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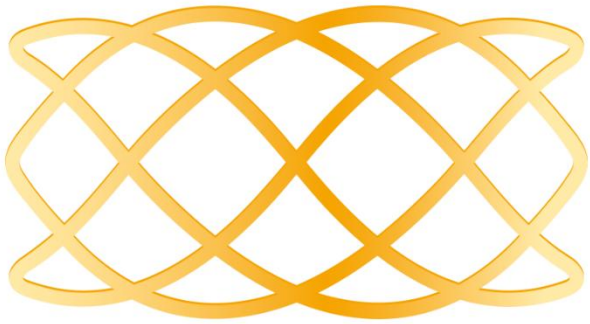
User manual



ANKYRAS

REV: 2025-08-07

ANKYRAS is a software tool for visualization and segmentation of cerebral blood vessels and computational modeling of the placement of specific validated flow diverters for preoperational planning and sizing for neurovascular interventions and surgery. If you have any questions about this product or its operation, please contact your local distributor or the manufacturer MENTICE SPAIN S.L.

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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.

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Important information for the user

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

All operators must read the complete User manual before using Ankyras. The product should be used only by physicians trained in medical procedures involving percutaneous and intravascular interventions and previously trained by an Ankyras expert from Mentice Spain S.L.

The ANKYRAS software is intended to assist the physician users in the preoperational planning and sizing of neurovascular interventions and surgery with specific validated flow diverters and cannot replace or substitute, in whole or in part, their clinical judgement and analysis of patient's condition.

The words "simulate" or "simulation" or "deploy" used for the modeling functions of this software are meant to say "computationally model" or "computational modeling". As used in this manual, they are NOT meant for predicting any surgical outcomes but are ONLY related to the computational ability of the software.

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

Symbols

Rx Only	Prescription Only
	Indicates information intended to help the user take the right steps to operate the software correctly: User manuals are available at the following web address: http://www.mentice.com/Ankyras/ifu in PDF Acrobat Reader format. The free PDF reader can be downloaded at https://get.adobe.com/uk/reader/
	Date of manufacture. indicates the date of manufacture of the Ankyras software manufactured.
	Manufacturer Information. Indicates the contact details of the Mentice Spain S.L manufacturer.
REF	Catalog number
VER	Software version
REV	Label version
MD	Medical Device Symbol
UDI	Unique Device Identifier Symbol
	Product License expiration date identifier symbol

CAUTION

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

Indication for Use

Ankyras enables visualization of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery.

Ankyras also allows for the ability to computationally model the placement of neurointerventional braided endovascular devices.

General functionalities are provided such as:

- Segmentation of neurovascular structures
- Semi-automatic centerline generation from segmented blood vessels
- Visualization of X-ray based images
- Placing and sizing tools for braided endovascular devices
- Save user data
- Download** and share simulation***

Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider´s judgment and analysis of the patient´s condition.

Ankyras is available in different platforms: Desktop, Web browser and Mobile App.
*Available for Desktop and Web browser platforms
**Available for Web browser platform
***Available for Web browser and Mobile App platforms

Intended Use

The ANKYRAS software is intended to be used by physicians trained in medical procedures involving percutaneous and intravascular interventions for preoperational planning and sizing and computational modelling of specific validated flow diverters for intracranial aneurysms treatment with endovascular braided devices.

ANKYRAS is intended to be used with 3D rotational angiography (3DRA) DICOM images from patients diagnosed with intracranial aneurysms.

The ANKYRAS software allows for segmentation of the target artery and measurement of the segment length to be treated with the implantable device and the cross-section diameters along the segmented vessel

ANKYRAS uses the segmented vessel outline to computationally model the placement of specific validated braided endovascular devices selected by the user inside the target artery for preoperational planning of the intervention with endovascular braided device.

Contraindications

- The ANKYRAS software should not be used when there are image artifacts in the region where the endovascular device placement is planned
- The Ankyras software should not be used when the spacing is higher than 150 µm or lower than 500 µm.
- The Ankyras software should not be used if the target artery where the physician plans to deploy the implantable medical braided device doesn't have adequate contrast level for segmentation (see **Annex A**).
- The Ankyras software should not be used if there is already an implanted medical device in the target artery where the physician plans to perform the endovascular device deployment.
- The Ankyras software should not be used for situations where more than one implantable medical braided device is being planned to be placed in the same area.
- The Ankyras software should not be used for giant intracranial aneurysms and other clinical scenarios that may result in poor reconstruction of the region where the neurointerventional device is being planned to be placed.
- The Ankyras software should not be used in the presence of fusion between parent vessel and the distal part of the aneurysm sac that cannot be corrected.

Precautions

- The Ankyras user must receive a training session given by the Mentice Ankyras expert before starting the clinical use of the software.
- The Ankyras user should read and understand the instructions for use given in this document before starting the clinical use of the software. These instructions can be followed during the intervention.
- Please carefully read the endovascular implantable braided device manufacturer's instructions for use before using the ANKYRAS for preoperational planning. These instructions must be followed during the medical procedure.
- It is recommended to know the protocol to export the image data needed for preoperational planning with Ankyras before starting using the software for clinical use.
- The Ankyras user should check if his/her account is active and able to login to Ankyras before starting using the software for clinical use.
- During the intervention, the physicians can perform various mechanical actions on the endovascular braided device, including but not limited to compression, elongation and modification of the landing zone. These mechanical actions can change the final state of the endovascular braided device and impact the accuracy of the simulated device placement by the ANKYRAS. These mechanical actions and methods of braided device placement are at the discretion of the physicians during the intervention and the reported metrics in this User Manual do not take this input into consideration. The reported accuracy and error ranges of ANKYRAS computed quantities based on simulated placements are based on a retrospective image analysis study.

Warnings

- Ankyras should only be used physicians trained in medical procedures involving percutaneous and intravascular interventions to assist them in the intracranial aneurysm treatment intervention planning.
- ANKYRAS is not intended in any way to eliminate, replace, or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

- The ANKYRAS software should be used with equipment having the listed minimum **system requirements**. If the minimum system requirements are not met the software may not work as expected.
- Changes in performance of the device are not expected since it is a software device.
- The user is committed to define a strong password by using a combination of uppercase, lowercase, number and special characters.
- The software should be used with good quality images as shown in **Annex A**.
- ANKYRAS must be used only with 3D rotational angiography (3DRA) medical imaging studies in DICOM format produced using the protocol for injecting contrast media supplied by the manufacturer when the scanner was installed.
- The ANKYRAS computational modelling of the braided endovascular device is based on the vessel segmentation. The ANKYRAS software should be used with 3DRA image data produced on the day of the intervention.
- The ANKYRAS computational modelling of the braided endovascular device is based on the vessel segmentation. If vasodilators are used, ANKYRAS must be used with medical imaging studies acquired only after the effect of the vasodilators on the patient has stabilized.
- It is highly recommended to use the software in a work environment avoiding any distractions.

Trademarks

Ankyras User manual, January 2025.

System requirements

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

System requirements for Ankyras	
Operating System	**Recommended:** ● [Web browser, Desktop]: 64-bit Microsoft® Windows® 11 ● [MobileApp]: iOS 18 (iPhone, iPad) ● [MobileApp] : Android 15 (Android Phone, Android Tablet) **Minimum:** ● [Web browser, Desktop]: 64-bit Microsoft® Windows® 10 ● [MobileApp]: iOS 11 (iPhone, iPad) ● [MobileApp] : Android 8.0 Oreo (Android Phone, Android Tablet)
Web browser	**Recommended:** ● [Web browser]: Google Chrome 107.0.5304.89 ● [Web browser]: Firefox 106.0.5 ● [Web browser]: MS Edge 107.0.1418.56 **Minimum:** ● [Web browser]: Google Chrome 70.0.3538.77 ● [Web browser]: Firefox 63.0 ● [Web browser]: MS Edge 16.0 ● [MobileApp – iOS]: Safari as the default browser
CPU type	**Recommended:** ● [Web browser, Desktop]: Intel ® Core (TM) i7-10750H CPU 2.60GHz (PC) **Minimum:** ● [Web browser, 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 browser, Desktop]: 16 GB RAM ● [MobileApp]: 8 GB RAM **Minimum:** ● [Web browser, Desktop]: 4 GB RAM ● [MobileApp]: 4 GB RAM
Graphics	**Recommended:** ● [Web browser, Desktop]: Microsoft® Direct3D 12 ● [Web browser, Desktop]: Intel HD Graphics 6000 1536MB **Minimum:** ● [Web browser, Desktop]: Intel® Iris® Xe Graphics
Screen resolution	**Recommended:** ● [Web browser, Desktop]: 1,920 x 1,080 (PC) ● [MobileApp]: 1080 x 2400 pixels

System requirements for Ankyras	
Mobile screen size	**Recommended:** ● [MobileApp]: 6,1'' or higher **Minimum:** ● [MobileApp]: 4,7''
Others	**Recommended:** ● [Web browser, Desktop]: Mouse
Internet connection	**Recommended:** [Web browser, MobileApp]: 100Mbps, 4G

Supported data formats

ANKYRAS has been validated to be used with 3D rotational angiography (3DRA) medical imaging studies in DICOM format produced using contrast and with a spacing higher than 150 µm or lower than 500 µm:

Image Type Attribute DICOM tag 0008,0008	Image Modality DICOM tag 0008,0060
DERIVED\SECONDARY\AXIAL\3DANGIO	XA
DERIVED\SECONDARY\AXIAL	XA
DERIVED\SECONDARY\AXIAL\NONE	XA
DERIVED\SECONDARY\AXIAL\3DRA_PROP	XA

Validated Flow Diverter devices

The table below indicates the name of the FDA approved braided devices for which the Ankyras simulation is validated with retrospective clinical data (**40 cases for foreshortening**, **31 cases for expansion** and **12 for porosity**). The acquisition of clinical images involved the utilization of different scanners, including the AXIOM-Artis™ system from Siemens (Germany) and the Allura™ System from Philips (Netherlands).

Ankyras is intended to simulate only these braided devices:

Manufacturer	PMA and Device	Marketed name
Medtronic, Inc. (Micro Therapeutics, Inc. d/b/a ev3 Neurovascular) (United States)	P100018/S015, Pipeline Flex Embolization Device[1] P100018/S026, Pipeline Flex Embolization Device with Shield Technology[2*]	Pipeline Flex (PED) Pipeline Flex Shield (PED2) *
Stryker Neurovascular (United States)	P170024/S003, Surpass Evolve Flow Diverter System[3]	Surpass Evolve
Terumo Neuro (United States)	P180027, Flow Re-Direction Endoluminal Device (FRED®) System[4] P180027/S002, Flow Re-Direction Endoluminal Device (FRED®) X System[5*]	FRED & FRED JR FRED X*

* Coated variants that exhibit geometric equivalence with their respective non-coated counterparts (PED and FRED), are defined equally to their non-coated equivalents in the ANKYRAS software, thereby manifesting identical behavior in the ANKYRAS software.

[1] Indications for use: The Pipeline™ Flex embolization device is indicated for the endovascular treatment of adults (22 years of age or older) with large or giant wide-necked intracranial aneurysms (IAs) in the internal carotid artery from the petrous to the superior hypophyseal segments.
The Pipeline™ Flex embolization device is also indicated for use in the internal carotid artery up to the terminus for the endovascular treatment of adults (22 years of age or older) with small and medium wide-necked (neck width ≥ 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysm (IAs) arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 5.0 mm

[2] Indications for use: The Pipeline™ Flex Embolization Device with Shield Technology™ is indicated for the endovascular treatment of adults (22 years of age or older) with large or giant wide-necked intracranial aneurysms (IAs) in the internal carotid artery from the petrous to the superior hypophyseal segments.

The Pipeline™ Flex Embolization Device with Shield Technology™ is also indicated for use in the internal carotid artery up to the terminus for the endovascular treatment of adults (22 years of age or older) with small and medium wide-necked (neck width ≥ 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysm (IAs) arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 5.0 mm.

[3] Indications for use: The Surpass Evolve Flow Diverter is indicated for use in the endovascular treatment of patients (18 years of age and older) with unruptured large or giant saccular wide-neck (neck width ≥ 4 mm or dome-to-neck ratio < 2) or fusiform intracranial aneurysms in the internal carotid artery from the petrous segment to the terminus arising from a parent vessel with a diameter ≥ 2.5 mm and ≤ 5.0 mm.

[4] Indications for use: The Flow Re-Direction Endoluminal Device (FRED®) System is indicated for use in the internal carotid artery from the petrous segment to the terminus for the endovascular treatment of adult patients (22 years of age or older) with wide-necked (neck width >= 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysms arising from a parent vessel with a diameter >= 2.0 mm and <= 5.0 mm.

[5] Indications for use: The Flow Re-Direction Endoluminal Device (FRED®) System is indicated for use in the internal carotid artery from the petrous segment to the terminus for the endovascular treatment of adult patients (22 years of age or older) with wide-necked (neck width ≥ 4 mm or dome-to-neck ratio < 2) saccular or fusiform intracranial aneurysms arising from a parent vessel with a diameter ≥ 2.0 mm and ≤ 5.0 mm.

Performance

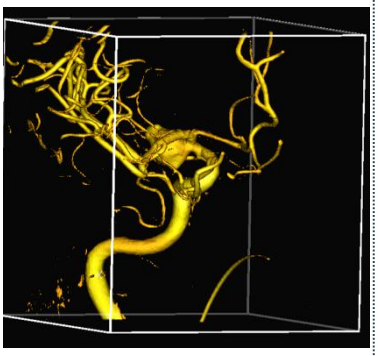
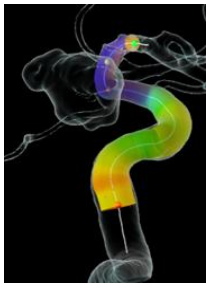
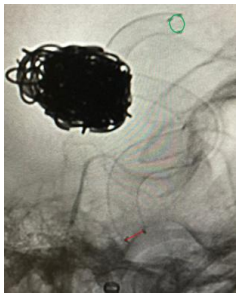
Ankyras Web browser is a web browser application, please check browser compatibility in https://docs.unity3d.com/Manual/Web browser-browsercompatibility.html

Web browser (Web Graphics Library) is an online tool that allows you to render 3D graphics. Google Chrome supports Web browser, 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 the 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.

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 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 browser (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

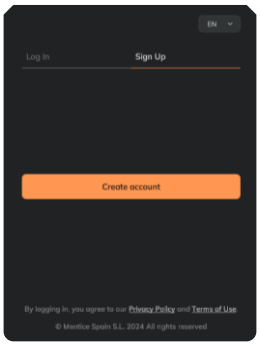
The available functionalities for each platform are indicated at each section in **Create a simulation in Ankyras** chapter in this manual.

Get Ankyras

User registration

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

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



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

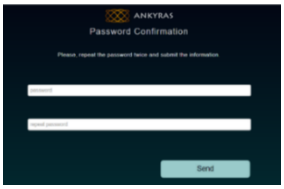
3. Click and read the ***Privacy Policy***

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”.

✉ Ankyras team accepts the registration, the user receives a new email with a link to set the password.

5. **Set password** to complete the registration:



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

Access/Download Ankyras

The user can access the Ankyras three different platforms:

- **Access Ankyras Web browser** (without installation): **www.us.ankyrasonline.com.**
- **Install Ankyras Desktop**: contact the Ankyras team: **ankyras@mentice.com** to get the installer.
    1. Access and login in www.us.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.

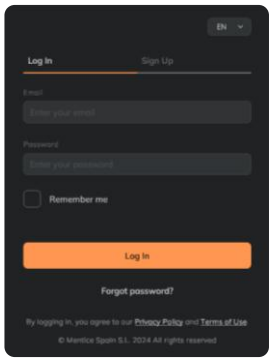
Download User Manual

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 browser**: after 2h of inactivity, the Ankyras page is frozen for security reasons. The user needs to restart/refresh the Ankyras page from the Web browser. Ankyras log in might be required.	
👉	A user who is not registered can use Ankyras Web browser 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 or through the MobileApp. To obtain the code, users must access the Web browser application 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 browser 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.

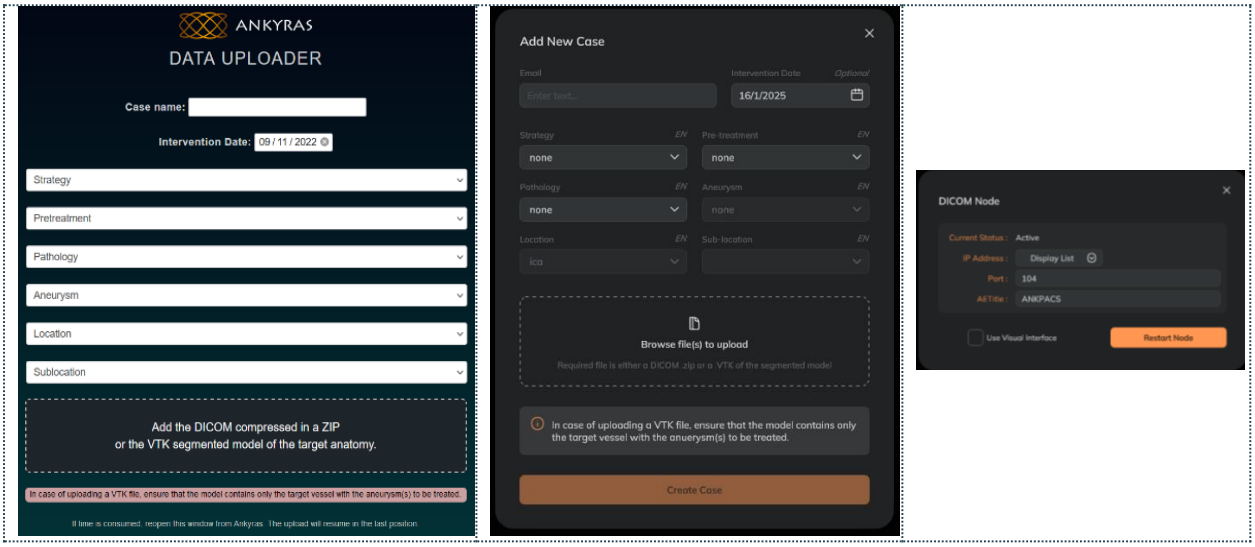
The next sections explain all the steps, from creating a new case to completing and saving the simulation results that a user with an Ankyras account can do. Last section

Import data

A registered user can create a new case by clicking ***New case*** on the Ankyras Web browser and Desktop platforms importing the DICOM 3D image or VTK data. If the user uses Ankyras Web browser, 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.

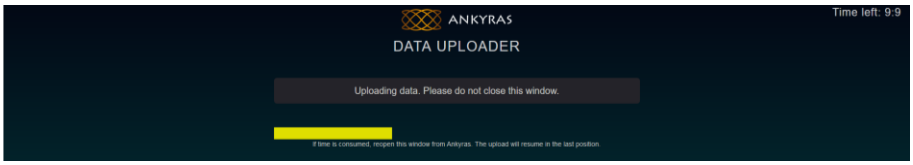
Import data: *New case*		
Desktop	✓	Click *New case* (Upper bar left corner)
Web browser	✓	Click *New case* (Upper bar left corner)
MobileApp	✗	Not available

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

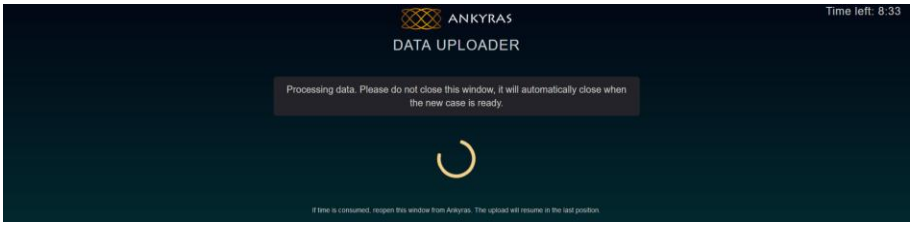


Ankyras Web browser

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 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.

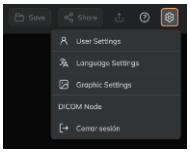
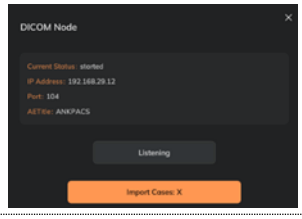
Ankyras Desktop

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 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.
4. When the user selects the file, file import and case creation start automatically.
5. **Import and processing:** The circular loading icon 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 the file cannot be processed, the software will send an error message. Similar, if the file has a not compatible format, the software sends an error message.
⚠	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.

Ankyras Desktop: DICOM node

Is possible to export the DICOM to Ankyras Desktop from the workstation through the DICOM node connection:

First, click on the settings button at the right top of the screen, and then, click DICOM node.	
The DICOM Node configuration data is shown. The user needs to introduce the data on the scanner following the hospital IT instructions. It is necessary to select the *Start listening* button so Ankyras DICOM node can start looking for new sent cases.	
Detected cases will show up on *Case List.*	

Open a case

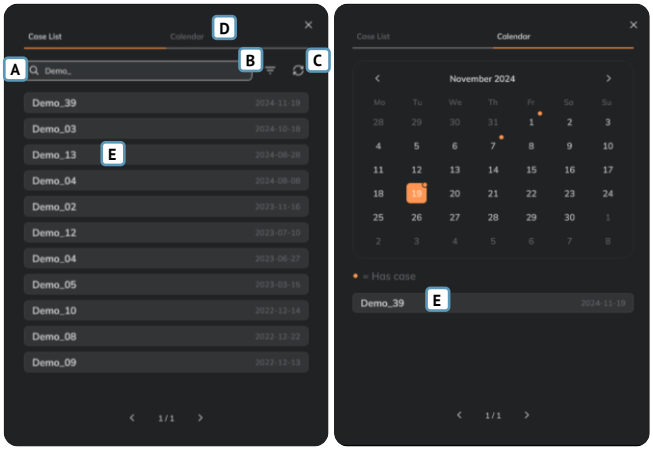
Open a case from *Cases*		
Desktop	✓	Click *Cases* (Upper bar left corner)

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).

Web browser	✓	Click *Cases* (Upper bar left corner)
MobileApp	✓	Click *Menu* (Lower left corner) and click *Case List*

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

***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

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.

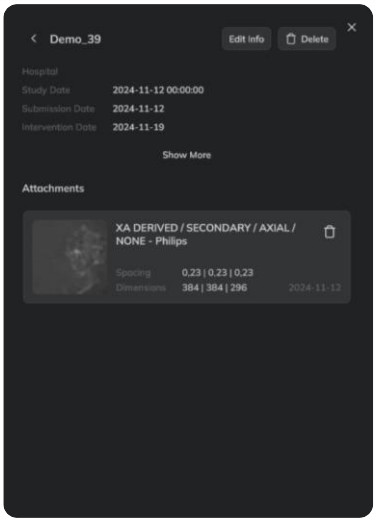
The attachments can be of type:

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:

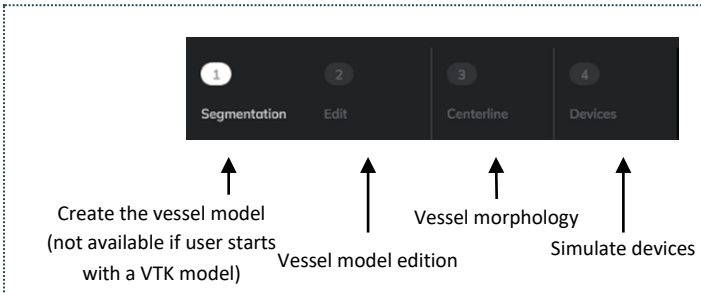
***Case Information* panel**	
A. Double click on the desired attachment to open it. **B.** Share the case with other Ankyras users or third parties. Find more details here about how to share a case. **C.** Delete the complete case. **D.** Delete one attachment **E.** Edit case information: edit fields such as Strategy, Pretreatment or intervention date and save changes by clicking save.	

Open the image or vessel model

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.

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

In the upper and central part of the interface, a brief description of the case (name, hospital and date of intervention) is displayed next to the ⓘ button (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 browser platform).

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

Create the vessel model

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.

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

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

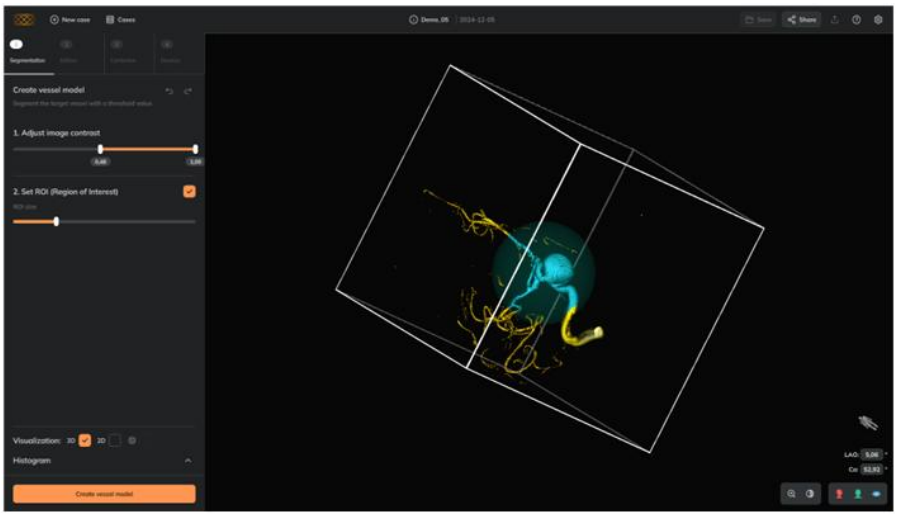
The user can create the vessel model by:

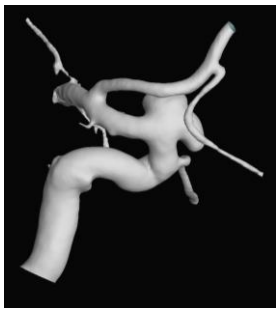
1. **Adjusting the image contrast**, moving the minimum value from the slider looking for an optimal visualization of the tissue corresponding to the vessel to be treated,
2. **Setting the ROI** (region of interest) activating (checking the box) and then positioning and resizing it (with the ROI size 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

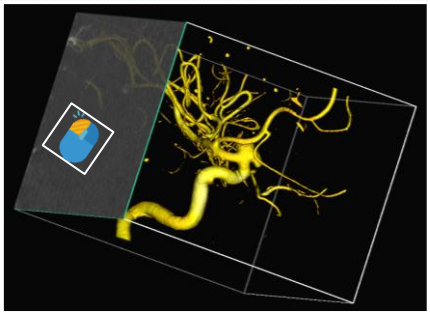
Optional tools

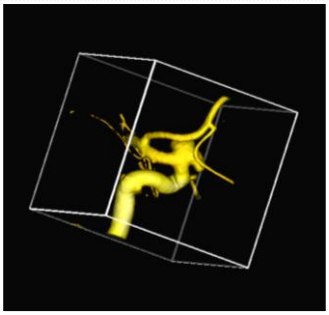
Crop the image

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

Cropping steps:

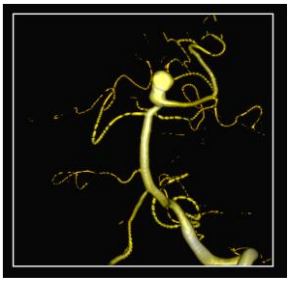
1. Place the mouse over one of the 3D cube's sides,
2. The slice is shown with transparency
3. Click on the left mouse button and drag the selected side of the cube towards its center.
4. Once a side has been cropped, the user can uncrop by dragging that side towards the outer part of the volume.





Cropping:

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



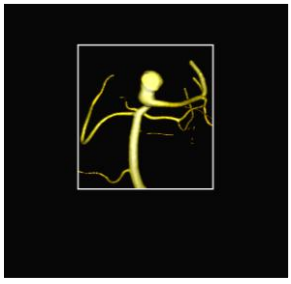


Image 2D view

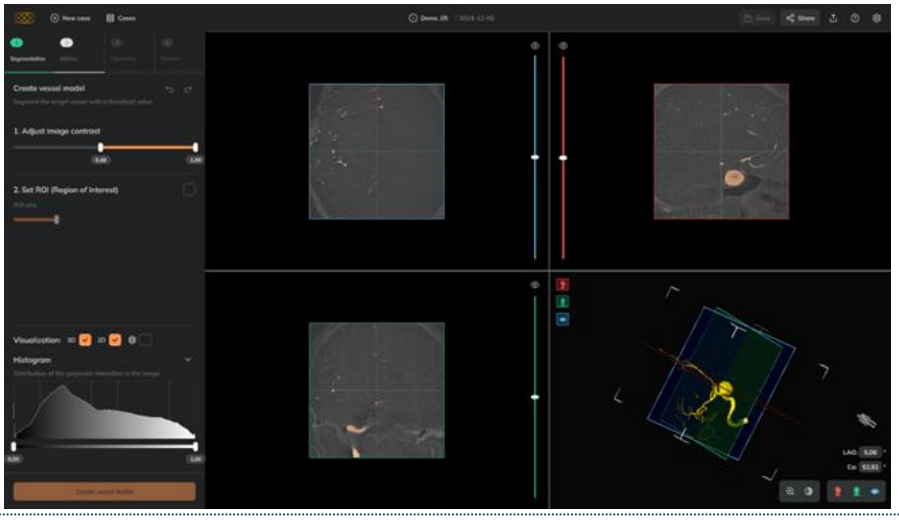
See image slices (2D view) to see the slices in axial, transversal and sagittal planes, as well as the histogram chart.

See image slices:

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

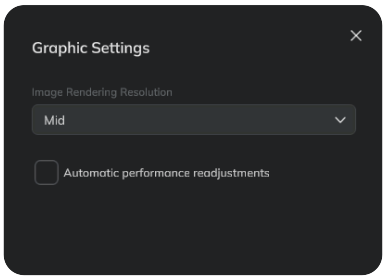
Functionalities and controls:

- **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

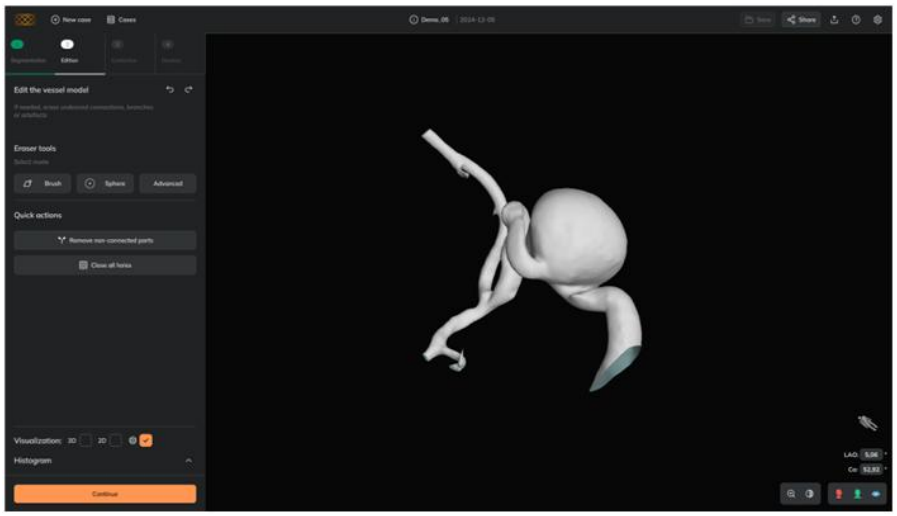
This stage is optional and allows to edit and clean the segmented vessel model or the VTK vessel model. The edition tools can be also used if a simulation is opened (see here).

Edit vessel model		
Desktop	✓	2-Edit vessel model
Web browser	✓	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.

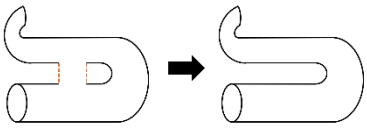
The tools allow to:

- **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.



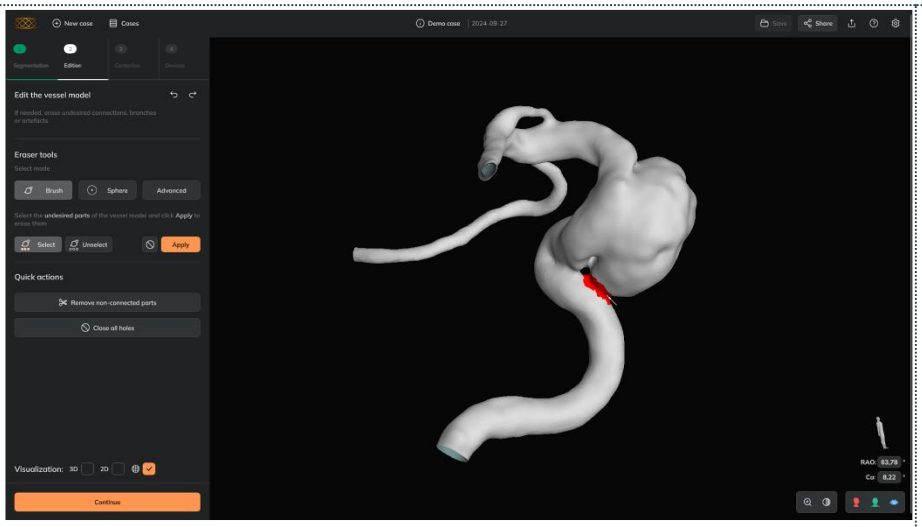
Brush

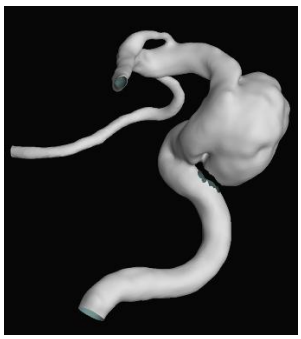
To remove imperfections and *opened connections* (those that have a free space within the connected model parts):



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.



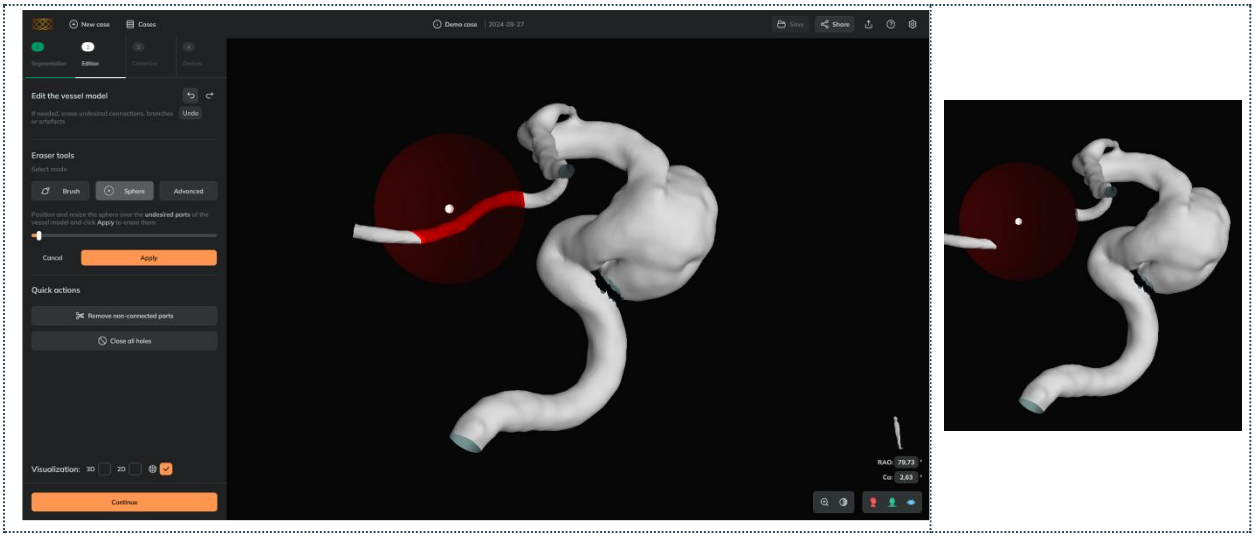


☛	**Recommended use**: erase all the undesired vessel parts and then use the *Remove non-connected parts* and *Close Holes.*

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.

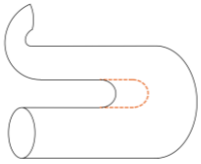
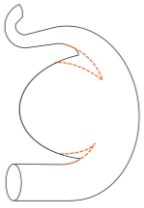


👉	**Recommended use**: erase all the undesired vessel parts and then use the *Remove non-connected parts* and *Close Holes.*
⚠	The software does not allow to remove the entire 3D model (it returns an error message).

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).

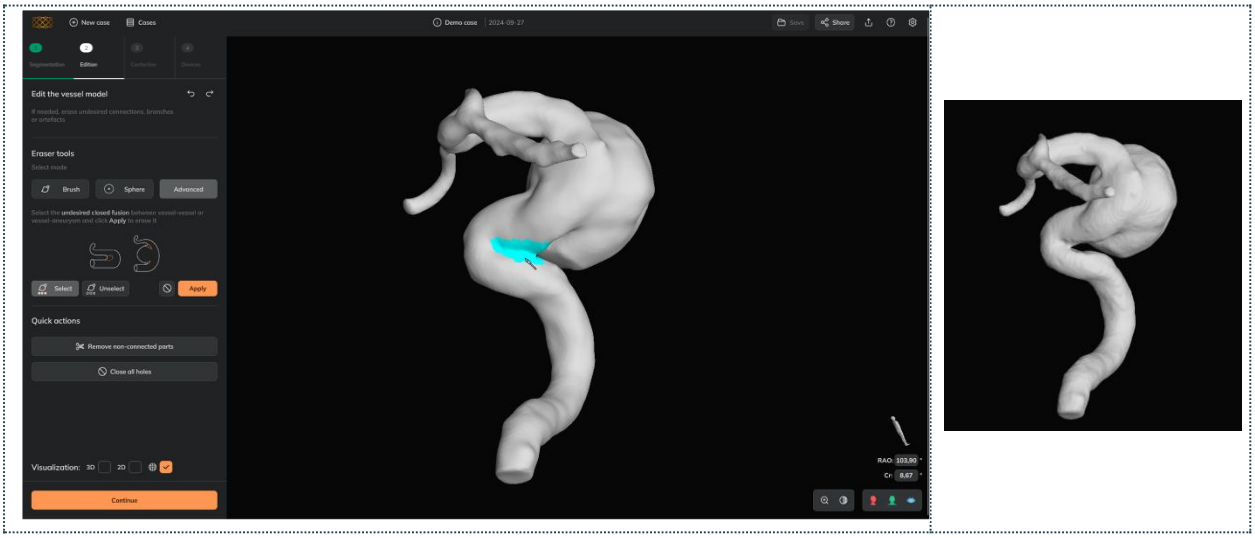
Two typical scenarios with closed connections that can be corrected with the *Advanced brush* (and not with the first *Brush*):

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*.

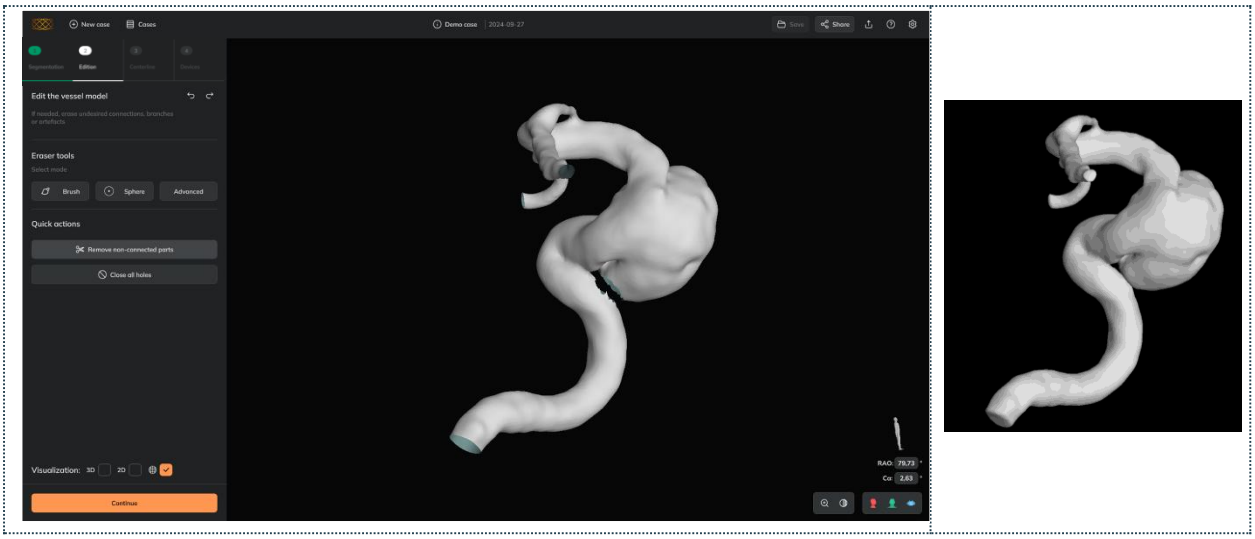
Remove non-connected parts

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 *Isolate main surface*.



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

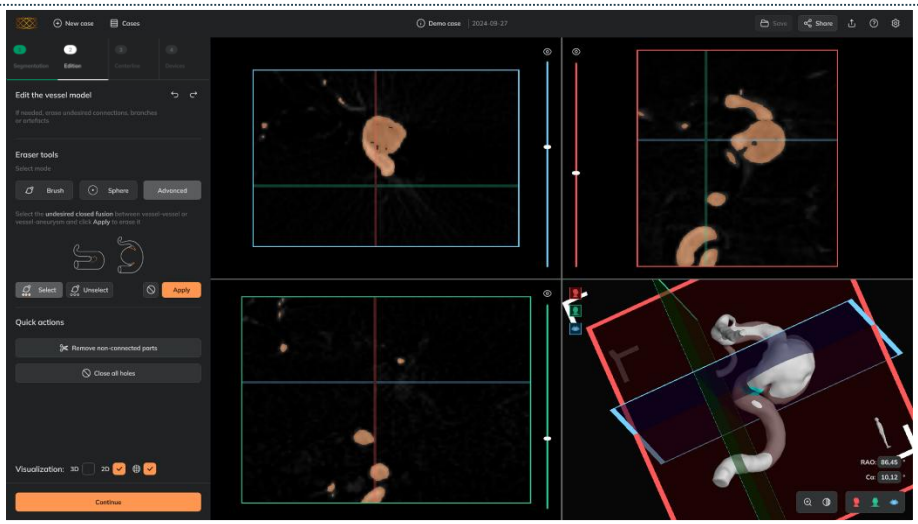
Undo / Redo

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

Other functionalities

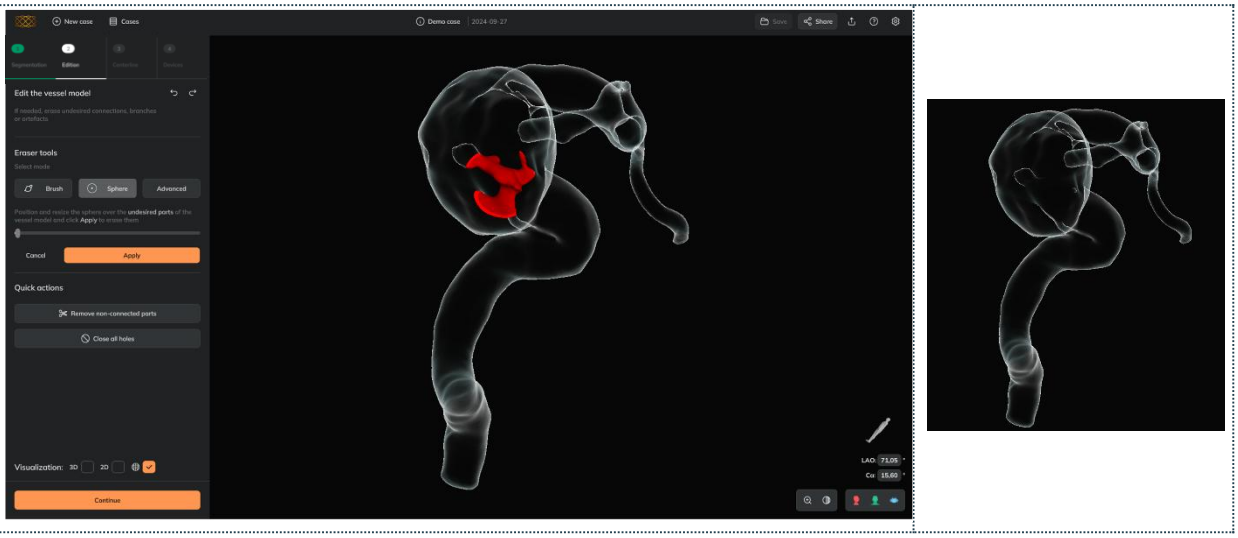
Image visualization

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):



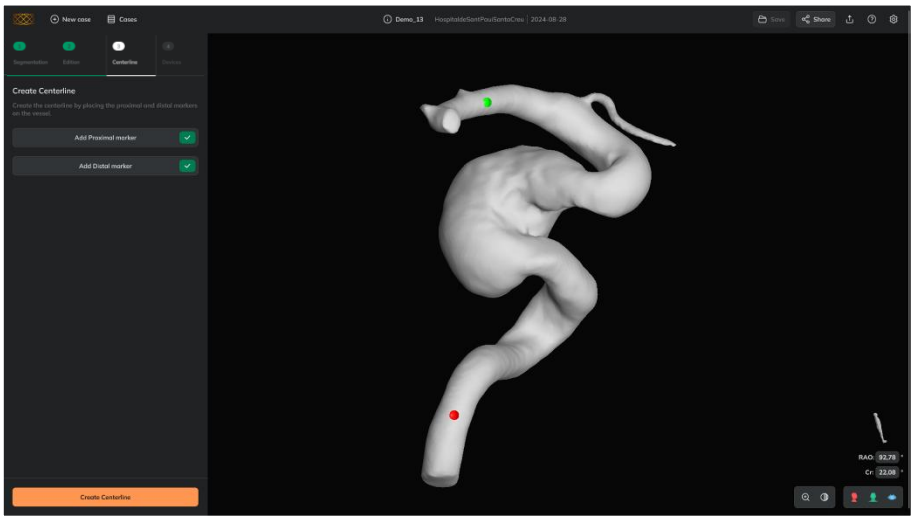
Create the vessel centerline

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

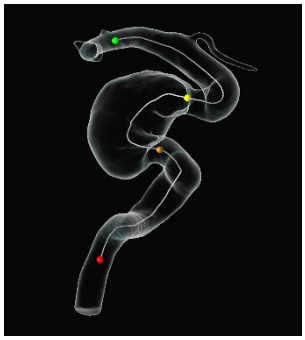
The centerline tools allow the definition of the vessel segment in which the morphology is going to be measured, and the braided devices are going to be simulated.

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**)

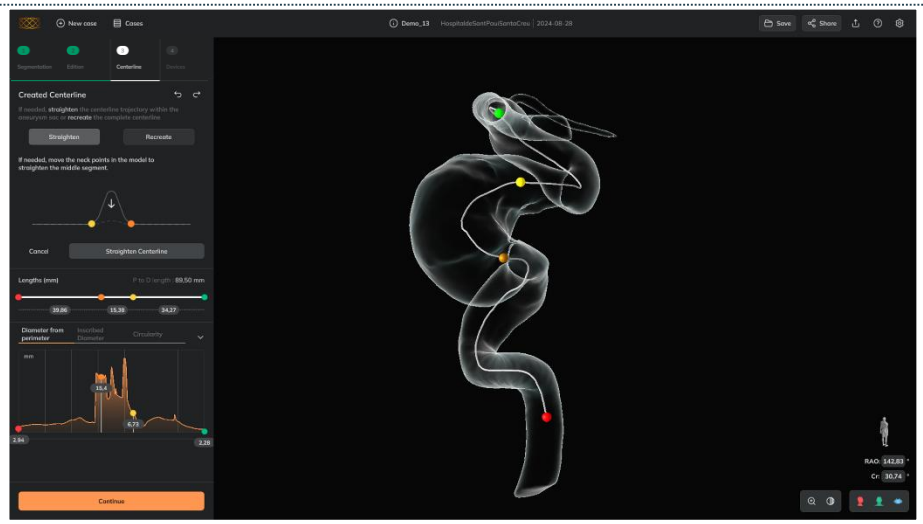
The user can move the points by dragging them along the centerline or the charts to do a vessel morphology analysis.

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

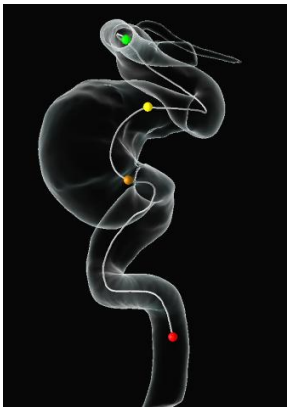
Edit the created centerline

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

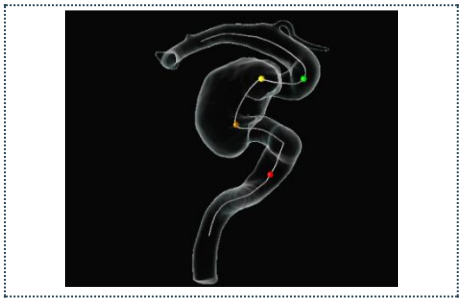


Vessel morphology results

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.

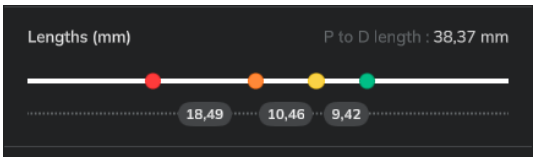
Vessel morphology		
Desktop	✅	In *3-Centerline*, or *4-Devices*
Web browser	✅	In *3-Centerline*, or *4-Devices*
MobileApp	✅	Click *Charts* icon (Lower right corner)

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

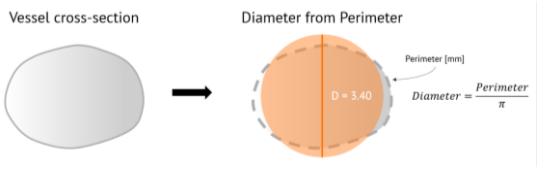


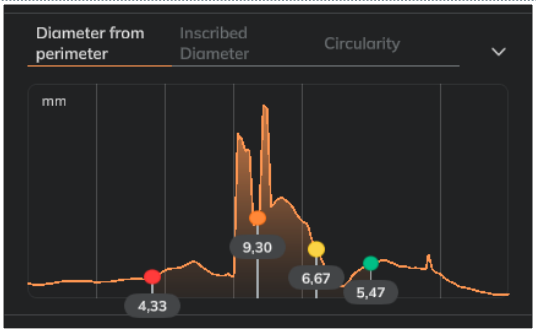
- **Segments lengths [mm]:** lineal chart showing the distance between the markers, indicating the:

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

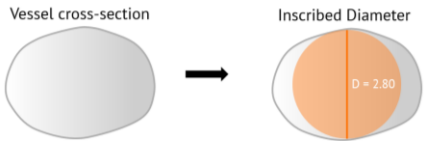


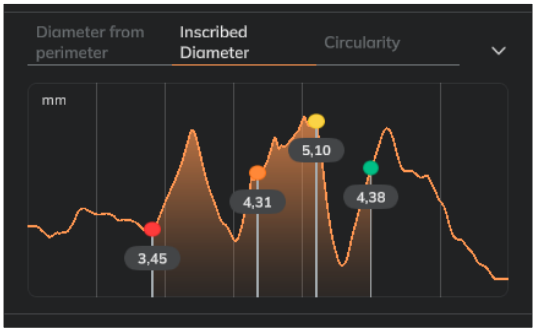
- **Diameter (from perimeter) [mm]**: diameter calculated with the cross-section perimeter:



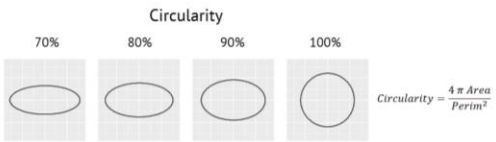


- **Diameter (Inscribed) [mm]:** diameter of the circumference inscribed in the vessel cross- section:





- **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

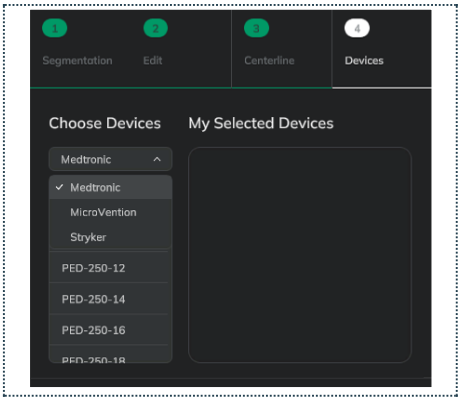
Stage 4, *Devices*, allows the user to select the desired braided devices while the vessel morphological information is visible in the charts.

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

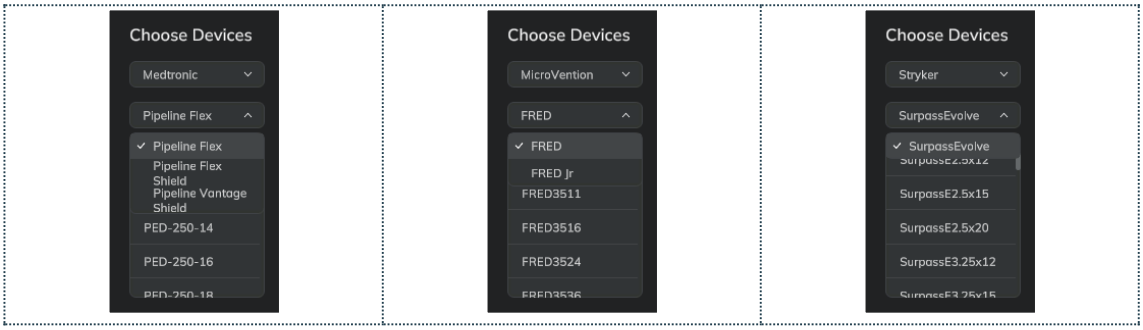
Simulate devices		
Desktop	✅	In *4-Devices*
Web browser	✅	In *4-Devices*
MobileApp	✅	Click *Devices* icon

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

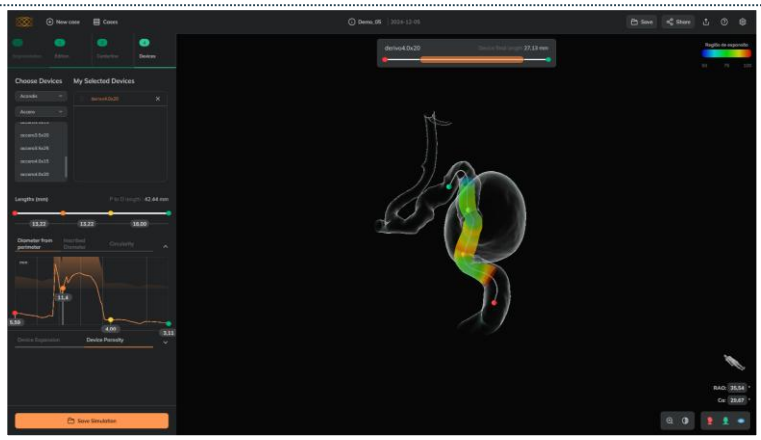
- **Select manufacturer:** the first dropdown menu allows to select the manufacturer of the desired device among the ones indicated in section **Validated Flow Diverter devices** as shown in following caption:



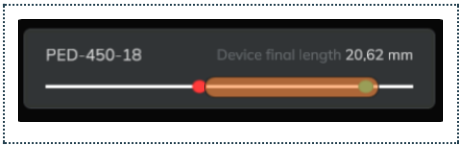
- **Select Device:** the second drop-down menu allows to select the desired device brand from the selected manufacturer among the three indicated in section **Validated Flow Diverter devices**:



- **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 browser	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 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.

The Ankyras final length or foreshortening is validated with a dataset of 54 clinical cases treated with the indicated devices in **Validated Flow Diverter devices**. The following table summarizes the dataset and the obtained foreshortening accuracy for each device:

PMA and Device	Foreshortening Accuracy*	N. of cases
P100018, Pipeline Flex Embolization Device	96.5 ± 2.7%	12
P170024, Surpass Evolve Flow Diverter System	95.2 ± 3.7%	13
P180027, Flow Re-Direction Endoluminal Device (FRED®) System	92.6 ± 4.1%	15

* During the intervention, the physicians may perform mechanical actions on the braided device, including compression, elongation and modification of the landing zone. These mechanical actions can change the final state of the braided device and impact the accuracy of the reported simulated placement. The methods of braided device placement are at the discretion of the physicians. The reported accuracy and error ranges of simulated placements are based on a retrospective in-vivo study and accuracy may differ according to clinical technique.

With 95% confidence level, the lower and upper limit related to the computed deployed length can be calculated within the range of [0.95,1.05] *L, meaning that for a deployed length of 22 mm the limits are within [20.9, 23.1] mm with a confidence interval of 95%.

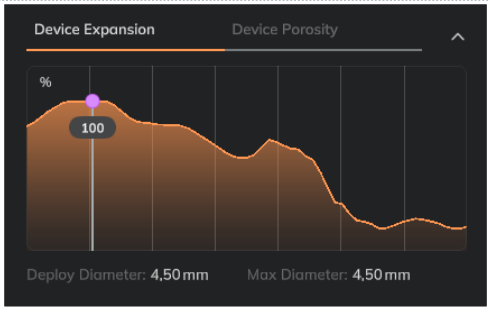
Device expansion and porosity

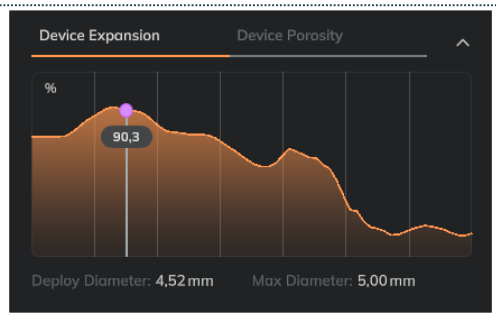
The user can explore the simulated expansion values and the simulated local porosity values of the active device in the charts that appear below the vessel morphology charts (or as a next chart for the MobileApp).

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.

Ankyras expansion accuracy is validated with clinical retrospective data as indicated in **Validated Flow Diverter devices** section. The Ankyras expansion is validated with a dataset of 45 clinical cases treated with the indicated devices in **Validated Flow Diverter devices**. The following table summarizes the dataset and the obtained accuracy for each device.

PMA and Device	Expansion Accuracy*	N. of cases	N. of points
P100018, Pipeline Flex Embolization Device	87.2 ± 7.0%	4	255
P170024, Surpass Evolve Flow Diverter System	87.5 ± 5.8%	13	824
P180027, Flow Re-Direction Endoluminal Device (FRED®) System	87.7 ± 5.6%	14	871

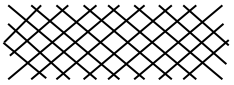
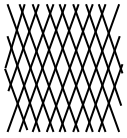
* During the intervention, the physicians may perform mechanical actions on the braided device, including compression, elongation and modification of the landing zone. These mechanical actions can change the final state of the braided device and impact the accuracy of the reported simulated placement. The methods of braided device placement are at the discretion of the physicians. The reported accuracy and error ranges of simulated placements are based on a retrospective in-vivo study and accuracy may differ according to clinical technique.

With 95% confidence level, the lower and upper limit related to the computed deployed expansion can be calculated within the range of [0.85,1.15] *E, meaning that for a deployed expansion of 80% the limits are within [68%, 92%] with a confidence interval of 95%.

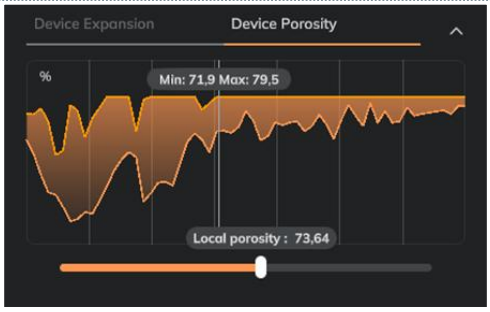
Local porosity

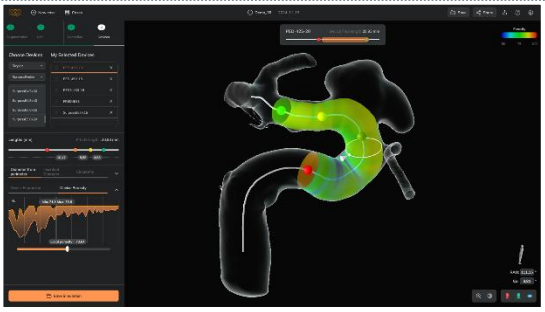
The user can expand the ***Device Porosity*** chart and analyze in a more detail the local porosity values with the graph.

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.

The Ankyras local porosity is validated with a dataset of 12 clinical cases treated with the indicated devices in **Validated Flow Diverter devices**. The following table summarizes the dataset and the obtained accuracy for each device:

PMA and Device	Porosity Accuracy*	N. of cases	N. of points
P100018, Pipeline Flex Embolization Device	94.6 ± 7.9%	3	728
P170024, Surpass Evolve Flow Diverter System	94.1 ± 15.4%	9	1749
P180027, Flow Re-Direction Endoluminal Device (FRED®) System	Not available**		

* During the intervention, the physicians may perform mechanical actions on the braided device, including compression, elongation and modification of the landing zone. These mechanical actions can change the final state of the braided device and impact the accuracy of the reported simulated placement. The methods of braided device placement are at the discretion of the physicians. The reported accuracy and error ranges of simulated placements are based on a retrospective in-vivo study and accuracy may differ according to clinical technique.
** Local porosity is not available because the P180027, Flow Re-Direction Endoluminal Device (FRED®) System is a two-layer braided device and Ankyras does not calculate the combined system.

With 95% confidence level, the lower and upper limit related to the computed deployed porosity can be calculated within the range of [0.8,1.2]*P, meaning that for a deployed porosity of 80% the limits are within [64%, 96%] with a confidence interval of 95%.

Save simulation

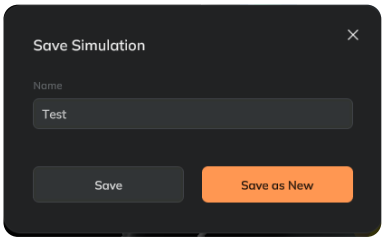
The user can save the simulation as an attachment to the case clicking on the ***Save simulation*** (orange button) once the devices have been selected in stage 4 or beforehand, once the centerline is created, with the ***Save*** button at the right side of the upper bar.

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

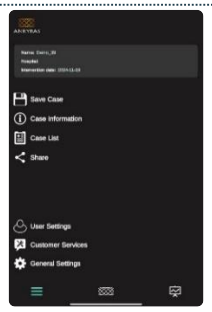
The user can define the simulation's name and:

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

Desktop / Web browser



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

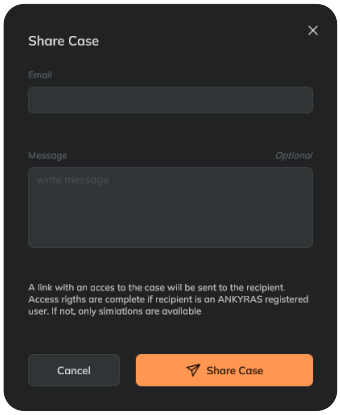
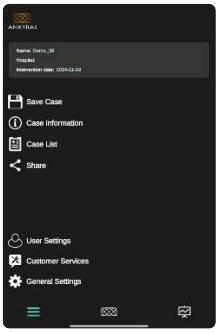
The ***Share*** button allows sharing the case with others, registered or non-registered people.

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

⚠	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.

The user, owner from the case or from the same institution as the case owner, has the sharing button enabled in the Ankyras Online 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 browser or Mobile App depending on the platform used).

Web browser		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. See more information **here**.
⚠	A registered user can Share a simulation from a case shared by a colleague belonging to the same institution.

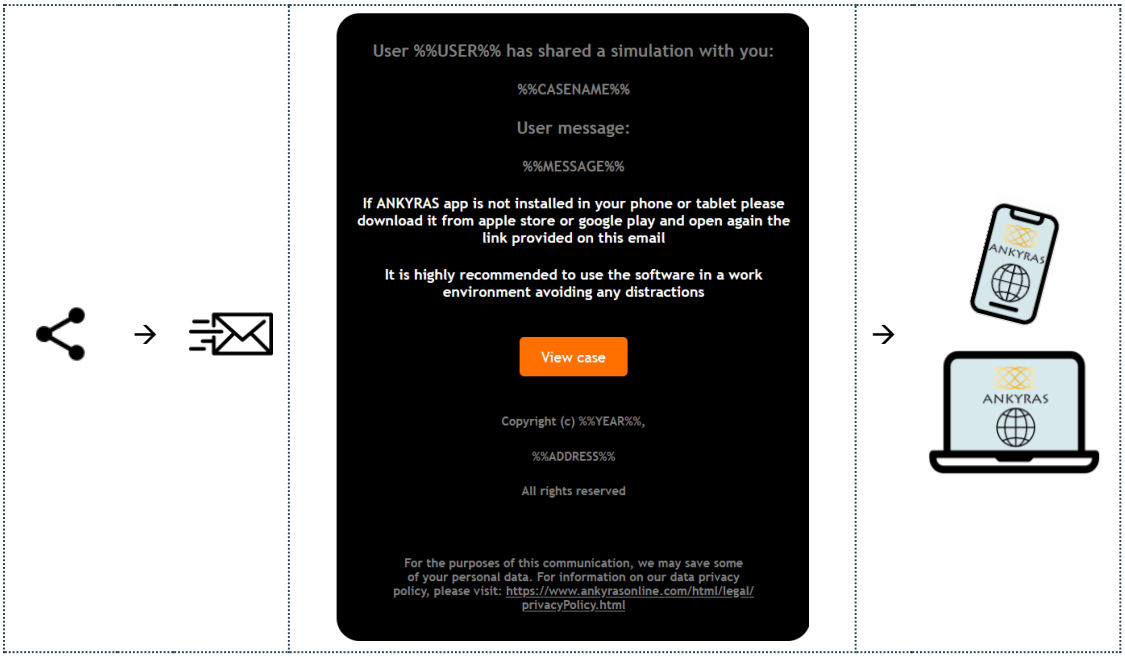
Open a shared case

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 browser or MobileApp) and shows the *case information* panel (see an example of the panel **here**).

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 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 browser	✓	In the upper bar (right side)
MobileApp	✗	Not available

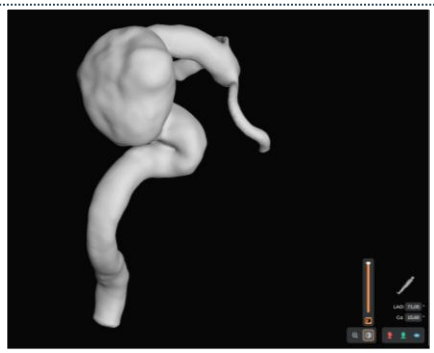
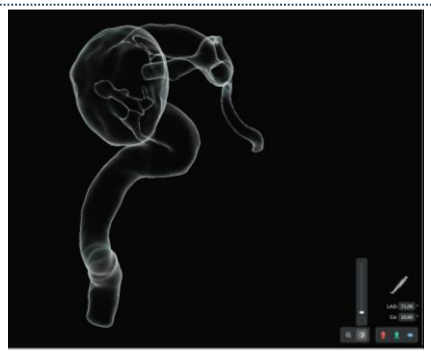
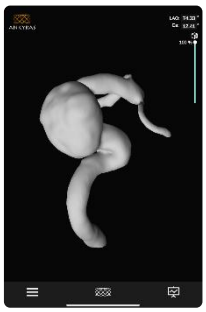
⚠	A registered user can Download a simulation from a case shared by a colleague belonging to the same institution.

View tools

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

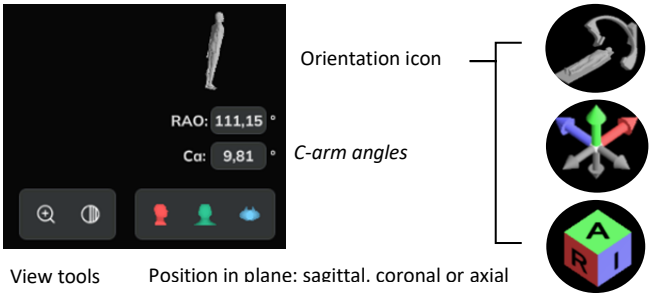
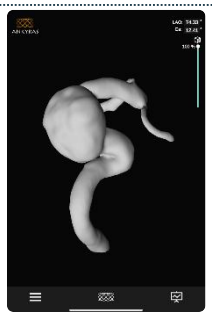
Desktop/Web browser		MobileApp
		

Orientation tools

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

The orientation tools allow to:

- **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 browser	MobileApp
	

Edit an existing simulation

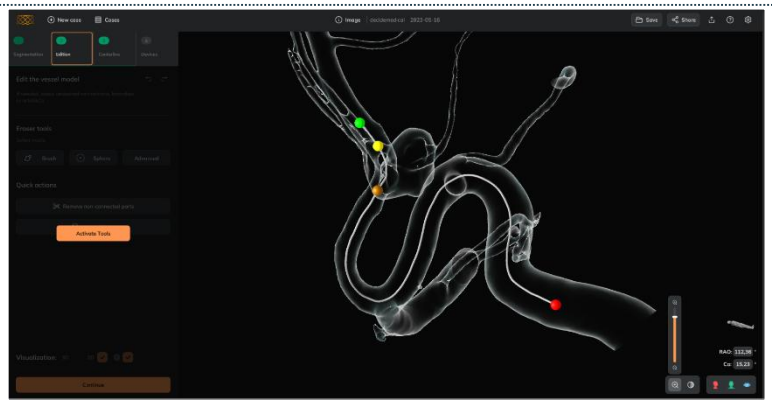
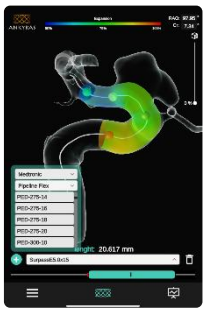
Edit simulation		
Desktop	✓	Edit Vessel model, Centerline and Devices
Web browser	✓	Edit Vessel model, Centerline and Devices
MobileApp	✓	Edit Devices only

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

- 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 browser 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 browser	MobileApp
	

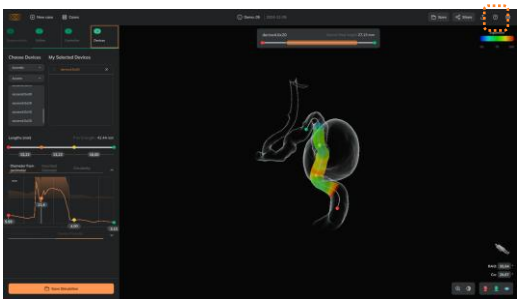
Customer Service Tools

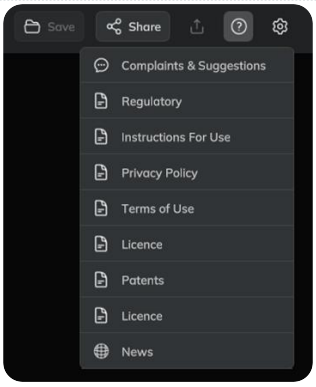
With the Customer Service tools (for registered users only) the user can contact the Ankyras support team to send a complaint, ask a question or send a suggestion and also access the following Ankyras documentation:

- Complaints and suggestions
- Regulatory (labelling)
- Instructions for Use
- Privacy Policy
- Terms of Use
- Licence
- Patents (Mentice webpage)
- News (Mentice webpage)

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

Web browser

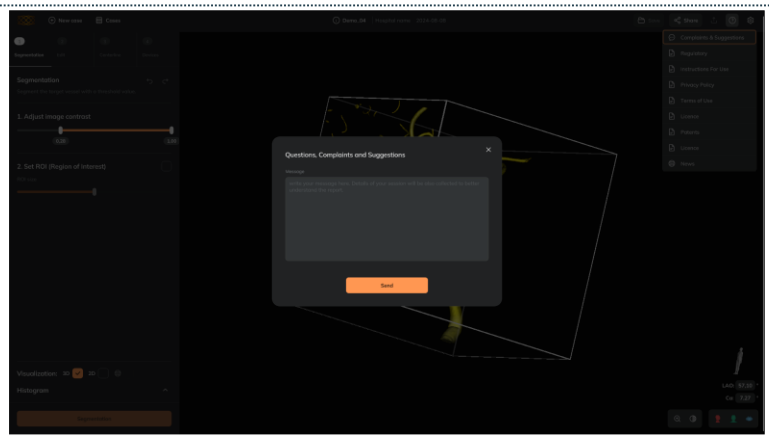




MobileApp

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 in Desktop platform.

Web browser



☛	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 browser, 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.

This section describes the measures taken by Ankyras to maintain safety and security.

Installation and security

Ankyras Web browser and Desktop are designed to run in a hospital computer, specifically for the Microsoft Windows operating system. Therefore, Ankyras must be installed or accessed on a computer running a Windows operating system with various cybersecurity controls 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 Ankyras is installed.
2. Users should protect the Ankyras database from unauthorized access because the local data contained in the Ankyras database contains private patient information.

Users should take care of the computer where Ankyras is installed:

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

Data Base

Ankyras Desktop 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.

Ankyras Web browser stores all patient data in an ISO 27001 certified server.

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 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 saving "hardcoded" password or 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 set up the screen saver to lock the screen after a period of inactivity. Avoid sharing your Ankyras password with others.

The launch of Ankyras is protected by a license associated with a unique user and for a unique computer (in the case of Desktop), 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 for Ankyras Desktop in Ankyras personal folder of the Windows user.

Encryption

Use the built-in feature of Windows 11 for device encryption in order to prevent unauthorized access to the Ankyras data.

Backup copies

In Desktop platform, please perform a periodically backup the Database to avoid the loss of data availability. Backups of Web browser server and done daily.

Update your device

Update the device where Ankyras is installed or accessed, including the security patches and improvements of Windows 11 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 anti-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.

Mobile App Security

Users are encouraged to:

- Always download apps from official app stores, in special from Apple App Store and Google Play Store.
- Ensure authenticity of the app by verifying the app publisher's identity (must be Mentice Spain)
- Enable app updates to ensure they have the latest security patches.
- Avoid sharing sensitive information in app reviews.

Avoiding phishing scams

Phishing emails are deceptive messages designed to trick recipients into revealing sensitive information, such as passwords. They often appear to come from legitimate sources and use tactics like urgent language or generic greetings to prompt quick action. To avoid phishing attacks, users are encouraged to apply the following measures:

- Examine the Sender's Email Address: Check for unusual or misspelled domains in the sender's email address. You will receive automatic Ankyras messages from the following source “no-reply@Ankyrasonline.com”
- Check for Spelling and Grammar Errors: Poor spelling, grammar, and punctuation can be indicators of phishing attempts.
- Be Cautious of Urgent Language: Phishing emails often create a sense of urgency, pressuring you to act quickly. Be wary of emails that claim immediate action is required.
- Inspect Links Before Clicking: Hover over links to see the actual URL. If it looks suspicious or does not match the purported sender's website, do not click it.

- Look for Unusual Requests: Be cautious of emails asking for sensitive information, such as passwords or personal details, especially if they come unexpectedly.
- Verify with us: If an email seems suspicious, contact us through a known, legitimate method (not by replying to the email) to confirm its authenticity.
- Use Anti-Phishing Tools: Employ browser extensions and email filters that detect and warn you about potential phishing attempts."

Phishing can also occur through fake webpages. Attackers may create fraudulent sites to trick users into revealing sensitive information, such as passwords.

To avoid these attacks, users are encouraged to verify the URLs of websites before entering their credentials. They should look for secure connections (https://) and check for correct spelling. Additionally, using browser bookmarks for frequently visited sites is recommended to help prevent phishing attempts.

MDS2

The Manufacturer Disclosure Statement for Medical Device Security (MDS2) is a standardized form that medical device manufacturers use to convey important security information about their devices.

It assists hospital IT departments in assessing security risks prior to integrating these devices into healthcare systems. The MDS2 includes details on data protection, user authentication, secure software updates, vulnerability management, access controls, and audit logs.

The MDS2 can be requested by the hospital IT security department by contacting Ankyras@mentice.com.

Third party licenses

Ankyras integrates various third-party software solutions to facilitate a range of functions within its system. A comprehensive overview of the licenses associated with the software used by Ankyras can be accessed at the following link: https://www.Ankyrasonline.com/html/legal/ThirdPartyLicenses.html. Additionally, a Software Bill of Materials (SBOM) in a machine-readable format is available upon request by contacting Ankyras@mentice.com.

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 Ankyras@mentice.com for assistance.

Maintenance

The IT department 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, display, keyboard, mouse and the operating system.

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

The database 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 appropriate measures to protect these data properly according to the legislation that applies to your country.

To update the software, please follow the Update Ankyras. 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 everything is working fine.

The lifetime of the software is set to 5 years. After 5 years, the IT department of your institution should be responsible for uninstalling the Ankyras software product. To uninstall the Ankyras Desktop product, follow the steps given by your device provider.

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).

Troubleshooting

If any case of malfunction 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 Case	Check with the IT department a solution for increasing the available hard disk space.
Failure of the hard disk	Restore last backup of the database.
The display device is not working properly	Check with the IT department the display device.
Cannot open DICOM	Check if the DICOM can be opened with other software to verify that the DICOM files are not corrupted.
Case cannot be segmented	Check image quality. Check the thresholds selected for segmentation
Centerline cannot be created	Improve mesh quality by applying "close holes" algorithm at editing tools.
Device cannot be simulated	Check devices included in the database. Check the length of the section on with the device will be deployed

Credentials

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

Annex A: DICOM image quality

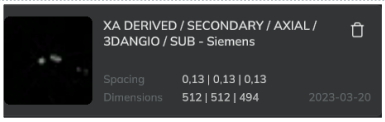
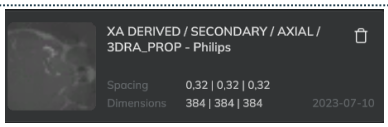
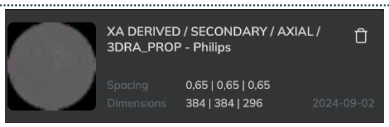
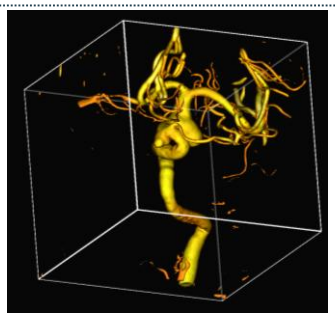
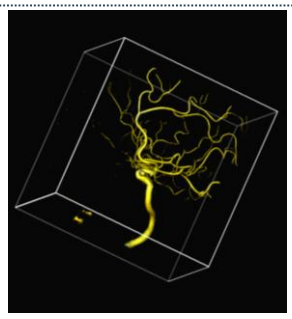
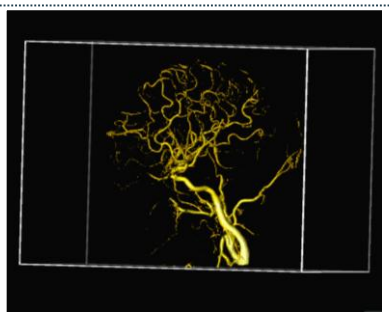
To create a reliable simulation with Ankyras, the DICOM has to be a 3DRA modality image. Also, the DICOM must meet some requirements in regard to the image quality concerning:

- 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:

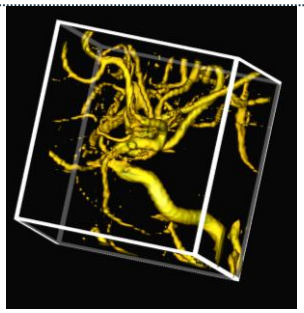
- Smaller than 0.15mm (image has higher resolution): the image will be very heavy thus Ankyras might be slower,
- Bigger than 0.5mm (image has lower resolution): the image will not have enough quality to obtain a realistic vessel model.

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)



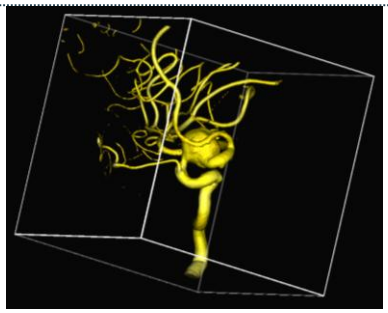
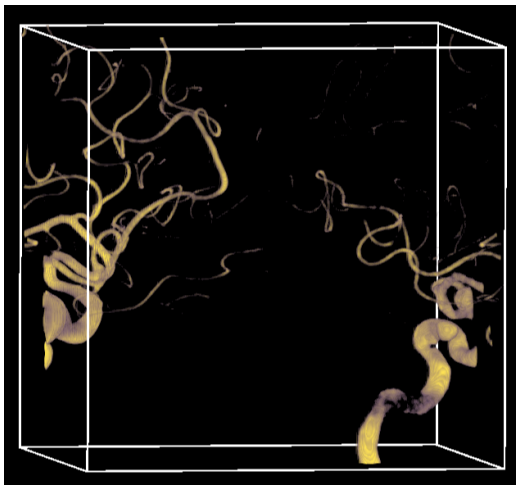


Image artefact

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:

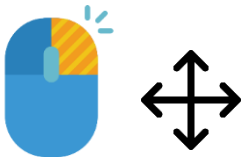


Annex B: interaction with 3D view

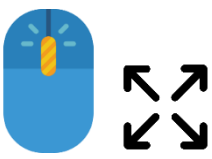
The user can move the 3D objects in Ankyras with the following **mouse controls**:

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.