OPTIS™
Mobile Next Imaging System

THE OPTIS™ MOBILE NEXT IMAGING SYSTEM is a transportable system designed for use in multiple cath labs via easy pre-installed connections. With the Ultreon™ 1.0 Software, this powerful OCT imaging system provides 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 and Dragonfly™ OPTIS™ Imaging Catheter

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

OPTIS™ Mobile Next

Drive-motor and Optical Controller (DOC)

OCT Connectivity Box

Wi-Box™ AO Transmitter

Tableside Controller

COMPONENT	DESCRIPTION	CONNECTIONS	DIMENSIONS / WEIGHT	MISCELLANEOUS SPECIFICATIONS
OPTIS™ Mobile Next Console	Contains imaging engine, computer, keyboard, mouse, monitors and isolated power supply Easy to move by a single user	Boom monitor video connection Angiography system connection DICOM‡ server via Ethernet	145 cm x 61 cm x 71 cm (H/W/D) 80 kg	Power consumption: 400 VA Max Input: 100-240 V~ 50/60 Hz Video Out: SXGA 1280 x 1024 DVI-D Angio Video Output Requirements: Video Types: Digital (DVI or HDMI), Analog (VGA, BNC-1 or BNC-3) Video output must be dedicated or properly split Video Resolution: minimum of 1024 x 1024, maximum 1920 x 1200 Frame Rate: 15-30 FPS CD/DVD Drive Mono plane
Tableside Controller (TSC)	Provides OCT and FFR/RFR control at tableside Clamps to table rail in procedure room	Wireless Bluetooth‡ connection or USB cable to OPTIS™ Mobile Next console	14 cm x 9 cm x 21 cm (H/W/D) 0.7 kg	Bluetooth‡ mode requires separate power source at tableside Input (Bluetooth Mode): 100–240 V~ 50/60 Hz 0.5 A
Drive-motor and Optical Controller (DOC)	Drives the OCT imaging catheter	Established connection with OPTIS™ Mobile Next Console	10 cm x 9 cm x 24 cm (H/W/D) 1.5 kg	While in operation, the DOC is bagged and placed on the procedure table When not in operation, it is stored in the OPTIS™ Mobile Next cart tray
Wi-Box™ System for FFR/RFR *optional*	Provides wireless aortic pressure	Wireless connection to OPTIS™ Mobile Next (Bluetooth‡)	8.7 cm x 10.8 cm x 3.3 cm (H/W/D) 0.13 kg	
Connectivity Box	Contains the interface to the angio and boom video for the OPTIS™ Mobile Next	Boom monitor video connection Angiography system connection	9 cm x 15 cm x 27.5 cm 2.5 kg	Power Input: 100-240 V~ 50/60 Hz 0.3 A maximum

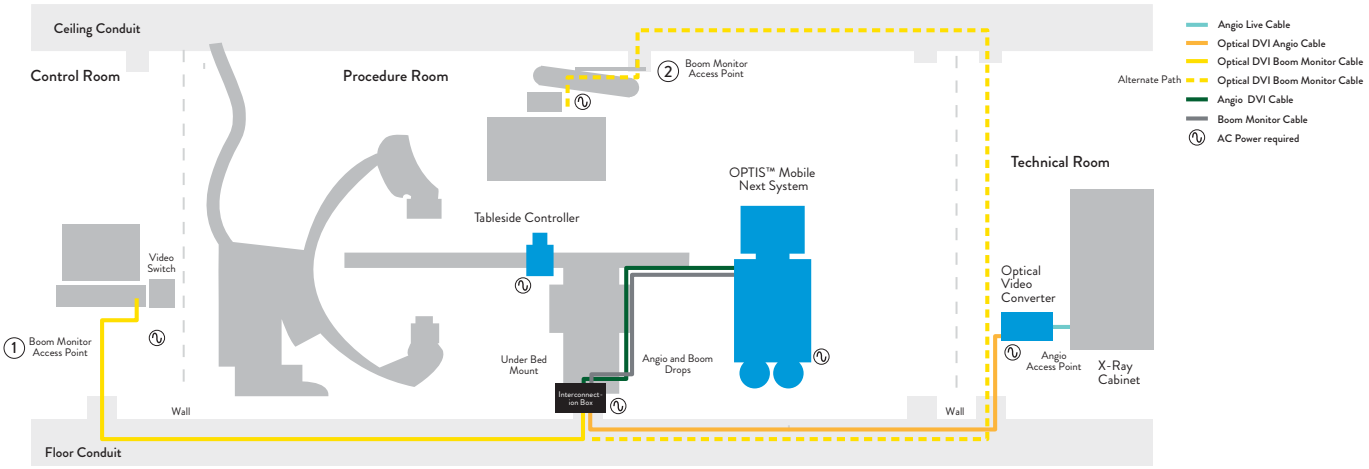
OPTIS™ Next Imaging System IFU. Refer to Instructions For Use (IFU) for additional information.

See Important Safety Information referenced within.

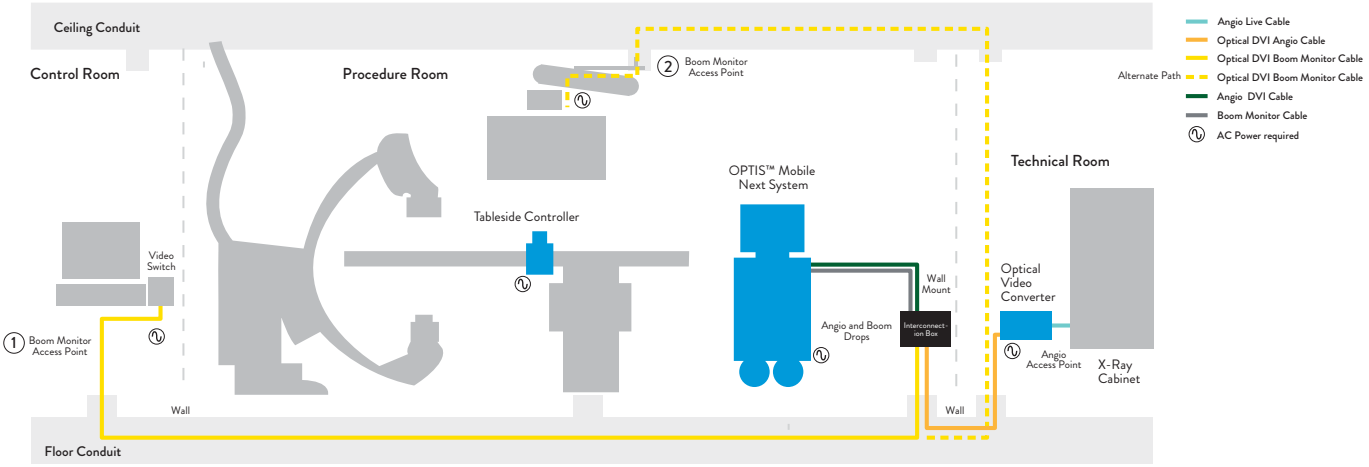
Information contained herein for DISTRIBUTION in the U.S. ONLY.

ROOM CONFIGURATIONS

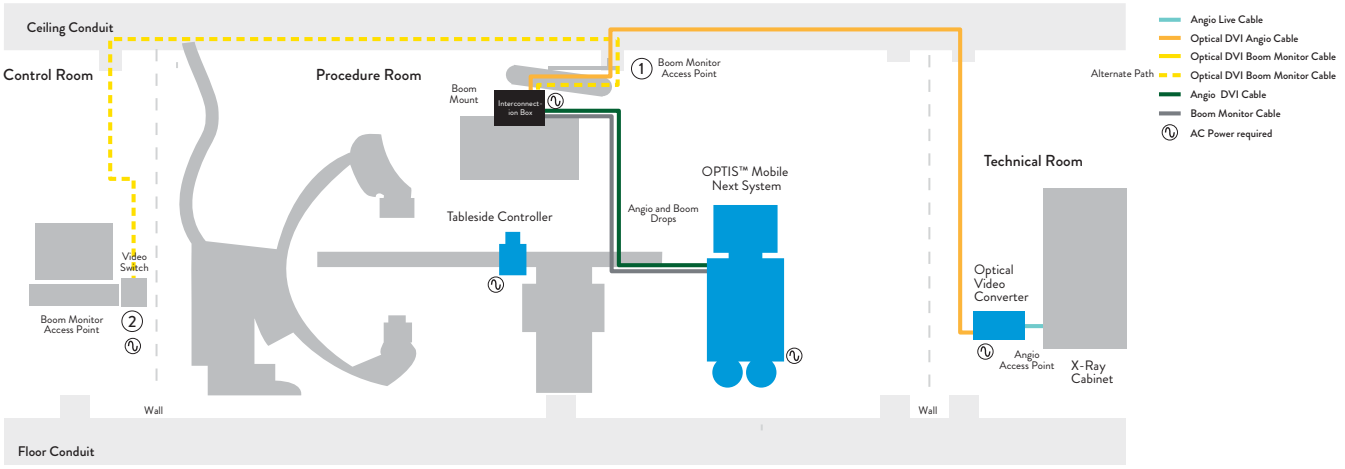
Configuration 1: OPTIS™ Mobile Next System under bed mount; video cables in floor or ceiling conduit



Configuration 2: OPTIS™ Mobile Next System wall mount; video cables in floor or ceiling conduit



Configuration 3: OPTIS™ Mobile Next System boom mount; video cables in ceiling conduit



See Important Safety Information referenced within.

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

ORDERING INFORMATION

ORDER NUMBER	DESCRIPTION
1014932	OPTIS™ Mobile Next Imaging System OPTIS™ Mobile Next console, Drive Motor and Optical Controller, OPTIS™ Next Tableside Controller, OPTIS™ Mobile Next Connectivity Kit (connectivity for a single cath lab allowing angio co-registration functionality)
1014934	OPTIS™ Mobile Next Upgrade Kit Includes all necessary components to upgrade an OPTIS™ Mobile System to OPTIS™ Mobile Next, OPTIS™ Next Tableside Controller, Ultreon™ 1.0 Software
1014936	OPTIS™ Tableside Controller Next Optional for additional cath labs
1014944	OPTIS™ Mobile Next Installation Kit Connectivity for an additional cath lab allowing angio co-registration functionality for the OPTIS™ Mobile Next

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