ADAS 3D

User Manual

ADAS 3D

Ver:2.8.1

21-04-2021

REF

ADAS 3D

A software for the visualization and analysis of enhancement in MR and CT cardiovascular images on patients with cardiovascular disease

VER: **2.8**

eIFU: www.adas3d.com/en/ifu.html 2021-03

Adas3D Medical SL
C/Paris 179, 2ª 2ª
08036 Barcelona - Spain
(+34) 933283964
info@adas3d.com

Rx Only

CE 2797

Thank you for choosing **ADAS 3D**!

ADAS 3D is a software intended to be used for the visualization and analysis of enhancement in MR and CT cardiovascular images on patients with cardiovascular disease.

If you have any questions about this product or its operation, please contact your local distributor or the manufacturer Adas3D Medical.

Regulatory Information

MANUFACTURER. MAIN OFFICE

Adas3D Medical S.L.
C/Paris 179, 2ª 2ª
08036 – Barcelona
Spain
Tel: +34 933283964
Email: info@adas3d.com
Website: www.adas3d.com

Distributed by

Circle Cardiovascular Imaging Inc.
Suite 1100, 800 5th Avenue SW
Calgary, AB
Canada
Tel: +1 403 33 1870
Email: support@circlecvi.com
Website: www.circlecvi.com

United States of America

This product received 510(k) clearance from the FDA with number **K210850**.

Consult instructions for use available at the following web address: www.adas3d.com/en/ifu.html in adobe acrobat pdf format. Free reader available at https://get.adobe.com/uk/reader/

Paper-format IFU are available from ADAS3D Medical upon request from the user at no additional cost. It should reach the user within a maximum of 7 days.
ADAS 3D Instructions for Use, March 4, 2021

Table of contents

1. Important user information 8

1.1. Acronyms 10

1.2. Intended use 10

1.3. Indications 11

1.4. Contraindications 11

1.5. Warnings 11

1.6. Precautions 11

1.7. Cautions 12

1.8. System requirements 12

1.9. Supported DICOM formats 13

1.10. Performance 15

1.11. Trademarks 15

2. Install steps 17

2.1. Step 1 17

2.2. Step 2 18

2.3. Step 3 19

2.4. Step 4 20

2.5. Step 5 22

3. Uninstall process 23

4. License 24

5. Workflow: processing a case 25

6. Starting ADAS 3D 25

7. Main Window 26

7.1. Study overview 27

8. Main menu 28

9. Preferences 29

9.1. ADAS Preferences 29

9.2. Visualization Preferences 30

10. Study storage database 31

10.1. Exporting ADAS 3D studies 32

10.1.1. Anonymization 32

10.2. Importing ADAS 3D Studies 34

11. Importing data 36

11.1. Importing DICOM data 37

11.1.1. DICOM Toolbar 38

11.1.2. Usage 38

12. Analysis and tools 42

12.1. Analysis 42

12.2. General tools 43

12.2.1. Image alignment 44

12.2.2. Compare 3D 47

13. Visualization views 48

13.1.1. Image view 48

13.1.2. 3D image view 52

13.1.3. 3D View 52

13.1.4. Multiple 2D view 53

13.1.5. Colormap options 54

14. LV enhancement 56

14.1. Segmentation module 56

14.1.1. Step 1: Model Creation 56

14.1.2. Step 2: slice-based adjustment 60

14.1.3. Step 3: model adjustment 63

14.1.4. Segmentation toolbar 65
14.1.5. 3D Visualization 65
14.1.6. Main visualization window 66
14.1.7. 3D General toolbar 67
14.1.8. 3D Visualization toolbar 68
14.1.9. General tools 69
14.1.10. Accuracy of the measurements 71
14.2. 3D Corridors module 71
14.2.1. 3D Corridor criteria 73
14.2.2. Accuracy of the measurements 83
14.7. Quantification 83
14.8. Export data 83

15. LV wall thickness 84

16. LA enhancement 85

16.1. Segmentation 85
16.1.1. Model creation 85
16.1.2. Model adjustment 91
16.2. 3D Visualization 93
16.2.1. Main visualization window 93
16.3. Export 96

17. Heart anatomy extraction 97

17.1. Manage the segmentations 97
17.2. Contour-based segmentation 99
17.3. Threshold-based segmentation 99
17.4. Automatic – based 101
17.5. Region segmentation 102
17.6. 3D Visualization 103
17.7. Accuracy of the measurements 104

18. **Quantification tool** 106

18.1. Accuracy of the measurements 109

19. **Export data** 110

19.1. Video export 110

19.2. VTK Export format 111

19.2.1. Configuration 1: CARTO® 3 system 111

19.2.2. Stereotaxis system 111

19.3. DIF Export format 114

19.4. Accuracy of the measurements 118

20. **Current study management** 118

20.1. Snapshots 119

20.2. Videos 120

21. **Integration of ADAS 3D with other systems** 121

21.1. SIEMENS OpenApps 121

21.2. CIRCLE cvi42 122

22. **Cyber security** 122

23. **Troubleshooting and maintenance** 124

23.1. Maintenance 124

23.2. Troubeshooting 125

24. **Appendix A. good quality DICOM images** 127

25. **Appendix B. bad quality DICOM images** 130

26. **Bibliography** 132

1. Important user information

The information in these Instructions for Use applies to ADAS 3D.

All operators must read the complete Instructions for Use before operating the ADAS 3D. The product should be used only by qualified and trained personnel.

ADAS 3D is intended for exclusive use by professional users. The software is intended to assist healthcare professionals in the diagnosis and cannot fully substitute their clinical judgement.

The software should only be used in combination with equipment with the listed minimum system requirements.

The lifetime of this software is established at 5 years.

Adas3D Medical and its distribution partners will provide customer training. This training will instruct physicians and technicians how to use the ADAS 3D software and will supplement this Instructions for Use document.

The training will be applicable to all ADAS 3D software users including cardiologists, electrophysiologists, radiologists, and technicians and may be tailored to the role of the user.

The training will cover the following key topics:

- General ADAS 3D software overview and workflow
- Importing DICOM data into ADAS 3D
- Using the Left Ventricle and Left Atrium Analysis tools
- Exporting ADAS 3D images for use with catheter navigation systems

SYMBOLS INFORMATION

CE 2797	CE marking for stand-alone software according to Directive 93/42/EEC
eIFu	Consult Instructions for Use: available at the following web address: https://www.galgomedical.com/en/ifu.html in adobe acrobat pdf format. Free reader available at https://get.adobe.com/uk/reader/
	Date of manufacture

	Manufacturer information
REF	Catalogue number
VER	Software version
Rx Only	Prescription only
	HINT: Provides helpful information or an alternative working method

Caution

Federal (USA) law restricts this device to sale by or on the order of a Physician.

1.1. Acronyms

The following definitions will be used throughout this manual:

- DE-MRI: Delayed Enhancement MRI. Please see (Vogel-Claussen and Rochitte 2006) for a detailed description.
- CE-MRI: Contrast Enhancement MRI. Please see (Vogel-Claussen and Rochitte 2006) for a detailed description.
- LGE-MRI: Late Gadolinium Enhancement MRI. Please see (Vogel-Claussen and Rochitte 2006) for a detailed description.
- DICOM: Digital Imaging and Communications in Medicine
- CTA: Computed Tomography Angiography

1.2. Intended use

ADAS 3D is a software tool intended to be used for post-processing cardiovascular enhanced Magnetic Resonance (MR) images and Computed Tomography Angiography (CTA) images that are formatted in the Digital Imaging and Communication in Medicine (DICOM) standard. ADAS 3D is intended for the non-invasive calculation, quantification and visualization of cardiac imaging data to support a comprehensive diagnostic decision-making process for understanding cardiovascular disease.

ADAS 3D analyzes the enhancement of myocardial fibrosis from DICOM MR Images to support:

- Visualization of the distribution of the enhancement in a three-dimensional (3D) chamber of the heart
- Quantification of the total volume of the enhancement within the Left Ventricle (LV) and the visualization of the enhancement area in multiple layers through the cardiac structure
- Calculation, quantification and visualization of corridors of intermediate signal intensity enhancement in the LV
- Quantification and visualization of the total area and distribution of the enhancement within the Left Atrium (LA)

Additionally, ADAS 3D imports DICOM CTA images to support:

- Quantification of LV wall thickness
- Identification and Visualization of other 3D anatomical structures

ADAS 3D exports information to multiple industry standard file formats suitable for documentation and information sharing purposes. The 3D data is exported into industry standard file formats supported by catheter navigation systems.

It is intended to be used by qualified medical professionals (cardiologists, electrophysiologists, radiologists or technicians) experienced in examining and evaluating cardiovascular MR and CTA images as part of the comprehensive diagnostic decision-making process.

ADAS 3D is a standalone software application.

1.3. Indications

ADAS 3D is indicated for use in clinical settings to support the visualization and analysis of MR and CT images of the heart for use on individual patients with cardiovascular disease.

ADAS 3D is indicated for patients with myocardial scar produced by ischemic or non-ischemic heart disease. ADAS 3D processes MR and CT images. The quality and the resolution of the medical images determines the accuracy of the data produced by ADAS 3D.

ADAS 3D is indicated to be used only by qualified medical professionals (cardiologists, electrophysiologists, radiologists or trained technicians) for the calculation, quantification and visualization of cardiac images and intended to be used for pre-planning and during electrophysiology procedures. The data produced by ADAS 3D must not be used as an irrefutable basis or a source of medical advice for clinical diagnosis or patient treatment. The data produced by ADAS 3D is intended to be used to support qualified medical professionals for clinical decision making.

The clinical significance of using ADAS 3D to identify arrhythmia substrates for the treatment of cardiac arrhythmias (e.g., ventricular tachycardia) or risk stratification has not been established.

1.4. Contraindications

ADAS 3D is contraindicated for patients without any myocardial scar.

1.5. Warnings

All operators must read the Instructions for Use prior to operating the ADAS 3D software and use ADAS 3D in accordance with the provided documentation.

1.6. Precautions

- This software is a tool to support clinicians for better visualization of cardiac images from MR and CTA. It is up to the clinicians to make their own interpretations of the information that is presented.

- The intermediate signal intensity “3D Corridor” detection tool is not intended for clinical patient management and its use has not been validated clinically.

- The results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis.

- The software has not been validated for identifying arrhythmia substrates and should not be used as the sole source of information for treatment planning.

- The clinical significance of using the software to identify arrhythmia substrates for the treatment of cardiac arrhythmias (e.g., ventricular tachycardia) or risk stratification has not been established.

1.7. Cautions

- ADAS 3D should only be used by qualified medical professionals (cardiologists, electrophysiologists, radiologists or technicians) to assist in the diagnosis and should not be the only data interpreted.
- Snapshots or videos that are exported may contain personal patient information (patient name and patient ID).
- Quantitative analysis is dependent on the quality and resolution of the original images. See the respective "Accuracy of the Measurements" sections for more details.
- The software should only be used on computer hardware that meets the minimum system requirements.
- The performance of the software may be affected by simultaneously performing other tasks on the computer. Please see the "Performance" section for more details.
- Data that is exported using industry standard formats (VTK and DIF) supported by catheter navigation systems contains personal patient information (patient name and patient id).

1.8. System requirements

Before installing ADAS 3D on a computer, it should meet these recommended and minimum system requirements:

Operating System	**Recommended:** Windows 10 with Code Page 1252 (Western European characters) **Minimum:** 64-bit Microsoft Windows 10
CPU Type	**Recommended:** Intel® Core i7 4790K or equivalent **Minimum:** Intel® Pentium® 4 or AMD Athlon™ 64, 3 GHz or faster or Intel® or AMD dual core 2 GHz or faster
Memory	**Recommended:** 16 GB RAM

	Minimum: 8 GB RAM
Disk Space	**Recommended:** 250 GB free disk space or more for local study database **Minimum:** 100 GB free disk space for local study database
Graphics	**Recommended:** Microsoft® Direct3D 11® or capable graphics card or higher (for example GeForce GT 730)[1] **Minimum:** Microsoft® Direct3D 10® capable graphics card or higher
Other	1280 x 1024 or higher screen resolution All file paths and input data used in the software must be limited to characters in Code Page 1252 TeamViewer[2] software and Internet connection for remote access during technical support and training

1.9. Supported DICOM formats

ADAS 3D supports medical images in the Digital Imaging and Communications in Medicine (DICOM) Standard format. See DICOM Conformance Statement.

ADAS 3D can import and process DICOM images obtained with Delayed-Enhancement Magnetic Resonance Imaging (DE-MRI). The Delayed-Enhanced images contain information of the presence of fibrosis in the myocardium. ADAS 3D supports the images acquired using the protocols MRI 3D-GRE Navigated and the 2D-GRE.

ADAS 3D supports DICOM images obtained with Computer Tomography Angiography (CTA). These images contain information on the anatomy of the vessels and heart chambers.

Typical ranges of acquisitions of the modalities supported by ADAS 3D:

[1] Please check with the graphics card manufacturer web site to check compatibility. For example: http://www.geforce.com/hardware/technology/dx11/supported-gpus
[2] https://www.teamviewer.com/en/

	3D-GRE DE-MRI	**2D-GRE DE-MRI**	**CTA**
Slice Thickness (mm)	up to 5.0	up to 10.0	0.25 to 0.6
***Pixel Spacing* on each slice (mm)**	0.6 to 2	0.6 to 2	0.4

HINT: Sample images for good and poor quality are discussed in appendices ¡Error! No se encuentra el origen de la referencia. and ¡Error! No se encuentra el origen de la referencia..

1.10. Performance

ADAS 3D has two major CPU and RAM intensive computations during the processing of a case: the computation of layers after the segmentation and the computation of 3D Corridors. The computation time depends on the CPU type and the available memory of the computer. It is recommended not to perform other CPU and RAM intensive tasks during the computation of ADAS 3D.

The computation time of the layers depends on the number of layers configured. The computation time of nine layers (default value) is typically 10 seconds[3] and consumes 4 GB of RAM.

The computation time for the 3D Corridor detection depends on the size and heterogeneity of the scar, especially the region in between the two thresholds. The 3D Corridor detection should take around 10 seconds[4] and up to 5GB of RAM. However, when the scar is big and heterogeneous, the computation time can increase up to 5 minutes or more.

The performance of the visualization depends on the number and complexity of the 3D objects visualized simultaneously. **The use of a non-dedicated graphics card will reduce the performance of the visualization and is not recommended as indicated in the system requirements.**

A case processed in ADAS 3D occupies typically 250 Mb of hard disk space[5]. After processing 1000 cases, the total size of the processed cases will be 250 GB. The size of the recorded videos depends on the chosen export resolution (rough or fine). For a rough resolution, the size is 15 Mb, while for fine resolution, the size of the video is 280 Mb.

1.11. Trademarks

ADAS 3D™ is a trademark of Adas3D Medical.

[3] CPU Intel Core i7 4GHz

[4] CPU Intel Core i7 4GHz

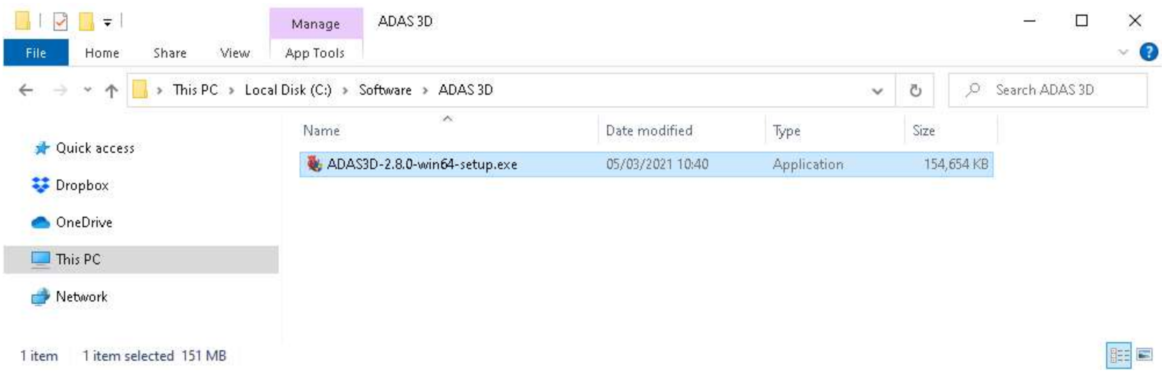
[5] Only considering the data without snapshots and videos.

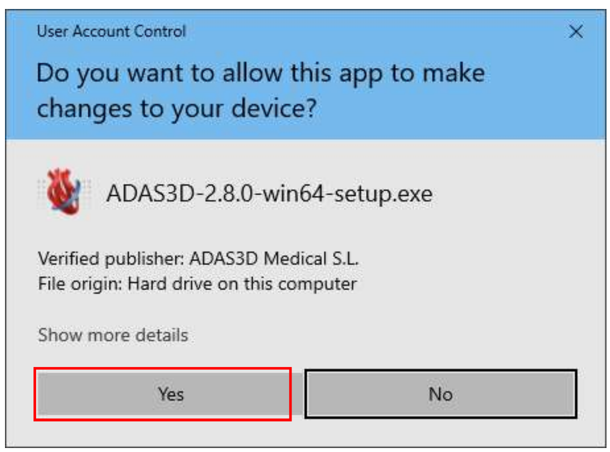
Printed in Barcelona.

2. Install steps

2.1. Step 1

Double-click the installer package. Windows will show a User Account Control window, click **Yes** to continue the installation process.



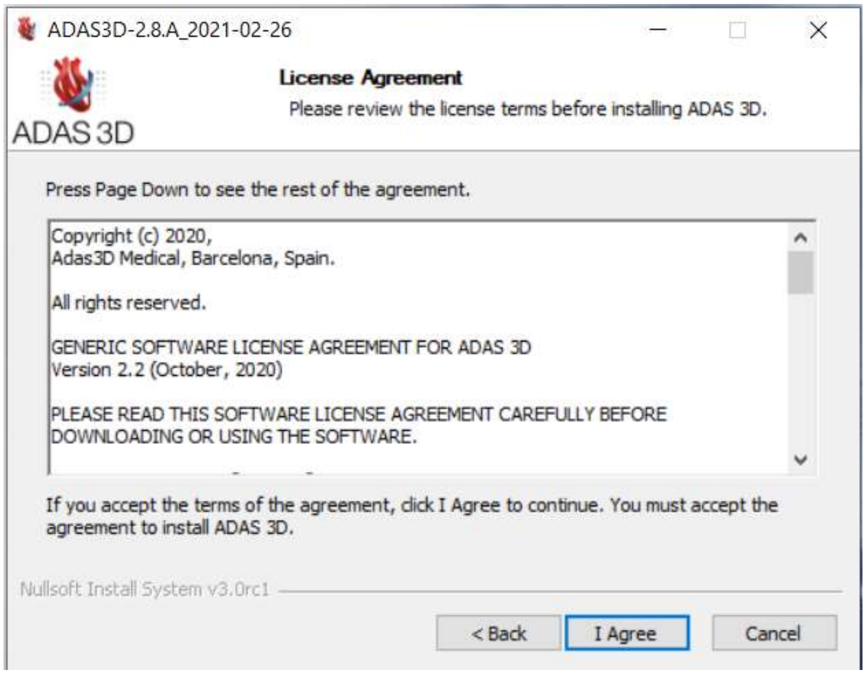


2.2. Step 2

The welcome screen is shown. Read the message and click **Next**.

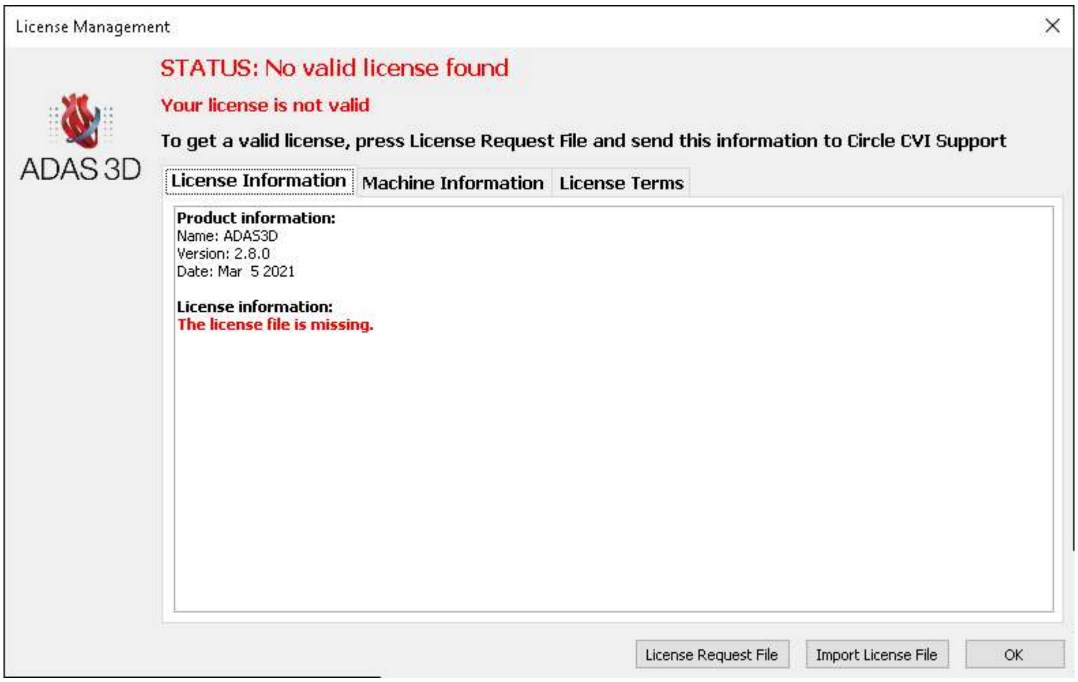
2.3. Step 3

After reading the License Agreement, select "**I Agree**" and follow the installer prompts to install the software.

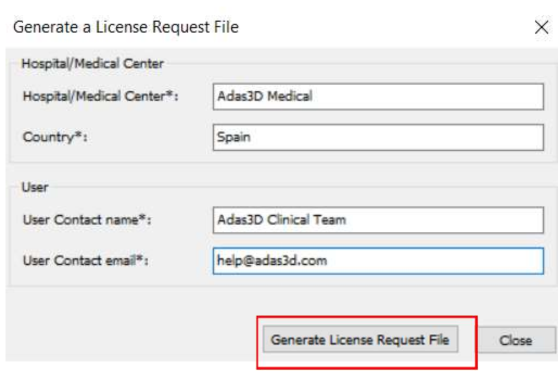


2.4. Step 4

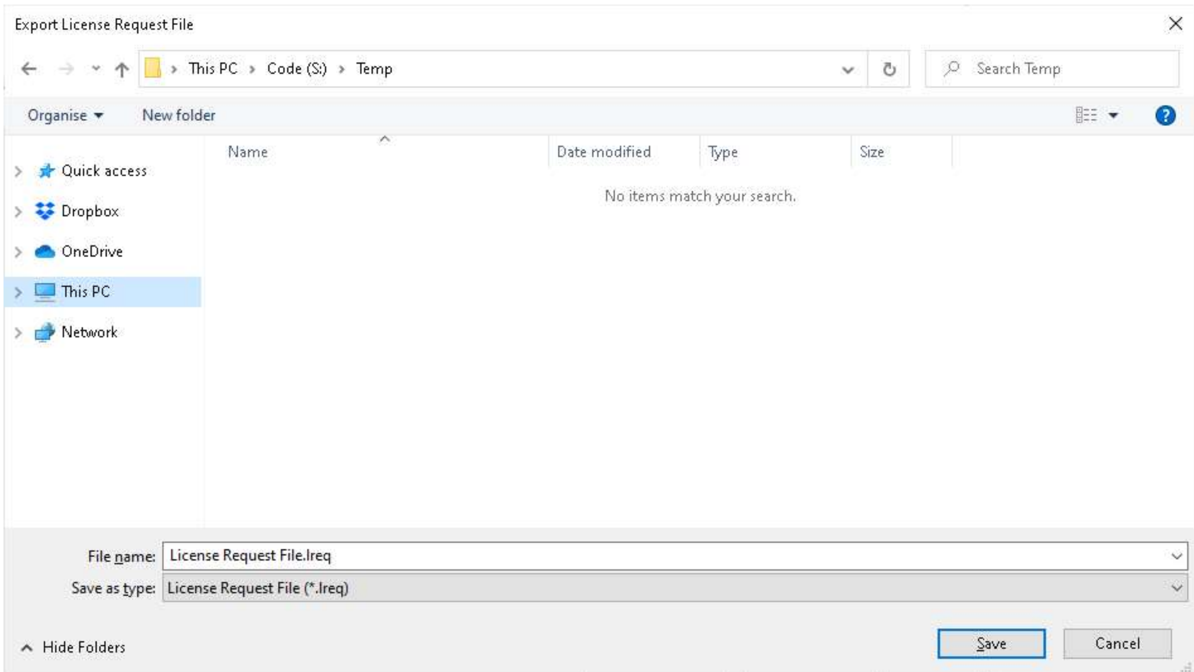
Launch **ADAS 3D** using your desktop shortcut. A license dialog will appear, requesting a valid license file.



Press the button **License Request File,** a windows dialog will ask information about the user to generate the license. Fill all the information and click on **Generate License Request File.**

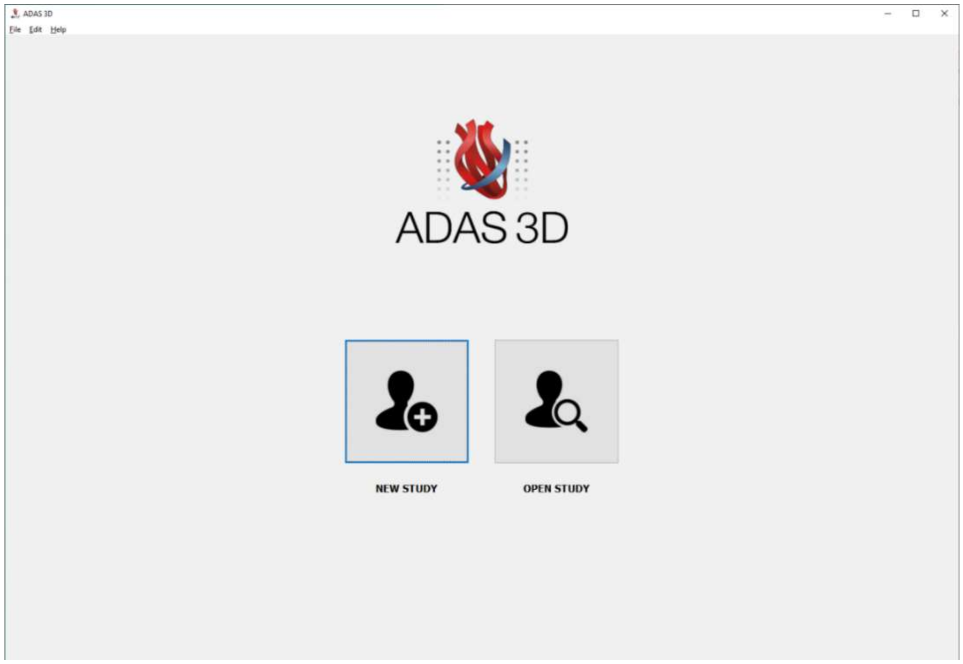


Save the generated license request file and email it to your local ADAS 3D representative.

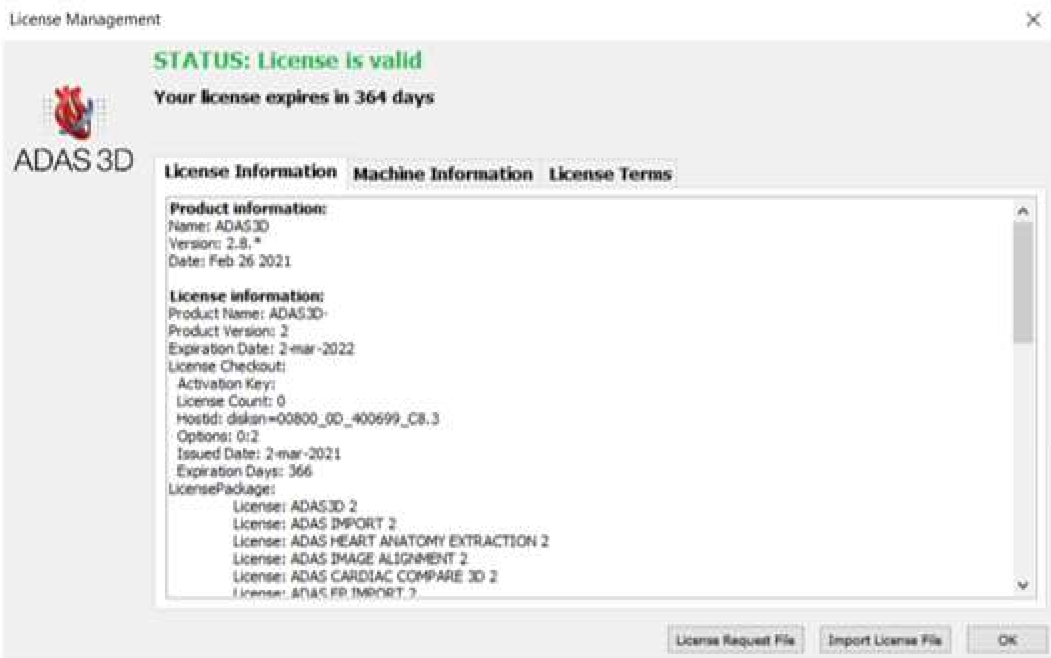


2.5. Step 5

You will receive a license file “license ADAS XX-XX-XX-XX-XX-XX-XX-XX-XX-XX.lic”. Save it in a known folder. Press the button **Import License File**–and select the received file. Accept the License Agreement and ADAS 3D will start.



To verify the STATUS of the license click on **Help** at the top of the screen and then, **License** and it will appear a windows with the License valid.



3. Uninstall process

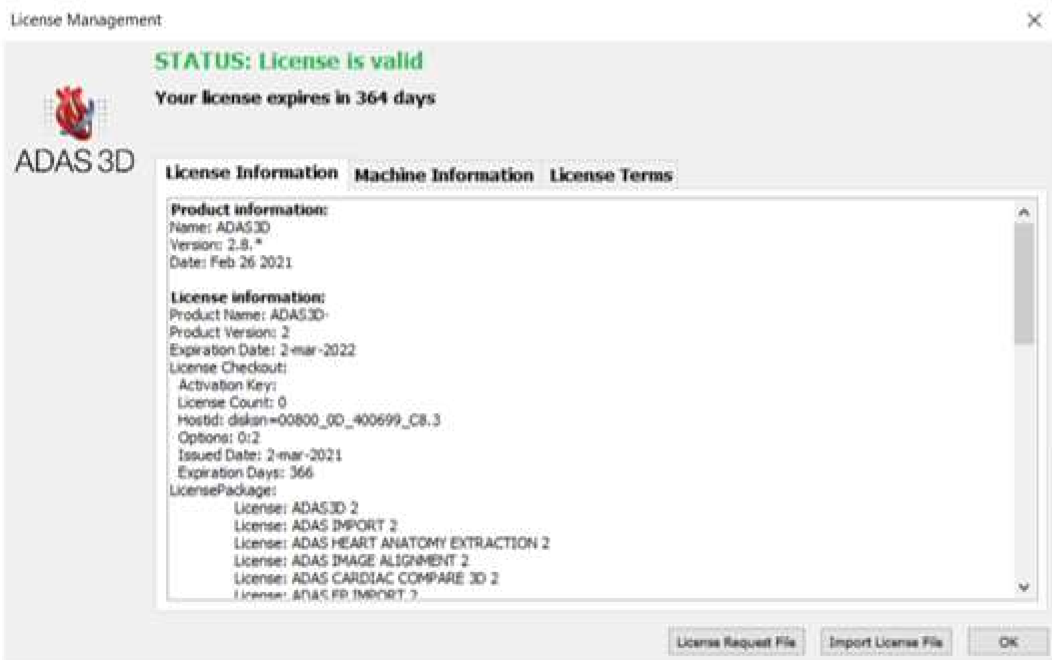
In the search box on the task bar of the PC, type “control panel”, then select Control Panel.

1. Select Programs > Programs and Features, then right-click on your ADAS 3D product, and choose Uninstall.

2. Eliminate all cases processed with ADAS 3D from all study databases. Open a Windows browser, go to the each of root folders of the database and delete all the files. You may want to back-up the data before deleting it.

4. License

ADAS 3D can only be used with a valid license file. The license file is specific to each computer.



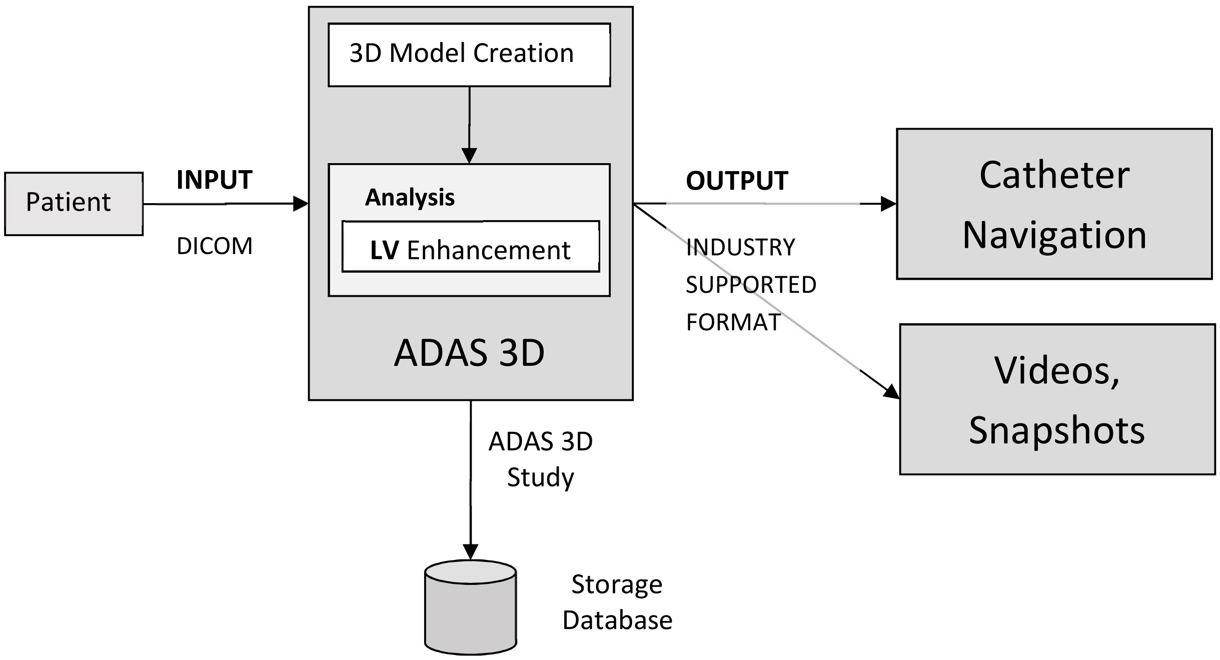
Using license dialog, the user can review the license information.

To import a license file, click the button Import License File.

5. Workflow: processing a case

A typical ADAS 3D workflow involves the following steps:

1. Importing a DICOM image into ADAS 3D.
2. Processing the DICOM image with ADAS 3D. This will create 3D Model of the patient's heart, and one or more analyses. The result is an **ADAS 3D Study** for that patient.
3. Exporting the **ADAS 3D Study** to industry standard file formats supported by catheter navigation systems. Videos and snapshots of the ADAS3D Study can also be exported.



Typical ADAS 3D workflow

6. Starting ADAS 3D

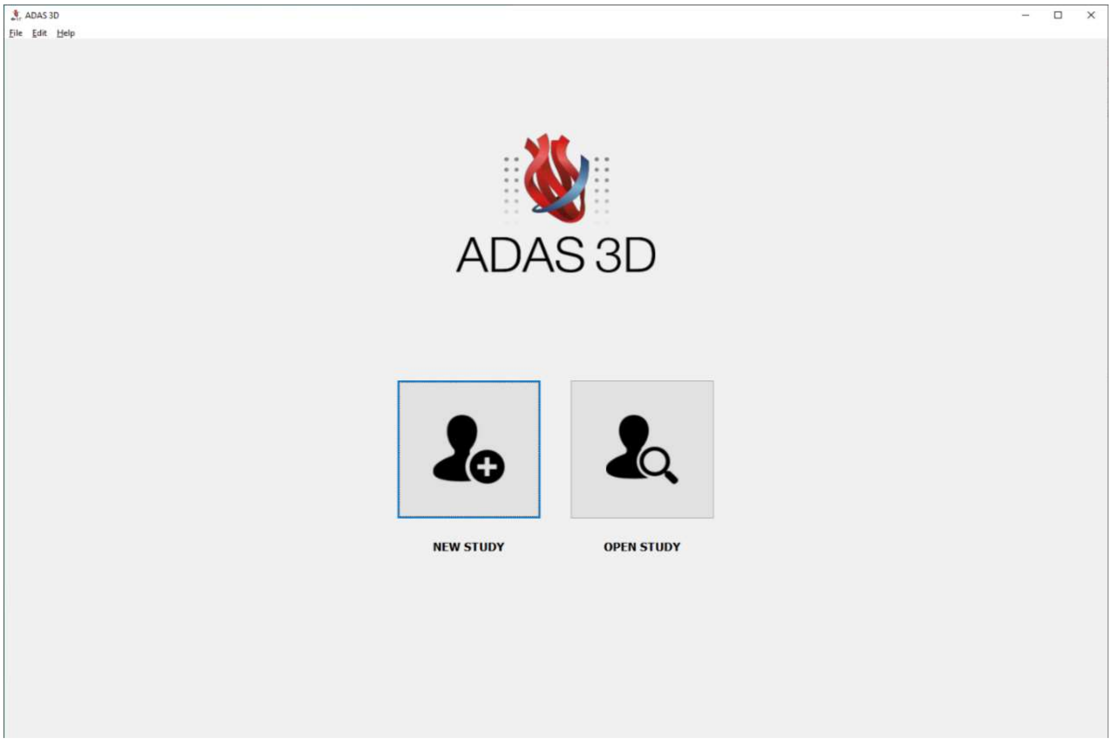
Double click the **ADAS 3D** desktop icon. ADAS 3D will start and show the main window.

7. Main Window

The main window shows two options:

1. New Study: allows the user to create a new study. The Overview page will be displayed, where the user can import new data and create new analysis.

2. Open Study: to open a previous study or manage the studies stored in the ADAS 3D database.

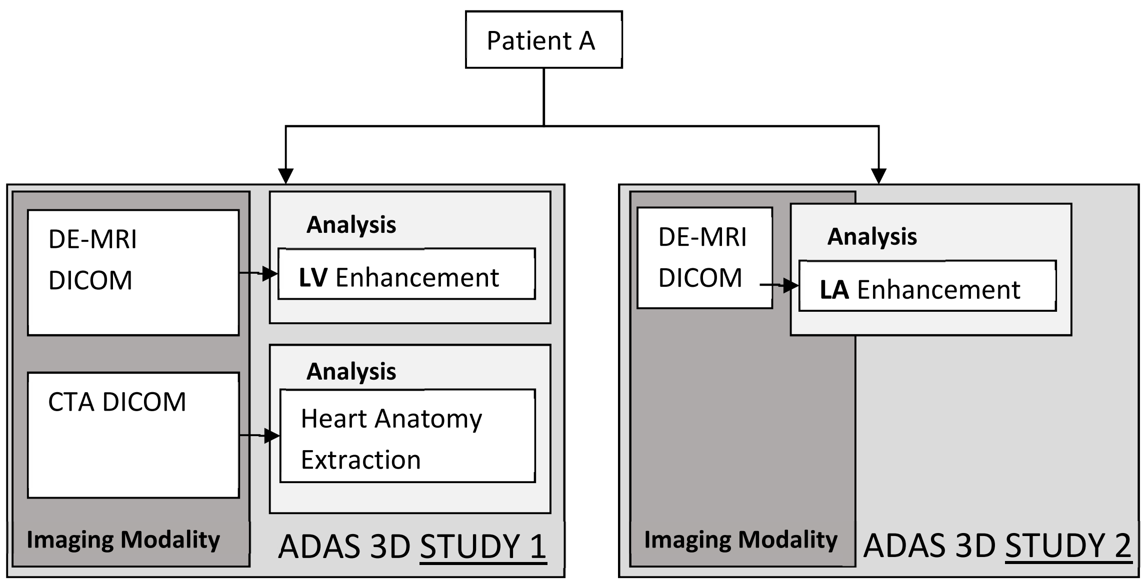


ADAS 3D Main Window

7.1. Study overview

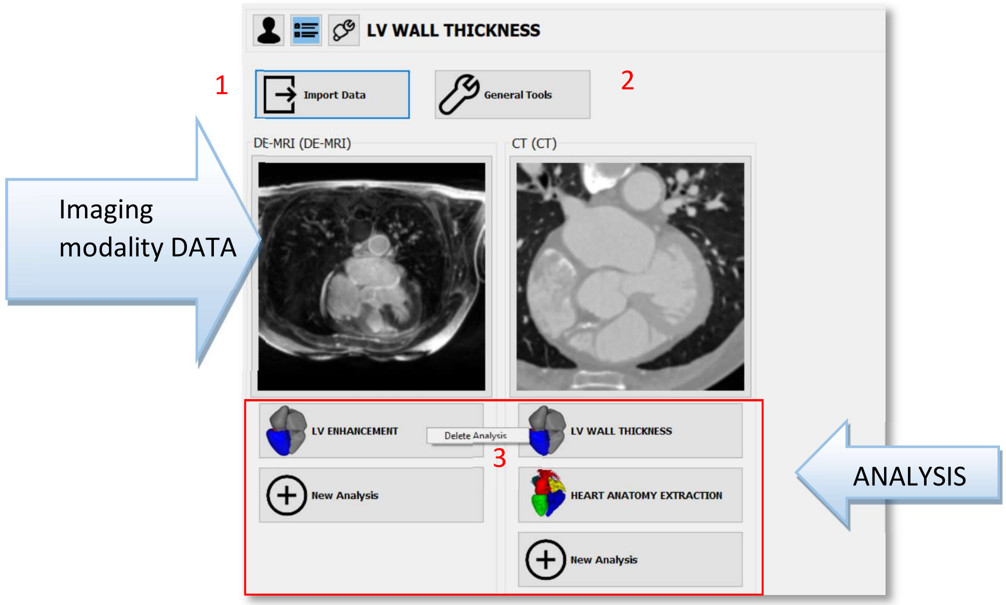
ADAS 3D allows the creation of multiple *studies* for individual patients.

An ADAS 3D study consists of a collection of imaging modalities (DICOM). For each imaging modality, the user can perform one or more analysis (LV Enhancement, Heart Anatomy Extraction, LV Wall Thickness, etc.). For example, for the same patient, there can be two different studies generated with ADAS 3D at two different times in the life of the patient. One study is for LV analysis using MRI and CTA imaging modalities. Another study for LA analysis with just MRI may also be created in ADAS 3D.



Organization of data in ADAS 3D: Patient->Study->Imaging Modality->Analysis

After importing new DICOM data or opening an existing study, the **Study Overview** page will allow the user to select the imaging modality data and the corresponding analysis for the current study. A new analysis can also be created from the imported DICOM data. The Study Overview page allows to manage the data and the analysis for the current study. The user can import new data, delete data, create new analysis, delete analysis and use the general tools.



Overview of the interface. Upper area appears the Imaging modality DATA and in the lower area the ANALYSIS. (1) is for importing DICOM or other studies, (2) the general tools and (3) how to delete an analysis using the right mouse button.

8. Main menu

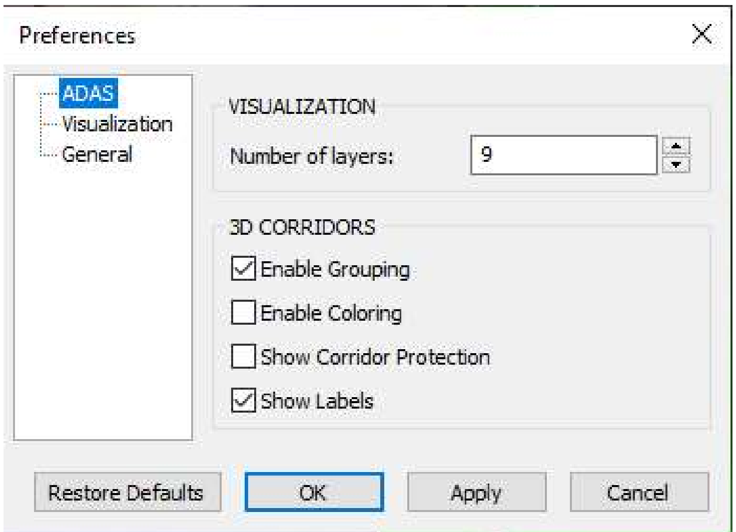
The main menu is found on in the top left corner of the ADAS 3D interface. It allows to see and modify multiple features.

- File:
  - Exit: Exit the application
- Edit
  - Preferences: Change ADAS 3D preferences
- Help
  - About: Show about dialog
  - License: Show license information
  - Regulatory: Regulatory Label
  - Instructions for Use: Open the Instructions for Use document

9. Preferences

The user can select various preferences in the ADAS 3D software. To show the preferences window, click on the main menu Edit and select Preferences.

There are two sets of preferences: ADAS and Visualization.



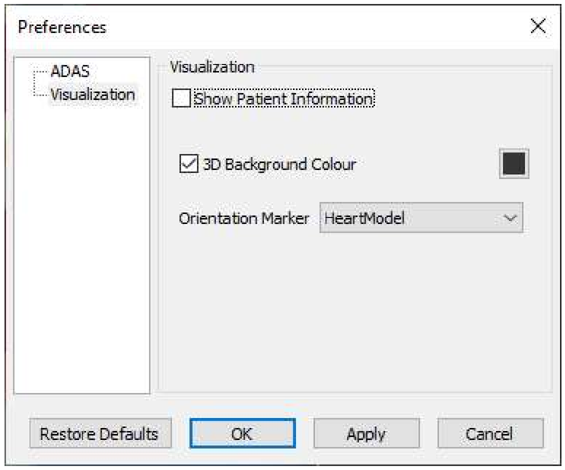
Preferences interface

9.1. ADAS Preferences

If there is a LV analysis performed, the user will be able to edit these preferences:

- **VISUALIZATION**
  - Number of layers: Number of layers to be computed, up to a maximum of 20.
- **3D CORRIDORS**
  - Enable Grouping: Group 3D Corridors using overlapping percentage of 3D Corridor volume.
  - Enable Coloring: Visualize each 3D Corridor with a different color for easy an easier identification.
  - Show Corridor Protection: Visualize each 3D Corridor as a variable radius tube depending on the degree of Protection at each location of the 3D Corridor.
  - Show labels: Show the labels of the corridors on the 3D model.

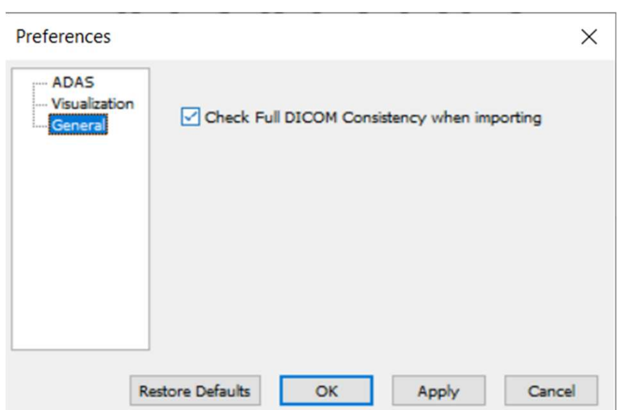
9.2. Visualization Preferences



Visualization preferences interface

- Show patient information: Show patient information at the top left corner of the 3D VISUALIZATION window.
- 3D Background Color: Select the background color that will be used in the 3D Visualization window.
- Orientation Marker: Select the orientation marker that will be used in the 3D Visualization window. Three options can be selected: Heart Model, Male Torso and Annotated cube.

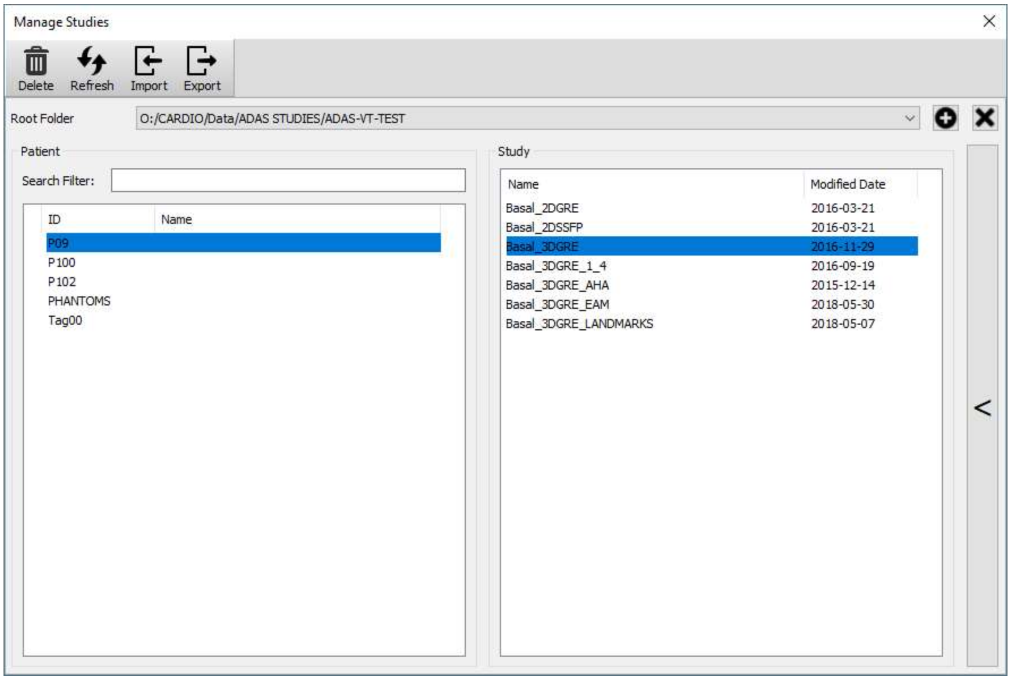
9.3. General Preferences



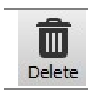
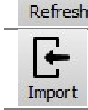
- Check full DICOM consistency when importing: select this option to check the DICOM consistency before importing a case. In case the slices are not exactly equally distributed, but the user thinks the quality of the acquisition is not affected by this fact, this option can be unselected.

10. Study storage database

From the main window, when selecting the option "Open New Study", the Study Storage Database window is shown. Study Storage lets the user manage **ADAS 3D Studies** for each patient and Import and Export studies.



Manage studies interface

Tool	Name	Description
	**Delete**	Delete the selected study
	**Refresh**	Refresh the current database
	**Import**	Import one or more studies from an external folder
	**Export**	Export one or more studies to an external folder. If the option "Anonymize exported

	data" is checked, the user will be able to set a new patient name and ID for the exported study.

10.1. Exporting ADAS 3D studies

ADAS 3D studies can be exported for sharing with other healthcare professionals. This option exports all the information that is stored in the local study storage for each ADAS 3D study that is selected:

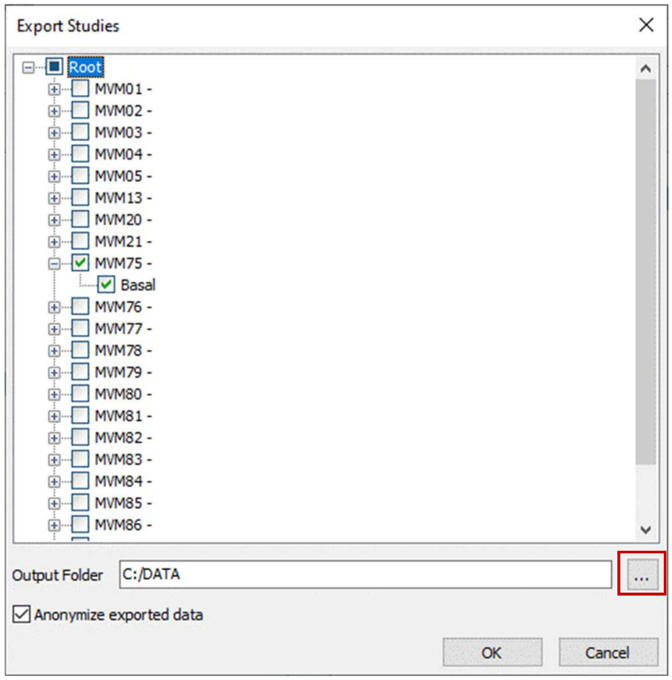
- **Data**: The data of the study, including the DICOM images, 3D models and numerical values. Use this option to share ADAS 3D data with other computers/healthcare professionals using ADAS 3D.
- **Snapshots:** The snapshots created from the study. Please find more details in the chapter ***¡Error! No se encuentra el origen de la referencia.***
- **Videos**: The videos generated from the study. Please find more details in the chapter ***¡Error! No se encuentra el origen de la referencia.***
- **VTK/DIF exported data**: The data exported to the navigation systems in VTK or DIF format. Please find more details in the chapter ***¡Error! No se encuentra el origen de la referencia.***
- **Exported numerical data**: The numerical data exported. Please find more details in the chapter *Quantification tool*
-

10.1.1. Anonymization

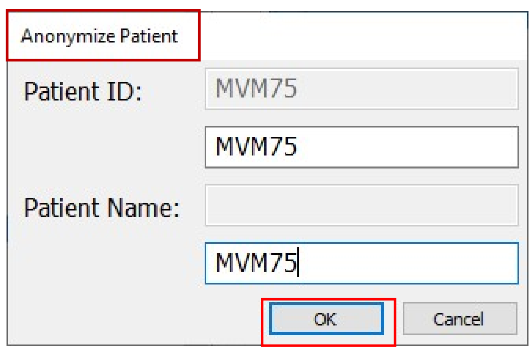
The exported ADAS 3D study data will contain personal patient information, such as the name of the patient or patient ID. To preserve the anonymity of the patient, select the **Anonymize exported data** option. This option will allow the user to anonymize the patient name and patient ID of the **Data of the study**.

To hide the patient information prior to generating a snapshot or video, click on the **Preferences** tab and uncheck the **Show Patient Information** box.

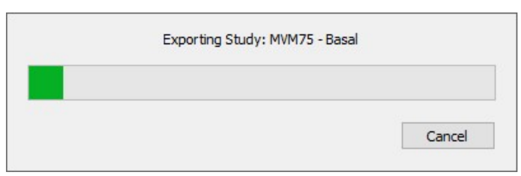
To anonymize an ADAS 3D patient data study, clicking on the **Export** button, a new window will appear. Select which study to export, then check the **Anonymize exported data** box. Then click on the button with the label "…" to specify the output folder for the exported study.



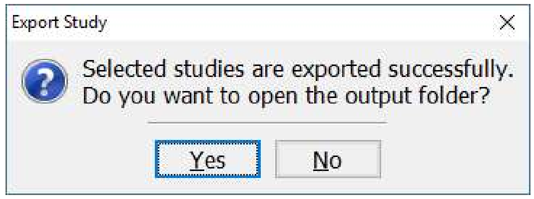
When the option **Anonymize exported data** is enabled the user will be asked to fill the name of the patient and the patient ID for each exported ADAS 3D study.



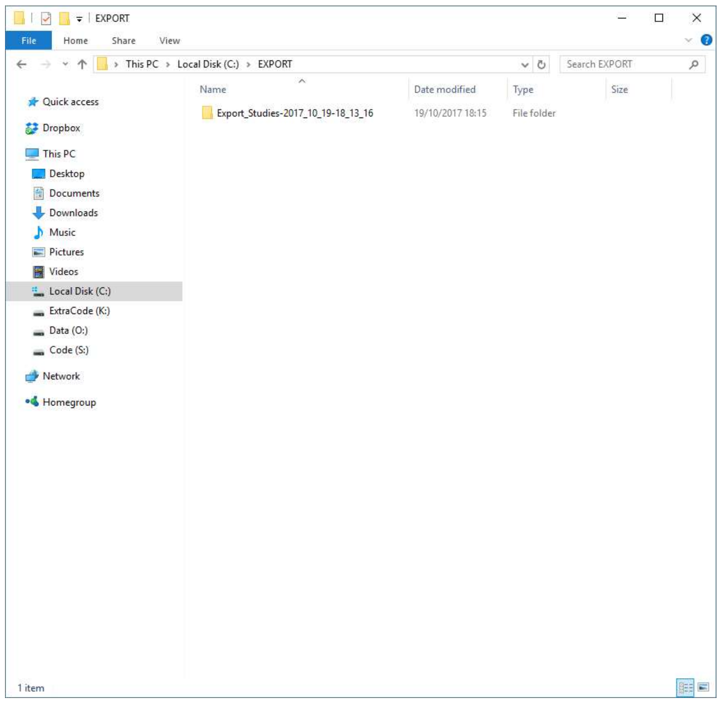
Press **OK** when done. A progress window will show the status of the export.



Once the data is exported, a new window will ask the user to open the output folder.

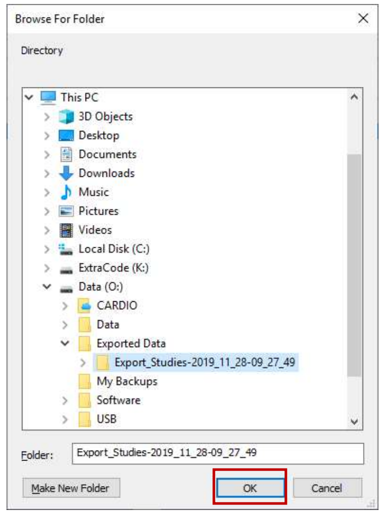


The output folder will contain a subfolder called “Export_Studies_<date>-<time>”. This folder can be compressed to a single file to transfer it to another computer.

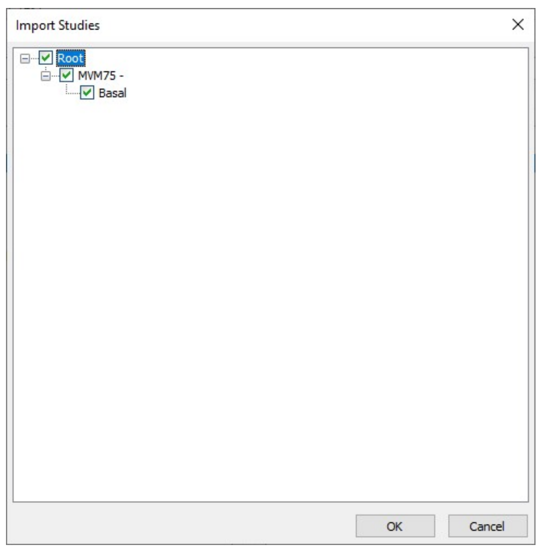


10.2. Importing ADAS 3D Studies

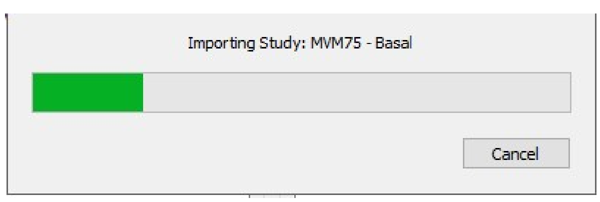
When clicking the **Import** button, a new window will appear where the user can select the import folder. Select the folder where the exported studies are located and press **OK**.



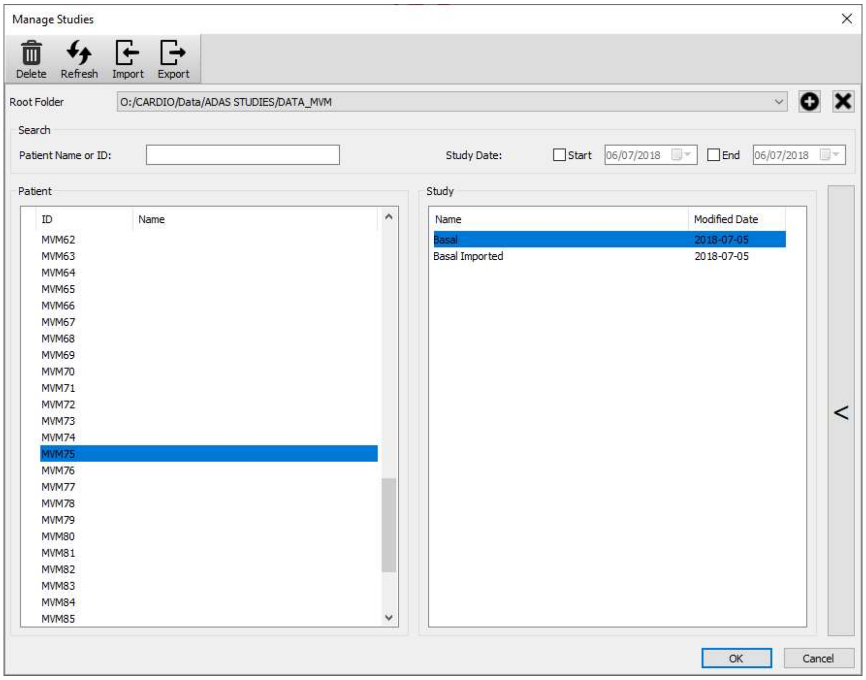
A new window will appear where the user can select the ADAS 3D studies to import. Once the studies are selected, click on **OK**.



A progress window will show the status of the import.



After the study has been imported, it will appear in the Study Storage list and the user will be able to normally open it with ADAS 3D by clicking on the patient and then on the desired study. Finally, click on OK.

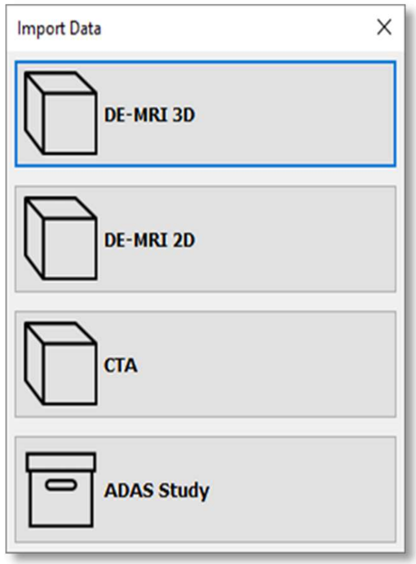


11. Importing data

Selecting NEW STUDY in the ADAS welcome screen will create an empty ADAS study to import data and analyze it. The first step is to import the data that needs to be analyzed, by clicking the **Import Data** button in the Overview page.

The Study Overview without any patient data

After clicking the button, a window to choose the type of data to import will be shown. For example, to import a DICOM DE-MRI 3D, click on the corresponding button.

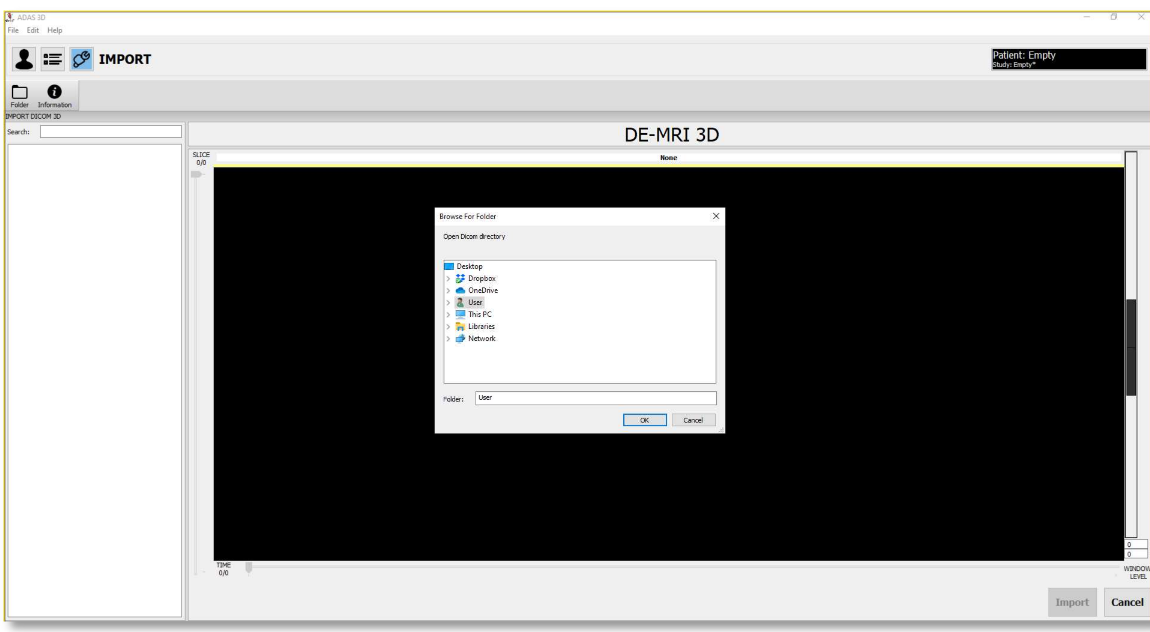


Import Data Pop-up Window

11.1. Importing DICOM data

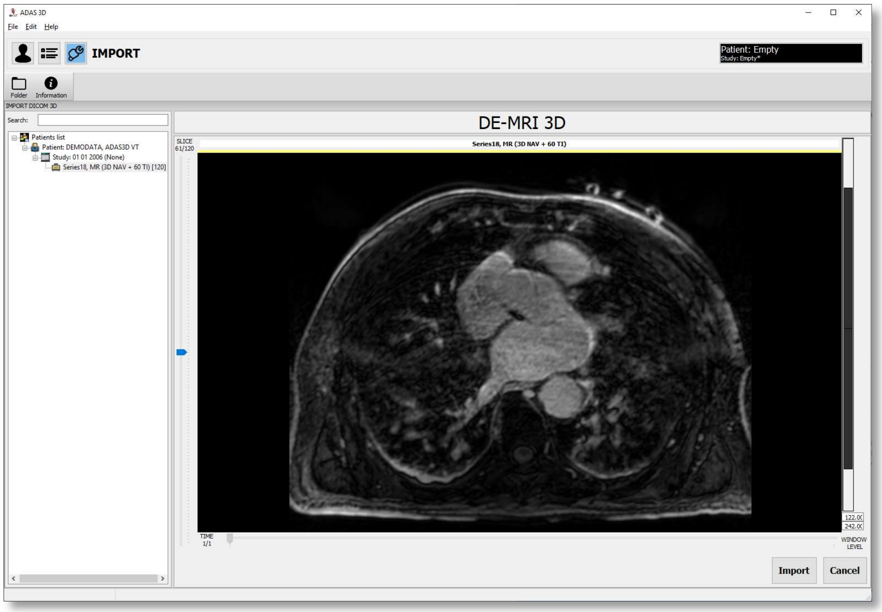
Once the Import Data button is clicked, the user can select any of the available DICOM modalities: DE-MRI 3D, DE-MRI 2D or CTA.

A pop-up window will ask the user to select the folder containing the DICOM data to be imported.



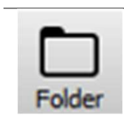
Window interface to select the DICOM folder to import

The import DICOM interface will show up.



DE-MRI 3D Interface

11.1.1. DICOM Toolbar

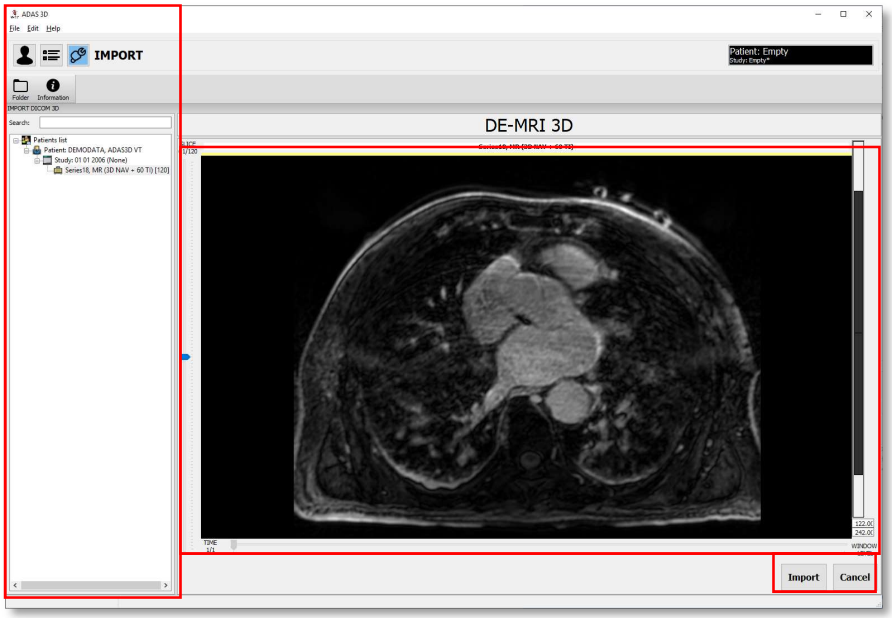
Tool	Name	Description
	**Open DICOM folder**	Import DICOM folder
	**DICOM information**	Show/Hide DICOM information window

11.1.2. Usage

To open a DICOM image for the following modalities: DE-MRI 3D and CTA, select the folder where the DICOM data is located.

Once the folder is selected, all the available DICOM data in the folder will be shown on the left tree. A DICOM corresponding to the selected series in the tree will be visualized on the left window.

Then select the series to import from the list and click on the **Import** button.



DE-MRI 3D Interface

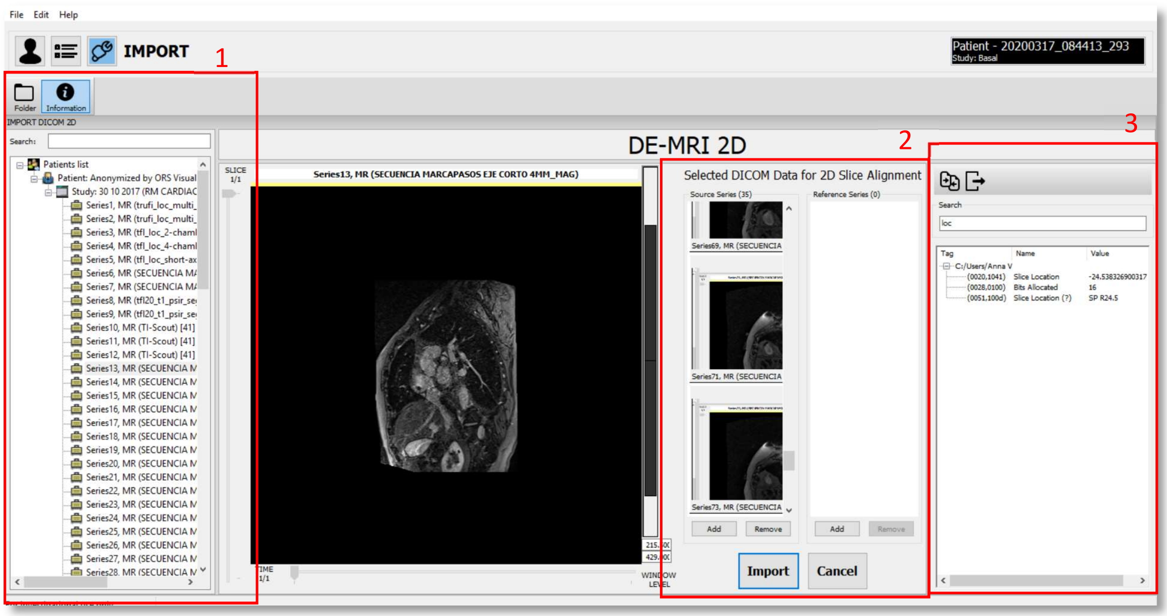
After clicking **Import** button, the system will return to the Study Overview page and display the imported DICOM.

Importing a DE-MRI 2D

To open a DE-MRI 2D image, select the folder where the DICOM data is located. When the folder is selected, all the available series in the folder will be shown on the left tree and the first series in the tree will be visualized on the right window.

This interface allows you to select multiple DICOM Series, where each DICOM series contains a single DICOM slice. The window “Selected DICOM Data for 2D Slice Alignment” will show the selected DICOM data that will be imported.

Select the DICOM Series on the left tree and press the button **Add**, located below the **Source Series** panel. You can select multiple DICOM series pressing Shift and Left mouse button or Ctrl and Left mouse button.



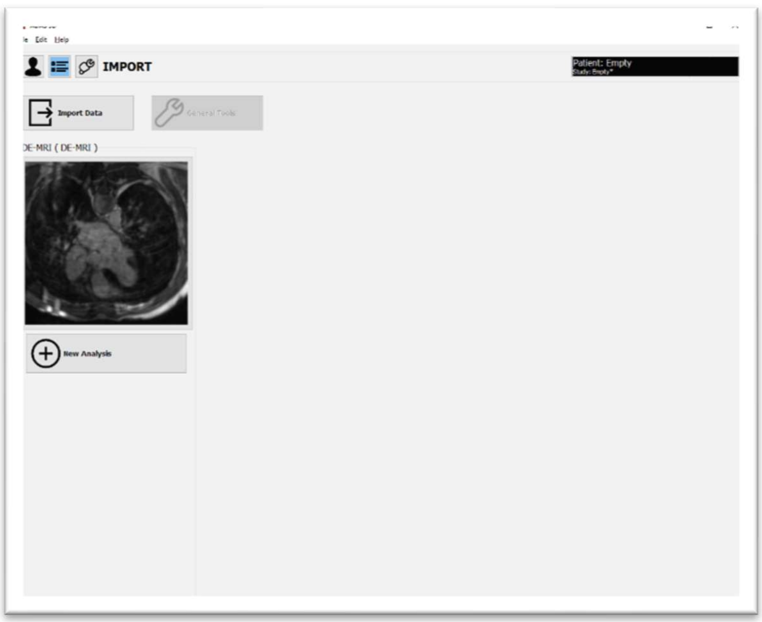
DE-MRI 2D interface. (1) DICOM series that can be selected. (2) The **Source Series** panel displays the selected DICOM Series. (3) The Information DICOM panel can display the slice location

When all the series are selected click on the **Import** button.

HINT: Click on the **DICOM Information** button and then in search, type “location”. The “slice location” should be approximately the same between all the series.

After clicking the **Import** button, the system will return to the Study Overview page and display the imported DICOM. A window will pop-up asking the user to save the study. The patient´s name and patient ID are automatically filled from the DICOM information. Edit these fields if necessary and press **OK**.

Window emerged after importing a DICOM to save the ADAS 3D study



The Study Overview with the DICOM recently imported

12. Analysis and tools

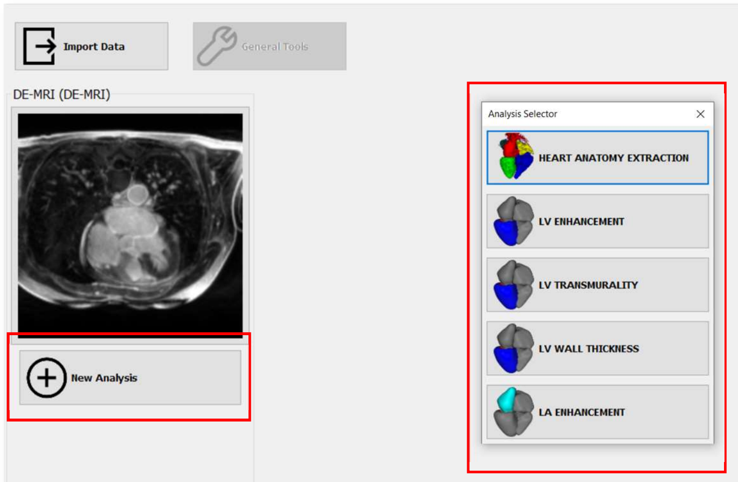
12.1. Analysis

There are four available types of **analysis** that are applicable to a specific input image modality data. Each described below:

Analysis	Image modality	Description
LV Enhancement	DE-MRI 3D, DE-MRI 2D	Analysis of the enhancement of the myocardial fibrosis from DICOM MR images in the myocardium of the Left Ventricle
LV Wall Thickness	CTA	Analysis of the wall thickness of the Left Ventricle
LA Enhancement	DE-MRI 3D	Analysis of the enhancement of the myocardial fibrosis from DICOM MR images in the myocardium of the Left Atrium
Heart Anatomy Extraction	CTA	Identification and Visualization of other 3D anatomical structures

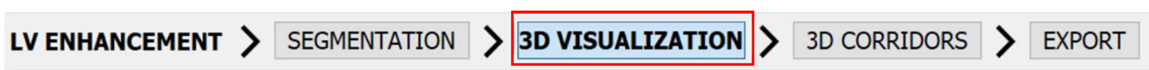
Additionally, there are two multimodal tools that can be used to work with image modalities.

Analysis	Image modality	Description
Image Alignment	ALL	Placing two images modalities to the same coordinate space
Compare 3D	ALL	Comparing side-by-side two analyses



Interface to select the analysis

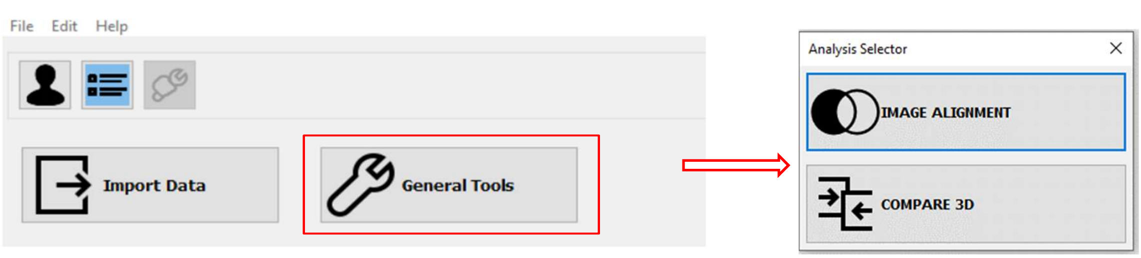
Each analysis has its own workflow that will guide the user through the steps to process the data. When an analysis is started, in the top part of the screen, the corresponding workflow is displayed. As an example, the workflow for the analysis LV Enhancement is shown below:



At the top left, the name of the current analysis is shown. The steps of the analysis are shown from left to right. The step colored in blue shows the active step. It is possible to change the active step by clicking on it.

12.2. General tools

In the Overview page the user can find the General Tools, which allows the user to select one of the following tools: **Image Alignment**, **Surface Alignment** and **Compare 3D** Tool.

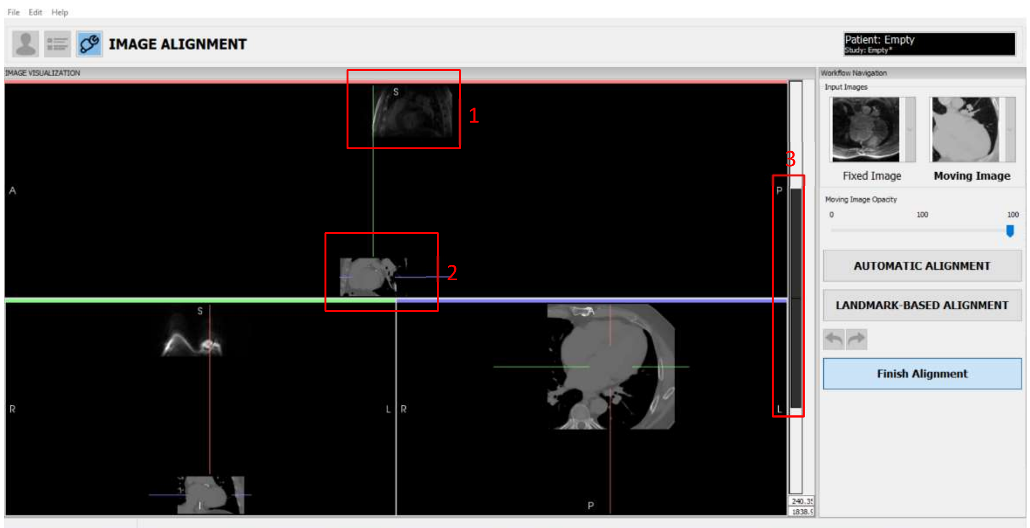


The General Tools button in the Overview page and the available tools.

12.2.1. Image alignment

The Image Alignment tool allows the user to bring two image modalities such as MRI and CTA to the same coordinate space. One image is the reference '**fixed'** image and does not change its coordinates. The other image, the '**moving'** image, is modified to fit into the coordinate space of the reference image.

When a second image is imported (see Importing Data), a pop-up window will ask the user to perform the alignment of the two images.



Before the alignment, the CTA and MRI images have different position and orientation.
See also the slide bar to adjust the opacity.

There are two options for the alignment:

- Automatic: The automatic method registers the two data sets based on the volumetric information and uses a rigid affine transformation. This method works only with 3D volumes that have PSI values.

- Landmarks: The manual method uses any identifiable set of corresponding landmarks set by the user on each 3D volume to align the two images.

After using either method, the user can use the **Moving Image Opacity** slider to check the alignment results, and then click on the **Finish Alignment** button.

When aligning two images, the Moving Image is modified using a rigid transformation (rotated and translated), while the Fixed Image is not modified. This rigid transformation will be propagated to all the data that depends on the Moving Image (segmentations, analysis, etc.).

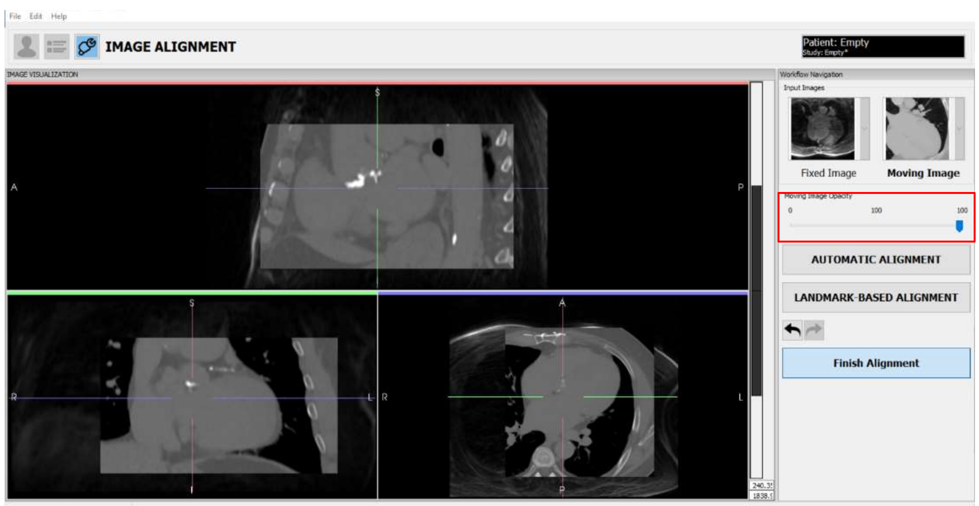
HINT: When aligning an MRI image with a CT image, select the MRI image as the Fixed Image to preserve the quality of the MRI and the results of analysis that depend on it.

Automatic alignment method

This method consists of two main steps:

1. Image Selection: select the Fixed Image and the Moving Image, then press the **AUTOMATIC ALIGNMENT** button.

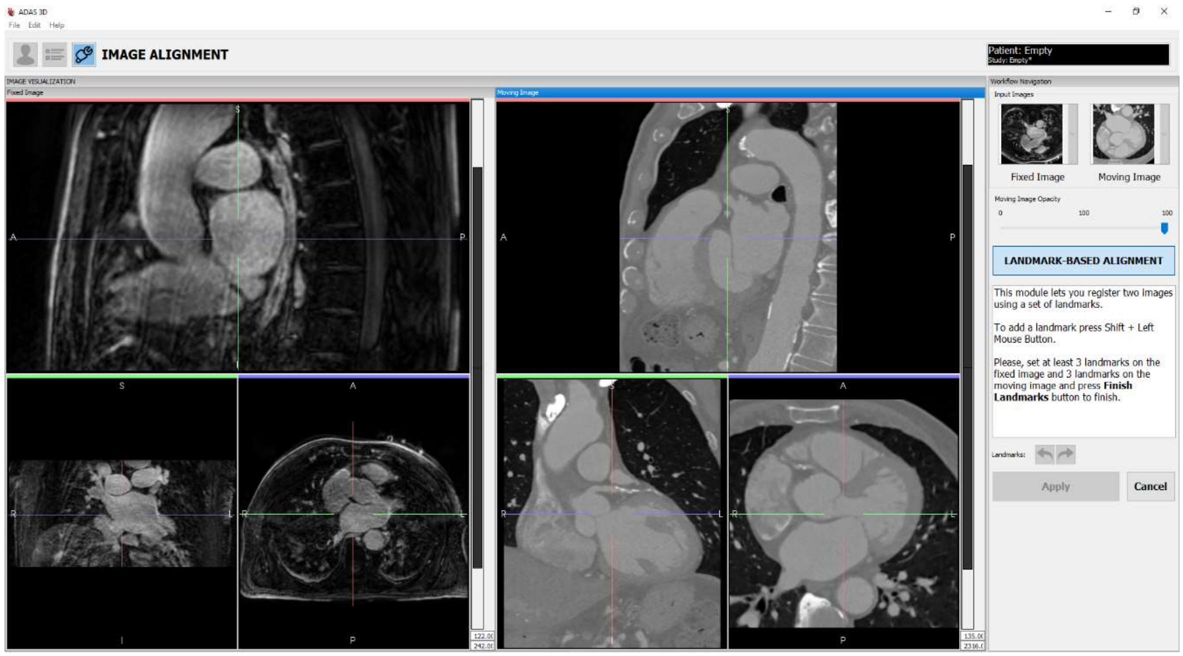
2. Alignment Verification: Move the Moving Image Opacity slider to visually verify that the position and orientation of the structures in the two images overlap correctly.



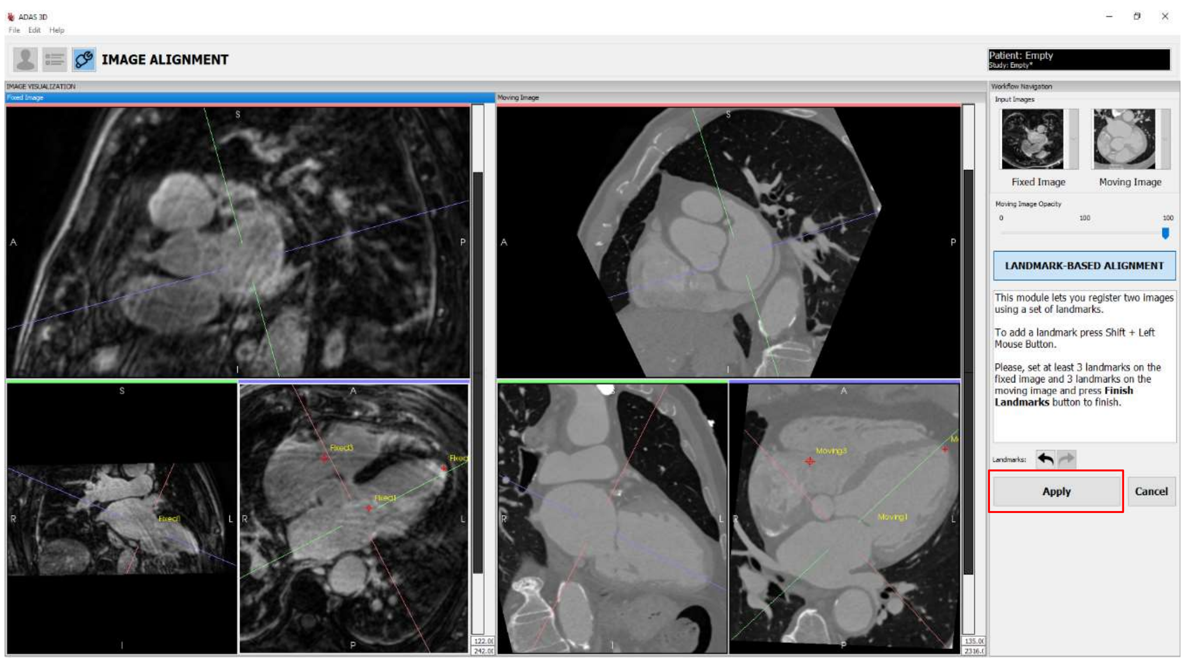
The Alignment tool after the alignment is applied.
Use the slider on the right panel to verify the overlap.

Landmark alignment method

To add a landmark press **Shift + Left Mouse button**. The user can orient the axes to identify the anatomical landmarks of interest. Set an equal number of landmarks on each image, making sure that each landmark is located at the same anatomical position in both sequences. To align the images, the user must add a minimum of 3 landmarks. We recommend to use more than 3 landmarks to obtain a more robust alignment.

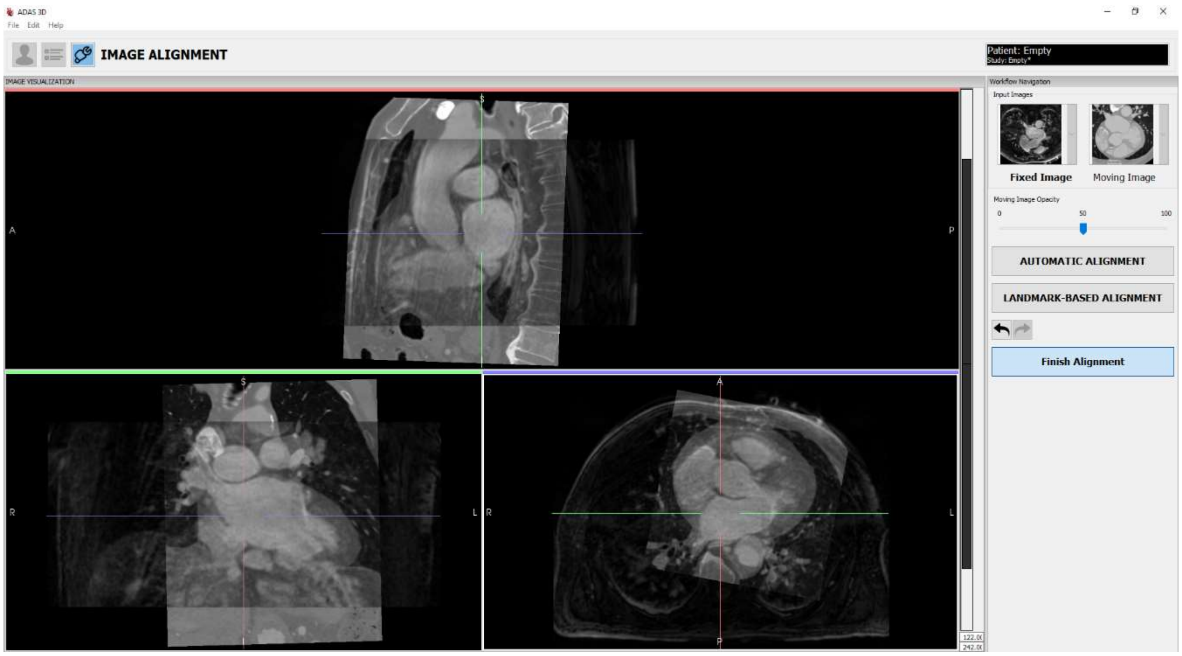


Landmark Alignment interface



Landmark Alignment interface: the landmarks are set on both images

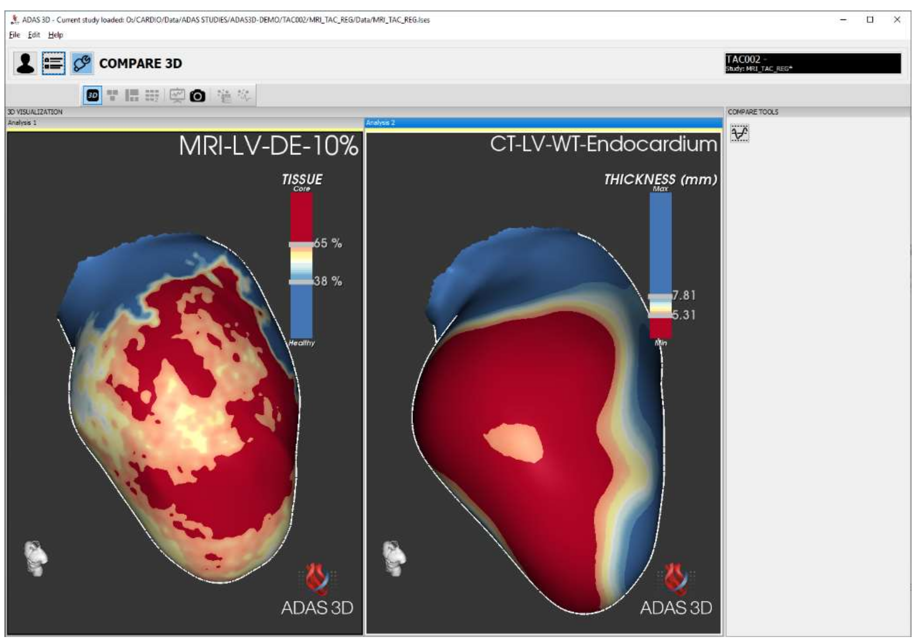
When satisfied with the position of the landmarks click on **Apply** to register the images and verify the alignment.



Landmark Alignment: Verification

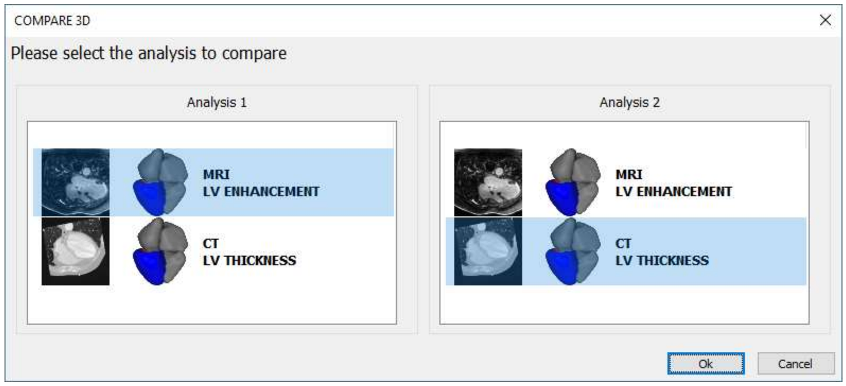
12.2.2. Compare 3D

The Compare 3D tool allows the user to compare two analysis side by side.



Compare 3D interface

To start the Compare 3D tool, select the two analysis to compare from the pop-up window and then click on **OK**.



Selecting the two analysis to compare.

13. Visualization views

13.1.1. Image view

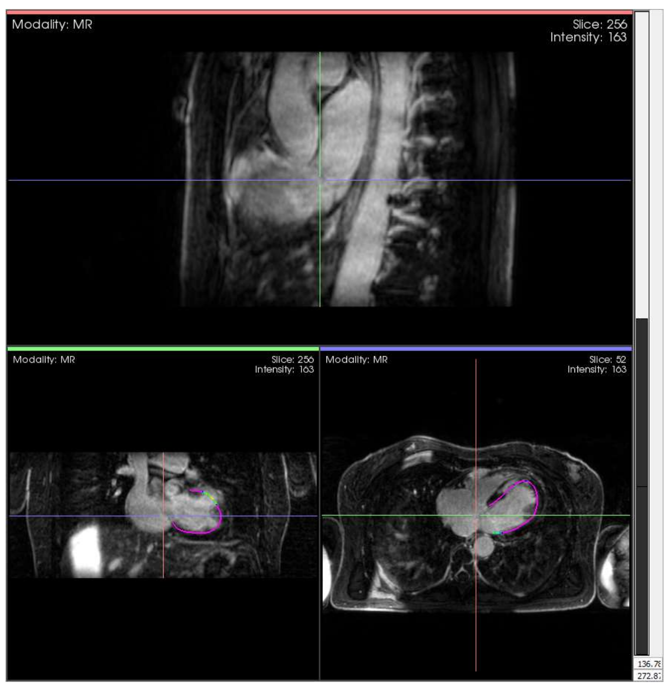
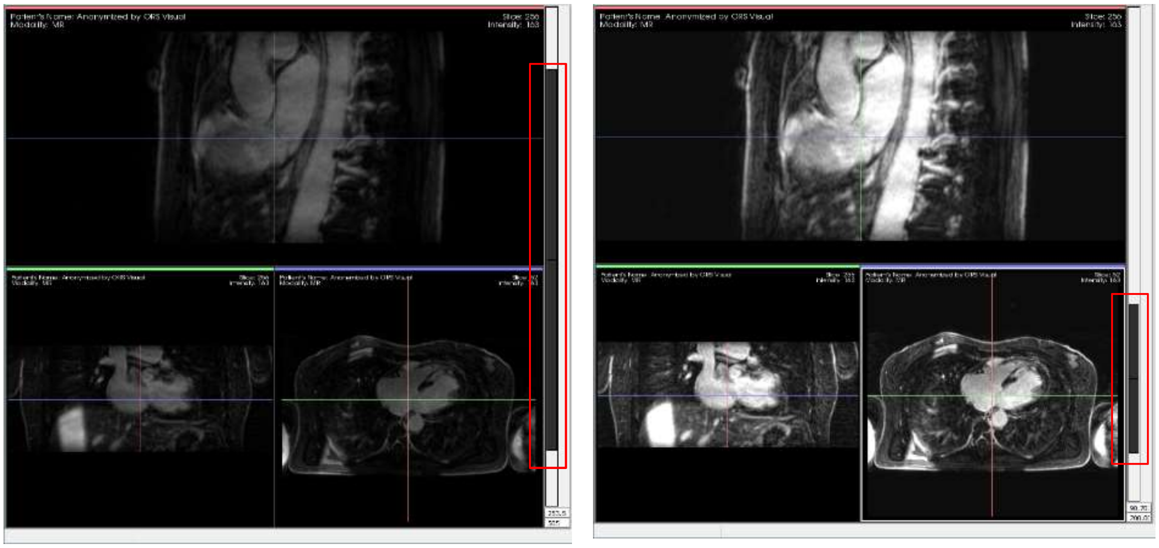


Image view interface

Interaction

- Adjust the **brightness and contrast levels** using the vertical bar or by pressing the **left mouse button** and moving the mouse on any of the visualization windows.

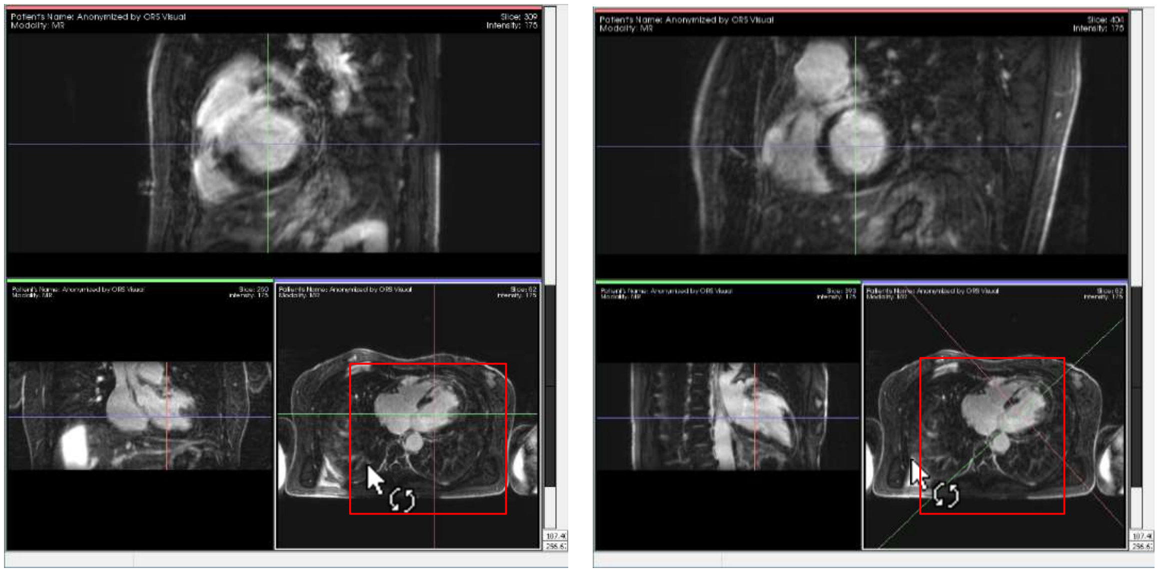


Scroll bar to adjust brightness and contrast

- To **move the axis**, move the mouse cursor to the center of the axis and press **left mouse button** while moving the mouse.

Moving the center of the axis

- To **reorient the axis**, move the mouse cursor to the end of the axis and press **left mouse button** while moving the mouse.

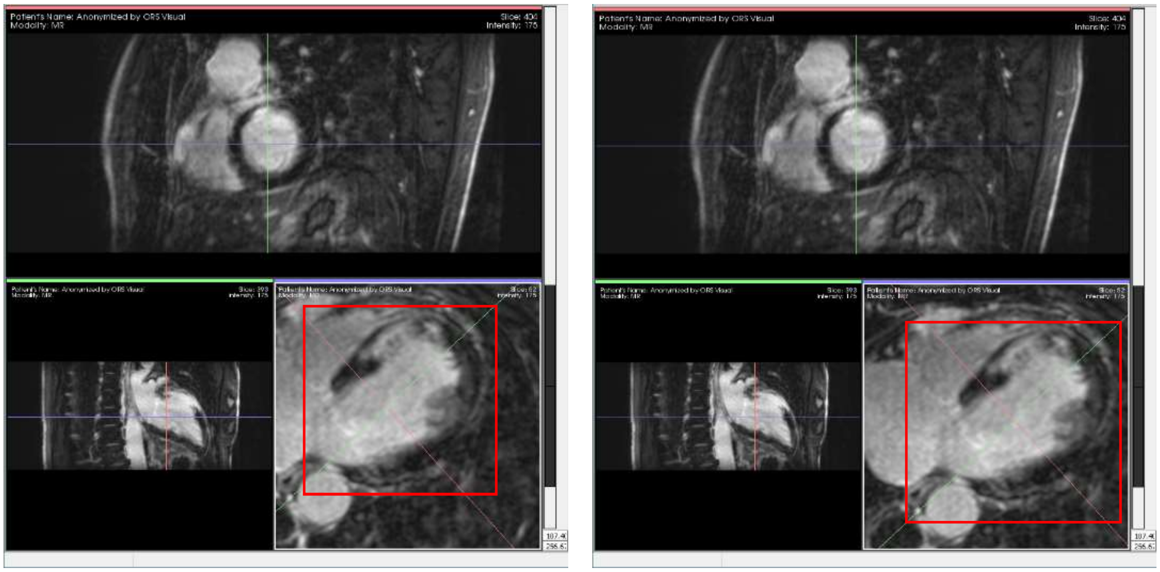


Reorienting the axis

- **Zoom** pressing **right mouse button** while moving the mouse up and down. The center of the zoom corresponds to the mouse cursor position.

Zooming in

- **Pan** the view by pressing wheel button while moving the mouse.



Center the view using the wheel button of the mouse

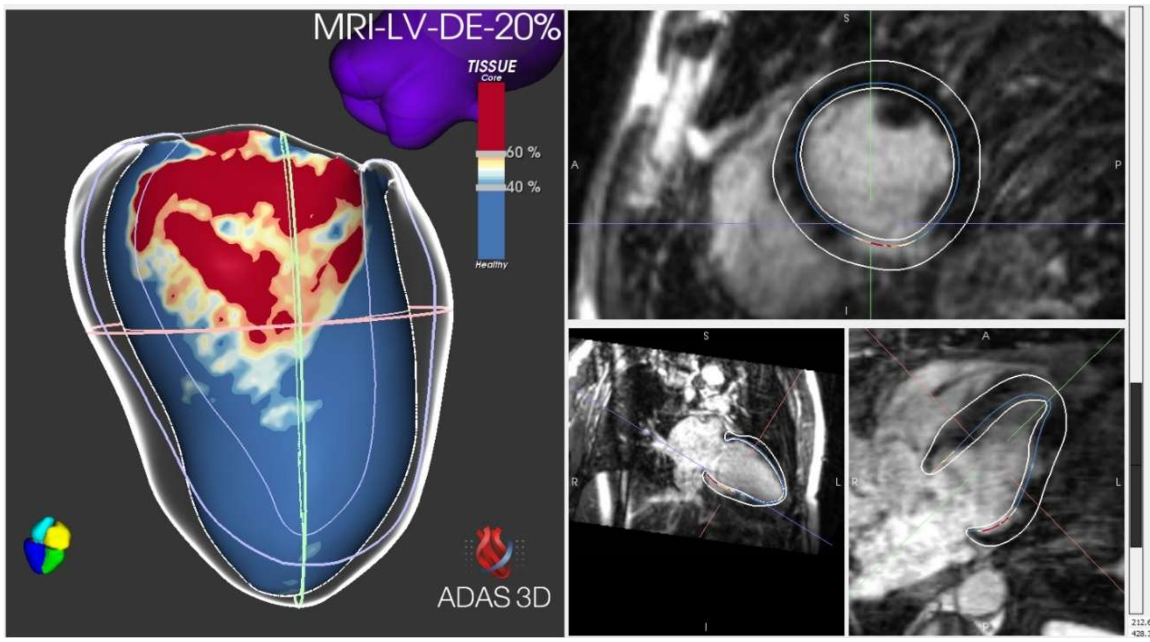
Toolbar

This toolbar is displayed when moving the mouse to the top-left corner of the view.

Tool	Name	Description
	**Reset Contrast**	Reset brightness and contrast to the default levels
	**Initialize Axis Orientation**	Initialize axis orientation to default
	**Refresh**	Initialize axis orientation and the zoom to fit the input image
	**Take a Screenshot**	Take a screenshot of the current view
	**Align Axis to LV**	Align axis to Left Ventricle

13.1.2. 3D image view

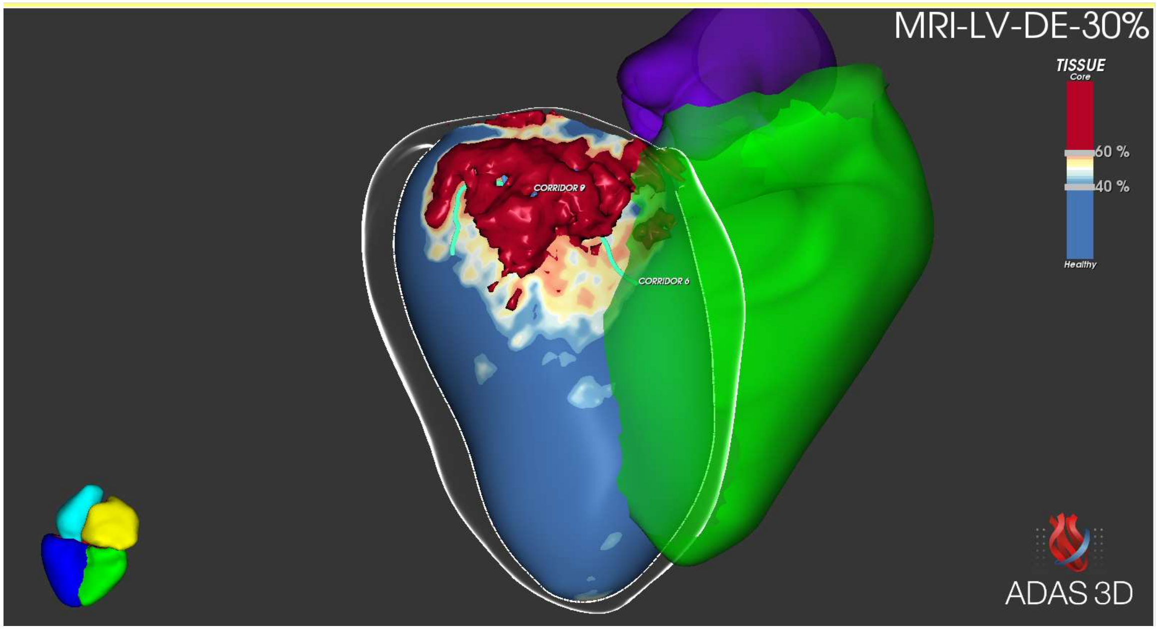
The 3D image view is shown to the user by selecting the option in the toolbar



3D Image View

13.1.3. 3D View

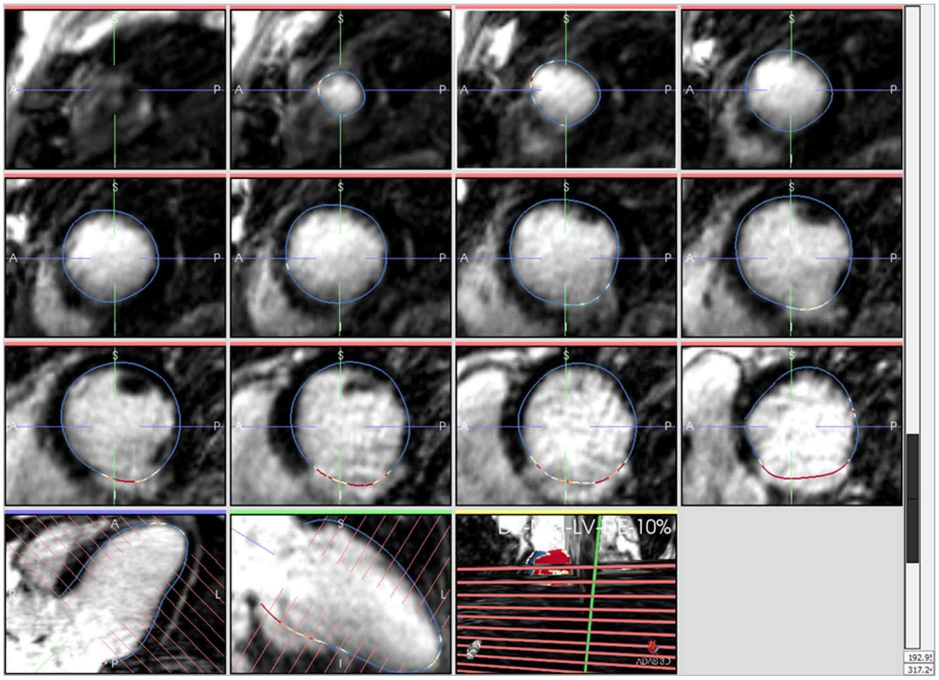
The user can also select the 3D Layer view in the toolbar



3D Layer View

13.1.4. Multiple 2D view

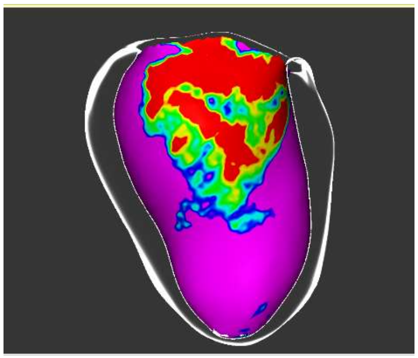
This option presents multiple 2D views



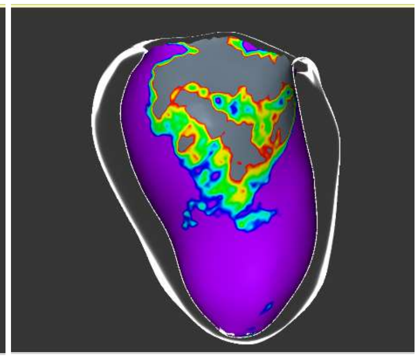
Multiple 2D view

13.1.5. Colormap options

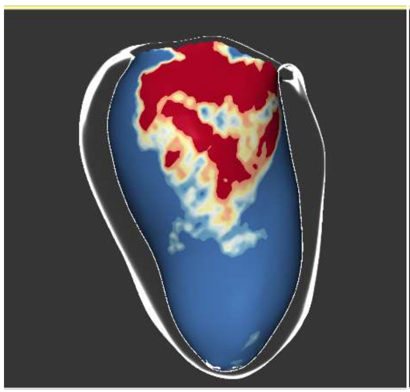
There are four color maps available to use for visualization of enhancement. To show the visualization toolbar, move the mouse on the top left corner of the 3D view window and select the dropdown menu in the toolbar.



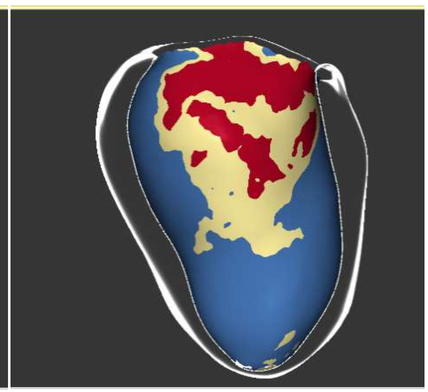
CARTO® colors



EnSite Precision™ cardiac mapping system colors



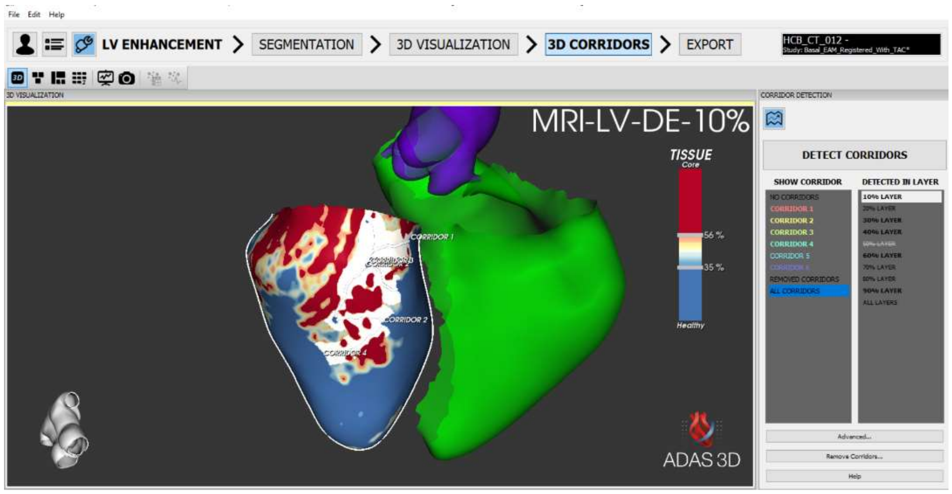
ADAS 3D default colors with smooth color grading



ADAS 3D 'trinary' colors

14. LV enhancement

The LV Enhancement analysis allows the quantification of the total volume of the enhancement within the Left Ventricle (LV) and the visualization of the enhancement area in multiple layers through the cardiac structure. Additionally, it allows the calculation, quantification and visualization of corridors of intermediate signal intensity enhancement in the LV.



LV Enhancement Analysis Interface

The LV enhancement analysis consists of 4 steps:

1. SEGMENTATION MODULE
2. 3D VISUALIZATION MODULE
3. 3D CORRIDORS MODULE
4. EXPORT MODULE

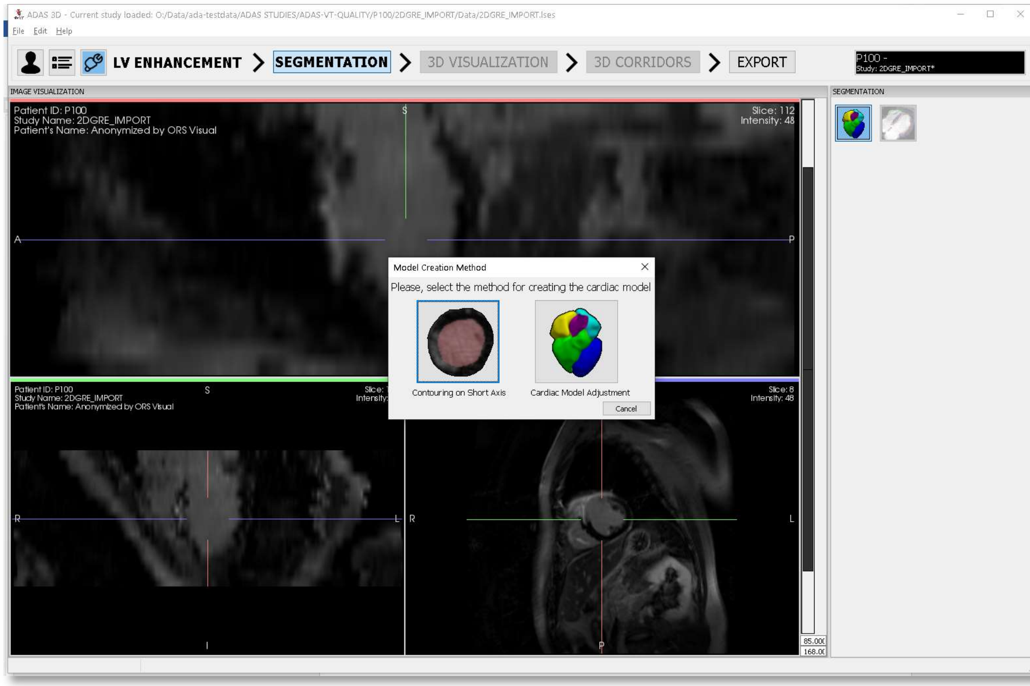
14.1. Segmentation module

This step allows the user to create a patient specific cardiac model of the imported image, based on the DICOM image modality selected. The steps involved are: 1) **Model Creation**, 2) **Slice-Based Adjustment** and 3) **Model Adjustment**.

14.1.1. Step 1: Model Creation

Select model creation method (only for 2D MRI images)

a. Contouring on Short Axis: recommended method for 2D MRI images with slice miss-alignment
b. Cardiac Model Adjustment: method for 3D MRI images or 2D MRI images without slice miss-alignment.



Interface to select the option for segmentation

The Contouring on Short Axis method enables the drawing of the endocardium and epicardium contours on each 2D DICOM slice, align the slices based on the drawn contours and create a model from these drawn contours.

The Cardiac Model Adjustment method allows to draw the contour on three short axis slices and the model will be adjusted to these three slices.

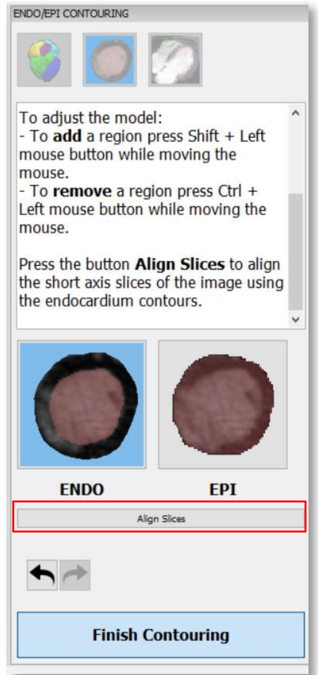
a. Model creation - contouring on short axis

This Contouring method asks the user to draw the endocardium and epicardium on each 2D MRI DICOM slice. Then it creates a model from these contours.

To draw the contour press **Shift + Left mouse button** and draw the contour with the mouse, to erase one, press **Ctrl + Left mouse button**.

After drawing the contours in all slices, the user can select the option **Align Slices**, to align the short axis slices of the image, based on the drawn endocardium contours.

If you follow this segmentation method, please jump to section 14.1.3 Step 3: model adjustment.

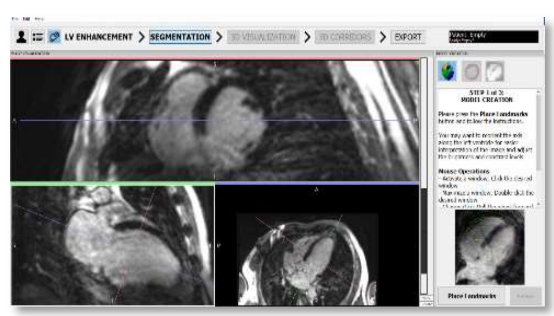


When satisfied with the drawings, select **Finish Contouring**

b. Model Creation- landmark based

This model creation is started with a landmark based model adjustment, and it is the recommended option for 3D DE-MRI sequences or 2D DE-MRI sequence without any slice miss-alignment.

- Adjust the view for the correct visualization of the left ventricle. Reorient the axis along the left ventricle for easier interpretation of the image. Adjust the brightness and contrast levels. Please see the section ¡Error! No se encuentra el origen de la referencia. for a detailed description of the interaction.



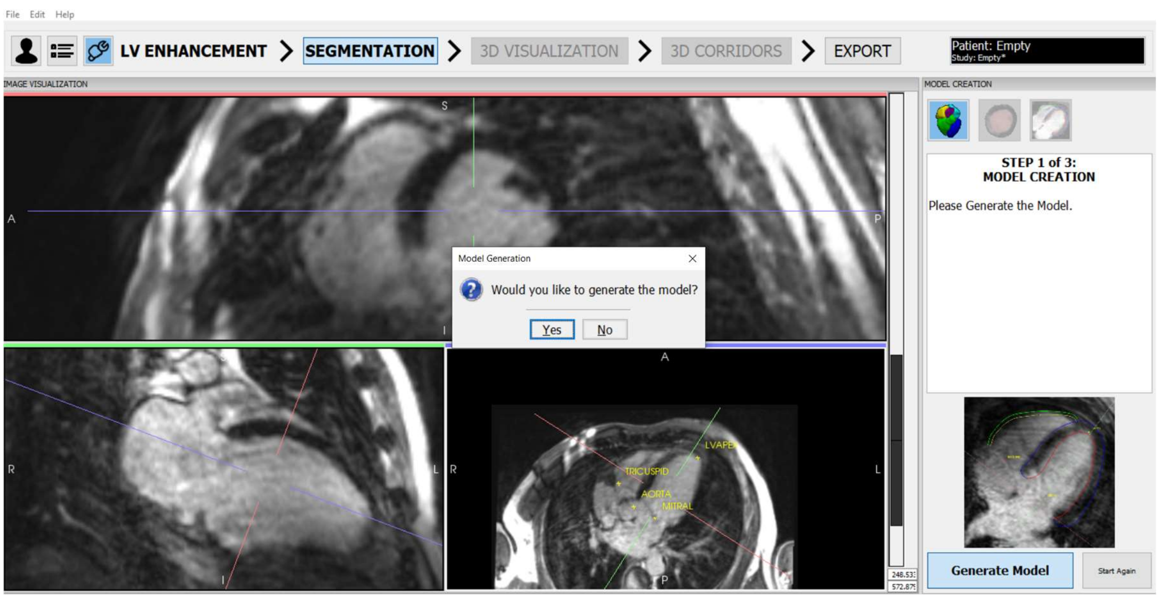
Initial visualization of the three axes to place the landmark

Axes aligned to the left ventricle. Easier view to place the landmarks

- Press the **Place Landmarks** button.
- Follow the right-panel instructions to place landmarks on any MRI data window in the order specified below. To place a landmark press: **Shift + Left mouse button.** To erase a landmark, press: **Shift + Right mouse button** on top of the just placed landmark. It can be done in any of the three planes.

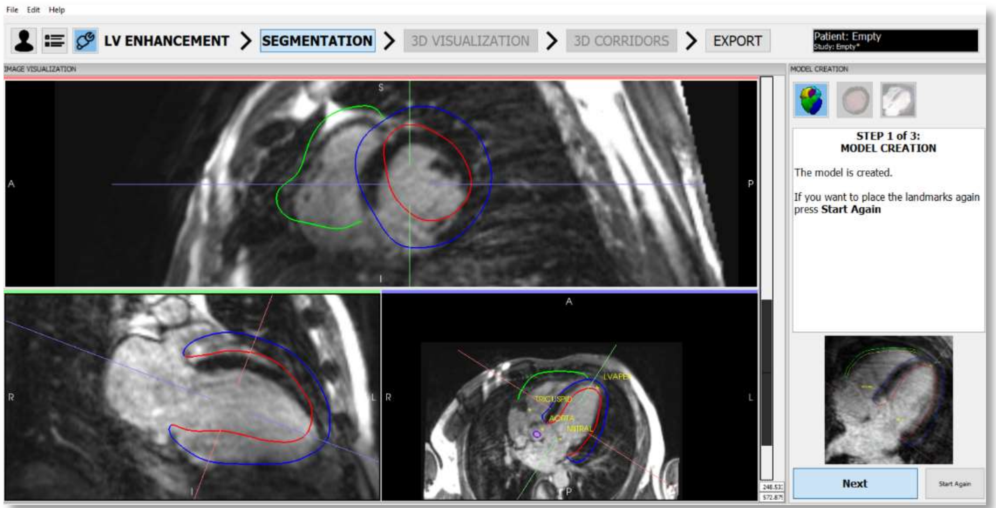
  a. Center of the Aortic Ring
  b. Center of the Mitral Ring
  c. Left Ventricle Apex (endocardial side)
  d. Center of the Tricuspid Ring

  Once the landmarks are placed, the user will be asked to generate the cardiac model. Answer **YES** if satisfied with the position of the landmarks, and **NO** if additional positioning is required.



Accept the emerge windows to generate the model

- Please, review the generated model. To place the landmarks again press **Start Again**. To continue with the generated model, press **NEXT** to go to Slice-Based Adjustment.



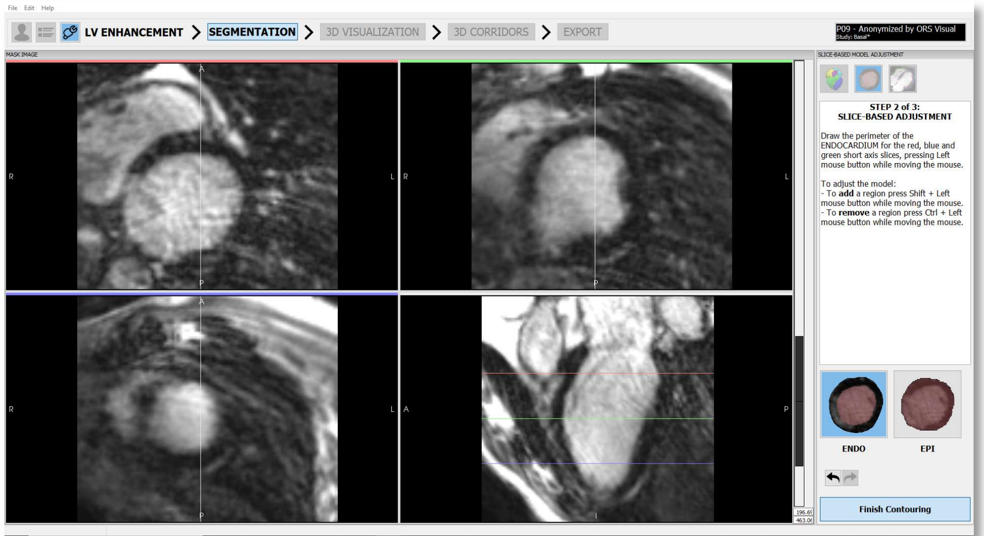
Model creation of the left ventricle, aorta and right ventricle

14.1.2. Step 2: slice-based adjustment

When using the cardiac model adjustment option, this step allows the user to adjust the cardiac model generated by contouring the endocardial and epicardial contours in three short axis slices.

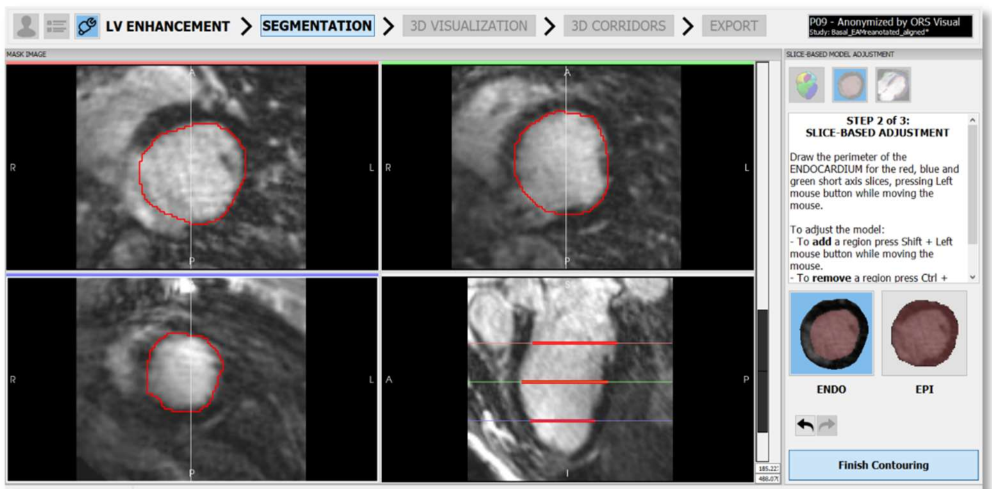
A detailed explanation about how to use it is displayed on the right sight of the screen. Click on the **ENDO** button and with **Shift + Left mouse button** draw the contour of the endocardium on the three axes. When finished, click on the **EPI** button and with **Shift + Left mouse button** draw the contour of the epicardium on the three axes. Delete contours using **Ctrl + left mouse button**.

It is possible to click on the undo button to go back to the last modification.



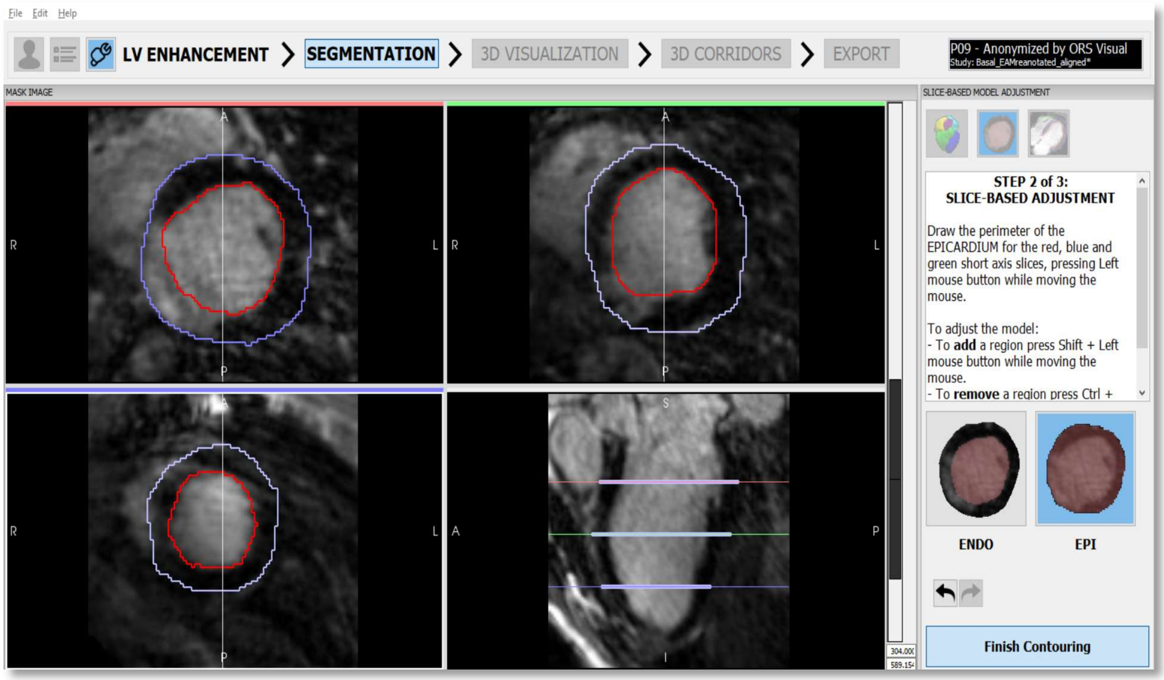
Initial Visualization of Slice-Based Adjustment tool

- Draw the contour of the endocardium for each slice



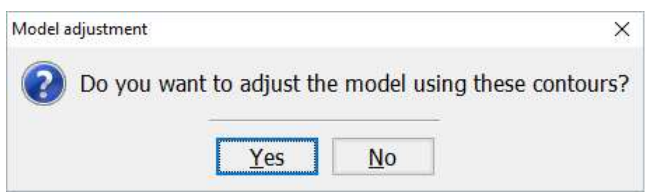
Endocardium segmentation of the three axes

- Press EPI button and draw the contour of the epicardium.



Endocardium and epicardium segmentation of the three axes

- Once satisfied with the drawn contours, press **Finish Contouring** button to proceed to the **Model Adjustment** step using these contours. Press **Yes** to continue.

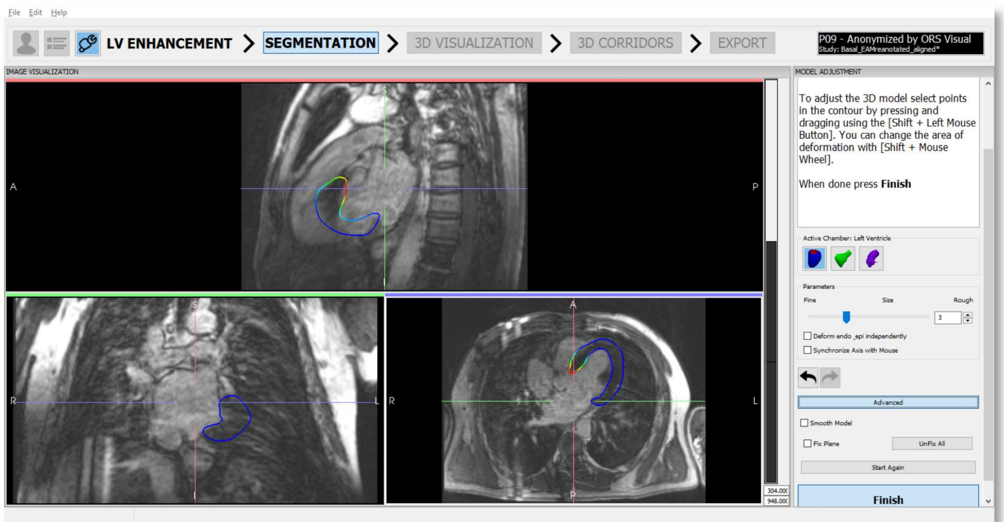


HINT:

The papillary muscles should be left in the blood-pool when drawing the endocardium contour.

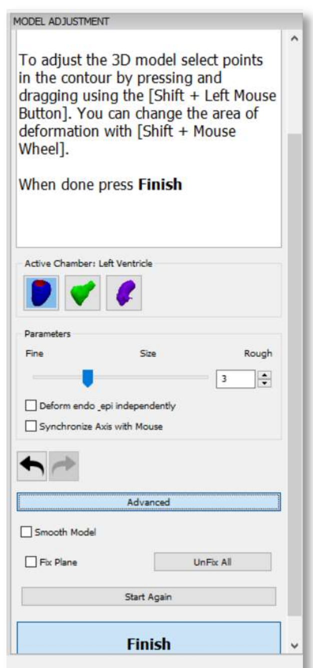
14.1.3. Step 3: model adjustment

- To adjust the 3D model, select points in either the endocardium or the epicardium contours using the **Shift + Left Mouse Button** and adjust them by pressing and dragging. The part that is being deformed is changed to red color.



Visualization of the Model Adjustment. The red color is the area of deformation

In the right corner the user finds several parameters and tools to modify the deformation.



- To adjust the right ventricle or the aorta, press the corresponding icon in the Active Chamber section in the panel on the right.

Parameters

- **Size**: Change the size of the affected region to deform. **Fine** changes to a small deformation area and **Rough** to a big one.
- **Deform endo and epi independently:** Deform either the endocardium or the epicardium wall when this option is selected, or deform them both together when it is disabled.
- **Synchronize axis with mouse:** Automatically change axis position to the deformed region.
- Undo/Redo: Undo/Redo last actions.
- **Advanced**
    - **Smooth model:** Smooth model when deforming a region.
    - **Fix plane**: Fix current selected plane, so that the deformation of other regions will not affect this plane.
    - **UnFix All**: Delete all fixed planes.

Smooth model and Fix plane are mutually exclusive tools.

HINTS:

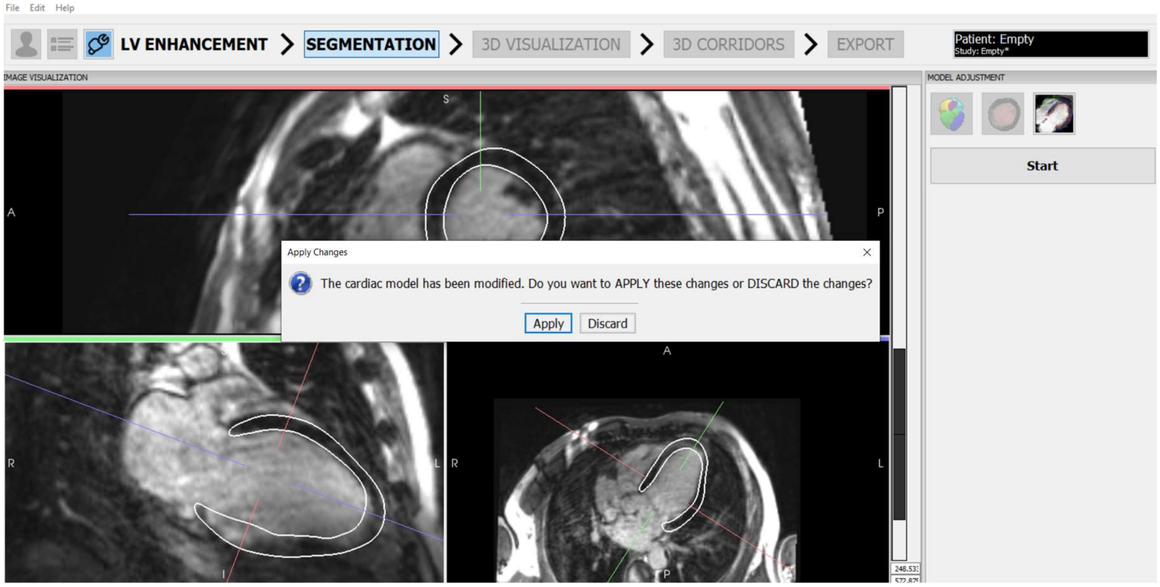
1. Start deforming the base and the apex with a big size of the deformation region (default size is fine). Following this, the size of the deformation can be adjusted iteratively.

2. The most important region to pay attention to is the one around the enhancement of myocardial fibrosis (scar). Focus on the areas of enhancement of myocardial fibrosis over the rest of the myocardium. Make sure that the borders are well adjusted and the scar is included into the myocardium borders.

3. Do not include blood pool or coronaries in the segmentation. These bright regions will appear as enhanced, similar to myocardial fibrosis.

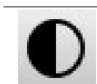
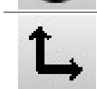
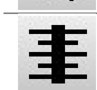
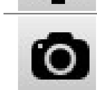
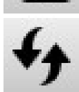
4. The endocardium wall of the enhancement of myocardial fibrosis region can be difficult to segment because it has the same intensity than the blood pool region. Try to follow the circular contour of the wall in the short axis.

Press the **Finish** button to complete Model Adjustment. Select **Apply** to continue to the 3D visualization.



Press apply to go to 3D visualization module.

14.1.4. Segmentation toolbar

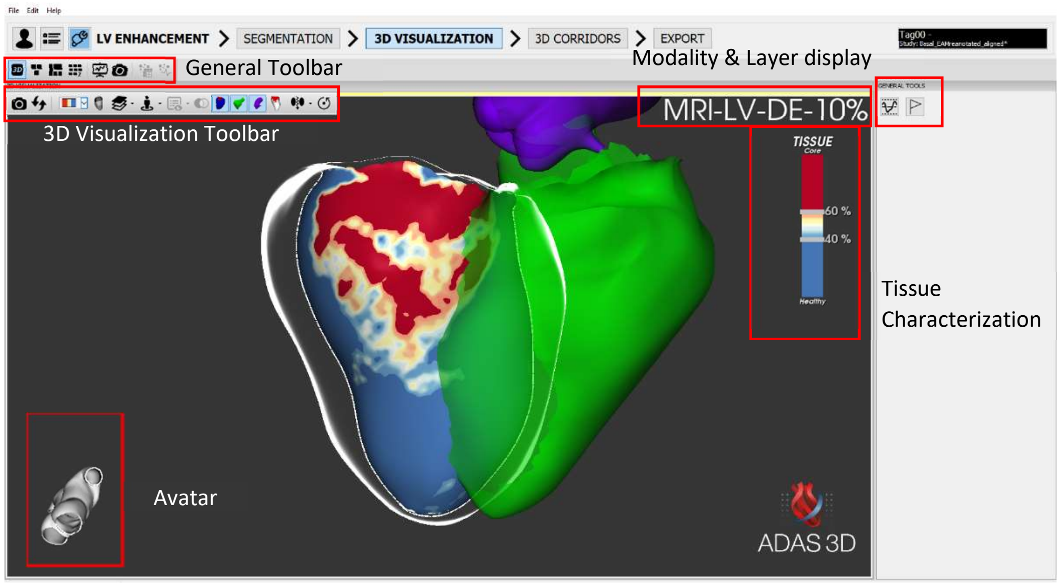
Tool	Name	Description
	**Reset Contrast**	Reset contrast levels to default
	**Initialize Axis Orientation**	Reset axis orientation to default
	**Align axis to LV**	Align 2D image view axis to the LV long axis
	**Take a Screenshot**	Take a screenshot of active view
	**Refresh**	Refresh visualization and show only the first layer

14.1.5. 3D Visualization

This step allows the user to specify the tissue characterization thresholds and visualize the processed data. It displays the enhancement distribution in a three-dimensional (3D) chamber of the heart obtained from the Segmentation Module. It provides quantification of the total volume of the enhancement within the Left Ventricle (LV) and the visualization of the enhancement area in multiple layers through the cardiac structure.

14.1.6. Main visualization window

The main visualization window shows the first computed layer (10%). On the bottom left side, a reference avatar provides a reference to the orientation of the displayed data. On the upper right side the active layer and the tissue characterization thresholds can be seen. Adjust the thresholds using the color bar or the sliders on the right.



Main Visualization Window of the 3D Visualization Module

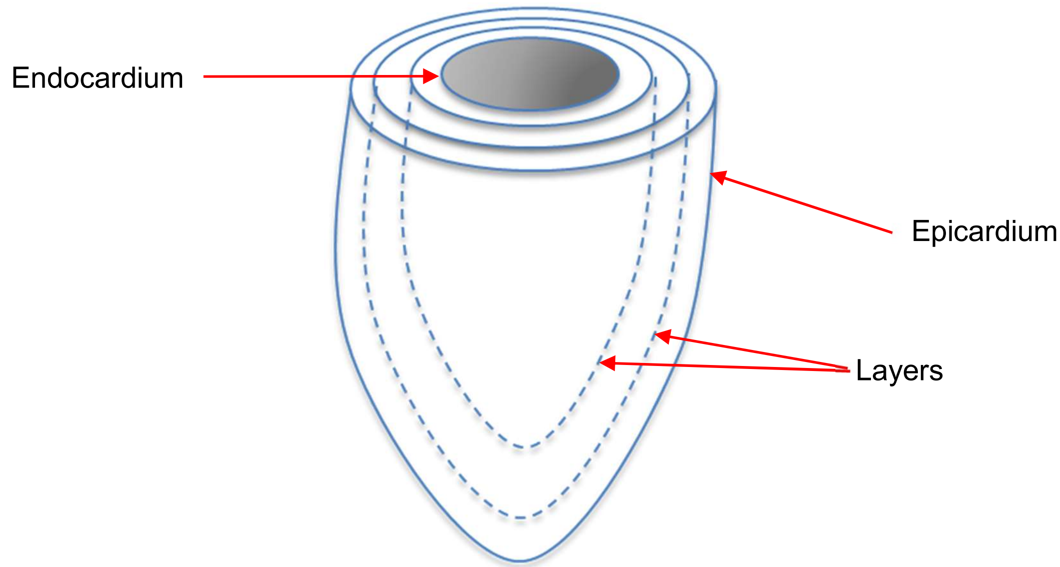
Layer visualization of LV myocardium

Layers is a tool to visualize the depth, structure, and transmurality of the **enhancement of myocardial fibrosis** of the LV. Following the actions in the Segmentation Module, ADAS 3D interpolates concentric layers (in an onion-like fashion), going from the endocardium to the epicardium (the number of layers can be defined by the user, see Preferences).

The layers can be visualized by interactively scrolling with the mouse or using the 3D Visualization Toolbar.

In the figure below, two layers interpolated between endocardium and epicardium boundaries are shown. The layers can be 'peeled' on and off interactively by the user to inspect the myocardium at different depths.

On the bottom left side of the Main Visualization Window of the 3D Visualization Module, a configurable reference (refer to Preferences) avatar provides the 3D orientation of the data. In the upper right side, the layer percentage is being displayed. The percentage corresponds to how deep in the myocardium the layer is, being 0% the endocardium and 100% the epicardium.



Layers generated for the Left Ventricle

Tissue characterization

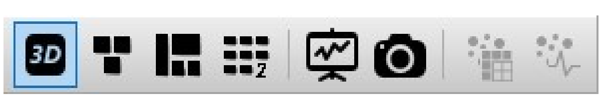
The Tissue Classification module helps the user visualize different Pixel Signal Intensities (PSI) in the myocardium according to intensity thresholds.

When DE-MRI is imported, highly enhanced areas correspond to Core Scar tissue (CS), whereas areas with enhancement below a certain threshold correspond to Healthy tissue (HT). Those areas in between CS and HT correspond to areas with intermediate intensity tissue (or Border Zone, BZ). **The areas of Core and Border Zone are collectively referred as 'scar' in this document.**

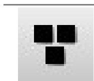
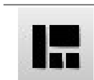
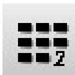
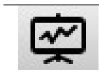
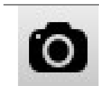
The tissue characterization is controlled by thresholds, which are set by default to 40 and 60% (±5%) with respect to the maximum intensity voxel in the myocardium (a modification of the full-width half-maximum. The thresholds can be adjusted using the **Threshold Adjustment** controls to match specific user needs. See the General tools section for a detailed explanation.

14.1.7. 3D General toolbar

The General Toolbar controls what is visualized in the Main Visualization Window.

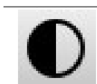
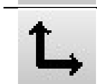
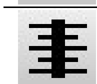
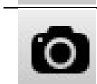
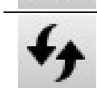
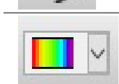
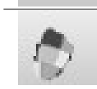


Tool	Name	Description
	**3D Layer View**	View for 3D data visualization

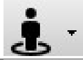
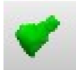
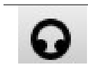
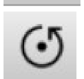
	**Image View**	Main image is shown using axial, coronal and sagittal planes
	**3D Image View**	Visualize 3D data on the left and image on the right
	**Multiple 2D View**	Multiple 2D views aligned with left ventricle short axis
	**Statistics Window**	Show/Hide statistics window
	**Take a Screenshot**	Take a Screenshot

3D Visualization toolbar

The 3D Visualization Toolbar controls what is displayed within each 3D window. If there are two 3D windows, each will have its own 3D Visualization Toolbar. This toolbar is usually hidden, and it appears when the user moves the mouse cursor to the left top corner of the visualization window.

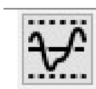
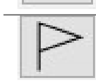
Tool	Name	Description
	**Reset Contrast**[6]	Reset contrast levels to default
	**Initialize Axis Orientation**[6]	Reset axis orientation to default
	**Align axis to LV**[6]	Align 2D image view axis to the LV long axis
	**Take a Screenshot**	Take a screenshot of active view
	**Refresh**	Refresh visualization and show only the first layer
	**Color selection**	Select color table for visualization: gray, red to purple or Red/Green/Purple
	**17 Segments**	Compute 17 segments over the layers
	**Layer selection**	Select active layer to visualize

[6] Only available for image view
[6] Only available for image view

	**Predefined Views**	Select a predefined anatomical view
	**Visibility**	Show/Hide anatomical structures
	**Left Ventricle**	Show/Hide left ventricle
	**Right Ventricle**	Show/Hide right ventricle
	**Aorta**	Show/Hide right aorta
	**3D Core**	Show/Hide 3D Core surface mesh
	**Show/Hide 3D Corridors**	Show/Hide 3D Corridors
	**Papillary Muscles**	Compute papillary muscles for the LV
	**Tissue Boundaries**[6]	Show/Hide tissue boundaries using tissue characterization thresholds
	**Pick Center of Rotation**	Select the center for moving the 3D model

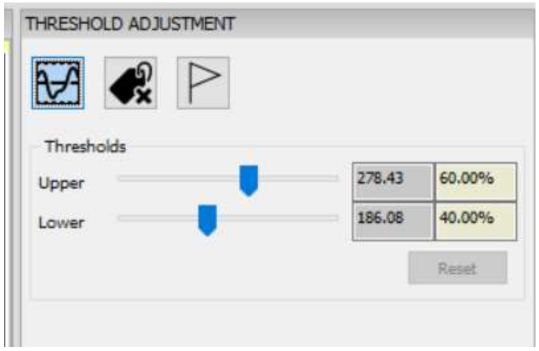
General tools

There are three available tools in the right panel:

Tool	Name	Description
	**Tissue Characterization**	Adjust tissue thresholds
	**Landmarks**	Add or remove anatomical landmarks

Tissue characterization

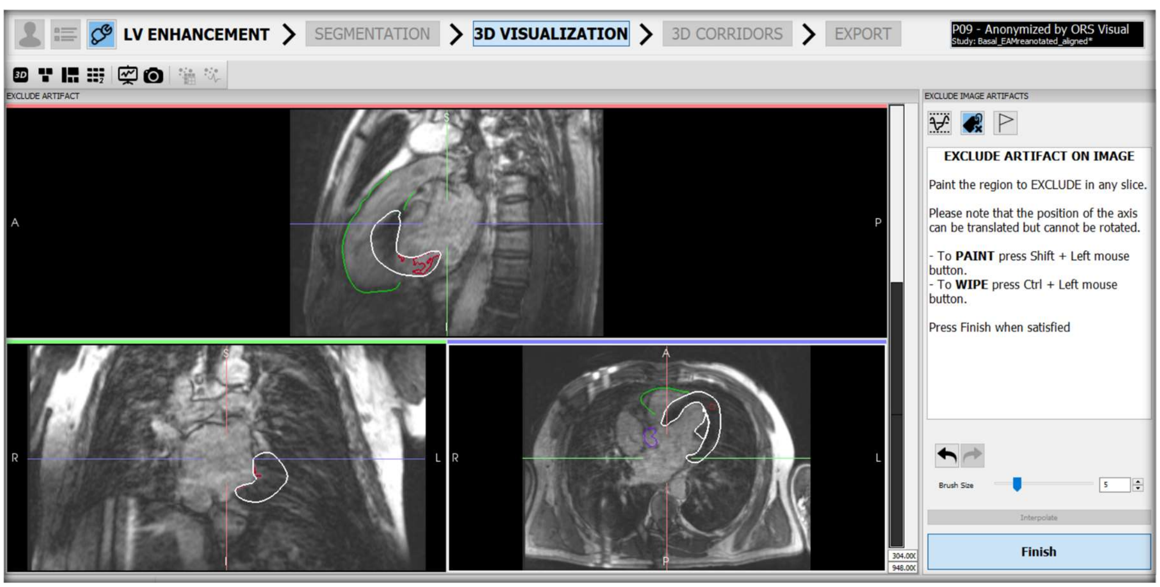
The tissue characterization tool adjusts the tissue thresholds by changing the number written in the box or using the scrolling sliders. The numbers in the grey boxes correspond to raw MRI values, whereas the percentages correspond to the percentage with respect to the maximum intensity voxel in the myocardium (modified full-width half-maximum).



Threshold Adjustment controls

Exclude image Region

Using the Exclude image Region the user can exclude a certain region of the DICOM from analysis (typically, because it is artefacted). By click on **Shift + Left mouse button** in the desired region of the axis, it will appear a little green square indicating the excluded region, the region being excluded will be displayed in red. When it is performed on different slices, then the user can click on the **interpolate** button.

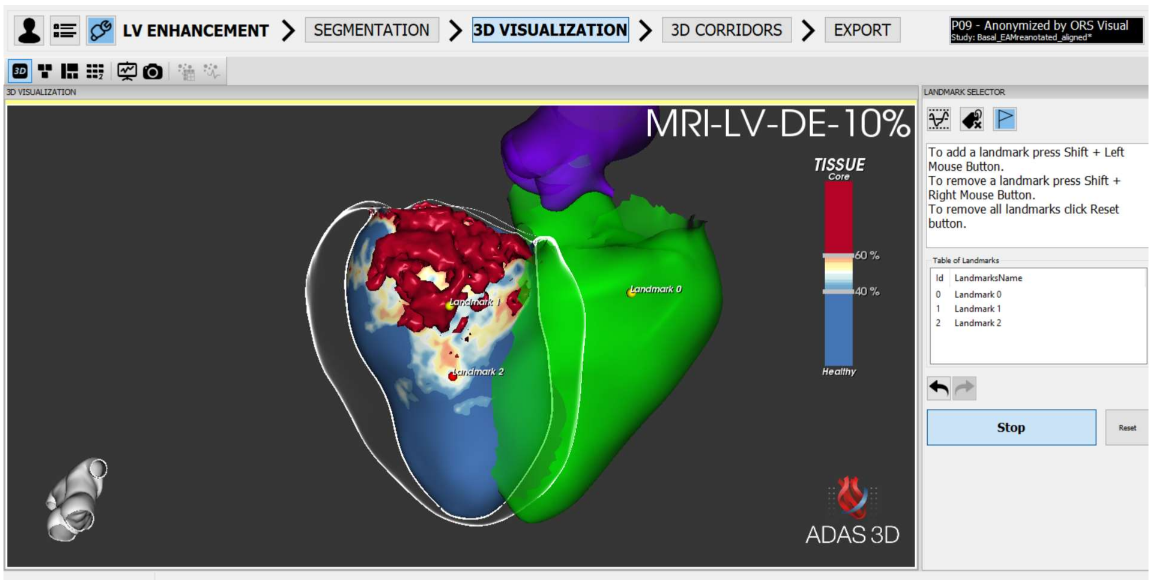


.

Visualization of the Exclude Image Region tool

Landmarks

Add different landmarks, either in the DICOM view or in the 3D visualization model, with **Shift + Left mouse Button.**



Visualization of the Landmarks in the 3D Visualization Module

14.1.8. Accuracy of the measurements

Using the segmented 3D Model, there are three interdependent parameters that the software uses to derive as much information from the input image as possible: the **number of layers**, the input image **voxel size** and the **wall thickness** of the myocardium. These parameters should be adjusted so that there is a correspondence between the input data and the 3D Model in order for the software to use as much of the input information as possible.

These are the recommendations for the parameters:

- **Layers**: The recommended number of layers is 9. Using 9 layers creates a 3D Model with a layer for every 10% of the myocardium.
- **Input Image voxel size:** The minimum recommended voxel size is 1.1 mm.
- **Wall thickness**: The maximum left ventricle thickness is 25 mm.

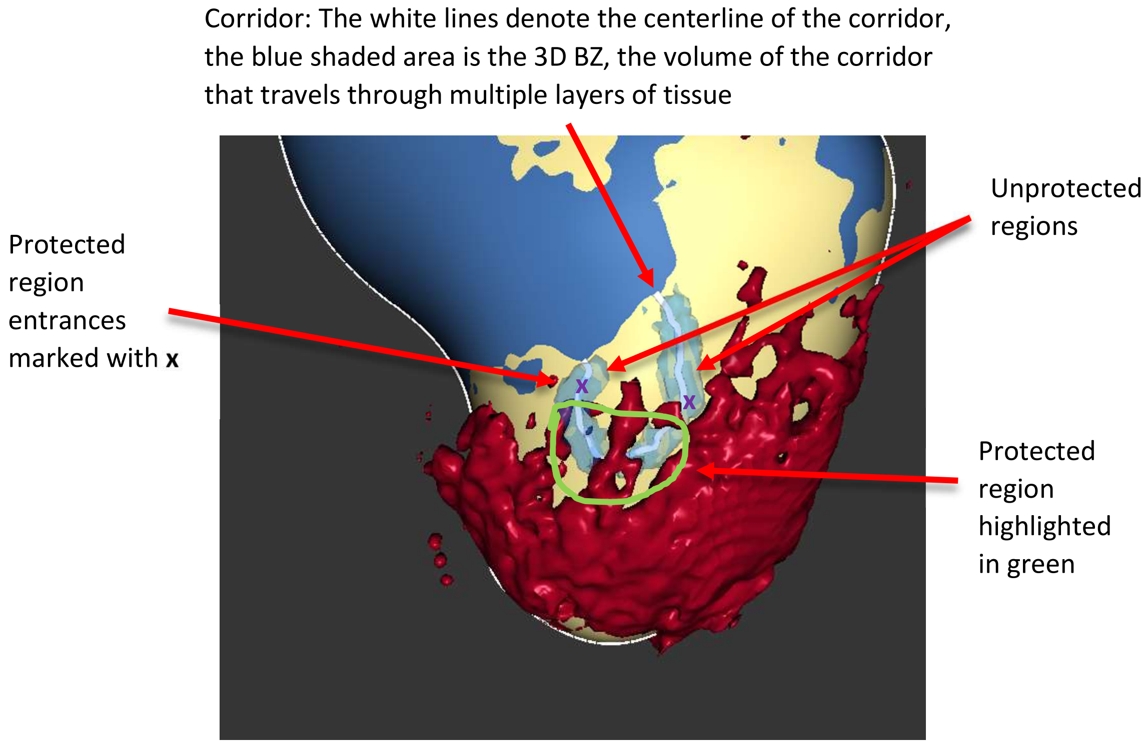
14.2. 3D Corridors module

The 3D Corridors Module is an automatic detection feature designed to help identify and visualize 3D corridors of BZ within the LV. The 3D Corridors algorithm generates visual representations of the corridors that may travel through multiple layers of the LV.

A 3D Corridor is defined as a path of BZ tissue (or an area of intermediate intensity on the MRI) that starts and ends in healthy tissue and travels between areas of CS tissue. A corridor is a three-dimensional path in the myocardium and has an associated volume. The ADAS 3D software distinguishes between protected and unprotected regions for a corridor.

- A protected region of BZ tissue is defined as the corridor that is embedded in an area of CS.
- An unprotected region of BZ tissue is defined as BZ tissue that is not surrounded by CS.

These regions are illustrated in the Figure below.



ADAS 3D image illustrating a corridor of BZ tissue that travels from HT in between CS tissue. There are two unprotected regions and two protected region entrances illustrated in the figure

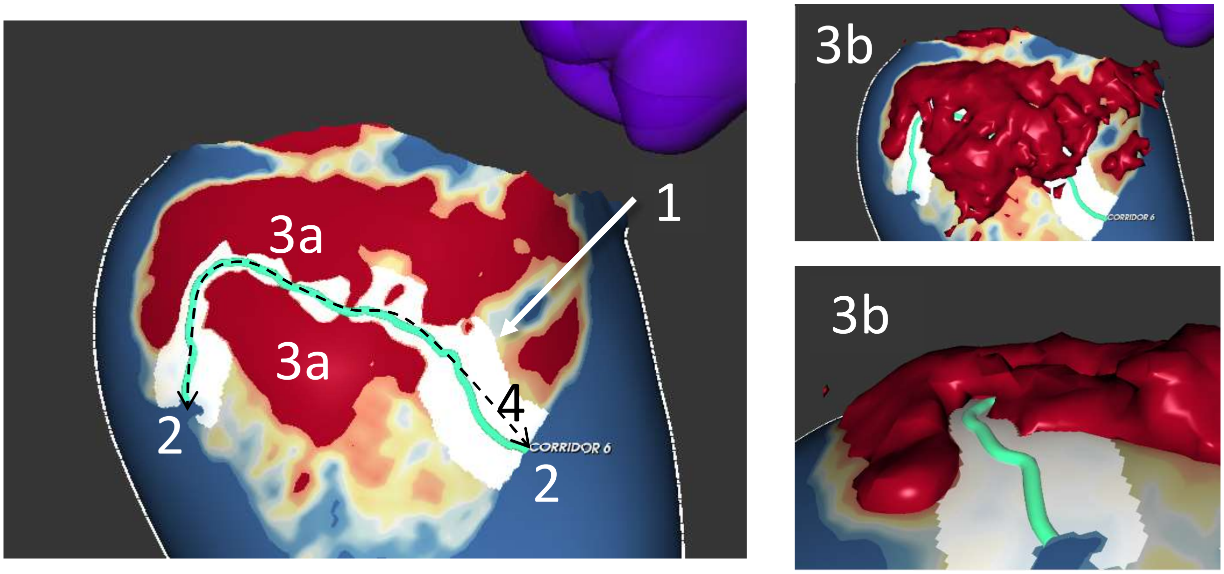
When viewing DE-MRI, highly enhanced areas correspond to CS, and areas with low enhancement correspond to HT. The ADAS 3D software only calculates 3D Corridors using the layers in between the endocardium and epicardium. The mitral value and the endocardial and epicardial surfaces define the boundaries for 3D Corridor detection, they are considered as CS tissue by the software.

To be automatically identified, by ADAS 3D, as a 3D Corridor, **four criteria** must be met in at least one layer:

1. It must pass through a BZ region
2. It must connect two HT regions

3. It must be **protected** by the CS region both
    a. Within its layer, on both sides and by a minimum CS size
    b. AND surrounding the layer
4. It must have a minimum length of 5 mm

The images below illustrate each of the four criteria.



The single layer image on the left image illustrates criteria 1, 2, 3a, and 4. The two 3D images on the right illustrate the remaining criterion (3b).

14.2.1. 3D Corridor criteria

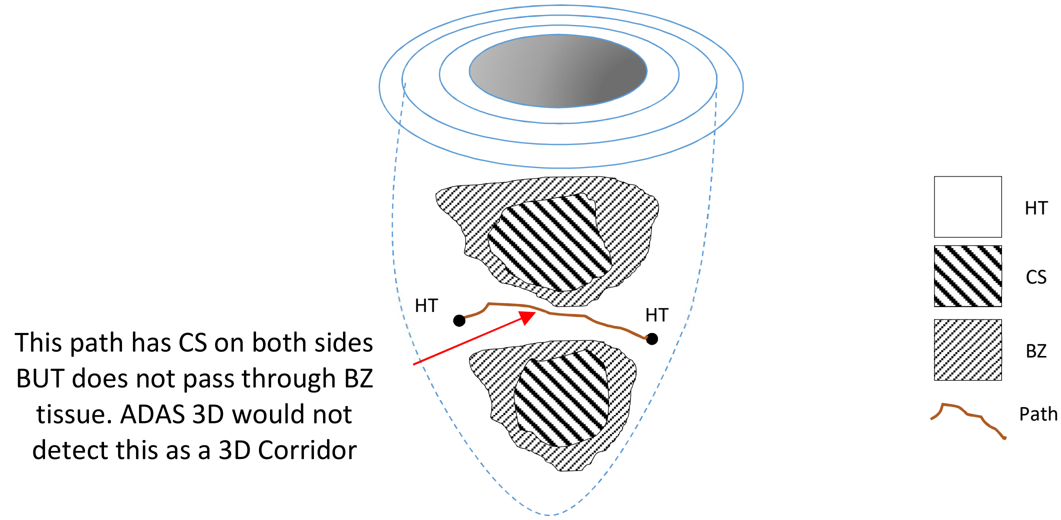
The four criteria are explained below in detail:

Criterion 1: It must pass through a BZ region

ADAS 3D only calculates 3D corridors in areas that contain BZ regions and does not automatically calculate 3D corridors in CS and HT regions.

Each individual BZ region is considered separately to find corridors that match the remaining criteria.

In the figure below, this criterion ignores the illustrated path. The top BZ is considered first, followed by the bottom BZ. The illustrated path is not considered because it travels through an area of HT.

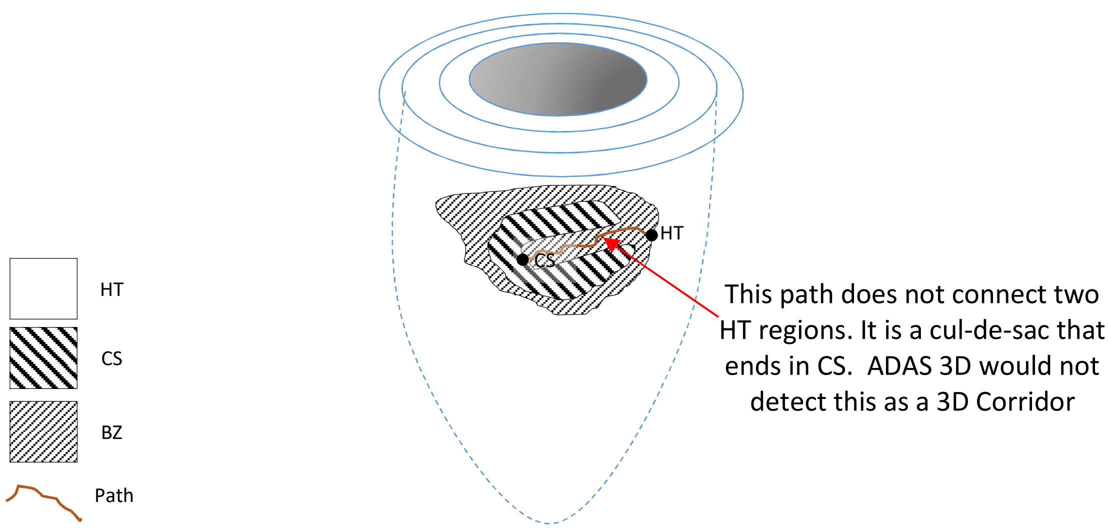


Criterion 2: It must connect two HT regions

ADAS 3D only calculates 3D corridors that connect two regions of HT.

ADAS 3D will exclude paths that are culs-de-sac (starting in HT, passing through BZ and ending in CS).

This criterion will ignore the path illustrated in the image below because it does not connect two HT regions.



Criterion 3: Both 3a and 3b must be met

Criterion 3a: It must be protected by the CS region within its layer, on both sides and by a minimum CS size

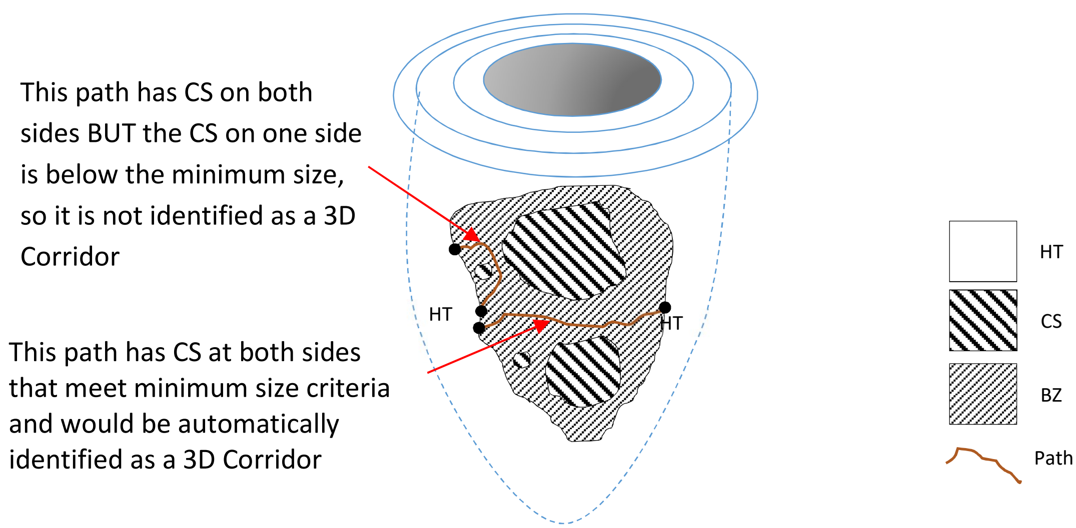
Within an individual layer, ADAS 3D only calculates a 3D corridor if both sides of the corridor have CS regions with a minimum size. Measuring just the area of CS is not sufficient to account for its impact in corridor detection as corridors tend to be formed along elongated CS instead of round ones of the similar area. In calculating the minimum CS size ADAS 3D considers three factors for each CS region to determine its impact value:

- **Shape:** an elongated shape (as defined by a threshold) will have a higher impact on the calculation than a round shape, of the same area.
- **Dimensions:** All things being equal for shape and intensity, a circular CS region of 2 cm in diameter will have a higher impact than a CS region of 1 cm in diameter.
- **Intensity**: If the surrounding BZ intensity falls off gradually (low gradient), ADAS 3D will consider the impact of the CS higher than a similarly shaped CS with the intensity of the surrounding BZ tissue falling off quickly (high gradient).

Each of these factors are combined to determine the impact value used in the minimum CS size calculation. For a CS region with a typical shape and intensity distribution, the cut-off value for the dimension would be approximately equivalent to a 16 mm perimeter.

After identifying if the CS on both sides of the corridor in the layer meets the minimum size, ADAS 3D then calculates the single shortest path through the two CS regions.

This criterion considers only the information in an individual layer and will only calculate 3D corridors that travel between CS areas that meet a minimum size.



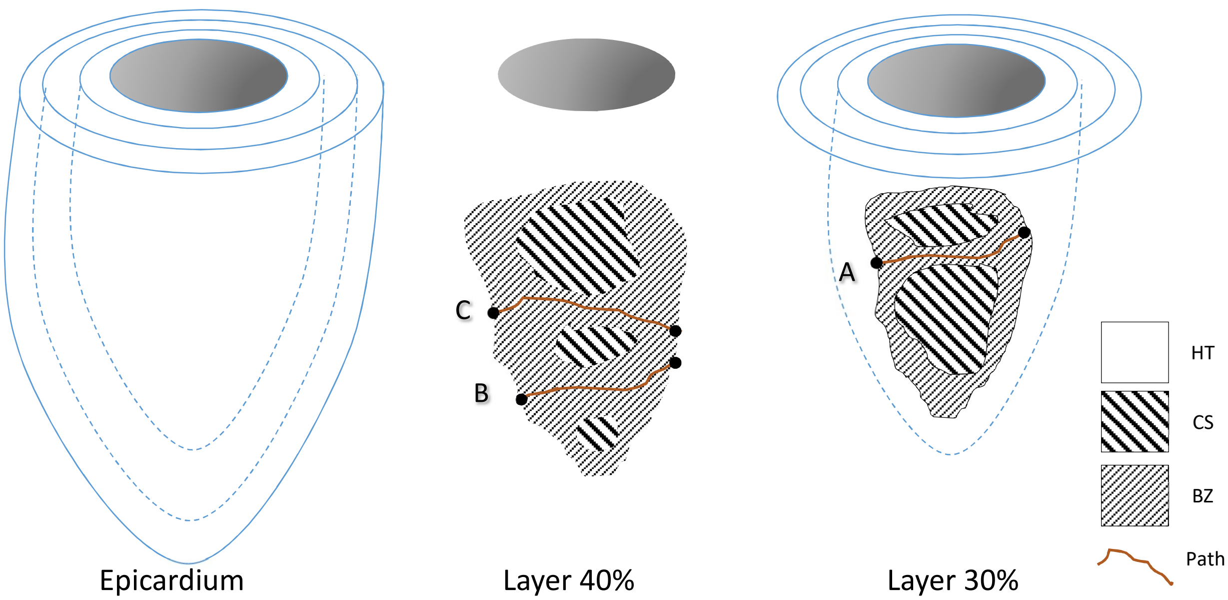
Criterion 3b: It must be protected by the CS region in 3D

Initially, ADAS 3D detects the 3D Corridors for each individual layer. Then ADAS 3D performs a 3D volumetric check of the 3D Corridors' protection in all directions. As it performs this step ADAS 3D checks the protection for each point in the 3D Corridor by checking the presence of CS in all directions.

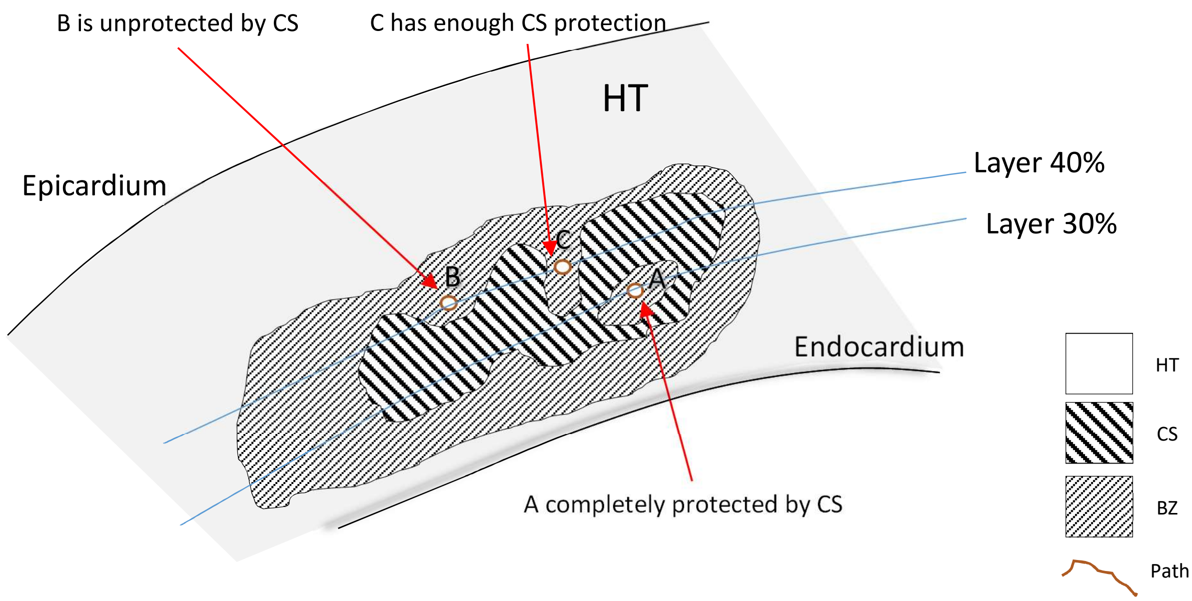
If ADAS 3D finds the presence of HT in any direction, then that portion of the 3D Corridor is considered unprotected and not denoted as a 3D Corridor.

The user can visualize this degree of protection in ADAS 3D (see Preferences **Show corridor protection**).

In the figure below, A, B and C in the displayed layers meets criteria 1, 2, 3a and 4.

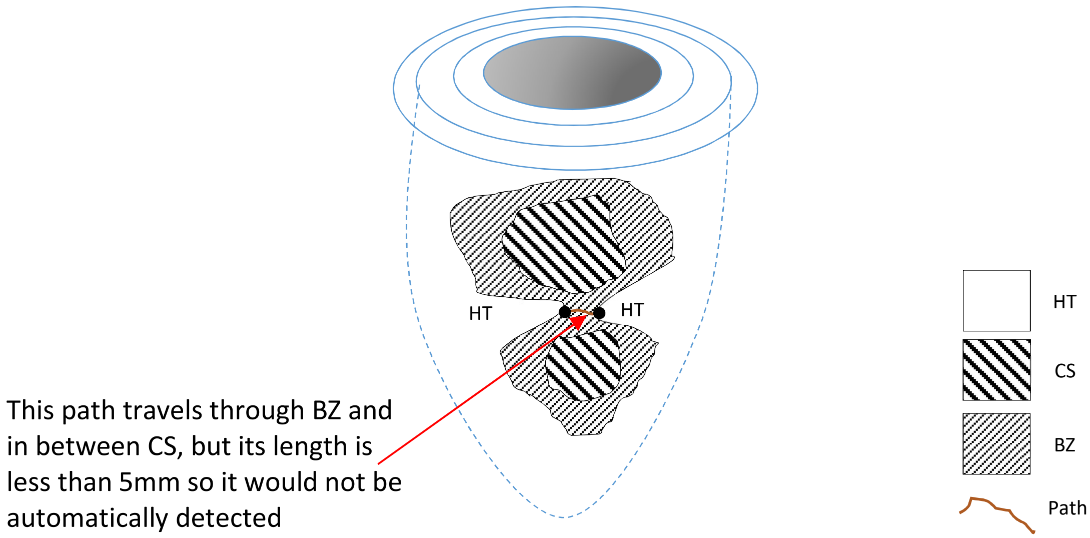


In the figure below, which is a cross-section of the myocardium from the figure above, A and C meet criterion 3b. However, B (in 40% layer does) not meet criterion 3b


B is unprotected by CS
C has enough CS protection
HT
Epicardium
Layer 40%
Layer 30%
C
B
A
Endocardium
A completely protected by CS
HT
CS
BZ
Path

Criterion 4: It must have a minimum length of 5 mm

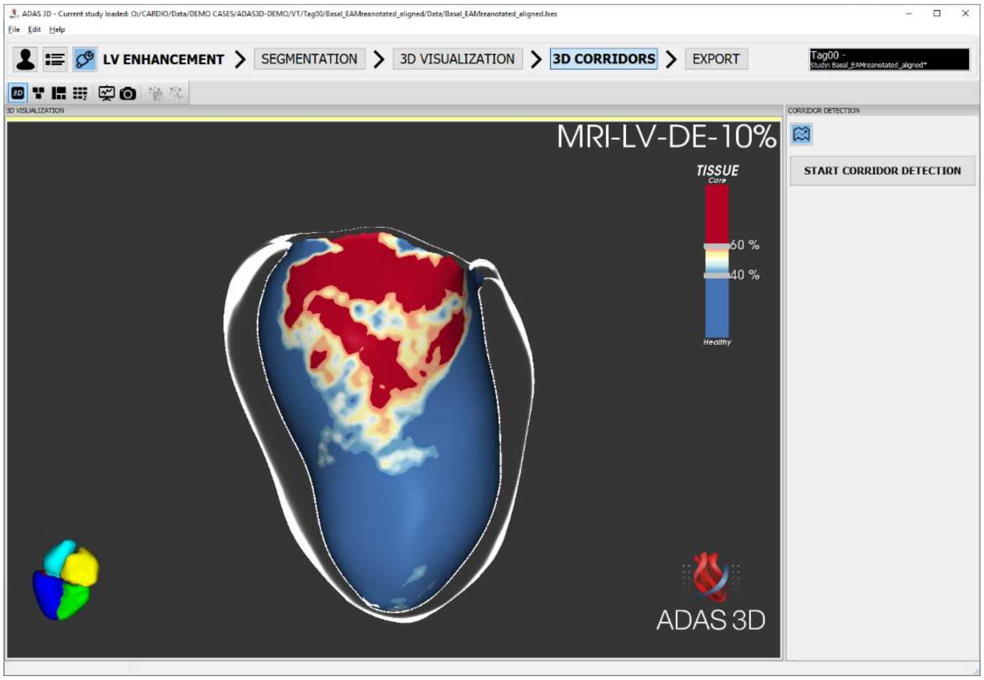
ADAS 3D only calculates 3D Corridors whose length of the path is at least 5 mm.



If the corridor **meets all four criteria**, then the ADAS 3D software will automatically detect it as a 3D Corridor.

See [Preferences](#) to get more tools for visualize 3D corridors.

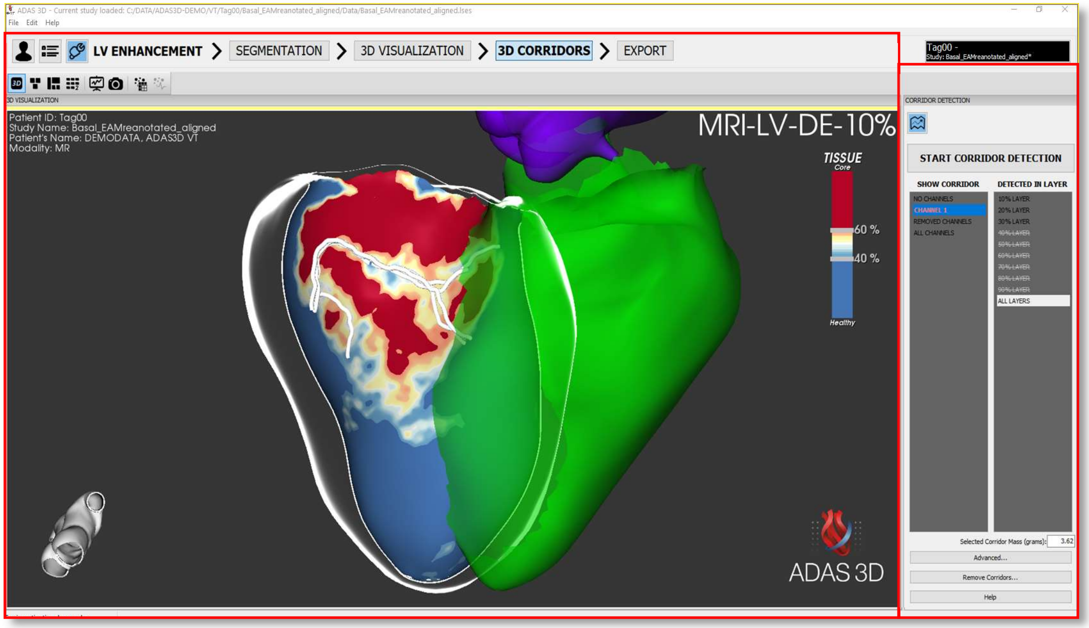
To start automatic 3D Corridor detection, once in the **3D CORRIDORS** working tab, click the **START CORRIDOR DETECTION** button in the 3D CORRIDOR Manager Window.



The 3D CORRIDOR Module before corridor detection has started

The 3D Corridor Module interface consists of two windows: the 3D Window and the 3D Corridor Manager Window.

On the right panel, the user can see all detected 3D Corridors, displayed on the left list and the corresponding layers on the right list. A specific 3D Corridor can be selected and a specific layer visualized.

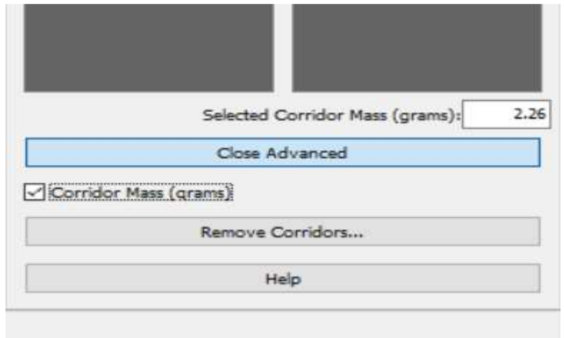


Visualization of the **3D Corridors** Module. Left square the 3D window and Right square the 3D Corridor Manager Window.

After the 3D Corridor detection is performed, the user will see the automatically detected 3D Corridors, unless there are no 3D Corridors detected. The 3D Corridor Manager Window shows two panels. The left panel contains a list of the 3D Corridors, and the right panel displays the corresponding layers on which the 3D Corridors are located. The user can select a specific 3D Corridor on the left list, and the corresponding layers will be displayed on the left. The 3D Window will also display the selected 3D Corridors.

3D Corridor Mass (grams)

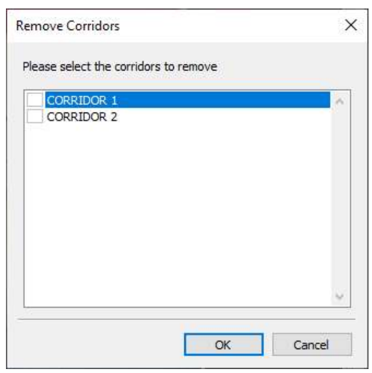
At the bottom of the 3D Corridor Manager, shows the mass of the volume of the selected corridor(s). In the right panel click on “advanced” button. Enable “Corridor Mass (grams)” to visualize the number.



Advanced tool to visualize 3D Corridor Mass (grams)

Options:

Remove of 3D Corridors: The user can remove a 3D Corridor by clicking on the **Remove Corridors** button. A window will show the full list of available corridors. Please select the corridors to remove and press ***OK***.



The user can select the corridors to remove

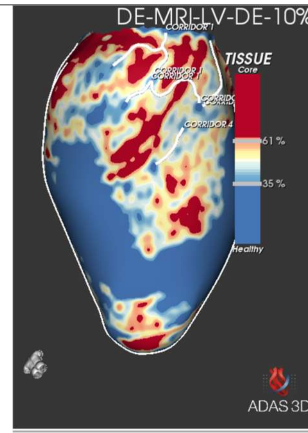
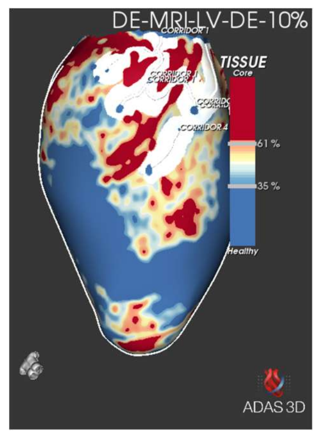
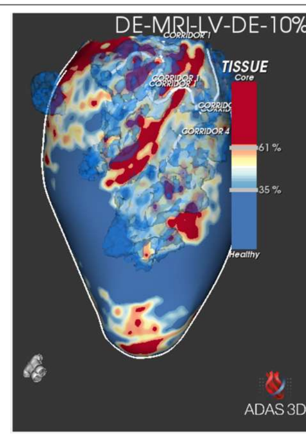
- Help: Show help information.

Visualization of 3D Corridors

In the 3D Visualization Toolbar you will find a tool to show/hide the 3D Corridors and the additional structures.

- As a line, called **Centerline,** displayed as a thin 3D tube (always on in the 3D CORRIDOR DETECTION working tab).

- As a surface, called **Border Zone on Layer,** displayed as the intersection of the 3D Corridor BZ with the surface of a layer.
- As a volume, called **3D Border Zone,** displayed as the 3D volumetric surface covering the 3D Corridor BZ.

Name	Description	Snapshot
Centerline	Shows a thin 3D tube, white in the figure	
Border Zone on Layer	Shows the intersection of the 3D Corridor BZ with the surface of a layer, white in the figure (centerline in white)	
3D Border Zone	Shows a 3D volumetric surface covering the 3D Corridor BZ, blue in the figure (centerline in white)	

HINT: The 3D Corridors automatically detected by the software depend on several parameters. These parameters include the quality and the resolution of the imported image, the accurate delineation of the walls of the left ventricle (as performed by the user), and the tissue thresholds (as chosen by the user).

14.2.2. Accuracy of the measurements

The accuracy of the 3D Corridor detection feature using patient data obtained a recall value of 87% and a precision of 87%. The accuracy for phantom dataset generated by Adas3D Medical obtained a recall value of 100% and a precision of 100%.

The following table shows the final results:

	Automatically Detected by ADAS 3D	Not automatically Detected by ADAS 3D
Identified in the Ground Truth	94	14
Not identified in the Ground Truth	14	N/A

The **recall** is computed dividing the true positive by the total manual: 94/108 = **87%.** The **precision** is computed dividing the true positive by the total computed by ADAS 3D: 94/108 = **87%.**

14.7. Quantification

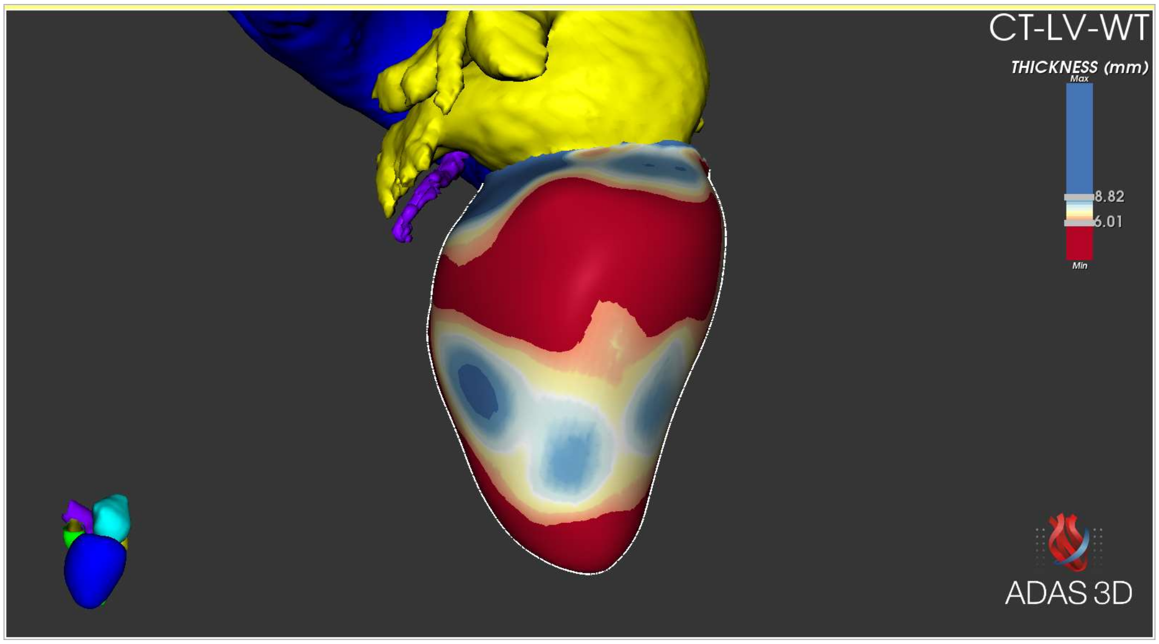
It is possible to make quantification using the statistics tool. Please refer to the Quantification tool chapter.

14.8. Export data

It is possible to export the processed data using the export tools. Please take a look at the chapter Export Data for a detailed explanation.

15. LV wall thickness

The LV wall thickness analysis allows to compute the thickness of the Left Ventricle wall.



The LV Wall Thickness Analysis Module

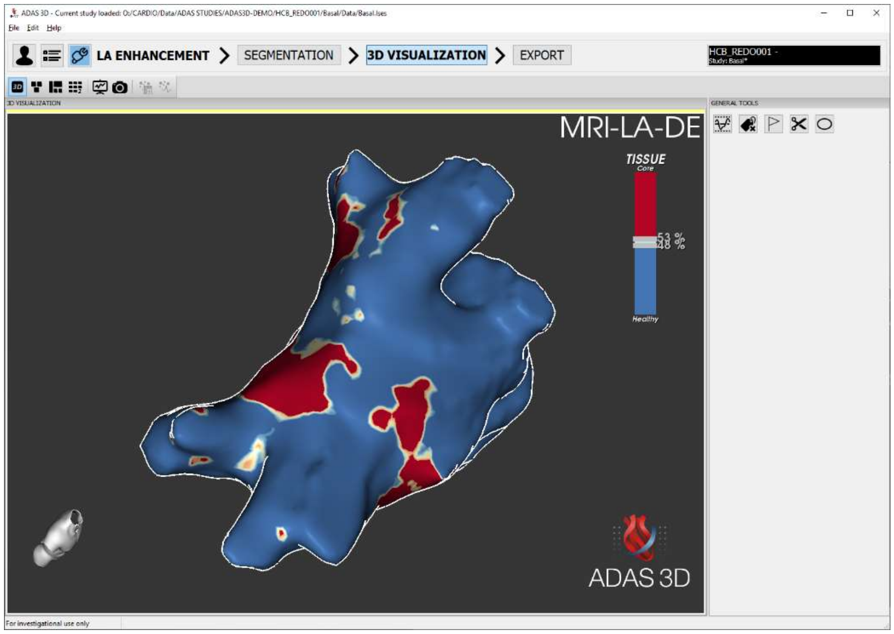
This analysis consists of 3 steps:

1. SEGMENTATION MODULE
2. 3D VISUALIZATION MODULE
3. EXPORT MODULE

Steps 1 and 3 are common to the LV Enhancement analysis steps. Please refer to that section for a detailed description. Step 2 will automatically generate the Wall Thickness visualization into the endocardial surface. All the tools are the same as in 3D Visualization Module from LV enhancement, please refer to that section for further information.

16. LA enhancement

LA Enhancement analysis module allows quantification in the Left Atrium (LA) by measuring the area of enhancement of myocardial fibrosis and the visualization of its distribution.



LA enhancement Analysis Module

The LA enhancement analysis consists of 3 steps:

1. SEGMENTATION, the user can perform this step by contouring on the DE-MRI or performing a heart anatomy extraction when both CTA and DE-MRI images are loaded.
2. 3D VISUALIZATION.
3. EXPORT.

16.1. Segmentation

This step allows the user to create a patient specific cardiac model of the imported image. The steps involved are: 1) **Model Creation**, 2) **Wall contouring** or **Heart anatomy extraction** (Angio + DE-MRI) and 3) **Model adjustment**.

16.1.1. Model creation

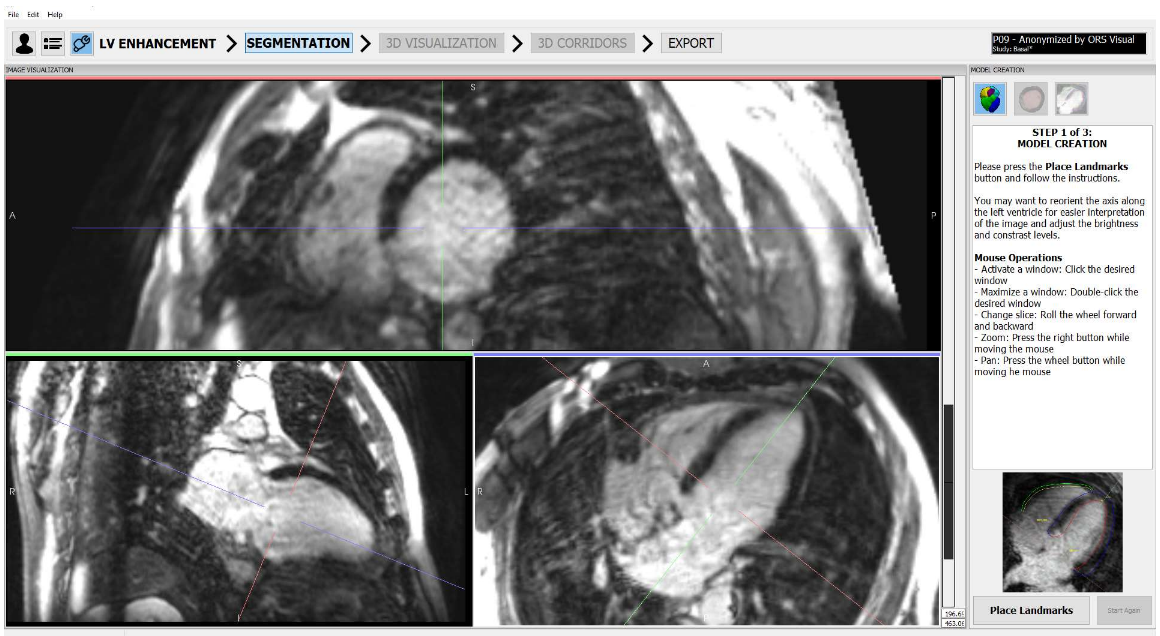
Landmark placing

The first step of the model creation consists in placing some Landmarks to identify some structures.

- To facilitate the segmentation, adjust the DICOM image view of the left ventricle

a) Reorient the axis along it for easier interpretation of the image.
b) Adjust the brightness and contrast levels.

Please see the Image view section for a detailed description of the interaction.



The three axes with the left ventricle aligned. Easy view to place the landmarks

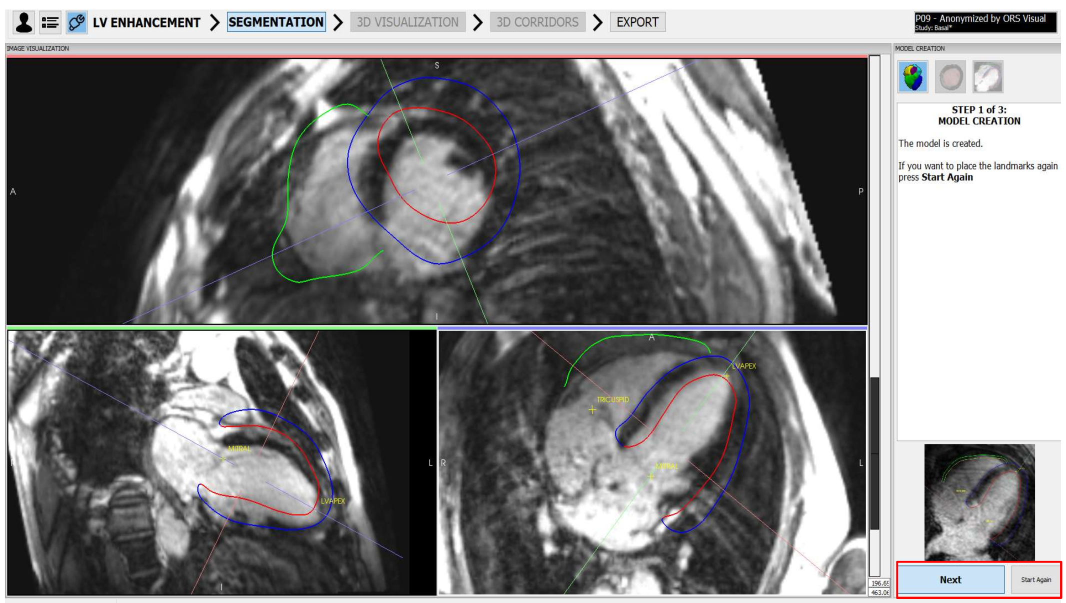
- Press the **Place Landmarks** button.
- Follow the right-panel instructions to place landmarks on any of the MRI data windows in the order specified below. To place a landmark press: **Shift + Left mouse button**. To erase a landmark, press: **Shift + Right mouse button** on top of the placed landmark. These actions can be done in any of the three plane views. The landmarks must be placed in:
    a. Center of the Aortic Ring
    b. Center of the Mitral Ring
    c. Left Ventricle Apex (endocardial side)
    d. Center of the Tricuspid Ring

If required, click on **Start again** to place the landmarks again.

- Once the landmarks are placed, the user will be asked to generate the cardiac model. Answer **YES** if satisfied with the position of the landmarks, and **NO** if additional positioning is required.

Select yes to continue with the model creation. Select no to re-do the landmarks

- Review the generated model. To continue with the generated model, press **NEXT** to go to Slice-Based Adjustment. To re-adjust the landmarks, press **Start Again**

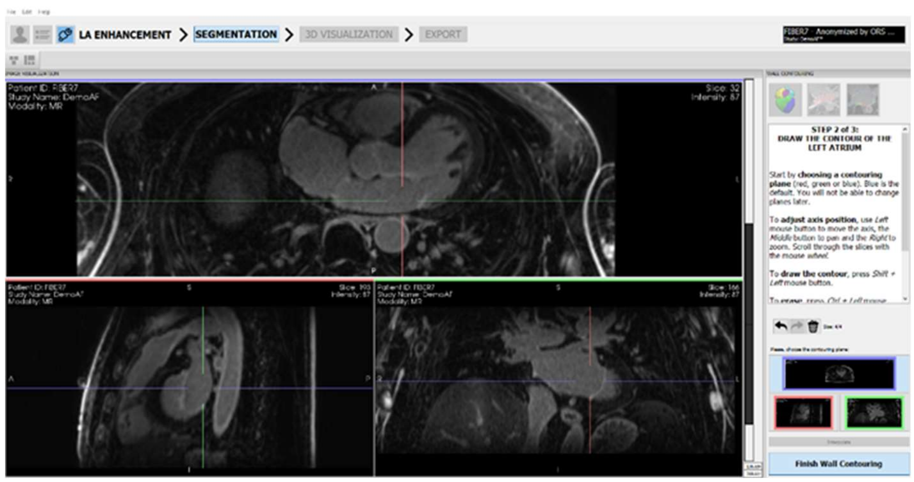


Review the generated model, press Next or Start Again.

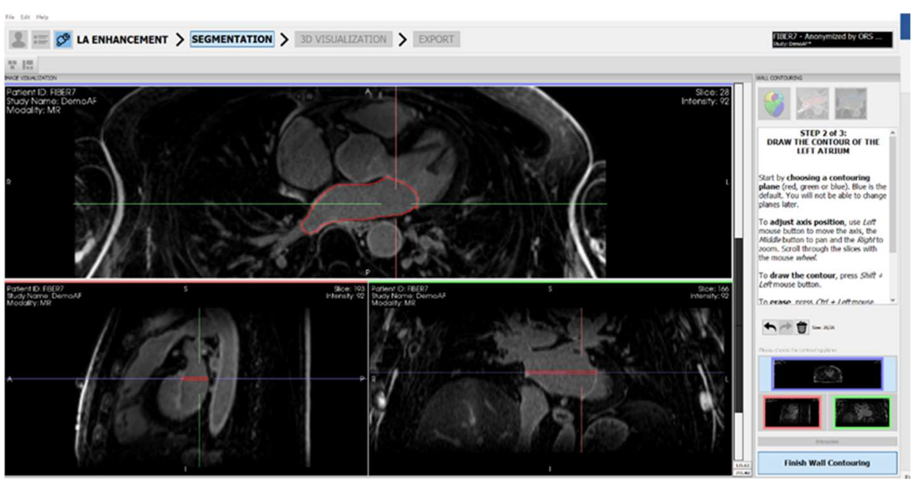
Wall contouring

If this option is selected, a patient specific left atrial model of the imported image, drawing contours on the slices of the input image, can be created. To draw the left atrial model, the user first needs to select the plane (either blue, red or green, see image below) that wants to use to draw the left atrial wall. Once a plane selected, the atrial wall needs to be delineated in the slices in the selected DICOM plane.

To draw, press **Shift+ Left mouse button**, erase pressing **Ctrl + Left mouse button**. The user does not need to draw the atrial wall in all slices, as ADAS 3D can interpolate the user generated contours for slices in between them.

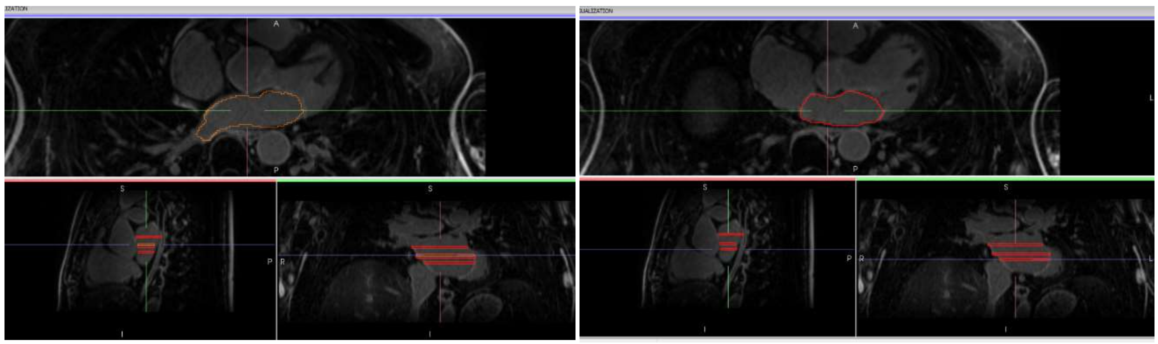


Wall contouring interface



Contour drawn on the left atrium

Interpolation: Once the contour is drawn in two different separate slices, the user can visualize the suggested interpolated contour in the slices between these two contours, in orange. To accept the interpolation, press the **Interpolate** button.



Two contours have been drawn by the user, in the in-between slices the contours have been automatically interpolated, displayed in orange (left). When pressing Interpolate button, interpolation is accepted and all the slices between the two contours are computed and are displayed in red (right).

The interpolated contours can be modified using the same commands used to draw and erase. When trying to modify an interpolated contour a pop-up window will appear and the user will be asked to accept the modification of the interpolated contour.

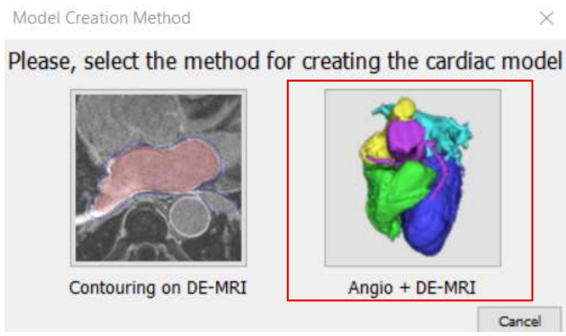
HINT:

1. The drawn contours do not need to be accurate. This step is a rough approximation that will be refined in the next step.
2. Draw the contour between the endocardium and epicardium of the atrium.

Once satisfied, press the button **Finish Wall Contouring** and a 3D model of the left atrium will be created.

Heart anatomy extraction: DE-MRI + CT

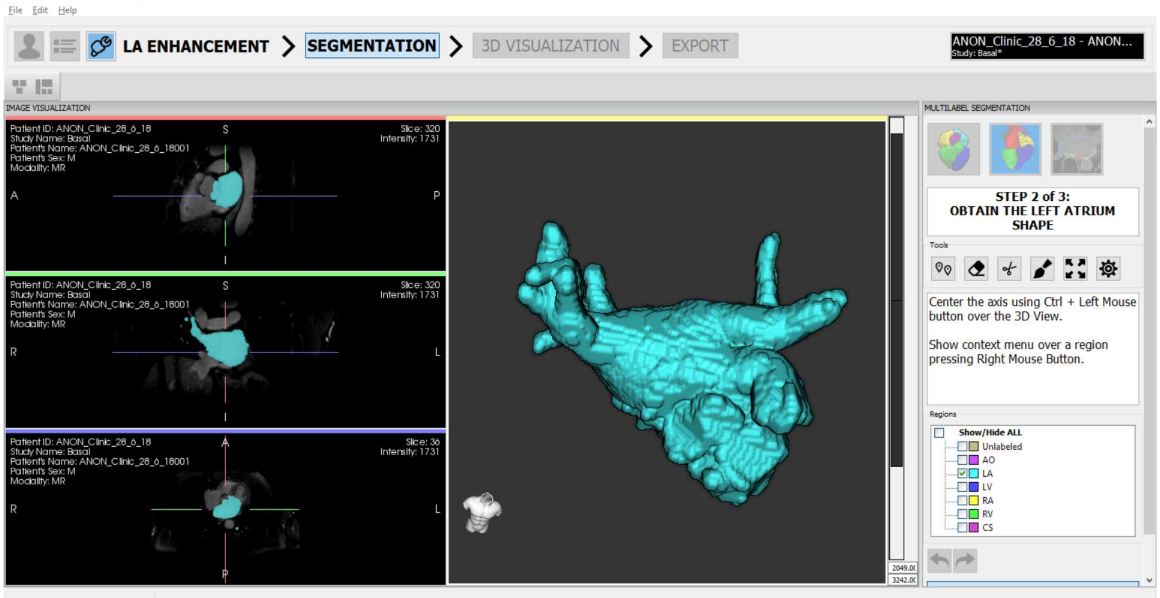
If a CTA is also loaded the user will have the possibility to select this option.



This step allows the user to create a patient specific cardiac model from the imported CTA by performing a left atrium anatomy extraction of the cardiac model instead of drawing it directly in the DE-MRI.

To obtain the left atrium shape, create a new segmentation using the threshold-based method, using the Heart Anatomy Extraction Analysis tool.

HINT: Image thresholding step: It is recommended to choose a threshold which fills the left atrium and the pulmonary veins completely, but without overflowing to other cardiac cavities.



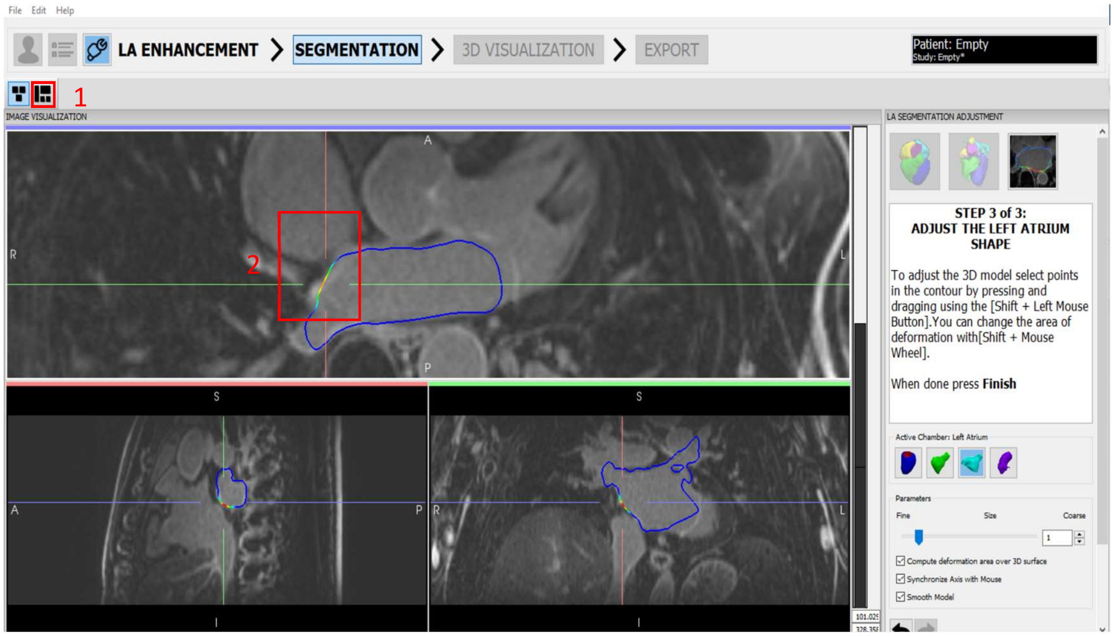
Example of the obtained left atrium shape using an ANGIO.

16.1.2. Model adjustment

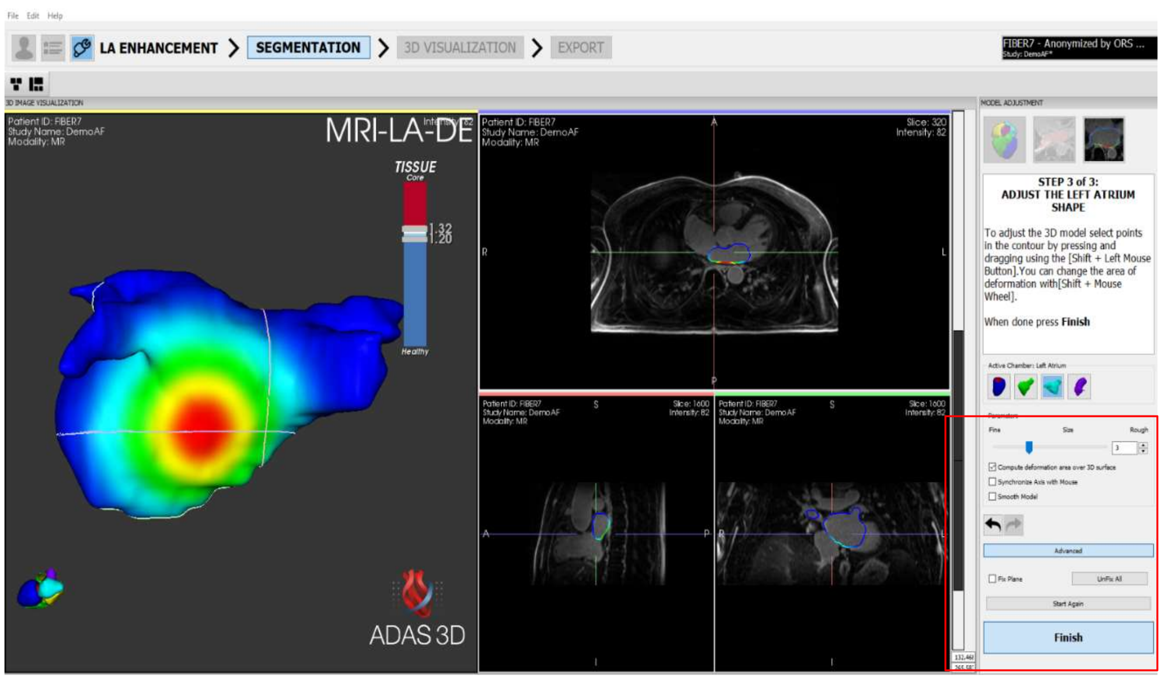
This step allows the user to adjust the model to the exact boundaries of the DE-MRI wall position. This is not a slice-by-slice process, but it operates directly in the 3D model.

In this step, there is an additional feature that enables the visualization in 3D of the model shape (and not only the images on the planes) by selecting the option in the toolbar (see image below). The area of deformation is displayed in a color scale, from red in the center of deformation to light-blue in the exterior area of it.

In this step, the user has to make sure that the left atrial wall line is placed exactly in the middle of the atrial wall of the DE-MRI, to ensure that all the intensities that ADAS 3D maps on the 3D atrial model correspond to real left atrial wall values.



Model adjustment interface. Press (1) to see the 3D model. (2) Deformation area in the slices to adjust the model.



Deformation of the model using both, the 2D slices and the 3D surface and in the red square the adjustable parameters.

Parameters: there are several parameters that can be changed to adjust the deformation of the model.

- **Size**: Adjust the amount of deformation of the 3D model.

- **Compute deformation area over 3D surface**: visualize in 3D the shape of the model and the region being deformed on it
- **Synchronize axis with mouse**: Automatically update the axis position to the region that is being deformed
- **Smooth model**: Smooth model surfaces when deforming a specific region.
- Undo/Redo: Undo/Redo last actions
- **Advanced**
    - **Fix plane**: Fix current selected plane, so that the deformation of other regions will not affect this plane.
    - **UnFix All**: Delete all fixed planes.

Once the model is properly adjusted, select **FINISH.** Or select **Start Again** to re-do the deformation.

HINT

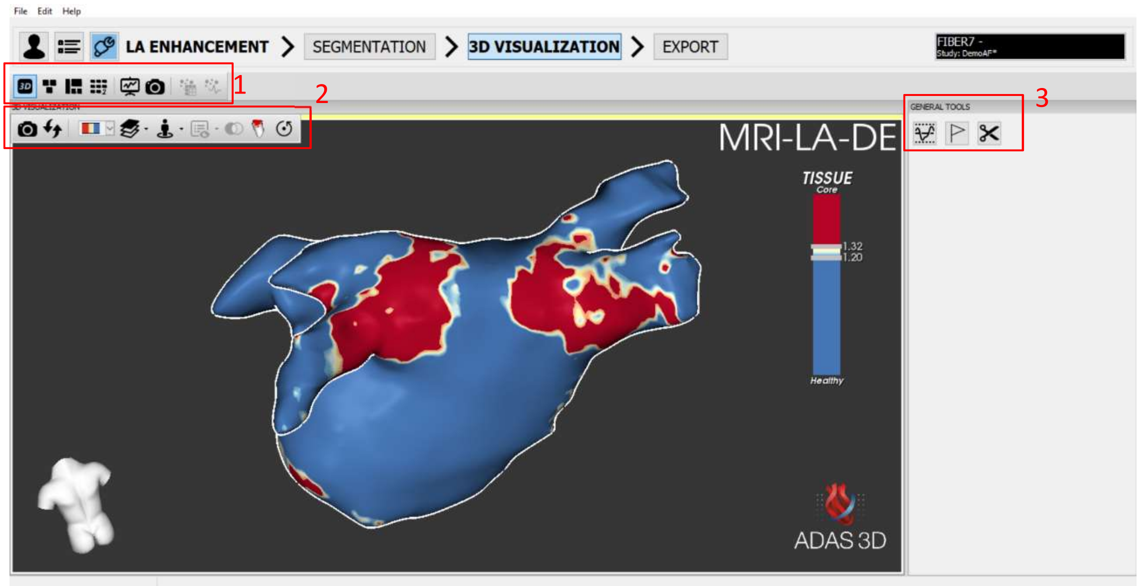
- Use **Ctrl+left mouse button** in a specific 3D region for analysis: Automatically update the 3-axis position to the region that is being selected.
- Select the option **smooth model** in the right corner to smooth the anatomy in the area that is being deformed.
- Make sure that the atrial wall model is delineated in the middle of the atrial wall in the DE-MRI DICOM image.

16.2. 3D Visualization

This step allows the user to specify the tissue characterization thresholds and visualize the processed data in a three-dimensional (3D) chamber of the heart obtained from the segmentation Module.

16.2.1. Main visualization window

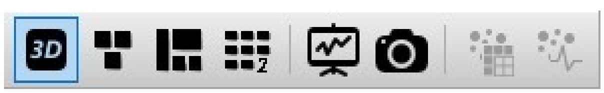
The main visualization window shows the 3D model of the LA.

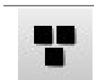
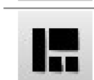
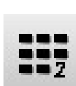
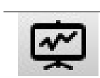
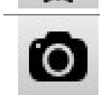


3D visualization Interface. (1) Main visualization Window General Toolbar, (2)3D visualization Toolbar (3) General Tools.

Main visualization window general toolbar

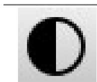
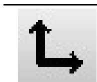
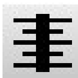
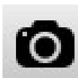
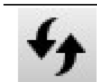
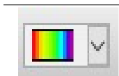
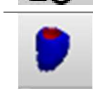
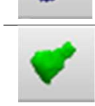
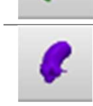
The General Toolbar controls what is visualized in the Main Visualization Window.



Tool	Name	Description
	**3D Layer View**	View for 3D data visualization
	**Image View**	Main image is shown using axial, coronal and sagittal planes
	**3D Image View**	Visualize 3D data on the left and image on the right
	**Multiple 2D View**	Multiple 2D views aligned with left ventricle short axis
	**Statistics Window**	Show/Hide statistics window
	**Take a Screenshot**	Take a Screenshot

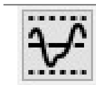
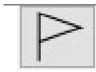
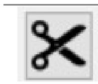
3D visualization toolbar

The 3D Visualization Toolbar controls the features displayed within each 3D window. If there are two 3D windows, each will have its own 3D Visualization Toolbar. This toolbar appears when placing the cursor on the top left corner on the interface.

Tool	Name	Description
	**Reset Contrast**[8]	Reset contrast levels to default
	**Initialize Axis Orientation**[8]	Reset axis orientation to default
	**Align axis to LV**[7]	Align 2D image view axis to the LV long axis
	**Take a Screenshot**	Take a screenshot of active view
	**Refresh**	Refresh visualization and show only the first layer
	**Color selection**	Select the color map for visualization
	**Layer selection**	Select active layer to visualize
	**Predefined Views**	Select a predefined view
	**Visibility**	Show/Hide anatomical structures
	**Left Ventricle**	Show/Hide left ventricle
	**Right Ventricle**	Show/Hide right ventricle
	**Aorta**	Show/Hide right aorta
	**3D Core Scar**	Show/Hide 3D Core Scar surface mesh
	**Pick Center of Rotation**	Select the center for moving the 3D model

[7] Only available for image view

General tools

Tool	Name	Description
	**Tissue Characterization**	Adjust tissue thresholds
	**Landmarks**	Add or remove anatomical landmarks
	**Mesh cutting tool**	Cut any 3D region like the pulmonary veins or the mitral (shift + left button)

Tissue characterization

The tissue characterization method used for the left atrium is the IIR (Image Intensity Ratio). This method normalizes the pixel signal intensity values of the surface defining the LA, dividing each intensity value by the mean intensity of the LA blood pool. This approach is used to reduce the inter-patient and inter-scan variability. The tissue characterization is controlled by thresholds, the default ones based on the IIR are 1.20-1.32. The thresholds can be adjusted using the **Threshold Adjustment** controls to match specific user needs. See the General tools section for a detailed explanation.

The statistics used for computation of the IIR can be found in the statistics window, displayed as the Blood Pool. For further information about the statistics, refer to the Quantification Tools section.

Landmarks

Add different landmarks, either in the DICOM view or in the 3D visualization model, with **Shift + Left mouse Button.**

Mesh cutting tool

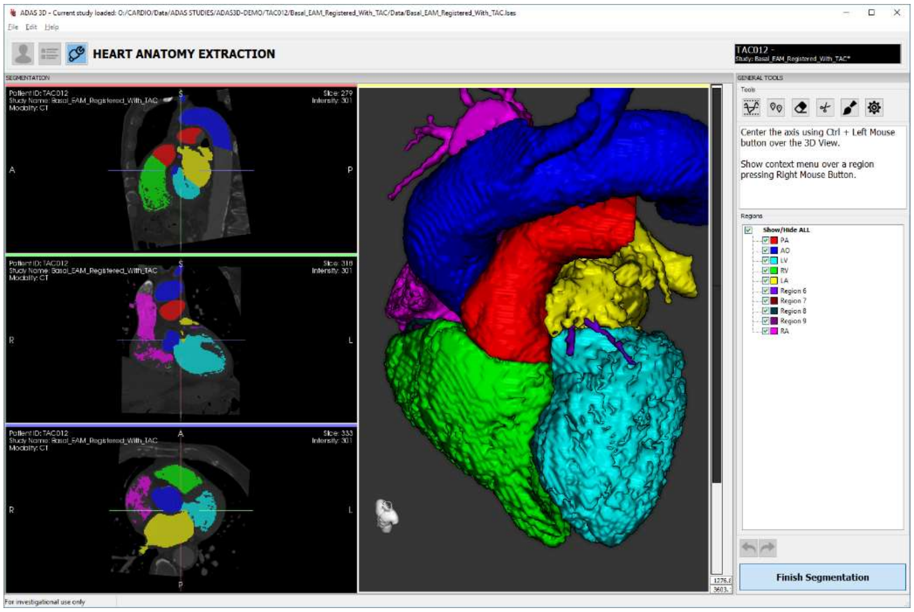
This tool lets the user cut from the surface mesh of the left atrium an area, creating a hole. In order to use it, click the **Mesh cutting tool** button and press **Shift + Left mouse button** to draw a contour. Every left atrial surface included inside the mesh cutting tool surface will then be deleted, leaving a hole. The tool cuts both the visible surface and the surfaces behind**.**

16.3. Export

You can export the processed data using the export tools. Please refer to the Exporting Data module.

17. Heart anatomy extraction

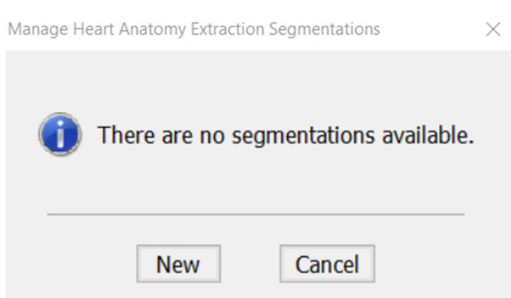
The Heart Anatomy Extraction analysis allows to extract the anatomy of the different heart structures.



Heart anatomy extraction interface

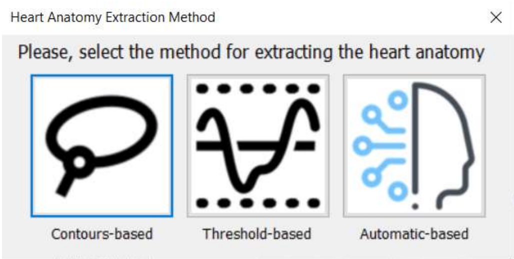
17.1. Manage the segmentations

If no segmentations are available, a pop-up window appears. To start the analysis, click on **New,** write the desired name for the segmentation and select the preferred method.



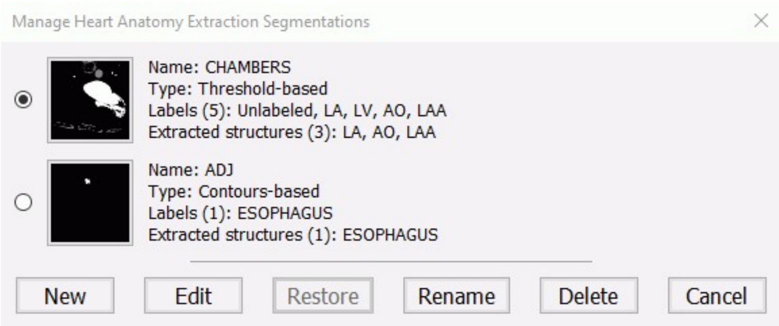
Dialog to start a segmentation

There are three methods to create segmentations: (1) contour-based, to delineate manually visible structures, (2) threshold-based or (3) automatic-based.



Dialog to select the type of method to start a segmentation

The user can create multiple segmentations groups, each containing different structures. The extracted structures from the groups are later available to the user for visualization purposes. Segmentations from earlier versions of the software can be edited (e.g., to add additional structures, change colors, etc.), renamed or deleted.



Dialog to manage multiple segmentations

The different options are:

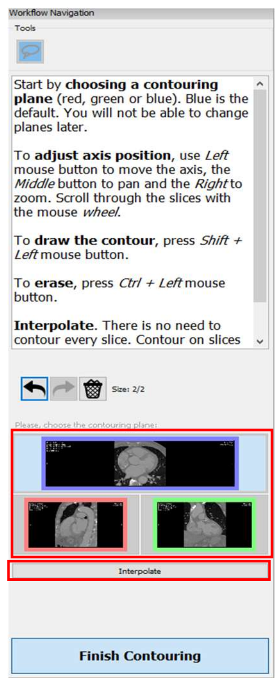
New	Create a new analysis. It must have a name that has not been already used.
Edit	Edit an existing segmentation.
Restore	To restore a segmentation made with a previous version of ADAS 3D.
Rename	Modify the name of the analysis.
Delete	Delete the selected analysis.
Cancel	Close this window.

17.2. Contour-based segmentation

Contour-based segmentation is useful to extract structures that although are visible in the image, are otherwise difficult to extract by thresholding. This contouring method requires the user to draw the perimeter of the structure on the 2D DICOM slices to defined what is segmented. Before starting, first select the desired drawing plane (blue, red or green in the bottom corner of the screen, see image below). The default plane is the blue. Once the user has started drawing, the plane cannot be changed. To draw the contour press **Shift + Left mouse button** and draw the contour moving the mouse. To erase, press **Ctrl+Left mouse button**: everything included in the lasso will be subtracted.

The user does not need to draw in all slices, ADAS 3D will automatically interpolate between two drawn slices. To accept the interpolation, click on the **Interpolate** button. These interpolations can be edited using the draw and erase contours tools described above.

When the segmentation is finished, click on **Finish Contouring.**



The three possible planes that the user can choose to draw the contour and the **Interpolate** button to interpolate between the drawn slices.

17.3. Threshold-based segmentation

This method allows the user to segment the regions of the image that contain the structures that may be of interest to extract.

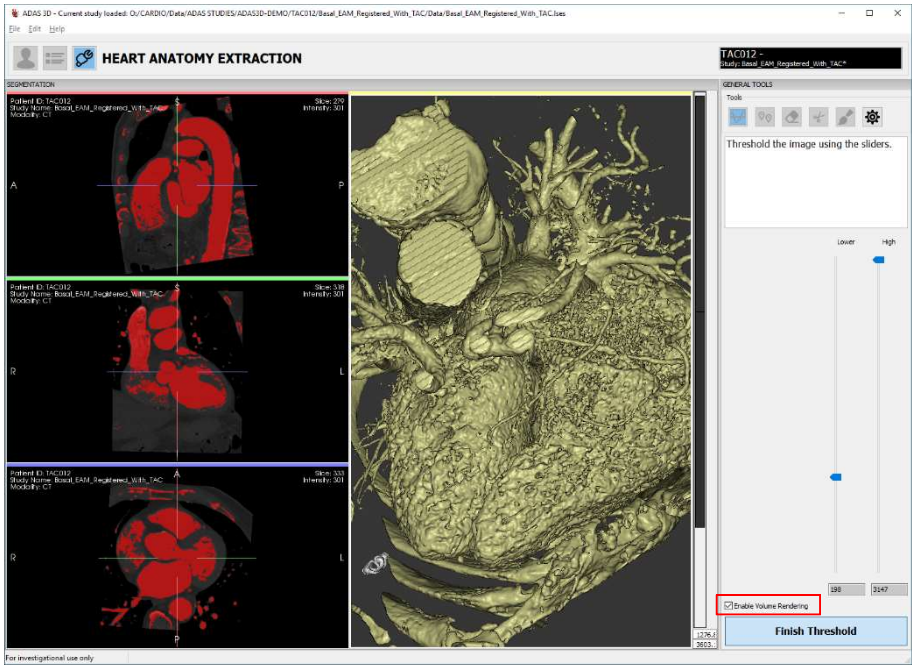


Image thresholding interface, in the left the three slice image planes, in the center the 3D view and in the right the thresholding tool with the volume rendering enabled.

The user can use the Lower and Higher thresholds to define the image intensity levels that contain the structures segment.

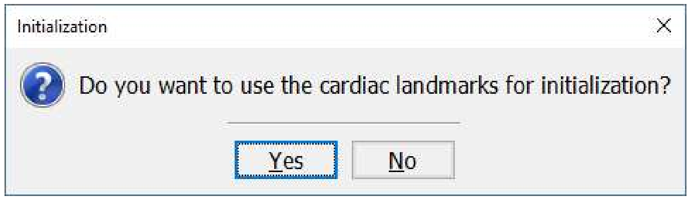
In the left side the user can visualize the original image and the segmentation in red. In the right side the volume rendering of the segmented image can be visualized, if the option is selected.

HINT

Try to find an optimal threshold where the different chambers are filled but they do not blend.

Once satisfied, press the button **Finish Threshold**.

As a final step before generating the model, if the cardiac model for this image has been already initialized, the user will be asked to use the cardiac landmarks for initialization.

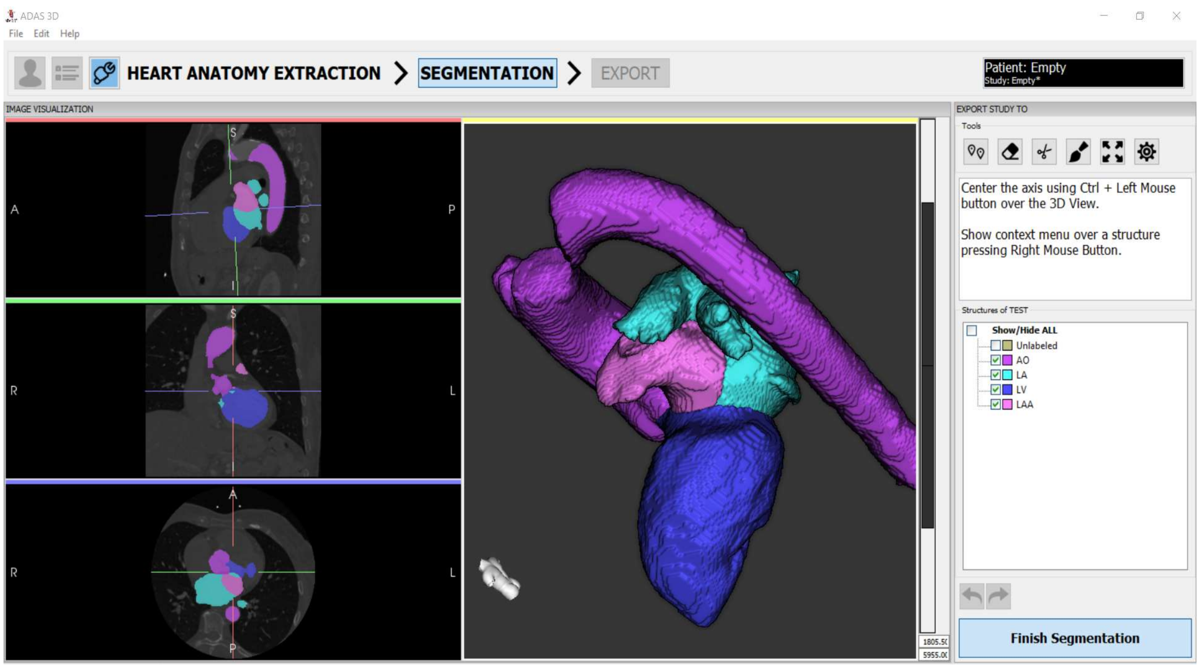


This allows to obtain the initial regions for LV, RV, LA, RA and AO based on the cardiac model initialization landmarks.

17.4. Automatic – based

This tool is designed to work with CTA data sets and should not be used with other modalities.

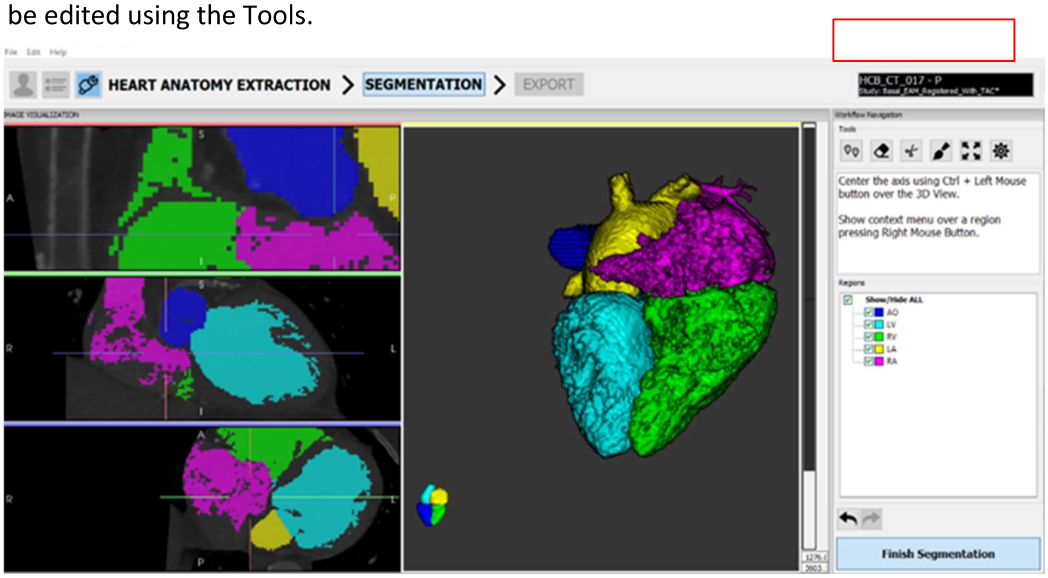
When the user selects this option, the software will automatically extract from the CTA the left ventricle (LV), left atrium (LA), aorta (AO) and left atrial appendage (LAA).



Heart Anatomy interface using the automatic-based method

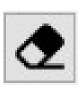
17.5. Region segmentation

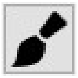
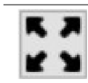
Once the structures are generated, using any of the three available methods, the different regions can be edited using the Tools.



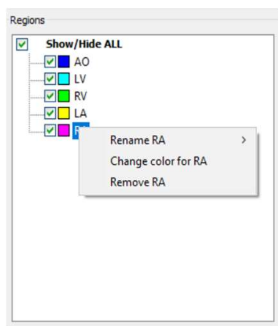
Heart Anatomy Extraction Interface, on the top right corner the tools to edit the segmentation.

The available tools for refining these regions are:

Tool	Name	Description
	**Seeds**	This tool lets the user manually set several seeds on the image to create separate regions. The user can set the seeds either on the 3D view or on the reformatted planes. To place the seeds, press **Shift + Left mouse button**
	**Extrusion**	This tool lets the user manually draw a contour over the 3D view (only, not on the 2D planes) to remove whatever information is contained in the extruded volume. The contour in the 3D view is used as a polygonal base that is projected (extruded) into the volume. Information contained in this projected volume is erased. To extrude, press **Shift + Left mouse button**
	**Split**	Like the Extrusion tool, but instead of erasing the information, it creates a separate 3D structure. To split two areas, press **Shift + Left mouse button**

	**Paint**	This tool lets the user manually paint a region over any existing structure using a sphere controlled by the mouse. Painting can be done on either on the 3D view or on the reformatted planes. The painted region becomes a separate structure. The user can adjust the sphere radius, and unpaint already painted regions. To paint, press **Shift + Left mouse button**
	**Settings**	Modify the settings of these tools
	**Dilate**	This tool lets the user to select a region to dilate and adjust de dilation factor by moving the slider

Clicking on a region with the right mouse button, the user can rename it, change the color or remove it.

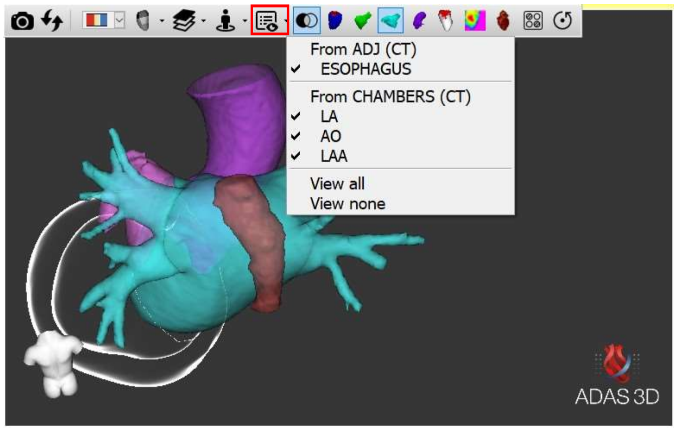


Rename, change color or Remove a region

Once the desired structures are created, click on **Finish Segmentation** and select the regions to extract. The visibility of the extracted regions can be changed under the **Visibility** tool of the 3D Visualization Toolbar.

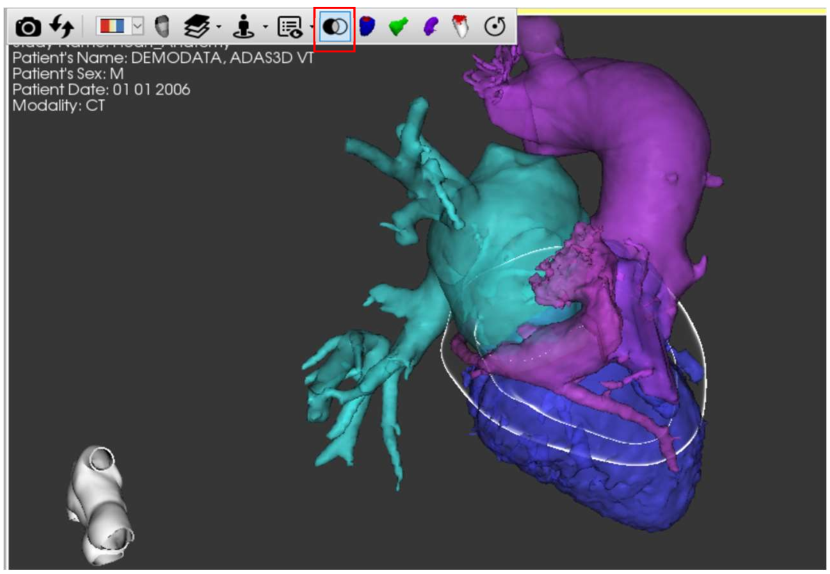
17.6. 3D Visualization

Once the segmentation step has finished, the user can visualize the extracted structures from all the segmentation groups created for the study. The structures will appear grouped according to the segmentation that was used to generate them and with a label (in brackets) to indicate the modality they were obtained from (CT, DE-MRI, etc.).



Rendering the segmented structures

The different structures can be visualized in a transparency mode, clicking on the transparency button.



Transparency button to enable the transparent visualization of the different structures

17.7. Accuracy of the measurements

The error of this tool is of ± 0.5 mm multiplied by the Input Image Spacing when all the parameters are disabled.

When the parameters are set to the default values, the error depends on multiple factors:

Parameter	Description	Error

Minimum Spacing (mm)	The input image is resampled to this resolution before any other processing.	When the input image spacing is below this parameter, this will generate an error of the output surface mesh between the input image spacing and the parameter. When the input image spacing is above this parameter, it has no effect.
Maximum Number of Points	When the output surface mesh is generated, the number of points is checked to be below this parameter. If the surface mesh does not meet the criteria, the mask image used to generate the surface mesh is resampled using higher voxel spacing until the criteria is met.	Depends on the number of points of the output surface mesh. For meshes below this parameter, this filter will have no effect. When number of points is above, the error will be proportional to the number of points.
Smooth Mesh	The output surface mesh is generated using an antialiasing image filter designed specifically for binary mask images.	This filter produces a fixed error proportional to the voxel size of the input image.
Minimum volume (mm3)	All isolated surface meshes with a volume less than this parameter will be removed from the output surface mesh.	This filter only has effect for isolated regions with a volume below this parameter.

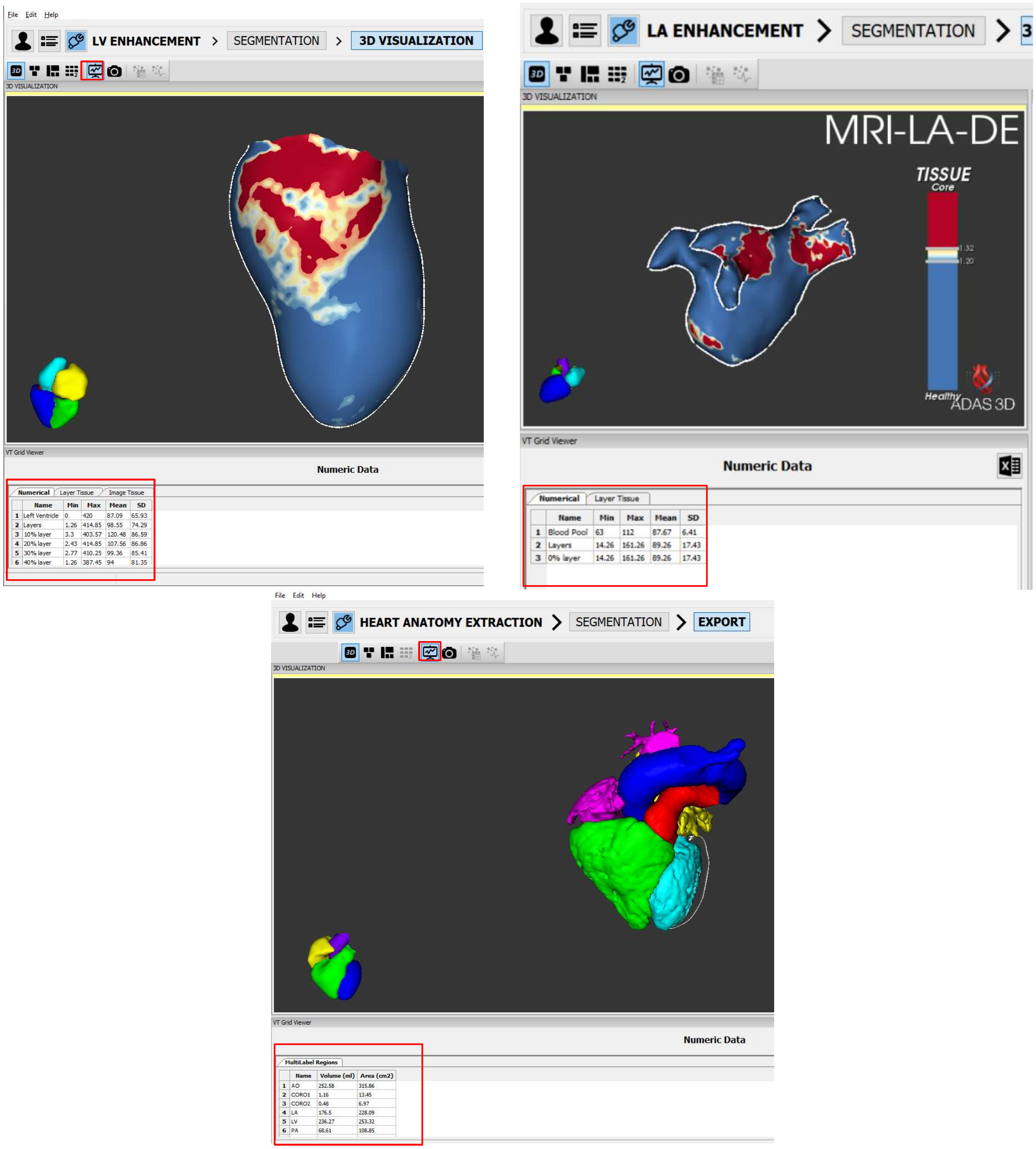
18. Quantification tool

The Statistics button enables a window that appears at the bottom of the 3D Window which provides the **Enhancement Quantification** for the LV and LA. When used for the LV, it provides the total volume of the enhancement of myocardial fibrosis and its area distribution at different depths as determined by layers. When used for the LA, it provides quantification in the Left Atrium (LA) by measuring the area of enhancement of myocardial fibrosis and visualization of its distribution (Mărgulescu et al. 2019)(Mărgulescu et al. 2019)(Mărgulescu et al. 2019)(Mărgulescu et al. 2019).

To compute the Enhancement Quantification press the Statistics button in the 3D general toolbar.

The following list shows the measurements computed:

1. **Layer Tissue**: For each layer, computes the area distribution (in square centimeters) of each enhancement of myocardial fibrosis type: high intensity CS and intermediate intensity BZ.
2. **Image Tissue**: Computes the total volume of the LV, expressed as mass (in grams), and the volume of the enhancement of myocardial fibrosis types: high intensity CS and intermediate intensity BZ.
3. **3D Corridor Mass**: Computes the mass of each 3D Corridor. If the 3D corridor detection is already performed, this value is displayed in the 3D Corridor Module.
4. **Numerical**: Computes statistics for all the layers and the segmented myocardium. For the LA enhancement it also computes the statistics of the Blood Pool.
5. **Multilabel Regions:** if the Heart Anatomy Extraction is performed, it computes the total volume and area of the different extracted regions.



Statistics information in LV enhancement (top-left) LA enhancement (top-right) and Heart anatomy extraction (bottom).

Click on the **Export** button to export the numerical data to a text file in Comma Separated Value (CSV) format. The Export button is located at the top right side of the window.

Tool	Name	Description
	Export	Export the numerical data to Excel Format (CSV)

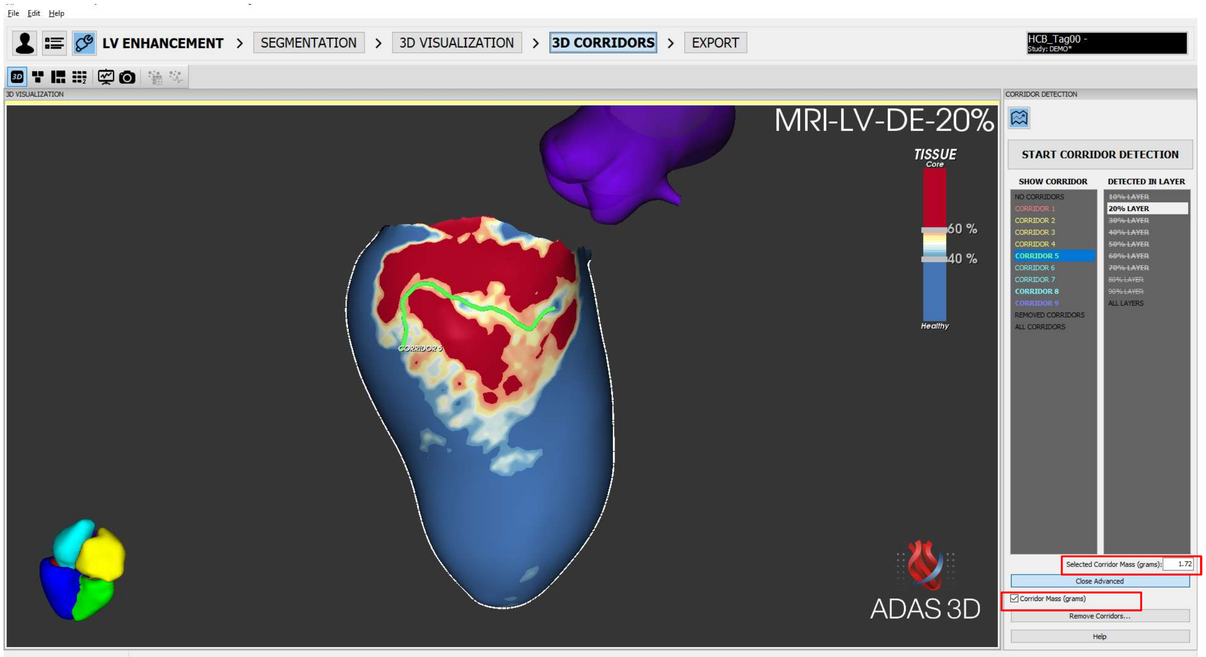
Example of **Layer Tissue** measurements:

Name	Total Area (cm2)	BZ+Core (cm2)	BZ+Core (%)	BZ (cm2)	BZ (%)	Core (cm2)	Core (%)	Invalid (cm2)	Invalid (%)
10% layer	155.45	30.06	19.34	23.34	15.01	6.72	4.32	0	0
20% layer	161.84	24.54	15.16	17.13	10.58	7.41	4.58	0	0
30% layer	168.56	22.26	13.2	14.55	8.63	7.7	4.57	0	0
40% layer	175.63	21.09	12.01	13.54	7.71	7.56	4.3	0	0
50% layer	183.06	20.39	11.14	13.56	7.41	6.83	3.73	0	0
60% layer	190.86	20.34	10.66	15.06	7.89	5.28	2.76	0	0
70% layer	199.01	19.81	9.95	16.56	8.32	3.24	1.63	0	0
80% layer	207.52	18.68	9	17.91	8.63	0.77	0.37	0	0
90% layer	216.38	24.34	11.25	24.18	11.17	0.16	0.07	0	0

Example of **Image Tissue** measurements:

Name	Total Volume (g)	BZ+Core (g)	BZ+Core (%)	BZ (g)	BZ (%)	Core (g)	Core (%)	Invalid (g)	Invalid (%)
Left Ventricle	167.65	24.43	14.57	19.4	11.57	5.04	3.01	0	0

To visualize the corridor mass from the 3D Corridor Module, click on the **Advanced** button, and then enable the option **3D Corridor Mass (grams).**



Example of corridor mass measurements:

Corridor	**Mass (grams)**
Corridor 1	1.10
Corridor 2	1.03
Corridor 3	0.69
Corridor 4	1.21
Corridor 5	1.72
Corridor 6	2.15
Corridor 7	0.26
Corridor 8	0.24
Corridor 9	0.48

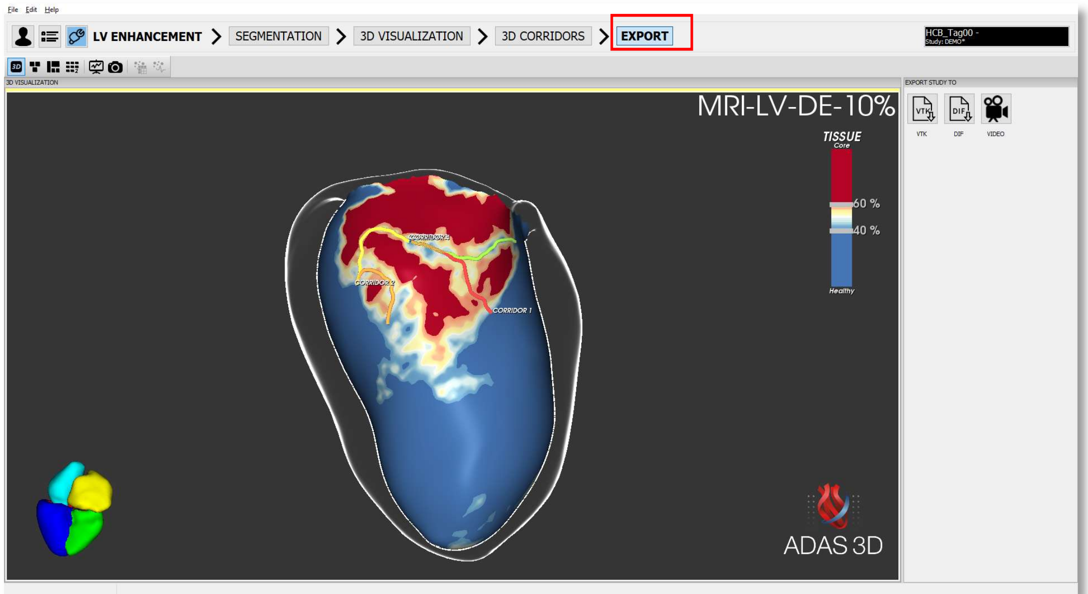
18.1. Accuracy of the measurements

The relative error of 3D Corridor mass using a phantom dataset generated by Adas3D Medical is 0.04 grams. The relative Error of Image Tissue Statistics using this phantom data is 0.0001 grams.

The smallest mass that can be measured is the mass corresponding to the volume of one voxel of the input image. For example, when the voxel size of the input image is 1.4 mm isotropic, it has dimensions of 1.4mm x 1.4mm x 1.4mm. Then, the volume of this voxel is 2.744mm3 and the mass is 2.744/1000 x 1.05 g/ml = 0.0029g. It is not possible to get higher resolution than this value for mass measurements. However, when the voxel size of the input image is 2.8 mm isotropic then the minimum mass measurement is 0.023g.

19. Export data

You can export the processed data using the export tools**, available in the EXPORT working tab**. It is available for all the analysis. ADAS 3D exports information to multiple industry standard file formats suitable for documentation and information sharing purposes, including formats supported by catheter navigation systems.



The Export Module

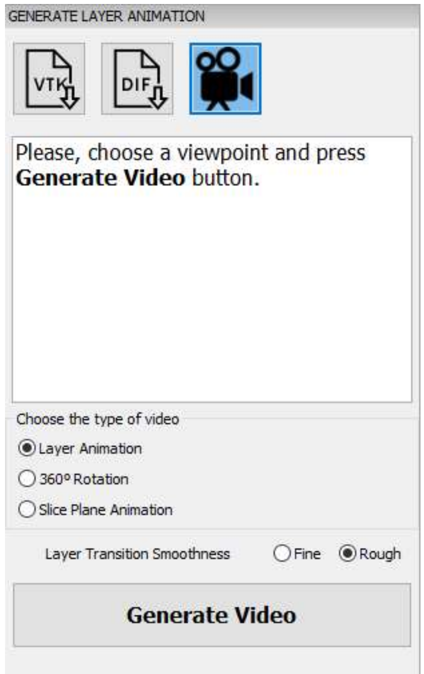
19.1. Video export

ADAS 3D creates three types of videos:

1) **Layer Animation**: for LV enhancement, a video that cycles through all layers of the model, in the fixed position that the user has set it; the layer transition smoothness is set with the **Fine** or **Rough** button. If there is only one layer, it turns to a snapshot.

2) **360º Rotation**: a video that rotates the object 360º around the position the user has set, but without changing layer.

3) **Slice Plane Animation**: a video that cycles through the slices.



Video export options

19.2. VTK Export format

The 3D data of the current study can be exported to the industry standard VTK format. To export data in VTK format, press the **VTK** button and then, select the configuration desired:

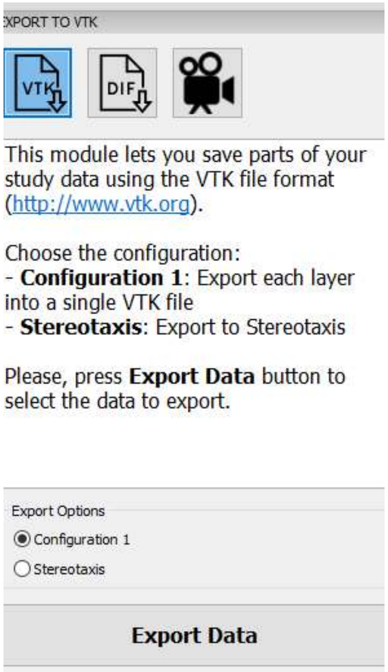
19.2.1. Configuration 1: CARTO® 3 system

This VTK format is compatible with Biosense Webster's CARTO® 3 system, version 6.0.

19.2.2. Stereotaxis system

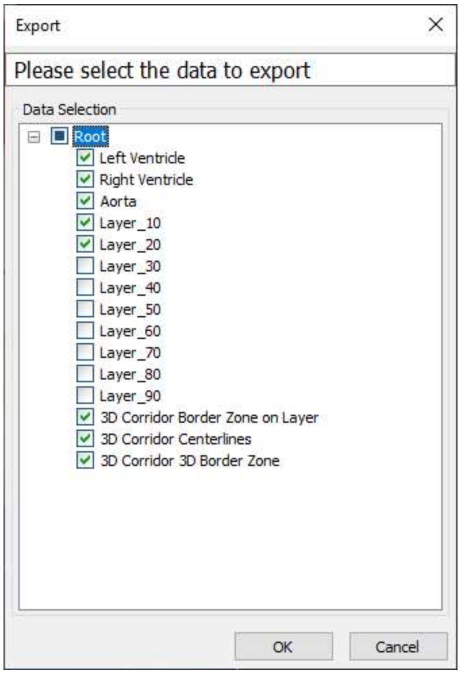
This VTK format is compatible with Stereotaxis Navigant™ system.

Press **Export Data** button:



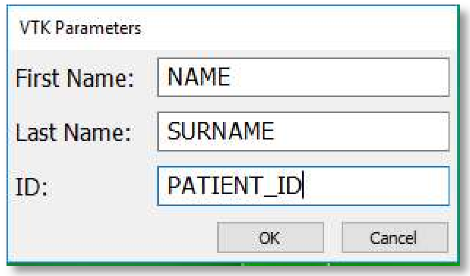
VTK Export Format

A selection menu will appear. Please select the items to export and press ***OK.***



Selection of the data to export

In the EXPORT tab, please enter the patient´s name (First Name and Last Name) and ID. Do not leave any blank spaces in any of the fields and only use Latin alphabet characters (Code Page 1252).



Press **OK** when done. The user will be prompted whether to examine the folder containing the exported items. Clicking **Yes** will open that folder.

CAUTION: Please note that the exported data contains the personal patient information that was entered in the VTK Parameters window: First Name, Last Name and ID

ADAS 3D VTK file format

When exporting to VTK format, each structure will be exported as a separate VTK file. This VTK format is compatible with the following Systems:

- Biosense Webster’s CARTO® 3 system, version 6.0.
- Stereotaxis Navigant™ system, version 5.0

Please find more details in the ADAS 3D Export File Format Specification Document.

HINT: Please check the compatibility of the EP Navigation System VTK file format with the ADAS 3D VTK File Format and contact Adas3D Medical with questions.

In order to ensure compatibility with CARTO® 3 system and the Navigant™, the following pre-processing is done for each exported data structure:

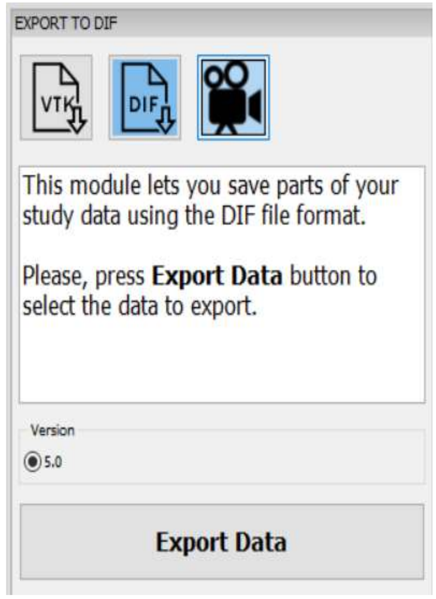
Data	Pre-processing

All data	The coordinate system of CARTO® is rotated -90º in X axis compared to the coordinate system of ADAS 3D. All structures will be rotated -90º in X axis When exporting to Navigant™, the data is not rotated
LV Enhancement Layer **LV Wall Thickness layer** **LA Enhancement Layer**	When exporting a LV layer, the layer is recomputed at low resolution (the number of points will be reduced from 250,000 to 65,045) The following processing is performed for LV and LA: • The scalars are converted to the range [0, 1]: All the intensity values that are below the lower threshold are transformed to 0, and all the intensity values that are above the higher threshold are transformed to 1. All the values in between are transformed to values from 0 to 1. • All excluded regions of the layer are converted to healthy color • If there are excluded regions in the layer, a new structure is created with the suffix _Excluded
3D Corridor Border Zone on Layer	3D Corridor Border Zone on Layer will be exported as a single VTK file per layer. This will allow displaying or hiding each corridor centerline per layer independently
3D Corridor Centerline	3D Corridor Centerline will be exported as a single VTK file per layer. This will allow displaying or hiding each corridor centerline per layer independently
Core Surface	This structure is exported without pre-processing
Left Ventricle, Right Ventricle, Aorta	This structure is exported without pre-processing
Heart anatomy structures	This structure is exported without pre-processing

19.3. DIF Export format

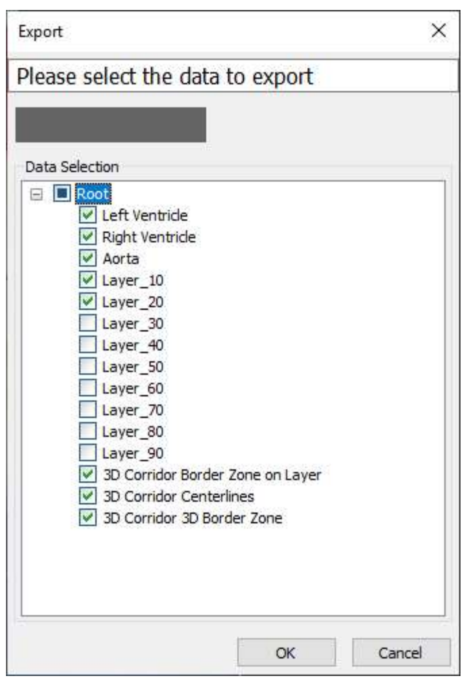
The 3D data of the current study can be exported in DIF file format supported by Abbott. There is an option: DIF 5.0 supported by EnSite Precision™ cardiac mapping system.

To export to DIF for Ensite Precision, select the DIF version 5.0 and press the **Export Data** button.



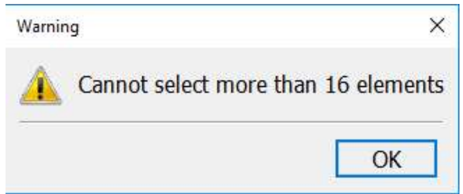
DIF Export Format

After pressing Export Data button, select the structures to be exported in the selection menu:

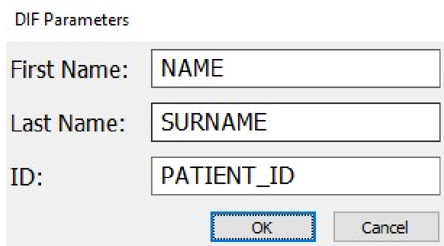


Selection of the data to export

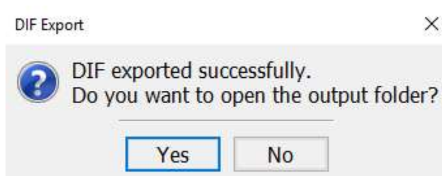
As the DIF format has a maximum the number of structures it supports, ADAS 3D indicates, using a gray bar, when no more structures can be exported. If the number exceeds the allowed amount, ADAS 3D will not allow any other structure to be added, and a warning message will be displayed.



Please, select the desired structures adjusting the number to the maximum allowed, and press **OK**. Fill in the patient data that needs to be included in the exported DIF file and press **OK**:



A menu will appear asking the user to open the folder where the file has been exported. Clicking **Yes** will open that folder.



CAUTION: Please note that the exported data contains the personal patient information entered in the DIF Parameters window: First Name, Last Name and ID

DIF-5.0

Please find more details of DIF-5 file format in the ADAS 3D Export File Format Specification Document.

HINT: Please check the compatibility of the EnSite Precision™ cardiac mapping system DIF file format with the ADAS 3D DIF-5.0 File Format and contact ADAS 3D Medical with questions.

In order to ensure compatibility with EnSite Precision™ cardiac mapping system, the following pre-processing is done for each exported data:

Data	Pre-processing
LV Enhancement Layer **LV Wall Thickness layer** **LA Enhancement Layer**	When exporting a LV layer, the following processing will be done: • Scalar information will be projected to the endocardium surface mesh for the layers between 0% and < 50%, to epicardium for the remaining layers • All excluded regions of the layer will be converted to core color • If there are excluded regions in the layer, a new color map will be created with the suffix “Excl” using white color for excluded region • The mitral valve of the endocardium and epicardium surface meshes will be closed
3D Corridor Border Zone on Layer	The visualization of the 3D Corridor Border Zone on Layer per layer in white color can only be achieved projecting the points to the layer and using a specific color map with fixed thresholds. This will reduce the quality of the visualization.
3D Corridor Centerline	• 3D Corridor Centerline will be exported as a single volume per layer, allowing to show or hide each corridor centerline per layer independently • Corridor centerlines will be projected to Endocardium/Epicardium surface meshes
Core Surface	This structure is exported without pre-processing

Left Ventricle, Right Ventricle, Aorta	The holes of each surface mesh will be closed
Heart anatomy structures	Heart anatomy structures are configured by default with a maximum of 15000 points to allow the importing to EnSite Precision™ cardiac mapping system without the need of preprocessing

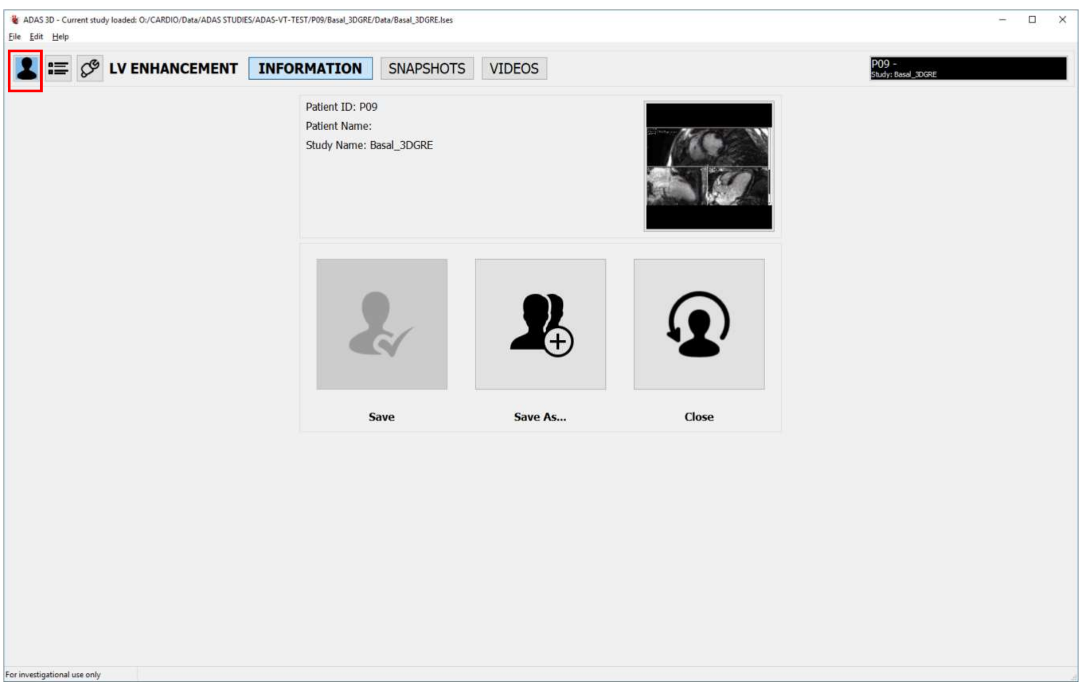
19.4. Accuracy of the measurements

ADAS 3D exports data with the following results:

- The absolute error when exporting to CARTO® Navigation System is ±0.0005 mm.
- The absolute error when exporting to EnSite Precision™ cardiac mapping system is ±0.00005 mm.

20. Current study management

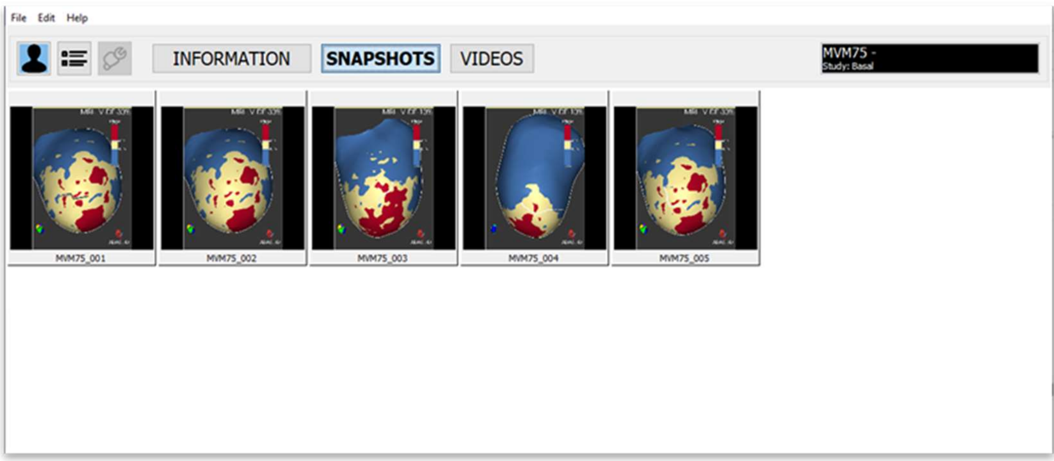
The Study button located at the bottom left corner allows the user to manage the current study. The user can **Save/Save as/Close** the current study, and review the snapshots and the videos that have been generated.



Current study management interface

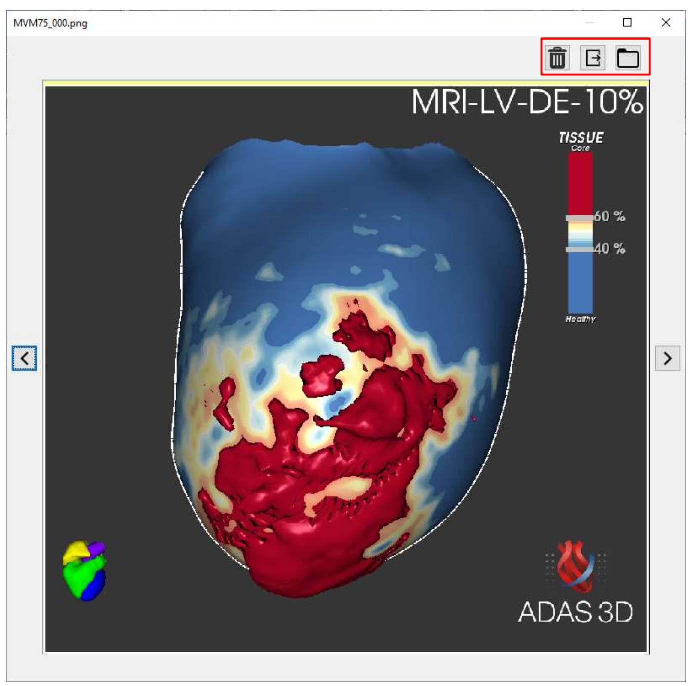
20.1. Snapshots

This window presents a collection of the snapshots taken from the current study.



Snapshots of a study

Double-click on a specific snapshot to maximize it. A new window will show the snapshot at bigger size.



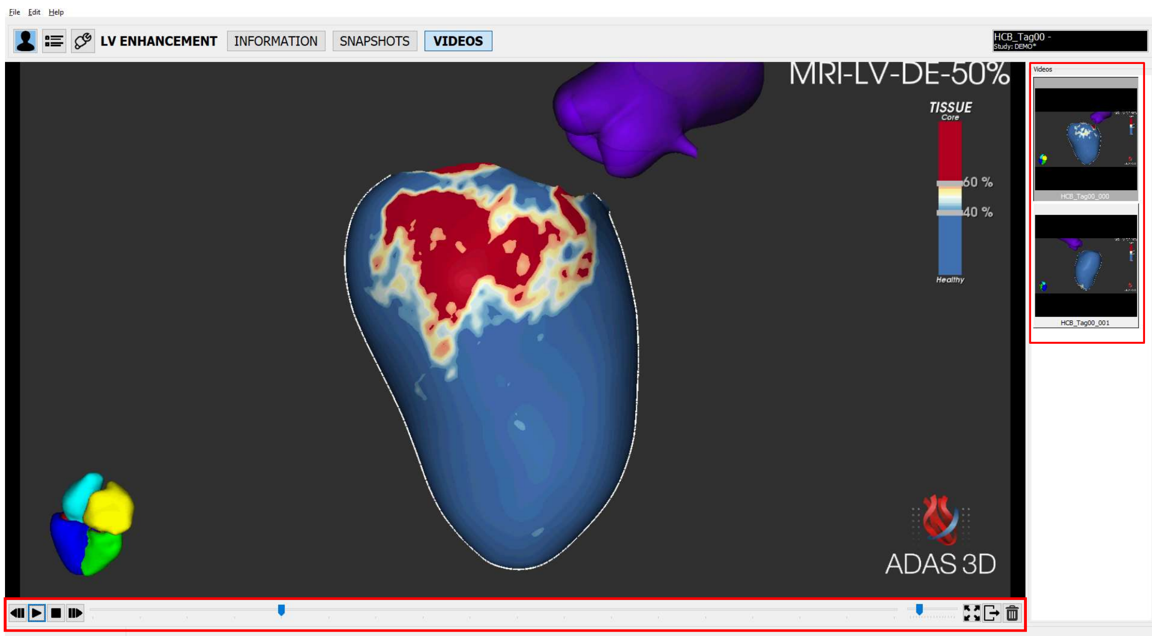
Maximized snapshot

In this window the following tools are available:

Tool	Name	Description
	Delete	Delete the snapshot
	Export	Export a snapshot from internal study storage database to a user defined folder
	Open	Open the folder of the snapshot
	Previous snapshot	Show previous snapshot
	Next snapshot	Show next snapshot

20.2. Videos

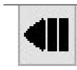
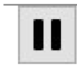
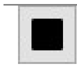
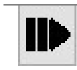
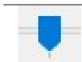
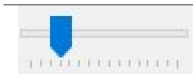
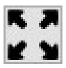
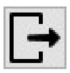
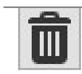
The user can visualize the videos generated of the current study.



View the selected video, all available videos of the study are available on the right and the controls to manage the selected video are on the bottom

The user can view the selected video in the center window. On the right-side window there is a window that shows all available videos generated of the current study. Clicking on a thumbnail, the video will be played.

The controls at the bottom allow the user to control the playback and to export/delete the video:

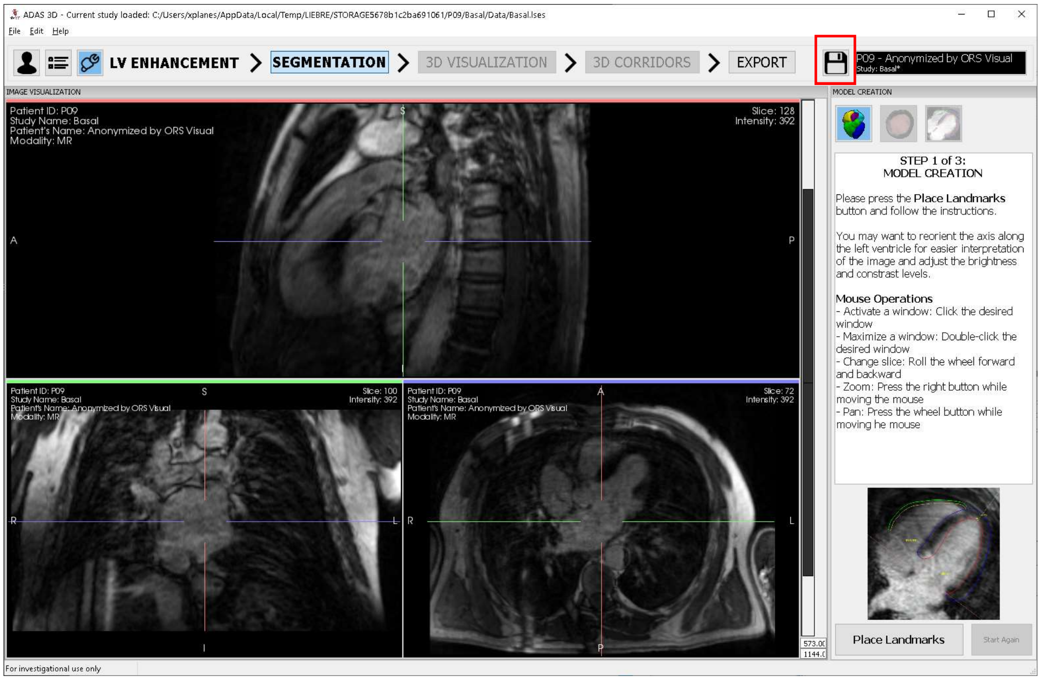
Tool	Name	Description
	**Previous frame**	Move to the previous frame
	**Play/Pause**	Play/pause the video.
	**Stop**	Stop the video.
	**Next frame**	Move to the next frame.
	**Frame Slider**	Move the slider to change current frame
	**Frame rate**	Adjust the play speed
	**Full screen**	Change to full screen. To exit full screen, press **ESC** key, double click or right button and click **Exit full screen.**
	**Export**	Export selected video from internal study storage database to a user defined folder. The exported video will be compressed using MPEG1 codec.
	**Delete**	Delete selected video.

21. Integration of ADAS 3D with other systems

21.1. SIEMENS OpenApps

When ADAS 3D is integrated with SIEMENS OpenApps, all data is stored in DICOM Format in SIEMENS syngo.via system. The ADAS Study will be stored inside the same DICOM study of the original DICOM image.

When using ADAS 3D inside SIEMENS OpenApps, the user will need to manually save the current study before closing ADAS 3D. Otherwise, the ADAS study will not be saved.



21.2. CIRCLE cvi42

When ADAS 3D is integrated with CIRCLE cvi42, all data is stored in DICOM Format in the cvi42 server. The ADAS Study will be stored inside the same DICOM study of the original DICOM image.

22. Cyber security

Medical device security is a shared responsibility between stakeholders, including health care facilities, patients, providers and manufacturers of medical devices. Failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal) availability or integrity or expose other connected devices or networks to security threats.

ADAS 3D must be installed on a computer with Windows operating system and most of the cybersecurity controls should be implemented at the Windows level.

The protection of information from unauthorized access is the responsibility of each user:

1. Users are requested to take steps to protect the secrecy and privacy of their own information, including all passwords and user credentials used to access the computer where ADAS 3D is installed.

2. Users should protect the ADAS 3D study storage database from unauthorized access because the local data contained in the ADAS 3D database contains private patient information.

Users should take care of the computer where ADAS 3D is installed:

3. Users should install, maintain and keep current with software updates, security patches, and malware (antivirus) detection on a regular basis.
4. Users should run anti-virus and malware software on a regular basis.
5. Users should avoid connecting to public networks
6. Users should utilize strong passwords and avoid saving “hardcoded” password.
7. Users should use a firewall.
8. Users should lock the computer when not using it and setup the screen saver to lock the screen after a period of inactivity.
9. Users should disable “auto run” functionality of the USB and CD/DVD devices. Users should prevent the installation of unauthorized third-party software applications.

23. Troubleshooting and maintenance

This section lists possible malfunctions, together with probable causes and corrective actions. Maintenance procedures are also described. For any problems not covered here, contact Adas3D Medical for assistance.

23.1. Maintenance

The IT deparment of your institution should be responsible for the maintenance of the computer where the software is running. This maintenance includes all the hardware equipment like the hard disk, dislpay, keyboard, mouse and the operating system.

All the studies processed by the application are stored in a database on the local hard disk called Study Storage. It is recommended to periodically backup this database. In case of failure of the hard disk, you can recover all the studies.

The Study Storage contains the medical images analyzed by the software. When creating a new entry on the database, you will be asked for sensitive personal information of the patient (like the Patient ID or the Patient Name). **Please, take the appropriate measures to protect these data properly according to the legislation that applies to your country.**

To update the software, please follow the

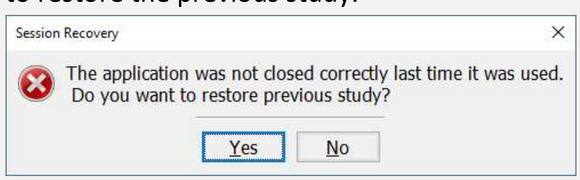
Printed in Barcelona.

Install steps. The current version will be automatically uninstalled before installing the new version. The current configuration of the application will not be removed. Please process a case with the new version to ensure that evertything is working fine.

The lifetime of the software is set to 5 years. After 5 years, the IT deparment of your institution should be responsible for uninstalling the ADAS 3D software product. To uninstall the ADAS 3D product, follow the steps in the Uninstall Process.

23.2. Troubeshooting

If any case of malfuntion happens, please inspect and dispel it according to the methods shown in the following table.

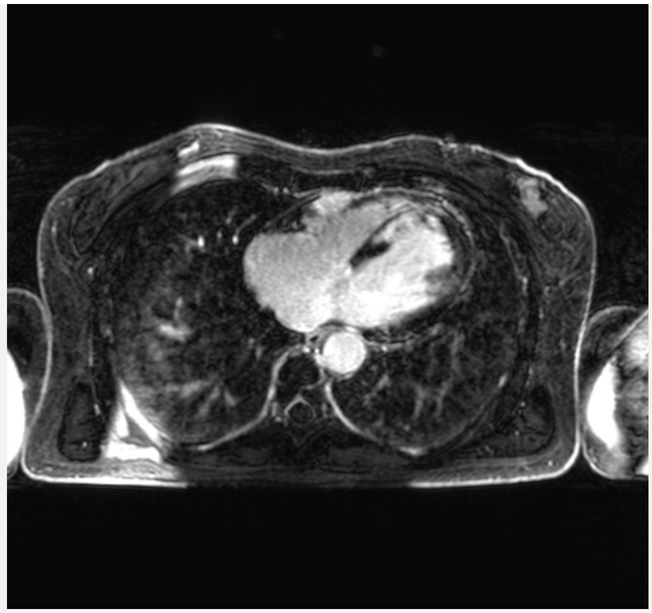
OBSERVATION	INSPECTION
COMPUTATION TIME IS VERY SLOW	Check with the IT department the available computer memory, hard disk space and any other issue that could slow down the computation time. Check if there are other running applications that are using the CPU intensively.
CANNOT SAVE A STUDY	Check with the IT department a solution for increasing the available hard disk space.
FAILURE OF THE HARD DISK	Restore last backup of the Study Storage.
THE DISPLAY DEVICE IS NOT WORKING PROPERLY	Check with the IT department the display device.
IN CASE OF POWER FAILURE DURING RUN	The next time the application is launched, it asks if the user wants to restore the previous study. 
CANNOT OPEN DICOM	Check if the DICOM can be opened with other software to verify that the DICOM files are not corrupted.
A CHANNEL IS NOT DETECTED PROPERLY	Check the removed 3D CORRIDORS category in the detected 3D CORRIDORS list. Sometimes the user can identify a CORRIDOR visually but it doesn't fulfill all necessary properties. For example, the CORRIDOR length or isolation. Check if the visually detected

	3D CORRIDOR is short, close to healthy tissue or not surrounded by Core in the adjacent layers. Check the segmentation to verify that the myocardium has been segmented correctly. Check the thresholds to verify that the enhanced regions are classified correctly in Core/Border Zone/Healthy.
THE SCAR REGION SEEN IN THE LAYERS IS NOT CORRECT	Check for artefacts in the input DICOM image that will distort the results. Check the segmentation. Sometimes there are errors in the segmentation that include bright objects like blood pool or aorta. Check the thresholds to verify that the enhanced regions are classified correctly in Core/Border Zone/Healthy. Use the “3D Image View” to click on the 3D view and check the corresponding image region.

24. Appendix A. good quality DICOM images

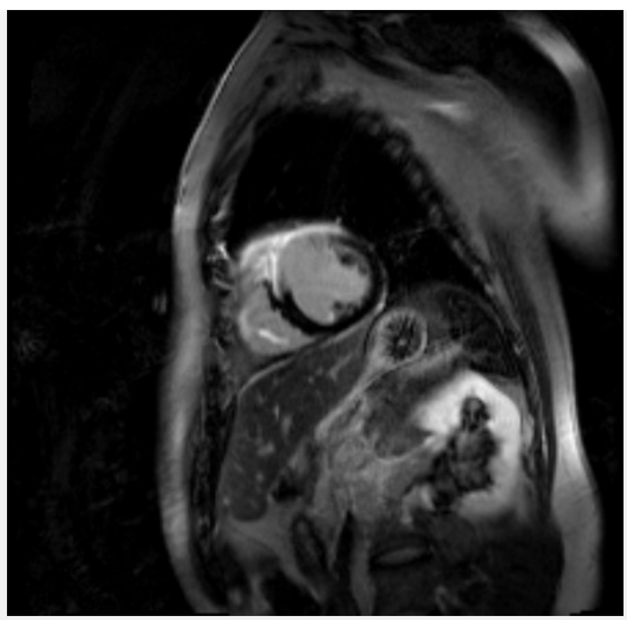
VT IMAGES

DE-MRI 3D-GRE



MRI SCANNER	SIEMENS TrioTim
SEQUENCE	3D-GRE navigated
RESPIRATORY NAVIGATOR	YES
ECG TRIGGERED	YES
MAGNETIC FIELD	3T
ROWS X COLUMNS	512x512
NUMBER OF SLICES	104
PIXEL SPACING	0.752x0.752 (interpolated)
SLICE THICKNESS	1.5
INVERSION TIME	Nulled normal ventricular myocardium
OBSERVATIONS	There is an artefact in the left side that is not affecting the left ventricle.

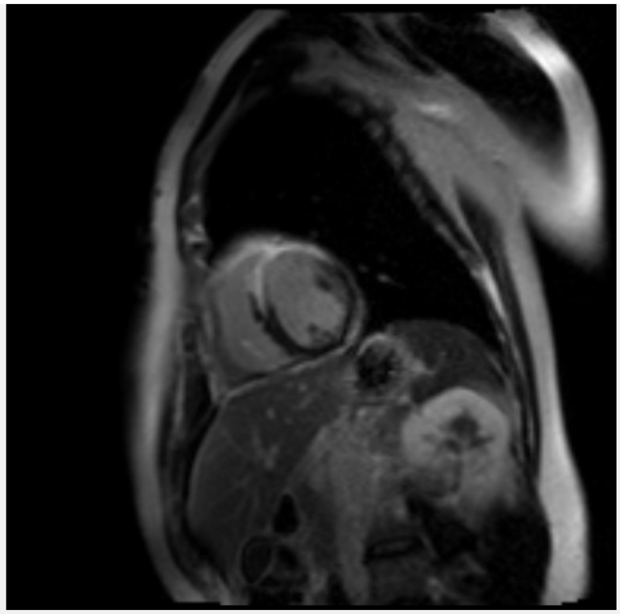
DE-MRI 2D-GRE



MRI SCANNER	SIEMENS TrioTim
SEQUENCE	2D-GRE
RESPIRATORY NAVIGATOR	NO. One slice per breath hold
ECG TRIGGERED	YES
MAGNETIC FIELD	3T
ROWS X COLUMNS	224x224
NUMBER OF SLICES	17
PIXEL SPACING	1.7x1.7
SLICE THICKNESS	6
INVERSION TIME	Nulled normal ventricular myocardium
OBSERVATIONS	None

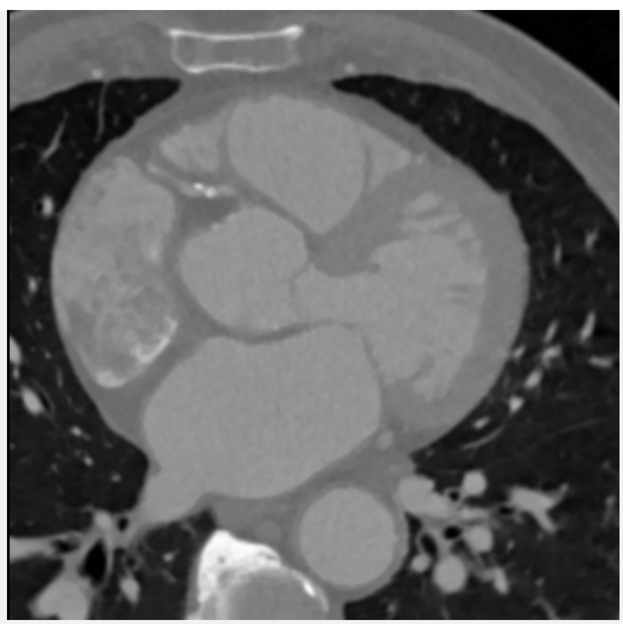
DE-MRI 2D-SSFP

MRI SCANNER	SIEMENS TrioTim
SEQUENCE	2D-SSFP
RESPIRATORY NAVIGATOR	NO. One single breath hold for all slices
ECG TRIGGERED	YES
MAGNETIC FIELD	3T
ROWS X COLUMNS	192x192
NUMBER OF SLICES	18
PIXEL SPACING	1.98x1.98
SLICE THICKNESS	6
INVERSION TIME	Nulled normal ventricular myocardium
OBSERVATIONS	None



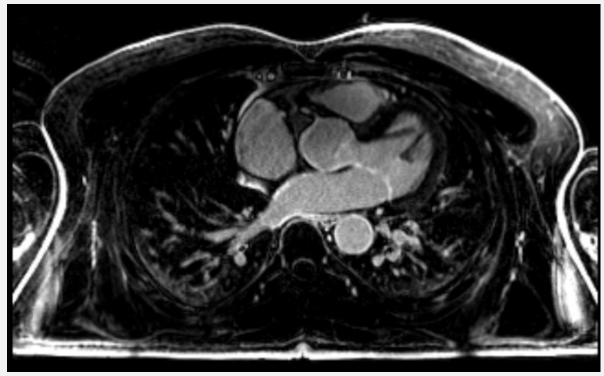
CT

MRI SCANNER	SIEMENS SOMATOM
SEQUENCE	-
RESPIRATORY NAVIGATOR	-
ECG TRIGGERED	-
ROWS X COLUMNS	512x512
NUMBER OF SLICES	596
PIXEL SPACING	0.375x0.375
SLICE THICKNESS	0.75
OBSERVATIONS	None



AF IMAGES

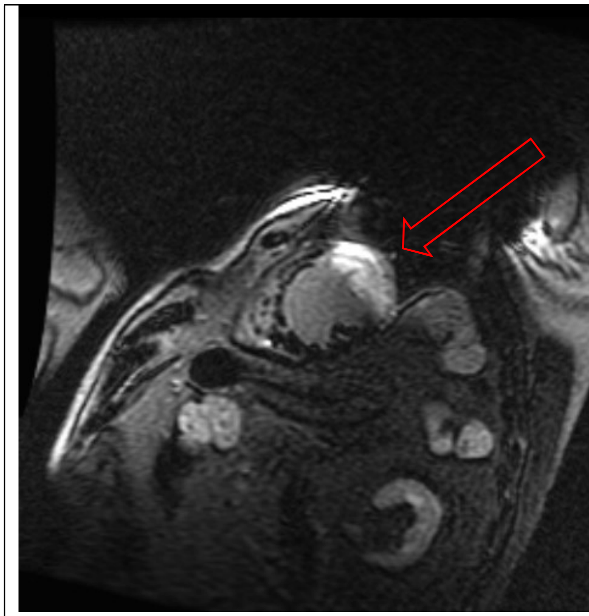
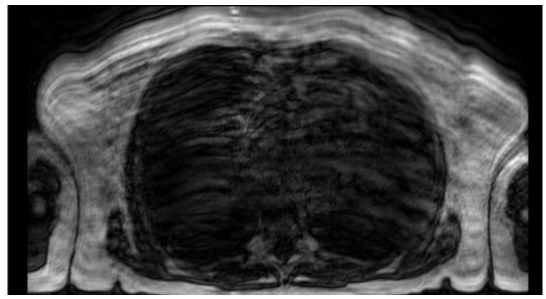
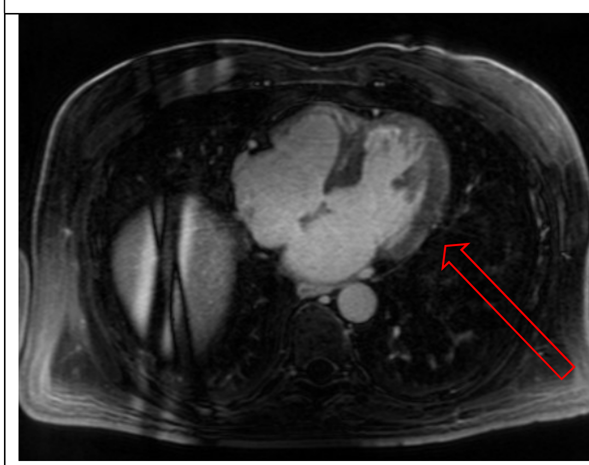
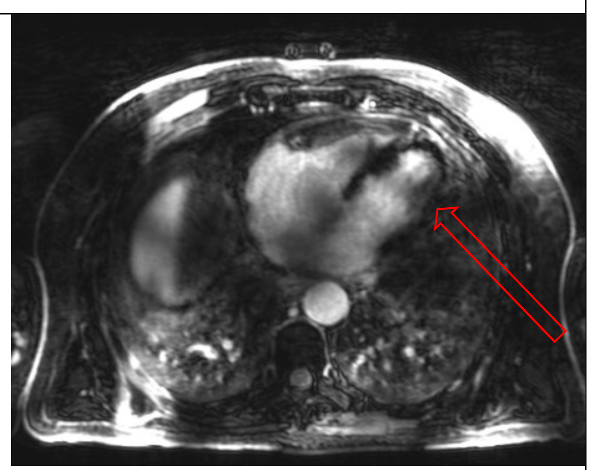
MRI SCANNER	SIEMENS TrioTim
SEQUENCE	3D
RESPIRATORY NAVIGATOR	YES
ECG TRIGGERED	YES
MAGNETIC FIELD	3T
ROWS X COLUMNS	320x320
NUMBER OF SLICES	64
PIXEL SPACING	1.25x1.25
SLICE THICKNESS	2.5
INVERSION TIME	Nulled normal ventricular myocardium
OBSERVATIONS	None

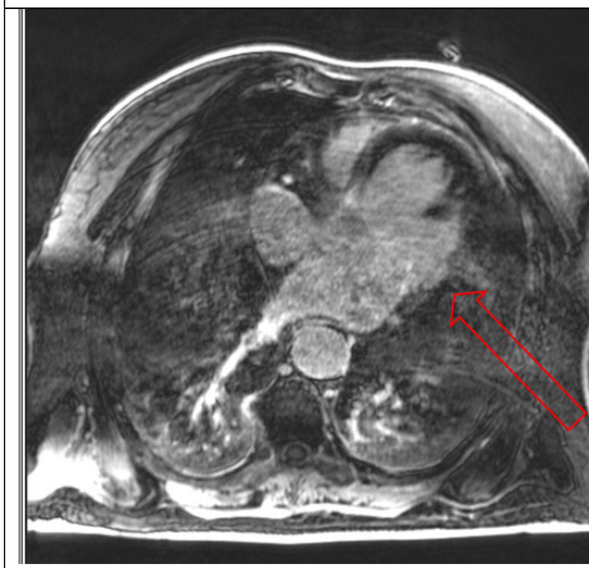
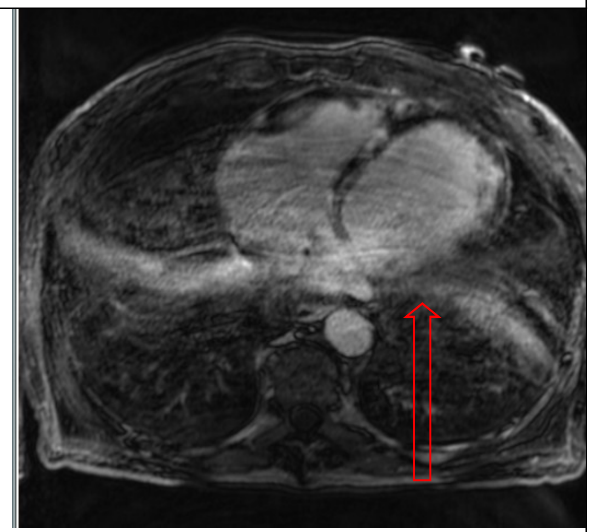
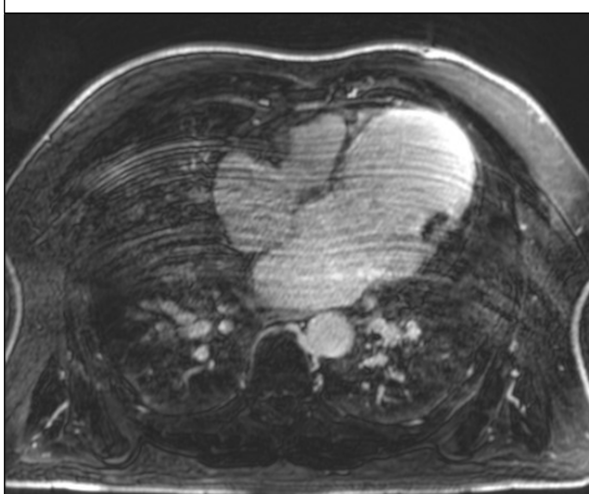


25. Appendix B. bad quality DICOM images

In this section you will find some examples of bad quality DICOM images.

VT IMAGES

	
ICD Artefact: The ICD artefact is affecting the myocardium	**Without contrast**: Myocardium not visible because there is no contrast or the acquisition has been performed too early.
	

Not nulling myocardium: Myocardium is not nulled	**Bad quality I**: The myocardium color is not uniform. There are bright and dark regions over the myocardium
	
Bad quality II: The myocardium is not visible at the mitral valve region	**Bad quality III**: There's a bright artifact over the myocardium
	
Bad Quality IV: There are horizontal bright lines over the myocardium	

26. Bibliography

Vogel-Claussen, J, and CE Rochitte. 2006. "Delayed Enhancement MR Imaging: Utility in Myocardial Assessment." …, 795–811.