AVVIGO™+
Multi-Modality Guidance System

Boston Scientific
Advancing science for life™

Reference Guide
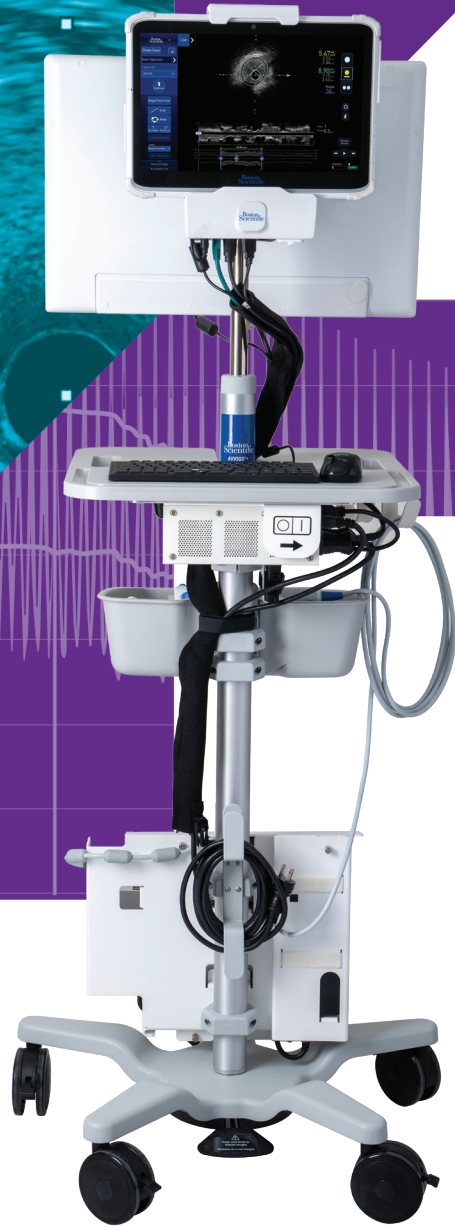
Table of Contents

Necessary Equipment

- AVVIGO™+ Multi-Modality Guidance System (Integrated or Mobile)
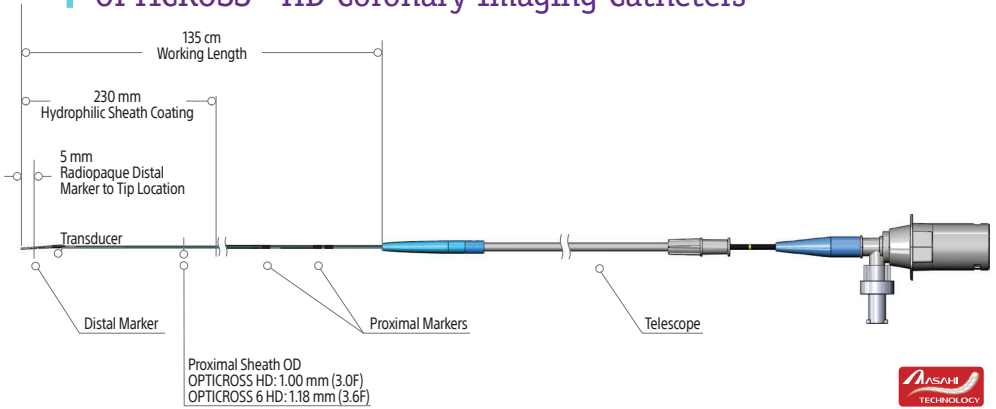- MDU Fast Pullback Motor Drive
- Tableside Control (For Integrated system only)
- FFR Link (Includes Hemodynamic Cable Kit)
- Permanent Sled
- Permanent Sled Bag
- OPTICROSS™ Imaging Catheter
- COMET™ II Pressure Guidewire

Ordering Information

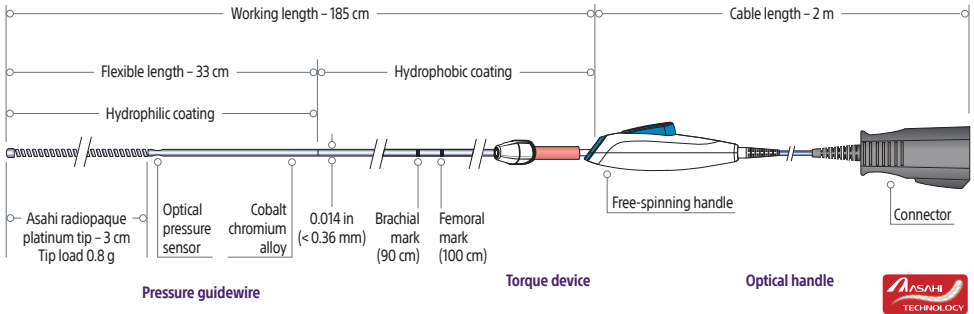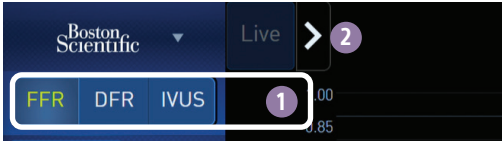| Ref/Catalog Number	Description
BUN30AVPLUSMOB	AVVIGO + Mob System, EU
BUN30AVPLUSINT	AVVIGO + Integrated System, EU (without Table Side Control)
BUN30AVPLUSINTTSC	AVVIGO + Integrated System, EU (with Table Side Control)
H749 3935931 0	COMET™ II Pressure Guidewire
H749 51812 0	OPTICROSS Imaging Catheter
H749 518126 0	OPTICROSS 6 Imaging Catheter
H749 3935202 0	OPTICROSS HD Imaging Catheter
H749 3935406 0	OPTICROSS HD 6 Imaging Catheter
H749 393270018 0	OPTICROSS 18 Imaging Catheter
H749 393280135 0	OPTICROSS 35 Imaging Catheter
M00499100	ULTRA ICE™ PLUS Imaging Catheter
H749 MDU5PLUSF 0	MDU - Fast pullback
H749 555100 0	FFR Link
H749 39316010 0	Permanent Sled
H749 39315010 0	Permanent Sled Bag

Product Specifications

+ OPTICROSS™ HD Coronary Imaging Catheters

135 cm
Working Length

230 mm
Hydrophilic Sheath Coating

5 mm
Radiopaque Distal
Marker to Tip Location

Transducer

Distal Marker

Proximal Sheath OD
OPTICROSS HD: 1.00 mm (3.0F)
OPTICROSS 6 HD: 1.18 mm (3.6F)

Proximal Markers

Telescope

ASAHI TECHNOLOGY

+ COMET™ II Pressure Guidewire

Working length – 185 cm

Cable length – 2 m

Flexible length – 33 cm

Hydrophobic coating

Hydrophilic coating

Asahi radiopaque
platinum tip – 3 cm
Tip load 0.8 g

Optical
pressure
sensor

Cobalt
chromium
alloy

0.014 in
(< 0.36 mm)

Brachial
mark
(90 cm)

Femoral
mark
(100 cm)

Free-spinning handle

Connector

Pressure guidewire

Torque device

Optical handle

ASAHI TECHNOLOGY

For technical support, contact your local representative, or the EMEA TECH SUPPORT +31 455 46 77 07.
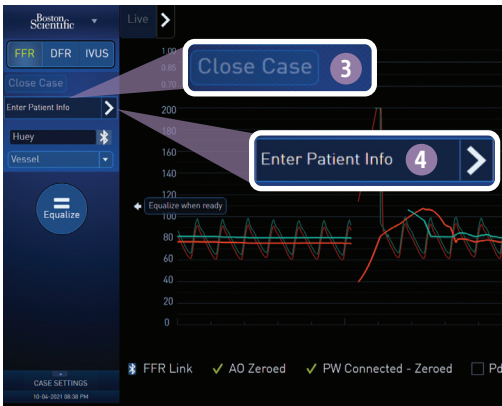
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Software Basics

1 Select FFR, DFR, or IVUS Modality

Within the Live/Record screen, select FFR, DFR, or IVUS Mode.

2 FFR, DFR, IVUS Ribbon

From the AVVIGO Main Menu, select chevron at top to expand all the recorded results by names such as IVUS-1, DFR-1 and FFR-1 and switch between modalities

3 Close a Case

- Click Close Case
- Choose Archive now or Close and Archive Later
- Enter patient ID, if not previously done

4 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.


5 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 (like a USB Flash Drive), or choose Delete to remove cases.
- Select Convert to Demo to create demo cases, create clip to export movie clips and image files to a USB Flash Drive.
- Choose Anonymous Archive to archive cases without identifying patient information.

6 Shut Down System

From the AVVIGO Main Menu, select Shut Down to turn the system off and after a few seconds, switch off the system's main AC power switch.

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Software Basics
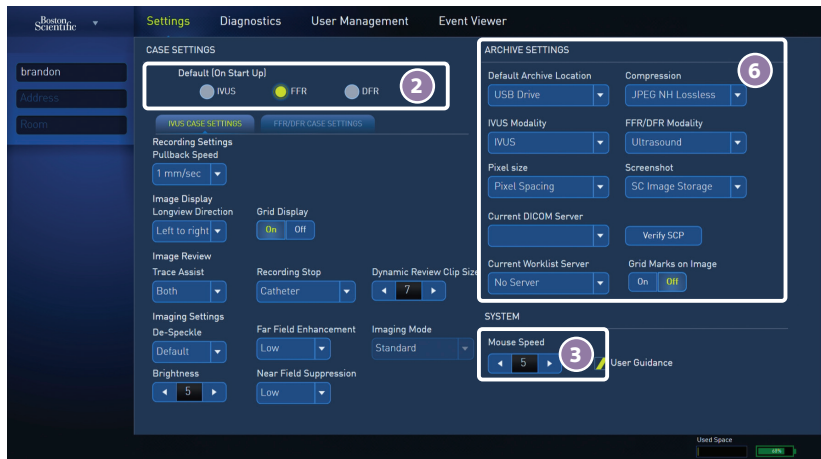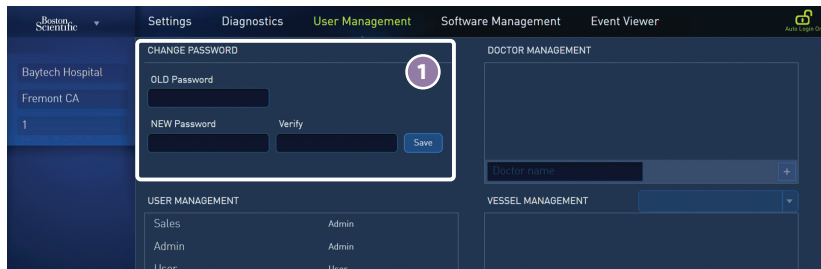
1 Changing Display Options

Select View Options buttons in the middle right to choose a cross sectional view with Longview (if the run was recorded using Auto Pullback) or Dual View.
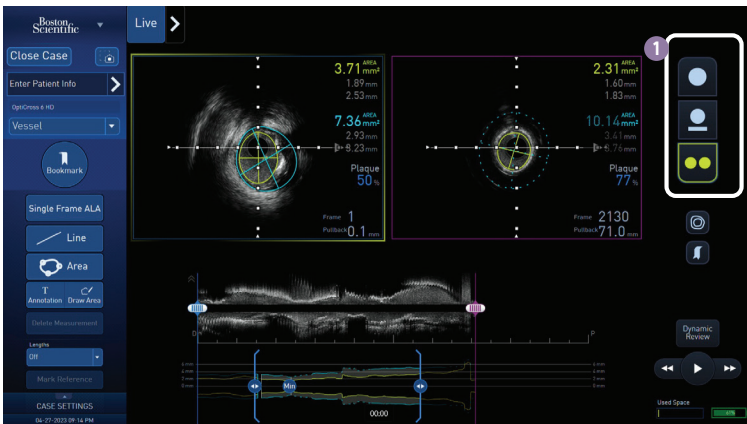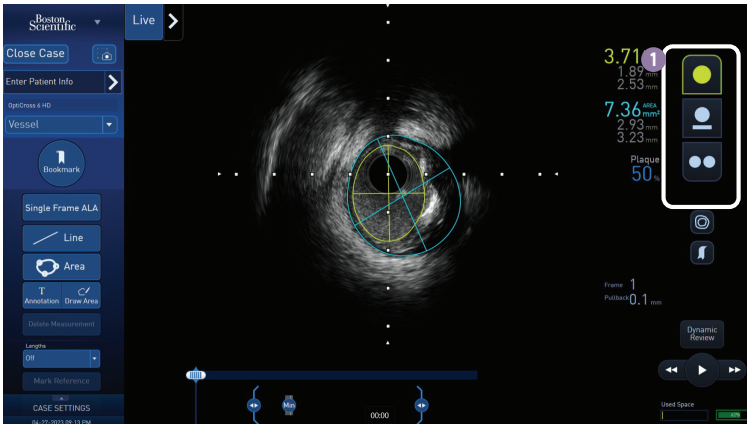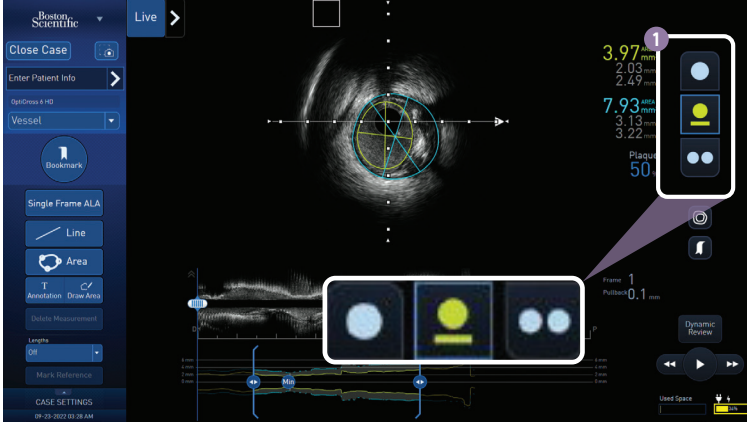
Software Basics

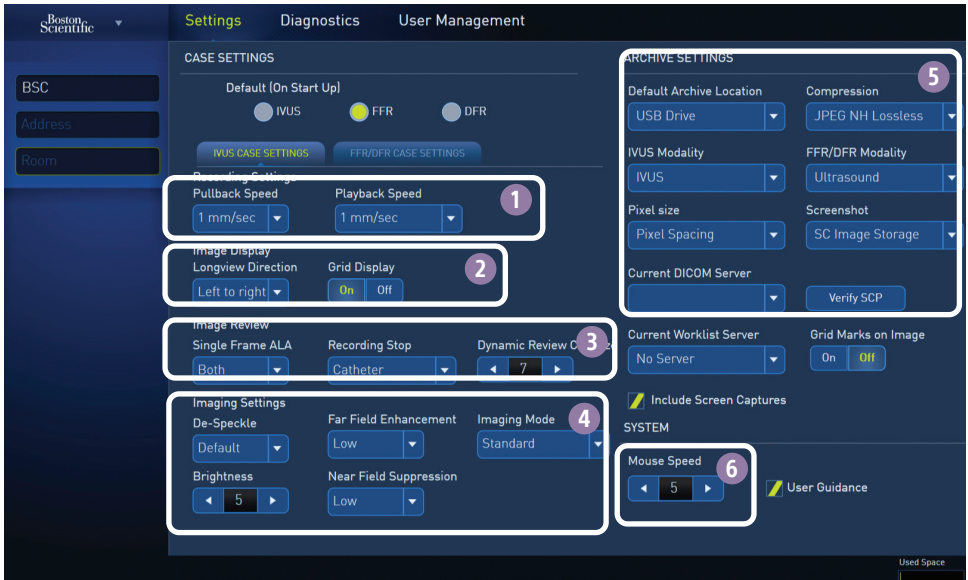## General Case Settings

In the AVVIGO Main Menu, click System Utilities to change default settings for IVUS, FFR, and DFR.

1 Password Management

2 Default Modality on Start Up

3 Mouse Speed Settings

4 Auto Login

5 Date and Time Settings

6 Archive Settings

For technical support, contact your local representative, or the EMEA TECH SUPPORT +31 455 46 77 07.

General IVUS Case Settings

1 Recording Settings   4 Image Settings

2 Image Display   5 Archive Settings

3 Image Review   6 Mouse Speed

Export
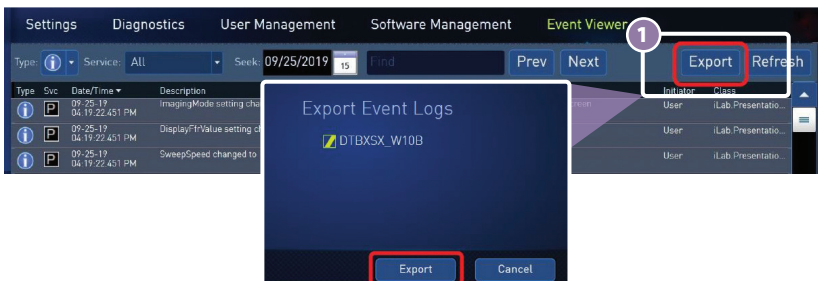
1 Insert USB, select files and select Export.

   Note: it is recommended to remove the data from the system
database upon completion of the interventional procedure.

Software Basics

IVUS Case Settings

1. Choose to start in IVUS, FFR, or DFR mode.

2. Set Auto-pullback speed: 0.5, 1,2, 3, 4, 6, 8 mm/sec

3. Display Longview from left or right side of screen.

4. Show 1 mm grid mark overlays.

5. For Single Frame Automated Lesion Assessment (ALA), draw lumen only, vessel only, or draw both

6. When the recording stops, choose Catheter from Review Mode, or choose Stay in Live/Record.
   Note: ICE catheters will always stay in Live Mode

7. Set number of frames in Dynamic Review Clip Size.

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, Noise Reduction, Advanced I, Advanced II and Advanced III modes.

11. Image Brightness Scale: 0 (darkest)–10 (brightest)

Software Basics

FFR/DFR Case Settings
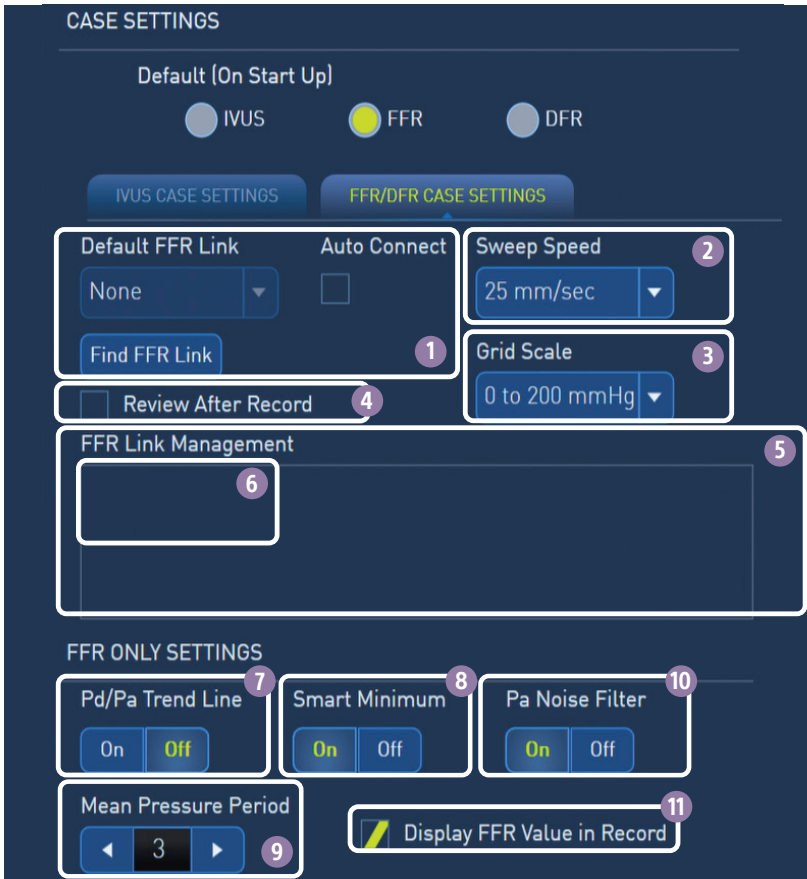
1. Choose Auto Connect FFR Link (for installed systems)
2. Set Sweep Speed (waveform refresh rate)
3. Blood pressure scale
4. Select to go to Review after Record
5. Manage FFR Links
6. Available FFR Links
7. Set Display Pd/Pa Trend Line
8. Set Smart Minimum
9. Set Mean Pressure Period (average heartbeats on trend lines)
10. Set Pa Noise Filter
11. Select to show or hide FFR Value in Record

For technical support, contact your local representative, or the EMEA TECH SUPPORT +31 455 46 77 07.

FFR Link Set Up

Basic FFR Link Set Up

IBP1

FFR Link

Hemodynamic System

Hospital
IBP to hemo
Cable

BSC
IBP-in
Cable

BSC
Pa-out
Cable

P1
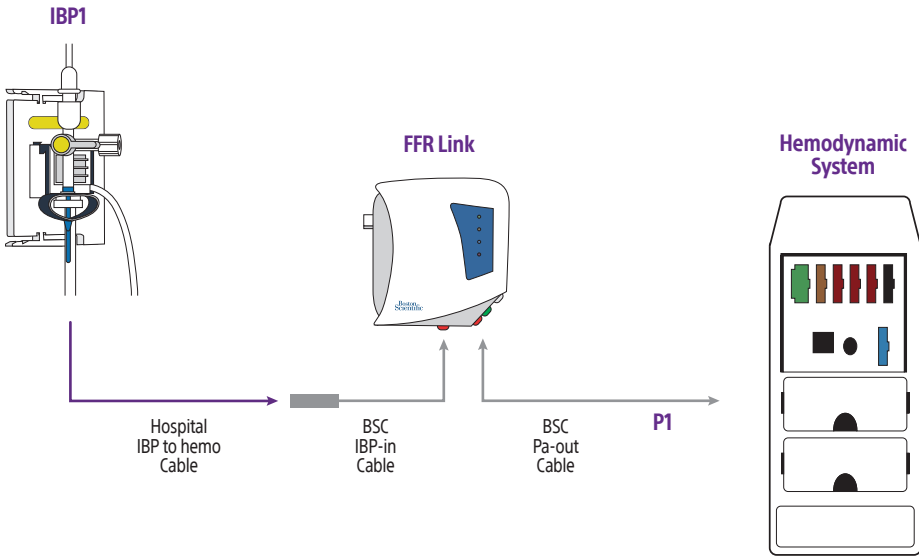
FFR Link Set-Up with ACIST Power Injector and Manual Manifold

ACIST Power Injector Manifold

**Hospital
IBP to Hemo
Cable**

Ao

FFR Link

Hemodynamic System

Manual Manifold

Ao

SWITCH

BSC IBP-in Cable

BSC Pa-Out Cable

P1

The FFR Link needs to be plugged into P1 or the pressure on the hemo screen.
You will need to switch between the ACIST power injector and manual manifold.

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FFR Link Set Up

FFR Link Set Up with Multiple IBPs

IBP3　**IBP2**　**IBP1**

FFR Link

Hemodynamic System

Hospital IBP to Hemo Cable

BSC IBP-in Cable

6 Feet

BSC Pa-Out Cable

12 Feet　　12 Feet　**P1**

12 Feet　　　　　　**P2**

12 feet　　　　　　**P3**

FFR Link Set-Up with St. Jude WiBox

IBP1

FFR Link

St. Jude WiBox

Hemodynamic System

P1

Hospital IBP to hemo Cable
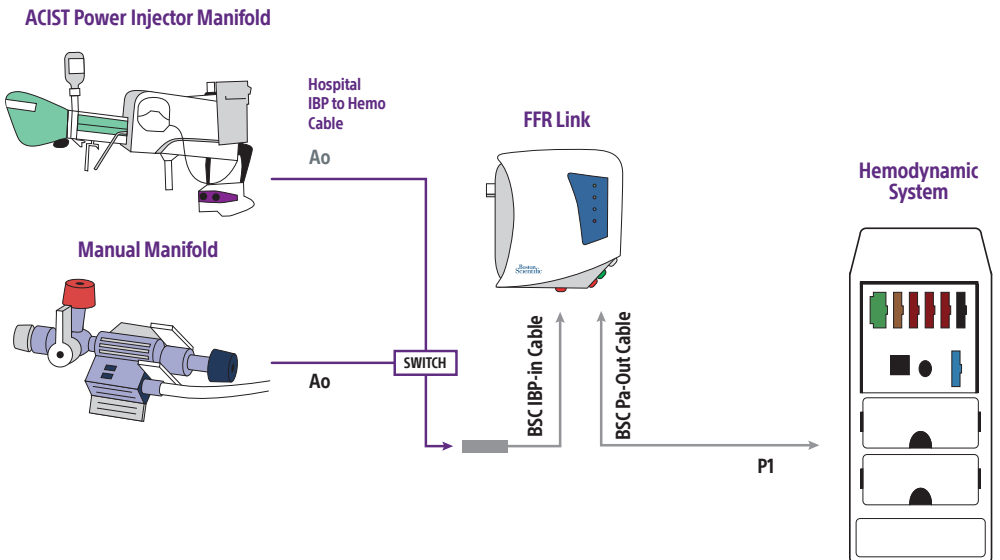
BSC IBP-in Cable

BSC Pa-out Cable

STJ Pa-out Cable

For technical support, contact your local representative, or the EMEA TECH SUPPORT +31 455 46 77 07.
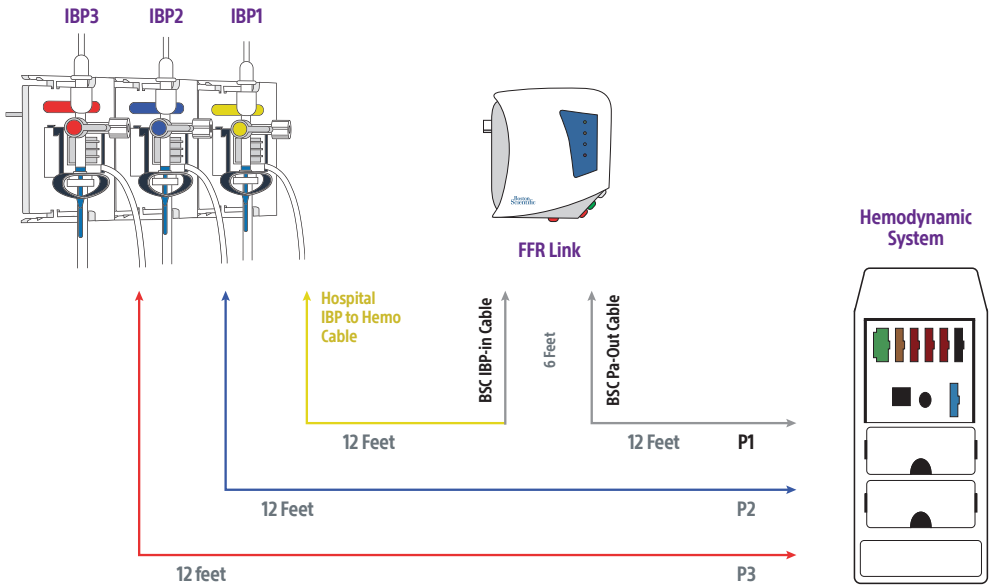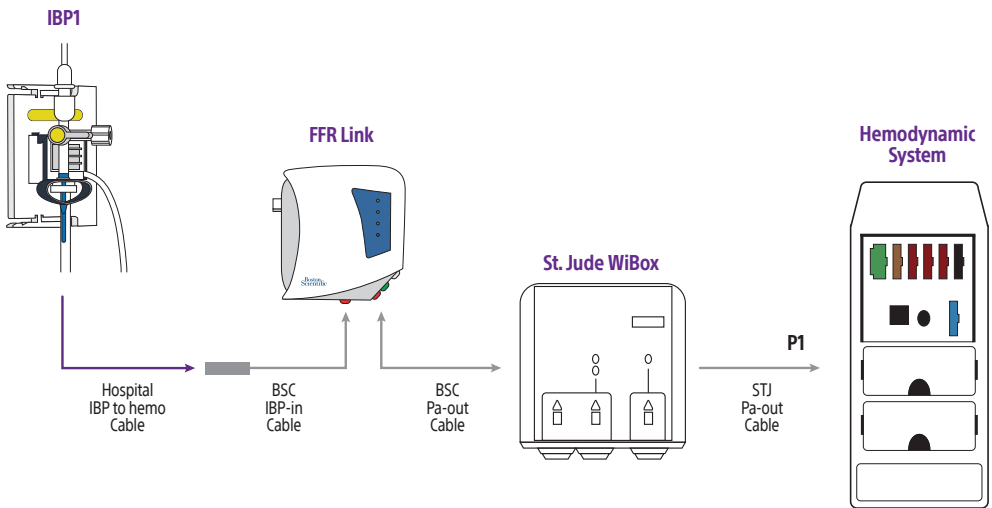
FFR Link Set Up

FFR Link Set-Up with Multi-Channel Transducer

IBP3   **IBP2**   **IBP1**

1 Foot

10 Feet

FFR Link

BSC IBP-in Cable

6 Feet

BSC Pa-Out Cable

12 Feet   P1

1 Foot

P2

P3

Hemodynamic System
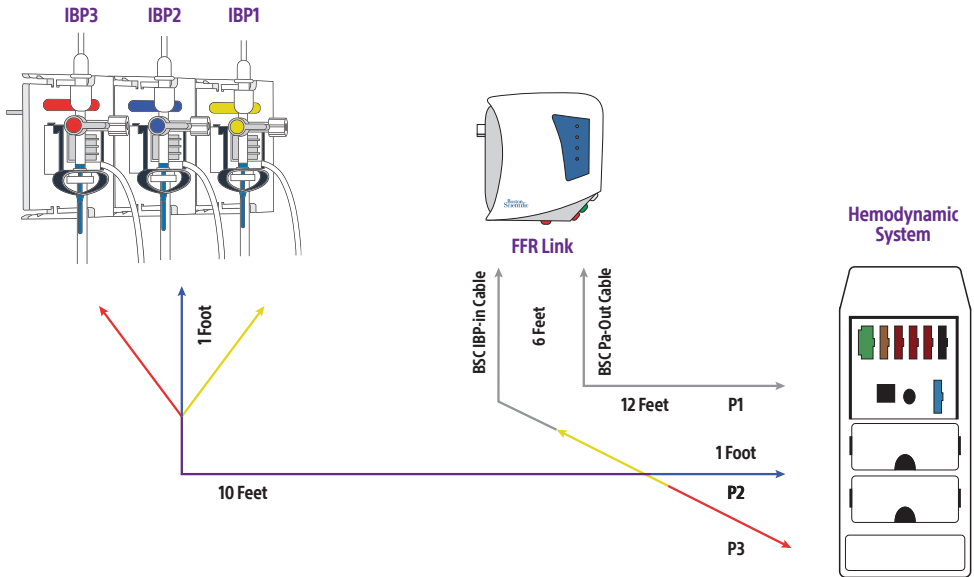
Cord Management
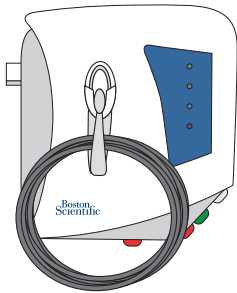
Managing Excess Cord

+ Remove the connections with care to ensure they continue to work properly.

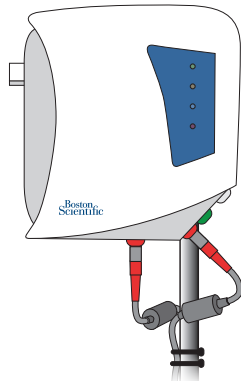+ Use bundles to manage cord length.

+ Ensure there is enough excess cord for the bed to move around.

Strain Relief

+ To avoid cables being pulled during bed movement, create slack between the connection and tie.

FFR Set Up and Workflow

FFR Workflow Checklist

Step 1: Select FFR Mode

Step 2: Open stopcock to air

Step 3: Zero Ao on AVVIGO+

Step 4: Close stopcock

Step 5: Lay the COMET™ II Pressure Guidewire flat on the table, flush wire.

Step 6: Firmly insert the COMET II Guidewire into the FFR Link (ensure it is fully seated) and allow it to auto-zero.

+ Wait for the "Zeroed" LED to flash green for five seconds and turn solid green.

+ If re-zeroing is required, remove the COMET II Pressure Guidewire from the FFR link and wait for the "Zeroed" LED to go dark. Fully insert the wire back into the FFR link and wait for a solid green LED.

+ If the "Zeroed" LED does not turn green, restart the FFR link, connect Bluetooth, and begin at Step 1 again.

Step 7: Equalization Prep

+ Flush contrast out of guide catheter

+ Take needle introducer out of hemostasis valve

+ Fully close hemostasis valve

+ If damped Ao waveforms are observed, make sure guide catheter is not deep seated and fully flushed from contrast

Step 8: Equalize Pressures

+ With the sensor just outside the guide catheter, press Equalize to remove any offset between the aortic and distal pressure reading

Step 9: After wire is advanced beyond the lesion, record

Step 10: Stop Record

Step 11: Review Run

NOTE: When withdrawing the Comet II Guidewire, remove from the proximal end of the wire, as sensor damage may occur if sufficient force is applied to the distal end of the wire.

FFR Set Up and Workflow

FFR Workflow Checklist

LED	Color	Indication When Lit or Blinking
Power	Red	The FFR Link has been powered on and is initializing.
	Blinking Red	The FFR Link has begun its self-test.
	Green	The FFR Link has passed its self-test and is in standby mode.
	Solid Red for more than 10 seconds	The FFR Link has failed its self-test.
Zeroed	Blinking Green	The wire has been detected and the zeroing process is initiated.
	Blinking Red	The wire has been detected but the zeroing process has failed.
	Red	The wire has been detected but the RFID verification has failed.
	Green	The wire has been successfully zeroed and the FFR Link is outputting a Pd signal.
Signal Strength	Yellow	The strength of the Pd signal is poor.
	Green	The strength of the Pd signal is good.
POLARIS Connected	Blue	Bluetooth connection to the POLARIS software is established.
	Blinking blue (LED blinks 5x, then reverts to solid blue)	The FFR Link has received an "identify" command from the AVVIGO II software.

FFR Set Up and Workflow

Ensure FFR Mode is selected.
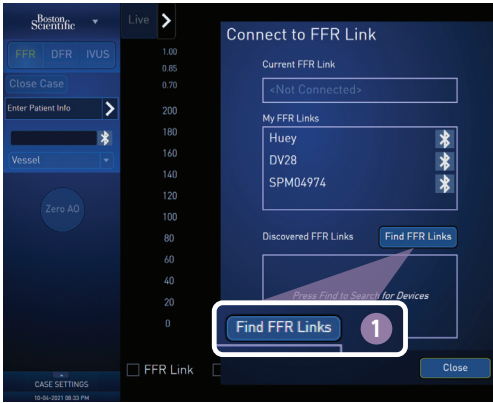
1 Connect Bluetooth

If the FFR Link does not auto-connect, this dialog box will appear. Select the correct FFR Link from the My FFR Links box.

If the correct FFR Link does not appear, click "Find FFR Links" for additional choices.

2 Zero Aortic Pressure

When connected, the aortic pressure waveform will be present on the screen.

✚ Open IBP stopcock.

✚ Click Zero Ao.

✚ Close the IBP stopcock.

The Ao Zeroed status indicator on the bottom left should now be checked.

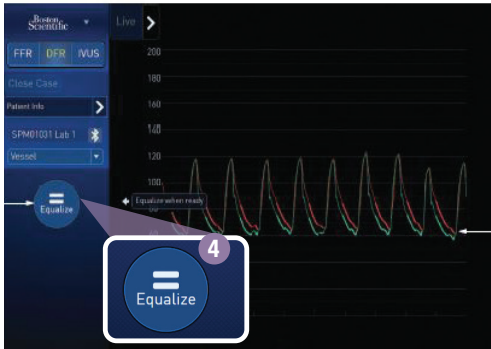**3** Connect the COMET™ II Pressure Guidewire

While the wire is in the hoop, flush the hoop and lay the COMET II Guidewire flat on the table.

With the COMET II Guidewire flat on the table, connect to the FFR Link. Allow the auto-zero process to complete before moving the wire.

Once zeroed, the distal pressure waveform will be on the screen. The PW Connected—Zeroed status indicator should now be checked.

For technical support, contact your local representative, or the EMEA TECH SUPPORT +31 455 46 77 07.
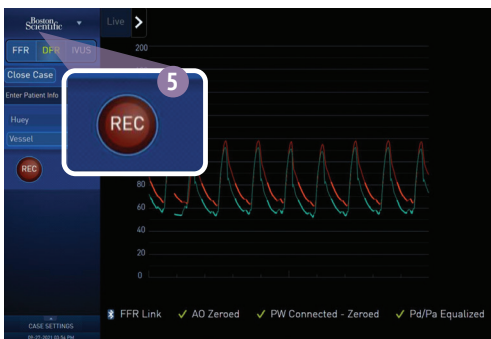
FFR Set Up and Workflow

4 Equalize Pressures

With the sensor just outside the guide catheter, press Equalize to remove any offset between the aortic and distal pressure reading.

Preparation is complete. Advance the wire distal to the lesion and you are now ready to record a run.

Equalization recommandations

+ Flush contrast out of guide catheter
+ Take needle introducer out of hemostasis valve

+ Fully close hemostasis valve
+ If damped AO waveforms are observed, make sure guide catheter is not deep seated and is fully flushed from contrast.

5 Record Run

Click REC to start recording.

Bookmark if desired.

FFR box latches to the lowest value in the run, the Pd/Pa box displays the live value.

The FFR value may be unlatched by clicking the RESET button.

FFR Set Up and Workflow

6 Review Run

View the entire recording on the Review screen.

+ Navigate with scrubber, mouse wheel, or by clicking on the desired location.

+ Zoom into areas of interest using handles.

+ Set bookmarks or annotations.

+ The FFR value may be changed by clicking the SET FFR button.

+ Click the "FFR Live / Record" button to start a new run.

+ The time scale of Physiology (FFR, DFR) recordings can be changed during review using the pinch zoom gesture.
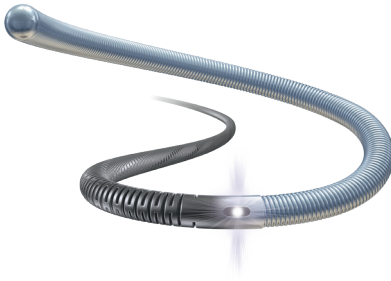
7 Wire Disconnection and Reconnection

Any 0.014" compatible device can be delivered over the COMET™ II Pressure Guidewire after disconnecting the cable.

Re-connect the wire to make additional FFR measurements (re-equalization is not necessary).

For technical support, contact your local representative, or the EMEA TECH SUPPORT +31 455 46 77 07.

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FFR Set Up and Workflow

Adjust FFR Case Settings During a Case

Click on the triangle (▲) in the bottom left of the screen.

Re-**Equalize**, if needed

Pd/Pa Trendline shows the Pd/Pa ratio spotted

Sweep Speed adjusts the speed of the waveform update

Grid Scale sets the max pressure on the grid

Mean Pressure Period averages the pressure values over the desired number of heartbeats

CASE SETTINGS

Equalize

Zero Pd   Zero AO

Graph Settings

Pd/Pa Trend Line
On   Off

Sweep Speed
25 mm/sec

Grid Scale
0-200 mmHg

Mean Pressure Period
◄   3   ►

FFR Link

06-09-2015 11:18 AM

DFR Set Up and Workflow

DFR Workflow Checklist

Step 1: Select DFR Mode

Step 2: Open stopcock to air

Step 3: Zero Ao on AVVIGO+

Step 4: Close stopcock

Step 5: Lay the COMET™ II Pressure Guidewire flat on the table, flush wire

Step 6: Plug the COMET II Guidewire into the FFR Link
(ensure it is fully seated) and allow it to auto-zero

Step 7: Equalization Prep

+ Flush contrast out of guide catheter

+ Take needle introducer out of hemostasis valve

+ Fully close hemostasis valve

+ If damped Ao waveforms are observed, make sure guide catheter
is not deep seated and fully flushed from contrast

Step 8: Equalize Pressures

+ With the sensor just outside the guide catheter, press Equalize to
remove any offset between the aortic and distal pressure reading

Step 9: Record

+ After the wire is advanced beyond the lesion, record.
To ensure the patient is in a resting state wait 45 seconds after
administration of contrast or saline and 3 minutes after adenosine
administration before recording.

Step 10: Review

DFR Set Up and Workflow

Ensure DFR Mode is selected. You can switch between DFR, FFR, and IVUS modes.

1 Connect Bluetooth

If the FFR Link does not auto-connect, this dialog box will appear. Select the correct FFR Link from the My FFR Links box.

If the correct FFR Link does not appear, click "Find FFR Links" for additional choices.

2 Zero Aortic Pressure

When connected, the aortic pressure waveform will be present on the screen.

✛ Open IBP stopcock

✛ Click Zero Ao

✛ Close the IBP stockcock

The Ao Zeroed status indicator on the bottom left should now be checked.
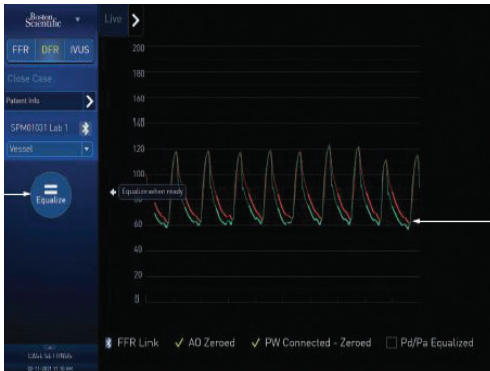

3 Connect the COMET™ II Pressure Guidewire

While the wire is in the hoop, flush the hoop and lay the COMET II Guidewire flat on the table.

With the COMET II Guidewire flat on the table, connect to the FFR Link. Allow the auto-zero process to complete before moving the wire.

Once zeroed, the distal pressure waveform will be on the screen. The PW Connected—Zeroed status indicator should now be checked.

For technical support, contact your local representative, or the EMEA TECH SUPPORT +31 455 46 77 07.
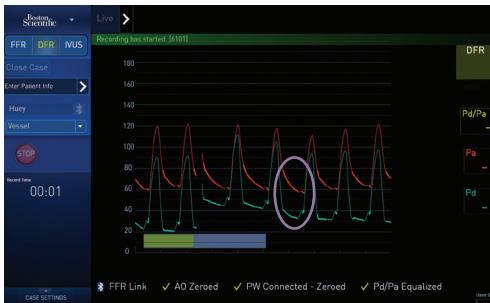
DFR Set Up and Workflow

4 Equalize Pressures

With the sensor just outside the guide catheter, press Equalize to remove any offset between the aortic and distal pressure reading.

Preparation is complete. Advance the wire distal to the lesion and you are now ready to record a run.

Equalization recommandations

+ Flush contrast out of guide catheter

+ Take needle introducer out of hemostasis valve

+ Fully close hemostasis valve

+ If damped AO waveforms are observed, make sure guide catheter is not deep seated and is fully flushed from contrast.

Area included in the calculation of DFR. A DFR recording captures 5 beats in the diastolic window.

5 Record Run

+ Press REC to start recording. AVVIGO+ will calculate a five-beat average for DFR, and when complete, return to live view. The DFR calculation can be repeated as often as desired.

+ The DFR value can be seen in the run tab at the top of the screen. Clicking on the run tab will take you to the DFR review screen.

+ If technical artifacts are detected during record, the system will exit the recording without saving the run. Press REC to start another recording

+ Note: DFR measurements are intended to be made without the administration of a hyperemic agent. Check that the patient is in a resting state.

You can choose to default to Review after Record in System Utilities. Click DFR Live / Record to capture a new run.

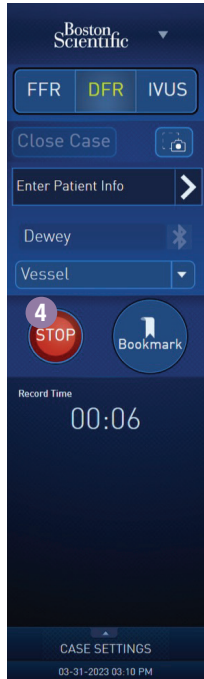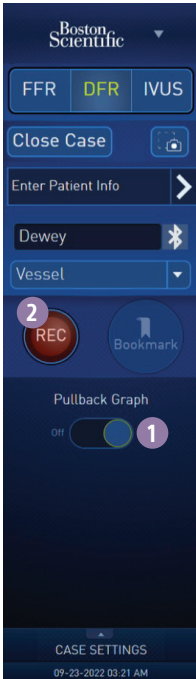# DFR Set Up and Workflow
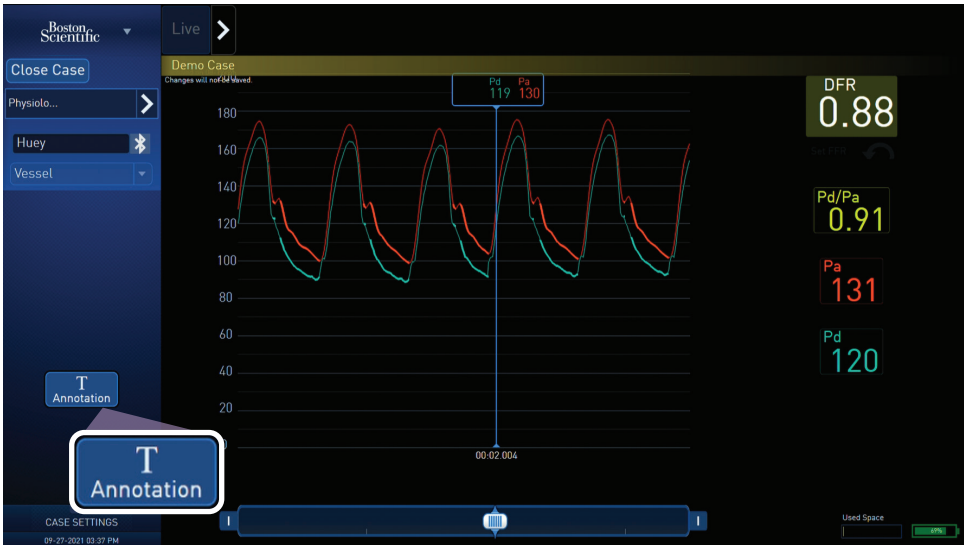
6 Review

In Review Mode, you can view the recording. The five-beat average DFR, Pd/Pa, and pressure values are shown in the upper right of the screen. Place the cursor elsewhere on the field to see average data values.

✚ Annotations may be added in Review Mode.

✚ The time scale of Physiology (FFR, DFR) recordings can be changed during review using the pinch zoom gesture.

Note: DFR does not provide all the features available with FFR, including reset values, bookmarks, SmartMinimum, or a ratio trendline

For technical support, contact your local representative, or the EMEA TECH SUPPORT +31 455 46 77 07.

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DFR Set Up and Workflow
PhysioMap™

① Turn pullback graph on

② Record

③ Perform COMET II wire pullback slowly and continuously

④ Stop recording
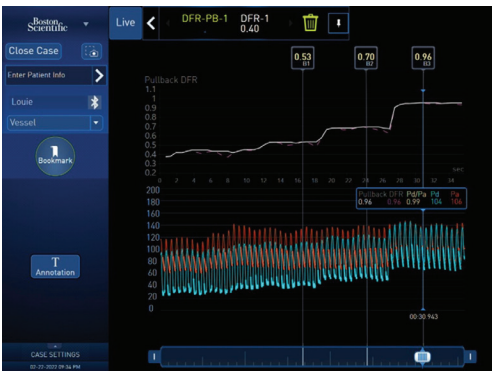
➕ In review mode, you can view the recording. The PhysioMap graph appears on the top of the screen. Place the cursor elsewhere on the field to see DFR data values.

➕ Annotations may be added in Review mode

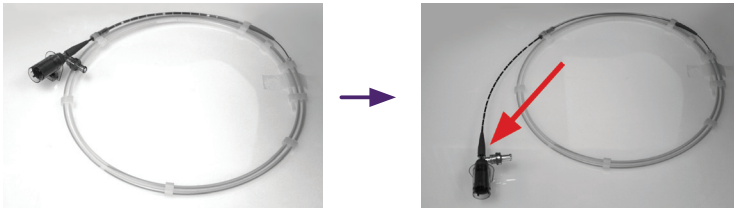➕ DFR 1 Beat trend line does not automatically archive. If it needs to be archived, take a screen capture.

IVUS Set Up and Workflow

Imaging Catheters Preparation Instructions

**1** Wet assemble the accessories (ensure air is removed from all the components)
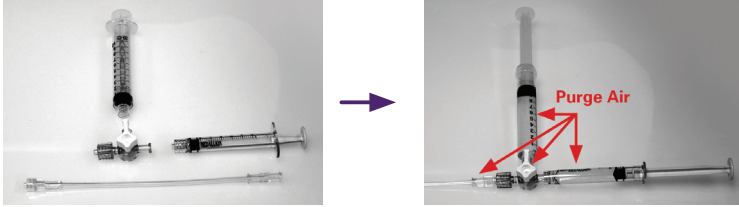
2 Fully open the telescope

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 (Optional) Connect the MDU Fast Pullback Motor Drive to the sled

6 Cover the MDU Fast Pullback Motor Drive with the sterile bag

7 Connect the Imaging Catheter to the MDU Fast Pullback Motor Drive

8 Turn on the MDU Fast Pullback Motor Drive by clicking on the Imaging button, confirm image quality, flush again if necessary
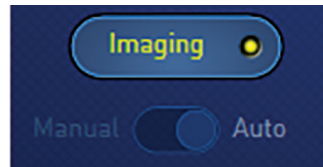
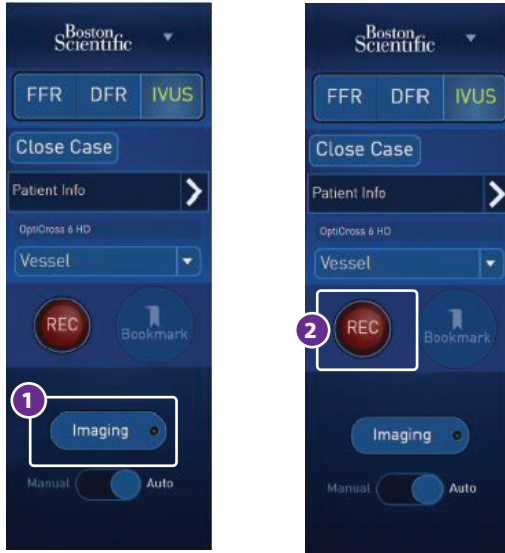**9** Close telescope

10 Turn off the MDU Fast Pullback Motor Drive by re-clicking on the Imaging button

11 Advance into patient

12 Turn on MDU to image lesion

Note: Optional to give a quick puff of saline before inserting into the body

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IVUS Set Up and Workflow
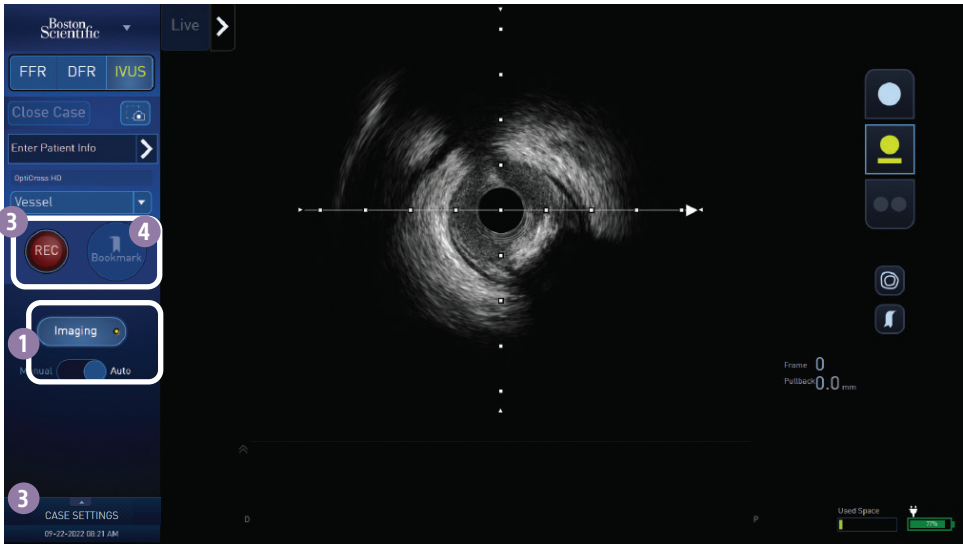
IVUS Software Workflow

① 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.

② Record New Run
- ✚ Click REC to start and stop recording.

③ Turn Imaging On
- ✚ Click IMAGING to start imaging.

IVUS Set Up and Workflow

IVUS Software Workflow

1 Turn Imaging On

➕ The pullback method is auto-selected, slide to manual to continue with manual pullback.

Click IMAGING to start imaging.

2 Case Settings

➕ If you wish to change the pullback speed, grid display, brightness, de-speckle or depth, click the triangle above "Case Settings" (details on page 29).

3 Record Image

➕ Click REC to start recording and pullback if applicable.

➕ Bookmarks can be added while recording by clicking on the Bookmark button (4).

➕ To stop recording, click the stop button.

Record New Run

Click REC to start and stop recording.

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IVUS Set Up and Workflow

IVUS Software Workflow

5 Review Image

➕ Navigate through the run with scrubber, VCR controls, mouse wheel or bookmark thumbnails.

➕ Measure area and diameter.
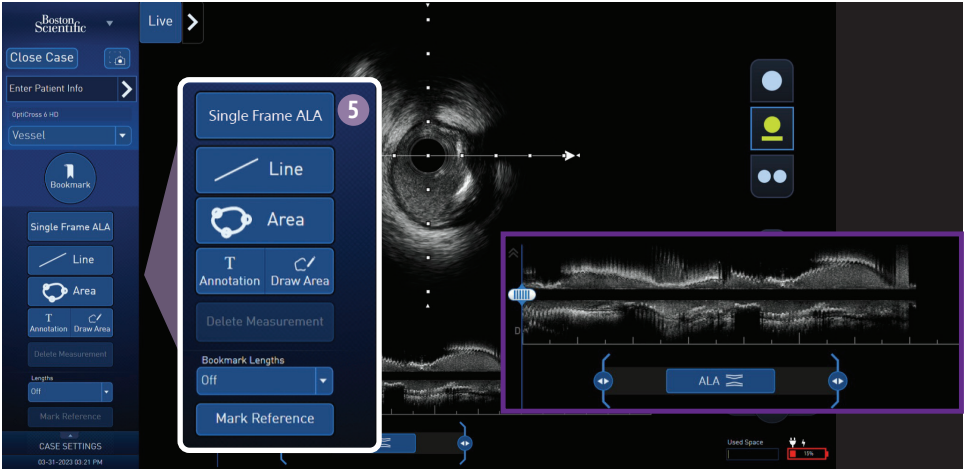
➕ Select ALA below the longview to apply Automated Lesion Assessment (ALA) to the run

➕ Lumen and Vessel borders, areas and diameters will be present on each frame in the run

➕ To edit borders: click on border, move and click again

➕ Proximal and distal key frame markers are placed at 50% or less plaque burden from the minimum frame

➕ Min frame is the minimum lumen area in the IVUS run

➕ Vessel Profile is the graphical representation of the average vessel and lumen diameters
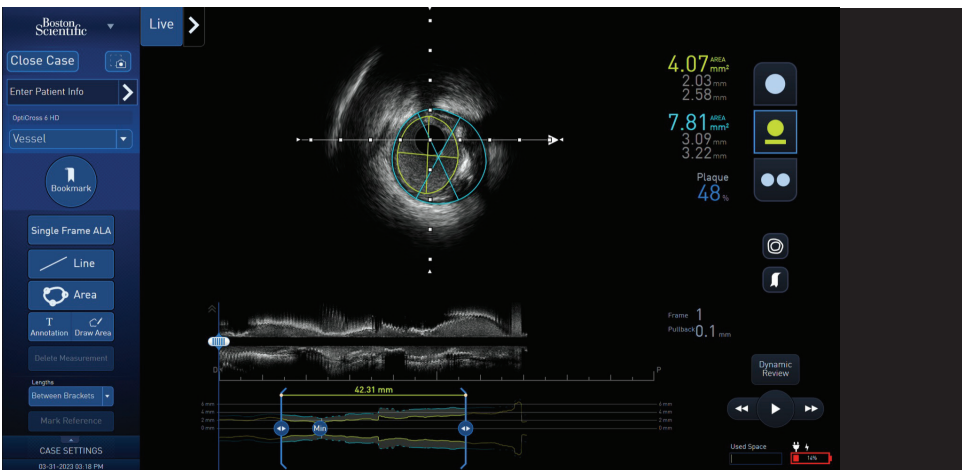
For technical support, contact your local representative, or the EMEA TECH SUPPORT +31 455 46 77 07.

Zoom Feature
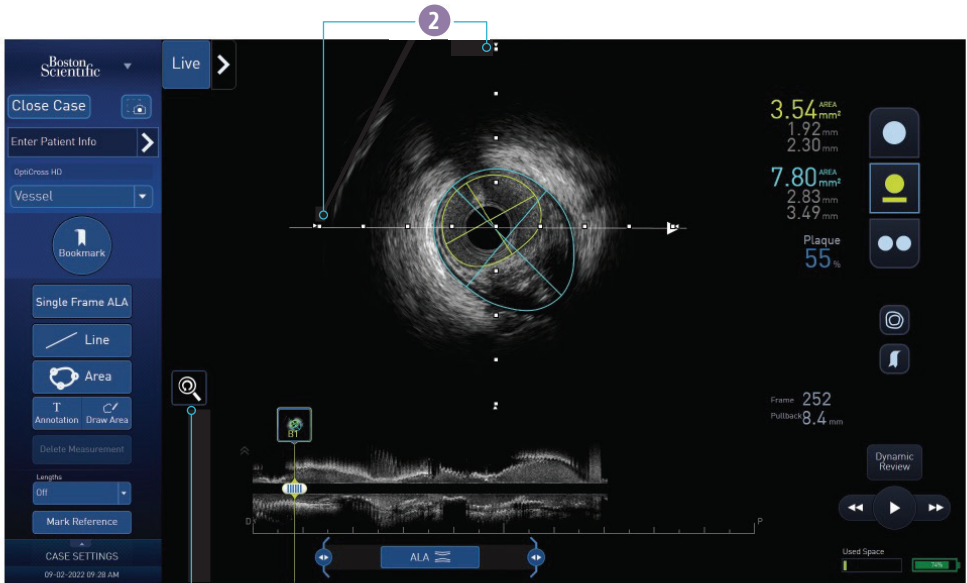
1 Reset Zoom/Pan/Rotate

2 Compass Points

- ✚ IVUS Images can be enlarged on the screen using the "Zoom" functionality of the system.

- ✚ The Zoom function is available at any time during Live Imaging, Recording, and Review.

- ✚ The Zoom function can be utilized using the mouse or using gestures while interacting with the tablet and tableside control touchscreens.

- ✚ Use two fingers on the IVUS cross-sectional image to manipulate the IVUS Image. Pinch to Zoom or two-finger drag to pan and rotate the image.

- ✚ Use the mouse wheel to zoom while hovering over the IVUS image. Use the middle button drag to pan the IVUS image.

- ✚ Note: Annotations and measurements maintain consistent scale while utilizing the zoom feature, the grid marks are always spaced at 1 mm intervals.

- ✚ Select the Reset Zoom icon to return the image to the default size and position.

IVUS Set Up and Workflow

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, grid display, and pullback speed.

Image Adjustment

De-Speckle

Depth
(Cannot be adjusted once the recording has started)

Brightness

Grid display

Pullback speed

CASE SETTINGS

Image Adjustment

De-Speckle

Default

Depth

◄ 9.50 ►

Brightness

◄ 5 ►

Grid display

On   Off

Recording Settings

Pullback speed

0.5 mm/sec

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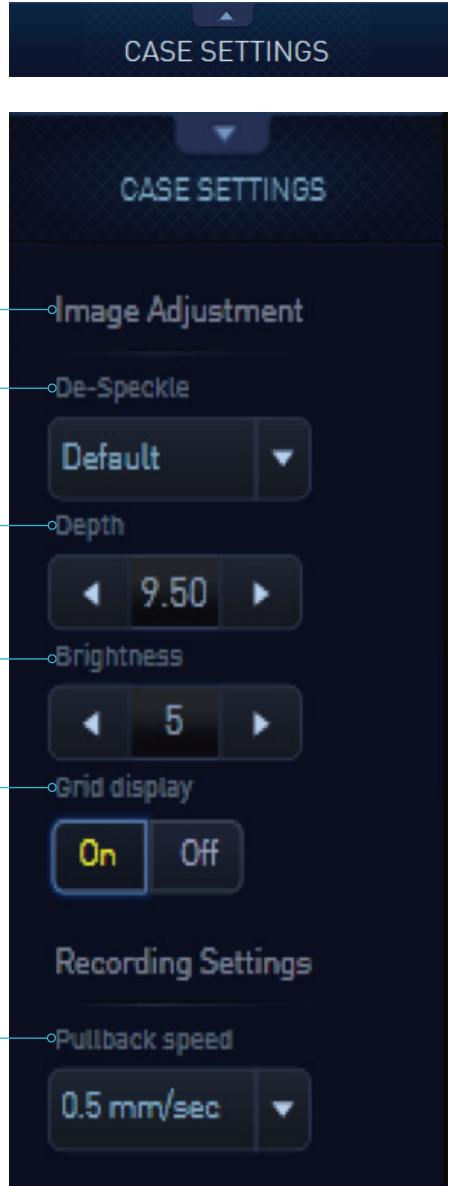
Tableside Control Display

Powering on and off the Tableside Control Display

+ The Tableside Control display should automatically power on when the Isolation Transformer is powered on.

+ If the Tableside Control display does not automatically turn on or is inadvertently powered off, use the power button that is located in the back of the Tableside Control display touchscreen monitor

+ The Tableside Control display should automatically power off when the Isolation Transformer is turned off.

+ If the Tableside Control display does not automatically turn off or is inadvertently powered on, use the power button to turn off.

+ Steps to attach and detach the tableside control assembly to the patient table:

    + Loosen /unscrew the knobs beneath the bracket assembly until the clamp opening is large enough to fits onto the patient table rail.

    + Position the bracket clamp onto the patient table rail and tighten /screw the knobs until secure.

    + To detach the tableside control bracket assembly, loosen /unscrew knobs until the assembly is able to be removed from the rail.

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Tips to Operate Tableside Control

When using the touchscreen in the sterile environment (draped and user gloved) follow these instructions to ensure successful operation:

+ Keep fingers from being too wet (damp fingers are acceptable but, remove excess water with sterile towel).

+ While using the touchscreen, it is recommended to move the draping with the screen for accurate feedback.

+ Adjust the drape around the touchscreen if screen view is obscured with unwanted liquid materials.

+ Wipe off touchscreen with a sterile towel if there is a large quantity of liquid present.

+ If unwanted actions are detected, wipe off the touchscreen with a sterile towel.

1. Secondary Display
2. FFR Link
3. Tableside Control
4. Acquisition Processor located either behind the monitor or on the floor
5. MDU Fast Pullback Motor Drive & Permanent Sled
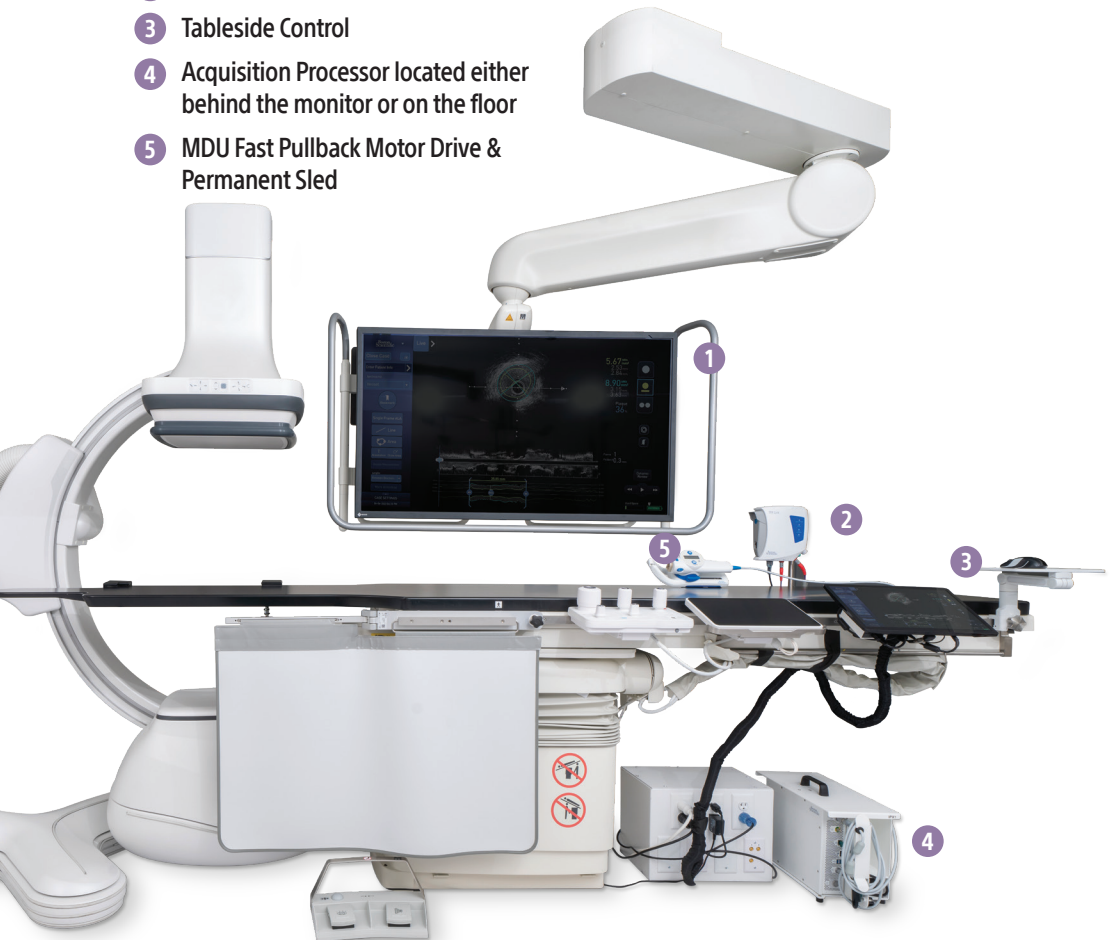
For technical support, contact your local representative, or the EMEA TECH SUPPORT +31 455 46 77 07.

Tips and Troubleshooting

FFR Link LED Summary

LED	Color	Indication When Lit or Blinking
Power	Red	The FFR Link has been powered on and is initializing.
	Blinking Red	The FFR Link has begun its self-test.
	Green	The FFR Link has passed its self-test and is in standby mode.
	Solid Red for more than 10 seconds	The FFR Link has failed its self-test.
Zeroed	Blinking Green	The wire has been detected and the zeroing process is initiated.
	Blinking Red	The wire has been detected but the zeroing process has failed.
	Red	The wire has been detected but the RFID verification has failed.
	Green	The wire has been successfully zeroed and the FFR Link is outputting a Pd signal.
Signal Strength	Yellow	The strength of the Pd signal is poor.
	Green	The strength of the Pd signal is good.
Bluetooth Connected	Blue	Bluetooth connection to the AVVIGO+ software is established.
	Blinking blue (LED blinks 5x, then reverts to solid blue)	The FFR Link has received an "identify" command from the AVVIGO+ software.

Tips and Troubleshooting

Why does drift occur?

✚ Drift occurs when there are imperfect conditions at time of equalization or when conditions are different at equalization than at drift check.

What should be done if drift is experienced?

✚ Re-equalize

What are the common causes of procedural drift?

✚ Wedging guide in ostium

✚ Needle in hemostasis valve and/or hemostasis valve is not fully closed.

✚ Contrast in the guide catheter

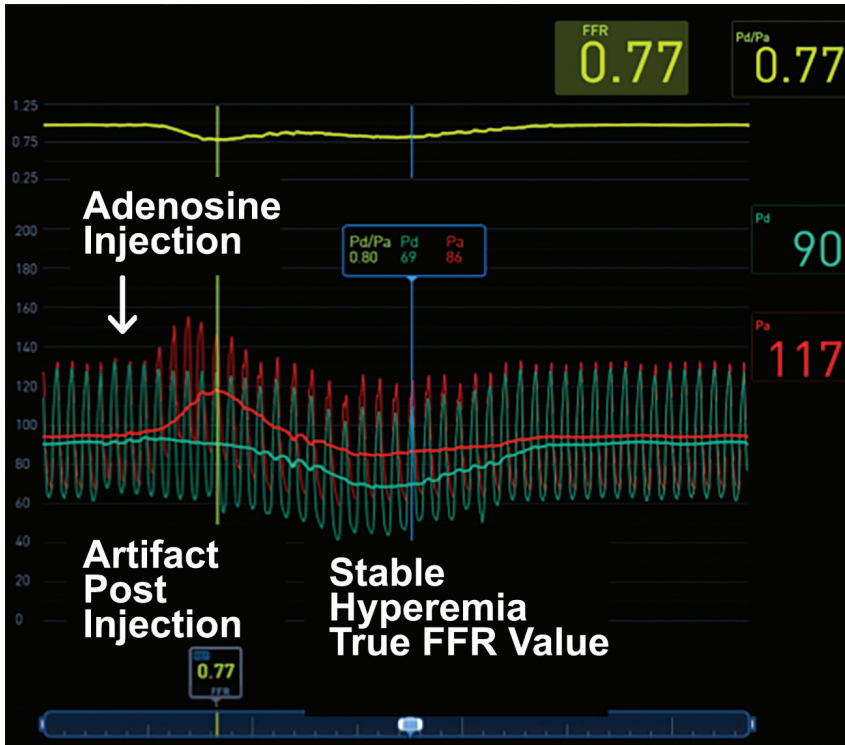✚ Moving the height of the Ao transducer

False FFR (wedged guide)

True FFR (disengaged guide)

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Tips and Troubleshooting

How to mitigate contrast issue

Contrast should be flushed at equalization, during FFR measurement, and at drift check.

Pa affected by flushing IC Adenosine

+ IC Adenosine bolus can increase Pa and cause an artificially low FFR value

+ It is important to review the recording and locate the region of stable hyperemia to determine the true FFR value

The Effect of Pd sensor being below the Pa sensor

+ When wiring a vessel with no stenosis, the FFR value may be above 1.0 since the sensor is below where it was equalized.

+ There is approximately 2 mmHg difference per 1 inch change in height. This may be evident in healthy vessels

Tips and Troubleshooting

The IVUS image displayed on screen is very dark

➕ Flush the catheter to eliminate air bubbles
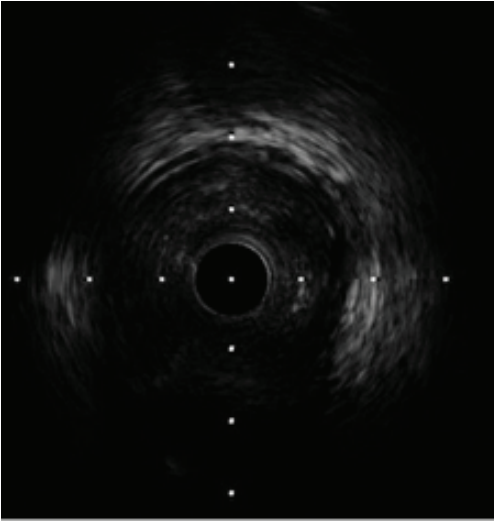
Dark image caused by air bubbles

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 MDU Fast pullback Motor Drive is all the way to the left before starting pullback and start over.

Software issues are interrupting the IVUS workflow

➕ Reboot the system. If problem persists, call your local representative or the EMEA TECH SUPPORT at +31 455 46 77 07

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

➕ Manual (pulling back on telescope) = 15 cm

➕ Auto (using pullback sled) = 10 cm

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Noise/Interference

What is Noise/Interference?

+ A random appearance of certain image patterns that does not originate from the vessel/anatomy

Why does Noise/Interference happen?

+ There are a number of electronic equipment running in a cath lab and it is possible that the system will receive some interference signals from this equipment

How does the system address Noise/Interference?

+ The default system imaging configuration is designed to provide noise suppression

+ There are also specific imaging settings that provide additional noise suppression ––– Noise reduction mode

Are there any downsides to using Noise Reduction mode?

+ Noise reduction mode helps to reduce noise but makes the image less crisp and sometimes lowers definition

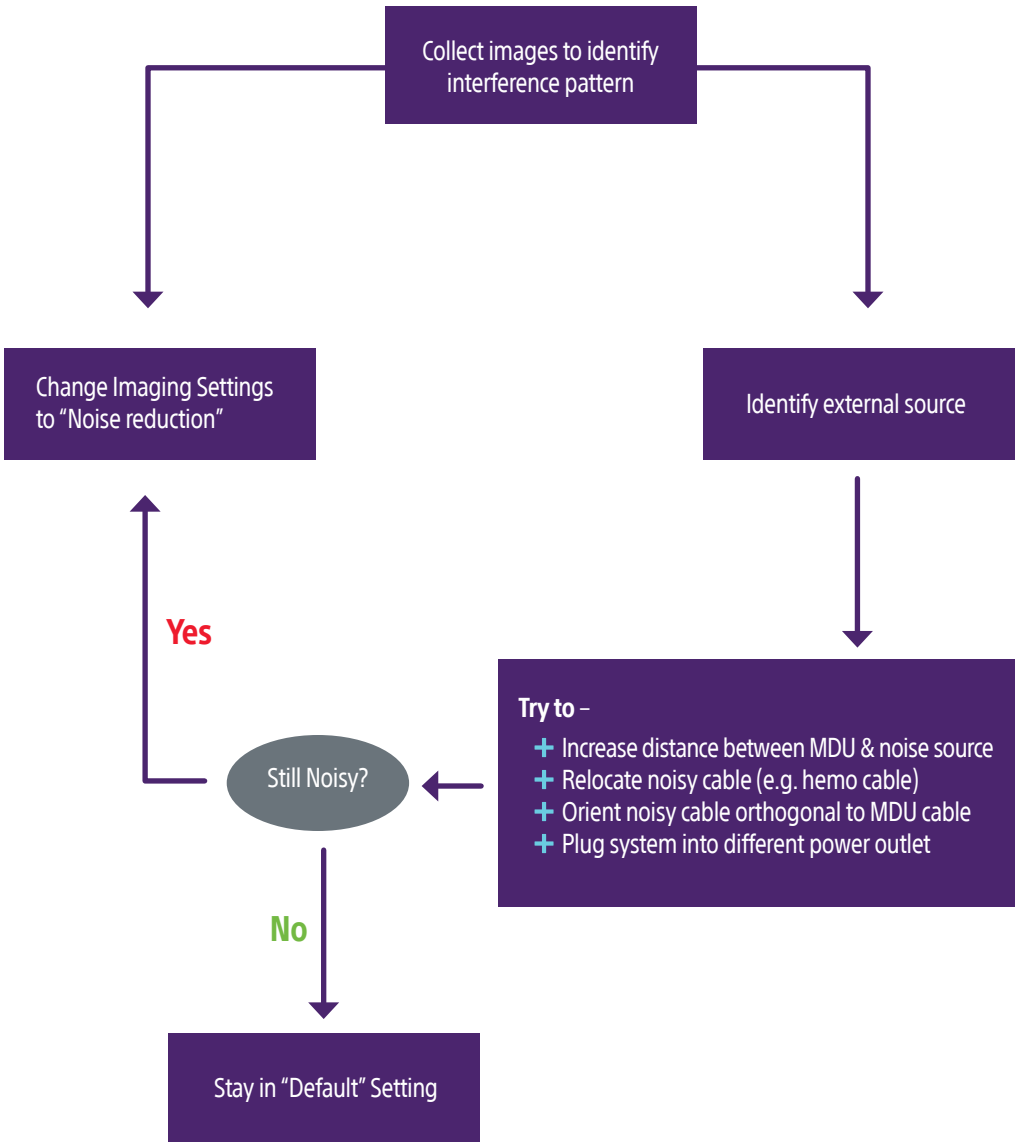+ However, this is not significant enough to cause a big difference and is usually recommended

How often will Noise/Interference be visible on an image?

+ In most cases noise will not be visible due to the noise suppression algorithm in the default imaging configuration

+ Depending on the strength of a noise signal and/or some customization of the imaging configuration, noise interference may become visible

Is there any difference in Noise/Interference between the 40mhz & 60mhz catheters?

+ Due to the wider bandwidth transducer and nature of the 60mhz frequency, the OCHD is more subject to noise interference

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Approaches to resolve Noise/Interference

Collect images to identify interference pattern

Change Imaging Settings to "Noise reduction"

Identify external source

Yes

Still Noisy?

Try to –
+ Increase distance between MDU & noise source
+ Relocate noisy cable (e.g. hemo cable)
+ Orient noisy cable orthogonal to MDU cable
+ Plug system into different power outlet

No

Stay in "Default" Setting

**Confirm visible noise patterns using multiple catheters when system settings = default settings

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