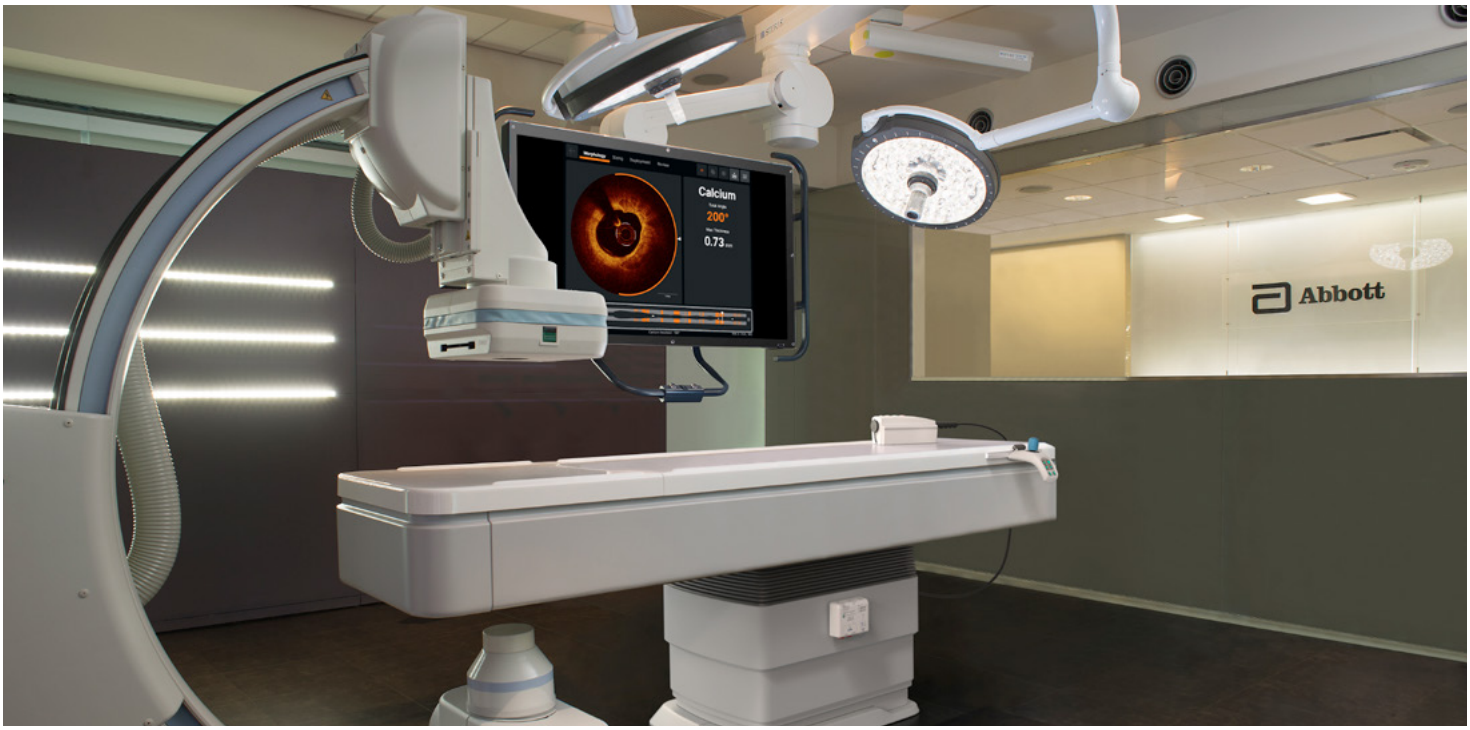
OPTIS™
Integrated Next Imaging System

THE OPTIS™ INTEGRATED NEXT IMAGING SYSTEM is always on and always ready to perform intravascular imaging and coronary physiology. With the Ultreon™ 1.0 Software, this powerful OCT imaging system is always ready to provide better insights to optimize patient outcomes through automation and an improved workflow.[1-4]



PRODUCT FEATURES

- High-powered processors supporting 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. Data on File at Abbott.
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. Hong M, et al., IVUS-XPL 5 Year Outcomes, TCT 2019.
4. Jones, et al. *JACC Cardiovascular Interventions,* 2018, vol 11 (14). "Angiography Alone Versus Angiography Plus Optical Coherence Tomography to Guide Percutaneous Coronary Intervention – Outcomes From the Pan-London PCI Cohort".

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

See Important Safety Information referenced within.

Information contained herein for DISTRIBUTION in the U.S. ONLY.

Abbott

PRODUCT COMPONENTS


System Cabinet


DOC Holster


Tableside Controller


Video In Converter


Control Room Monitor, Keyboard, Mouse


Wi-Box™ AO Transmitter


Drive-motor and Optical Controller (DOC)


USB Extender

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 TC, 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	
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	
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

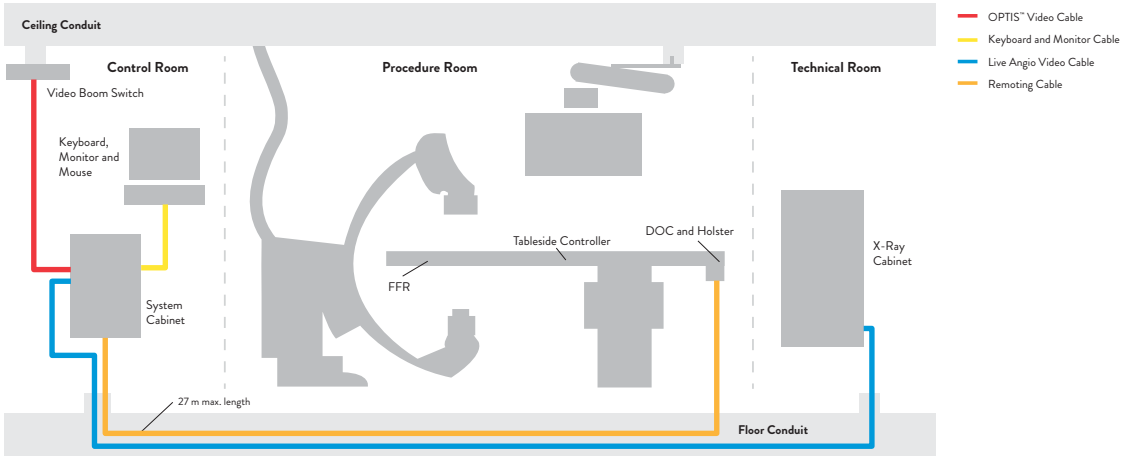
OPTIS™ Next Imaging System IFU. Refer to Instructions For Use (IFU) for additional information.

See Important Safety Information referenced within.

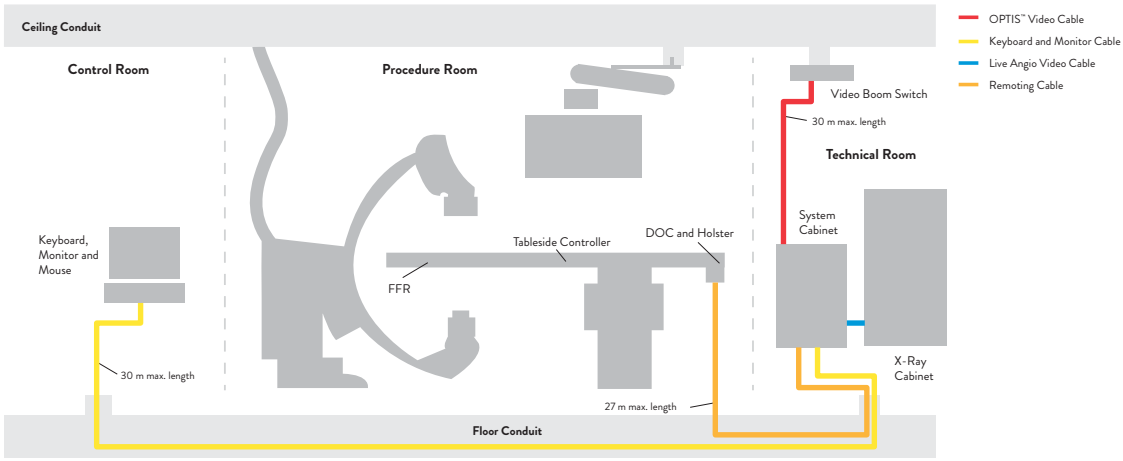
Information contained herein for DISTRIBUTION in the U.S. ONLY.

ROOM CONFIGURATIONS

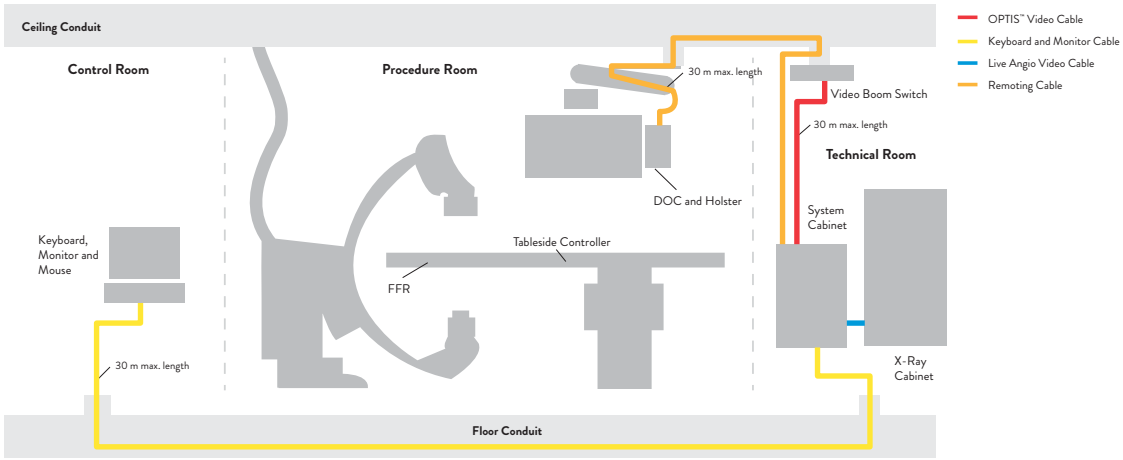
Configuration 1:
OPTIS™ Integrated Next System cabinet in control room; remoting cable in floor conduit



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)



See Important Safety Information referenced within.

Information contained herein for DISTRIBUTION in the U.S. ONLY.

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.

IMPORTANT SAFETY INFORMATION

℞ ONLY

OPTIS™ Next Imaging Systems and Software

INDICATIONS

The Ultreon™ 1.0 Software is intended to be used only with compatible OPTIS™ Next Imaging Systems. The OPTIS™ Next Imaging System with a compatible Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The OPTIS™ Next Imaging System is intended for use in the catheterization and related cardiovascular specialty laboratories and will further compute and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. The physician may use the acquired physiological parameters, along with knowledge of patient history, medical expertise, and clinical judgment to determine if therapeutic intervention is indicated.

CONTRAINDICATIONS

Use of the Ultreon™ 1.0 Software is contraindicated where introduction of any catheter would constitute a threat to patient safety.

Contraindications include:

- Bacteremia or sepsis
- Major coagulation system abnormalities
- Patients diagnosed with coronary artery spasm
- Patients disqualified for coronary artery bypass graft (CABG) surgery
- Patients disqualified for percutaneous transluminal coronary angioplasty (PTCA)
- Severe hemodynamic instability or shock
- Total occlusion
- Large thrombus
- Acute renal failure
- Inability to tolerate systemic anticoagulation is a contraindication to use of OCT for coronary imaging.
- PressureWire™ Guidewire is contraindicated for use in the cerebral vasculature.
- The system has no patient alarm functions. Do not use for cardiac monitoring.

COMPLICATIONS

The risks involved in vascular imaging include those associated with all catheterization procedures. The following complications may occur as a consequence of intravascular imaging and may necessitate additional medical treatment including surgical intervention.

- Abnormal heart rhythm or arrhythmias
- Acute myocardial infarction
- Allergic reaction to the contrast media or drug administered for the procedure
- Arterial dissection, injury, or perforation
- Bleeding
- Catheter access site reactions: sterile inflammation or granuloma
- Coronary artery spasm
- Death
- Embolism
- Myocardial ischemia
- Renal insufficiency or failure from contrast media use
- Repeat revascularization
- Thrombus formation, abrupt closure, or total occlusion
- Tissue necrosis
- Unstable angina
- Hypotension

WARNINGS

- Refer to the contrast media Instructions for Use for general warnings and precautions relating to use of contrast media.
- The heart rate and mean pressure values shown on the OPTIS™ Next Imaging System are for reference only and are not intended to be used as the primary display.
- The system may place the point of index value at the wrong location due to pressure artifacts, for example: abnormal heartbeats, artifacts in AO (Pa) caused by flushing of guiding catheter, or valve opening / closing. The physician should always confirm that the point selected by the system is a valid point for the calculation of index value.
- Inside the catheterization laboratory, only port-powered USB drives may be connected to the USB port. Connecting externally powered devices to the USB port in the patient vicinity may compromise electrical isolation and cause patient injury.
- To protect the privacy and security of sensitive information, including electronic protected health information (EPHI), and to protect the integrity of the system itself, the system should be located in a physically secure, access-controlled environment. Do not use the OPTIS™ Next Imaging System if there is reason to believe the system's security has been compromised or if the system was unaccounted for during a period of time (i.e., misappropriated, modified, or tampered with).

PRECAUTIONS

- Safety and effectiveness have been established for the following patient population: adult patients undergoing non-emergent percutaneous coronary interventions in lesions with reference vessel diameters between 2.0 to 3.5 mm, which were not located in the left main coronary artery or in a target vessel which has undergone previous bypass procedures.
- Monitor the OCT image for indications of Dragonfly™ Imaging Catheter optical failure. If optical failure is suspected, remove the Dragonfly™ Imaging Catheter from the patient, press "Unload" on the drive motor and optical controller (DOC), detach the catheter, and replace it with a new one.
- If the pullback triggers before contrast is injected, repeat the pullback.
- For optimal imaging, only use 100% contrast media.

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.

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

Information contained herein for DISTRIBUTION in the U.S. ONLY.

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1.800.227.9902

www.cardiovascular.abbott

Abbott