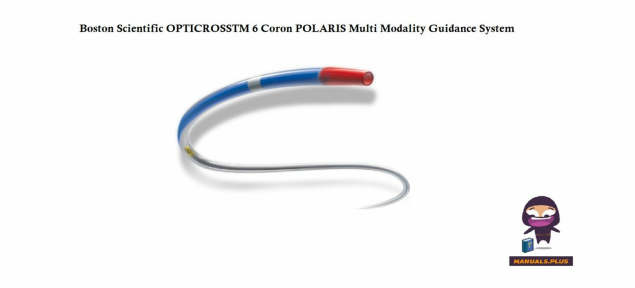
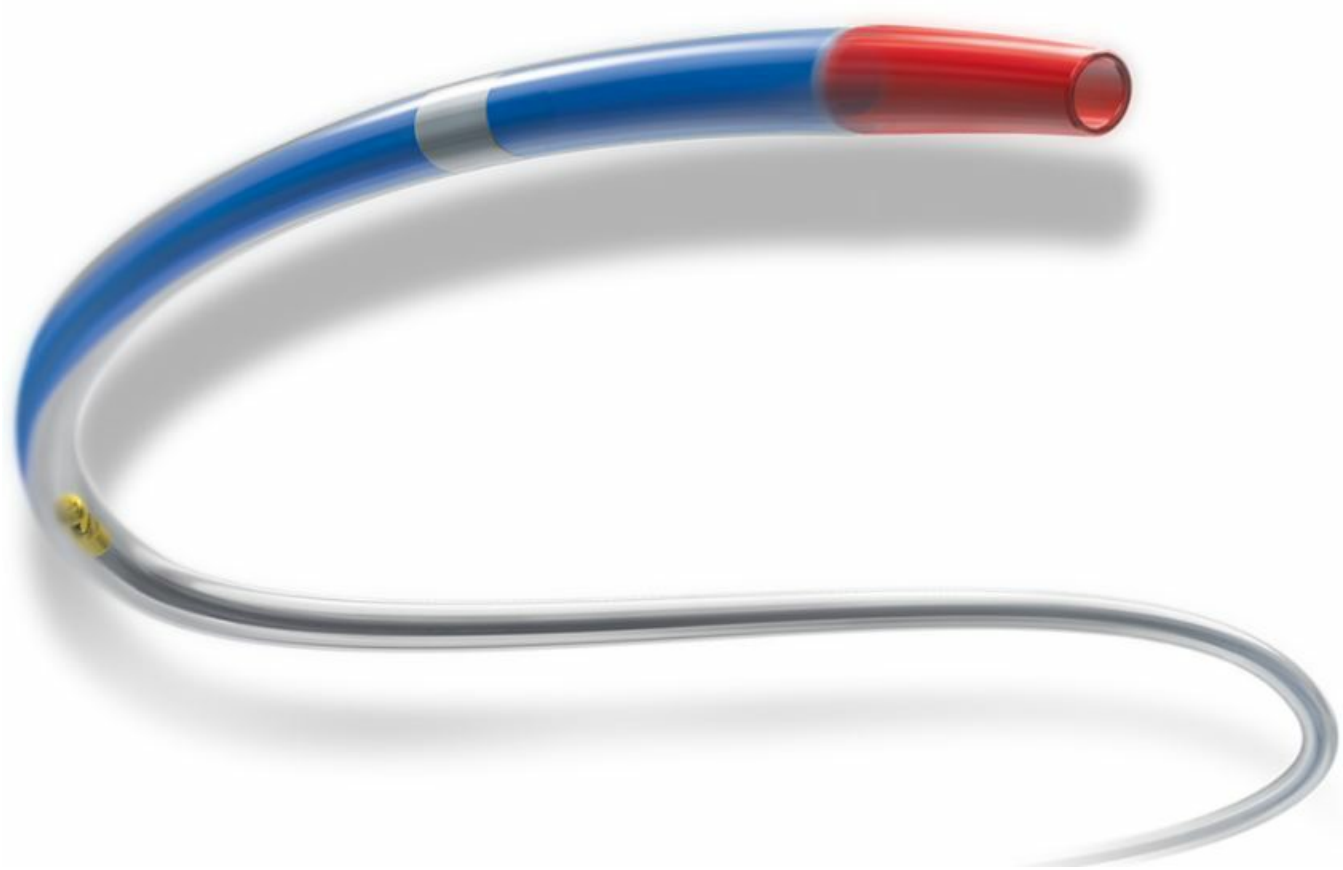


Boston Scientific OPTICROSSTM 6 Coron POLARIS Multi Modality Guidance System User Guide

Contents

Boston Scientific OPTICROSSTM 6 Coron POLARIS Multi Modality Guidance System



For full operating instructions, please review the complete set of iLab™ POLARIS Multi Modality Guidance System directions for use.

SYSTEM OVERVIEW

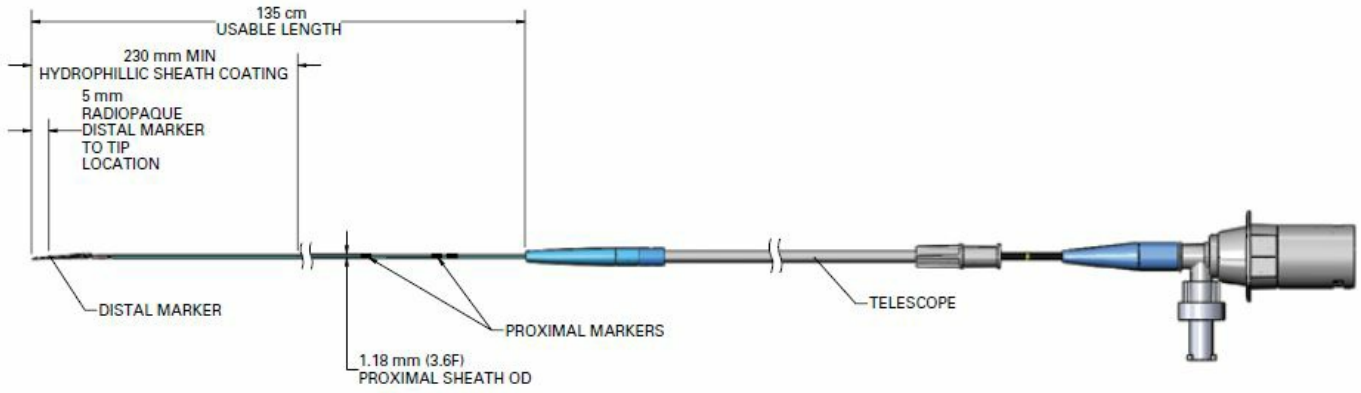
Mobile POLARIS System

Integrated POLARIS System

POLARIS Software

Touch Panel

OPTICROSS™ 18 Imaging Catheters Product Specifications



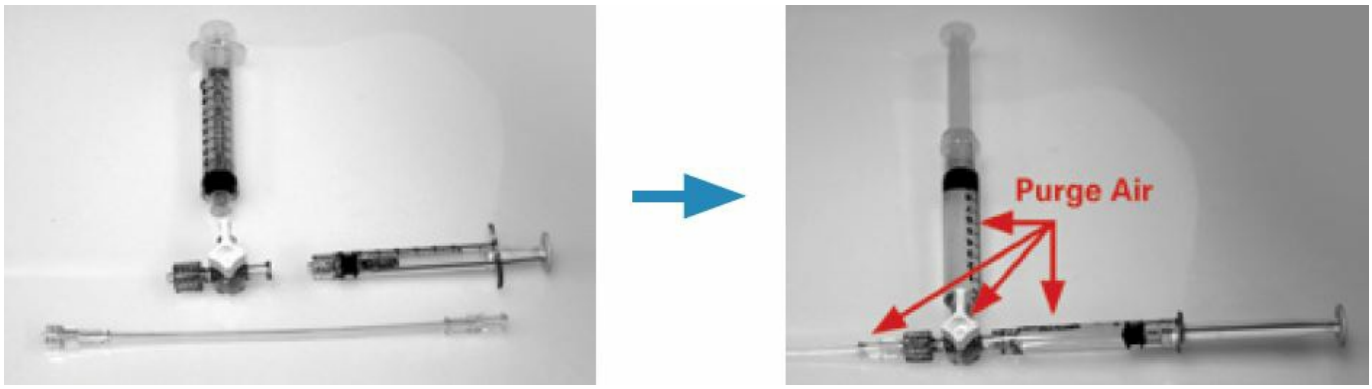
OPTICROSS™ 18 Imaging Catheter

Typical Use	Transducer Frequency	Maximum Imaging Diameter	Guidewire Compatibility	Sheath Compatibility (with max wire)
SFA, Popliteal, Tibial, Renal	30 MHz	up to 22 mm*	£.018	4F

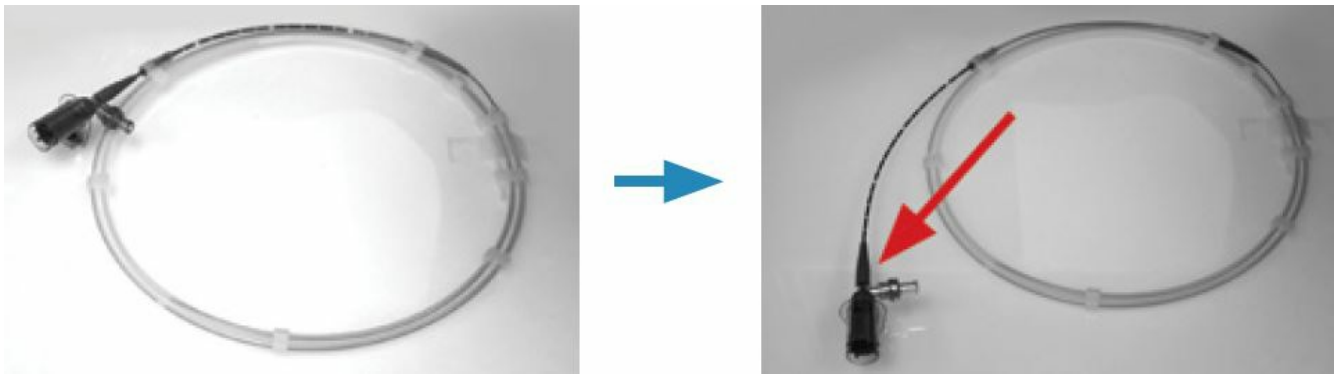
*when catheter is centered to vessel

IVUS SET-UP AND WORKFLOW

Imaging Catheters Preparation Instructions



1. Wet assemble the accessories (ensure air is removed from all the components)



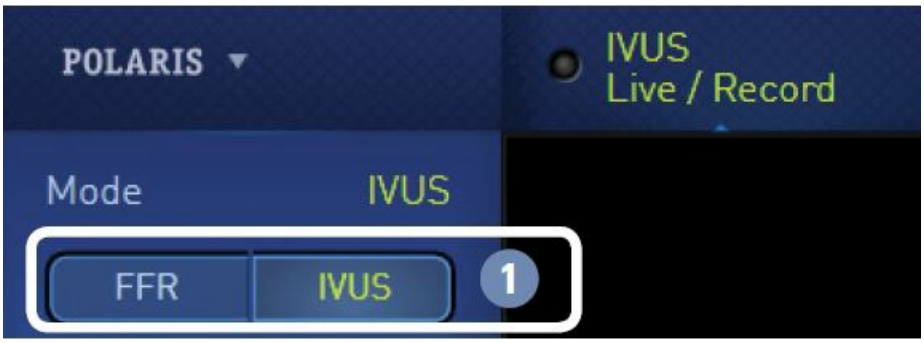
2. Fully open the telescope

3. Flush the first 3 cc syringe slowly (first 1 cc is the most important to flush slowly)
4. Refill the 3 cc syringe and flush a second time with the telescope open and then fully close telescope.
5. Cover the MDU5 PLUS™ Motor Drive with the sterile bag
6. (Optional) Connect the MDU5 PLUS Motor Drive to the sled

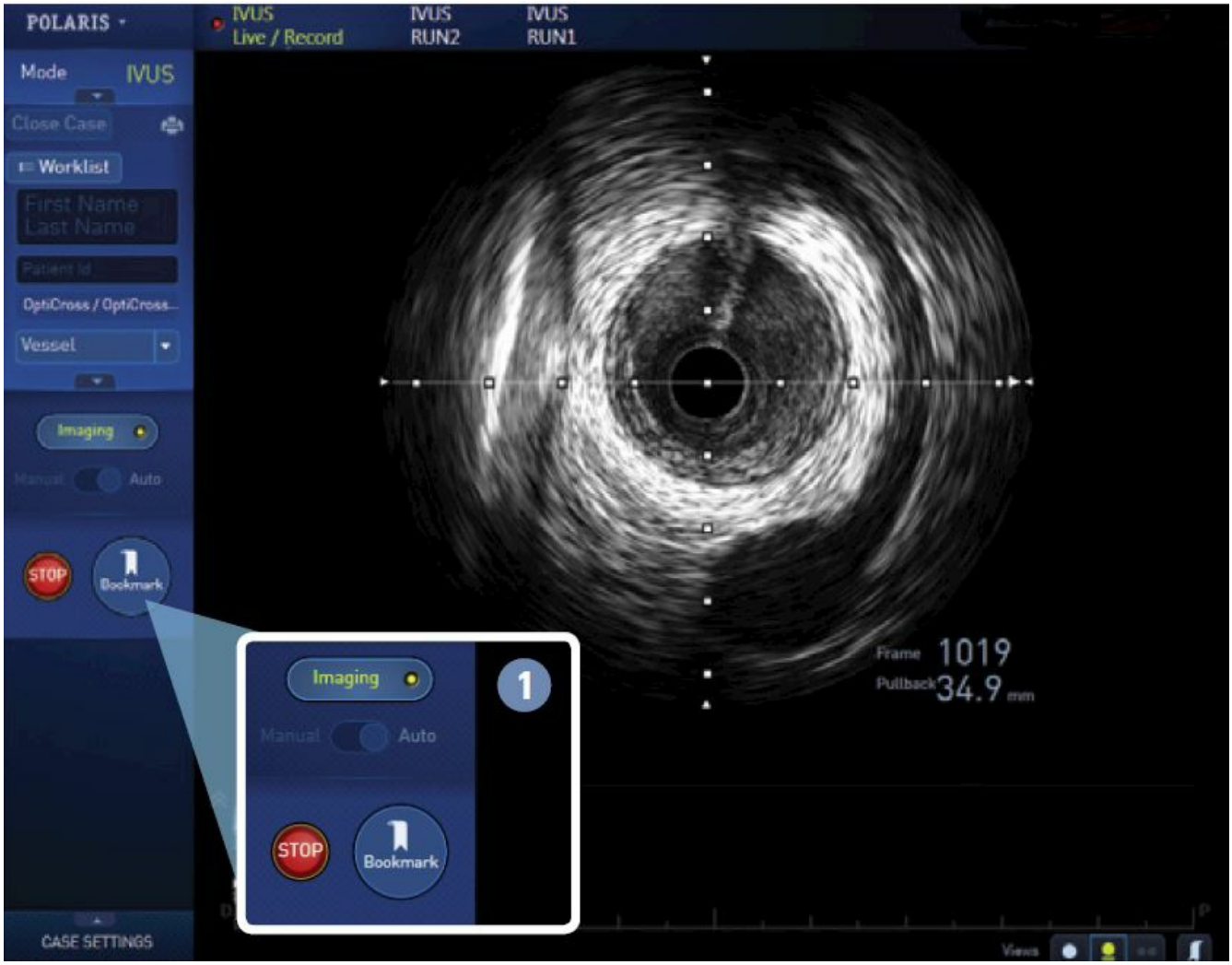
7. Connect the Imaging Catheter to the MDU5 PLUS Motor Drive

8. Turn on the MDU5 Plus Motor Drive and confirm image
9. (Optional) Give a quick puff of saline before inserting into the body

IVUS Software Workflow



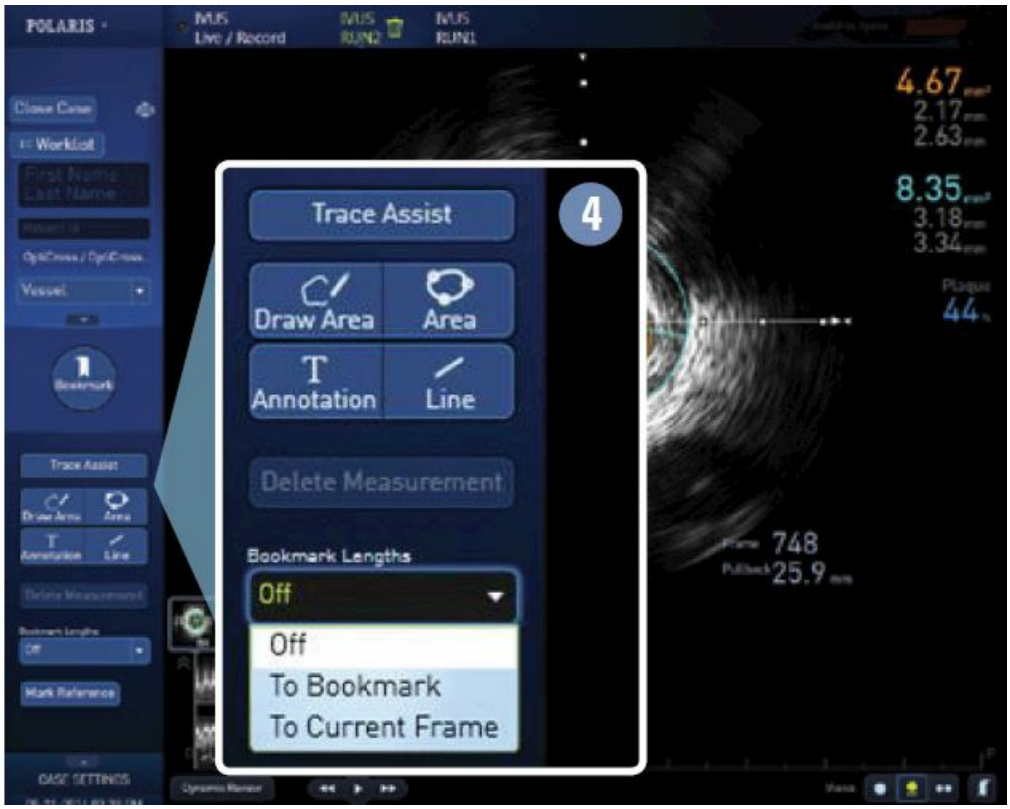
1. Select IVUS Modality



- Within the Live/Record screen, click the Mode button and select IVUS.

2. Record Image
    - Click REC to start and stop recording.
    - The pullback method is auto-selected, slide to manual to continue with manual pullback.
    - Bookmarks can be added while recording. To stop recording, click the stop button.
3. Record New Run
    - Click REC to start and stop recording.
4. Review Image
    - Navigate through the run with scrubber, VCR controls, mouse wheel or bookmark thumbnails.
    - Measure area and diameter.

IVUS Software Workflow



Automatic Measurements:

- Select TraceAssist to display system generated area and diameter measurements
- **To edit:** Click on border, move and click again
- Set Bookmark Lengths to To Bookmark for auto-distance measurements
- **Mark Reference:** Navigate to the healthy reference, and select mark reference.

If lumen areas have already been calculated for the reference frame and the diseased frame(s), the percent area stenosis of the diseased portion of the vessel will be automatically calculated.

Manual Measurement:

- **Area:** Click Area to place points and click Done (in center) or click the pencil tool to draw the border by hand; click again to close the border. If changes are needed, the previous area must be deleted and redrawn.
- **Diameter:** Click Line and draw desired diameter
- **Length:** Select line to measure length

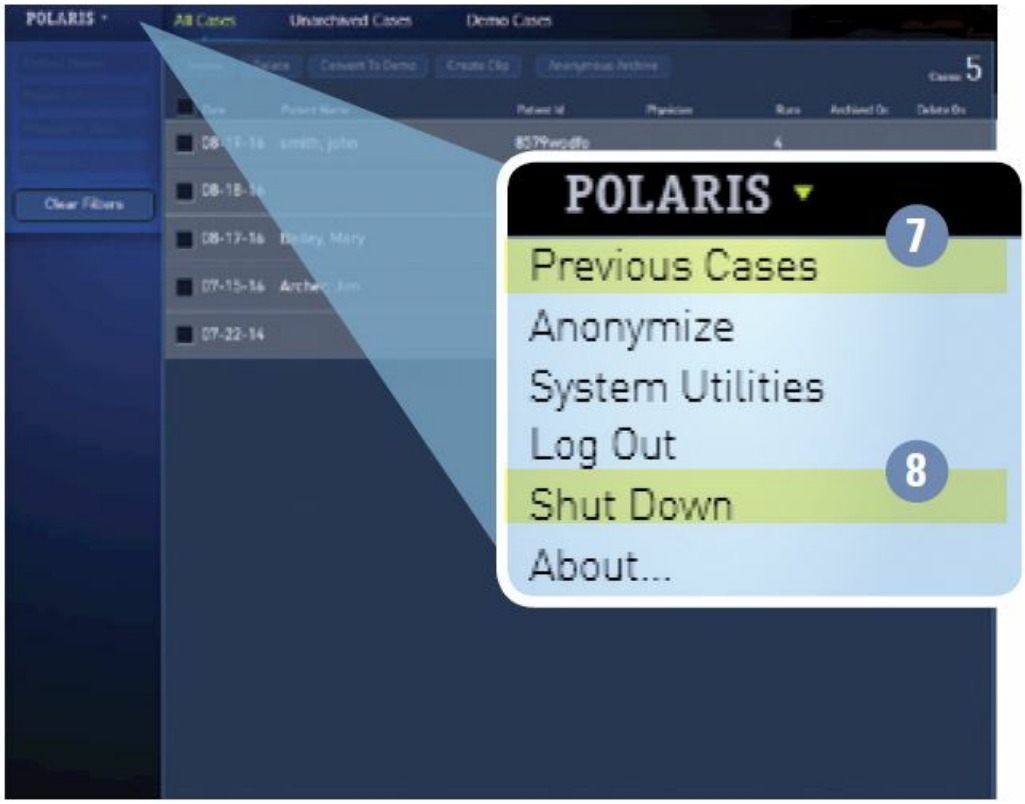
Close a Case

- Click Close Case
- Choose Archive Now or Close and Archive Later
- Enter patient ID, if not previously done
- If you chose to archive now, confirm archive location and de-select any runs you do not wish to save.

Enter Patient Information

- Click in the text fields to edit patient or run information anytime during the case.
- If Modality Worklist has been set up, select the Worklist button to choose the patient.

Previous Case Management



- Filter and sort previous cases in the previous cases screen.
- Select cases and choose Archive to batch archive to a network or hard drive location, or choose Delete to remove cases.
- Select Convert to Demo to create demo cases, create clip to export movie clips and image files to DVD.
- Choose Anonymous Archive to archive cases without identifying patient information.

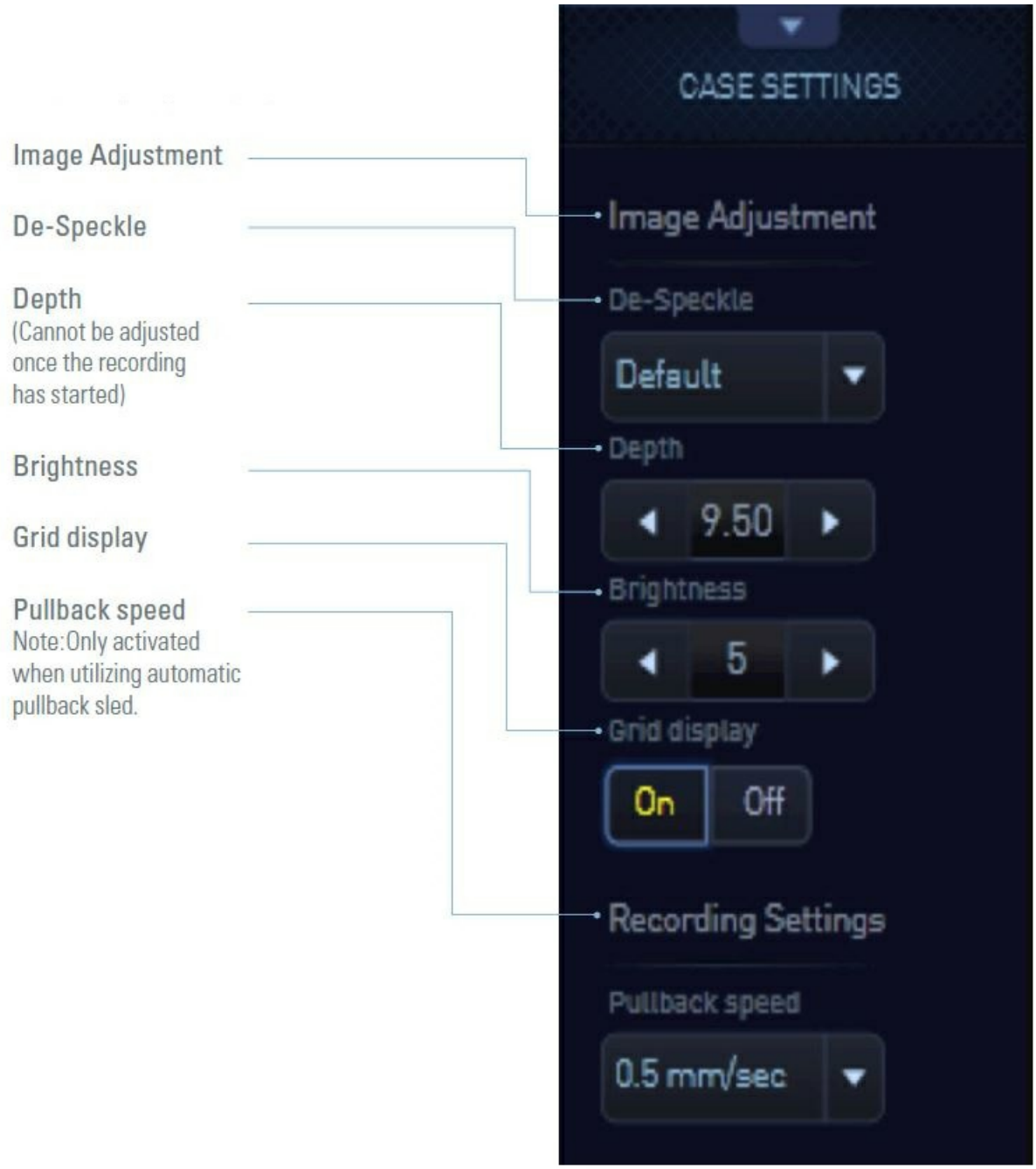
Shut Down System

- From the POLARIS Main Menu, select Shut Down to turn the system off.

SOFTWARE OVERVIEW

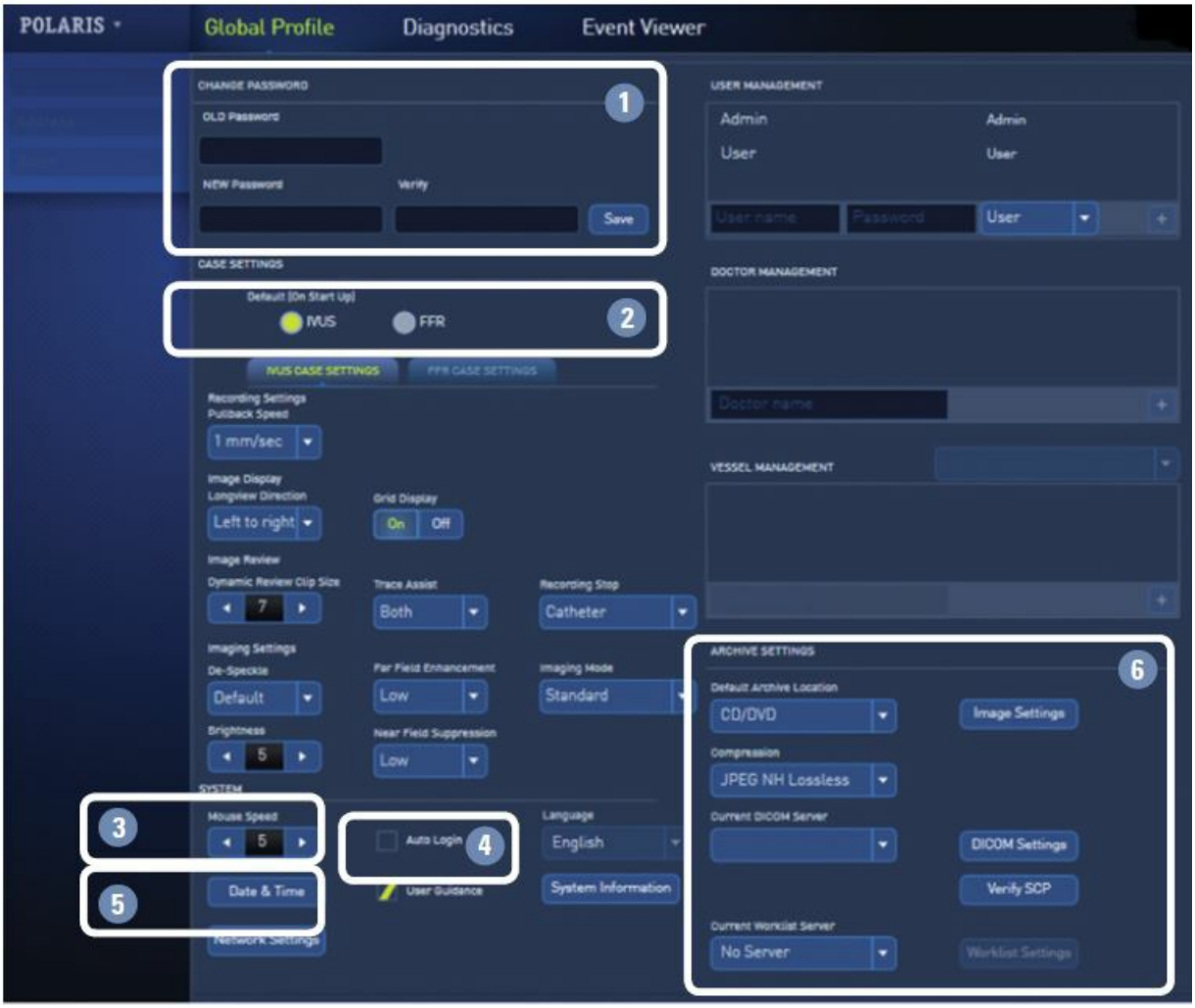
Adjust IVUS Case Settings During a Case

In Review Mode, click on the triangle (▲) in the bottom left of the screen to adjust brightness, de-speckle, or grid display.



General Case Settings

In the POLARIS Main Menu, click System Utilities to change default settings for IVUS for every case.



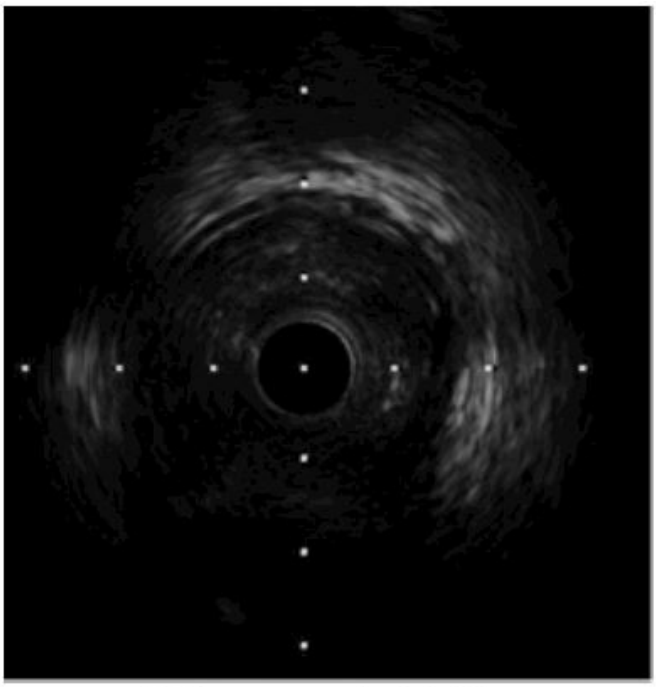
1. Password Management
2. Default Modality on Start Up
3. Mouse Speed Settings
4. Auto Login
5. Date and Time Settings
6. Archive Settings

IVUS Case Settings

1. Choose to start in IVUS mode.
2. Set Auto-pullback speed: 1.0 or 0.5 mm/sec*
3. Draw Longview from left or right side of screen.*
4. Show 1 mm grid mark overlays.
5. Set number of frames in Dynamic Review Clip Size.
6. For Trace Assist, draw lumen only, vessel only, or draw both
7. When the recording stops, choose Catheter from Review Mode, or choose Stay in Live / Record.
    - **Note:** ICE catheters will always stay in Live mode.
8. Set De-Speckle to OFF to see more blood speckling, or choose HIGH for less blood speckling.
9. Far Field Enhancement brightens only the outer portion of the image.
    - Near Field Suppression minimizes ring-down.
10. Imaging Mode alternate preferences include Dark Lumen or Noise Reduction settings.
11. Image Brightness Scale: 0 (darkest) – 10 (brightest)
    - *Only active when utilizing an automatic pullback sled.

TIPS AND TROUBLESHOOTING / IVUS

The IVUS image displayed on screen is very dark



Dark image caused by air bubbles

- Flush the catheter to eliminate air bubbles

The imaging catheter name is not recognized by the system

- Most likely, the current POLARIS software installed has not been updated.
- Call Technical Support at 1-800-949-6708

Software issues are interrupting the IVUS workflow

- Reboot the system. If problem persists, call Technical Support at 1-800-949-6708

What is the pullback distance of Auto-Pullback and Manual?

- Manual (pulling back on telescope) = 15 cm
- Auto (using pullback sled) = 10 cm

The automatic pullback device is not working*

- Check that the gear on the bottom of the sled is not impeded by the sterile bag

The pullback measurement stopped early*

- Ensure the MDU5 PLUS Motor Drive is all the way proximal before starting pullback and start over.

*Only applicable with utilization of Automatic Pullback Sled

ORDERING INFORMATION

DESCRIPTION	REF/CATALOG NO.	ORDER NUMBER (GTIN)
iLab™ System (Cart Version)	H749ILAB120C2710	08714729847885
OptiCross™18 IVUS Catheter	H7493932800180	08714729904366
MDU5+ Motor Drive	H749MDU5PLUS0	08714729842279
MDU5+ Sterile Bag	H749MDU5PLUSBAG0	08714729842255
Sterile Pullback Sled	H749A70200	08714729228684
Sterile Sled Bag	H749A70170	08714729263074

Necessary Equipment

- iLab™ POLARIS Multi-Modality Guidance System (Integrated or Mobile)
- MDU5 PLUS™ Motor Drive
- Automatic Pullback Sled (optional)

Contact a Boston Scientific sales representative or visit **www.bostonscientific.com** to learn more.

IVUS CPT Codes

Starting in 2016, new bundled codes +37252 and +37253 are used to report non-coronary IVUS. Medicare has established a non-facility (in-office) valuation for the new codes. The new codes bundle RS&I services which are no longer separately reportable.

CPT® Code	DESCRIPTION
+ 37252	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic i ntervention, including radiological supervision and interpretation; initial noncoronary vessel (List separately in addition to code for primary procedure)
+ 37253	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic i ntervention, including radiological supervision and interpretation; each additional noncoronary v essel (List separately in addition to code for primary procedure)

RS&I is included within the new codes shown above 37250, 75945, 37251 and 75946 have been deleted

Important Information

- Add-on code (+) must be performed in addition to a primary procedure;
    - (i.e., stent, PTA, atherectomy, embolization, thrombolysis, thrombectomy)

- Add-on codes are exempt from multiple procedure reduction
- Coding is per vessel evaluated; however, contiguous vessel abnormalities
    - (i.e., DVT, diffuse atherosclerotic disease) are described by a single code
- Check your payer guidelines closely, as there may be limitations for the use of these codes- contractors will define SPECIFIC PRIMARY CODES

OPTICROSS 18 CATHETER AND MDU5 PLUS BAG

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.

INTENDED USE/INDICATIONS FOR USE

OptiCross 18 Catheter

This catheter is intended for intravascular ultrasound examination of peripheral vessels only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.MDU5 PLUS Sterile Bag: The MDU5 PLUS Sterile Bag is intended to cover the motordrive during intravascular ultrasound procedures to maintain the sterile field and prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker

CONTRAINDICATIONS

Use of this product is contraindicated in the presence of conditions which create unacceptable risk during catheterization.

WARNINGS

- Intravascular ultrasound examination of vascular anatomy should be performed only by physicians fully trained in interventional radiology and in the techniques of intravascular ultrasound, and in the specific approach to be used, in a fully-equipped cardiac catheterization lab.
- The catheter has no user serviceable parts. Do not attempt to repair or to alter any component of the catheter assembly as provided. Using an altered catheter can result in poor image quality or patient complications.
- No modification of this equipment is allowed.
- Do not pinch, crush, kink or sharply bend the catheter at any time. An insertion angle greater than 45° is considered excessive.
- Do not manipulate, advance and/or withdraw the coated device through a metal cannula or needle. Manipulation, advancement and/or withdrawal through such a metal device may result in destruction and/or separation of the outer hydrophilic coating, resulting in coating material remaining in the vasculature, which may cause adverse events and require additional intervention.
- Do not advance the catheter if resistance is encountered. The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis.
- When advancing the catheter through a stented vessel, catheters that do not completely encapsulate the guidewire may engage the stent between the junction of the catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation.
- If resistance is met upon withdrawal of the catheter, verify resistance using fluoroscopy, then remove the entire

system simultaneously.
- When readvancing a catheter after deployment of stent(s), at no time should a catheter be advanced across a guidewire that may be passing between one or more stent struts. A guidewire may exit between one or more stent struts when recrossing stent(s). Subsequent advancement of the catheter could cause entanglement between the catheter and the stent(s), resulting in entrapment of catheter/guidewire, catheter tip separation and/or stent dislocation.
- Use caution when removing the catheter from a stented vessel.
- Inadequately apposed stents, overlapping stents, and/or small stented vessels with distal angulation may lead to entrapment of the catheter with the stent upon retraction.
- When retracting the catheter, separation of a guidewire from an imaging catheter or bending of the guidewire may result in kinking of the guidewire, damage to the catheter distal tip, and/or vessel injury. The looped guidewire or damaged tip may catch on the stent strut resulting in entrapment.

PRECAUTIONS

- Do not attempt to connect the catheter to electronic equipment other than the designated Systems.
- Never attempt to attach or detach the catheter while the motor is running.
- If difficulty is encountered when backloading the guidewire into the distal end of the catheter, inspect the guidewire exit port for damage before inserting the catheter into the vasculature.
- Never advance the imaging catheter without guidewire support.
- Never advance the distal tip of the imaging catheter near the very floppy end of the guidewire.
- Never advance or withdraw the imaging catheter without the imaging core assembly being positioned at the most distal portion of the imaging window.
- During and after the procedure, inspect the catheter carefully for any damage which may have occurred during use.
- Multiple insertions may lead to catheter exit port dimension change/distortion which could increase the chance of the catheter catching on the stent. Care should be taken when re-inserting and/or retracting catheter to prevent exit port damage.
- Turn the MDU5 PLUS™ “OFF” before withdrawing the imaging catheter.

ADVERSE EVENTS: The risks and discomforts involved in vascular imaging include those associated with all catheterization procedures. These risks or discomforts may occur at any time with varying frequency or severity. Additionally, these complications may necessitate additional medical treatment including surgical intervention and, in rare instances, result in death.

- Allergic reaction
- Device entrapment requiring surgical intervention
- Embolism (air, foreign body, tissue or thrombus)
- End organ infarction
- Hemorrhage/Hematoma
- Hypotension and/or bradycardia (vasovagal syndrome)
- Infection
- Peripheral ischemia
- Stroke and Transient Ischemic Attack
- Thrombosis

- Vessel occlusion and abrupt closure
- Vessel trauma including, but not limited to dissection and perforation (REV AA)

This reference guide is intended to provide a basic understanding of how the product works. It is not intended to be an instructional guide. Prior to use, please review the device Directions for Use including Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operating Instructions.

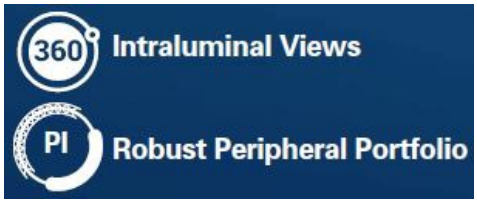
Contact

Technical Support: 1-800-949-6708

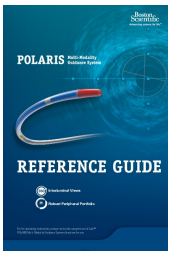
Peripheral Interventions

- 300 Boston Scientific Way
- Marlborough, MA 01752-1234
- www.bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001.



Documents / Resources

	Boston Scientific OPTICROSSTM 6 Coron POLARIS Multi Modality Guidance System [pdf] User Guide OPTICROSSTM 6 Coron POLARIS Multi Modality Guidance System, OPTICROSSTM 6 Coron, POLARIS Multi Modality Guidance System, Multi Modality Guidance System, Modality Guidance System, Guidance System, System

References

- User Manual