WATCHMAN™ TruPlan™
CT IMAGING SOFTWARE

Boston Scientific
Advancing science for life™

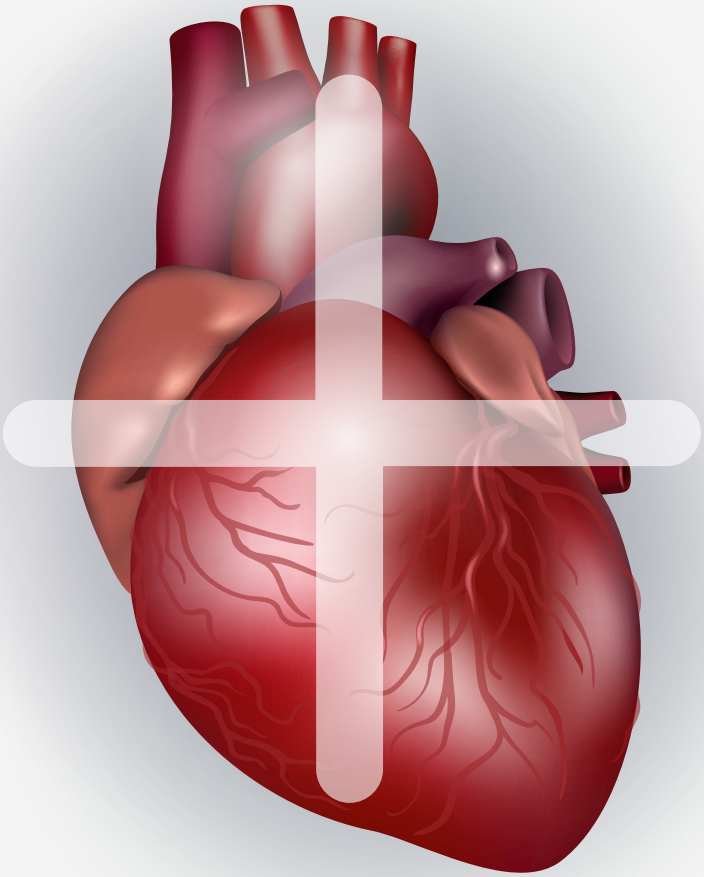
circle CARDIOVASCULAR IMAGING

USER MANUAL

JANUARY 2023

TruPlan™ Computed Tomography (CT) Imaging Software Application

VERSION 3.1



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.

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REGULATORY INFORMATION

MD

MANUFACTURED BY:

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bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

United States of America
The following 510K clearances applicable for this product: K222593

Canada
Health Canada Medical device license (MDL) number: 105406

UDI

UDI-DI: 00882916000530

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

℞ Only

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REGULATORY

Agency	Authorized Representative	Approval/Clearance Reference
Health Canada	N/A	MDL: 105406
US FDA	N/A	TruPlan – 510k (K222593)

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2. 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
PDL	Peri-device leak
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
	Important Information: identifies useful information
	Consult Instructions for Use: Indicates that the user shall read Instructions for Use
	Unique Device Identifier (UDI): Indicates a carrier that contains Unique Device Identifier information
	Medical device: Indicates this product is a medical device

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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
- Post-procedural evaluation for the 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.

IMPORTANT: TruPlan is intended to be used as a pre-procedural planning aid, and LAAC procedures should be performed per the chosen LAAC device's approved IFU.

IMPORTANT: TruPlan is intended to be used as a post-procedural assessment aid, and all clinical decisions should be made per the chosen LAAC device's approved IFU.

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CONTRAINDICATIONS

None known.

05
INSTALLATION AND NETWORK SECURITY

See TruPlan Installation and Configuration Guide.

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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).
- Any serious incident that has occurred in relation to this software as a medical device should be reported to the Circle Cardiovascular Imaging Inc. and the competent authority of the Member State in which you are established, see Support section for contact information.

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USER SYSTEM REQUIREMENTS

The minimum system requirements for TruPlan™ are:

Requirement	Standalone app	Desktop Client (in enterprise solution – 3 CCU)	TruPlan Server
CPU	Windows:Intel i5 7th Gen Mac:	Windows: Intel i5 7th Gen Mac:	4-core Xeon
	Intel Core i5 7th gen+, Apple silicon	Intel Core i5 7th gen+, Apple silicon	
RAM	16GB	8GB	16GB
DISK	200GB SSD-class storage	2GB SSD-class storage	200GB SSD-class storage, capable of 500 IOPS, storage should support the ability to grow over time dependent on local workflows
VIDEO	Intel Integrated HD Graphics 630+	Intel Integrated HD Graphics 630+	n/a
MAC	macOS 10.15 and 11.X	macOS 10.15 and 11.X	n/a
WINDOWS	Windows 10, 11	Windows 10, 11	Windows Server 2016 or newer
NETWORK-LAN	1Gb	1Gb	1 Gb minimum, 10 Gb preferred
Display	1920x1080	1920x1080	n/a

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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 has a Follow-up module, that can be used for LAAC post-procedural analysis using CT imaging. It offers, peri-device leak (PDL), and distal LAA opacification.

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.

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MEASUREMENT ACCURACY

TruPlan allows for manual measurement of lengths (in mm), angles (in degrees), and areas (in mm2) with an accuracy of 95%. 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.

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GETTING STARTED

After installing TruPlan and activating the license per the Installation and Configuration Guide, launch the TruPlan application. Login is required, you can connect to a Local Server or to a Remote Server in case your IT department has setup a TruPlan Server on your facility.

The first page that appears is the Study List page.

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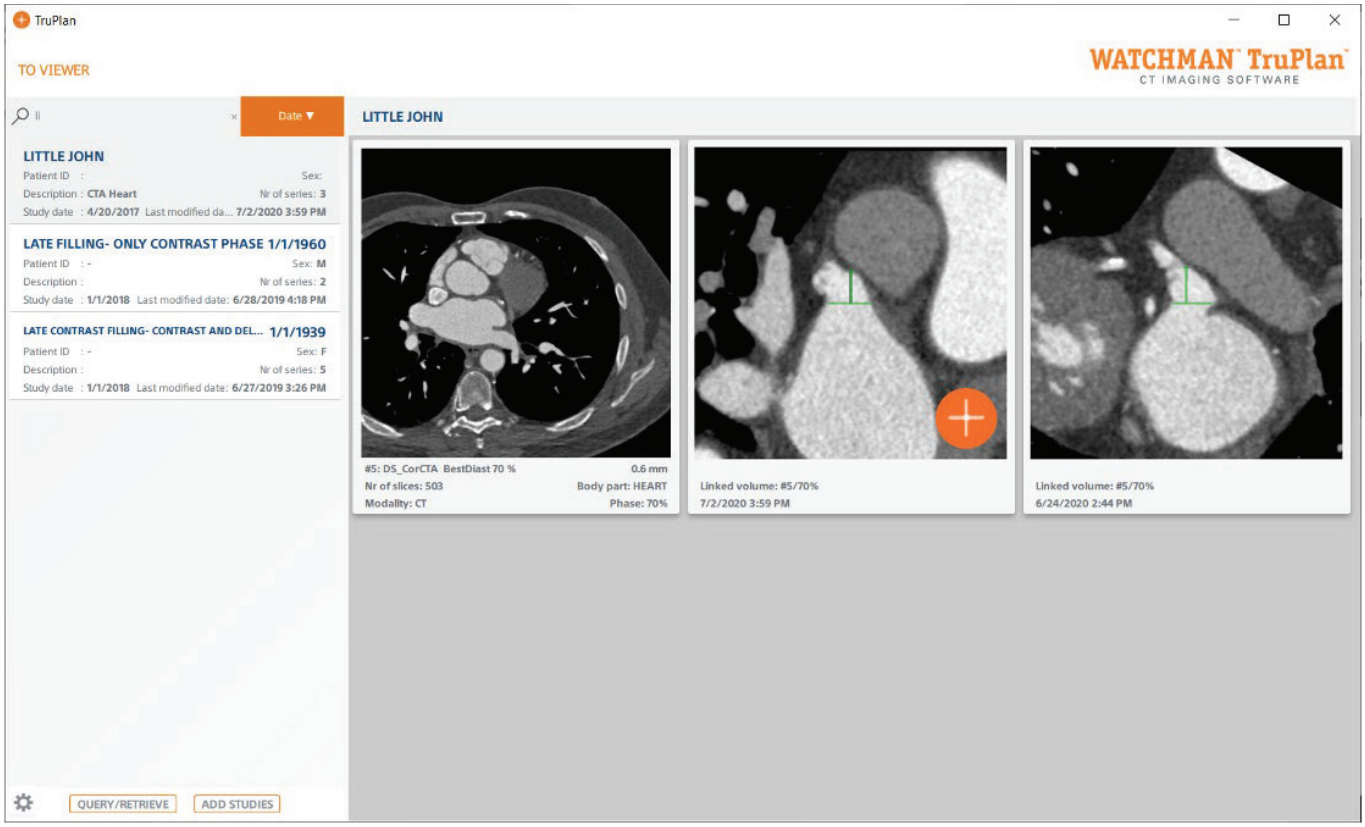
WORKING WITH THE STUDY LIST



11.1 IMPORTING AND VIEWING STUDY DATA

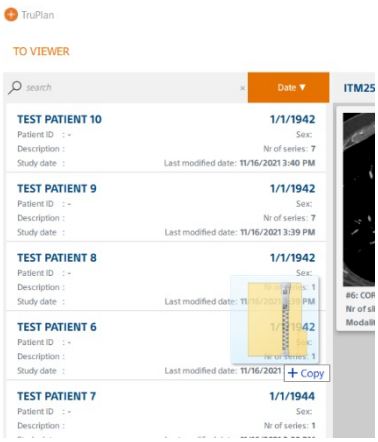
Use the button ADD STUDIES to import data, select a folder that contains one or more studies and press select folder to start the import.

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.

11.2 IMPORT USING "DRAG AND DROP"

Folders and zip files containing DICOM images can be dragged and dropped on the UI of TruPlan, this way the data will be added to the study list.

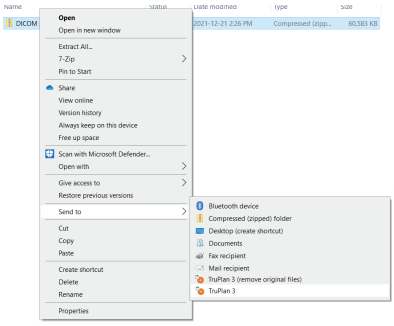


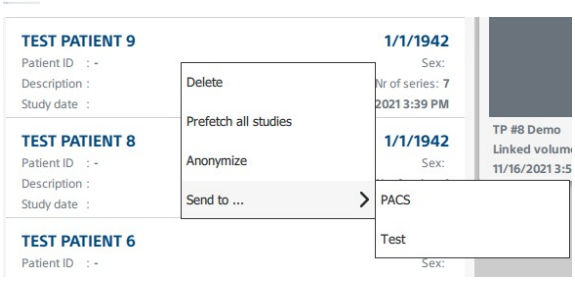
11.3 ALTERNATIVE IMPORT: SEND TO TRUPLAN™ UTILITY

In Windows Explorer right click on a folder or zip file that contains DICOM studies and select “Send to > TruPlan 3”; a progress dialog will appear. Once finished the study is imported into the TruPlan study list.

TruPlan 3 (remove original files) option, deletes the source file after it is transferred to TruPlan Server. This alternative is suitable for when there is low disk space available. If during the transferring, deleting of source files fails, an error message is presented to the user and transfer is aborted.

After the transfer operation is completed, a summary result of the transfer is presented to the user.





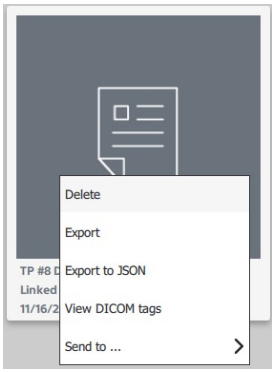
11.5 SAVED SESSION

The purpose of Saved Session is to have a dynamic alternative for a static report or save the state of a specific dataset to continue 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.

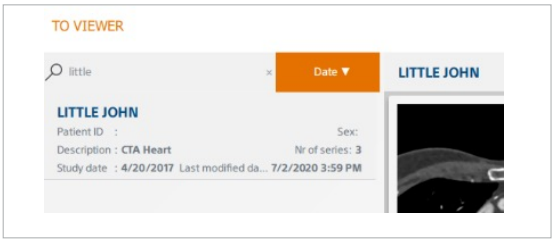
A saved session file is a DICOM compatible file, it can be transferred easily.

When exporting a Saved Session, volumes that are referenced by the Saved Session are also exported. However, if you send the Saved Session to a remote DICOM Node, you should also send the referenced volume, so whoever opens the sent Saved Session, will be able to see the content.



11.4 ADDITIONAL STUDY LIST 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.
  - Export to JSON: Exports a saved session as JSON file.
  - View DICOM tags: Shows the DICOM information for this series.
  - Send to ...: Send study, series to a remote DICOM node.



- 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.

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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.

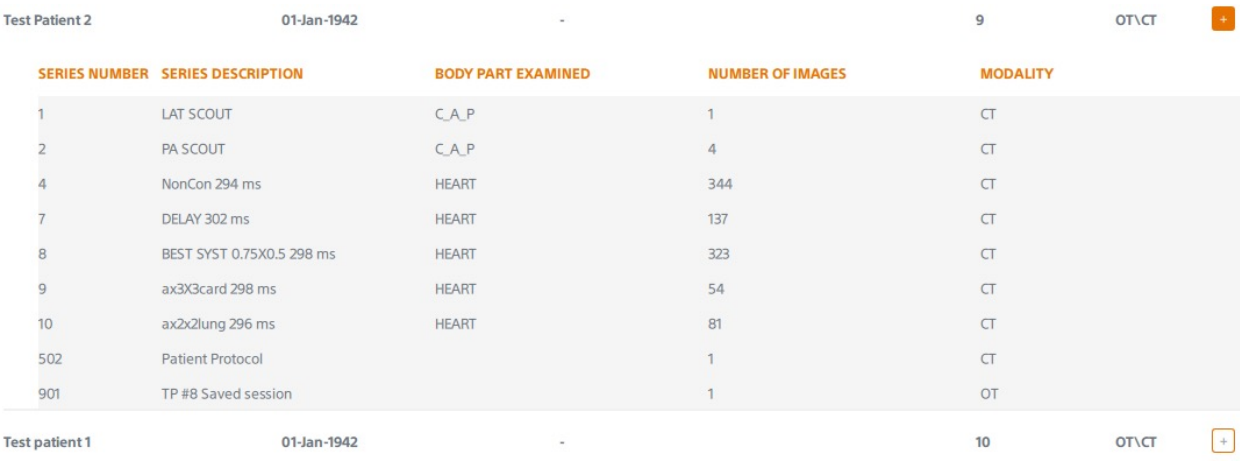
If there is no PACS configured on your system, the button QUERY / RETRIEVE will be disabled.

TruPlan supports QUERY / RETRIEVE 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 QUERY / RETRIEVE 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.

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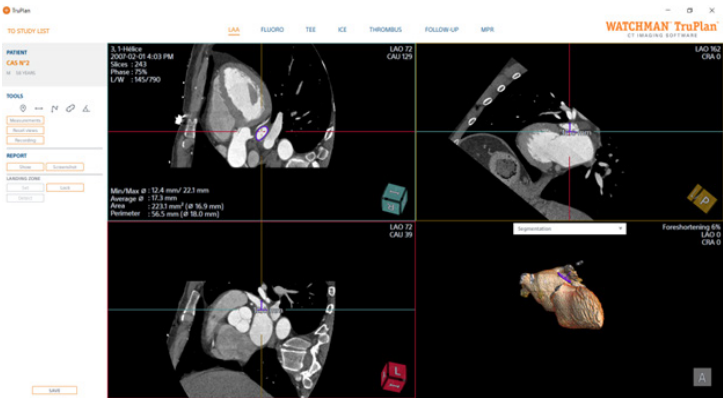
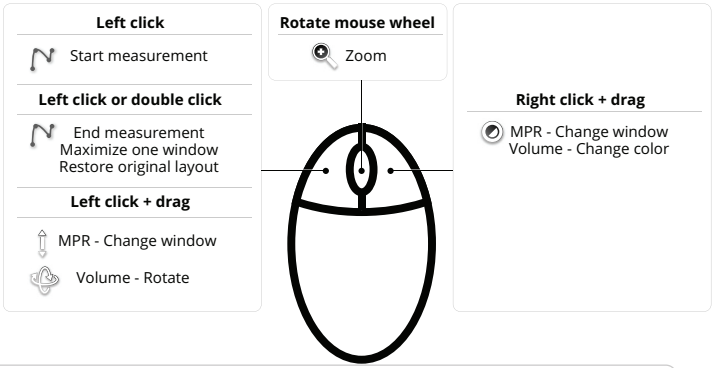
WORKING WITH THE VIEWER

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.



The colors of the lines and borders are corresponding with the orthogonal intersection planes of the MPR. In the example left side, the two red lines in the upper viewport are representing the intersection with the view in the lower left viewport.

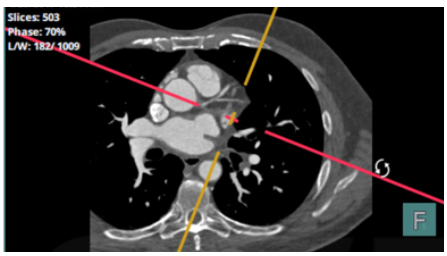


13.1 STANDARD MOUSE INTERACTION

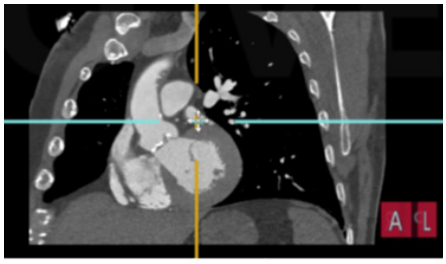
Cursor shape	Action	Mouse	Windows trackpad	Apple trackpad
	MPR - Translate	Left click + drag	1 finger press + slide	1 finger press + slide
	Volume - Rotate	Left click + drag	1 finger press + slide	1 finger press + slide
	Zoom	Rotate mouse wheel	2 fingers slide up /down	2 fingers slide up/down
	MPR - Change window	Right click + drag	2 fingers press + slide or 1 finger press on lower right part of trackpad + slide	2 fingers press + slide
	Volume - Change color	Right click + drag	2 fingers press + slide or 1 finger press on lower right part of trackpad + slide	2 fingers press + slide
	Maximize one window/ restore original layout	Double click left	Double tab	Double tab
	Start measurement	Left click	Tab	Tab
	End measurement	Left click or double click	Tab or double tab	Tab or double tab
	Context menu	Right click	2 fingers tab or tab on lower right of trackpad	2 fingers tab

Behavior of Windows trackpad might vary depending on model and vendor

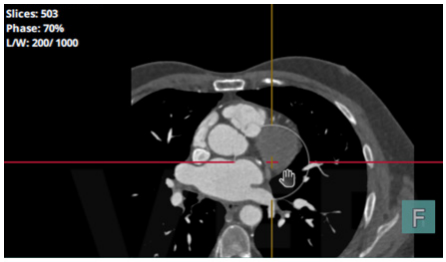
13.2 GENERIC TOOLS AND LAYOUT



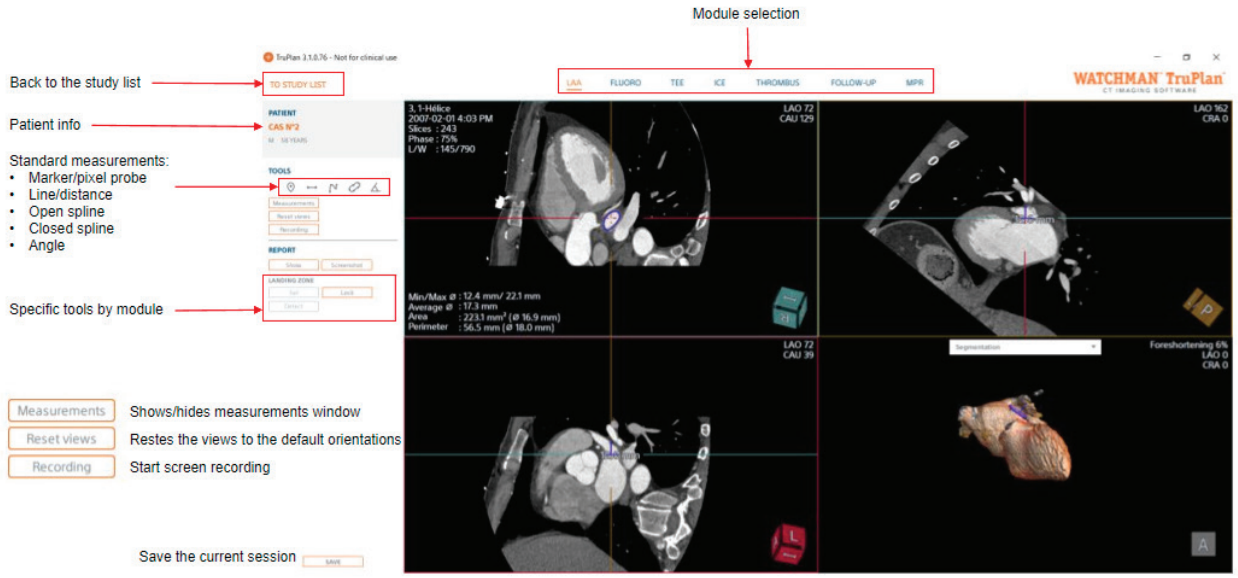
Left click drag the sides of the crosshair to rotate the crosshair.



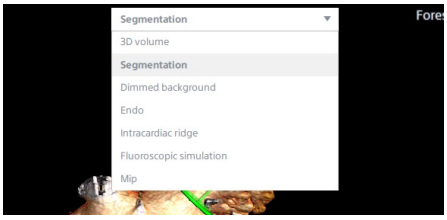
Left click drag the center of the crosshair to move the crosshair.

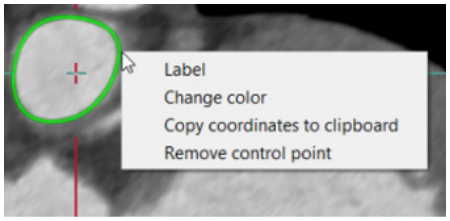


Left click drag the center of the image to pan the image.



Right mouse click will show a context sensitive menu with various options:





You can perform different measurements on the Viewport by using the standard measurement tools. All created measurements will become visible in the measurement list. You access the list by clicking “Measurements” button on the left-hand panel.

The dropdown menu in the volume viewport has the following options:

3D volume	Will show all image data in a 3D view
Segmentation	Shows the left side of the heart in 3D
Dimmed background	As segmentation, but will also show the background semitransparent
Endo	Shows the whole volume cut with the last clicked MPR will act as cutting plane
Intracardiac ridge	An endo view looking from the left atrium into the LAA and LUPV
Fluoroscopic simulation	3D volume shown as if it is an interactive 2D x-ray
Mip	MIP rendering (only in MPR module)

The availability of these options depend on the state of the application and the module

14

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.)

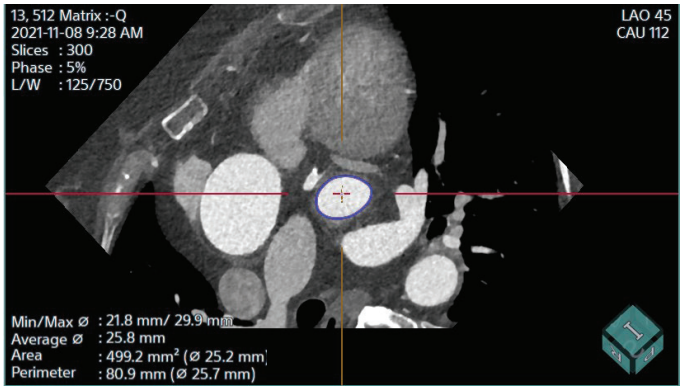
This workflow provides MPR views and 3D rendering of the original CT data. It displays two long-axis MPR views and a short-axis MPR view of the LAA, on which manual lines and regions of interest (ROIs) can be drawn for quantitative measurements (e.g., distance, area, and perimeter). Additionally, a 3D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

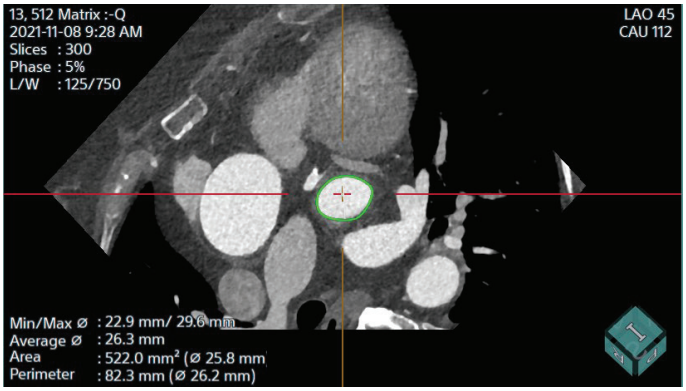
Once the image data is loaded an auto segmentation of the left side of the heart runs in the background and will display when ready.

14.1 AUTOMATED LANDING ZONE PLACEMENT

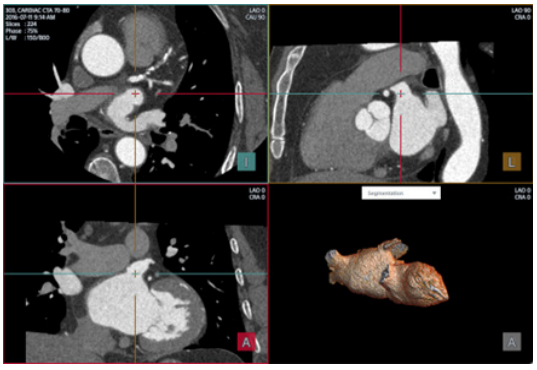
When a series is opened in LAA, landing zone is automatically placed in the ostium of the LAA with purple contour color. User can modify or replace the automated landing zone annotation if desired. Depth marker placement is also automated.

When the user manually modifies the automated landing zone, or locks the automated landing zone, the annotation color changes to green.

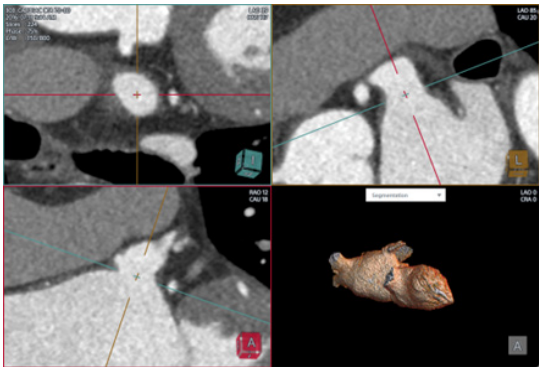




14.2 MANUAL LANDING ZONE PLACEMENT

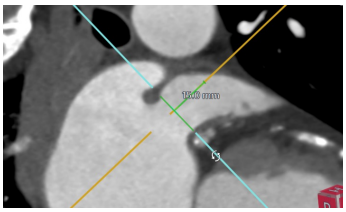


In the case that the landing zone is deleted, the user can manually set the landing zone. In the lower left viewport, scroll until the LAA is visible and place the crosshair at the base of the LAA.

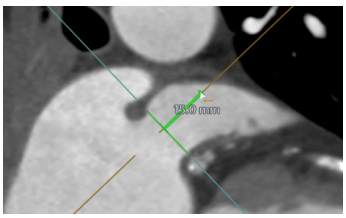


Align the blue line of the crosshair with the base of the LAA, in both the lower left and the upper right viewport.

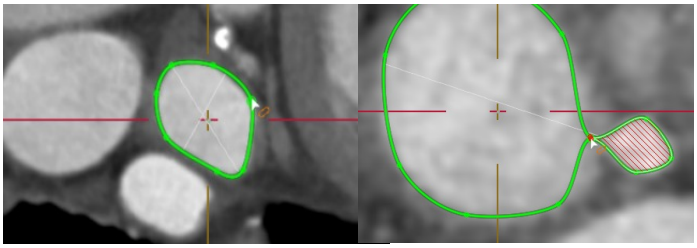
Once the LAA is identified, press the Set Landing zone button and identify the landing zone by clicking on it in the short axis view.



The depth measurement of the LAA will automatically update as the landing zone positioning is edited. To manually measure the depth of the LAA, drag the endpoint of the depth measurement to the desired location.



The landing zone can be altered by moving or rotating the crosshairs in the long axis views until the Lock button is pressed.

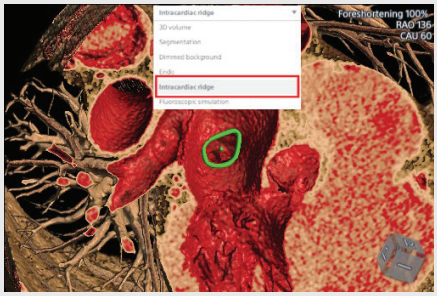


The landing zone contour can be adjusted by dragging the control points that appear when hovering over the green line with the mouse.

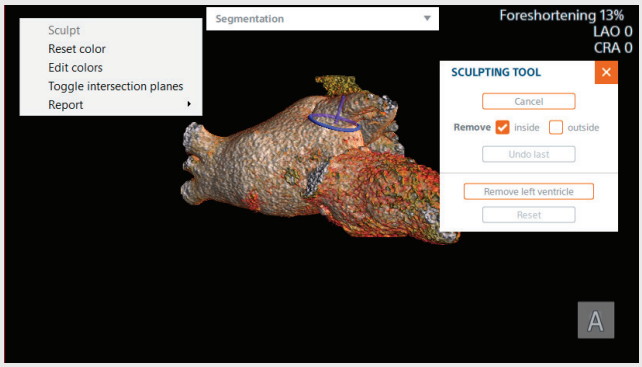
By dragging two control points on top of each other loops can easily be removed.

14.3 INTRACARDIAC RIDGE VIEW

When the landing zone is defined, the intracardiac ridge view will be available in the dropdown list of the volume window.



14.4 SCULPTING

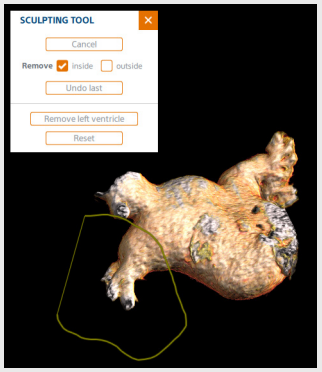


To remove parts of the segmentation, use the sculpting feature, by selecting this option from the right mouse button menu in the volume window.

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.

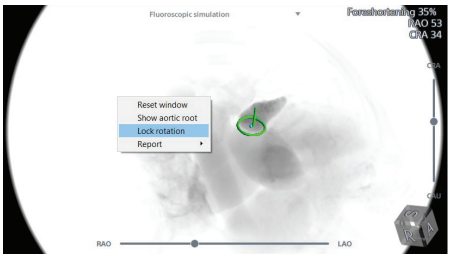
It is possible to undo the last action or use Reset to start all over again.



15

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 and the automated home positions in the ICE module.

User can also lock 3D rotation around LAA axis by selecting Lock rotation from the right-click context menu

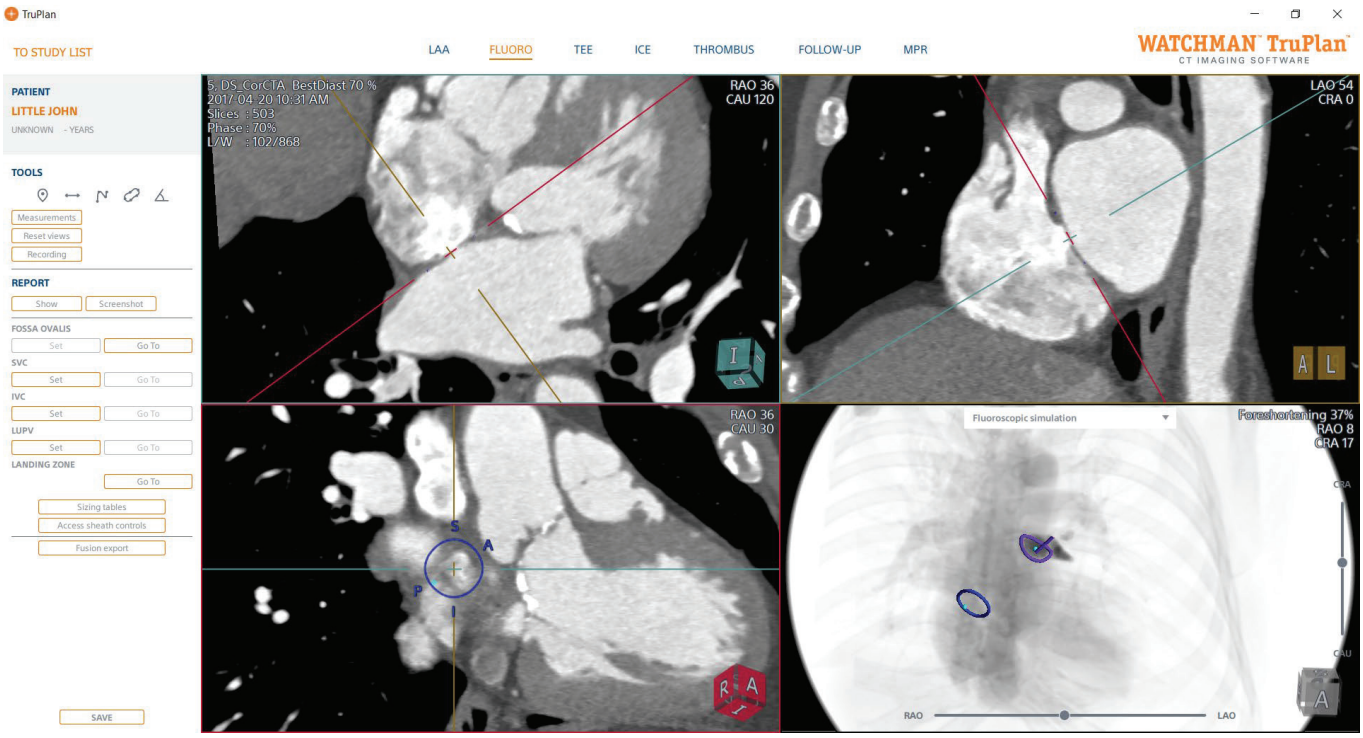
WARNING: The Fluoro module provides a simulated, not real, fluoroscopy image. The actual image modality is CT.

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

15.1 FOSSA OVALIS

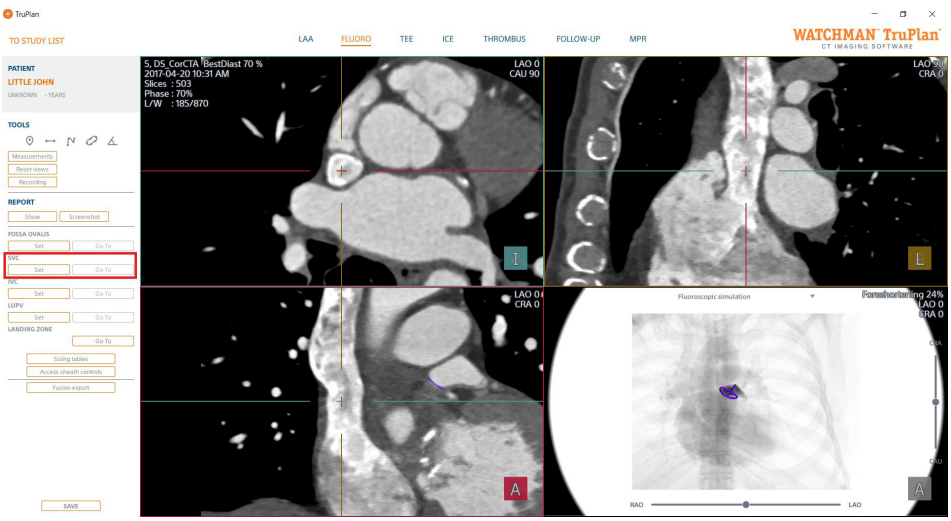
In the upper left viewport, scroll until a 4-chamber view is visible. Align the red line of the crosshair with the inter atrial septum, do the same in the upper right viewport.

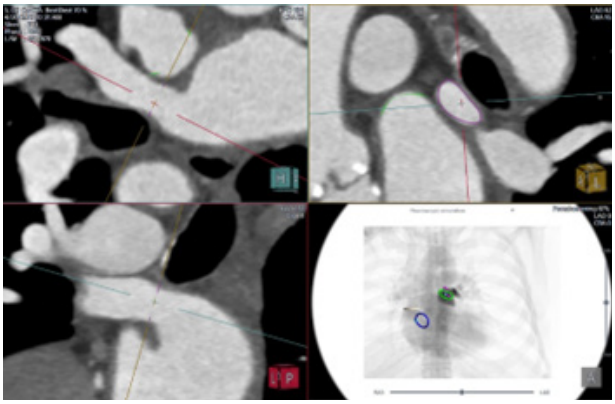
Press the Set button for Fossa Ovalis and click on the center of the lower left viewport. A circle will be placed at the location of the fossa.



15.2 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 button for SVC and on the center of the SVC in the upper left viewport.





15.3 INFERIOR VENA CAVA (IVC)

Use the same approach as for the SVC

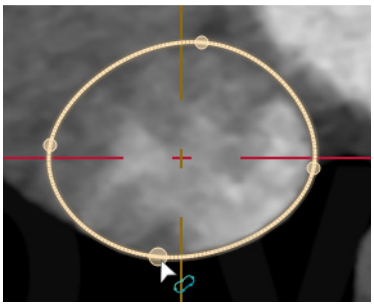
15.4 LEFT UPPER PULMONARY VEIN (LUPV)

Locate the LUPV in one of the MPR views, place the crosshair on the base, align the crosshair in two viewports with the long axis, so the short axis view will become visible in the third viewport, and mark the LUPV there.

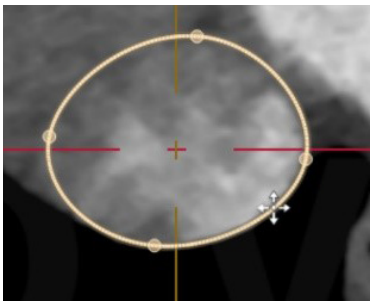
15.5 REMARKS

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.

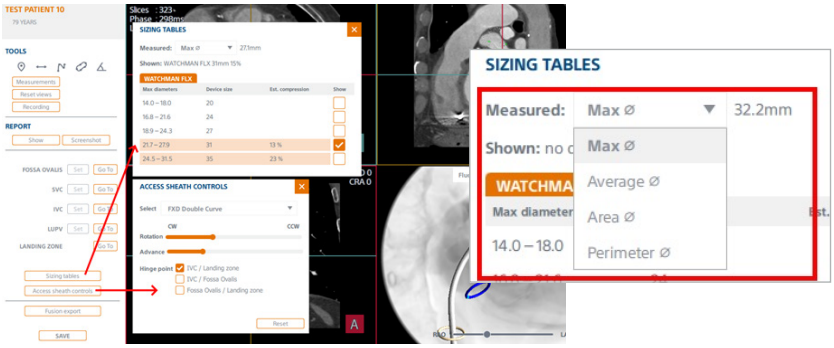


It is possible to resize the contour by dragging the control points that become visible when hovering the mouse over the annotation. It is also possible to insert additional control points.



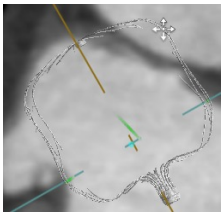
Using the Ctrl + left mouse drag makes it possible to move the annotation without deforming it.

15.6 SIZING TABLE, VIRTUAL DEVICE, VIRTUAL ACCESS SHEATH

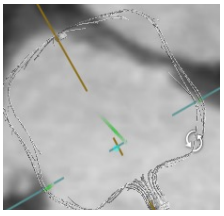


Open the Sizing tables dialog for the available devices, select the desired device. (Support for the WATCHMAN 2.5 can be enabled via the configuration menu.)

With the virtual device the following interactions are possible:



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

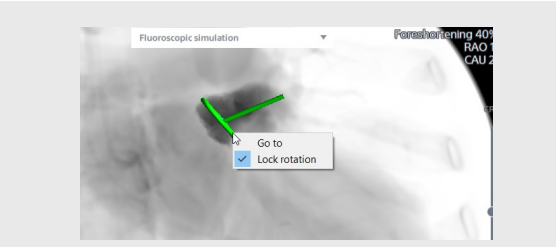


Ctrl + Left mouse drag to tilt the device in the MPR viewport.

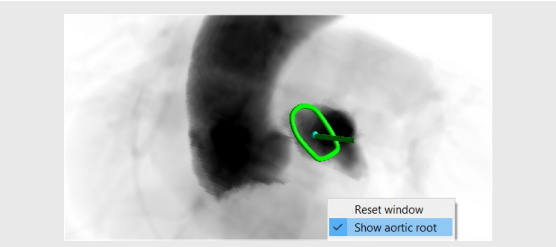
Use the Access sheath controls dialog box to select the virtual catheter. The Rotation slider will rotate the sheath, the Advance slider will move the virtual sheath over selected hinge points.

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

(In the configuration either the TruSeal or FXD sheaths can be selected.)



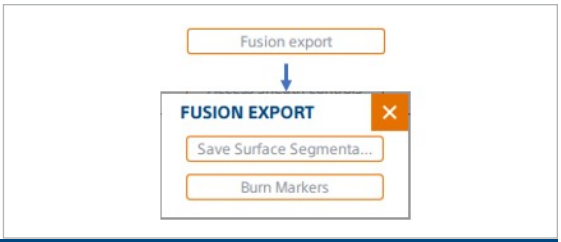
When the Lock rotation option is enabled, the rotation in the fluoro view will be limited to the angles that will show the landing zone in a perpendicular way.



Enable Show aortic root to show the aorta in the fluoroscopic simulation.

15.7 FUSION EXPORT

Use the Fusion export functionality to export the markers (Landing zone, IVC, SVC, Fossa). There is an option to save them as a DICOM surface segmentation object, or to burn them in the pixel data of a regular CT series.



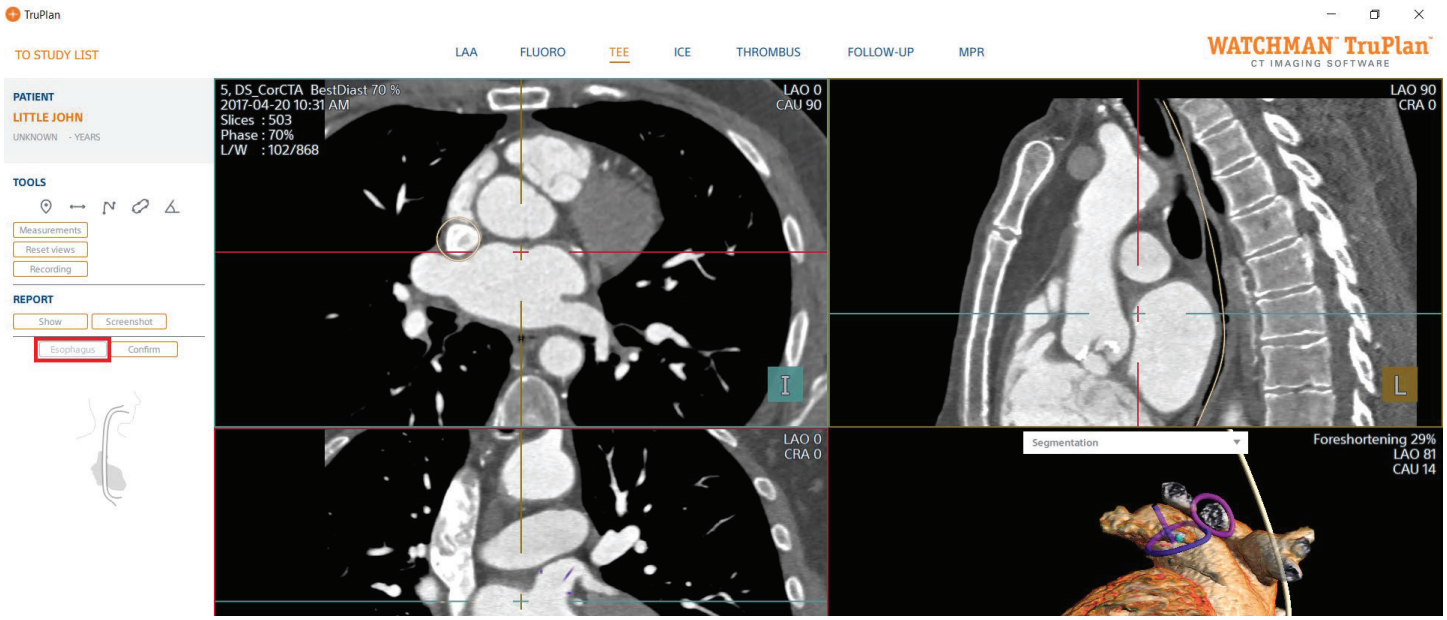
WARNING: The virtual 3D models of the device and virtual catheter (access sheath) are shown as-is and will not adjust their shape to the shown anatomy.

16

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.

16.1 DEFINING THE ESOPHAGUS



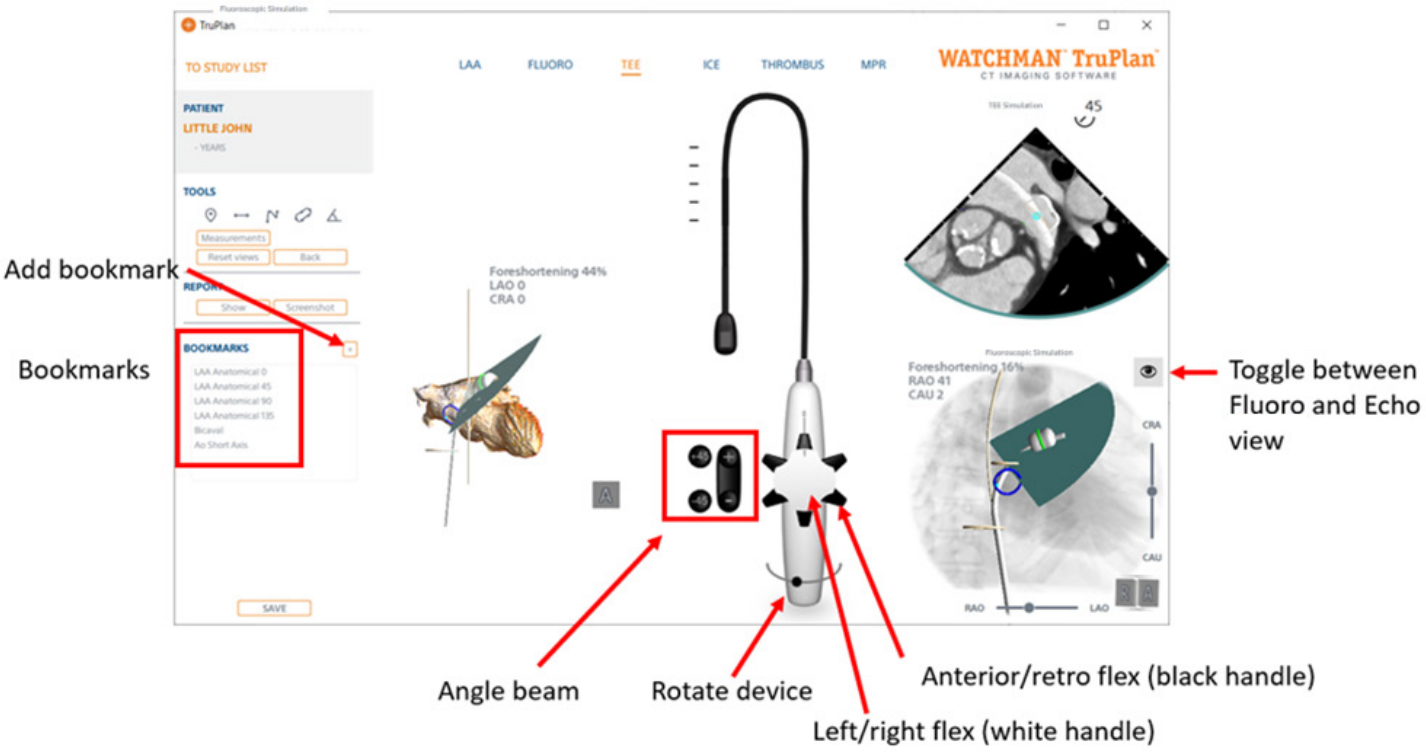
The esophagus can be defined in any orientation, when it is clearly visible in the sagittal view (upper right) this is the easiest way. Click the Esophagus button, and trace it in the image, end the drawing mode with a double click. Press the Confirm button to proceed to the next step of the module.

(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 TEE module makes no diagnosis or clinical decision in place of the physician.

16.2 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; select Overwrite bookmark or create a new bookmark using the + button.

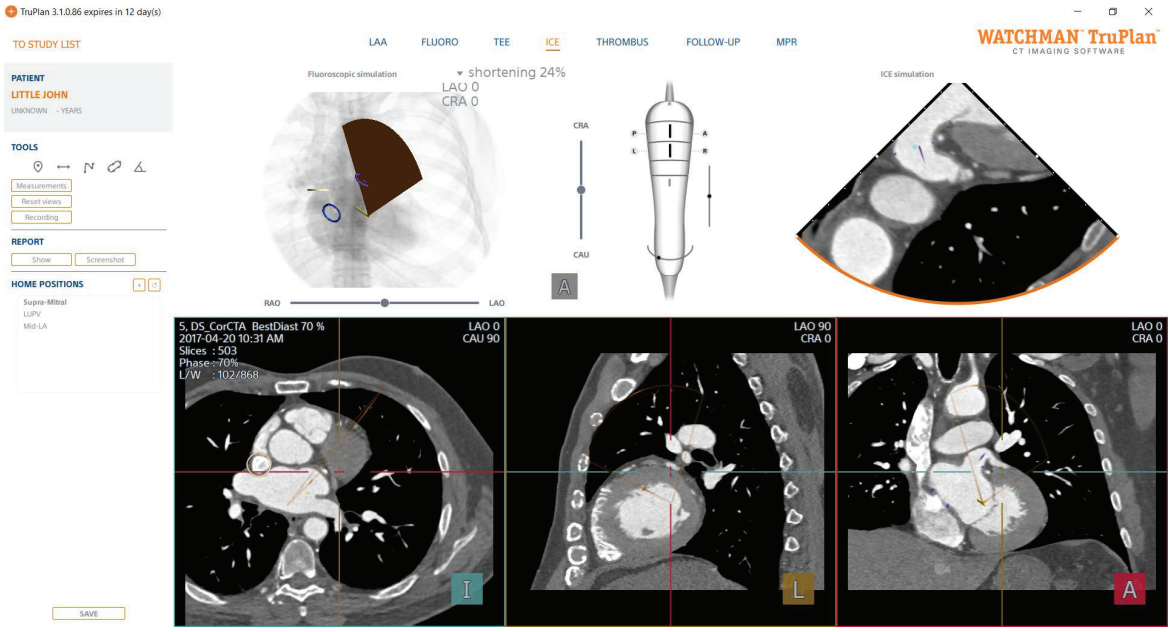
- The TEE probe can be moved along the esophagus line by dragging the probe.
- The TEE angle can be changed by pressing the + and – or -45 and +45 buttons left of the probe handle.
- The TEE probe can be rotated by dragging the rotate button at the lower end of the probe handle.
- Rotating the probe 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.

17

INTRACARDIAC ECHOCARDIOGRAPHY (ICE) WORKFLOW

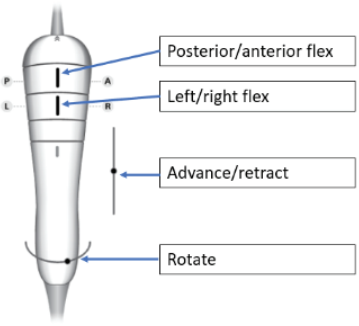
This module simulates ICE devices and their corresponding views, to aid the physician and supporting clinical staff during LAAC pre-procedural planning with familiar views seen during the standard of care. The software will automatically suggest 4 home positions, when the needed structures (Landing zone, SVC, IVC, Fossa and LUPV) are defined in the fluoro workflow. It is possible to adjust the automated home positions and create new ones.

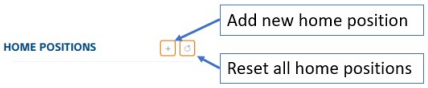
17.1 ICE-SIMULATION



The home positions are listed on the left side and can be selected by clicking on them. Then the probe can be controlled using the virtual probe handle.

A new ICE probe can be laced by clicking the + icon, click in the MPR on the position for the distal tip of the probe, and then click towards the more proximal location.





Reset will restore the home positions; it can also be used when some structures in the Fluoro module are added or changed after the initial home positions are created.

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.

18

THROMBUS WORKFLOW

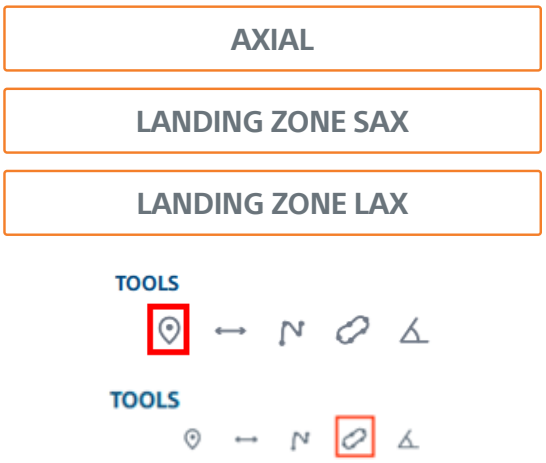
This module facilitates the detection of thrombus in the LAA by allowing visual comparison of a regular contrast-enhanced CT scan with a time-delayed contrast-enhanced CT scan as done in standard radiology practice. TruPlan makes no suggestion, diagnosis, or decision regarding the presence of thrombus,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

18.1 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 closed spline measurement tool to determine the Hounsfield values in specific areas.



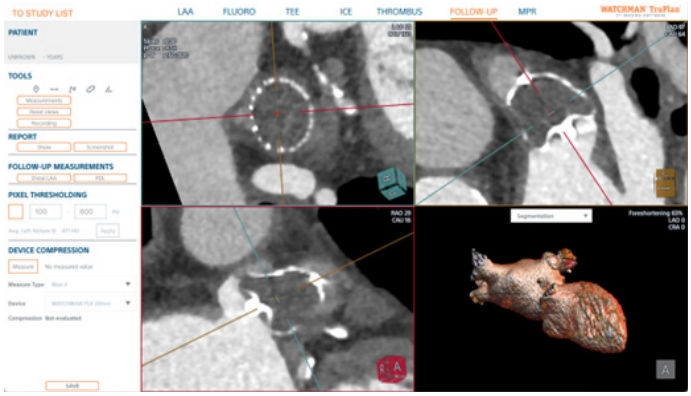
19

FOLLOW-UP MODULE

This module supports post-operative follow-up for the LAAC procedure and provides tools to easily assess for correct position of the LAAC device, and for any peri-device leaks.

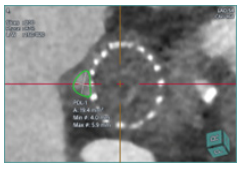
After loading a CT follow-up study from the Study List, select the FOLLOW-UP module.

Manually adjust the MPR views to visualize the LAAC device in a cross-sectional view. In this orientation, various tools in the left panel may be used to assess the device in the image.

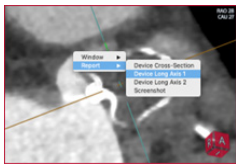


19.1 PERI-DEVICE LEAK (PDL) MEASUREMENT

To measure peri-device leak, select the PDL tool, and click to drop points around any peri-device leak. The first PDL annotation will automatically be added to the report.



To measure peri-device leak, select the PDL tool, and click to drop points around any peri-device leak. The first PDL annotation will automatically be added to the report.

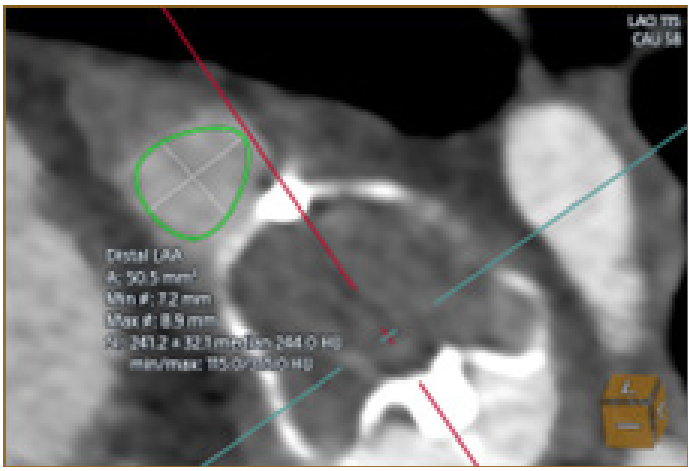


Add images of the long-axis device views to the report using the right-click context menu.

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.

19.2 DISTAL LAA MEASUREMENT

To assess distal LAA patency, select the Distal LAA tool, and place a measurement in one of the long-axis views. For comparison purposes, the average signal intensity of the left atrium is shown in the left panel, and in the report.

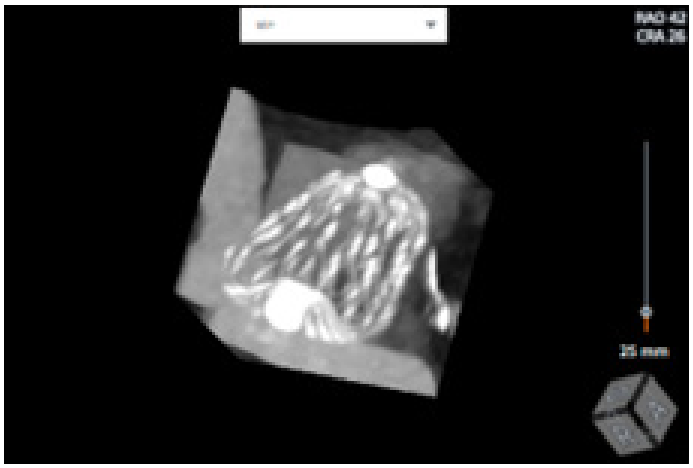


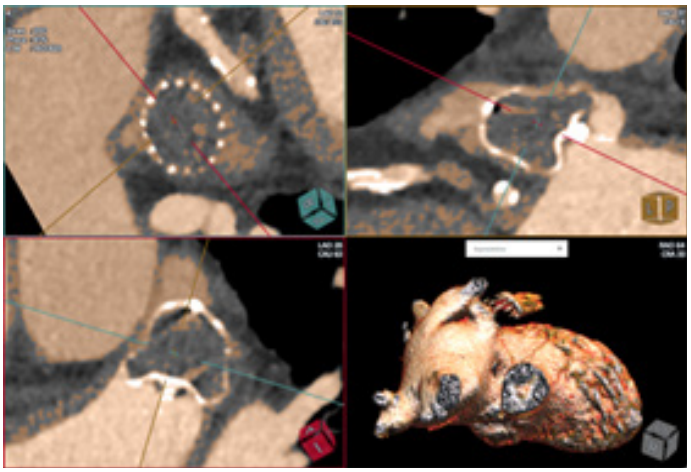
19.3 PIXEL THRESHOLDING TOOL

The Pixel Thresholding tool may aid in visualizing suspected leaks. Set upper and lower thresholds to highlight the desired range of pixels based on Hounsfield Unit values.

19.4 ADJUSTABLE MIP BOX TO VISUALIZE LAAC DEVICE

The MIP feature will render a part of the volume in MIP (Maximum intensity projection). The center of the box is linked to the center of the MPR crosshairs and the size can be adjusted using the slider on the right side of the viewport.



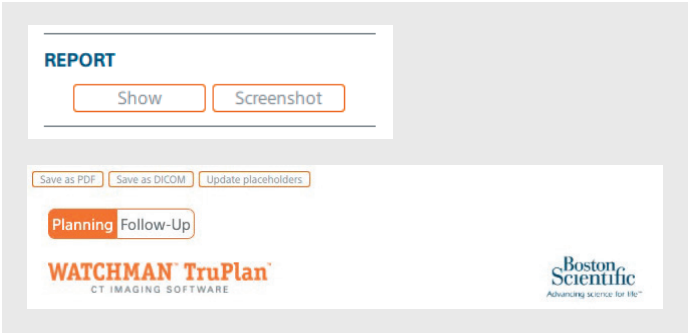


20
MPR MODULE

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.

21
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.



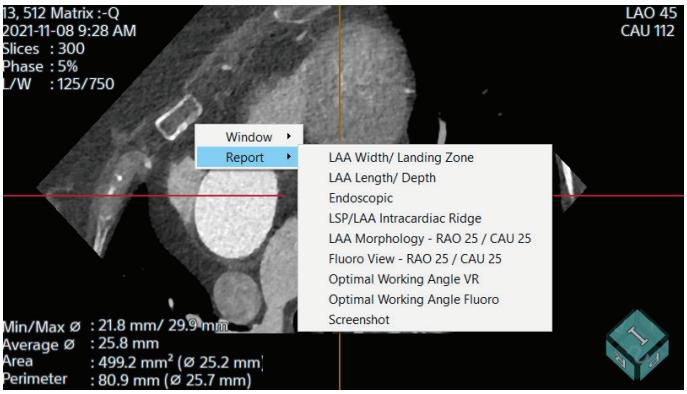
Use the Show button to open the report window.

TruPlan has two types of report: Planning and Follow Up. When report is opened you can select one of them using the template selector at the top of the report.

The default views in the report are filled automatically, use the Update placeholders button to reset the original views.

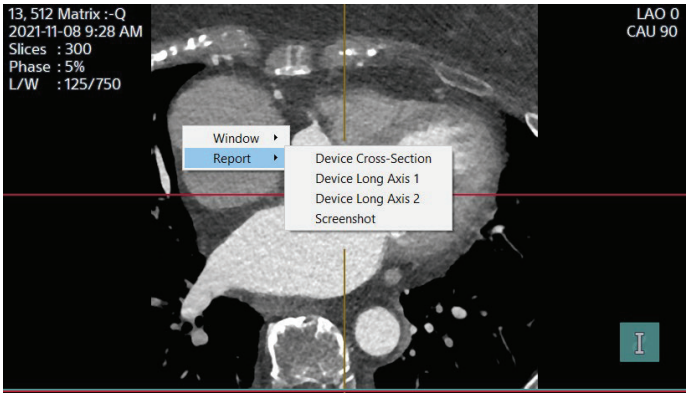
Press the Screenshot button to add a manual screenshot to the report. This button will copy all visible viewports to the report, from there it is possible to remove images that are not needed in the report.

On the LAA report:



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

On the Follow Up report:



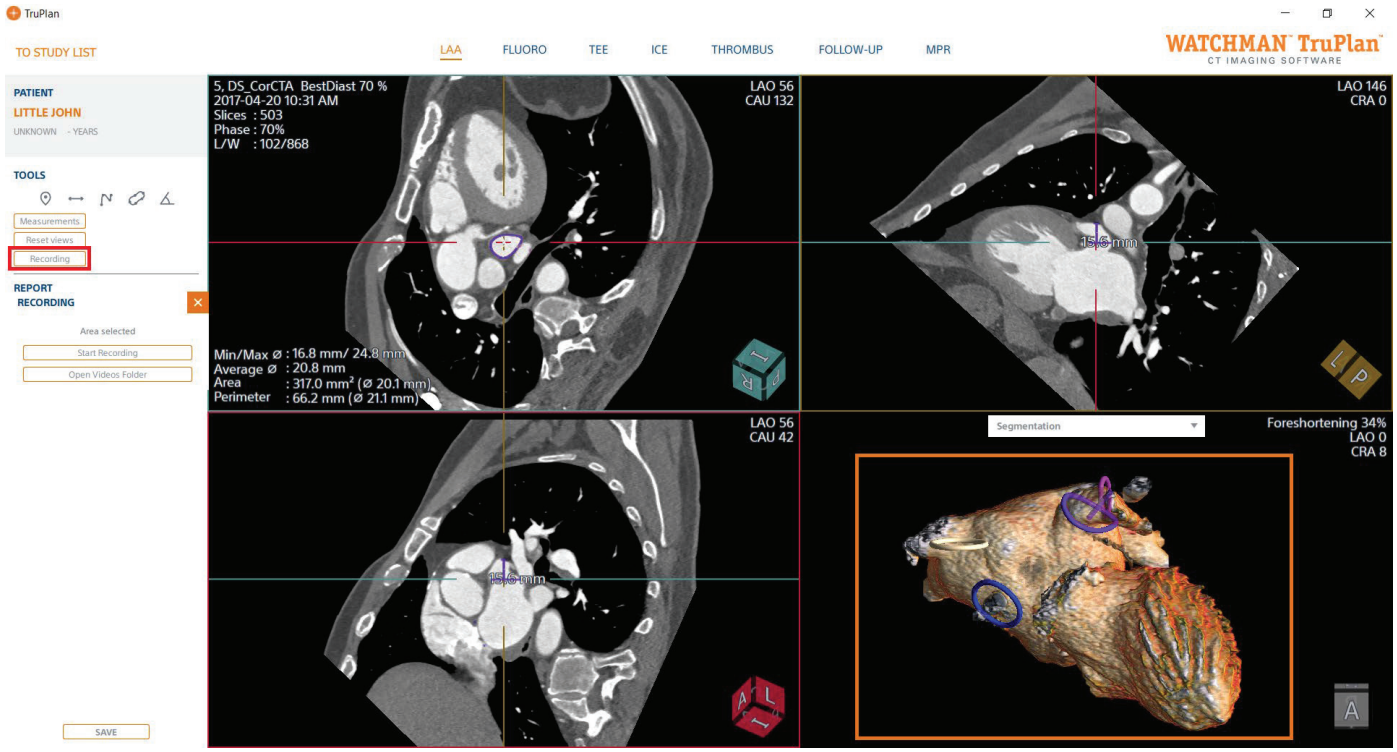
When FOLLOW-UP module is selected, context menu options for report matches the placeholders available in the Follow Up report.

Report can be saved as PDF on the file system for local use, or saved as DICOM to be sent to PACS.

22

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 Videos Folder button to find the saved movie. The file size of the video is determined by the recording time and the size of the recording area.

23

SUPPORT

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

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Report a problem: support@circlecvi.com

Website: www.circlecvi.com