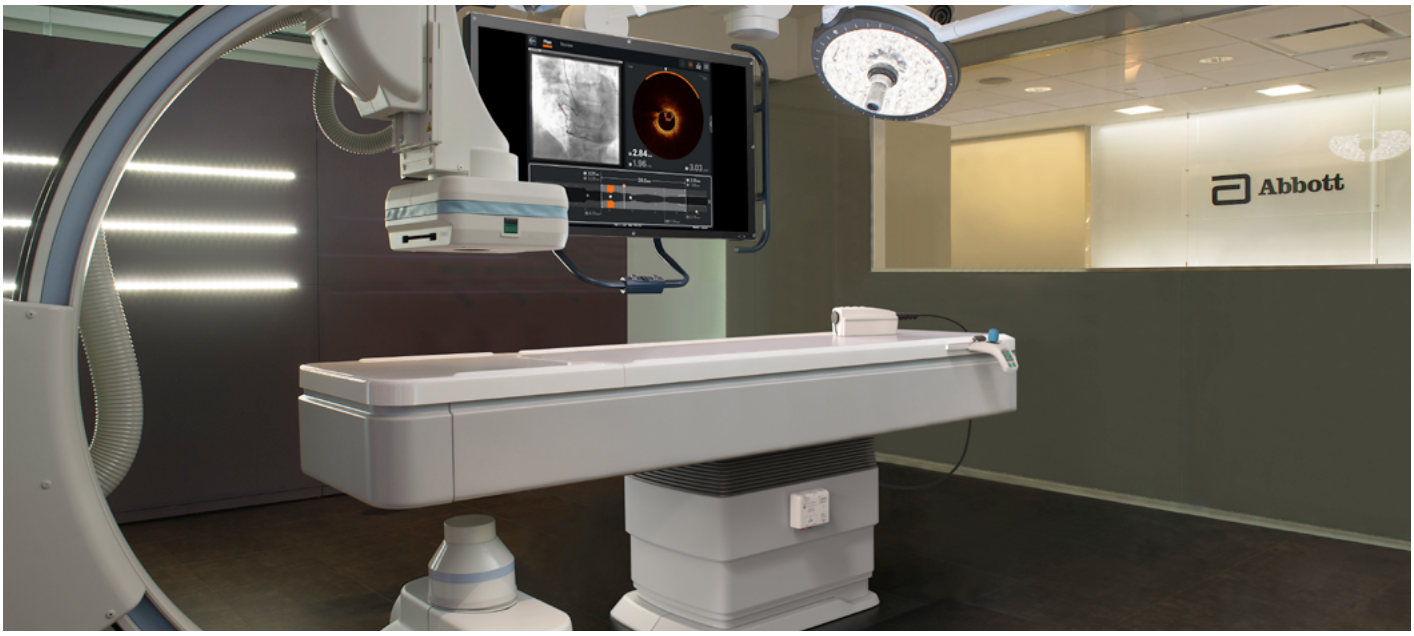
OPTIS™
Integrated Next Imaging System

THE OPTIS™ INTEGRATED NEXT IMAGING SYSTEM is always on and always ready to perform intravascular imaging and coronary physiology. With the Ultreon™ 2.0 Software, this powerful OCT imaging system provides you with actionable OCT and angiographic insights to enable PCI procedural efficiencies and better outcomes.[1-5]



PRODUCT FEATURES

- High-powered processors supporting artificial intelligence (AI) technology for faster information display and workflow efficiency
- Wireless tableside controller (TSC) for full control of image acquisition and analysis at the bedside
- OCT with FFR/RFR are immediately available during percutaneous coronary intervention (PCI)
- Seamless and secure integration with cath lab IT system and DICOM
- Compatible with Dragonfly OpStar™ Imaging Catheter, Dragonfly™ OPTIS™ Imaging Catheter

Control Room **Technical Room**

1. Hong, SJ., et al., on behalf of the IVUS-XPL Investigators. Effect of Intravascular Ultrasound–Guided vs Angiography-Guided Everolimus-Eluting Stent Implantation: The IVUS-XPL Randomized Clinical Trial. *JAMA* 2015;314:2155-63. 2. Zhang, J., et al. Intravascular ultrasound versus angiography-guided drug-eluting stent implantation: the ULTIMATE trial. *J Am Coll Cardiol*. 2018;72(24):3126-3137. 3. Lee, JM., et al., on behalf of the RENOVATE-COMPLEX-PCI Investigators. Intravascular Imaging–Guided or Angiography-Guided Complex PCI. *N Engl J Med* 2023;Mar 5. 4. Truesdell, AG., et al., Intravascular Imaging During Percutaneous Coronary Intervention: JACC State-of-the-Art Review. *J Am Coll Cardiol*. 2023;81(6):590-605. doi:10.1016/j.jacc.2022.11.045, 2023 ACC/AHA/SCAI Advanced Training Statement on Interventional Cardiology (Coronary, Peripheral Vascular, and Structural Heart Interventions): A Report of the ACC Competency Management Committee | *Circulation: Cardiovascular Interventions* (ahajournals.org). 5. West, DM., Allen, JR., How Artificial Intelligence is Transforming the World, 4/19/2023, https://www.brookings.edu/research/how-artificial-intelligence-is-transforming-the-world/, page 1.

OPTIS™ Next Imaging System Instructions for Use (IFU). Refer to IFU for additional information.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of the device in areas where CE marking is not the regulation in force.

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PRODUCT COMPONENTS

System Cabinet

Wi-Box™ AO Transmitter

DOC Holster

Drive-motor and Optical Controller (DOC)

Tableside Controller

USB Extender

Video In Converter

Control Room Monitor, Keyboard, Mouse

COMPONENT	DESCRIPTION	CONNECTIONS	DIMENSIONS / WEIGHT	MISCELLANEOUS SPECIFICATIONS
System Cabinet (SC)	Contains computer PC, imaging engine and power supply Resides in control room or technical closet	Boom monitor or boom monitor video switch Control Room monitor, keyboard, mouse DOC Holster Output from angiography system DICOM‡ server	61 cm x 34 cm x 60 cm (H/W/D) 51 kg	Power Consumption: 400 VA Max Input: 100 - 240 V~ 50/60 Hz CD/DVD Drive
Tableside Controller (TSC)	Provides OCT and FFR/RFR control at tableside Clamps to table rail in procedure room	Connects to DOC Holster (Bluetooth‡ or USB)	14 cm x 9 cm x 21 cm (H/W/D) 0.7 kg	Bluetooth‡ Compatible (Requires separate power source in Bluetooth‡ configuration.) Input (Bluetooth‡ Mode): 100 - 240 V~ 50/60 Hz 0.5 A
Wi-Box™ System for FFR/RFR Optional	Provides wireless aortic pressure	Installed between the AO-transducer and hemodynamic recording system DOC Holster (wireless)	8.7 cm x 10.8 cm x 3.3 cm (H/W/D) 0.13 kg	ANSI/AAMI-BP22 compatible hemodynamic recording system
DOC Holster	Holds the DOC when not in use Interfaces the SC with the TSC, DOC, Physiology PressureWire™ X Guidewire and Wi-Box™ unit Clamps to table rail or back of monitor boom in procedure room	SC Tableside controller (Bluetooth‡ or USB) Wi-Box™ (wireless) PressureWire™ X Guidewire (wireless)	25 cm x 12 cm x 16 cm (H/W/D) 1.4 kg	N/A
Drive-motor and Optical Controller (DOC)	Drives the OCT imaging catheter	Connects to DOC Holster (Bluetooth‡ or USB) OCT Imaging Catheter	10 cm x 9 cm x 24 cm (H/W/D) 1.6 kg	N/A
Control Room Monitor, Keyboard, Mouse	Provides OPTIS™ system functionality from the control room Resides in control room	Connects to SC USB port for flash drive USB Extender	48 cm diagonal monitor 41 cm x 41 cm x 22 cm 4.0 kg	1280 x 1024 SXGA Resolution Input: 100 - 240 V~ 0.8 - 0.4 A
Remoting Cable	Resides in the floor, ceiling or wall conduit	Connects the SC to the DOC Holster at tableside	27 meters long 0.95 cm cable diameter Connector diameter 2.22 cm	The remoting cable connection to DOC Holster is rated for IP54
USB Extender	Used to connect SC to control room keyboard and mouse when SC is in the technical closet	Connects to SC Connects to control room keyboard and mouse	30 meters maximum length	Input: 100 - 240 V~ 50/60 Hz 0.4 A
DVI Extender	Used to connect SC to control room keyboard and mouse when SC is in the technical closet Can also be used to connect SC to monitor boom video interface that requires a long distance to connect	Connects to SC Connects to control room monitor or video switch	30 meters maximum	Video Out: SXGA 1280 x 1024 DVI or VGA Video In (Live Angio): Native X-ray 1024 x 1024 frame rates 15 Hz, 30 Hz Input: 100 - 240 V~ 50/60 Hz 0.3 A
Video In Converter	Used to connect SC to angiography system video output	SC Angiography system	30 meters maximum	Video In Formats: VGA, DVI-A, DVI-D, Mono-chrome BNC, RGB BNC, Mono/ Hsync/Vsync BNC Video Resolution: 1024 x 1024, 1280 x 1024, 1600 x 1200 Input: 100 - 240 V~ 50/60 Hz 0.5 A

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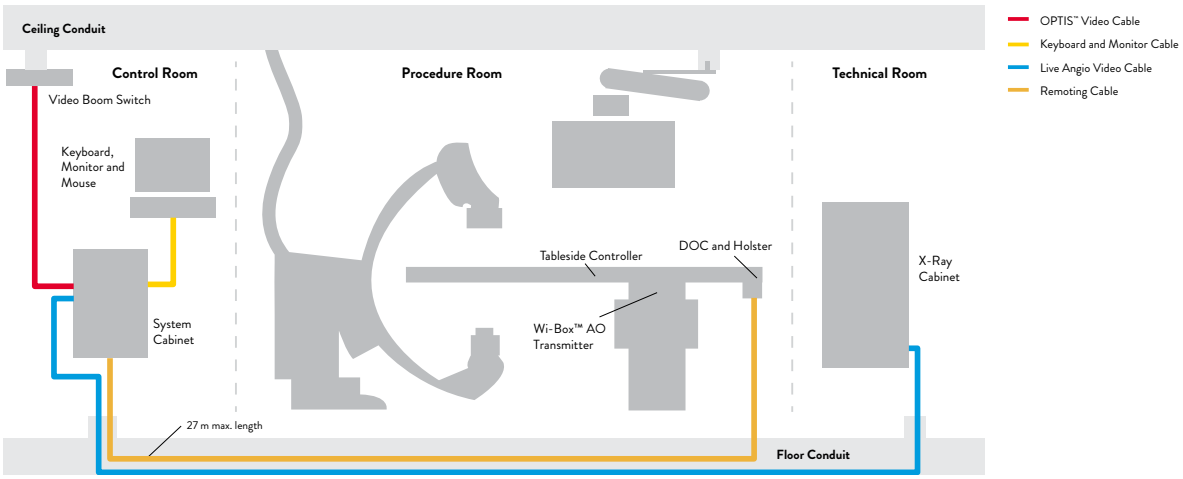
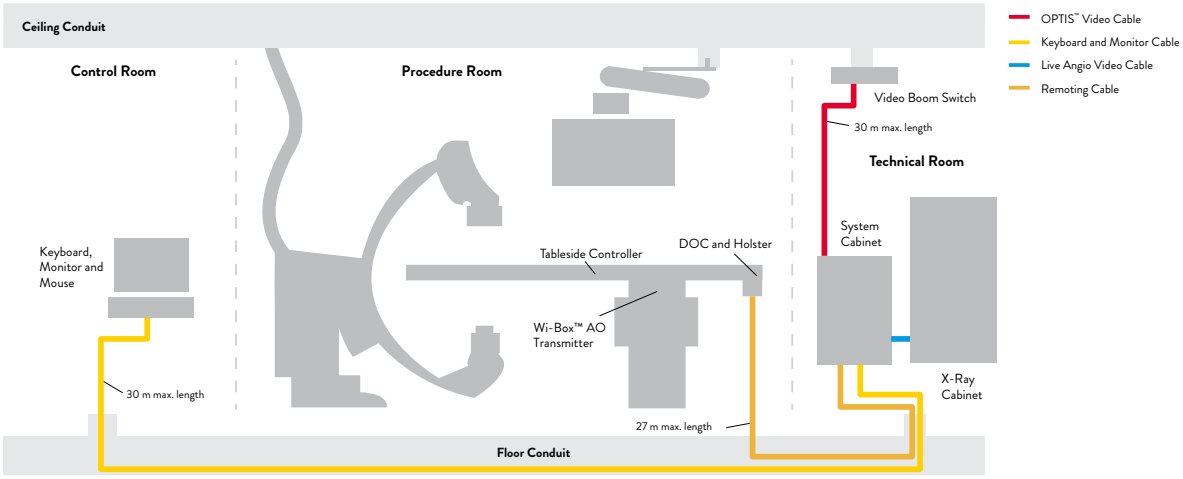
ROOM CONFIGURATIONS

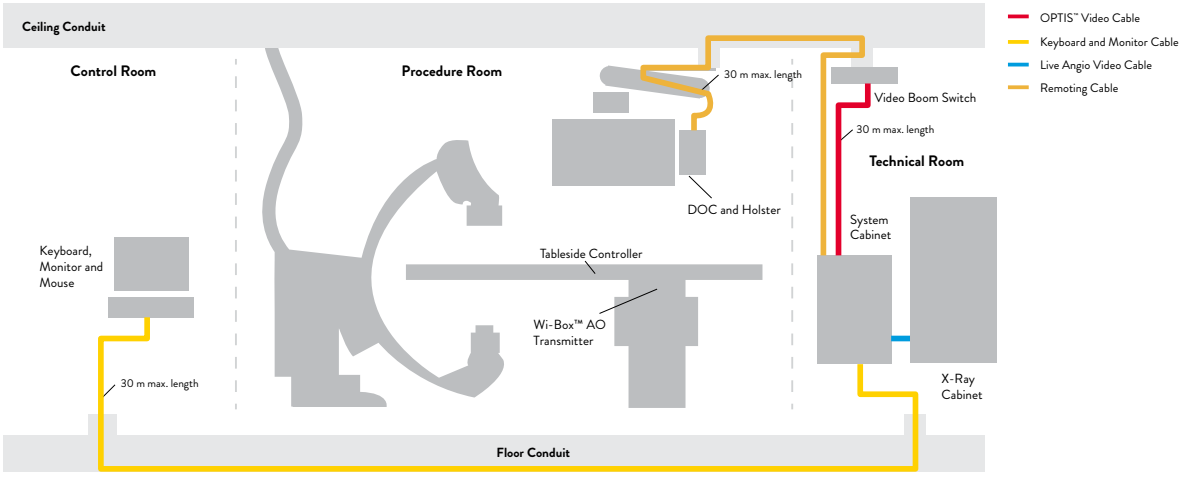
Configuration 1:
OPTIS™ Integrated Next System cabinet in control room; remoting cable in floor conduit



Configuration 2:
OPTIS™ Integrated Next System cabinet in technical closet; remoting cable in floor conduit



Configuration 3:
OPTIS™ Integrated Next System cabinet in technical closet; remoting cable in ceiling conduit (MAVIQ Boom Only)



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ORDERING INFORMATION

ORDER NUMBER	DESCRIPTION
1014933	OPTIS™ Integrated Next Imaging System
1014935	OPTIS™ Integrated Next Upgrade Kit

The OPTIS™ Integrated Next Imaging System is a customized product. Please contact your local sales representative for more information.

Data on file at Abbott.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at vascular.eifu.abbott or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

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Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Abbott International BVBA
Park Lane, Culliganlaan 2B, 1831 Diegem, Belgium, Tel: 32.2.714.14.11

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