EndoSize

User Manual

Author: Therenva

Date: 2022-11-25

Version: UMES-EN 2.2

Version	Date	EndoSize
UMES-EN 1.0	2015-04-22	3.0 r9149
UMES-EN 1.1	2015-07-30	3.0 r9480
UMES-EN 1.2	2015-12-18	3.1.0
UMES-EN 1.3	2016-05-13	3.1.3
UMES-EN 1.4	2016-07-20	3.1.4
UMES-EN 1.5	2016-12-19	3.1.9
UMES-EN 1.6	2017-07-20	3.1.13
UMES-EN 1.7	2017-11-08	3.1.14
UMES-EN 1.8	2018-07-25	3.1.22
UMES-EN 1.9	2019-07-02	3.1.26
UMES-EN 1.10	2019-09-18	3.1.27
UMES-EN 1.11	2019-10-23	3.1.30
UMES-EN 1.12	2020-01-15	3.1.31
UMES-EN 1.13	2020-06-07	3.1.37
UMES-EN 1.14	2020-09-16	3.1.38
UMES-EN 1.15	2020-11-13	3.1.39
UMES-EN 1.16	2021-05-27	3.1.42

UMES-EN 2.0	2021-10-14	3.1.44, 3.1.45, 3.1.46
UMES-EN 2.1	2022-03-01	3.1.47
UMES-EN 2.2	2022-11-25	3.1.48

Therenva SAS
74 F rue de Paris
35000 Rennes
France

Phone: +33 9 72 52 29 18
Fax: +33 9 72 52 54 16
contact@therenva.com
www.therenva.com

Technical support:
+33 9 72 52 29 18
support@therenva.com

CE
0476

EndoSize is a Class IIa medical device in accordance with the European Medical Device Directive (MDD) 93/42/EEC, Appendix IX.

TABLE OF CONTENTS

DIRECTION FOR USE

I. Intended Use

EndoSize is a software solution that is intended to provide Physicians and Clinical Specialists with additional information to assist them in reading and interpreting DICOM CT scan images of structures of the heart and vessels.

EndoSize enables the user to visualize and measure (diameters, lengths, volumes, angles) structures of the heart and vessels.

II. Minimum System Requirements

This software runs on a Windows or macOS based computer that meets the minimum requirements (see below) and does not need additional resources.

Component	Minimum System Requirements
Operating System	macOS 10.15, 11, 12, 13 Windows 10, 11 (64 bits)
RAM	8 GB
Graphics	Intel HD 4000 or better
Screen Resolution	1280*768
Hard Drive	1 GB (free space for patient data not included: 500MB per patient)
Processor	2 Ghz DualCore

Warning: The use of EndoSize on any operating system software other than those specified, on server, or on hardware platforms inferior to the minimum requirements will violate the safety, effectiveness and design controls of this medical device. Such use may result in an increased risk to patients. Installing any other software may also result in the malfunctioning of EndoSize and induce an increased risk for patients.

III. Indication For Use

EndoSize enables visualization and measurement of structures of the heart and vessels for pre-operational planning and sizing for cardiovascular interventions and surgery, and for postoperative evaluation.
General functionalities are provided such as:

- Segmentation of cardiovascular structures
- Automatic and manual centerline detection
- Visualization of CT scan images in every planes, 2D review, 3D reconstruction, Volume Rendering, MPR, Stretched CMPR
- Measurement and annotation tools
- Reporting tools

IV. Contra-Indications

The EndoSize software should not be used for the diagnostic and the planning of interventions nor the sizing of an endograft other than those relative to EVAR, FEVAR, TEVAR, TAVI and Peripheral interventions.

V. Classification

EndoSize is a Class IIa CE marked medical device according to annex IX of the 93/42/EEC Medical Devices Directive.

VI. Lifetime

EndoSize is designed for use as a medical device with a limit of 5 years after the date of manufacture and from the first use.

Therenva SAS wishes to regularly offer its customers a new version of its solution in order to integrate functional and technical evolutions adapted to the needs of end users and the constraints of their environments but also bug fixes, workarounds or fixes for critical bugs.

The third-party systems or software used on which EndoSize is based are regularly reviewed to offer the best compromise in terms of performance and security.

When a new EndoSize version is available, our customers are informed, and we are available to support them in the deployment of this new version.

Provided that maintenance contract has been signed and is valid, Therenva SAS provides maintenance of the device for a period of 5 years after commissioning.

Beyond this period of 5 years:

- Therenva SAS no longer guarantees the essential performance of the device and compatibility with obsolete third-party systems or software.
- Therenva SAS reserves the right to no longer provide support and maintenance for the end-of-life device.
- Therenva SAS assumes no responsibility for any adverse event, incident or otherwise, which would cause damage to users or beneficiaries.

It is the customer's responsibility to verify that they have a valid maintenance contract.

In the event of the end of the maintenance contract, its non-renewal or its suspension at the initiative of the customer, the use of the device is under the sole responsibility of its operator.

Therenva SAS is nevertheless available to support its customers in an upgrade / update process.

VII. Information and cautions

1. Convention

Notice	Symbol
Situations that at worst will only result in property damage and will not result in physical injuries.	

Caution	Symbol
Situation could result moderate or minor injury.	

Warning
Situation could result in serious injury or death.

Danger
Situation that will result in serious injury or death.

2. Printed version of user guide

Notice
You have a right of access to this user guide on a paper support at no additional cost within 7 calendar days upon receipt of your request by our after-sales service

or delivery of the solution if the request was made during the order.

3. User guide translated copies

Notice

The original copy of this user guide is in English and is controlled by Therenva.

4. Measurements

Caution

When using EndoSize to assess a patient's anatomy for potential endovascular repair, it is important to remember that several factors can impact the accuracy of the measurements made on the scan data. Such as:

- The quality of the CT scan data, especially in terms of slice spacing (should be no greater than 2.5 mm) and contrast agent delivery (should be homogeneous along the vascular structures of interest)
- The time that may have passed since the scan was taken.
- The endograft being considered
- The technique to be used in its deployment.

For example, stiff guide wires can straighten both the aorta and the iliac arteries. Such straightening can shorten the overall length of the anatomy from the renal arteries to the internal iliac arteries by several millimeters.

Therefore, use caution when evaluating measurements made on pre-operative anatomy, especially length measurements. Be sure to take into account both the type of device and deployment technique you plan to use.

Preferred CT scan data for EndoSize use:

- High-resolution, contrast-enhanced Spiral CT data. The preferred protocol is easier to attain using a multi-detector scanner.
- Data must be uncompressed DICOM.
- 2 mm slice spacing (no greater than 3 mm).
- Patient motion should be avoided during scan. If possible, avoid scanning non-patient objects in field of view. Do not change patient position, table height, or field of view during scan. If patient moves, repeat the study entirely.

Preferred CT scan protocol for EndoSize use:

Parameter	Preferred Protocol	Alternate Protocol
Scan mode	Helical/Spiral	
Scan parameters	140 kVp Auto mA 0.5 sec	140 kVP 280 mA minimum 1 sec
Thickness	0.625 –2 mm	3 mm
Interval	0.625 –2 mm	3 mm
Pitch	0.984:1	1.375:1
Superior extent AAA	2 cm above celiac origin	
Inferior extent	Lesser trochanter of femur	
Patient instruction	Single breath hold	1st hold: celiac to bifurcation 2nd hold: bifurcation to lesser trochanter
Contrast	Standard non-ionic Contrast agent administered in accordance with approved drug label	
Field of view	Large body	

Reconstruction algorithm	Standard

The differences between the recommended and the alternate protocols are mainly related to the interval and thickness parameters which directly influence the precision of the measurements. A warning is displayed when the user imports an exam with an interval superior to 2.5mm.

Only CT series made of axial images in DICOM format can be loaded in the software. The importation of series not complying with these constraints is prevented by the software, and a message is displayed to inform the user.

Spiral CT and axial CT acquisition methods are both suitable, as long as they output axial image series or axial reconstructions series in DICOM format.

5. Catalogs

Notice

The contents of the catalogs could have evolved or not be available for your commercial area. Please check with your stent sales manager.

VIII. General functionalities

5-steps planning procedure:

- DICOM CT data import and management
- Centerline Extraction
- Dedicated Measurements
- Interventional Strategy Selection
- Sizing Report

IX. Undesirable events

The undesirable events which can appear with the use of the “EndoSize” software are the events related to a potential failure of the software:

- No chance for importing or treating the data of the patient.
- Reconstruction of bad quality or erroneous leading to a bad interpretation or an erroneous measurement carried out by the user.

These undesirable events are detectable by the user who validates (or not) the proposals carried out by the software. In the event of failure of the software, the restarting of this one permits, generally, to solve the problem. If this one persists, a hotline service is proposed by the manufacturer.

X. Known Issues

1. Patient Database

- Smart folders are language dependent. If a user changes EndoSize language, smart folders will appear empty. User's sizing data are preserved.
- Simultaneous use of a database can lead to database corruption.

2. Operating System Issues

- On Windows systems, the use of datasets containing more than 750 images can fill system memory and lead to system slowness or application crash. Avoid running other demanding applications when running EndoSize. If you have problems with slow responses from EndoSize, or if EndoSize displays low memory alerts, quit your other applications and restart EndoSize. If problems persist, restart your machine.

- The software does not run under macOS 10.15.7 combined with Intel HD 4000 graphics due to driver issues.

If needed or for more information, contact the technical support at support@therenva.com or by phone at +33 9 72 52 29 18.

INSTALLATION AND CONFIGURATION

I. Software installation

- Open and execute the file Setup_EndoSize_3.1.XX.exe (Windows) or Setup_EndoSize_3.1.XX.pkg (macOS).
- Select the language in the drop-down list then click on OK. The dialog box “Setup – EndoSize” opens. Click on Next.
- Check the box «I accept the agreement» and click on Next.
- Check your system meets the minimal requirements and click on Next.
- On Windows, the wizard enables to select a destination location for EndoSize installation. It is recommended to use the folder proposed by default. Click on Next.
- Verify the box «Create a desktop icon» is ticked then click on Next.
- Click on Install to start software installation.
- After installation is complete, click on Finish. If « Launch Quick Start Guide» is ticked, a web page opens with tutorial videos. If « Launch EndoSize » is ticked, the software is automatically launched.

II. License registration

At the first EndoSize launching, license registration is requested. The dialog box «EndoSize Registration» opens. This step requires an internet connection.

- Select a language and click on Continue.
- Internet connection is automatically checked:
  - If the connection to endosize.com failed, please find out about your Proxy configuration. Click on Test the connection. If it fails again, tick the box “I do not have an internet connection”, then click on Continue.
  - If the connection to endosize.com succeeded, click on Continue.
- Check the box « I have read, understood and accepted the End-User License Agreement » then click on Continue.
- Check the box **«** My system meets the minimum requirements » then click on Continue.
- Enter the license key you received and click on Continue.
- Fill the contact form and click on Validate then Finish.

III. Software configuration

1. Default database

- Once your license is registered, the software starts up. A window appears in which you can select the folder which will contains the sizing data.
- Click on Default directory. The patient manager opens.

2. Configuration of the local databases

- Click on Preferences icon in the right part of the top toolbar then click on Local Database tab.
- Add Database then give it a name.
- Select a folder.
- Then, you can rename, move, remove or (dis)connect the existing databases.

Automatic backup: For each database, you can require **periodic backups** by selecting among *Weekly, Monthly, or Never*. Except if you choose *Never,* every week or month a backup of the current database state will be done at the software closing.

By default, the primary database backup preference is set on *Weekly* while others are set on *Never* if any.

Manual backup: For each database, you can ask for one-time backups by clicking on the button “Manual backup”. A progress bar will be displayed during the generation times.

Notice

In this context, the backup process only regards sizing data, i.e., the es_patient.db file. Any deletion of patient or exam within the EndoSize interface or into the ESlocalDatabase folder will result in the permanent loss of the data in question. Patient or exam data are saved according to the Data Controller backup policy.

3. General Settings

This tab allows you to configure general settings of the software, such as application settings (language, text size, rendering type, display of patient information...), operator information, and proxy settings.

- Click on the Preferences icon in the right part of the top toolbar then click on the General Settings tab
- Make the desired changes among the settings:

Setting	Impact
Language	The software language is setting in the selected language.
Date format	All dates are setting in the selected date format.
Hide patient information	Hide patient names in the patient manager without erasing them
Limit to 750 slices	Imported data volume is cropped if exceed 750 slices
Enable notification	Accept/Deny being warned by notification about software
Anonymization: select DICOM field(s) to anonymize/erase	Anonymization process (before or after the import) erases only selected fields (see figure 2). Partial anonymization.
PDF Report Image Quality	Compromise between snapshots quality and report generation burden.
Allow automatic snapshots in the report	Default snapshot display in the report: The snapshots taken automatically at measurements captures can be displayed or not in the report.
Volume Rendering	Optimize volume rendering according to the computer graphic card.
High quality rendering	Optimize quality rendering according to computer capacities.
Default Window/Level	Define the transfer function for 2D visualization. The default is set at 700/150.
Display all 2D information	Image features are displayed in the top left corner of the 2D views including image size and spacing, cursor position, index, and related hounsfield value.

snapshot lecture.	
3D background color	Define the color of the background of the 3D view.

- Customize the report by choosing a logo and a user/operator name to display or not.
- Define the Proxy settings by entering the IP address, port, login and password.
- Reset license information to proceed to a new registration process at the next launching.
- Click Ok.

A restart notification is displayed. The software requires to be relaunched to apply global settings.

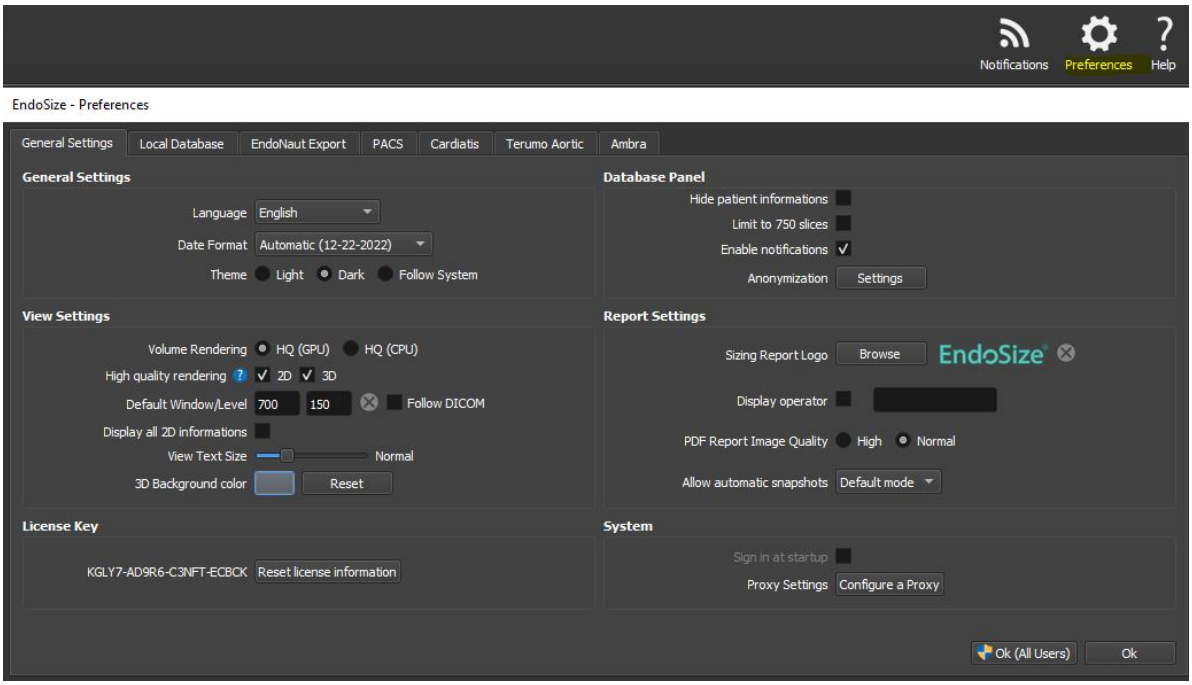

Figure 1. General settings interface

Figure 2. Pop-up “Anonymization”

4. PACS configuration

In order to configure connection between EndoSize and PACS server, you will need the following information:

1. AETitle of PACS server and client machine (EndoSize)
2. IP address of PACS server and client machine (EndoSize)
3. Server port and reception port

- Click on Preferences icon in the right part of the top toolbar then click on PACS tab.
- Click on Add a node and fill the fields of PACS server:
  - Give a name to the server in the description field.
  - Enter AETitle, IP address and the port of the PACS server
  - Click on OK.
- Click on Test nodes for checking PACS server state.
- Check / Edit software DICOM receptor configuration.
- The pair AETitle / IP must be unique in the PACS network.
- Click Ok and Restart the software to take the changes into account.
- Keep in mind DICOM receptor information for the PACS server.
- We recommend checking the data import from the PACS server. For that, import a data serie. Click on OK.

The client machine must be declared and authorized on the PACS server to be able to use DICOM Query/Retrieve service between EndoSize and the PACS server.

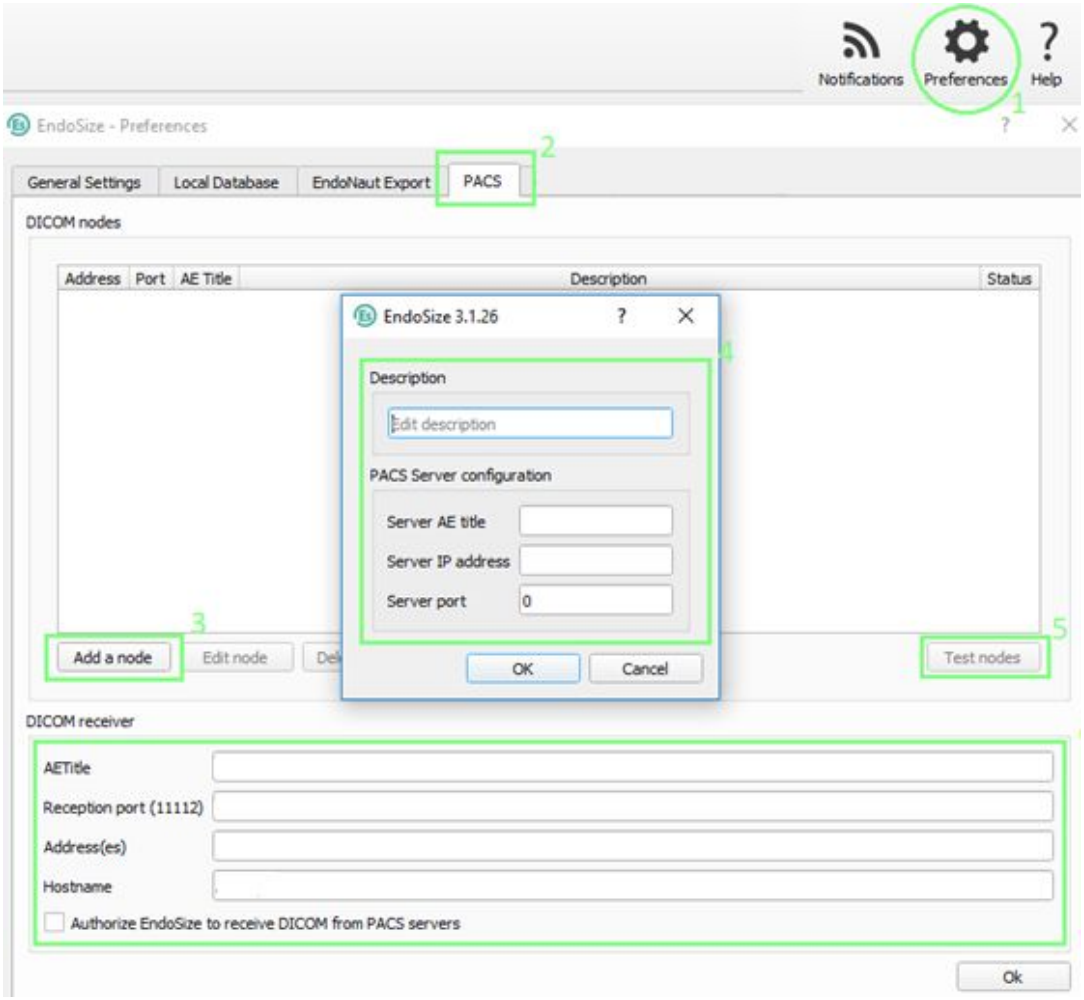

Figure 3. PACS configuration

IV. Use of an EndoSize license on Windows multiple sessions

Note: The actions described below require you to have administrator privileges on the machine.

1. Multi-user installation

During the software installation phase (I.) when launching the installation file, you will be recommended to install it for all users. Follow the recommendation.

2. Multi-user license

At the end of the license registration phase (II.), you will be able to activate the license for other users of the machine.

3. Multi-user configuration

From the administrator session:

- Start EndoSize
- Open preferences
- Make any modifications to the general parameters (optional) - III.3
- Make any modifications to the local databases (optional) - III.2
- Make any modifications to the PACS parameters (optional) - III.4
- Click on “Ok (all users)”.

By following these instructions, existing and future users of this machine will benefit from EndoSize with the same license and the same configurations.

Alternative - AdvancedConfig.exe

- In the installation folder, launch the AdvancedConfig.exe application.
- Select the settings to be taken into account.
- You can copy the settings of the current user to the other users of the machine.
- You can reset the settings selected for the other users.

SOFTWARE UPDATES

The EndoSize software is constantly evolving, hence new versions of the program are regularly released. The last version and related documentation are delivered from the EndoSize Download Center (https://download.endosize.com).

If you are connected to the internet, an update wizard opens automatically at the software launching. Updates are recommended but you are free to install or postpone the update.

If you cannot be connected to the internet (“offline license”), the person in charge of the maintenance of the software, whose contact data was given to Therenva at the time of the first installation of the software, is informed by the Therenva teams that an update is available. In this case, Therenva will provide the installation file for the update, preferably by secure online transfer or other means (to be agreed upon).

Note: if you run into problems updating your device, download the last setup (https://download.endosize.com) and reinstall it by following the installation procedure. No data will be lost. If the problem persists, please contact support@therenva.com

PATIENT DATA MANAGER

The patient manager is the entry point of the software. You can either consult case planning procedures previously made or import new data using the tools on the upper toolbar.

Figure 4. Patient Data Manager interface

Various information about the patient and sizing characteristics are presented and you can sort the database by clicking the header of the desired column, you can search patients using the search field on top.

I. Import CT scan data

EndoSize allows you to use several ways to import CT data. Use the different Import tools from the upper toolbar to import data from CD, local directory and PACS.

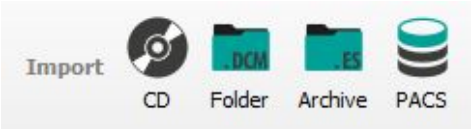

Figure 5. Data sources available in the Patient Data Manager

EndoSize does not use any image compression techniques which result in the loss of image quality.

1. CD

Insert the CD in your CDROM drive and click the CD icon. CT exams are displayed, and you can use the preview window to select the series you want to import. Double-click on a series or click Import to start the importation.

If the CD does not contain a suitable DICOMDIR file, no series will be displayed by the **CD** importer. Use the **Folder** importer to parse the CD and import DICOM series.

2. Folder

You can use this tool to import data from a local directory, a usb flash drive or an external hard drive. Select the directory by clicking on the button and the content will be displayed in the table. Double-click on a series or click Import to import the series to the local database.

Note: Select and import several exams at once by using the system shortcut (ctrl+clic or cmd+clic).

3. Archive

You can use this tool to import EndoSize archive which contains CT and sizing data.

4. PACS

You can retrieve data from a PACS server. Use the configuration utility to configuration PACS access. You can request data through PACS queries by patient name or exam dates. Double-click on a series to start the importation.

II. Organize patient data

1. Filter image series

Click on a **Smart folder field** of the left panel to filter image series by consultation period.

Click on a **Module field** of the left panel to filter image series to retrieve all data series which have been already processed through the related module.

2. Sort image series

Click the **column header** corresponding to the **desired sort field** to sort the image series by patient name, birth date, exam date, importation date, physician, etc.

3. Filter by bookmarks

1. Click **[+] below the Bookmarks tab** of the left panel and enter a bookmark name.
2. **Drag and drop image series** to the created bookmark in order to group and easily trace your data.
3. **Remove the link to the bookmark by doing a right-click on the series** then “Delete bookmark >”.

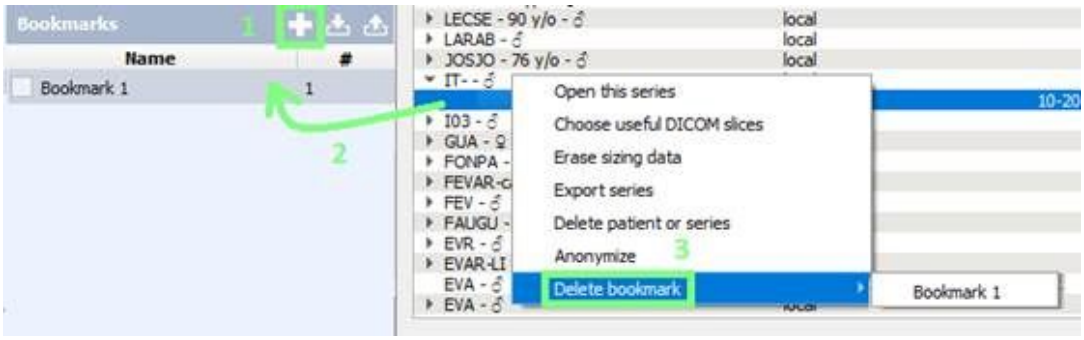

Figure 6. Managing patient data using bookmarks

4. Edit patient and series information

Click on a series and fill in the **editable fields of the lower panel** in order to edit some information attached to the image series, such as the physician name and the institution.

Click on a patient name and fill in the **editable field of the lower panel** in order to **add comments** on the patient care and follow-up.

5. Search image series

Fill in the **upper Search bar** with a patient name, physician name, institution or any keyword to get associated image series. The Search tool retrieves information from the DICOM fields and the editable patient and series fields.

III. Manipulate data series

Select a data serie,and use either top left icons or right-click menu to open, reset, export the sizing data or to select slices, delete, anonymize the serie.

Pdf reports associated to a series can be retrieved through the **List of reports** in the lower panel.

Figure 7. Manipulate data series from top toolbar action buttons

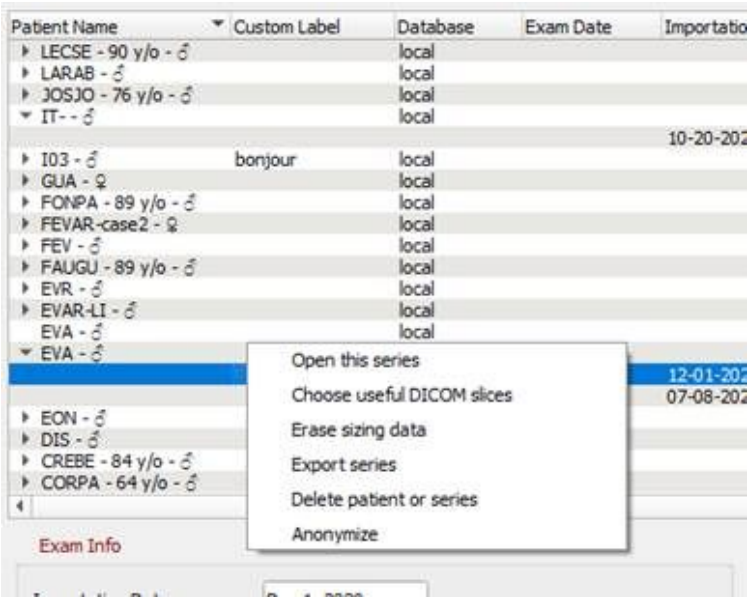

Figure 8. Manipulate data series with the right-click

Note: Transfer data from one database to another by selecting the data, and doing a drag-and-drop to the new database (bottom left corner). The system will ask if you want to migrate or copy the data.

SIZING WORKFLOW AND TOOLS

This part presents the 2D/3D interface common to all the specific treatment modules. It enables the visualization of 2D CT slices, MPR, and slices perpendicular to the vessel centerlines, as well as 3D CT rendering.

Note: The 2D visualization presents the original data which has not been modified or compressed in any way. The 3D rendering presents the original data in a custom way to make it easier to read by the physician. The information content of the original image will never be modified or compressed.

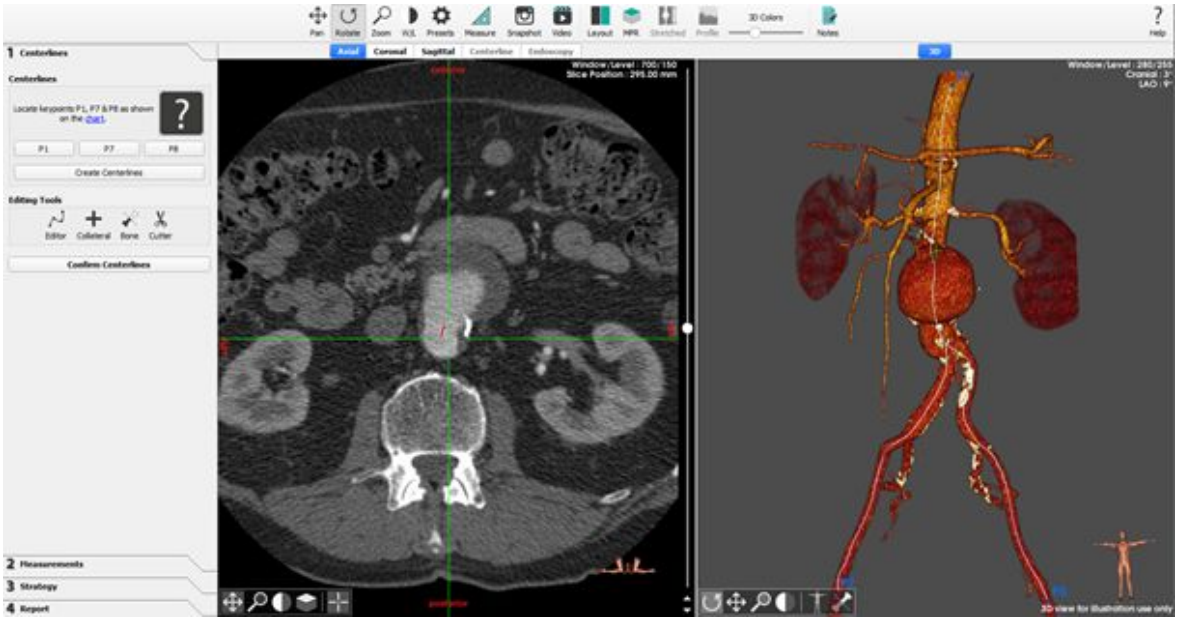

Figure 9. 2D/3D Interface

I. Left panel: sizing steps

Specific sizing steps are detailed for each treatment module in a specific section. Here are described the common steps:

- Step 1: centerline extraction
- Step 2: specific measurements
- Step 3: interventional strategy definition and devices
- Step 4: sizing report generation and export tools

1. Step 1: centerline extraction

An explicit instruction scheme to position keypoints is available for each module.

To extract vascular structures and centerlines, click **Create Centerlines** then **Confirm Centerlines** to go to the measurement step.

To modify, create, remove or smooth a centerline, click **Edit centerlines** . Click on **Help** for detailed instructions.

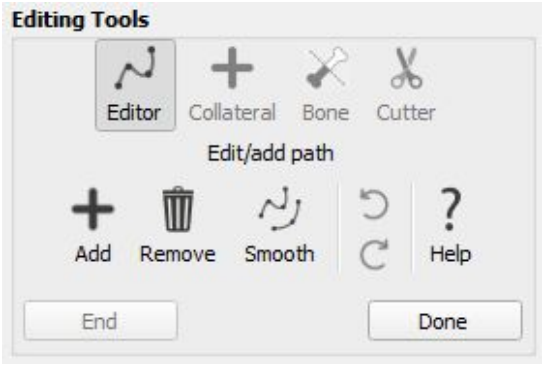

Figure 10. Edit, add, remove, smooth centerlines

2. Step 2: specific measurements

An explicit instruction scheme to position additional keypoints is available for each module.

Move along the centerline through the right slider attached to the 2D cross-section view, and position the keypoints. Key diameters, lengths and angulation mesures will be proposed in the left panel table.

To edit, set and validate measurements:

- Edit a key measurement: on the 2D view, use the arrows to modify a key measurement
- Set a measurement: the current diameter visible on the 2D view can be assigned to a key measurement or a new custom key measurement through the "**Set measurement to...**" button or the right-click menu on the 2D view.

3. Step 3: interventional strategy definition and devices

A **sizing sheet** including the measurements and procedure-specific criteria is displayed. Measurements values out of the criteria range appear in red.

Interventional choices can be recorded by clicking on the radio buttons.

Device selection among device references can be made by choosing the device model and adding the references to the "basket".

These choices are saved into the report upon clicking **Confirm Strategy**.

4. Step 4: sizing report generation and export tools

The report can be printed or exported into pdf format. It is automatically saved within the database, so you can access it later.

Screenshots and 3D animation videos can be selected and saved anywhere through the left panel icons.

Comments can be added to the report through the icon **Notes**.

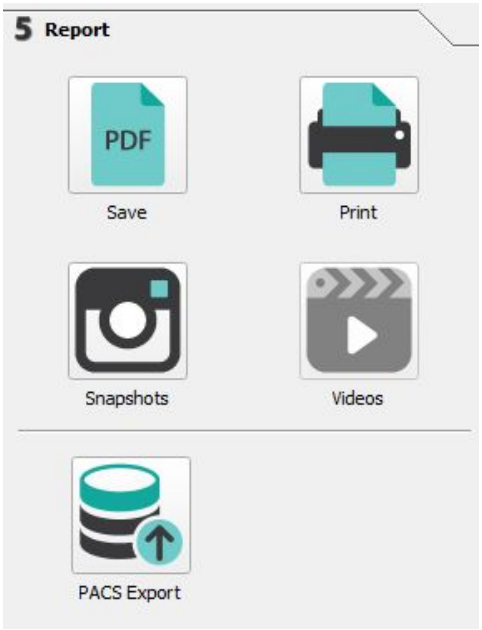

Figure 11. Report tools

II. Top Toolbar

This toolbar enables to choose the displayed views (2D/3D), the way to interact within these views, and to do custom measurements.

Figure 12. Top Toolbar

1. 2D/3D interactions

The first icons define the action made with the left-mouse button (panning, rotation, zoom, change contrast).

Tips: The "T" key activates the "Pan" mode, "R" "Rotation", "Z" "Zoom" and "W" "Window/Level".

2. Presets

The presets menu includes default configurations, contrast presets and viewing presets.

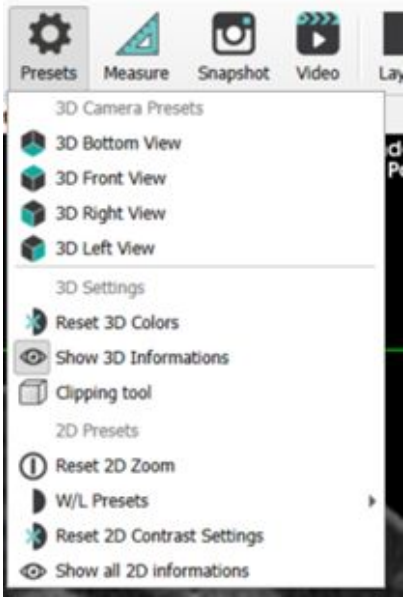

Figure 13. Presets Menu

3. Measurements

It enables to realize custom diameter, length or angle measurements. For each measurement type, a pop-up opens to record your custom measurement by giving it a name:

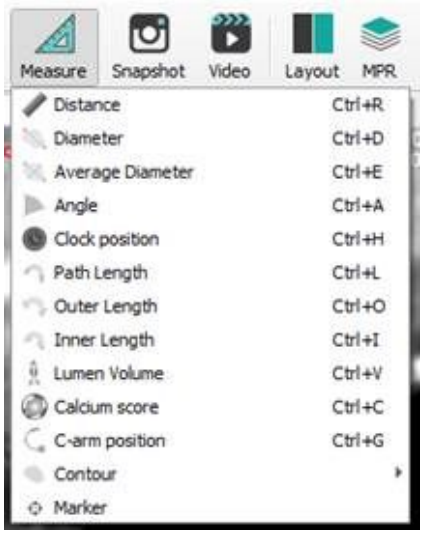

Figure 14. Measure Menu

- **Distance**: free measurement on any 2D view
  On the 2D view of your choice, click on a first point. While keeping the mouse pressed, drag the mouse to a second point. The distance between these two points is represented on the image by a double-colored arrow, and the measurement appears in the Distance window. Click on Ok if the measurement suits you or click on New measure if you want to perform other measurements. All measurements can be edited using the pencil icon.

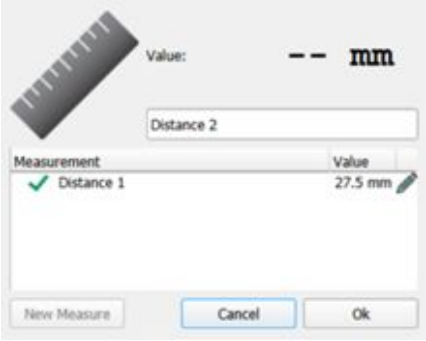

Figure 15. Distance pop-up

- **Diameter**: free measurement on any 2D view .
  On the 2D view of your choice, click on a first point. While keeping the mouse pressed, drag the mouse to a second point. The distance between these two points is represented on the image by a double-colored arrow, and the measurement appears in the Diameter window. Click on Ok if the measurement suits you or click on New measure if you want to perform other measurements. All measurements can be edited using the pencil icon.

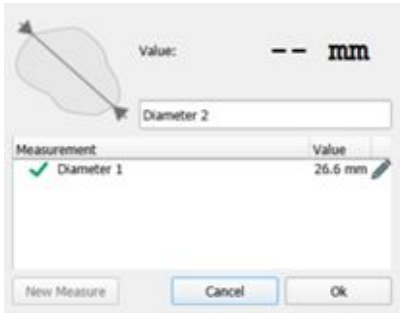

Figure 16. Diameter pop-up

- **Average diameter**: free measurement of minimum and maximum diameters on any 2D view.

Figure 17. Average diameter pop-up

- **Angle**: on the 3D or 2D views, position and validate A, B, C points by clicking on the associated buttons. If you select **Invert the angle**, the opposite angle is displayed.

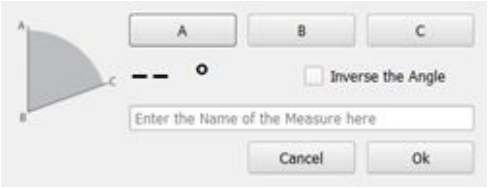

Figure 18. Angle pop-up

- **Clock position**: on the 2D view, click on an ostium to measure its clock position regarding the centerline. The clock can be dragged to a new place.

Figure 19. Clock position pop-up

- **Path length**: on the 3D view, position and select **A** and **B** by clicking on the associated buttons. This path length measurement applies to created lines only. You can create a free path line (not necessarily a centerline) at the Extraction step.

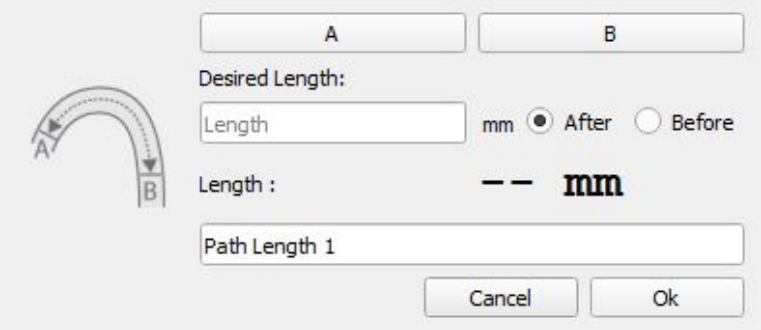

Figure 20. Path length pop-up

- **Manual length (or Open polygon):** Draw a line by double-clicking on a 2D view. At least 2 points are required to define a straight length and more for a curved length. Drag and drop the points to adjust the line then the length.

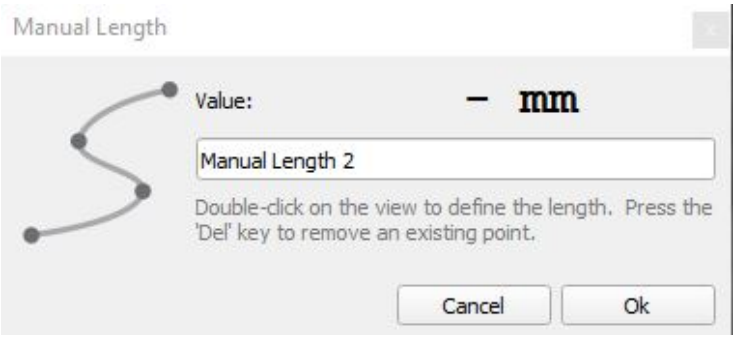

Figure 21. Manual length pop-up

- **Outer length**: on the 3D view, position and select **A** and **B** by clicking on the associated buttons. The diameter can be variable (based on the lumen diameter) or fixed (default).

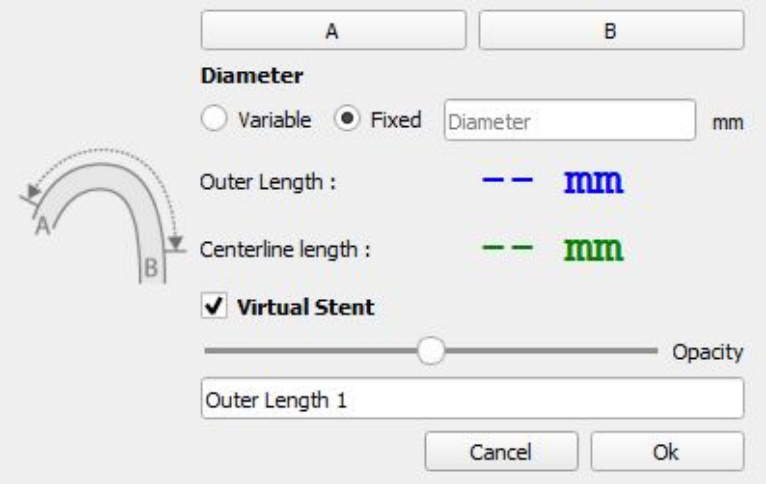

Figure 22. Outer length pop-up

- **Inner length**: on the 3D view, position and select **A** and **B** by clicking on the associated buttons. The diameter can be variable (based on the lumen diameter) or fixed (default).

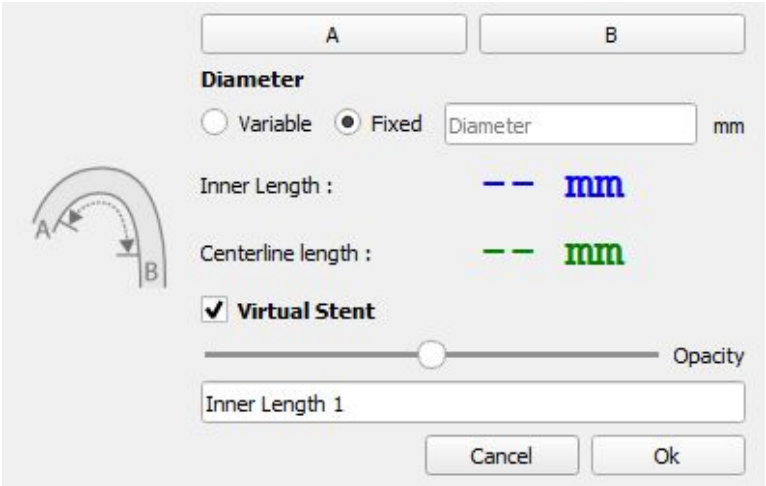

Figure 23. Inner length pop-up

- **Portion analysis**: on the 3D view, position and select **A** and **B** by clicking on the associated buttons. This measurement applies to created lines only. Define a distance/interval to compute a number of diameters into the portion.

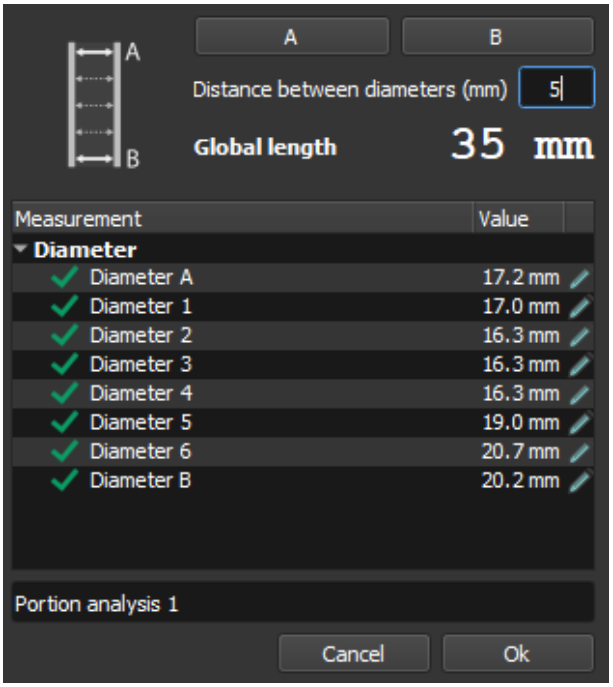

Figure 24. Portion analysis pop-up

- **Lumen volume**: on the 2D or 3D view, position and select A, B, C points in the lumen by clicking on the associated buttons. The visibility of the result can be turned on/off. The opacity of the resulting model can be changed.

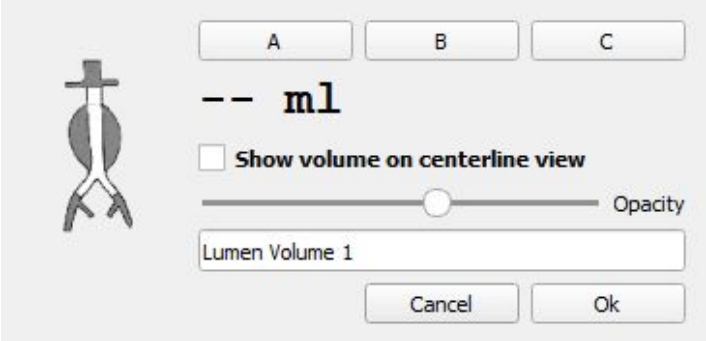

Figure 25. Lumen volume pop-up

- **Calcium score**: on the 2D or 3D view, position and select A and B points in the lumen by clicking on the associated buttons. A and B define the ends of the vessel portion you want to quantify. The measurement parameters can be adjusted by defining a threshold in Hounsfield units. This threshold is applied within a volume of interest (VOI) based on the centreline :
  - with a fixed diameter (**Fixed**); or
  - with a variable diameter (**Lumen based**).

  The visualization parameters can also be modified: calcifications, lumen and volume of interest can be displayed or hidden on the 3D view, and their opacities can be adjusted using sliders.

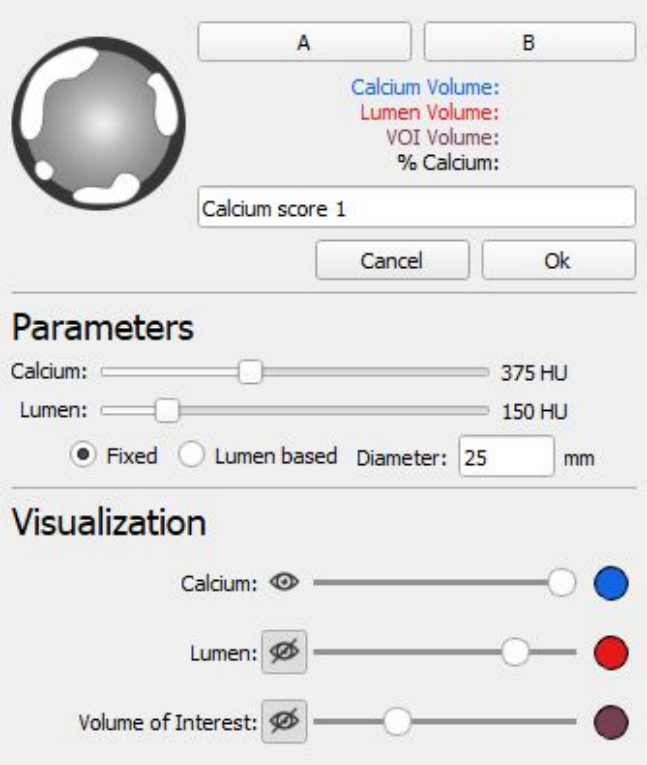

Figure 26. Calcium score pop-up

- **C-arm angle**: Save C-arm angle (CRA/CAU and LAO/RAO angles) corresponding to the current 3D view position.

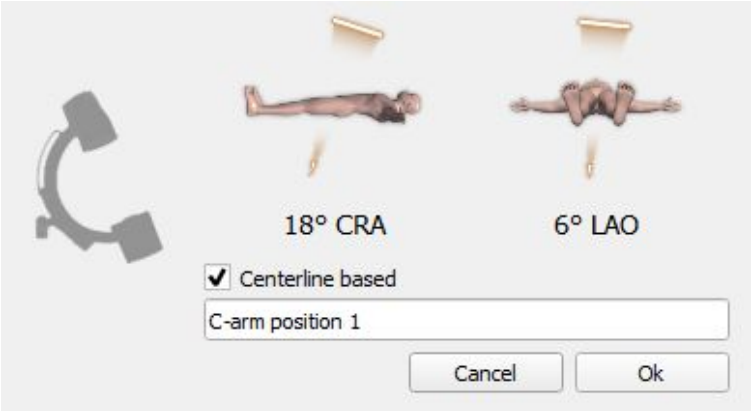

Figure 27. C-arm angle pop-up

- **Contour:** Measurement of a diameter, a perimeter or an area, based on a contour. Chose the type of measurement you want to perform. On the 2D view of your choice, double click to create points in order to define the contour of the structure of interest. When the contour is closed, the measurement is automatically calculated.
  You can either measure one quantity or all of them at the same time. For that, use the option “Advanced”. With this option, the minimum and maximum diameters are also calculated.

Figure 28. Tool “Measure > contour”

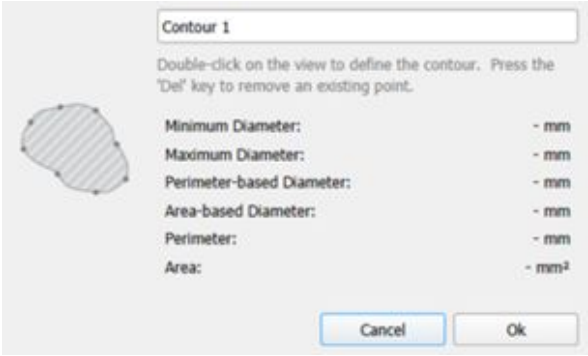

Figure 29. Pop-up “Contour > Advanced”

- **Marker**: on the 2D or 3D view, position **A** to get the space coordinates.

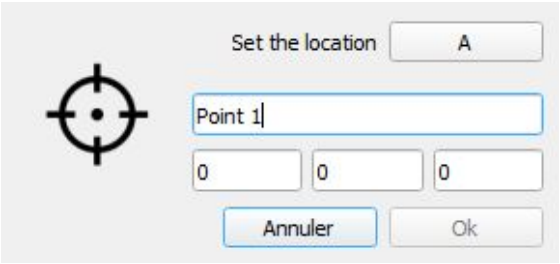

Figure 30. Marker pop-up

4. Snapshot and video

It enables to grab and comment images of the different views (**Camera** icon), and to create a 3D animation video (**Clap** icon).

a) Snapshots

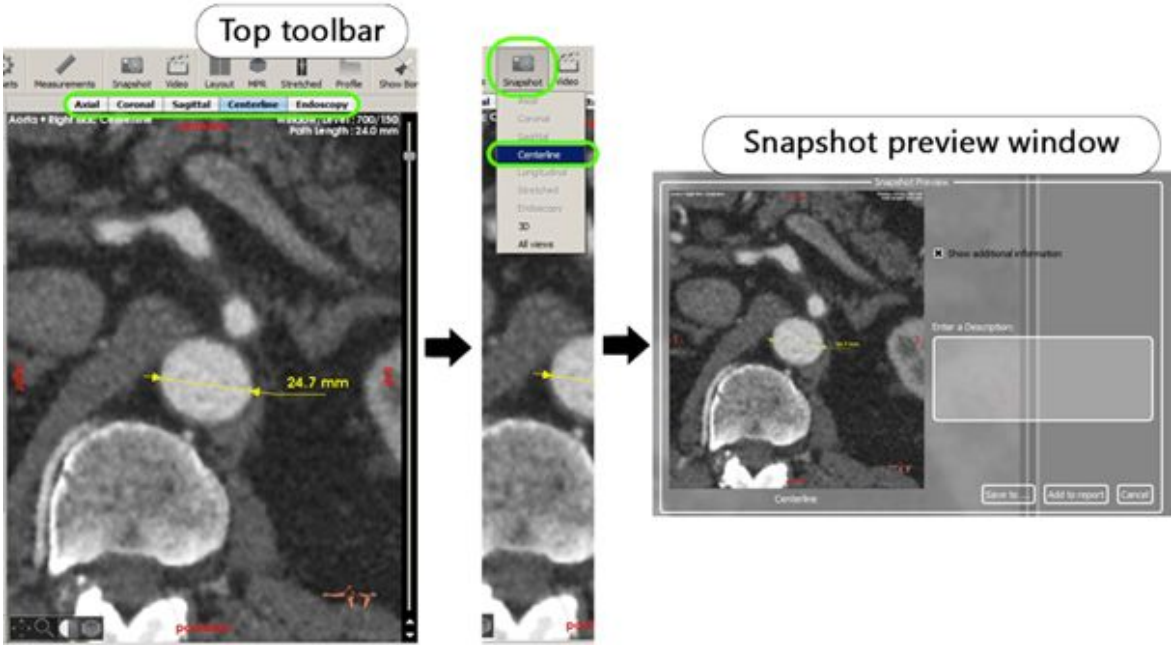

Figure 31. Snapshot capture

Snapshots can be **added to the report**, **exported**, and/or **annotated** with text or geometric shapes (arrow, circle).

1. Select the view you want to take a snapshot of by clicking on the corresponding button above the 2D viewer). (Note: You don't need to select the view if you choose **All views** at the next step)
2. Click on the **Snapshot icon** in the **top toolbar** and select the view you want to take a snapshot of.
3. The **Snapshot preview window** will pop-up and you can choose your saving options. **Save to...** will save your capture to a chosen location and **Add to report** will add your capture to the report.

The **Snapshot Manager** tab allows you to sort your screenshots, export them and save them. You can also import images or annotate some screenshots by clicking on the pencil icon at the top right of the screenshot.

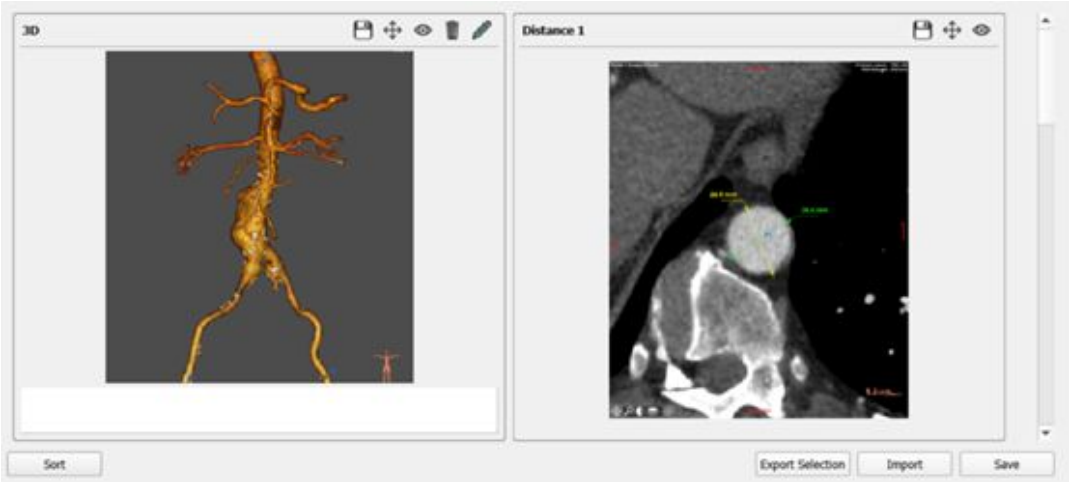

Figure 32. Window “Snapshot Manager”

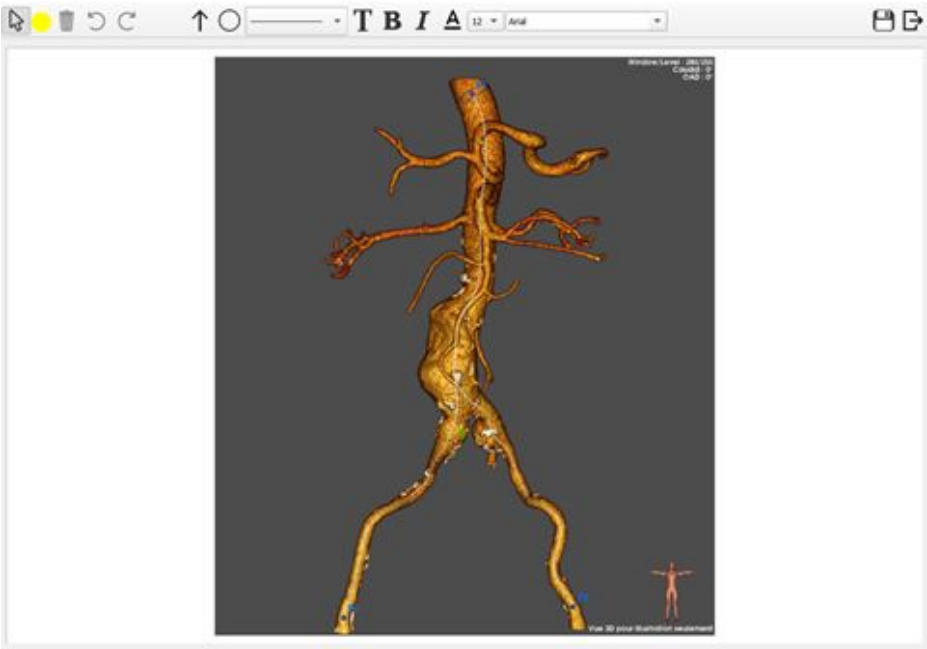

Figure 33. Window “Annotation Tool”

b) Videos

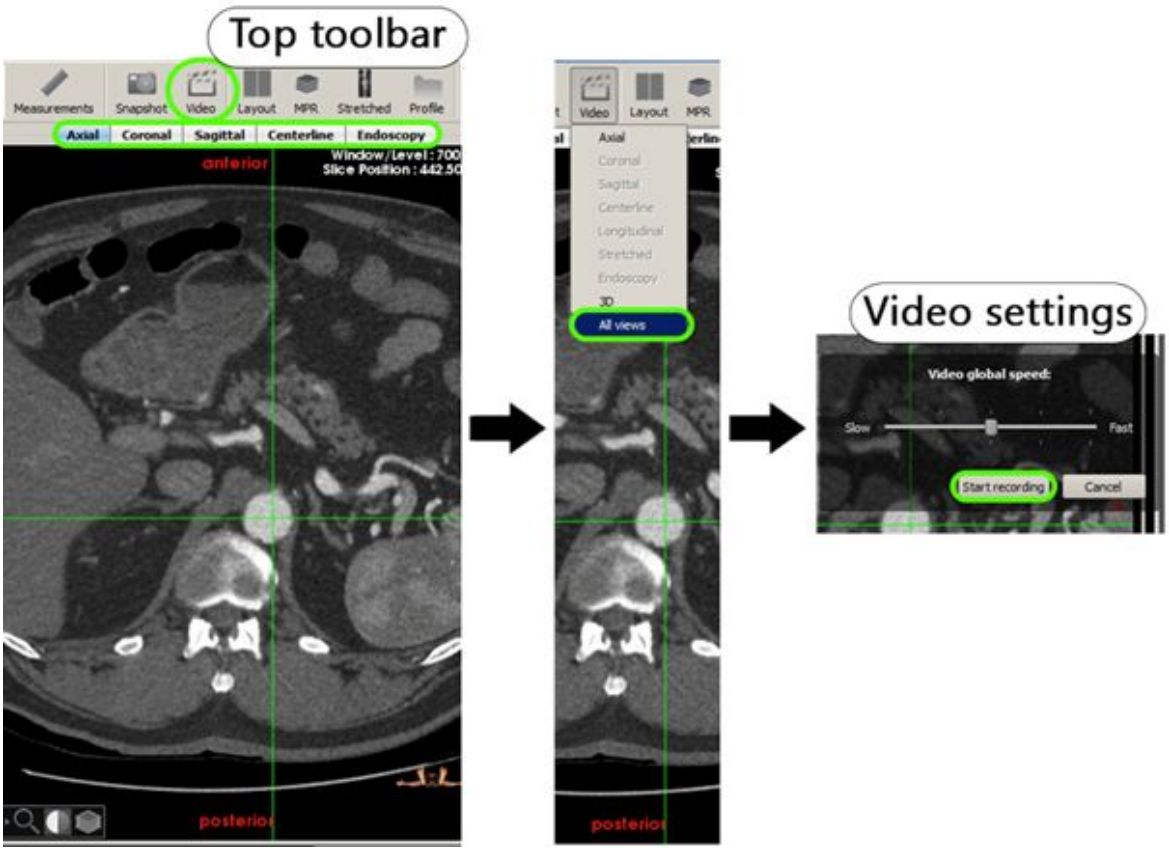

Figure 34. Video capture

1. Select the view you want to take a video of by clicking on the corresponding button above the 2D viewer. (Note: You don't need to select the view if you choose **All views** at the next step)
2. Click on the **Video icon** in the **top toolbar** and select the view you want to take a video of.
3. The **Video settings window** will pop-up and you can choose your recording options. You can save the video capture to a chosen location and also find it attached in the report.
4. The **Video Manager** tab allows you to see all your videos, watch them, delete them and save them.

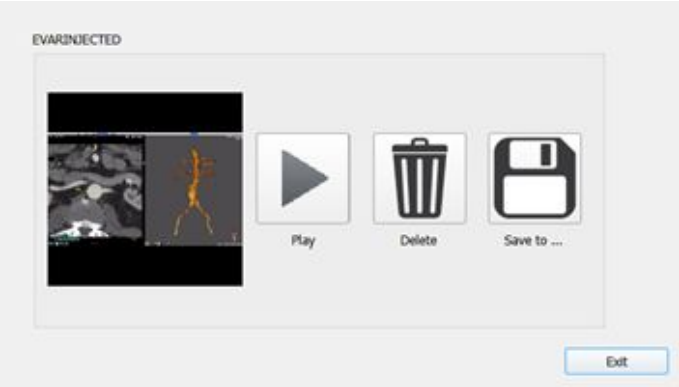

Figure 35. Window “Video Manager”

5. Layout

This menu enables to choose between different 2D/3D viewing options depending on your needs. You can switch between these configurations anytime you want.

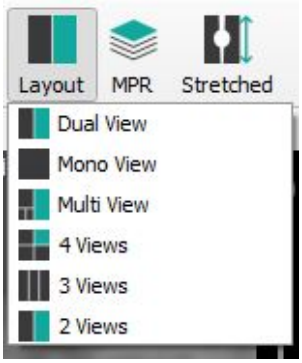

Figure 36. Layout Menu

6. Other views

4 other views can be displayed during the sizing.

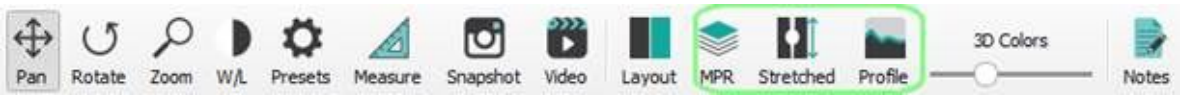

Figure 37. Other view accessible in the top toolbar

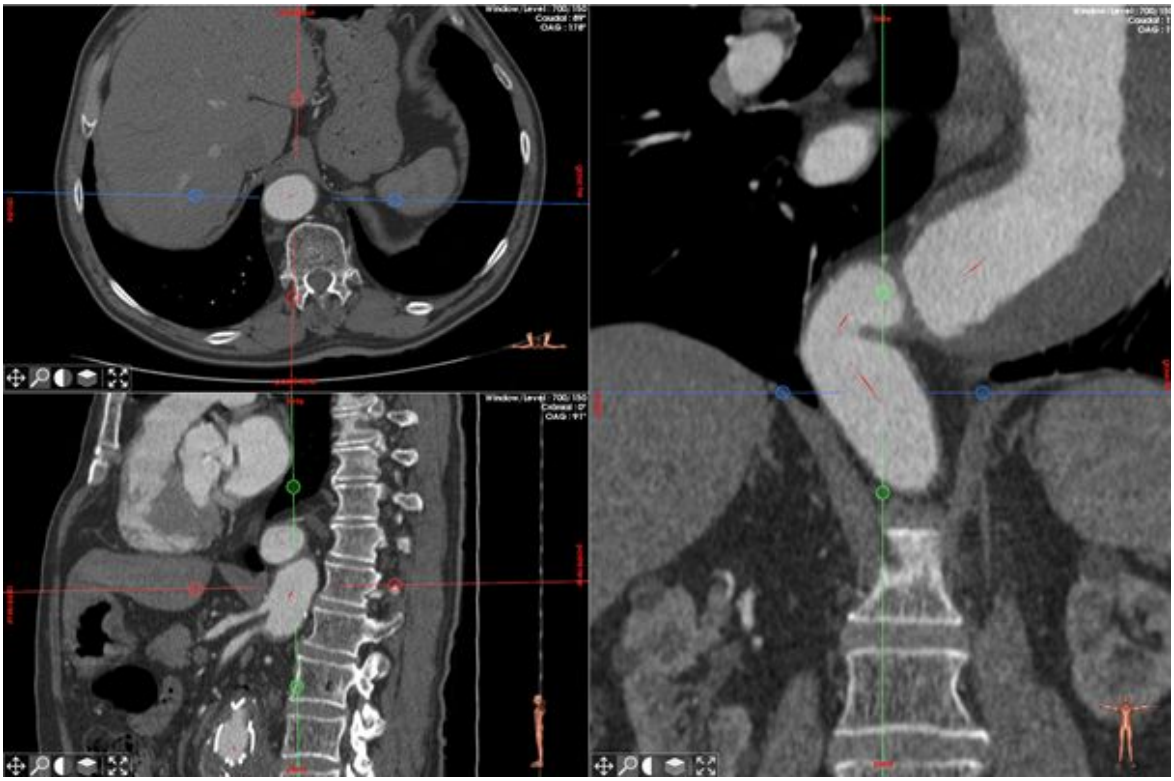

Figure 38. MPR (Multiplanar Reconstruction) view

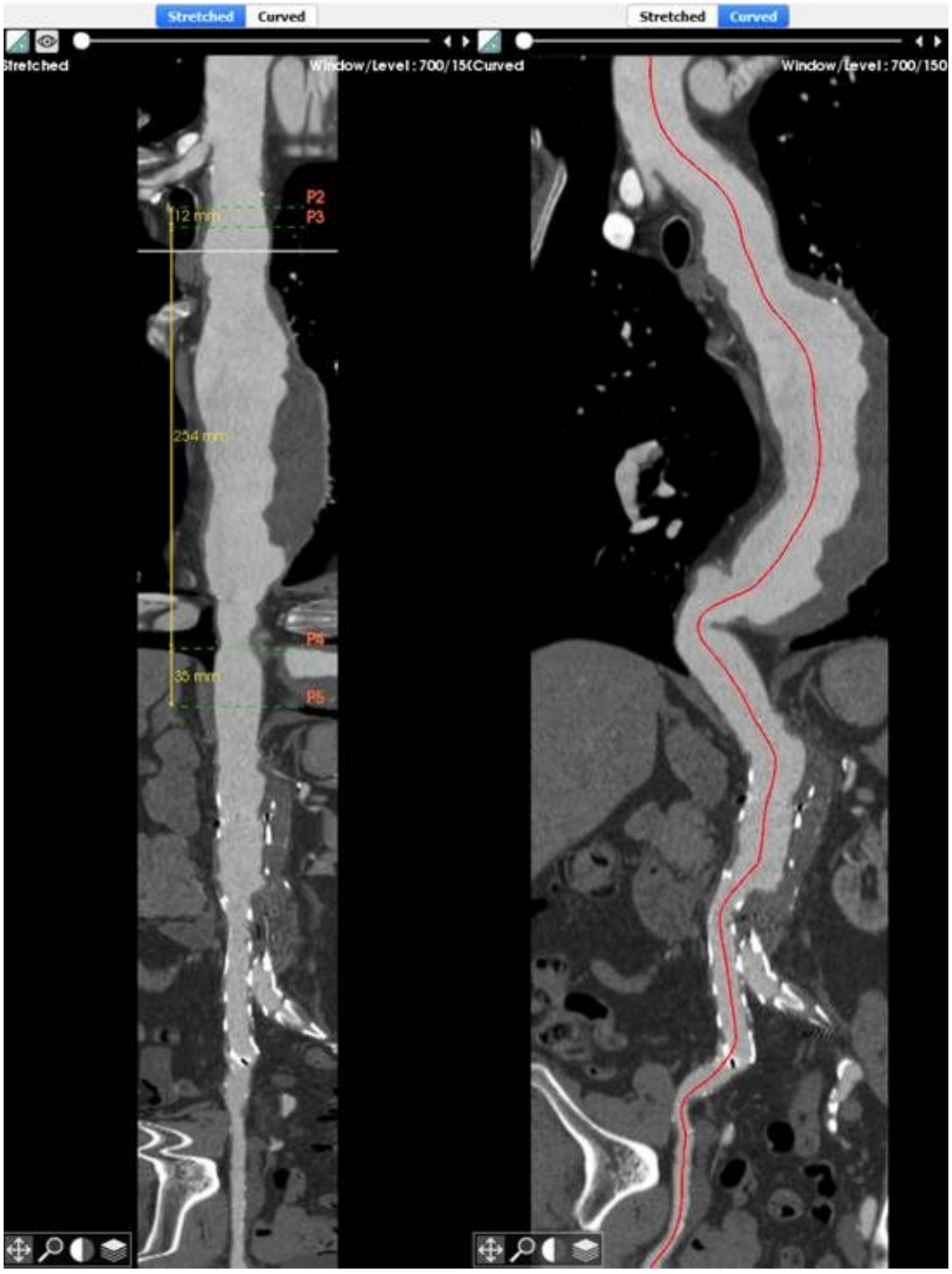

Figure 39. Stretched and Curved view accessible clicking on Stretched

Figure 40. Profile view of vessel

7. Notes

Notes can be taken all along the sizing. These notes are automatically added in the report in the corresponding section.

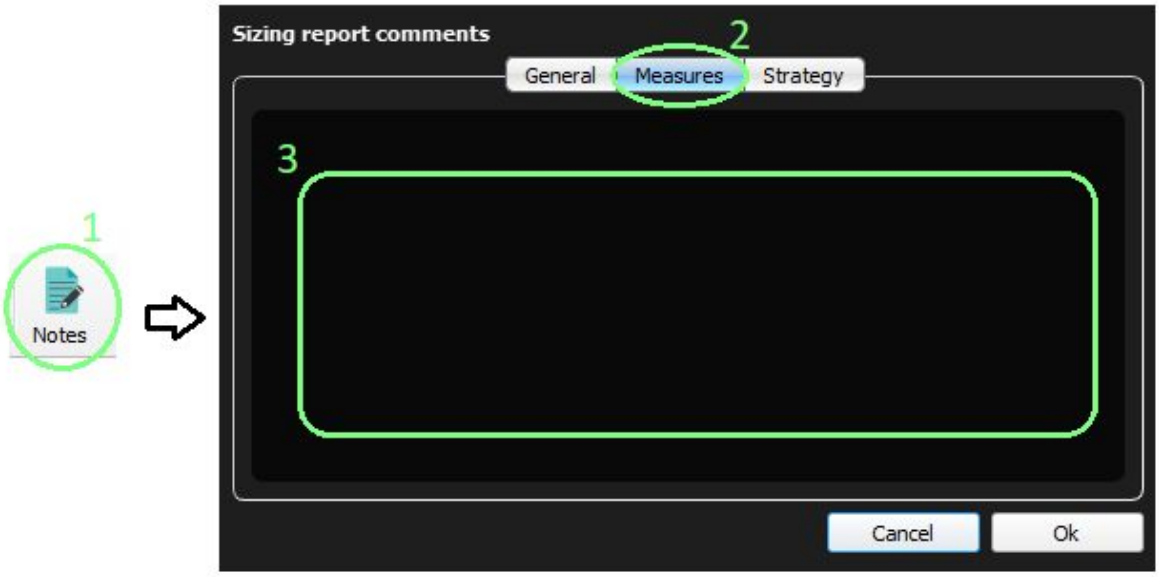

Figure 41. Add a note during the sizing

Interoperability and Cybersecurity

I. EndoSize software system and external interfaces

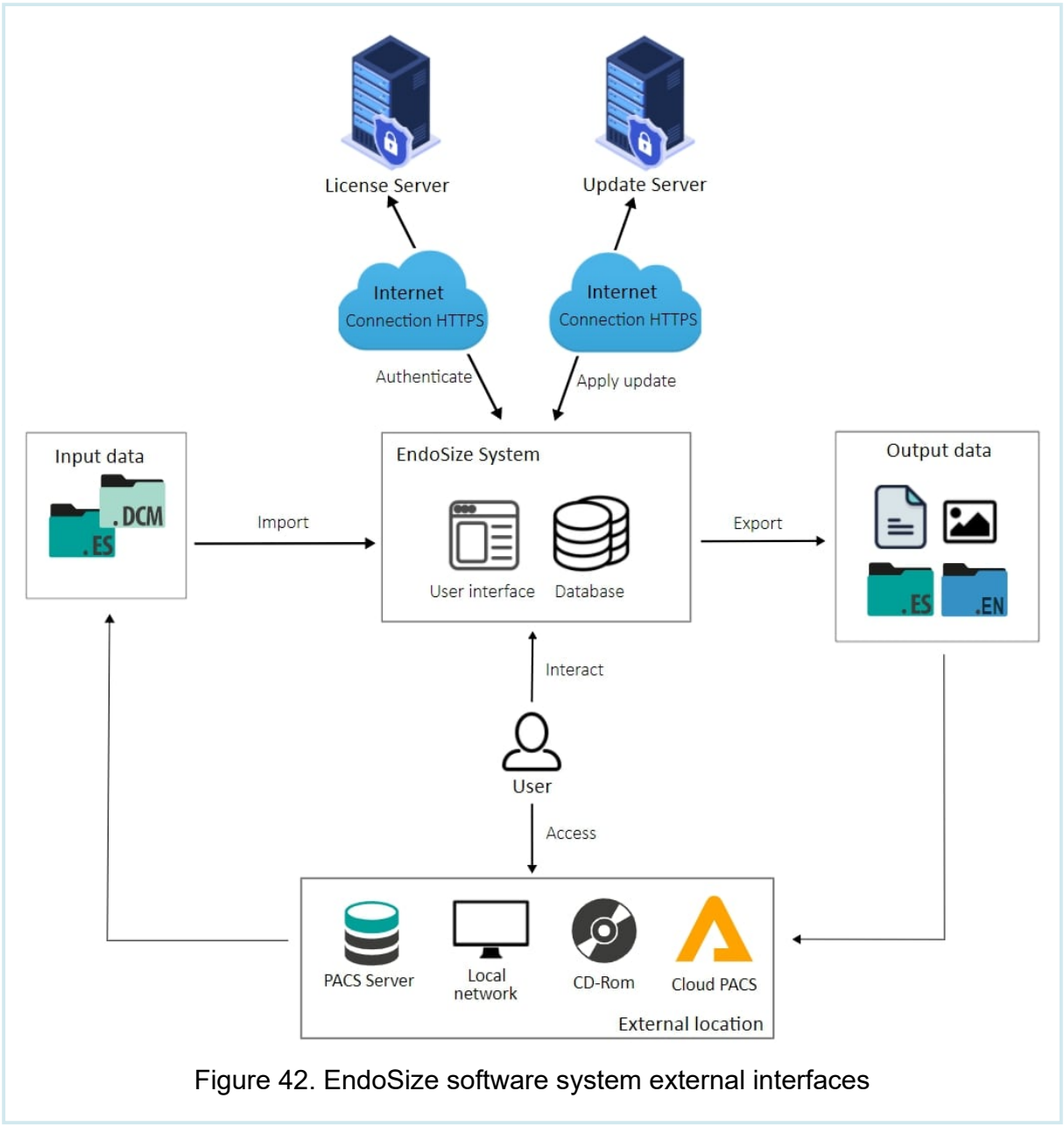

Figure 42. EndoSize software system external interfaces

EndoSize is a standalone (on-premises) software installed on end-user computers (individual or staff (protected) machine), thus requiring computer access rights. It may interact with external entities, as summarized in the figure above.

II. Interoperability

1. External data flow

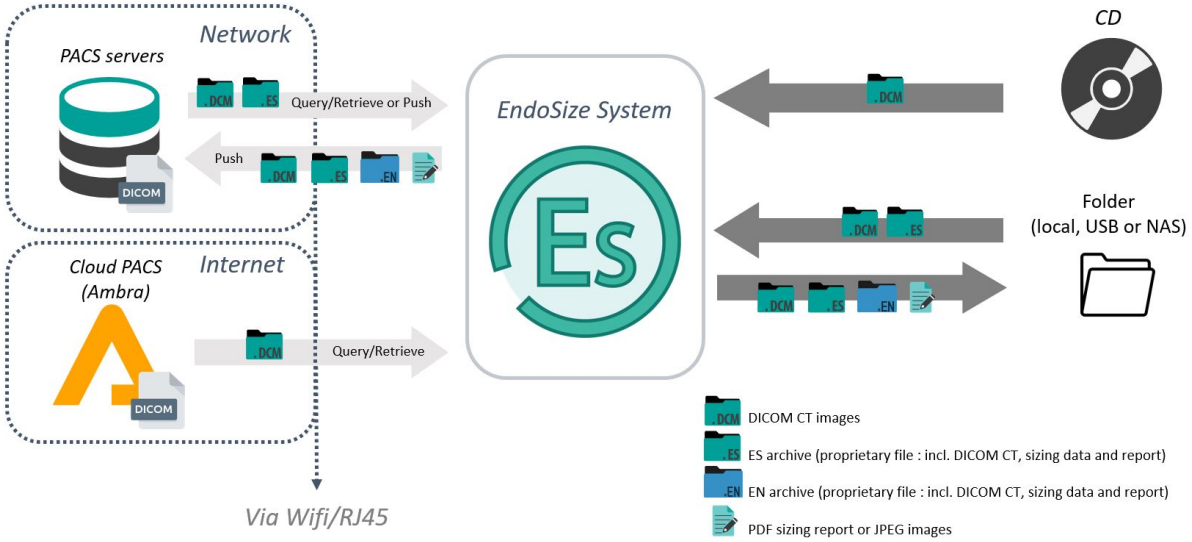

Figure 43. External data flow overview

EndoSize allows data transfer through the following entities:

1. CD-ROM Drive
2. Hard or removable drives
3. NAS (via local network)
4. PACS systems (via local network or internet)

2. Data type

Data import and export are allowed toward all entities, except CD-ROM (import only).

- DICOM data import is the entry point for performing planning.
- Processed data, i.e. sizing reports, snapshots and archives, as well as raw data, are exportable for sharing, printing or research purposes, and can be dicomized.

The DICOM network protocol (through Query/Retrieve and Push requests) is used for data exchange with PACS. All DICOM data (*dcm* extension) are retrieved or pushed according to the DICOM conformance statement.

3. Data exchange

a) Local disk, NAS, USB, CD

Basic parsing, reading, and writing functions are used for data transfer.

b) PACS servers

Communication with PACS systems is performed by Query/Retrieve and Push services, based on DICOM messages.

- From EndoSize to PACS: Query/Retrieve (input data); Push (output data)
- From PACS to EndoSize: Push (input data)

Prerequisite:

- PACS server AE Title, TCP/IP address and port must be filled in PACS configuration settings.
- The client machine must be declared and authorized on the PACS server to be able to use DICOM Retrieve and Push services.

c) Ambra (cloud solution)

Communication with the Ambra cloud platform is possible via RESTful API and especially using attributes for fetching and downloading data.

Prerequisite: Ambra credentials must be entered to get access to the Ambra system from EndoSize.

III. Cybersecurity

1. Operation security

3-level audit trail to prevent unauthorized system access:

1. Only qualified clinicians or medical device industry professionals are allowed to access EndoSize. User identification is systematically performed before procurement.
2. At installation, the user must proceed to the registration via a unique license key (encrypted process).
3. At each launch, the user has to authenticate by entering a password. By default, this additional security process can be disabled by the user. On the contrary, it can be made mandatory on demand, via our license management system (e.g. useful for the generation of a local recording file for users' traceability).

The users are given training and have access to a comprehensive user manual for self-learning to ensure proper and safe use.

2. Information security

a) User data

Personal data

For regulatory issues, user data (name, e-mail, location, professional status) are requested as identification proof.

This information is acquired during the registration step before the user starts using the software. User acceptance is required to securely send data to the license server.

The user data are stored on the license server.

Non-personal data

At each software launching:

- a secure request is sent to the license server for checking license permissions (validity of use, update access...)
- a secure request is sent to the update server for detecting a potential system update,
- a log file is sent to the license server if an error has occurred in the last session. This file, searchable on the LMS, gathers all execution information and can help to detect software issues.

At each closing, use data are sent to the license server to populate software statistics (e.g. number of software launching).

Offline license: No data is shared between user and server.

No sensitive data are exchanged with servers when using EndoSize.

b) Patient data

EndoSize system relies on DICOM images including patient and exam meta-information (image information is not considered as sensitive).

EndoSize offers several features to safeguard patient data:

- Anonymization* upon import: no patient/exam data are imported into EndoSize.
- Anonymization* after import: patient/exam data are removed from the EndoSize database.
- Anonymization* at export: no patient/exam data are exported from EndoSize.
- Pseudonymization: Partial anonymization. Only a part of patient/exam is removed during the anonymization process. Data to preserve are customizable in EndoSize settings.
- Patient information hiding: Option available in EndoSize settings. Allow hiding all patient data in the EndoSize interface. Reversible action (data are preserved but not displayed).

*Anonymization means the permanently erasing of all patient-related and exam-related information. The user identifies the anonymized case with a replacement name.

DICOM and sizing data are contained in the Database folder located by default in the installation folder. Access restriction is up to the IT policy of Data Controller so far. Data encryption work will be carried out to increase sensitive data protection.

EndoSize archives allow sharing sizing cases between two users. As a proprietary file (.es), the archive is only readable by EndoSize systems.

3. IT security

1. Collected data, i.e., license and user information, are hostedon a secured server (restricted access, backup process).
2. Communication between EndoSize and servers is based on a secured protocol (HTTPS).
3. Access to software sources is strictly restricted to Therenva employees.
4. Protection against malware is up to the data controller policy.
5. The remote accesses of nomadic IT devices of Therenva staff are secured by VPN protocol.

THIRD-PARTY LICENSES

I. Visualization Toolkit (VTK)
II. Insight Segmentation and Registration Toolkit (ITK)
III. Qt
IV. Qwt
V. Eigen
VI. FFmpeg
VII. DCMTK
VIII. OpenSSL
IX. OpenJPEG
X. LibZip

I. Visualization Toolkit (VTK)

Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met:

- Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.
- Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.
- Neither name of Ken Martin, Will Schroeder, or Bill Lorensen nor the names of any contributors may be used to endorse or promote products derived from this software without specific prior written permission.

THIS SOFTWARE IS PROVIDED BY THE COPYRIGHT HOLDERS AND CONTRIBUTORS ``AS IS'' AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE AUTHORS OR CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

II. Insight Segmentation and Registration Toolkit (ITK)

Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met:

- Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.
- Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.
- Neither the name of the Insight Software Consortium nor the names of its contributors may be used to endorse or promote products derived from this software without specific prior written permission.

THIS SOFTWARE IS PROVIDED BY THE COPYRIGHT HOLDERS AND CONTRIBUTORS "AS IS" AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE COPYRIGHT OWNER OR CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

III. Qt

Qt is licensed under the GNU Lesser General Public License (LGPL) version 2.1 .

IV. Qwt

Qwt is licensed under the QwtLicense version 1.0.

V. Eigen

Eigen is licensed under the MPL2

VI. FFmpeg

FFmpeg is licensed under the GNU Lesser General Public License (LGPL) version 2.1

VII. DCMTK

This software and supporting documentation were developed by
OFFIS e.V.
R&D Division Health
Escherweg 2
26121 Oldenburg, Germany

Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met:

- Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.
- Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.
- Neither the name of OFFIS nor the names of its contributors may be used to endorse or promote products derived from this software without specific prior written permission.

THIS SOFTWARE IS PROVIDED BY THE COPYRIGHT HOLDERS AND CONTRIBUTORS "AS IS" AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE COPYRIGHT HOLDER OR CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

VIII. OpenSSL

Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met:

- 1. Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.
- 2. Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.
- 3. All advertising materials mentioning features or use of this software must display the following acknowledgment: "This product includes software developed by the OpenSSL Project for use in the OpenSSL Toolkit. (http://www.openssl.org/)"
- 4. The names "OpenSSL Toolkit" and "OpenSSL Project" must not be used to endorse or promote products derived from this software without prior written permission. For written permission, please contact openssl-core@openssl.org.
- 5. Products derived from this software may not be called "OpenSSL" nor may "OpenSSL" appear in their names without prior written permission of the OpenSSL Project.
- 6. Redistributions of any form whatsoever must retain the following acknowledgment: "This product includes software developed by the OpenSSL Project for use in the OpenSSL Toolkit (http://www.openssl.org/)"

THIS SOFTWARE IS PROVIDED BY THE OpenSSL PROJECT ``AS IS'' AND ANY EXPRESSED OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE OpenSSL PROJECT OR ITS CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

==========

This product includes cryptographic software written by Eric Young(eay@cryptsoft.com).
This product includes software written by Tim Hudson (tjh@cryptsoft.com).

IX. OpenJPEG

Copyright (c) 2002-2020, Communications and Remote Sensing Laboratory, Universite catholique de Louvain (UCL), Belgium
Copyright (c) 2002-2014, Professor Benoit Macq
Copyright (c) 2002-2014, Antonin Descampe
Copyright (c) 2003-2009, Francois-Olivier Devaux
Copyright (c) 2005, Herve Drolon, FreeImage Team
Copyright (c) 2001-2003, David Janssens
Copyright (c) 2002-2003, Yannick Verschueren
Copyright (c) 2011-2014, Centre National d'Etudes Spatiales (CNES), France

X. LibZip

- 1. Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.
- 2. Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.
- 3. The names of the authors may not be used to endorse or promote products derived from this software without specific prior written permission.
  THIS SOFTWARE IS PROVIDED BY THE AUTHORS ``AS IS'' AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE AUTHORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

USE OF SYMBOLS ON LABELLING

Symbol	Description
	CE mark (93/42/CEE – Annex XII)
	Medical Device
	ISO 7000-1641: Consult the instructions for use
	ISO 7000-3082: Manufacturer and Manufacturing date
	Swiss Authorized Representative as per Art. 4 para. 1 let. g of Swiss Medical Devices Ordinance (MedDO)