Boston Scientific
Advancing science for life™

AVVIGO™
Guidance System II

A New Era in Every Lab

The AVVIGO Guidance System II offers the game-changing performance of the COMET™ II Pressure Guidewire along with high-definition IVUS using the OPTICROSS™ HD Imaging Catheter, all in a flexible platform.

A streamlined multi-modality guidance system platform.

AVVIGO Guidance System II Mobile Platform with Tablet

High-Performance Product Portfolio

- A full suite of high-definition IVUS imaging catheters and a true workhorse pressure guidewire offer best-in-class deliverability.

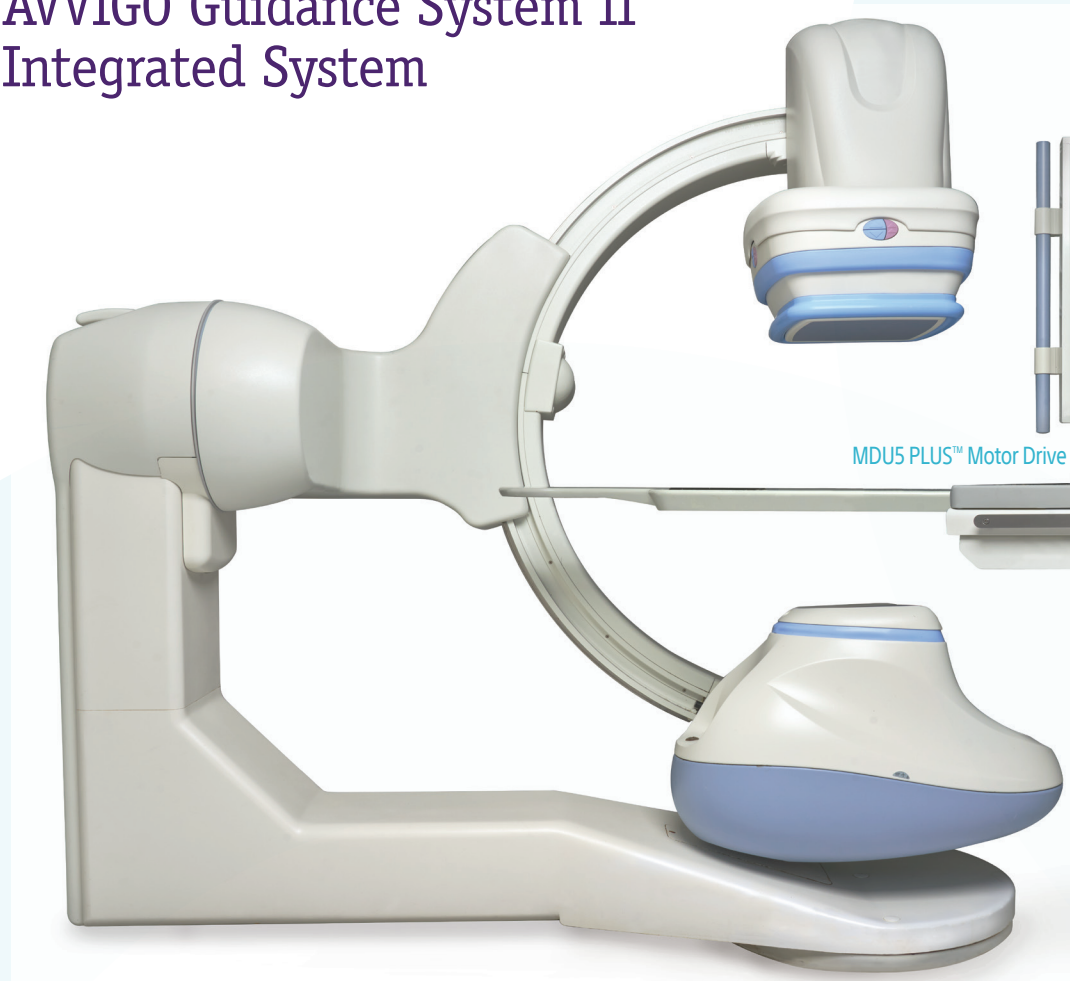
Intuitive Software

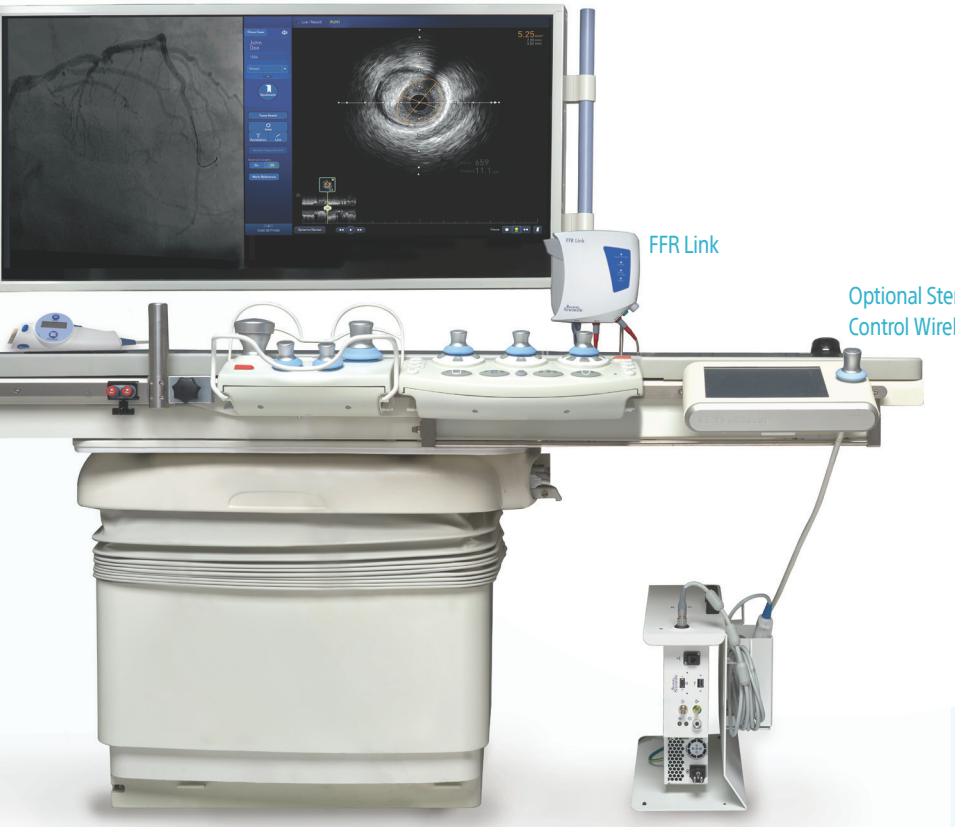
- User friendly software features an easy workflow and specialized tools for IVUS and coronary physiology.

Flexible Integration

- Fully integrated and mobile options available to fit seamlessly in any lab.

AVVIGO Guidance System II Integrated System




FFR Link
Optional Sterile Field
Control Wireless Mouse
Acquisition PC with Floor Mount

COMET™ II Pressure Guidewire:
Total Confidence in Your Treatment Decision.

Deliverability
- Shapeable and atraumatic Asahi tip
- Precision cut body for 1:1 torque

Accuracy
- Optical technology for exceptional drift performance and reliable signal connection

Usability
- Optimized rail support for device delivery
- Free-spinning, quick-release handle
- One wire for the entire procedure

ASAHI TECHNOLOGY

OPTICROSS™ HD Imaging Catheter: Visualize better outcomes with IVUS.

OPTICROSS™ HD
60 MHz Coronary Imaging Catheter

Advanced 60 Mhz Composite Transducer

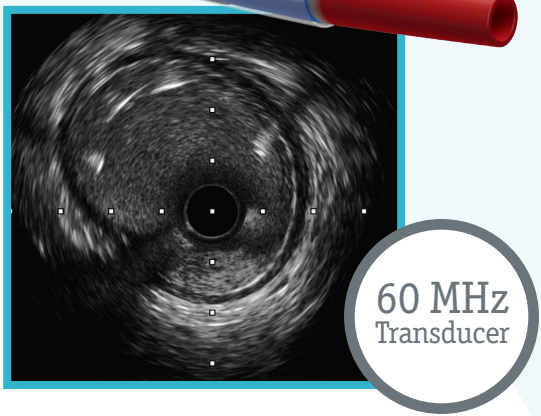
- Precise image with 6 mm depth for small to large vessel assessment

Exceptional Deliverability

- Well-balanced engineering design

5F And 6F Compatible

- Assist in more cases



Advanced Software Features

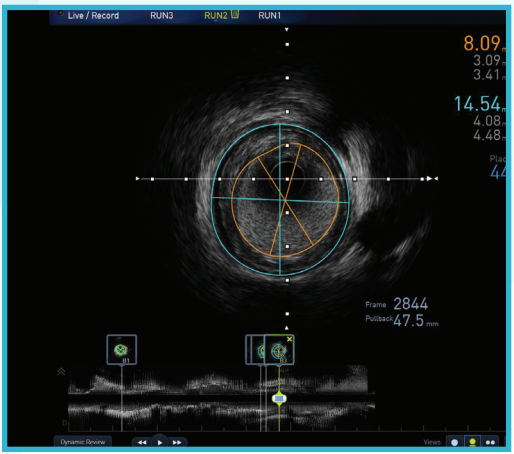
- DFR calculates a diastolic portion of the cardiac cycle at rest. DFR uses a cutoff of 0.89 and is numerically equivalent to iFR. The DFR window uses two criteria: Pd < mean Pa and down-sloping Pa. No ECG signal is required.
- smFFR automatically excludes certain artifacts (e.g., flushing, opening AO stopcock or hemostasis valve, pulling out guidewire during recording) to latch to the true FFR value.

DFR

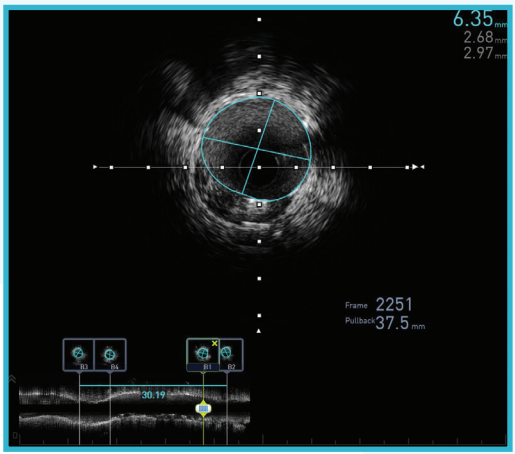
smFFR

- An aid to automatically draw lumen and vessel borders.
- IVUS LongView provides a user the ability to guide PCI with length measurements and visualization of bifurcations.

Trace Assist™



LongView™



Ordering Information

The AVVIGO Guidance System II provides digital IVUS imaging for coronary, peripheral and intracardiac applications.

Description	Ref/Catalog Number	GTIN
AVVIGO™ Guidance System II Mobile Cart System	H749 **009881C** 0	00191506015152
AVVIGO Guidance System II Integrated System	H749 **009881I** 0	00191506015183
FFR Link	H749 **555100** 0	08714729890010
COMET II Pressure Guidewire	H749 **3935911** 0	08714729960140
OPTICROSS HD Imaging Catheter	H749 **3935204** 0	08714729960737
OPTICROSS 6 HD Imaging Catheter	H749 **3935408** 0	08714729960775
OPTICROSS Imaging Catheter	H749 **51811** 0	08714729847878
OPTICROSS 6 Imaging Catheter	H749 **51811**6 0	08714729904762
OPTICROSS 18 Imaging Catheter	H749 **393280018** 0	08714729904266
OPTICROSS 35 Imaging Catheter	H749 **393280035** 0	08714729984542
ULTRA ICE PLUS Imaging Catheter	M004 **9912** 0	08714729904380
Automatic Pullback Sled	H749 **A7020** 0	08714729339328
MDU5+ Motor Drive	H749 **MDU5PLUS** 0	08714729842279
MDU5+ Sterile Bag	H749 **MDU5PLUSBAG** 0	08714729842255


POWERTRONIX
Isolation Station
Boston Scientific

FFR LINK: INTENDED USE/INDICATIONS FOR USE The FFR Link is intended to condition physiological signals from measuring devices (BSC Pressure Guidewire or an external pressure transducer), transmit and receive via radiofrequency, and recondition the signals so they can be displayed on and/or recorded in a receiving device (iLab™ POLARIS Multi-Modality Guidance System or other monitoring device). The physiological signals can also be distributed by cable. **CONTRAINDICATIONS** The FFR link has no patient alarm functions and should not be used for cardiac monitoring. **WARNINGS AND PRECAUTIONS** Use only a Boston Scientific Comet™ Pressure Guidewire or other Boston Scientific pressure guidewire with the FFR Link. Use of pressure guidewires from other manufacturers will provide inaccurate pressure readings. The FFR link maintains a floating double-insulated patient isolation connection. This connection is intended for defibrillator-proof direct cardiac application (type CF), and includes circuitry to limit the patient leakage current to the levels specified in UL2601-1, EN60601-1, and JIS-T-060101.

COMET II Pressure Guidewire: INTENDED USE/INDICATIONS FOR USE The Comet II Pressure Guidewire measures blood pressure gradient across coronary and peripheral lesions during endovascular procedures. FFR (Fractional Flow Reserve) pressure guidewire may also be used as a coronary or peripheral guidewire for interventional treatments. The Comet II Pressure Guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels. **CONTRAINDICATIONS** The Comet II Pressure Guidewire is contraindicated for use in the cerebral vasculature. **WARNINGS** • Resulting pressure guidewire fractures/separations might require additional percutaneous intervention or surgery. • Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated. • Severe reaction may occur in response to contrast agents that cannot be adequately premedicated. **PRECAUTIONS** Maintain diligent control of the distal tip at all times during an intervention to avoid vessel dissections and perforations. Wire damage may occur when the pressure guidewire is manipulated in a sharp bend, such as that caused by incomplete coaxial alignment of the delivery catheter and ostium, creating a sharp bend of the pressure guidewire between the delivery catheter and the vessel wall. Sharp bends are more likely to occur when using a less supportive delivery catheter, such as a diagnostic catheter. When crossing a stent, exercise care to avoid entanglement between the pressure guidewire and the stent. Avoid abrasion of the pressure guidewire coating. - To avoid damage to the hydrophilic coating, do not withdraw or manipulate the pressure guidewire in a metal cannula or sharp object. - Excessive tightening of the torque device onto the pressure guidewire may result in abrasion of the coating on the pressure guidewire. Use only the optical cable provided to connect the pressure guidewire to FFR Link. Use of a different optical cable will produce inaccurate pressure readings. The accuracy of the diagnostic information is affected by, but not limited to: - Failure to achieve maximum coronary and myocardial hyperemia if using FFR (Fractional Flow Reserve) modality. - Interventional devices, such as balloon catheters, which are positioned so as to affect the blood flow or guidewires that stretch the vessel. - Pressure wire positioning relative to the lesion. - Microvascular resistance. Carefully check and match therapeutic device compatibility to the pressure guidewire prior to use. Do not use the pressure guidewire in conjunction with atherectomy catheters. **ADVERSE EVENTS** Potential adverse events which may result fromа the use of the device include but are not limited to: • Abrupt closure • Allergic reaction • Embolism • Exposure to biohazardous material • Infection • Prolonged procedure • Restenosis (reocclusion) • Spasm • Stroke/cerebral vascular accident (CVA)/transient ischemic attack (TIA) • Vascular thrombus • Vessel trauma (dissection, perforation, rupture or injury) In addition, when used for interventional procedures: • Angina or unstable angina • Arrhythmias • Cardiac tamponade/pericardial effusion • Contrast induced renal insufficiency or renal failure • Death • Myocardial infarction or ischemia Some of the above potential adverse events may require additional surgical intervention. **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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
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OPTICROSS™ HD, 6 HD 60 MHz Coronary Imaging Catheters and MDU5 PLUS™ Sterile Bag INTENDED USE/INDICATIONS FOR USE: OPTICROSS HD, 6 HD: This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures. **MDU5 PLUS STERILE BAG:** The MDU5 PLUS Sterile Bag is intended to cover the motor drive 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 imaging catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety. The contraindications also include the following: • Bacteremia or sepsis • Major coagulation system abnormalities • Patients diagnosed with coronary artery spasm • Patients disqualified for CABG surgery • Patients disqualified for PTCA • Severe hemodynamic instability or shock • Use of the imaging catheter to cross a total occlusion **WARNINGS:** • Intravascular ultrasound examination of coronary anatomy should be performed only by physicians fully trained in interventional cardiology or 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 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 position 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 • Angina • Cardiac arrest • Cardiac arrhythmias including, but not limited to ventricular tachycardia, atrial/ventricular fibrillation and complete heart block • Cardiac tamponade/Pericardial effusion • Death • Device entrapment requiring surgical intervention • Embolism (air, foreign body, tissue or thrombus) • Hemorrhage/Hematoma • Hypotension • Infection • Myocardial infarction • Myocardial Ischemia • Stroke and Transient Ischemic Attack • Thrombosis • Vessel occlusion and abrupt dosure • Vessel trauma including, but not limited to dissection and perforation 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.
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AVVIGO II Indications for System Use The IVUS modality of the System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy. FFR and DFR are intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. FFR and DFR are indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters. Refer to the Catheter Instructions for Use provided with all Boston Scientific Ultrasound Imaging Catheters to determine compatibility with the System. All Ultrasound Imaging Catheters will be referred to as Imaging Catheters throughout the remainder of this User Guide. The Imaging Catheters genaerate ultrasound images and are intended for ultrasound examination of vascular and cardiac pathology. Boston Scientific manufactures a wide variety of catheters for different applications. The recommended use of each of these catheters may vary depending on the size and type of the catheter. Please refer to the Imaging Catheter Instructions for Use, packaged with each catheter. **Indications for Auto Pullback Use (IVUS Only)** Automatic Pullback is indicated when the following occurs: • The physician/operator wants to standardize the method in which intravascular ultrasound images are obtained and documented: procedure-to-procedaure, operator-to-operator. • The physician/operator wants to make linear distance determinations post-procedurally, which requires the imaging core of a catheter to be pulled back at a known uniform speed. • Two-dimensional, longitudinal reconstruction of the anatomy is desired. **CONTRAINDICATIONS** The System has no patient alarm functions and should not be used for cardiac monitoring. Consult the Imaging Catheter, Guidewire, FFR LINK, Motordrive Unit, and the Sled Instructions for Use for a complete list of Contraindications, Adverse Events, Warnings and Precautions. **WARNINGS** Carefully read all instructions prior to use. Observe all indications, contraindications, warnings, and precautions noted in these directions before attempting to use the AVVIGO System. • The System can only be used with Boston Scientific specified accessories, imaging catheters, pressure guidewires and cables. The use of accessories and cables other than the items provided by Boston Scientific may result in increased emission or decreased immunity of the System. For questions regarding this matter, please contact Boston Scientific for technical assistance. • In an emergency, cut off the main electric supply to the System by switching the power OFF on the Isolation Station. • The System is not intended for use in the sterile field. • Only Use the HDMI-DVI cable provided with the system for duplicating display. Use of a different cable could result in increased electromagnetic emissions. **PRECAUTIONS** • In case of abnormal System operation, the System may require shutdown and restart to bring it to normal operation. Follow the normal shutdown and startup procedures listed in the Operating Instructions. • If an Imaging Catheter that has not been approved for use with the System is connected, or if an Imaging Catheter is not properly connected, the corresponding Imaging Catheter identification data and Displayed Depth will not be displayed. Imaging will be disabled. Resolve this issue before continuing use. **ADVERSE EVENTS** Please consult the Imaging Catheter and Pressure Guidewire Instructions for Use.
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