WATCHMAN™ TruPlan™
CT IMAGING SOFTWARE

Boston Scientific
Advancing science for life™

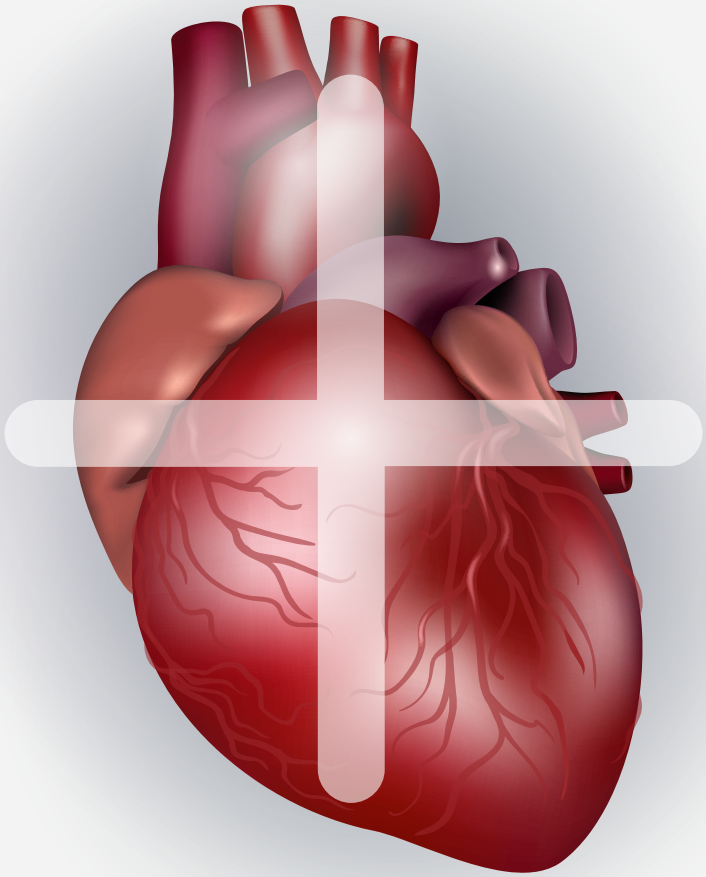
circle CARDIOVASCULAR IMAGING

USER MANUAL

AUGUST 2021

VERSION 1.1

WATCHMAN™ TruPlan™ software is developed and owned by Circle Cardiovascular Imaging Inc. (Calgary, AB, Canada), and Boston Scientific is the exclusive reseller of WATCHMAN™ TruPlan™ software.



00

REGULATORY INFORMATION

MANUFACTURED BY

Circle Cardiovascular Imaging Inc.
1100, 800 5th Avenue SW Calgary
Alberta, T2P 3T6

Telephone 1 (403) 338-1870
Fax 1 (403) 338-1895
Website http://www.circlecvi.com

bsi. ISO 13485;2016 Medical Device Quality Management

FM 539204

UDI: 00882916000516

Health Canada Device Licence: 105406

US FDA 510K: K202212

European Office

Circle Cardiovascular Imaging B.V.

Phone + 31 (800) 265 898

IMPORTANT: US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

℞ Only

TABLE OF CONTENTS

01
GLOSSARY

Term or Symbol	Definition
CT	Computed tomography: X-ray based three-dimensional medical imaging modality
DICOM	Digital Imaging and Communications in Medicine: Standard for the communication and management of medical imaging information and related data
Fluoro	Fluoroscopy: Continuous planar x-ray imaging
ICE	Intracardiac Echocardiography: Ultrasound based medical imaging technique
IVC	Inferior Vena Cava
LAA	Left Atrial Appendage
LAAC	Left Atrial Appendage Closure
MPR	Multiplanar Reformation or Reconstruction
SVC	Superior Vena Cava
TEE	Transesophageal echocardiography: Ultrasound based medical imaging technique
	US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Warning Information: Identifies potential hazards
	Manufacturer symbol: Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC
	Important Information: Identifies useful information
	Consult Instructions for Use

02
INDICATIONS FOR USE / INTENDED USE

TruPlan enables visualization and measurement of structures of the heart and vessels for pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure.

To facilitate the above, TruPlan provides general functionality such as:

- Segmentation of cardiovascular structures
- Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR
- Simulation of TEE views, ICE views, and fluoroscopic rendering
- Measurement and annotation tools
- Reporting tools

TruPlan's intended patient population is comprised of adult patients.

03
CONTRAINDICATIONS

None known.

04
INSTALLATION & NETWORK SECURITY

See TruPlan Installation and Configuration Guide.

05
GENERAL WARNINGS

WARNING:

- TruPlan should not be used for purposes other than those indicated in the Indications for Use/ Intended Use section
- Please review the patient and study information carefully to ensure the correct patient case is being evaluated
- The TruPlan software is not intended to perform a diagnosis, nor to replace any duties of the physician.
- Measurements made in TruPlan should only provide additional information to, not replace, measurements made during the typical clinical workflow (e.g., intra-procedural imaging using fluoroscopy, TEE, and/or ICE).
- The Fluoro, TEE, and ICE modules provide simulated, not real, images of fluoroscopic, TEE, and ICE views, respectively.
- Quantitative analysis is dependent on the quality and correctness of the image source data (i.e, CT scans).
- Software may slow down when other software applications are being run on the same machine.
- OS system updates might require an updated version of TruPlan (see System Requirements).

06
USER SYSTEM REQUIREMENTS

The minimum system requirements for TruPlan are:

Requirement	Minimum Requirements
Operating System	Windows 10 64bit
Processor	Intel Core i5 or better
GPU	Intel HD 620 or better (Dedicated GPU is recommended)
System RAM	8 GB (16 GB Recommended)
Display	1280x800

It is advised to download and install the latest GPU driver when using TruPlan.

07
BASIC COMPONENTS, FUNCTIONALITY

The Left Atrial Appendage Closure (LAAC) procedure involves implanting a device into Left Atrial Appendage (LAA) of the heart to close off the LAA. Clinical professionals familiar with LAAC understand the importance of visualizing and measuring the anatomy of the LAA and surrounding cardiac structures. As part of the current standard of care, visualization and measurements are performed using intra-procedural Trans Esophageal Echo (TEE) and/or Intra Cardiac Echography (ICE), in conjunction with Fluoroscopy. TruPlan software is adjunctive to these techniques and helps physicians plan the LAAC procedure, providing visualization and measurement tools based on Computed Tomography (CT) images. Involving both qualitative and quantitative features, TruPlan provides insight into the shape, size, angle, and positioning of the anatomy prior to the procedure and helps determine the appropriate size of the closure device to be implanted.

TruPlan is intended to be used after the decision to implant a LAA closure device is already made. It does not perform a diagnosis. TruPlan does not replace any part of the clinical workflow around the LAAC procedure, nor does it replace any part of what a physician does; it simply provides additional information and hence supports the preprocedural planning process.

The measurements made in TruPlan (including those in the simulated imaging modules) are either manual or user-modifiable and can only be performed as an overlay on MPR images as per good radiology practice. These measurements are not to be relied upon solely for LAAC procedural planning; users are to perform the required measurements on the anatomy, device (implant) sizing, etc. using currently accepted clinical methodology (e.g., intra-procedural transoesophageal echocardiography (TEE) or intracardiac echocardiography (ICE) in conjunction with fluoroscopy). If an incorrect measurement is performed using TruPlan, the intra-procedural measurements via fluoroscopy, TEE, and/or ICE are available to the physician upon which they can make procedural decisions. Pre-procedural image processing using TruPlan is therefore adjunctive to the typical clinical workflow.

The simulated modalities (Fluoro, TEE and ICE) do not replace the real modalities during the procedure; only CT data is loaded into TruPlan, and these CT images are modified to mimic the images physicians are used to seeing using fluoroscopy, TEE, and ICE. The modules containing simulations are clearly labelled as such.

08
MEASUREMENT ACCURACY

TruPlan allows for measurement of lengths (in mm), angles (in degrees), and areas (in mm2) with an accuracy of 5%. All calculations and measurements in TruPlan are done in the DICOM patient coordinate system. On-screen pixel coordinates are converted into the DICOM patient coordinate system by the inverse operation as the rendering. This ensures that the coordinates of the measurement match the coordinates of the image. All measurements are converted into the DICOM patient coordinate system before doing any computations. This ensures that accuracy is independent of image resolution.

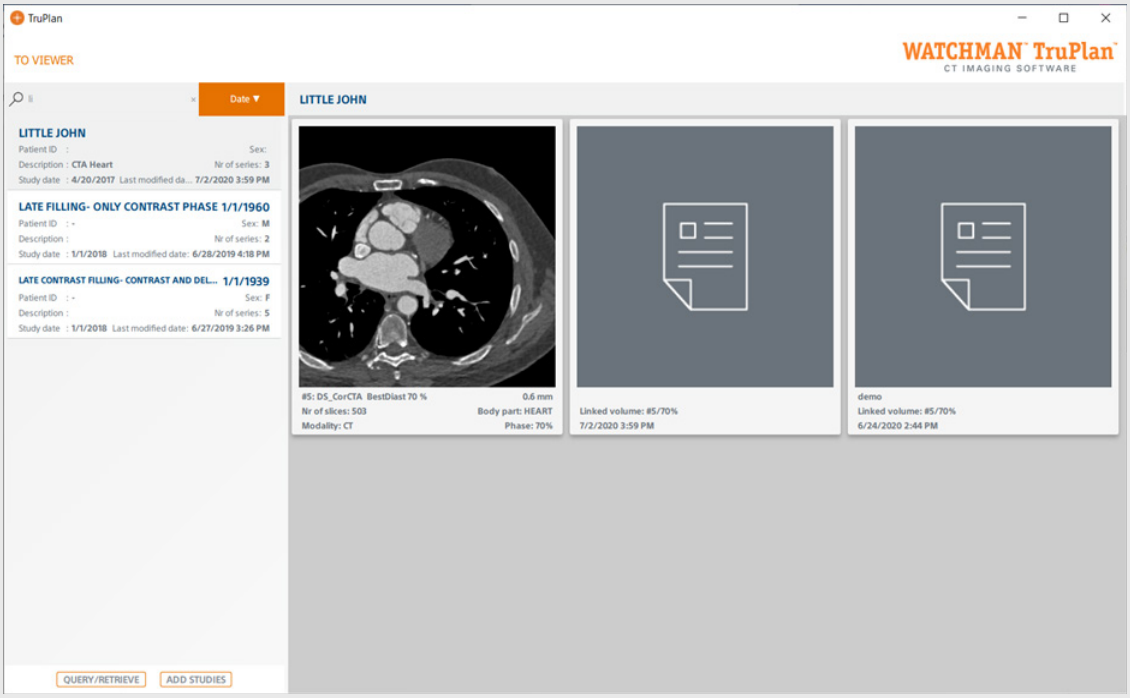
09
GETTING STARTED

After installing TruPlan and activating the license per the Installation and Configuration Guide, launch the TruPlan application. Login is not required; use of the software may begin immediately upon launch.

The first page that appears is the Study List page.

WARNING: Software may slow down when other software applications are being run on the same machine.

10
WORKING WITH THE STUDY LIST



10.1 IMPORTING AND VIEWING STUDY DATA

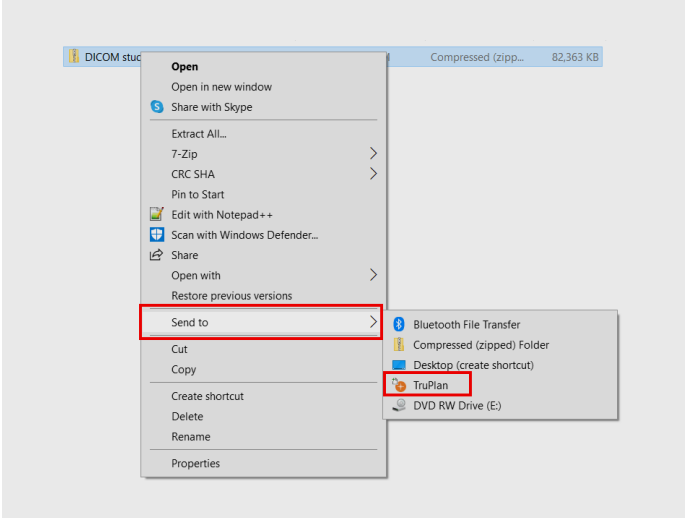
Use the **Add Studies button to import data,** select a folder that contains one or more studies and **press Select Folder to start the import**.

Once the studies are imported, they will be shown as above, double click a thumbnail to open the series in the viewer.

When selecting a newly imported study for the first time, it might take some time before all thumbnails are shown.

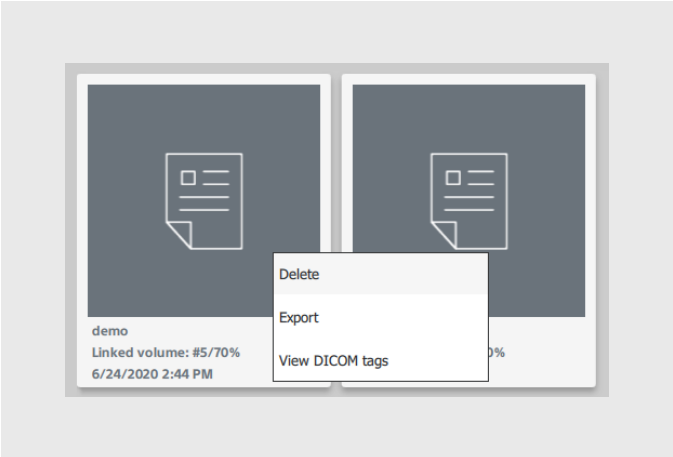
10.2 ALTERNATIVE IMPORT: SEND TO TRUPLAN UTILITY

In windows explorer right click on a folder or zip file that contains DICOM studies and **select "Send to > TruPlan"**, a progress dialog will appear. Once finished the study is imported into the TruPlan study list.



10.3 ADDITIONAL FUNCTIONALITY

- Right click on a thumbnail to open the context sensitive menu:
  - **Delete:** Deletes the image series.
  - **Export:** Exports ‘Saved session’ to a DICOM file that can be imported into another TruPlan system.
  - **View DICOM tags:** Shows the DICOM information for this series.
- Sorting and searching
  - Enter (a part of) the patient name to search for a specific study.
  - The study list can be sorted on patient name and last modified date/time. By default, the last imported study will be at the top of the list.



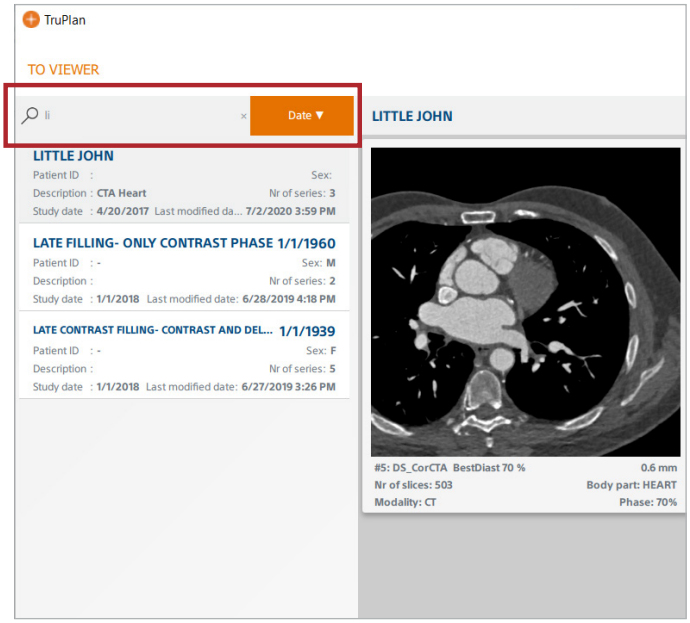
10.4 SAVED SESSION

The purpose of ‘saved session’ is to have a dynamic alternative for a static report or to save the state of a specific dataset to continue to analyze the scan at a later moment.

‘Saved session’ will save the state of the work session, including measurements, sculpting of volume, bookmarks (TEE), home views (ICE), and other relevant work.

A ‘saved session’ file is a DICOM compatible file, it can be transferred easily.

To restore a ‘saved session’ on a different system, the original study data should be present as well.



11
WORKING WITH A PACS

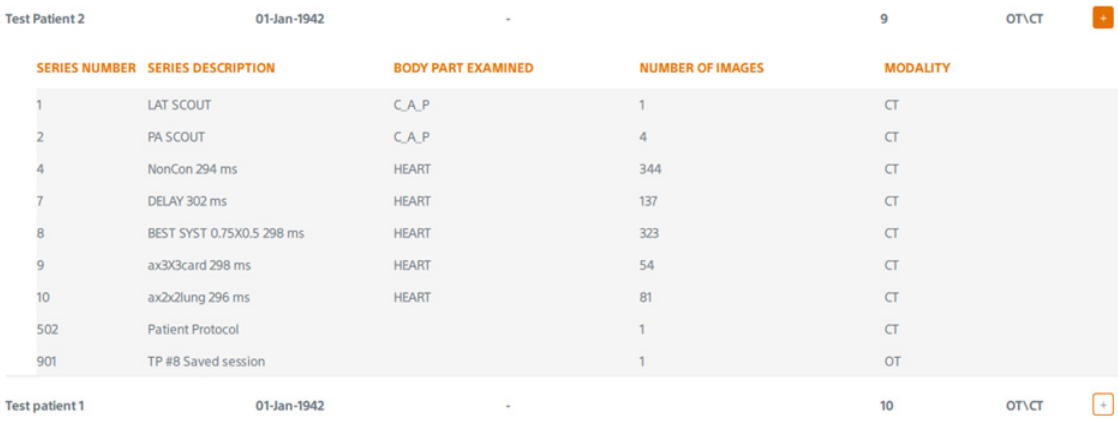
A PACS (Picture Archiving and Communication system) is typically used as storage location for medical images in a hospital. The configuration is described in the TruPlan Installation and Configuration Guide.

TruPlan supports query and retrieving studies from the PACS. Studies or series can also be sent back to the PACS, this is mainly useful for the saved session created in TruPlan.

Use the following button to open the Query retrieve window: 

The search fields are on the right side of the dialog, at least one of these fields need a value to enable the “Search studies” button. When the CT checkmark is checked only studies containing a CT will be shown. The patient name will automatically be appended with a wildcard, so only the first part of the name needs to be entered.

The right part of the screen will show the results of the query. To see the individual series click the + button to expand. Or right click and select “Retrieve study” to import the complete study.



Individual series can be imported by right clicking and selecting the option “retrieve series”.

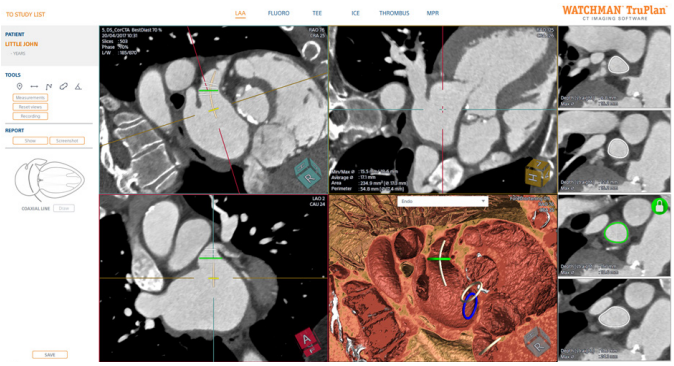
Saved sessions created by TruPlan v1.1 can be recognized by the series number and series description. Series number will be 901, and the series description will start with TP and then the series number of the linked series followed by the description the user entered while saving.

Right click on a local study, series, or saved session to send it to PACS.

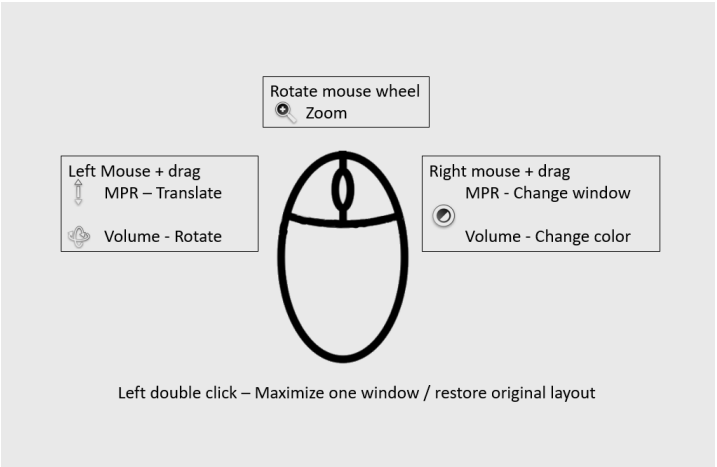
12

WORKING WITH THE VIEWER

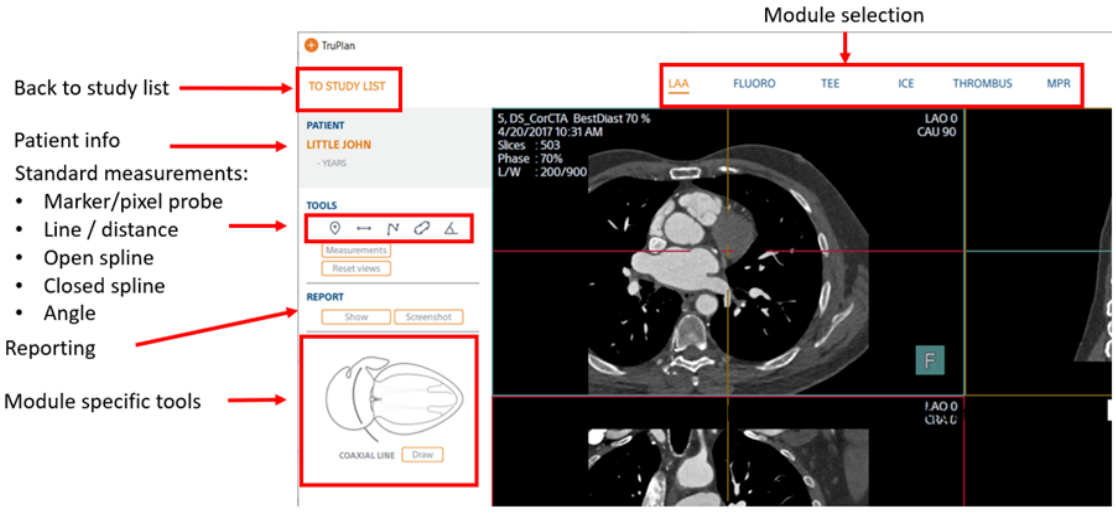
The following image (captured from the LAA module) is representative of the MPR viewer functionality that is present in several TruPlan modules. Below the image are standard mouse interactions for navigating such views.



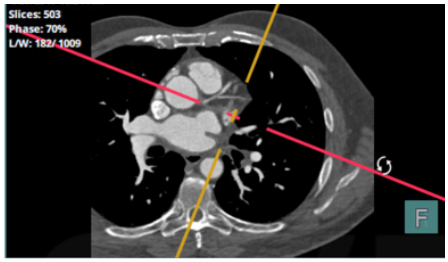
12.1 STANDARD MOUSE INTERACTION



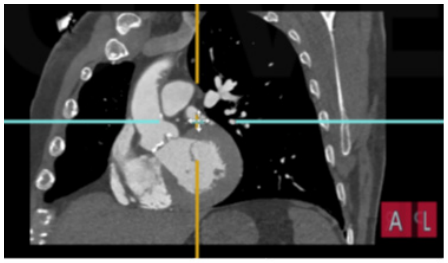
12.2. GENERIC TOOLS AND LAYOUT



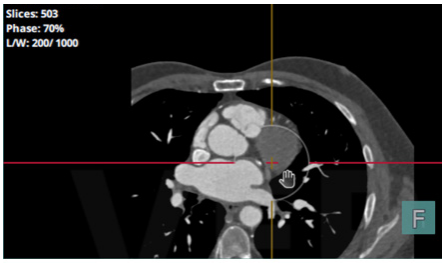
12.2 GENERIC TOOLS AND LAYOUT



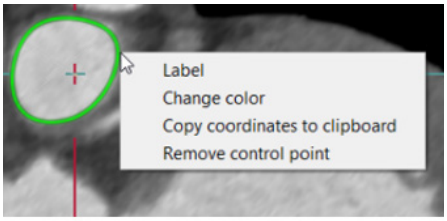
Left click drag the sides of the crosshair to rotate the crosshair.

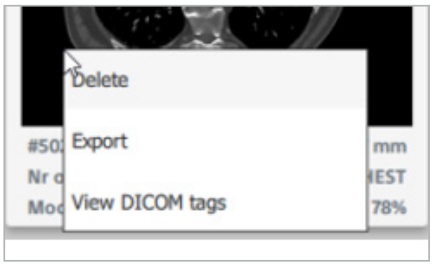


Left click drag the center of the crosshair to move the crosshair.



Left click drag the center of the image to pan the image.





Right mouse click will give a context sensitive menu with various options

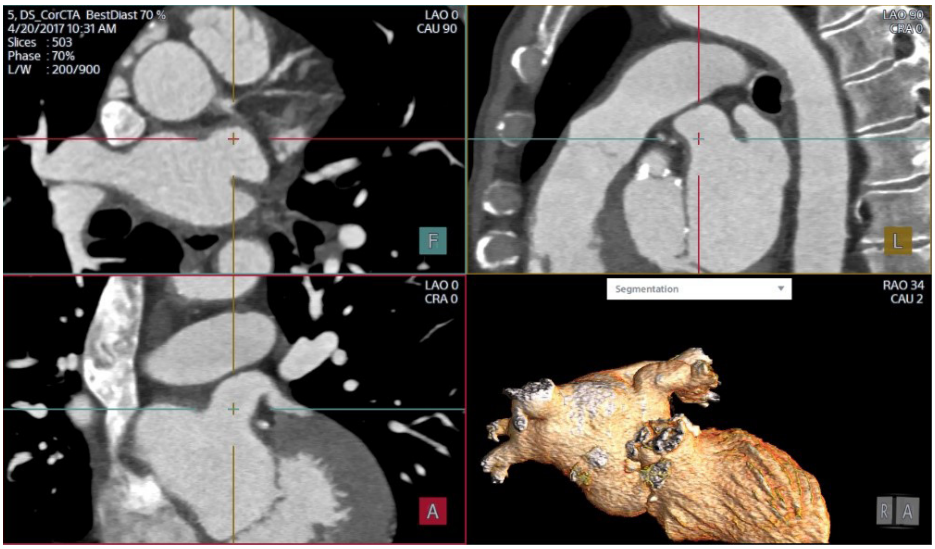
13
LEFT ATRIAL APPENDAGE (LAA) WORKFLOW

The purpose of this workflow is to determine the location, orientation and dimensions of the landing zone for the LAAC closure device to be implanted. (An example of a LAA closure device is the WATCHMAN FLX device, a major commercially available implantable device for LAAC manufactured by Boston Scientific.)

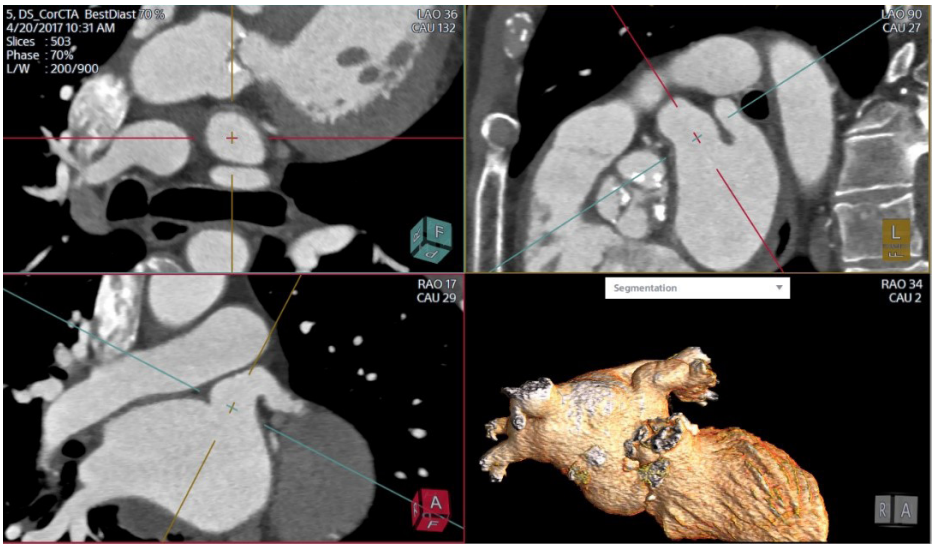
This workflow provides MPR views and 3D rendering of the original CT data. It displays two long-axis MPR views and a short-axis MPR view of the LAA, on which manual lines and regions of interest (ROIs) can be drawn for quantitative measurements (e.g., distance, area, and perimeter). Additionally, a 3D rendering of the left side of the heart (including the left ventricle, left atrium, and LAA) is displayed for visualization purposes.

Once the image data is loaded an auto segmentation of the left side of the heart runs in the background and will display when ready.

13.1 FINDING THE LAA



In the sagittal (lower left) viewport scroll until the LAA is visible and place the crosshair at the base of the LAA.

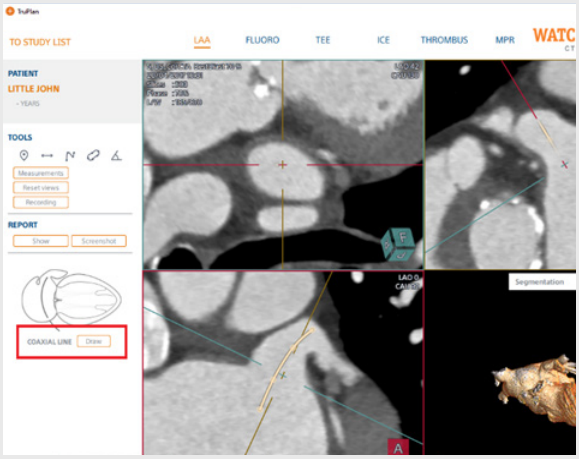


Align the blue line of the crosshair with the base of the LAA, in both the lower left and the upper right viewport.

13.2 PLACING THE CO-AXIAL LINE

Once the LAA is identified **press the Draw button** and draw the co-axial line in the LAA. Each single click adds a control point defining the trajectory of the co-axial line. End with a double click. The initial landing zone will be placed as close as possible to the crosshair on the co-axial line.

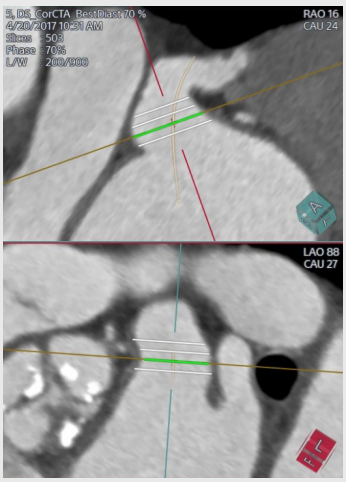
In the next step drag and tilt the landing zone (green bar) in the left viewports to its desired location.



The dimensions of the landing zone can be adjusted and read at the upper right main viewport.

The gallery view shows two distal measurements (white), the landing zone (green) and a proximal measurement (white) all 3 mm apart.

Once the landing zone is set correctly, click the lock icon in the gallery view to lock it so the landing zone cannot be altered accidentally.



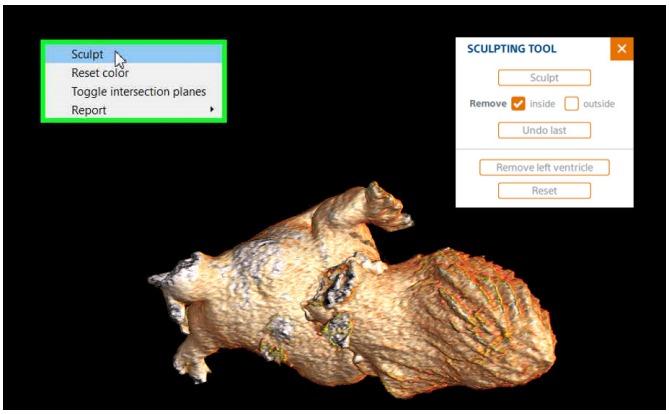
13.3 SCULPTING

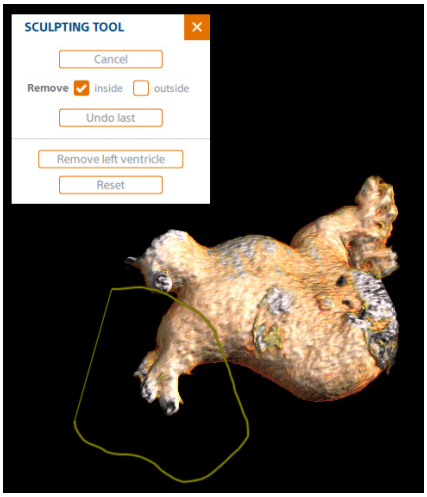
To remove parts of the segmentation, use the sculpting feature by selecting this option from the right mouse button menu in the volume window.

The Sculpt/Cancel button toggles the sculpt mode on or off. Select whether the inside or outside of the sculpt contour should be removed.

The "Remove Left Ventricle" button will remove the complete ventricle with one click.

It is possible to undo the last action or use **Reset to start all over again**.





14
FLUORO WORKFLOW

The purpose of this workflow is to simulate a view normally seen during fluoroscopy to indicate the location of anatomical landmarks relevant to the LAAC procedure, to get an understanding of their locations and orientations. Understanding how the different structures relate to each enables clinical professionals to plan a possible path for the LAA closure device to be implanted into the LAA.

The module starts by displaying three standard MPR views (axial, sagittal, and coronal). These images can be browsed through to locate and annotate the anatomical landmarks. From there, the landmarks and the dimensions of the landing zone (determined in the LAA workflow) can be used to overlay a virtual device and access sheath. This step can also be used to determine the fluoro angles, and anatomical landmarks will also be used for transesophageal echocardiography (TEE) simulations in the TEE module.

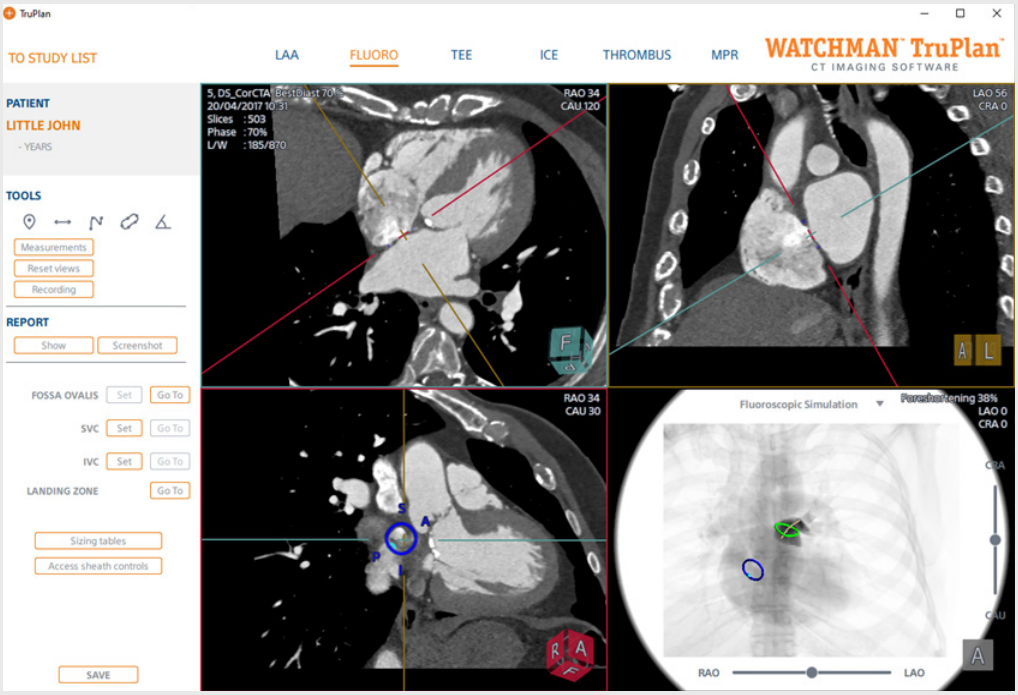
WARNING: The Fluoro module provides a simulated, not real, fluoroscopy image. The actual image modality is CT.

WARNING: The Fluoro module makes no diagnosis or clinical decision in place of the physician.

14.1 FOSSA OVALIS

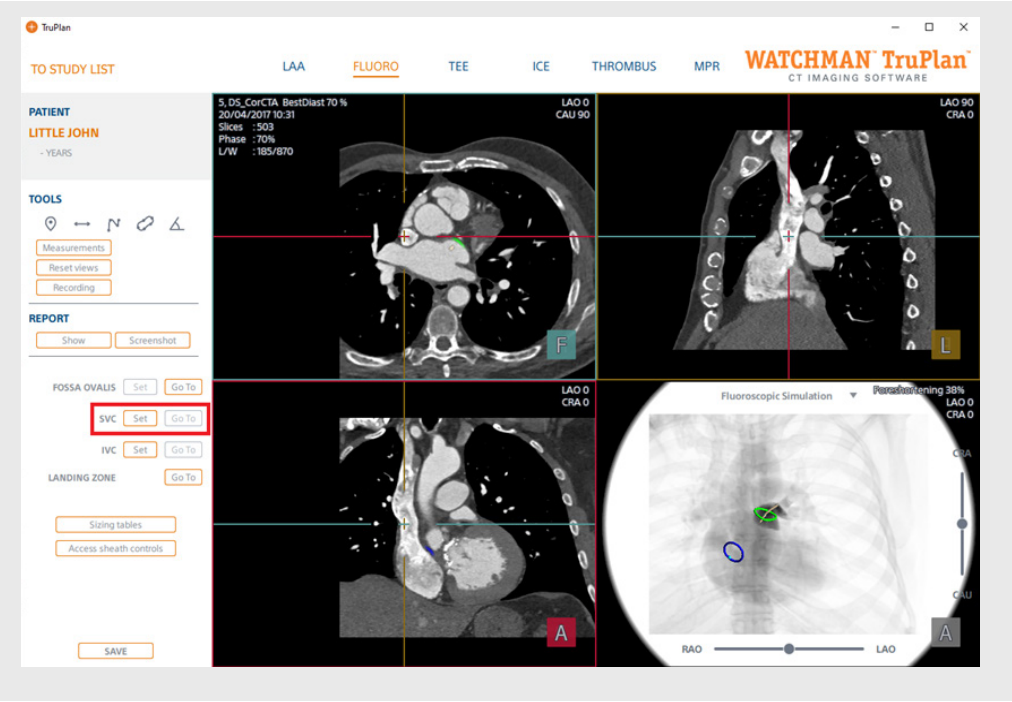
In the upper left viewport scroll until a 4-chamber view is visible. Align the red line of the crosshair with the inter atrial septum, do the same in the upper right viewport.

Press the "Set" Fossa Ovalis button and click on the center of the lower left viewport. A circle will be placed at the location of the fossa.



14.2 SUPERIOR VENA CAVA (SVC)

Use the "Reset views" button to start with default orientations. In the lower left (coronal) viewport scroll until the SVC becomes visible. Place the crosshair on the SVC, close to the heart and optionally tilt the blue line a bit to create a plane perpendicular to the vessel. **Click the Set SVC button** and click on the center of the SVC in the upper left viewport.



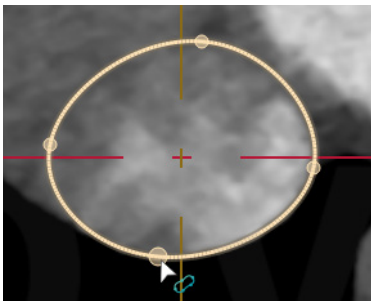
14.3 INFERIOR VENA CAVA (IVC)

Use the same approach as for the SVC.

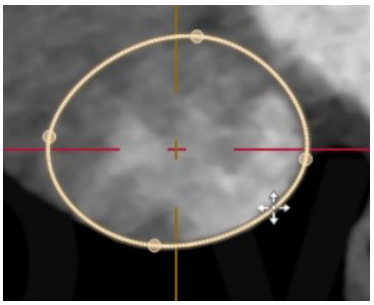
14.4 REMARKS

The purpose of this workflow is to indicate some anatomical structures; therefore, the software will place a circle with a pre-fixed size at the indicated locations.

For orientation purposes it is not necessary to have exact contouring of the structures, this workflow serves as a visualization aid rather than for measurements.



It is possible to resize the contour by dragging the control points that become visible when hovering the mouse over the annotation. It is also possible to insert additional control points.



Using the Ctrl + left mouse drag makes it possible to move the annotation without deforming it.

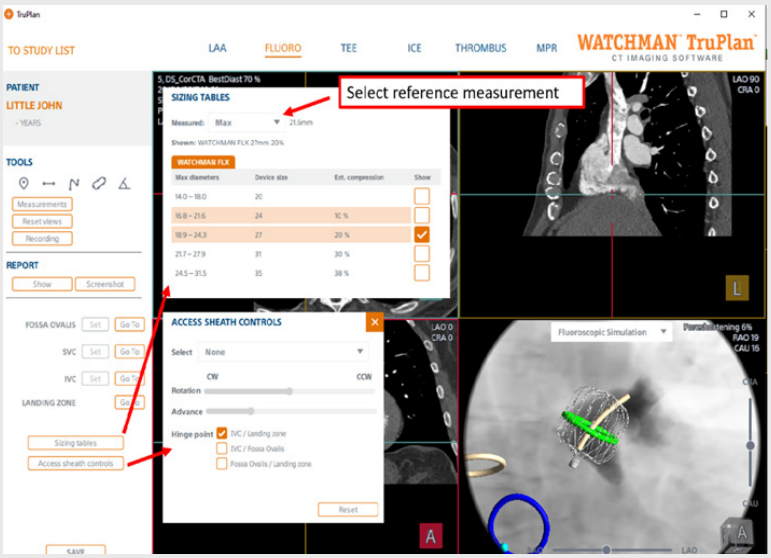
14.5 SIZING TABLE, VIRTUAL DEVICE, VIRTUAL ACCESS SHEATH

Depending on the configuration the WATCHMAN option may be disabled, in that case only the WATCHMAN FLX will be available

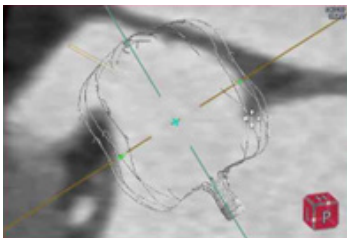
Open the sizing tables dialog for the available devices, select the desired device.

Use the access sheath controls to select the virtual catheter. The rotation slider will rotate the sheath, the advance slider will move the virtual sheath over selected hinge points.

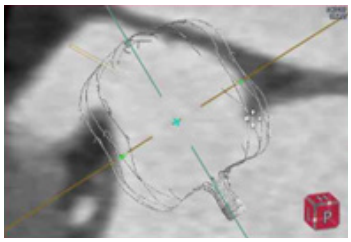
When needed the hinge points can be moved in the MPR views, **use the "Go To" buttons to easily find the structures** that need to be adjusted.



With the virtual device the following interactions are possible:



Left mouse – drag, to move the device in the multiplanar reconstruction (MPR) viewport.



Ctrl + Left mouse drag to tilt the device in the MPR viewport.

WARNING: The virtual 3D models of the device and virtual catheter (access sheath) are shown as-is and will not adjust their shape to the shown anatomy.

15
TEE WORKFLOW

This module simulates the views that can be obtained with TEE, to aid the physician and supporting clinical staff during LAAC pre-procedural planning with familiar views seen during the standard of care. In this module, the MPR views of the CT scan are used to locate the position of the TEE probe in the esophagus, and subsequently the corresponding TEE simulation screen (including simulated TEE image in actual modality CT) is created with the anatomical structures defined in the Fluoro module (LAA, FO, IVC, SVC, etc.) highlighted. Visualization and manual measurements are possible in this workflow.

15.1 DEFINING THE ESOPHAGUS

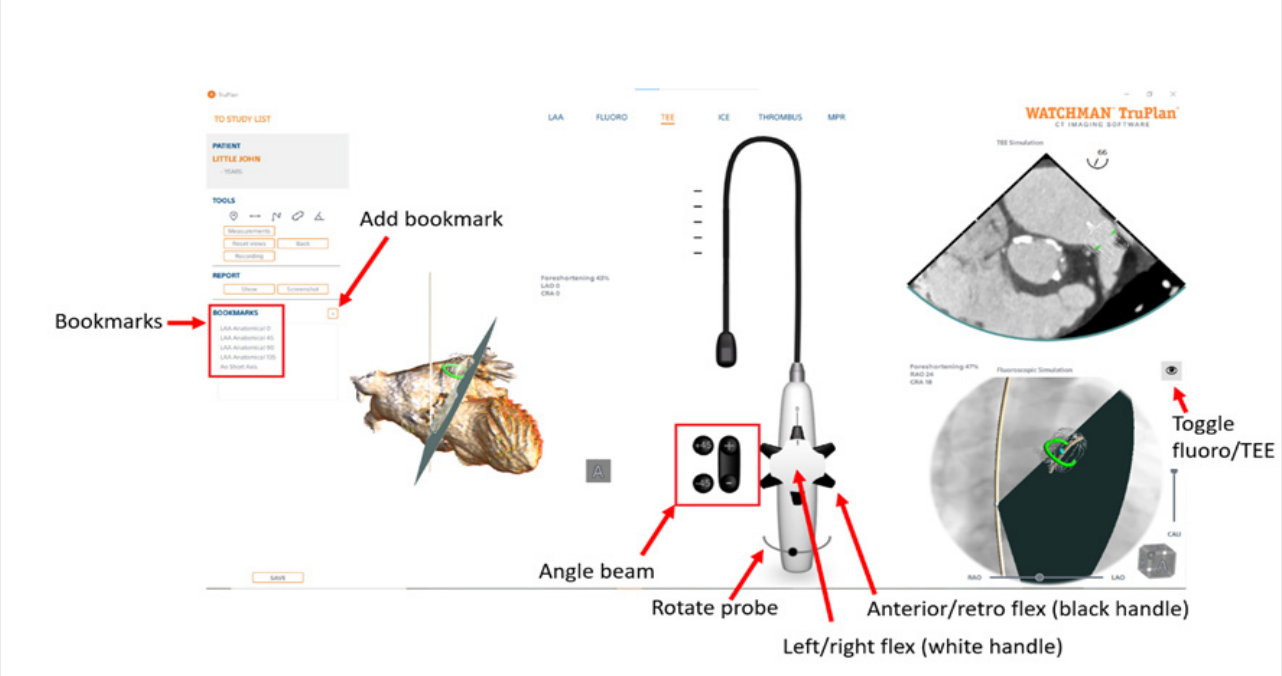
The esophagus can be defined in any orientation, when it is clearly visible in the sagittal view (upper right) this is the easiest way. **Click the Esophagus button**, and trace it in the image, end the drawing mode with a double click. **Press the confirm button** to proceed to the next step of the module.

(The esophagus can also be drawn in the other MPR views when needed.)

WARNING: The TEE module provides a simulated, not real, TEE image. The actual image modality is CT.

WARNING: The Fluoro module makes no diagnosis or clinical decision in place of the physician.

15.2 TEE SIMULATION



Several bookmarks are pre-populated based on the Landing zone and structures defined in the Fluoro module. When needed it is possible to overwrite these bookmarks by updating the echo view and then right click on the bookmarks then select **"Overwrite bookmark"** or create a new bookmark using the **"+" button**.

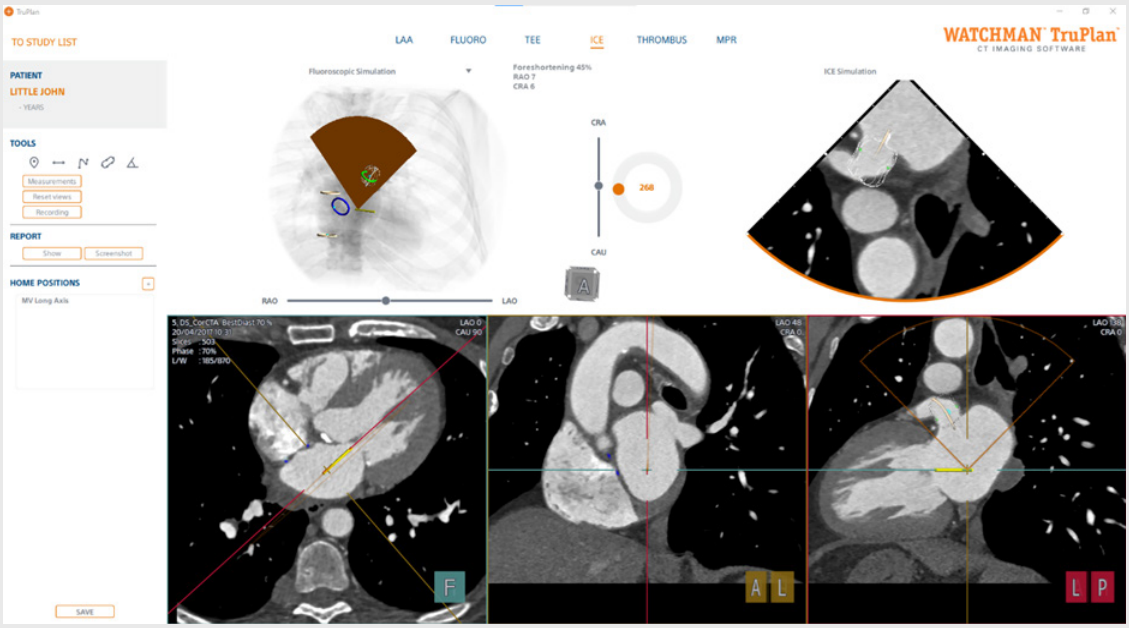
- The TEE probe can be moved along the esophagus line by dragging the probe.
- The TEE angle can be changed by pressing the + and – or -45 and +45 buttons left of the probe handle.
- The TEE probe can be rotated by dragging the rotate button at the lower end of the probe handle.
- Rotating the probe can also be done by left mouse dragging the simulated echo view (top right).
- Change the depth, by using the scroll wheel in the simulated echo view.
- Flexing of the probe can be done by turning the white or black knob on the probe handle.

16

INTRACARDIAC ECHOCARDIOGRAPHY (ICE) WORKFLOW

This module simulates ICE devices and their corresponding views, to aid the physician and supporting clinical staff during LAAC pre-procedural planning with familiar views seen during the standard of care. In this module, the MPR views of the CT scan are used to place the ICE probe on a ROI, and subsequently the corresponding ICE simulation screen (including simulated ICE image in actual modality CT) is created with the anatomical structures defined in the Fluoro module (LAA, FO, IVC, SVC, etc.) highlighted. Visualization and manual measurements are possible in this workflow.

16.1 ICE SIMULATION



To place an ICE probe, make sure that one of the MPR views is oriented in such a way that the probe can easily be placed. **Click the "+" icon**, select the name of the home position from the list, click in the MPR on the position for the distal tip of the probe, and then click towards the more proximal location (only the last 2.5cm of the ICE probe will be shown).

Use the orange handle of the rotation tool, to rotate the beam.

Using the same method multiple home positions can be defined.

WARNING: The ICE module provides a simulated, not real, ICE image. The actual image modality is CT.

WARNING: The ICE module makes no diagnosis or clinical decision in place of the physician.

17
THROMBUS WORKFLOW

This module facilitates the detection of thrombus in the LAA by allowing visual comparison of a regular contrast-enhanced CT scan with a time-delayed contrast-enhanced CT scan as done in standard radiology practice. TruPlan makes no suggestion, diagnosis, or decision regarding the presence of thrombus, nor does it allow measurements in this module. It is for visualization purposes only.

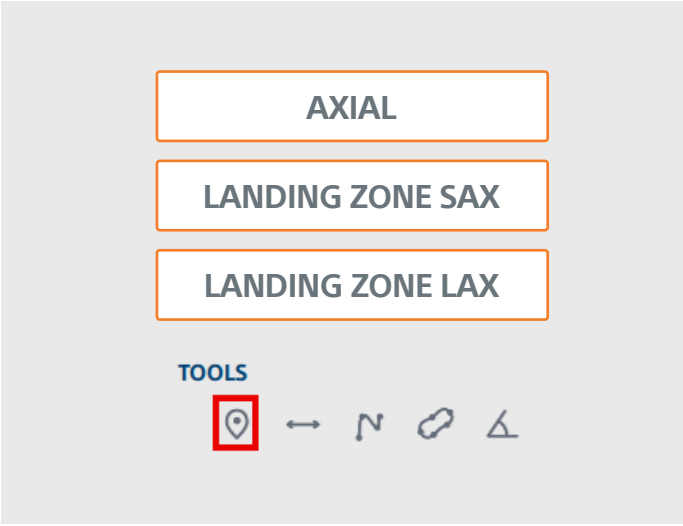
WARNING: TruPlan makes no suggestion, diagnosis, or decision regarding the presence of thrombus. The interpretation of the images and resulting decisions are under the user's control.

17.1 SIDE BY SIDE VIEW

When enabling the Thrombus module, the active scan that has been analyzed will be shown on the left side, on the right side a button is visible that states: "**Load another volume"**, when this button is pressed the study list will be activated. The delayed scan that corresponds to the active scan can now be selected.

Now the two scans are displayed side-by-side and most interactions will be synchronized. Use the buttons on the left side to select the default orientations. And from there it is possible to scroll through the dataset.

Use the pixel probe to determine the Hounsfield values in specific areas .



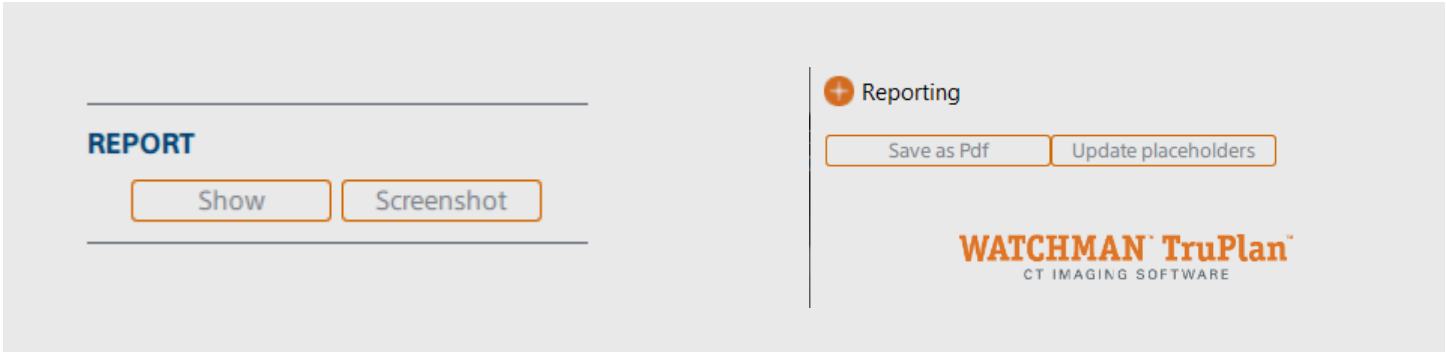
18
MPR MODULE

The MPR module provides generic MPR views (axial, sagittal, and coronal) and a 3D rendering view to freely visualize the images (browsing through images, panning, zooming, tilting, etc.) and perform basic measurements. This can be done independently from the actions performed in the other workflows.

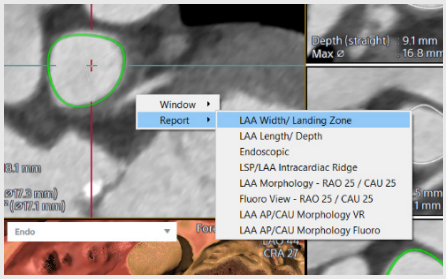
Measurements done in the MPR module will also be saved in **'saved session**'.

19
REPORTING

Each of the modules offer the ability to capture screenshots, measurements, etc. and send them to the report. The report also shows some patient information derived from the DICOM information of the CT scans, and there is a section to enter comments.



Use the Show report button to open the report window, use the **"Update placeholders" button** to import the default views in the report.



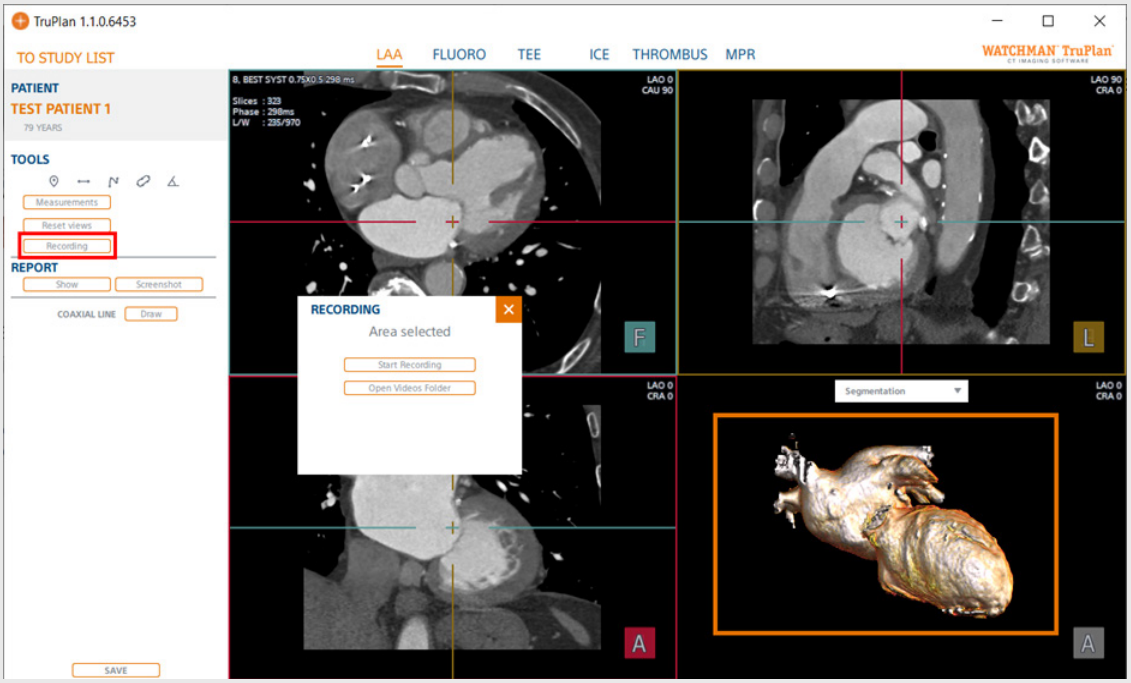
Use the Show report button to open the report window, use the **"Update placeholders" button** to import the default views in the report.

The placeholders in the report can also be filled by right clicking in the viewport and selecting the desired placeholder from the report section.

Press the "Screenshot" button to add a manual screenshot to the report. The screenshot button will copy all visible viewports to the report, from there it is possible to remove images that are not needed in the report.

20
SCREEN RECORDER

With the built-in screen recorder it is possible to record a part of the screen to create a movie clip.



Press the "Recording" button, then define the area that needs to be recorded, left click on the top left corner of the target area keep the mouse button down and drag the area of interest.

Press "Start Recording", interact with the viewport or use the arrow keys on the keyboard to rotate the volume in an absolute horizontal or vertical direction. Stop the recording when finished. Use the "Open Video Folder" to find the saved movie. The file size of the video is determined by the recording time and the size of the recording area.

20
SUPPORT

For technical questions please contact our team by phone or e-mail:

North America
Circle Cardiovascular Imaging Inc.
1100, 800 5th Avenue SW Calgary
Alberta, Canada, T2P 3T6
P: +1 403 338 1870
F: +1 403 338 1895

Europe
Circle Cardiovascular Imaging B.V.
P: + 31 (800)265 8982

Report a problem: support@circlecvi.com
Website: www.circlecvi.com