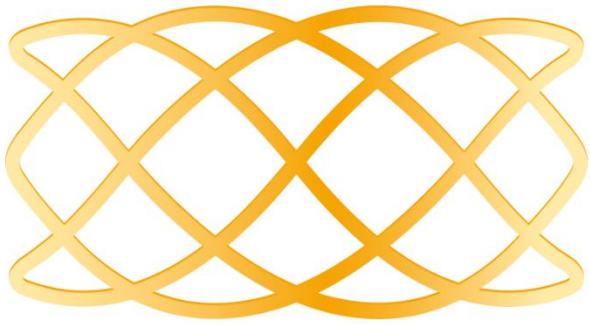
mentice

Instructions for use



ANKYRAS

ANKYRAS is a software tool for planning endovascular treatment of intracranial aneurysms. If you have any questions about this product or its operation, please contact your local distributor or the manufacturer MENTICE SPAIN S.L.

MANUFACTURER	**DISTRIBUTOR**
MENTICE SPAIN S.L. Rambla Catalunya 53, 4H 08007 – Barcelona Spain Tel: +34 933283964 www.mentice.com ankyras@mentice.com	MENTICE AB Odinsgatan, 10 411 03 Gothenburg Sweden Tel: +44 20 3885 1601 www.mentice.com ankyras@mentice.com

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

Paper-format IFU are available from MENTICE SPAIN S.L upon request from the user in a maximum period of 7 days at no additional cost.

Table of contents

Important information for the user

The information in this User manual applies to the Ankyras software.

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

ANKYRAS is intended for exclusive use by professional users. The software is intended to assist healthcare professionals in the planning of endovascular treatment with flow diverters and cannot fully substitute their clinical judgement.

The software should only be used in combination with equipment with the minimum system requirements listed. If the minimum system requirements are not met the system may not work as expected.

The lifetime of this software is established at 5 years.

Summaries of safety and clinical performance of clinical studies can be consulted in EUDAMED.

Symbols

CE 2797	CE marking for standalone software according to Regulation (EU) 2017/745
	Consult the instructions for use: available at the following web address: https://www.mentice.com/ankyras/ifu 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
REV	Last revision date of instructions for use
MD	Symbol “Medical Device”
UDI	Symbol “Unique Device Identifier”
	Symbol to identify the expiration date of the product license

Intended use

ANKYRAS is a medical software intended to assist healthcare professionals in the selection of a proper braided device for treatment of intracranial aneurysms. ANKYRAS allows to explore and quantify the vessel morphology and to assess the fit of the desired braided device in the patients' anatomy based in the device information provided by the device manufacturer. The software allows to add braided devices designed by the manufacturer and to simulate the final position of each selected braided device and its geometrical characteristics such as the radial expansion and the local surface porosity after being placed inside the vascular patient anatomy.

ANKYRAS is intended to be used by trained healthcare professionals experienced in examining and evaluating volumetric neurovascular images, for the purpose of obtaining diagnostic information as part of a comprehensive treatment planning decision-making process. ANKYRAS can be also used by trained medical device manufacturers for supporting healthcare professionals during the simulation procedure before the intervention.

ANKYRAS is intended to be used with 3D rotational angiography (3DRA) images, 3D magnetic resonance angiography (MRA) images or with surface vessel models obtained from medical image data

Indications

The software is intended to provide the measurement, among others, of the arterial morphological descriptors (local vessel diameter, cross sectional diameter from perimeter and circularity) and calculating the final shape of a device after being placed inside the patient.

The data produced by ANKYRAS must not be used on an irrefutable basis or a source of medical advice for clinical diagnosis or patient treatment. The data produced by ANKYRAS is intended to be used to support qualified healthcare professionals for clinical decision making.

Contraindications

The software works only for 3D rotational angiography and 3D MR angiographies images with a spacing lower than 500 µm and higher than 250 µm. Lower spacings can be used if your computer complies with recommended system requirements.

Warnings

- The software should only be used in combination with equipment with, at least, the listed minimum system requirements.
- All operators must read the complete Instructions for Use before operating the ANKYRAS. The product should be used only by qualified and trained personnel.
- ANKYRAS is intended for exclusive use by professional users. The software is intended to assist healthcare professionals in the treatment and cannot fully substitute their clinical judgement.

Precautions

- The software should be used with good quality images as shown in **Annex A**.
- It is highly recommended to use the software in a work environment avoiding any distractions

Measurement accuracy

ANKYRAS will provide a mean anatomy reconstruction accuracy (point-to-surface distances) equivalent to that of the acquisition system, typically 200µm for a 3D rotational angiography [doi:10.1148/rg.287085004]

Regarding diameter and perimeter measurements, ANKYRAS provides an accuracy above 99% (SD: 0,59% and 0,086% respectively).

The software will provide the length, expansion and porosity of the device, with an average accuracy of 94.35% (SD: 6,6%), 90.38% (SD: 7.18%), 97.11% (SD: 4,11%) respectively.

NOTE: The key parameters over which these accuracies are valid are listed below:

- using images that accomplish what is indicated in Annex A: DICOM image quality
- simulating the flow diverter models indicated in section “Flow diverter models” of the IFU (foreshortening, expansion and porosity)
- using contrast images of neurovascular region
- using 3DRA and MRIs images acquired using the listed scanners in “Supported data formats”

Flow Diverter models

The table below indicates the name of the devices for which the ANKYRAS simulation is validated with the technical information provided by each manufacturer. This technical validation consists of validating the devices final length under the different diameter conditions available in the product brochures. The devices marked with * are validated with clinical retrospective data and are those that are available in the software.

Manufacturer	Device name
Acandis GmbH (Germany)	Accero
	Accero Rex
	* Derivo
	* Derivo Mini
	Derivo2
Balt Extrusion (France)	Silk Plus
	* Silk Vista
	* Silk Vista Baby
	Leo Plus
	Leo Plus Baby
Phenox GmbH (Germany)	* P64
	P48-MW
	P64-MW
MicroPort Medical Company (China)	* Tubridge
Stryker Neurovascular (United States)	* Surpass Streamline
	Surpass Evolve
MicroVention, Inc. (United States)	FRED & FRED Jr
	FRED X

Medtronic, Inc. (Micro Therapeutics, Inc. Neurovascular) (United States)	Pipeline Flex with SHIELD (PED2)
	Pipeline Flex (PED)
	Pipeline Vantage[1]

[1]⚠Only models with a diameter smaller than 3.5 mm are available for simulation. Please refer to the latest updated Instructions for Use from the manufacturer and any recommendations issued by your Health Authority.

Supported data formats

ANKYRAS software has been validated with the 3DRA and MRIs acquired using the following scanners:

Manufacturer	Manufacturer's Model Name	3D-RA Acquisition Type	Image Modality
Siemens	AXIOM	5sDR – 5sDSA	XA
Philips	Integris Allura System	3DRA	XA
General Electric	AW4.6_0.5.003_SLED_11	3DRA	XA
Toshiba	Infinix-i	3DRA	XA
Siemens	Aera	MRA 3D	MR
Philips	Ingenia	MRA 3D	MR

Performance

ANKYRAS is a web browser application, please check browser compatibility in https://docs.unity3d.com/Manual/webgl-browsercompatibility.html.

WebGL (Web Graphics Library) is an online tool that allows you to render 3D graphics. Google Chrome supports WebGL, and it needs to be enabled. To enable go to chrome://settings in your browser → Show advanced settings → System and check the checkbox Use hardware acceleration when available.

The computation time of the vessel segmentation depends on the size of the region to be segmented.

The performance of visualization depends on the number and complexity of the 3D objects visualized simultaneously. It is recommended, during the computation of ANKYRAS, not perform other CPU and RAM intensive tasks.

Trademarks

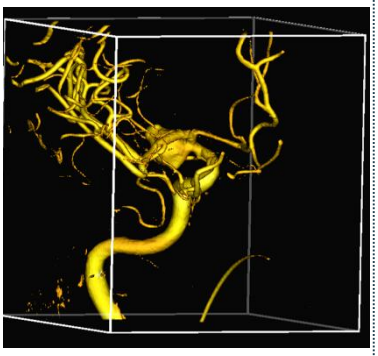
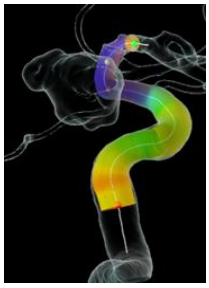
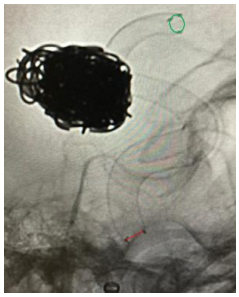
Ankyras® is a trademark of Mentice Spain S.L.
Copyright © 2025 Mentice Spain S.L. All rights reserved.
No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of Mentice Spain S.L. The information in this publication is provided for information only, is subject to change without notice, and should not be construed as a commitment by Mentice Spain S.L. assumes no responsibility or liability for any errors or inaccuracies that may appear in this publication. The software described in this book is furnished under license and may only be used or copied in accordance with the terms of that license. Information in this guide is subject to change without notice. Intel, Pentium 4, and Intel Xeon are trademarks or registered trademarks of Intel Corporation or its subsidiaries in the United States and other countries. NVIDIA and NVIDIA Quadro are registered trademarks or trademarks of NVIDIA Corporation in the United States and/or other countries. Microsoft and Windows are registered trademarks of Microsoft Corporation in the United States and/or other countries.
All other products and company names may be the trademarks or registered trademarks of their respective owners. Ankyras User manual, October 2025.

System requirements

Please, be sure that your system fulfils these requirements before using Ankyras:

System requirements for Ankyras	
Operating System	**Recommended:** ● [Web, Desktop]: 64-bit Microsoft® Windows® 11 ● [MobileApp]: iOS 18 (iPhone, iPad) ● [MobileApp] : Android 15 (Android Phone, Android Tablet) **Minimum:** ● [Web, Desktop]: 64-bit Microsoft® Windows® 10 ● [MobileApp]: iOS 11 (iPhone, iPad) ● [MobileApp] : Android 8.0 Oreo (Android Phone, Android Tablet)
Web browser	**Recommended:** ● [Web]: Google Chrome 107.0.5304.89 ● [Web]: Firefox 106.0.5 ● [Web]: MS Edge 107.0.1418.56 **Minimum:** ● [Web]: Google Chrome 70.0.3538.77 ● [Web]: Firefox 63.0 ● [Web]: MS Edge 16.0 ● [MobileApp – iOS]: Safari as the default browser
CPU type	**Recommended:** ● [Web, Desktop]: Intel ® Core (TM) i7-10750H CPU 2.60GHz (PC) **Minimum:** ● [Web, Desktop]: Intel ® Core (TM) i7-2600K CPU 3.40GHz (PC) ● [MobileApp]: Chip A10 Fusion (iPhone, iPad) ● [MobileApp]: Qualcomm Snapdragon 730 (Android Phone, Android Tablet)
Memory	**Recommended:** ● [Web, Desktop]: 16 GB RAM ● [MobileApp]: 8 GB RAM **Minimum:** ● [Web, Desktop]: 4 GB RAM ● [MobileApp]: 4 GB RAM
Graphics	**Recommended:** ● [Web, Desktop]: Microsoft® Direct3D 12 ● [Web, Desktop]: Intel HD Graphics 6000 1536MB **Minimum:** ● [Web, Desktop]: Intel® Iris® Xe Graphics
Screen resolution	**Recommended:** ● [Web, Desktop]: 1,920 x 1,080 (PC) ● [MobileApp]: 1080 x 2400 pixels
Mobile screen size	**Recommended:** ● [MobileApp]: 6,1'' or higher **Minimum:** ● [MobileApp]: 4,7''
Others	**Recommended:** ● [Web, Desktop]: Mouse
Internet connection	**Recommended:** [Web, MobileApp]: 100Mbps, 4G

Introduction to Ankyras

Patient angiography	→	Vessel model and FD simulation	→	FD implantation
		 The information from the braided device design is used to predict the distal and proximal landing position, local porosity and device expansion	Flow diverter selection assisted by simulation	

Ankyras allows to simulate the treatment of intracranial aneurysms with braided devices by means of the patient's anatomical information and device design parameters. Given a 3D DICOM image (3DRA) or a segmented model of the patient's vessel, Ankyras quantifies the morphological parameters of the anatomy and simulates the implantation of one or more braided devices inside.

Ankyras allows the registered users to create, save, download and share their simulated cases. The Ankyras non-registered users can receive and see the simulations shared by the Ankyras registered users. to save their simulations to be able to access them in the future as well as to share them with other users or third parties.

Ankyras platforms

Ankyras is a solution available on 3 different platforms, allowing the user to use Ankyras in the most favorable way:

	Web (or WebGL) 	Mobile App 	Desktop (or Standalone) 
Requires internet	Yes	Yes	No
Access to software (more details **here**)	No installation, accessible from the Web browser	App installed on mobile/tablet (available for iOS and Android)	Software installed on your laptop/PC
Ideal platform for	Prepare a simulation and share it	View and share the result of a simulation	Prepare a simulation without internet connection

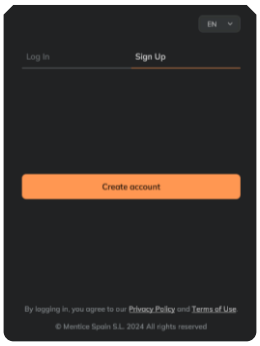
The available functionalities for each platform are indicated at each section in **Create a simulation in Ankyras** chapter in this manual.

Get Ankyras

User registration

Start using Ankyras by accessing **www.eu.ankyrasonline.com** and creating a user account following the steps:

1. From a PC/laptop, access **www.eu.ankyrasonline.com**, click the ***Sign Up*** and ***Create account***:

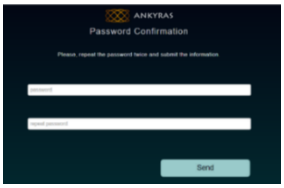


2. **Fill** the registration form in the pop-up window:

3. **Click** and read the ***Privacy Policy***
4. **Click *Send*** in the registration page

✉ The user receives a confirmation email: “Your ANKYRAS registration request has been received, we will contact you as soon as possible”.

5. ✉ Ankyras team accepts the registration, the user receives a new email with a link to set the password, which is valid for 48 hours.**Set password** to complete the registration:



Once the registration is completed, the user can log in in any of the three Ankyras platforms: Web, Mobile App and Desktop.

☛	During registration, the user's country must be introduced. The country defines the default language of the software, which can be changed and saved later during usage

Access/Download Ankyras

The user can access the Ankyras three different platforms:

- **Access Ankyras Web** (without installation): **www.eu.ankyrasonline.com.**
- **Install Ankyras Desktop**: the installer for Ankyras Desktop is accessible for registered users from Ankyras Web:
    1. Access and login in **www.eu.ankyrasonline.com**
    2. Click on the  *Customer Service* button (top-right corner)
    3. Click *Download Installer* (at the bottom of the menu).
        - Once the download is complete, a .exe file will appear in your downloads folder.
    4. Double-click the file to launch the installer and follow the standard installation steps.
        - During the installation process, you will be prompted to enter a password. If you do not have this password, please contact us at **ankyras@mentice.com** to request it.
- **Install the Ankyras MobileApp**: download it from the App Store or Google Play.

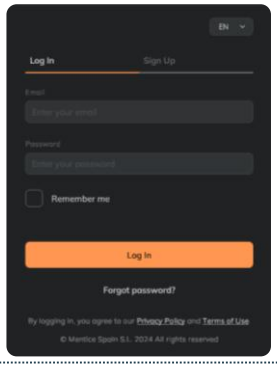
Download User Manual

This User Manual is available for Ankyras registered users. It can be accessed from the software in the *Customer Service* menu (upper right corner), either by clicking *Instructions For Use*, which will open the Ankyras-Mentice IFU webpage (Ankyras credentials are needed to access), or *Regulatory* and then *Request User Manual*. The User Manual will be automatically sent to the e-mail used for registration.

Start Ankyras

Sign in

The user must log in to Ankyras to use the software. The Ankyras home panel allows the user to log in with the email and password defined in the **registration process**.

⚠	**Conditions to login in Ankyras Desktop:** • The first time a user starts Ankyras Desktop, **internet connection is required to log in.** • Recurrent Log in will be required after 2h of inactivity. This login does not require internet connection. • Logging in with an internet connection is required **once per year**.	Ankyras Initial Panel 
⚠	**Ankyras Web**: after 2h of inactivity, the Ankyras page is frozen for security reasons. The user needs to restart/refresh the Ankyras page from the Web. Ankyras log in might be required.	
☛	A user who is not registered can use Ankyras Web or Mobile App (without need to login) to open and view a simulation that has been shared, see more details in **Share case** section.	

Reset password

The registered user can reset the password by clicking on the ***Forgot password?***. A new email will be sent to the user to complete this process.

In the Desktop application, users can reset their password without an internet connection by using a code sent via email. To obtain the code, users must access the Online platform on another computer or use the MobileApp to request it.

Sign out

The user can log out clicking on ***Settings*** (upper right corner) and ***Log Out***. The program will automatically return to the Ankyras start menu. It is recommended to close the session once the use of the device is finished.

⚠	The program will automatically sign out after two hours of inactivity and will request to sign-in again.

Create a simulation in Ankyras

The user can create a simulation from a DICOM 3D image or a VTK vessel model using Ankyras Web or Ankyras Desktop platforms. For that, the first step is clicking *new case* or, if the data has been previously imported, the user can access the list of *Cases* to start the desired case from there.

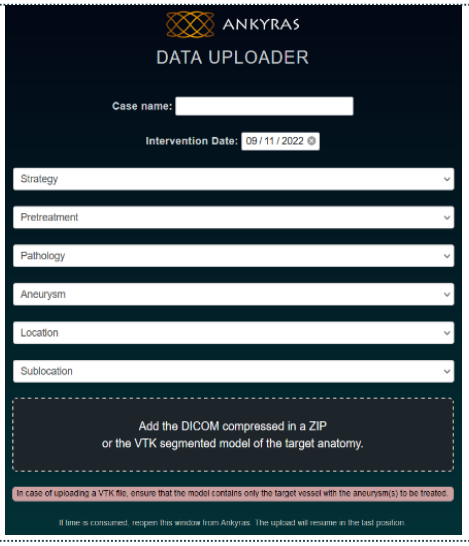
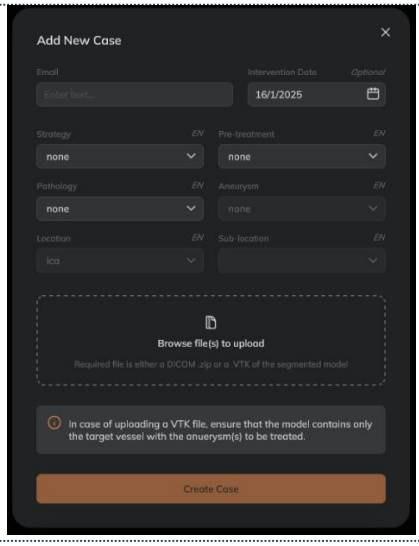
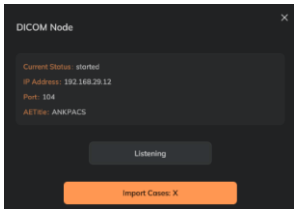
The next sections explain all the steps, from creating a new case to completing and saving the simulation results that a user with an Ankyras account can do. Last section

Import data

A registered user can create a new case by clicking ***New case*** on the Ankyras Web and Desktop platforms importing the DICOM 3D image or VTK data. If the user uses Ankyras Web, the *Data Uploader* window opens*; in Desktop, the Data Import panel opens. The user can also import the DICOM 3D image to Ankyras Desktop directly from the scanner's workstation export panel by configuring the DICOM node connection.

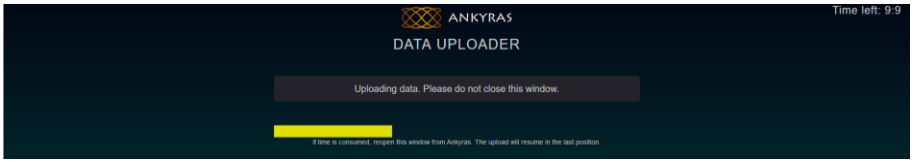
Import data: *New case*		
Desktop	✓	Click *New case* (Upper bar left corner)
Web	✓	Click *New case* (Upper bar left corner)
MobileApp	✗	Not available

⚠ *Make sure your browser has permission to open new windows from links in the software

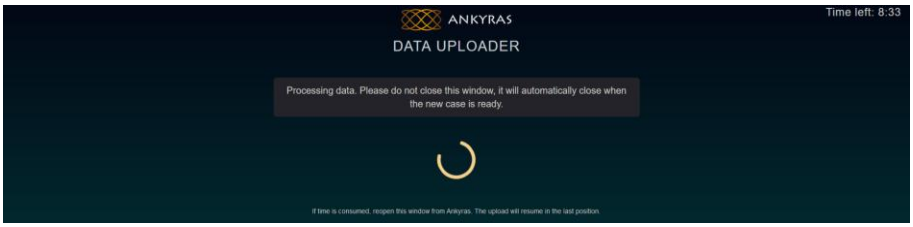
Data upload window (Web)	Data import panel (Desktop)	DICOM node configuration (Desktop)
		

Ankyras Web

1. **Case name**: It is mandatory to define the name of the case.
2. **Case Information**: It is recommended to define an intervention date and fill in the form (*Strategy Pretreatment*, etc, to facilitate the identification of the case in the future.
3. **Select DICOM / VTK file**: it is mandatory to upload a DICOM 3D file (3DRA or MRA) or a VTK model of the vessel with the aneurysms to be treated.
   - If a DICOM is uploaded, the user must upload the **DICOM compressed in a zip file**. It is recommended to pre-compress only the desired 3D image to speed up the loading process.
4. When the user selects the file, file upload and case creation start automatically.
5. **Upload status**: a progress bar indicates the status of the file submission under the message *Uploading data. Please do not close this window*. The window is valid for 10 minutes (see timer in the upper right corner). If time expires before the file has been completely sent, the user can resume the sending: open a new window from Ankyras and select the same zip file or VTK model. Charging will resume at the stage where it stopped earlier. When the bar reaches 100%, the file has been sent.



6. **Data processing:** as long as the *Data Uploader* window remains open under the message *Processing data...*, the case is being processed. It is important not to close the window because the user will be informed through the same window if there is an error during the processing of the case.



7. **Case created successfully**: the *Data Uploader* window closes automatically.
8. **Case in the *Case list***: refresh the *Case List* to see the new case.

Ankyras Desktop

1. **Case name**: it is not mandatory to define the name of the case. If it is not defined, the case will appear with no name.
2. **Case Information**: It is recommended to define an intervention date and fill in the form (*Strategy Pretreatment*, etc, to facilitate the identification of the case in the future.
3. **Select DICOM / VTK file:** it is mandatory to import a DICOM 3D file (3DRA or MRA) or a VTK model of the vessel with the aneurysms to be treated.
   - If a DICOM is imported, the user must select the **DICOM directory without compression (no zipped)**. It is recommended to import only the desired 3D image to speed up the loading process.
   - Important: in the panel that opens to find the DICOM, select or access the **DICOM folder** and click "**Load**". (Please don't select the DICOM file(s)!).
4. Click the orange **Create case** button
5. **Import and processing:** The 3-dots loading animation indicates that the file is being imported and processed. Do not close the *Data Import* panel.

6. **Case created successfully**: the *Data Import* panel closes automatically.
7. **Case in the *List of Cases***: The user can update their list of cases and search for the new case.

⚠	If a case is not visible in the *Case list* just after it has been uploaded/imported, please see **here** how to *Refresh* button to update the *Case list*.
⚠	If you receive the error message "*The uploaded DICOM does not contain a 3D volume*" but your image is indeed a 3D volume, it is likely that a DICOM tag is not being read correctly. We recommend using a different DICOM viewer to verify that the image is 3D. If the image is confirmed to be 3D, please contact ANKYRAS support.
⚠	Case name: When defining a case name, avoid using special characters (e.g., ö, â, or similar), as they may cause errors later if you want to download the simulation.
⚠	If you upload two different DICOM files from the same patient, even at different times, the software will recognize them as belonging to the same case. The second upload will not create a new case; instead, its images will be added to the original case.

Ankyras Desktop: DICOM node

It is possible to export the DICOM directly to Ankyras Desktop from the workstation through a DICOM node connection.

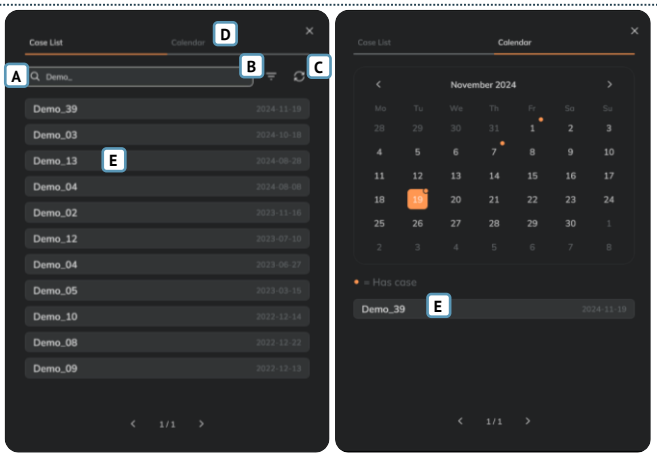
Please contact **ankyras@mentice.com** if you are willing to enable this feature.

Open a case

The *Cases* panel allows the user to access all the cases previously created by the user.

In Cases list, the cases appear by creation date and can be filtered by name or other options using the filtering button as indicated in image below. The case list is also available in a calendar view; cases appear on the intervention date (defined during New case creation).

Open a case from *Cases*		
Desktop	✓	Click *Cases* (Upper bar left corner)
Web	✓	Click *Cases* (Upper bar left corner)
MobileApp	✓	Click *Menu* (Lower left corner) and click *Case List*

***Cases* panel**	
A. Search a case by name **B.** Sort by **C.** Refresh the case list **D.** See cases on the calendar **E.** Open the case	

Case information panel

***Case Information* panel**		
Desktop	✓	From *Cases* or in Case info ⓘ (Upper bar center)
Web	✓	From *Cases* or in Case info ⓘ (Upper bar center)
MobileApp	✓	Click *Menu* (Lower left corner) and click *Case Information*

When the user clicks a case from the list or calendar, the Case Information panel is opened showing the information introduced during case creation and the list of attachments from that case.

The attachments can be of type:

3D DICOM image: there are as many attached images as 3D images were included in the selected DICOM during New case creation. The thumbnail is a slice from the 3D image.

Model VTK: the VTK vessel model selected during New case creation. The attachment is called *vtkModel*. The thumbnail is the Ankyras logo.

Simulation: Created from one of the images or VTK model from the case. Different simulations can be stored within the same case. The thumbnail is the Ankyras logo.

The caption below shows a *Case Information* panel with only one attachment type image:

***Case Information* panel**

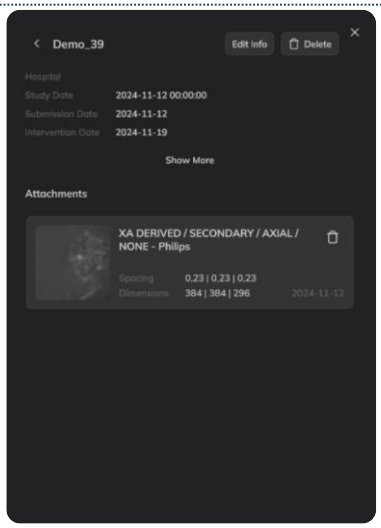
A. Double click on the desired attachment to open it.

B. Share the case with other Ankyras users or third parties. Find more details **here** about how to share a case.

C. Delete the complete case.

D. Delete one attachment

E. Edit case information: edit fields such as Strategy or Pretreatment

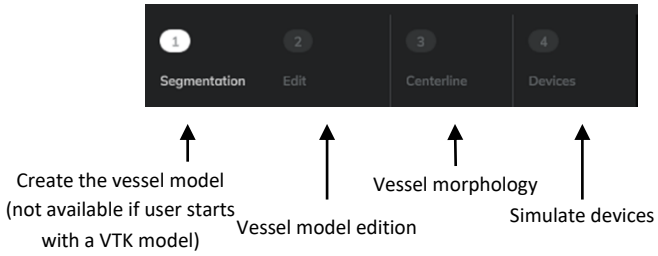


Open the image or vessel model

Open image or vessel model		
Desktop	✓	From *Case information*, double click the attachment
Web	✓	From *Case information*, double click the attachment
MobileApp	✗	Only simulation attachments can be opened

From the **Case information**, the user can open the attachment (DICOM image or VTK vessel model) by double clicking on it. This is opened in the center of the Ankyras interface as a 3D object. **Annex B** explains how to interact with the 3D object using the mouse control and the touchpad.

In the upper and central part of the interface, the ⓘ button can be found(click it to see the Case Information panel). Next, the user can start preparing the simulation using the processing tools (stages 1-4 in the left panel):



- If a simulation is created **from a DICOM image** the user must start using the image tools, **1: Segmentation** (the only active stage, in white)
- If a simulation is created **from a VTK vessel model**, the user start in **3: Centerline** (or in **2: Edit** tools if the model needs to be edited).

Once the vessel is segmented (Setps 1 and 2) and the centerline is created (Step 3), the user can simultaneously explore the morphological values of the anatomy and simulate different FDs in *Simulate devices* (Step4). Finally, the user can save the simulation as an attachment to the case and share it (the sharing functionality is only available for the Web platform).

All tools are explained in the next sections following the workflow to create a simulation.

Create the vessel model

Create vessel model		
Desktop	✓	1-Create vessel model
Web	✓	1-Create vessel model
MobileApp	✗	Not available

The processing stage 1, *Segmentation*, is creating the vessel model from the DICOM image (3DRA) from the patient. For

that, the user needs to open (double click) the image attachment in **Case Information panel** to enable the segmentation tools to create the vessel model.

When an image is opened, the 3D volume (rendering) is shown.

- See **here** how to move the 3D image and objects
- See the **orientation tools** (lower right corner) to position the image at Axial, Coronal or Sagittal views
- See here how to adjust the **image 3D rendering quality**

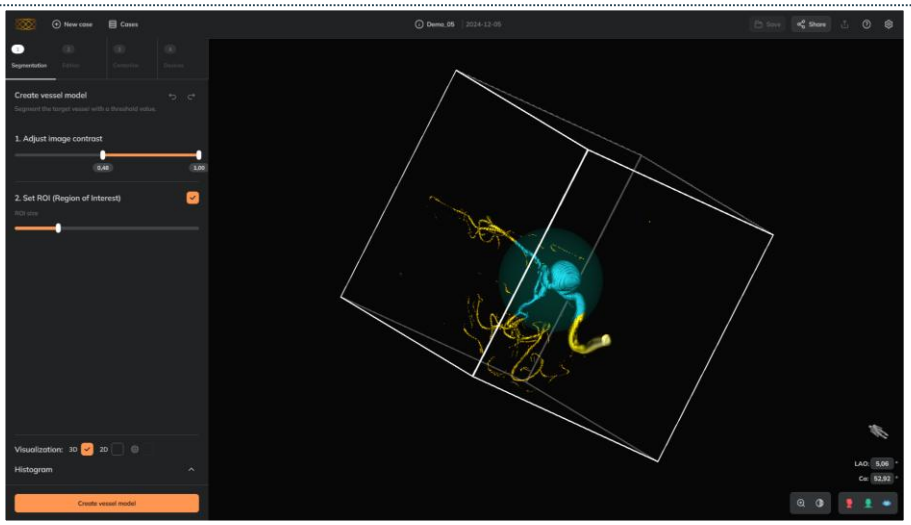
Image segmentation tools

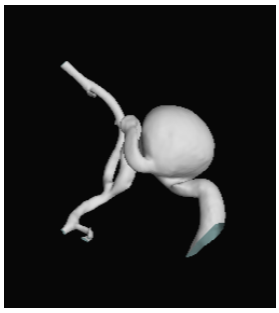
The user can create the vessel model by:

1. **Adjusting the image contrast**, moving the minimum value from the slider looking for an optimal visualization of the tissue corresponding to the vessel to be treated,
2. **Setting the ROI** (region of interest) activating (checking the box) and then positioning and resizing it (with the ROI size slider) in a way that the ROI sphere contains the desired aneurysm and artery to be treated,
3. Clicking the **Create vessel model** orange button at the bottom to obtain the vessel model (white surface).

Once the vessel model is created, the software hides the image and moves to next processing stage (**2: Edit vessel model**). If needed, the user can go back to stage 1 and repeat the previous 1-3 steps considering:

- If the vessel model is too wide: in **1. Adjust image contrast**, increase the minimum value from the slider
- If the vessel model is too thin: in **1. Adjust image contrast**, decrease the minimum value from the slider
- In **1. Adjust image contrast**, it is recommended to keep the maximum threshold always to 1.0.





Please note that if there are two separate vessels in the region being segmented, the software will segment the larger one. To segment the smaller vessel, a smaller portion of the unwanted vessel must be selected

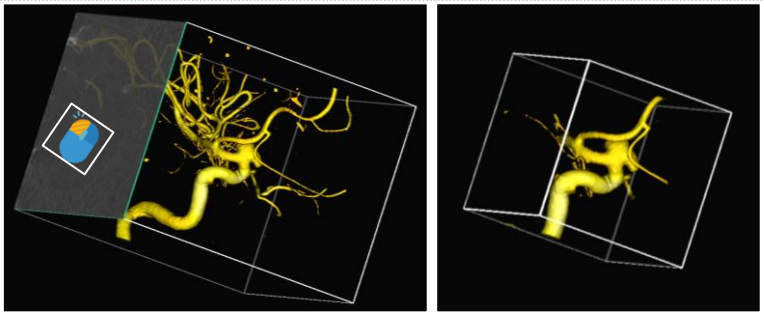
Optional tools

Crop the image

Crop the image to enhance the visualization of the vessel and aneurysm (see below two examples and the steps):

Cropping steps:

1. Place the mouse over one of the 3D cube's sides,
2. The slice is shown with transparency
3. Click on the left mouse button and drag the selected side of the cube towards its center.
4. Once a side has been cropped, the user can uncrop by dragging that side towards the outer part of the volume.



Cropping:

Example to see how the **image rendering quality improves** with cropping

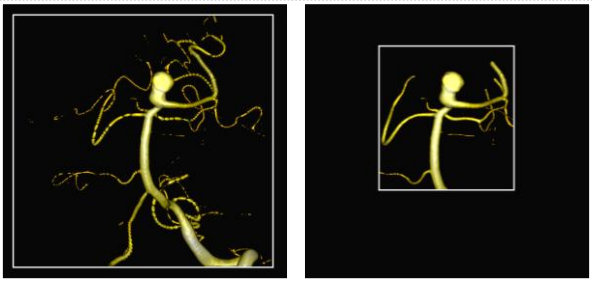


Image 2D view

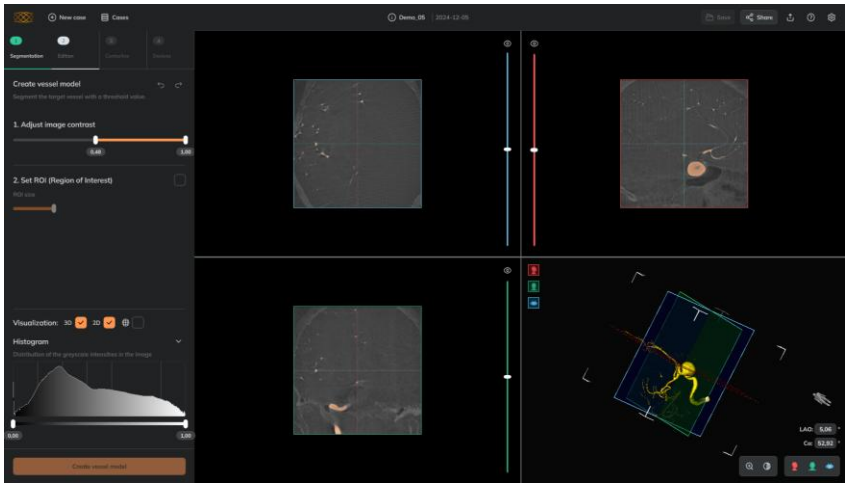
See image slices (2D view) to see the slices in axial, transversal and sagittal planes, as well as the histogram chart.

See image slices:

In visualization, **check the 2D** box to see the image slices

Functionalities and controls:

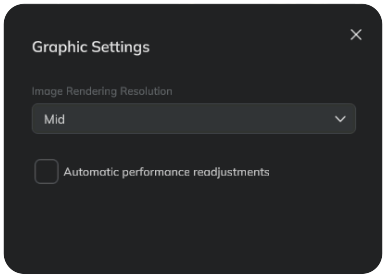
- **Go through the slices** (scrolling with the mouse wheel or using each vertical).
- **See/hide the threshold** painted pixels in orange clicking the eye icon for each view
- Adjust the image grayscale with the **contrast slider** to see the image darker or brighter.



Adjust image 3D render quality

In settings (upper bar, right corner), the image 3D rendering quality can be changed between Low, Medium or High.

☛	Chose Low for a better performance (image rotation, zoom)
⚠	Ankyras automatically sets the 3D render quality to Low if a bad software performance is detected
⚠	The intrinsic image quality does not change, it only changes the 3D render visualization



Edit the vessel model

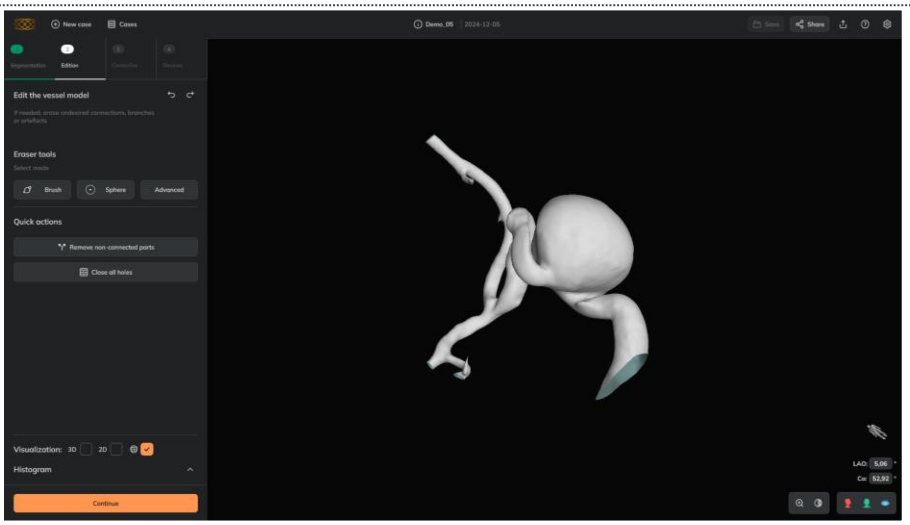
This stage is optional and allows to edit and clean the segmented vessel model or the VTK vessel model. The edition tools can be also used if a simulation is opened.

Edit vessel model		
Desktop	✓	2-Edit vessel model
Web	✓	2-Edit vessel model
MobileApp	✗	Not available

The **edit vessel model tools** allow erasing undesired connections, branches or artefacts in the vessel model. If the vessel model does not require edition, the user can click Continue to move to stage 3.

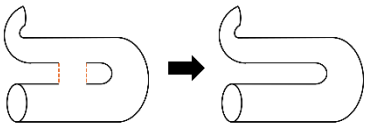
The tools allow to:

- **Erase tools**: to manually erase undesired parts of the vessel model with a Brush or Sphere.
- **Quick action tools**: Automatic tools to finish the cleaning processing (to remove non-connected parts and closing holes).
- **Undo/redo** actions with the arrows (upper right corner).
- **Visualization** tools: it's possible to see the image, in 3D or 2D.
- **Continue** if edition is not needed / when finished.



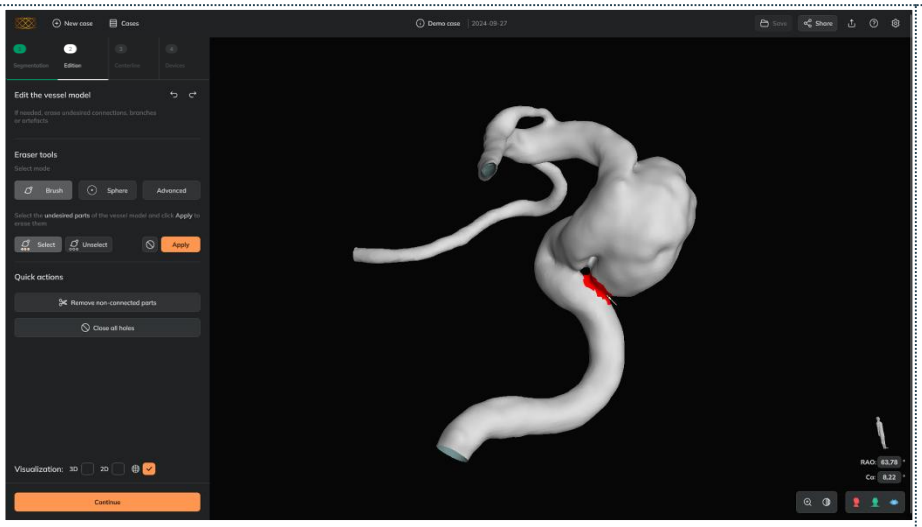
Brush

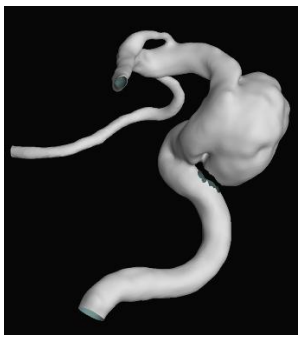
To remove imperfections and *opened connections* (those that have a free space within the connected model parts):



The user can:

- **Select** the vessel model cells (in red color) that wish to be removed,
- If needed, **unselect** some of the cells painted in red,
- Discard all selection,
- **Apply** the erase effect: remove all the mesh cells painted in red.



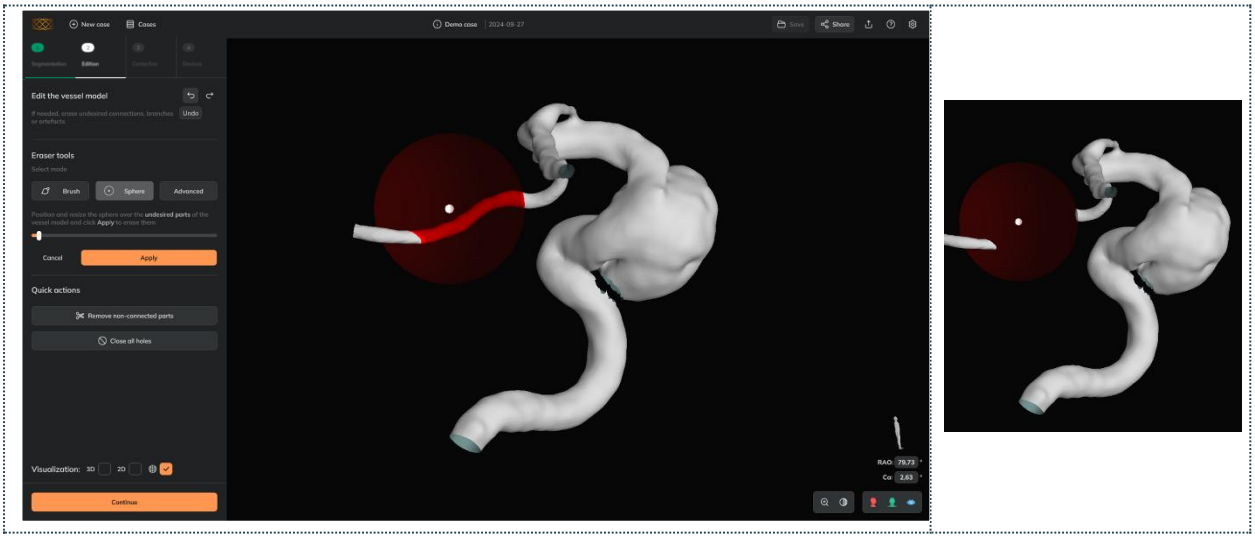


☛	**Recommended use**: erase all the undesired vessel parts and then use the *Remove non-connected parts* and *Close Holes.*

Sphere

To remove bigger parts of the vessel by selecting them with the red sphere. The user can:

- **Translate the sphere**: left mouse click over the sphere and move,
- **Resize the sphere**: using the ROI size slider or the right mouse click over the sphere and move up to increase the size; move down to decrease the size,
- Cancel the process,
- **Apply** the sphere erase effect: remove all the mesh cells contained in the sphere.

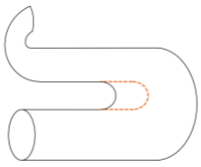
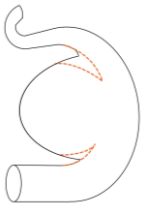


☛	**Recommended use**: erase all the undesired vessel parts and then use the *Remove non-connected parts* and *Close Holes.*
⚠	The software does not allow the entire 3D model to remove (it returns an error message).

Advanced brush

To remove **closed connections**. The *closed connections* are those that do not have a free space within the connected model parts (the connection completely fuses two parts of the model that are not connected in reality).

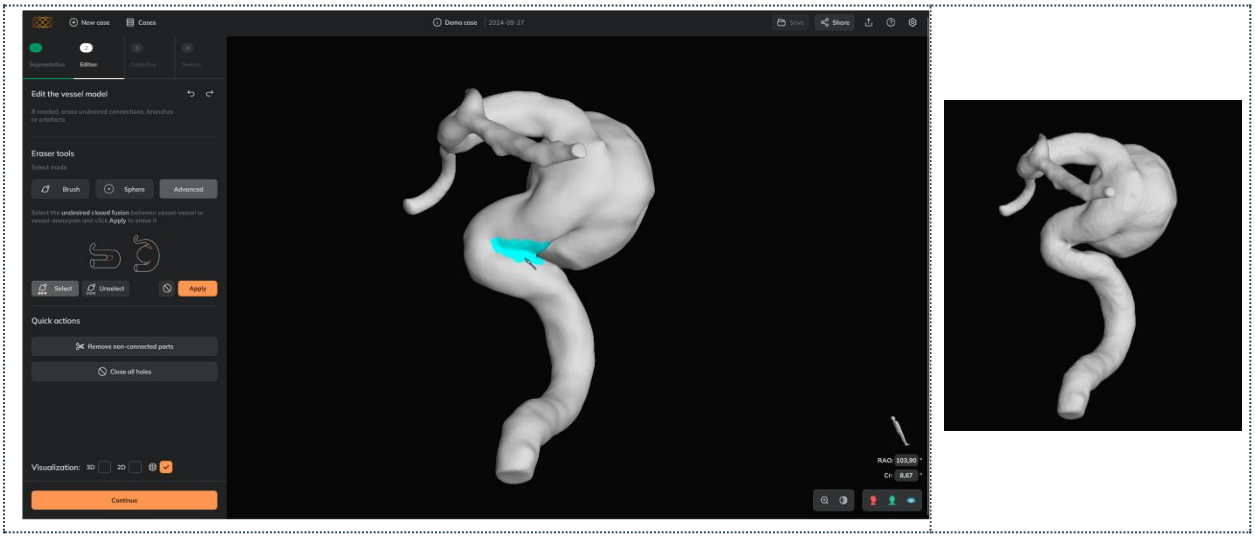
Two typical scenarios with closed connections that can be corrected with the *Advanced brush* (and not with the first *Brush*):

Vessel-vessel closed connection: can happen within the same artery when this has a very sharp curvature.	**Aneurysm-vessel** closed connection: can happen if the aneurysm is in the inner part of the vessel curve.
	

The user can:

- **Select** the vessel model cells (in cyan color) that wish to be removed,

- If needed, **unselect** some of the cells painted in red,
- Discard all selection,
- **Apply** the erase effect: remove all the mesh cells painted in cyan.



👉	**Recommended use**: before using the *Advanced brush*, check if the closed connection disappears by increasing the intensity value in **segmentation** (**1. Adjust image contrast**) while preserving the target vessel.
👉	**Recommended use**: select all the vessel model section to be removed at once and then click Apply.
👉	**Recommended use**: after using the *Advanced brush*, it is not needed to use the *Remove non-connected parts* or *Close Holes* because the resulting model is already a single closed surface.
⚠	Closed connections can not be removed with the first brush.
⚠	If the vessel model has multiple closed connections in different segments, each connection must be treated independently from the others (the *Advanced brush* effect must be applied as many times as closed connections are in the model).
⚠	Before using the *Advanced brush*, it is recommended to use the *Remove non-connected parts* tool and have removed (if any) the opened connections with the *Brush remove*.

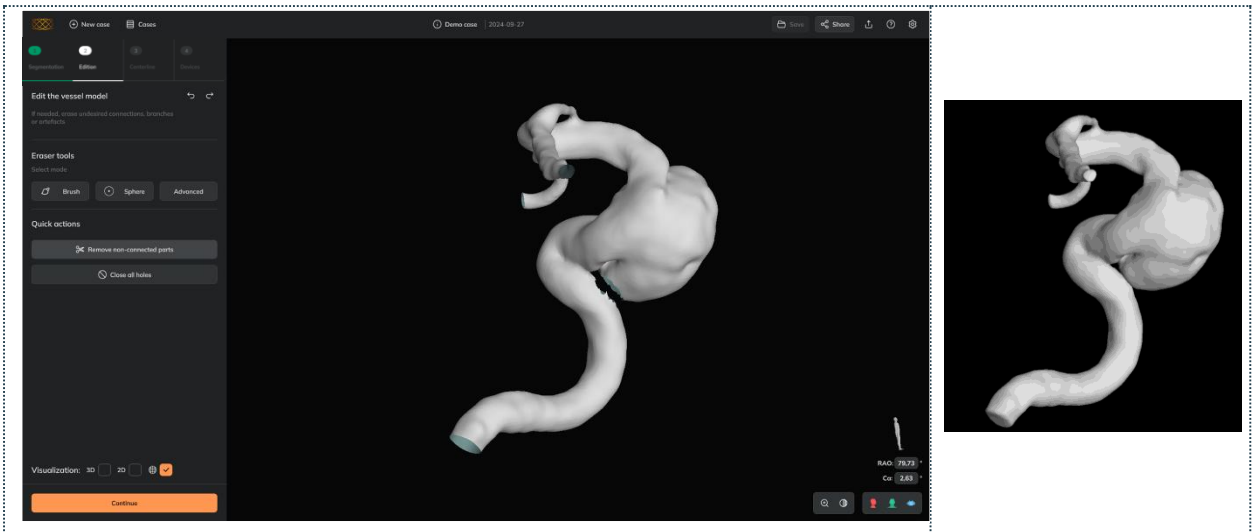
Remove non-connected parts

To remove surfaces that are not connected to the biggest (main) surface. The removing effect is applied directly when the user clicks the button.

👉	Recommended use: after using *Brush* or *Sphere* remove and before *Close holes*

Close holes

To close all the holes in the surface. The effect is applied directly when the user clicks the button. It is recommended to use this tool after using the *Brush remove* or the *Sphere remove* and *Remove non-connected parts*



👉	Recommended use: as a last edition step (after *Brush, Sphere* or *Remove non-connected parts*).

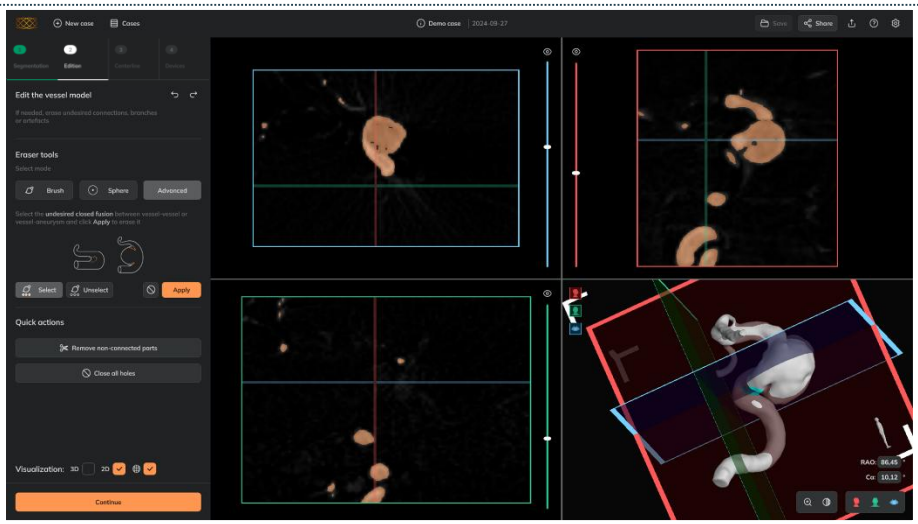
Undo / Redo

The user can undo/ redo changes applied with vessel model edition tools.

Other functionalities

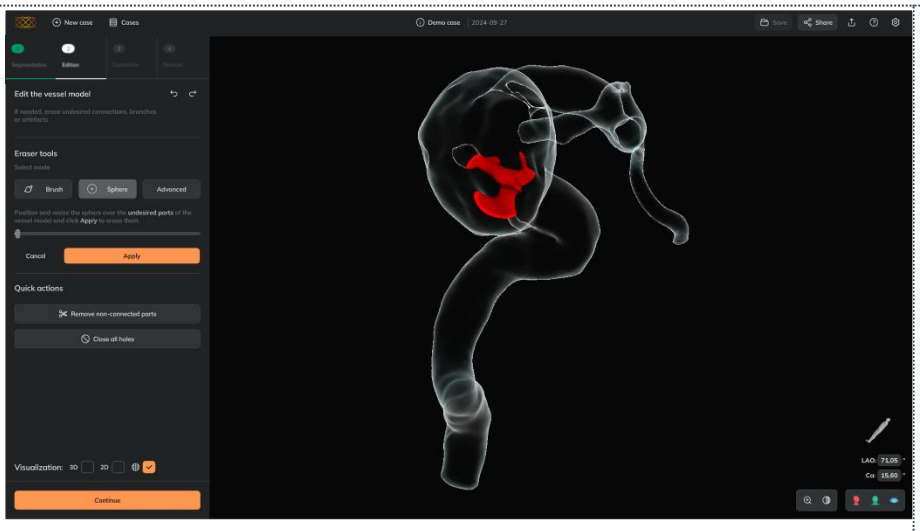
Image visualization

The user can visualize the image checking the 3D and/or 2D boxes. Checking the image might be helpful for complex anatomies to see in detail if a part of the vessel model should be erased or not.



Edit inner vessel model parts

The user can reduce the vessel model opacity to check if some parts of the model need to be removed. In **View tools**, see how to change vessel model opacity/transparency. For example, setting the vessel model transparent, the Sphere can be used to remove the inner undesired parts (in red):



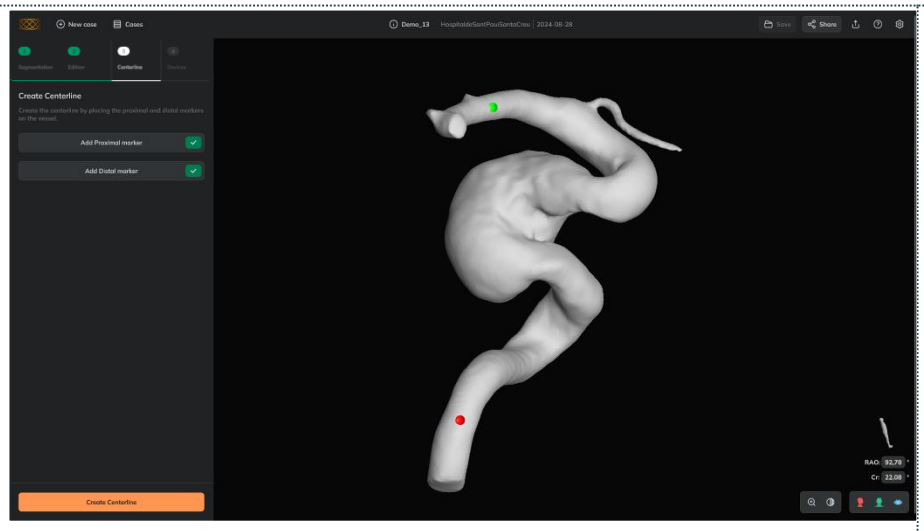
Create the vessel centerline

Create vessel *Centerline*		
Desktop	✓	In *3-Centerline*
Web	✓	In *3-Centerline*
MobileApp	✗	Not available

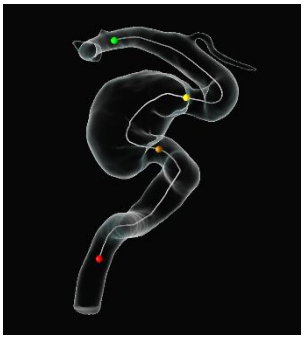
The centerline tools allow the definition of the vessel segment in which the morphology is going to be measured, and the braided devices are going to be simulated.

To create the centerline, the user needs to:

1. Click **Add Proximal marker** and click over the proximal part of the vessel (proximal point shown in red, 🔴)
2. Click **Add Distal marker** and click over the distal part of the vessel (distal point is shown in green, 🟢)
3. Click **Create Centerline**: the calculation can take from a few seconds to a couple of minutes depending on the size of the region),



Centerline result:



👉	Recommended: create a centerline longer than the vessel segment to be treated.
⚠	If centerline returns an error, it is recommended to go back to Stage 2, close holes and redo steps 1-3 above.

Vessel centerline results

Once the centerline is created, the Ankyras shows:

- Proximal marker in red: 🔴
- Aneurysm neck markers in orange and yellow: 🟠 - 🟡
- Distal market in green: 🟢
- Morphological charts (more information in **Vessel morphology results**)

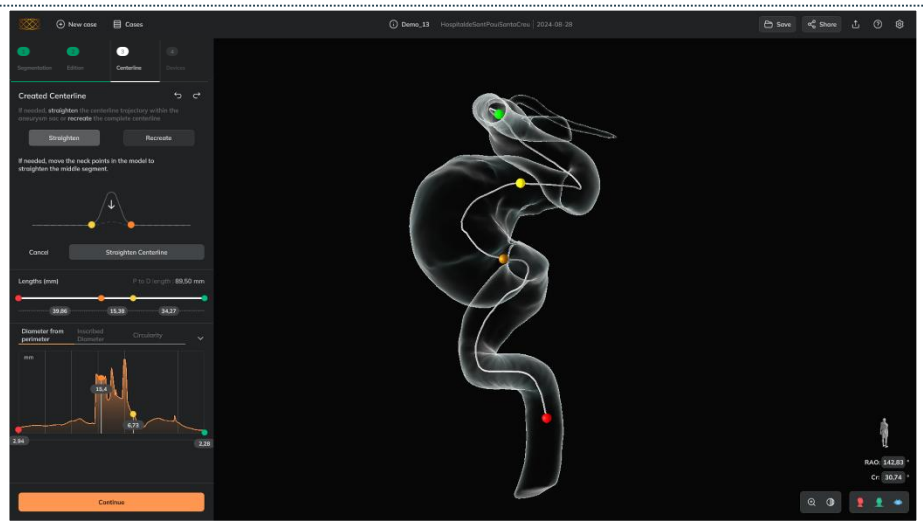
The user can move the points by dragging them along the centerline or the charts to do a vessel morphology analysis.

👉	Recommended: save the simulation once the centerline is created. See here how to save a simulation.

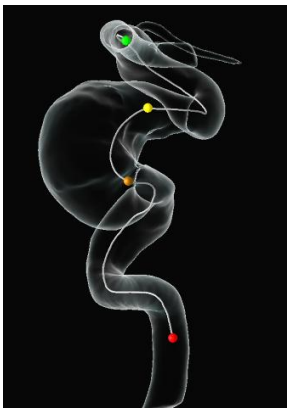
Edit the created centerline

If needed, once the centerline is created, the user can edit the centerline in two different ways:

- **Straightening the centerline**: The trajectory of a centerline segment can be straightened and smoothed (usually in the aneurysm neck) defining the segment with the neck points (orange and yellow markers) and clicking the Straighten Centerline button (see example below).
- **Recreate** the complete centerline by Adding again the Proximal and Distal marker and click Recreate centerline.
- **Undo/redo** the user can undo/ redo changes applied with centerline tools.



Straighten centerline result: segment between ● - ● is straightened and smoothed

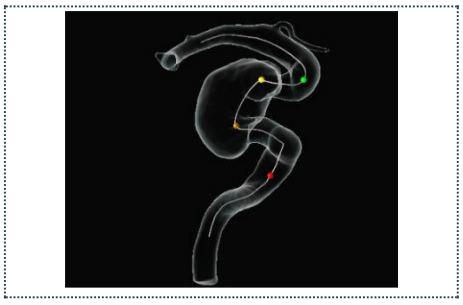


Vessel morphology results

The user can explore the vessel morphology through the charts that appear once the centerline is calculated. The charts contain the anatomical information along the centerline as well as the proximal, neck and distal markers, which can be moved over the charts (or along the centerline) to explore the vessel morphology descriptors at the desired vessel positions.

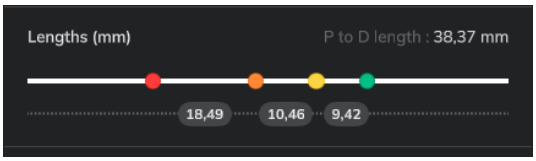
Vessel morphology		
Desktop	✓	In *3-Centerline*, or *4-Devices*
Web	✓	In *3-Centerline*, or *4-Devices*
MobileApp	✓	Click *Charts* icon (Lower right corner)

The charts contain the following vessel morphology descriptors in the 4 movable markers:

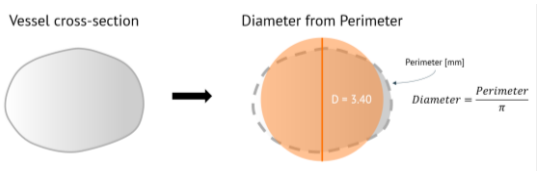


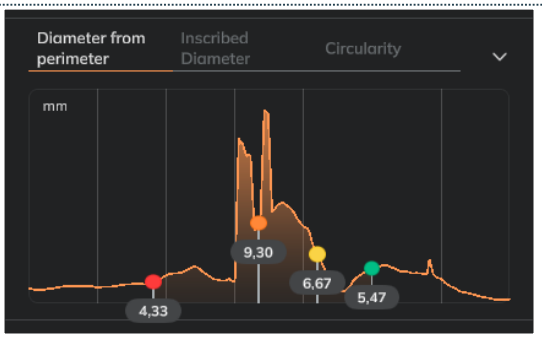
- **Segments lengths [mm]:** lineal chart showing the distance between the markers, indicating the:

  🔴-🟢: Total length (Proximal to Distal length)
  🔴-🟠: Proximal segment length
  🟠-🟡: Aneurysm neck length
  🟡-🟢: Distal segment length

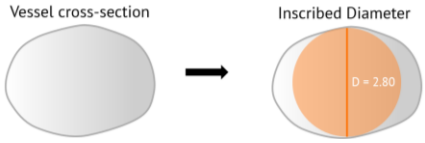


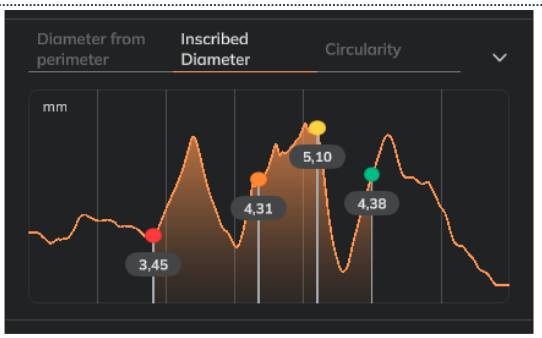
- **Diameter (from perimeter) [mm]**: diameter calculated with the cross-section perimeter:



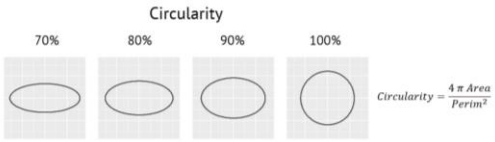


- **Diameter (Inscribed) [mm]:** diameter of the circumference inscribed in the vessel cross- section:





- **Circularity [%]**: quantifies how much the cross-section shape approximates to a perfect circle. Circularity 100%: the vessel cross-section is a perfect circular; Circularity 0%: the vessel cross-section is completely flat; Intermediate values: indicate that the vessel has an elliptical shape:



☛	Recommended: select the FD diameter based on **Diameter from perimeter** to ensure that the device has enough surface to get good vessel apposition.
☛	Recommended: check the **Inscribed diameter** to know the minimum diameter from the vessel.
☛	Recommended: check **Circularity** to: • Analyse how circular/elliptical is the artery (usually vessels have a circularity around 95%) • Identify the segments where device apposition can be more complicated, • Chose a safe **landing zone** (as circular as possible) in the proximal end.

Simulate devices

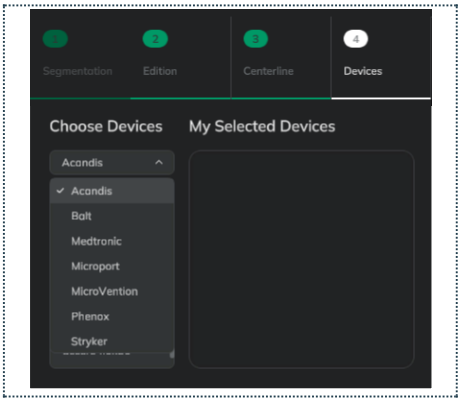
Stage 4, *Devices*, allows the user to select the desired braided devices while the vessel morphological information is visible in the charts.

☛	Recommended: Place the **distal marker** ● at the desired device distal position (the simulated devices will start from that marker).

Simulate devices		
Desktop	✓	In *4-Devices*
Web	✓	In *4-Devices*
MobileApp	✓	Click *Devices* icon

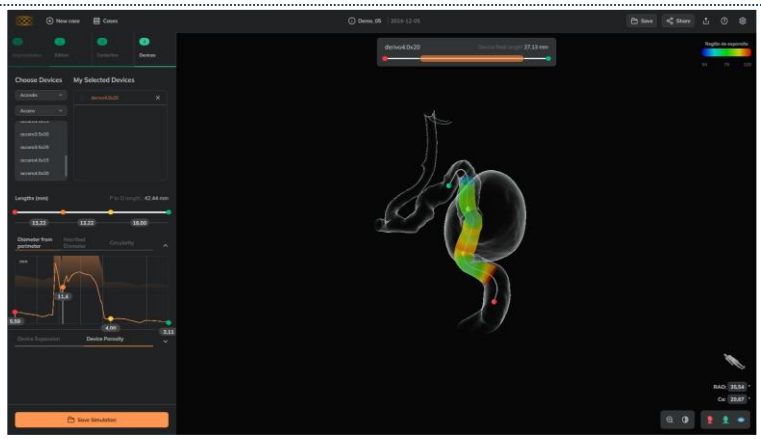
The user can add devices to ***My selected devices*** list from the ***Choose Devices*** dropdowns and list:

- **Select manufacturer:** the first dropdown menu allows the manufacturer of the desired device among the ones indicated in section **Flow Diverter devices** as shown in following caption:

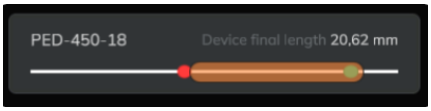


- **Select Device:** the second drop-down menu allows to select the desired device brand from the selected manufacturer among the indicated in section **Flow Diverter devices**:

- **Select sizes**: click on the desired sizes from the ***Choose Devices*** list. Each time the user clicks on a new sizing, this device is added to the ***My selected devices*** and simulated in the vessel model. The user can select devices from different brands and manufacturers
- **My Selected Devices**: List of all simulated devices. The device highlighted in orange is the one that is active and visible. By default, the expansion of the device is shown over the device surface with a colormap (see more details about the expansion **here**).

Desktop/Web	MobileApp
	

- **Adjust device position**: use the Device slider control to move the active device. The final device foreshortening due to vessel constriction at that position is indicated in the box and changes as the user moves the devices with the slider:



- **Remove a device**: the user can remove devices from ***My selected devices*** list by clicking with the **X** icon.

⚠	The *Devices* panel is completely functional for the registered users and partially functional for the **non-registered users** (that can open simulations through a shared case link).
⚠	**Non-registered** users can open shared simulations and see the sizings in the *My selected devices* list (selected by the registered user who prepared and shared the simulation). The non-registered user will be able to see those devices and adjust their position.

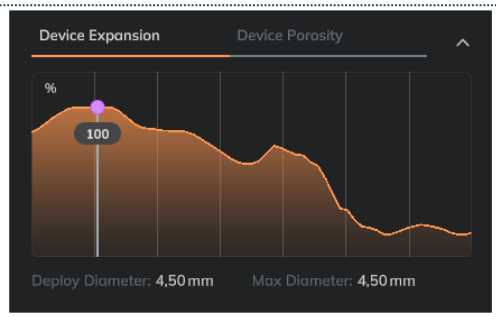
Device expansion and porosity

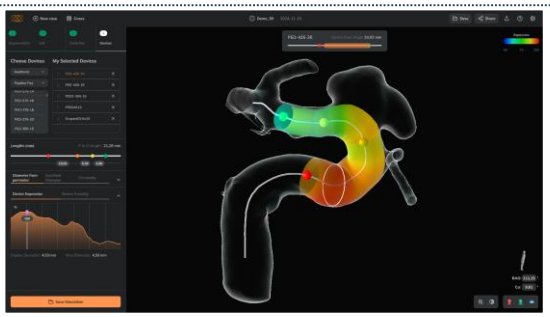
The user can explore the simulated expansion values and the simulated local porosity values of the active device in the charts that appear below the vessel morphology charts (or as a next chart for the MobileApp).

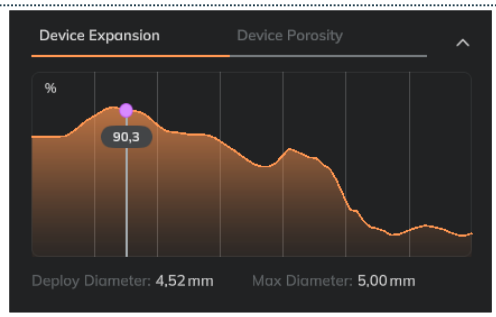
Expansion

When a device is simulated, by default, the expansion is shown at each cross-section over the surface with a colormap. The expansion is calculated as a percentage of the device final diameter with respect to its maximum and represented according to the colormap: red colors indicate that the device is fully expanded (100%, not anchored to the vessel wall) while blue colors indicate that the device is quite constricted by the vessel (50% or less expanded).

The user can expand the ***Device Expansion*** chart and analyze in a more detail the expansion values with the graph. The user can move the purple marker along the graph (the white ring above the device surface moves) to know the expansion value in a certain device cross section.





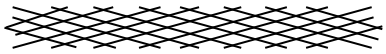
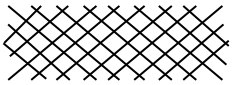
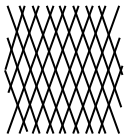


☛	Recommended: select the FD diameter with expansion values around 80-90% (yellow, orange colours) to ensure good device expansion and apposition to the vessel.
⚠	Green colors don't suggest "good expansion" and red colors "bad expansion". The colors represent the expansion values as indicated in the colormap legend.

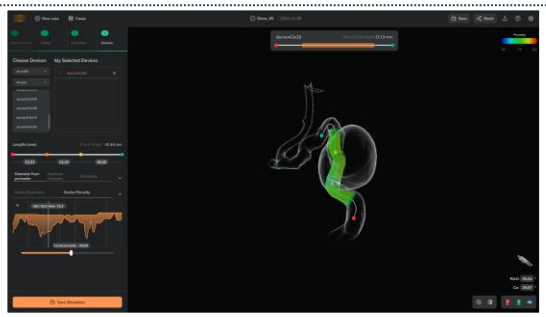
Local porosity

The user can expand the ***Device Porosity*** chart and analyze in a more detail the local porosity values with the graph.

Porosity is the device parameter that indicates how porous (free space) is the device in a certain position. The porosity ranges from 0 to 100 and would be the inverse parameter to *coverage ratio*:

Low porosity (high coverage):	High porosity (low coverage):	Low porosity (high coverage):
		

In Ankyras, porosity is displayed on the surface of the simulated device as shown by the colormap: The blue color indicates a porosity close to 50%, the red indicates a porosity of 100% (impossible value). Normally the FD devices have a porosity around 70-80% (represented with green colors):



- The **Device porosity chart** shows two lines: the minimum and the maximum porosity values for each device cross-section (the local porosity might be different within the cross-section depending on device curvature).
- The user can move the vertical marker along the graph (the white ring above the device surface moves) to know the minimum and the maximum porosity in a given device cross-section.
- The user can analyze the **local porosity** in a more detail by moving the slider below the graph (the white pointer within the white ring over the device surface moves) for a local evaluation of the porosity.

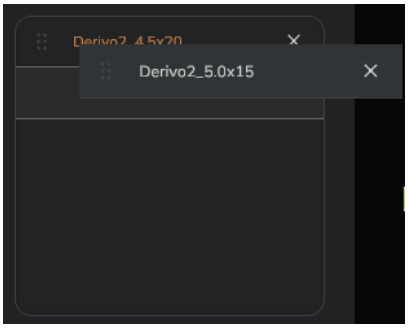
Telescope devices

The user can see and/or telescope multiple devices:

Telescope		
Desktop	✓	In *My Selected Devices* list, drag and drop
Web	✓	In *My Selected Devices* list, drag and drop
MobileApp	✓	In *Devices*, *See Devices*, drag and drop

- Telescope: Add the two (or more) devices in the *My Selected Devices* list and then drag the device to be telescoped (child) towards the first implanted device (parent) from the same list (caption below on the left).
    - Telescoped structure: the "parent" device is implanted first, the "child" device is telescoped inside the parent device.
- Move devices: the two devices can be moved with the slider but only one device (the active device highlighted in orange in *My Selected Devices list*) can be moved at a time.
- Device colors: each device has a single colour to be better differentiated.
    - Expansion colormap over device surface can be visualized by opening the *Device Expansion* chart.
- Untelescope: drag the device out from the structure in the list.
- Save: the telescoping structure is not saved in the simulation. The user will need to drag one device into another one in the device's list.

My Selected Devices list:



⚠	When telescoping multiple large devices (e.g., longer than 30 mm) over a long centerline, a WebGL memory error may occur. This happens because the computational load exceeds WebGL's processing capacity. If you plan to simulate telescope large devices (longer than 30mm), we recommend using the mobile or standalone platform instead of the web version.
⚠	If you encounter the following error while telescoping large devices in WebGL "An error occurred running the Unity content on this page. See your browser JavaScript console for more info. The error was: RuntimeError: table index is out of bounds." please refresh the page and try running the simulation again.

Save simulation

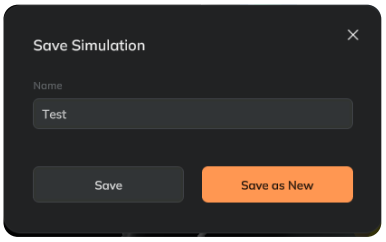
The user can save the simulation as an attachment to the case clicking on the ***Save simulation*** (orange button) once the devices have been selected in stage 4 or beforehand, once the centerline is created, with the ***Save*** button at the right side of the upper bar.

Save		
Desktop	✓	In the upper bar (right side) or as last step in *4-Devices*
Web	✓	In the upper bar (right side) or as last step in *4-Devices*
MobileApp	✓	Click *Menu* (Lower left corner) and click *Save case*

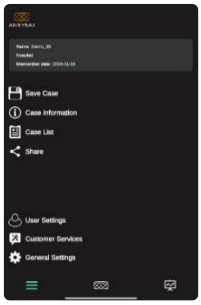
The user can define the simulation's name and:

- **Save as new**: a new attachment will be added to the case,
- **Save**: replacing the current opened (and previously saved) simulation

Desktop / Web



MobileApp



Once a simulation is saved, the user can open it from the **Case information panel.**

⚠	A registered user can Save as a New, a simulation attachment from a case shared by a colleague belonging to the same institution. This applies only for the online solution, see here how to **share** simulations.

Share a case

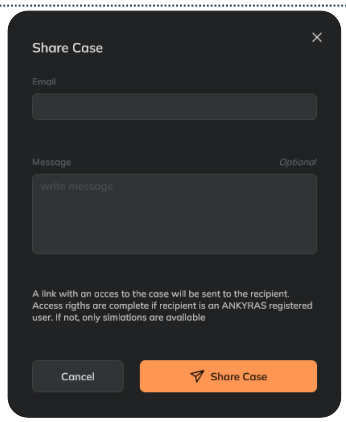
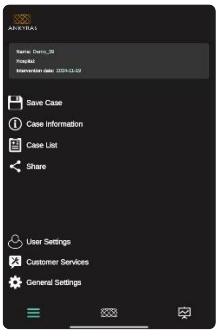
The ***Share*** button allows sharing the case with others, registered or non-registered people.

⚠	Everybody can open a simulation attachment from a shared link. Instead, medical image attachments are protected for registered users only and within the same institution.

Share		
Desktop	✗	Not available
Web	✓	In the upper bar (right side) or in *Case information* panel
MobileApp	✓	Click *Menu* (Lower left corner) and click *Share*

The user, owner from the case or from the same institution as the case owner, has the sharing button enabled in the Ankyras Web platforms.

The sharing panel allows to introduce the email of the recipient(s). The user can send a description, this will be attached in the email along with the link that will allow the receiver to directly open Ankyras (Web or Mobile App depending on the platform used).

Web		MobileApp
		

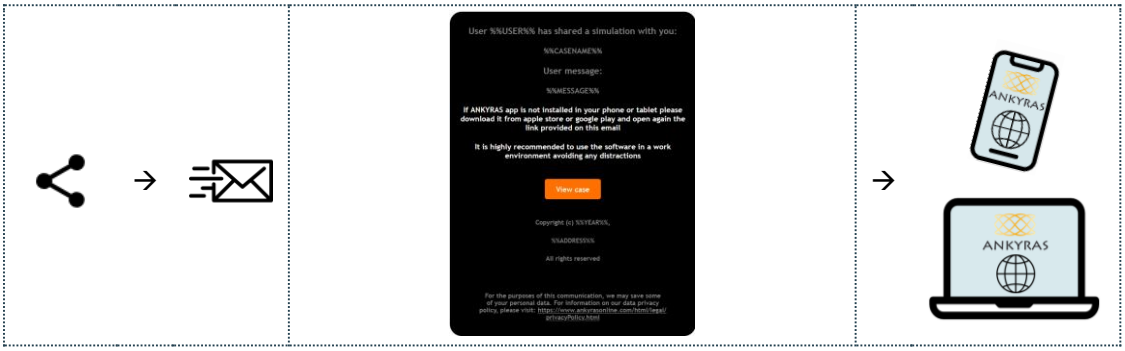
⚠	The user who is sharing must know that the whole case will be shared, not only one simulation. The user who receives the case, if not registered, will have some functionalities restricted.
⚠	A registered user can Share a simulation from a case shared by a colleague belonging to the same institution.

Open a shared case

Everyone (registered or non-registered Ankyras users) can open an Ankyras simulation shared through a link (clicking the *View case* button in the mail). By clicking the *View Case* button, Ankyras is directly opened (Web or MobileApp) and shows the *case information* panel.

Any user (registered or not) can open the simulations attached to the case and:

- View and interact with the 3D model and centerline of the segmented vessel,
- See the Charts to know the morphological parameters of the vessel,
- View selected simulated devices and adjust their position along the centerline,
- View the foreshortening, expansion, and porosity of selected devices.



If the user that is opening the shared case is a registered Ankyras user (and is logged in), the user has all Ankyras functionalities enabled, so the user can also:

- Open the simulations attached to the case and edit the list of simulated devices (add or remove devices),
- Open the images and/or VTK models, create and save the simulation.

Export a simulation

The ***Export*** button allows downloading of the vessel model, the centerline and the active simulated devices.

A zip containing the files in VTK format is downloaded.

Export		
Desktop	✗	Not available
Web	✓	In the upper bar (right side)
MobileApp	✗	Not available

⚠ A registered user can Download a simulation from a case shared by a colleague belonging to the same institution.

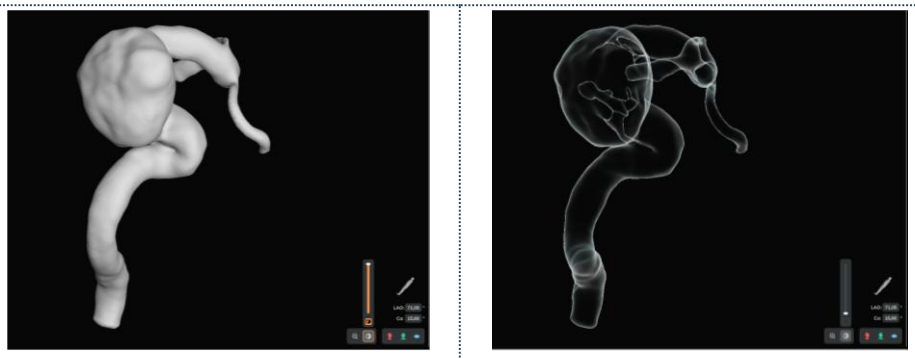
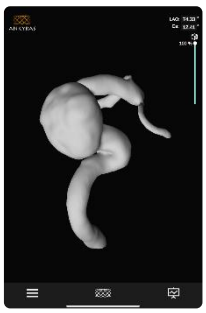
Opacity and zoom		
Desktop	✓	Bottom right corner
Web	✓	Bottom right corner

View tools

MobileApp	✓	Upper left corner (only the vessel opacity)

The view tools consist of:

- **Adjusting zoom** (especially if the user doesn't have a mouse): click on the magnifying glass and move the slider. In the MobileApp, the zoom is controlled by magnifying/reducing with 2 fingers.
- **Vessel opacity:** The user can Change the vessel model opacity by adjusting the slider on the left.
    - Control the **front/back** surface opacity: Click on the surface icon to only change the opacity of the front surface only, thus allowing the visualization of the model's inner part.

Desktop/Web	MobileApp
	

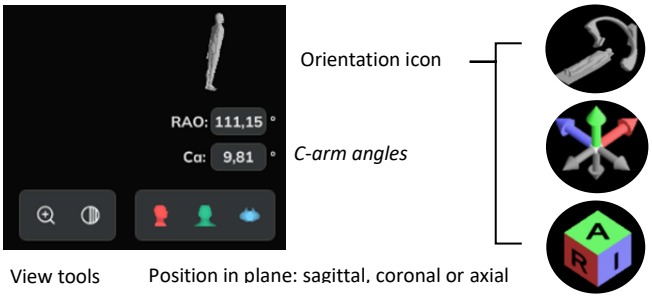
Orientation tools

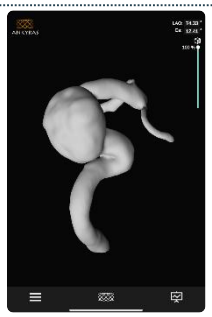
The orientation tools allow to:

Opacity and zoom		
Desktop	✓	Bottom right corner
Web	✓	Bottom right corner
MobileApp	✓	Upper left corner (only the C-arm angles)

- **Position** objects in sagittal, coronal or axial plane,
- **C-arm angles:** The user can enter the values of the LAO/RAO & Cr/Ca angles related to the orientation of the image acquisition system (C-arm) to display the image in a certain orientation or use the sliders to change the values.
    - To switch from RAO to LAO or from Cr/Ca the user must enter the negative sign "-" in front of the angle value.
- **Orientation icon:** click the icon to see the it as a patient, C-arm with patient, spatial axes or cube with anatomical directions.

Desktop/Web	MobileApp





Edit an existing simulation

An Ankyras registered user can open a previously saved simulation and edit it by:

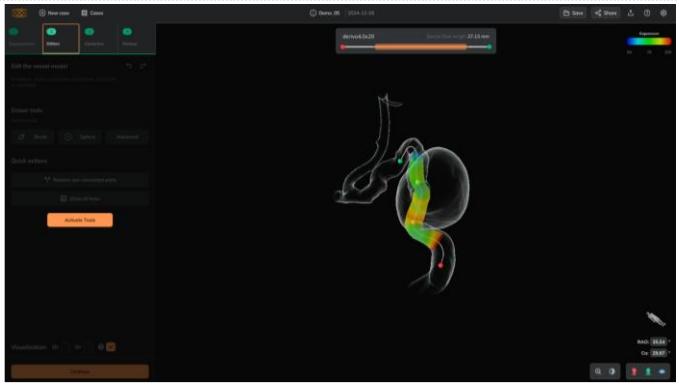
Edit simulation		
Desktop	✓	Edit Vessel model, Centerline and Devices
Web	✓	Edit Vessel model, Centerline and Devices
MobileApp	✓	Edit Devices only

- Editing the *selected devices list*,
- Editing the vessel model with the *Edit* tools. In that case, the user will need to calculate again the centerline afterwards,
- Editing the centerline (correct it or create a new one) with the *Centerline tools.*

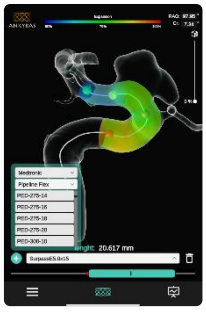
In the last two points the user needs to click the *mesh tools* or *centerline tools* and click the *Edit Simulation* button. These types of editions are only available for Web and Desktop platforms (not the MobileApp).

Finally, the user can save the simulation as a new attachment or replace the one that was opened.

Desktop/Web



MobileApp



Customer Service

Desktop	✓	Upper bar, right side
Web	✓	Upper bar, right side
MobileApp	✓	Click *Menu* (Lower left corner) and click *Share*

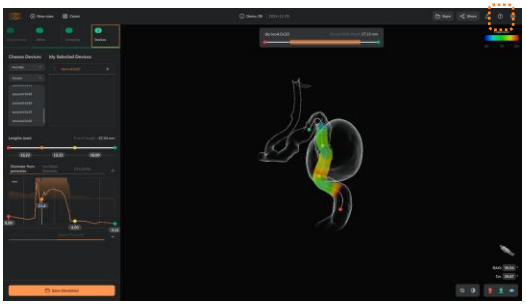
Customer Service Tools

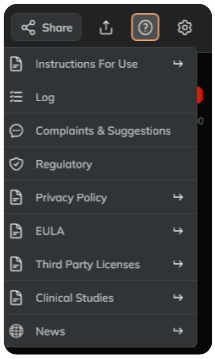
With the Customer Service tools (for registered users only)

the user can contact the Ankyras support team to send a complaint, ask a question or send a suggestion and also access the following Ankyras documentation:

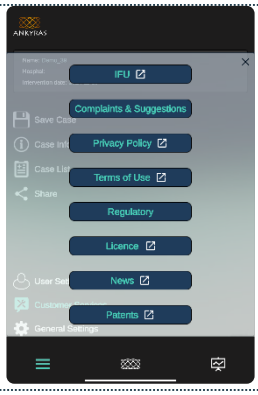
- Instructions for Use
- Log
- Complaints and suggestions
- Regulatory (labelling)
- Privacy Policy
- EULA
- Third Party Licenses
- Clinical Studies
- News (Mentice webpage)

Web



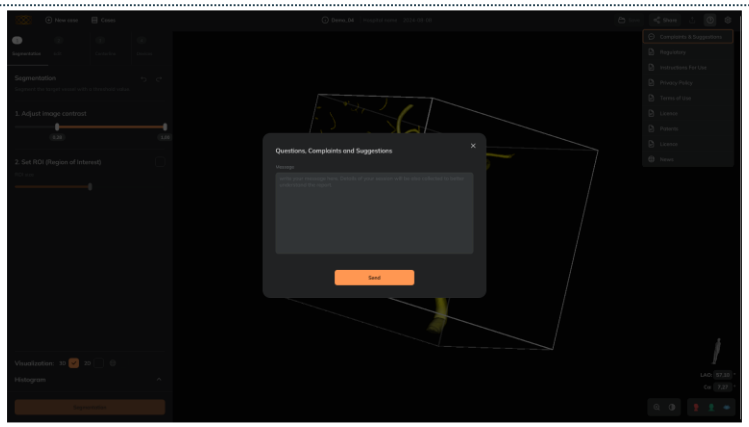


MobileApp



In **Complaints and Suggestions**, the user can send a message to the Ankyras team reporting a problem/question related to the case opened. This option is not available on the Desktop platform.

Web



👉	The user can contact the Ankyras team through **Ankyras@mentice.com** if support is needed.
👉	Case support: If the user uploaded the case in Ankyras Web, the Ankyras team can provide case support by receiving the case link through the sharing functionality.

Cybersecurity

Medical device safety is a shared responsibility among manufacturers and users, including healthcare facilities, patients, providers, and medical device manufacturers. Failure to maintain cybersecurity can result in compromised device functionality, loss of data (medical or personal), data availability or integrity, and even exposing other connected devices or networks to security threats.

The protection of information from unauthorized access is the responsibility of each user. Therefore, ANKYRAS must be used on computers that at least comply with the minimum system requirements and meet the cybersecurity controls listed below.

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 ANKYRAS is installed.
2. User is committed to define a strong password by using a combination of uppercase, lowercase, numbers and special characters.
3. In ANKYRAS Standalone, users should protect the ANKYRAS database from unauthorized access because the local data contained in the ANKYRAS database contains private patient information.
4. In ANKYRAS WebGL and Mobile App, users must avoid connecting to public or non-trusted private networks.
5. It is highly recommended to use the software in a work environment avoiding any distractions.
6. All network communications are done using user credentials, data and service backups are continuously done in order to being able to recover the service in the event of a catastrophe.
7. Users must regularly install and maintain software updates, security patches and malware detection (antivirus).
8. Users should use antivirus and malware software and should run additional scans periodically.
9. All users must use a firewall and a session lockout password protected screen saver due to operating system idle timeout.
10. Users must disable the "autorun" functionality of USB, CD/DVD and all removable devices. Therefore, a removable device that may be infected by a virus can be detected in advance and cannot be used to automatically run, activate, or load this virus into the operating system.
11. Users should lock the computer when not using it and setup the screen saver to lock the screen after a period of inactivity.
12. Users must use ANKYRAS Mobile App in work devices or in devices having minimum security measurements in order to avoid data access after a subtraction.

Local Data Base

ANKYRAS stores all patient data using a centralized database. This database is stored in the local hard disk of the computer where ANKYRAS has been installed into a hidden location at the specific user's folder of the computer.

When processing a patient with ANKYRAS, the user imports a DICOM image of the patient, processes it and stores the processed data as a new case in the local database. 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).

This local database is shown as a list of the processed cases. The user can open an ANKYRAS case again for reviewing purposes.

Security Policy

It's strongly recommended to establish a security policy to regulate the use of ANKYRAS in your institution. This security policy must specify the measures to be applied in order to minimize the risk of a personal data security breach.

These measures may include the description of the data stored in the devices, authorizing only those that are strictly necessary, maintaining an inventory of these devices, guaranteeing the security of these devices and/or equipment that are connected to them, and to train and spread awareness among employees regarding risks, encryption and backup copies.

In the following sections we provide a set of recommendations to be considered when establishing this security policy.

Protect access to ANKYRAS

Use the Windows User Access Control to protect the access to the personal patient information stored by ANKYRAS from unauthorized access. Create a Windows User Account for each user that should have access to ANKYRAS.

A good password policy needs to be established to access the ANKYRAS. Utilize strong passwords and avoid common words and passwords which are the same for each device and vulnerable to public disclosure. Users are requested to take steps to protect the secrecy and privacy of the passwords and user credentials used to access ANKYRAS.

Lock the computer when not using it and setup the screen saver to lock the screen after a period of inactivity.

The launch of ANKYRAS is protected by a license file associated to a unique user and for a unique computer, if the user wants to use the license on another computer, he needs to contact ankyras@mentice.com. This user will download the license file in ANKYRAS personal folder of the Windows user.

Encryption

Use the built-in feature of Windows 10 for device encryption in order to prevent unauthorized access to the ANKYRAS data.

Backup copies

Periodically backup the Database to avoid the loss of data availability.

Update your device

Update the device where ANKYRAS is installed, including the security patches and improvements of the operative system and the malware (antivirus) detection on a regular basis. Establish a routine of frequent updates that is documented and traceable.

Antivirus

Run anti-virus and malware software on a regular basis.

Unauthorized third-party applications

Disable "auto run" functionality of the USB and CD/DVD devices to prevent the installation of unauthorized third-party software applications.

Expose to services on the Internet

Define a strict policy of the services exposed on the Internet in the computer where ANKYRAS is installed, use a firewall and avoid connecting to public networks.

Data security Breach

Establish an action plan for a rapid and effective response in case of data security breach. This action plan should be in accordance to the legislation that applies to the country of the customer.

Remote measurements

ANKYRAS WebGL and the ANKYRAS Mobile App software application are accessible online from the web browser or from the application downloaded from the mobile store. This software works with a remote host server in Germany. The company that provides this hosting service presents all the necessary ISO certifications for data protection and is up to date with all cybersecurity regulations. All communications with the server use https protocols and all personal transferred data is encrypted.

Troubleshooting and maintenance

In the event of a problem, contact Mentice Spain S.L. for assistance.

The Ankyras software has a useful life of 5 years, during which the company makes the necessary updates for its operation, considering the obsolescence of the equipment on which the software runs. The characteristics of the hardware and/or software on which the platform runs may undergo significant changes during its useful life (5 years) in accordance with the EN62304 standard. For this reason, software functionalities that may limit the life of the software are evaluated during the development process.

After 5 years, the user should be responsible for uninstalling the ANKYRAS software product in the Desktop and Mobile App platforms. To uninstall the ANKYRAS product, follow the steps indicated by your device manufacturer.

Your institution's IT department should be responsible for maintaining the computer where the software runs.

All studies processed by Ankyras Web are stored in a remote database that is regularly maintained.

The database contains medical images analyzed by the software. When a new case is created in the database, patients' personal information (such as the patient's ID or name) can be stored in the case of non-anonymized DICOM files. Please take appropriate measures to protect this data in accordance with the laws of your country. The treatment of patient data is regulated according to the Ankyras privacy policy, accessible through the web application accepted during the registration process.

Credentials

Ankyras can only be used with credentials provided by Mentice Spain S.L.

Update Ankyras

When a new version is released, a notification email is sent to the users with active accounts summarizing the changes and providing information on how to access the updated version:

- Ankyras Web: the link to Ankyras automatically redirects to the new version.

☛	**Recommended**: Clear the browser cache before accessing the new released version. To clear the cache, follow the steps recommended by your browser provider.

- Ankyras Desktop: a link is provided in the email to download the new installer.
- Mobile App: the app update will be either automatic or manual, depending on user's settings for accessing the store (App Store or Play Store).

Annex A: DICOM image quality

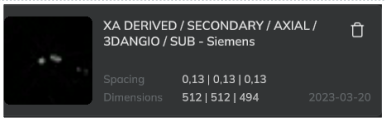
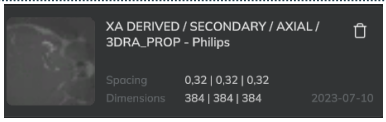
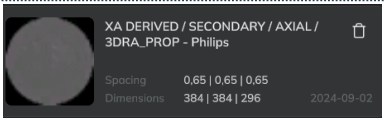
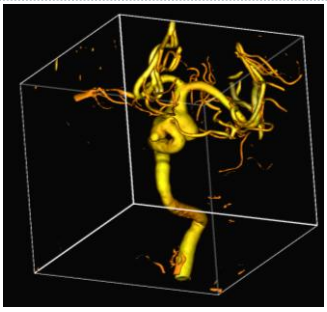
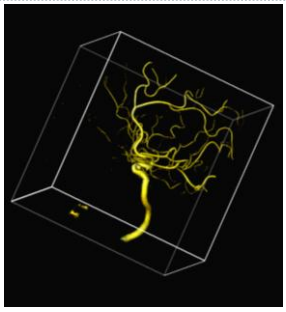
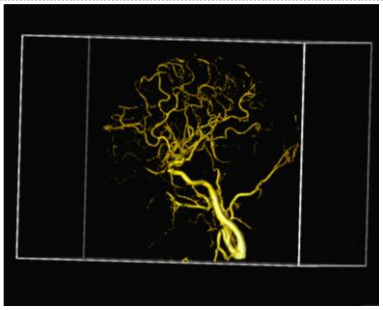
To create a reliable simulation with Ankyras, the DICOM has to be a 3DRA modality image. Also, the DICOM must meet some requirements in regard to the image quality concerning:

- Spacing and distance between slices,
- Contrast level in the vessel,
- Artefact caused by another implanted device.

Spacing and distance between slices

The spacing (distance between pixels and slices) determine the image resolution. For a proper Ankyras use, the DICOM spacing must be in the range of: **0.15-0.5mm**. Out of this range, if spacing is:

- Smaller than 0.15mm (image has higher resolution): the image will be very heavy thus Ankyras might be slower,
- Bigger than 0.5mm (image has lower resolution): the image will not have enough quality to obtain a realistic vessel model.

Spacing to small (< 0.15mm)	Good quality (0.15 – 0.5mm)	Spacing too high (>0.5mm)
		
		

Vessel contrast level

The target artery and aneurysm must have enough good contrast level to see the vessel morphology and aneurysm properly. The contrast must completely fill the vessel and the aneurysm. Examples:

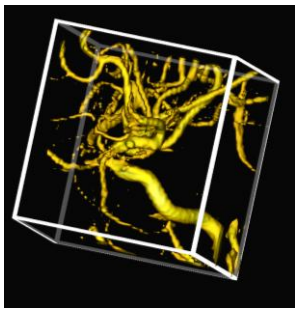
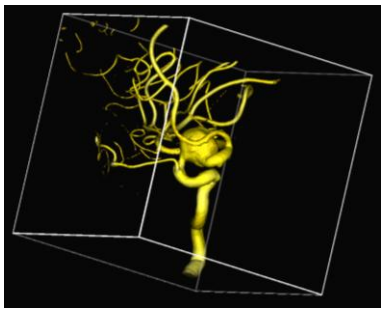
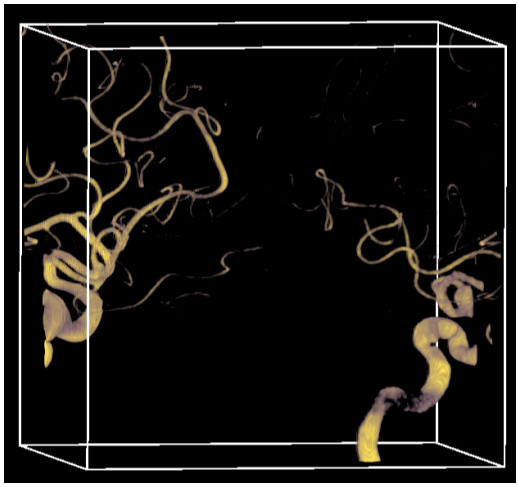
Low contrast level (bad quality image)	High contrast level (good quality image)
	

Image artefact

If the patient has a device implanted, it might be that the DICOM image does not have enough quality to create a realistic vessel model. Specially if the device that is already implanted is in the same vessel/aneurysm that is going to be treated.

Other

The DICOM must be exported correctly, this is an example of a bad exportation:

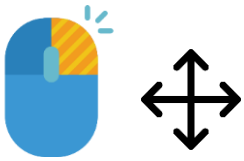


Annex B: interaction with 3D view

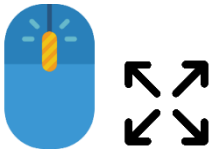
The user can move the 3D objects in Ankyras with the following **mouse controls**:

Rotation

Translation



Zoom



(the wheel must be clicked, not scrolled)

Without a mouse, rotation and translation can be controlled with the touchpad's left and right click. For controlling the zoom, the zooming slider (lens button) in the **View tools** is available.

Either with a mouse or with a touchpad, always start out of the 3D object (image or vessel model) for a proper rotation/translation/zoom control.