# 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 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 and Dragonfly™ OPTIS™ Imaging Catheter

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.

**See Important Safety Information referenced within.**

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# 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<br>Easy to move by a single user | Boom monitor video connection<br>Angiography system connection<br>DICOM‡ server via Ethernet | 145 cm x 61 cm x 71 cm (H/W/D)<br>80 kg | Power consumption: 400 VA Max<br>Input: 100-240 V~ 50/60 Hz<br>Video Out: SXGA 1280 x 1024 DVI-D<br>Angio Video Output Requirements: Video Types: Digital (DVI or HDMI), Analog (VGA, BNC-1 or BNC-3)<br>Video output must be dedicated or properly split<br>Video Resolution: minimum of 1024 x 1024, maximum 1920 x 1200<br>Frame Rate: 15-30 FPS<br>CD/DVD Drive<br>Mono plane |
| **Tableside Controller (TSC)** | Provides OCT and FFR/RFR control at tableside<br>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)<br>0.7 kg | Bluetooth‡ mode requires separate power source at tableside<br>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)<br>1.5 kg | While in operation, the DOC is bagged and placed on the procedure table<br>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)<br>0.13 kg | |
| **Connectivity Box** | Contains the interface to the angio and boom video for the OPTIS™ Mobile Next | Boom monitor video connection<br>Angiography system connection | 9 cm x 15 cm x 27.5 cm<br>2.5 kg | Power Input: 100-240 V~ 50/60 Hz 0.3 A maximum |

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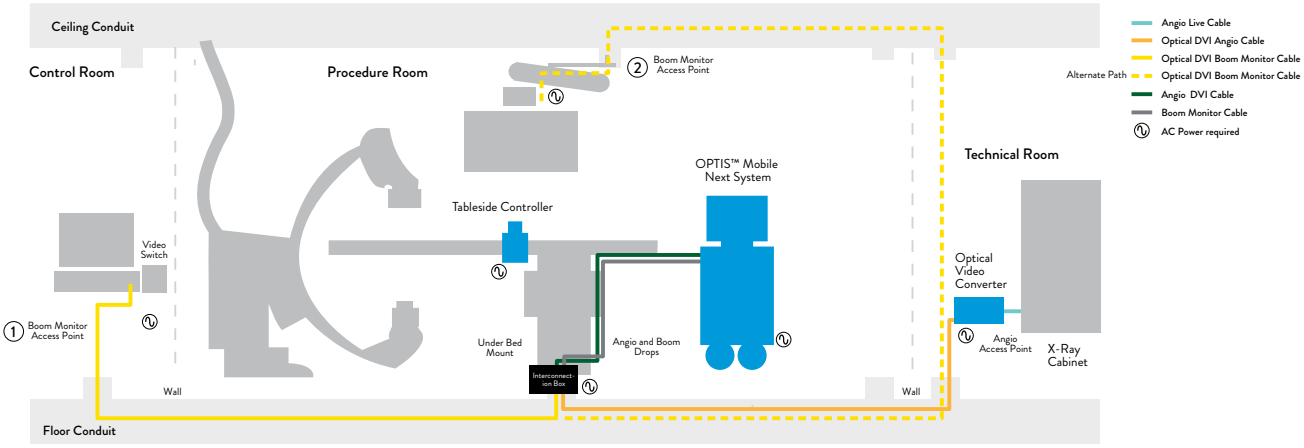
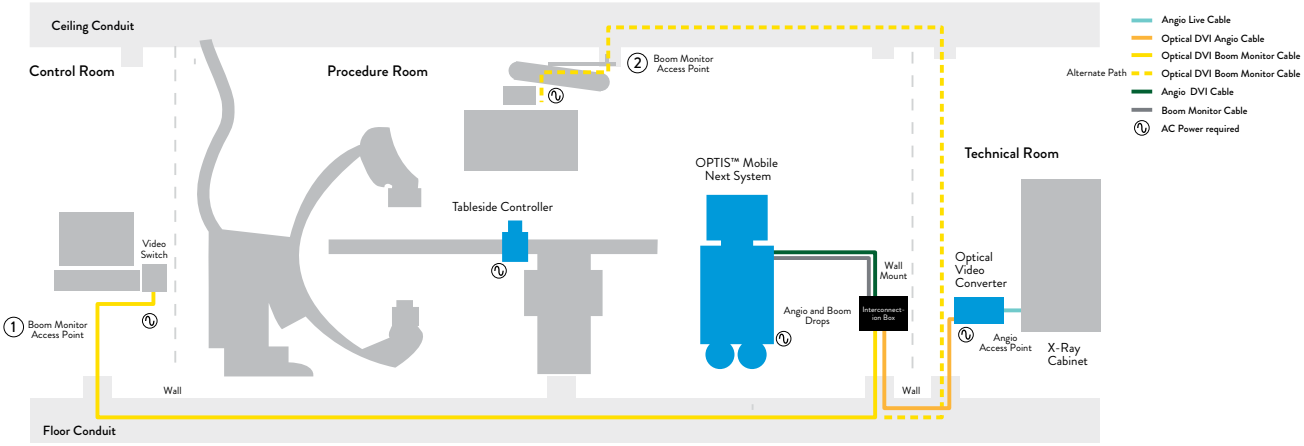
# ROOM CONFIGURATIONS

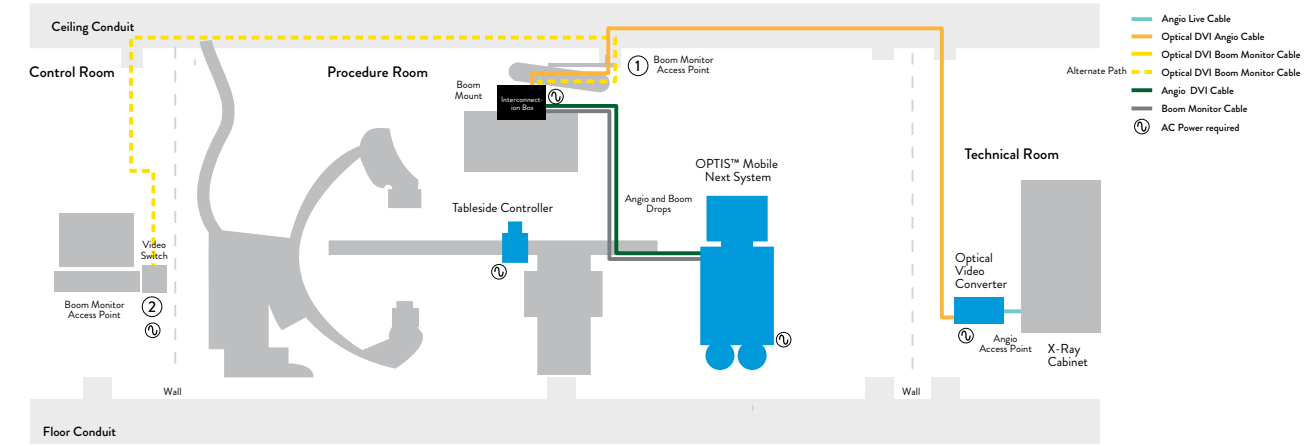
**Configuration 1:** OPTIS™ Mobile Next System under bed mount; video cables in floor or ceiling conduit




**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

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# ORDERING INFORMATION

| ORDER NUMBER | DESCRIPTION |
|---|---|
| **1014932** | OPTIS™ Mobile Next Imaging System<br>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<br>Includes all necessary components to upgrade an OPTIS™ Mobile System to OPTIS™ Mobile Next, OPTIS™ Next Tableside Controller, Ultreon™ 2.0 Software |
| **1014936** | OPTIS™ Tableside Controller Next<br>Optional for additional cath labs |
| **1014944** | OPTIS™ Mobile Next Installation Kit<br>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™ 2.0 Software is intended to be used only with compatible OPTIS™ Next Imaging Systems.

The OPTIS™ Next Imaging Systems 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 Systems are 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™ 2.0 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.
- The system has no patient alarm functions. Do not use for cardiac monitoring.

**COMPLICATIONS**

The following complications may occur as a consequence of intravascular imaging and catheterization procedure:

- 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: inflammation or granuloma
- Coronary artery spasm
- Death
- Embolism
- Hypotension
- Infection
- Myocardial ischemia
- Renal insufficiency or failure from contrast media use
- Repeat revascularization
- Thrombus formation, abrupt closure, or total occlusion
- Tissue necrosis
- Unstable angina

**WARNINGS**

- Prior to use, please review the Instructions for Use supplied with the Dragonfly™ Imaging Catheter for more information.
- Appropriate anticoagulant and vasodilator therapy must be used during the procedure as needed.
- Ensure that no air is introduced into the system during the Dragonfly™ Imaging Catheter insertion.
- Observe all advancement and movement of the Dragonfly™ Imaging Catheter under fluoroscopy. Always advance and withdraw

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the catheter slowly. Failure to observe device movement fluoroscopically may result in vessel injury or device damage. To ensure proper placement, do not move the guide wire after the Dragonfly™ Imaging Catheter is in place.

- If resistance is encountered during advancement or withdrawal of the Dragonfly™ Imaging Catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the Dragonfly™ Imaging Catheter and guidewire together as a unit from the patient.
- Leave the guide wire engaged with the Dragonfly™ Imaging Catheter at all times during use. Do not withdraw or advance the guide wire prior to withdrawing the Dragonfly™ Imaging Catheter.
- The Dragonfly™ Imaging Catheter should never be forced into lumens that are narrower than the Dragonfly™ Imaging Catheter body or forced through a tight or heavily calcified lesion.
- The Dragonfly™ Imaging Catheter should not be advanced through abnormally tortuous anatomy.
- When advancing or retracting a Dragonfly™ Imaging Catheter with a monorail tip through a stented vessel, the Dragonfly™ Imaging Catheter may engage the stent between the junction of the Dragonfly™ Imaging Catheter and guide wire, resulting in entrapment of catheter / guide wire, catheter tip separation, stent dislocation, and / or vascular injury.
- Refer to the contrast media Instructions for Use for general warnings and precautions relating to use of contrast media.
- Before creating an OCT recording, review "Performing an OCT Procedure" for additional warnings and cautions in the IFU.

**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 are not located in the left main coronary artery or in a target vessel which has undergone previous bypass procedures.
- Follow all instructions, warnings, and cautions provided in "Patient Safety" in the IFU.
- All operators must be knowledgeable in performing OCT and physiological procedures prior to using the Ultreon™ 2.0 Software, OPTIS™ Next Imaging System, and the Dragonfly™ Imaging Catheter.
- When using saline, heparinized saline is recommended.
- 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.
- Use the minimum flush rate and volume required to image the desired anatomy.
- To obtain accurate measurements, be sure the selection for the Flush Medium is the same as the medium in which you are imaging.
- The Dragonfly™ Imaging Catheter must be purged prior to connection to the DOC to prevent damage to the imaging core.
- Do not insert or remove the Dragonfly™ Imaging Catheter while the DOC is scanning. Do not attempt to disconnect the catheter from the DOC while the "lock" LED is blinking as it could damage the catheter or the DOC. Refer to "Removing the Dragonfly™ Imaging Catheter" in the IFU.
- Never attempt to attach or detach a catheter to the DOC while the "lock" LED is lit.
- Take care in handling the Dragonfly™ Imaging Catheter to prevent breaking the fiber-optics within the catheter. Kinking and bending of the catheter can cause damage. While connecting, ensure the proximal catheter segment is straight and aligned with the DOC. Never attempt to connect and operate the catheter while the catheter remains coiled within the hoop.
- Do not kink, sharply bend, pinch, or crush the Dragonfly™ Imaging Catheter at any time.
- The Dragonfly™ Imaging Catheter has no user serviceable parts. Do not attempt to repair or alter any part of the catheter assembly as provided.
- If you want to make measurements on files that will be exported to standard formats, you must make the measurements BEFORE exporting the images. Using non-OCT software to measure standard format images will not produce accurate measurements.
- Do not use images that have been exported to JPEG or Compressed AVI formats for clinical decision making. These formats use compression methods that may degrade the image quality.
- Artifacts may result in misrepresentation of L-mode data, so L-mode is not recommended for quantification of clinical information.
- It is the user's responsibility to confirm the lumen contours of all the frames within the reference segment, and to make adjustments if necessary. Red frames indicate low confidence in the detected contours.
- Deleted files cannot be restored. After files have been deleted, they can only be imported back to your system from your archived copies.
- Restoring factory default settings resets ALL user-entered configuration values except the date and time. This button should be used only under the direction of qualified service personnel.

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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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