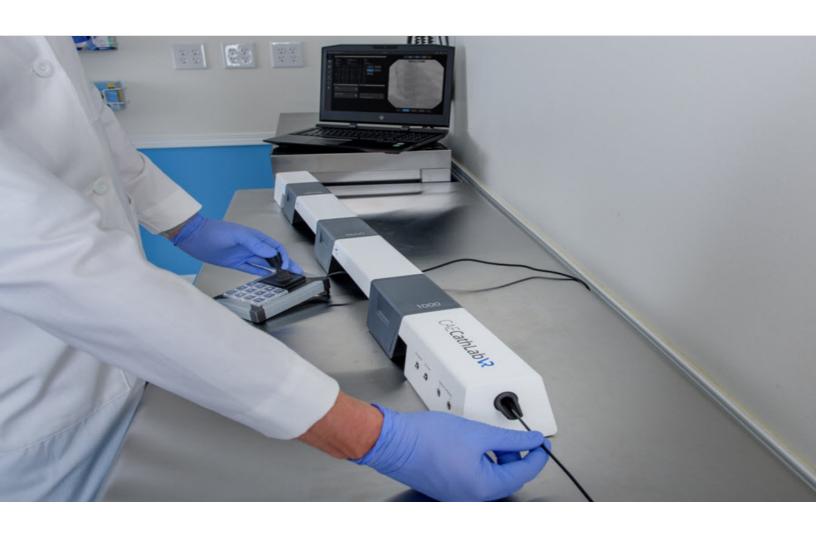
CAECathLabVR

User Guide







CAUTIONS/WARNINGS

Please read and understand these cautions and warnings before you begin using the simulator.

- Keep all electronic equipment free from high humidity or liquids.
- Avoid weighing down the equipment with any tools or accessories not relevant to the immediate exercise.
- Always ensure laptop is plugged into a power source during simulator operation. The battery-powered Laptop is insufficient to run the laptop.
- When installing equipment near an electric socket, ensure cables do not represent a hazard.
- Do not use or connect any USB device or cable to the simulator or laptop other than the USB cable provided.
- Do not operate the equipment with any covers removed.
- Do not use equipment in a manner that is not specified by the manufacturer.
- Improper or prolonged keyboard use may result in injury.
- Viewing a monitor screen for extended period of time may result in eye strain.
- Modified endovascular tools included with the simulator can be very sharp. Pay attention while handling them.
- Refrain from bending, stepping on or kinking the endovascular tools.
- Do not insert an end of an endovascular guidewire in a power outlet
- During tool manipulation the endovascular guidewire extends out of the rear end module, ensure that the area around the rear end module is clear of obstacles or people.
- Ensure you have a table with the minimum recommended width and length to keep the Tracking System and Laptop.
 - ° Basic three-tracker unit: is 130 cm X 50 cm (52 inches x 20 inches).
 - Four-tracker unit is 170 cm X 50 cm (67 inches x 20 inches)
- Do not leave the hardware powered on when the simulator is not being used.



SPECIFICATIONS

All hardware and software needed for the operation of the simulator are supplied. If you want to extend the Instructor tablet to other manikins or computers, contact CAE Healthcare.

CathLabVR Base Unit

The base unit contains an access module, 2 bridges, 3 trackers, and an end module.

Dimensions	46.75" W x 4" D x 3.25" H	
	118.74cm W x 10.16cm D x 8.26cm H	
Weight		
Electrical	12 V DC, 500mA	
Environmental Conditions	Operating temperature: 32° to 131° F (0° to 55° C)	
	Relative Humidity: 95% non - condensing	
Storage Conditions	Non-Operating temperature: -40° to -185° F (-40° to 85° C)	
	Relative Humidity: 95% non - condensing	

Tracker Unit

Dimensions	3.93" W x 4.69" D x 2.76" H	
	9.98cm W x 11.9cm D x 57.7cm H	
Weight		
Electrical	12 V DC, 100mA	
Environmental Conditions	Operating temperature: 32° to 131° F (0° to 55° C)	
	Relative Humidity: 95% non - condensing	
Storage Conditions	Non-Operating temperature: -40° to -185° F (-40° to 85° C)	
	Relative Humidity: 95% non - condensing	

Bridge Unit

Dimensions	14.06" W x 4" D x 3.25" H	
	35.71cm W x 10.16cm D x 8.26cm H	
Weight		

Laptop

Dimensions	16.73" W x 12.88" D x 1.43" H	
	118.74cm W x 10.16cm D x 8.26cm H	
Weight		
Electrical	Please refer to the laptop manufacturer documentation for power specifications.	

Transportation Case

Dimensions	32.58" W x 18.40" D x 10.02" H	
	82.8cm W x 46.7cm D x 28cm H	
Weight	14.06 lbs. (6.4 kg)	
Weight with foam	17.6 lbs. (8 kg)	
Wight with Equipment	50 lbs. (23 kg)	



Cautions/Warnings	iii
Specifications	v
CathLabVR Base Unit	
Tracker Unit	
Bridge Unit	
Laptop	
Transportation Case	
Introduction	
Contained in this Guide	
CathLabVR Simulator Setup	3
Before Beginning Setup	
Equipment	
CathLabVR Setup	
Step 1. Remove the Equipment from the Travel Case	
Step 2. Assemble the Hardware	
Step 3. Connect the Accessories	
Connect the Joystick 9	
Step 4. Connect the Laptop to the Hardware	
Step 5. Connect the Portable Touchscreen Monitor	
Step 6. Power on the Laptop	
Step 7. Power on the CathLabVR Tracking System	
Step 8. Launch the Software	
Tips	
Tool Selection	
Tracking Indication	
Hardware Warnings	
Connecting the Touchscreen Monitor	
Secondary Screen Usage	
Troubleshooting	
Hardware Configuration	
Cardiac Surgery (TAV)	
Simulations	17
Starting a Simulation	
Pages Menu Tool Bar	
Fluoro Page	

$\mathsf{CAE} \textbf{CathLabVR}^{\mathsf{TM}}$

Action Controls	20
Smart Tracker	21
Tools and Actions	21
Dual Monitor Controls	22
Tool Page	22
Selecting a Tool in the Software	23
Smart Tool Tracker	25
Deselecting and Removing a Tool	26
Cine Page	26
Review Controls	27
Display Controls	28
Playback Controls	28
Accessing the Cine Gallery	29
Stills Page	30
Review Controls	31
Display, Browse and QCA Controls	32
QCA Calibrating the Measurement Feature	32
Road Mapping	33
Create a Roadmap 33	
Create DSA 33	
C-Arm and Table Controls Page	35
C-Arm Buttons and Controls	35
Physio Page	37
Case History Page	37
Treatments Page	38
Administer Treatment	38
Using the Analyzer Functionality	39
Analyzer Buttons and Controls	39
The Simulation Screen - Right Monitor	
Monitor Configurations	41
Using the Pedals	42
Using the Accessories	42
Contrast Syringe	42
Inflation Device	43
Preparing the Inflation Device 44	
Using the Inflation Device 44	



Venogram Balloon	
Using the Embolic Protection Devices	45
Calibrating the TAV Delivery System	45
Supported Tool Action	46
Ending a Simulation	
Viewing Results	48
Shutting Down	48
Appendix A: Module Descriptions	49
Cardiac Rhythm Disease Management (CRDM)	50
Cardiac Surgery	50
Percutaneous Coronary Interventions (PCI)	51
Percutaneous Peripheral Interventions (PPI)	
Appendix B: Keyboard Shortcuts	53
Appendix C: Troubleshooting	55
Tracking System	
Dual Monitor Configuration	56
Known Bugs	57



INTRODUCTION

The CAE Healthcare CathLabVR Simulator is one of a series of didactic tools that can be used to improve training for endovascular diagnostic and intervention procedures. Using modified endovascular tools, trainers can navigate through virtual anatomy based on actual patient data. This simulator is not intended to replace any courses or hands-on sessions with live subjects, but should be implemented as part of a blended learning solution.

IMPORTANT: The simulator is not intended to diagnose the condition of a live human being or identify a life-threatening situation.

The Simulator includes:

- CathLabVR hardware interface Device. This device is instrumented to track the manipulation of up to four coaxial endovascular tools and provides computer controlled feedback based on the interaction with simulated patient anatomy
- Laptop computer for running the simulation software with Bluetooth mouse.
- **Modified endovascular tools**, such as catheters, leads, guide wires for performing different simulated endovascular procedures.
- **Accessories** that are shared amongst all of the procedures are foot pedals that plug into the hardware interface, contrast syringe, and a balloon inflation device.

The current version of the software does not provide haptic feedback.



The CathLabVR Simulator

Contained in this Guide

This User Guide has been designed for quick access to information on how to use and maintain the CathLabVR Simulator. Please be sure to read and follow the **Cautions and Warnings** on the pages preceding the **Table of Contents**. This is for the safety of users as well as for the protection of the simulator.

- The Equipment Overview outlines the items that come standard with the purchase of a CathLabVR base unit.
- The **Using the Simulator** section provides instructions on the use of the various tools and hardware features integrated into the simulated experience. This section also includes information on how the simulator and software components work and the functionality that each supports. Various surgical procedures are explained, along with how these procedures isolate critically important learning objectives.
- The Frequently Asked Questions section addresses some of the more common troubleshooting concerns.
- The **Module Descriptions** appendix outlines the specific tools and accessories that should be used in each of the procedures for the CathLabVR.
- The **Keyboard Shortcuts** appendix describes the shortcut keys and their functions for the CathLabVR.

NOTE: As you would with any shipment, check the inventory against the packing invoice to verify that all components have been received.



CATHLABVR SIMULATOR SETUP

Before Beginning Setup

Proper operation of the CathLabVR simulation requires correct configuration. Before setting up the system, keep in mind these basic guidelines:

- Read and understand the Cautions and Warnings in the beginning of this guide.
- Follow and complete the sequence of Setup steps carefully.
- Do not power on any components until instructed in the text.
- Do not install any Windows updates or anti-virus software when connecting to the network.
- When unpacking the simulator for the first time, carefully remove the top components from the Travel Case packaging, and then remove the bottom components.

NOTE: Keep all original shipping materials, including boxes. Warranty and repair items must be returned and shipped in their original packaging.

Equipment

The CathLabVRTM Simulator comes standard with the necessary equipment, tools, and accessories for using the base unit.

NOTE: Always check the inventory against the packing invoice to verify that all components have been received.

Standard Equipment

Travel Case

CathLabVR Tracking system

- 4 Tracking modules
 - ° 1500
 - ° 1000
 - ° 0500
 - ° 001W
- · Access Module
- · Back End Module
- · 2 Bridges
- USB C Cable

Laptop with Power Cable and Bluetooth Mouse

Portable Touchscreen Monitor with connection cable

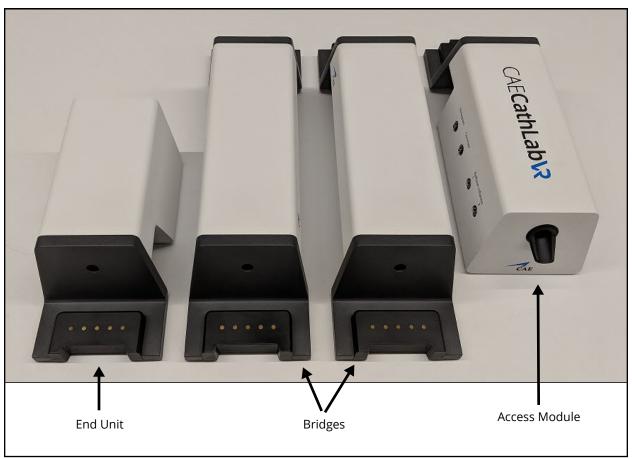
Standard Equipment

Accessories

- 3 Syringes
 - ° Venogram Balloon Inflation Syringe
 - Contrast Syringe
 - ° High-pressure balloon/stent inflation device
- Foot Pedals
- Joystick

Modified endovascular tools

- 15F Catheter for "1500" Tracker
- 10F Catheters for "1000" Tracker
- 5Fr Catheters for "0500" Tracker
- 0.035 and 0.014 wires for "001W" Tracker



CathLabVR Hardware





CathLabVR Trackers

CathLabVR Setup

CathLabVR Setup		
1	Remove the equipment from the travel case	
2	Assemble the hardware	
3	Connect the accessories	
4	Connect the laptop to the hardware	
5	Connect the touchscreen monitor	
6	Power on the laptop	
7	Power on the CathLabVR tracking system	
8	Launch the software	

Step 1. Remove the Equipment from the Travel Case

The travel case has three layers: a top, a bottom, and a flap.



CathLabVR Equipment in Travel Case: Bottom Layer, Top Layer and Flap

Step 2. Assemble the Hardware

- The tracking unit is a modular system that can easily be assembled or disassembled using magnetic connectors.
- The tracking unit assembly will depend on the procedure being performed.
- Configure the Access module, bridges, and End module.
- Once completed add the magnetic tracking units per procedure specifications
- The magnetic tracking units should connect firmly.



To assemble the hardware:

1. Assemble the Access Module, End Module and two Bridges.

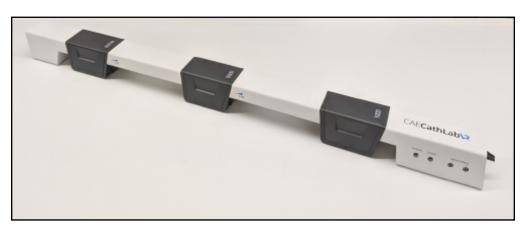
After assembling these pieces, the tracking modules go on top according to the procedure being performed. Below are the Tracking Module configuration for the procedures.



Access Module Connections

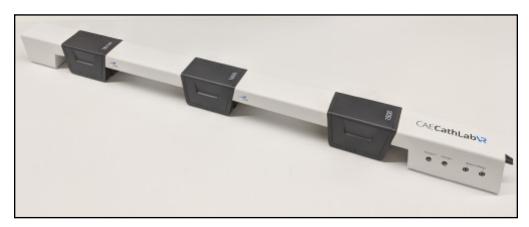
2. Assemble the Tracking Modules according to the simulated procedure.

For CRDM, PCI and PPI procedures, Tracking Modules are assembled according to this image.



Configuration for CRDM, PCI, and PPI

For the TAV procedure, Tracking Modules are assembled according to this image.



Configuration for TAV

Step 3. Connect the Accessories

The following accessories are included:

- Dual foot pedals for fluoroscopy and cine
- Venogram balloon inflation syringe (CRDM)
- Contrast syringe
- · High-pressure balloon/stent inflation device
- Joystick

Warning; Do not connect the balloon syringe to other ports.

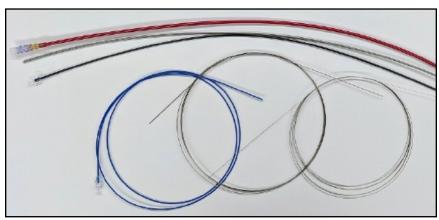


CathLabVR Accessories

Modified Tools include:

- 15F Catheter for "1500" Tracker
- 10F Catheters for "1000" Tracker
- 5Fr Catheters for "0500" Tracker
- 0.035 and 0.014 wires for "001W" Tracker

Note: The colors shown below for different diameter catheters are subject to change.



Catheter Wires



Connect the Joystick

Connect the joystick to the laptop using the USB cable **prior** to running the simulation.



Joystick Connection

Step 4. Connect the Laptop to the Hardware

A single USB C cable is required to connect the laptop to the hardware. This cable can be inserted into a port at the back of the laptop.

- 1. Connect the power supply tip to the laptop.
- 2. Connect the hardware unit to the laptop using the USB C cable. The USB C port is at the back of the laptop.



USB C Connection

USB C Connection on the Access Module

Step 5. Connect the Portable Touchscreen Monitor

Connect the touchscreen to the laptop using the mini HDMI cable and USB C cable. See "Connecting the Touchscreen Monitor" on page 14 for more information.



Second Monitor Connection

Step 6. Power on the Laptop

Turn on the power to the laptop using the Power button on the top left hand. Let the machine boot up fully, until you see the CAEHealthcare screen on your monitor.

Note: When you run a simulation, ensure that the laptop is plugged in to a power source.

Step 7. Power on the CathLabVR Tracking System

- 1. Connect all needed accessories, such as foot pedals and syringes, to the tracking system.
- 2. Press the Power button to turn the hardware unit on. A blue light around the Power button indicates that the power is on.



Step 8. Launch the Software

1. Verify that the CathLabVR hardware is powered on. The CAE Healthcare screen displays.



CAE Home Screen

2. Double-click the **CathLabVR** shortcut icon.



3. Accept the End User License Agreement. The login screen appears.



The CathLabVR Login Screen

- 4. Enter the assigned username and password in the **Username** and **Password** fields.
- To log in as a guest, enter **guest** in the **Username** and **Password** fields.

Note: Any tasks performed while using the guest login will only be recorded in the guest account.

- If you are using the simulator as an administrator to adjust settings or set up curriculum, enter **admin** in both the **Username** and **Password** fields.
- If you have been assigned an administrator username and password, enter those assigned names in the **Username** and **Password** fields.
- 5. Click Login.



Tips

Tool Selection

A tool to be selected will show the associated tracking module.

The selection can be completed by either double-clicking the tool or by using the **Select Tool** button. The Tracking Module that you should be used to track the selected tool is indicated to the right side of the tool.



Tracking Module Associated with Tool

Tracking Indication

When a tracking module detects a tool, the Smart Tool Tracker highlights the associated Tracker in blue.



Smart Tool Tracker

Hardware Warnings

If the hardware is in a non-functional state, a warning button informs you of the issue.

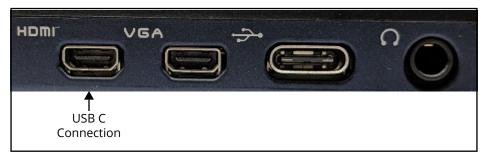


Warning Button

Connecting the Touchscreen Monitor

The simulator comes with a GeChic Portable Touchscreen Monitor.

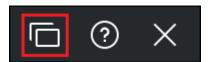
- The touchscreen is powered via cabled USB connection to the laptop: USB C connector on the monitor to 1 (or 2) USB connector(s) on the laptop.
- Under normal use, the monitor can be powered via a single USB connection to the laptop.
- If a second USB connection to the laptop is required, an extension is provided to allow the second USB connection to reach a port on the laptop.



Ports for Touchscreen Setup

Secondary Screen Usage

When a second screen is connected, the highlighted button will be enabled and can be used to expand the window to use both screens.



Use Both Screens Button

When a second screen is being used, the content of the screens can be swapped or the window can return to the single screen configuration.



Swap Screen and Single Screen Buttons

Troubleshooting

- When applicable, connect the joystick to the laptop before starting the simulation.
- Ensure that the hardware is on a flat, level surface.
- Ensure that all cables are properly connected.
- Ensure that the laptop is plugged into a power source. Slow performance may occur if the laptop is using battery power.



Hardware Configuration

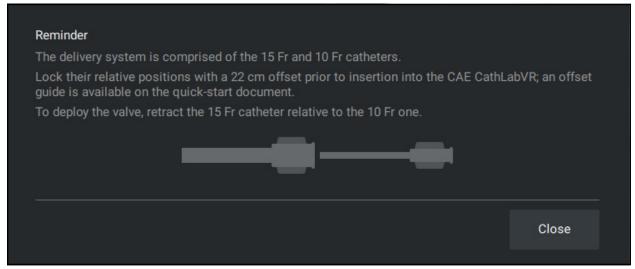
Depending on the procedure different tracking modules are required.

	First	Second	Third
CRDM	1000	0500	001W
PCI	1000	0500	001W
PCI Advanced Cases	1000	0500	001W
PPI	1000	0500	001W
PPI Advanced Cases	1000	0500	001W
Cardiac Surgery (TAV)	1500	1000	001W

Cardiac Surgery (TAV)

When using the Delivery System, this module requires that two tools are tracked simultaneously. To support this, the 10Fr catheter must be inserted 22 cm into the 15fr catheter and locked in before inserting into the hardware.

NOTE: Please use the 10F white catheter with 15F black catheter for the delivery system.



Delivery System Configuration



SIMULATIONS

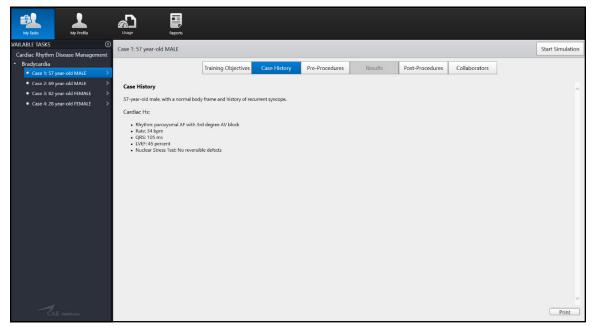
Prior to running a simulation, prepare for the simulation by completing the following steps. See the Admin Guide for more information.

- Select the desired task
- · Review the Case History
- Review the Pre-Procedure steps

After the preparation steps are completed, start the simulation.

Starting a Simulation

To start a simulation, click the Start Simulation button from any screen within the selected task.



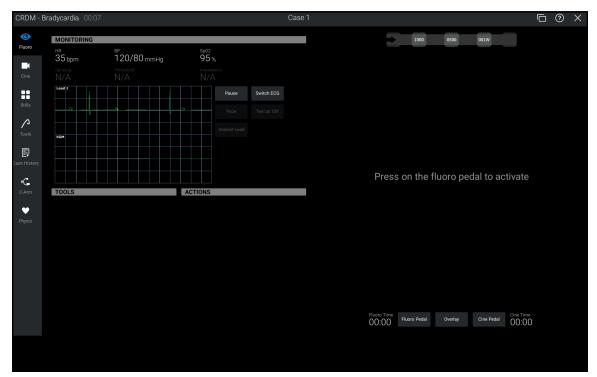
The Case History Screen

The simulation launches and the initialization screen appears.



The Initialization Screen

Once the initialization is complete, the simulation start screen appears.

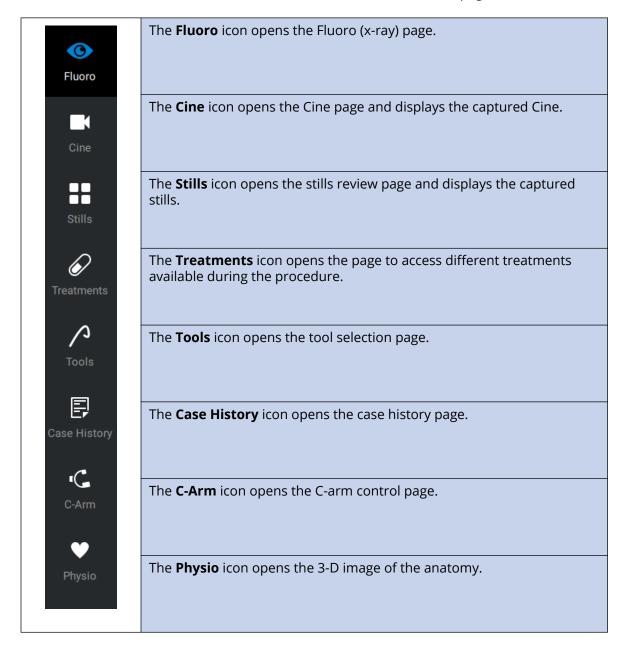


The Simulation Start Screen -Single Monitor



Pages Menu Tool Bar

The left-side tool bar can be used to access various simulation content pages.



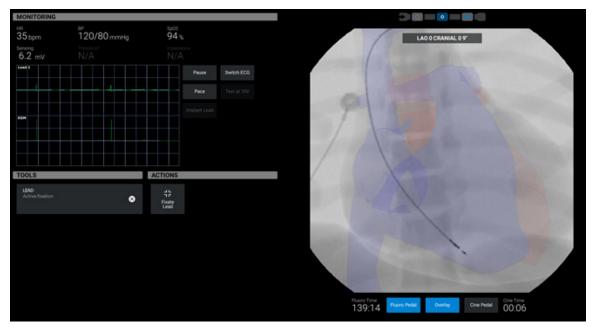
Fluoro Page

To activate the Fluoro (x-ray) feature, press the Fluoro pedal or click the Fluoro Pedal button.



Activate Fluoro Feature

NOTE: In all procedures, press down the LEFT pedal (labeled FLUORO) activate fluoro imaging.



Fluoro Page with Overlay

Action Controls

These controls appear below the image on the Fluoro page.

Fluoro Pedal	The Fluoro Pedal button starts and stops fluoroscopic imaging. Click once to start, and then click again to end.
Cine Pedal	The Cine Pedal button starts and stops Cine capture. Click once to start a capture, and then click again to end the capture. When a cine capture has ended, the simulator automatically open the cine review page.





The **Overlay** button displays the physio view over the real-time fluoroscopic image.

To activate overlay mode, activate fluoro imaging, and then click the Overlay Button.

Note: If the C-arm angles are changed, the overlay of the Physio view also change.

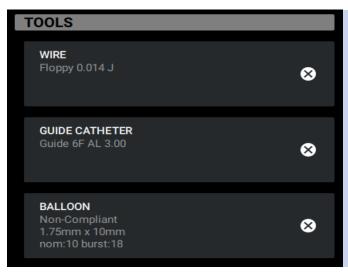
Smart Tracker

Smart Tracker (above the image) indicates when a tracking element is actively tacking a tool (indicated by color change of the tracking element).



Smart Tracker

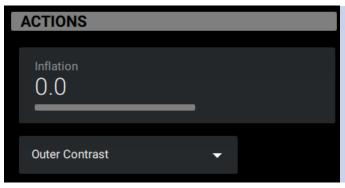
Tools and Actions



When a tool is selected, TOOLS list on the fluoro page populated. The list is on the left side of the page under Monitoring section.

Deselect a tool by clicking the x on the tool name display box.

See the Tool Page section for more details.

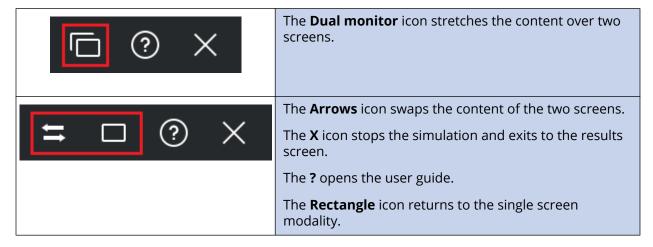


When a tool is selected, the ACTIONS list is populated with the Actions associated with the tool.

See the Tool Actions section for more details.

Dual Monitor Controls

When an additional screen is connected, the Dual monitor icon is enabled in the monitor controls in the top-right corner of the page.



Tool Page

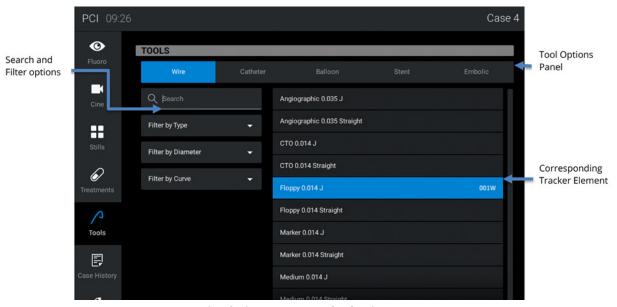
Access the Tool Page by selecting the Tools icon from the Pages tool bar.

The CathLabVR offers a selection of multiple virtual tools for successfully completing a procedure. Each virtual tool has a corresponding physical tool that is indicated by the tracking element displayed

Tracking Unit Indicator on Virtual Tool Menu	Associated Physical Tool
001W	0.014" or 0.035" guidewire
0500	5 Fr catheter
1000	10 Fr catheter
1500	15 Fr catheter



Learners select the virtual endovascular tools that they deem appropriate for the task and then insert their corresponding physical tool into the CathLabVR in order to manipulate it.



Simulation Screen -Tool selection menu

Selecting a Tool in the Software

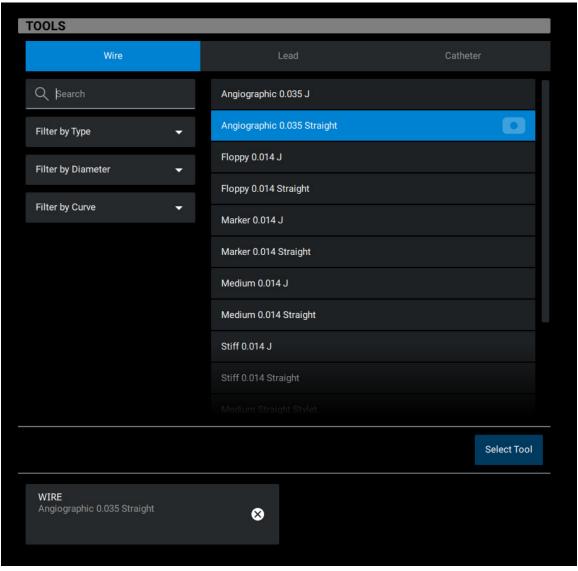
On the Tools page:

- Different tool types can be visualized using the tool option panel.
- Filters and a search functionality are available to facilitate finding the desired tool.
- Learners can also select a tool directly from the filter results panel without selecting different options.
- The tracking element associated with the new tool is shown when the tool name is selected.

To select a tool:

- 1. Click enabled Select Tool button.
- 2. After a tool is selected, it appears in a separate Tool Display Box in the Tool page as well as the Fluoro page.

NOTE: Pay attention to any Tool Warning Messages. Clear the message by following the directions, and then Select Tool Button will be enabled to select the tool.



Tool insertion and tracking

3. Select the tool from the menu and pick the correct modified tool associated with the tracking module



4. Insert into the Access Module by gently feeding the tool into the hole.



The Tool Insertion

- 5. Press the Fluoro foot pedal to activate the x-ray feature
- 6. Continue to slowly insert the tool until the relevant light on the Smart Tool Tracker turns on.

 This indicates that the simulator has engaged the tool properly.

Smart Tool Tracker

A tracking element status widget on the top of the Fluoro Page monitors the status of the tracking modules

• Blue represents that the tool is engaged properly and is being tracked correctly.



Smart Tracker Engaged with a Tool

• White represents that the tool is not engaged properly, so it will not be tracked correctly.



Smart Tracker Not Engaged with any Tool

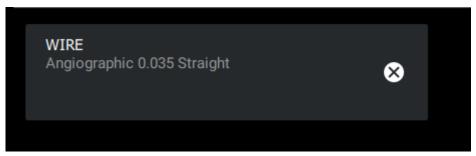
- To view the path of the tool, activate x-ray intermittently and navigate appropriately.
- To manipulate the tool, insert the end of the tool slowly to ensure no damage or perforation occurs.

NOTE: If the new tool the learner wants to select conflicts with any of the previous selected tools, the Tool Warning Message appears. Pay attention to the Tool Warning Message. Select a new appropriate tool, or deselect the conflicting tool and proceed to select a new tool.

The tool tracking starts as the tool passes through the associated tracking element. Insertion until the tool reaches the tracking element is not tracked.

Deselecting and Removing a Tool

To remove a tool from the simulator, click the X icon on the selected tool display box either on the Tool Page or Fluoro Page.



Tool Display Box

The physical tool can now be removed from the simulator. The Smart Tracker is updated accordingly to show the status.

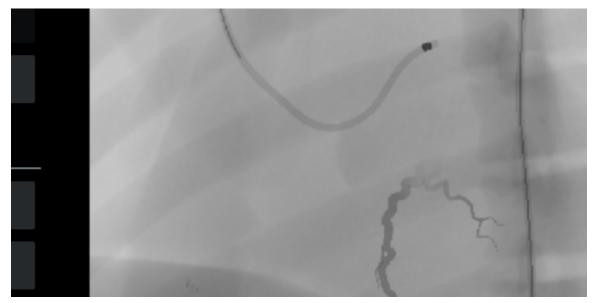
Cine Page

To capture a video of the procedure, press the Cine Pedal and hold for the desired length of the recording. When the pedal is release, the Cine page appears.

NOTE: You can also click the Cine Pedal button to start recording, and then click it again to stop recording.



On the Cine page, the selected recording displays in a loop on the left monitor until another page from the Pages tool bar is selected.



The Simulation Screen - Cine Feature

NOTE: In all procedures press the RIGHT pedal (labeled CINE) to use the Cine feature.

On the Cine page screen, cines can be:

- Run
- Saved
- Erased
- Browsed

Also, frames can be extracted as stills.

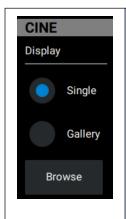
TIP: Remember to click on a cine to highlight it before review.

Review Controls



- **Export Cine** button saves the cine to a folder.
- Capture Still button captures a still during a cine playback.
- Erase Cine button erases the selected cine.
- **Erase All** erases all the cine in the gallery.

Display Controls



Display:

- Single display one selected Cine
- Gallery display all captured Cine

The **Browse** button opens the files folder where the cines are saved.

Playback Controls



Playback Controls



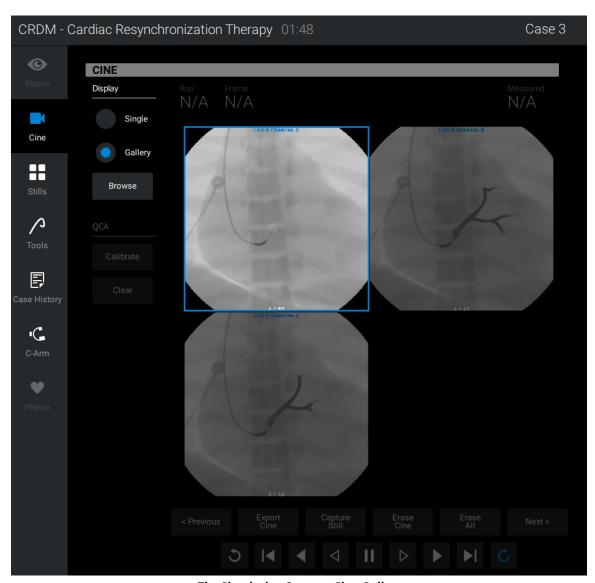


Accessing the Cine Gallery

Video captures are stored in the Cine gallery.

To access the Cine Gallery:

- 1. From the Pages tool bar, select **Cine** Icon.
- 2. From the Cine menu, select **Gallery**.
- 3. Double-click the desired Cine image in the gallery to access a single Cine recording.



The Simulation Screen - Cine Gallery

NOTE: In all procedures, press the RIGHT pedal to use the Cine feature.

Stills Page

To access the Stills Page:

1. From the Pages tool bar, select **Stills** icon.

NOTE: The still frame is the last image frame captured by pausing a Cine recording. The stills feature also captures the frame displaying the most contrast injection from the most recent Cine video or the selected Cine video.

- 2. From the Stills menu, select **Gallery**.
- 3. Double-click a Stills image in the gallery to access a single Stills frame.



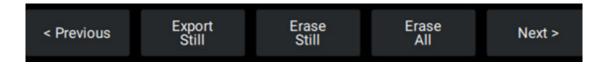
Stills Gallery



On the Stills review page, stills can be:

- Viewed
- Saved
- Erased
- Browsed

Review Controls



- **Export Still** button saves the still to a folder.
- **Erase Still** button erases the current still.
- Erase All button erases all stills for the current cine.

The Browse button opens the files folder where the stills are saved.

Display, Browse and QCA Controls



Display:

- Single displays one selected still
- Gallery displays all captured stills

The **Browse** button opens the files folder where the stills are saved.



QCA calibration:

- Calibrate button allows calibration of the system before measuring size of vessel
- Clear button clears the measurement



Roadmap functionality:

- Create button superimpose single cine frame over the real-time fluoro image
- Stack button superimposes multiple cine frames over the realtime fluoro image
- DSA button starts or stops Digital Subtraction Angiography enhancements
- **Disable** button remove superimpose mask from fluoro image

QCA Calibrating the Measurement Feature

QCA (Quantitative Cine Angiometrics) should be performed prior to obtaining any measurement from a Still image.

The learner should calibrate so that measurements are accurate in the chosen angle and zoom magnification. Use a catheter or tool with a known dimension, such as the diameter of the guide catheter, and use this tool to calibrate the QCA measurement.



To calibrate a measurement:

- 1. Record a cine image.
- 2. Pause the cine loop to obtain a "still" image.
- 3. Right-click on one side of the catheter and right-click again on the opposite side of the catheter. A blue line appears, representing the diameter of the catheter.
- 4. From the QCA Calibration menu on Cine/Still Pages, select **Calibrate**.
- 5. The QCA dialog box prompts the Learner to input the desired measurement: the known diameter of the catheter, in millimeters.

Once this valued is entered, any new measurements are corrected in the current view and magnification.

NOTE: If the anatomy is viewed in a new Fluoro angle, or a different Zoom magnification, the QCA measurements should be re-calibrated in the new view prior to any new measurements.

Road Mapping

Additional imaging capabilities such as Road Mapping and creating a (DSA) Digital Subtraction Angiography are available from the Cine and Stills pages.

Create a Roadmap

- 1. Inject contrast while recording the cine, then select a cine frame with maximal contrast.
- 2. Click **Create** button to capture a single Roadmap image. This image is superimposed over real-time, simulated fluoroscopic image.
- 3. To add additional cine frames, pause the cine on the desired frame, and click **Stack** to add extra cine frames to the Roadmap.
- 4. Click **Disable** to remove the superimposed mask from fluoroscopic image.

Create DSA

The DSA button provides the ability to add Digital Subtraction Angiography enhancement to the simulated angiographic images. Enabling this feature isolates the vessel of interest (vessel containing contrast) while removing other structures in the periphery.

- 1. Create a single roadmap.
- 2. Click **DSA** to display the subtracted image over the real-time fluoro image.

3. Click **DSA** again to return the original Roadmap image over the real-time fluoro image.

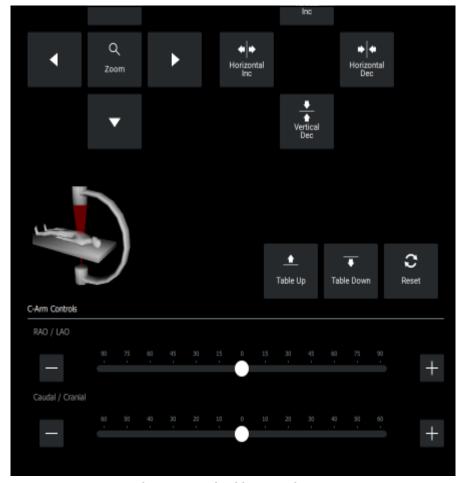


PPI Page



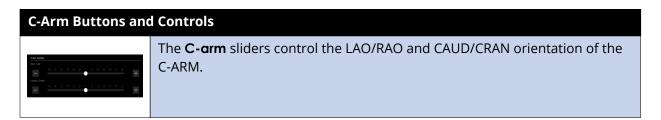
C-Arm and Table Controls Page

To access the C-Arm and Table controls page, select the **C-Arm** icon from the Pages tool bar. The control box allows learners to adjust different C-Arm and Table settings.



The C-Arm and Table Controls Page

C-Arm Buttons and Controls



C-Arm Buttons and Controls

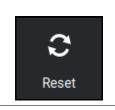


The **Pan** arrows control the position of the table (up, down, left, right).

The **Zoom** control adjusts the field-of-view of the fluoro image.



The **Shutter** arrows crop the field-of-view of the fluoro image.



The **Reset** button resets the fluoro image to default view.



Physio Page

- Access the Physio page by selecting the Physio Icon from the Pages tool bar.
- The Physio page displays a 3-D image of the anatomy for the module.
- The anatomy beats in rhythm with the virtual patient's pulse, and rises and falls according to the patient's breathing.

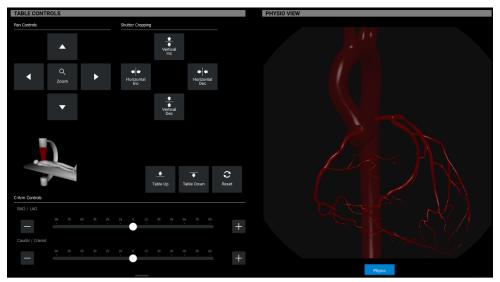


Table Controls

Case History Page

- Access the page by selecting the **Case History** icon from the Pages tool bar.
- The Case History page displays the same case history information available in the Content Menu.

Treatments Page

- Access the page by selecting the **Treatments** icon from the Pages tool bar.
- The Treatments page allows learners to select various pharmacologic and non-pharmacologic therapies.
- These treatments may be given to prevent or treat complications occurring within the simulation.
- Not available for all procedures.



The Treatments Page

Administer Treatment

- · Select treatment from option panel
- Click the **Administer** button to administer treatment
- Click **Discontinue** button to discontinue the treatment

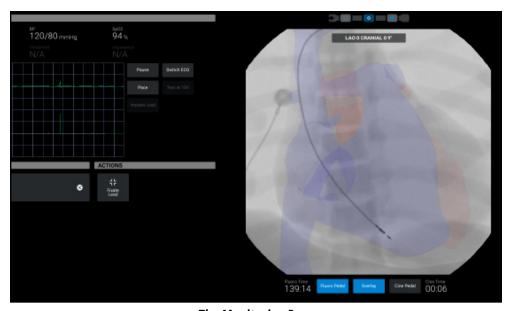
Note: The treatment selection may not change the vital signs of the patient during times of non-complications; however, selections of all therapies are tracked by the software and will appear in the Results screen.



Using the Analyzer Functionality

For procedures that require lead placement, the analyzer function tests the pacing and sensing thresholds to determine if the location is acceptable.

For CRDM procedures the Analyzer page is included in the fluoro page.



The Monitoring Page

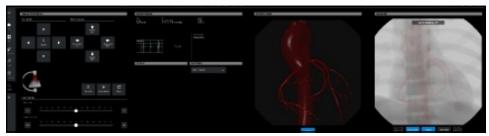
Analyzer Buttons and Controls

Pace Click the Pace button to begin pacing. Monitoring will include the following electrical values depending on the lead tip location. Impedance Threshold Sensing Once acceptable electricals are achieved and no extra-cardiac stimulation is present, click Pace to stop pacing. Electrical values, pace ECG tracing and Fluoro image are saved in the final Results. Click the Test at 10V button to evaluate for extra-cardiac stimulation

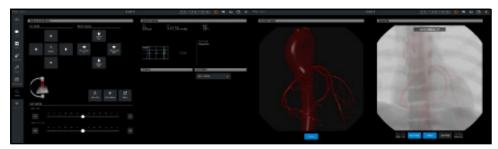
Analyzer Buttons and Controls			
Pause	Click Pause ECG to freeze the current ECG and ECG tracing. Note : Selecting Pause Display again will resume real-time ECG.		
Switch ECG	Click the Switch ECG Leads button to view different surface ECGs. Lead 1 and AVF are available.		
Implant Lead	Click the Implant Lead button to implant and additional lead.		
Distral Electrode Distral Electrode Proximal Electrode	Dual electrode leads enable the Electrode selection menu. Distal Electrode is selected by default.		



The Simulation Screen - Right Monitor Monitor Configurations



Single Monitor



Dual Monitor

Note: With dual monitor configuration, be sure to observe the content on both monitors.

When learners choose a feature from the pages menu, the content populates the left monitor.

The content in the dual monitors should not be identical.

Note: For dual monitor configuration, refer to the Troubleshooting section.

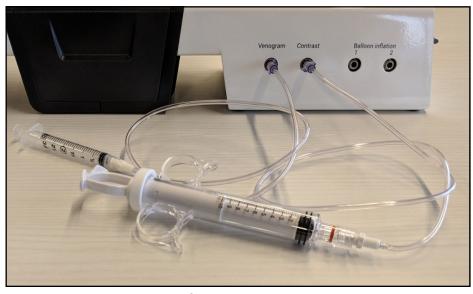
Using the Pedals

- The dual foot pedals are used to control the x-ray and video capture tools.
- Connect the foot pedal to the Access Module of the CathLabVR Tracking unit.



The Foot Pedals

Using the Accessories



The Accessory Ports

Contrast Syringe

- Allows learners to see a vascular structure more clearly on the x- ray by injecting contrast dye into the vessels.
- The contrast syringe assembly comprises a 10 cc syringe attached the CathLabVR Access Module.



To use the contrast syringe:

- 4. Pull back on the syringe.
- 5. Ensure that the contrast syringe is connected to Contrast port in the Access module.
- 6. Depress the Fluoro pedal to activate the x-ray feature and show a live x-ray of the anatomy.
- 7. Push the contrast syringe to "inject" the contrast dye. The contrast dye pulses through the vessels on the x-ray.

Note: The Cine feature can be activated in place of the Fluoro feature to use the x-ray during a contrast dye injection. Using the Cine feature allows the learner to record the injection and view it in a loop on the left monitor.

Inflation Device



The Inflation Device

- The inflation device assembly comprises a 20 cc syringe, trigger, pressure gauge, and piston knob.
- Attaches to the CathLabVR Access Module.
- Connect the inflation device ONLY to the port labeled Balloon Inflation #1
- Prior to using/connecting the inflation device, the device should be prepared by drawing water into the syringe and tube leading to it.

Preparing the Inflation Device

Water is drawn into the syringe and tube leading from it; this provides realistic pressure forces through the inflation syringe.

To fill the inflation tool:

- 1. Disconnect the tubing from the CathLabVR device.
- 2. Submerge the end of the tubing in a cup of clean water.
- 3. Depress the release "trigger" and pull back on the piston knob. Water will be drawn in to the syringe.

Note: Connecting the inflation device to the venogram or contrast syringe results in sending water inside the access module. If this happens accidentally, Contact CAE Healthcare Tech Support for instructions.

Using the Inflation Device

- Once a virtual balloon is in place at the desired anatomical location, it is deployed by rotating the piston knob clockwise until the desired pressure is achieved.
- The expansion of the balloon/stent can be viewed on-screen.
- To reduce the balloon pressure quickly, slide the trigger and draw back fully on the piston knob.

Note: Inflation of the balloon to pressures greater than the indicated "burst pressure" results in rupture of the balloon within the virtual coronary anatomy.

Venogram Balloon

- This feature is only used during the CRDM module.
- The venogram balloon is inflated by a syringe during a venogram procedure to identify the anatomy of the veins and properly place a lead.

To use the venogram syringe:

- 1. Connect the venogram balloon syringe tubing to the Venogram port on the access module.
- 2. Pull back on the syringe.
- 3. On the contrast syringe, push the contrast syringe to "inject" the contrast dye. The contrast dye pulses through the vessels on the x-ray.
- 4. Depress the venogram syringe to inflate the balloon.



Using the Embolic Protection Devices

The embolic protection devices are used during coronary and carotid intervention procedures. The specific tools include:

- Embolic Protection Filter
- · Embolic Occlusion Balloon
- · Embolectomy Catheter

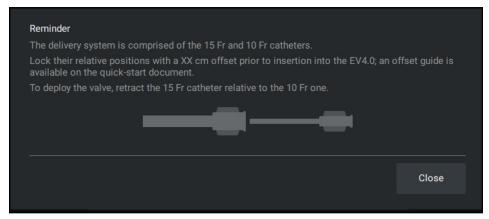
To use an embolic protection tool:

- 1. Click the Embolic link inside the Tools selection panel.
- 2. Select the desired embolic protection tool from the Tools page.
- 3. Use the action associated with the tool to inflate/deploy tool or to aspirate.

Calibrating the TAV Delivery System

The delivery system is used during Transcatheter Aortic Valve procedure under Cardiac Surgery.

- 1. Select a delivery system from the Tools page.
- 2. Calibrate the physical tools according to the diagram.
- 3. Insert both tools together to manipulate the delivery system.
- 4. Withdraw the 15 Fr outer catheter to deploy the stent.



Action Buttons and Controls

5. Use (+) and (-) in Embolic Inflation under Actions to deploy and undeploy the Embolic protection devices.

Note: If the Embolectomy Catheter is selected, the **Aspirate** button will be enabled. You can click the Aspirate link to aspirate the patient during the simulation. To cease aspiration, click the Aspirate link again.

Supported Tool Action

Supported Tool Ac	tion
Guide Deflection — +	Deflectable Guide Catheter Control to manipulate catheter tip deflection. (CRMD procedure)
ngnostic Deflection — +	Deflectable Diagnostic Catheter Control to manipulate catheter tip deflection. (CRMD procedure)
⊒ ∟ ¬ ⊏ Fixate Lead	 Place the active-fixation lead tip in the desired anatomical location. Click Fixate Lead. When you click the Fixate Lead button, rotation of the stylet does not cause the lead body to rotate, but instead enables the lead's fixation mechanism. As the stylet is rotated, the radio opaque markers on the distal portion of the lead move to indicate that the fixation mechanism has been deployed. (CRDM Procedure)
Outer Contrast Outer Contrast Inner Contrast	Select contrast injectable tool. The default selection is the Outer Tool contrast injection. (PCI and PPI Procedures)
Embolic Inflation — +	Embolic Inflation control for Embolic Protection Filter and Embolic Occlusion Balloon deployment. (PCI and PPI Procedures)
Aspirate	Aspirate control to engage Aspiration with Embolic Catheter. (PCI and PPI Procedures)
Duck Squeeze	Perform a Duck Squeeze for a neuro status check after deploying a tool. (PPI Procedure)
stlation Deploy	Control to deploy self-expanding stents. (PPI Procedures)



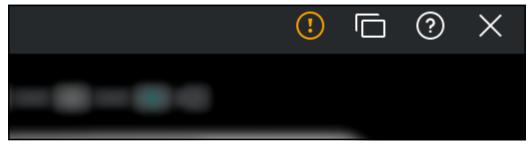
Supported Tool Action			
C Toggle Pigtail	Control to insert and withdraw Pigtail catheter. (TAV Procedure)		
0.0	 Display inflation range for venogram balloon inflation. (CRDM Procedure) Display inflation range for high pressure balloon inflation. (PCI, PPI, and TAV Procedures) 		

Ending a Simulation

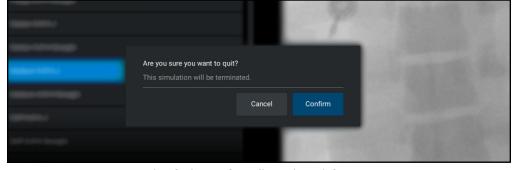
The CathLabVR simulator has two ways in which a simulation can end. In some cases, the learner makes a procedural error and is unable to correct the error within the allotted time for the simulation. If a learner performs a fatal error, the simulation ends before the time expires. Learners also have the option to stop a simulation at any time during the procedure.

To end a simulation manually, from the simulation screen, click the **X** button on the top right hand corner of the Fluoro page.

A simulation end confirmation box appears. Click **Confirm** to end the simulation and exit to the results page.



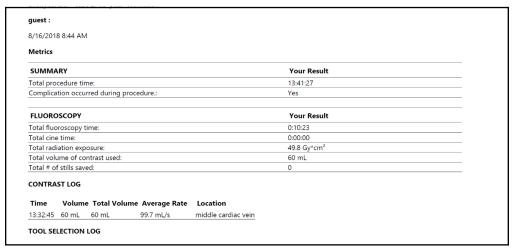
The Simulation Screen



Simulation End Confirmation Dialog Box

Viewing Results

When the simulation is complete, the Results screen appears.



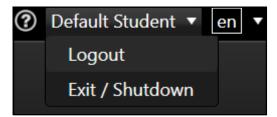
The Results Screen

Learners can review the different metrics recorded from the procedure, including but not limited to, total fluoroscopy time, times and amounts of contrast dye injections, and other procedure-specific information.

Shutting Down

Before you shut down the software, ensure that all simulations have been stopped. To shut down the software:

- 1. From the home screen, click the **Username** drop-down in the upper-right corner of the screen.
- 2. Click **Logout** to log out and return to a new login window.
- 3. Log in to the admin account.
- 4. Select Exit / Shutdown to exit the software and return to the computer desktop, shut down the computer, or restart the computer.



The Username Drop-down list



APPENDIX A: MODULE DESCRIPTIONS

The CathLabVR simulator contains several modules for learners to practice performing endovascular procedures using different techniques and tools. Modules are bundled in four separate categories: Cardiac Rhythm Disease Management, Cardiac Surgery, Percutaneous Coronary Intervention, and Percutaneous Peripheral Interventions.

The following table outlines the categories and modules offered for the CathLabVR simulator.

Category	Module	Description
Cardiac Rhythm Disease	Bradycardia	Complete common tasks involved in resolving bradycardia in a patient.
Management	Cardiac Resynchronization Therapy	Complete common tasks involved in cardiac resynchronization therapy.
Cardiac Surgery	Transcatheter Aortic Valve	Complete common tasks associated with a transcatheter aortic valve intervention (TAVI).
Percutaneous Coronary	Coronary Interventions (Basic)	Complete common tasks associated with a basic coronary intervention.
Intervention	Coronary Interventions (Advanced)	Complete common tasks associated with an advanced coronary intervention.
Percutaneous Peripheral	Carotid Interventions	Complete common tasks associated with a basic carotid intervention.
Interventions	Carotid Interventions (Advanced)	Complete common tasks associated with an advanced carotid intervention.

Cardiac Rhythm Disease Management (CRDM)

The Cardiac Rhythm Disease Management (CRDM) modules give learners an opportunity to practice and master techniques required to perform a CRDM corrective procedure.

Module	Available Instruments	Available Features	
Bradycardia	• Catheters	• Fluoro	
	• Lead	• Analyzer	
	• Wire	• Fixate Lead	
		Deflect Catheters	
Cardiac Resynchronization Therapy	• Catheters	• Fluoro	
	• Lead	• Analyzer	
	• Wire	• Fixate Lead	
		Deflect Catheters	

Cardiac Surgery

The Cardiac Surgery modules give learners an opportunity to practice and master techniques required to perform a transcatheter aortic valve corrective procedure.

Module	Available Instruments	Available Features
Transcatheter Aortic Valve	• Catheters	• Fluoro
	• Wire	
	Delivery System	
	Valvuloplasty Balloon	



Percutaneous Coronary Interventions (PCI)

The Percutaneous Coronary Interventions (PCI) modules give learners an opportunity to practice and master techniques required to perform basic and advanced PCI procedure.

Module	Available Instruments	Available Features
PCI: Coronary Interventions	Guidewire	• Fluoro
(Basic)	• Catheters	• Cine
	• Balloon	• Stills
	• Stent	
PCI: Advanced Coronary	Guidewire	• Fluoro
Interventions	• Catheters	• Cine
	• Balloon	• Stills
	• Stent	• Physio
	Embolic Protection	
	• Aspirate	
	• Treatments	

Note: In recent CathLabVR software versions, the "Coronary Interventions" module (under the "Percutaneous Coronary Intervention" task) has been replaced by the "Basic PCI" module. All data related to the legacy "Coronary Interventions" module will not be available when updating to the new CathLabVR software even if the previous database is backed up and restored in the new software.

Percutaneous Peripheral Interventions (PPI)

The Percutaneous Peripheral Interventions (PPI) modules give learners an opportunity to practice and master techniques required to perform a basic and advanced PPI procedure.

Module	Available Instruments	Available Features
PPI: Percutaneous Peripheral	Guidewire	• Fluoro
Interventions	• Catheters	• Cine
	• Balloon	• Stills
	• Stent	• Physio
	Embolic Protection	
	• Aspirate	
	• Treatments	
PPI: Advanced Percutaneous	Guidewire	• Fluoro
Peripheral Interventions	• Catheters	• Cine
	• Balloon	• Stills
	• Stent	• Physio
	Embolic Protection	
	• Aspirate	
	• Treatments	



APPENDIX B: KEYBOARD SHORTCUTS

General Hot Keys	Action
0	Enable/Disable Overlay
Z	Fixation Debug
F1	Help
Т	Case History
Р	Physio Content
S	Stills Content
1	Horizontal Crop Increase
*	Horizontal Crop Decrease
-	Vertical Crop Decrease
+	Vertical Crop Increase
0	Reset
5	Zoom
Arrows	Manipulate Table Pan
Num. Pad Arrows	Manipulate C-Arm Angle

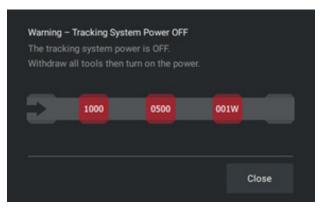


APPENDIX C: TROUBLESHOOTING

Tracking System

CathLabVR Tracking system powered off

If the Tracking system is not turned off, the following message appears.



Tracking System Power Off

Press the power button on the Access module to turn the power on to the system.

Incorrect Tracking Modules Used

If the tracking modules are placed in the incorrect order, the following message appears.



Tracking System Disconnected

After correctly replacing the modules, pressing refresh allows the hardware to be reconfigured. The window will close after 20 seconds.

Correctly Placed Tracking Module

The following message appears when the modules are correctly placed and the system is powered.



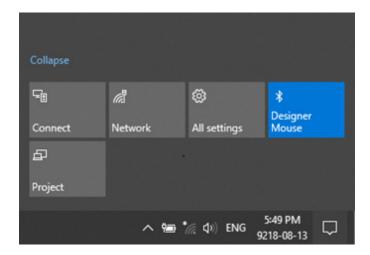
Correctly Place Tracking Module

Dual Monitor Configuration

When a secondary monitor is connected to the Laptop, the software default to dual monitor configuration. If the dual monitor software is not set up, both monitors have the same image.

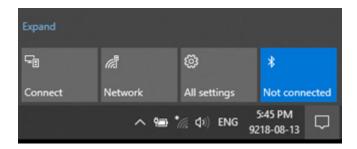
To configure the monitors.

- 1. Click the Windows Notification button on the bottom right hand corner of the monitor.
- 2. Select Project Option.
- 3. If you do not see the Project Option, click **Expand** to view more options.





4. Select Extend Option.



Known Bugs

- Contrast will flow to an artery when the tip of the catheter is not actually close enough
- Contrast can be injected with a wire
- Catheter can be withdrawn bent when there is no 35" wire support
- Wires can still be physically inserted although they are at the end of a vein virtually

