Abbott

OPTIS™ Integrated Next
Imaging System

CE 2797

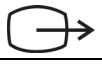
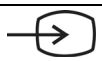
REF 1014933

Operation and Maintenance Manual

Contents

Symbols

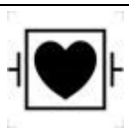
The following symbols may be found on the product or product label:

Symbol	Definition
	Equipotentiality
	For indoor use only
IPX3	Protection from a spray of water in any direction when the device is up to 60° any direction from vertical for at least 5 minutes.
	Bureau Veritas (Nationally Recognized Test Laboratory)
	Warning; laser beam
	Video Out
	Video In
	Network
	Universal serial bus port/plug
	No pushing
	Japan Technical Conformity Mark Japanese RF identifier for the transmitter.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
R-NZ	New Zealand Radio Spectrum Management (RSM) compliance mark for products that have radio transmitters of conformity level A1, A2, or A3
	KCC identifier
	FCC Identifier
IC:	IC identifier for transmitter This device complies with RSS-210 of the IC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation

Symbols (continued)

Symbol	Definition
	Separate collection for waste electrical / electronic equipment.
	Mass; weight
	Fuse
	Software
	Unique device identifier
	Medical device
	Manufacturer
	Consult instructions for use
	Caution
	Do not use if package is damaged
	Keep dry
	Humidity limitation
	Temperature limit
	Packaging unit

Symbols (continued)

Symbol	Definition
	Date of manufacture
	Catalogue number
	Serial number
	Non-ionizing electromagnetic radiation
	Japan Ministry of Internal Affairs and Communications High Frequency Mark
	Refer to instruction manual/booklet
	Symbol with certification number denotes radio type approval for Brazil by Agência Nacional de Telecomunicações (Anatel)
	Defibrillation-proof type CF applied part
	Authorized representative in the European Community

OPTIS™ Integrated Next Imaging System

About This Manual

This manual describes the Abbott Medical OPTIS Integrated Next system and accessories. It provides information on:

- Safety and risk statements
- System components
- Cleaning and maintenance
- Specifications

Pictures shown are for example only.

Note:

- For a full description of Optical Coherence Tomography (OCT) and physiology procedures, including a list of compatible Dragonfly™ Imaging Catheters, refer to the installed software User Manual.
- Details of the imaging catheter are covered in the Dragonfly Imaging Catheter Instructions for Use provided with the catheter and are not covered in this manual.
- Details of the PressureWire™ X Guidewire and the PressureWire™ Aeris™ FFR Measurement System with Agile Tip Technology are covered in the Instructions for Use provided with these items, and are not covered in this manual.
- Refer to the Wi-Box™ AO Transmitter Instructions for Use for set-up procedures for the Wi-Box AO Transmitter.
- This manual does not provide detailed discussion of system components, except as they are used with the OPTIS Integrated Next.

Safety Information

CAUTION: Before using the OPTIS™ Integrated Next for the first time, be sure to read and understand all of the information in this chapter. Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions; otherwise, complications may occur.

Although the OPTIS Integrated Next conforms to laser emission standards and both international and European safety and electromagnetic compatibility standards, the system is intended for use only by medical personnel who are knowledgeable in OCT and physiology procedures. Only a knowledgeable operator can determine if OPTIS Integrated Next use is appropriate. An awareness of system limitations is essential to making that determination and ensuring safe operation for both operator and patient.

This section provides information on:

- Patient safety
- Operator safety
- Moving the system
- Avoiding electrical hazards
- Electromagnetic interference
- Built-in safety functions

Patient Safety

The OPTIS Integrated Next is intended for use only by medical personnel who are familiar with its operation and skilled in the clinical procedures to be used.

To avoid any potential hazard to patients, follow the precautions outlined in this section.

CAUTION: Use only the compatible Dragonfly™ Imaging Catheter with the OPTIS Integrated Next. Use of other types of catheters may result in unsafe conditions for the patient and damage the OPTIS Integrated Next.

General

WARNING: Failure to follow the guidelines described in these Instructions for Use and in the Instructions for Use provided with the accessories may result in injury to patients and damage to equipment.

WARNING: Failure to abide by the precautions detailed below causes the system and its use to be out of compliance with regulations and places the patient and the operator at risk of injury or death.

WARNING: Connecting to External Equipment / Accessories - When used in the patient environment, all equipment connected to the OPTIS Integrated Next must meet the requirements for medical isolation according to the IEC 60601 safety standards. Connection of equipment that does not follow relevant IEC standards (e.g., IEC 60601 series for medical electrical equipment) may lead to patient injury or death.

WARNING: Failure to secure the DOC holster to the procedure table rail may present a hazard to the patient, due to movement of the monitor boom, which could pull on a catheter while it is in the patient.

WARNING: Electrical Shock Hazard - Do not remove OPTIS Integrated Next covers. To avoid electrical shock, use only the power cord supplied with the system and connect only to properly grounded wall outlets. Refer to “System Setup” and “Safety Information” for electrical safety information.

WARNING: The Dragonfly Imaging Catheter is sterilized by ethylene oxide and is intended for one-time use only. Non-pyrogenic. Do not use if the package is opened or damaged. Do not reuse or re-sterilize. Any attempt to reuse or re-sterilize may compromise the structural integrity of this device. Adverse effects of using a non-sterile or re-sterilized catheter may include, but are not limited to: local and / or systemic infection, mechanical damage, inaccurate results.

WARNING: Do not use the PressureWire™ Guidewire if there are any signs of damage.

CAUTION: Please note Abbott Medical makes no representation or warranty that use of the OPTIS Integrated Next complies with applicable privacy, security, and confidentiality laws, but encourages you to assess your own risk as you use, disclose, control, process, or transfer patient health information with the OPTIS Integrated Next.

- Use only compatible Dragonfly Imaging Catheters. Always use under appropriate imaging guidance (endoscopy, x-ray fluoroscopy, or other appropriate guidance method).
- Use only compatible wireless PressureWire Guidewires to report aortic distal pressure. Always use under appropriate imaging guidance (endoscopy, x-ray fluoroscopy, or other appropriate guidance method).
- Always read and follow the Instructions for Use supplied with the Dragonfly Imaging Catheter and with the PressureWire Guidewire.
- Always use controls, make adjustments, and perform procedures as specified in these Instructions for Use.

Techniques to Minimize Patient Exposure

The OPTIS Integrated Next meets the performance standards of laser-emitting products as established by IEC 60825-1. Although no harmful effects have been demonstrated for the near-infrared light wavelengths, intensities, and exposure times used during examinations with the OPTIS Integrated Next, Abbott Medical recommends that you carefully read the warning labels on the system (refer to “Avoiding Operator Light Emission Hazards” [page 8]) and follow these examination guidelines:

- Use OCT only when there is a good reason to do so.
- Use techniques that enable quick collection of clinical data and shorten procedure time.

Operator Safety

Avoiding Operator Light Emission Hazards

To avoid any potential light emission hazards to you or to patients, adhere to the information provided in the safety labels that are located on the system (figure below) and observe the precautions outlined in this section.

WARNING: Failure to follow any of these precautions may cause possible serious damage to your eyes.

Figure 1. Connector Panel Laser Safety Label

- Avoid eye exposure. Do not look at or stare directly into the beam. Doing so may damage your eyes.

WARNING: Viewing the laser output with telescopic optical instruments (e.g., telescopes and binoculars) may pose an eye hazard and thus the user should not direct the beam into an area where such instruments are likely to be used.

- Use controls, make adjustments, and perform procedures only as specified in these Instructions for Use.

Repetitive Strain Injury (RSI)

Repetitive use of a mouse and keyboard has been associated with Carpal Tunnel Syndrome (CTS) and related musculoskeletal problems. Follow these suggestions to help prevent these problems:

- Maintain your joints in optimum positions with a balanced posture, avoiding:
  - Static postures
  - Exertion of force during repetitive motions
  - Wrist flexion or deviation
- Position the keyboard and monitor to minimize reaching and stretching.
- Take frequent breaks to give tissues time to recuperate from awkward positions and repetitive movements.

Avoiding Electrical Hazards

WARNING: All system components **MUST** be powered as directed in these Instructions for Use **ONLY**. Do not modify how the system components are connected to power without first contacting an Abbott Technical Service representative.

WARNING: Failure to abide by the precautions detailed below causes the system and its use to be out of compliance with regulations and places the patient and the operator at risk of injury or death.

Do not use additional cables, extension cords, or outlet strips with the OPTIS Integrated Next.

When transferring files inside the catheterization laboratory, use only port-powered USB drives.

WARNING: 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.

Note: Outside the catheterization laboratory, IEC 60950-compliant, externally powered USB hard drives may be connected to the USB port.

Do not remove system covers. Only qualified personnel should service the system. Accidentally contacting the electrical circuits inside the housing could cause serious injury.

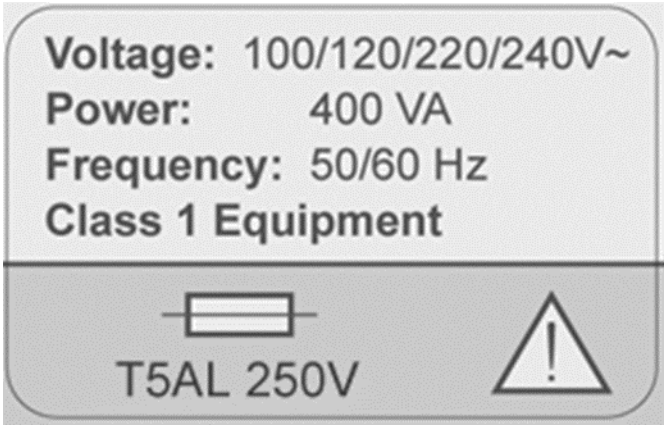
Making Proper Electrical Connections

Ensure that the electrical connection for the system is properly rated (figure below). Carefully follow the safety guidelines described in this section when connecting the system power cord to the hospital or laboratory AC outlet.

WARNING: Failure to follow the electrical connection precautions detailed in this section causes the system and its use to be out of compliance with regulations and places the patient and the operator at risk of injury or death, and may damage the equipment.

WARNING: Do not allow the tableside controller (TSC) power supply to get wet.

Figure 2. Electrical Label



- Connect the system only to properly grounded (three-hole) hospital-grade AC outlets:
  - The circuit must accommodate an additional load of up to 400 VA.

- Replacement fuses are available through Abbott Medical.
- The power cord is to be used for disconnection from main power.
- Make sure any devices that connect to the network interface of the OPTIS Integrated Next comply with the appropriate IEC / national standard and are certified to IEC 60950.
- Use no electrical peripherals within 6 feet (1.83 m) of a patient unless the peripherals receive power from an isolation transformer that meets medical safety standards.

Note: If the OPTIS Integrated Next is used with peripherals that are powered from a separate wall outlet, the combination is considered to be a Medical System. It is the user's responsibility to comply with IEC 60601-1 and test the Medical System according to the requirements.

Explosion Hazard

WARNING: Do not operate the OPTIS Integrated Next in the presence of flammable anesthetics. Doing so could lead to an explosion.

System Imaging Limitations

The OPTIS Integrated Next is intended for use by medical personnel who are knowledgeable in OCT and Physiology procedures. To determine if system use is appropriate, the user must be aware of system imaging limitations.

Considerations for Optimal Vessel Imaging

The OPTIS Integrated Next can be used to image through vessels or to image the inner surface of certain vessels. Because the Dragonfly Imaging Catheter is smaller than the diameter of the vessel being imaged, the position of the catheter in the vessel has an effect on the portion of the vessel that can be imaged.

- Imaging range is greatest when the Imaging Catheter is centered in the lumen.
- Imaging range is least when the Imaging Catheter is placed off-center in the lumen, against the wall of the vessel.

Considerations for Optimal Tissue Imaging

The maximum imaging depth within a vessel wall ranges from approximately 0.9 mm to 1.3 mm and is limited by optical attenuation caused by scattering of the optical beam by microstructures in the vessel. For example, penetration of the OCT beam is deepest in calcified tissue and shallowest in dense fibrotic tissue.

Electromagnetic Interference

The system produces images by using digital signal processing techniques that operate in the radio frequency (RF) energy range. The system is therefore susceptible to interference generated by other RF energy sources such as medical devices, information technology products, or radio / television transmission towers. Tracing the source of radiated interference can be difficult.

The user must determine if an artifact caused by radiated interference will negatively impact image quality and the subsequent study results.

To help identify the source of electromagnetic interference, ask the following questions:

- Is the interference intermittent or constant?
- Does the interference occur with one catheter only, or with other imaging catheters?
- Is the interference present if the system is moved to a different location in the facility? Examples: Placing the system close to an ECG cable can increase electromagnetic interference. Moving the cable or other medical equipment away from the system can reduce electromagnetic interference.

Please answer these questions before contacting Abbott Service. The answers will help determine if the problem is in the system or in the imaging environment.

Safety Functions Built Into the OPTIS Integrated Next

The following safety functions have been built into the system:

- The system disables light output and disables all motors in these situations:
  - The optical fiber stops rotating due to mechanical failure.
  - Communication is lost between the imaging engine and the drive motor and optical controller (DOC).
  - Communication is lost between the computer and the imaging engine.
- Pressing the Stop button on the DOC disables power to the DOC and laser output. Refer to “Drive Motor and Optical Controller (DOC)” on page 23.

Indications for Use

The OPTIS™ Integrated Next with a compatible Dragonfly™ OPTIS™ or Dragonfly OpStar™ Imaging Catheter is indicated for:

- For qualitative and quantitative evaluation of vascular morphology in the coronary arteries
- As an adjunct to conventional angiographic procedure to provide an image of vessel lumen and wall structures
- For imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedure

The system further computes and displays various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices.

CAUTION: The OPTIS Integrated Next is intended for use by medical personnel who are knowledgeable in OCT and physiological procedures. Abbott Medical and its employees cannot give instructions in the interpretation or diagnosis of recordings and makes no attempt to do so.

CAUTION: All operators must be knowledgeable in performing OCT and physiological procedures prior to using the installed software, OPTIS Integrated Next, and the Dragonfly Imaging Catheter.

Contraindications

Use of the OPTIS™ Integrated Next 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 and Precautions

Warnings

- Prior to use, please review the installed software User Manual and the Instructions for Use supplied with the OPTIS™ Integrated Next, Dragonfly™ Imaging Catheter, Wi-Box™ AO Transmitter, and PressureWire™ Guidewire for more information on warnings, limitations, cautions, and setup instructions.
- 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.

Warnings (OCT)

- Appropriate anticoagulant and vasodilator therapy must be used during the procedure as needed.
- Observe all advancement and movement of the Dragonfly Imaging Catheter under fluoroscopy. Always advance and withdraw 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 guide wire as a unit from the patient.
- 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 the installed software User Manual for additional warnings and cautions.

Precautions (OCT)

- Follow all instructions, warnings, and cautions provided in “Patient Safety” on page 6 and in “Operator Safety” on page 8.
- Protect the exposed connector inside the DOC from fluids at all times. Fluid contact can disable the DOC and require service.
- For optimal imaging, only use 100% contrast media.
- When using saline, heparinized saline is recommended.
- Use the minimum flush rate and volume required to image the desired anatomy.
- Never attempt to attach or detach a Dragonfly Imaging Catheter to the DOC while the "lock" LED is lit.
- Do not kink, sharply bend, pinch, or crush the Dragonfly Imaging Catheter at any time.
- After use, the Dragonfly Imaging Catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.
- The Dragonfly Imaging Catheter has no user serviceable parts. Do not attempt to repair or alter any part of the catheter assembly as provided.

Warnings and Precautions (Fractional Flow Reserve [FFR], Resting Full-Cycle Ratio [RFR])

WARNING:

- The PressureWire Guidewire is sterilized by ethylene oxide and is intended for one-time use only. Non-pyrogenic. Do not use if the package is opened or damaged. Do not reuse or re-sterilize. Any attempt to reuse or re-sterilize the PressureWire Guidewire may compromise the structural integrity of this device. Adverse effects of using a non-sterile or re-sterilized guide wire may include, but are not limited to: local and / or systemic infection, mechanical damage, inaccurate results.

CAUTION:

- Patients with potential microvascular dysfunction and borderline index values should be interpreted with caution, and management strategies should be guided not only by pressure measurement, but also by possibly supplementary clinical risk stratification and other tests.
- Before performing a physiological parameter procedure, review the installed software User Manual for additional warnings and cautions.
- After use, the PressureWire Guidewire may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.
- The system may place the point of index value at the wrong location due to abnormal heart beat or artifact in Pa from flushing the guiding catheter. The responsible physician should confirm that the point selected by the system is a valid point of index value.
- If the cursor position has been saved, the index value is changed accordingly.
- Before creating a physiological parameter recording, review the installed software User Manual for additional warnings and cautions.

Connecting to External Equipment / Accessories

WARNING:

- When used in the patient environment, all equipment connected to the OPTIS Integrated Next must meet the requirements for medical isolation according to the IEC 60601 safety standards. Connection of equipment that does not follow relevant IEC standards (e.g., IEC 60601 series for medical electrical equipment) may lead to patient injury or death.
- 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.

CAUTION:

- No connections to other systems or components are to be made to the OPTIS Integrated Next except through the Connector Panel. No connections are to be made through the Connector Panel except as described in this manual. In addition, all such combinations of systems shall comply with the standard IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. Any person who connects external equipment to the OPTIS Integrated Next has formed a medical system and is therefore responsible for compliance of the system with the requirements of IEC 60601-1. If in doubt contact a qualified technician. Only the PressureWire Guidewire and the Wi-Box AO Transmitter are intended to be used with the OPTIS Integrated Next wireless receivers.
- To connect to the correct Wi-Box AO Transmitter, you must select the room where the system is being used. The first time you connect to a room, you must enter the room's information into the system. Refer to the installed software User Manual for more information.

Mechanical Enclosure

WARNING:

- Do not use the OPTIS Integrated Next if it has been dropped or in another way exposed to mechanical or electrical damage or if liquids have penetrated the housing, or the user or patient may be exposed to electrical shock or faulty readings may appear. Contact your supplier for further action.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

CAUTION:

- Ensure that all ventilation holes are unblocked to avoid system overheating and false readings.

Electrical

WARNING:

- Electrical Shock Hazard - Do not remove OPTIS Integrated Next covers. To avoid electrical shock, use only the power cord supplied with the system and connect only to properly grounded wall outlets. Refer to "System Setup" and "Safety Information" for electrical safety information.
- The main power remains switched on when the system is in Standby mode. Avoid direct or indirect (e.g., via the operator) conductive connection between other electrical equipment and the OPTIS Integrated Next. Conductive connection may cause leakage currents to induce ventricular fibrillation. High frequency surgical equipment must not be used on a patient at the same time as PressureWire Guidewire and the OPTIS Integrated Next.

- Never use a converter adapter to connect the AC plug to an ungrounded wall outlet. Doing so may result in electric shock to the patient or operator and damage to equipment.

CAUTION:

- Do not unplug from AC power or set system cabinet standby button to Standby until the shutdown is complete, the screens turn black, and the monitor LEDs turn amber. Disconnecting from AC power before the shutdown is complete may damage the system.

Electronic Interference

CAUTION:

- Radio transmitting equipment, cellular phones, and strong emission sources such as high frequency surgical equipment shall not be used in close proximity to the OPTIS Integrated Next since this could influence the performance of the device.

  Note: The device should be used in a hospital environment except for near active high frequency (HF) surgical equipment and the radio frequency (RF) shielded room of a medical equipment system for magnetic resonance imaging, where the intensity of electromagnetic (EM) disturbances is high.

Aortic Reference Pressure

CAUTION:

- Check that the monitor cables and aortic pressure transducer (AO) adapter delivered with the OPTIS Integrated Next interface are compatible with the catheterization laboratory system to be used. The AO should be in accordance with ANSI/AAMI BP22-1994. Once the laboratory monitor system has been zeroed, use only the OPTIS Integrated Next to calibrate the AO and PressureWire Guidewire.

Defibrillation

CAUTION:

- The OPTIS Integrated Next is a CF Class I equipment and protected against the effects of a discharge of a defibrillator. PressureWire Guidewire readings may be affected by defibrillation. Recalibrate the PressureWire Guidewire after defibrillation use.

System Security

WARNING:

- 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 Integrated Next 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).

System Overview

System Features

Optical Coherence Tomography (OCT) is an imaging modality that uses fiber-optic technology. The OPTIS™ Integrated Next uses optical imaging catheters that emit near-infrared light to produce high-resolution real-time images.

Fractional Flow Reserve (FFR) is the ratio of distal coronary arterial pressure (Pd) to aortic pressure (Pa), measured during hyperemia. It provides the maximal blood flow in the presence of a stenosis as a fraction of the achievable blood flow that would exist in the hypothetical situation that the stenosis was not present. Pd / Pa at rest is the ratio of distal coronary arterial pressure to aortic pressure measured at resting conditions.

Resting Full-Cycle Ratio (RFR) is the ratio of Pd to Pa at a point in the cardiac cycle where the Pd / Pa ratio is minimal. RFR is designed to be used at rest and, in contrast to Pd / Pa at rest, is a sub-cycle metric.

The physician may use the FFR, Pd / Pa at rest, and RFR parameters, along with knowledge of patient history, medical expertise, and clinical judgment, to determine if therapeutic intervention is indicated.

The OPTIS Integrated Next is built into the catheterization laboratory so that OCT and Physiology are immediately available without the need to find, connect, position, and power-on a mobile console. The system allows either the sterile operator or non-sterile operator to control system functions during image and Physiology acquisition and review, and to view the OCT and Physiology images on the main catheterization laboratory monitor boom. In addition, the system incorporates Angio Co-registration, which allows the user to visualize the position of OCT image data on angiography images, tightening the linkage between anatomical assessment with OCT and subsequent therapeutic actions.

CAUTION: Medical personnel who use the OPTIS Integrated Next software must be aware of the system's limitations. Only operators knowledgeable in OCT and physiologic procedures can determine if use of the OPTIS Integrated Next software and OPTIS Integrated Next are appropriate. Be sure to read Safety Information before operating the OPTIS Integrated Next software for the first time.

CAUTION: Medical personnel who use the OPTIS Integrated Next must be aware of the system's limitations. Only medical personnel who are knowledgeable in OCT and physiologic procedures can determine if use of the OPTIS Integrated Next is appropriate. Be sure to read Safety Information before operating the OPTIS Integrated Next for the first time.

System Components

The OPTIS Integrated Next includes the following components, integrated into a catheterization laboratory:

- System cabinet, which includes an isolation transformer
- Laser imaging engine
- Computer
- Drive motor and optical controller (DOC)
- DOC holster
- Keyboard, monitor, mouse
- Tableside controller (TSC)

Note:

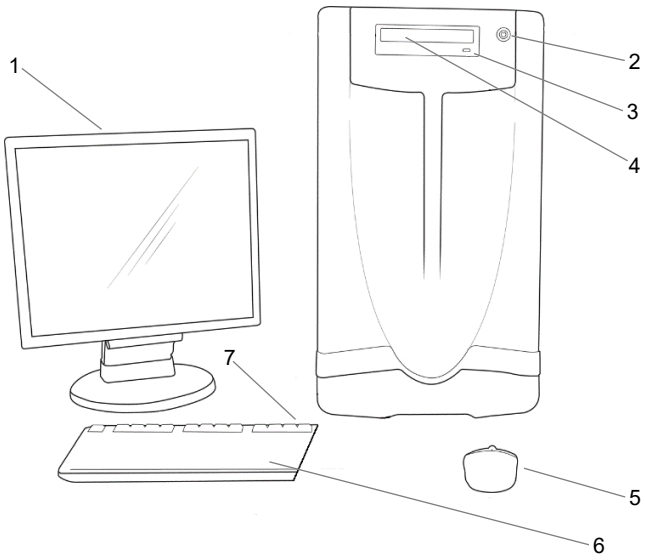
- Use only the power cable and accessories provided with the system. Use of other cables or accessories may negatively affect electromagnetic compatibility performance.
- Physiology procedures require a Wi-Box™ AO Transmitter installed in the catheterization laboratory. Contact Abbott Service for more information.

CAUTION: The above components are integral parts of the OPTIS Integrated Next. The hardware and software must not be modified in any way by the customer. Making such modifications may interfere with correct operation and will void system warranties. Contact an Abbott Technical Service representative for more information.

Note: The OPTIS Integrated Next can only be installed and serviced by an Abbott Technical Service representative. The Service representative has access to all necessary maintenance instructions and component parts lists. Contact an Abbott Technical Service representative whenever there is new construction in the catheterization lab.

OPTIS Integrated Next - Cabinet and Control Room Components

Figure 3. OPTIS Integrated Next - Cabinet and Control Room Components



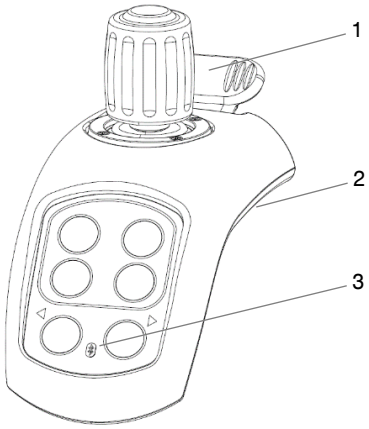
1. Control room monitor
2. Standby button/indicator
3. CD/DVD eject button
4. CD/DVD tray
5. Wired mouse
6. Wired keyboard with USB ports
7. USB ports

Note:

- Standby button / indicator: Activate to put the system into Standby state (indicator is off). Press to exit Standby state and turn on the system (indicator turns green).
- A potential equalization conductor post (located on the back of the system cabinet, compliant to IEC 60601- 1:2005 cl.8.6.7) provides a direct connection between the electrical equipment and the potential equalization buss bar of the electrical installation.

Tableside Controller (TSC)

Figure 4. Tableside Controller (TSC)



1. Rail clamp
2. USB connection
3. Wireless connectivity indicator

Note:

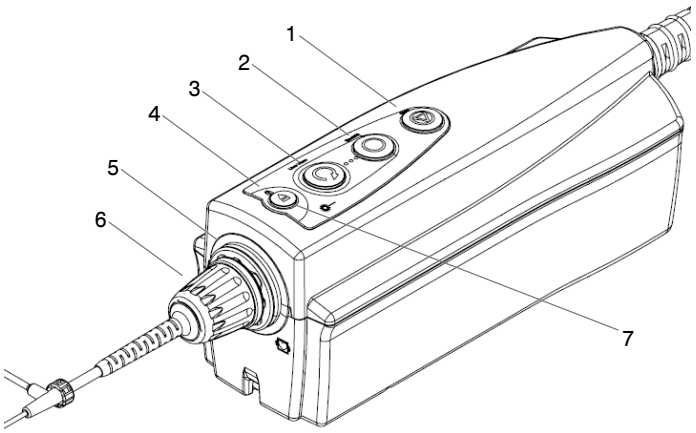
- If the TSC is connected by USB cable, the wireless connectivity indicator does not illuminate.
- Improper handling of the USB connection can damage the port on the connector panel.

CAUTION: A yellow “no connection” Wireless Connectivity Indicator LED means the tableside controller (TSC) is not connected to the system. Refer to “User Troubleshooting” on page 36 to reconnect.

Drive Motor and Optical Controller (DOC)

The DOC provides bed-side control of the most important OCT imaging functions. Refer to the installed software User Manual for Dragonfly™ Imaging Catheter connection details.

Figure 5. Drive Motor and Optical Controller (DOC)

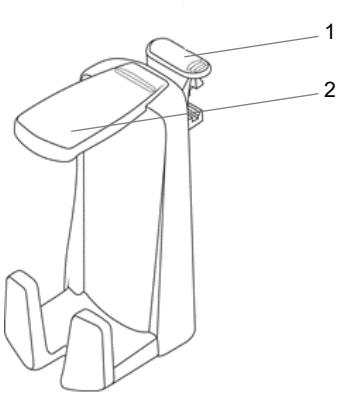


1. Stop button
2. Enable button
3. (button not used)
4. Lock indicator light
5. Catheter connection port
6. Catheter connector hub
7. Unload button

DOC Holster

The DOC holster clamps onto the procedure table rail and serves as the signal hub for Physiology and OCT. It also serves as a storage cradle for the DOC when it is not in use.

Figure 6. DOC Holster



1. Rail clamp
2. Dust cover

Wi-Box AO Transmitter

The Wi-Box AO Transmitter is installed in the catheterization laboratory between the hemodynamic recording system and the aortic pressure transducer (AO).

The wireless connection to the Wi-Box AO Transmitter is made during setup for the procedure. Refer to the installed software User Manual for more information.

System Accessories

- PressureWire™ Guidewire
- Wi-Box AO Transmitter
- Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter
- Sterile DOC cover
- 3 ml syringe

Note: Contact Abbott Service for order numbers of accessories.

System Setup

Positioning the System

Confirm that the OPTIS™ Integrated Next cabinet is on a level surface inside the control room or x-ray room. Confirm that the control room monitor, keyboard, and mouse are located on the control room table.

The system cabinet should be positioned such that the back panel, equipotential grounding post, and power mains are easily accessible. The system cabinet should have space around it so that air can circulate to cool the chassis. Free space must be available in front of the system cabinet to allow the CD/DVD tray to open and close freely. The AC mains disconnect (wall outlet connection) to the power mains must also be easily accessible.

Note: USB ports are located on the keyboard.

Mount the TSC and DOC holster onto the procedure table rail in locations that are comfortable for the physician to use during the procedure. Drape the TSC with a protective sterile barrier to maintain sterile technique.

WARNING: Failure to secure the DOC Holster to the procedure table rail may present a hazard to the patient, due to movement of the monitor boom, which could pull on a catheter while it is in the patient.

The TSC and DOC holster are custom fit during installation. If either component is not clamped onto the rail securely, contact Abbott Service.

System components that are suitable for use within the patient environment are the DOC, DOC holster, TSC, and catheter as specified in the Instructions for Use.

Attaching and Removing Components (Table Rail)

To attach the TSC or DOC holster to (or remove it from) the patient procedure table rail:

Attach

1. Ensure that the clamp is fully open.
2. Place the clamp side of the component onto the rail and continue to hold.
3. Gently push down on the grooved end of the clamp to secure the component onto the rail.
4. Gently test the component to ensure that it is securely fastened to the rail.

Note: If a TSC is moved to a different table, a shim may be required to allow it to clamp properly.

5. (TSC only) Plug the USB cable from the TSC power supply into the bottom of the TSC.

WARNING: Do not allow the TSC power supply to get wet.

Remove

1. (TSC only) Unplug the USB cable from the TSC power supply from the bottom of the TSC.
2. Grasp the component from the bottom in one hand (supporting the weight) and lift the grooved end of the clamp to release from the rail.
3. Holding the clamp open, gently pull the component from the rail. To avoid damaging cables, components, or connections that may expose the user to harm, do not drop the component.

DOC Holster Boom Mount Configuration

In some installations, Abbott Medical may install the DOC holster directly onto the monitor boom (DOC holster boom mount configuration).

When performing a procedure using the OPTIS Integrated Next with a DOC holster boom mount configuration, remove the DOC holster from the DOC holster boom mount and secure it to the procedure table rail. When the procedure is complete, remove the DOC holster from the rail and return it to the DOC holster boom mount. When the DOC holster is secured to the rail, ensure that the remoting cable is not placed in a walkway or operator area.

WARNING: Failure to secure the DOC Holster to the procedure table rail may present a hazard to the patient, due to movement of the monitor boom, which could pull on a catheter while it is in the patient.

Connecting the System

WARNING: All connections to the OPTIS Integrated Next except the TSC in Bluetooth‡ mode must be made through the System Connector Panel. Making connections directly to internal components of the system may bypass isolation features and compromise patient safety.

WARNING: If the external monitor is being used in the patient vicinity, it must use an isolated power source or it may compromise electrical isolation and cause patient injury.

The system cabinet and monitors are normally always connected to power.

Powering On

WARNING: Never use a converter adapter to connect the AC plug to an ungrounded wall outlet. Doing so may result in electric shock to the patient or operator and damage to equipment.

For detailed information on electrical requirements, refer to “Making Proper Electrical Connections” on page 10.

1. Make sure the power cords are connected to the system cabinet and to the control room monitor, and that they are plugged into grounded electrical outlets.
2. Confirm that all monitors are powered by observing that the appropriate power indicators are on.
3. Turn ON system power by pressing the Standby button located at the upper-right side of the front of the cabinet. The startup screen appears.
4. The first time the software runs, select a language (if prompted). If necessary, refer to the installed software User Manual to change this selection.
5. The first time the software runs, the End User License Agreement (EULA) displays. Read and agree to the EULA to proceed.
6. Adjust monitor brightness and contrast as necessary.

Shutting Down

CAUTION: Do not unplug from AC power or turn off main power until the shutdown is complete, the screens turn black, and the green monitor LEDs turn amber. Disconnecting from AC power before the shutdown is complete may damage the system.

Note: Use the Shutdown button at the top of the screen to shut down the system. Use of the On / Standby key is not recommended to shut down the system.

1. Click the Shutdown button located at the top of the screen. The system shutdown menu appears.
2. Click Yes to begin the system shutdown, or No to continue using the system.

   If you choose Yes, the computer begins the system shutdown. After 15 seconds, the screens turn black, the green monitor LEDs turn amber, and the system enters Standby mode.
3. After the screens turn black and the green monitor LEDs turn amber, press the main power switch at the base of the cart to turn off system power.
4. If necessary, disconnect the power cord from AC power.

Cleaning and Maintenance

CAUTION: Do not perform cleaning or maintenance on the system during a patient case or in the patient environment.

CAUTION: The OPTIS™ Integrated Next accessories should be appropriately classified as a biohazard and disposed of in compliance with applicable facility procedures, local and country laws and regulations. Return the OPTIS Integrated Next to Abbott Medical at the end of its operating life.

Cleaning

The following OPTIS Integrated Next items require cleaning:

- DOC and DOC optical cable
- TSC
- DOC holster and cables

The DOC, DOC holster, and TSC should be cleaned following the facility's standard cleaning schedule, or at least every 30 days under normal use.

1. Turn off (or Standby) all system components with accessible power controls and unplug the power cables.
2. Clean system surfaces and the keyboard with a dry cloth.
3. Clean the LCD surface of the monitor with a lint-free, non-abrasive cloth.

CAUTION: Do not clean the LCD surface with detergents or other cleaning solutions.

4. Clean the TSC, DOC, DOC holster, and DOC optical cable with a disinfectant wipe (1:10 Hypochlorite solution) or Cidex‡ (Glutaraldehyde 3.4%) and a soft cloth. Be particularly careful not to stress or sharply bend the DOC optical cable.

   Note:

   - Though enclosed in a bag during use, the DOC is the system component most exposed to dirt, fluids, and debris.
   - The TSC and DOC are not waterproof. Be careful not to use excessive moisture when cleaning these devices. Wipe only. Do not soak or spray.

Maintenance

Contacting Abbott Technical Service

CAUTION: Only a qualified Abbott Technical Service representative can perform maintenance or service components of the system. Any attempt to open the system components by anyone other than a qualified Abbott Technical Service representative will void the warranty.

Service can be contacted at:

Email: OCTservice@abbott.com

Phone (Outside US): +1 651 490 4410

Maintenance Procedures

Maintenance of the system consists of:

- Cleaning the optical connection in the DOC and in the Dragonfly™ Imaging Catheter
- Replacing the optical adapter in the DOC
- Inspecting exposed cable connections
- Transferring log files
- Identifying the installed software version

Optical Connection Cleaning Procedure

The optical connection between the DOC and the catheter should be cleaned whenever a loss of image quality occurs. Image quality should also be checked every 3 months, and the connection should be cleaned if there is a loss of quality.

CAUTION: This procedure should not be performed during a patient case on a sterile Dragonfly Imaging Catheter.

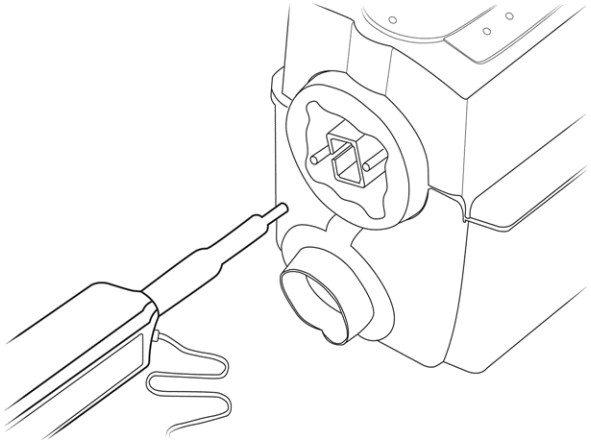
Note:

- Before beginning this procedure, ensure that the Abbott Medical optical fiber connector cleaner is available.
- Do not touch any of the optical connectors or the end of the optical fiber connector cleaner as this may damage them.

1. If a catheter is connected to the DOC, press the Unload button on the DOC and wait until the "lock" LED stops flashing. When the "lock" LED is off, remove the catheter.
2. Click the Menu button and select the Setup option. The Setup dialog box displays.

3. Click Service. The Service menu displays.
4. In the DOC Service section of the Service menu, click Enter.
5. The DOC optical carriage moves all the way to the front and locks into position for one minute. Rotation of the DOC rotary motor stops, and the laser source turns off.
6. Remove the sizing cap from the end of the optical fiber connector cleaner (figure below).
7. Insert the cleaner into the center of the optical adapter in the DOC, ensuring that it seats fully, and press until it clicks. The cleaning material in the optical fiber connector cleaner is moved over the optical connection.

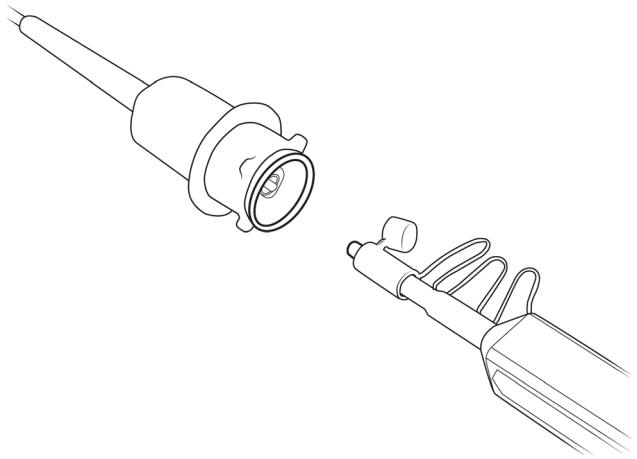
Figure 8. Inserting Cleaner into Optical Adapter



8. Remove the cleaner from the DOC.

9. In the DOC Service section of the Service menu, click Exit. The DOC optical carriage moves all the way to the back and all DOC functions are returned to their normal state.
10. Click OK or Cancel to close the Setup dialog box.
11. Open the sizing cap and place it on the end of the optical fiber connector cleaner (figure below).
12. Insert the cleaner into the optical connection in the catheter, ensuring that it seats fully, and press until it clicks. The cleaning material in the optical fiber connector cleaner is moved over the optical connection.

Figure 9. Inserting Cleaner into Catheter



13. Remove the cleaner from the catheter.
14. Reconnect the catheter to the DOC.
15. Return the system to normal operation.

Optical Adapter Replacement Procedure

The optical adapter should be replaced every 200 cycles or 1 year (whichever occurs first), or if cleaning does not improve image quality. Contact Abbott Service to purchase optical adapters.

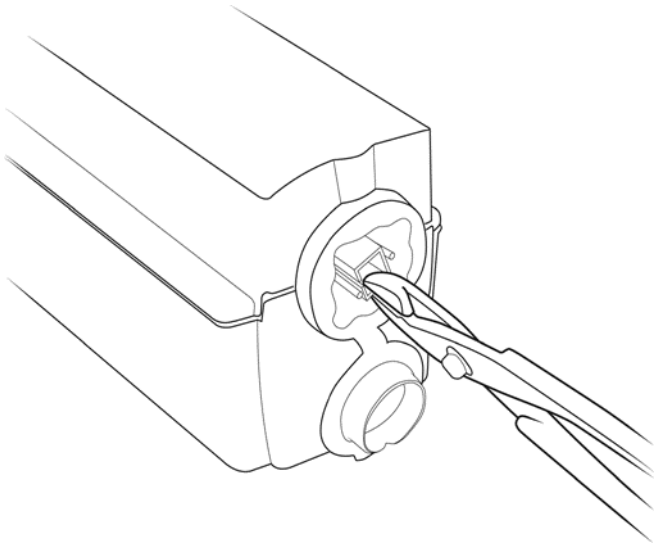
CAUTION: This procedure should not be performed during a patient case on a sterile Dragonfly Imaging Catheter.

Note:

- Before beginning this procedure, ensure that a replacement Abbott Medical optical adapter and supplied pliers are available.
- Do not touch any of the optical connectors, as this may damage them.

1. If a catheter is connected to the DOC, press the Unload button on the DOC and wait until the "lock" LED stops flashing. When the "lock" LED is off, remove the catheter.
2. Click the Menu button and select the Setup option. The Setup dialog box displays.
3. Click Service. The Service menu displays.
4. In the DOC Service section of the Service menu, click Enter. The DOC optical carriage moves all the way to the front and locks into position for one minute. Rotation of the DOC rotary motor stops and the laser source turns off.
5. Use pliers to grip either short surface of the adapter as shown (figure below). Ensure that the pliers seat over the lip on the end of the adapter.

Figure 10. Proper Gripping of Adapter for Removal



6. Pull the adapter straight out of the DOC.

   Note: Ensure that the adapter does not rotate while it is being removed, as this could damage the DOC or break the adapter.

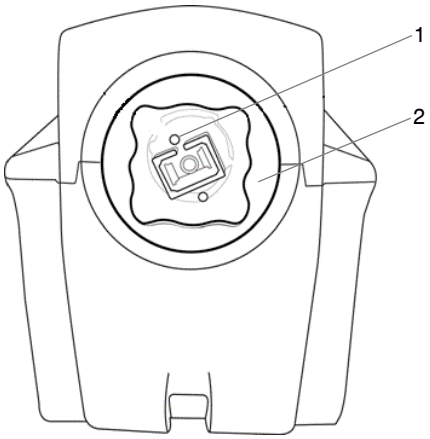
7. Remove the cap and plug from the replacement optical adapter.

   Note: Do not touch any of the optical connectors, as this may damage them.

8. Using fingers, align the new adapter with the DOC, ensuring that the key is aligned with the slot in the optical carriage, and firmly press it into place. An audible click is produced when the adapter seats.

   Note: If the carriage moves when you press on the adapter, click the Exit button in the DOC Service section of the Service menu. When it changes to Enter, click it again. When the optical carriage is locked into position at the front of the DOC, firmly press the adapter into place.

Figure 11. Alignment of Optical Adapter with Optical Carriage



1. Engagement pin
2. Catheter connection port

9. In the DOC Service section of the Service menu, click Exit. The DOC optical carriage moves all the way to the back and restores all DOC functions to their normal state.
10. Click OK or Cancel to close the Setup dialog box.
11. Return the system to normal operation.

Cable Connection Inspection Procedure

1. Ensure that the power connection to the system is fully seated and secured with the strain-relief clip.
2. If a secondary ground connection is being used, ensure that both ends of the cable are secure.
3. Ensure that all other connectors are fully seated and properly secured.

Infection Control

Follow the infection control procedures established in your institution for protection of both staff and patient.

Blood on system components, panels, and cables should be removed by using a gauze pad with soap and water and drying with a soft cloth to prevent corrosion. The DOC cable can be cleaned with a disinfectant wipe or 1:10 Hypochlorite solution and a soft cloth.

User Troubleshooting

The table below provides basic guidelines for troubleshooting the OPTIS Integrated Next. Refer to the installed software User Manual for additional troubleshooting procedures.

If the problem is not resolved after attempting the suggested remedies, contact Abbott Service or email OCTservice@abbott.com.

Table 1. User Troubleshooting Tips

Symptom	Possible Causes	Remedy
General		
Screen blank, power indicator on monitor not lit.	Display not turned on.	Press the power button on the monitor to turn on monitor power.
	Display power cord unplugged.	Plug the monitor power cord into the back of monitor.
	System power not turned on.	Turn on the system power with the main power switch.
	System power cord not plugged in or not tight at either system end or wall connection.	Check to make sure plug is tightly connected to both the system and the wall outlet.
	Main system power fuse is blown.	Refer to the Electrical label on the system (located next to the power cord connection) for fuse information. Contact Abbott Service for instructions.
	Outlet power disrupted.	Check voltage at the wall outlet.
Screen blank, power indicator on monitor lit.	PC auto boot failed.	Turn off the main power switch and wait fifteen seconds. Turn the main power switch back on and press the On / Standby button on the right side of the keyboard to start the system. If the system still does not start, contact Abbott Service for instructions.
	Monitor not enabled.	Click <Alt+C> on the keyboard to enable the display. If the screen remains blank, turn off the main power switch and wait fifteen seconds. Turn the main power switch back on and press the On / Standby button on the right side of the keyboard to start the system.
Connections		
During data export, the system does not list the USB drive plugged into the USB port.	The connected USB drive is not compatible with the system, or the USB drive requires formatting.	Connect only a USB Drive supported by Windows 10 OS. Refer to the Instructions for Use that came with the USB drive to determine if formatting is required.
Screen message "Imaging engine initialization failed" is displayed at startup.	This message can be caused by several problems, including loose or damaged system connections.	Shut down the system, turn off the main system power, and wait 15 seconds. Then turn the system back on. If the error is displayed again, contact Abbott Service for instructions.
DOC		
DOC makes excessive noise without imaging catheter connected.	DOC mechanism failure.	Contact Abbott Service to obtain a replacement DOC.

Table 1. User Troubleshooting Tips (continued)

Symptom	Possible Causes	Remedy
Imaging		
OCT image dim, with no background noise visible.	Monitor contrast and brightness set incorrectly.	Set monitor contrast and brightness using monitor controls.
	Image contrast levels set incorrectly.	Check the Presentation Settings on the Settings tab of the OCT Settings menu (normal settings are: Black level = 5%, White level = 90%). With the optical fiber rotating (scanning mode), reduce the Black level until background noise just becomes visible. Lack of background noise during optical fiber rotation indicates a defective imaging engine. See other possible causes and remedies below.
	Defective imaging catheter causing system saturation.	Remove imaging catheter from DOC. If background noise appears, the imaging catheter is defective. Replace catheter.
	Dirty connection between DOC and imaging catheter.	Refer to “Optical Connection Cleaning Procedure” on page 30 to clean the connection.
Tableside Controller		
Wireless Connectivity Indicator LED illuminates yellow color.	No wireless connection to tableside controller.	Click Menu / Setup. Select Room Manager. Ensure the tableside controller is added as a wireless device and the serial number displayed matches the device serial number on back label. If the serial numbers match and the wireless connectivity Indicator LED on the tableside controller remains yellow, reconnect the tableside controller as follows: Remove the tableside controller device by clicking the Remove button. After successful removal, click the Add button to add the tableside controller device.

System Disposal

Disposal of the equipment must be in accordance with local laws.

System Specifications

System - Safety and Regulatory

Table 2. System Safety and Regulatory Specifications

Category	Specifications
Regulatory Approvals	US 510(k) clearance CE 2797 European conformity, affixed according to the relevant provisions of EU MDR 2017/745 and 2011/65/EU, and RED directive 2014/53/EU Annex II. Hereby, Abbott Medical declares that this device complies with the essential requirements and other relevant provisions of these directives. The OPTIS Integrated Next complies with FDA performance standards for laser products except for deviations pursuant to laser Notice No. 50, dated June 24, 2007. Abbott Medical hereby declares that OPTIS Integrated Next is in compliance with the essential requirements and other relevant provisions of EU MDR 2017/745, 2011/65/EU, and RED directive 2014/53/EU. A copy of the Full Declaration of Conformity can be obtained by contacting the EU Representative.
Safety Standards	IEC 60601-1:2005/A1:2012 (per Annex ZZ) Medical electrical equipment Part 1: General requirements for basic safety and essential performance CAN/CSA C22.2 No. 60601-1:2008, Medical electrical equipment Part 1: General requirements for basic safety and essential performance IEC 60825-1, 3rd Ed., 2014 Safety of Laser Products Part 1: Equipment classification and requirements IEC 60601-1-2:2014 Ed.4 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests – Group 1 Equipment, Class A ANSI/AAMI ES60601-1:2005/(R)2012, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
Environmental	RoHS Directive 2011/65/EU REACH Directive EC 1907/2006 WEEE Directive 2012/19/EU
Electromagnetic Compatibility (EMC)	Refer to Electromagnetic Emission and Electromagnetic Immunity for detailed specifications.
Classifications	
Type of Protection, Shock	Class 1
Degree of Protection, Shock	Type CF, De-fib proof DOC with catheter (CF, De-fib-proof label at catheter connection point)
Degree of Protection, Ingress	System Cabinet - IPX0 DOC - IPX0, use with Sterile DOC cover for ingress protection Tableside Controller - IPX3 DOC Holster - IPX0 **Note:** The 27 m remoting cable connection to DOC Holster is rated for IP54.
Method of Disinfection	System Cabinet and DOC will withstand without damage or deterioration disinfection by wiping with common hospital disinfectants, including Cidex‡ (Glutaraldehyde 3.4%).
Flammable Mixtures	Not for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
Mode of Operation	Continuous

Table 2. System Safety and Regulatory Specifications (continued)

Category	Specifications
Leakage and Auxiliary Current	
Chassis Leakage Current	< 100 µa rms normal condition < 500 µa rms single-fault condition
Patient Leakage Current	Measured at patient end of DOC: < 10 µa rms normal condition < 50 µa rms single-fault condition

System - Electrical and Physical

Table 3. System Electrical and Physical Specifications

Parameter	Specification
System Cabinet Power Input	
Line Voltage	100/120/220/240 VAC ±10%, user selectable 50/60 Hz ±1 Hz
Power Consumption	Active: < 400 VA Standby: <60 VA
Radio Specifications	
Drive Motor and Optical Controller (DOC)	
Frequency Range	13.553 - 13.567 MHz (ISM-band)
Type	Amplitude-Shift Keying (ASK)
Radiated Power	Effective Radiated Power (ERP):-43.05 dBm
Tableside Controller (TSC) Bluetooth‡ Module	
Frequency Range	2.400 - 2.4835 GHz (ISM-band)
Type	GFSK, DQPSK, 8-DPSK
Radiated Power	Bluetooth‡ power Class 1
FFR Receivers	
Frequency Range	2.4 - 2.4835 GHz (ISM-band)
Type	Frequency hopping spread spectrum (FHSS)
Range	Up to 4 m **Note:** Radio range is reduced by objects and walls. Keep Transmitter and receiver in line of sight wherever possible.
Delay Time	<20 ms
Transport and Storage Conditions (permissible ranges)	
Ambient Temperature	-20 to +50 degrees C
Relative Humidity	25% - 90%, non-condensing
Operating Conditions	
Ambient Temperature	+10 to +32 degrees C
Relative Humidity	30% to 85%, non-condensing
Mechanical Specifications - System Cabinet	
Weight	50.8 kg (112 lbs)
Dimensions	60 x 34 x 61 cm
Mechanical Specifications - 19” Monitor	
Weight	9 lbs (4 kg)
Dimensions	22 x 41 x 41 cm
Mechanical Specifications - DOC Holster	
Weight	3.0 lbs (1.4 kg)
Dimensions	16 x 12 x 25 cm

Table 3. System Electrical and Physical Specifications (continued)

Parameter	Specification
Mechanical Specifications - DOC	
Weight	3.5 lbs (1.6 kg)
Dimensions	24 x 9 x 10 cm
Mechanical Specifications - TSC	
Weight	1.5 lbs (0.7 kg)
Dimensions	21 x 9 x 14 cm
Lifetime of Device	
Device Life (System)	1000 cases minimum (385 cases / yr., ≥ 2 yrs.)

Imaging Specifications

Table 4. Imaging Specifications

Parameter	Specification
Optical Parameters - Measured at System Aperture (DOC Optical Port)	
Scanning Laser Source Optical Power	22.6 mW maximum @ 1305 nm ± 55 nm (Class 1M Laser Output per IEC 60825-1)
Visible Laser Optical Power	1.45 mW maximum @ 670 nm ± 30 nm (nominal) (Class 1M Laser Output per IEC 60825-1)
Pullback Parameters	
Pullback Range	54 mm, 75 mm
Pullback Speed Settings	18.0 mm/sec, 36.0 mm/sec
General Scan Parameters	
A-Scan Range in Air	7.0 mm
A-Scan Range in Contrast	4.83 mm
Diameter Measurement Accuracy	7% ± 0.1 mm
Area Measurement Accuracy	10% ± 0.1 mm^2
Axial Resolution	≤ 20 µm in tissue
Optical Sensitivity	100 dB minimum
A-Scans per Second	81 kHz minimum
Frame Rate	180 frames/second (Hz)

Physiology Specifications

Table 5. Physiology Specifications

Parameter	Specification
Aortic Pressure Transducer Pressure (Wi-Box™ AO Transmitter to OPTIS™ Integrated Next)	
Operating pressure	-200 to +450 mm Hg
Accuracy	± 1 mm Hg or ± 1% of reading, whichever is greater
PW Pressure	
Operating pressure	-30 to +300 mm Hg
Accuracy	±1 mm Hg plus ±1% of reading (-30 to 50 mm Hg) ±3% of reading (50 to 300 mm Hg)
Aortic Pressure Transducer Pressure (Wi-Box to hemodynamic recording system) Direct galvanic connection	
Max pressure shift	<2 mm Hg

Electromagnetic Emissions

Table 6. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The OPTIS Integrated Next is intended for use in the electromagnetic environment specified below. The customer or user of the OPTIS Integrated Next should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The OPTIS Integrated Next uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	The emission characteristics of the OPTIS Integrated Next are suitable for use in industrial areas and hospitals (CISPR 11 class A). System should not be used in a residential (domestic) environment (CISPR 11 class B is required in support of domestic use).
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC-61000-3-3	Complies	

Note: The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic Immunity

Table 7. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) EN 61000-4-2 (IEC 61000-4-2)	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst EN 61000-4-4 (IEC 61000-4-4)	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5 (IEC 61000-4-5)	±1 kV differential mode ±2 kV common mode	±1 kV ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variation on power supply input lines. IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; for 5 sec @ 60 Hz (300 cycles) 0% U_T; 250/300 cycles	100% dropout in VNOM for 0.5 cycle at listed phase angles 100% dropout in VNOM for 1 cycle at 0° 30% dropout in VNOM for 25/30 cycles at 0° 100% dropout in VNOM for 5 sec 100% interrupt in VNOM for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Table 7 (continued). Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level.

Table 8. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the Transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms [V_1 = 3]	Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [1.2]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m [E_1 = 3]	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [1.2]\sqrt{P}$ $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz $d = [2.3]\sqrt{P}$ where *P* is the maximum output power rating of the Transmitter in watts (W) according to the Transmitter manufacturer and *d* is the recommended separation distance in meters (m) Field strengths from fixed RF Transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Immunity to Proximity Fields from RF wireless communications equipment IEC 60601-1-2 (Clause 8.10)	385-5785 MHz	9-28 V/m	Per IEC 60601-1-2 (Per Table 9 of Standard)

Table 8 (continued). Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed Transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF Transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Recommended Separation Distances

Table 9. Recommended separation distances between portable and mobile RF communications equipment and the OPTIS Integrated Next

The OPTIS Integrated Next is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OPTIS Integrated Next can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OPTIS Integrated Next as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of Transmitter	**Separation distance according to frequency of Transmitter m**		
W	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.7 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

FCC Statement

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by Abbott Medical could void the user's authority to operate the equipment.

Essential Performance

Imaging

Will compute the diameter of a lumen:

- Accuracy of measurements presented must meet Product Requirements specified in the Design History File (DHF).
- The lumen must be displayed on the screen.

Will compute the length of a lumen:

- Accuracy of measurements presented must meet Product Requirements specified in the DHF.
- The lumen must be displayed on the screen.

Physiology

Pressure measurement and ratio display:

- Accuracy of measurements presented must meet Product Requirements specified in the DHF.

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