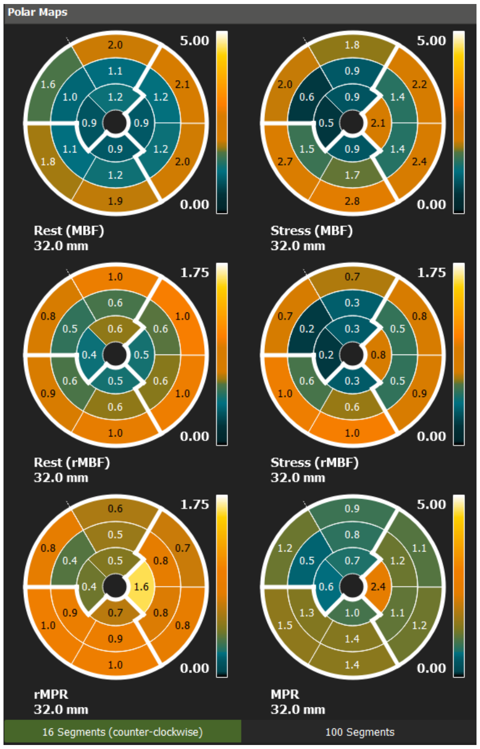


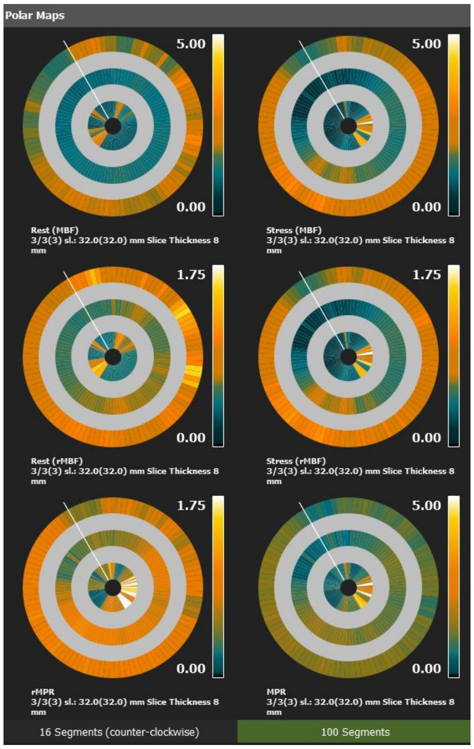
Slope:	72.4869	90.6196
Peak:	252.738	224.119
Time to Peak (sec):	16.5	13.5
Time to 20-80% Peak (sec):	13-15	11-12

1. Hovering over a colored coded segment in the slice specific segment icon will display associated segment perfusion curves.
2. Clicking the segment in the icon will hide the curve.
3. Click and hold a data-point to display the associated values.

4. Review Perfusion parameters:
    - Baseline
    - Slope
    - Peak
    - Time to Peak
    - Time to 20 to 80 % of peak value
    - Full Width Half Max

21.2.5 Polar maps





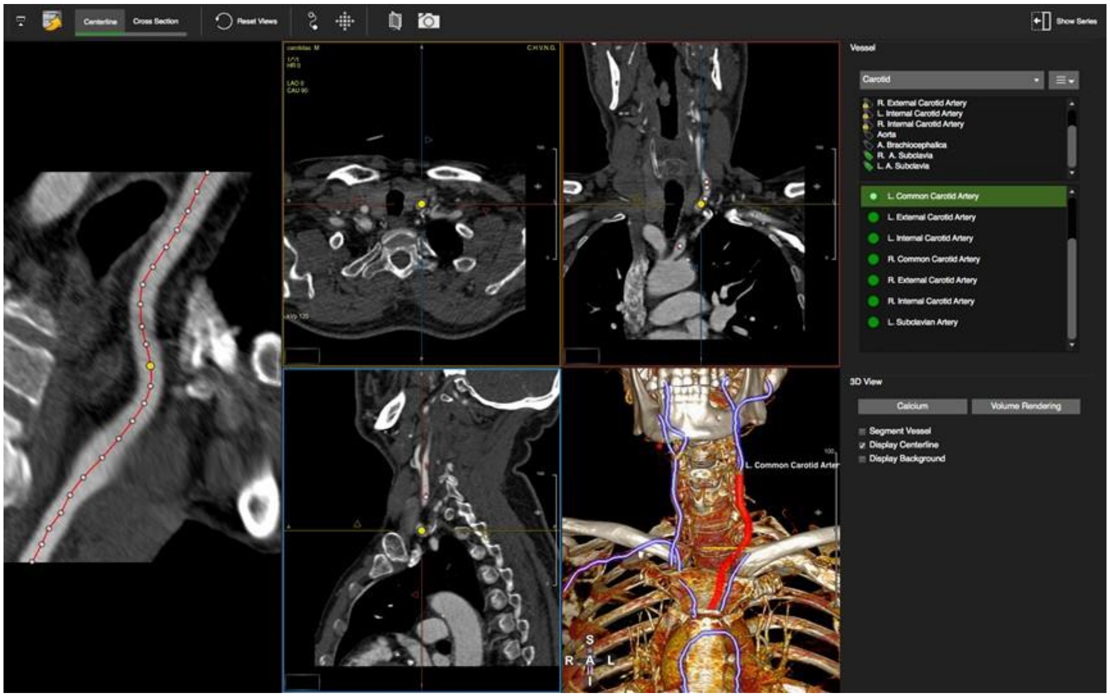
1. Review polar maps, checking the various segmentation options (100 Segments (clockwise), 16-segments (counter clockwise) Coronary Territories).

   Add the results to the scientific report.

22 Vascular Module

The module covers two topics:

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

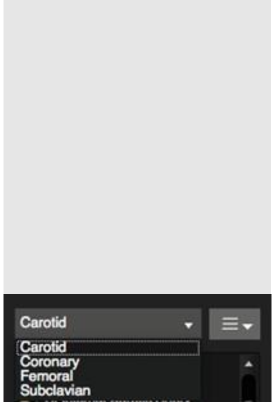


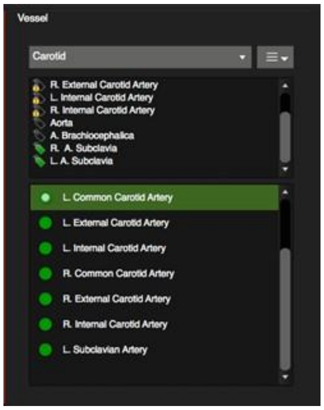
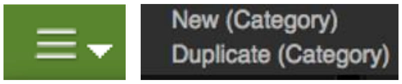
22.1 Centerline Page

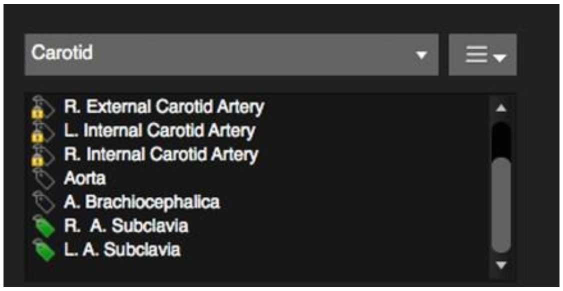
22.1.1 Main Page

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

22.1.2 Vessel Lists

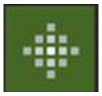
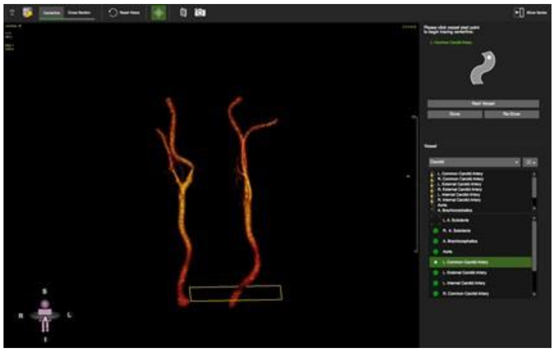
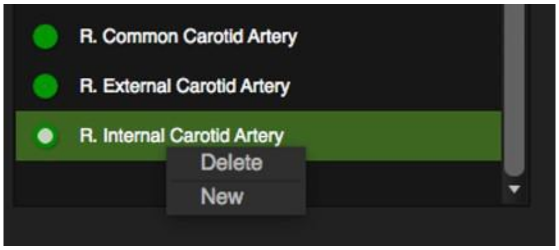
<table>
<tr>
<td>Lists of predefined labels for standard measurements. The software comes with lists for:
• Carotid Arteries
• Coronary Arteries
• Femoral Arteries
• Subclavian Arteries</td>
<td>


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

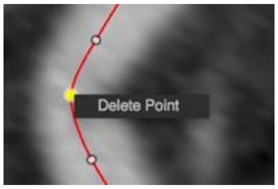

</td>
</tr>
<tr>
<td>A list can display three label icons:
• Labels with a lock: predefined.
• Green: unused.
• Outlined labels: used.</td>
<td>
</td>
</tr>
</table>

22.1.3 Region Growing

Trace a centerline via region growing.

• Click the *Region Growing* button in the top toolbar. The software will open the image in an enlarged view.	
• The top right panel will guide you through the steps.	  
• Grow the vessel by dragging on the 3D surface. • Click *Trace vessel*, to extract the vessel. • 'Alt' key allows to turn, *Ctrl* (*Command* Mac) allows to pan the image. • In the segmented vessel, extract the centerline by placing a start and an endpoint. • 'T' toggles the centerline on/off.	
• Click Next Vessel to proceed to the next vessel in your list. • Right-click to add or delete a centerline. The label will be updated to 'un-used'.	
• *Done* will go back to the Main page.	

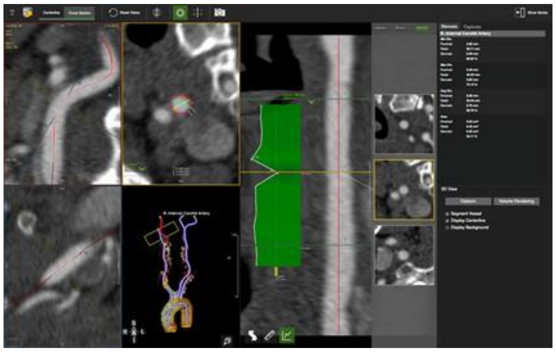
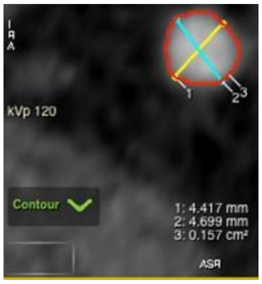
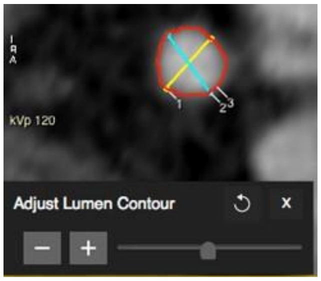
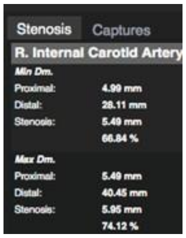
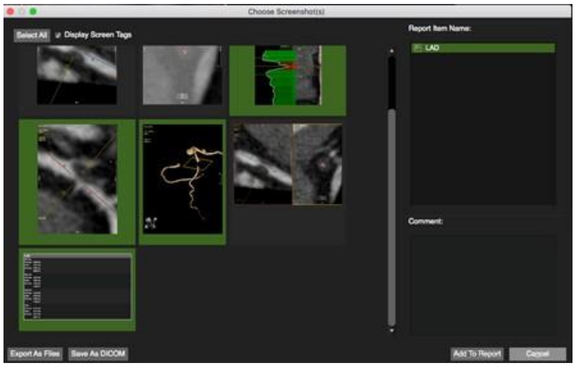
22.1.4 Edit the Centerline

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

22.2 Cross Section

Stenosis Assessment

22.2.1 How to Do a Stenosis Assessment

• Select the vessel by clicking on the respective vessel in the reference viewer ('T' – toggles the centerline on/off). • Start in *Browse* view and drag the yellow line down the vessel. • Switch to *Stenosis* View and place the stenosis marker either by dragging or by double-clicking in the stenosis.	
• Adjust the plane to accurately display a cross-sectional view. • Move to the MPR view and use the *Auto Vessel Lumen* tool to contour the stenosis and the 2 reference images. • To adjust the threshold, click the green *contour* label. It will open a slider that allows to adjust the contour.	 1: 4.417 mm 2: 4.699 mm 3: 0.157 cm² 
• Stenosis measurements will be filled in automatically.	Stenosis Captures R. Internal Carotid Artery *Min Dm.* Proximal: 4.99 mm Distal: 28.11 mm Stenosis: 5.49 mm 66.84 % *Max Dm.* Proximal: 5.49 mm Distal: 40.45 mm Stenosis: 5.95 mm 74.12 % *Avg Dm.* Proximal: 5.28 mm Distal: 32.43 mm Stenosis: 5.70 mm 69.76 % *Area* Proximal: 0.22 cm² Distal: 8.43 cm² Stenosis: 0.25 cm² 94.11 %
• Images can be captured via context menu. • Multi-Frame Screen Captures (F3) Use the *Multiframe Capture* to save the stenosis measurements and optionally some images.	

23 Strain

Module overview:

Assessment of myocardial deformation.

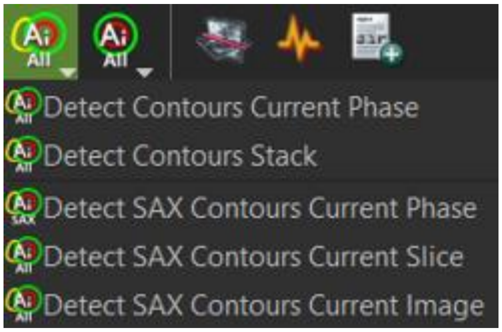
When using the Strain Analysis Module, if *Auto Load Series in Module* is enabled, **cvi42** will identify and auto-load appropriate SAX and LAX series.

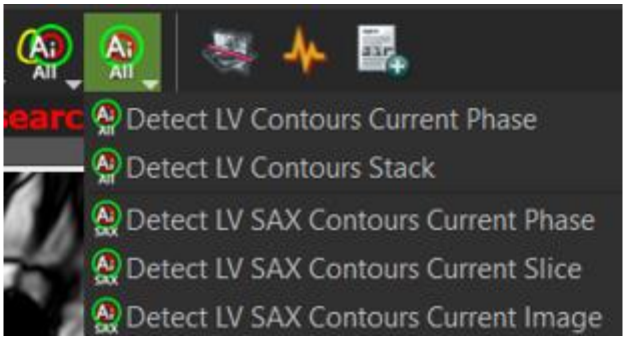
WARNING: The 3D Strain results are to be used for research purposes only, and not for primary diagnostics and direct patient care.

23.1 Auto Contour Detection Using AI

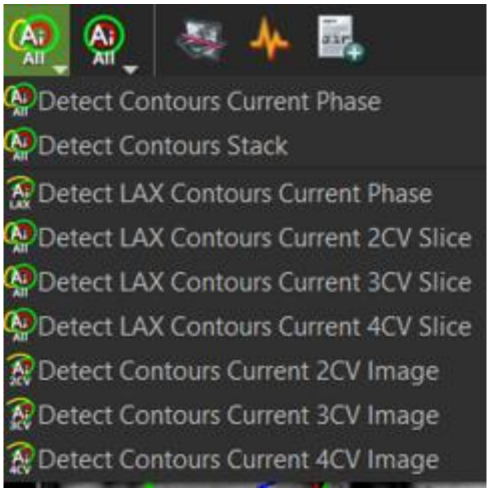
- There are two main AI icon tools, the left-hand tool will detect LV (endocardial and epicardial) and RV (endocardial) contours, and the righthand will detect LV contours only.

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

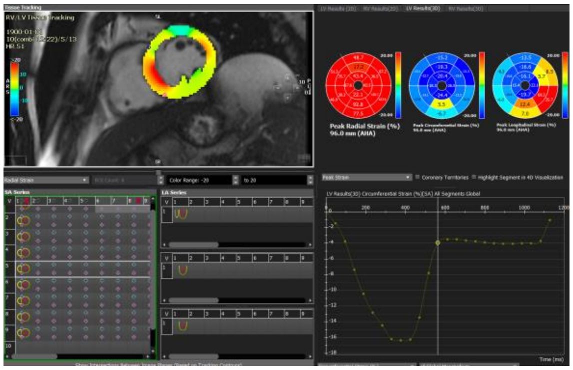




- *AI All* means that **cvi42** will detect the contours on the selected phase for all loaded series (SAX and LAX). If a SAX image is selected, it is possible to run the automatic contour detection on the selected phase of the SAX series only. Whenever the SAX contours are detected, the respective anterior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



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



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

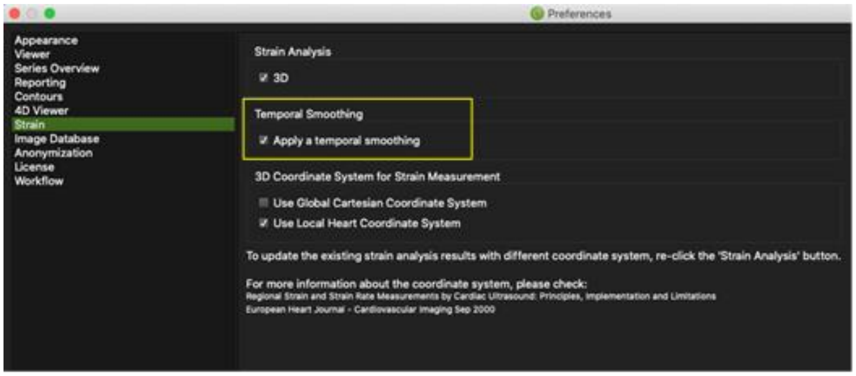
23.2 Strain Analysis

23.2.1 How to do LV 2D Strain Analysis

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

Contouring the Reference Phases

- Visually select end-systolic and end-diastolic phase. Alternatively, check in the function module which phase has been identified as diastole and systole based on minimum and maximum volume. Make a note of the phase number.
- Zoom in as far as possible and window properly.
- Display an image in end-diastole.
- Go to the AI button and make sure it is set to *Detect LV Contour in Current Phase*. This will segment LV in the end-diastolic phase in all series simultaneously.
- For better tracking performance we recommend to additionally contour the systolic phase, which will serve the system as a guidance. Make sure you have activated the preference *Apply Temporal Smoothing*.



Strain Analysis

☑ 3D

Temporal Smoothing

☑ Apply a temporal smoothing

3D Coordinate System for Strain Measurement

☐ Use Global Cartesian Coordinate System
☑ Use Local Heart Coordinate System

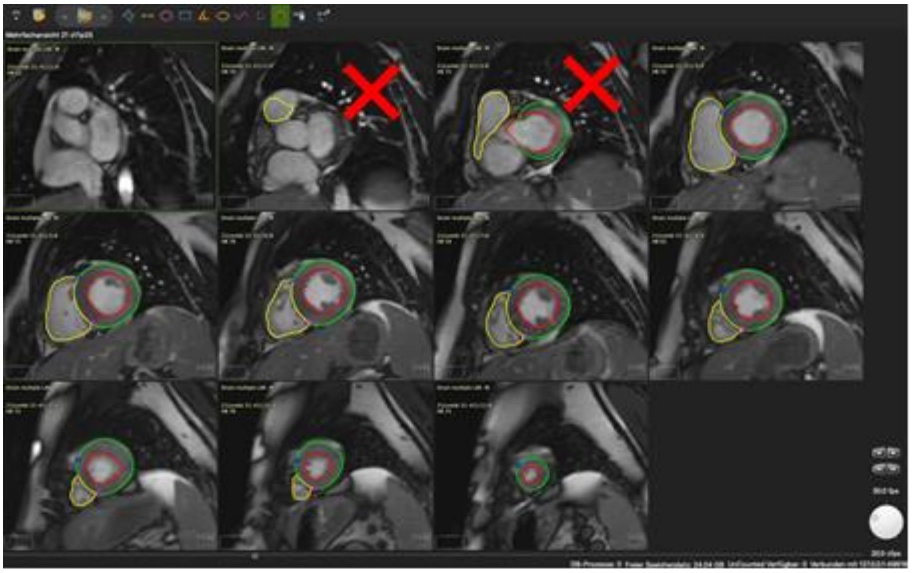
To update the existing strain analysis results with different coordinate system, re-click the 'Strain Analysis' button.

For more information about the coordinate system, please check:
Regional Strain and Strain Rate Measurements by Cardiac Ultrasound: Principles, Implementation and Limitations
European Heart Journal - Cardiovascular Imaging Sep 2000

- Repeat step 5 for systole.

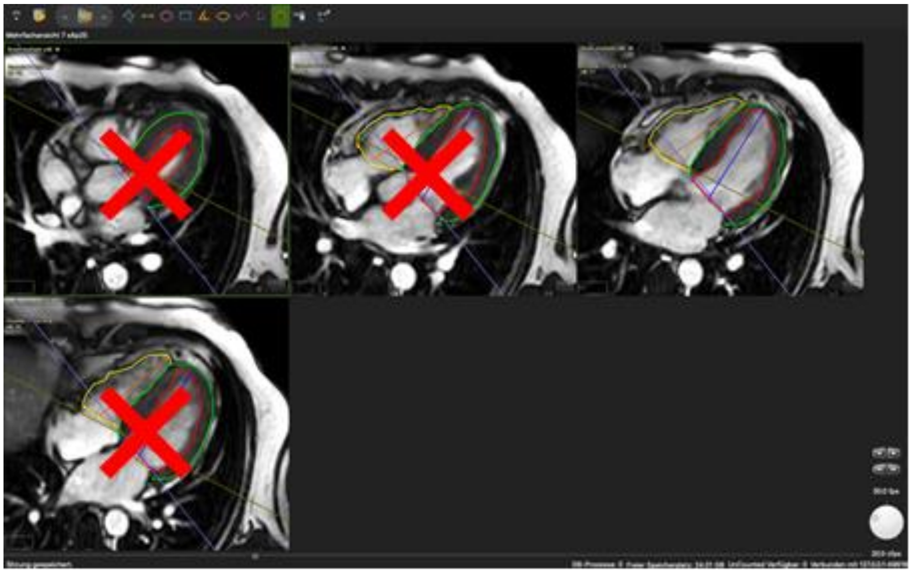
Contour Check

Short Axis

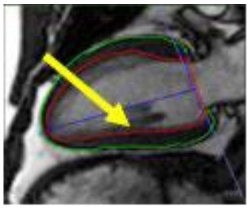


- In short axis go to *multiview* and click through the phases. Delete contours in phases where the LVOT comes into view or where the apex moves out of the plane.
- Zoom in and carefully check your borders. Ensure contours are placed in the myocardium avoiding chemical shift artefact or pericardium.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

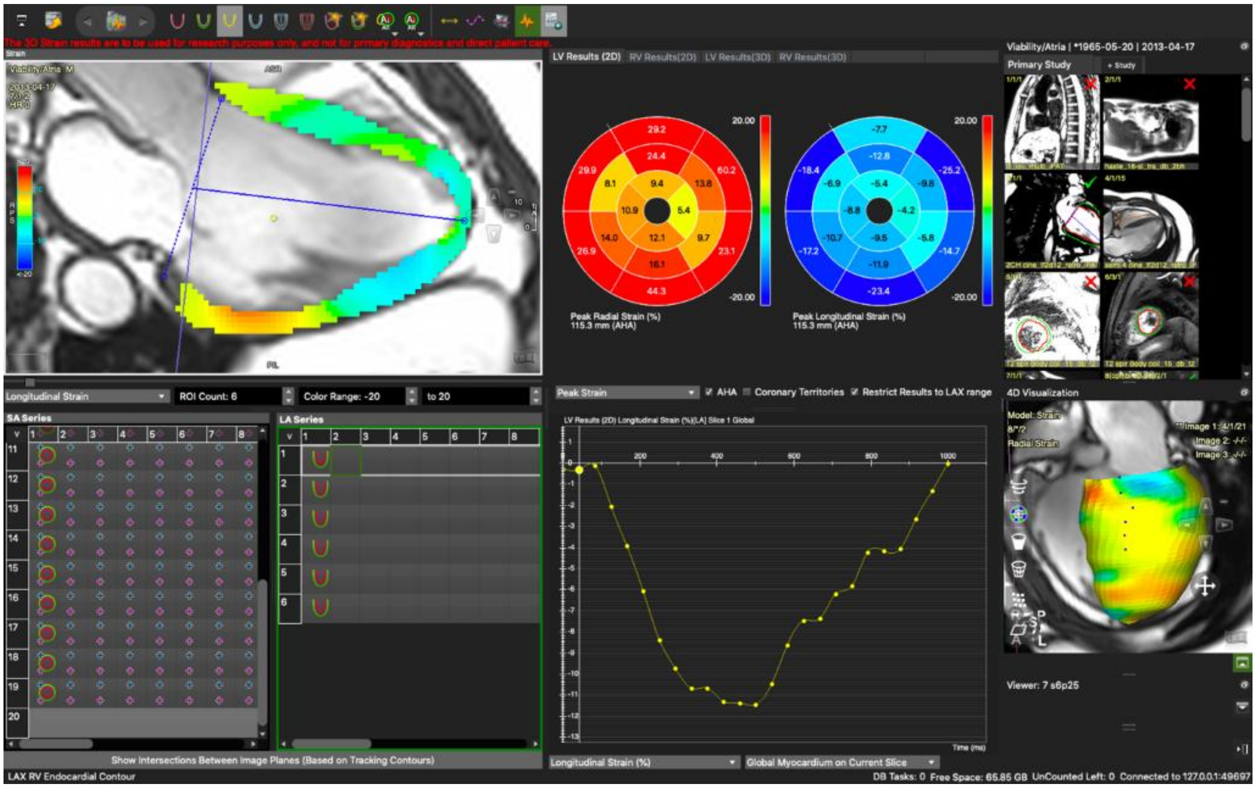
Long Axis



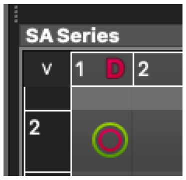
- Verify that contours in end-diastole and end-systole have to be in the same phase as in the short axis!
- In case of multiple parallel long axis slices, only contour the slice that cuts through the true apex (see above). Otherwise, the other slices will falsify the mean global strain values.
- Papillary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



Perform Strain Analysis

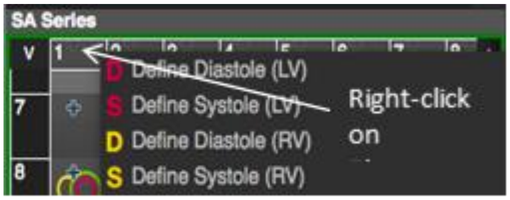

The 3D Strain results are to be used for research purposes only, and not for primary diagnostics and direct patient care.

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



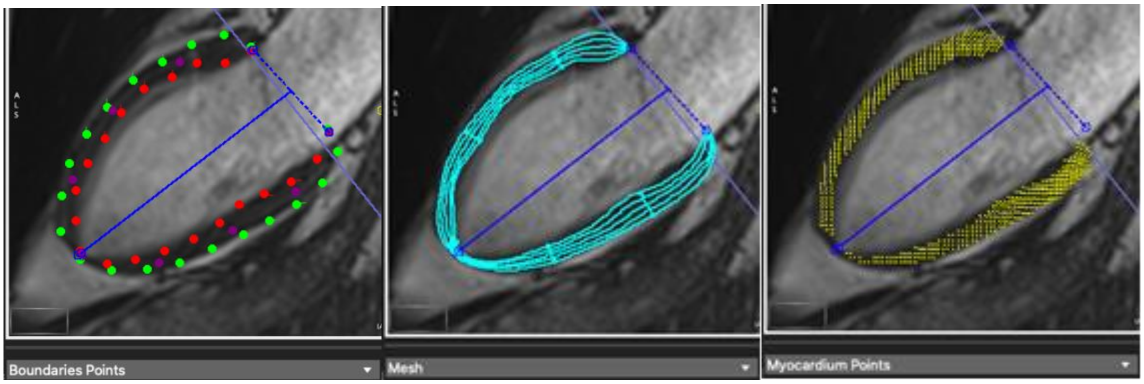
- Click the *Perform Automatic Strain Analysis* button.
- Strain will be calculated with reference to diastole.
- Based on the tracked borders, the system runs a volume calculation in the background and might now identify a different phase as diastole or systole.

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

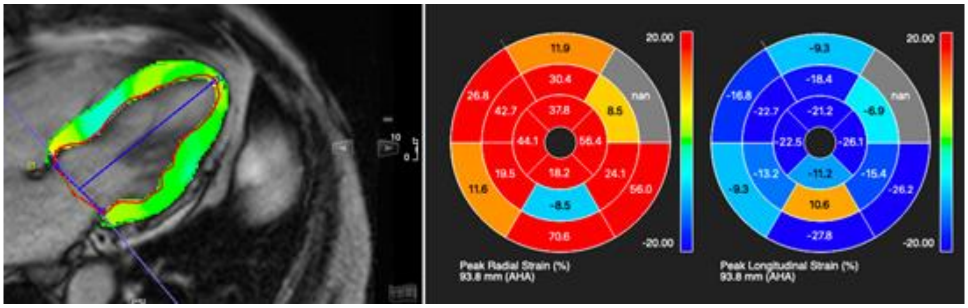


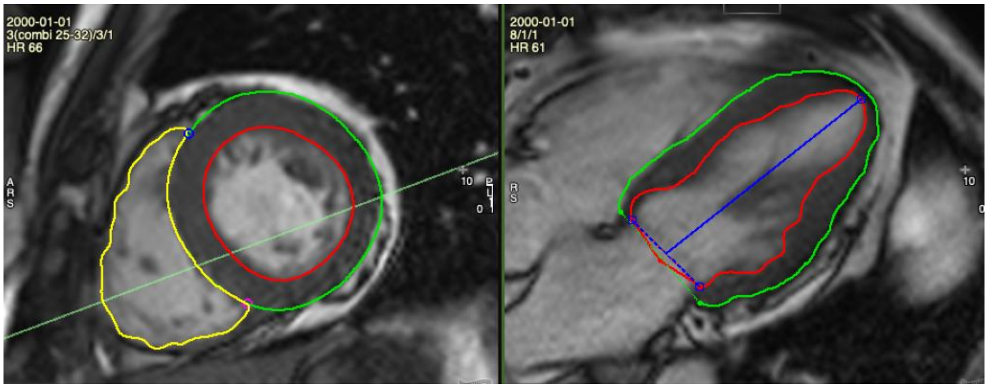
Tracking Quality Assurance

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



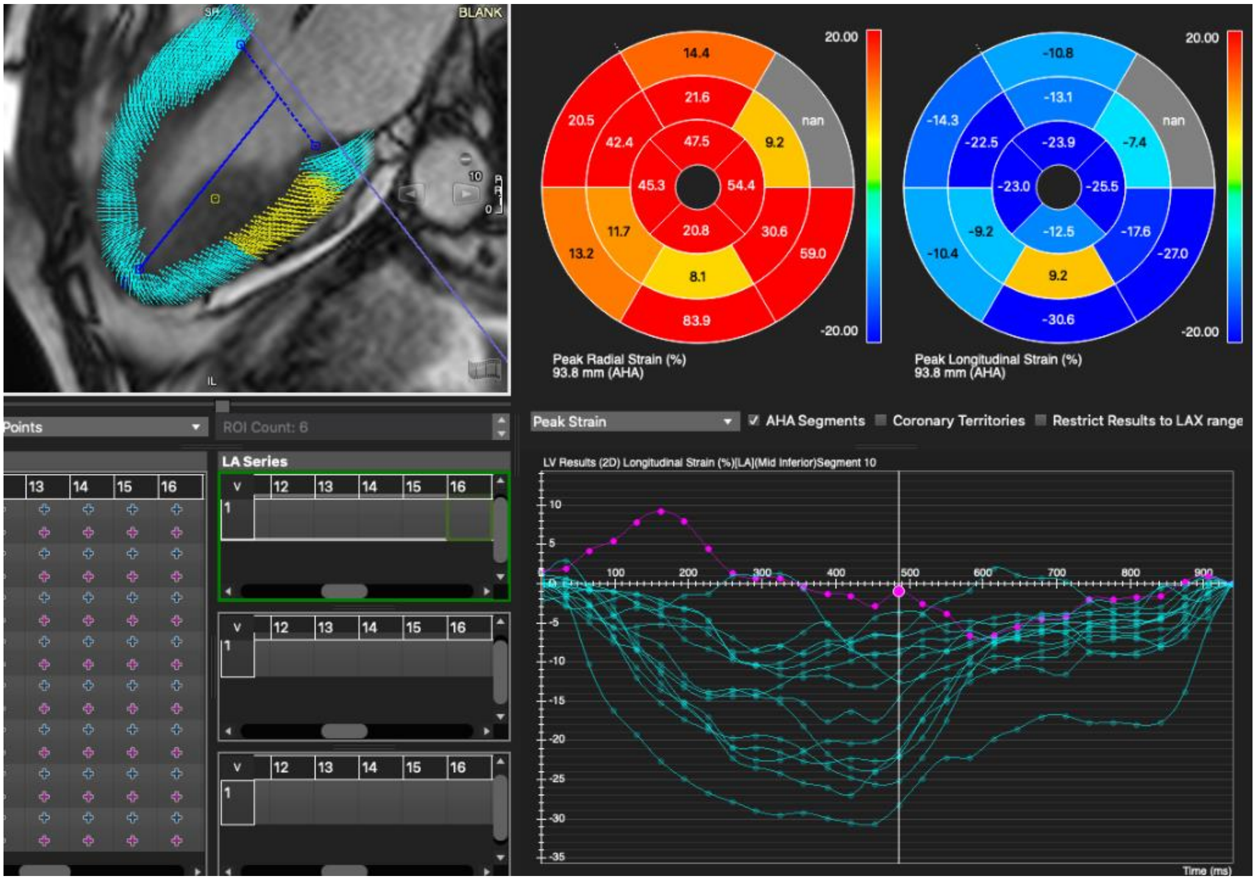
- In long axis, check the tracking of the blue T-Line, which is indicative of tracking quality.
- In short axis, check the tracking of the anterior insertion point.
- Check polar maps: Below an example where the basal, antero-lateral segment displays a grey segment (non-analysable), indicative insufficient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





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

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



Options to enhance the tracking

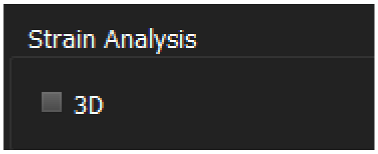
- Set the overlay to boundary points.
- Add contours where the tracking starts to deviate. Only correct the contour that is affected and keep to the boundary points where you had good tracking.
- Go back to the end-diastolic phase and re-run the strain analysis.

Saving

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

23.2.2 How to do 3D Strain Analysis

Check the 3D strain option in the Strain preferences.



Strain Analysis

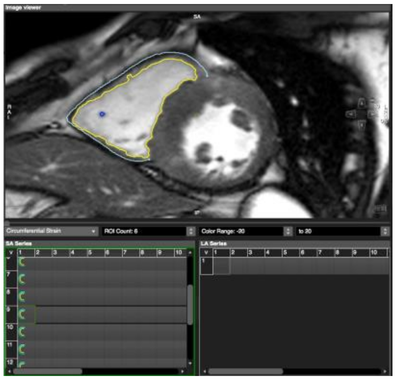
☐ 3D

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

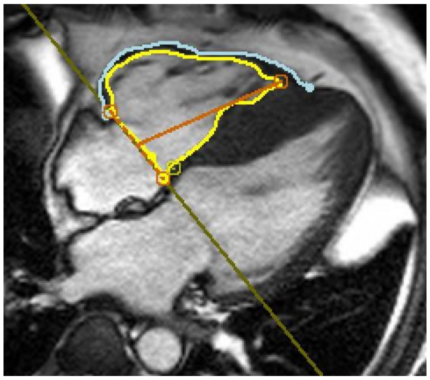
1. Sequentially load short and long axis (either a stack or 3 different radial cines) in the analysis frame.
2. Define endo- and epicardial SAX contours in all slices that that cover the LV. Make sure not to include blood volume.
3. Define the anterior *SAX reference point* at the insertion of the right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

23.2.3 How to do RV Strain Analysis

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



Circumferential Strain
ROI Count: 6
Color Range: -20
to 20



3. For a segmental analysis:

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

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

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

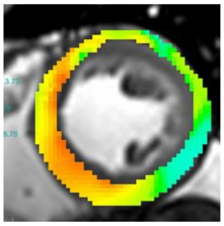
23.3 Performance Check and Adjustments

- 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.

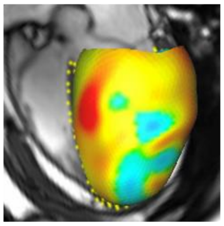
23.4 4D LV Visualization

23.4.1 How to View a Strain Cine Loop

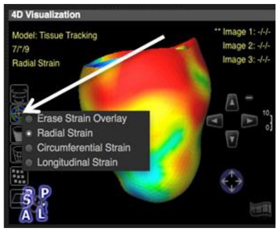
- After the strain analysis, you can view a cine loop of radial/longitudinal or circumferential strain in the *4D visualization Viewer*.
- Click the film icon or spacebar to run the movie. Cines are synchronized with the image viewer.



2D Radial Strain



2D/3D Visualization



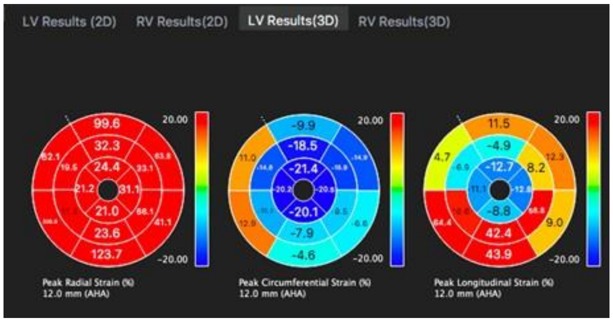
4D Visualization

Model: Tissue Tracking
7/*/9
Radial Strain

** Image 1: -/-/-
Image 2: -/-/-
Image 3: -/-/-

23.5 Regional LV Analysis

23.5.1 How to Display Polar Maps

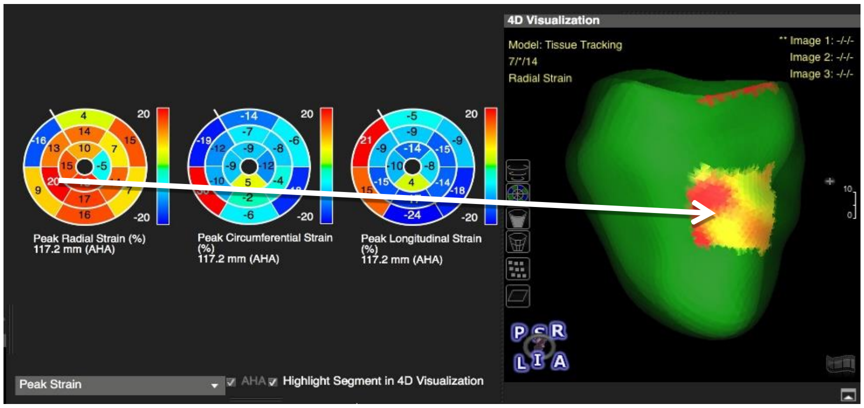


Polar maps display different values, which can be chosen from a drop-down menu.

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

23.5.2 How to Evaluate a Single Segment

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

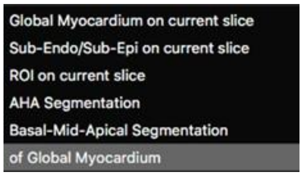


23.6 Diagrams for Strain, Displacement and Torsion

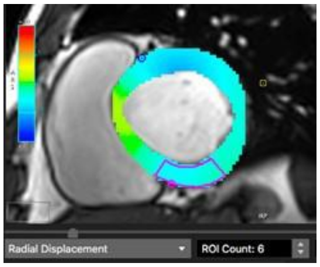
23.6.1 How to Display Strain and Displacement Diagrams

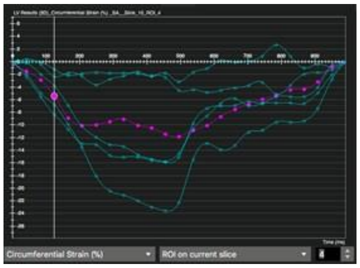
1. Start with selecting the region for which you would like to display the parameter:

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



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





Torsion:

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

24 Flow|4D

Module overview:

4D Flow CMR allows simultaneous acquisition of 3D morphology and time-resolved blood flow velocities in three spatial directions. This module enables a variety of options for visualizations of complex blood flow patterns. It also facilitates the retrospective quantification of flow parameters with its flexible plane placement function.

⚠ **WARNING**: The following parameters are to be used for research purposes only, and not for primary diagnostics and direct patient care: Kinetic Energy, Pulse Wave Velocity, 2D and 3D Wall Shear Stress, Ventricular Flow parameters, Particles Quantification, Pressure Mapping, Energy Loss.

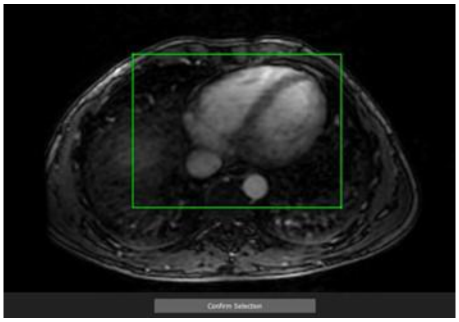
24.1 Data Cropping

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

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

Note: Once the bounding box is fixed, all the further analysis (besides static tissue mask definition) will be done within the bounding box. If the bounding box is deleted or modified before saving workspace, all the measurements will be changed.

2. Select the box by clicking the green line.
3. Grab the green dots at the left top and right bottom corner of the box and drag to confine the region of interest.

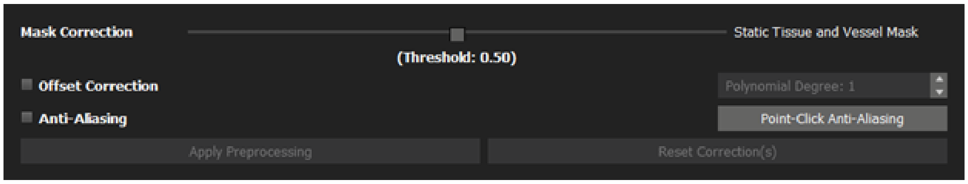


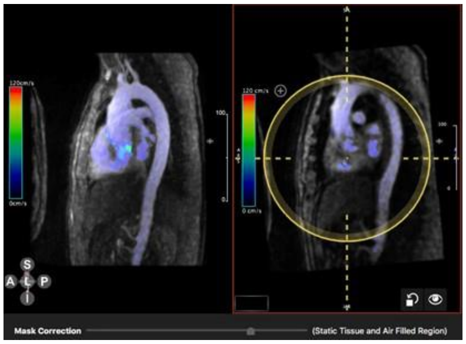
4. Use the *Erase Mask with Contour* tool to manually exclude regions that should not be part of the static tissue mask, e.g. spatial aliasing or regions of high flow inside of the green bounding box. The static tissue mask is not restricted to the bounding box. The pixels inside of the region defined by the *Erase Mask with Contour* will not be included in the air-filled mask.

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

24.2 Preprocessing

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



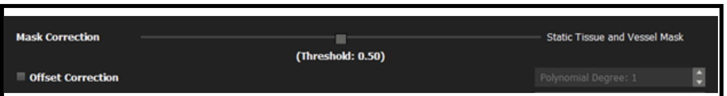


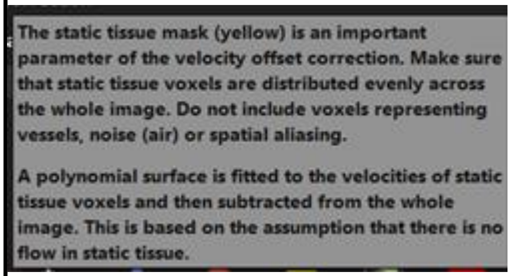
1. Run the cine and scroll through the slices. The left central View port displays the time averaged MRA. The right MPR Viewer allows for navigation in any plane and direction with synchronized magnitude and velocity views (see MPR Viewer).
2. Adjust the color bar: Left-mouse button click on the bar will open a dialog.

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

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

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



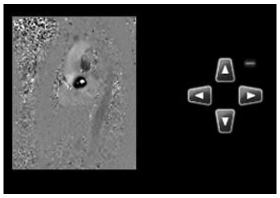


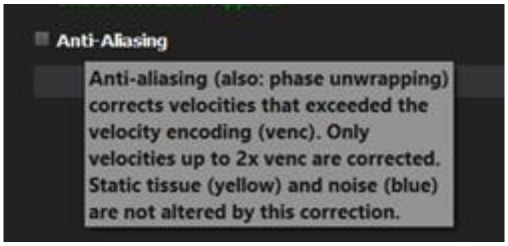
The static tissue mask (yellow) is an important parameter of the velocity offset correction. Make sure that static tissue voxels are distributed evenly across the whole image. Do not include voxels representing vessels, noise (air) or spatial aliasing.

A polynomial surface is fitted to the velocities of static tissue voxels and then subtracted from the whole image. This is based on the assumption that there is no flow in static tissue.

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

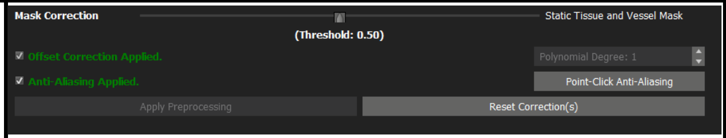
- In case of aliasing, check *Anti-Aliasing*.





Anti-aliasing (also: phase unwrapping) corrects velocities that exceeded the velocity encoding (venc). Only velocities up to 2x venc are corrected. Static tissue (yellow) and noise (blue) are not altered by this correction.

- Click *Apply Preprocessing*.
- Green font indicates preprocessing has been applied.



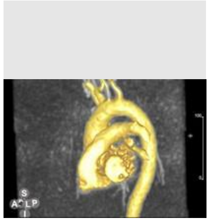
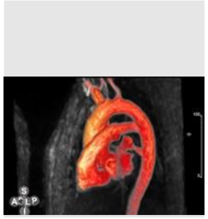
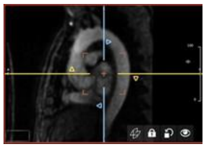
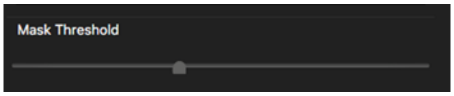
- Once the offset correction has been performed, the estimated offset field can be visualized for all 3 dimensions, by selecting *Show Correction Field* in the top toolbar.

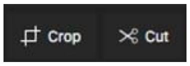
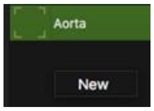
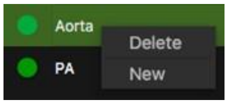
24.3 Segmentation

Module overview:

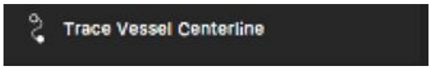
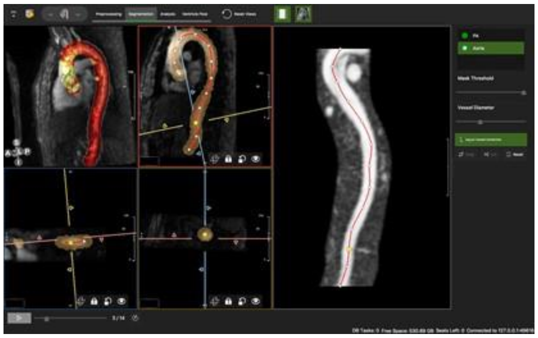
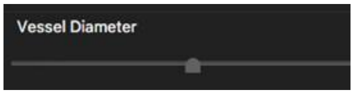
- Segmentation of structures for flow assessment.

24.3.1 How to Segment a Vessel

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

4. Use 3D cut and crop to refine the MRA segmentation in the PC MRA. • Define one or several masks/structures with, or without creating a centerline. • Right-click to add or delete a structure. • Double-click on a title to rename.	   
5. Once you have created several masks and/or centerlines you can easily switch back and forth between the vessels by simply clicking on the vessel title.	

24.3.2 How to Extract a Centerline

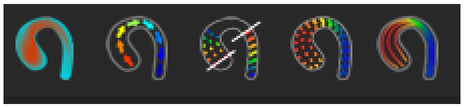
1. Click *Trace Vessel Centerline*.	
2. Set a start and an endpoint in the PC image. 3. Select if you are about to trace a small or large vessel (coronaries are small, everything larger is classified as large). 4. Adjust the control points in any view port. 5. Rotate around the centerline with a left mouse drag next to the line in the CPR view. **Note:** Only the spline and control points within the slab range is visible.	
6. Use the *Vessel Diameter* slider to grow the mask from the centerline.	

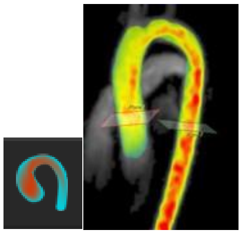
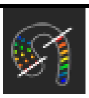
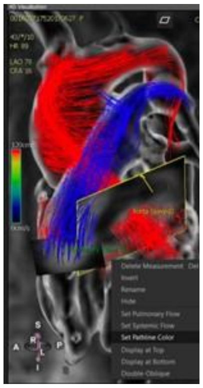
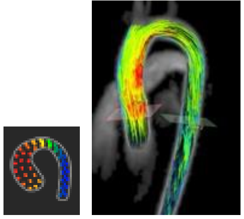
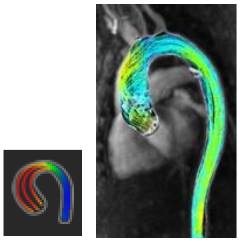
24.4 Analysis

Module overview:

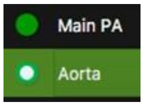
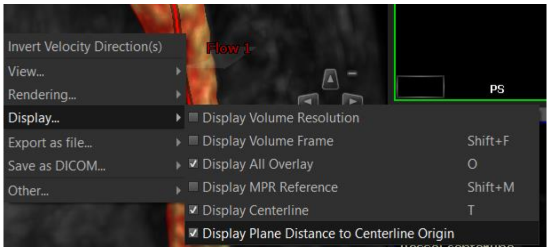
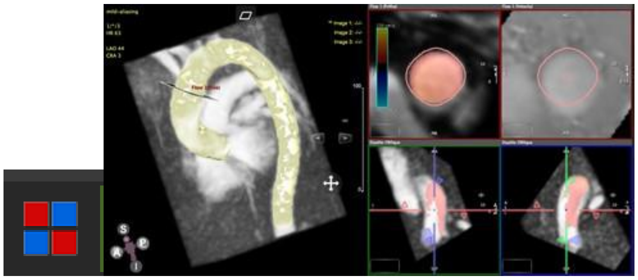
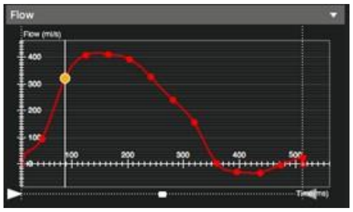
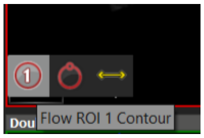
- Flow visualizations
- Quantitative Flow analysis

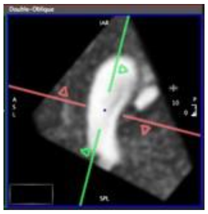
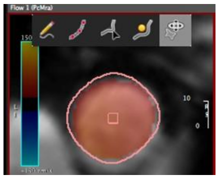
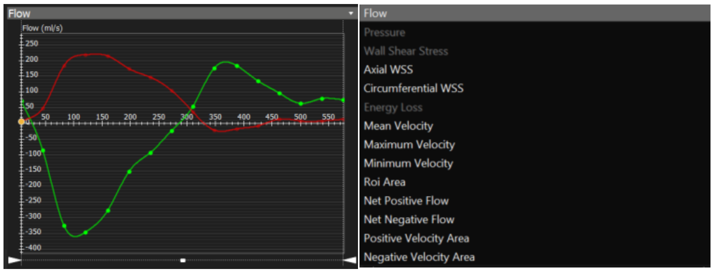
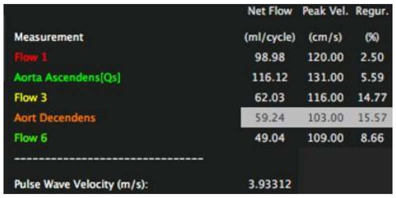
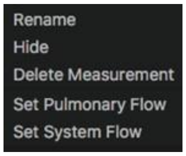
24.4.1 How to Visualize Flow in 4D

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

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

24.4.2 How to do a Flow Measurement

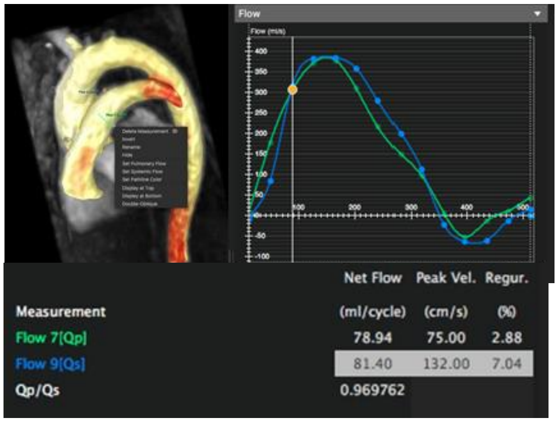
1. Select a mask/structure from the list.	
2. Place a plane in your ROI. Planes will follow a center- line, if present. To toggle on/off the centerline display use the short-cut key 'T' or viewport's context menu. To display the distance of the active plane to the origin of the centerline, use the display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

3. Adjust the double oblique views to accurately display cross-sectional images.	
4. Run a cine to check for correct edge detection. 5. Single-click the contour to adjust it. **Note:** The modified contour is only forwarded to the end of the cycle or until it finds another manually edited contour.	
- Different contouring modes, such as *Point-Click* or *Thresholding* will be available by dragging the mouse on the top position tag.	
- The graph allows to display different parameters in function of time for each Flow ROI. Use the graph dropdown menu to select a different parameter.	
- Adding a measurement, locks the position of the current free plane and triggers the flow calculation. Net, peak and regurgitant flow values will be automatically calculated. - 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.	
- To label a contour right-click on the plane in the PC MRA, or right-click on the flow measurement in the report, select *Rename* from the menu.	
- Click on *Add to report* to add the measurements to the scientific report.	

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

Pulse Wave Velocity (m/s):	3.93312		

24.4.3 How to do a Shunt Calculation (Qp/Qs)



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

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

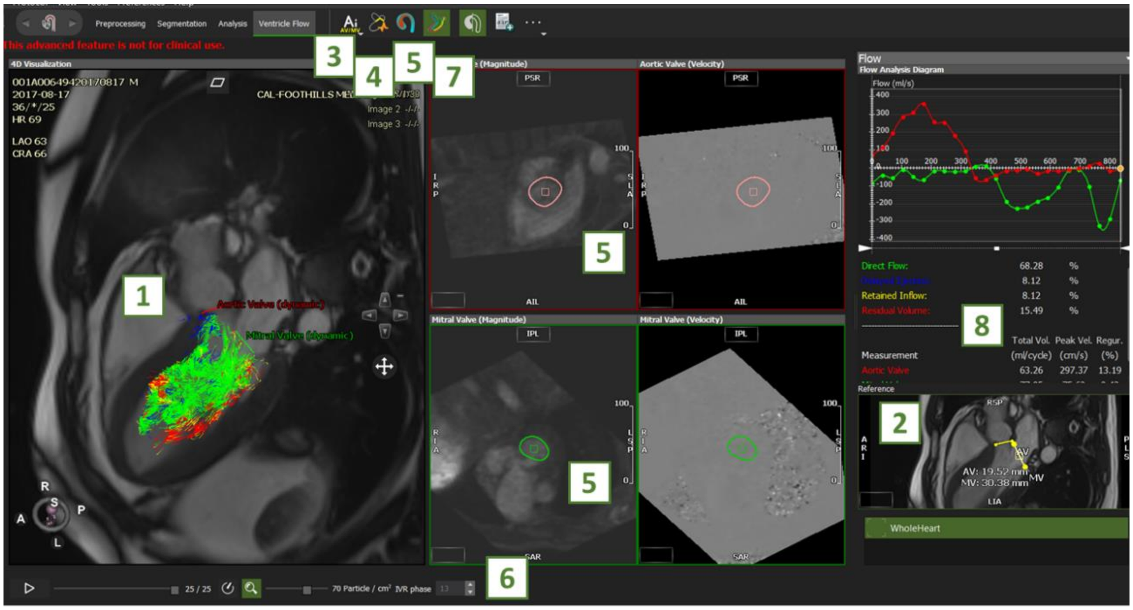
1. Segment the vessels (no centerline) and move to the analysis page.
2. Place a plane in the aorta and in the pulmonary artery.
3. Scroll through the phases and correct contours if necessary.
4. Open the context menu by clicking on the respective plane, e.g. in the ascending Aorta and select *Set Systemic Flow*.
5. Add measurement.
6. Place a second plane in the Pulmonary artery and select *Set Pulmonary Flow*.
7. Add measurement.

24.4.4 Ventricular Flow Analysis

In order to calculate the LV functional flow components (Direct Flow, Delayed Ejection, Retained Inflow, Residual Volume (%, ml)) 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



Direct Flow: 68.28 %
Delayed Ejection: 8.12 %
Retained Inflow: 8.12 %
Residual Volume: 15.49 %

Measurement	Total Vol. (ml/cycle)	Peak Vel. (cm/s)	Regur. (%)
Aortic Valve	63.26	297.37	13.19

AV: 19.52 mm
MV: 30.38 mm

IMPORTANT: The ventricular flow algorithm is implemented according to the latest, state of the art publications, however the algorithm is still sensitive to:

- quality of velocity field and additional corrections performed on velocity field by the user
- noise level / artefacts present in velocity field
- IVR phase number
- mitral / aortic valve planes and contours
- completeness of cardiac cycle

Valve regurgitation is not modeled yet, which means that results may be inaccurate in cases of valve regurgitation.

IMPORTANT: The ventricular flow page is to be used for research purposes only.

24.5 How to report Kinetic Energy (KE)

24.5.1 Analysis Page

In the Analysis Page, for each mask/structure, the volume (ml) and the KE (μJ) will be calculated per time point and added to the scientific 4D Flow report, upon clicking on *Add to report*.

24.5.2 Ventricular Flow Page

In the Ventricular Flow page, the KE (μJ) of each LV component will be calculated per time point and added to the Ventricular Flow scientific report, upon clicking on *Add to report*.

24.6 How to do 2D Wall Shear Stress (WSS) analysis

24.6.1 Global 2D WSS

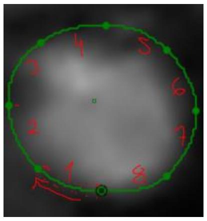
1. Place a plane in the 3D volume and contour the vessel of interest on all phases using cross-sectional views.
2. On the graph dropdown menu select axial or circumferential WSS to display the 2D global WSS values (mean across the 2D contour) in function of time.
3. Add the results to the report.

24.6.2 Regional 2D WSS (8 segments of the vessel contour)

1. **Go to the first image of the cycle** and turn on one of the planar WSS options from the graph dropdown menu.
2. Select the Flow Reference Point tool from the toolbox on the bottom left of the cross-sectional viewport.

3. Place a reference point on the contour. The reference point will automatically generate the other 7 points, equally spaced out along the contour. The reference point will be forwarded to all the other phases and the other 7 points will be generated for each phase.
4. Editing a reference point on a phase contour is only forwarded to the end of the cycle or until it finds another manually edited reference point. If the reference point is edited such that it does not lay on the contour, it will be automatically snapped to the closest point on the contour.

The 8 points on the contour are used to divide the contour into 8 segments. The first segment starts on the reference point and ends in the next point in clock-wise direction.



5. Upon clicking on *Add to report* the results will be added to the *Planar Wall Shear Stress* scientific report.

24.7 How to visualize and quantify Blood Flow Particles

24.7.1 Visualization

In order to track the path of particles emitted by a plane, using pathline colors:
Right-mouse click on each desired plane, and select *Set Pathline Color* option from the context menu and run cine to visualize the custom color-coded flow.

24.7.2 Quantification

Upon clicking *Add to the report*, the path of each particle will be calculated and the quantitative results will be added to the report in table format, for each selected mask/structure. The table shows the % of blood flow particles that each plane emits/receives from all the other planes on the mask. Each plane on the mask is consider as an emitter and as a receiver of particles.

Note: The particles are emitted and received in the area defined by the contours on the planes.

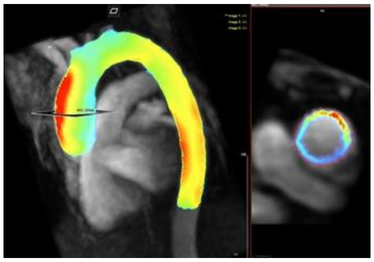
24.8 Advanced 4D Flow Parameter Analysis

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

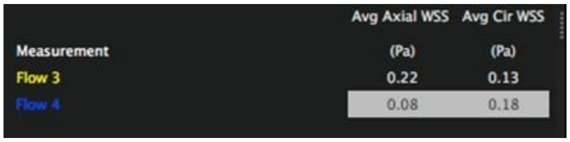
The following advanced parameters are computed from the 3D structure mask.

24.8.1 How to Assess Wall Shear Stress

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



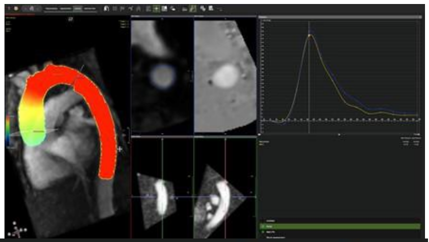
1. To visualize 3D wall shear stress, activate the button in the top tool bar and run the cine.
2. The stress curve will be updated as you drag the plane along the centerline.
3. Add a measurement to the report.
4. WSS components will be calculated automatically and the curves and their respective measurements can be selected from the *Flow* Menu.



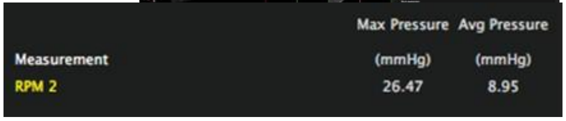
Measurement	Avg Axial WSS (Pa)	Avg Cir WSS (Pa)
Flow 3	0.22	0.13
Flow 4	0.08	0.18

24.8.2 How to do Relative Pressure Mapping

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



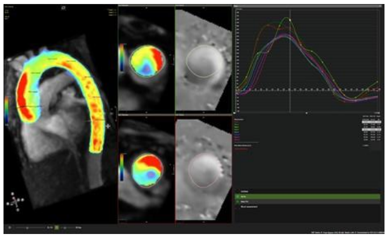
1. Activate the *Pressure Visualization* button.
2. You will be given a reference and a free plane. Position them in your ROI.
3. Add a measurement.
4. Pressure curves from the measurement and the free plane will be displayed in a graph. The relative pressure difference to the *Reference* plane will be reported.

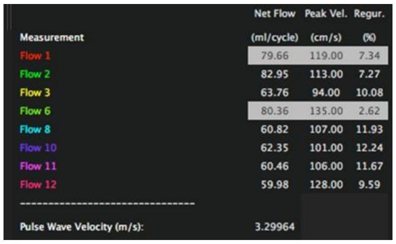


Measurement	Max Pressure (mmHg)	Avg Pressure (mmHg)
RPM 2	26.47	8.95

24.8.3 How to Calculate Pulse Wave Velocity

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



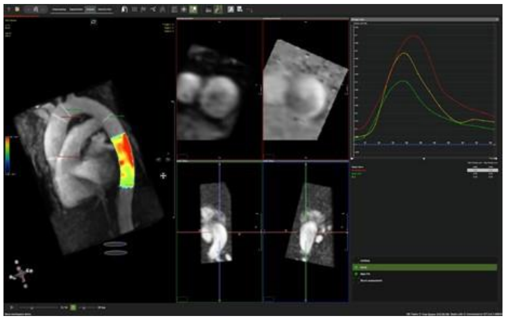
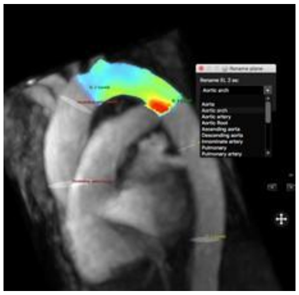
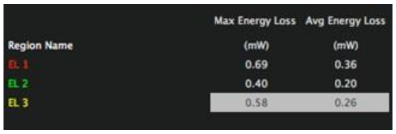
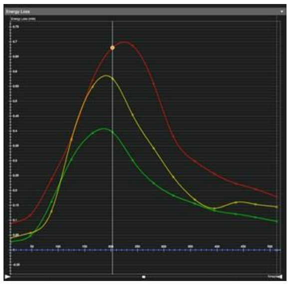


Measurement	Net Flow (ml/cycle)	Peak Vel. (cm/s)	Regur. (%)
Flow 1	79.66	119.00	7.34
Flow 2	82.95	113.00	7.27
Flow 3	63.76	94.00	10.08
Flow 6	80.36	135.00	2.62
Flow 8	60.82	107.00	11.93
Flow 10	62.35	101.00	12.24
Flow 11	60.46	106.00	11.67
Flow 12	59.98	128.00	9.59

Pulse Wave Velocity (m/s): 3.29964

24.8.4 How to Analyze Energy Loss

Note: Not for clinical use.

<table>
<tr>
<td>
1. Activate the button.
2. Define a region by placing 2 planes.
3. Add a measurement.
</td>
<td></td>
</tr>
<tr>
<td>
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.
</td>
<td></td>
</tr>
<tr>
<td>
6. Maximum and average energy loss over time will be reported and the curves per region (limited to 6) are displayed.
</td>
<td>

<table>
<tr><th>Region Name</th><th>Max Energy Loss (mW)</th><th>Avg Energy Loss (mW)</th></tr>
<tr><td>EL 1</td><td>0.69</td><td>0.36</td></tr>
<tr><td>EL 2</td><td>0.40</td><td>0.20</td></tr>
<tr><td>EL 3</td><td>0.58</td><td>0.26</td></tr>
</table>

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

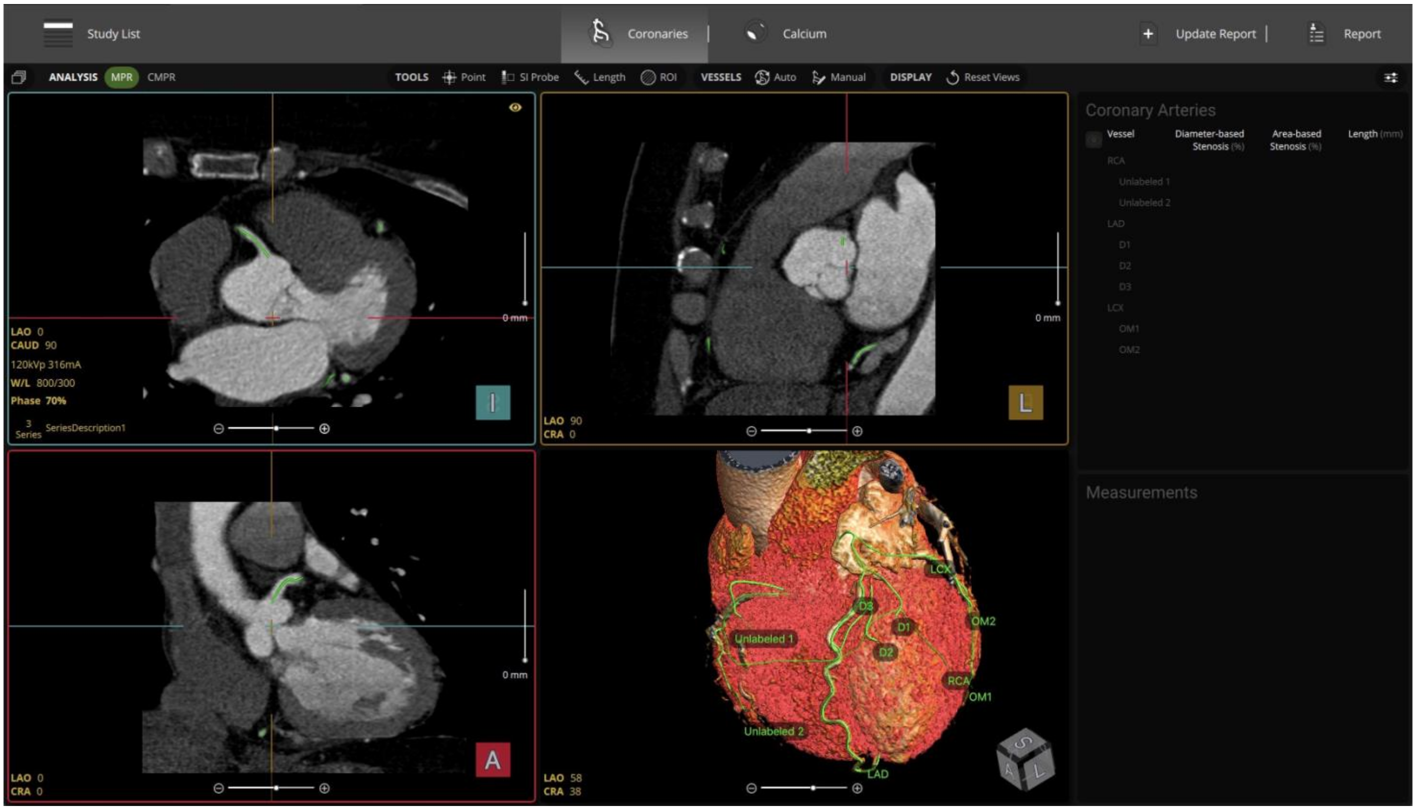
25 CORE CT

cvi42 | CORE CT includes tools for assessing CT studies for coronary artery disease. CT studies sent to **cvi42** are automatically pre-processed to determine the following:

- Segmentation and labeling of coronary artery centerlines in contrast-enhanced CTA.
- Volume rendering segmentation of the heart and coronary tree in contrast-enhance CTA.
- Calcium scoring of non-contrast CT (Agatston score, mass, volume).

If pre-processing is disabled, these automated results are processed when a study is loaded in CORE CT.

25.1 Coronaries



The coronaries module provides the following functionality:
An MPR page with three MPR viewports and a viewport which showing the anatomy in 3D, allows assessment the anatomy as well as basic measurements and allows a user to verify and adjust the centrelines found automatically. Users can semi-automatically or manually define vessel centerlines.
The CMPR page allows the user to finetune centerlines, extend centerlines, assess vessels in detail, and measure stenoses.

25.1.1 Interacting with Images

FUNCTION	MOUSE CLICKS	ALTERNATIVE
Scrolling through MPR	LMB + Drag up/down	Scroll wheel Up/down arrow keys
Window/Level	RMB + Drag up/down, left/right	
Zoom	MMB + Drag up/down	On-screen slider bar and +/- at bottom of viewport
Pan	Shift + LMB Drag	
Rotate Volume	LMB + Drag	Click on orientation cube faces
Rotate MPR	*Command/Ctrl* + Click to free rotate MPR view	LMB + Drag reference lines in other MPR views
Re-center MPR views	*Command/Ctrl* + LMB double-click	LMB + Drag MPR crosshairs

FUNCTION	MOUSE CLICKS	ALTERNATIVE
Maximize viewport	LMB double-click (repeat to restore multi-view layout)	
Context Menu	RMB click	

25.1.2 MPR Tools

Clicking on a tool section title (tools, vessels, display) expands or collapses the correspondent options.

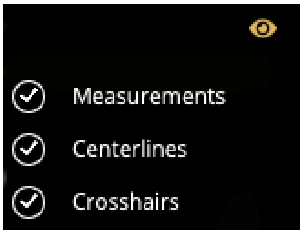
TOOL	Description
Point	Place a 3D point to indicate a structure.
SI Probe	Place a pixel probe to measure Hounsfield Units.
Length	Measure the distance between two points.
ROI	Place points around the area of interest and close the spline by double-clicking.
Vessels: Auto	Semi-automated vessel detection. Place a point on a vessel in MPR or 3D View and the software will detect the centerline.
Vessels: Manual	Manually trace a centerline by placing control points in the MPR view.
Reset Views	Resets the MPR views. (To reset a volume, use the RMB menu).

25.1.3 Selecting series and phase

The software will attempt to load a suitable series in the viewer by default, but by opening the series panel it is possible to select a different series by dragging one in the viewer area.

When a multiphase study is loaded arrows will be shown next to the phase information. Use the arrows to select a different phase.

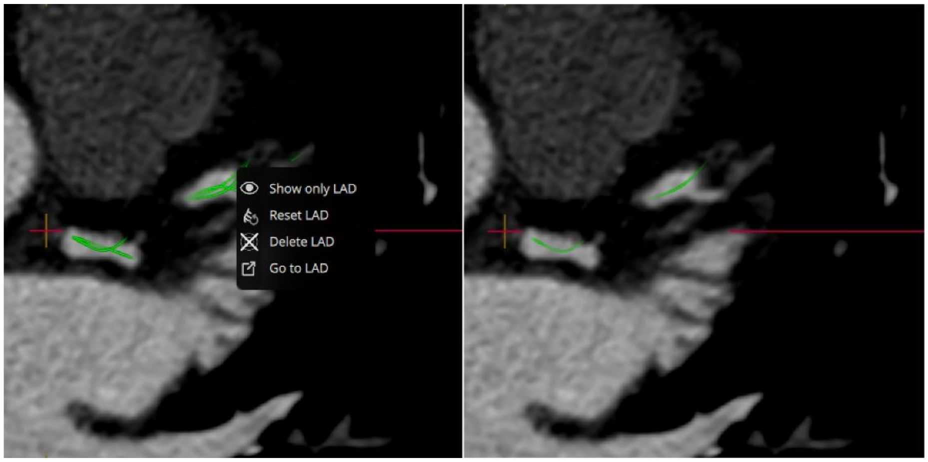
25.1.4 MPR Viewports



The eye icon in the upper right corner provides access to toggle visibility of various on-screen elements (shortcut keys are provided:

- Measurements (M)
- Centerlines (V)
- Crosshairs (C)

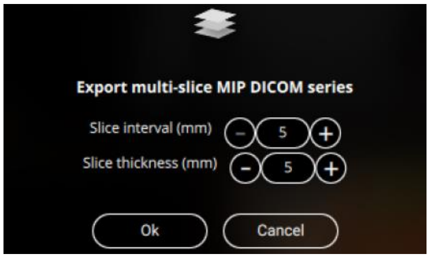
To create a new centerline, either use the *Auto* tool and single-click in a vessel to automatically create a centerline, or use the *Manual* tool to drop points along the vessel. Centerlines may be edited by dragging control points. Right-click on a centerline to see other options for re-naming, deleting, or resetting the vessel centerline to its original state.



To hide all other centerlines, right-click on a vessel centerline and select “Show only…”.

When holding the *Ctrl* key (*Command* on Mac), *trackball* mode will be activated, in the mode the MPR can be freely rotated around the center point of the image. The center point can be moved by double clicking on the desired location while pressing *Ctrl* key (*Command* on Mac). This mode is useful for traversing a vessel in the MPR view.

Adjust the slab thickness using the thickness slider on the right side of the viewport. The thick slab will be rendered as a maximum intensity projection (MIP).



Export multi-slice MIP DICOM series

Slice interval (mm) 5

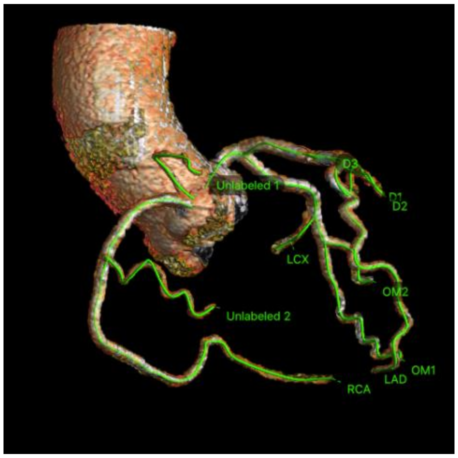
Slice thickness (mm) 5

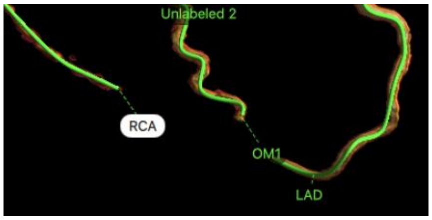
To export a MIP series, select *Export MIP Slices* from the right mouse button menu. The thickness and slice interval can be entered in the dialog that pops up. The orientation will be taken from the actual orientation of the viewports.

25.1.5 3D View

The 3D view provides segmentation options for viewing the coronary anatomy, including the default heart segmentation view, and coronary tree view.

To edit the vessel label on the 3D view, double-click the label and update the text.





The centerline can be extended by clicking the original end point and dragging it to the desired end point of the vessel.

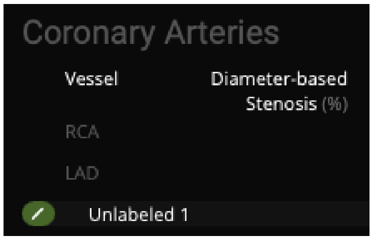
25.1.6 Measurements

After placing a measurement, a reference will be added to the measurement panel:

- Clicking on a measurement in the list will bring the measurement into view in one of the MPR viewports.
- Hovering over a measurement will reveal the delete icon.
- Double-click the label in a viewport to rename a label.

25.1.7 Vessel Centerlines

All vessels that have been detected automatically or are added manually later are listed in the Coronary Arteries table. The RCA, LCX, LAD, and several other vessels will be labeled automatically. Any vessels not automatically classified will be unlabeled and can be labeled manually.



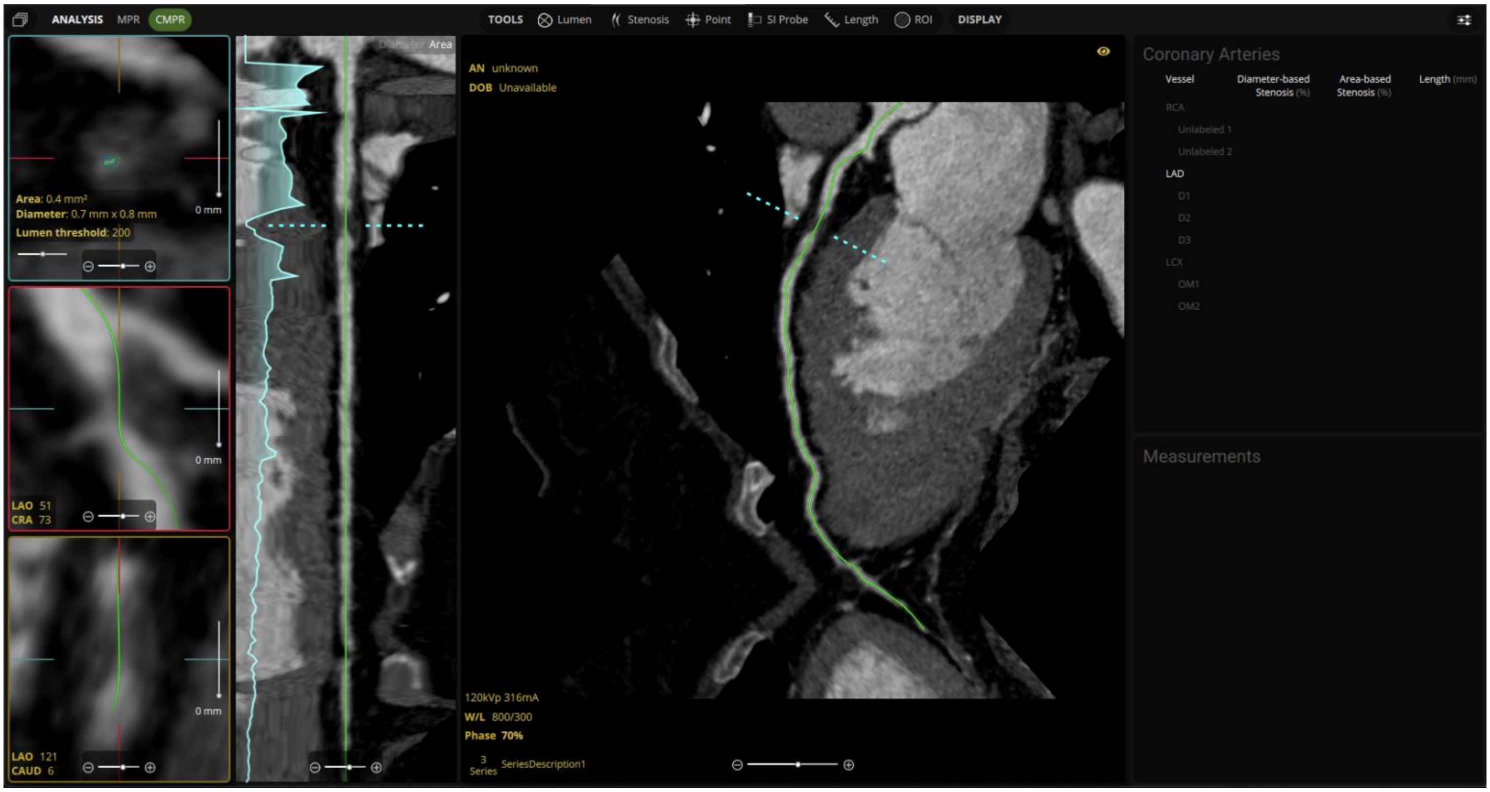
Coronary Arteries

Vessel	Diameter-based Stenosis (%)
RCA	
LAD	
✎ Unlabeled 1	

Hover over the label that needs to be adjusted and click the pencil icon. Clear the content a dropdown will open from which the correct label can be selected.

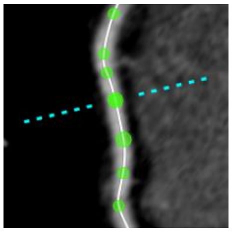
25.1.8 Curved MPR (CMPR)

Vessels can be inspected in greater detail in the CMPR page, this page can be reached by double clicking a vessel in the Coronary Arteries table or clicking on *CMPR* in the toolbar.



The main viewport shows the CMPR view of the selected vessel, which is highlighted in the Coronary Arteries table. To the left is a straightened MPR view and to the far left 3 orthogonal MPR viewports are shown, the leftmost MPR viewport is perpendicular to the centerline, at the location of the dotted blue line (Shown on the straightened and curved MPR).

To export the CMPR, select *Export Vessel Rotation* in the right mouse button menu of the CMPR viewport. The number of images can be selected, the degree of rotation will be calculated automatically.



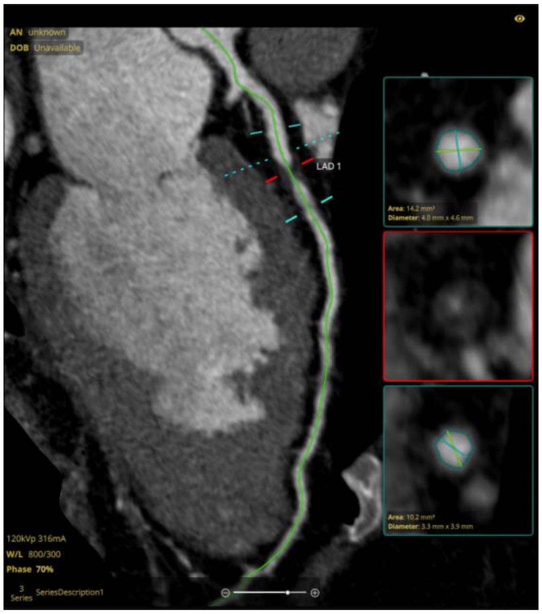
The centerline can be easily adjusted by moving the mouse over it, the control point will be highlighted and can be dragged by using left mouse-drag.

Control points can be added by a left mouse click on a piece of the centerline that does not contain a control point. A control point can be deleted by right clicking on it and select *Delete control point*.

Centerline edits can be undone by selecting Undo from the right-click menu, or pressing *Ctrl* + *Z* (*Command* + *Z* on Mac).

25.1.9 Measuring Stenoses

To measure stenosis select the Stenosis tool from the toolbar. Left click on the proximal reference location, keep the left mouse button pressed and drag over the stenosis until the distal reference location is reached, release the mouse button. The stenosis marker will be placed in the middle by default, this marker can be dragged to the location of the maximal stenosis, the reference markers can still be dragged as well.



To edit the lumen at the location of the stenosis or reference location. Click on the marker for which the lumen needs correction, and edit the lumen in the upper left cross sectional view by moving the mouse over the contour and left drag to draw a new contour.

The lumen threshold slider can be used that is considered lumen.

When no lumen is detected it is possible to manually draw a lumen contour using the tool from the toolbar.

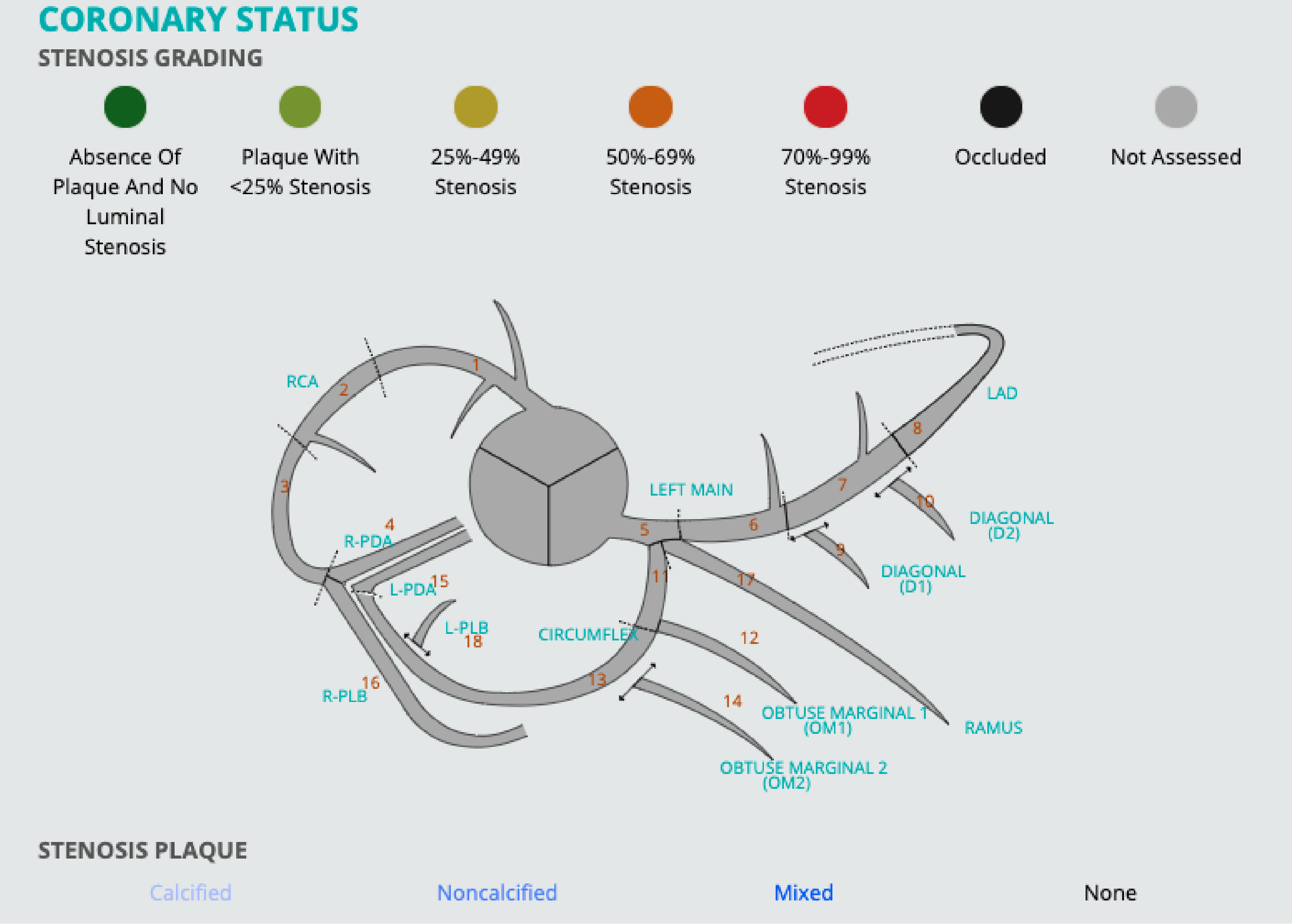
The stenosis values will be shown in the Coronary Arteries table under the name of the vessel:

The stenosis percentage based on the minimal diameter and based on the area will be shown here. The last value is the length between the proximal and distal reference marker.

The Add to report button will add all stenosis measurement including screenshots of the CMPR and cross-sectional views to the report.

25.1.10 Coronary Reporting

Use the Coronary Summary section to indicate severity of any stenoses found and presence of plaque in each segment of the coronary tree.



CORONARY STATUS

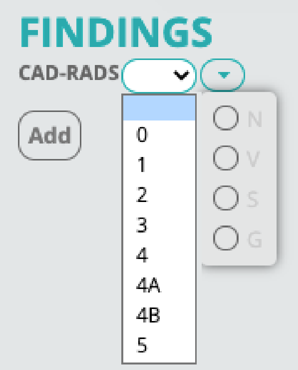
STENOSIS GRADING

●	●	●	●	●	●	●
Absence Of Plaque And No Luminal Stenosis	Plaque With <25% Stenosis	25%-49% Stenosis	50%-69% Stenosis	70%-99% Stenosis	Occluded	Not Assessed

STENOSIS PLAQUE

Calcified Noncalcified Mixed None

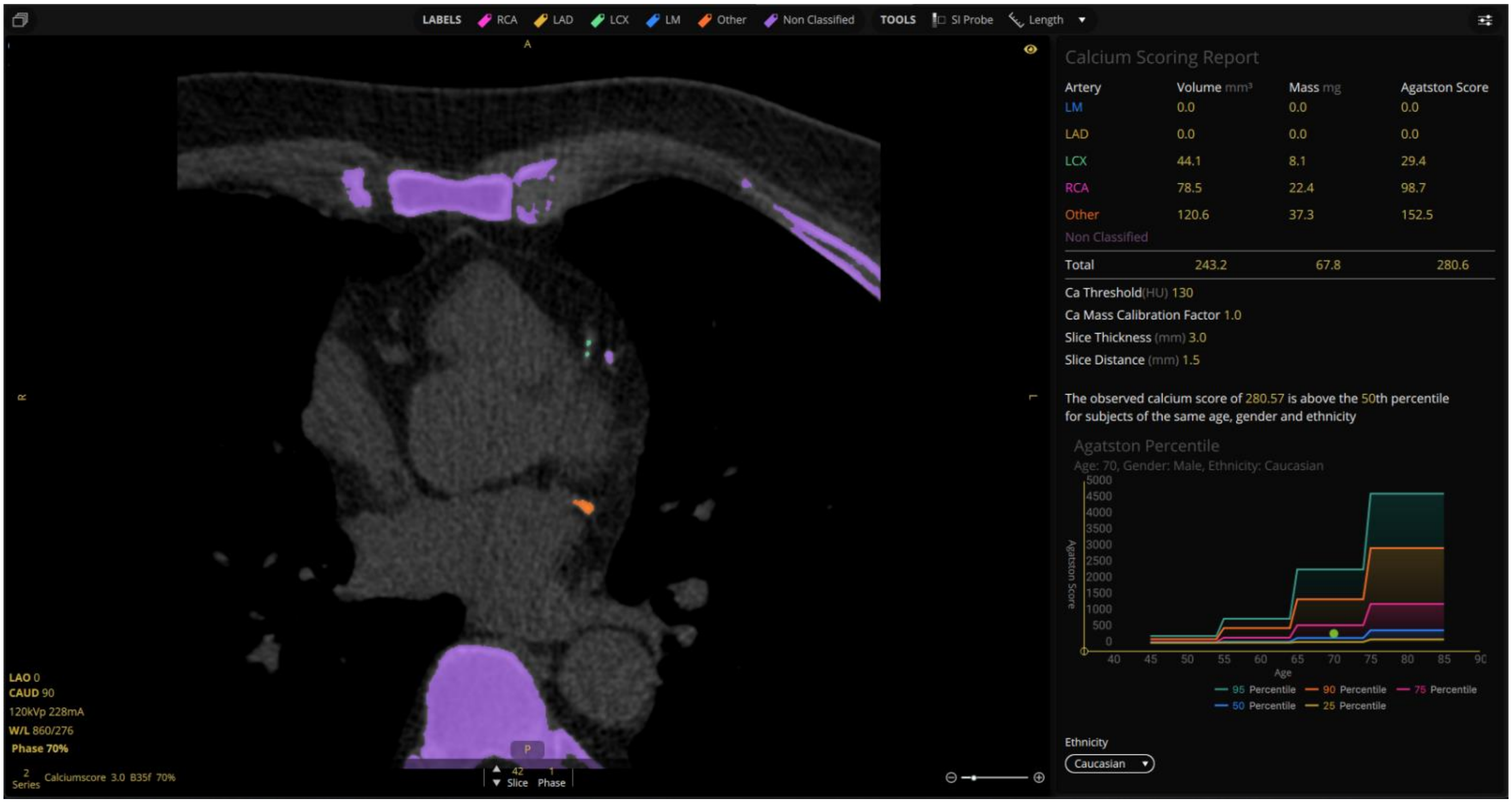
CAD-RADS score can be reported in the Findings section of the report.



FINDINGS

25.2 Calcium

Note: Validation of the semi-automated labeling in the Calcium Module was done with data from GE and Siemens.



Calcium Scoring Report

Artery	Volume mm³	Mass mg	Agatston Score
LM	0.0	0.0	0.0
LAD	0.0	0.0	0.0
LCX	44.1	8.1	29.4
RCA	78.5	22.4	98.7
Other	120.6	37.3	152.5
Non Classified			
Total	243.2	67.8	280.6

Ca Threshold(HU) 130
Ca Mass Calibration Factor 1.0
Slice Thickness (mm) 3.0
Slice Distance (mm) 1.5

The observed calcium score of 280.57 is above the 50th percentile for subjects of the same age, gender and ethnicity

The calcium scoring module can be used to determine the amount of calcified plaque (Volume and mass) and to determine the Agatston score.

By default, the best suitable scan will be loaded in the viewer, however it is still possible to select another series from the series panel.

The software will automatically detect the calcium by selecting all pixels with a Hounsfield value of 130 or higher and then labeling them to indicate in which vessel the calcium is located. When no adequate vessel is found for a bundle of calcium it will be labeled as “Non classified” and excluded from all calcium scoring calculations.

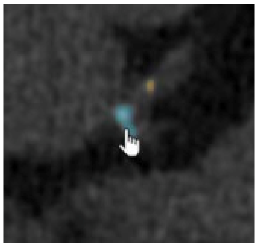
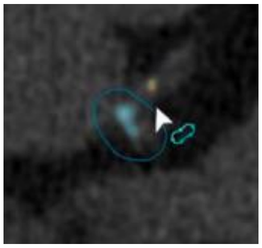
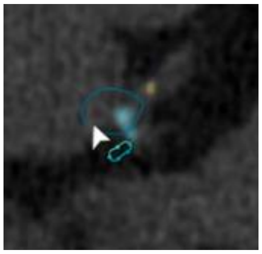
To verify and correct the labeling of calcium bundles scroll through the dataset, the mouse wheel facilitates slice-by-slice scrolling.

A legend describing which color is corresponds to which vessel can be found in the Calcium scoring report window on the top right of the application.

25.2.1 Assigning Calcium Labels

To assign a label to calcium, select the desired label from the toolbar at the top of the window:

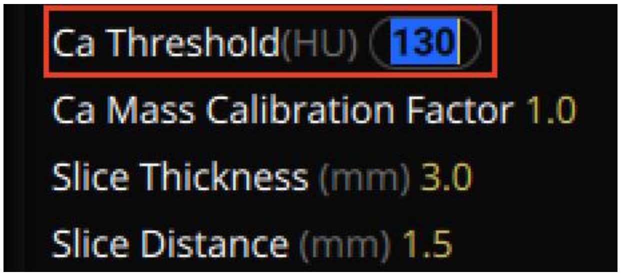
There are three methods to perform the labeling, always start by selecting the label.

1. **Click**: Click a bundle of calcium, the whole bundle will be labeled. The labeling will be automatically applied to the neighboring slices.	
2. **Contour Around**: Draw a contour around one or more pieces of calcium, all calcium will be labeled. The labeling will only be applied to the slice and **not** to the neighboring slices.	
3. **Contour Through**: Draw a contour through a calcium bundle to split it, only the part inside the contour will be labeled. The labeling will only be applied to the slice and **not** to the neighboring slices.	

25.2.2 Adjusting Calcium Threshold and Mass Calibration Factor

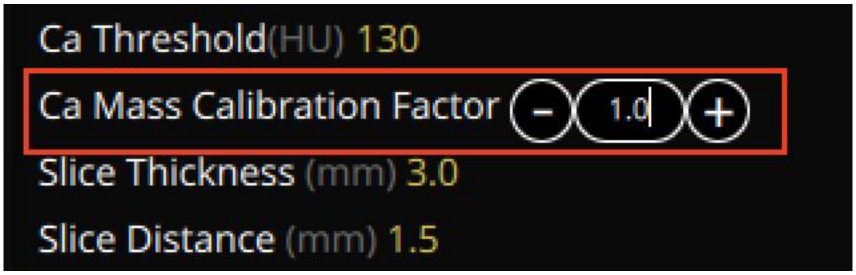
The calcium threshold and the mass calibration factor can be manually adjusted.

Change the calcium threshold by clicking on the calcium threshold number (in yellow, default 130 HU) and enter the desired calcium threshold. Editing the threshold will reset the calcium contours and any manually classified labels.



Ca Threshold(HU) 130
Ca Mass Calibration Factor 1.0
Slice Thickness (mm) 3.0
Slice Distance (mm) 1.5

The mass calibration factor can be adjusted by clicking on the mass calibration factor (in yellow, default 1.0) and enter the desired factor



To revert back to the values with the original calcium threshold and mass calibration factor, reset the workspace.

25.2.3 Calcium Reporting

All results can be read from the calcium scoring report table as well as the percentile graph, which will both be added to the report when using the *Add To Report* option. The percentile graph requires the patient's age, gender, and ethnicity.

The calcium-annotated images and the table can be exported as a DICOM Secondary Capture (SC). Right-click on the image and select the option *Export Calcium Series.* The saved SC will appear in the series list.

Note: The Calcium Module presents a comparison of calcium score against published reference data [1]; this comparison is for informational purposes. Based on the existing science and standard care of practice, these reference data can offer insight into the potential for developing future coronary disease; however, **cvi42** Auto does not claim to make a prediction regarding whether or not the patient will develop coronary disease.

[1] McClelland RL, Chung H, Detrano R, Post W, Kronmal RA. Distribution of coronary artery calcium by race, gender, and age: results from the Multi-Ethnic Study of Atherosclerosis (MESA). Circulation. 2006 Jan 3;113(1):30-7. doi: 10.1161/CIRCULATIONAHA.105.580696. Epub 2005 Dec 19. PMID: 16365194.

25.3 Workspaces

Series loaded in each viewport, as well as existing contours, measurements, and annotations at a specific time point can be saved in a study workspace.

The workspace menu on the top bar allows a user to:

1. *Clear the Study Workspace*
   Clears all viewports, contours, measurements and annotations of the loaded study.
2. *Restore the Auto Workspace*
   Restores the series loading and contouring that were automatically defined by the system for all modules.
3. *Load Study DICOM Workspace*
   Allows to load a different user DICOM Workspaces for the loaded study.
4. *Save Study DICOM Workspace*
   Allows to save the current status of the study to a user-specific DICOM Workspaces.

26 Legacy Coronary Module (including Auto plaque)

The Coronary Module includes the following pages:

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

Auto-plaque assessment requires a separate license.

26.1 Landmark Page

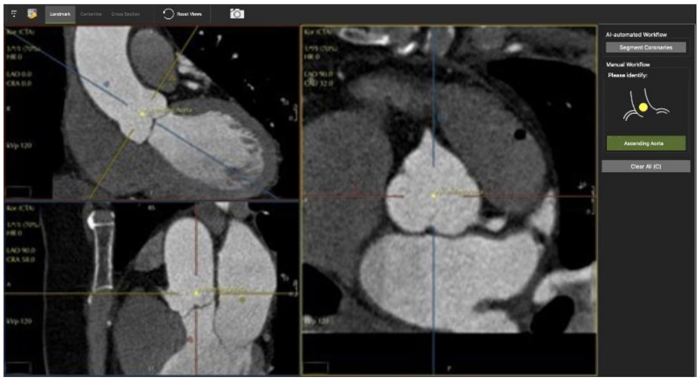
The Landmark Page allows the user to either use an automated workflow to segment and label the major coronary arteries, or a manual workflow to identify various vessel centerlines, starting with identifying the aorta.

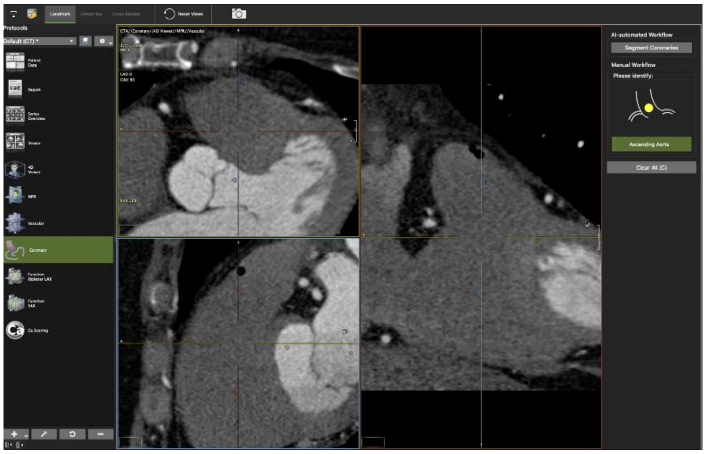
26.1.1 Automated Workflow

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

26.1.2 Manual Workflow

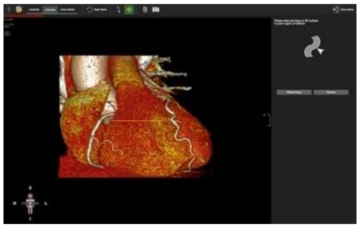
- Placing a Landmark in the ascending aorta will support the centerline generation.





26.2 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 .



26.2.1 How to Define a Centerline via Region Growing

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

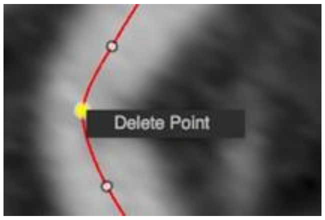
1. The *Region Growing* tool is activated by default. Define a single vessel or the entire coronary tree.
2. Drag on the 3D surface to define a vessel or a vessel tree.
3. The modifier key *alt* will rotate, *Ctrl/* (*Command* for Mac) will pan the volume.
4. Click *Trace Vessel* when you are done.
5.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

Please click vessel end points to trace centerline:

26.2.2 Define a Centerline via Seed Points

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

26.2.3 Edit the Centerline

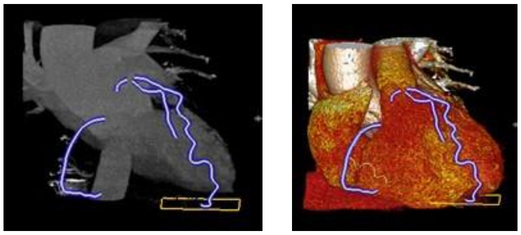
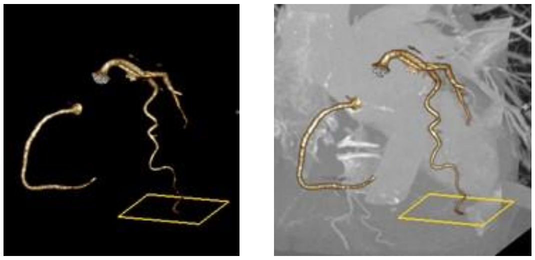
1. *Shift*, add (single left-click), *Delete* (right-click) control points in the CPR or the oblique views. 2. Rotate around the centerline with a left mouse drag close to the centerline. 3. Pan the image by moving the cursor away from the centerline until the hand symbol appears.	

26.2.4 Save Options

- *Save rotational images*.

- *Multi Frame Captures* (See *MPR Viewer*).

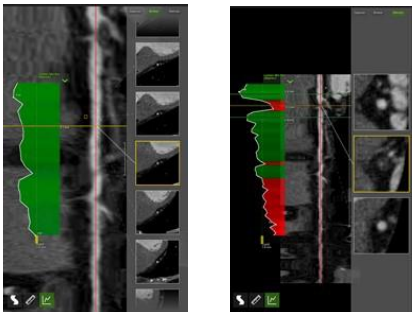
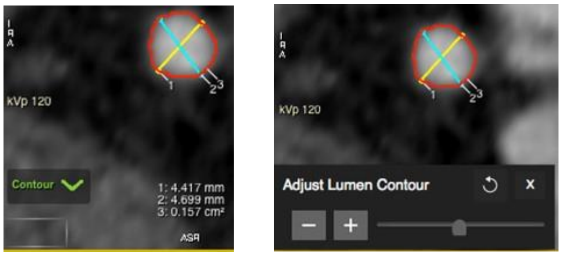
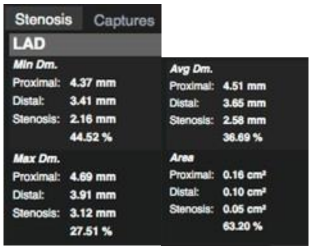
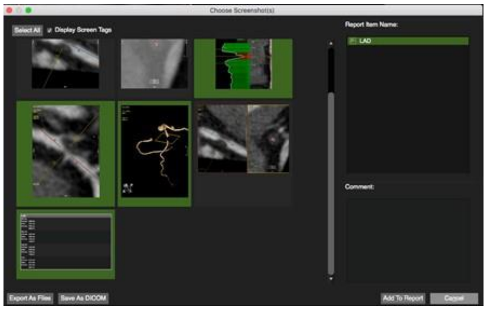
26.2.5 3D View

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

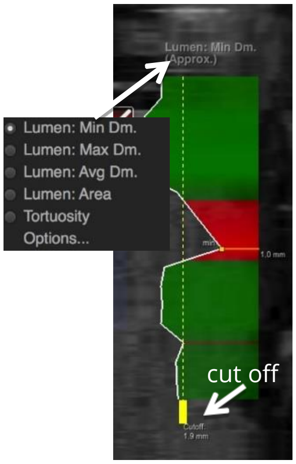
26.3 Cross Section

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

26.3.1 How to do a Stenosis Assessment

1. Start in *Browse* view and drag the yellow line down the vessel. 2. Switch to *Stenosis* View and place the stenosis marker either by dragging or by double-clicking in the stenosis.	
3. Move to the MPR view and use the *Auto Vessel Lumen* Contour to contour the stenosis and the 2 references images. 4. To adjust the threshold, click the green contour label. It will open a slider that allows to adjust the contour.	
5. Stenosis measurements will be filled in automatically.	 **LAD** *Min Dm.* Proximal: 4.37 mm Distal: 3.41 mm Stenosis: 2.16 mm 44.52 % *Avg Dm.* Proximal: 4.51 mm Distal: 3.65 mm Stenosis: 2.58 mm 36.69 % *Max Dm.* Proximal: 4.69 mm Distal: 3.91 mm Stenosis: 3.12 mm 27.51 % *Area* Proximal: 0.16 cm² Distal: 0.10 cm² Stenosis: 0.05 cm² 63.20 %
6. Use the *Multiframe Capture* to save the measurements and images	

26.3.2 How to Use the Centerline Graph



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

Options:

- *Lumen* menu, offering display options.
- *Cut off*: Drag the yellow handle to set a cut off.
- The ruler measures a custom defined distance.
- The context menu offers viewing, rendering, saving, export and more options.

26.4 Plaque Analysis

WARNING: Auto-Plaque
The use of the Auto-Plaque is for non-clinical, scientific use only.

26.4.1 How to Perform Plaque Analysis

The image part with relationship ID rId506 was not found in the file.

1. Load the study into the Vessel module.
2. Define a *Lesion* range by dragging the shaded area over the lesion.
3. Click on auto plaque.

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

4. Select frames and add them to the report.

27 Legacy Calcium Scoring

27.1 Toolbar

27.1.1 How to Do Calcium Scoring

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

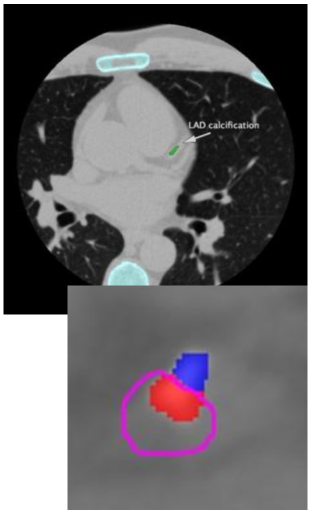
Post processing for Calcium Scoring requires the detection of calcium and assignment to a coronary.

27.1 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.

27.1.1 How to do Calcium Scoring

1. Open the on-screen navigation buttons or use your keyboard arrow keys to scroll through the slices.
2. Toggle the *Overlay Display* and scroll through the volume.
3. When you have detected Ca, select the respective coronary ROI-button and simply click in the calcified area.
4. To re-do the region selection, click again.
5. To reset all region selections, use the *Reset Selection* button in the toolbar.
6. To assign calcification to two different coronaries:
7. Split the lesion with the Ca Scoring Selection Contour.
8. Select the first matching ROI (e.g. LM) and click into the respective section.
9. Then, select the second ROI (e.g. LAD) and click into the other part of the lesion.
10. Add the analysis to your report.

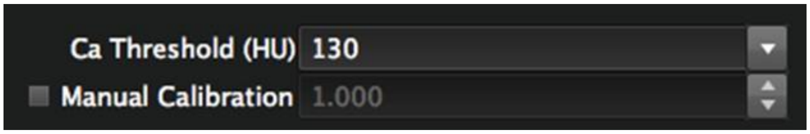


Threshold:

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

Calibration Factor:

- The Calibration Factor will be retrieved from the DICOM header or can be entered manually (Calibration Factors are specific to scanner, protocol and patient weight).



Ca Threshold (HU) 130

☐ Manual Calibration 1.000

Agatston Classification:

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

Ca Scoring Report

Artery	Volume mm³	Mass mg	Score Agatston
LM	0.00	0.00	0.00
LAD	75.44	27.55	100.59
CX	0.00	0.00	0.00
RCA	54.44	19.51	72.59
Total	129.88	47.06	173.18

Ca Threshold: 130.00

Ca Mass Calibration Factor: 1.00

Agatston Score Classification:

Moderate Coronary Artery Calcification

Percentiles:

- The percentile graph requires the patient’s age, gender, and ethnicity.

Note: The Calcium Module presents a comparison of calcium score against published reference data [1]; this comparison is for informational purposes. Based on the existing science and standard care of practice, these reference data can offer insight into the potential for developing future coronary disease; however, **cvi42** Auto does not claim to make a prediction regarding whether or not the patient will develop coronary disease.

[1] McClelland RL, Chung H, Detrano R, Post W, Kronmal RA. Distribution of coronary artery calcium by race, gender, and age: results from the Multi-Ethnic Study of Atherosclerosis (MESA). Circulation. 2006 Jan 3;113(1):30-7. doi: 10.1161/CIRCULATIONAHA.105.580696. Epub 2005 Dec 19. PMID: 16365194.

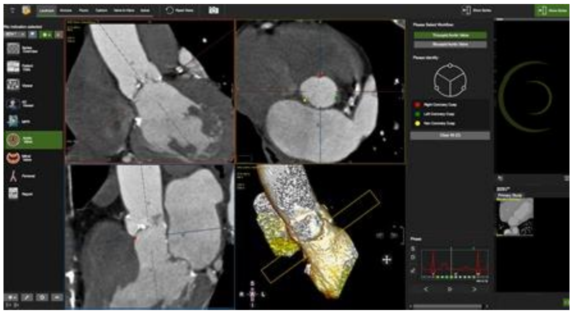
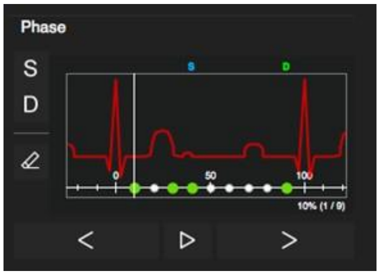
28 Aortic Valve Module

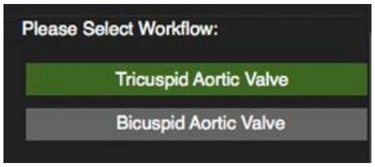
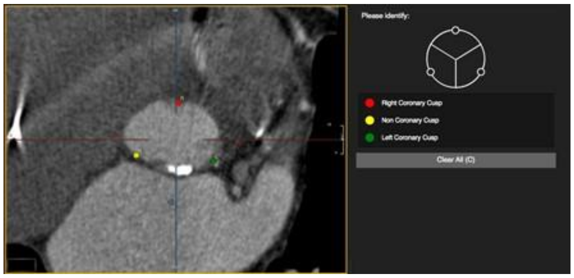
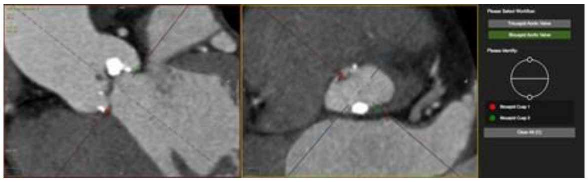
Module overview

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

28.1 Landmark page

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

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

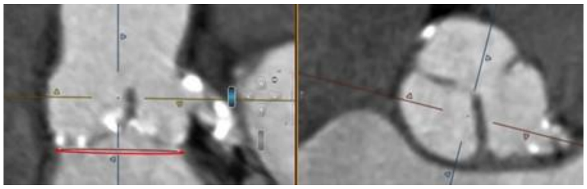
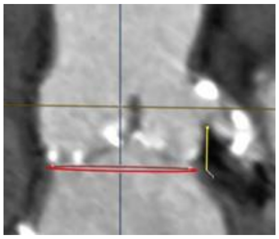
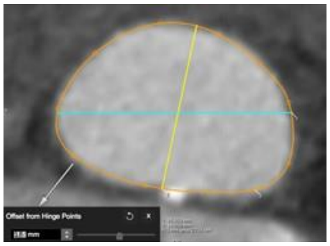
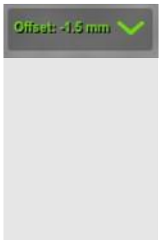
3. Select *Workflow*: • Choose between a bi- or tricuspid valve.	
4. Identify the cusps (tricuspid). In random order, place three points at the hinge of the right, left and non-coronary cusp. The software will identify and label the cusp points.	
5. Identify the cusps (bicuspid). • Clicking on one of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

28.2 Annulus Page

28.2.1 Measurements

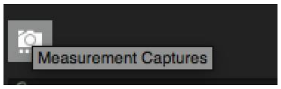
Aortic Annulus

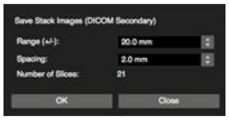
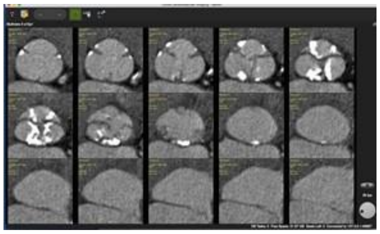
1. Use the *Perimeter* tool and set control points around the annulus. You can maximize the view with a spacebar-click, or by clicking in the top right corner of the view port. 2. To edit the perimeter, single-click on the control points. Single-click in the background to disengage. 3. The annulus will be the only measurement that is labelled automatically.	
Ancillary measurements: • *Reset View* button in the toolbar will take you back to the annulus plane.	
• Tools are in the top tool bar and the pencil box in the left bottom corner of the viewer frame. Measurements can be done in any viewer frame.	
• Measurements and images are captured automatically. • Drag the appropriate label from the predefined list on the capture. • To review a measurement, simply click on the capture. • Right-click to delete the capture. Alternatively, use the *Delete* key.	Aortic Annulus ST Junction LVOT Sinus of Valsalva Coronary Ostium Height (Left) Coronary Ostium Height (Right) Sinus of Valsalva Height Aortic Annulus 1: Pe. 93.0 mm 1: Area 6.544 cm^2 2: Min Dm. 24.1 mm 3: Max Dm. 33.5 mm Coronary Ostium Height (Left) 1: Length 17.4 mm

4. Ostium Height measurement. - Using the *Ostium Height* measurement tool, drop a point at the height of the ostium with a left mouse click. - Drag the label on the measurement capture. - Repeat for the other coronary artery.	 
5. LVOT measurement. - Open the small *Offset* box in the bottom left corner (see white arrow), and use the slider to scroll down into the LVOT. - Using the perimeter tool, measure at narrowest portion of the LV outflow tract.	  Offset: -1.5 mm

28.2.2 Reporting Options

28.2.2.1 Capture Measurements and Images

- Worklist measurements, labelled with the tags provided, will automatically be entered into an infographic (see below) in the report module. - Measurements changes will be updated.	 Aortic Annulus ST Junction LVOT Sinus of Valsalva Coronary Ostium Height (Left) Coronary Ostium Height (Right) Sinus of Valsalva Height
Measurement Captures (Report Panel):  - Activating the measurement capture camera will allow to add respective pictures to the report.	 Image Comment: Series 2, Phase 4
Multi Frame Screen Captures (Tool Bar): - Captures images of the current layout e.g. corresponding cross-sectional images of a particular plane or measurement.	 Reset Windowing Add image to report Save DICOM SC Export MIP Slices

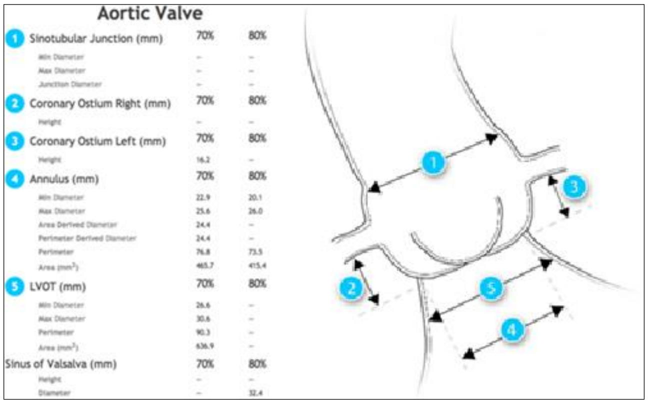
• *Save Multi stack Images* (toolbar) as a secondary DICOM capture. • Individual frames can be added to the report by selecting the *Add to Report* option in the context menu.	 

Save Stack Images (DICOM Secondary)
Range (+/-): 20.0 mm
Spacing: 2.0 mm
Number of Slices: 21

28.2.2.2 Standard Report

Upon opening the default report module:

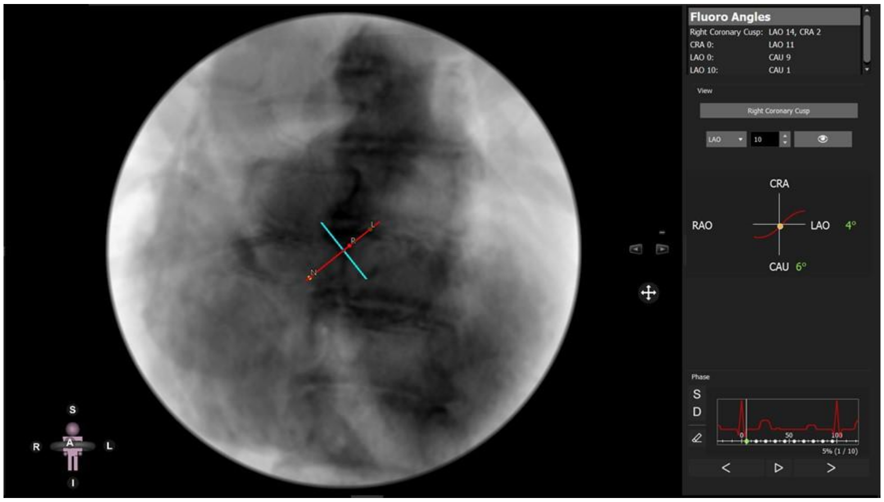
- Review the infographic and related measurements.



Aortic Valve

	70%	80%
① Sinotubular Junction (mm)	70%	80%
Min Diameter	–	–
Max Diameter	–	–
Junction Diameter	–	–
② Coronary Ostium Right (mm)	70%	80%
Height	–	–
③ Coronary Ostium Left (mm)	70%	80%
Height	16.2	–
④ Annulus (mm)	70%	80%
Min Diameter	22.9	20.1
Max Diameter	25.6	26.0
Area Derived Diameter	24.4	–
Perimeter Derived Diameter	24.4	–
Perimeter	76.8	73.5
Area (mm²)	465.7	415.4
⑤ LVOT (mm)	70%	80%
Min Diameter	26.6	–
Max Diameter	30.6	–
Perimeter	90.3	–
Area (mm²)	636.9	–
Sinus of Valsalva (mm)	70%	80%
Height	–	–
Diameter	–	32.4

28.3 Aorta Fluoro Page



Fluoro Angles

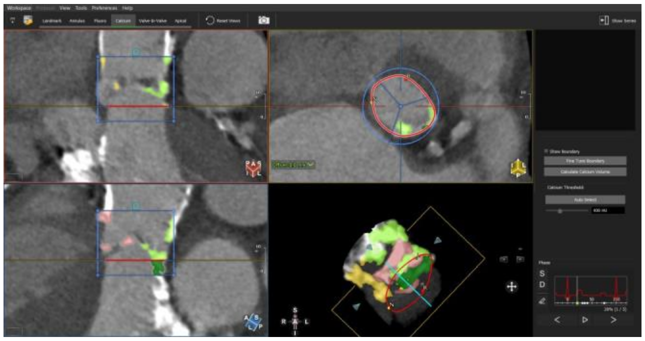
Right Coronary Cusp:	LAO 14, CRA 2
CRA 0:	LAO 11
LAO 0:	CAU 9
LAO 10:	CAU 1

View: Right Coronary Cusp
LAO 10

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.

28.4 Calcium Page

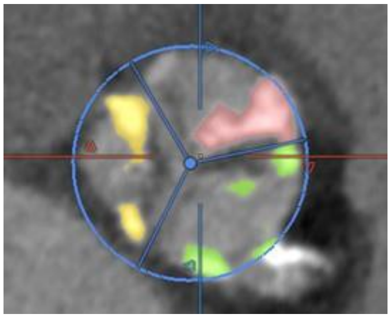


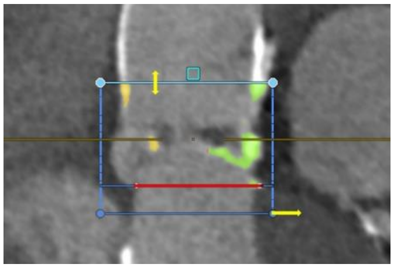
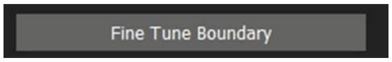
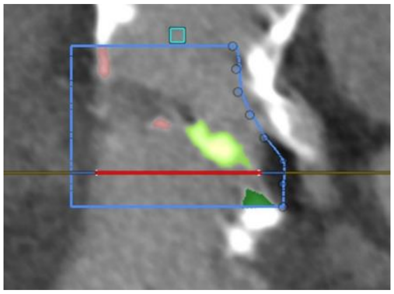
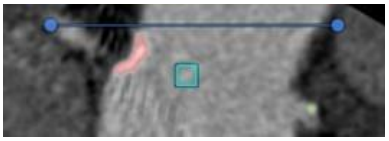
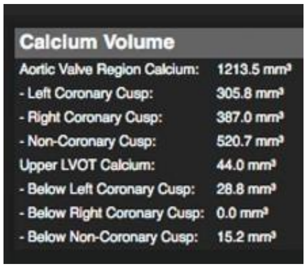
- 3 MPR and a 3D Viewer.
- Auto detect or manually adjust the calcium threshold.
- Cusp specific color-coded calcium overlay.
- Calcium volume report per cusp, in aorta and LVOT.

28.4.1 Control Feature

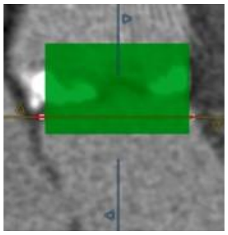
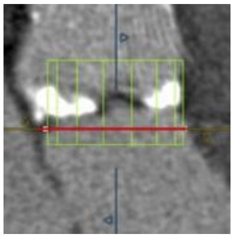
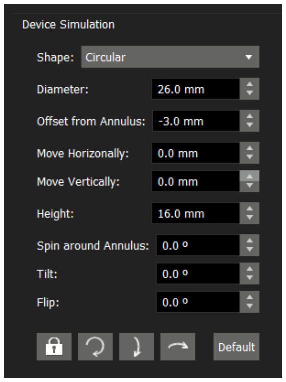
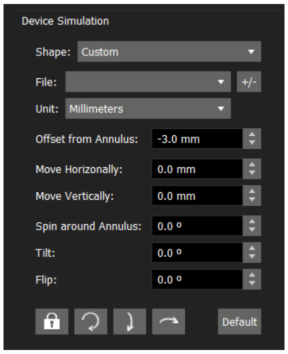
1. Mouse drag in the long axis will rotate around the valve center.
2. Mouse drag in the short axis will scroll up/down the Aorta/LVOT.
3. Press the *Ctrl* (*Command* in Mac) key to pan the image in the view port.

28.4.2 How to Detect Calcium

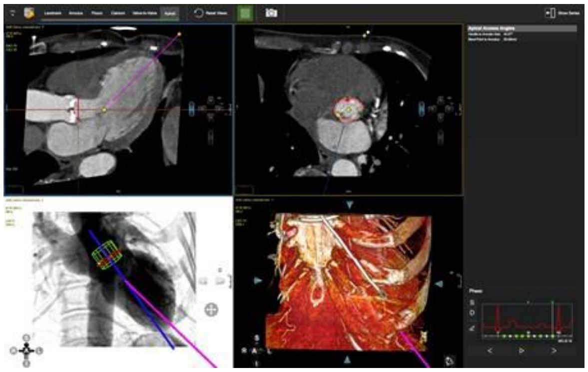
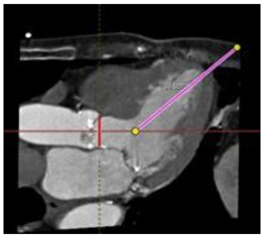
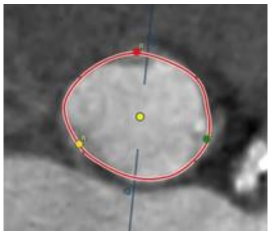
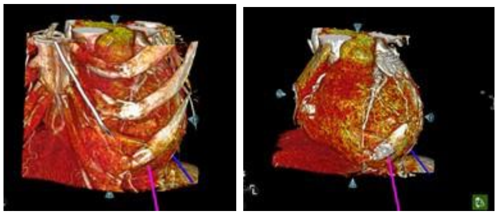
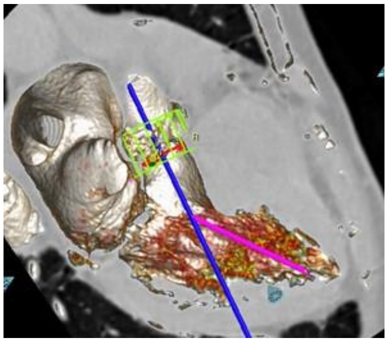
1. In the valve view, scroll up to the sinus to display the commissures. 2. The calcium color corresponds to the nadir point colors. Adjust the center and move the arms of the cusp divider, so that the colors are properly assigned to a cusp.	

3. Drag horizontal lines to increase or decrease height. 4. Drag control points to increase or decrease width.	
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.	 
6. Using the *Auto Detect* button, the software will automatically place a sample area (blue square) above the annulus in the log axis view. From that sample, a threshold will be determined to auto detect calcium. (According to the formula: average HU + 4.0 *standard deviation). 7. Alternatively, drag the slider to manually change the threshold for HU.	  Calcium Threshold: 485 HU
8. In the report pane click *Calculate Calcium Volume* for a calcium report. 9. Click on the camera to add the *Calcium Volume* and images to your report.	 **Calcium Volume** Aortic Valve Region Calcium: 1213.5 mm³ - Left Coronary Cusp: 305.8 mm³ - Right Coronary Cusp: 387.0 mm³ - Non-Coronary Cusp: 520.7 mm³ Upper LVOT Calcium: 44.0 mm³ - Below Left Coronary Cusp: 28.8 mm³ - Below Right Coronary Cusp: 0.0 mm³ - Below Non-Coronary Cusp: 15.2 mm³

28.5 Valve in Valve

- Device simulation. - Additional measurements.	
For device simulation choose between: - Display *Device* intersection. - *Display Device Mesh*.	 
- In the report pane choose *Circular* shape and use the options provided to position the device. - 🔒 Lock device position across different phases.	 Device Simulation Shape: Circular Diameter: 26.0 mm Offset from Annulus: -3.0 mm Move Horizonally: 0.0 mm Move Vertically: 0.0 mm Height: 16.0 mm Spin around Annulus: 0.0 º Tilt: 0.0 º Flip: 0.0 º Default
Custom Shape: - Allows to import vendor specific image files. - Change units from metric to imperial.	 Device Simulation Shape: Custom File: +/- Unit: Millimeters Offset from Annulus: -3.0 mm Move Horizonally: 0.0 mm Move Vertically: 0.0 mm Spin around Annulus: 0.0 º Tilt: 0.0 º Flip: 0.0 º Default

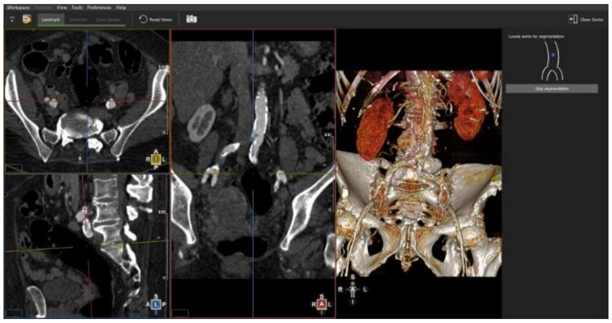
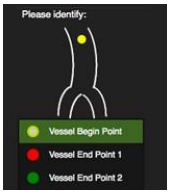
28.6 Apical Page

• Apical access planning.	
• A red line in the top left viewer indicates the central axis perpendicular to the annulus (trajectory), the ideal access path. • Rotate around the trajectory line to display the apex.	 
• The purple line can be adjusted to the manual access route. • Adjust the yellow control point that slides along the red trajectory line, to accommodate for bending of the manual access route.	 **Apical Access Angles** Handle to Annular Axis: 45.26° Bend Point to Annulus: 25.00mm
• Record the intercostal space. • Assess the course of the coronary arteries.	
Display Device Mesh: • Toggles to an endoluminal view to display the device. • The context menu allows to change viewing and/or clippings.	

29 Femoral Module

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

29.1 Landmark Page

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

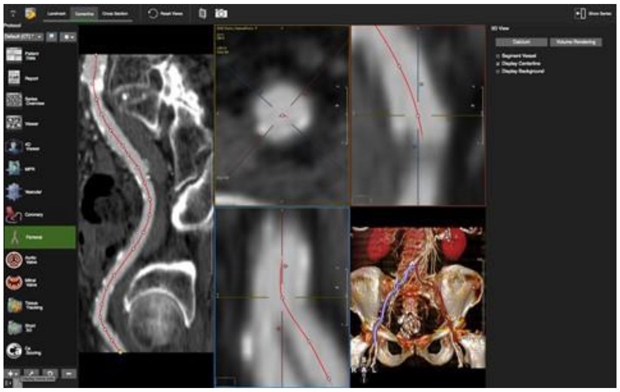
29.2 Centerline Page

- 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 ofinterest 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.



29.2.1 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.

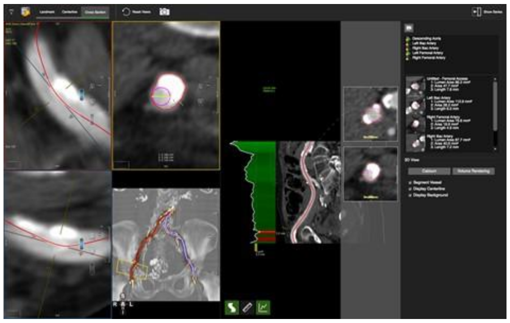
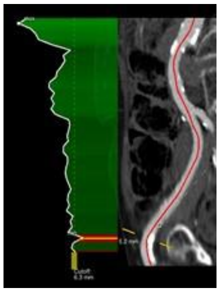
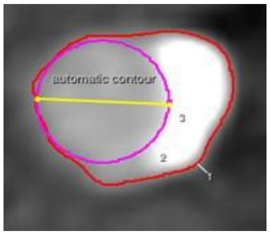
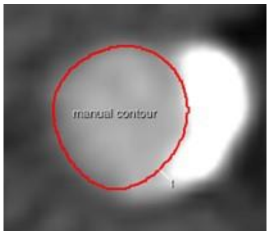
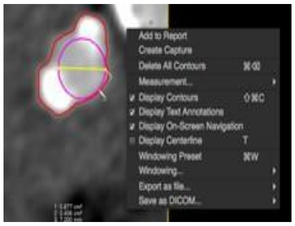
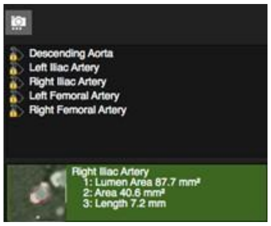
29.2.2 Assessment of the Puncture Site

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

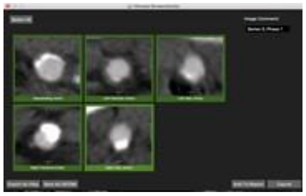
☐ Segment Vessel
☑ Display Centerline
☐ Display Background

- 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.

29.3 Cross Section

1. Display the centerlines in the reference viewer. 2. Select a vessel by clicking on the centerline in the reference image.	
3. Open the centerline graph. The graph is based on the diameter of the best fitting circle inside the lumen, excluding calcium. The calcium threshold is calculated dynamically based on centerline points. Therefore, during centerline generation, attention should be paid that the centerline is not crossing any calcium. 4. Drag the yellow cursor line along the vessel. The diameter is displayed continuously on the right side of the cursor line.	
5. Measurements will be done automatically as soon as the centerline graph is activated, and you halt the cursor line. 6. A contour can be drawn manually. In that case, the assumption is made that the contour is drawn excluding calcium and no circle will be fitted. 7. Take captures via context menu. 8. Use the predefined tags to label them. 9. Click on the captures to review axial and orthogonal views. 10. Captures will be displayed as cross-sectional images right of the CPR.	    Right Iliac Artery 1: Lumen Area 87.7 mm² 2: Area 40.6 mm² 3: Length 7.2 mm

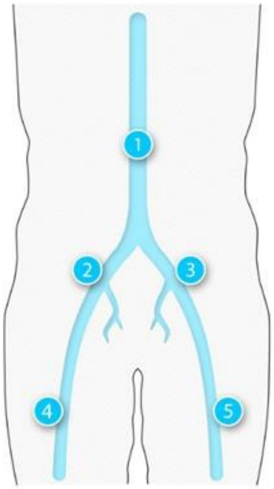
29.3.1 Reporting



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.



Femoral Access

Phase	0
1 Descending Aorta	
Diameter (mm)	16.3
2 Right Iliac Artery	
Diameter (mm)	9.0
3 Left Iliac Artery	
Diameter (mm)	9.5
4 Right Femoral Artery	
Diameter (mm)	6.4
5 Left Femoral Artery	

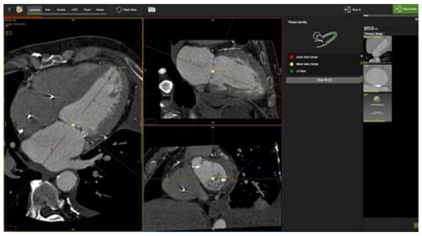
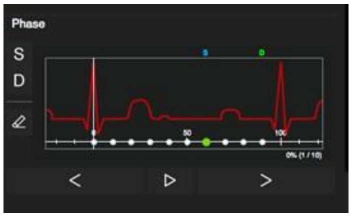
30 Mitral Valve Module

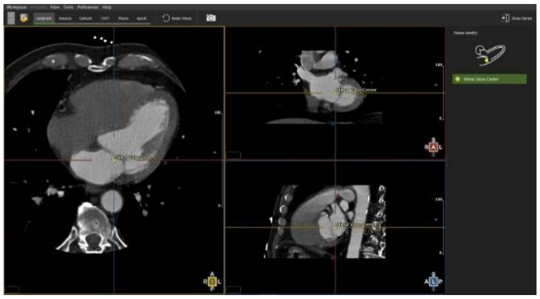
Module overview

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

30.1 Landmark Page

Set landmark for the assisted generation mitral valve plane.

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

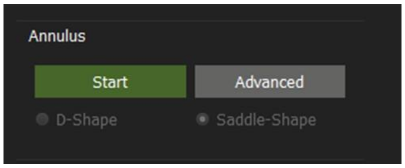
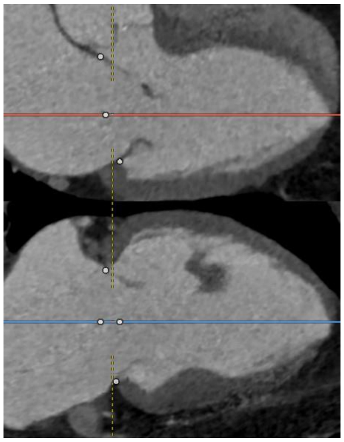
• The Aortic Root center will be detected automatically. • Slice through the images by dragging the mouse in the axial image, to display the mitral valve center. Click to set the second landmark. • The LV Apex will be placed automatically. • Use the crosshairs and swing around the apex to check for correct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

30.2 Annulus Page

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

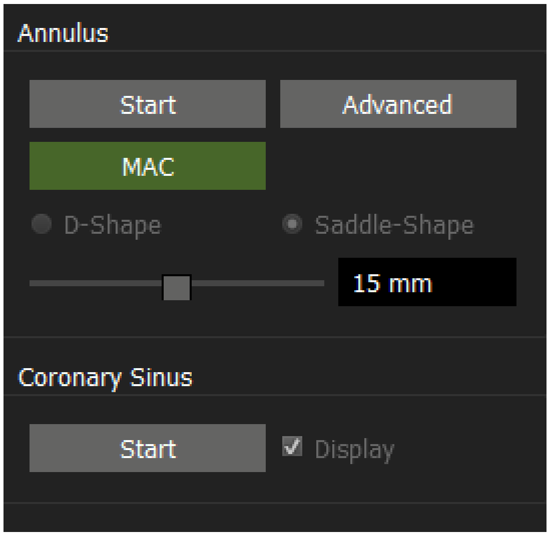
Note: When needed adjust the mitral valve center point and apex point.

30.2.1 How to Define the Mitral Annulus (MA) Plane

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

30.2.2 Mitral Annular Calcification (MAC) Assessment

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



Annulus

Start
Advanced
MAC

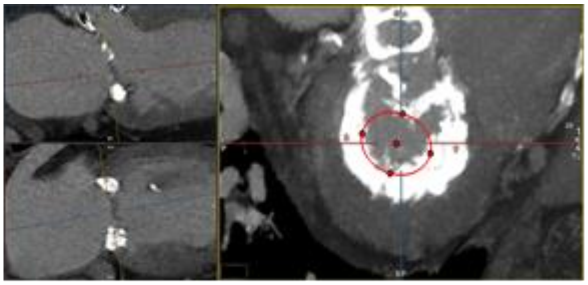
○ D-Shape ● Saddle-Shape

15 mm

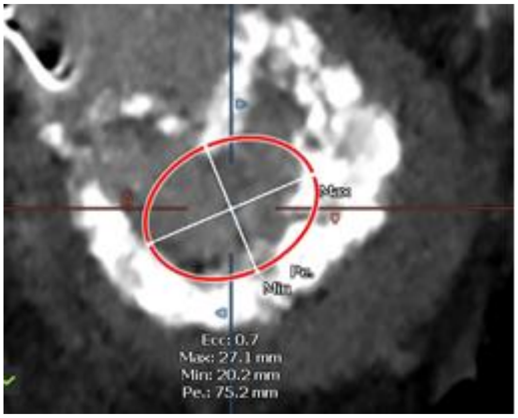
Coronary Sinus

Start ☑ Display

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

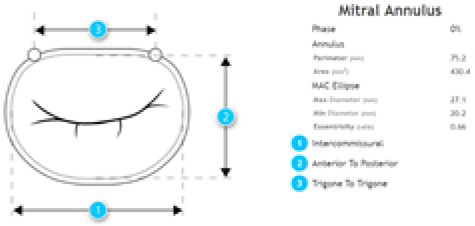


    - Click outside the ellipse, to finalize the measurement.
    - Min/max diameter, perimeter and eccentricity will be reported on screen.



Ecc: 0.7
Max: 27.1 mm
Min: 20.2 mm
Pe.: 75.2 mm

    - The report will be updated accordingly.

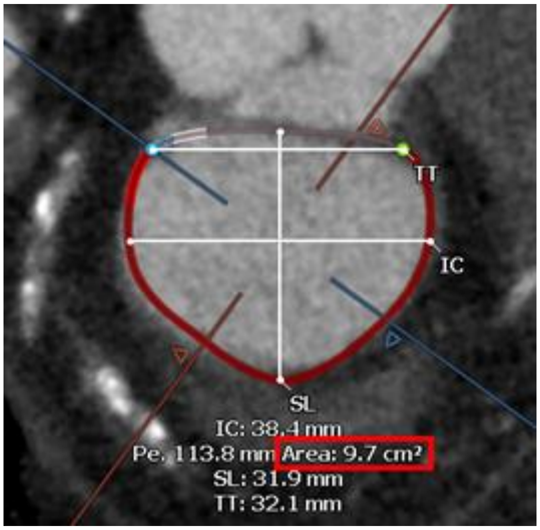


Mitral Annulus

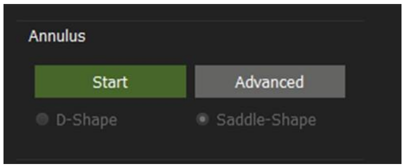
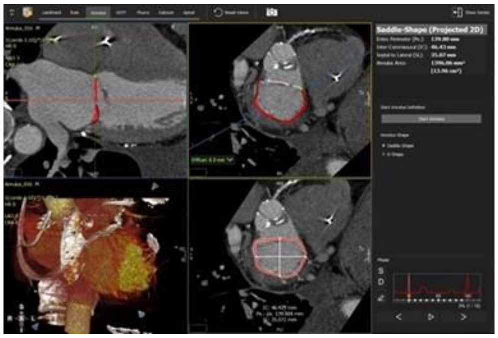
Phase	0%
Annulus	
Perimeter (mm)	75.2
Area (mm²)	430.4
MAC Ellipse	
Max Diameter (mm)	27.1
Min Diameter (mm)	20.2
Eccentricity (ratio)	0.66

1 Intercommissural
2 Anterior To Posterior
3 Trigone To Trigone

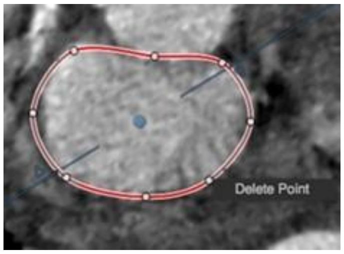
- Annulus area is now shown in the User interface.



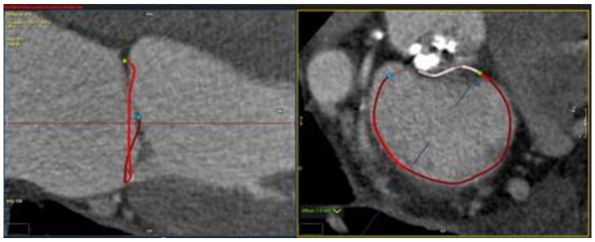
30.2.3 How to Define the Mitral Annulus (MA) Plane – Advanced

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

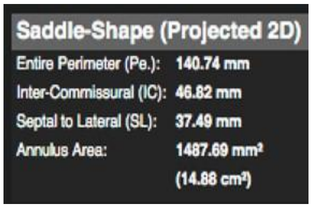
Note: Both the regular and the advanced Annulus can be edited

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

- Exiting the editing mode, allows to adjust the trigones to the LVOT.

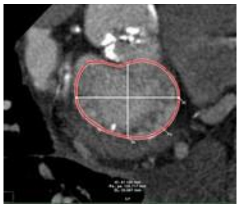


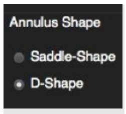
- Measurements are done automatically.



Saddle-Shape (Projected 2D)

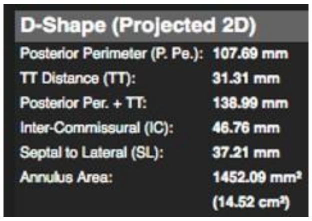
Entire Perimeter (Pe.):	140.74 mm
Inter-Commissural (IC):	46.82 mm
Septal to Lateral (SL):	37.49 mm
Annulus Area:	1487.69 mm² (14.88 cm²)



- 

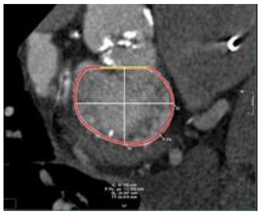
  Annulus Shape
  ○ Saddle-Shape
  ● D-Shape

  Switch between *Saddle* and *D-Shape*.

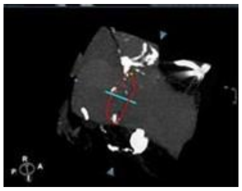


D-Shape (Projected 2D)

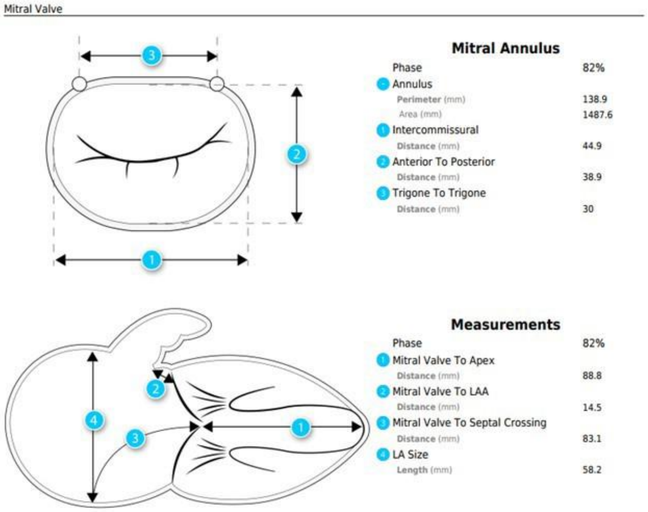
Posterior Perimeter (P. Pe.):	107.69 mm
TT Distance (TT):	31.31 mm
Posterior Per. + TT:	138.99 mm
Inter-Commissural (IC):	46.76 mm
Septal to Lateral (SL):	37.21 mm
Annulus Area:	1452.09 mm² (14.52 cm²)



- In the *4D Visualization* viewer adjust the cylindrical clipping cone to define the annular region. Visually inspect the calcification around the valve.



- Labeled measurements will be shown in the infographic in the report.



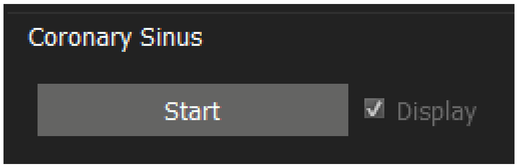
Mitral Annulus

Phase	82%
Annulus	
Perimeter (mm)	138.9
Area (mm)	1487.6
① Intercommissural	
Distance (mm)	44.9
② Anterior To Posterior	
Distance (mm)	38.9
③ Trigone To Trigone	
Distance (mm)	30

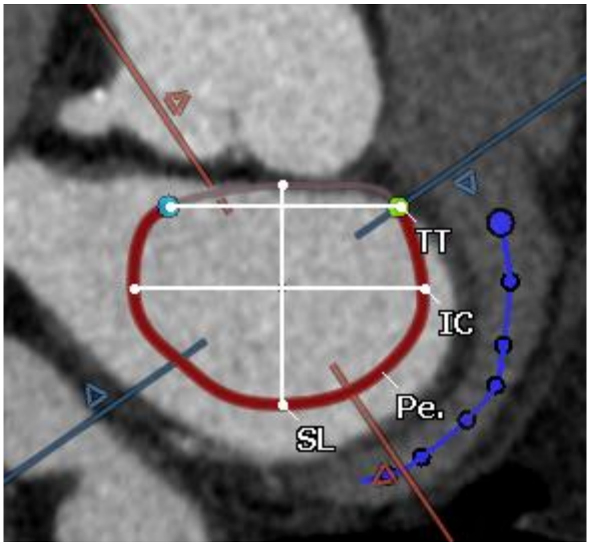
Measurements

Phase	82%
① Mitral Valve To Apex	
Distance (mm)	88.8
② Mitral Valve To LAA	
Distance (mm)	14.5
③ Mitral Valve To Septal Crossing	
Distance (mm)	83.1
④ LA Size	
Length (mm)	58.2

30.2.4 Guide Wire Simulation

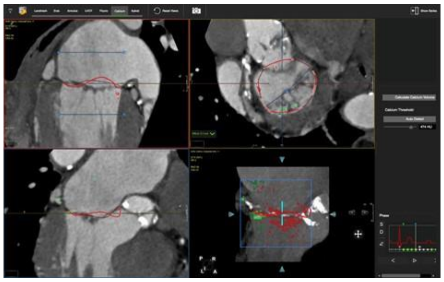


1. Press *Start* to begin defining the *Coronary Sinus*.
2. Scroll through the data set in the short-axis view or rotate around the horizontal axis in the long-axis view and click to add key points along the sinus.
3. Double-click on the last point to finish.



30.3 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.

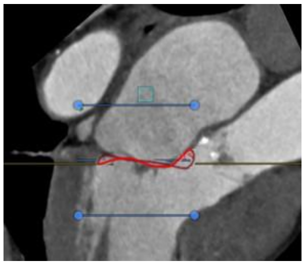


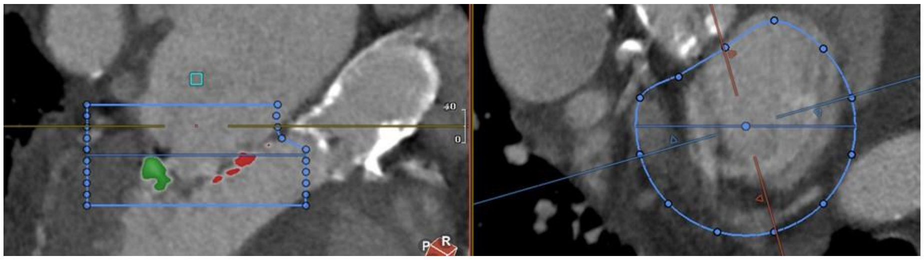
30.3.1 Control Feature

- 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.

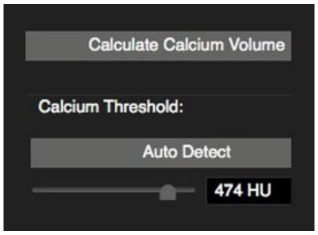
30.3.2 Three Chamber View

- 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.

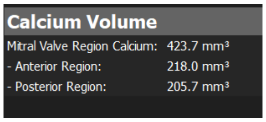




30.3.3 Quantify the Calcium Load



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



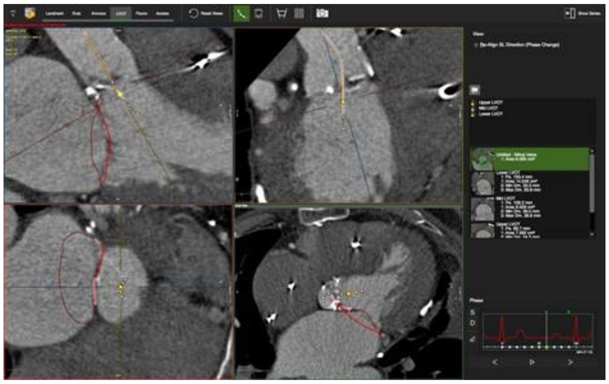
Calcium Volume

Mitral Valve Region Calcium:	423.7 mm^3
- Anterior Region:	218.0 mm^3
- Posterior Region:	205.7 mm^3

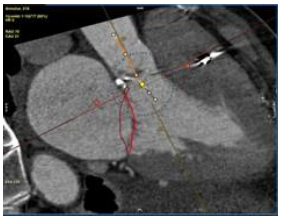
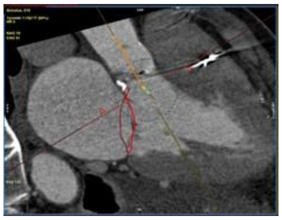
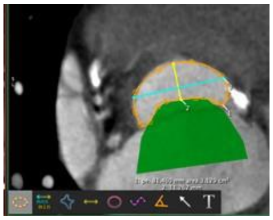
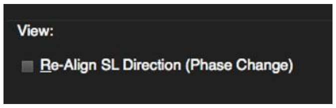
- Click on the camera to add the *Calcium Volume* and images to your report.

30.4 LVOT Page

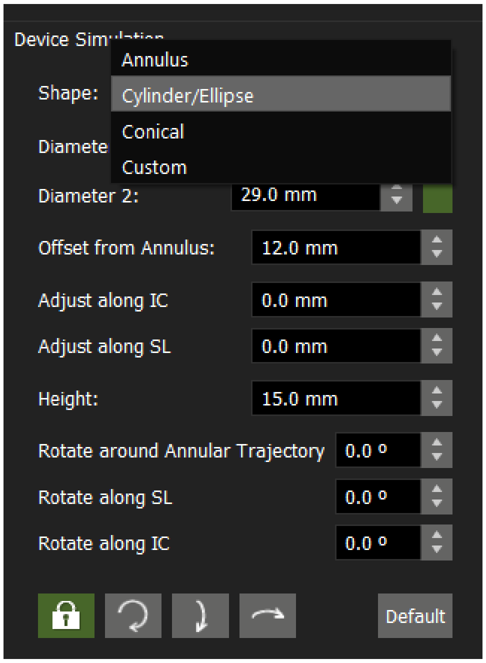
- Assessment of the LVOT.
- Device simulation.
- Planimetric measurement of LVOT and neo-LVOT.



30.4.1 LVOT Assessment

1. Activate the *Centerline Control Points*. 2. Place points in the Aorta and the LVOT.	
3. De-activate the centerline points and use the green bar to scroll along the centerline.	
4. Using the measurement tools provided in the tool box (white box in the lower left corner), measure the upper-, mid-, and lower LVOT.	
5. Use the phase diagram to inspect the LVOT in different phases. Optionally, realign the view to SL direction with every phase change.	 View: ☐ Re-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 Mid LVOT Lower LVOT neo-LVOT New Label Untitled - Mitral Valve 1: Area 6.085 cm² Lower LVOT 1: Pe. 153.4 mm 1: Area 14.546 cm² 2: Min Dm. 33.3 mm 3: Max Dm. 50.8 mm Mid LVOT 1: Pe. 109.2 mm 1: Area 8.529 cm² 2: Min Dm. 26.0 mm 3: Max Dm. 39.6 mm Upper LVOT 1: Pe. 99.7 mm 1: Area 7.292 cm² 2: Min Dm. 24.5 mm

30.4.2 Device Simulation



Shape: Cylinder/Ellipse
Diameter 2: 29.0 mm
Offset from Annulus: 12.0 mm
Adjust along IC: 0.0 mm
Adjust along SL: 0.0 mm
Height: 15.0 mm
Rotate around Annular Trajectory: 0.0 º
Rotate along SL: 0.0 º
Rotate along IC: 0.0 º

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

30.5 Fluoroscopy Page

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

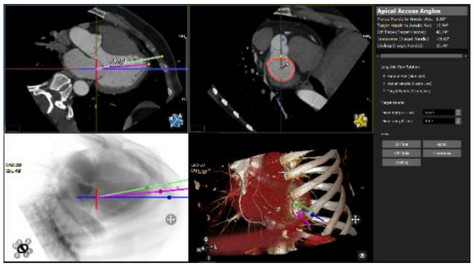
30.5.1 Optimal Viewing Curve

1. Display views perpendicular to the annulus.	

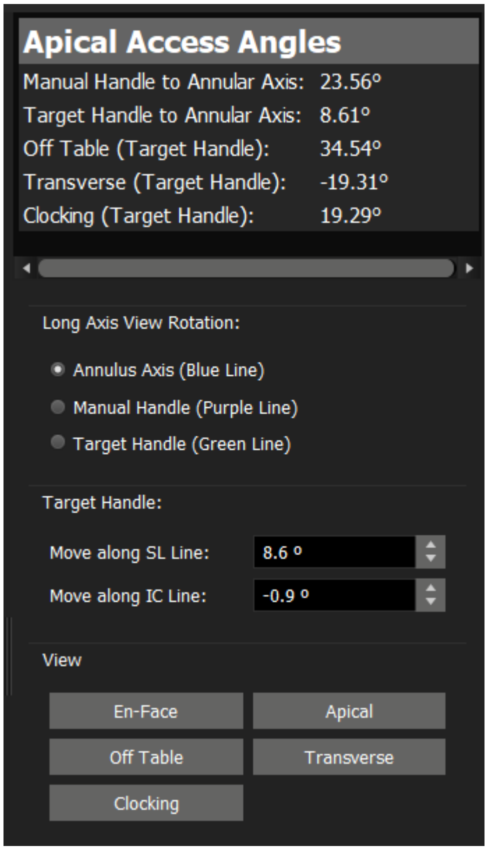
2. Use the pre-set buttons or drag the cursor line over the curve.

30.6 Apical Page

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



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



Apical Access Angles

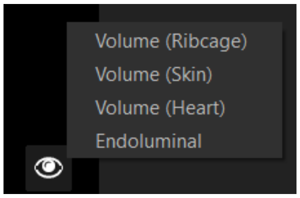
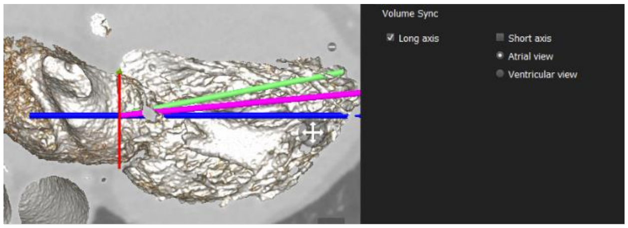
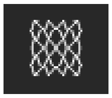
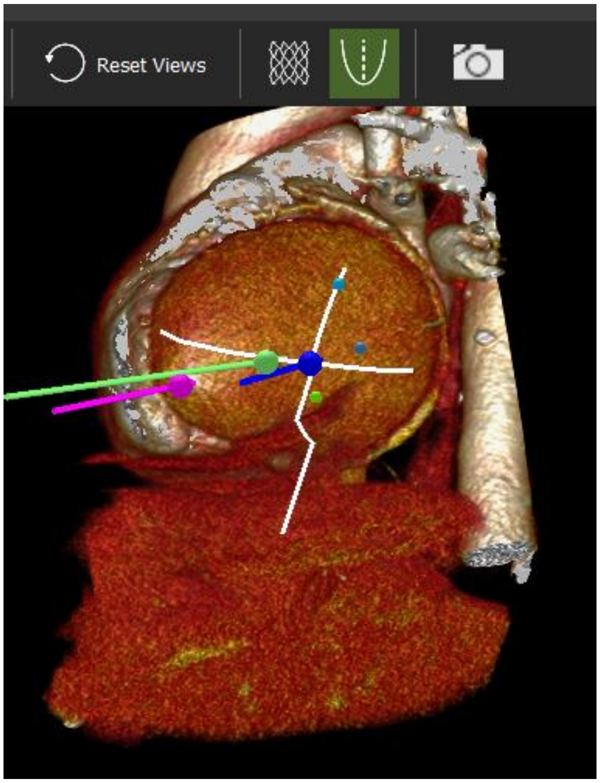
Manual Handle to Annular Axis: 23.56°
Target Handle to Annular Axis: 8.61°
Off Table (Target Handle): 34.54°
Transverse (Target Handle): -19.31°
Clocking (Target Handle): 19.29°

Long Axis View Rotation:

● Annulus Axis (Blue Line)
○ Manual Handle (Purple Line)
○ Target Handle (Green Line)

Target Handle:

Move along SL Line: 8.6 °
Move along IC Line: -0.9 °

5. Switch between different visualization techniques.	
6. When the endoluminal view is active, select the *Volume Sync* options to synchronize the endoluminal view with the long or the short axis MPR.	Volume Sync ☑ Long axis ☐ Short axis ● Atrial view ○ Ventricular 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.	

31 Trans-Septal Module

Module overview

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.

31.1 Contours Page

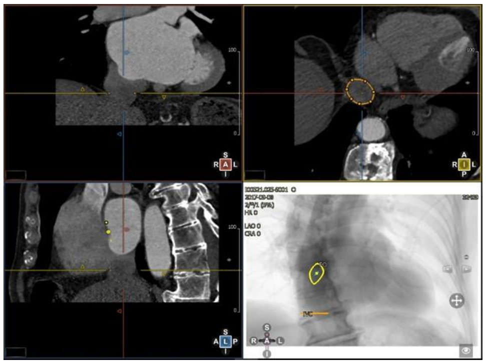
31.1.1 Finding the Fossa Ovalis

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

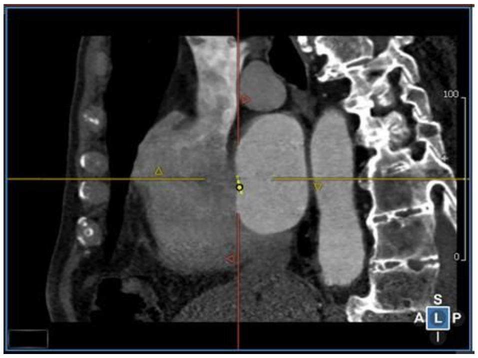
6. In the en-face view rotate the intersection lines to verify in the orthogonal views that the center of the crosshair is in the middle of the Fossa.
7. Click the *Fossa Ovalis* button and then click on the center of the crosshair in the en-face view to mark the Fossa.
8. When needed, resize the annotation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

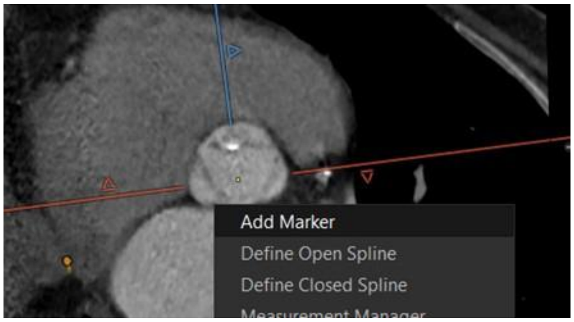
31.1.2 Marking the Vena Cava Inferior and Superior and Other Structures

1. Reset views.
2. In the lateral viewport translate until the IVC is visible.



3. Place the crosshair on the IVC.
4. On the axial image, the IVC contour can be traced.
5. Do the same for the SVC.



6. Use the catheter feature to draw a spline to indicate the catheter path or use the automatic option for an automated suggestion.	
7. Use markers to identify other anatomical markers, like the aorta. In case the Mitral annulus has been detected in the Mitral workflow, the annotation will be transferred to the septal crossing workflow.	

32 Technical Support

Technical Support

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