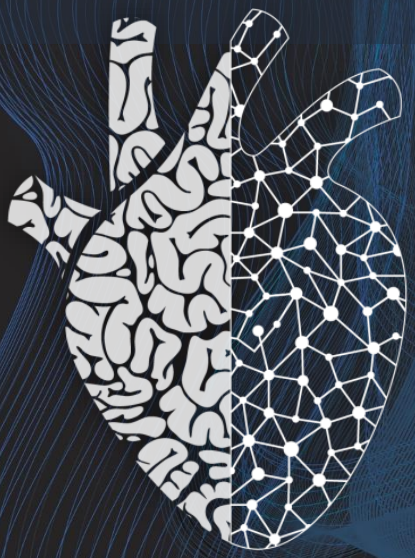
XSPLINE
CLOUD VERSION 0.6.0
&
SIMULATOR

USER MANUAL



XSPLINE

IMPROVING CRT.
BEYOND PREDICTION.

Date:
09-02-2024

Version 1.0

Author:
XSpline SpA

INFORMATION ON THE MANUFACTURER:

XSpline S.p.A.

Via Ressel 2/F, 39100 – Bolzano, Italy

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SOFTWARE LICENSE

Your licensing agreement with XSpline, which is included in the product, specifies the permitted and prohibited uses for the product.

WARNING

The information contained herein is subject to change without notice. XSpline reserves the right to make changes to each product described in order to improve its functions or performance.

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DOCUMENT VERSIONS

#.	Date	Description	Written by	Approved by
1.0	09/02/2024	XSpline Cloud User Manual	XSpline	XSpline

1 INTRODUCTION

1.1 NAME OF THE DEVICE

This user manual refers to the device named XSpline (below called "the device" or "the system"), composed by a cloud platform (below called "XSpline Cloud") and a simulator which can be accessed through the platform (below called "XSpline Simulator").

Version of the device: 0.6.0

1.2 NAME OF THE MANUFACTURER AND HEADQUARTERS

XSpline is manufactured by:

XSpline S.p.A., via Ressel 2F, 39100, Bolzano – Bozen (Italy).

Tel. +39-0471-200372 Fax +39-0471-539338
E-mail: info@xspline.com Website: www.xspline.com
XSpline specializes in the development, production and marketing of innovative solutions in the field of software as a medical device.

1.3 GENERAL FEATURES OF THE DEVICE

1) The device DOES NOT contain:

- *Medicinal products, human blood products or plasma*
- *Tissues or cells of human origin or their derivatives*
- *Tissues or cells of animal origin or their derivatives, as referred to in Regulation (EU) 722/2012.*

2) The device DOES NOT imply specific conditions of preservation or handling.

3) The device IS NOT provided in a sterile state.

4) The device IS NOT disposable.

5) The device DOES NOT consist of substances or substance aggregates intended to be introduced in the human body through an orifice or applied on the skin, or that are absorbed by the human body or locally dispersed within it.

The manual contains information for the safe handling of the device with the components listed.

- *Always read the instructions for use before using XSpline®.*
- *The manual is part of the product and should always be at hand.*
- *Illustrations show functions by way of example and may differ from the actual look of the XSpline®.*

These instructions have been designed to help you gain an understanding of the operation and possible applications of our device. For optimal utilization of all functions, we recommend that you thoroughly study this manual prior to beginning operation.

2 BEFORE STARTING

2.1 INTENDED USE AND FUNCTIONAL DESCRIPTION

The XSpline medical device is used for:

“XSpline Cloud is intended for analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.”

It is therefore an active medical device - non-therapeutic - used for image and data elaboration purposes in the office of the physician.

The clinical benefits expected for CRT-destined patients is to receive the intervention with higher prior knowledge of the surgeon regarding heart and veins anatomy and electrical functionality, with the potential of a more accurate intervention and reduced time.

2.2 INDICATIONS FOR USE

N.I.C.E. is indicated for pre-procedural evaluation by cardiologists and cardiac electrophysiologists in patients undergoing electrophysiological procedures. It facilitates visualization of cardiac anatomy and morphology of coronary veins through 3D reconstruction from DICOM CT images, generates electrical activation maps, aids in planning Cardiac Resynchronization Therapy (CRT) procedures, and assists in ideal LV lead placement using routine clinical data.

2.3 CONTRAINDICATIONS

The use of the N.I.C.E. software does not have any known contraindications.

2.4 DATA SECURITY

2.4.1 AVAILABILITY

The system is based on a regularly backed-up server platform which guarantees data availability.

2.4.2 CONFIDENTIALITY

Passwords and sensitive data are protected and not easily accessible. Data separation is guaranteed, and the system complies with the current privacy legislation.

2.4.3 INTEGRITY

The database features all the referential integrity functions existing in all the versions of Oracle Databases.

2.5 SAFETY ISSUES

As XSpline® has no interactions with the patient or with the clinical protocols, the device does not constitute a risk for the patient, also the use of XSpline® does not cause any additional risk for the operator.

2.5.1 TRAINING

The use of the device is restricted to authorized hospital staff duly trained for its use.

2.6 SOFTWARE AND HARDWARE SPECIFICATIONS

2.6.1 HARDWARE SPECIFICATIONS

Minimum display resolution: HD ready – 1280x720 (recommended Full HD – 1920x1080), display and browser zoom set to 100%.

2.6.2 SOFTWARE SPECIFICATIONS

- *Compatible OS: Windows 10*
- *Compatible browser: Mozilla Firefox 72.x or more recent, Chrome 80.x or more recent, Edge 90.x or more recent*

2.7 WARNINGS AND PRECAUTIONS

⚠ *Warning! Only XSpline S.p.A. qualified personnel are authorized to perform configuration, installation, maintenance, and repairs.*

- ⚠ *Warning! Make sure all persons tasked with operating the device have read and understand the safety information and operating instructions.*
- ⚠ *Warning! XSpline® must be used in conformity with hospital information management procedures.*
- ⚠ *Warning! The Internal code of the patient chosen by the user shall not contain any data of the patient, including name, surname, date of birth or any other sensitive data that can lead to losing the patient's confidentiality (i.e. health card code).*
- ⚠ *Warning! Make sure of loading and inserting the actual data and images coherently for the patient. The correctness of the data inserted and uploaded is unique responsibility of the user.*
- ⚠ *Warning! Strictly follow CT Protocol provided together with this manual. Any CT image that does not respect the protocol standards might not provide high quality segmentations and simulation results might be unreliable.*

Only authorized staff may use the product. The User Manual is exhaustive. Any use different from what is described in this User Manual is strictly prohibited as it may lead to unexpected results.

The screenshots must be taken purely as examples.

2.7.1 HOW TO REQUEST MORE COPIES

To request for more copies of this manual, please get in touch with XSpline S.p.A.

2.7.2 HOW TO REPORT A PROBLEM

If you encounter any problem, malfunctions, or any other issue on the device or about this manual, please let us know by getting in touch directly with XSpline SpA.

Any feedback or suggestions for improvement is also welcome.

3 ICONS LEGEND

	Manufacturer
	Medical Device
	Read the instructions for use

4 ACCESS TO THE SYSTEM

The XSpline Cloud application can be accessed from the following URL:

https://nice.xspline.com/

When accessing the system, user credentials are required:

Figure 1 XSpline Cloud access page

After inserting the credentials (Username and password), the user can access the application main page:

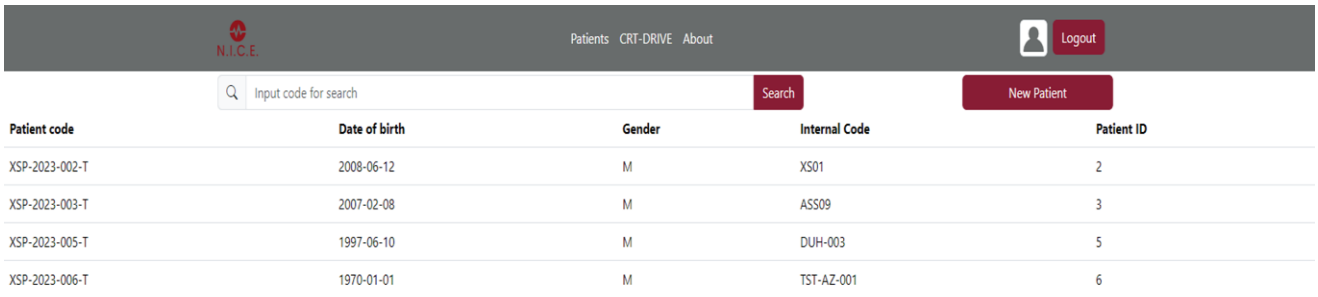


Figure 2 Main Page

From the main page, it is possible to access the following sections using the corresponding widgets:

- *New patient button to create a new patient case*

- *Patient Search to search a patient by "Patient Code" or parts of it*
- *Patient List, shows all the patients created*

On the main page, through the top right menu,

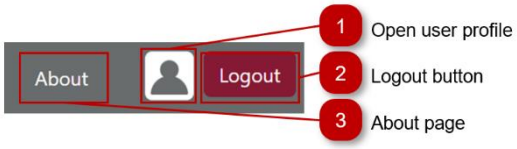


Figure 3 User Menu

It is possible to:

- *Go to a page where to edit user credentials*
- *Log out*
- *Go to "About" page*

When the user selects the icon that directs to the page where to edit user credentials, the following form appears:

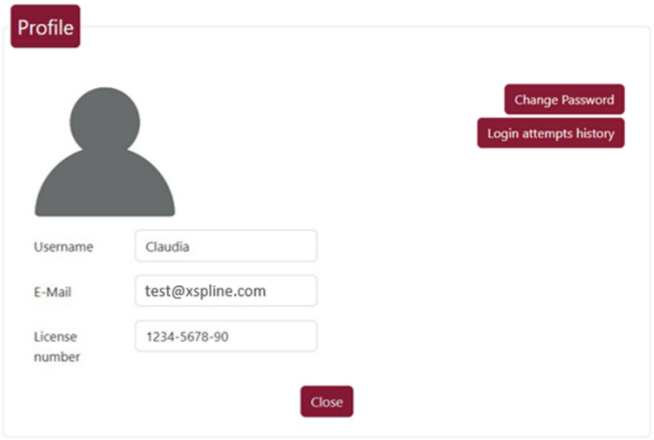


Figure 4 Editing the password

After filling out the fields with the old password and the new password and saving the changes, the user receives a confirmation of the password change and, from that moment onwards, the user can enter the system using the new password.

In addition, the system informs the user of the expiration date of their password. Passwords expire after 90 days and the system pre-alerts the user 7 days before expiration.

The password entered by the user must comply with the following requirements:

- *Be at least 8 characters*
- *Contain at least one digit*
- *Contain at least an uppercase character*
- *Contain at least a lowercase character*
- *Contain at least a special character*

4.1 AUTOMATIC LOG OFF

After 30 minutes of no activity, the system automatically logs off and the login page is displayed. The user has to enter the username password again.

5 ABOUT PAGE

When user clicks the button “About Page”, it opens in a new tab.

This page contains the version of the device, a description of the device, manufacturer information and the button to open the manual.

6 SYSTEM STATUS PAGE

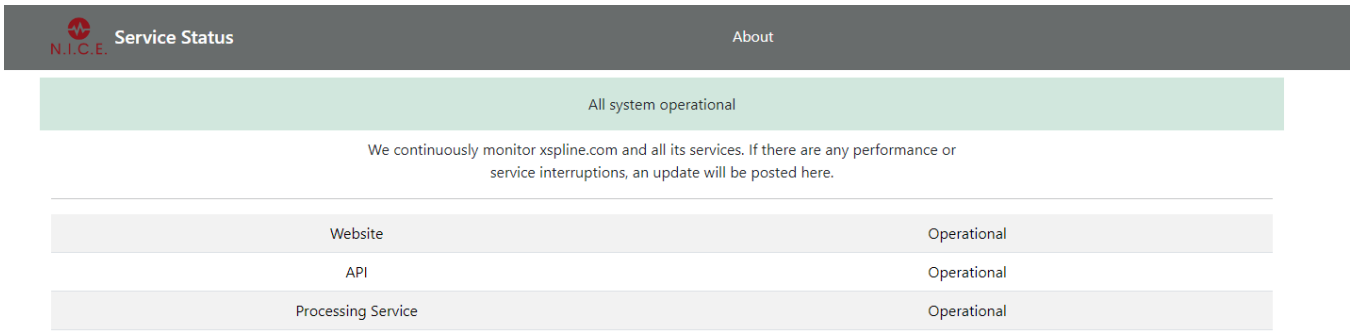


Figure 5 Service status page

This page contains the status of various systems: website, API, and Processing Service.

7 PATIENT LIBRARY

After inserting the credentials (Username and password), the user automatically accesses the PATIENT LIBRARY:

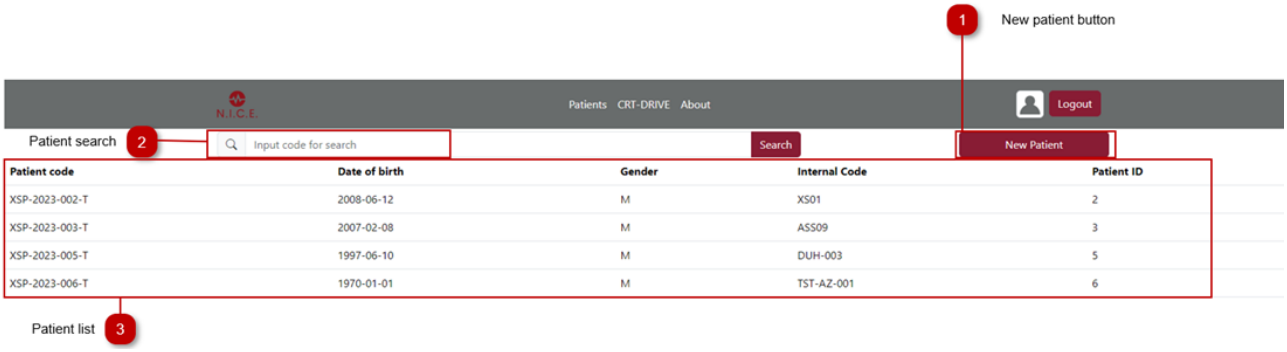


Figure 6 Patient Library page

On the patient library page, patients are listed. The list includes patient identifier information as following; “Patient code”, “Date of birth”, “Gender”, “Internal Code” and “Patient ID”. By selecting the related row from the list, the user can access the patient’s clinical information.

From this page, the user can create a new patient, search for a patient by selecting the corresponding icon.

By selecting 

, the user can enter the data of a new patient candidate for recruitment.

This button displays a window where it is possible to fill out the following fields:

- *Enrollment for the trial*
- *Internal code*
- *Date of birth*
- *Gender*
- *Signed informed consent*

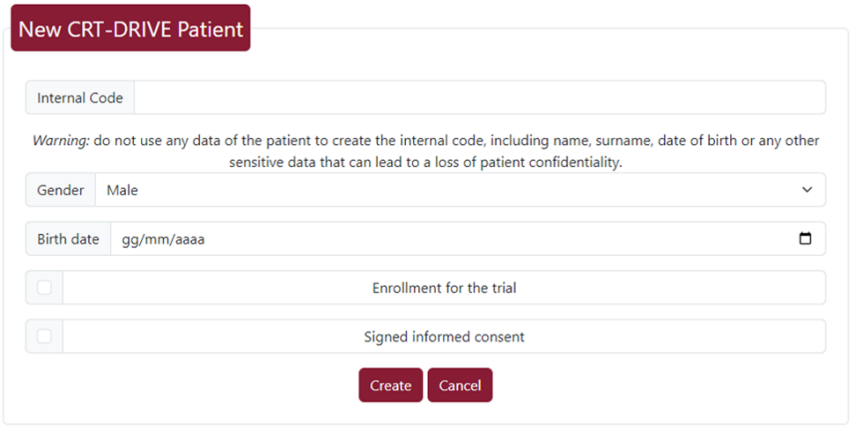


Figure 7 Patient Library – New Patient

The user can select the date of birth from the calendar using the appropriate button. It is not possible to insert a date later than the current one, in this case the system shows an error.

When the user selects 

, the system automatically generates a unique code associated with the CRT project (as specified in the warning message on the form) and adds the new patient to the list.

8 MEDICAL RECORD

By selecting the “Folder” icon, the user can access the patient’s clinical information.

From this page, the user can always go back to the Main Page or Patient Search by selecting the corresponding icon or access the user menu as in the Main Page (Figure 2).

8.1 CLINICAL DATA

The user automatically accesses the “Patient Study” page, which displays the patient’s clinical events from the oldest to the most recent. When the user selects a clinical document, the system highlights it in dark brown.

For each event, the following set of information is displayed:

- *Visit ID*
- *Visit Type*
- *Event registration date*

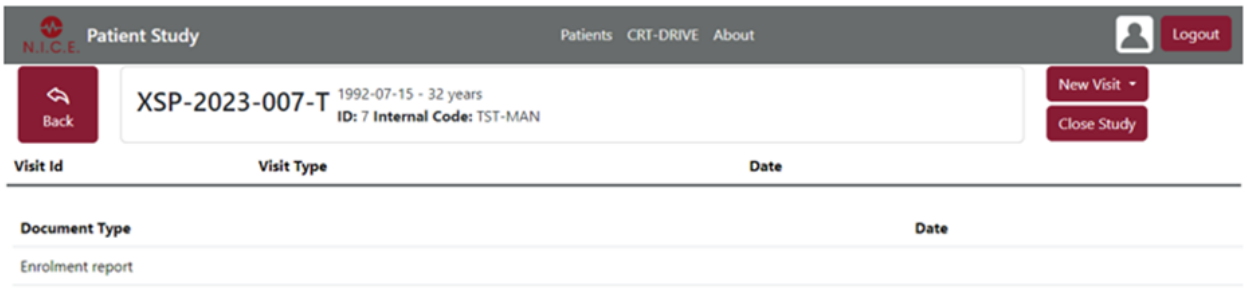


Figure 8 Patient Study Page

The top section shows a summary of the identification data (unique code of the CRT project, date of birth, age, internal code, XSpline code).

By selecting the Edit icon, the user can go to the window in which to edit the data.

The lower section provides information on the document type and creation date, specifying documents generated for the patient as result of their visits.

When the user accesses the menu to add a new document, XSpline Cloud shows a list of the new documents that it is possible to create:

Clinical documents will be created by following the procedural order of the list shown above:

1) Screening
2) Enrollment
3) CRT Implantation
4) Follow-Up Visit
5) Clinical Study Closure

When creating a new document, the system checks whether the document that precedes it in a procedural order is present in the record.

8.2 ENROLLMENT REPORT

The Enrollment Report document is generated concurrently with patient creation. The information is divided into “Inclusion Criteria” and “Exclusion Criteria”.

When this report is presented before any visit documents are created, the system automatically evaluates two inclusion criteria pertaining to the informed consent and the patient's age, which is calculated automatically by the system.

On the enrollment report page, users are restricted from making changes to the collected data. The system automatically assesses whether the specified criteria are met based on the entered values from previous visit documents.

When criteria values are empty, the corresponding rows are displayed in yellow with empty boxes. When previously entered values meet the inclusion or exclusion criteria, they appear in green with a checkmark in the box. Conversely, if the values do not meet the criteria, they are shown in red with a cross in the box.

"Summary" section is located on the top of the report to display the status of the enrollment. When there are missing documents, the system displays the box as empty and summary as: "Documentation is not submitted".

After all enrollment documents are filled, the report is considered complete. For eligible patients who meet both inclusion and exclusion criteria, the system displays a box with a checkmark and states, "The patient is Eligible according to the CRT DRIVE clinical trial enrollment criteria.".

For patients not meeting the criteria, the system displays a box with a cross and states, "The patient is NOT Eligible according to the CRT DRIVE clinical trial enrollment criteria.".

Summary

☑ The patient is Eligible according to the CRT DRIVE clinical trial enrollment criteria.

Inclusion Criteria

Conform	Criterion
☑	Appropriately signed and dated informed consent
☑	Age ≥18 years at time of consent
☑	CRT indication according to the 2021 ESC guidelines on cardiac pacing and CRT (class I and IIA indication in patients with LBBB QRS morphology) or to 2017 AHA/ACC/HFSA guidelines (COR I)
☑	Patients in Sinus Rhythm, who are scheduled for CRT device implantation in less than 3 months
☑	QRS duration ≥130 ms
☑	Left bundle branch block
☑	Left ventricular ejection fraction <= 35%
☑	Symptomatic heart failure NYHA class >= II
☑	Documented stable medical treatment for at least 6 months
☑	No cardiovascular intervention during the last 6 months

Exclusion Criteria

Conform	Criterion
☒	Atrial fibrillation
☒	Previous pacemaker or ICD implantation
☒	Indication to pacing due to bradycardia
☒	Patients considered for His bundle pacing or cardiac conduction pacing
☒	Patient with unstable angina
☒	Subject experienced a recent myocardial infarction, within 40 days prior to enrollment
☒	Subject underwent coronary artery bypass graft or valve surgery, within 90 days prior to enrollment
☒	Subject after a heart transplant or on the waiting list
☒	Subject with an implanted left ventricular assist device
☒	Subject is on continuous or uninterrupted infusion (inotropic) therapy for heart failure
☒	Subject has severe aortic stenosis (with a valve area of < 1.0 cm2 or significant valve disease expected to be operated within study period)
☒	Subject has congenital heart disease
☒	Subject has a mechanical right-sided heart valve
☒	Subject has a life expectancy of less than one year in the opinion of the investigator
☒	Pregnant or breastfeeding women, or women of child bearing potential and who are not on a reliable form of birth control
☒	Subject is enrolled in one or more concurrent studies that would confound the results of this study
☒	Subject has contraindications for contrast computed tomography
☒	Patient with chronic kidney diseases and estimated glomerular filtration rate (eGFR) calculated based on CKD-EPI 2022 < 45 ml/min/1.73m2
☒	Patients with diseases of the thyroid gland with impaired T3 and T4 levels

Figure 9 Enrollment Report Sample

8.3 SCREENING VISIT

In the Screening Visit, the user can record the data collected during the patient's screening visit for the CRT project.

The following documents can be created from Screening Visit page:

- Anamnesis
- Laboratory Analysis
- Echo Data

8.3.1 ANAMNESIS

For the "Anamnesis" document, the user can report the patient's medical history data.

The following is a summary of the information items that can be entered and the corresponding values (the mandatory values are written in red).

Anamnesis		
Items	**Possible values**	**Prerequisites**
Genesis	Dilated Cardiomyopathy / Ischemic Heart Disease	
Recommendation class of CRT implantation (ESC/EHRA 2021) or (AHA/ACC/HFSA 2022)	I /IIA /IIB /III	
Anamnesis vitae	*notes*	
Anamnesis morbi	*notes*	
Hypertension	Yes / no	
Chronic kidney disease	Yes / no	
Diabetes mellitus	On a diet / oral therapy / insulin/ No Diabet (Default)	
Lifestyle habits	Sedentary / active / sport	
Eating habits	Regular / Excessive	
Smoking	Yes / no / previous	
Alcohol drinking0.	No / moderate / excessive	
Known allergies	*text*	
Known drug intolerance	*text*	
Known other non-cardiac pathologies	*text*	
Atrial fibrillation	Yes / no	
Indication to pacing due to brady-cardia	Yes / no	
Previous pacemaker or ICD implanta-tion	Yes / no	
Subject after a heart transplant or on the waiting list	Yes / no	

Anamnesis		
Items	**Possible values**	**Prerequisites**
Subject with an implanted left ventricular assist device	Yes / no	
Subject has severe aortic stenosis (with valve area of <1.0 cm^2 or significant valve disease expected to be operated within study period)	Yes / no	
Subject has congenital heart disease	Yes / no	
Subject has a mechanical right-sided heart valve	Yes / no	
Subject has a life expectancy of less than one year in the opinion of the investigator	Yes / no	
Pregnant or breastfeeding women, or women of childbearing potential and who are not on a reliable form of birth control	Yes / no	
Subject is enrolled on one or more concurrent studies that would confound the results of this study	Yes / no	
Subject has contraindications for contrast computed tomography	Yes / no	
Planned CRT Type	Conventional CRT / Conduction system pacing / Leadless pacing system	

When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.3.2 LABORATORY ANALYSIS

In the “Laboratory Analysis” page the user can report the parameters found by lab tests that were previously carried out on the patient.

Lab tests		
Items	**Possible values**	**Prerequisites**
Creatinine blood test	Numerical value (µmol/L)	
Estimated glomerular filtration rate	Numerical value (mL/min/1.73m^2)	

Thyroid Dysfunction: Impaired T3/T4 Levels	Yes / no	
Total cholesterol	Numerical value between 0 - 700 (mg/dL)	
Dyslipidemia	Yes / no	
High density cholesterol	Numerical value between 0 – 200 (mg/dL)	
Low density cholesterol	Numerical value between 0 – 500 (mg/dL)	
Triglycerides	Numerical value between 0 - 700 (mg/dL)	

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.3.3 ECHO DATA

In the “ECHO Data” page, parameters measured during examinations can be recorded.

For the acquisition date the user can select the date from the calendar using the appropriate button or can manually write in DD/MM/YYYY or MM/DD/YYYY format depending on the user’s browser/computer settings. It is not possible to insert a date later than the current one.

ECHO Measurements		
Items	**Possible values**	**Prerequisites**
End diastolic diameter	Numerical value (10 – 120 mm)	
End systolic diameter	Numerical value (10 – 120 mm)	
End diastolic volume	Numerical value (10 – 1000 mL)	
End systolic volume	Numerical value (10 – 1000 mL)	
Left ventricular ejection fraction	Numerical value (10 – 80 %)	

The system enables users to adjust numerical values by utilizing the in-crease/decrease buttons located at the end of the respective row. When

the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.3.4SCREENING VISIT REPORT

In the “Study Report” page, Screening Visit report can be displayed. The system automatically retrieves all the information entered in the previous pages of the visit and shows the user the content of the Screening Visit report.

This page is a preview of the report and cannot be edited by the user.

8.4 ENROLLMENT VISIT

In the Enrollment Visit clinical document, the user can record the data collected during the patient’s enrollment visit for the CRT project. It is possible to create this document for the trial patients only. Therefore, the outcome of the visit defines whether the patient can be enrolled. Such information is clearly displayed in the Clinical Data section:

The Enrollment Visit document comprises the following pages:

- *Physical Examination*
- *ECG Data*
- *CT Scan Data*

8.4.1 PHYSICAL EXAMINATION

In the “Physical Examination and Lab Tests” page, the user can report the parameters found by specialist examinations that were previously carried out on the patient.

Following is a summary of the information items that can be entered and the corresponding values (the mandatory values are written in red).

Physical examination		
Items	**Possible values**	**Prerequisites**
Height	Numerical value (cm)	
Weight	Numerical value (Kg)	
BMI (Body Mass Index)	Numerical value	The field is automatically filled out by the system when the user enters Weight and Height
BSA (Body Surface Area)	Numerical value (m^2)	The field is automatically filled out by the system when the user enters Weight and Height
Systolic blood pressure	Numerical value (mmHg)	
Diastolic blood pressure	Numerical value (mmHg)	
Heart rate	Numerical value (bpm)	
Own Rhythm	Sinus / Atrial fibrillation / Atrial flutter / AAI / DDD / VVI	
Bypass surgery	No / < 3 months / 3-6 months / > 6 months	
Angioplasty (PCI) before		
Myocardial infarction	No / < 3 months / 3-6 months / > 6 months	
NYHA Class	I / II / III / IV / 0	
Own rhythm ECG pattern	LBBB / RBBB / LAFB / LPBF / IVCD	

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.4.2 ECG DATA

In the “ECG Data” clinical document, the user can upload the electrocardiogram which will be useful to produce the cardiac activation map.

For file uploading process, please see §8.4.4. At the end of the file upload, the system displays the ECG on the screen.

Warning: only upload ECG files in one of the following formats: DICOM (.dcm), SierraECG (.xml), MuseXML (.xml). Any ECG file of a different format is not suitable for Activation Map generation and the automatic processing will not be initiated. For requests regarding alternative file formats, please contact the manufacturer directly.

Following is a summary of the information items that can be entered and the corresponding values (the mandatory values are written in red).

ECG Measurements		
Items	**Possible values**	**Prerequisites**
QRS duration	Numerical value (ms)	

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.4.3CT SCAN DATA

In the “CT Data” page, the user can upload the CT scans on which the segmentation procedure will be carried out and which will be useful to produce the cardiac activation map.

For file uploading process, please see §8.4.4.

The user also can enter the clinical information relating to the CT examination on the same page.

CT Data		
Items	**Possible values**	**Prerequisites**
DLP	Numerical value (mGycm)	
CTDI vol	Numerical value (mGy)	
Contrast volume	Numerical value (mL)	
Duration of CT procedure	Numerical value (minutes)	
Contrast Agent name	*text*	

In the bottom section a “Checklist” is placed which consists of CT scan sequences. The Checklist includes the following:

- *Topogram*
- *Torso*
- *Test bolus*
- *Heart*
- *Ecg*
- *Dose report*
- *Patient protocol*
- *Test bolus curve*

This section is filled by selecting the relative buttons.

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray

boxes signify that the data is finalized and cannot be altered by the user.

Warning: only upload CT studies obtained by following the CT protocol. Any CT image that does not respect the protocol standards might not provide high quality segmentations and simulation results might be unreliable.

The successful upload operations automatically start the segmentation process, the Activation Map generation, and the Target Point calculation, which can be viewed “Segmentation and EAM “page which can be found from the tab in the Patient Card.

8.4.4 UPLOADING FILE

To upload a file, the user should first click on the 'Choose a file' button and then locate the desired file.

It is possible to select the files from the local PC and move them to the window using the “drag and drop” functionality.

The user must select the files that they want to upload and move them to the window. Then, the system acquires the data and shows the upload progress.

Once the selection is complete, clicking the 'Upload' button will initiate the file upload process. Then, the system acquires the data and shows the upload progress.

While acquiring the files, the system deactivates the buttons used to proceed or interrupt the process.

At the end of the file upload, the system updates the counter informing the user that the process is completed. Then, the user can proceed with the following step.

The user can delete the uploaded file by selecting “Delete” button which appears after the uploading process is completed. At the end of the deleting, the system updates the counter informing the user that the file is deleted.

For the acquisition date of the data the user can select the date of acquisition from the calendar using the appropriate button or can manually write in DD/MM/YYYY or MM/DD/YYYY format depending on the user’s browser/computer settings. It is not possible to insert a date later than the current one.

8.4.5 ENROLLMENT VISIT REPORT

In the “Study Report” page, Enrollment Visit report can be displayed. The system automatically retrieves all the information entered in the previous pages of the visit and shows the user the content of the Enrollment Visit report.

This page is a preview of the report and cannot be edited by the user.

8.5 SEGMENTATION AND EAM

The Segmentation and EAM document is created automatically when the user uploads CT Scan data or ECG data during the Enrollment Visit.

The Segmentation and EAM opens automatically on the “General information" tab when selected from the document types. This tab shows the identification details, processing status and a space for comments, as shown in **Error! Reference source not found.**:

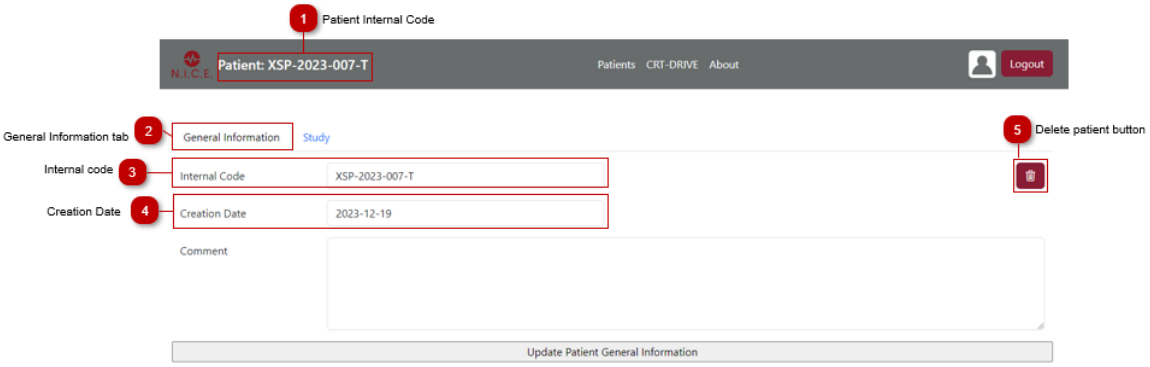


Figure 10 Patient General Information Page

The user can add comments about study in this tab by using "Update Patient General Information" button.

1	PATIENT INTERNAL CODE	Patient Internal Code, to trace the patient and the relative results to your hospital archives.
2	GENERAL INFORMATION TAB	When a patient is created, this tab opens by default.
3	INTERNAL CODE	Patient Internal Code for hospital tracking purposes, inserted during patient creation.
4	CREATION DATE	Information on the date of creation of the patient in the database.
5	DELETE PATIENT BUTTON	Use this button to delete the patient from the library: this will open a confirmation window.

In the "Study" tab, immediately after its creation, the event does not show the result yet, which is replaced by a circle to visualize progress and a note for "Status" as "Wait".(see Figure 11 & Figure 12)

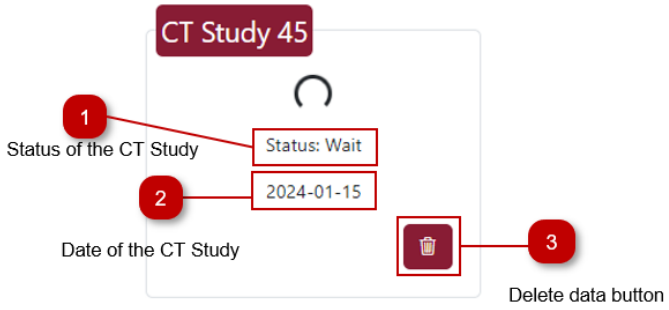


Figure 11 CT Study in progress

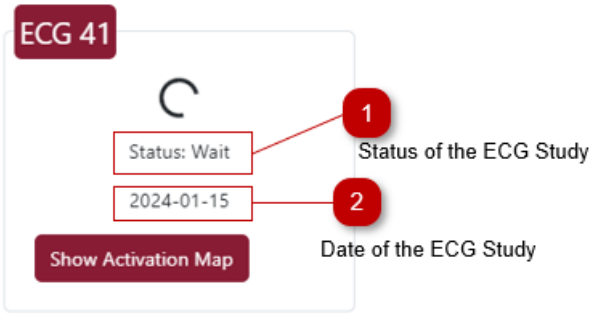


Figure 12 ECG Study in progress

After the processes are completed, it is possible to visualize the results of simulations by clicking the corresponding button.

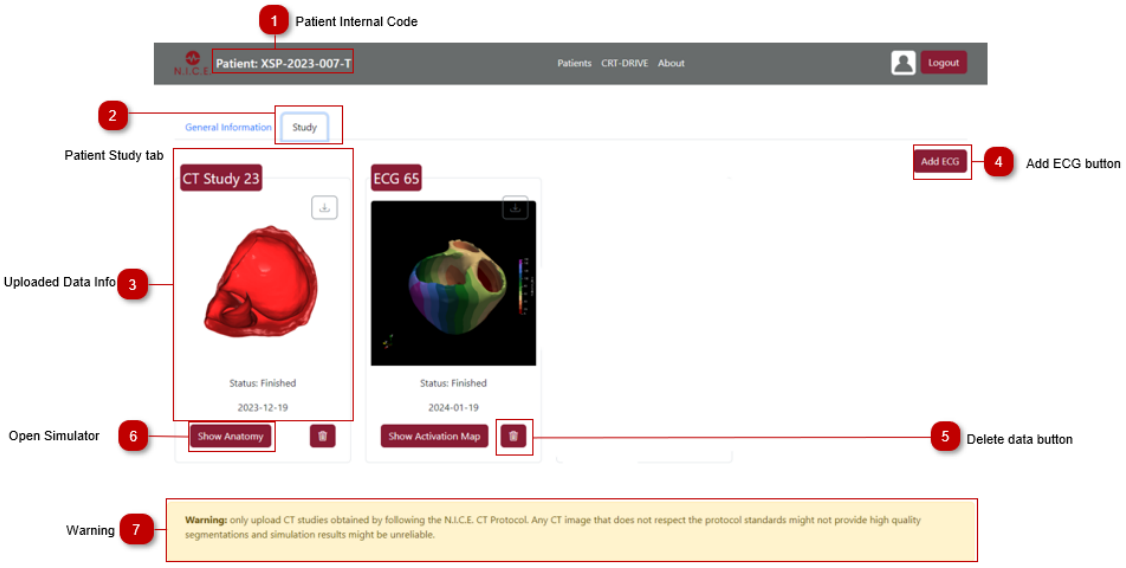


Figure 13 Patient Study Page

1	PATIENT INTERNAL CODE	Patient Internal Code, to trace the patient and the relative results to your hospital archives.
2	PATIENT STUDY TAB	Use this page to upload CT/ECG data or to visualize the simulation results.
3	UPLOADED DATA INFO	This window shows information about the corresponding study: the data file name and the date of upload. Here also the status of the elaboration is shown.
4	ADD DATA BUTTON	Use this button to upload a CT study (only one allowed) or an ECG of the same patient.
5	DELETE DATA BUTTON	Use this button to delete the selected patient data from the library: this will open a confirmation window.
6	OPEN SIMULATOR	Use this button to open the simulator with the corresponding data: on the CT Study it will show only the geometry, on the ECG study it will show the geometry and the corresponding activation map. This button is only active if data has been loaded and the data elaboration is finished.
7	WARNING	Warning about CT study upload: please read carefully before uploading

To delete the patient, after clicking the "Delete Patient Button" a new window is opened for the confirmation. To proceed with patient deletion, insert the patient ID (this is a safety precaution).

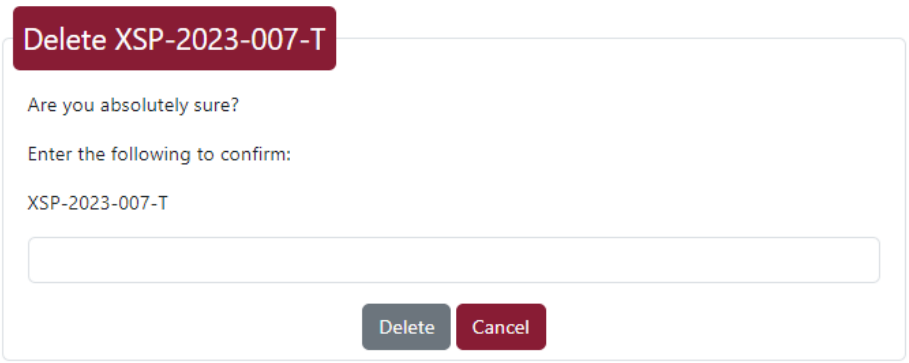


Figure 14 Delete Patient Window

8.6 CRT IMPLANTATION

In the “CRT Implantation” page user can report the clinical information on the CRT implantation intervention.

The “CRT Implantation Visit” document consists of the following pages:

- *ECG Data*
- *Implantation Data*
- *CRT Settings*

8.6.1 ECG DATA

In the “ECG Data” clinical document, the user can upload the electrocardiogram which will be useful to produce the cardiac activation map.

For file uploading process, please see §8.4.4. At the end of the file upload, the system displays the ECG on the screen.

Warning: only upload ECG files in one of the following formats: DICOM (.dcm), SierraECG (.xml), MuseXML (.xml). Any ECG file of a different format is not suitable for Activation Map generation and the automatic processing will not be initiated. For requests regarding alternative file formats, please contact the manufacturer directly.

Following is a summary of the information items that can be entered and the corresponding values (the mandatory values are written in red).

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

ECG Measurements		
Items	**Possible values**	**Prerequisites**
QRS duration	Numerical value (ms)	

8.6.2IMPLANTATION DATA

For the "Implantation data", user can upload fluoroscopy files and enter the details about the implantation intervention to the CRT Implantation Form.

To upload the fluoroscopy files, please see §8.4.4.

Following is a summary of the information items that can be entered and the corresponding values (the mandatory values are written in red).

CRT Implantation Form		
Items	**Possible values**	**Prerequisites**
Fluoroscopy dose	Numerical value (0 – 40) (mGy)	
Fluoroscopy time	Numerical value (0 – 120) (min)	
Fluoroscopy contrast volume	Numerical value (ml)	
Number of coronary sinus branches during venography (if known)	Numerical value (1 – 6)	
LV lead name	ACUITY X4 SPIRAL S 4675-95 Boston/ 1456Q Abbot/ 1456Q -86Abbot/ 1458Q -86Abbot/ 1458Q -92Abbot/ Acuity Spiral 4592-90 Boston/ Acuity Spiral Boston/ Acuity X4 Spiral L 4675-95 Boston/ Acuity X4 Spiral L 4678 Boston/ Acuity X4 Spiral L Boston/ Acuity X4 Sprial S 4675 Boston/ Acuity X4 Sprial S 4675-95 Boston/ Acuity X4 Spiral S Boston/ Acuity X4 Straight 4672 Boston/ Acuity X4 Straight 4672-95 Boston/ Acuity X4 Straight Boston/	

	Attain 4194-88 OTW Medtronic/ Attain Ability 4196-78 Medtronic/ Attain Ability 4196-88 Medtronic/ Attain Ability 4296-78 Medtronic/ Attain Ability Plus 4296-78 Medtronic/ Attain Ability Plus 4296-88 Medtronic/ Attain OTW 4193-78 Medtronic/ Attain OTW 4194-78 Medtronic/ Attain Performa 4298-78 Medtronic Attain Performa 4298-88 Medtronic Attain Performa MRI SureScan 4298/ Attain Performa S 4598-78 Medtronic/ Attain Performa S 4598-88 Medtronic/ Attain Performa straight Medtronic/ Attain Stability Quad 4798-88/ Attain Stability Quad -88/ Medtronic/ Attain Star Fix 4195 Medtronic/ Attain Star Fix 4195 -78 Medtronic/ CapSureFix Novuc Medtronic/ Corox OTW 75-BP Biotronik/ Corox OTW 75-UP Biotronik/ Corox OTW BP Biotronik/ Corox Pro OTW 75-BP Biotronik/ Corox ProMRI OTW-L 75-BP Biotronik/ Easytrak 4543-90 Boston/ Easytrak-2 4543-90 Boston/ QUA147547V-88 Medtronic/ Sentus ProMRI OTW BP/ Sentus ProMRI OTW BP L-75 Biotronik/ Situs OTW BW28D Sorin/ Stentus ProMRI OTW QP L-85/49 Biotronik	
LV lead position	Text	

LV poles N	Numerical value (1- 4)	
RV lead position	Apex / anteroseptal apical / anteroseptal middle / anterior middle / lateral / inferior / inferoseptal / His selective / His nonselective / LBB selective / LBB nonselective	
Implantation procedure duration	Numerical value (10 – 360) (min)	
Skin to CS-cannulation time	Numerical value (min)	
Time to final LV lead placement	Numerical value (min)	
Time from CS-cannulation to LV lead placement	Numerical value (min)	
Comment	*notes*	

If you are unable to find the lead you previously used, please reach out to the manufacturer for assistance.

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.6.3 CRT SETTINGS FORM

In the “CRT Settings Form”, the user enters the details about the CRT device settings for the implantation.

Following is a summary of the information items that can be entered and the corresponding values (the mandatory values are written in red).

While entering the VV delay value, take consideration that if LV is first, then VV delay is negative; if RV is first, the value is positive.

CRT Settings		
Items	**Possible values**	**Prerequisites**
Active LV pole	Numerical value (1 – 4)	
Mode of pacing	DDD As(Ap)-biV / DDD As(Ap)-LV only / VVI	
VV delay	Numerical value (-50 – 50) (ms)	
AV delay (Apace)	Numerical value (40 – 300) (ms)	
AV delay (Asense)	Numerical value (40 – 300) (ms)	
Comment	*text*	

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.6.4 CRT IMPLANTATION VISIT REPORT

In the “Study Report” page, CRT Implantation Visit report can be displayed. The system automatically retrieves all the information entered in the previous pages and shows the user the content of the CRT Implantation Visit report.

This page is a preview of the report and cannot be edited by the user.

8.7 FOLLOW-UP VISIT

In the Follow-up Visit, the user can report the clinical information relating to the follow-up visit, which happens about 6 months after the implantation intervention. It is possible to create more than one Follow-Up visit.

8.7.1 PHYSICAL EXAMINATION

In the “Physical Examination” page, the user can report the parameters found by examinations.

Following is a summary of the information items that can be entered and the corresponding values (the mandatory values are written in red).

Physical examination		
Items	**Possible values**	**Prerequisites**
Height	Numerical value (cm)	
Weight	Numerical value (Kg)	
BMI (Body Mass Index)	Numerical value	The field is automatically filled out by the system when the user enters Weight and Height
BSA (Body Surface Area)	Numerical value (m^2)	The field is automatically filled out by the system when the user enters Weight and Height
Systolic blood pressure	Numerical value (mmHg)	
Diastolic blood pressure	Numerical value (mmHg)	
Heart rate	Numerical value (bpm)	
Own Rhythm	Sinus / AF / pacing	
Bypass surgery	Yes / no	
Angioplasty (PCI) before	No / < 3 months / 3-6 months / > 6 months	
Myocardial infarction	No / < 3 months / 3-6 months / > 6 months	
NYHA Class	I / II / III	
Own rhythm ECG pattern	LBBB / RBBB / LAFB / LPBF / IVCD	

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.7.2 ECG DATA

In the “ECG Data” clinical document, the user can upload the electrocardiogram which will be useful to produce the cardiac activation map.

For file uploading process, please see §8.4.4. At the end of the file upload, the system displays the ECG on the screen.

Warning: only upload ECG files in one of the following formats: DICOM (.dcm), SierraECG (.xml), MuseXML (.xml). Any ECG file of a different format is not suitable for Activation Map generation and the automatic processing will not be initiated. For requests regarding alternative file formats, please contact the manufacturer directly.

Following is a summary of the information items that can be entered and the corresponding values (the mandatory values are written in red).

ECG Measurements		
Items	**Possible values**	**Prerequisites**
QRS duration	Numerical value (ms)	

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit" the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.7.3 ECHO DATA

In the “ECHO Data” page, parameters measured during specialist examinations can be recorded.

For the acquisition date the user can select the date from the calendar using the appropriate button or can manually write in DD/MM/YYYY or MM/DD/YYYY format depending on the user’s browser/computer settings. It is not possible to insert a date later than the current one.

ECHO Measurements		
Items	**Possible values**	**Prerequisites**
End diastolic diameter	Numerical value (10 – 120 mm)	
End systolic diameter	Numerical value (10 – 120 mm)	
End diastolic volume	Numerical value (10 – 1000 mL)	
End systolic volume	Numerical value (10 – 1000 mL)	
Left ventricular ejection fraction	Numerical value (10 – 80 %)	

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The user then either returns to the previous screen, closes the system, and revisits to make modifications or add new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.7.4 CRT SETTINGS

In the “CRT Settings Form”, the user enters the details about the CRT device settings.

Following is a summary of the information items that can be entered and the corresponding values (the mandatory values are written in red).

While entering the VV delay value, take consideration that if LV is first, then VV delay is negative; if RV is first, the value is positive.

CRT Settings		
Items	**Possible values**	**Prerequisites**
Active LV pole	Numerical value (1 – 4)	
Mode of pacing	DDD As(Ap)-biV / DDD As(Ap)-LV only / VVI	
VV delay	Numerical value (-50 – 50) (ms)	
AV delay (Apace)	Numerical value (40 – 300) (ms)	
AV delay (Asense)	Numerical value (40 – 300) (ms)	
Comment	*text*	

The system enables users to adjust numerical values by utilizing the increase/decrease buttons located at the end of the respective row. When the user selects the "Save" option, the information entered in the designated areas will be saved. The use then either returns to the previous screen, closes the system, and revisits to make modifications or adds new data later.

When the user selects "Submit," the entered information is submitted, and the corresponding rows transform into gray-colored boxes. These gray boxes signify that the data is finalized and cannot be altered by the user.

8.7.5 FOLLOW-UP VISIT REPORT

In the "Study Report" page, Follow-Up Visit report can be displayed. The system automatically retrieves all the information entered in the previous pages of the visit and shows the user the content of the Fol-low-Up Visit report.

This page is a preview of the report and cannot be edited by the user.

8.8 STUDY CLOSURE

The event Clinical Study Closure states the final point of the patient journey. In the Patient Study page, the user can create a study closure form by selecting "Close Study" button.

In the closure study page, the user can enter the reasons for the closure of the study.

The following is a summary of the information items that can be entered and the corresponding values (the mandatory values are written in red).

Closure Study		
Items	**Possible values**	**Prerequisites**
Clinical Study Completed	Yes / no	
Withdrawal of consent	Yes / no	
Pregnancy	Yes / no	
Decease	Yes / no	
Other	Yes / no	The text field in Comments activates only if the item is set to "yes"
Responsible	*text*	

8.9 STUDY REPORT

On the top of the Study Report page, patient information is summarized; "Internal Code", "Date of Birth", "Age", and "Gender" are displayed. Study Report page cannot be edited by the user.

8.9.1 VISIT REPORTS

The Study Report page allows users to review reports for each visit. The system automatically retrieves all the information entered in the previous pages of the visit and shows data to the user. Uploaded ECGs are also displayed in the related visit report's content.

8.9.2CONCLUSION OF THE STUDY

When the user fills and submits Follow-Up visit form, "Conclusion of the Study" report is automatically created by the system with the previously entered information.

Closure Study		
Items	Possible values	**Prerequisites**
Difference in QRS duration before and after CRT implantation	Numerical value (ms)	
Difference in QRS duration before and after CRT implantation	Numerical value	
Difference in Left ventricular ejection fraction before and after CRT implantation	Numerical value (%)	
Difference in Left ventricular ejection fraction before and after CRT implantation	Numerical value	
Difference in End systolic volume before and after CRT implantation, ml	Numerical value (ml)	
Difference in End systolic volume before and after CRT implantation	Numerical value	
Difference in End diastolic volume before and after CRT implantation	Numerical value (ml)	
Difference in End diastolic volume before and after CRT implantation	Numerical value	
Decreasing of left ventricular (LV) end-systolic volume (ESV) of ≥15%	Yes/ No	
Response to CRT	Yes/ No	
Clinical Study Completed	Yes/ No	

When the user creates the Patient Study Closure Form, "Clinical Study Completed" row is automatically filled by the system with the information from the form.

9 XSPLINE SIMULATOR - INTRODUCTION

XSpline® Simulator is a software package that allows 3D visualization of segmented cardiac districts: coronary veins and ventricles (Fig. 1).

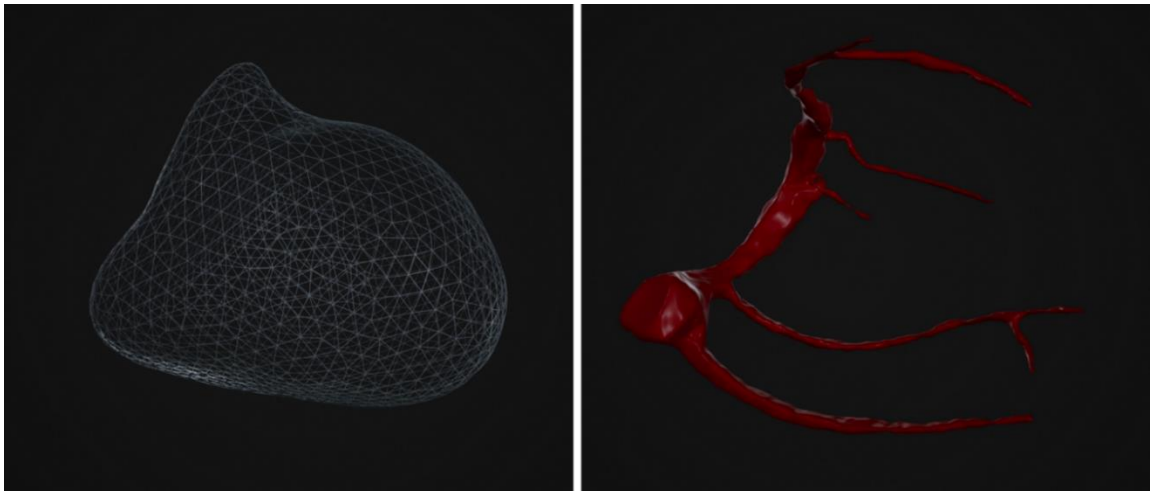


Fig. 1 - Segmented Ventricles (left) and coronary veins (right)

This includes dimensional color maps, measuring functions and tracing of a path for the catheter to insert in the vein.

A software 3D simulation also allows to follow the catheter on its way from defined entrance point to endpoint from 2 points of view, external to the vein and internal (Fig. 2).

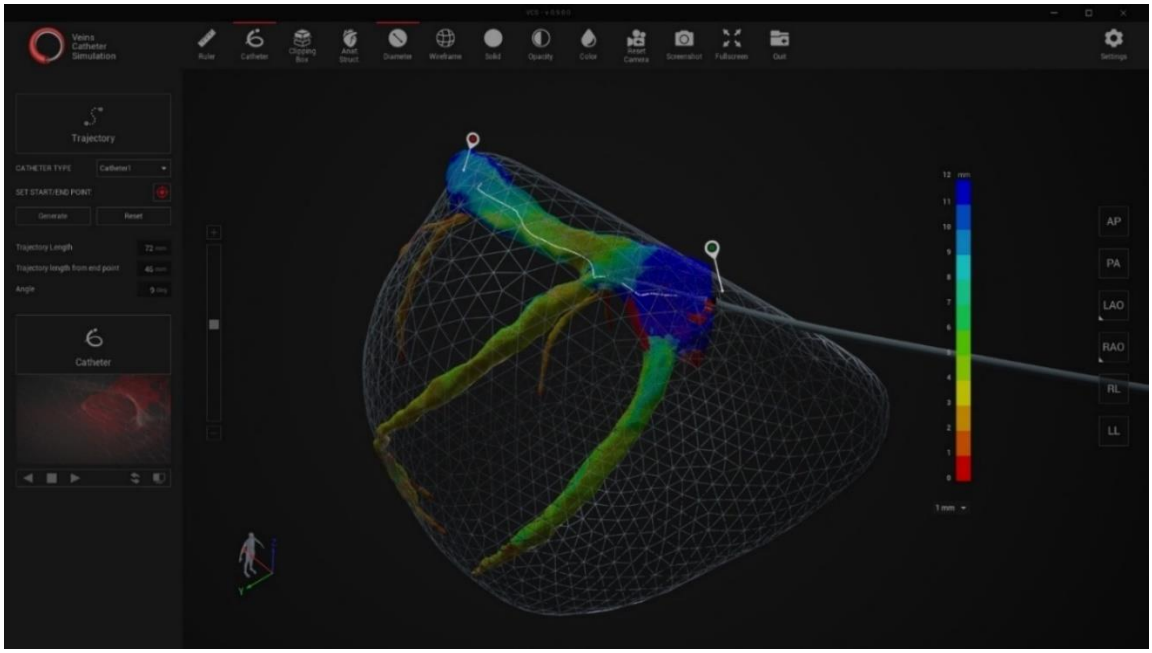


Fig. 2 - Simulation of catheter insertion

9.1 MAIN VIEW

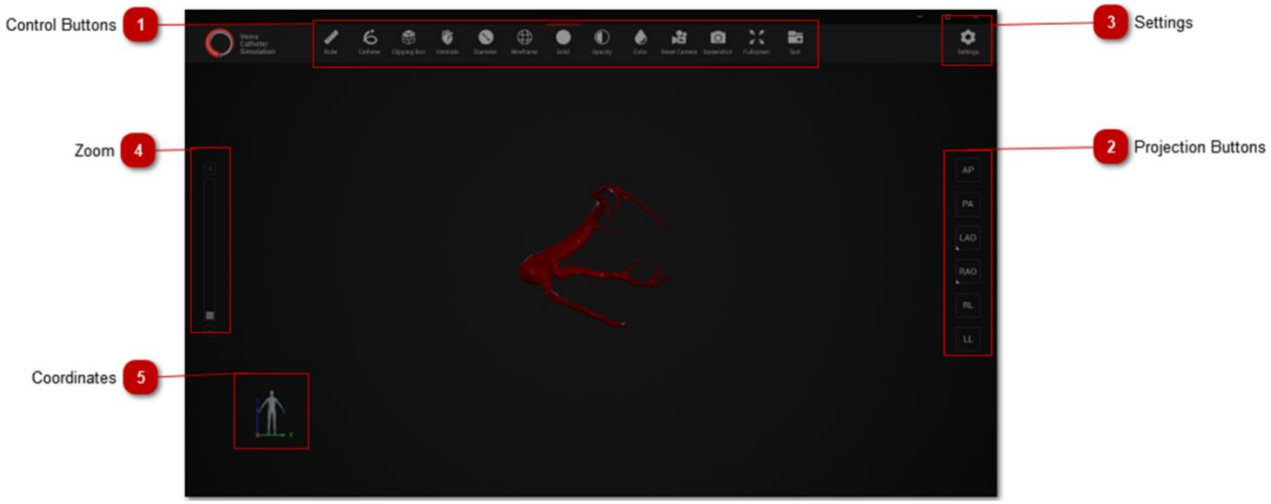


Fig. 3 - Main View of the XSpline Simulator

1	CONTROL BUTTONS	The control buttons enable/disable the visualization properties and functions included in the program. These properties and functions are the main components of the program, designed to assist the operator in their decision-making process. See “Control Buttons” paragraph.

2	PROJECTION BUTTONS	The Projection Buttons rotate the view to a position correspondent to the standard heart projections. See "Projection Buttons" paragraph.
3	SETTINGS	The Settings button toggles the Settings menu, where the user can customize the properties of the program. See "Settings" paragraph.
4	ZOOM	The Zoom bar adjusts the zoom level of the camera. Default setting is the lowest (bottom position).
5	COORDINATES	Coordinates Reference animation indicates the orientation of the (rotated) 3D image of the heart, relative to the body.

9.2 COMMANDS TO INTERACT WITH THE 3D OBJECTS

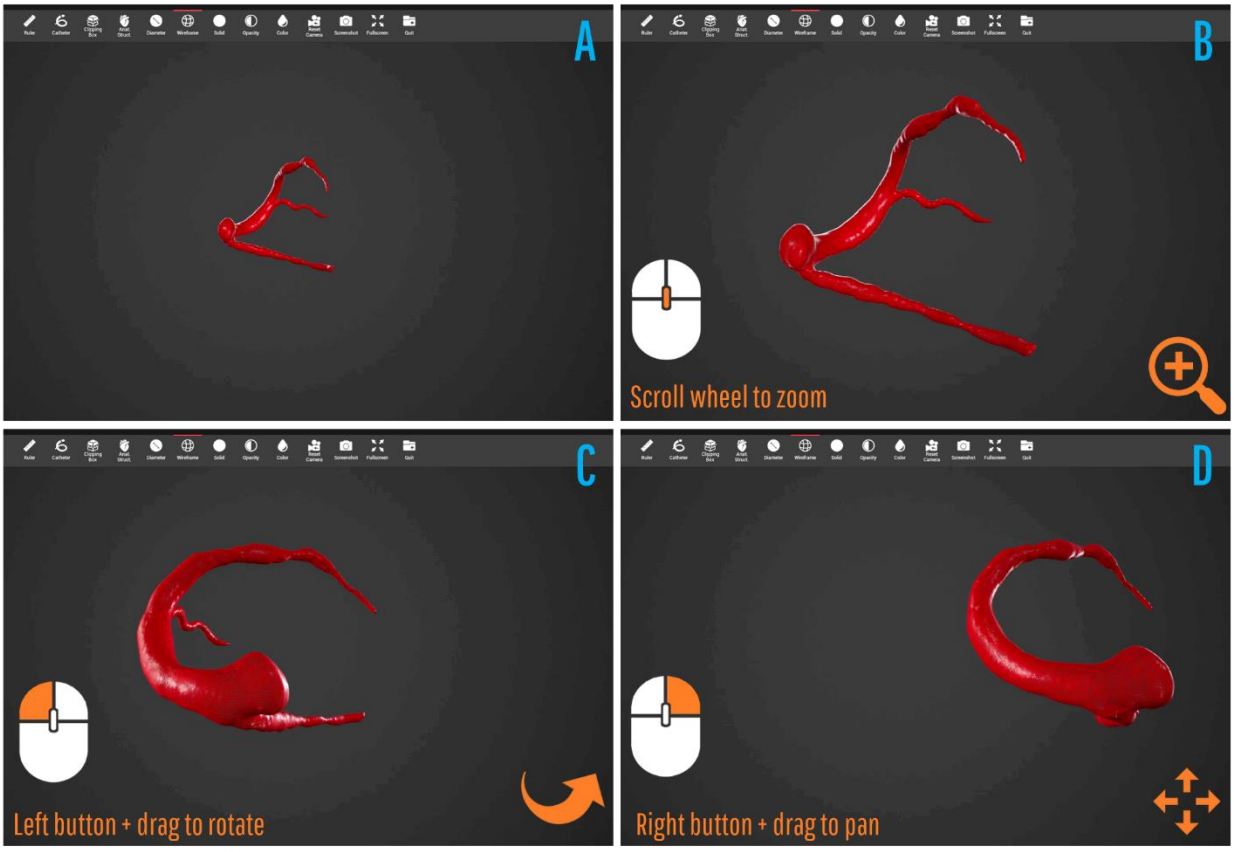


Fig. 4 - Commands to interact with the object

The user can interact with the visualized 3D object (Fig. 4.A) using the mouse:

- *zooming it using the mouse wheel (Fig. 4.B)*
- *rotating it by left click & drag (Fig. 4.C)*
- *panning by right click & drag (Fig. 4.D).*

10 CONTROL BUTTONS

The Control Buttons (Fig. 5) can be found at the top of the screen (Fig. 3). These represent all the main functions of the software.

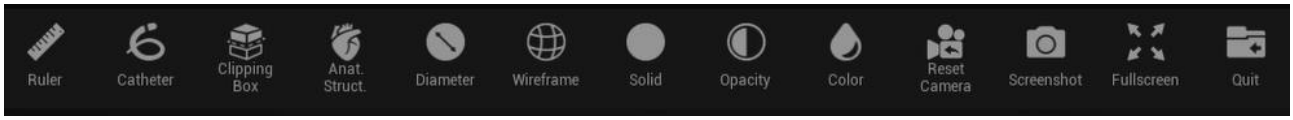


Fig. 5 - Control Buttons at the top of the screen

10.1 RULER

Ruler is a function to measure distances between two points of the veins, directly on the 3D image.

The Euclidean or Geodesic distance path between two end points (A and B), chosen by clicking with the left mouse button right on the image, will be visualized on the vein segmentation (Fig. 6). Their calculated distance (Distance output) will be visible on the ruler menu.

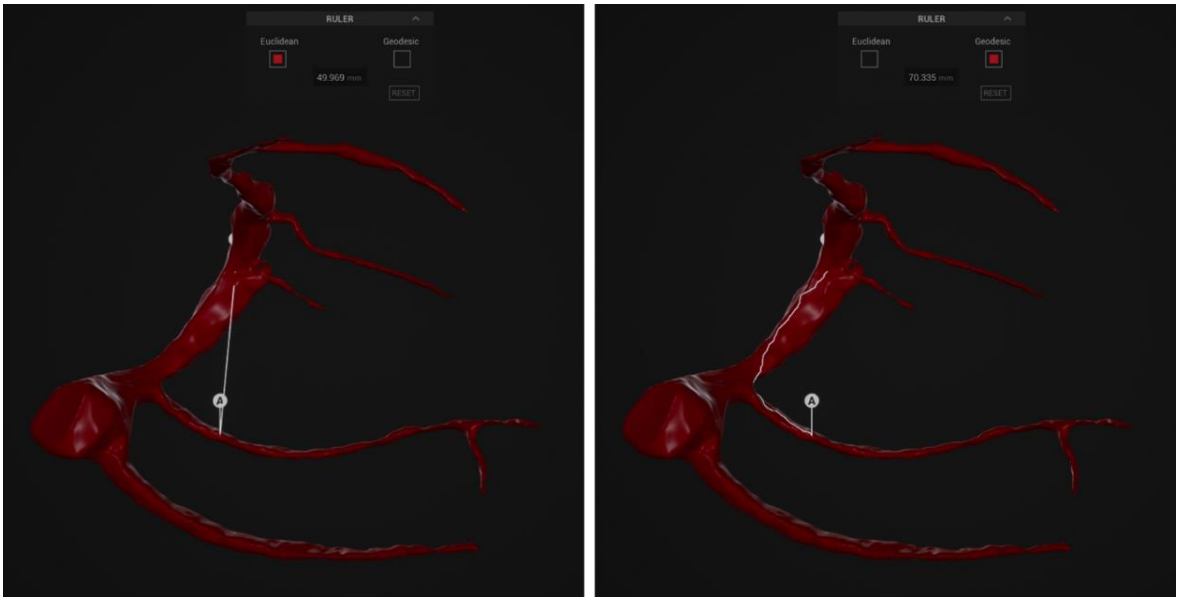


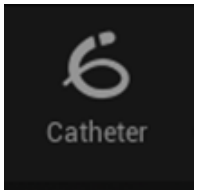
Fig. 6 -Visualization of Euclidean (left) and Geodesic (right) distance between point A and point B

The Ruler button toggles the Ruler menu (Fig. 7). The Ruler menu provides tools to pick either Euclidean or Geodesic distance and to read the relative measure.

Fig. 7 - Ruler menu

1	MINIMIZE MENU	The Minimize button toggles the minimization of the menu.
2	DISTANCE SELECTION	Pick the type of distance to calculate between two selected points (A to B) using the relevant tick box: Euclidean (straight line) or Geodesic (shortest path on the vessel wall surface). After choosing, you may pick points A and B on the 3D image
3	DISTANCE OUTPUT	In the distance output box, the numerical value of the measure (Euclidean or Geodesic) is displayed.
4	RESET BUTTON	The reset button sets the ruler options to their default values.

10.2 CATHETER



Catheter is a function that simulates the delivery of the catheter for the implantation of the pacemaker lead.

One of the main functions of the software is the Catheter simulation: pick an entrance point and an endpoint, read the trajectory stats, pick a catheter type, and watch the animation of the catheter moving through the trajectory (Fig. 8), from two different points of view (external and internal). To visualize the path more clearly, it is suggested to use this function with wireframe rendering.

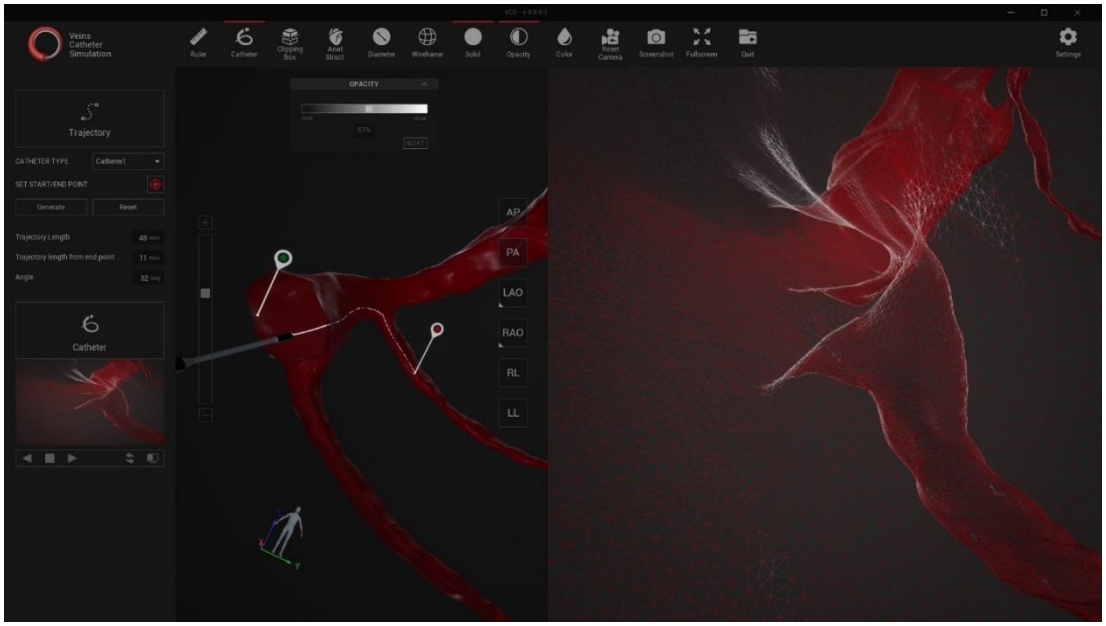


Fig. 8 - Catheter insertion simulation

The Catheter button toggles the catheter menu, which allows to customize the catheter delivery simulation (Fig. 9).

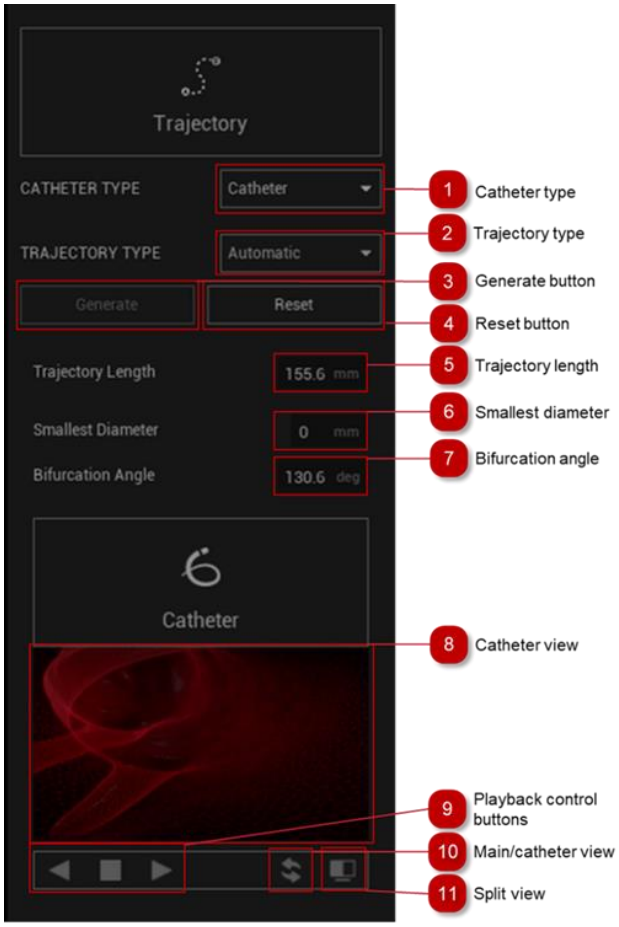


Fig. 9 - Catheter menu

1	CATHETER TYPE	Choose the type of catheter to visualize in the simulation through a drop-down menu.
2	TRAJECTORY TYPE	Choose between “Automatic”, where start and end point are automatically calculated, and “Manual” to be able to pick the points. A crosshair icon will appear, click to pick the entrance point first and the end point after.
3	GENERATE BUTTON	Start the simulation of the catheter delivery. This operation might take some time.
4	RESET BUTTON	Reset the variables of catheter delivery simulation to their default values.
5	TRAJECTORY LENGTH	Length of the calculated trajectory between start and end points.
6	SMALLEST DIAMETER	Smallest coronary diameter in the calculated trajectory between start and end points.
7	BIFURCATION ANGLE	Bifurcation angle in the calculated trajectory between start and end points.
8	CATHETER VIEW	Catheter view shows the point of view from the catheter tip. During the catheter introduction simulation, it moves inside the vessel according to the catheter movement.
9	PLAYBACK CONTROL BUTTONS	The playback control buttons start, stop, and reverse the playback of the catheter introduction simulation.
10	MAIN/CATHETER VIEW	The main/catheter view button toggles the main view between the standard external view and the catheter tip view.
11	SPLIT VIEW	The split view button splits the main view into two sections, arranged side by side: one portraying the view from the standard camera, one from the catheter tip.

10.3 CLIPPING BOX

Clipping Box is a function that allows to visualize sections of the 3D segmented vein and ventricle.

The Clipping Box button toggles the clipping Box function, which creates a bounding box delimiting the area containing the 3D image (Fig. 10).

Moving the clipping planes along the 3D axes of the image will cut out the parts of image that remain outside the clipping box, showing the resulting section of the vein/ventricle.

It is possible to hold shift + left mouse button to select a specific plane and drag it in the desired direction.

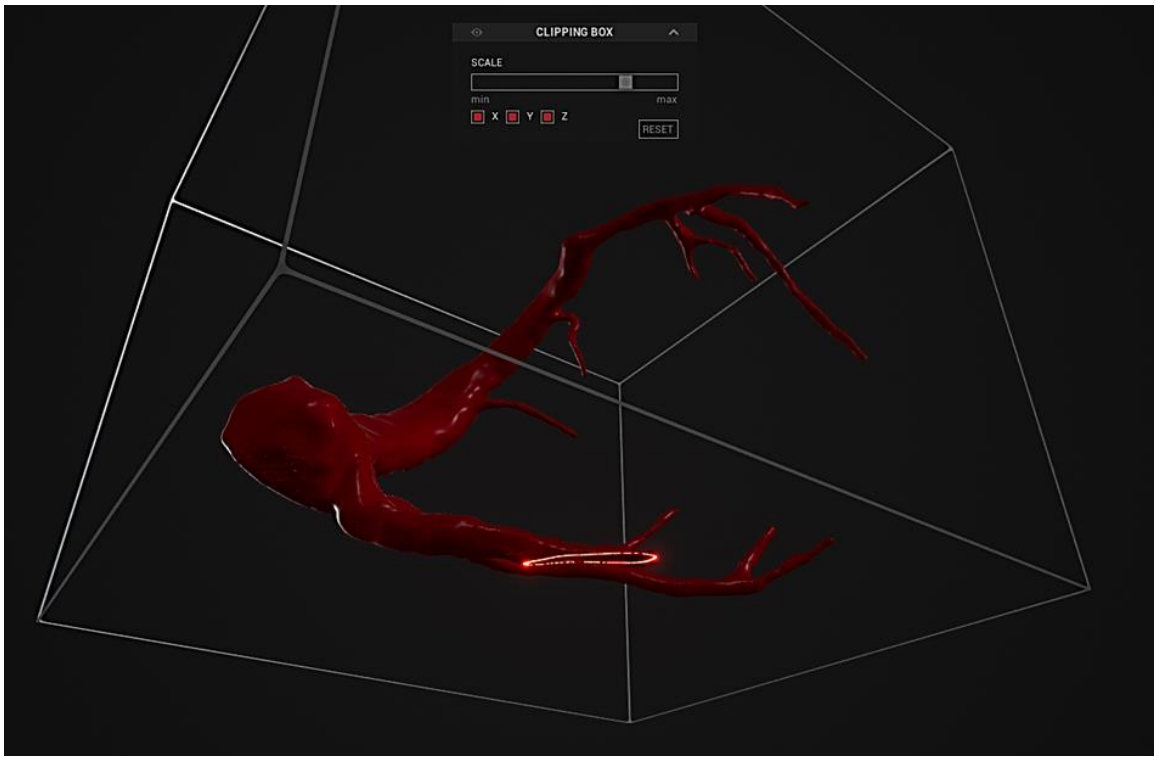


Fig. 10 - The Clipping box function creates a bounding box around the 3D image.

Additionally, the Clipping Box button toggles the Clipping Box menu, which can be used to select additional options to move the clipping planes:

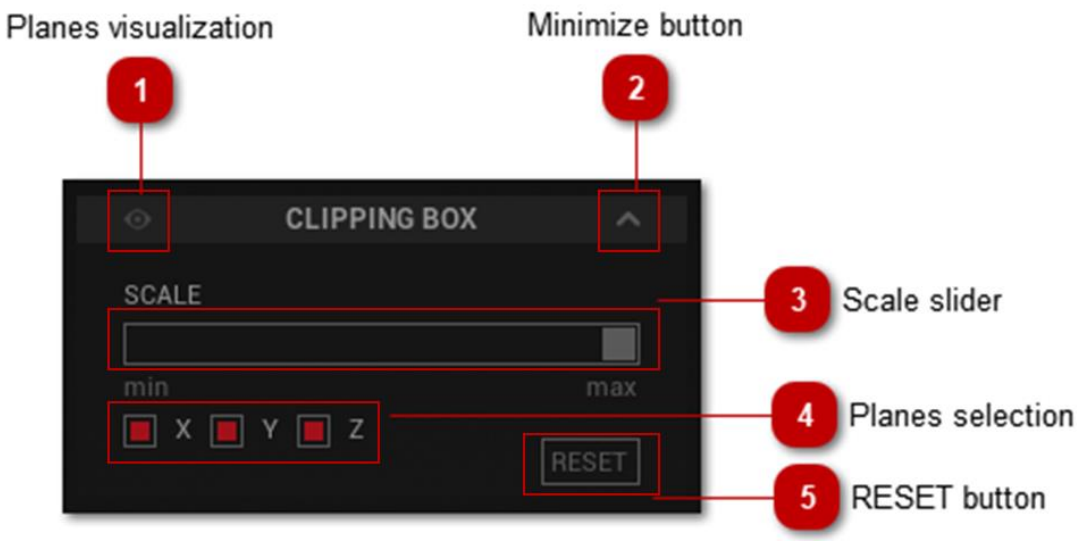


Fig. 11 - Clipping Box menu

1	PLANES VISUALIZATION	Toggles the visualization of the clipping planes.
2	MINIMIZE BUTTON	The Minimize button toggles the minimization of the menu.
3	SCALE SLIDER	Adjust the position of the clipping planes along the selected axis, symmetrically.
4	PLANES SELECTION	Choose along which axes the clipping planes can move.
5	RESET BUTTON	The reset button sets the clipping planes position to the default value.

10.4 MODELS

This function allows to select the preferred anatomical visualization.

The Models button toggles the visualization of: veins only (Vein), ventricles and veins (Vein + Ventricle), or segmented ventricles only (Ventricle) (Fig. 12).

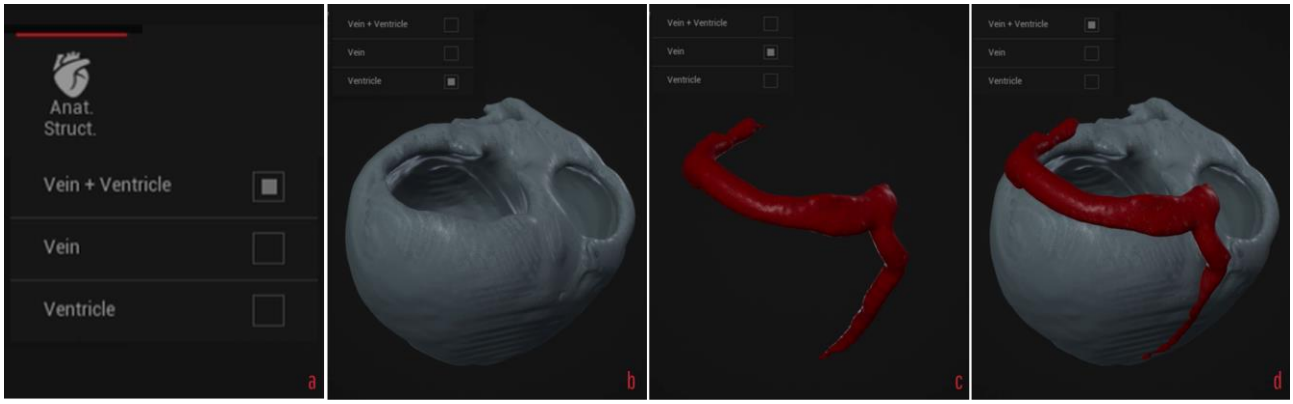
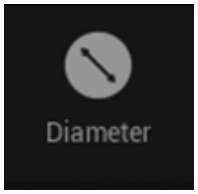


Fig. 12 - Anatomical Structure menu (a) and visualizations: Ventricle (b), Vein (c), Vein + Ventricle (d).

10.5 DIAMETER



This button shows a colormap of the veins based on the diameter of the vessel. Each color shows the diameter of the vein in millimeters at the selected level (Fig. 13).

To activate this function, please select Wireframe first.

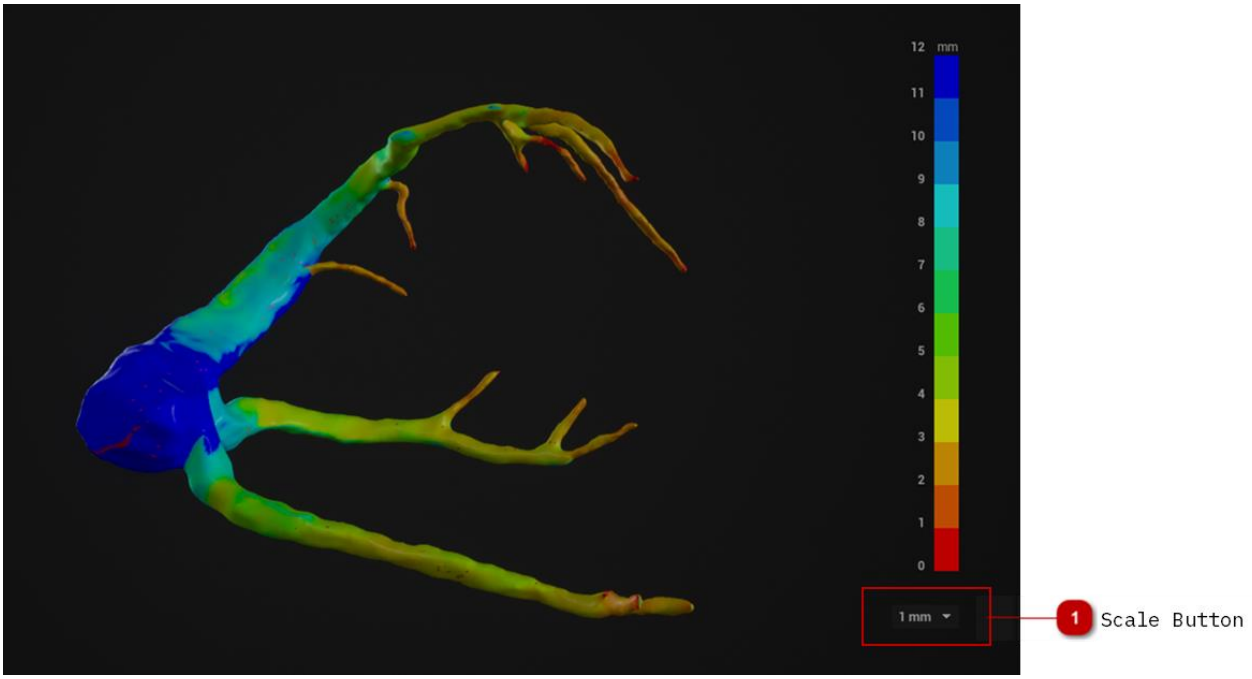


Fig. 13 - Scale button (on the bottom right) adjusts the distance color scale.

1	SCALE BUTTON	This button allows to adjust the color scale by assigning a specified number of millimeters to each color (1, 2, 3, 4 or 5 mm).

10.6 RENDERING BUTTONS

WIREFRAME

The Wireframe button enables the wireframe rendering of the segmented vein and ventricle (Fig. 14, left).

SOLID

The Solid button enables the solid rendering of the segmented vein and ventricle (Fig. 14, right).

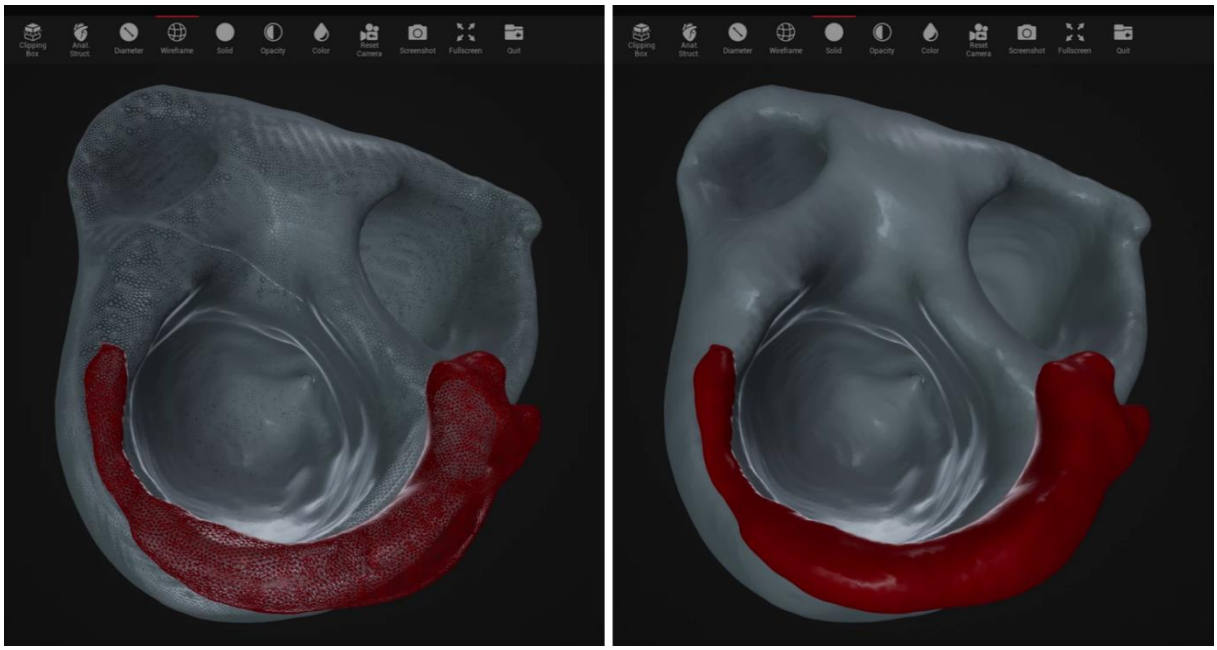
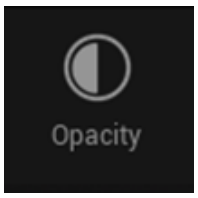


Fig. 14 - Segmented vein and ventricle with wireframe (left) and solid (right) rendering

10.7 OPACITY



The Opacity button toggles the Opacity menu, which sets the opacity level for the segmented vein or ventricle (Fig. 15).

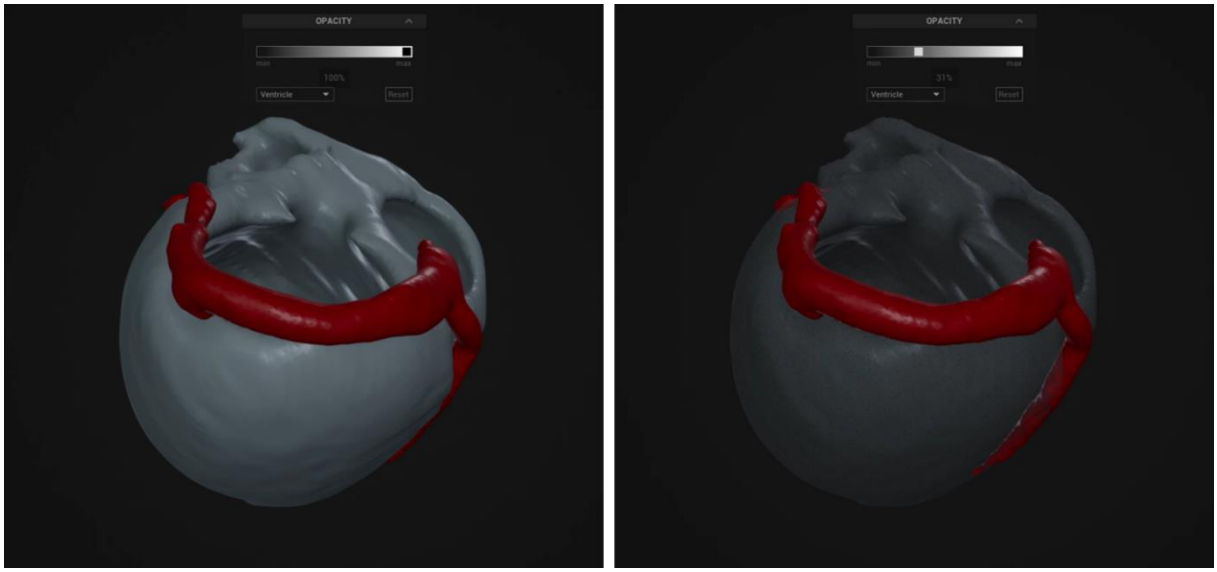


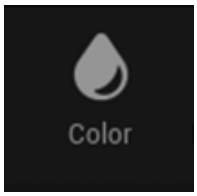
Fig. 15 - Changing the opacity of the ventricle from 100% (left) to 30% (right)

Through the Opacity menu the opacity setting can be modified for each anatomical structure (Fig. 16)

Fig. 16 - Opacity Menu

1	MINIMIZE MENU	The Minimize button toggles the minimization of the menu.
2	OPACITY SLIDER	The opacity slider adjusts the opacity of the segmented vein or ventricle.
3	RESET BUTTON	The RESET button sets the opacity level to the default value (100%).
4	ANATOMICAL STRUCTURE	Pick between vein and ventricle what structure you are changing the opacity of

10.8 COLOR



The Color button toggles the Color menu, which allows the user to customize the color of the segmented vein (Fig. 17) or ventricle.

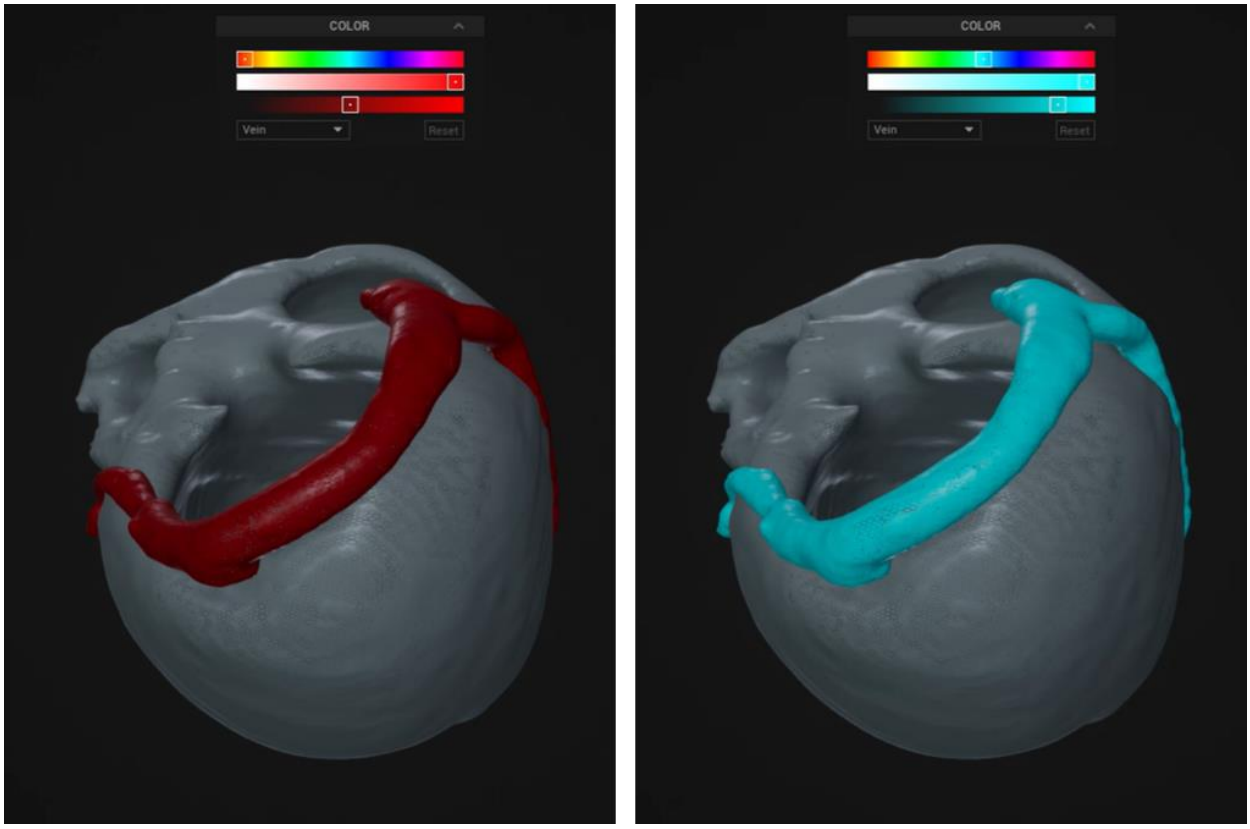


Fig. 17 - Color function on the Vein. Default color (left), light-blue color with higher contrast (right).

Through the Color Menu the color, brightness and contrast settings can be modified for each anatomical structure (Fig. 18)

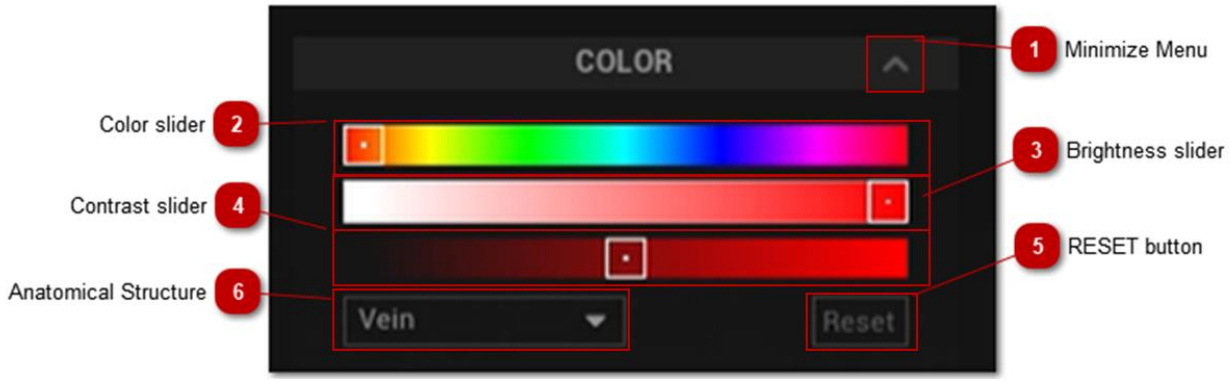
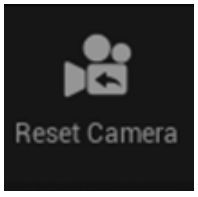


Fig. 18 - Color Menu

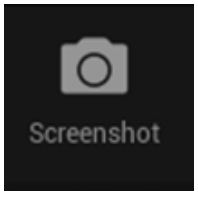
1	MINIMIZE MENU	The Minimize button toggles the minimization of the menu.
2	COLOR SLIDER	Pick the color of the segmented vein or ventricle.
3	BRIGHTNESS SLIDER	Adjust the brightness of the vein or ventricle.
4	CONTRAST SLIDER	Adjust the contrast of the vein or ventricle.
5	RESET BUTTON	Set Color, Brightness and Contrast levels to default.
6	ANATOMICAL STRUCTURE	Pick between vein and ventricle what structure you are changing the color of

10.9 RESET CAMERA



This button resets the image to the center of the visualization area and to default plane (AP, AnteroPosterior) and rotation.

10.10 SCREENSHOT



Take a screenshot of the view, with the visualization options that are active on the screen.

A confirmation window will appear (Fig. 19)

Fig. 19 - Screenshot Confirmation Window

Example in Fig. 20:

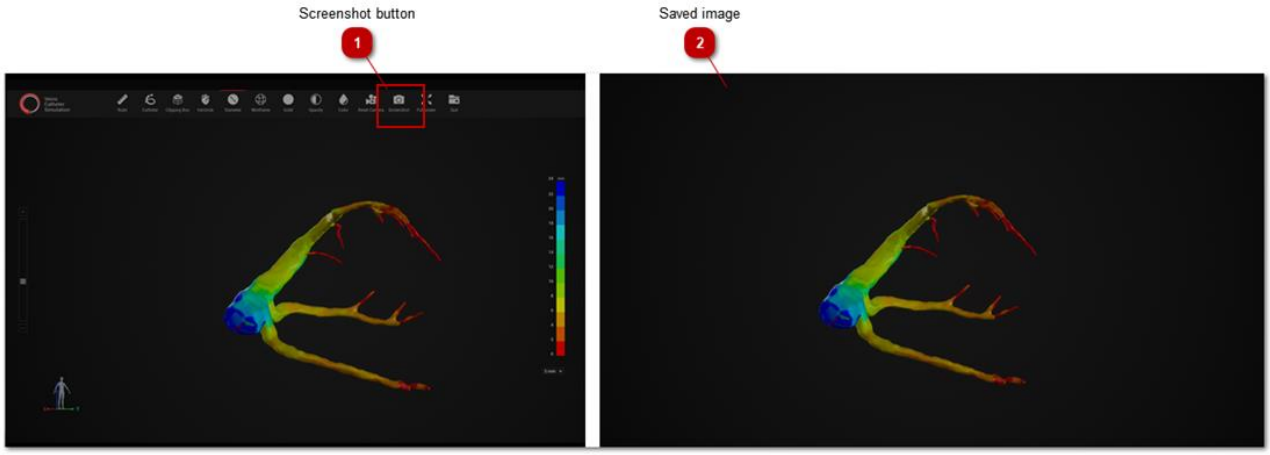


Fig. 20 - Example of figure as seen on the screen (left) and the saved image (right)

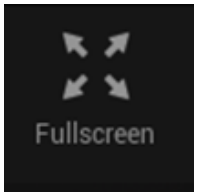
10.11 SKELETON

The Skeleton Button shows the center line of the Coronary Sinus, used to calculate the Trajectory (see relevant paragraph) and its length.

By selecting this option, the center line appears in the model of the vein.

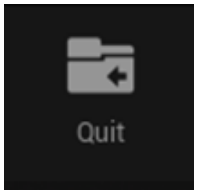
By hovering with the mouse on the center line, an info box appears: the diameter of the vein in that point, and the bifurcation angle of that branch with the main branch.

10.12 FULLSCREEN



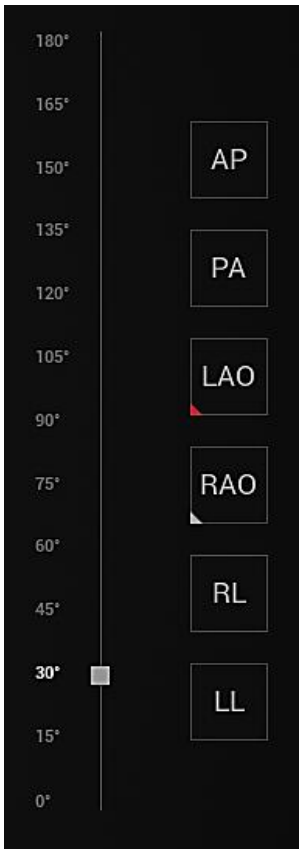
The Fullscreen Button toggles your window into and out of full-screen mode.

10.13 QUIT



Press the Quit button to quit and close the program.

11 PROJECTIONS BUTTONS



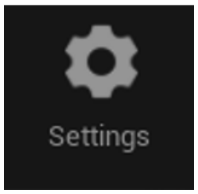
The Projection Buttons rotate the object to a position correspondent to the standard heart projections:

- ***Frontal plane:*** *Anterior-Posterior (AP) or Posterior-Anterior (PA) axis*
- ***Oblique plane:*** *Left Anterior Oblique (LAO) or Right Anterior Oblique (RAO) axis. For these 2, it is possible to pick the rotation angle (Oblique) from the Frontal plane towards either its Left side or its Right side (see image).*
- ***Sagittal plane:*** *Right to Left (RL) or Left to Right (LR) axis.*

It is possible to rotate the view or shift from the central point also using the mouse:

- *left button - rotate*
- *right button - pan*
- *scroll wheel up - zoom in*
- *scroll wheel down - zoom out*

12 SETTINGS



The Settings button toggles the Settings menu, which is subdivided into four sub-menus: GAME and GRAPHICS. Click on the single entries to display the submenus.

12.1GAME

The settings menu "Game" (Fig. 21) shows the Game settings.

Fig. 21 – Game settings menu

Game settings can be adjusted through three commands:

- ***Rotate Sensitivity*** *regulates the software sensitivity to the rotation command (mouse movement with left button pressed).*
- ***Zoom Sensitivity*** *regulates the software sensitivity to the zoom command (mouse scroll wheel).*
- ***Pan Sensitivity*** *regulates the software sensitivity to the panning command (mouse movement with right button pressed).*

12.2 GRAPHICS

The settings menu “Graphics” (Fig. 22) is divided in two submenus, Display () and Graphics ().

Fig. 22 - Graphics settings menu

Display settings can be modified through the command **Rendering resolution** to adjust the resolution.

Graphics quality can be changed among the different modes (Low, Medium, High, Ultra) using the arrows. The **Preset quality** is set to Ultra.